Anexa 5

Specificația Tehnică Completată
Model: ARC-400; Reg. SDM: DM000569537; Producător: BOWA-ELECTRONIC GMBH & CO. KG;
Tara: Germania.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificația tehnică propusă de operatorul economic
Descriere: Unitatea electrochirurgicală este unitate universală care asigură energii adaptate în etansarea și tăierea vaselor, destinată procedurilor laparoscopice și chirurgicale deschise, bazată pe generarea de energie pentru aplicare generală, urologie, inclusiv ginecologie, colorectal, cardiac, ORL, artroscopie	**DA** Descriere: Unitatea electrochirurgicală este unitate universală care asigură energii adaptate în etansarea și tăierea vaselor, destinată procedurilor laparoscopice și chirurgicale deschise, bazată pe generarea de energie pentru aplicare generală, urologie, inclusiv ginecologie, colorectal, cardiac, ORL, artroscopie. **Ref. Brosura BOWA ARC 400**
Specificație tehnică:	Specificație tehnică:
1. Porturi de operare: Monopolar, Bipolar, Sigilare vaselor;	1. **DA** Porturi de operare: Monopolar, Bipolar, Sigilare vaselor; **pag. 3 din Brosura BOWA ARC 400**
2. Monopolar cu conexiune internațională cu 3 pini: 1 priză;	2. **DA** Monopolar cu conexiune internațională cu 3 pini: **2 prize**; **pag. 14 din Brosura BOWA ARC 400 mai mult ca atit la fabricare paote fi configurat si in alt standart necear utilizatorului**
3. Etanșarea bipolară și a vaselor: 2 prize;	3. **DA** Etanșarea bipolară și a vaselor: 2 prize; **cu 2 standarte incluse pentru c 2 pin de tip international si de tip ERBI sau VIO/ICC**
4. Funcție de autotestare;	4. **DA** Funcție de autotestare; **pag. 35 din Operating Manual ARC 400**
5. Indicatori: visual/acustic;	5. **DA** Indicatori: visual/acustic; **pag. 37, 113 din Operating Manual ARC 400**
6. Memorie a minim 3 combinații de valori pentru parametrii de lucru;	6. **DA** Memorie a 300 de programe fiecare setabila pentru instrumente puterea de cuagulare tăiere, nivel de guagulare in timpul tăierei activare intre moduri de lucru cu ajutorul a 3 buton de pe pedala cu 3 butoane de picior.; **pag. 112 , 88 ,90 din Operating Manual ARC 400**
7. Încărcarea și salvarea programelor personale;	7. **DA** Încărcarea și salvarea programelor personale; **pag. 50 din Operating Manual ARC 400**
8. Controlul volumului sunetului;	8. **DA** Controlul volumului sunetului; **pag. 83 din Operating Manual ARC 400**
9. Software încorporat pentru rezecția bipolară în mediu salin;	9. **DA**Software încorporat pentru rezecția bipolară în mediu salin; **va fi activata pag. 73 din Operating Manual ARC 400**
10. Prizele de lucru sunt de tip „SMART”, recunosc automat sculele conectate și au configurație automată a energiei;	10. **DA** Prizele de lucru sunt de tip „SMART”, recunosc automat sculele conectate și au configurație automată a energiei; **in cazul care se folosesc cabluri de comunicar cu instrumentele labaroscopiece de la alti producatori denumita la BOWA CONFORT System pag. 4 din Brosura BOWA ARC 400** **Si** **Pag. 52 din Operating Manual ARC 400**
11. Recunoașterea automată a finalizării ciclului de etanșare a vaselor (fuziunea țesuturilor, etanșarea vaselor);	11. **DA** Recunoașterea automată a finalizării ciclului de etanșare a vaselor (fuziunea țesuturilor, etanșarea vaselor); **pag. 76 din Operating Manual ARC 400**
12. Comunicarea erorilor;	12. **DA** Comunicarea erorilor; **pag. 16, 101 din Operating Manual ARC 400**

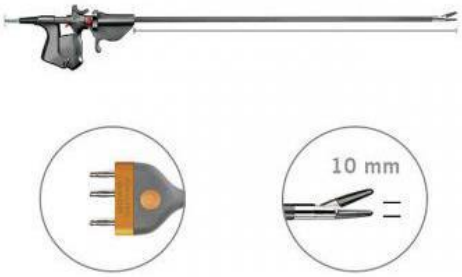
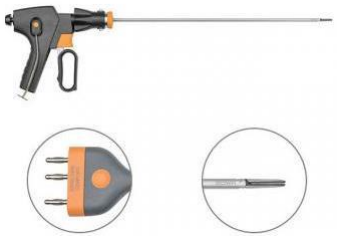
Anexa 5

Canale de ieșire: 13. Comutator de picior bipolar și etanșare a vaselor;	Canale de ieșire: 13. **DA** Comutator de picior bipolar și etanșare a vaselor; **inlcus comutator cu 3 butoane (2 de tip pedala (cut si cog) + 1 de tip programabil pentru schimbarea in programe si porturi in care este necesar sa fie activ. Poate fi folostia si in regim Monopolar** **PN: 901-031** 
14. Comutator de picior monopolar și comutator de mână;	14. Comutator de picior monopolar și comutator de mână; **inlcus comutator cu 3 butoane (2 de tip pedala (cut si cog) + 1 de tip programabil pentru schimbarea in programe si porturi care este necesar sa fie activ. Poat fi folostia si in regim bipolar** **PN: 901-031**  **la fel inclus comutator pentru mina numit pistruiu electric cu 2 butoane taiere si cugulare** **PN: 215-145** 
Moduri de lucru: - Monopalar: 15. Tăiere pură: Putere maximă: 360-370W / 450 Ohm; 16. Tăiere cu efect de hemostază: Putere maximă: 330-340W / 450 Ohm; 17. Modul de coagulare „FULGURATION”. Putere maximă: 100-110W / 750 Ohm;	Moduri de lucru: - **Monopalar fiecare protocol poate fi modificat si redactata puterea conform necesitatilor utilizatorului**: 15. Tăiere pură: Putere maximă: 400W / 200 Ohm; **Nivelul de hemostază poate fi controlat in nivele ”Effect” de la 1 la 9 pag. 115 din Operating Manual ARC 400.** 16. Tăiere cu efect de hemostază: Putere maximă: 400W / 200 Ohm; **Nivelul de hemostază poate fi controlat in nivele ”Effect” de la 1 la 9 pag. 115 din Operating Manual ARC 400.** 17. Modul de coagulare „FULGURATION” **Spay**. Putere maximă: 120 / 500 Ohm; **pag. 117 din Operating Manual ARC 400.**

Anexa 5

18. Coagulare moale Putere maximă: 340-350W / 450 Ohm;	18. Coagulare moale Putere maximă: 400W / 75 Ohm; **pag. 114 din Operating Manual ARC 400. – puterea maxima setabila**
19. Rezecție salină (TUR-P) Putere maximă: 340-350W / 450 Ohm;	19. Rezecție salină (TUR-P) Putere maximă: 120W / 500 Ohm; **pag. 117 din Operating Manual ARC 400. Puterea maxima care a fost testa in lcucru dar aceasta valoare paote sa fi si mai mar ein cazul incare ca utilizatorula re necesitate.**
20. Coagularea cu argon, Putere maximă: 100-110W / 750 Ohm;	20. Coagularea cu argon, Putere maximă: **120W / 500 Ohm; pag. 117 din Operating Manual ARC 400**
- Bipolar:	- **Bipolar fiecare protocol poate fi modificat si redactata puterea conform necesitatilor utilizatorului**:
21. Coagularea cu plasmă salină (rezecție sau vaporizare), Putere maximă: 120-140W/75 Ohm;	21. Coagularea cu plasmă salină (rezecție sau vaporizare), Putere maximă: 125,200,275,350 W/25 Ohm; **pag. 120 din Operating Manual ARC 400**
22. Coagulare forțată, Putere maximă: 170-175W / 75 Ohm;	22. Coagulare forțată, Putere maximă: 120W / 50 Ohm; **pag. 120 din Operating Manual ARC 400**
23. Coagulare moale, Putere maximă: 100-110W / 30 Ohm;	23. Coagulare moale, Putere maximă: 40W / 50 Ohm; **pag. 120 din Operating Manual ARC 400**
Sigilare vaselor (fuziune de țesut, sigilarea vaselor de legătură sau echivalent):	Sigilare vaselor (fuziune de țesut, sigilarea vaselor de legătură sau echivalent):
24. Putere maximă: 140-150W / 30 Ohm;	24. Putere maximă: 200W /25 Ohm; **pag. 119 din Operating Manual ARC 400**
25. Sigilează vasele de sânge și limfatice până la 7mm în diametru;	25. **DA** Sigilează vasele de sânge și limfatice până la 7mm în diametru; **pag. 2 din broshura ERGO 315R**
26. Electrod neutru reutilizabil din cauciuc siliconic;	26. **DA** Electrod neutru reutilizabil din cauciuc siliconic; **PN 242-003** 
27. Mâner monopolar reutilizabil (creion) pentru electrod, cu cel puțin două butoane de operare, min. 3 cablu – 1 buc.;	27. Mâner monopolar reutilizabil (creion) pentru electrod, cu cel puțin două butoane de operare, min. 3 cablu – 1 buc.; **DA inclus PN 215-145**
28. Set de electrozi (min. 3 buc.) de diferite dimensiuni și forme (minge, lama, ac) – 2 buc.;	28.**DA** Set de electrozi (**12 buc.**) de diferite dimensiuni și forme (minge, lama, ac **etc. cu container**) – 2 buc.; **PN 500-000** 

Anexa 5

29. Cablu monopolar de cel puțin 3 m. lungime (pentru conectarea instrumentelor laparoscopice) -3 buc.;	29. Cablu monopolar de cel puțin 3 m. lungime (pentru conectarea instrumentelor laparoscopice) -3 buc.; **PN: 360-050 sau alt cablu daca este neceasr pentru resetoscop sau alt instruemnt paote fi ales de pe sitiul oficial: https://int-shop.bowa-medical.com/en/Instruments-Accessories/Cables/** 
30. Pensă pentru tăierea și sigilarea vaselor de sânge (sistem de tăiere integrat), diametru 10 mm, utilizată în chirurgia laparoscopică, lungime minimă 30 cm, reutilizabilă, autoclavabilă, cu cablu de recunoaștere automată – 1 buc.;	30. **DA** Pensă pentru tăierea și sigilarea vaselor de sânge (sistem de tăiere integrat), diametru 10 mm, utilizată în chirurgia laparoscopică, lungime 360 cm, reutilizabilă, autoclavabilă, cu cablu de recunoaștere automată – 1 buc.; **PN:770-301 NightKNIFE** 
31. Lame pentru vase cu diametrul de 10 mm pensă pentru etanșare – 10 buc.;	31. **DA** Lame pentru vase cu diametrul de 10 mm pensă pentru etanșare – 10 buc.; **PN 770-999** 
32. Pensă pentru tăierea și sigilarea vaselor de sânge (sistem de tăiere integrat), diametru 5 mm, utilizată în chirurgia laparoscopică, lungime minimă 30 cm, reutilizabilă, autoclavabilă, cu cablu de recunoaștere automată – 1 buc.;	32. **DA** Pensă pentru tăierea și sigilarea vaselor de sânge (sistem de tăiere integrat), diametru 5 mm, utilizată în chirurgia laparoscopică, lungime 360 mm, reutilizabilă, autoclavabilă, cu cablu de recunoaștere automată – 1 buc.; **PN: 770-503 ERGI 315** 
33. Lame pentru vase cu diametrul de 5 mm pensă pentru etanșare – 10 buc.;	33. Lame pentru vase cu diametrul de 5 mm pensă pentru etanșare – 10 buc.; **PN: 770-998** 

BOWA
MEDICAL

ERGO 315R

Bipolar sealing and cutting with added value

ERGO 315R

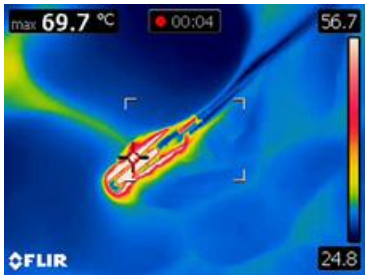
Multifunctional
Bipolar vessel sealing up to 7 mm with integrated cutting blade

Cost-effective
A reusable instrument with disposable blades for reliable cutting performance

Highest surgical performance
Thin, atraumatic geometry of the jaws for fine tissue preparation

Thermal lesions are prevented
Low temperature at the back of the jaw

Minimal thermal spread
Insulated electrode surfaces for greatly reduced thermal spread



"Bipolar vessel sealing devices reduce intraoperative instrument replacement during laparoscopic procedures. However, the costs must also be considered in terms of the reusability of an instrument."

Dr. Karl-Günter Noé

Individual positioning

The manual activation switch can be positioned on the left or right side as desired.

Order information (REF)

	275 mm Shaft length	360 mm Shaft length
ERGO 315R complete instruments		
ERGO 315R complete instrument incl. 20 x sterile blades	770-502	770-503
ERGO 315R complete instrument with reprocessing basket incl. 20 x sterile blades	770-552	770-553
ERGO 315R individual components		
Handle	770-510	
Jaw	770-522	770-523
Push rod, Ø 5.5 mm	770-532	770-533
Blade rod	770-542	770-543
Blade, sterile, 10 pcs. (2 x)	770-998	
Cable	358-245	
ERGO 315R reprocessing basket as accessory		
Cleaning adapter set	723-050	
Cleaning brush set (4 units)	723-000	

BOWA MEDICAL

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4–10
72810 Gomaringen, Germany

Phone +49 7072 6002-0

bowa-medical.com
info@bowa-medical.com

The energy-based system for the highest surgical performance.

Contact your authorised
BOWA medical product consultant.

support@bowa-medical.com

Made in Germany

BOWA
ARC
400

ARC 400

Electrosurgical device

Performance at your fingertips

ARC 400

Putting heart and soul into the operating theatre

The best doesn't cut it. You have to look beyond to discover new insights and new solutions.

Discover the new generation of electrosurgical devices with the ARC 400.
Discover true passion and ultimate performance for the operating theatre.

Ideal areas of application for the ARC 400 in HF surgery

Individual set-up

Each discipline comes with specific requirements, each team works differently, each procedure is individual.

- User interface can be easily configured to your requirements with the interactive touchpad
- Depending on the indication, select the pre-configured standard values or create an individual favourite setting for your specific discipline and working style

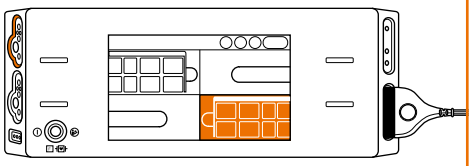
Touchpad technology for more intuition in the operating theatre

With the ARC 400, you can control all device functions at the touch of a finger via the interactive touchpad using clearly arranged icons.

Intuitive operation

Get an overview – in any situation

- Clear instrument assignment
- Plug'n Cut COMFORT automatically preselects the correct basic settings of connected COMFORT instruments



Each assigned socket is clearly allocated to a quadrant of the display

Efficient performance

Save valuable operating theatre time through simple operation

- Special LIGATION function
- Up to 5 instruments simultaneously on the ARC 400
- Fast communication with other system components and simple software updates using USB and several standard ports

The COMFORT SYSTEM

Process reliability, quality assurance, monitoring –
the COMFORT SYSTEM documents its use directly in the instrument

Smart RFID technology
The ARC 400 or the COMFORT BOX read out the information. You can see at a glance how many times the instrument has already been used and how often it may still be used. This prevents users from exceeding the maximum number of uses. In addition, the system simplifies repeat orders by displaying the order information.

Maximum efficiency with reduced operating theatre time
The Plug'n Cut functionality of the COMFORT SYSTEM means the generator automatically recognises the instrument and checks and selects the correct device settings. The Plug'n Cut COMFORT function avoids incorrect settings.

Individual set-up

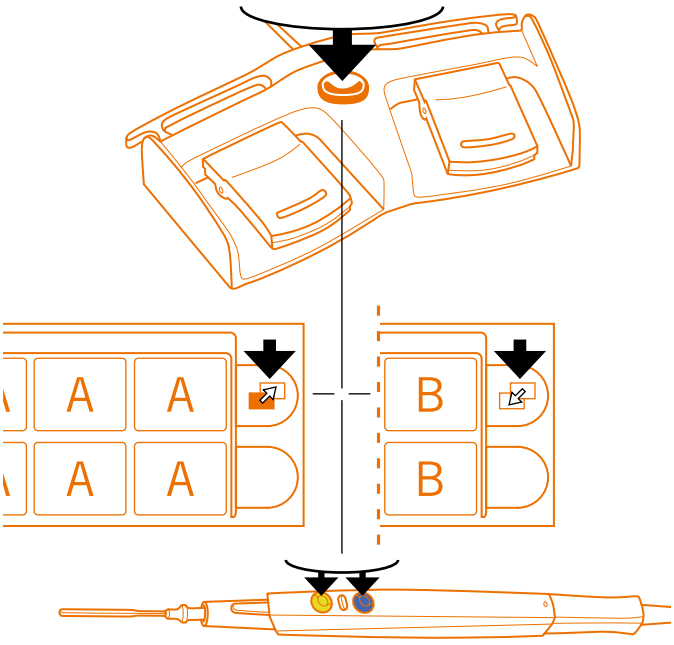
You can save numerous personal favourite settings and call them up from the favourites menu at the touch of a finger.

Select your favourite
300 device settings can be saved.

At the touch of a finger: Quickly create and call up favourites

Directly in your specific application
The ARC 400 offers a wide range of standard electrosurgical and indication-oriented current types enabling the surgical team to operate efficiently.

Experts work together: Use KARL STORZ OR1™ to set the power, the current type and the activation type



ZAP mode – changing programs by hand or foot

Surgeons benefit from simple operation using the foot switch or the buttons on the electrode handle to choose between two presets during the operation without the need for non-sterile personnel.

Applications

Top quality monopolar and bipolar electrosurgery

Gynaecology applications:

- Hysterectomy – open and vaginal, laparoscopic hysterectomy
- TLH: Total laparoscopic hysterectomy
- LASH: Laparoscopic supracervical hysterectomy
- Mastectomy

For example, MetraLOOP & ARC 400 for fast, safe and precise surgery

The ARC 400 offers a special function for gynaecology with the MetraLOOP mode. The mode is used for laparoscopic supracervical removal of the uterus (LSH). In conjunction with the BOWA MEDICAL MetraLOOP, it is possible to quickly transect the uterus. This means you can work safely, quickly and precisely – even with large loops.

Surgery applications:

- Colectomy
- Gastrectomy
- Liver resection
- Thyroidectomy
- Lobectomy
- Cholecystectomy

For example, ARC 400 and ERGOact / ERGOeco – the perfect system for laparoscopy

ARC 400 together with ERGOact or ERGOeco are the perfect system for the special requirements of laparoscopic procedures. ERGOact / ERGOeco can be used for all laparoscopic operations in gynaecology, urology, general and visceral surgery. For bariatric surgery, the laparoscopic instrument is also available with a working length of 460 mm.

Urology applications:

- Prostatectomy
- Cystectomy
- Nephrectomy

For example, BiZZER and Plug'n Cut COMFORT for maximum operating comfort

The BiZZER COMFORT version features integrated RFID technology for communication with the ARC 400 with Plug'n Cut COMFORT instrument recognition. Instrument recognition and preselection of the device settings are automatically available immediately after connecting the instrument. Plug'n Cut COMFORT combines maximum ease of use with excellent application safety – inefficient or even hazardous settings are avoided from the outset. In addition, BiZZER COMFORT enables consistent monitoring of the usage cycles on the ARC 400.

Special applications

Four of many

Bipolar resection* for urology

- Extremely reliable incision behaviour and high resection speed
- Avoiding the danger of a TUR syndrome by using saline solution as the medium
- Monopolar transurethral prostate resections (TUR-P), surgical treatment of bladder tumors (TUR-BT), vaporisation of prostate tissue (TUR-VAP)

*option

Resection CUT

Resection COAG

Quadruple specialisation: Functions for cardiac surgery

Four highly specialised functions for effective performance

Monopolar SimCOAG for simultaneous coagulation and preparation with two monopolar handles

Cardiac Thorax for forced coagulations during the opening of the thorax

Cardiac Mammaria for forced coagulation in the area of the mammary

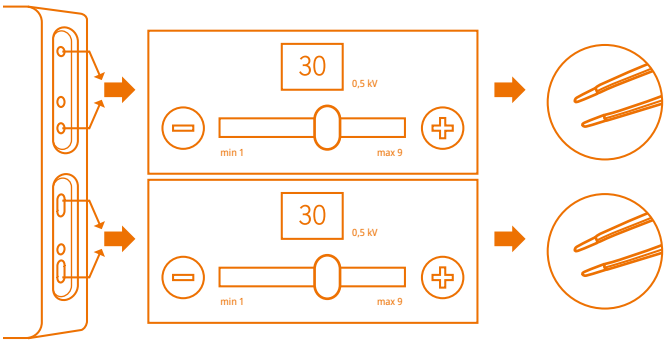
Dry cut with strong haemostasis

Simultaneous operation

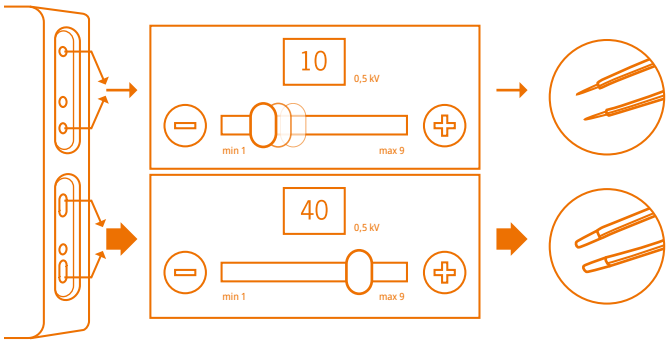
In contrast to conventional generators, two bipolar instruments can now be activated simultaneously:

- Uninterruptible
- Individual parameters
- Precise and safe

SimCoag for ARC 400



- Simultaneous instrument activation
- Individual power output



- Individual settings
- Individual power output

For gynaecology: faster hysterectomy

- Modes for vessel sealing and for monopolar and bipolar resection
- Special function for laparoscopic supracervical removal of the uterus (LSH)
- Mode used with the BOWA MetraLOOP, enables a quick transection of the uterus.

▶ Work safely and precisely – even with large loops

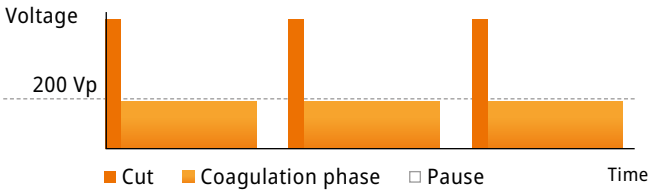
MetraLOOP

GastroCut for gastroenterology

- GastroCut modes offer the best results in polypectomy, papillotomy and endoscopic resections with loops or knife electrodes
- Series of cutting and coagulation current pulses in three variable speeds "**slow**", "**medium**" and "**fast**" adapted to requirements
- Coagulation effect of the cut is controlled across nine levels

▶ Allows careful work so as to avoid complications where necessary as well as fast work where possible, depending on the situation

Current type GastroCut



Argon workstation

for argon plasma coagulation (APC)
and argon-assisted electrosurgery

Easy handling
Safe argon ignition > 10 mm

Effective haemostasis
Non-contact and large-area

Interdisciplinary use
with rigid and flexible probes

Optimised flow properties for
excellent ignition

Argon-assisted cutting
Homogeneous tissue effects

ARGON COAG and CUT

for argon-assisted cutting and coagulation in open and laparoscopic applications in surgery and gynaecology

- Abdominal surgery
- Laparoscopy
- Liver surgery
- Breast surgery
- Visceral surgery

Argon CUT

Argon COAG

Benefits of argon-assisted electrosurgery in surgery and gynaecology

- Non-contact coagulation
- Fast superficial coagulation of large areas
- Ignition distance >10 mm

Argon FLEX / Argon PULSED

for applications in internal medicine with flexible probes

Argon FLEX

Argon PULSED
with fine control over several effect levels

Benefits of argon-assisted electrosurgery in internal medicine

- Minimal risk of perforation due to reproducible dosing via power and pulse sequence
- Especially fine coagulation from 1 W in gastroenterology
- Low odour due to reduction of surgical smoke
- Flexible coagulation zone
- Very easy handling due to large ignition distance > 10 mm
- Minimal argon flow rates of 0.4 l/min
- Limited penetration depth

ARC CART & argon workstation

provides a highly mobile argon workstation
with useful detailed solutions

Benefits of argon-assisted electrosurgery in surgery and gynaecology

- Non-contact coagulation in parenchymal tissues, e.g. liver
- Rapid coagulation of large surfaces
- Flexible, homogeneous coagulation zone
- Controlled handling due to large ignition distance > 10 mm

ARGON COAG and CUT

for argon-assisted cutting and coagulation in open and laparoscopic applications in surgery and gynaecology:

- Abdominal surgery
- Laparoscopy
- Liver surgery
- Mammary surgery
- Visceral surgery

SHE SHA filters surgical smoke with an efficiency of **99.999 %**

SHE SHA smoke evacuation system

- Combination option for open surgery applications
- Combats the health hazards posed by surgical smoke gases. For clean air in the operating theatre

Recommended basic accessories

ARC CART

Equipment trolley

REF 902-054

SHE SHA

SHE SHA smoke evacuation system

REF 950-001

SHE SHA filter

REF 951-001

SHE SHA smoke handle

REF 802-033

Foot switch

Twin-pedal foot switch

with clip

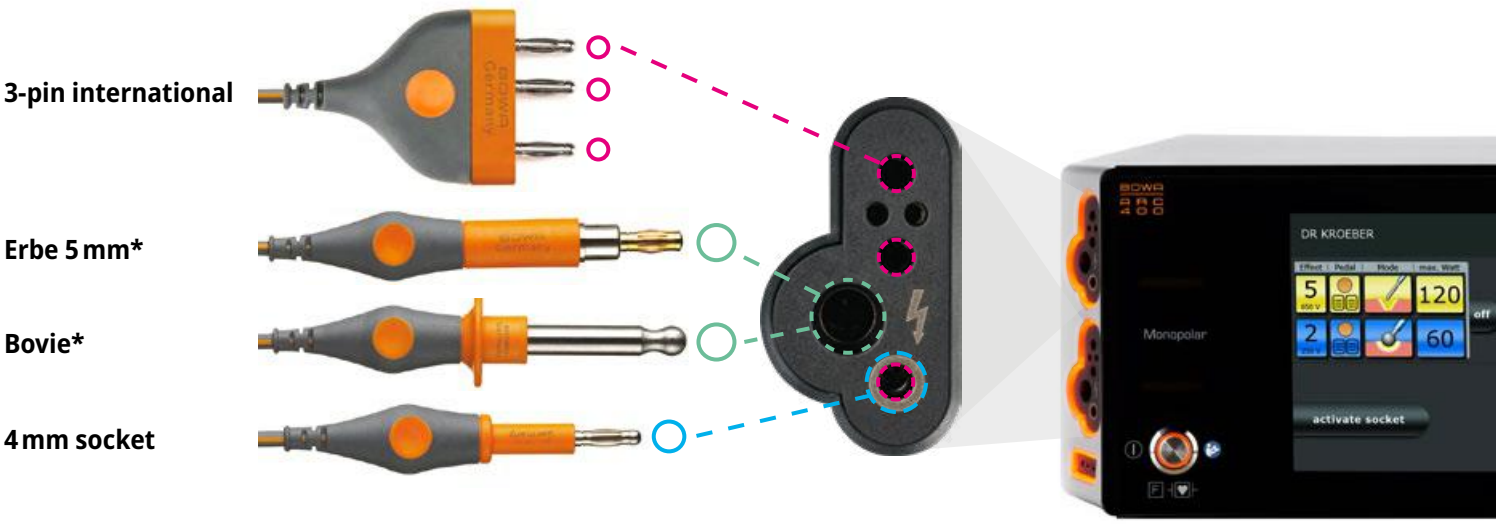
REF 901-032

Single-pedal foot switch

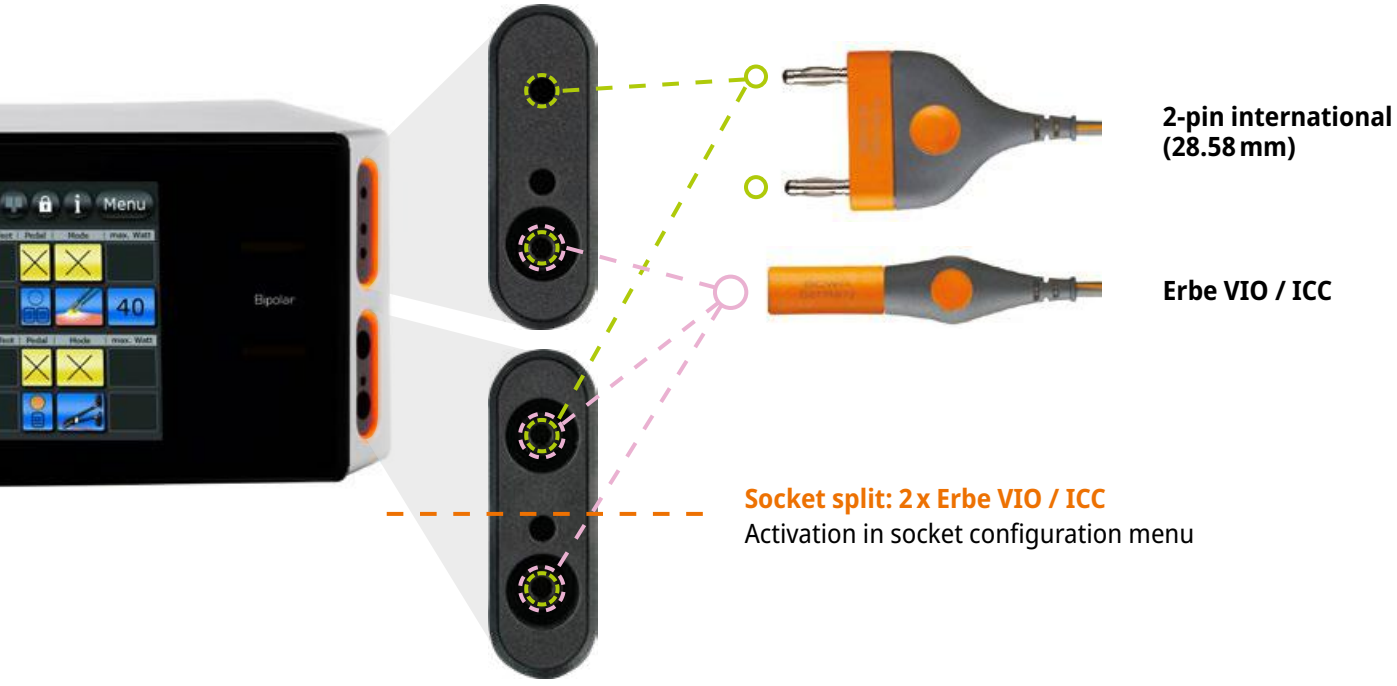
REF 901-011

Sockets
for instruments

Monopolar sockets



Bipolar sockets



Socket split: 2 x Erbe VIO / ICC
Activation in socket configuration menu

BOWA SERVICE

We are there for you. ✔ Global service network

Repairs
Fast service in case of technical problems

Service packages
Adapted to your individual requirements

Training
Medical technician training at the BOWA Service Centre

Devices on loan
Loan devices during repair or service

Disposal
Sustainable disposal of waste equipment

For more information:
www.bowa-service.com

TECHNICAL DETAILS

Type of insulation / classification	
Protection class according to EN 60601-1	I
Type of applied part (EN 60601-1)	CF
CE in accordance with 2017/745 EU (MDR)	CE 0123

Key data	
Max. MONOPOLAR power	400 W (at 200 Ω)
Max. BIPOLAR power*	400 W (at 75 Ω)
Output frequency	350 kHz

Mains input	220–240 V / 100–127 V
Min. power input	3 W / 40 VA
Max. power input (at 400 W)	700 W / 1150 VA
Mains frequency	50 / 60 Hz
Mains current	max. 5 A @ 230 V | max. 8 A @ 127 V | max. 10 A @ 100 V
Line fuse	2 x T5 AH 250 V

Dimensions:	Weight:
430 x 180 x 475 mm	**12.5 kg (net)**

* depending on the configuration

BOWA MEDICAL

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4–10
72810 Gomaringen, Germany

Phone +49 7072 6002-0

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OPERATING MANUAL
ELECTROSURGICAL UNIT

BOWA ARC 400

12214EN-S0

Contents

1. Using this operating manual

This operating manual is part of the device.

BOWA-electronic GmbH & Co. KG, referred to in the following simply as BOWA, assume no liability nor provide any warranty whatsoever for damage and consequential damages that arise due to non-compliance with the operating manual.

Read the operating manual carefully and thoroughly before using this device.

Store the operating manual in a safe place throughout the service life of the device.

Keep the operating manual accessible to operating room personnel.

Give the operating manual to each successive owner and/or user of this device.

Always update the operating manual whenever you receive additional information from the manufacturer.

1.1. Revision index

Unit version	Last revised
Valid from version 2.2.0	2019/01

1.2. Validity

This operating manual applies only to the devices designated in chapter 3.2.1 Nameplate (see page 24).

1.3. Other applicable documents

Comply with other applicable documents in the appendix or in the other sections.

1.4. Icons and labeling

1.4.1. Structure of warning instructions

⚠ SIGNAL WORD

"Risk type, source and consequences there of" (Personal injury)!

▶ Measure for risk prevention.

NOTE

"Risk type, source and consequences there of" (Property damage)!

▶ Measure.

1.4.2. Risk levels in warning instructions

Symbol	Risk level	Probability of occurrence	Consequences of non-compliance
	**DANGER**	Immediate risk	Death, serious injuries
	**WARNING**	Possible risk	Death, serious injuries
	**CAUTION**	Possible risk	Minor injuries
	**NOTE**	Possible risk	Property damage

1.4.3. Tips

Tips and additional information to facilitate tasks

1.4.4. Other symbols and marks

Symbol or mark	Meaning
☑	Prerequisite for an activity
▶	Activity with one step
• • •	Activity with several steps in a binding sequence
⇨	Result of preceding activity
•	List (first level)
•	List (second level)
Emphasis	Emphasis
....., see Section xxx, page xxx	Cross reference

2. Safety

2.1. Intended use

The HF device is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation on tissue structures in surgical operations.

It is used in the following areas:

- General surgery
- Endoscopy (GastroCut mode)
- Gynecology
- Hand surgery
- ENT
- Cardiac surgery (including open-heart surgery)
- Neurosurgery
- Pediatric surgery
- Plastic surgery and dermatology
- Thoracic surgery
- Orthopedics
- Urology, including transurethral resection (TUR)

Do not use the HF device if, in the opinion of an experienced physician or according to current professional literature, such use would endanger the patient, due for example to the general condition of the patient, or if other contraindications are present.

BOWA requires that the HF device is operated under the supervision of qualified and authorized personnel. The surgeon and medical staff must be trained in the fundamental principles, rules for use and risks of HF surgery and must be familiar with these in order to safely and reliably prevent putting patients, staff and equipment at risk.
Contact your BOWA distributor for trainings and training material.

Any other use is neither intended nor proper and must be effectively prevented.

When setting up the HF device, ensure easy access to the power cable so it can be disconnected from the device.

2.2. General safety instructions

- ► Ensure that no electronic devices that are subject to interference from electromagnetic fields are set up in the vicinity of the HF device.
- ► Observe the instructions on electromagnetic compatibility provided in section EMC, page 161.
- ► Always connect the HF device to a mains power system with a protective earth lead in order to prevent electric shock.

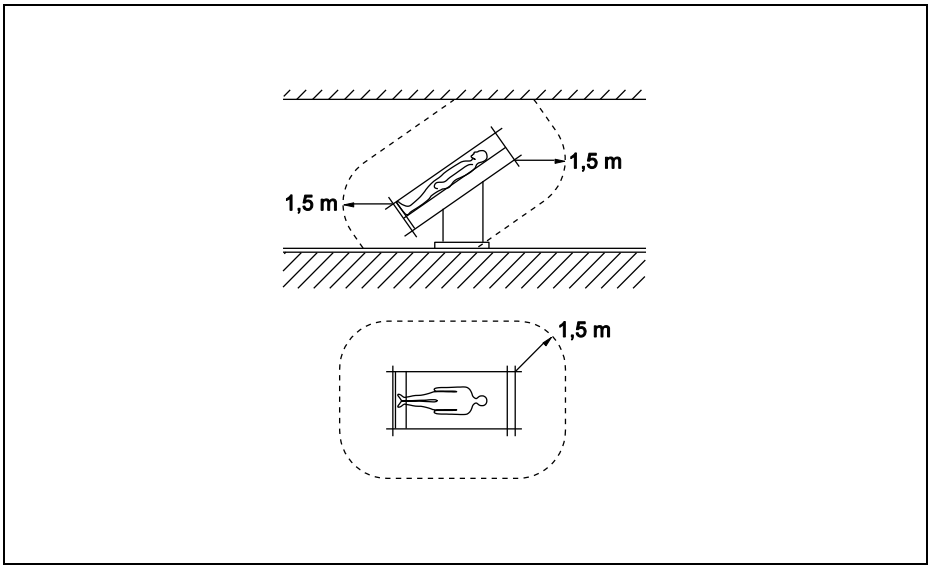
Additional devices that are connected to electrical medical devices must satisfy relevant IEC or ISO standards (e.g. IEC 60950 for data processing devices). Furthermore, all configurations must comply with the standardised requirements for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1 as relevant). Anyone who connects additional devices to electrical medical devices is automatically a system configurator and thus responsible for meeting standardised system requirements. Please note that local laws prevail over the aforementioned standard requirements. In case of questions, please contact your local dealer or Technical Service, see section Technical service, page 111.

To protect personnel, BOWA recommends the use of a smoke evacuator to extract electrosurgical smoke, e.g. BOWA SHE SHA.

2.3. Personal safety instructions

2.3.1. Ambient conditions

- ► Do not use the HF device in the immediate vicinity of the patient. Observe the minimum distances recommended by BOWA, as shown in the following figure.



2.3.2. Patients with pacemakers

Malfunction or destruction of the pacemaker can endanger the life of the patient or result in irreversible injuries to the patient.

- ► In the case of patients with pacemakers, consult the cardiologist before carrying out HF surgery.
- ► Use bipolar HF methods.
- ► Attach the HF neutral electrode close to the operating field.
- ► Set the demand pacemaker to a fixed frequency.
- ► Ensure that the pacemaker does not come into contact with the HF electrode.
- ► Keep a fully operational defibrillator within reach.
- ► Carry out a postoperative pacemaker check.

2.3.3. Hazard-free patient positioning

- ► Position patients so that they are not touching any metal parts that are grounded or have considerable capacitance relative to ground (e.g. operating table brackets). If necessary, place anti-static cloths between the patient and the bedding.
- ► Ensure that the patient does not touch any wet clothes or bedding.
- ► Place anti-static cloths between areas with heavy sweating and skin-to-skin contact areas on the patient's torso.
- ► Ensure that the patient is resting on a suitable surface in order to prevent pressure necrosis.
- ► Drain urine via a catheter.

2.3.4. Correct connection of the HF device

- ► Always ground the HF device to the equipotential rail.
  Also observe the requirements in Section 8.6.7 of IEC 60601-1 regarding medical electrical systems.
- ► Do not use needle electrodes for monitoring.
- ► Physiological monitoring equipment with integrated limitation of the HF currents is expressly recommended.
- ► Attach the electrodes from physiological monitoring equipment without protective resistors or HF chokes as far as possible from the HF electrodes. Place lines from monitoring devices so that they do not lie on the patient's skin.
- ► Keep the leads to the HF electrodes as short as possible and position them so that they do not touch the patient or other leads.
- ► Do not place any objects on the HF device.

2.3.5. Correct use of the HF device

Inadvertent activation of the HF device outside the user's field of vision can injure the patient.

- ► Activate the HF device only when the electrode is in your field of vision and you can quickly deactivate the HF device at all times.
- ► If the HF device is activated inadvertently, switch it off immediately using the on/off switch.
- ► Take particular care when using a foot switch or manual switch.

Improper preparation, user errors or faults in the HF device can cause damage to the HF device.

- ► Use the automatic monitoring functions to ensure that the HF device is working properly. See Section Functional testing, page 35 for information on the auto test functions.
- ► Ensure that no conductive fluids (e.g. blood or amniotic fluid) have penetrated the foot switch or the manual switch.
- ► Ensure that the cables for the foot switch and the manual switch are free from short circuits and broken leads.

For patient protection, avoid touching the patient and any of the following parts at the same time:

- exposed contacts of plug-and-socket connectors.

2.3.6. Configuring HF device settings and using accessories

“An obviously low output value or functional failure of the HF surgical device in normal operation may be caused by insufficient skin contact of the neutral electrode or insufficient contact with its connecting cables.”

Therefore, before you increase the output power, ensure that:

- the neutral electrode is attached properly;
- the working electrodes are clean;
- the plug connections are all correct.

Setting the HF device correctly

- To prevent inadvertent (thermal) tissue damage during operations on body parts with small cross sections and in areas with high resistance (bones or joints), use the bipolar method in these areas.
- Set the level of the acoustic signal that sounds when the electrode is activated so that it is always clearly audible.

Risk of nerve or muscle excitation by low-frequency currents!
During HF surgical operations (especially when an arc is formed), part of the HF current is converted into a low-frequency current. This current can trigger muscle contractions in the patient.

- To minimize the risk of injury to the patient, set the power and the effect as low as possible.

Correct use of accessories

- Use only insulated accessories.
- Check all electrodes for sharp edges and projecting parts before use.
- Use only electrodes that are free of defects and in good working order.
- Never place active electrodes on or near the patient.
- Do not remove hot electrodes from the patient’s body directly after cutting or coagulation.
- Ensure that there is sufficient distance between the patient cables and the cables of the HF device.
- Do not run the patient cables along the front of the device or across the patient.

2.4. Product-related safety instructions

Devices manufactured by BOWA are developed in accordance with the current state of technology and generally accepted safety rules. Despite this, using these products can lead to risks to the life and health of the user or third parties and/or damage to the device or other objects.

- Use only accessories approved by BOWA, see Accessories and replacement parts, page 160.
- Use the device only when it is in free of technical defects and in good working order and only for the intended purpose, always remaining aware of safety requirements and risks and complying with this operating manual.
- Have malfunctions that can adversely affect safety (e.g. deviations from the permissible operating conditions) repaired without delay.
- Wipe down the HF device only with cleaning agents and disinfectants that are approved in the country of use for surface cleaning. See Section Disinfection and cleaning, page 108.
- Never immerse the device in water or cleaning agents.
- Never boil the device and never disinfect it mechanically.
- If any fluids penetrate the device, drain them immediately.

Damage to the device can lead to an undesirable increase in output power due to improper operation of the device.

Certain units or accessories can cause danger in lower power settings. For example, the risk of gas embolism in argon assisted coagulation rises, if the hf-power is insufficient for the fast creation of an impenetrable eschar layer on the target tissue.

2.5. Safe handling (general instructions)

- Before each use of the device, check to ensure that it is functioning properly and is in good working order and connected properly.
- Observe the instructions on intended use in conformance with standards (see Section Fault indications for EASY monitoring , page 107.
- During use, always observe and comply with the acoustic signals and/or error messages of the HF device (see Section Fault indications for EASY monitoring , page 107).
- The device and accessories may be operated and used only by people who have the necessary training, knowledge and experience.
- Regularly inspect the accessories, especially the electrode cables, endoscopic accessories and neutral electrodes, for damage to the insulation, proper operation and expiration date.
- Instruments must not be laid upon the patient or devices.
- Ensure that no instruments are being cleaned when AUTOSTART is activated.
- Wear suitable gloves during operations.

2.5.1. Operation area: avoiding ignition and explosions

Sparks are generated when the HF device is used as intended.

- Do not use the HF device in areas where there is a risk of explosion.
- Do not use any flammable or explosive liquids.
- If the display fails, do not use the HF device any longer.
- During operations (e.g. in the head or thoracic regions), avoid using ignitable anaesthetics and gases that support combustion (e.g. nitrous oxide or oxygen) or extract them using a vacuum system.
- Use exclusively non-flammable cleaning agents, disinfectants and solvents (for adhesives). If you use flammable cleaning agents, disinfectants or solvents, ensure that they have fully evaporated before using HF surgical equipment.
- Ensure that no flammable liquids collect beneath the patient or in body cavities (e.g. the vagina). Suction and/or flush body cavities before activating the device.
- Wipe off all liquids before using the HF device.
- Ensure that no ignitable endogenous gases are present.
- Ensure that all materials saturated with oxygen (e.g. cotton or gauze) are kept far enough away from the HF environment that they cannot ignite.

2.5.2. Applying the neutral electrode

Observe the instructions on the use of the neutral electrode in the user guide and the information on the package of the neutral electrode.

In the monopolar HF method, the neutral electrode feeds the current introduced into the patient's body at the surgical site back to the HF device.

- To prevent a rise in temperature at the current exit point, the following conditions must be ensured:
  - sufficiently large contact surface between the neutral electrode and the patient's body;
  - high electrical conductivity between the neutral electrode and the patient's body.

▶ To prevent the patient being burned by the neutral electrode, you must comply with the following conditions:

- Select the application point for the neutral electrode so that the current paths between the active and neutral electrodes are as short as possible and run longitudinally or diagonally through the patient's body (because muscles are more conductive in the direction of the fibrils).

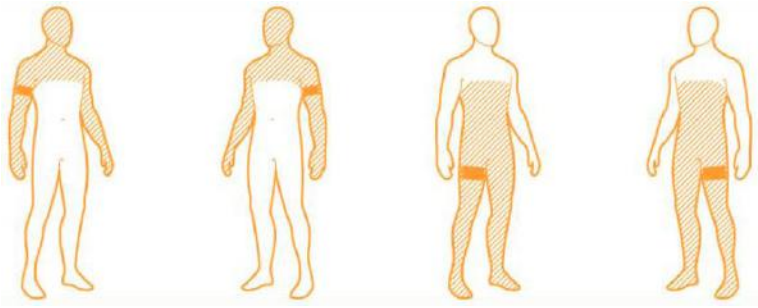


Figure 2-1: Application point of neutral electrode

- For surgery in the thoracic region, do not run the current path transversely across the patient's body and ensure that the patient's heart is never in the current path.
- Depending on the surgical site, apply the neutral electrode to the nearest upper arm or thigh if possible, but never closer than 20 cm.
- In the case of self-adhesive disposable electrodes, comply with any further manufacturer instructions regarding the point of application.
- Ensure that the application area is free of scar tissue, bony protuberances, surface hair and ECG electrodes.
- Ensure that there are no implants (e.g. bone nails, bone plates or endoprostheses) in the current path.
- Ensure that no short circuits can occur at the neutral electrode connection.
- Avoid areas where fluids may collect.
- Use split neutral electrodes with a sufficiently large surface area (patient age and max. output power during operation have to be considered).

Before applying the neutral electrode

▶ Shave the area where the neutral electrode will be applied.

▶ Clean the application site, but do not use any alcohol, since it dries out the skin and increases the contact resistance.

▶ If the patient has poor circulation, massage or brush the application site.

- Attach the neutral electrode over the entire contact surface evenly. Secure reusable neutral electrodes with rubber bands or elastic straps so that they do not loosen when the patient moves. Ensure that the patient's circulation is not impaired (risk of necrosis).
- Never use wet clothes or conductive pastes.
- Ensure that no liquids (e.g. cleaning fluids, disinfectants, blood or urine) penetrate between the patient and the neutral electrode.
- Do not place the neutral electrode under the patient's buttocks or back.
- Ensure that there are no ECG electrodes in the current path of the HF device.
- Check the neutral electrode before and after use for damage and to ensure that they are working properly.
  Replace defective accessories immediately

Example application using a disposable electrode

- Remove the protective film and attach the self-adhesive disposable electrode to the patient. Ensure that the long edge of the disposable electrode faces the operation site and the electrode is fully in contact with the skin. This avoids excessive current concentration on the short edge.
- Using both hands, press the self-adhesive disposable electrode firmly against the patient's skin.
- Clamp the electrode tab to the neutral electrode cable.
- After the operation, remove the disposable electrode carefully to avoid skin damage.

With a one-piece neutral electrode

- Check the one-piece neutral electrode during surgery.
- Ensure that the one-piece electrode is not blocked at the device.

With a split neutral electrode

- Apply the split neutral electrode correctly and without any additional objects, as otherwise the HF device may detect a path between the two sections due to other objects.
- See that the current flows equally to both parts of the split neutral electrode.
- When the EASY indicator is illuminated yellow, heating at the current exit point may be present depending on the indication.

See Section EASY neutral electrode monitoring (EASY monitoring) , page 37 regarding monitoring of the neutral electrode.

3. Description

3.1. User interface components

3.1.1. Front panel user interface components

1	On/-Off button
2	"On/-Off button" icon
3	Neutral electrode isolated from ground for HF
4	Symbol "Defibrillation-proof type CF applied part"
5	Symbol "Observe instructions for use"
6	Touchscreen with mode selection buttons
7	Activation bar upper monopolar socket
8	Activation bar lower monopolar socket
9	Activation bar upper bipolar socket
10	Activation bar lower bipolar socket

While activating an instrument, the activation bar of the corresponding socket illuminates yellow or blue.

3.1.2. Monopolar connector module (left)

11	Socket connector for monopolar instruments with hand or foot switch*
12	Socket connector for monopolar instruments with hand or foot switch*
13	Socket connector for neutral electrode *

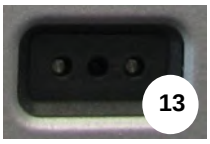
* Applied part type CF according to IEC 60601-1

Monopolar connection socket

Version 1
14 3-pin US type
15 Bovie connector (for foot switch)
16 4-mm socket (for foot switch)

Version 2
14 3-pin US type
15 Erbe 5 mm
16 4-mm socket (for foot switch)

Connection socket for neutral electrode



13 Neutral (US type)

3.1.3. Bipolar connector module (right)

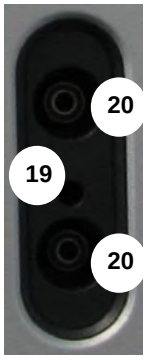
17 Socket connector for bipolar instruments with foot switch, finger switch or AUTOSTART*
18 Socket connector for bipolar instruments with foot switch, finger switch or AUTOSTART*

Bipolar connection sockets

Upper bipolar socket:

19 2-pin US type (28.58 mm)
20 1 x Erbe VIO/ICC

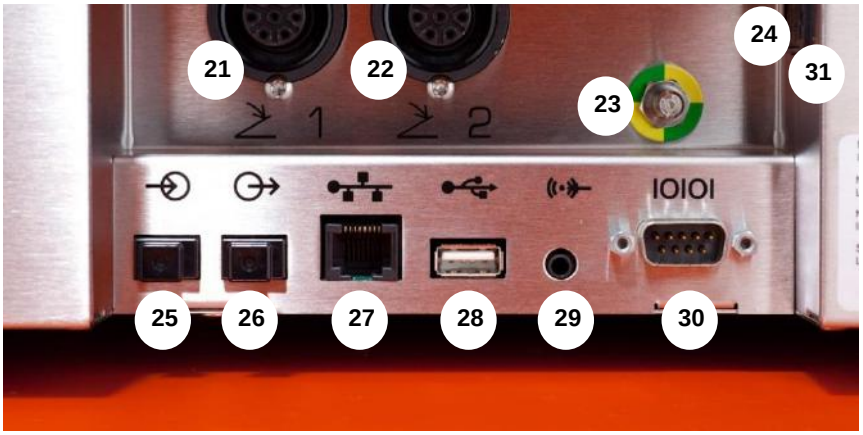
Lower bipolar socket:



19 2-pin US type (28.58 mm)
20 2 x Erbe VIO/ICC

* Applied part type CF according to IEC 60601-1

3.1.4. Rear panel user interface components



21 Foot switch socket connector 1
22 Foot switch socket connector 2
23 Equipotential bonding terminal
24 IEC power cord connector
25 Fiber-optic signal input socket connector
26 Fiber-optic signal output socket connector
27 Ethernet connector
31 Power switch

Use the following connections only for service and training purposes:
28 USB connector
29 Audio In (not occupied)
30 UART communication interface

The USB connector can be used to perform software updates.

The maximum voltage at the SIP/SOP ports is 15 V_{DC}.

3.2. Symbols used on the device

Symbol	Designation
	Foot switch connector
	Neutral electrode isolated from ground for HF
	Defibrillation-proof type CF applied part
	Alternating current
	"ON" / "OFF" (push-push)
	During activation (of the HF device) RF energy in the radio frequency range 9 kHz to 400 GHz is applied, which produces electromagnetic radiation.
	Labeling of electrical and electronic devices in accordance with Directive 2002/96/EC (WEEE); see "Disposal"
	(Active) HF output; caution: hazardous voltage
	Caution!
	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner. Only for the attending physician.
	Manufacturer
	Date of manufacture
	Observe use instructions
	Equipotentiality
	Fiber-optic signal input
	Fiber-optic signal output
	Ethernet connector
	USB connector
	Audio In
IOIOI	UART communication interface
REF	Catalogue number
SN	Serial number
CE	CE-marking with number of notified body Product conforms with the essential requirements in the European Medical Devices Directive 93/42/EEC.
IP 21	Protection Class

3.2.1. Nameplate

Depending on the destination country (intended sales destination) or the specific purchase order, the ARC 400 (REF 900-400) is configured for the corresponding necessary voltage range and delivered with the associated nameplate.

Mains voltage 220 – 240 V~

Figure 3-1: Nameplate ARC 400 for 220 – 240 V~

Mains voltage 100 – 127 V~

Figure 3-2: Nameplate ARC 400 for 100 – 127 V~

3.3. Scope of delivery

You'll find detailed information on the scope of delivery in the current catalogues.

3.4. Components required for operation

- Power cable
- Foot switch
- Neutral electrode for monopolar applications
- Connection cable for neutral electrode or instrument
- Instrument (monopolar or bipolar)
- Dr. Dongle as an individual memory stick

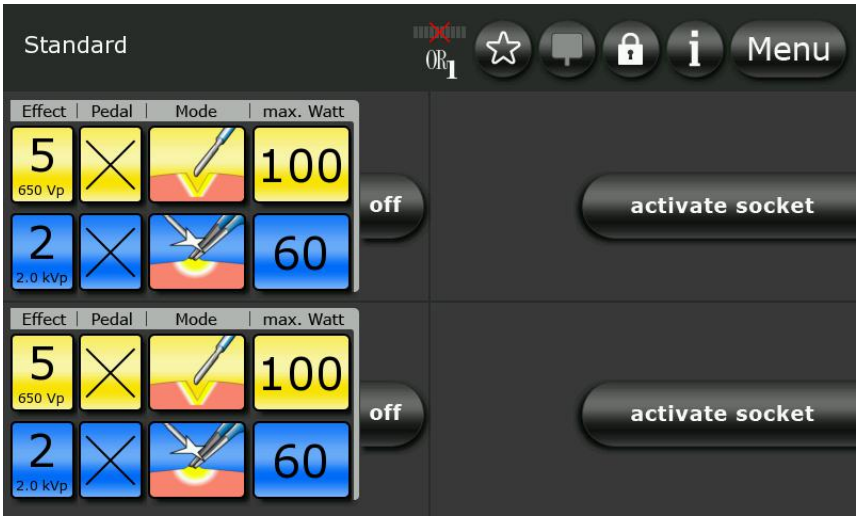
3.4.1. OR1 Storz

When you couple the HF device to an OR system:

▶ Correct coupling of the OR system and the HF device can be checked with the “sign of life” (status icon).

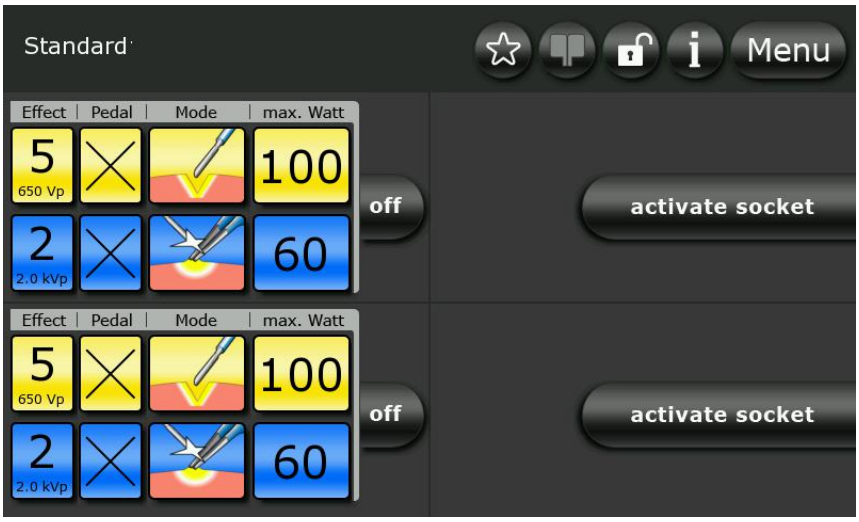
The following states are signalled:

1. On the ARC 400 the connection to OR1 is enabled. There is no connection to the OR system.



2. On the ARC 400 the connection to OR1 is enabled. There is a correct connection to the OR system. The device can be adjusted from the OR system. The white bar sweeps cyclically from left to right.

3. On the ARC 400 the connection to OR1 is not enabled. In this case the sign-of-life icon (status icon) is not displayed.



The following points should be observed when integrating the ARC400 into the Karl Storz OR1 system:

- Use the BOWA network cable (ref 900-045).
- Network cable CAT 5e F/UTP or better; maximum total length 100 m
- OR1 ControlNEO Release 200900 01-46 or later
- BOWA ARC 400 Version 2.1.0 or later
- Only one BOWA ARC 400 can be connected to an OR1. Connection of a second BOWA ARC 400 at the same time is not supported.

Use the network port of the BOWA ARC 400 and the network cable for the connection. Unlike other devices integrated into the OR1 system, there is no SCB connection.
The system operator is responsible for compliance with the applicable EMC requirements for the overall system.

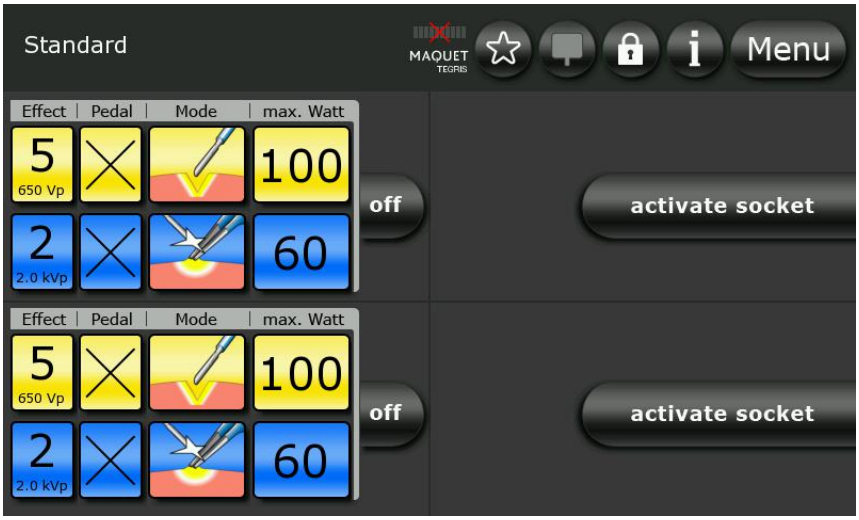
3.4.2. MAQUET TEGRIS:

When you couple the HF device to an OR system:

▶ Correct coupling of the OR system and the HF device can be checked with the “sign of life”(status icon).

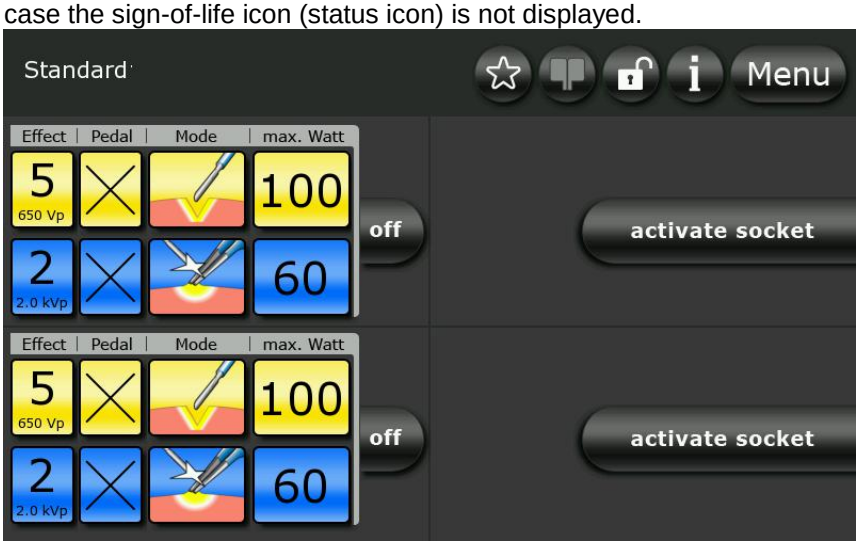
The following states are signaled:

1. On the ARC 400 the connection to TEGRIS is enabled. There is no connection to the OR system.



2. On the ARC 400 the connection to TEGRIS is enabled. There is a correct connection to the OR system. The device can be adjusted from the OR system. The white bar sweeps cyclically from left to right.

3. On the ARC 400 the connection to TEGRIS is not enabled. In this case the sign-of-life icon (status icon) is not displayed.



The following points should be observed when integrating the ARC400 into the MAQUET TEGRIS system:

- Use the BOWA network cable (ref 900-045).
- Network cable CAT 5e F/UTP or better; maximum total length 100 m
- BOWA ARC 400 Version 2.1.0 or later
- To activate support for the BOWA ARC 400 by your Maquet TEGRIS system, please contact your Maquet dealer.

Use the network port 27 of the BOWA ARC 400 and the network cable for the connection.
The system operator is responsible for compliance with the applicable EMC requirements for the overall system.

3.5. Operating conditions

Temperature:	+10 °C to +40 °C
Relative humidity:	30 to 75%, non-condensing
Atmospheric pressure:	700 to 1060 hPa
Operating altitude (max.)	3000 m above sea level

3.6. The basis of modern HF surgery

Depending on its nature, value and frequency, the action of electrical current on tissue may be described as electrolytic (destructive), faradic (stimulating muscles and nerves) or thermal. HF surgery is based on alternating currents with a frequency of at least 200 kHz, with the thermal effect dominating. Its effect is primarily dependent on the time for which the tissue is exposed to the current, the current density and the specific resistance of the tissue, which on the whole falls with increasing water content or increasing blood circulation. In practice, it is also necessary to consider that portion of current which flows past the target tissue and can heat up and damage other regions (such as during irrigation, seen more with monopolar techniques than with bipolar ones).

Monopolar Method

Monopolar HF surgery deploys a closed current circuit in which current flows from the active electrode of the instrument through the patient to a neutral electrode with a large surface area and then back to the generator.

The contact area between the tip of the monopolar instrument and the tissue is small so that the highest current density of the current circuit is seen here, and brings about the desired thermal action.

Localized heat build-up is reduced to a minimum through the large surface area and the special design of the neutral electrode.

Bipolar Method

With bipolar HF surgery two active electrodes are integrated into the instrument and current flow is restricted to the tissue between the two electrodes rather than the entire body of the patient.

No neutral electrode is therefore required.

4. Prearrangement

4.1. Setting up the HF device

NOTE

Electromagnetic fields are generated during normal use of the HF device. This can adversely affect other devices.

▶ Ensure that no electronic devices are placed in the vicinity of the HF device.

WARNING

Shock hazard

▶ Always connect the HF device to a grounded power distribution system in order to prevent electric shock.

DANGER

Risk of burns to patients due to excessive leakage current

▶ Locate the HF device outside the immediate vicinity of the patient, see section Ambient conditions, page 13.

HF devices may be used only in rooms used for medical purposes that meet the requirements of DIN VDE 0100-710.

If the HF device was previously stored or transported at temperatures below +10 °C or a relative humidity above 75%, non-condensing, it will take approximately three hours to adjust to room temperature.

1. Observe the specified operating conditions (see Section Operating conditions, page 28).
2. Place the HF device on one of the following platforms:
   - a table;
   - an equipment trolley;
   - a console suspended from a ceiling support or wall-mounted brackets.
3. Place the HF device a sufficient distance away from other electronic equipment, see Section EMC, page 161.
4. Position the HF device with the front of the device facing the patient and surgeon.
5. Do not place any other devices on the HF device.

6. Do not place any other objects on or above the HF device.
7. Place the HF device on top of ARC PLUS only, do not place it on other devices.
8. Connect the power cord.

4.2. Switching on the HF device

Do not use the HF device if the display components are not working. See Section Detecting and correcting faults, page 101 for troubleshooting instructions.

☑ The line voltage must match the voltage specified on the nameplate.

Connect the power cord to the generator and plug the cord into a grounded AC power outlet.

1. Switch the HF device on using the power switch **31** on the rear side of the unit and touch the On/Off button on the front panel.

- The HF unit performs a self-test: All user interface components light up.
- The bars of the activation display light up, while the connector surrounds light up orange.
- Full functionality of the loudspeaker is indicated by the start melody.
- The individually configurable start screen appears if it has been set up.

2. Check all controls and indicators for proper operation:
   - Touchscreen
   - Activation bar for monopolar and bipolar sockets

- The main screen appears, and the HF device is ready for use.
- The parameters of the most recently selected program appear on the display.

NOTE

Standby mode

The standby mode of the HF device is described as follows:
The power switch 31 on the rear panel of the HF device is switched on and the front-panel On/Off button 1 is switched on, with the on/off button 1 illuminated orange. The display is on the main screen.

4.3. Connecting instruments

Before connecting instruments, ensure that the following conditions are met:

- Combinations of accessories not mentioned in the operating manual may be used only if they are explicitly designed for the intended use. Always observe performance characteristics and safety requirements.
- The insulation of the accessories (e.g. HF cables and instruments) must be sufficient for the maximum peak output voltage.
- Do not use accessories with defective insulation.

4.3.1. Instruments for monopolar use

1. Plug the neutral electrode cable into the socket for the neutral electrode and choose the corresponding neutral electrode type, see chapter Selecting the neutral electrode, page 48.

↳ The socket illumination goes dark.

↳ The neutral electrode button changes from grey to the measurement colour (green, yellow or red).

2. Connect the electrode handle to one of the two monopolar socket connectors.
   – or –
   In the case of an accessory without a finger button, connect a footswitch to the socket connector. Connect the Bovie connector of the monopolar cable to the socket connector.
   – or –
   Connect the monopolar cable for endoscopy to one of the two monopolar socket connectors for monopolar instruments.

4.3.2. Instruments for bipolar applications

1. Connect the bipolar cable to the instrument (e.g. forceps).
2. Connect the bipolar cable to one of the two bipolar socket connectors.
3. For bipolar use without AUTOSTART, connect a footswitch to the socket connector.
   – or –
   Use the AUTOSTART mode for the appropriate socket connector.

↳ Once the instrument is connected, the application starts after the configured delay time.

4.3.3. Connecting a foot switch

In addition to the manual switch, a foot switch can be used to activate various operating modes.

Connect the desired foot switch only during operation to one of the two socket connectors for foot switches.

↳ The HF device automatically detects the connected foot switch and indicates this on the front panel display, including the selected socket connector.

One double-pedal foot switch and one single pedal foot switch can be connected. Foot switches without an orange changeover switch cannot be used.
During the operation, the ARC PLUS may only be connected to the foot switch and if necessary to an OP system (see Section 3.4.1/3.4.2) by fibre-optic cables plugged in at the rear of the device.

The following foot switch systems can be connected to the HF device:

Item no.	Designation
901-011	Single-pedal foot switch with switch
901-031	Double-pedal foot switch with switch
901-032	Double-pedal foot switch with switch and clip

4.4. Functional test

4.4.1. Auto test function

The HF device automatically performs cyclic testing during operation. If any faults occur, see Section “Detecting and correcting faults”, page 101.

4.4.2. Functional testing

Perform the following functional test before putting the device into service:

The accessories must be designed for the specified maximum voltage.

1. Connect the neutral electrode and attach it securely to the patient’s arm.

↳ The EASY neutral electrode indicator changes to green.

2. Remove the neutral electrode.

↳ The indicator changes to red, acoustic signals sound.

The neutral electrode used for this test may not later be used for an operation.

3. Connect a monopolar HF handle to a monopolar socket connector if there is a green EASY indicator and use the manual switch and footswitch to individually activate "Cut" and "Coag".
4. Check the settings on the display.
5. Now change to the bipolar output and connect bipolar forceps.
6. Select a mode with AUTOSTART, grasp moist gauze with the forceps, and check the display.
7. Change to a mode without AUTOSTART and activate the bipolar output using the foot switch. Pay attention to the settings and displays in the bipolar section.

4.4.3. Actions in case of problems

In the case of operating errors, follow the steps below:

1. Immediately disconnect the patient from the HF device.
2. Inspect the HF device and perform a functional test.
3. Report incidents and near-accidents to the German Federal Institute for Medications and Medical Products in accordance with Section 3 of the German Ordinance on the Installation, Operation and Use of Medical Products (MPBetreibV). Observe the provisions of the in-house reporting system in this regard.
4. Consult the Technical Service department, see Section Technical service, page 111.

In an emergency, the HF device can be switched off at any time by the power switch 31, which fully disconnects the device from the mains. An error in the HF device can result in an unintentional increase in the output power.

4.5. Neutral electrode monitoring

Always use the largest possible electrode when attaching a neutral electrode.

4.5.1. General information

BOWA recommends using split neutral electrodes, since only this type of electrode allows the HF device to detect detachment of the neutral electrode if this occurs.

Monitoring of the neutral electrode minimizes the risk of burns at the site where the neutral electrode is attached.

Two types of neutral electrodes can be monitored:

- Split electrodes for infants (for use with reduced power)
- Split neutral electrodes

The type of neutral electrode and its contact quality are selected and/or shown in Neutral Electrode Modes menu.

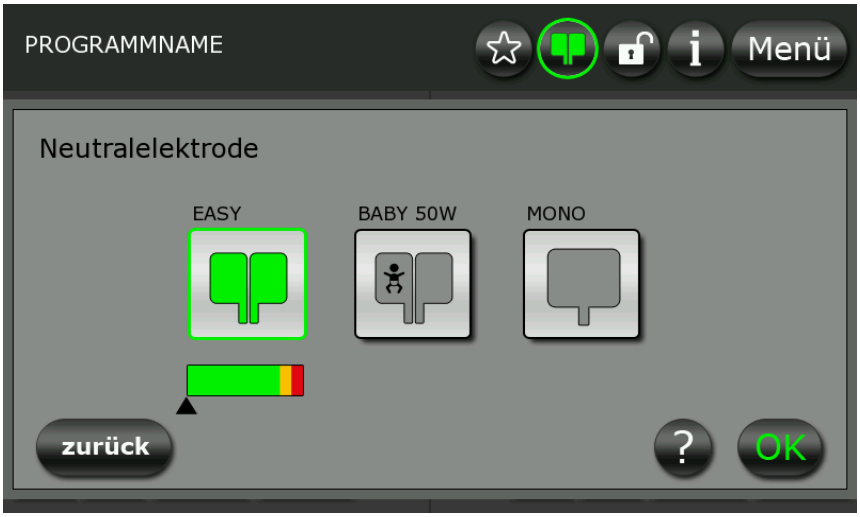


Figure 4-1: Neutral electrode modes

Faults related to the neutral electrode and possible remedies are shown on the display, see Section “Detecting and correcting faults”, page 101.

4.5.2. EASY neutral electrode monitoring (EASY monitoring)

The maximum output power of monopolar current types is reduced to 50 W when a children’s electrode is selected.

The EASY monitoring function measures changes in the resistance between the patient and the high-frequency surgery device before and during HF activation. If necessary, it generates visual and audible alarms to request staff intervention. This requires using a split neutral electrode with appropriate contact areas and suitable contact resistance, attached to the patient according to the manufacturer’s instructions. The EASY system does not monitor the currents through the individual contact surfaces of the split neutral electrode.

A BOWA electrode with a surface area of at least 90 cm² must be used for the "Resection" programs and the "Moderate Coagulation" mode.

If an error message is generated, the display changes from green via yellow to red, depending on the type of fault.

NOTE

Risk of incorrect application of the neutral electrode!

- ▶ Ensure compliance with the specifications for correct attachment of the neutral electrode with regard to size, adhesive properties and full-surface contact of the complete electrode.

4.6. Turning the device off

Press the On/Off button (1) to switch off the device. Also switch off the power switch (31) on the rear panel (mains disconnection).

NOTE

Switching off the device with the front panel On/Off button (Suspend Mode)

- After the medical device has been switched off and on by the On/Off button 1 on the front panel, the last (most recently) saved parameters (defined settings) are reloaded.
- In an emergency, an enabled output can be disabled at any time by switching off the On/Off button 1 on the front panel.

NOTE

Switching off the device with the power switch on the rear panel (power interruption longer than 15 seconds)

- After a supply voltage interruption longer than 15 seconds, the parameter settings for the currently selected program that were last saved in non-volatile memory are reloaded.

NOTE

Brief power interruption shorter than 15 seconds

- After a supply voltage interruption shorter than 15 seconds, the parameter settings for the currently selected program that were last saved in volatile memory are reloaded.

5. Operation

5.1. Program overview

5.1.1. Display

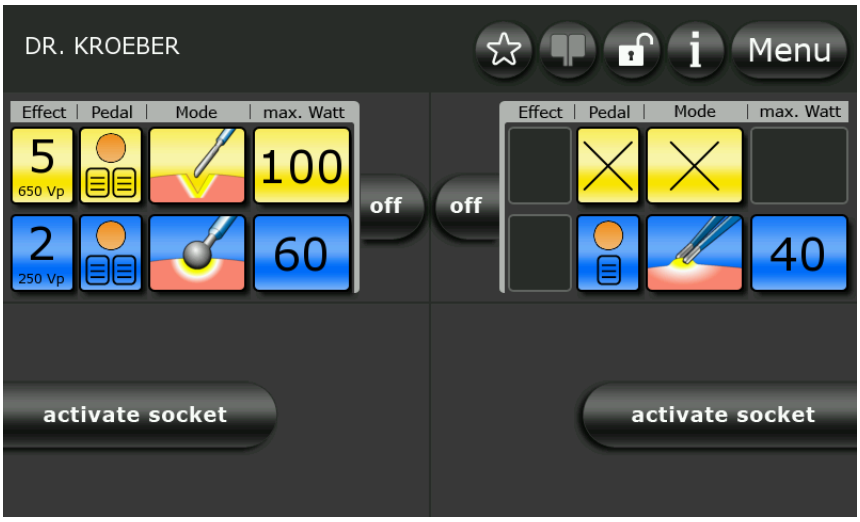


Figure 5-1: Main screen

The status bar is located at the top of the display.

The settings of the four socket connectors are shown below the status bar.

Settings can be configured for each of the connectors.

The "Effect" button is used to set the effect of electrosurgical cutting.

The "Pedal" button allows the activation of specific functions to be assigned to the foot pedal.

The "Mode" button allows the desired type of current to be selected.

The "max. Watt" button is used to set the maximum output power.

5.1.2. Status bar

Figure 5-2: Status bar with Favourite

Five buttons are located on the status bar: "Favourite", "EASY", „Keylock“, "Help" and "Menu".

The “Argon” button is also displayed in conjunction with ARC PLUS and selection of an Argon mode.

Figure 5-3: Status bar with Argon

5.2. Activating and deactivating connectors

Figure 5-4: Deactivated socket

▶ To activate a deactivated socket connector, plug a connecting cable into the connector.
– or –
Press the "activate socket" button.

↳ An overview of the connector settings appears.

Figure 5-5: Unused socket

The overview is greyed out if no instrument is connected to the socket connector.

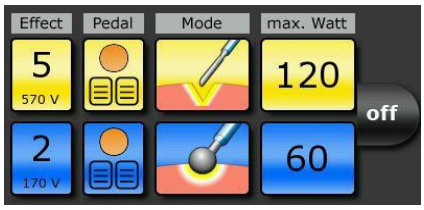


Figure 5-6: Activated socket

The socket illumination extinguishes and connector lights up when an instrument is plugged in.

▶ To hide the selection, press the "off" button next to the connector settings overview.

The socket cannot be hidden when an instrument is plugged in.

5.3. Unlocking the screen

The device screen is locked automatically. To unlock it, press any key and then drag the slider from left to right. An open padlock icon will appear on the status bar.

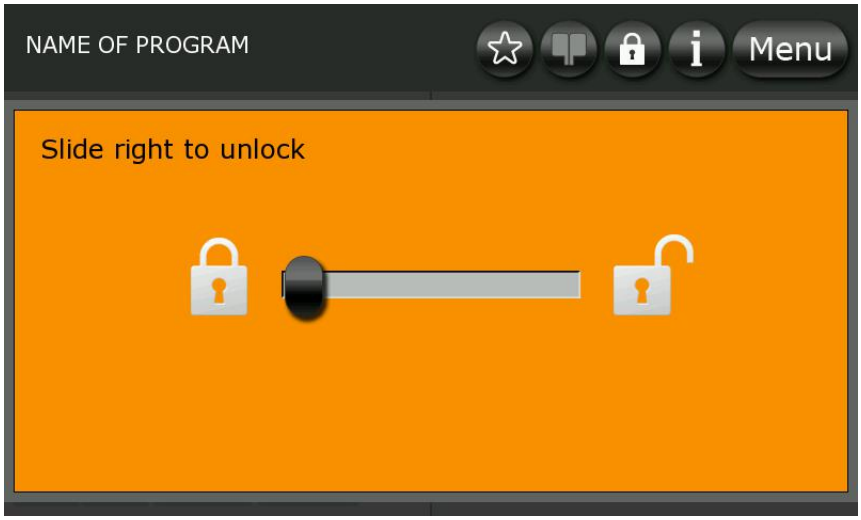


Bild 5-7: Unlocking the screen

You can disable key locking or change the time delay for automatic screen locking; see Section Menu "System Settings" dialog", page 82.

5.4. Configuring output currents

ℹ	All selection windows are closed 10 seconds after the last screen touch.
ℹ	If selection windows are open, all screen areas outside this area have the same effect as the “Back” button. Activations also have the same effect as the “Back” button.
ℹ	A change to the currently loaded program, e.g. by adjusting the output, is indicated by the information “changed” below the program name.

5.4.1. Selecting the mode

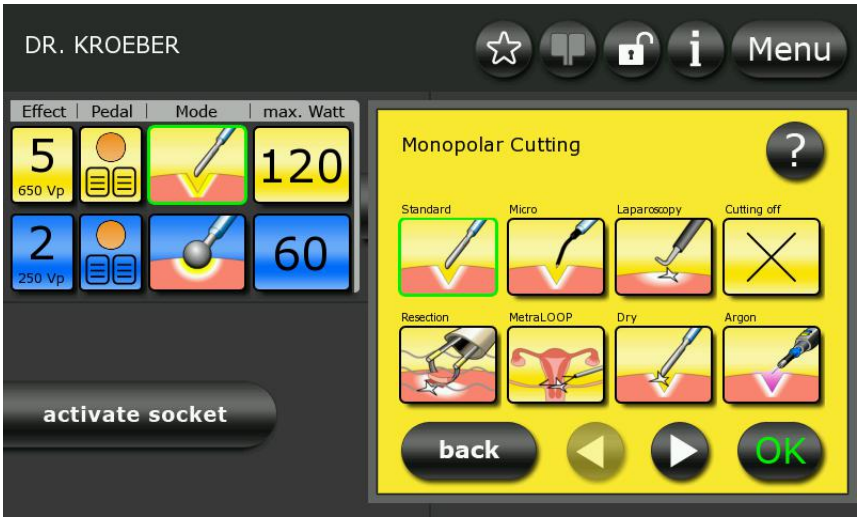


Figure 5-8: Modes monopolar cutting

1. To select the type of current for monopolar cutting, first select one of the two socket connectors on the left side.
2. Press the yellow icon under the "Mode" button.

↳ A selection screen appears for the available modes, and the rim of the associated connector starts blinking.

3. Select the desired mode by pressing the corresponding button.
   - or -
   Deactivate the mode by pressing the button “mode off”.
4. Press the "?" button for more information on this selection.
5. Additional options in the selection window can be accessed with the arrow keys..
6. Confirm your selection by pressing the "OK" button.

↳ The main screen will be displayed.
- or -

Press the "Back" button to return to the main screen without changing the selection.

If a mode is changed within a socket, the set parameters, e.g. effect and max. Watt, remain the same for the respective mode. However, if, for example, the factory default setting of a mode is adapted and subsequently changed to a different mode and then back again, the user changes are not undone.

5.4.2. Specifying power limits

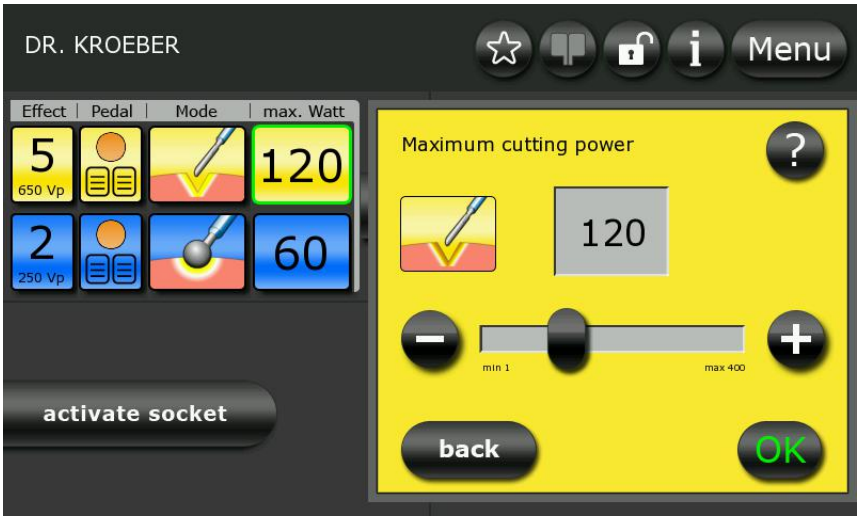


Figure 5-9: Maximum power monopolar cutting

1. To select the maximum current for monopolar cutting, first select one of the two socket connectors on the left side and press the yellow icon under the “max. Watt” button.
2. Use the "+" and "-" buttons to adjust the power level in single steps.
   – or –
   Use the slider to set the power level in steps of 10.
3. Press the "?" button for more information on this selection.
4. Confirm your selection by pressing the "OK" button.

   - or -
   Press the "Back" button to return to the main screen without changing the selection.

5.4.3. Selecting the effect

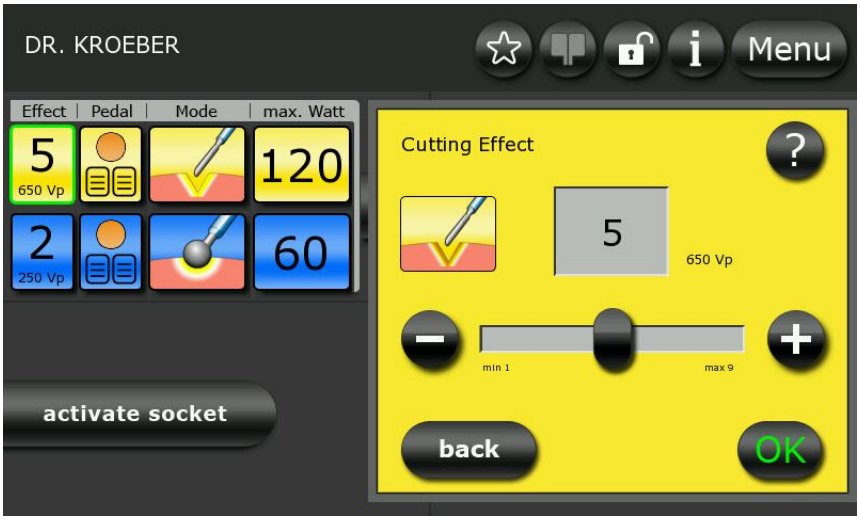


Figure 5-10: Effect monopolar cutting

1. To select the effect for monopolar cutting, first select one of the two socket connectors on the left side and press the yellow icon under the “Effect” button.
2. Use the "+" and "-" buttons to adjust the effect in individual steps.
   – or –
   Use the slider to set the effect.
3. Press the "?" button for more information on this selection.
4. Confirm your selection by pressing the "OK" button.
   - or -
   Press the "back" button to return to the main screen without changing the selection.

5.4.4. Assigning the foot pedal

Handles and instruments with manual switches can be activated without a configuration setting.

A single-pedal foot switch and/or double-pedal foot switch, each with a changeover switch, can be connected,

The changeover switch enables switching between pedal levels.

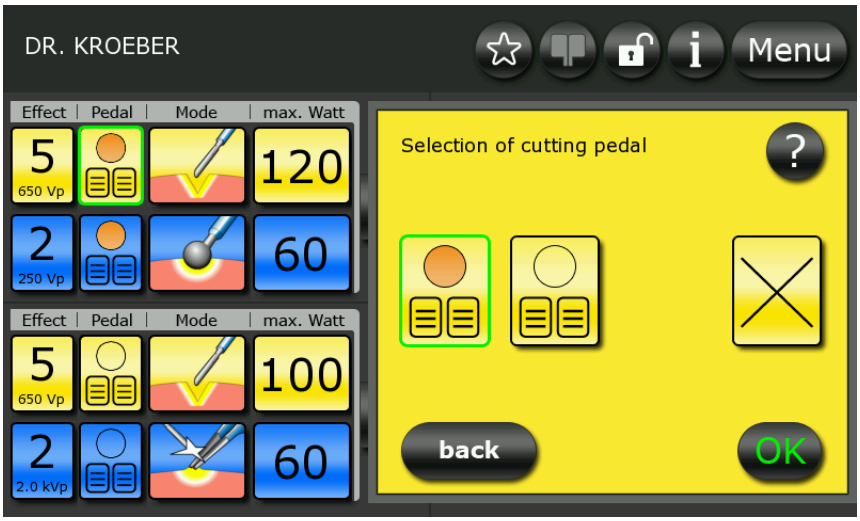


Figure 5-11: Foot switch selection cutting

1. Select the footswitch menu by pressing the button “Pedal”.
2. Select the desired foot switch by pressing the corresponding button.
   For example, choose the active pedal level for cutting and coagulation of the upper left socket.
   - or -
   Deactivate the foot switch by pressing the button marked with a „x“.

↳ The edge of the selected button lights up green.

3. Confirm the selection by pressing the "OK" button.
   - or -
   Press the "Back" button to return to the main screen without changing the selection.

↳ The socket is assigned to the active pedal level.

4. Pedal levels can be changed using the foot switches. Press the orange button to change the socket.

↳ The orange background indicates that the lower left-hand socket is activated.

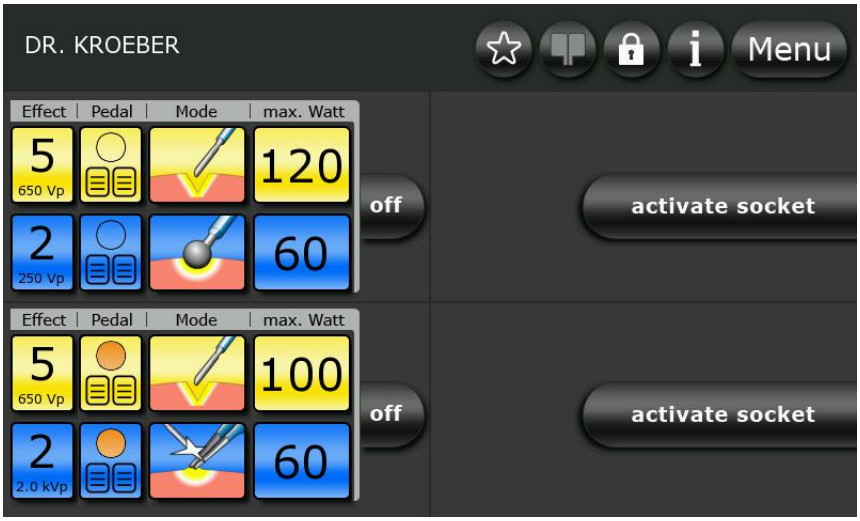


Figure 5-12: Foot switch changeover

If two footswitches are connected, either a single-pedal footswitch or a double-pedal footswitch can be selected for coagulation.

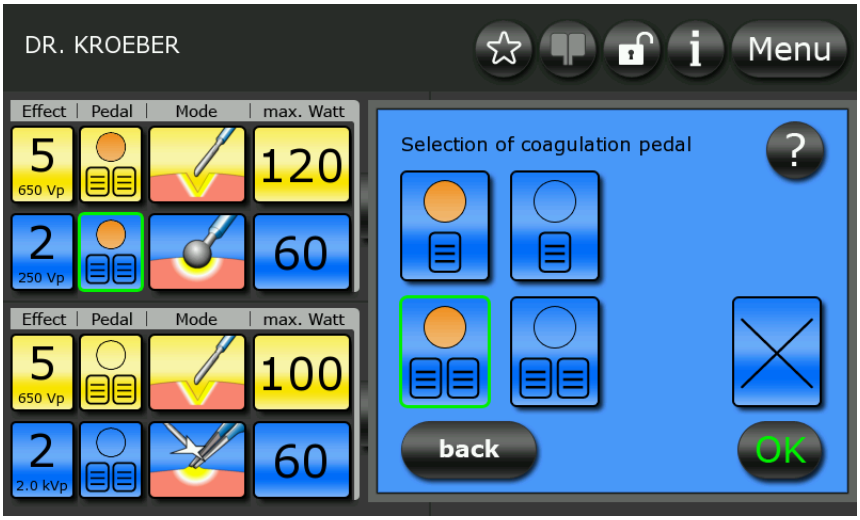
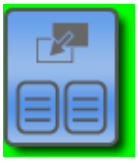


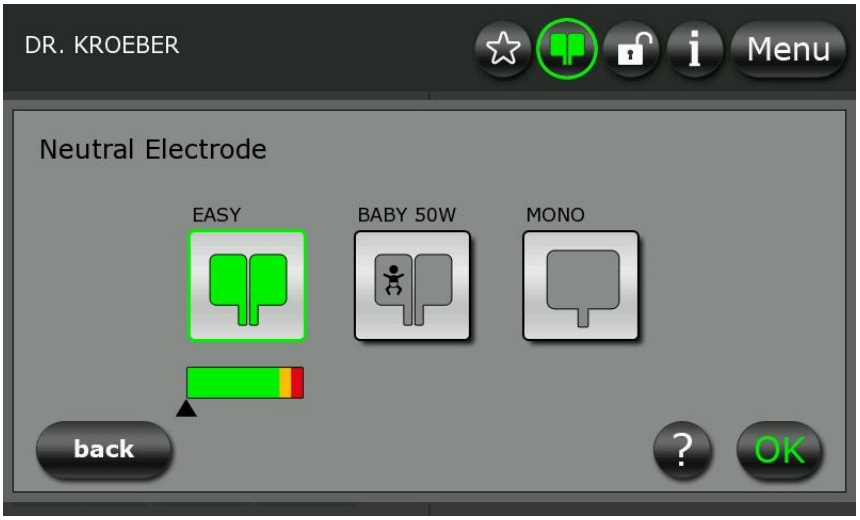
Figure 5-13: Foot switch selection coagulation

The following pedal icons can be differed:

Icon / Button	Description	Icon / Button	Description	Icon / Button	Description
	Double pedal foot switch CUT active		Double pedal foot switch CUT active not connected		Double pedal foot switch CUT inactive
	Double pedal foot switch not connected		Deactivate foot switch CUT		Deactivate foot switch COAG
	Double pedal foot switch COAG active		Double pedal foot switch COAG active not connected		Double pedal foot switch COAG inactive
	Double pedal foot switch not connected		Single pedal foot switch not connected		Single pedal foot switch COAG inactive
	Single pedal foot switch COAG active		Single pedal foot switch COAG active not connected		
	Double pedal ZAP Mode COAG active		Double pedal ZAP Mode COAG inactive		Single pedal ZAP Mode COAG active
	Single pedal ZAP Mode COAG inactive		Double pedal ZAP Mode CUT active		Double pedal ZAP Mode CUT inactive

5.4.5. Selecting the neutral electrode

1. Press the "EASY" button on the status bar to select the neutral



electrode.

Figure 5-14: Neutral electrode

The maximum power output of monopolar current types is reduced to 50 W when a children's electrode is selected.

2. Select the type of connected electrode by pressing the corresponding icon:
   EASY: for monitoring split neutral electrodes
   BABY: for monitoring split neutral electrodes for infants
   MONO: to select a one-piece neutral electrode
3. Press the "?" button for more information on this selection.
4. Confirm your selection by pressing the "OK" button.
   - or -
   Press the "Back" button to return to the main screen without changing the selection.

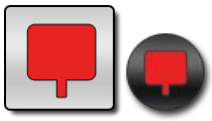
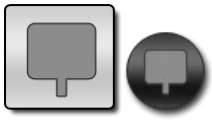
↳ The selected type of neutral electrode in connection with a colour-indicator for the contact quality is shown in the status bar.

When using the „EASY“ and „BABY“ mode, no unsplit electrodes are accepted.

Using the „MONO“ mode, no split electrodes are accepted.

The “Monopolar Resection” and “Metraloop” programs are not allowed when the Baby electrode is selected.

According to the contact quality, several icons are shown for neutral electrodes:

Icon / Button	Description	Icon / Button	Description
	Split neutral electrode contact quality OK		Non split neutral electrode contact quality OK
	Split neutral electrode contact quality not optimum		Non split neutral electrode not detected or contact quality insufficient
	Split neutral electrode contact quality insufficient		Non split neutral electrode not connected / recognised
	Split neutral electrode not connected / recognised		Display contact quality
	Split baby neutral electrode contact quality OK		
	Split baby neutral electrode contact quality not optimum		
	Split baby neutral electrode contact quality insufficient		
	Split baby neutral electrode not connected / recognised		

5.4.6. Dr. Dongle®

Dr. Dongle is an individual memory stick on which up to six programs can be saved for subsequent use.

▶ Insert your Dr. Dongle with your personal settings into every ARC 400 at any **bipolar socket**.

↳ The data is read as soon as you insert Dr. Dongle or after changing a program with Dr. Dongle inserted:

Figure 5-15: COMFORT function detected

↳ After a short loading period, an overview of the saved programs appears automatically as a new user interface.

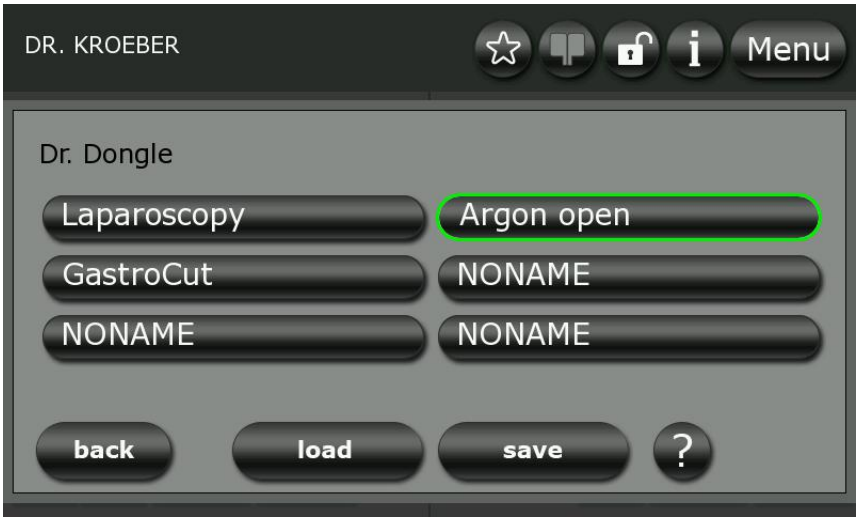


Figure 5-16: Dr. Dongle program selection

Save current program on Dr. Dongle:

The program currently loaded in ARC 400 can be saved on Dr. Dongle:

1. In the overview, select a program storage space to be overwritten.
2. Press “save” to save the currently loaded program at the selected space.
3. A keyboard appears which can be used to enter a name for the program.

↳ The program is now saved on Dr. Dongle.

4. Press the "back" button to return to the main screen.

▶ Dr. Dongle can now be removed

If the Dr. Dongle is plugged in, the Dr. Dongle screen is displayed after you touch the program name, “Program” or “Save program”.

Load a program from Dr. Dongle:

A program saved on Dr. Dongle can be loaded onto any ARC 400:

1. Select a program saved on Dr. Dongle from the overview by touching the program name.
2. “Load” is used to load the selected program.

– or –
Press “Back” to return to the main screen
without changing the selection.

↳ The selected program is now active on the main screen of the ARC 400.

▶ Dr. Dongle can now be removed again

– or –
If required, save the loaded program in the program list, see section Menu “Save Program”, page 88.

5.4.7. Plug’n Cut COMFORT

The automatic instrument identification Plug’n Cut COMFORT recognises the connected BOWA COMFORT instrument and selects the default parameters automatically.

1. Insert the COMFORT instrument into a socket of ARC 400.

↳ The instrument data is read

Figure 5-17: Plug’n Cut COMFORT

↳ A description of the instrument appears:

- Instrument name
- Recognised socket
- Item number
- Lot number
- Remaining use cycles with reusable instruments. Remaining use cycles are not displayed with disposable instruments.

↳ The parameters are accepted automatically after 5s and shown on the main screen.

- If the COMFORT instrument is connected to a socket **without preset parameters**, the ideal settings for the BOWA COMFORT instrument are loaded via Plug’n Cut COMFORT.
- If the COMFORT instrument is connected to a socket **with preset parameters**, a plausibility check is carried out. The preset values for the COMFORT instrument are not overwritten if they are within a permissible range. The COMFORT instrument can now be used with the preset parameters.

- or-

Press "OK" to accept the selection.
Press "back" to return to the main screen without carrying changes to the selection.

↳ The COMFORT instrument can now be used.

↳ The permissible parameters for the BOWA COMFORT instrument remain accessible; all other modes are greyed out.

5.4.8. Playing videos

1. Plug the delivered BOWA USB stick into the connection on the rear side of the ARC 400.
2. To play the video, press the “Play” button in the operating manual dialog.

Figure 5-18: Operating manual dialog

3. To stop the video, switch off the device.

The device restarts normally.

5.4.9. Configuring the startup screen

ARC 400 offers the possibility to display a personalized start screen. This start screen appears after each switching on of the unit for a configurable period of time.

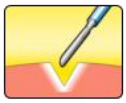
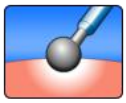
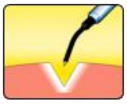
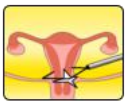
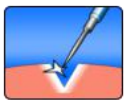
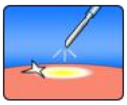
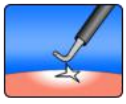
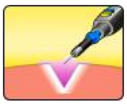
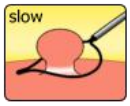
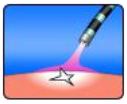
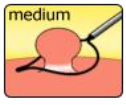
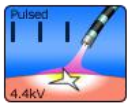
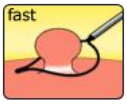
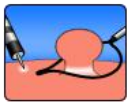
1. Create a folder with the name "arc_logo" on the USB flash drive (REF 900-402).
2. Open the Windows program " Notepad.exe " and enter a number between 5 and 60 for the displayed duration in seconds.
3. Save this file on the USB flash drive in the folder "arc_logo" under the name "KH_Logo.conf". Make sure that the file is stored as type "All Files (*. *)" and encoding "UTF -8".
4. Create a startup screen with a resolution of 800 x 480 pixels and save it under the name "KH_Logo_arc400.png" in the folder "arc_logo".
5. Plug the USB flash drive with the files created in the USB port of the ARC 400 and turn the unit on using the main switch.
   Make sure that there are no other data on the USB flash drive.
6. Wait until the ARC 400 is fully booted and the user interface appears.
7. To configure the start screen, select Service Level 1 under Menu / Service (see section 5.10.4).
8. Press the “Add Logo” button to add the start screen.
9. Switch the ARC 400 off and then on to check correct acceptance.

↳ Now your generated startup screen is permanently stored in the device and appears after every switching-on for the specified duration.

5.5. Mode overview

An overview of the programs that can be executed with the HF device is shown below.

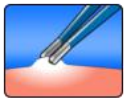
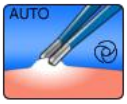
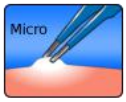
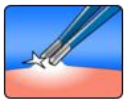
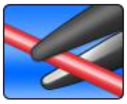
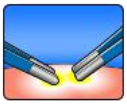
5.5.1. Monopolar modes

Cutting mode icon	Designation	Coagulation mode icon	Designation
	Standard		Moderate
	Micro		Forced non cutting
	Dry		Forced mixed
	MetraLOOP		Forced cutting
	Resection		Spray
	Laparoscopy		Laparoscopy
	Argon*		Argon*
	GastroLOOP 1		Argon flexible*
	GastroLOOP 2		Argon flex. pulse*
	GastroLOOP 3		Gastro Coag

* These modes can only be used in connection with the argon coagulation unit ARC PLUS (900-001).

Cutting mode icon	Designation	Coagulation mode icon	Designation
	GastroKNIFE 1		Resection
	GastroKNIFE 2		Cardiac Mammary
	GastroKNIFE 3		Cardiac Thorax
			SimCoag

5.5.2. Bipolar modes

Cutting mode icon	Designation	Coagulation mode icon	Designation
	Standard		Standard forceps
	Bipolar resection [R]		Standard forceps AUTO
	Bipolar scissors		Micro forceps
	Vaporisation [R]		Forceps forced
			LIGATION [L]
			TissueSeal PLUS [L]
			ARCSeal [L]
			Bipolar scissors
			Laparoscopy
			Micro laparoscopy
			Bipolar resection [R]
			SimCoag [S]

Cutting mode icon	Designation	Coagulation mode icon	Designation
			Vaporisation [R]

[R] These modes are available with the option Bipolar Resection (900-395).

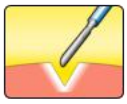
[L] These modes are available with the option LIGATION (900-396).

[S] This mode is available with the option Bipolar SimCoag (900-399).

The information and data regarding settings, application points, application duration and instrument use are based on clinical practice. However, these are only basic guidelines which must be tested for suitability by the operator. Depending on individual conditions, it may be necessary to deviate from the provided data.
Medical practice is continuously evolving as a result of R&D and clinical experience. This may also make deviations from the provided data necessary.

5.6. Monopolar cutting modes

5.6.1. Standard



In this mode a high-performance HF current with a low crest factor is used for cutting biological tissue. ARC CONTROL quickly adjusts the power output to the minimum required level in response to variations in tissue type and changes in the cutting area or speed.

Application areas

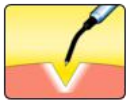
Cutting tissue with low electrical resistance, such as muscle tissue or vascular tissue.

Cutting or preparing fine structures

Suitable instruments

- Needle electrodes
- Knife electrodes
- Spatula electrodes
- Sling electrodes

5.6.2. Micro



This mode is used for electrosurgical cutting using micro-electrodes. It enables extremely fine control of the power level and precise work.

Application areas

Pediatric surgery, neurosurgery, plastic surgery

Suitable instruments

- Micro needle electrodes

5.6.3. Dry

This mode is used for monopolar dry cutting. A large, controlled arc is generated, which allows significantly deeper coagulation to be obtained.

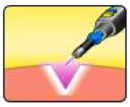
Application areas

Cardiac surgery and blood coagulation in retracting blood vessels in the sternum region.

Suitable instruments

- Knife electrodes

5.6.4. Argon



This mode is used to perform open surgical interventions in combination with the ARC PLUS companion device for argon-assisted cutting. With suitable instruments connected, argon-assisted cutting can be performed using rigid electrodes.

Application areas

Visceral surgery

Suitable instruments

- Rigid argon electrodes
- Argon handle

5.6.5. Resection

This mode is used in gynecology and urology. ARC control generates the cutting effect with simultaneously minimized output power. ARC control facilitates direct cutting and prevents electrode adhesion.

Use non-conductive irrigation fluids.

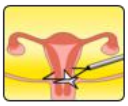
Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP).

Suitable instruments

- Resectoscope (monopolar)
- Resection sling
- Rollerblade electrode

5.6.6. MetraLOOP



This mode is used in gynecology for laparoscopic hysterectomy. Removal of the uterus can be achieved by applying monopolar cutting current and pulling on the sling at the same time.

Application areas

Gynecology; laparoscopic hysterectomy

Suitable instruments

- Gynecological slings

5.6.7. Laparoscopy

This mode is used in laparoscopy and arthroscopy for monopolar cutting.

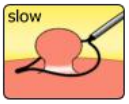
Application areas

Laparoscopy, arthroscopy

Suitable instruments

- Arthroscopy electrodes
- Laparoscopy electrodes

5.6.8. GastroLOOP 1



This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a relatively slow pulse rate of 1 cutting pulse per second, this mode is suitable for especially cautious work.

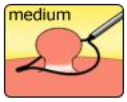
Application areas

Polyp removal using polypectomy snares and flexible endoscopy

Suitable instruments

- Polypectomy snares

5.6.9. GastroLOOP 2



This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With an accelerated pulse rate of 1.5 cutting pulses per second, this mode is suitable for experienced users.

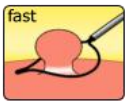
Application areas

Polyp removal using polypectomy snares and flexible endoscopy, with accelerated pulse rate for experienced users.

Suitable instruments

- Polypectomy snares

5.6.10. GastroLOOP 3



This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With an accelerated fast pulse rate of 2.2 cutting pulses per second, this mode is suitable for advanced users.

Application areas

Polyp removal using polypectomy snares and flexible endoscopy, with accelerated fast pulse rate for advanced users.

Suitable instruments

- Polypectomy snares

5.6.11. GastroKNIFE 1

This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a pulse sequence of cutting current and coagulation phase. With a relatively slow pulse rate of 1.3 cutting pulse per second, this mode is suitable for especially cautious work.

Application areas

Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; slow pulse rate for cautious work.

Suitable instruments

- Papillotome
- Needle knives

5.6.12. GastroKNIFE 2

This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a pulse sequence of cutting current and coagulation phase. With an accelerated pulse rate of 1.8 cutting pulses per second, this mode is suitable for experienced users.

Application areas

Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; accelerated pulse rate for experienced users.

Suitable instruments

- Papillotome
- Needle knives

5.6.13. GastroKNIFE 3

This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. ARC control generates the cutting effect with simultaneously minimized output power. This mode consists of a pulse sequence of cutting current and coagulation phase. With an accelerated fast pulse rate of 2.2 cutting pulses per second, this mode is suitable for advanced users.

Application areas

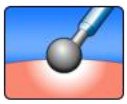
Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; accelerated fast pulse rate for advanced users.

Suitable instruments

- Papillotome
- Needle knives

5.7. Monopolar coagulation modes

5.7.1. Moderate



This mode is used with contact coagulation to stop hemorrhagic oozing, for hemostasis of relatively large tissue areas, and for small-area coagulation. Tissue carbonization is prevented and electrode adhesion to the tissue is strongly reduced. Greater coagulation depth is achieved in this mode than in other coagulation modes. The degree of surface scabbing can be controlled by adjusting the "Effect" setting in the range of 1 to 3.

Application areas

Coagulation with relatively high penetration depth; low electrode adhesion to tissue

Suitable instruments

- Electrodes with large contact areas, such as ball electrodes

5.7.2. Forced non cutting

This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves a high degree of coagulation with low cutting tendency.

Application areas

Fast coagulation with small penetration depth

Suitable instruments

- Ball electrodes
- Knife electrodes
- Spatula electrodes

5.7.3. Forced mixed

This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves a high degree of coagulation with moderate cutting tendency.

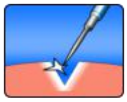
Application areas

Fast coagulation with small penetration depth and moderate cutting tendency

Suitable instruments

- Knife electrodes
- Spatula electrodes
- Insulated monopolar forceps

5.7.4. Forced cutting



This mode is used for contact coagulation with low tissue penetration, preferably using fine electrodes and electrodes with small contact areas. It achieves good hemostasis with very good cutting tendency.

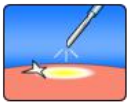
Application areas

Fast coagulation with small penetration depth and very good cutting tendency

Suitable instruments

- Knife electrodes
- Spatula electrodes
- Needle electrodes

5.7.5. Spray



This mode is used with non-contact surface coagulation using an arc, for hemostasis in parenchymal tissue, in poorly accessible crevices, and in conjunction with argon coagulation.

Application areas

Promoting coagulation of diffuse bleeding

Suitable instruments

- Ball electrodes
- Knife electrodes
- Spatula electrodes
- Needle electrodes

5.7.6. Argon

This mode is used for open surgical interventions in conjunction with the ARC PLUS accessory device for argon-assisted electrocoagulation.

This is the current type Spray.

With suitable instruments connected, argon-assisted coagulation can be performed using rigid electrodes.

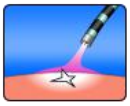
Application areas

Visceral surgery

Suitable instruments

- Rigid argon electrodes
- Argon handle

5.7.7.Argon flexible



This mode is used for argon-assisted electrosurgery in conjunction with the ARC PLUS accessory device.

This is the current type Spray.

For argon-assisted coagulation, flexible probes are used in combination with endoscopes.

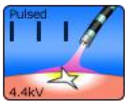
Application areas

Gastroenterology, homogeneous surface coagulation

Suitable instruments

- Flexible argon probes

5.7.8. Argon flex. pulse



This mode is used for argon-assisted electrosurgery in conjunction with the ARC PLUS accessory device.

This is the current type Spray.

For argon-assisted coagulation, flexible probes are used in combination with endoscopes.

The puls frequency changes with the effect setting. The higher the effect level, the faster the pulse sequence.

Application areas

Gastroenterology, homogeneous surface coagulation

Suitable instruments

- Flexible argon probes

5.7.9. Resection

This mode is used for monopolar hemostasis in gynecology and urology.

Use non-conductive irrigation fluids.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP).

Suitable instruments

- Resectoscope (monopolar)
- Resection sling
- Rollerblade electrode

5.7.10. Cardiac Mammary

This mode is used in mammary surgery and cardiac surgery. It produces forced coagulation.

Application areas

Mammary surgery and cardiac surgery

Suitable instruments

- Knife electrodes

5.7.11. Cardiac Thorax

This mode is used in thoracic surgery. It produces forced coagulation.

Application areas

Thoracic surgery

Suitable instruments

- Knife electrodes

5.7.12. SimCoag

This mode is used for simultaneous preparation. Two monopolar socket connectors can be activated at the same time to enable the simultaneous use of two manually switched instruments. Both handpieces can be switched on and off independently.

The current type changes with the effect setting:
Effect 1: Forced cutting
Effect 2: Forced mixed
Effect 3: Spray

The output power setting applies to both output sockets, and the power is distributed according to the tissue structure.

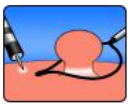
Application areas

Simultaneous coagulation and preparation, e.g. for cardiac or mammary surgery

Suitable instruments

- Ball electrodes
- Knife electrodes
- Spatula electrodes

5.7.13. Gastro Coag



This mode is used in gastroenterology with contact coagulation for the coagulation of small areas.

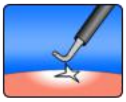
Application areas

After bleeding associated with polypectomies or papillotomies.

Suitable instruments

- Polypectomy snares
- Papillotome

5.7.14. Laparoscopy



This mode is used in laparoscopy and arthroscopy for monopolar coagulation.

Application areas

Laparoscopy, arthroscopy

Suitable instruments

- Arthroscopy electrodes
- Laparoscopy electrodes

5.8. Bipolar cutting modes

5.8.1. Standard

This mode is used for cutting with bipolar laparoscopic instruments.

Application areas

Laparoscopic cutting

Suitable instruments

- Laparoscopic instruments

5.8.2. Bipolar resection (optional)

This bipolar mode is used in gynaecology and urology for resection with loop electrodes under conductive rinsing liquid (saline solution). ARC control technology generates the cutting effect with simultaneously minimized output power. ARC Control facilitates immediate cutting and prevents electrode adhesion.

Make sure that NaCl is used as an irrigation medium.
Secure a continuous irrigation during the application.
Always use conductive lubricants to avoid damages of the urethra.
Avoid continuous activations.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP).

Suitable instruments

- Resectoscope (bipolar)
- Resection sling

This function is available if the device has the option Bipolar Resection (900-395).

Optimum results are provided exclusively when using BOWA COMFORT resection cables.

5.8.3. Bipolar scissors

This mode is used with bipolar scissors. It can be used for coagulation before or during cutting, point coagulation, coagulation of cuts and surface coagulation.

Application areas
Preparation, coagulation and cutting of tissue

Suitable instruments

- Bipolar scissors

Bipolar scissors should only be operated with the current type bipolar scissors cutting or bipolar scissors coagulation.

5.8.4. Vaporisation

This bipolar mode is used in gynaecology and urology for vaporisation. An arc is struck immediately on tissue contact, enabling fast tissue vaporisation with low heat propagation into surrounding tissue.

Make sure that NaCl is used as an irrigation medium.
Secure a continuous irrigation during the application.
Always use conductive lubricants to avoid damages of the urethra.
Avoid continuous activations.

Application areas

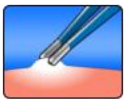
Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP).

Suitable instruments

- Resectoscope (bipolar)
- Vaporisation electrode

5.9. Bipolar coagulation modes

5.9.1. Standard forceps



This mode is used for arcless contact coagulation with forceps.

Application areas

Bipolar coagulation

Suitable instruments

- Bipolar forceps

5.9.2. Standard forceps AUTO

This mode is used for arcless contact coagulation with forceps. Activation starts automatically on contact with tissue. The adjustable delay time can be set under MENU – SYSTEM SETTINGS – AUTOSTART DELAY (see 5.10.2).

Setting the AUTOSTART mode can result in unintentional coagulations, e.g. when bipolar forceps are used for gripping while the AUTOSTART Mode is on.

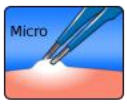
Application areas

Bipolar coagulation with AUTOSTART

Suitable instruments

- Bipolar forceps

5.9.3. Micro forceps



This mode is used for arcless contact coagulation with micro forceps. It enables extremely fine control of power output down to 0.1 W and precise work for tightly restricted bipolar contact coagulation.

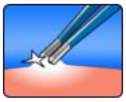
Application areas

Bipolar coagulation in pediatric surgery, neurosurgery, plastic surgery, etc.

Suitable instruments

- Bipolar forceps
- Micro forceps

5.9.4. Forceps forced



This mode is used for forced coagulation with forceps.

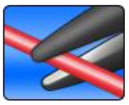
Application areas

Fast bipolar coagulation

Suitable instruments

- Bipolar forceps

5.9.5. LIGATION (optional)



This mode is used for the permanent sealing of veins, arteries and tissue bundles. Conventional instruments cannot be used in this mode. The output power is preconfigured and automatically regulated.

Application areas

Vessel sealing open and laparoscopic

Suitable instruments

- TissueSeal®
- TissueSeal® PLUS
- NightKNIFE®
- LIGATOR®
- ERGO 310D
- ERGO 315R

This function is available if the device has the option LIGATION (900-396).

5.9.6. TissueSeal PLUS (optional)

This mode is used for the permanent sealing of veins, arteries and tissue bundles with TissueSeal PLUS® for open surgical applications. Conventional instruments cannot be used in this mode. The output power is preconfigured and automatically regulated.

Application areas

Vessel sealing in open surgery

Suitable instrument

- TissueSeal PLUS®

This function is available if the device has the option LIGATION (900-396).

5.9.7. Bipolar scissors

This mode is used with bipolar scissors. It can be used for coagulation before or during cutting, point coagulation, coagulation of cuts and surface coagulation.

Application areas

Preparation, coagulation and cutting of tissue

Suitable instruments

- Bipolar scissors

Bipolar scissors should only be operated with the current type bipolar scissors cutting or bipolar scissors coagulation.

5.9.8. Laparoscopy

This mode is used for coagulation in combination with bipolar laparoscopic instruments.

Application areas

Laparoscopic coagulation

Suitable instruments

- Bipolar laparoscopic instruments

5.9.9. Laparoscopy Micro

This mode is used for coagulation in combination with fine bipolar laparoscopic instruments.

Application areas

Laparoscopic coagulation

Suitable instruments

- Fine bipolar laparoscopic instruments

5.9.10. Bipolar resection (optional)

This mode is used for bipolar blood coagulation in gynaecology and in urology for resection under conductive rinsing liquid (saline solution).

Be sure to use NaCl as the rinsing liquid.
Perform continuous rinsing during the application.
Use only conductive gel to avoid damage to the urinary tubes.
Avoid continuous activation.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP)

Suitable instruments

- Resectoscope
- Resection sling
- Rollerblade electrode

This function is available if the device has the option Bipolar Resection (900-395).

Make sure that the instrument has contact with the tissue while activating bipolar coagulation to avoid an unintended heating of the irrigation fluid.

5.9.11. Vaporisation (optional)

This mode is used for bipolar blood coagulation in gynaecology and in urology for vaporisation.

ℹ	Be sure to use NaCl as the rinsing liquid. Perform continuous rinsing during the application. Use only conductive gel to avoid damage to the urinary tubes. Avoid continuous activation.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-B), vaporization of prostate tissue (TUR-VAP)

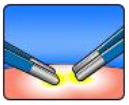
Suitable instruments

- Resectoscope
- Rollerblade electrode
- Vaporisation electrode

ℹ	Make sure that the instrument has contact with the tissue while activating bipolar coagulation to avoid an unintended heating of the irrigation fluid.

ℹ	This function is available if the device has the option Bipolar Resection (900-395).

5.9.12. Bipolar SimCoag (optional)



This mode is used for coagulation when using two bipolar instruments, e.g. forceps. The power is individually selectable for each instrument without any loss in power output during simultaneous activation.

The powercan be set in steps of 5 watt.

Application areas

Simultaneous coagulation and preparation with two bipolar instruments in general surgery, vascular surgery, plastic surgery, traumatology, Neuro surgery and Orthopedics.

Suitable instruments

- Bipolar forceps
- Bipolar scissors

ℹ	This function is available if the device has the option Bipolar SimCoag (900-399).

5.10. Menu dialogs

The menu dialogs specify the settings of basic parameters, such as the user interface language and audio, display and memory options.

5.10.1. Overview

The following menu dialogs are available:

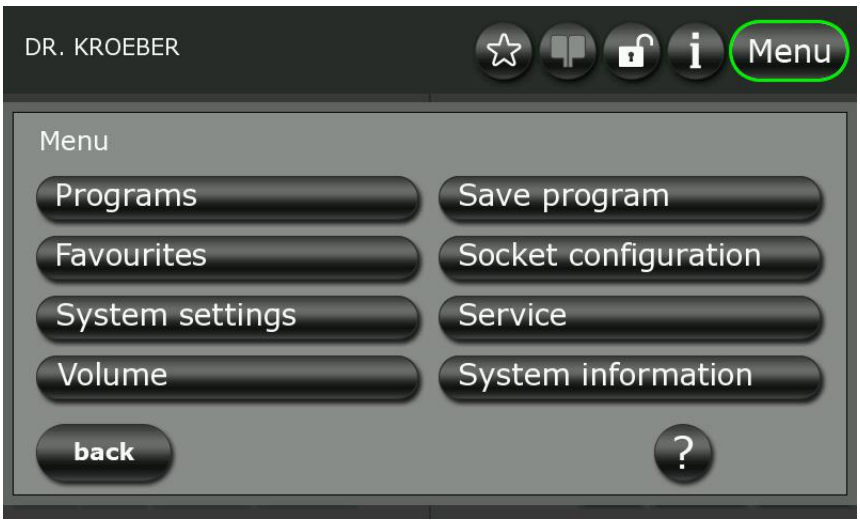


Figure 5-19: Menu dialogs

Selecting a dialog

Press the button of the desired dialog to launch the program.

Exiting a dialog

Press the "back" button to return to the main screen.

5.10.2. "System Settings" dialog

The following parameters can be configured in the "System Settings" dialog:

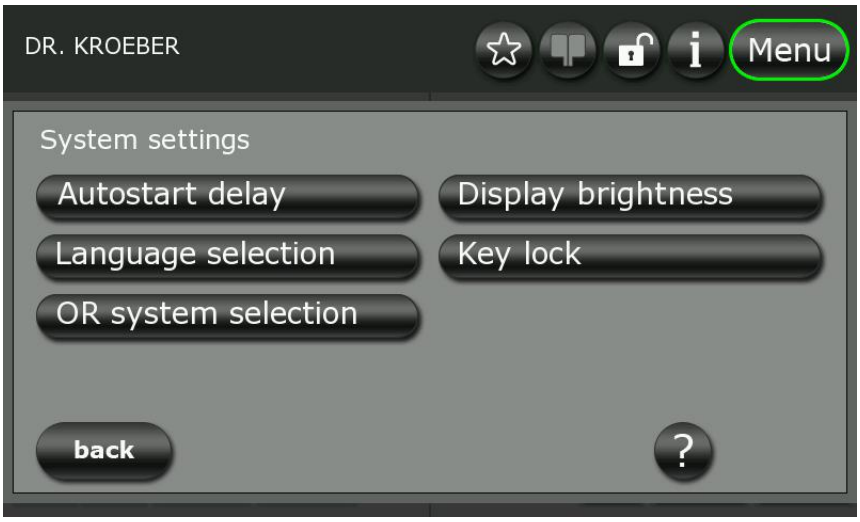


Figure 5-20: “System settings” dialog

The following languages are selectable in „language selection“:

German, English, French, Italian, Spanish, Russian, Polish, Turkish, Japanese, Korean, Thai, Indonesian, Chinese, Portuguese, Czech, Arabic, Hungarian, Danish, Finnish, Vietnamese, Swedish, Dutch, Bulgarian, Serbian, Romanian, Slovakian and Kazakh.

Under “Key lock” you can disable automatic screen lock or set its duration. The duration can be set from 30 seconds to 5 minutes.

A link to an optional OP system can be made under “OR system selection”.

5.10.3. "Volume" dialog

Use the "Volume" dialog to set the volume of the individual acoustic signals.

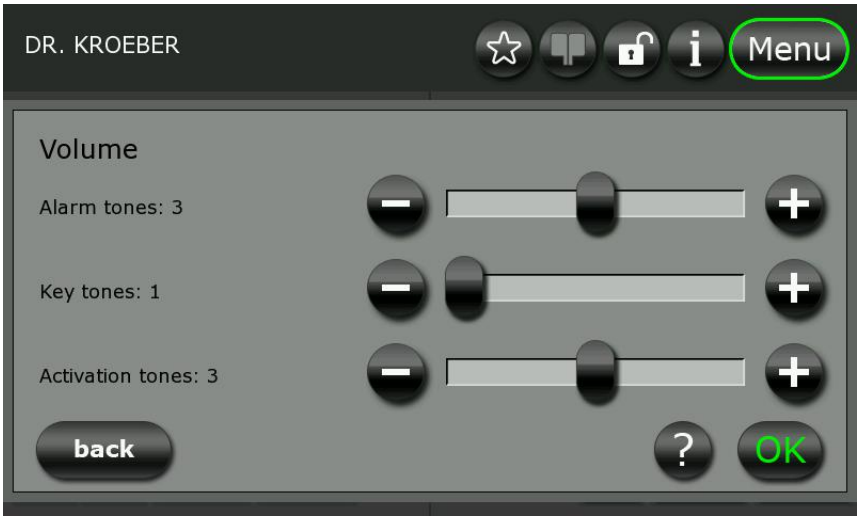


Figure 5-21: "Sound Level" dialog

Incremental setting

► Press the "+" and "-" buttons.

Fast setting

► Move the slider in the desired direction.

The volume of the activation signal should be increased as necessary for use in relatively noisy surroundings. The alarm tones have a minimum volume and limited changeability.

Mode	Category	Frequency (Hz)	Signal type
Monopolar Cut	Activation tones	635	Continuous sound
Monopolar Coag	Activation tones	475	Continuous sound
Bipolar Cut	Activation tones	565	Continuous sound
Bipolar Coag	Activation tones	505	Continuous sound
Sim Coag	Activation tones	755	Continuous sound
LIGATION end	Activation tones	-	Alternating sound
Foot switch changeover	Alarm tones	-	Signal tone
ZAP Mode	Alarm tones	-	Signal tone
Error	Alarm tones	-	Signal tone
Warning	Alarm tones	-	Signal tone
Note	Alarm tones	-	Signal tone

5.10.4. "Service" dialog

After entering a password, you can use the "Service" dialog to access additional options, such as resetting the device to the factory default configuration or viewing the instructions of use.

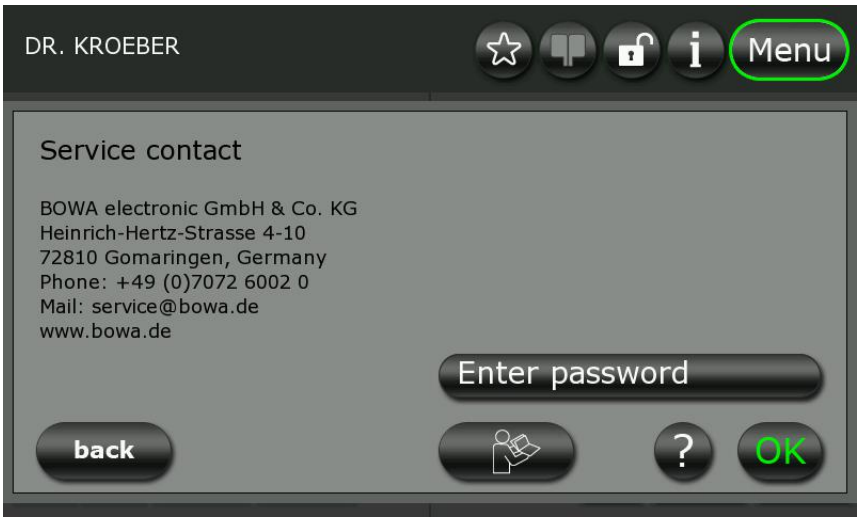


Figure 5-22: "Service" dialog

Opening the operating instructions:

1. Press the "Operating instructions" button.

↳ The operating instructions are displayed chapter for chapter.

2. Use the arrow buttons to select the desired chapter.
3. Press "OK" to open the selected chapter.
   Use the arrow buttons to open the individual pages of the chapter.
4. Press "back" to return to the chapter overview.

With the password **001224** you enter the service level 1.

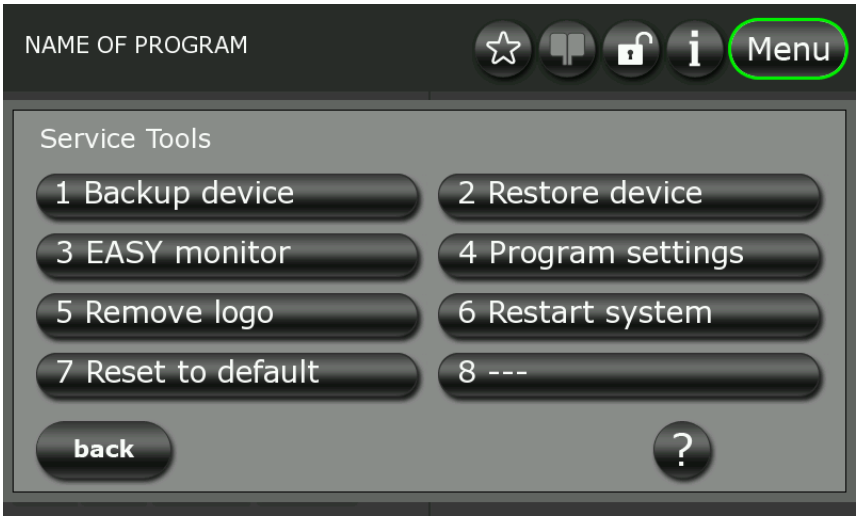


Figure 5-23: "Service Tools" dialog

Saving device settings

With the function "Backup device" device settings can be saved on the BOWA USB Stick (REF 900-402). This includes all stored programs and system settings.

Transferring device settings

Use "Restore device" to transfer saved device settings from a BOWA USB Stick (REF 900-402) to the ARC 400 unit.

Program settings

The “Program settings” function can be used to configure permissions for saving, deleting and editing programs.

Deleting the startup screen

In the service menu, the stored startup screen can be deleted using "Remove logo".

Add logo

See 5.4.9.

Resetting to factory settings

The "Reset to default" function allows you to reset all settings and programs to factory settings.

Save logfiles

This function can be used to save data on a BOWA-approved USB stick. This data can be used for a system analysis and can be sent by email to service@bowa.de, for example.

5.10.5. "System information" dialog

The "System information" dialog displays various System parameters such as version, serial number, TSI date for ARC 400 and if applicable ARC PLUS, as well as options.

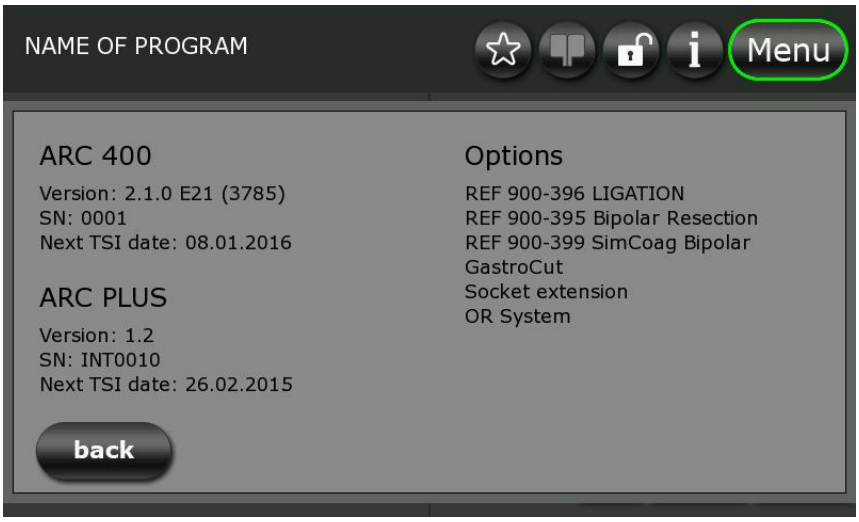


Figure 5-24: "System information" dialog

Moreover, the software version and the next TSI date is displayed, see chapter Safety inspection, page 109.

5.10.6. "Select program" dialog

1. Use the "Select program" dialog to select programs from a list and to add them to the favourites.
   - or -
   Fast settings of this menu are possible by tapping on the present program name in the main screen.
2. For the selection of a program, tap on the desired program name.
3. The horizontal navigation is possible using the arrows. The programs are always arranged alphabetically in the right column.
4. Use the star symbols at the bottom of the screen to assign programs to the Favourites list. The green arrow is for adding programs to the favourites, and the red arrow is for removing them.
5. The assignment to the favourites is possible using the star button in the lower area of the screen.
6. Press "OK" to load the selected program.
   - or -
   To return to the main screen click on "back".

Figure 5-25: "Select program" dialog

Up to 300 programs can be put on the favourites list.

Saved programs can be deleted under “Program”.

1. In the program list, select the program to be deleted by touching the program name.

   You can also navigate horizontally with the arrows.
2. Touch the “Wastebin” symbol to permanently delete the selected program.

↳ The selected program is deleted after you confirm this in a confirmation prompt.

↳ The default program cannot be deleted.

5.10.7. "Favourites" dialog

Use the "Favourites" dialog to select previously defined favourite programs. A fast selection of the favourites is possible using the star button in the main screen.

Figure 5-26: "Favourites" dialog

Use the arrow buttons at the bottom of the screen to navigate to the next page of the Favourites list.
Confirm with "OK" to accept the selection.
To return to the main screen click on "back".

5.10.8. "Save Program" dialog

Use the "Save Program" dialog to save the current program settings under the same name or a different name.

Figure 5-27: "Save program" dialog

With a keypad program names can be created. Several symbols, capital or small letters or numbers are selection options.

You can use the “Enter” button to assign two-line program names.

Confirm with "OK" to accept the selection.

To return to the main screen click on "back".

5.10.9. Socket extension

The bottom bipolar socket can be extended. This allows a total of three bipolar instruments to be connected.

With socket extension active, it is only possible to work with two bipolar ERBE plugs on the bottom bipolar socket.
Autostart mode is not available on the extended top socket.

↳ Select “Socket configuration” to access the socket extension screen.

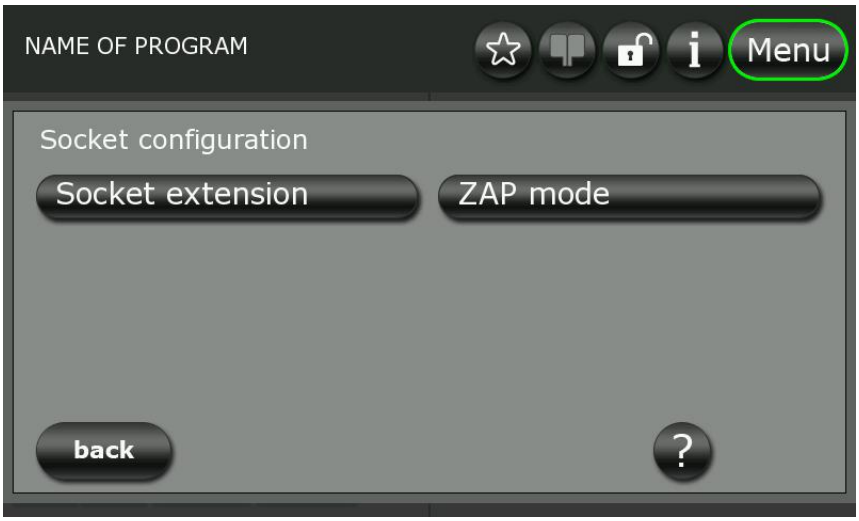


Bild 5-28: Menu "Socket configuration"

↳ Select socket extension for the bottom bipolar socket by touching the right-hand selection area next to the two individual plugs.

Press “OK” to confirm your selection.
Press “Back” to return to the main screen.

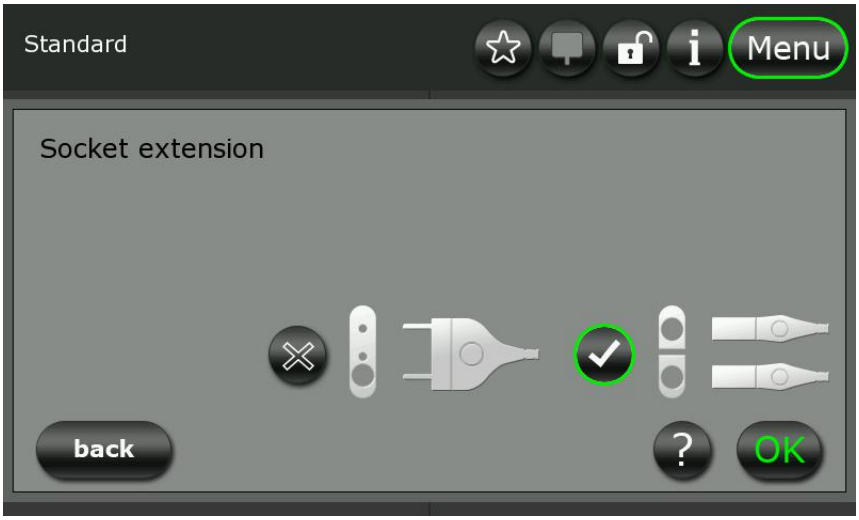


Bild 5-29: Menu "Socket extension"

- You now have three bipolar ports available.
- A socket extension indicator is displayed next to the “Effect” key.

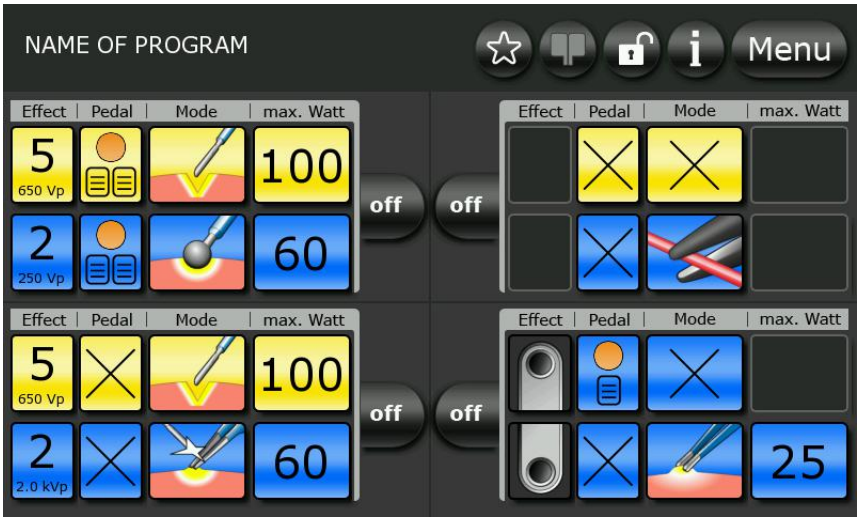


Bild 5-30: Dual operator interface for bottom socket.

5.10.10. ZAP Mode

You can use Zap Mode to switch between two predefined settings for the same instrument.

1. Select Zap Mode on the “Socket configuration” screen.
2. Enable or disable switching for an individual socket by touching the check mark next to the socket.

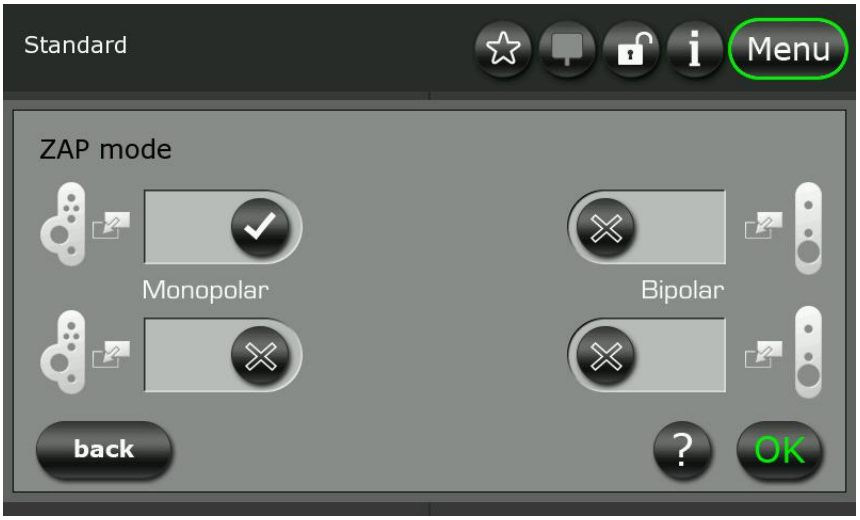


Bild 5-31: Menu "ZAP Mode"

The check mark is filled in when Zap Mode is enabled.

Press “OK” to confirm your selection.
Press “Back” to return to the main screen.
On the main screen, active Zap Mode is indicated by an additional button.

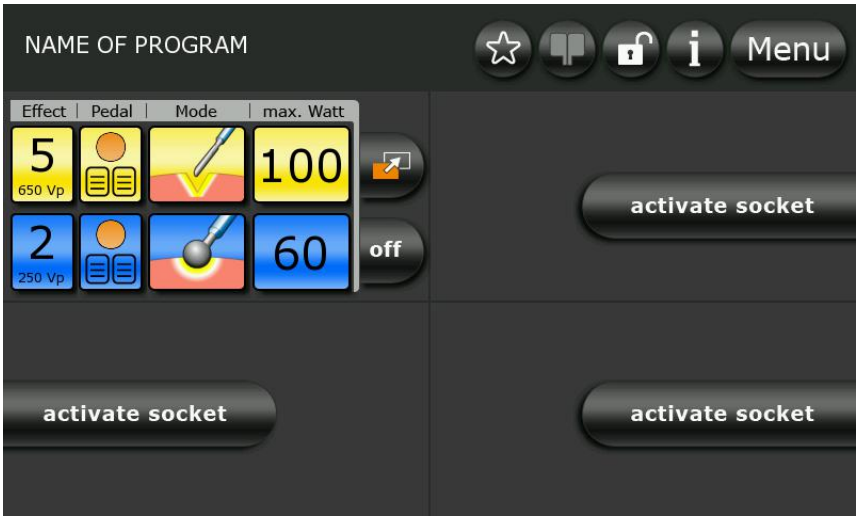


Bild 5-32: Top monopolar socket in Zap Mode

To configure the second socket setting, touch the Zap Mode symbol above the “Off” button.

The colour of the symbol changes from orange to white and the current settings are copied.

Now you can edit the parameters for the second socket setting as desired.

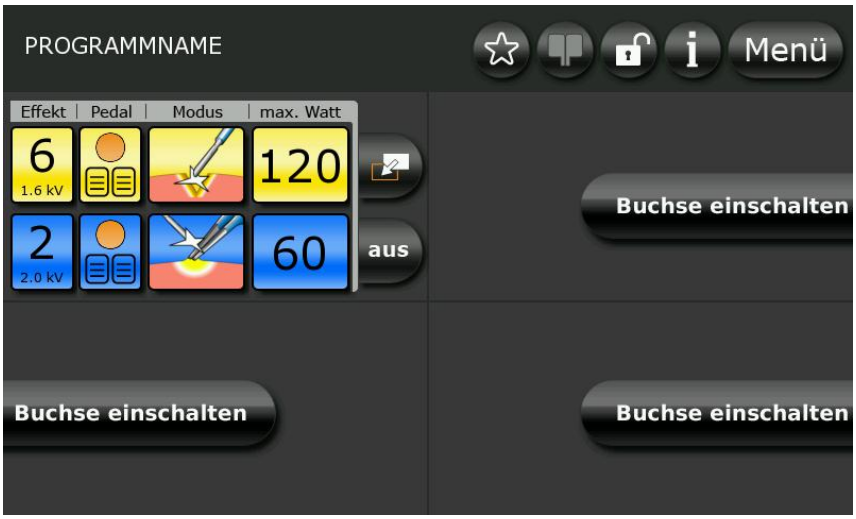


Bild 5-33: Top monopolar socket in Zap Mode Change

Touching the Zap Mode symbol again takes you back to the previous socket setting.

In addition to the described option for switching the setting on the main screen, the setting can be switched with the handle or the foot switch.

Switching with the handle

To switch the setting with the monopolar handle, press the two buttons for cutting and coagulation at the same time and hold them pressed for more than one second.

Switching with the foot switch

You can also switch the levels with the orange button on the foot switch.

For this purpose, select the Zap Mode symbol below the “Pedal” icon.

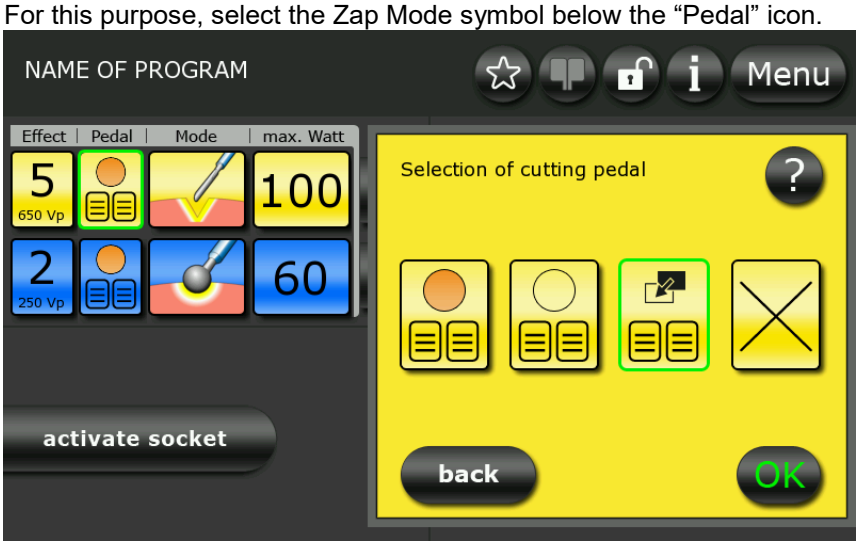


Bild 5-34: Zap Mode foot switch selection for cutting

Now the Zap Mode symbol appears on the main screen below the “Pedal” icon.

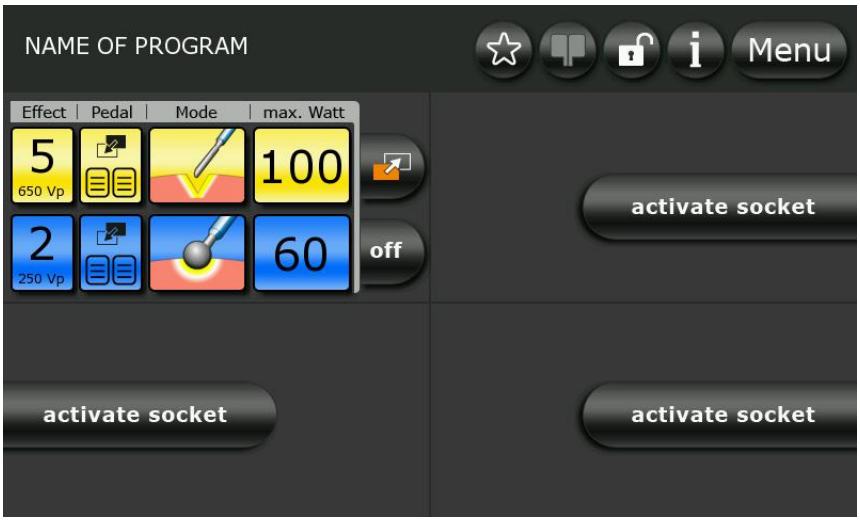


Bild 5-35: ZAP Mode foot switch

You can switch between the two socket settings by pressing the orange button on the foot switch.

The orange button on the foot switch is now dedicated to Zap Mode switching.

5.10.11. "System messages" dialog

In the "System messages" dialog, it is possible to open the saved system messages which have occurred since switching on the HF device.

These messages are not saved when switching off the HF device.

Opening saved system messages:

1. Select a system message.
2. The selected system message is displayed again with "?".
3. Press "OK" to return to the overview.

Opening the instructions of use:

1. Press the "instructions of use" button.

↳ The instructions of use are displayed chapter for chapter

2. Use the arrow buttons to select the desired chapter.
3. Press "OK" to open the selected chapter.

   Use the arrow buttons to open the individual pages of the chapter.

4. Press "back" to return to the chapter overview.

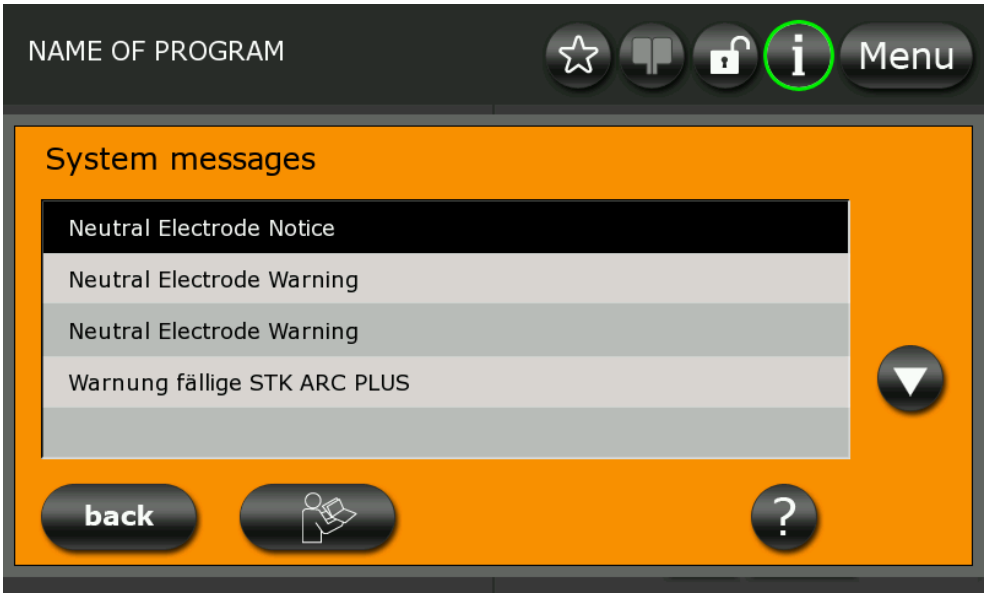


Figure 5-36: "System messages" dialog

5.10.12. "Argon" dialog

In case of the selection of an argon mode and a successful connection to ARC PLUS, this dialog is selectable in the status bar.

The "Argon" dialog enables the selection of argon flow rates for cutting and coagulation, as well as the selection of argon bottles and the display of filling levels.

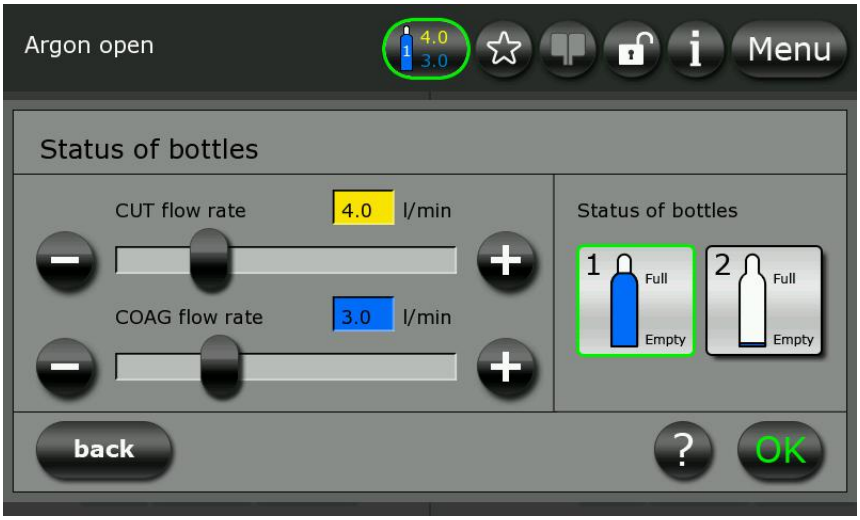


Figure 5-37: "Argon" dialog

1. Use the "+" and "-" buttons to adjust the argon flow rate for cutting (Cut) or coagulation (Coag).
   - or -
   Use the slider to set the flow rate.
2. In case of two connected argon bottles use the buttons for output "1" or "2" to select the desired gas source.

Pressure reducers with electronic pressure sensor enable the display of exact filling levels of argon bottles.

3. Press the "?" button for more information on this selection.
4. Confirm your selection by pressing the "OK" button.

   - or -
   Press the "Back" button to return to the main screen without changing the selection.

Default settings for argon flow rates according to the different modes are selected automatically:

Argon open:
CUT flow rate: 4.0 l/min
COAG flow rate: 3.0 l/min

Argon flexible:
COAG flow rate: 0.4 l/min

5.11. Basic programs

The following basic programs are provided with the full version of ARC 400 (incl. the resection bipolar option and the LIGATION option):

- 3 Bipolar
- Argon flexible
- Argon
- Cardiac
- GastroCut
- Laparoscopy
- Ligation
- Macro
- Micro
- Open Surgery
- Resection bipolar
- Resection monopolar
- SimCoag
- SimCoag bipolar
- Standard
- Open surgery ZAP Mode

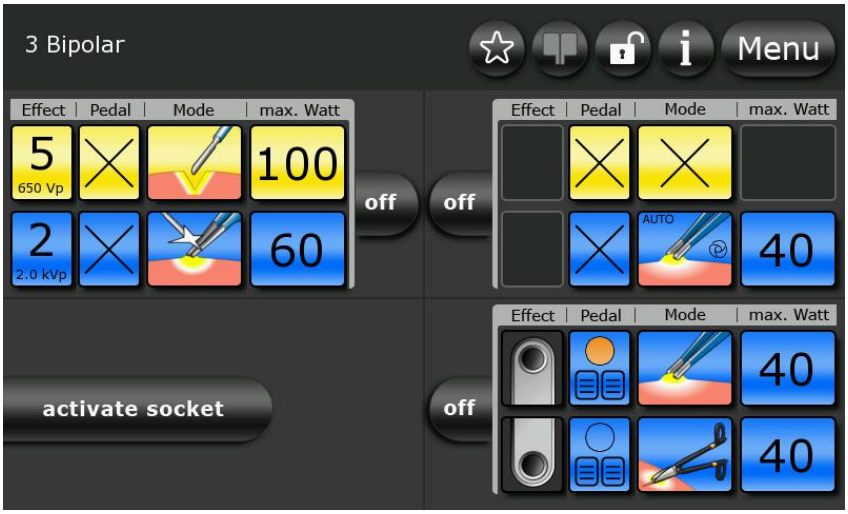


Figure 5-38: Basic program "3 Bipolar"

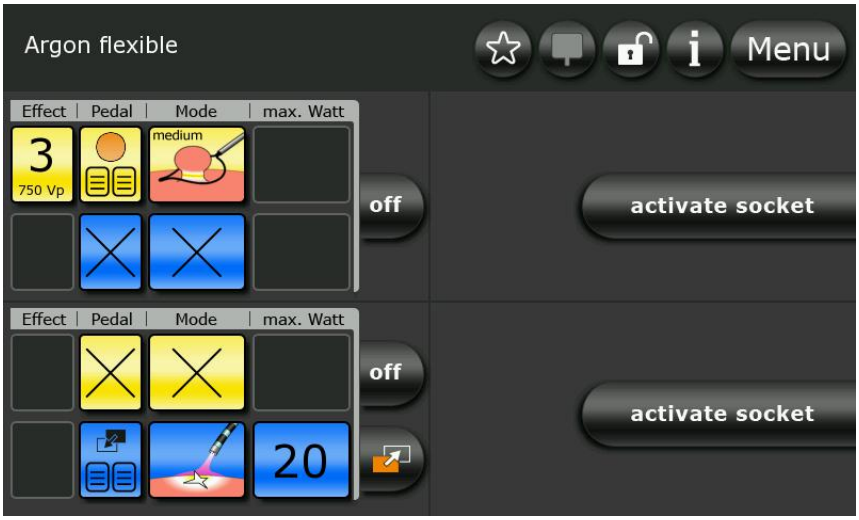


Figure 5-39: Basic program "Argon flexible"

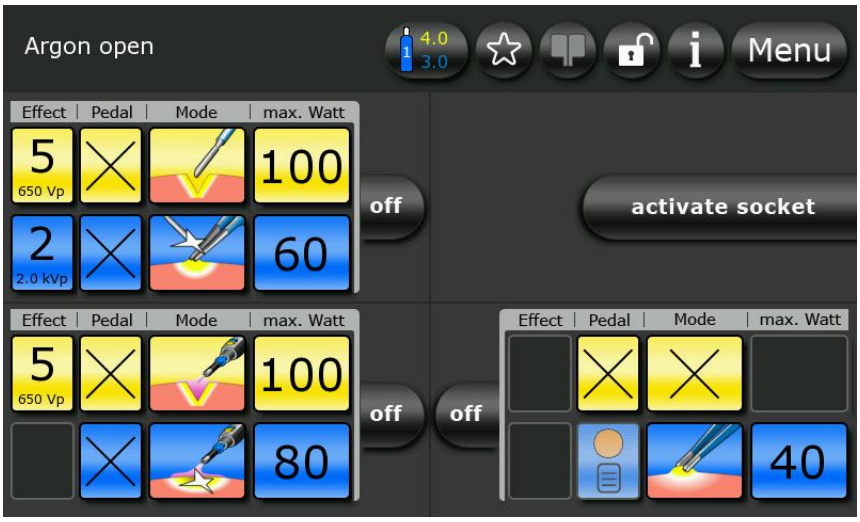


Figure 5-40: Basic program "Argon open"

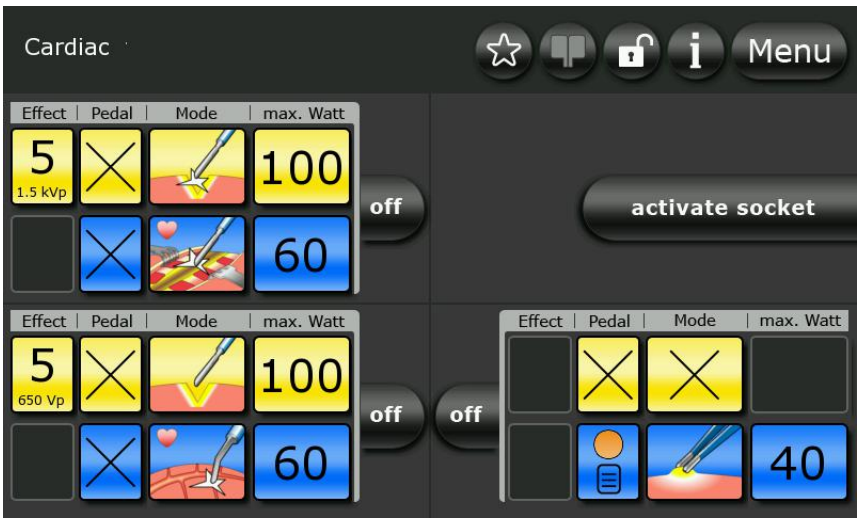


Figure 5-41: Basic program "Cardiac"

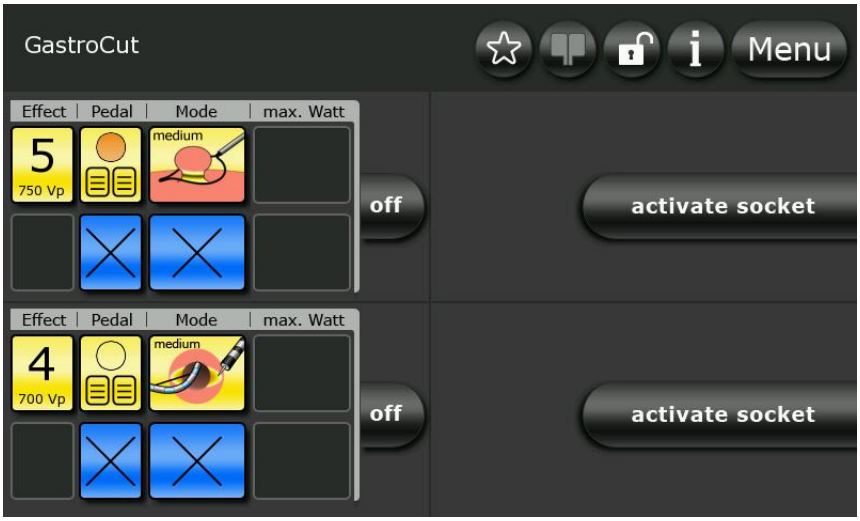


Figure 5-42: Basic program "GastroCut"

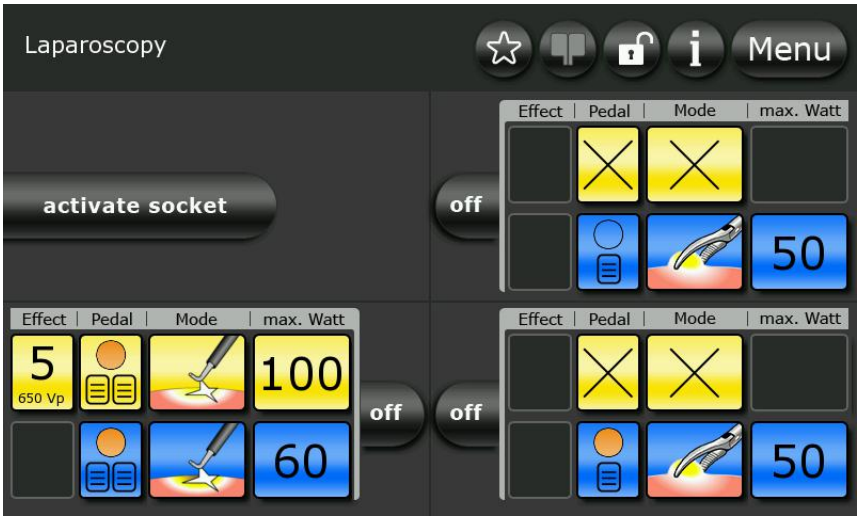


Figure 5-43: Basic program "Laparoscopy"

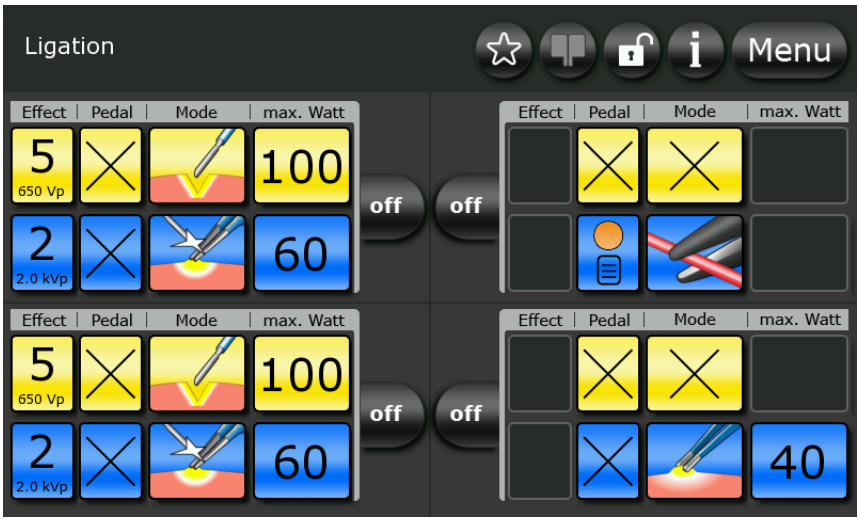


Figure 5-44: Basic program "Ligation"

The LIGATION program is only available when the LIGATION option is present.

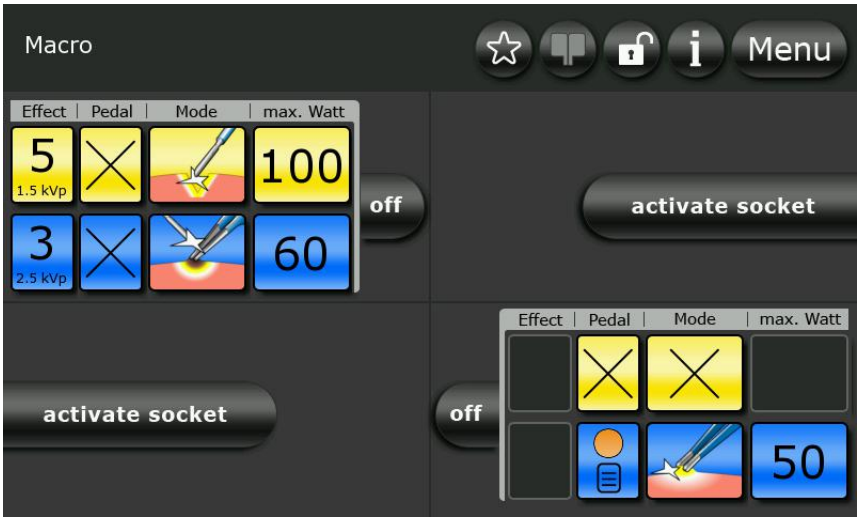


Figure 5-45: Basic program "Macro"

Figure 5-46: Basic program "Micro"

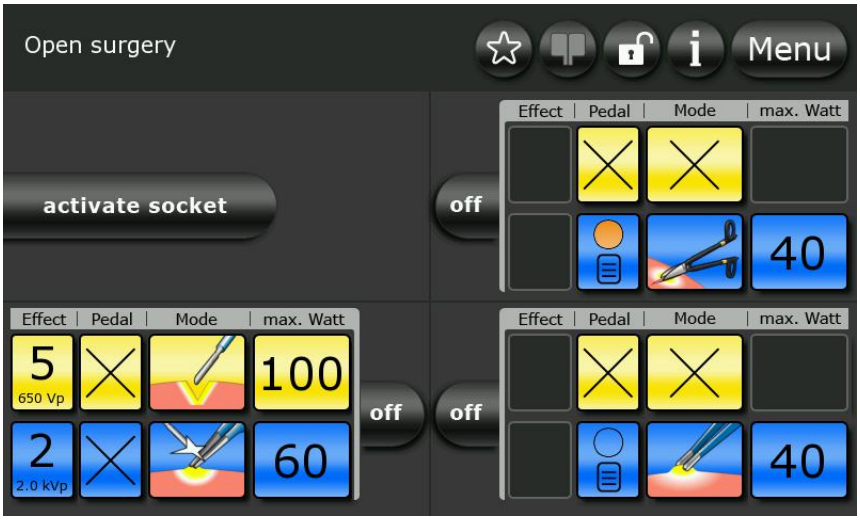


Figure 5-47: Basic program "Open Surgery"

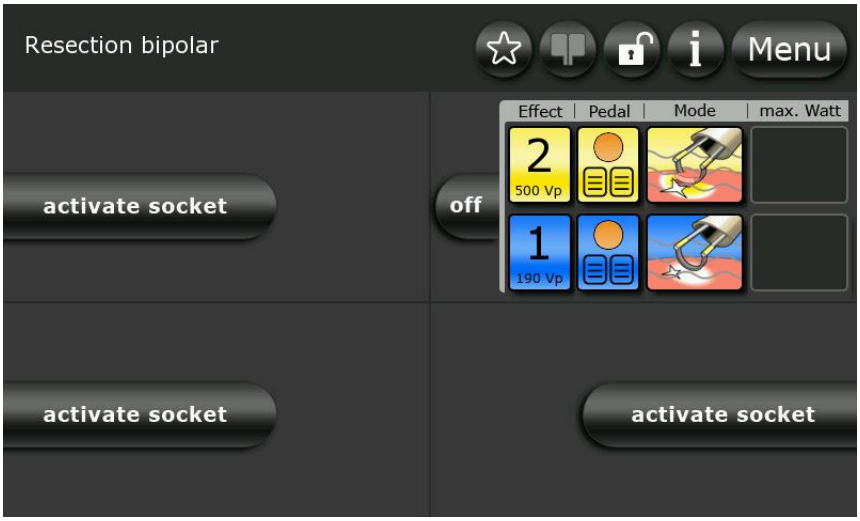


Figure 5-48: Basic program "Resection bipolar"

This program is only available with the resection bipolar option.

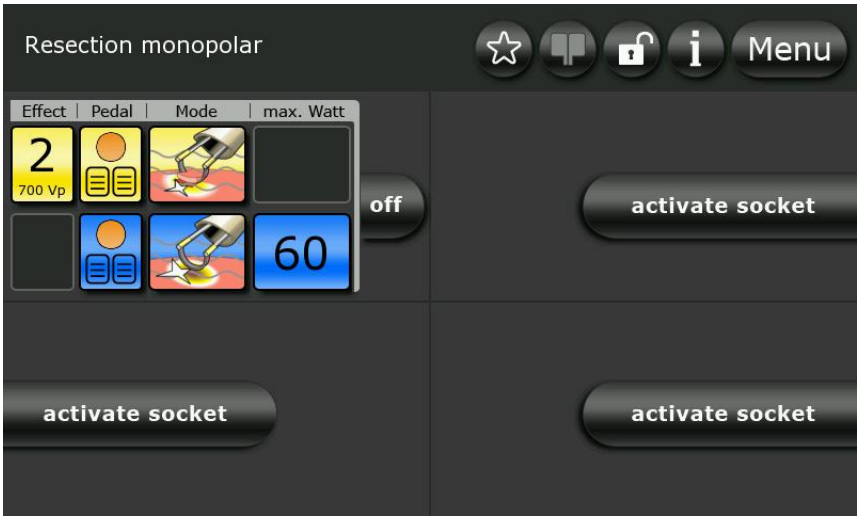


Figure 5-49: Basic program "Resection monopolar"

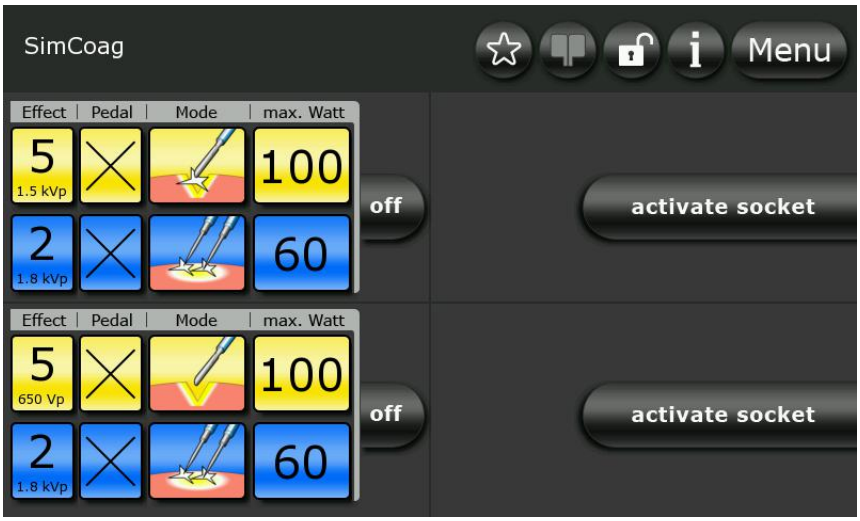


Figure 5-50: Basic program "SimCoag"

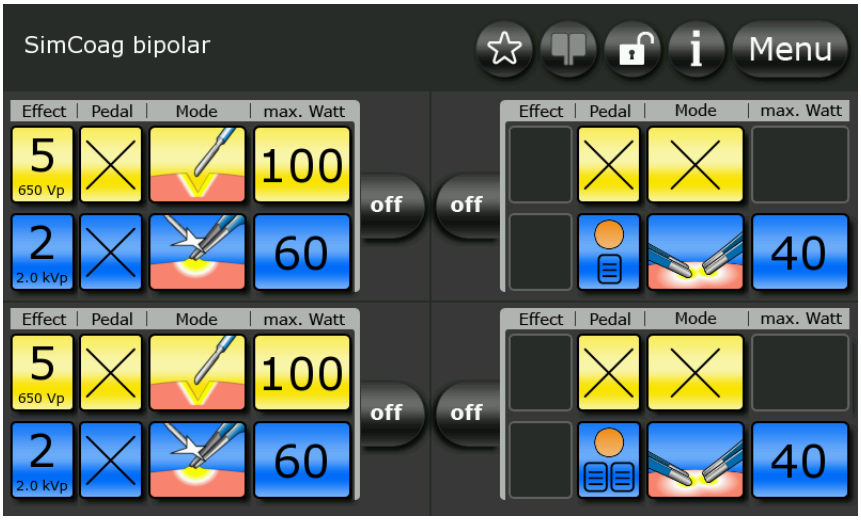


Figure 5-51: Basic program "SimCoag bipolar"

This program is only available with the SimCoag bipolar option.

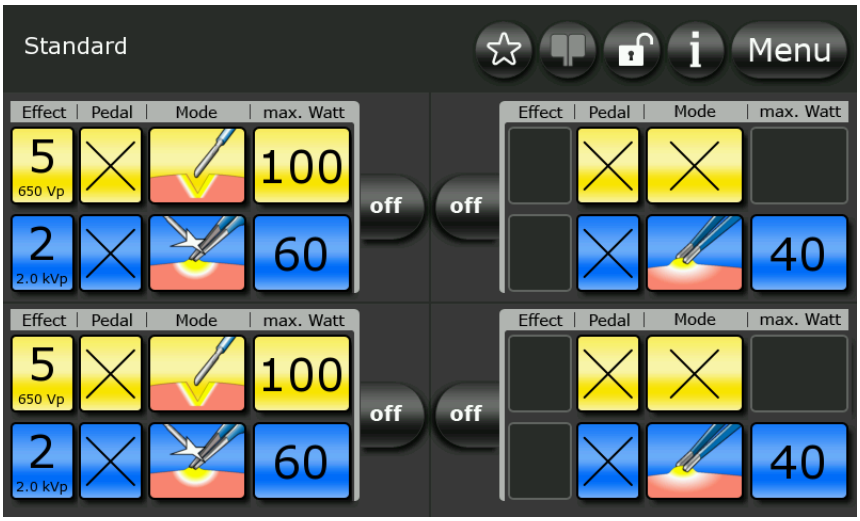


Figure 5-52: Basic program "Standard"

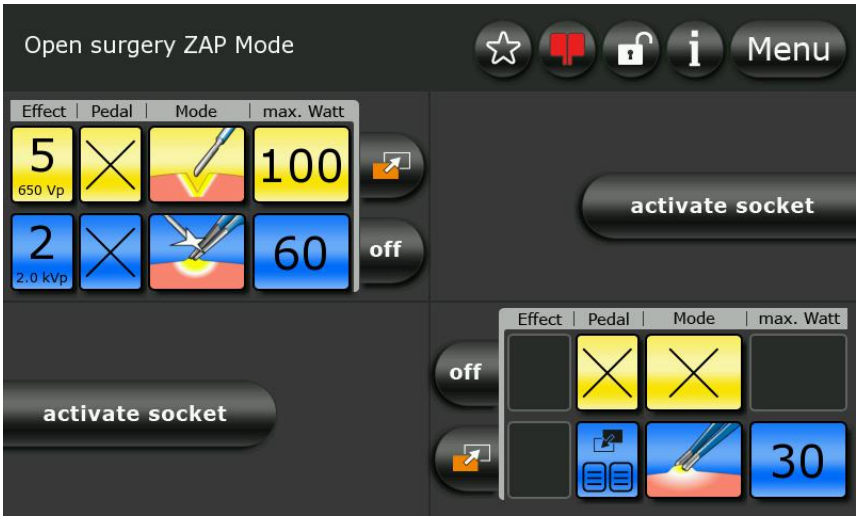


Figure 5-53: Basic program "Open surgery ZAP Mode"

6. Detecting and correcting faults

Two types of faults can occur:

- system faults
- EASY monitoring faults

6.1. System information

A warning message appears on the display when a system fault occurs.

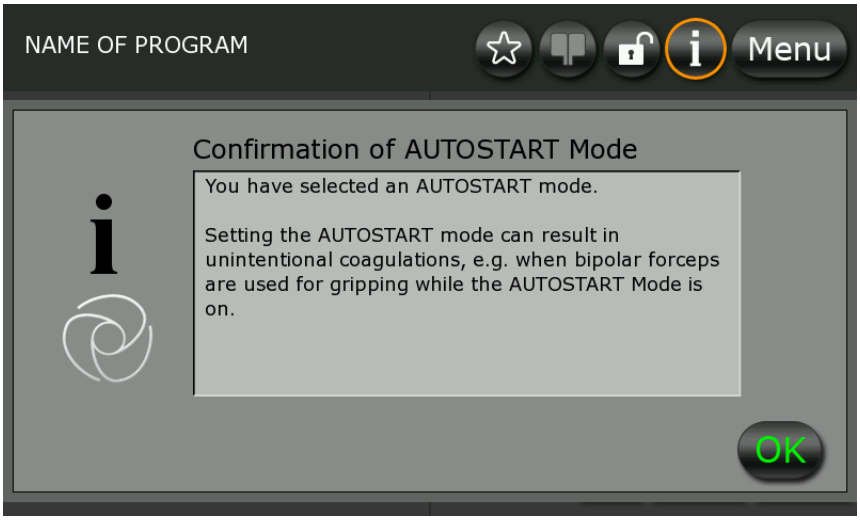


Figure 6-1: Confirmation of AUTOSTART Mode

System information has three different categories:

- Notice (grey screen)
- Warning (orange screen)
- Error (red screen)

Notices are shown for five seconds on the display. Warnings and errors are shown for ten seconds.

While an error is present, activations are prohibited.

The message is available using the orange marked „i“ in the system bar.

The following table describes the cause of the fault and the appropriate corrective action.

Heading	Fault message
Confirmation of AUTOSTART Mode	You have selected an AUTOSTART mode. Setting the AUTOSTART mode can result in unintentional coagulations, e.g. when bipolar forceps are used for gripping while the AUTOSTART Mode is on.
AUTOSTART Fault	The instrument is in contact with tissue. AUTOSTART cannot be selected when the instrument is in contact with tissue. Open up the instrument.
TSI Warning	The annual Technical Safety Inspection (TSI) is due.
Neutral Electrode Fault	No neutral electrode connected. No neutral electrode connected. Connect a neutral electrode.
Neutral Electrode Fault	Wrong neutral electrode connected. The selection does not match the neutral electrode connected. Connect the neutral electrode which matches the selected mode, or change the mode to match the neutral electrode.
Neutral Electrode Fault	Poor contact with the patient. The resistance between the neutral electrode and the patient is too high. Establish better contact of the neutral electrode.
Neutral Electrode Warning	Poor contact with the patient. The contact resistance between the neutral electrode and the patient is increasing. Establish better contact of the neutral electrode.
Neutral Electrode Fault	No cable for neutral electrode connected. No cable for neutral electrode connected. Connect a cable for neutral electrodes.
Neutral Electrode Notice	No cable for neutral electrode connected. The cable for neutral electrode has been removed. Monopolar activation is not possible.
Mode Fault	No mode selected. No mode was selected for this type of activation. Select the desired mode or change the foot switch assignment.
Mode Fault	This mode is not allowed for baby neutral electrodes. Use split neutral electrodes with a large conductive surface for this mode.
Mode Fault	This mode is not allowed for this socket. The current mode remains active. Choose another socket for this mode.
Foot Switch Fault	No compatible foot switch connected. The connected foot switch is not compatible with this device. Connect a compatible foot switch with an orange button.
Foot Switch Fault	Foot switch not assigned to a socket. The foot switch has not been assigned to a socket yet. Assign a socket to the foot switch using the "Pedal" button.

Heading	Fault message
Foot Switch Fault	Fault on foot switch connection. Check the foot switch. If this message appears again, please contact the Technical Support. Contact: MENU - SERVICE.
Finger Switch Fault	Fault on finger switch connection. Check the handle and the connection cable. Please replace them if damaged. If this message appears again please contact the Technical Support. Contact: MENU - SERVICE.
Temperature Warning	The temperature of the device is higher than normal. The temperature of the device is elevated. This leads to a reduction of the maximum power.
Limitation of Continuous Activation	The maximum activation time has been exceeded. Please only activate the generator in short intervals, in order to avoid harming the patient and damaging the connected instruments or the generator.
Activation Fault	While switching on the device, there is an activation by foot switch, finger switch or AUTOSTART. Check the handles or foot switches for malfunctions. Disconnect the handles / foot switches from the device. If the error persists, please contact the Technical Support. Contact: MENU - SERVICE.
Activation Fault	There is an activation while connecting the foot switch or finger switch. Check the handles or foot switches for malfunctions. Disconnect the handles / foot switch from the device. If the error persists, please contact the Technical Support. Contact: MENU - SERVICE.
Activation Fault	There is no instrument connected on the activated socket. Connect an instrument on the designated socket.
Activation Warning	The mode for safety inspections is active. Activation is not possible. Quit this mode before activating again.
Bipolar Resection Warning	Use a BOWA COMFORT resection cable. Be sure to use NaCl as the rinsing liquid. Perform continuous rinsing during the application. Use only conductive gel to avoid damage to the urinary tubes. Avoid continuous activation.
GastroCut Warning	Polypectomy snare not in contact with tissue, or check connection cable at snare or generator. Please apply the snare and reactivate. First of all establish contact between tissue and polypectomy snare, or check the connection cable at the snare or the generator. Then activate with the yellow foot pedal.
LIGATION Notice	Grasp tissue again.

Heading	Fault message
LIGATION Warning	There is a short-circuit in the area of the sealing instrument. Possible remedies: Clean the inner surface of the jaw. The jaw and sealing area must be free of foreign objects such as clamps and tissue residues. Check the instrument and cable for damage. Check the connection to the generator. Follow the instructions for use for the instrument.
LIGATION Warning	The sealing instrument is not in contact with tissue. Possible remedies: Clean the inner surface of the jaw. The jaw and sealing area must be free of foreign objects such as clamps and tissue residues. Check the instrument and cable for damage. Check the connection to the generator. Follow the instructions for use for the instrument.
ARC PLUS Fault	Connect the argon device to the generator and switch it on. The argon device is connected to the generator by fibre optic cables. The active argon device is automatically connected via the generator when an argon mode is activated.
ARC PLUS 5100 Internal Fault	ARC PLUS not operational. Connect an operational argon device to the generator. If the warning message persists, please contact the Technical Support. Contact: MENU - SERVICE.
ARC PLUS Fault	Please check if the argon bottles are connected and open. Empty bottles should be replaced. Subsequently restart ARC PLUS by activating the flashing "Purge" button. You can connect two argon bottles. A change to the replacement bottle occurs automatically.
ARC PLUS Fault	The argon inlet pressure is too high. Max. inlet pressure: <4.5bar Connect a source of argon gas in the appropriate pressure range. Subsequently restart ARC PLUS by activating the flashing "Purge" button.
ARC PLUS Fault	The argon inlet pressure has exceeded the permissible limits. Inlet pressure range: 2 - 4.5bar Connect a source of argon gas in the appropriate pressure range. Subsequently restart ARC PLUS by activating the flashing "Purge" button.
ARC PLUS Warning	Mixed operation of argon bottles with and without an electric bottle pressure gauge is not recommended Connect two identical pressure reducers.
ARC PLUS Warning	Check if the instrument is free of adhesions, and purge it with argon. If repeated purging does not solve the problem, the instrument and cable must be replaced.

Heading	Fault message
ARC PLUS Fault	Check if the argon bottles are connected and open. Empty bottles should be replaced. You can connect two argon bottles. A change to the replacement bottle occurs automatically.
ARC PLUS Warning	The filling level of the argon bottle is low. Please make sure that a replacement is available. You can connect two argon bottles. The unit shifts automatically to the second bottle.
ARC PLUS Fault	The argon bottle is empty. Connect a replacement bottle to enable activation. You can connect two argon bottles. The unit shifts automatically to the second bottle
ARC PLUS Notice	The argon bottle is empty. The unit has shifted automatically to the replacement bottle. Please make sure that a replacement is available.
ARC PLUS Notice	The argon bottle is empty. The unit shifts automatically to the replacement bottle. Please make sure that a replacement is available.
ARC PLUS Fault	Please check if the argon bottles are connected and open. Empty bottles should be replaced. Subsequently restart ARC PLUS by activating the flashing "Purge" button.
TSI ARC PLUS Warning	The annual Technical Safety Inspection (TSI) for ARC PLUS is due.
Plug'n Cut COMFORT Notice	The lifetime of the instrument is ending soon. Please order a replacement in good time. Any use of the instrument beyond its lifetime is not covered by warranty. Please contact your BOWA dealer in good time to purchase a new instrument.
Plug'n Cut COMFORT Warning	The maximum lifetime of the instrument has been reached. Any further use is not covered by warranty. The maximum service lifetime of the instruments must not be exceeded, in order to guarantee safe usage. Any further use is at the user's risk.
Plug'n Cut COMFORT Warning	A software update is necessary to use Plug'n Cut COMFORT with this instrument. Only carry out manual settings at this instrument. Please contact the Technical Support. Contact: MENU - SERVICE.
Plug'n Cut COMFORT Warning	Unable to load the preference parameters of the COMFORT instrument. Configure the instrument settings manually. Please contact the Technical Support. Contact: MENU - SERVICE.

Heading	Fault message
Dr. Dongle Warning	A fault occurred while loading the program. No changes have been made. If the warning message persists, please contact the Technical Support. Contact: MENU - SERVICE.
Dr. Dongle Warning	The selected program does not have any parameters. Put a valid program in this memory or select a different memory location.
Internal Error XXXX (z.B. mit XXXX = 4183)	If this message appears again, please contact the Technical Support. Contact: MENU - SERVICE.

Internal Errors have a number next to the description.
Please advise the Technical Service of this number.

6.2. Fault indications for EASY monitoring

Fault indications are displayed in three stages (green, yellow and red) when problems occur.

When working with a split neutral electrode, the following faults may occur:

EASY monitoring	Cause	Indication	Corrective measures
Flashes yellow	Significant increase in resistance Depending on the indication, there may be heating under the neutral electrode	–	Stopping the application is not necessary. ►Check the proper application of the neutral electrode.
Switches from green to continuous red	A significant problem occurred when the monopolar current was activated	An acoustic signal sounds. A warning message appears on the display	►Check the neutral electrode and neutral electrode cable (see Section EASY neutral electrode monitoring (EASY monitoring), page 37. ►Check the neutral electrode cable for proper connection and external damage.
	Loosened electrode	An acoustic signal sounds. A warning message appears on the display	►Reattach the neutral electrode. If the fault persists, replace the neutral electrode.

7. Preparation

7.1. Preparation of the accessories

- Prepare the accessories (e.g. surgical handles, instruments, active electrodes, neutral electrodes and cables) as described in the corresponding operating manuals.
- Check the accessories before and after use for damage and to ensure that they are working properly.

7.2. Disinfection and cleaning

NOTE

Incorrect handling of the HF device can cause damage to the unit!

Never sterilize the ARC 400 device. Instead, clean or disinfect it.

WARNING

Risk of electric shock and fire!

- Unplug the power connection before cleaning the device.
- For cleaning surfaces, use the approved cleaning agents/disinfectants only as specified by the manufacturer.
- Ensure that no liquid penetrates the device.
- Ensure that the AUTOSTART function is deactivated.

1. Apply the cleaning agent and disinfectant.
   BOWA recommends the use of cleaning and disinfection agents which are suitable for surface cleaning of medical devices made of plastic, metal and glass.

The manufacturer accepts no responsibility if other types of cleaning and disinfecting agents are used.
Follow the instructions provided by the manufacturer of the cleaning agent.

2. Wipe the agent off with a sponge moistened with clean water or with a cloth.
3. Dry the device using a clean, lint-free cloth.

8. Maintenance and repair

8.1. Maintenance

⚠ DANGER

Infection hazard!

- ▶ Carry out a surface disinfection and wrap the device in addition to the shipping packaging material before allowing the device to leave the hospital or office to avoid spreading germs and infections.

- ▶ Check the device, the device trolley and the accessories (e.g. foot switch, cable) after each use for damage or defects. In particular, make sure that the insulation is intact on all cables.
- ▶ Do not use any damaged device, damaged device trolley or damaged accessories.
- ▶ Replace defective accessories immediately.
- ▶ Have the safety inspection for the device performed once a year. Please consult and comply with the respective service instructions for additional technical information.

8.1.1. Safety inspection

Safety inspections must be performed once a year.

- ▶ The next safety inspection date of ARC 400 can be displayed in the dialog, see section 5.10.5 "System information" dialog, page 86.
- ↳ A warning message appears during system start-up if a safety inspection is due.

  Press OK to confirm this message.

Any shorter safety inspection cycles specified in national regulations must be observed.

- ▶ The device and accessories may be inspected only by persons who have the required training, knowledge or experience and who can perform the inspection independently.
- ▶ With regard to the safety inspection, you must comply with the country-specific rules and regulations.

The tester documents the inspection results and measured values according to the printed test record in the service manual. If you do not have a copy of the service manual, please contact your dealer or one of the service addresses listed below.

In the case of severe deviations from the values of the service test record, or if the specified maximum values were exceeded:

- ▶ Send the HF device to the service center, see section Technical service, page 111.

8.2. Repairs

NOTE

You can damage the HF device by doing your own repairs and modifications of medical equipment!

- ▶ If a repair is necessary, have it done only by the service center specified below.
- ▶ Never carry out any repairs yourself.

BOWA is liable for safety, reliability and performance of the HF device under the following conditions:

- Full compliance with all instructions regarding the installation and proper use for the intended purpose contained in this operating manual was maintained.
- Changes, repairs, new settings and similar procedures were carried out only by persons authorized to do this work by BOWA.
- The electrical installations in the relevant room meet the local requirements and statutory provisions.

Fast and satisfactory repairs can only be guaranteed when all required data have been supplied in full.

The following information is required for returning the device:

- complete address
- model number
- serial number
- software version

- ▶ Describe the problem, the appropriate application and the accessories used.

– or –

- ▶ Describe the repairs to be made.

9. Storage

- If you store the HF device for longer than one year, pay specific attention to the indicators during automatic functional testing, see section Functional test, page 35.
- Clean the HF device thoroughly before you put it into storage.
- Store the HF device in a clean, dry place in accordance with the storage conditions.

Storage conditions:

- Temperature: -20 °C to +50 °C
- Relative humidity 0 to 90 %, non-condensing
- Atmospheric pressure: 500 to 1060 hPa

9.1. Technical service

Servicing and repairs must not be performed in the vicinity of the patient.

Contact the following service center for maintenance and repair work:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4–10

72810 Gomaringen, Germany

Phone +49 (0) 7072-6002-0

Fax +49 (0) 7072-6002-33

Email service@bowa.de

or visit our website:

www.bowa-medical.com

10. Technical specifications

10.1. ARC 400 technical data (REF 900-400)

Insulation type / Classification	
EMC	IEC 60601-1-2: 2014
Level of protection provided by the housing	IP 21
Protection class according to EN 60601-1	I
Application component type according to EN 60601-1	CF
Standards compliance	IEC 60601-1: 2005 + Cor.1(2006) + Cor.2 (2007) + A1:2012 IEC 60601-2-2: 2009; IEC 62366: 2007 ISO 14971: 2007 ISO 13485: 2003 + Cor.1 (2009)
Classification according to EC Directive 93/42/EEC	IIb

Power connection	**220 V - 240 V**	**100 V - 127 V**
Min. Power consumption	3 W / 40 VA	3 W / 40 VA
Min. Current consumption	200 mA	400 mA
Max. power consumption (at 400 W)	700 W / 1150 VA	700 W / 1150 VA
Max. current consumption (at 400 W)	5 A	10 A @ 100 V~ 8 A @ 127V~
Line fuses	2 x 5 AH slow-blow	2 x 5 AH slow-blow
Mains frequency	50 / 60 Hz	50 / 60 Hz
Terminal for potential equalization	√	√

Dimensions and weight	
Dimensions	430 x 180 x 475 mm
Net weight	12,5 kg
Packaging information /dimensions	Carton 685 x 497 x 280 mm
Gross weight	18 kg

Programs	
Number of programs in the device	300
Default programs, factory set	Yes
Individually programmable	Yes
Information shown on the display	√

Neutral electrode monitoring	
EASY (Electrode Application System)	Yes
Display indication of one-piece or split or Baby electrode	Main and neutral electrode menu
Contact resistance between individual sections of split neutral electrodes shown on display	Using color and contact indicator
Lead resistance shown on the display when a non-split neutral electrode is used	Yes
Maximum allowable resistance between the sections of a split electrode	300 Ω
Warning signal for hazardous conditions concerning neutral electrode	Visual, acoustic
Warning message on the display	Text message with further information

Safety features	
ISSys (Integrated Safety System)	Yes
Spark regulation	ARC CONTROL
Continuous monitoring of HF leakage current and fault indication	Text message with further information
Dosage monitoring with fault indication on the display	Yes
Continuous self-test	Yes
Continuous status indication on the display	Yes
System faults shown on the display	Text message with further information
Technical Safety Inspection (TSI)	Automatic memory function (optional)
Operating manual	Direct access in the display, additionally provided as hardcopy and USB-Stick incl. PDF

Documentation	
Data acquisition and storage in the device	System information
Documentation of fault states	Yes
Retrieval of system information via the display	Text message with further information

Communication	
Display	Capacitive touchscreen 9‘‘
External interface for communication of HF generator and ARC PLUS	Light wire cables
USB interface for software updates	Yes
External PC port for use of BOWA software for service support	√

Service support	
Service support by service programs integrated in the device	Yes
Service support via ISSys	Yes

Cooling	
Convection	Yes
Temperature-controlled fan	Yes

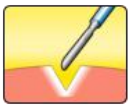
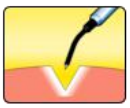
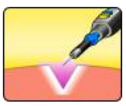
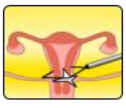
Duty factor	
Duty factor	Intermittent 10 s / 30 s (on / off)

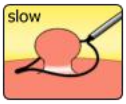
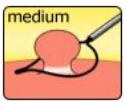
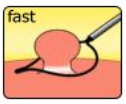
Characteristics	
Max. MONOPOLAR power	400 W (at 200 Ω)
Max. BIPOLAR power	400 W (at 75 Ω)
Output frequency	350 kHz / 1 MHz
Monopolar sockets	2x (footswitch and finger switch)
Bipolar sockets	3x (3x footswitch and 2x finger switch)
Connection for footswitch	2x
AUTOSTART	Yes
Options	Bipolar Resection M098-900395, LIGATION M098-900396, Bipolar SimCoag M098-900399
Scope of delivery	Incl. Dr. Dongle, USB Stick, operating manual, mains cable, PE-line

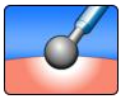
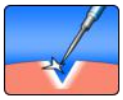
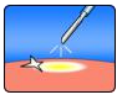
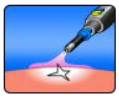
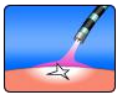
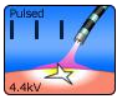
RFID	
Transmitter frequency	13,56 MHz
Duty cycle	0-100%
Modulation scheme	AM
Antennas	Four internal antennas (antenna diversity – no simultaneous transmission on both antennas)
Number of channels	1
Max. RF output power	33dBm (<< 42 dBµA/m at 10m)
Applied RF standards	ETSI EN 300330-1 V1.7.1 (2010-02) ETSI EN 300330-2 V1.5.1 (2010-02)

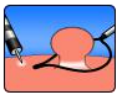
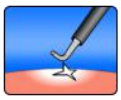
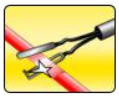
Compatibility	
Permitted combinations	ARC PLUS (900-001), footswitch (901-031, 901-032, 901-011)

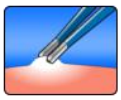
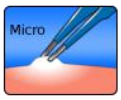
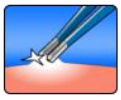
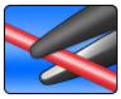
Conditions of operation, transport and storage	Operation	Transport and storage
Temperature	+10°C to +40°C	-20°C to +50°C
Relative humidity	30 to 75%, non-condensing	0 to 90%, non-condensing
Atmospheric pressure	700 to 1060 hPa	500 to 1060 hPa
Operating altitude (max.)	3000 m above sea level	

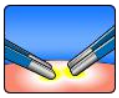
Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
Modes Monopolar Cutting												
	Standard	Yes	Yes	sinusoidal constant	1 2 3 4 5 6 7 8 9	1 W – 400 W	400 Vp 450 Vp 560 Vp 650 Vp 650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	5	100	200 Ω	---	---
	Micro	Yes	yes	sinusoidal constant	1 2 3 4 5 6 7 8 9	1 W – 50 W	280 Vp 340 Vp 380 Vp 400 Vp 400 Vp 400 Vp 450 Vp 450 Vp 450 Vp	5	20	500 Ω	---	---
	Dry	Yes	yes	sinusoidal modulated	1 2 3 4 5 6 7 8 9	1 W – 200 W	1.4 kVp 1.4 kVp 1.4 kVp 1.4 kVp 1.5 kVp 1.6 kVp 1.6 kVp 1.6 kVp 1.6 kVp	5	100	500 Ω	20 kHz	30 % 30 % 30 % 30 % 25 % 20 % 20 % 20 % 20 %
	Argon	Yes	yes	sinusoidal constant	1 2 3 4 5 6 7 8 9	1 W – 300 W	400 Vp 450 Vp 560 Vp 650 Vp 650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	5	100	500 Ω	---	---
	Resection	Yes	yes	sinusoidal constant	1 2 3 4 5	250 W	650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	2	---	500 Ω	---	---
	MetraLOOP	Yes	Yes	sinusoidal constant	1 2 3	300 W 350 W 400 W	650 Vp	1	---	100 Ω	---	---
	Laparoscopy	Yes	Yes	sinusoidal constant	1 2 3 4 5 6 7 8 9	1 W - 200W	400 Vp 450 Vp 560 Vp 650 Vp 650 Vp 700 Vp 700 Vp 700 Vp 750 Vp	5	100	500 Ω	---	---

Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
	GastroLOOP 1	Yes	Yes	sinusoidal alternating Cut, Coag and break phases	1 2 3 4 5	400 W	750 Vp	3	---	500 Ω	---	---
	GastroLOOP 2	Yes	Yes	sinusoidal alternating Cut, Coag and break phases	1 2 3 4 5	400 W	750 Vp	3	---	500 Ω	---	---
	GastroLOOP 3	Yes	Yes	sinusoidal alternating Cut, Coag and break phases	1 2 3 4 5	400 W	750 Vp	3	---	500 Ω	---	---
	GastroKNIFE 1	Yes	Yes	sinusoidal alternating Cut and Coag phases	1 2 3 4 5	300 W	650 Vp 650 Vp 650 Vp 700 Vp 750 Vp	3	---	500 Ω	---	---
	GastroKNIFE 2	Yes	Yes	sinusoidal alternating Cut and Coag phases	1 2 3 4 5	300 W	650 Vp 650 Vp 650 Vp 700 Vp 750 Vp	3	---	500 Ω	---	---
	GastroKNIFE 3	Yes	Yes	sinusoidal alternating Cut and Coag phases	1 2 3 4 5	300 W	650 Vp 650 Vp 650 Vp 700 Vp 750 Vp	3	---	500 Ω	---	---

Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
Modes Monopolar Coagulation												
	Moderate			sinusoidal constant	1 2 3	1 W – 120 W	250 Vp	2	60	75 Ω	---	---
	Forced non cutting			pulsed modulated	-	1 W - 80 W	3.5 kVp	---	50	1000 Ω	20 kHz	1 pulse
	Forced mixed			sinusoidal modulated	1 2 3	1 W – 120 W	1.5 kVp 2.0 kVp 2.5 kVp	2	60	500 Ω	30 kHz	sinusoidal 1 pulse
	Forced cutting			sinusoidal modulated	1 2 3 4	1 W – 250 W	1.5 kVp 1.5 kVp 1.3 kVp 1.3 kVp	2	80	500 Ω	20 kHz	30 % 35 % 40 % 50 %
	Spray			pulsed modulated	1 2 3 4	1 W – 120 W	3.0 kVp 3.8 kVp 4.6 kVp 5.0 kVp	2	80	500 Ω	20 kHz	sinusoidal 1 pulse 1 Impuls 1 Impuls 1 Impuls
	Argon			pulsed modulated	-	1 W – 120 W	4.6 kVp	---	80	500 Ω	20 kHz	1 pulse
	Argon flexible			pulsed modulated	-	1 W – 120 W	4.4 kVp	---	20	500 Ω	Power dependent 1 kHz - 20 kHz	1 pulse
	Argon flex. pulse			pulsed modulated	1 2 3	1 W – 80 W	4.4 kVp	2	20	500 Ω	Power dependent 1 kHz - 20 kHz	1 pulse 1 pulse 1 pulse
	Resection			sinusoidal modulated	-	1 W -120 W	2.2 kVp	---	60	500 Ω	30 kHz	sinusoidal 1 pulse

Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
Modes Monopolar Coagulation												
	Cardiac Mammary			sinusoidal modulated	-	1 W - 60 W	1.8 kVp	---	15	500 Ω	30 kHz	sinusoidal 1 pulse
	Cardiac Thorax			sinusoidal modulated	-	1 W – 100 W	1.8 kVp	---	40	500 Ω	30 kHz	sinusoidal 1 pulse
	SimCoag			sinusoidal modulated pulsed modulated pulsed modulated	1 2 3	1 W – 120 W	2.0 kVp 2.5 kVp 4.6 kVp	2	60	500 Ω	30 kHz 30 kHz 20 kHz	sinusoidal 1 pulse sinusoidal 1 pulse 1 pulse
	Gastro Coag			sinusoidal modulated	1 2 3	1 W - 50 W	1.8 kVp 2.2 kVp 2.8 kVp	2	15	500 Ω	30 kHz	sinusoidal 1 pulse
	Laparoscopy			sinusoidal modulated	-	1 W – 120 W	1.8 kVp	---	60	500 Ω	20 kHz	5%
Modes Bipolar Cutting												
	Standard	Yes	Yes	sinusoidal constant	-	1 W – 200 W	400 Vp	---	100	75 Ω	---	---
	Bipolar resection	Yes	Yes	sinusoidal constant	1 2 3	250 W	500 Vp	2	---	75 Ω	---	---
			Initial incision phase			860 W						
	Bipolar scissors			sinusoidal constant	-	1 W – 120 W	200 Vp	---	40	75 Ω	---	---
	Vaporisation	Yes	Yes	sinusoidal constant	1 2 3	300 W 300 W 400 W	350 Vp 400 Vp 450 Vp	2	---	75 Ω	---	---

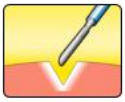
Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
Modes Bipolar Coagulation												
	Standard forceps			sinusoidal constant	-	1 W – 120 W	150 Vp	---	40	50 Ω	---	---
	Standard forceps AUTO			sinusoidal constant	-	5 W – 120 W	150 Vp	---	40	50 Ω	**---**	**---**
	Micro forceps			sinusoidal constant	-	0.1 W – 40 W	90 Vp	---	10	50 Ω	---	---
	Forceps forced			sinusoidal modulated	-	1 W – 100 W	550 Vp	---	50	50 Ω	20 kHz	10%
	LIGATION			sinusoidal modulated	-	200 W	190 Vp	---	---	25 Ω	1 - 2 Hz	sinusoidal
	TissueSeal PLUS			sinusoidal modulated	-	200 W	190 Vp	---	---	25 Ω	1 - 2 Hz	sinusoidal
	ARCSeal			sinusoidal constant	-	150 W	200 Vp	---	---	50 Ω	---	---
	Bipolar scissors			sinusoidal constant	-	1 W – 120 W	200 Vp	---	40	75 Ω	---	---

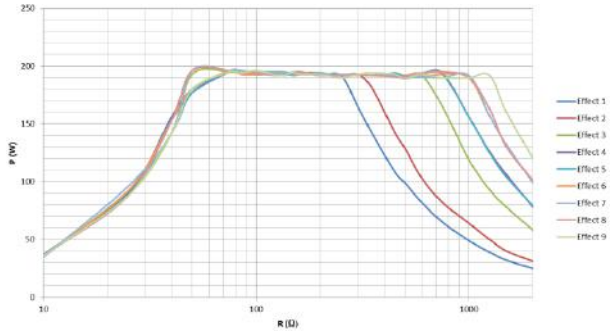
Mode icon	Description	CCS	ARC CONTROL	Form of HF voltage	Max. power output		Peak voltage	Default values		Rated load resistance	Modulation	
					Effect	Power range		Effect	Max. Watt		Frequency	Duty cycle
Modes Bipolar Coagulation												
	Laparoscopy			sinusoidal constant	-	1 W – 120 W	150 Vp	---	50	50 Ω	---	---
	Laparoscopy Micro			sinusoidal constant	-	1 W – 100 W	110 Vp	---	40	25 Ω	---	---
	Bipolar resection			sinusoidal constant	1 2 3 4	125 W 200 W 275 W 350 W	190 Vp	2	---	25 Ω	---	---
	SimCoag			sinusoidal modulated	-	5 W - 60 W	550 Vp	---	40	50 Ω	20 kHz	50%
	Vaporisation			sinusoidal constant sinusoidal modulated sinusoidal modulated	1 2 3	250 W	190 Vp 400 Vp 500 Vp	2	---	25 Ω	- 20 kHz 20 kHz	---- 50% 50%

The max. values are not necessarily created at rated load resistance.
The HF power is subject to a tolerance limit of ± 20%.

10.2. Output, voltage and current diagrams

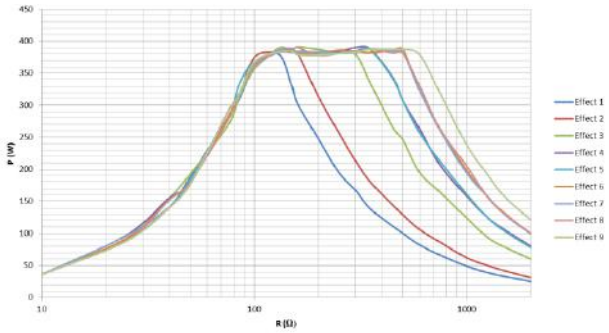
Monopolar Cutting – Standard





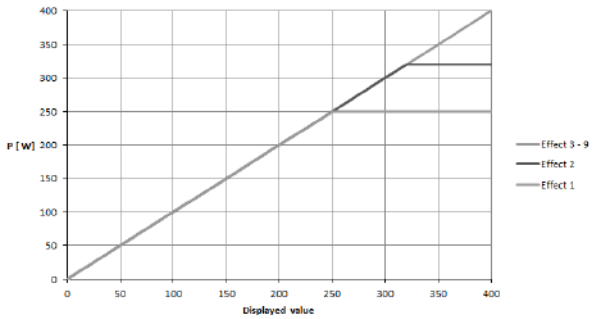
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Standard"
  = 200 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Standard"
  = 400 W

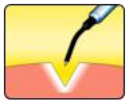


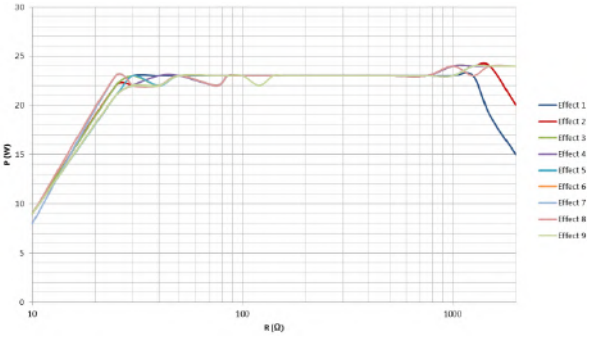
- Diagram of power output P [W] as a function of the setting "Monopolar Cutting Standard"
  Rated load resistance = 200 Ω

Effect	U (Vp)
1	400
2	450
3	560
4	650
5	650
6	700
7	700
8	700
9	750

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Standard" (idle mode)

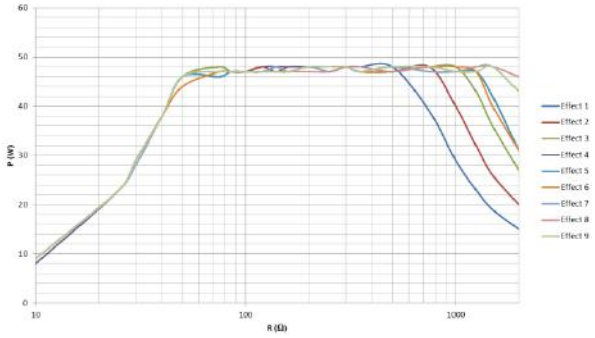
Monopolar Cutting – Micro





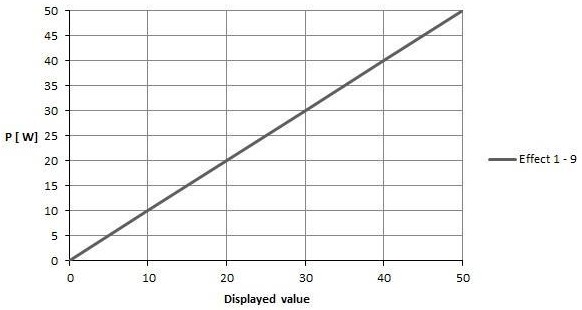
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Micro" = 25 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Micro" = 50 W

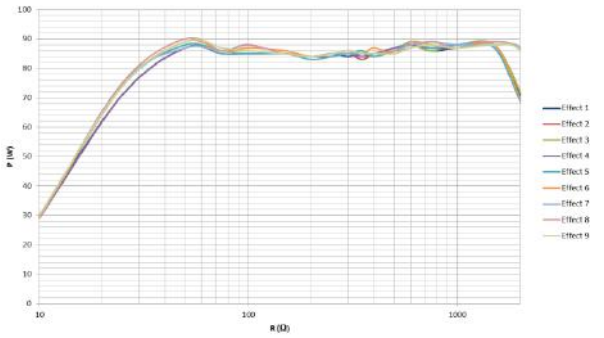


- Diagram of power output P [W] as a function of the setting "Monopolar Cutting Micro"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	280
2	340
3	380
4	400
5	400
6	400
7	450
8	450
9	450

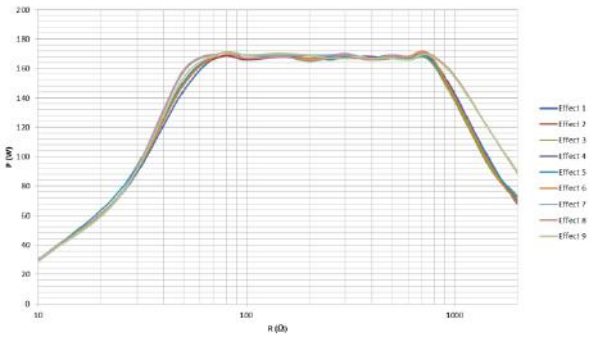
- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Micro" (idle mode)

Monopolar Cutting – Dry



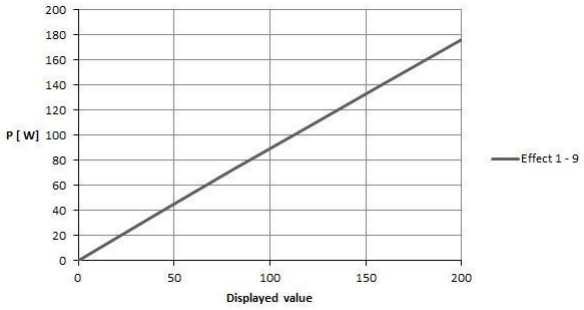
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Dry" = 100 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Dry" = 200 W

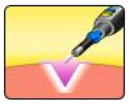


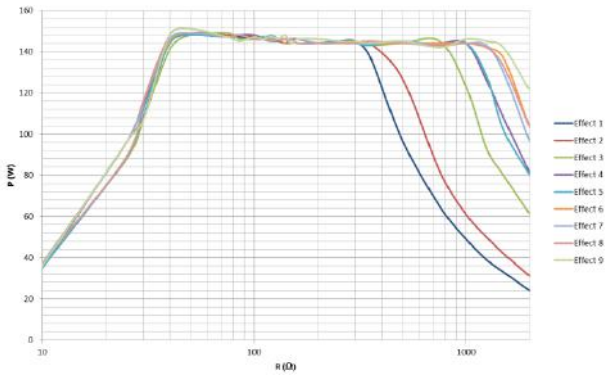
- Diagram of power output P [W] as a function of the setting "Monopolar Cutting Dry"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	1400
2	1400
3	1400
4	1400
5	1500
6	1600
7	1600
8	1600
9	1600

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Dry" (idle mode)

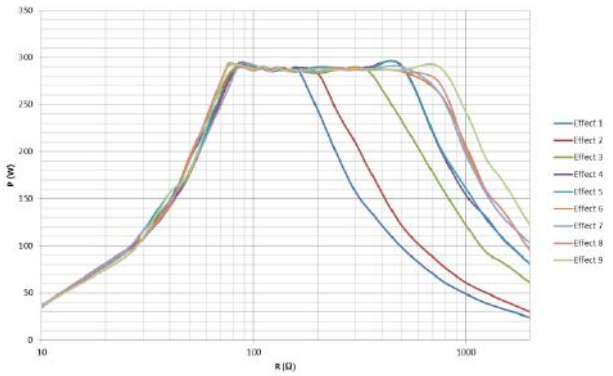
Monopolar Cutting – Argon





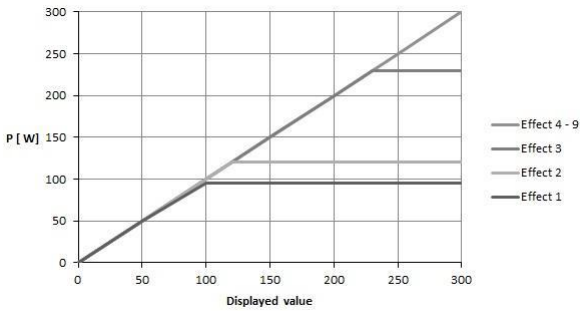
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Argon" = 150 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Argon" = 300 W

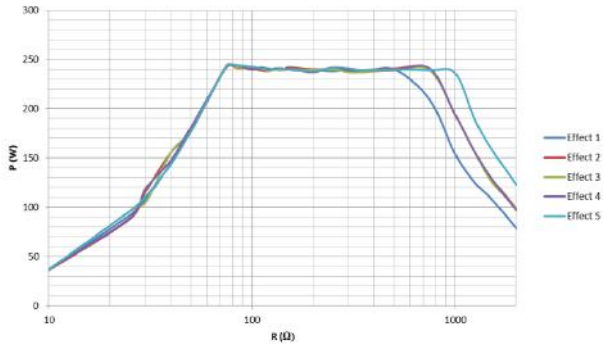


- Diagram of power output P [W] as a function of the setting "Monopolar Cutting Argon"
  Rated load resistance= 500 Ω

Effect	U (Vp)
1	400
2	450
3	560
4	650
5	650
6	700
7	700
8	700
9	750

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Argon" (idle mode)

Monopolar Cutting – Resection



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Resection"

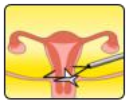
Effect	P (W)
1	250
2	250
3	250
4	250
5	250

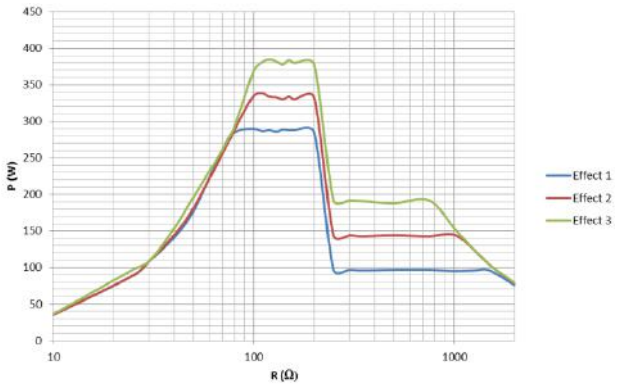
- Table of power output P [W] as a function of the setting "Monopolar Cutting Resection"
  Rated load resistance= 500 Ω

Effect	U (Vp)
1	650
2	700
3	700
4	700
5	750

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Resection" (idle mode)

Monopolar Cutting – MetraLOOP





Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting MetraLOOP"

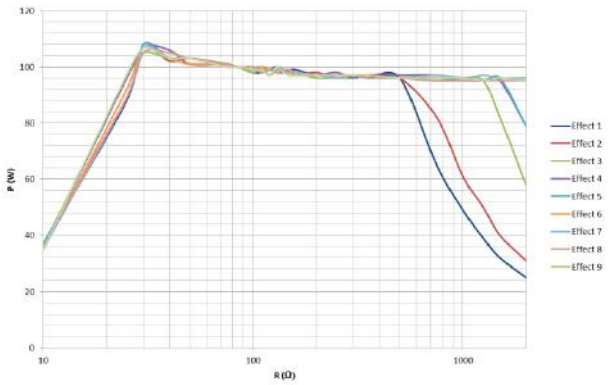
Effect	P (W)
1	300
2	350
3	400

- Table of power output P [W] as a function of the setting "Monopolar Cutting MetraLOOP".
  Rated load resistance= 100 Ω

Effect	U (Vp)
1	650
2	650
3	650

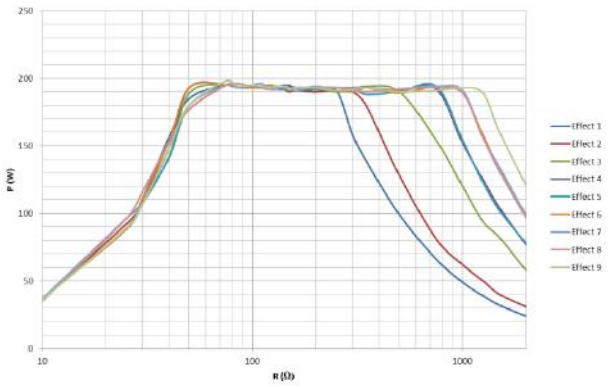
- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting MetraLOOP" (idle mode)

Monopolar Cutting – Laparoscopy



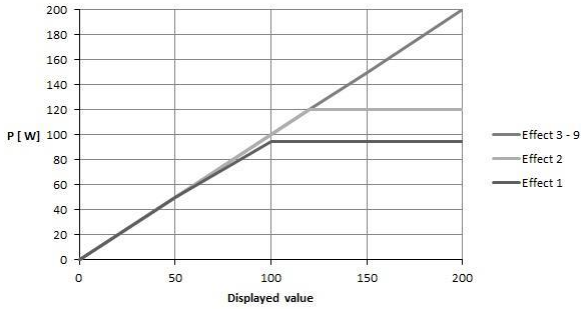
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Laparoscopy"
  = 100 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting Laparoscopy"
  = 200 W

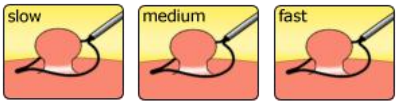


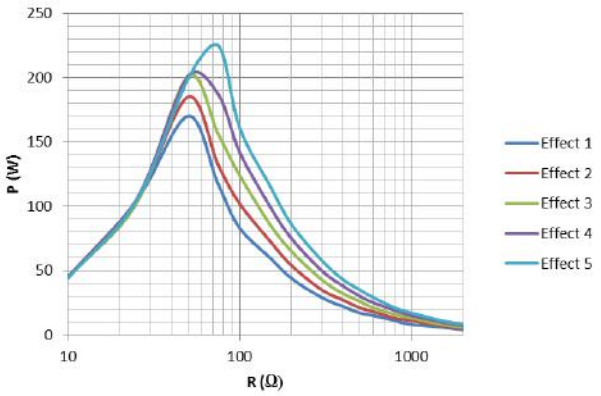
- Diagram of power output P [W] as a function of the setting "Monopolar Cutting Laparoscopy"
  Rated load resistance= 500 Ω

Effect	U (Vp)
1	400
2	450
3	560
4	650
5	650
6	700
7	700
8	700
9	750

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting Laparoscopy" (idle mode)

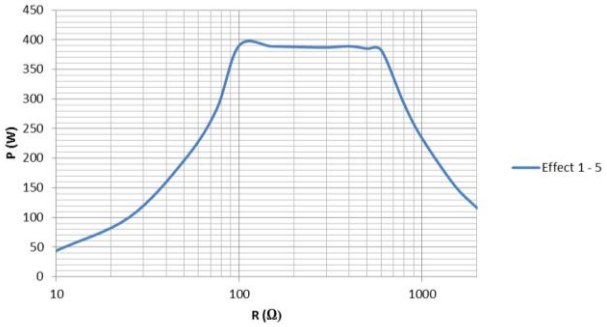
Monopolar Cutting – GastroLOOP 1, 2, 3





Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting GastroLOOP 1, 2, 3"
  coag phase



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting GastroLOOP 1, 2, 3"
  cut phase

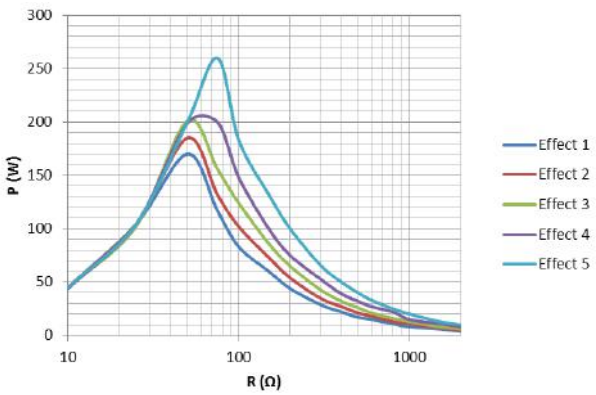
Effect	P (W) coag phase	P (W) cut phase
1	17	400
2	21	400
3	26	400
4	30	400
5	35	400

- Table of power output P [W] as a function of the setting "Monopolar Cutting GastroLOOP 1, 2, 3"
  Rated load resistance= 500 Ω

Effect	U (Vp)
1	750
2	750
3	750
4	750
5	750

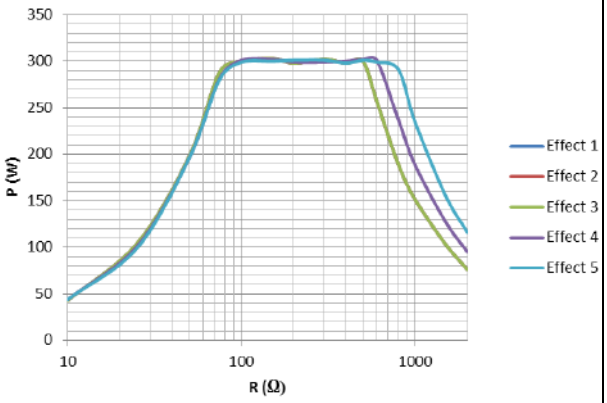
- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting GastroLOOP 1, 2, 3"
  (idle mode)

Monopolar Cutting – GastroKNIFE 1, 2, 3



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting GastroKNIFE 1, 2, 3"
  coag phase



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Cutting GastroKNIFE 1, 2, 3"
  cut phase

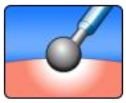
Effect	P (W) coag phase	P (W) cut phase
1	17	300
2	21	300
3	26	300
4	32	300
5	40	300

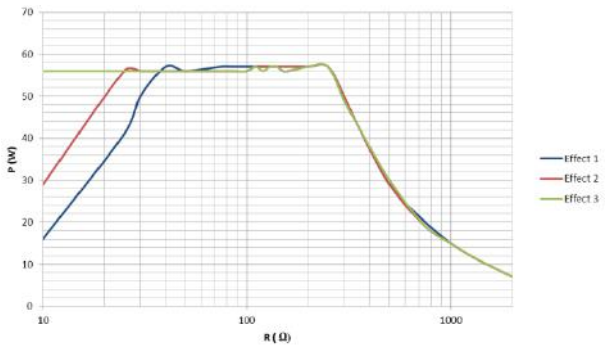
- Table of power output P [W] as a function of the setting "Monopolar Cutting GastroKNIFE 1, 2, 3"
  Rated load resistance= 500 Ω

Effect	U (Vp)
1	650
2	650
3	650
4	700
5	750

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Cutting GastroKNIFE 1, 2, 3"
  (idle mode)

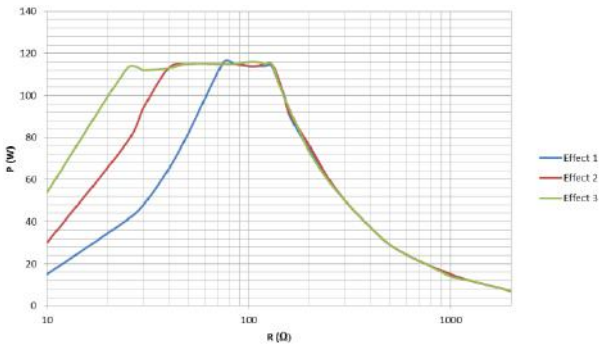
Monopolar Coagulation – Moderate





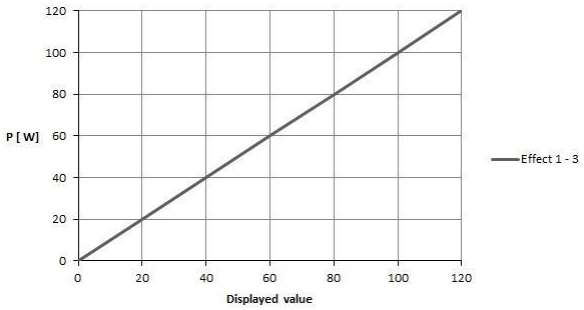
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Moderate"
  = 60 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Moderate"
  = 120 W

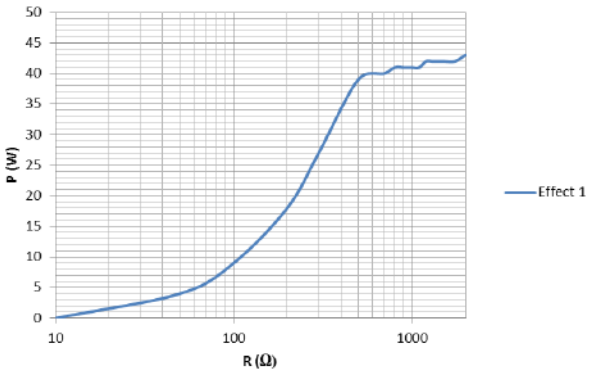


- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Moderate"
  Rated load resistance= 75 Ω

Effect	U (Vp)
1	250
2	250
3	250

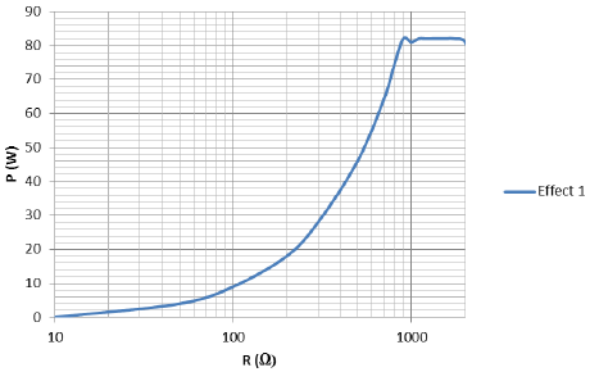
- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation Moderate"
  (idle mode)

Monopolar Coagulation – Forced non cutting



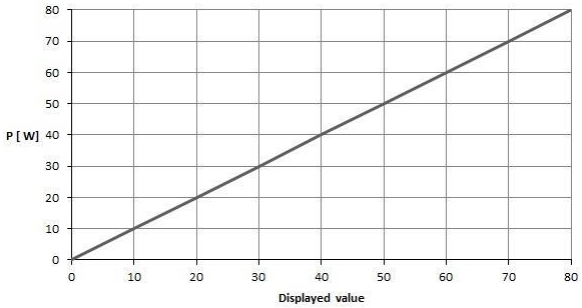
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced non cutting"
  = 40 W



Measurement at ohmic resistances

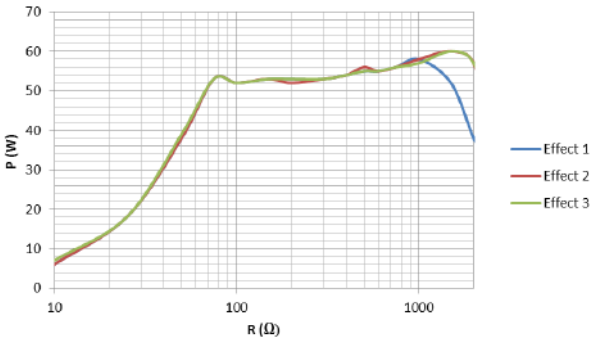
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced non cutting"
  = 80 W



- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Forced non cutting"
  Rated load resistance = 1000 Ω

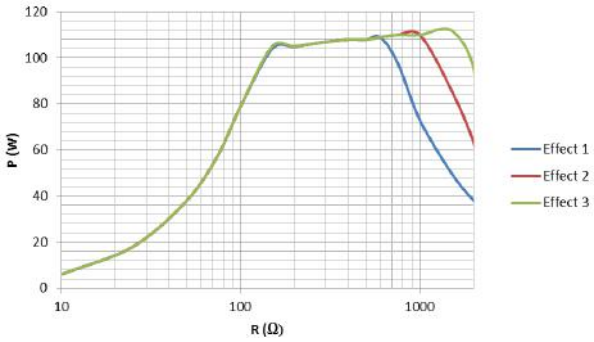
- HF output voltage U [Vp] for the setting "Monopolar Coagulation Moderate" (idle mode)
  = 3500 Vp

Monopolar Coagulation – Forced mixed



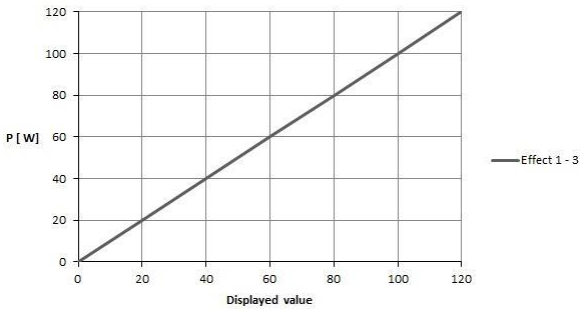
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced mixed"
  = 60 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced mixed"
  = 120 W

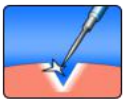


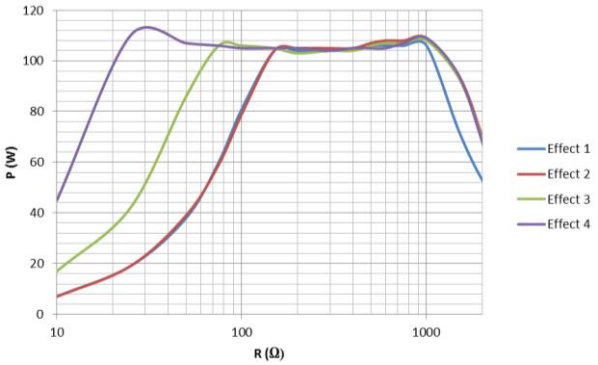
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Forced mixed"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	1500
2	2000
3	2500

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation Forced mixed"
  (idle mode)

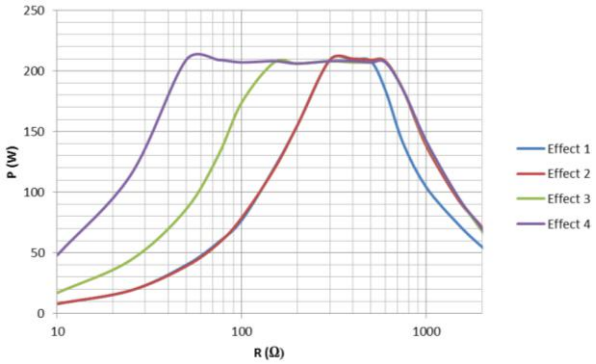
Monopolar Coagulation – Forced cutting





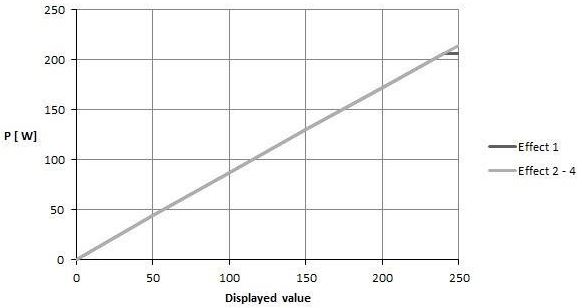
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced cutting"
  = 125 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Forced cutting"
  = 250 W

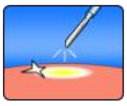


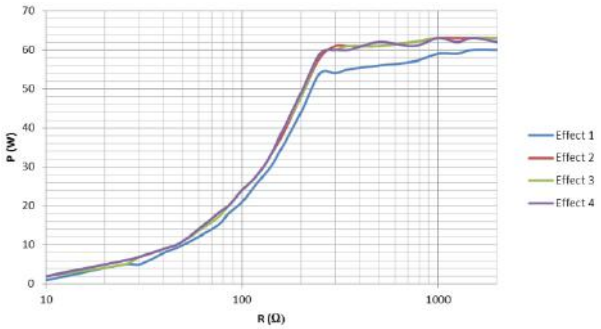
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Forced cutting"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	1500
2	1500
3	1300
4	1300

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation Forced cutting"
  (idle mode)

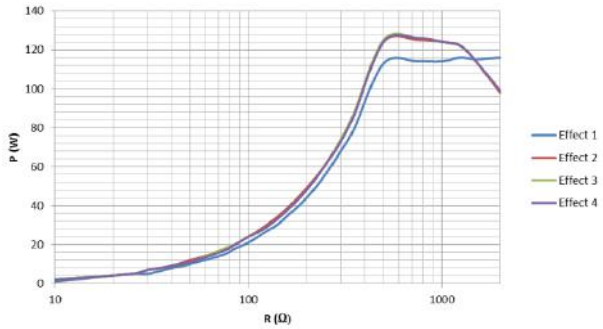
Monopolar Coagulation – Spray





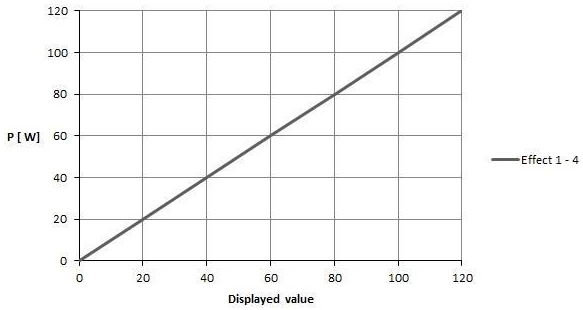
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Spray"
  = 60 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Spray"
  = 120 W

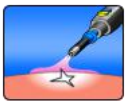


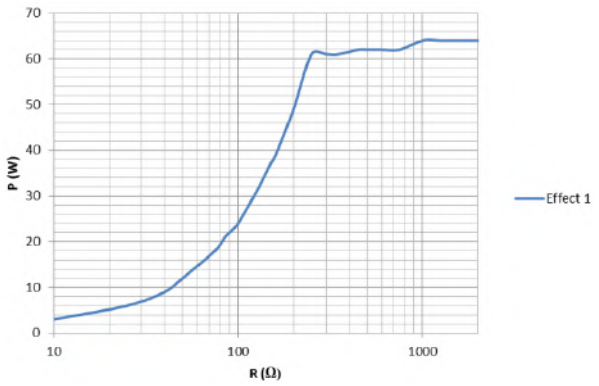
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Spray"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	3000
2	3800
3	4600
4	5000

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation Spray" (idle mode)

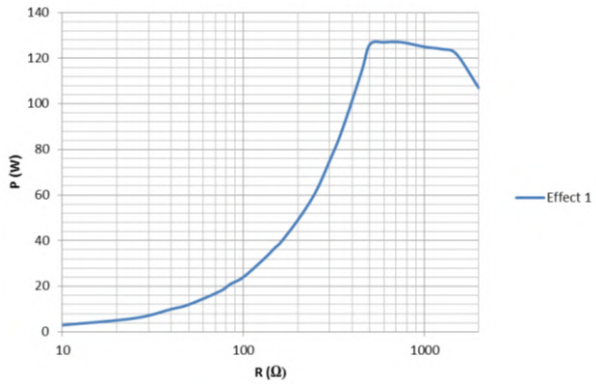
Monopolar Coagulation – Argon





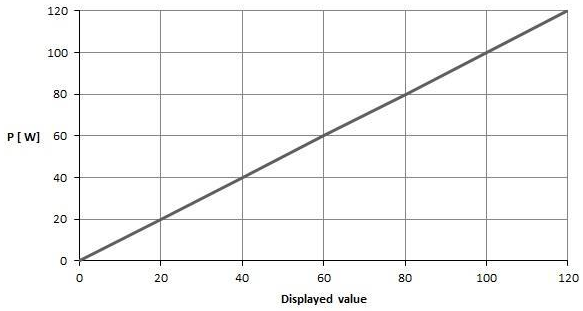
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon open"
  = 60 W



Measurement at ohmic resistances

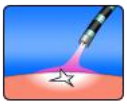
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon open"
  = 120 W

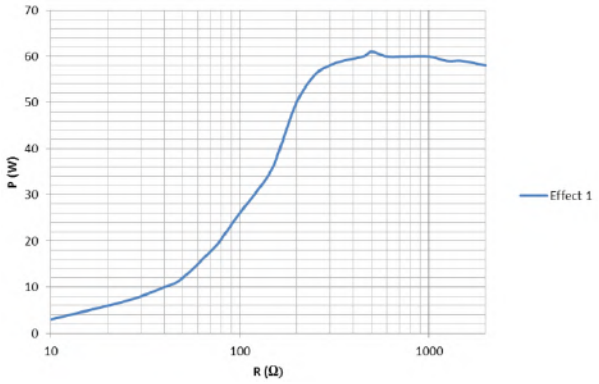


- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Argon open"
  Rated load resistance = 500 Ω

- HF output voltage U [Vp] for the setting "Monopolar Coagulation Argon open" (idle mode)
  = 4600 Vp

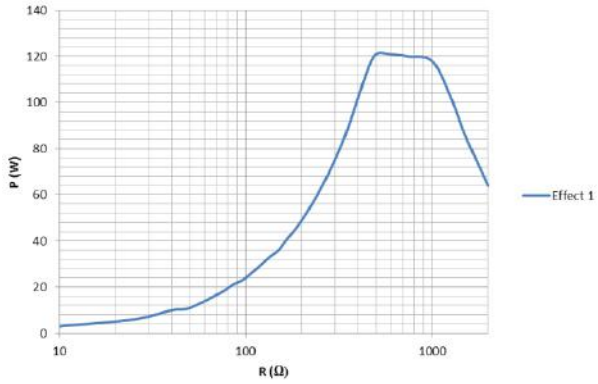
Monopolar Coagulation – Argon flexible





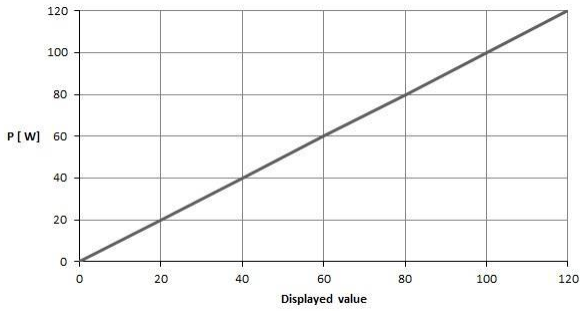
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon flexible"
  = 60 W



Measurement at ohmic resistances

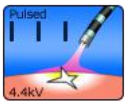
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon flexible"
  = 120 W

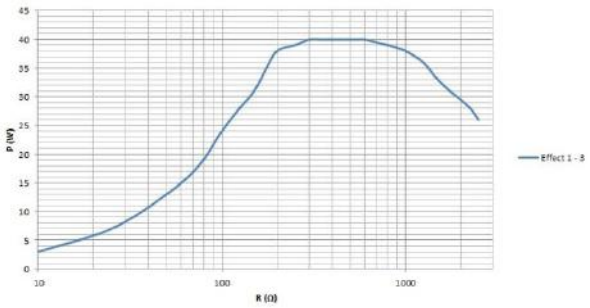


- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Argon flexible"
  Rated load resistance = 500 Ω

- HF output voltage U [Vp] for the setting "Monopolar Coagulation Argon flexible" (idle mode)
  = 4400 Vp

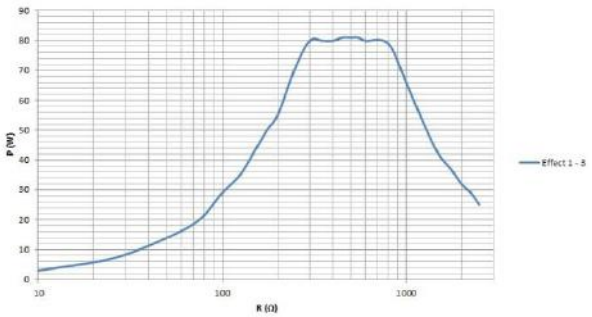
Monopolar Coagulation – Argon flex. pulse





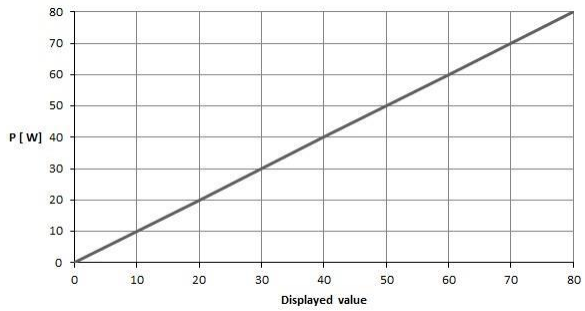
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon flex. pulse"
  = 40 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Argon flex. pulse"
  = 80 W



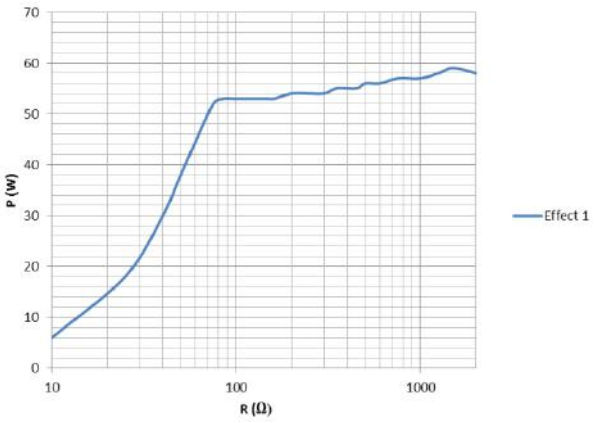
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Argon flex. pulse"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	4400
2	4400
3	4400

- Table HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation Argon flex. pulse" (idle mode)

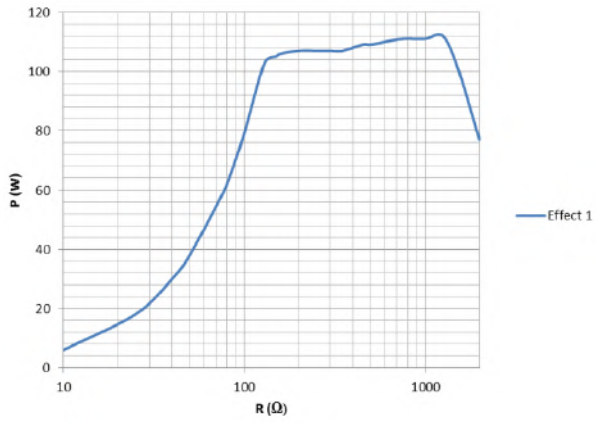
The puls frequency changes with the effect setting. The higher the effect level, the faster the pulse sequence.
Effect 1: 1 Hz, effect 2: 5 Hz, effect 3: 10 Hz
The mode "Argon flexible" is paused due to the pulse sequence.

Monopolar Coagulation – Resection



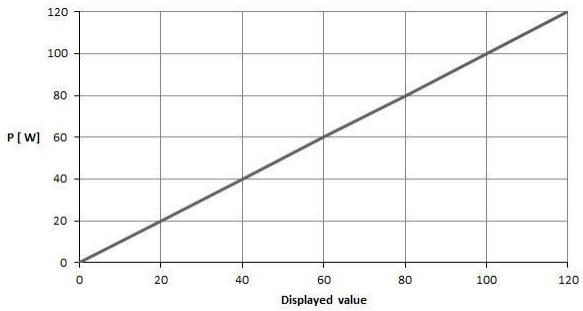
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Resection"
  = 60 W



Measurement at ohmic resistances

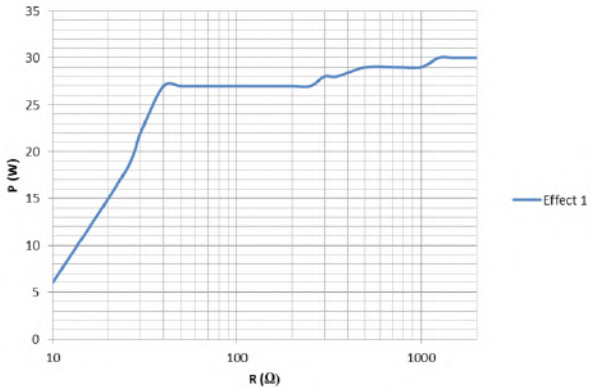
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Resection"
  = 120 W



- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Resection"
  Rated load resistance = 500 Ω

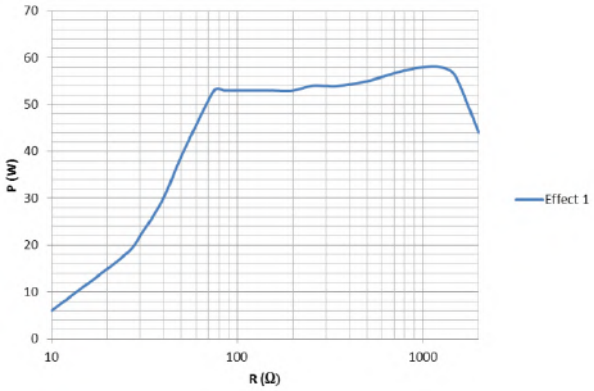
- HF output voltage U [Vp] for the setting "Monopolar Coagulation Resection" (idle mode)
  = 2200 Vp

Monopolar Coagulation – Cardiac Mammary



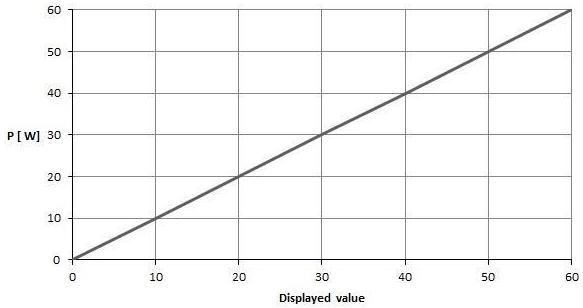
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Cardiac Mammary"
  = 30 W



Measurement at ohmic resistances

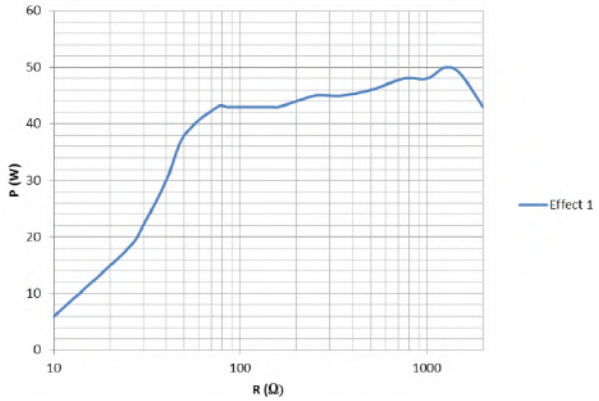
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Cardiac Mammary"
  = 60 W



- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Cardiac Mammary"
  Rated load resistance = 500 Ω

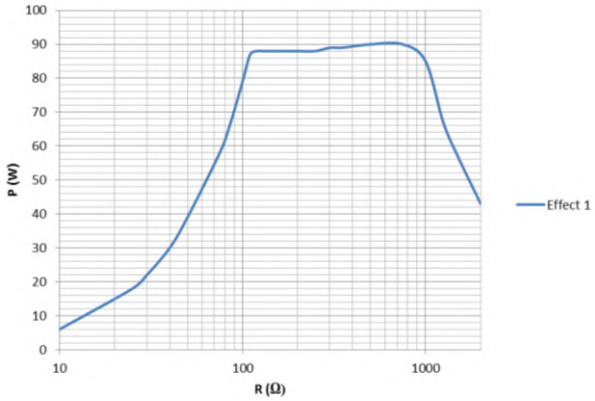
- HF output voltage U [Vp] for the setting "Monopolar Coagulation Cardiac Mammary" (idle mode)
  = 1800 Vp

Monopolar Coagulation – Cardiac Thorax



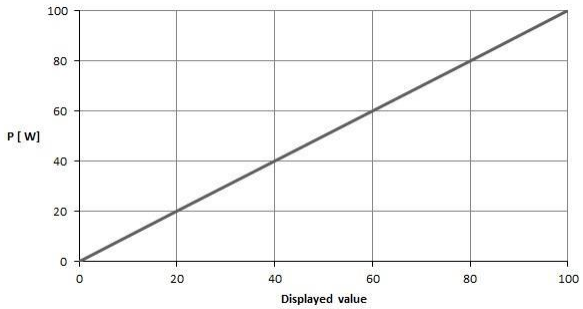
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Cardiac Thorax"
  = 50 W



Measurement at ohmic resistances

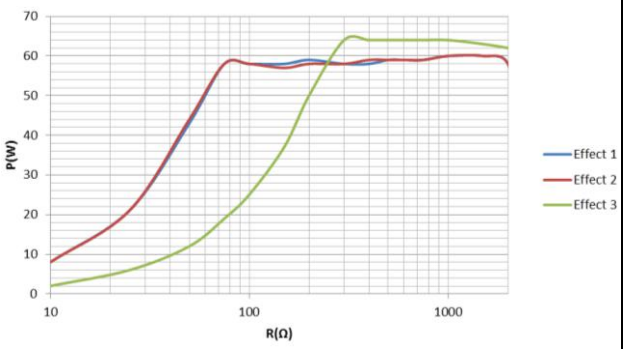
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Cardiac Thorax"
  = 100 W



- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Cardiac Thorax"
  Rated load resistance = 500 Ω

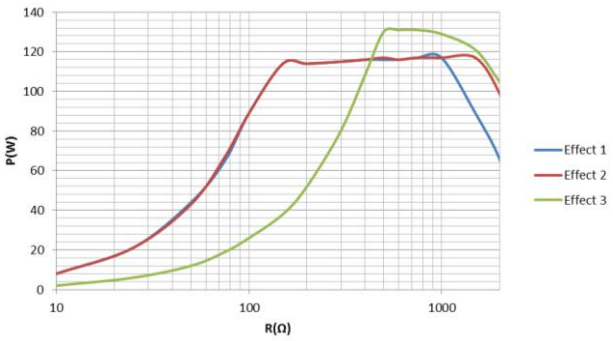
- HF output voltage U [Vp] for the setting "Monopolar Coagulation Cardiac Thorax" (idle mode)
  = 1800 Vp

Monopolar Coagulation – SimCoag



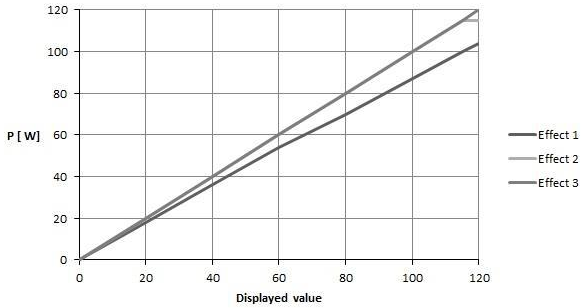
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation SimCoag"
  = 60 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Mon opolar Coagulation SimCoag"
  = 120 W

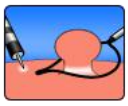


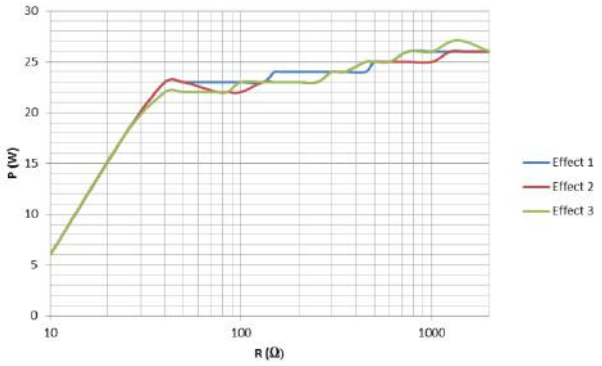
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation SimCoag"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	2000
2	2500
3	4600

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation SimCoag" (idle mode)

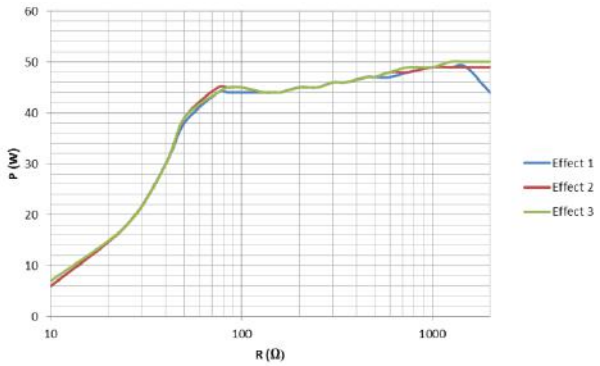
Monopolar Coagulation – Gastro Coag





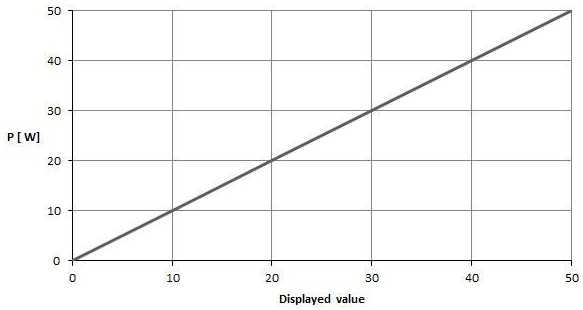
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation GastroCut Coag"
  = 25 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation GastroCut Coag"
  = 50 W

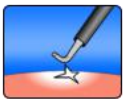


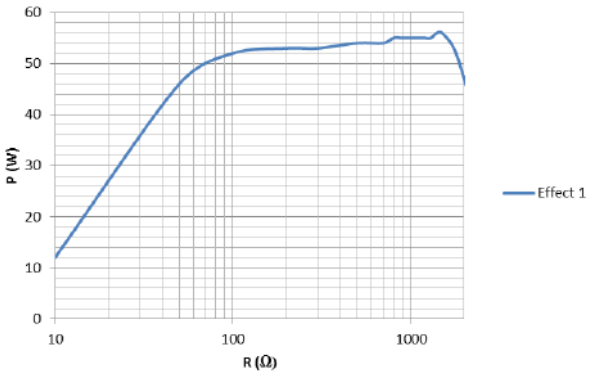
- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation GastroCut Coag"
  Rated load resistance = 500 Ω

Effect	U (Vp)
1	1800
2	2200
3	2800

- Table of HF output voltage U [Vp] as a function of the setting "Monopolar Coagulation GastroCut Coag"
  (idle mode)

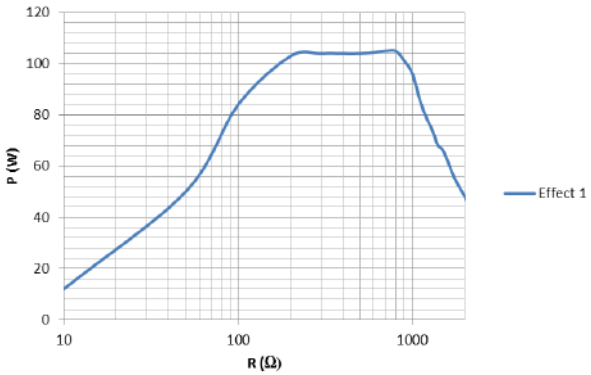
Monopolar Coagulation – Laparoscopy





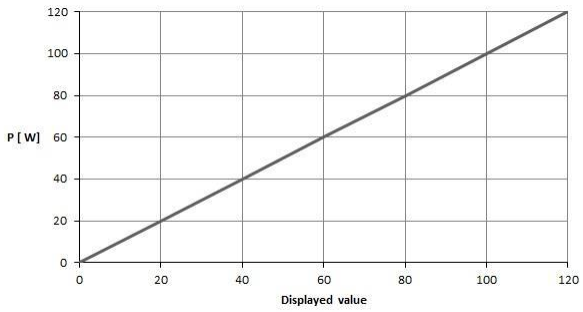
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Laparoscopy"
  = 60 W



Measurement at ohmic resistances

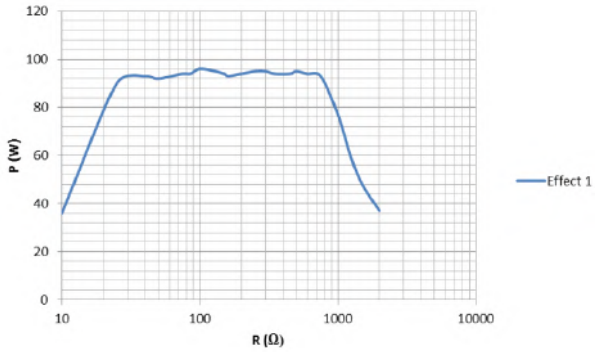
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Monopolar Coagulation Laparoscopy"
  = 120 W



- Diagram of power output P [W] as a function of the setting "Monopolar Coagulation Laparoscopy"
  Rated load resistance = 500 Ω

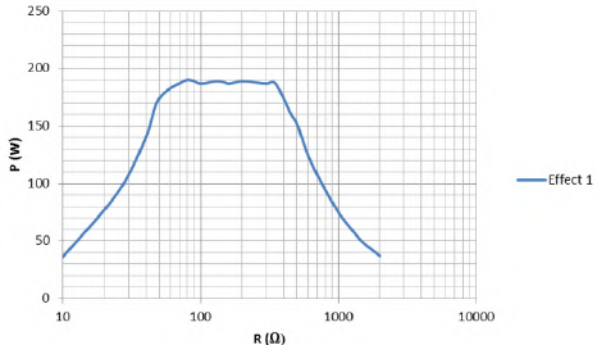
- HF output voltage U [Vp] for the setting "Monopolar Coagulation Laparoscopy" (idle mode)
  = 1800 Vp

Bipolar Cutting – Standard



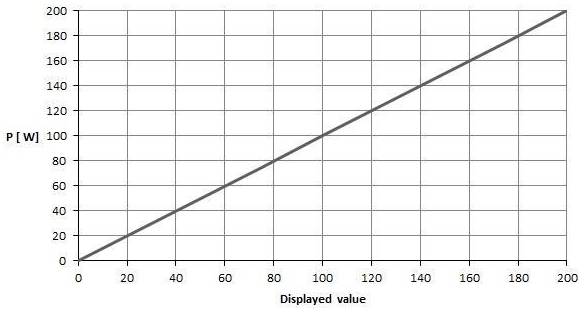
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting Standard" = 100 W



Measurement at ohmic resistances

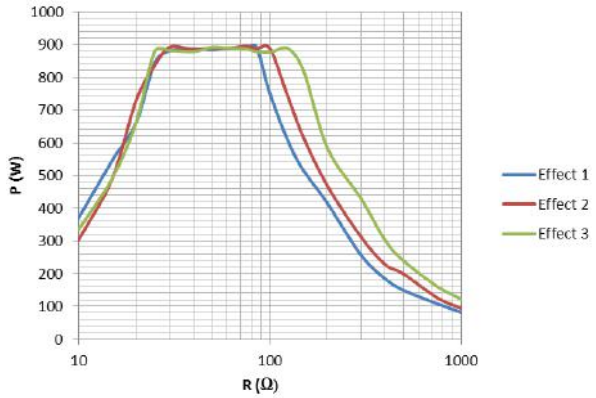
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting Standard" = 200 W



- Diagram of power output P [W] as a function of the setting "Bipolar Cutting Standard"
  Rated load resistance = 75 Ω

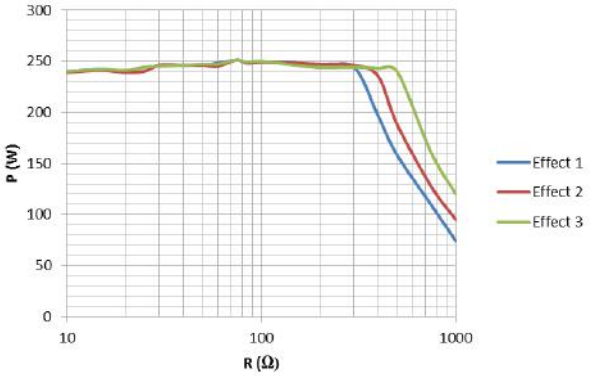
- HF output voltage U [Vp] for the setting "Bipolar Cutting Standard" (idle mode) = 400 Vp

Bipolar Cutting – Resection



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting Resection" Initial cut phase



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting Resection" Phase after the initial cut.

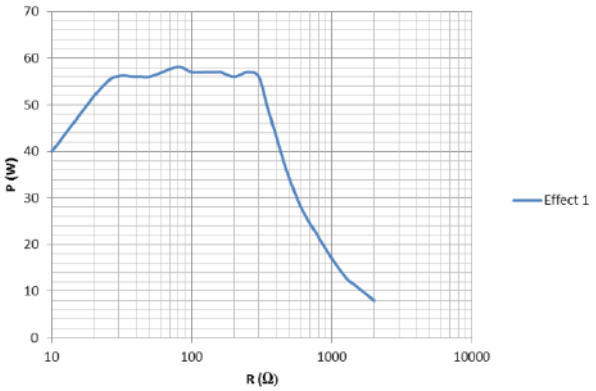
Effect	P (W)
1	250
2	250
3	250

- Table of power output P [W] as a function of the setting " Bipolar Cutting Resection "
  Rated load resistance = 75 Ω

Effect	U (Vp)
1	500
2	500
3	500

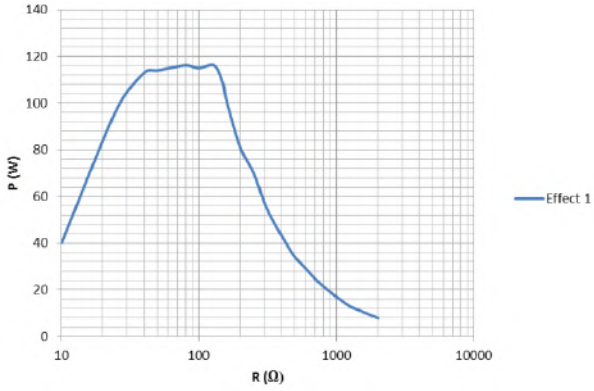
- Table of HF output voltage U [Vp] as a function of the setting " Bipolar Cutting Resection " (idle mode)

Bipolar Cutting – Bipolar scissors



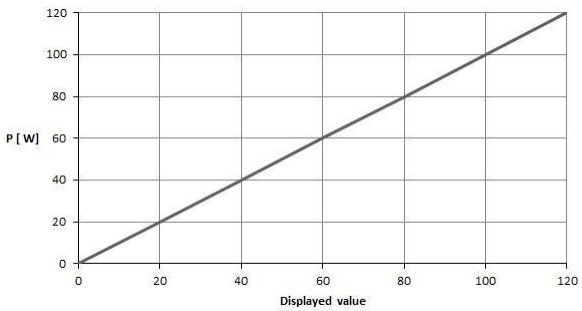
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting n bipolar scissors"
  = 60 W



Measurement at ohmic resistances

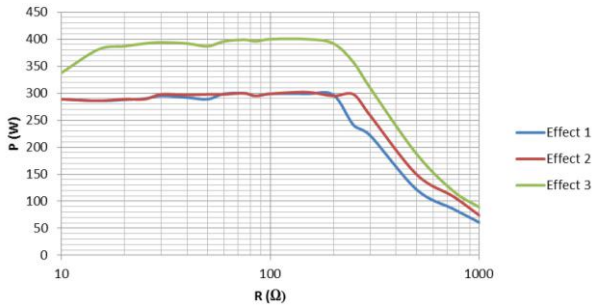
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting bipolar scissors"
  = 120 W



- Diagram of power output P [W] as a function of the setting " Bipolar Cutting bipolar scissors "
  Rated load resistance = 75 Ω

- HF output voltage U [Vp] for the setting " Bipolar Cutting Bipolar scissors " (idle mode)
  = 200 Vp

Bipolar Cutting – Vaporisation



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Cutting Vaporisation"

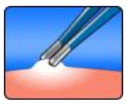
Effect	P (W)
1	300
2	300
3	400

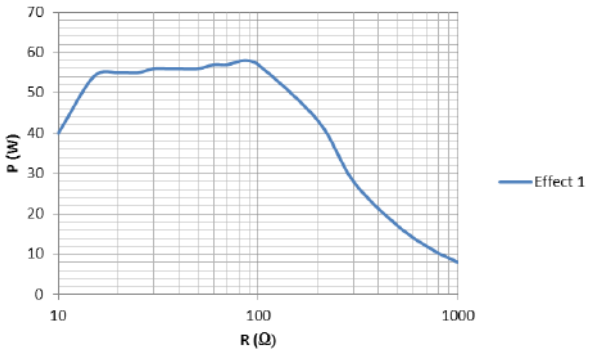
- Table of power output P [W] as a function of the setting " Bipolar Cutting Vaporisation " Rated load resistance = 75 Ω

Effect	U (Vp)
1	350
2	400
3	450

- Table of HF output voltage U [Vp] as a function of the setting " Bipolar Cutting Vaporisation " (idle mode)

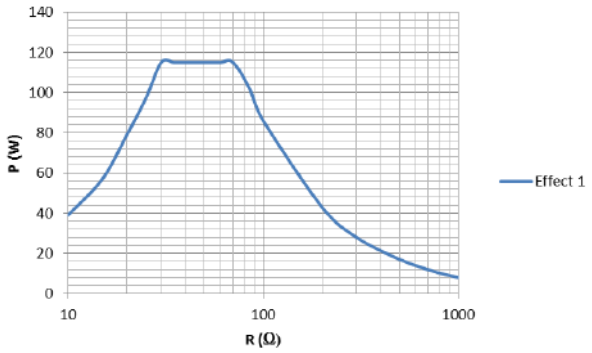
Bipolar Coagulation – Standard forceps





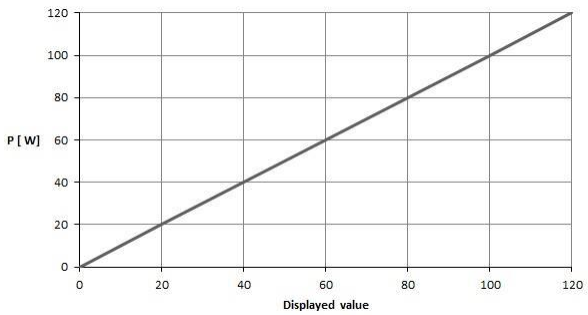
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Standard forceps"
  = 60 W



Measurement at ohmic resistances

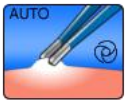
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Standard forceps"
  = 120 W

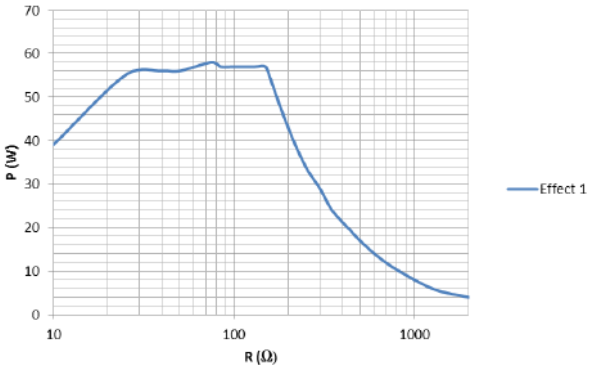


- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation Standard forceps "
  Rated load resistance = 50 Ω

- HF output voltage U [Vp] for the setting " Bipolar Coagulation Standard forceps " (idle mode)
  = 150 Vp

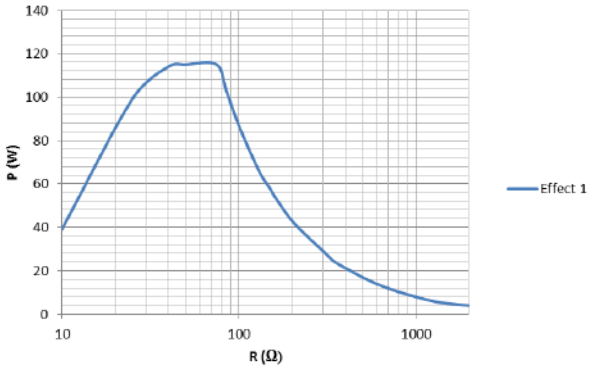
Bipolar Coagulation – Standard forceps AUTOSTART





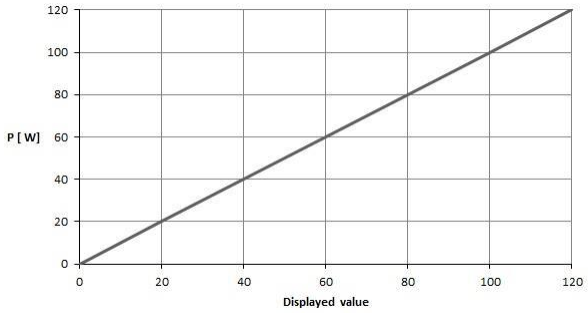
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Standard forceps AUTOSTART"
  = 60 W



Measurement at ohmic resistances

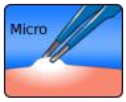
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Standard forceps AUTOSTART"
  = 120 W

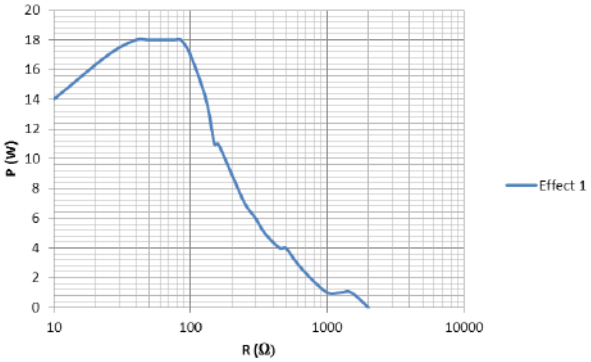


- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation Standard forceps AUTOSTART"
  Rated load resistance = 50 Ω

- HF output voltage U [Vp] for the setting " Bipolar Coagulation Standard forceps AUTOSTART"
  (idle mode)
  = 150 Vp

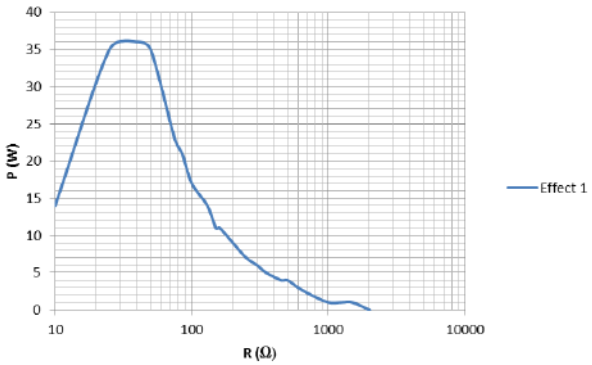
Bipolar Coagulation – Micro forceps





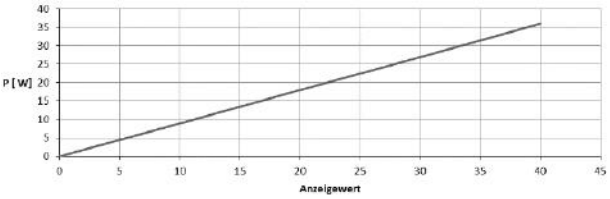
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Micro forceps"
  = 20 W



Measurement at ohmic resistances

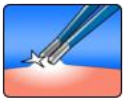
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Micro forceps"
  = 40 W

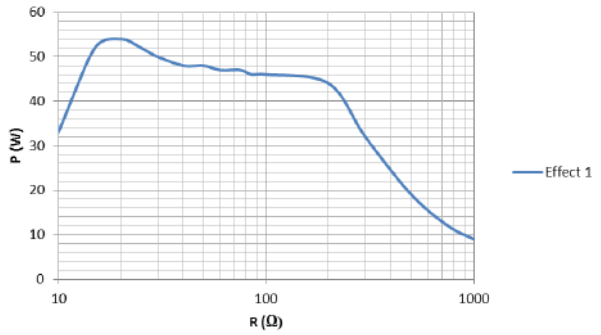


- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation Micro forceps "
  Rated load resistance = 50 Ω

- HF output voltage U [Vp] for the setting " Bipolar Coagulation Micro forceps " (idle mode)
  = 90 Vp

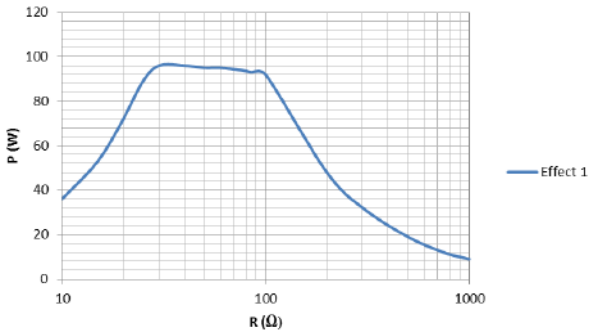
Bipolar Coagulation – Forceps forced





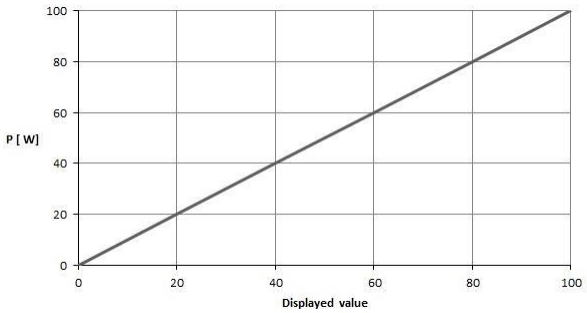
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation forceps forced"
  = 50 W



Measurement at ohmic resistances

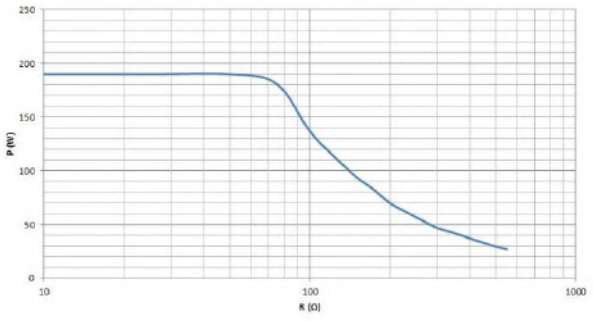
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation forceps forced"
  = 100 W



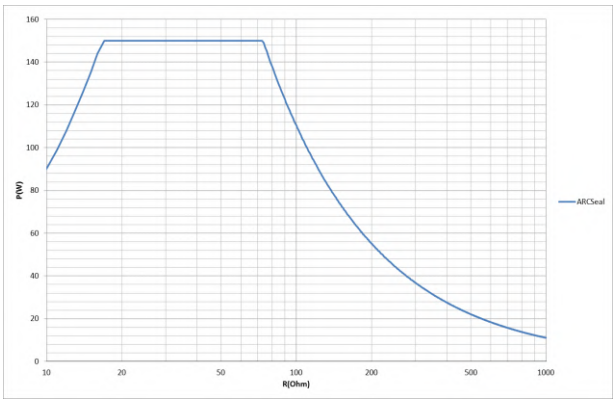
- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation forceps forced "
  Rated load resistance = 50 Ω

- HF output voltage U [Vp] for the setting " Bipolar Coagulation forceps forced " (idle mode)
  = 550 Vp

LIGATION / TissueSeal PLUS

 Measurement at ohmic resistances • Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "LIGATION"	
• Power output P [W] as a function of the setting " LIGATION " Rated load resistance (25 Ω) = 200 W	• HF output voltage U [Vp] for the setting " LIGATION " (idle mode) = 190 Vp

LIGATION – ARCSeal



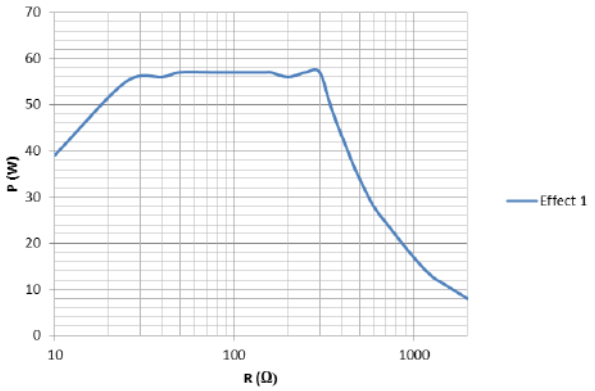
Measurement at ohmic resistances

- Diagram of output power P [W] as a function of the load resistance R [Ω] with the setting “ARCSeal”

- Output power P [W] with the setting “ARCSeal” (Rated load resistance = 50 Ω)
  = 150 W

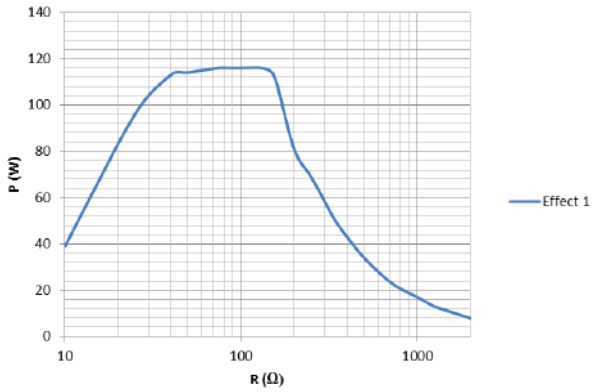
- HF output voltage U [Vp] with the setting “ARC Seal” (idle mode)
  200 Vp

Bipolar Coagulation – Bipolar scissors



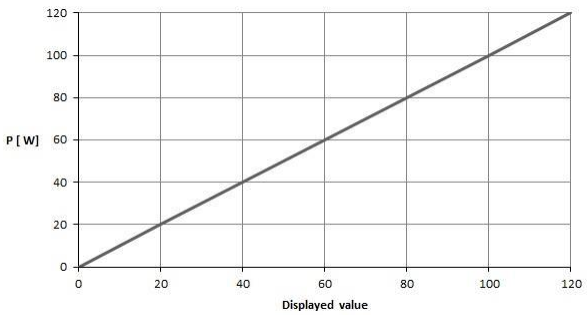
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation bipolar scissors"
  = 60 W



Measurement at ohmic resistances

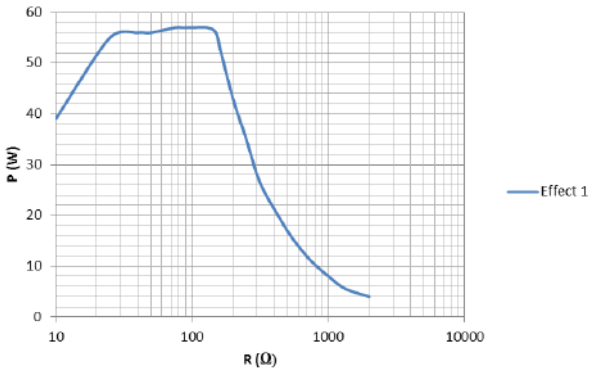
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation bipolar scissors"
  = 120 W



- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation bipolar scissors"
  Rated load resistance = 75 Ω

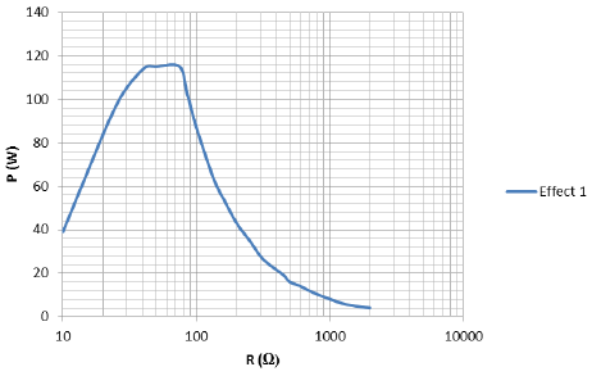
- HF output voltage U [Vp] for the setting " Bipolar Coagulation Bipolar scissors " (idle mode)
  = 200 Vp

Bipolar Coagulation– Laparoscopy



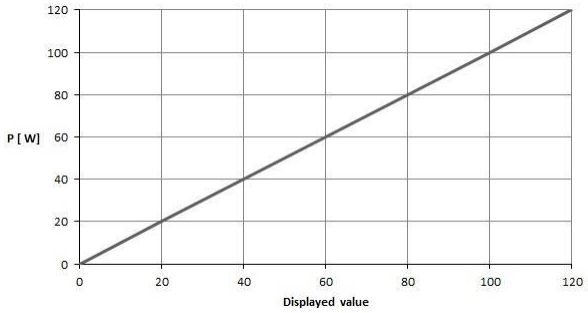
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Laparoscopy"
  = 60 W



Measurement at ohmic resistances

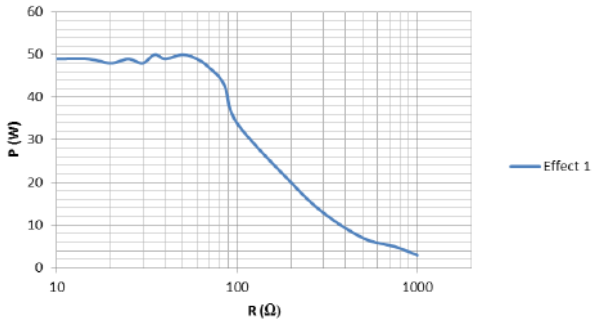
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Laparoscopy"
  = 120 W



- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation Laparoscopy "
  Rated load resistance = 50 Ω

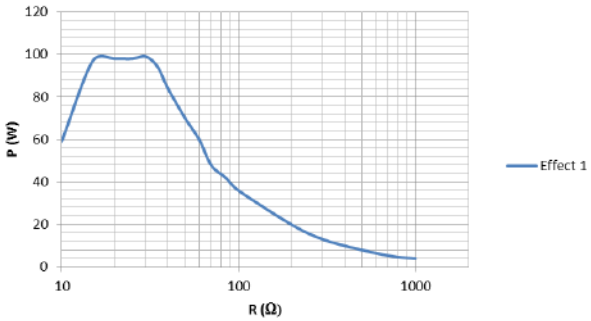
- HF output voltage U [Vp] for the setting " Bipolar Coagulation Laparoscopy " (idle mode)
  = 150 Vp

Bipolar Coagulation – Laparoscopy Micro



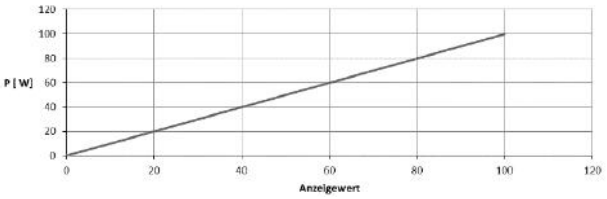
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω]for the setting "Bipolar Coagulation - Laparoscopy Micro"
  = 60 W



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [□]for the setting "Bipolar Coagulation - Laparoscopy Micro"
  = 120 W

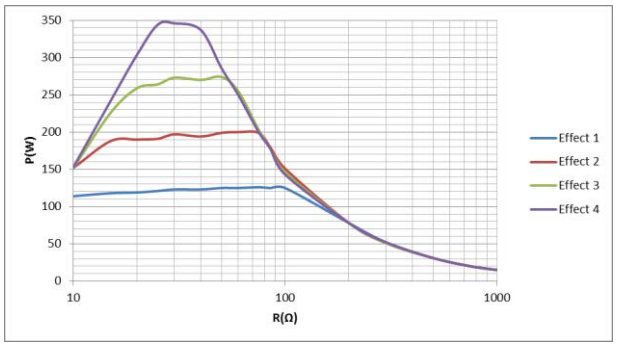


- Diagram of power output P [W] as a function of the setting “Bipolar Coagulation - Laparoscopy Micro"

  Rated load resistance = 25 Ω

- HF output voltage U [Vp] for the setting "Bipolar Coagulation - Laparoscopy Micro" (idle mode)
  = 110 Vp

Bipolar Coagulation – Bipolar Resection



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Bipolar Resection"

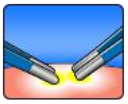
Effect	P (W)
1	125
2	200
3	275
4	350

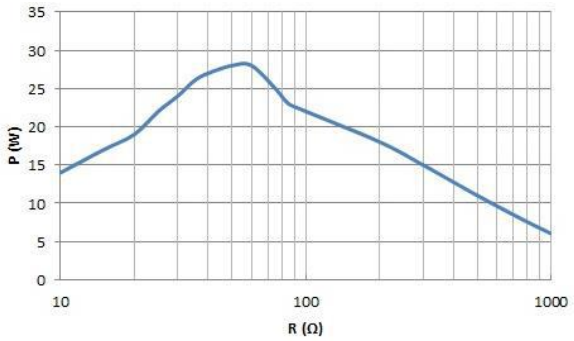
- Table of power output P [W] as a function of the setting " Bipolar Coagulation Bipolar Resection " Rated load resistance = 25 Ω

Effect	U (Vp)
1	190
2	190
3	190
4	190

- Table of HF output voltage U [Vp] as a function of the setting "Bipolar Coagulation Bipolar Resection" (idle mode)

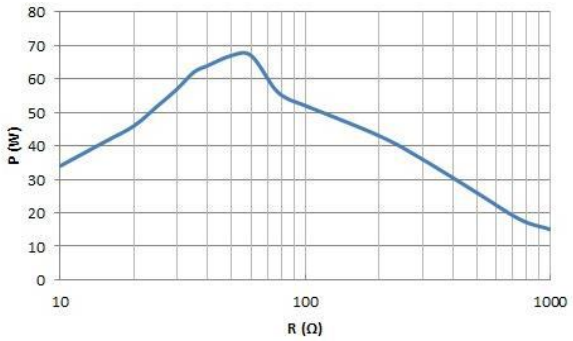
Bipolar Coagulation – SimCoag bipolar





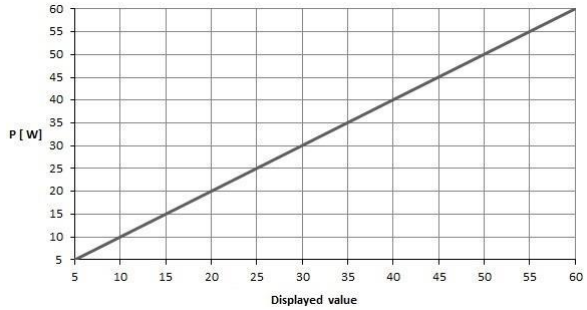
Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Sim Coag"
  = 30 W



Measurement at ohmic resistances

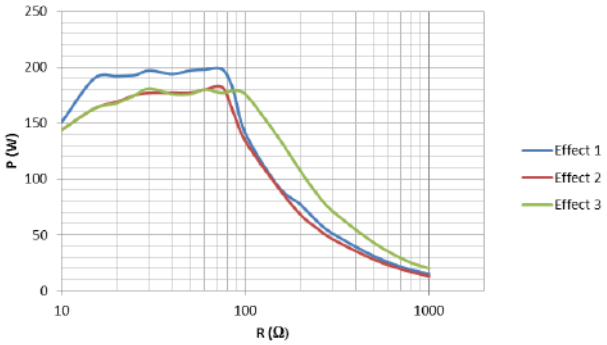
- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation SimCoag"
  = 60 W



- Diagram of power output P [W] as a function of the setting " Bipolar Coagulation SimCoag "
  Rated load resistance = 50 Ω

- HF output voltage U [Vp] for the setting "Bipolar Coagulation SimCoag" (idle mode)
  = 550 Vp

Bipolar Coagulation – Vaporisation



Measurement at ohmic resistances

- Diagram of power output P [W] as a function of the load resistance R [Ω] for the setting "Bipolar Coagulation Vaporisation"

Effect	P (W)
1	250
2	250
3	250

- Table of power output P [W] as a function of the setting " Bipolar Coagulation Vaporisation "
  Rated load resistance = 25 Ω

Effect	U (Vp)
1	190
2	400
3	500

- Table of HF output voltage U [Vp] as a function of the setting "Bipolar Coagulation Vaporisation" (idle mode)

11. Accessories and replacement parts

Original BOWA accessories are suitable for use with the ARC Series[1] and ARC PLUS[1] devices. When using accessories made by other manufacturers, the user must ensure that they are designed for and compatible with the maximum HF peak voltage of the HF device.

For the use and correct preparation of the autoclavable devices, compliance with the relevant instruction manuals accompanying these devices is required.

Detailed information on accessories and replacement parts is available in the current accessories catalogue.

[1] This includes compliance to IEC 60601-1-2:2007; Ch. 5.2.2.1a)

12. EMC

- Medical electrical devices are subject to special precautionary measures with regard to EMC and must be installed and commissioned in accordance with the EMC specifications in this operating manual.
- Portable and mobile RF communication devices can interfere with medical electronic equipment and should not be used at distances of less than 30 cm from the HF surgical device.
- The HF device must not be set up immediately adjacent to or stacked together with other electrical equipment. Should it prove necessary to use the HF device alongside or stacked together with other devices, its normal operation in the employed configuration must be monitored.
- Using accessories and cables in ways other than described can result in higher emission levels or reduced interference immunity.
- This HF device is exclusively intended for use by medical professionals. This HF device can cause radio interference or affect the operation of devices in its immediate vicinity. It may prove necessary to implement suitable corrective measures such as reorientation, repositioning of the HF device, or screening.

12.1. Guidelines and manufacturer's declaration in accordance with IEC 60601-1-2:2014

Electromagnetic disturbances (IEC 60601-1-2, Table 1) (DIN EN 60601-1-2:2007; Kap. 5.2.2.1c)		
The ARC 400 is intended to be used in an electromagnetic environment as set out below. The client or user of the ARC 400 should make sure that operation of this device only occurs under such conditions.		
Disturbance measurements	**Compatibility**	**Guideline on electromagnetic environment**
HF emissions pursuant to CISPR 11	Group 2	The ARC 400 must emit electromagnetic energy in order to ensure its intended functionality. This may have an impact on adjacent electronic devices.
HF emissions pursuant to CISPR 11	Class A	The EMISSIONS-based properties of this device allow for its use in the industrial sector and in hospitals. When used within homes, this device might not offer adequate radio protection. The user might have to take remedial measures such as repositioning or readjusting the device.
Harmonic emission pursuant to IEC 61000-3-2	Class A+D	
Emission of voltage fluctuations / flicker pursuant to IEC 61000-3-3	Compatible	

13. Disposal

Always comply with the national regulations of the relevant country when disposing of or recycling the device or its components.

Symbol	Designation
	A device marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Disposal is carried out free of charge by the manufacturer within the European Union.

If you have any questions regarding product disposal, contact the service center, see section Technical service, page 111.

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4–10
D-72810 Gomaringen │ Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com │ www.bowa-medical.com

CE 0123

CE marked according to
Medical Device
93/42/EWG

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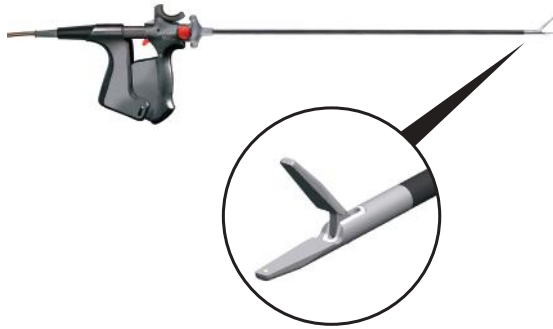
Printed in Germany

Gebrauchsanweisung

NightKNIFE®

LIGATOR®



BOWA

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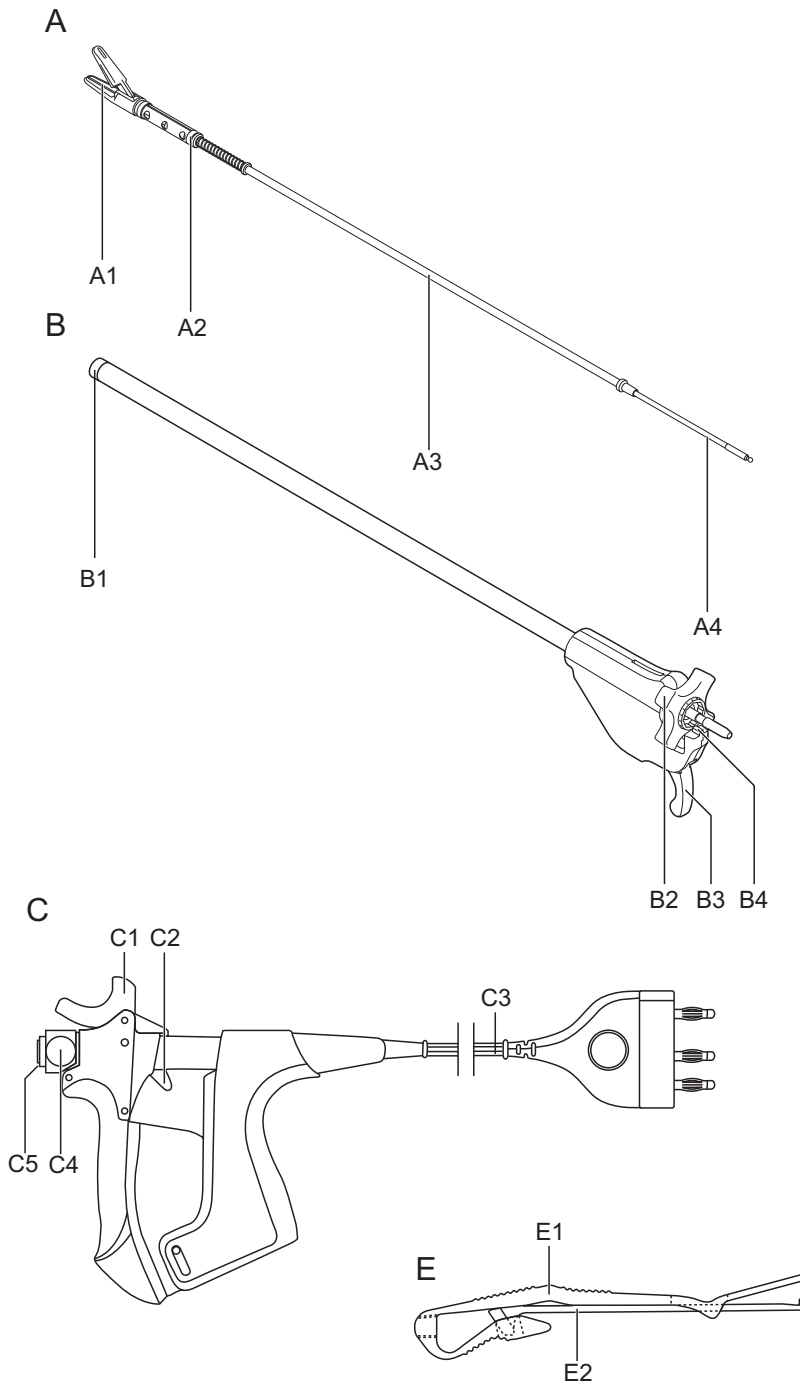
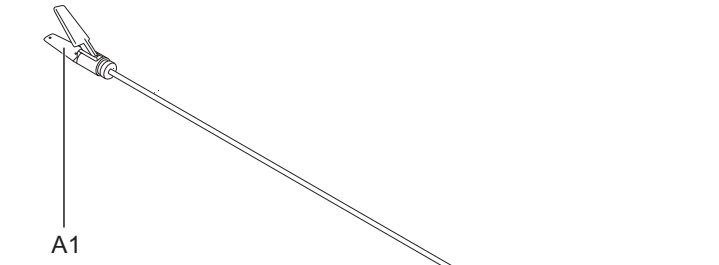
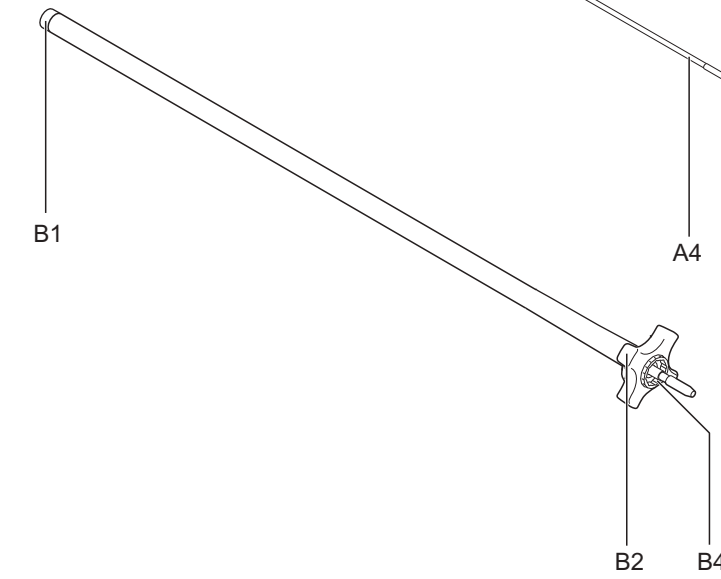

A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

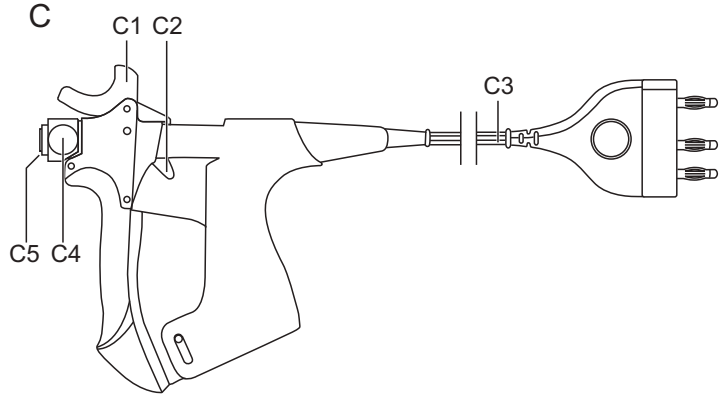
A



B



C



Legende

A	**Mauleinsatz (bei NightKNIFE mit Klinge)**
A1	Maulteil mit Elektrode (1x feststehend, 1x beweglich)
A2	Dichtring
A3	Schubrohr
A4	Zugstange
B	**Schaftrohr**
B1	Gewindehülse
B2	Sternrad
B3	Abzug
B4	Ausrichtungsfeder
C	**Handgriff**
C1	Rasthebel
C2	Verriegelungshebel
C3	HF-Kabel
C4	Druckknöpfe
C5	Aufnahme für Schaftrohr mit Mauleinsatz
E	**Klinge mit Einführhilfe**
E1	Einführhilfe
E2	Klinge

Inhalt

1. Umgang mit dieser Gebrauchsanweisung

Diese Gebrauchsanweisung ist Teil des Produkts.

Für Schäden und Folgeschäden, die durch Nichtbeachtung der Gebrauchsanweisung entstehen, übernimmt die BOWA-electronic GmbH & Co. KG keinerlei Haftung oder Gewährleistung.

- Lesen Sie die Gebrauchsanweisung, insbesondere das Kapitel "Sicherheit" (siehe Kapitel 2, Seite 12) vor der Anwendung aufmerksam durch.
- Bewahren Sie die Gebrauchsanweisung während der Lebensdauer des Produkts sicher auf.
- Bewahren Sie die Gebrauchsanweisung für das OP-Personal zugänglich auf.
- Geben Sie die Gebrauchsanweisung an jeden nachfolgenden Besitzer oder Benutzer des Produkts weiter.
- Aktualisieren Sie die Gebrauchsanweisung bei jeder vom Hersteller erhaltenen Ergänzung.

1.1. Gültigkeit

Diese Gebrauchsanweisung ist nur gültig für die auf der Titelseite bezeichneten Produkte.

1.2. Symbole und Kennzeichnungen

1.2.1. Aufbau von Warnhinweisen

⚠ WARNUNG

Art, Quelle und Folgen der Gefahr (Personenschäden)!

▶ Maßnahme zur Vermeidung der Gefahr.

1.2.2. Gefahrenstufen in Warnhinweisen

Symbol	Gefahrenstufe	Eintretens-Wahrscheinlichkeit	Folgen bei Nichtbeachtung
	**GEFAHR**	Unmittelbar drohende Gefahr	Tod, schwere Körperverletzung
	**WARNUNG**	Mögliche drohende Gefahr	Tod, schwere Körperverletzung
	**VORSICHT**	Mögliche drohende Gefahr	Leichte Körperverletzung
	**HINWEIS**	Mögliche drohende Gefahr	Sachschaden

1.2.3. Tipps

Tipps zum leichteren Arbeiten oder Zusatzinformationen zur Erklärung eines Arbeitsschritts.

1.2.4. Sonstige Symbole und Kennzeichnungen

Symbol/ Kennzeichnung	Bedeutung
☑	Voraussetzung einer Handlung
▶	Handlung mit einem Schritt
1. 2. 3.	Handlung mit mehreren Schritten in verbindlicher Reihenfolge
⇳	Resultat aus vorangehender Handlung
•	Aufzählung (erste Ebene)
•	Aufzählung (zweite Ebene)
Hervorhebung	Hervorhebung
..., siehe Kapitel xxx, Seite xxx	Querverweis

2. Sicherheit

2.1. Bestimmungsgemäße Verwendung

Die Ligationsinstrumente dienen zur Gefäßversiegelung von Arterien und Venen sowie von vaskularisierten Gewebestrukturen bei laparoskopischer und offener Anwendung in der Gynäkologie, Urologie, Allgemeinchirurgie und anderen chirurgischen Disziplinen unter Verwendung von HF-Strom und mechanischem Druck.

Die Ligationsinstrumente sind außerdem für die klassische bipolare Koagulation geeignet.

Die Ligationsinstrumente sind für die bipolare Betriebsweise "Ligation" bestimmt.

Der Einsatz ist an die Ligationsprogramme der BOWA ARC-Generatoren gebunden.

Das Ligationsinstrument NightKNIFE dient zusätzlich zum Schneiden von Gewebe.

Jegliche andere Verwendung der Ligationsinstrumente gilt als nicht bestimmungsgemäß und ist auszuschließen!

Bei dem COMFORT Artikel 770-000 ist das Anschlusskabel fest mit dem Handgriff verbunden.

Generatoren mit Plug'n Cut COMFORT erkennen BOWA COMFORT Instrumente und wählen automatisch die entsprechenden Parameter vor.

Bei bipolaren Ligationsinstrumenten ist die Verwendung einer Neutralelektrode nicht notwendig.

2.2. Allgemeine Sicherheitshinweise

Das HF-Gerät darf nur durch ausgebildetes medizinisches Fachpersonal angewendet werden. Der Chirurg und das medizinische Fachpersonal müssen in Grundlagen, Anwendungsregeln und Risiken der HF-Chirurgie geschult und damit vertraut sein.

- Lesen Sie vor dem Einsatz der Produkte die Gebrauchsanweisung aufmerksam durch!

Im Rahmen ihrer Verantwortung für die Sterilität der Ligationsinstrumente ist bei der Anwendung Folgendes zu beachten:

- Reinigen und sterilisieren Sie das Ligationsinstrument vor der ersten Anwendung. Es wird unsteril geliefert.
- Reinigen und sterilisieren Sie das Ligationsinstrument vor jeder weiteren Anwendung.
- Setzen Sie nur ausreichend geräte- und produktspezifisch validierte Verfahren für die Reinigung, Desinfektion und Sterilisation ein.
- Halten Sie die validierten Parameter bei jedem Zyklus ein.
- Beachten Sie die in Ihrem Land gültigen Rechtsvorschriften sowie die Hygienevorschriften des Krankenhauses.

Bei der Reinigung im Ultraschallbad und bei manueller Vorreinigung besteht durch Wasserspritzer und Dämpfe Infektionsgefahr:

- Tragen Sie einen Gesichtsschutz und Schutzkleidung.

Eine ausreichende Belüftung wird emfohlen.

Verletzungsgefahr durch die scharfe Klinge:

- Achten Sie während der Montage/Demontage auf die Klinge.
- Bauen Sie auswechselbare Klingen vor der Reinigung des Mauleinsatzes aus.
- Führen Sie Montage und Demontage nur mit der Einführhilfe durch, um Stich- oder Schnittverletzungen zu vermeiden.

2.2.1. HF-Gerät

- Verwenden Sie nur zugelassene HF-Geräte und Programme (siehe Kapitel 8, Seite 51).
- Beachten Sie die Gebrauchsanweisung des HF-Geräts sowie die allgemeinen Hinweise zu elektrochirurgischen Eingriffen!

Der unsachgemäße Einsatz von HF-Strom kann zu endogen und exogen Verbrennungen sowie zu Explosionen führen:

- Führen Sie elektrochirurgische Eingriffe nur bei Insufflation nicht brennbarer Gase (CO_2) durch.
- Vermeiden Sie den direkten Hautkontakt mit HF-Kabeln.
- Vermeiden Sie den Kontakt mit entzündlichen Gasen und Flüssigkeiten.

2.2.2. HF-Kabel

Falscher Umgang mit dem HF-Kabel kann zu Verletzungen des Patienten führen.

- Legen Sie das HF-Kabel niemals auf die Haut des Patienten.
- Schließen Sie das Ligationsinstrument für die Koagulation an und schalten Sie den HF-Generator ein.
- Fassen Sie das HF-Kabel zum Ein- und Ausstecken nur am Stecker an.
- Verwenden Sie nur technisch einwandfreie HF-Kabel. Defekte HF-Kabel dürfen nicht verwendet werden.

Das HF-Kabel kann am Monitor Bildstörungen hervorrufen:

- Führen Sie das HF-Kabel nicht unmittelbar parallel mit Kamerakabeln.
- Verlegen Sie das HF-Kabel nicht in Schleifen.

2.2.3. Aktive Elektroden

Defekte oder verschlissene Elektroden können zu Verbrennungen beim Patienten führen:

- Verwenden oder reparieren Sie niemals verschlissene oder defekte Maulteile oder Elektrodenflächen. Entsorgen Sie diese.

Heiße Elektrodenoberflächen können zur Verletzung des Patienten führen:

- Halten Sie Abstand zwischen den Instrumentenspitzen und empfindlichen Gewebestrukturen (z. B. Pankreas, Darm).
- Stellen Sie sicher, dass zum Präparieren keine heißen Instrumente verwendet werden.

Versehentliche Aktivierung des Ligationsinstruments kann Verletzungen beim Patienten verursachen:

- Legen Sie kein Ligationsinstrument auf dem Patienten ab.

Verschmutzte Elektroden können zum Kurzschluss und damit zum Funktionsausfall des Ligationsinstruments führen.

- ▶ Säubern Sie die Elektroden der Maulteile regelmäßig mit einem feuchtem Tuch.
- ▶ Ersetzen Sie den Mauleinsatz bei beschädigten Elektroden.

2.2.4. Auswechselbare Klinge mit Einführhilfe (nur bei NightKNIFE mit auswechselbarer Klinge)

Auswechselbare Klinge und Einführhilfe dürfen nicht wiederaufbereitet werden:

- ▶ Verwendete Klingen und Einführhilfen entsorgen bzw. ersetzen.

2.2.5. Reparatur/Wartung

Defekte Produkte dürfen nicht repariert bzw. gewartet werden:

- ▶ Defekte Produkte entsorgen bzw. ersetzen.

2.3. Personenbezogene Sicherheitshinweise

Falsche Einstellungen des HF-Generators und eingeschränkte Sicht können zur Verletzung des Patienten führen:

- ▶ Wählen Sie den HF-Generator und das HF-Kabel den Anforderungen des Ligationsinstruments entsprechend aus.
- ▶ Operieren Sie nur bei ausreichender Sicht.
- ▶ Betreiben Sie Ligationsinstrumente nie im Autostart-Modus.

2.3.1. Patienten mit Herz-Schrittmacher

Fehlfunktionen oder die Zerstörung des Herz-Schrittmachers können zur Lebensgefahr oder zu irreversibler Verletzung des Patienten führen.

- Führen Sie niemals ambulante Eingriffe bei Patienten mit Herz-Schrittmachern durch.
- Konsultieren Sie bei Patienten mit Herz-Schrittmachern vor der Anwendung der HF-Chirurgie den Kardiologen.
- Stellen Sie den Demand-Schrittmacher auf Festfrequenz ein.
- Stellen Sie sicher, dass der Herz-Schrittmacher nicht mit der HF-Elektrode in Kontakt kommt.
- Halten Sie einen einsatzfähigen Defibrillator griffbereit.
- Führen Sie eine postoperative Herz-Schrittmacher-Kontrolle durch.

3. Funktionsweise

Bei der bipolaren HF-Chirurgie erfolgt die Koagulation des Gewebes durch Anlegen eines hochfrequenten Wechselstroms, der Wärme erzeugt.

Die Ligationsinstrumente NightKNIFE und LIGATOR sind chirurgisch-invasive Instrumente für den laparoskopischen sowie offenen chirurgischen Einsatz. Sie werden in Verbindung mit endoskopisch verwendbaren Produkten (z. B. Trokare und Optiken) durch chirurgisch hergestellte Zugänge eingesetzt.

Die aktiven Elektroden (Branchen) sind die nicht isolierten Bereiche des Maulteils.

Der HF-Strom fließt von einer Branche des Instruments über das Biogewebe zur zweiten Branche und erzielt lokal begrenzt den gewünschten Koagulationseffekt.

Bei diesem Verfahren wird durch HF-Strom unter zusätzlichem Anpressdruck eine Versiegelung eines blutdurchströmten Gefäßes/Gewebesegments erreicht.

Die Versiegelungsstelle ist gegenüber dem systolischen Blutdruck hämostatisch dicht und dauerhaft verschlossen.

Beim NightKNIFE kann durch die integrierte Schneidfunktion, zu behandelndes Gewebe direkt im Anschluss an die Versiegelung ohne vorherigen Instrumentenwechsel durchtrennt werden.

Durch Betätigung des Handgriffs können die Maulteile am Mauleinsatz geöffnet oder geschlossen und mit dem Rasthebel arretiert werden.

Der Mauleinsatz kann über das Sternrad am Schaftrohr gedreht und arretiert werden (8x45°).

4. Montage

⚠ WARNUNG

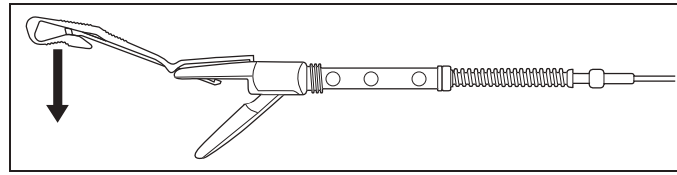
Verletzungsgefahr des Patienten durch unsteriles Ligationsinstrument!

▶ Reinigen und sterilisieren Sie das Ligationsinstrument vor der Anwendung, da es unsteril geliefert wird.

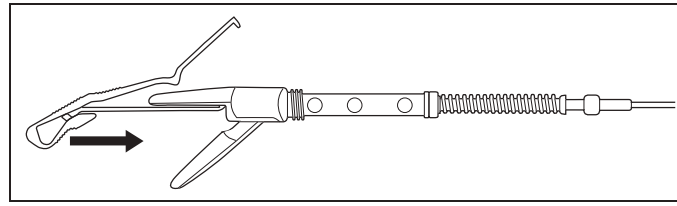
4.1. Klinge mit Einführhilfe montieren (nur bei NightKNIFE mit auswechselbarer Klinge)

☑ Klinge mit Einführhilfe ist gereinigt und desinfiziert (siehe Kapitel 7.5, Seite 41)

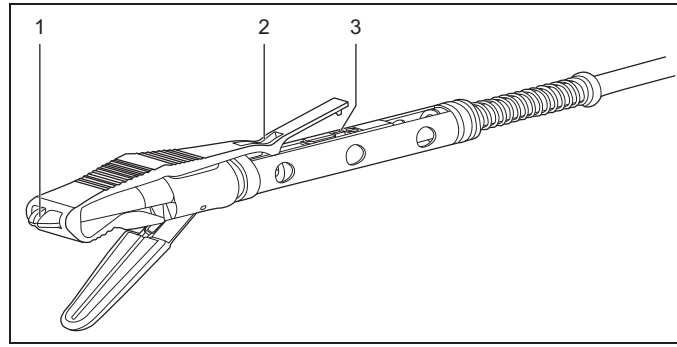
1. Entnehmen Sie die Klinge mit Einführhilfe **E** aus der sterilen Verpackung.



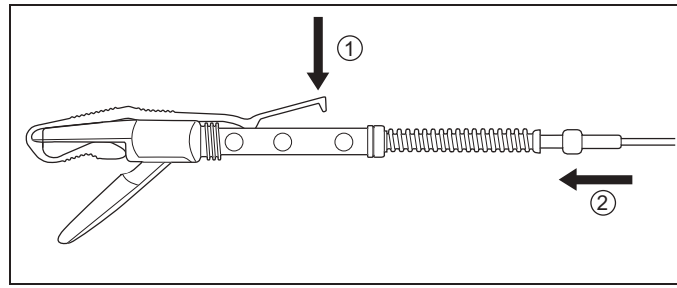
2. Drehen Sie den Mauleinsatz **A** mit dem feststehenden Maulteil **A1** nach oben, um die Maulteile zu öffnen.
3. Führen Sie das feststehende Maulteil **A1** zwischen Klinge **E2** und Einführhilfe **E1** ein und drücken Sie die Einführhilfe **E1** in Pfeilrichtung nach unten, um die Klinge zu lösen.



4. Schieben Sie auf dem feststehenden Maulteil **A1** die Klinge mit der Einführhilfe **E** in Pfeilrichtung bis zum Anschlag.

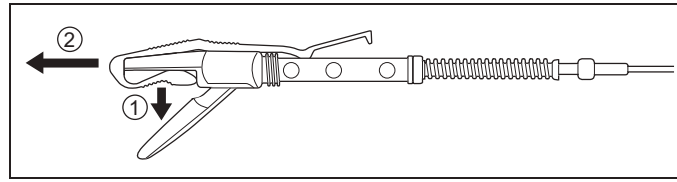


5. Stellen Sie sicher, dass die Klinge mit Einführhilfe **E** an den gekennzeichneten Positionen mittig positioniert ist.
6. Positionieren Sie die Einführhilfe **E1** gegebenenfalls mit den Fingern mittig.



7. Halten Sie die Einführhilfe **E1** fest und drücken Sie die Einführhilfe **E1** leicht in Pfeilrichtung nach unten **1**.
8. Schieben Sie das Schubrohr **A3** in Pfeilrichtung **2** bis die Klinge **E2** hörbar/spürbar und sichtbar einrastet.

↳ Die Feder bleibt im komprimierten Zustand.



9. Ziehen Sie den kurzen Teil der Einführhilfe **E1** nach unten **1**, um die Klinge in die Grundstellung zurück zu ziehen.
10. Entfernen Sie die Einführhilfe **E1** in Pfeilrichtung **2** vom feststehenden Maulteil.

▶ Bewahren Sie die Einführhilfe auf. Sie wird für den Ausbau der Klinge benötigt.

4.2. Ligationsinstrument zusammensetzen

1. Schrauben Sie den Mauleinsatz **A** vollständig in das Schaftrohr **B** ein.
2. Stellen Sie sicher, dass kein Spalt zwischen dem Mauleinsatz **A** und dem Schaftrohr **B** vorhanden ist.
3. Schließen Sie die Maulteile **A1** mit den Fingern und führen Sie das Schaftrohr **B** in den Handgriff **C** ein:
   - Bei NightKNIFE: Achten Sie darauf, dass die Ausrichtungsfeder **B4** und die Ausrichtungsnut **C5** gleich ausgerichtet sind.
   - Lassen Sie das Schaftrohr **B** im Handgriff **C** einrasten.
4. Prüfen Sie die Greiffunktion des Ligationsinstruments durch Betätigen des Handgriffs **C**.
5. Öffnen Sie mit Hilfe des Rasthebels **C1** die Maulteile **A1**.
6. Bei NightKNIFE: Prüfen Sie die Leichtgängigkeit und Grundstellung der Klinge durch Betätigen des Abzugs **B3**.
7. Prüfen Sie, ob sich das Sternrad **B2** drehen lässt.

5. Bedienung

5.1. Vor Gebrauch

☑ Das Ligationsinstrument ist montiert (siehe Kapitel 4, Seite 19) und aufbereitet (siehe Kapitel 7, Seite 32).

⚠ WARNUNG

Verletzungsgefahr des Patienten!

- ▶ Verwenden Sie nur zugelassene BOWA ARC-Generatoren mit Ligationsfunktion (siehe Kapitel 8, Seite 51).
- ▶ Verwenden Sie nur geeignete Produkte und Zubehör, gemäß Systemübersicht.
- ▶ Verwenden Sie nur einwandfreie und sterilisierte Produkte.

⚠ WARNUNG

Verletzungsgefahr des Patienten durch Verbrennungen und Explosionen entzündlicher Flüssigkeiten und Gase!

- ▶ Führen Sie elektrochirurgische Eingriffe nur bei Insufflation nicht brennbarer Gase (CO_2) durch.
- ▶ Vermeiden Sie Kontakt mit entzündlichen Gasen und Flüssigkeiten (z. B. Hautreinigungs-, Desinfektionsmittel und Narkosegase).

---

1. Schließen Sie das HF-Kabel **C3** an das HF-Gerät an und schalten Sie das HF-Gerät ein.
2. Stellen Sie die Ausgangsleistung des HF-Geräts ein.

3. Führen Sie vor jedem Gebrauch des Ligationsinstruments eine gründliche Sicht- und Funktionskontrolle durch (siehe Kapitel 7.6, Seite 44).

In der Grundstellung sind die Maulteile **A1** geöffnet.

4. Schließen Sie mit Hilfe des Handgriffs **C** die Mauteile **A1**.
5. Führen Sie den Mauleinsatz **A** in die Trokarhülse ein.

5.2. Während des Eingriffs

⚠ WARNUNG

Verletzungsgefahr des Patienten durch falsche Einstellungen des Geräts und eingeschränkte Sicht!

- ▶ Stellen Sie die Ausgangsleistung des HF-Geräts auf den für den Eingriff erforderlichen Wert ein.
- ▶ Verwenden Sie nur zugelassene Programme (siehe Kapitel 8, Seite 51).
- ▶ Operieren Sie nur bei ausreichender Sicht.

⚠ WARNUNG

Verletzungsgefahr des Patienten durch heiße Elektrodenoberflächen und Dampfaustritt!

- ▶ Halten Sie Abstand zwischen den Gerätespitzen und empfindlichen Gewebestrukturen (z. B. Pankreas, Darm).
- ▶ Stellen Sie sicher, dass zum Präparieren keine heißen Ligationsinstrumente verwendet werden.
- ▶ Legen Sie kein Ligationsinstrument auf dem Patienten ab.

- ▶ Führen Sie das Ligationsinstrument unter Sichtkontrolle in den Körper ein.

Gewebe fassen, klemmen, versiegeln

⚠ WARNUNG

Verletzungsgefahr des Patienten durch unbeabsichtigte Aktivierung des Ligationsinstruments!

- ▶ Verwenden Sie niemals die Funktion AUTOSTART.
- ▶ Schalten Sie den HF-Strom erst dann ein, wenn die aktiven Elektroden Kontakt mit dem zu koagulierenden Gewebe haben.

1. Platzieren Sie den Mauleinsatz **A** am Operationsfeld.

Der Mauleinsatz **A** ist drehbar und in 45°-Winkeln arretierbar.

2. Drehen Sie das Sternrad **B2**, um den Winkel des Mauleinsatzes **A** einzustellen.
3. Platzieren Sie das zu versiegelnde Gewebe zwischen den Elektroden der Maulteile **A1**.
4. Schließen Sie die Maulteile **A1**, um das Gewebe zu fassen.

↳ Das Gewebe ist gefasst.

5. Nutzen Sie die dreistufige Rastung des Handgriffs **C**, um den Druck auf das Gewebe optimal an die Menge des gefassten Gewebes anzupassen.

↳ Das Gewebe ist eingeklemmt.

6. Aktivieren Sie mit dem Fußschalter des HF-Geräts den HF-Strom zur Koagulation:
   - Ein Dauerton signalisiert den Energieeintrag über die gesamte Versiegelungsdauer.
   - Ein Wechselton signalisiert das Versiegelungsende.
7. Lassen Sie den Fußschalter los, um die Energiezuführung zu stoppen.
8. Öffnen Sie mit Hilfe des Rasthebels **C1** die Maulteile **A1**.

↳ Das Gewebe ist koaguliert.

Gewebe schneiden (nur bei NightKNIFE)

⚠ **WARNUNG**

Starke Blutungen durch Schneiden des gefassten Gewebes ohne vorhergehende Koagulation oder Ligation!

- ▶ Setzen Sie bei Gefäßen mindestens 2 Versiegelungen links und rechts von der Schnittstelle.
- ▶ Stellen Sie sicher, dass das Gewebe vor dem Schneidvorgang sicher versiegelt ist.
- ▶ Schneiden Sie nur im versiegelten Bereich.

☑ Das Gewebe wird von den Maulteilen gefasst und ist koaguliert.

1. Betätigen Sie zum Schneiden den Abzug **B3** und lassen Sie ihn los.

↳ Das Gewebe ist geschnitten.

2. Öffnen Sie mit Hilfe des Rasthebels **C1** die Maulteile **A1**.

Ausgangsleistung des HF-Geräts verändern

▶ Prüfen Sie vor der Erhöhung der Ausgangsleistung des HF-Geräts:

- den einwandfreien Kontakt aller HF-Kabel sowie Stecker,
- ob das Ligationsinstrument korrekt angeschlossen ist (siehe Gebrauchsanweisung des HF-Geräts),
- die Funktion des Fußschalters,
- die Isolation des HF-Kabels **C3**, der Maulteile **A1**, des Schaftrohrs **B** und der Trokarhülse,
- die Sauberkeit und Abnutzung der aktiven Elektroden an den Maulteilen **A1**.

5.3. Entnahme

⚠ WARNUNG

Verletzungsgefahr des Patienten durch abgebrochene oder beschädigte Teile!

▶ Prüfen Sie nach jeder Entnahme den Mauleinsatz. Alle Teile müssen vorhanden sein.

1. Schließen Sie die Maulteile **A1**.
2. Entnehmen Sie das Ligationsinstrument aus der Trokarhülse.

5.4. Nach Gebrauch

⚠ WARNUNG

Verschmutzte Elektroden können zu einem Funktionsausfall des Ligationsinstruments führen!

- ▶ Säubern Sie die Elektroden der Maulteile **A1** regelmäßig mit einem feuchtem Tuch.
- ▶ Ersetzen Sie den Mauleinsatz **A** bei beschädigten Elektroden.
- ▶ Bei NightKNIFE mit auswechselbarer Klinge: Ersetzen Sie die Klinge **E2** nach jedem Eingriff.

1. Bereiten Sie das Ligationsinstrument nach dem Gebrauch auf (siehe Kapitel 7, Seite 32).

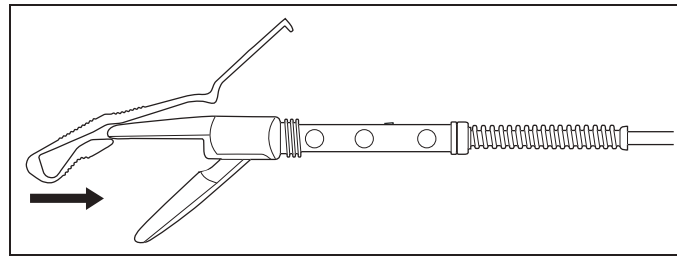
6. Demontage

6.1. Ligationsinstrument demontieren

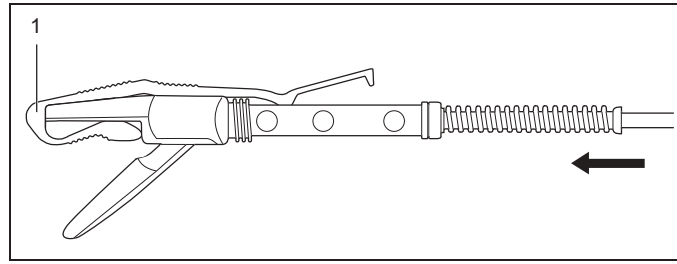
1. Halten Sie am Handgriff **C** die Druckknöpfe **C4** und den Verriegelungshebel **C2** gedrückt und ziehen Sie den Handgriff **C** vom Schaftrohr **B** ab.
2. Schrauben Sie den Mauleinsatz **A** vom Schaftrohr **B** ab.
3. Bei NightKNIFE mit auswechselbarer Klinge: Entfernen Sie die Klinge mit Einführhilfe **E** (siehe Kapitel 6.2, Seite 29).

6.2. Klinge mit Einführhilfe entfernen (nur bei NightKNIFE mit auswechselbarer Klinge)

1. Drehen Sie den Mauleinsatz **A** mit dem feststehenden Maulteil **A1** nach oben, um die Maulteile zu öffnen.

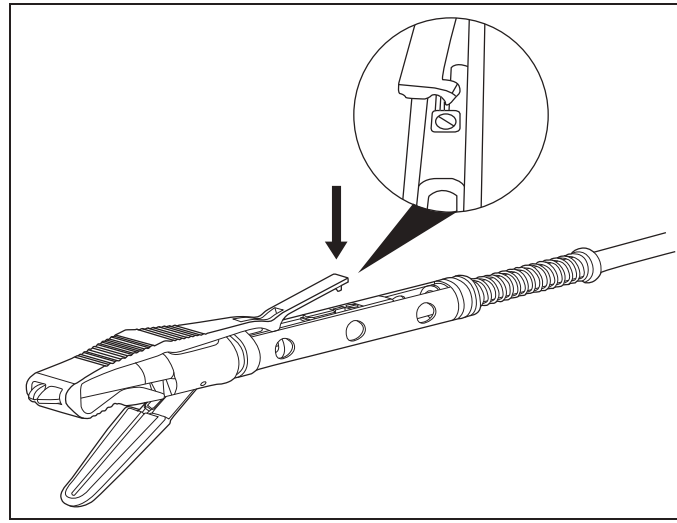


2. Halten Sie die Einführhilfe **E1** seitlich fest und schieben Sie die Einführhilfe **E1** auf dem feststehenden Maulteil **A1** bis zum Anschlag in Pfeilrichtung.



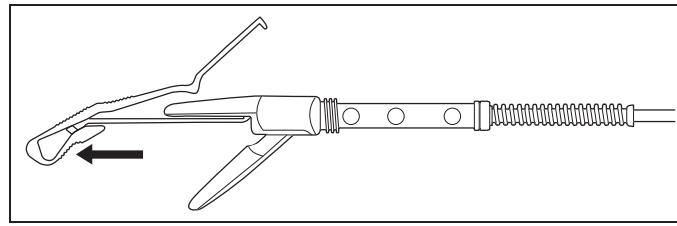
3. Stellen Sie sicher, dass die Klinge mit Einführhilfe **E** am feststehenden Maulteil **A1** an Position **1** mittig ausgerichtet ist.
4. Richten Sie die Einführhilfe **E1** gegebenenfalls mit den Fingern mittig aus.
5. Halten Sie die Einführhilfe **E1** an Position **1** seitlich fest und schieben Sie das Schubrohr langsam in Pfeilrichtung, bis die Klinge **E2** spürbar einrastet.

↳ Bei festsitzender Klinge bleibt die Feder im komprimierten Zustand.



6. Lösen Sie mit Hilfe des Keils an der Einführhilfe **E1** die Klinge **E2** aus der Rastung.

↳ Die Feder entspannt sich und das Schubrohr schnappt zurück.



7. Ziehen Sie die Einführhilfe mit der Klinge **E** in Pfeilrichtung heraus und entsorgen Sie die Klinge mit Einführhilfe **E**.

Wiederaufbereitung von Klinge und Einführhilfe ist nicht zulässig.

7. Aufbereitung

Ligationsinstrumente dürfen nicht ohne vorherige Reinigung, Desinfektion und Sterilisation eingesetzt werden. Eine wirksame Reinigung und Desinfektion ist Voraussetzung für eine effektive Sterilisation der Ligationsinstrumente.

1. Beachten Sie, dass nur ausreichend geräte- und produktspezifisch validierte Verfahren für die Reinigung, Desinfektion und Sterilisation eingesetzt werden und dass die validierten Parameter bei jedem Zyklus eingehalten werden.
2. Beachten Sie die gültigen Rechtsvorschriften des Landes und die Hygienevorschriften des Krankenhauses/der Klinik.

Die folgenden Angaben zur Anzahl der möglichen Aufbereitungszyklen sind Richtwerte. Die Anzahl kann je nach Beanspruchung variieren.

Die Anzahl der Aufbereitungszyklen der einzelnen Instrumententeile beträgt bei einer Sterilisationszeit von 20 Minuten und bei einer Sterilisationstemperatur von 134 °C:

- Mauleinsatz **A**: 20 Mal,
- Schaftrohr **B**: bis zu 200 Mal,
- Handgriff **C**: bis zu 100 Mal.

Die Aufbereitung des Ligationsinstruments umfasst folgende Schritte:

- Einweichen
- Demontage
- Vorbehandlung im Ultraschallbad
- Manuelle Entfernung der Verschmutzungen
- Maschinelle Aufbereitung im RDG
- Kontrolle
- Verpacken
- Autoklavieren
- Lagern
- Funktionstest im OP

7.1. Einweichen

⚠ VORSICHT

Infektionsgefahr durch Wasserspritzer und Dämpfe aus dem Ultraschallbad und bei manueller Vorreinigung!

- ▶ Tragen Sie einen Gesichtsschutz und Schutzkleidung.
- ▶ Eine ausreichende Belüftung wird empfohlen.

⚠ VORSICHT

Bei NightKNIFE: Verletzungsgefahr durch scharfe Klinge!

- ▶ Achten Sie während der Reinigung auf die Klinge.
- ▶ Bei NightKNIFE mit auswechselbarer Klinge: Entfernen Sie die Klinge vor der Reinigung aus dem Mauleinsatz.

HINWEIS

Sachschaden am Mauleinsatz durch Scheuermittel und Metallbürsten!

- Reinigen Sie den Mauleinsatz niemals mit Scheuermitteln.

- Entfernen Sie bei Bedarf vorab Schmutzreste mit einem Vlies.
- Weichen Sie das Ligationsinstrument sofort, spätestens jedoch 2 Stunden nach der Anwendung ein.
- Verwenden Sie nur aldehydfreie Desinfektionsmittel, die für die Desinfektion von Ligationsinstrumenten geeignet sind (z. B. DGHM-, FDA-Zulassung oder CE-Kennzeichnung).

Das beim Einweichen eingesetzte Desinfektionsmittel dient nur dem Personenschutz und ersetzt spätere Desinfektionsschritte nicht.

7.2. Demontage

1. Demontieren Sie das Ligationsinstrument (siehe Kapitel 6.1, Seite 29).
2. Bei NightKNIFE mit auswechselbarer Klinge: Entfernen Sie die Klinge aus dem Ligationsinstrument und entsorgen Sie die Klinge (siehe Kapitel 6.2, Seite 29).

7.3. Vorbehandlung im Ultraschallbad

⚠ VORSICHT

Infektionsgefahr durch Wasserspritzer und Dämpfe aus dem Ultraschallbad!

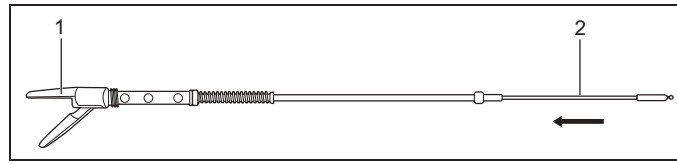
- ▶ Tragen Sie einen Gesichtsschutz und Schutzkleidung.
- ▶ Eine ausreichende Belüftung wird empfohlen.

1. Legen Sie Mauleinsatz **A**, Schaftrohr **B** und Handgriff **C** für mindestens 5 Minuten in das Ultraschallbad. Positionieren Sie großflächige Instrumententeile so im Ultraschallbad, dass sich keine Schallschatten bilden.
2. Verwenden Sie für die Ultraschall-Reinigung geeignete Reinigungs- und Desinfektionsmittel (siehe Kapitel 7.11, Seite 50).
3. Halten Sie die vom Hersteller des Reinigungs- und Desinfektionsmittel angegebenen Konzentrationen und Einwirkzeiten ein.

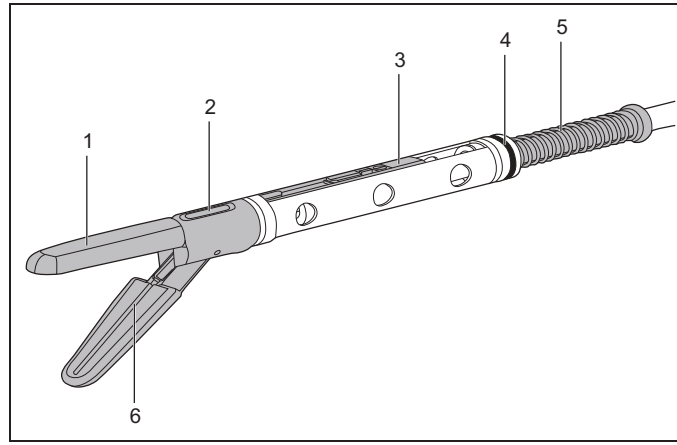
7.4. Manuelle Entfernung der Verschmutzungen

In diesem Kapitel wird exemplarisch das Ligationsinstrument NightKNIFE dargestellt.

Mauleinsatz



1. Schieben Sie die Zugstange **2** in Pfeilrichtung, um die Maulteile **1** zu öffnen.



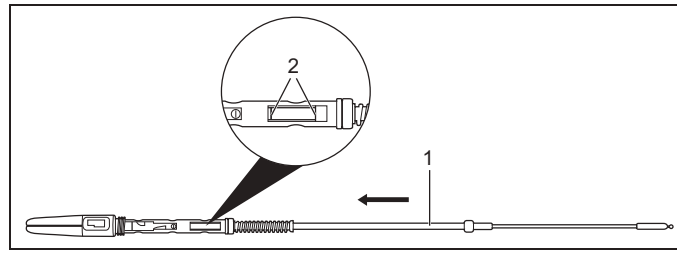
HINWEIS

Sachschaden am Mauleinsatz durch Metallbürste!

▶ Reinigen Sie den Mauleinsatz nur mit einer Kunststoffbürste.

2. Entfernen Sie mit einer Kunststoffbürste und einem Dampfstrahler die Verschmutzungen an den grau markierten Stellen:
   - Maulteile **1**: Außenflächen oben und unten, Elektrodenflächen
   - Gelenk **2**: Öffnungen oben und unten
   - Bei NightKNIFE: Rastmechanismus **3**
   - Bei NightKNIFE: Feder **5**
3. Bei NightKNIFE: Reinigen Sie mit einem spitzen Gegenstand die Innenkanten der beiden Nuten **6**.

4. Bei NightKNIFE: Entfernen Sie mit einem spitzen Gegenstand die Verschmutzungen unter dem Dichtring **4**. Achten Sie darauf, dass der Dichtring dabei nicht beschädigt wird.



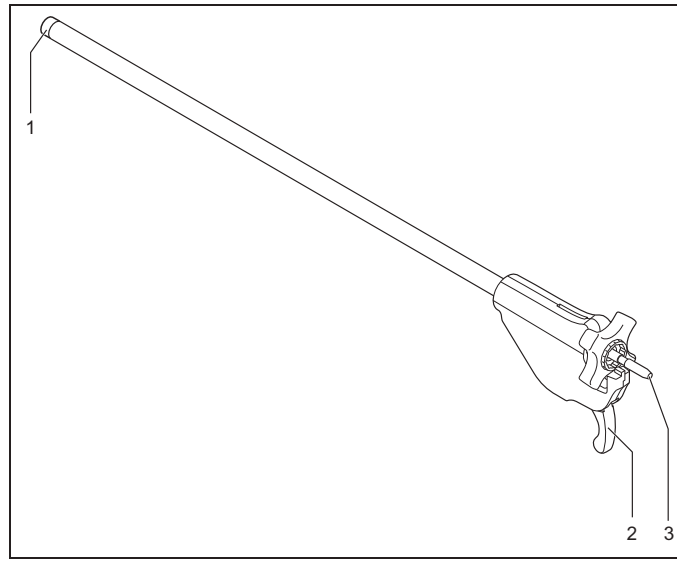
5. Schieben Sie das Schubrohr **1** in Pfeilrichtung und reinigen Sie mit einem Dampfstrahler die freistehenden Auflageflächen **2**.

Schaftrohr

HINWEIS

Sachschaden am Schaftrohr durch Metallbürste!

- ▶ Reinigen Sie das Schaftrohr nur mit den mitgelieferten Kunststoffbürsten.
- ▶ Verwenden Sie bei Bedarf einen Dampfstrahler zur Reinigung.



1. Reinigen Sie das Schaftrohr mit der kleinen Reinigungsbürste am proximalen Ende **3** von innen.
2. Reinigen Sie das Schaftrohr mit der großen Reinigungsbürste am distalen Ende **1** von innen.

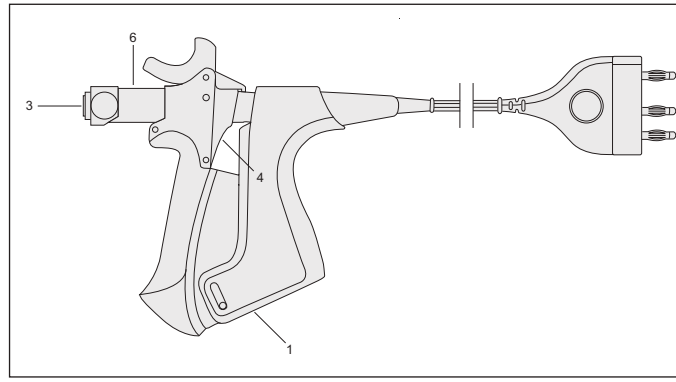
3. Spülen Sie das Schaftrohr **B** am distalen Ende mit vollentsalztem oder destilliertem Wasser, um das Gehäuse von innen zu reinigen. Betätigen Sie dabei den Abzug **2**, um den Betätigungsmechanismus im Gehäuse zu reinigen.

Handgriff

HINWEIS

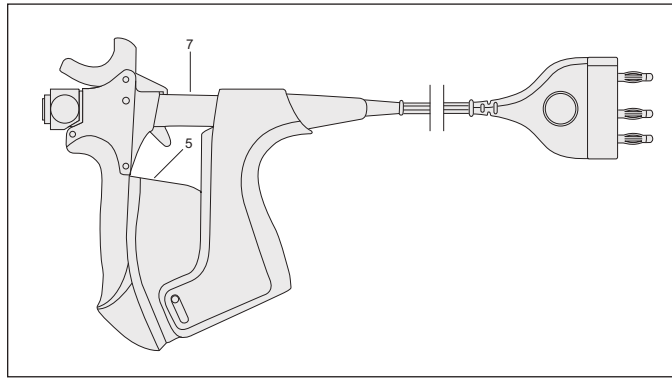
Sachschaden am Handgriff durch Metallbürste!

- Reinigen Sie den Handgriff mit den mitgelieferten Kunststoffbürsten.
- Verwenden Sie bei Bedarf einen Dampfstrahler zur Reinigung.



1. Betätigen Sie den Handgriff bis er einrastet und reinigen Sie mit der Reinigungsbürste die Führungsschienen **6**.

2. Reinigen Sie mit der Reinigungsbürste alle gekennzeichneten Positionen des Handgriffs von innen.



3. Lösen Sie die Einrastung am Handgriff.
4. Reinigen Sie mit der Reinigungsbürste die Rastzähne und Führungsschienen **7** im hinteren Bereich des Handgriffs.
5. Reinigen Sie mit der Reinigungsbürste die gekennzeichnete Position **5** des Handgriffs von innen.

Spülen

▶ Spülen Sie nach der Vorreinigung alle Instrumententeile gründlich mit vollentsalztem oder destilliertem Wasser ab.

7.5. Maschinelle Aufbereitung im RDG

Geeignete Reinigungs- und Desinfektionsverfahren

▶ Setzen Sie für die Reinigung und Desinfektion des Ligationsinstruments ein Reinigungs-Desinfizierungs-Gerät (RDG) ein.

Ein manuelles Verfahren wird aufgrund der deutlich geringeren Wirksamkeit nicht empfohlen.

▶ Achten Sie bei der Auswahl des RDG darauf, dass:

- eine geprüfte Wirksamkeit (z. B. DGHM-, FDA-Zulassung oder CE-Kennzeichnung entsprechend DIN EN ISO 15883) vorliegt.
- ein geprüftes Programm zur thermischen Desinfektion (mindestens 5 Minuten bei 90 °C oder A_0-Wert > 3000) eingesetzt wird. Bei der chemischen Desinfektion besteht die Gefahr von Desinfektionsmittelrückständen auf den Instrumententeilen.
- eine instrumentengeeignete Programmwahl mit ausreichenden Spülzyklen eingesetzt wird.
- steriles/keimarmes (max. 10 Keime/ml) und endotoxinarmes (max. 0,25 Endotoxineinheiten/ml) Wasser zum Nachspülen eingesetzt wird.
- eine Filterung der Trockenluft durchgeführt wird.
- eine regelmäßige Wartung und Prüfung des RDG durchgeführt wird.

Geeignetes Reinigungsmittel

▶ Achten Sie bei der Auswahl des eingesetzten Reinigungsmittelsystems darauf, dass:

- das Reinigungsmittel für das Ligationsinstrument geeignet ist.
- sofern nicht thermisch desinfiziert wird, zusätzlich ein geeignetes Desinfektionsmittel mit geprüfter Wirksamkeit (z. B. DGHM- oder FDA-Zulassung bzw. CE-Kennzeichnung) eingesetzt wird, das kompatibel mit den Reinigungsmitteln ist.
- die eingesetzten Chemikalien mit den Instrumententeilen kompatibel sind (siehe Kapitel 7.11, Seite 50).

▶ Halten Sie die vom Hersteller des Reinigungs- und Desinfektionsmittel angegebenen Konzentrationen und Einwirkzeiten ein.

Reinigen und Desinfizieren

HINWEIS

Beschädigung des HF-Kabels durch falsche Lagerung im RDG!

▶ Achten Sie dabei darauf, dass das HF-Kabel nicht geknickt oder eingequetscht wird.

1. Legen Sie die Instrumententeile in das RDG ein. Beachten Sie Folgendes:
   - Instrumententeile so positionieren, dass kein Spülschatten entsteht
   - Schaftrohr und Mauleinsatz mit dem distalen Ende in die Spülhülse stecken

- Zugstange am Mauleinsatz einschieben, um die Maulteile möglichst weit in der Spülhülse zu öffnen
- Handgriff eingerastet reinigen
- HF-Kabel in einer Siebschale mit Deckel lose positionieren

2. Bei NightKNIFE mit auswechselbarer Klinge: Nehmen Sie eine neue Klinge mit der Einführhilfe aus der Verpackung und legen Sie die Klinge mit Einführhilfe in eine Siebschale mit Deckel.
3. Starten Sie das Programm.
4. Entnehmen Sie die Instrumententeile nach Programmende aus dem RDG.

HINWEIS

Beschädigung des Handgriffs durch Pressluft!

▶ Trocknen Sie den Handgriff nur mit maximal 3 bar Pressluft.

5. Trocknen Sie die Instrumententeile mit gefilterter Pressluft ab.

7.6. Kontrolle

Diese Produkte unterliegen bei bestimmungsgemäßem Gebrauch, je nach Verwendungsintensität, einem Verschleiß. Dieser Verschleiß ist technisch bedingt und unvermeidlich.

Weist das Produkt äußerlich erkennbare Mängel auf oder arbeitet es nicht wie in dieser Anleitung beschrieben, so ist es zu ersetzen. In diesem Fall benachrichtigen Sie bitte den Hersteller oder dessen zuständigen Repräsentanten.

- ▶ Führen Sie nach der Reinigung eine Sicht- und Funktionskontrolle der einzelnen Instrumententeile durch.
- ▶ Ersetzen Sie beschädigte Teile.

7.6.1. Kontrolle bei NightKNIFE

⚠ GEFAHR

Verbrennungsgefahr des Patienten bei brüchiger oder defekter Isolierung!

- ▶ Ersetzen Sie Instrumententeile bei beschädigter Isolierung.

Mauleinsatz

1. Bei NightKNIFE mit auswechselbarer Klinge: Setzen Sie eine neue Klinge **E2** ein (siehe Kapitel 4.1, Seite 19).
2. Prüfen Sie die Maulteile **A1** auf die Funktion Öffnen/Schließen.
3. Prüfen Sie visuell die Kugel an der Zugstange **A4** auf Beschädigung.
4. Bewegen Sie das Schubrohr **A3** im Mauleinsatz **A**, um die Leichtgängigkeit und Grundstellung der Klinge **E2** zu prüfen.

5. Prüfen Sie visuell die Klinge **E2** auf Beschädigung.
6. Prüfen Sie die Isolierung der Zugstange **A4** auf Beschädigung.
7. Prüfen Sie die Beschichtung des Mauleinsatzes **A** auf Beschädigung.
8. Prüfen Sie den Dichtring **A2** auf Beschädigung.
9. Prüfen Sie, ob Zugstange **A4** und Schubrohr **A3** verbogen sind.

Schaftrohr

1. Prüfen Sie visuell die Isolierung auf Beschädigung.
2. Prüfen Sie, ob das Schaftrohr verbogen ist.
3. Prüfen Sie, ob sich das Sternrad **B2** leicht drehen lässt.
4. Prüfen Sie den Abzug **B3** auf Funktion.

Handgriff

1. Prüfen Sie Rasthebel **C1**, Verriegelungshebel **C2** und Druckknöpfe **C4** auf Leichtgängigkeit.

HF-Kabel

1. Prüfen Sie den Anschluss auf Beschädigung und Korrosion.
2. Prüfen Sie visuell die Isolierung auf Beschädigung.

7.6.2. Kontrolle bei LIGATOR

⚠ GEFAHR

Verbrennungsgefahr des Patienten bei brüchiger oder defekter Isolierung!

▶ Ersetzen Sie Instrumententeile bei beschädigter Isolierung.

Mauleinsatz

1. Prüfen Sie die Maulteile **A1** auf die Funktion Öffnen/Schließen.
2. Prüfen Sie die Kugel an der Zugstange **A4** auf Beschädigung.
3. Prüfen Sie die Isolierung der Zugstange **A4** auf Beschädigung.
4. Prüfen Sie, ob die Zugstange **A4** verbogen ist.

Schaftrohr

1. Prüfen Sie visuell die Isolierung auf Beschädigung.
2. Prüfen Sie, ob das Schaftrohr **B** verbogen ist.

Handgriff

1. Prüfen Sie die Rasthebel **C1**, Verriegelungshebel **C2** und Druckknöpfe **C4** auf Leichtgängigkeit.

HF-Kabel

1. Prüfen Sie den Anschluss auf Beschädigung und Korrosion.
2. Prüfen Sie visuell die Isolierung auf Beschädigung.

7.7. Verpacken

Die Verpackung muss folgenden Kriterien entsprechen:

- DIN EN (ANSI AAMI) ISO 11607/
  DIN EN 868-2...10 (bisher DIN EN 868/
  ANSI AAMI ISO 11607)
- geeignet für die Dampfsterilisation
  (Temperaturbeständigkeit bis 137 °C, ausreichende Dampfdurchlässigkeit)
- regelmäßig gewartet (Sterilisationscontainer)

▶ Verpacken Sie das Ligationsinstrument in eine geeignete Einmalsterilisationsverpackung und/oder einen geeigneten Sterilisationscontainer.

Eine Sterilisation in der Transportverpackung ist nicht zulässig.

7.8. Autoklavieren

▶ Sterilisieren Sie das Ligationsinstrument nur im zerlegten Zustand.

HINWEIS

Zerstörung des Ligationsintruments durch Heißluftsterilisationsverfahren!

▶ Achten Sie auf ein geeignetes Sterilisationsverfahren.

Für die Sterilisation nur die Dampfsterilisation mit folgenden Spezifikationen einsetzen:

- fraktioniertes Vakuumverfahren (mit ausreichender Produkttrocknung)
- entspricht der DIN EN 13060 bzw. DIN EN 285
- Validierung entsprechend DIN EN ISO/ ANSI AAMI ISO 17665 (bisher DIN EN 554/ ANSI AAMI ISO 11134) (gültige IQ/OQ (Kommissionierung) und produktspezifische Leistungsbeurteilung (PQ))
- maximale Sterilisationstemperatur 134 °C (zuzüglich Toleranz entsprechend DIN EN ISO/ ANSI AAMI ISO 17665 (bisher DIN EN 554/ ANSI AAMI ISO 11134))
- Sterilisationszeit mindestens 20 Minuten bei 121 °C bzw. 5 Minuten bei 132/134 °C

Der Einsatz des weniger wirksamen Gravitationsverfahrens muss durch eine zusätzliche Validierung abgesichert werden (gegebenenfalls längere Sterilisationszeiten erforderlich).

Der Einsatz anderer Sterilisationsverfahren (z. B. Ethylenoxid-, Formaldehyd-, Strahlen- und Niedertemperaturplasma-Sterilisation) geschieht außerhalb der Verantwortung des Herstellers.

1. Beachten Sie im Anwendungsfall:
   - DIN EN ISO 14937/ANSI AAMI ISO 14937,
   - Verfahrensspezifische Normen.
2. Weisen Sie die Eignung und Wirksamkeit des Verfahrens unter Berücksichtigung der spezifischen Produktgeometrie im Rahmen der Validierung nach (gegebenenfalls einschließlich Rückstands-untersuchungen des Sterilisiermittels).

7.9. Lagern

1. Lagern Sie das Ligationsinstrument an einem Ort, an dem es geschützt ist vor:
   - starken mechanischen Einwirkungen wie Stoß, Fall oder Schlag,
   - direkter Sonnenbestrahlung,
   - Röntgenstrahlen.
2. Lagern Sie das Ligationsinstrument trocken und bei Raumtemperatur.

Die Lagerdauer des sterilisierten Ligationsinstruments hängt von der Verpackungsart und den Lagerbedingungen ab.

Der Versandkarton ist nicht für die Aufbewahrung des Produkts vorgesehen.

7.10. Funktionstest im OP

1. Setzen Sie das Ligationsinstrument zusammen (siehe Kapitel 4, Seite 19).
2. Prüfen Sie die Funktionen des Ligationsinstruments (siehe Kapitel 7.6, Seite 44).

7.11. Empfohlene Betriebsstoffe

BOWA empfiehlt den Einsatz von neutralen bis leicht alkalischen Reinigungsmitteln bzw. Reinigungs- und Desinfektionsmitteln ohne kritische Inhaltsstoffe. In Abhängigkeit von der Konzentration sind alkoholische und/oder aldehydische Inhaltsstoffe zulässig.

Vorbehandlung im Ultraschallbad

Die Eignung der Ligationsinstrumente für eine wirksame Vorbehandlung im Ultraschallbad (5 min) wurde unter Verwendung von einem aldehydfreien, kombinierten Reinigungs- und Desinfektionsmittel (Gigasept Instru AF) durch BOWA nachgewiesen.

Maschinelle Reinigung

Die Eignung der Ligationsinstrumente für eine wirksame Reinigung/Desinfektion mit dem maschinellen Verfahren (90 °C, 5 min) wurde unter Verwendung von einem alkalischen Reinigungsmittel mit Tensidzusatz (neodisher MediClean forte) durch BOWA nachgewiesen.

Die Verwendung weiterer Reinigungs- und Desinfektionsmittel geschieht außerhalb der Verantwortung des Herstellers.

8. Technische Daten

8.1. NightKNIFE und LIGATOR

Technische Daten	
HF-Strom	4 A
Wechselspannung	> 330 kHz
Max. Spannung	200 Vp sinoidal
Zugelassenes HF-Gerät	BOWA ARC-Generatoren mit LIGATION Software
Zugelassene Programme	LIGATION Bei BOWA ARC 350L (900-350): LIGATION ab der Software V2.6 Effekt 2 bis Effekt 4

9. Entsorgung

Die Entsorgung der Medizinprodukte, des Verpackungsmaterials sowie des Zubehörs muss nach den jeweils geltenden länderspezifischen Vorschriften und Gesetzen erfolgen.

10. Systemübersicht

10.1. NightKNIFE

Ohne auswechselbare Klinge:

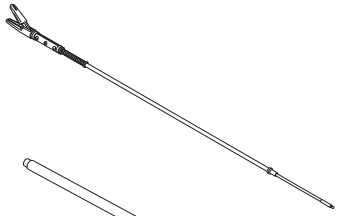
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

Mit auswechselbarer Klinge:

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Bestellung beim Fachhändler

▶ 723-020 ☒ 3

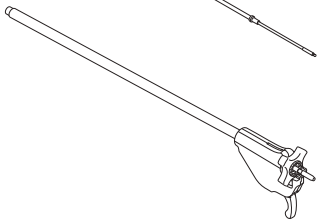


Mauleinsatz ohne auswechselbare Klinge

- 771-136 ☐ ....
- 771-120 ☐ ....

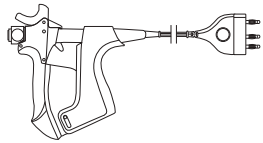
Mauleinsatz mit auswechselbarer Klinge

- 771-137 ☐ ....
- 771-121 ☐ ....



Schaftrohr

- 770-336 ☐ ....
- 770-320 ☐ ....

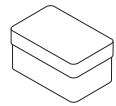


Handgriff mit HF-Kabel

- 770-000 ☐ ....

Reinigungsbürsten-Set

- 723-030 ☐ ....



Handgriff-Ersatzteile

- 723-020 ☐ ....

Auswechselbare Klinge (5 Stück)

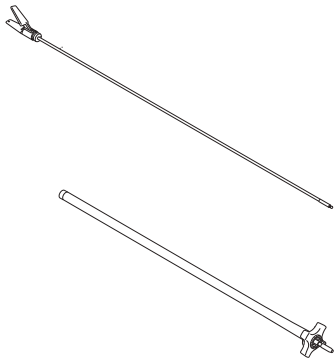
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000+770-236+723-020)

Bestellung beim Fachhändler

▶ 723-020 ☒ 3

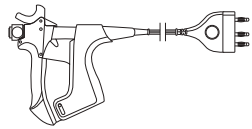


Mauleinsatz

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Schaftrohr

- 770-236 ☐ ....
- 770-211 ☐ ....

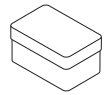


Handgriff mit HF-Kabel

- 770-000 (neu) ☐ ....

Reinigungsbürsten-Set

- 723-000 ☐ ....



Handgriff-Ersatzteile

- 723-020 ☐ ....

BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

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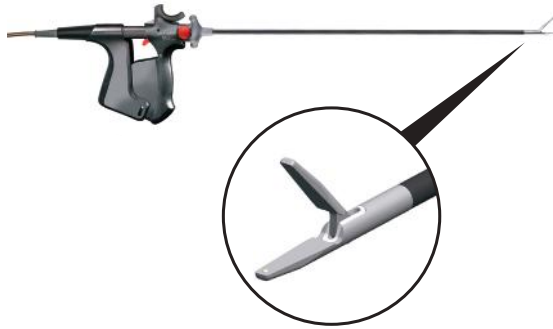
Operating Manual

NightKNIFE®

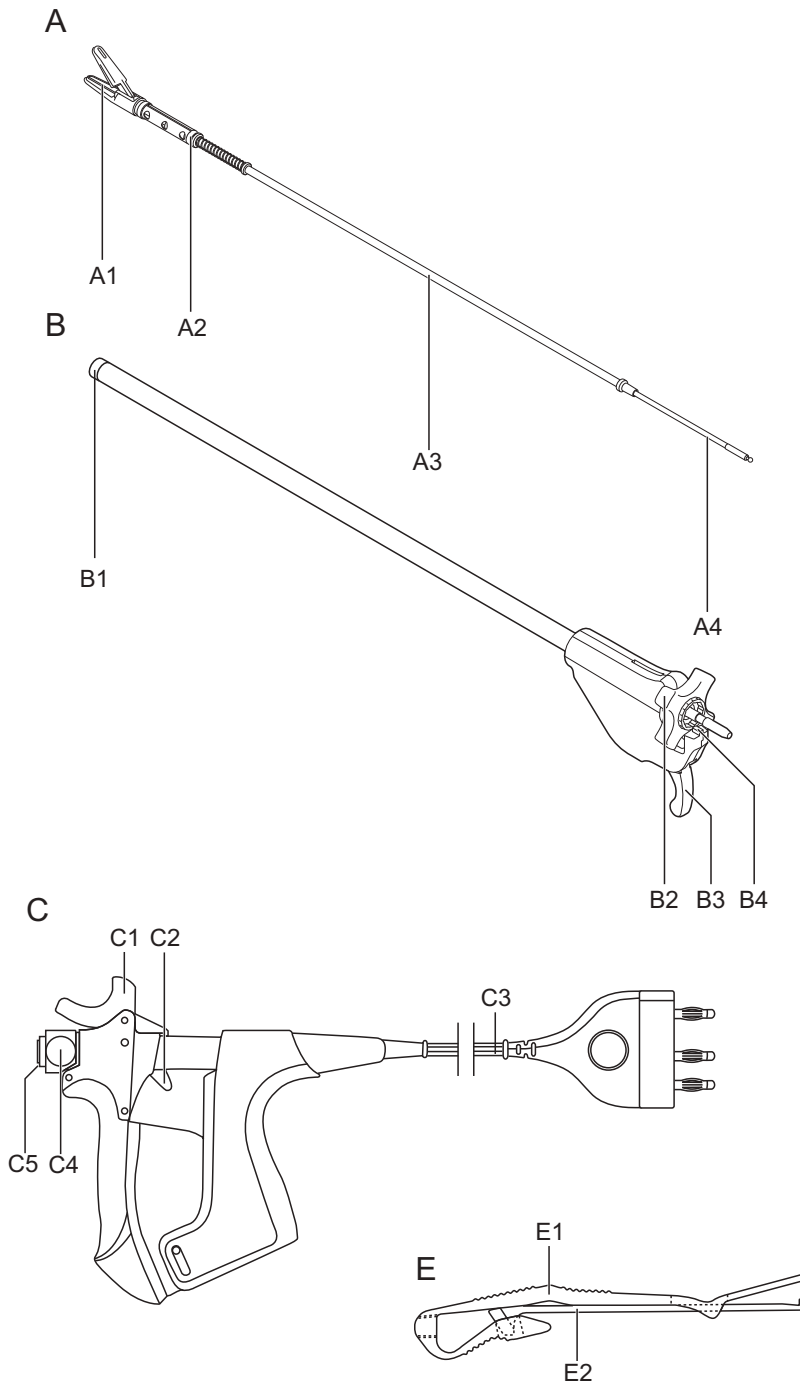
LIGATOR®



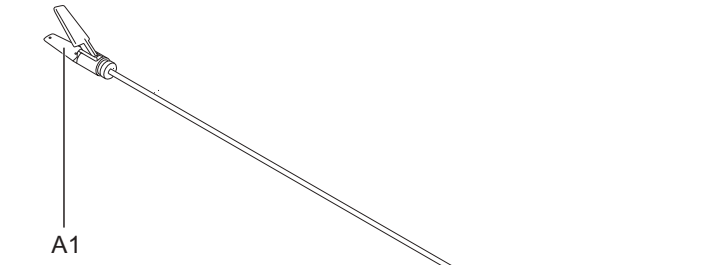
BOWA

EINFACH SICHER

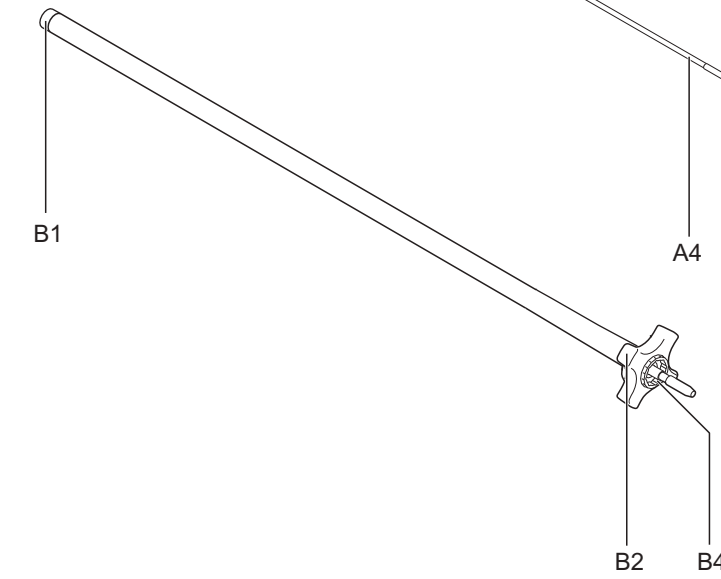
EN


A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

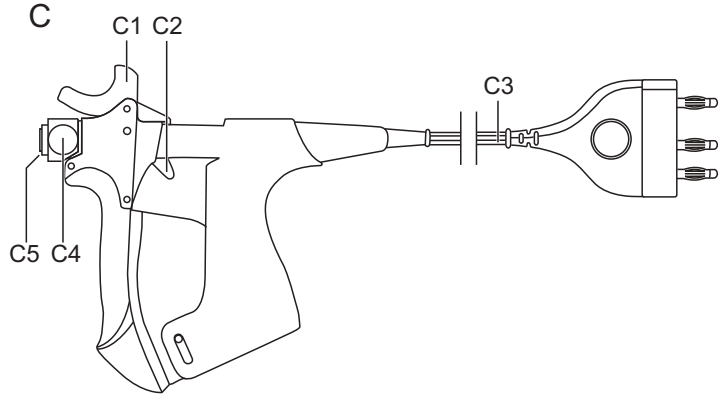
A



B



C



Legend

A	**Jaw insert (for NightKNIFE with blade)**
A1	Jaws with electrode (1 fixed, 1 moveable)
A2	Seal ring
A3	Sliding tube
A4	Drawrod
B	**Shank tube**
B1	Threaded bush
B2	Fluted knob
B3	Trigger
B4	Alignment spring
C	**Handle**
C1	Ratchet lever
C2	Locking lever
C3	HF cable
C4	Pushbuttons
C5	Holder for shank tube with jaw insert
E	**Blade with insertion aid**
E1	Insertion aid
E2	Blade

Contents

1. Using this operating manual

This operating manual is part of the device.

BOWA-electronic GmbH & Co. KG assume no liability nor provide any warranty whatsoever for any damage or consequential damage arising from non-compliance with this operating manual.

- ▶ Read the operating manual, in particular the safety instructions (see section 2, page 12)carefully and thoroughly before use.
- ▶ Store the operating manual in a safe place throughout the service life of the device.
- ▶ Keep the operating manual accessible to operating room personnel.
- ▶ Give the operating manual to each successive owner and/or user of this device.
- ▶ Always update the operating manual whenever you receive additional information from the manufacturer.

1.1. Validity

This operating manual applies only to the devices designated on the title page.

1.2. Icons and labeling

1.2.1. Structure of warning instructions

⚠ WARNING

"Risk type, source and consequences there of" (Personal injury)!

- ▶ Measure for risk prevention.

1.2.2. Risk levels in the warning instructions

Symbol	Risk level	Probability of occurrence	Consequences of non-compliance
	**DANGER**	Immediate risk	Death or serious injuries
	**WARNING**	Possible risk	Death or serious injuries
	**CAUTION**	Possible risk	Minor injuries
	**NOTE**	Possible risk	Property damage

1.2.3. Tips

Tips to make your work easier or supplementary explanatory information for a procedure.

1.2.4. Other icons and labeling

Icon/Label	Meaning
☑	Prerequisite for an activity
▶	Activity with one step
1. 2. 3.	Activity with several steps in a binding sequence
⇩	Result of preceding activity
•	List (first level)
•	List (second level)
Emphasis	Emphasis
..., see section xxx, page xxx	Cross reference

2. Safety

2.1. Intended use

The ligature instruments are intended to be used to seal arterial and venous blood vessels and vascular tissue structures in laproscopic and open surgical procedures in gynecology, urology, general surgery, and other surgical disciplines with the aid of an HF current and mechanical pressure.

In addition, the ligature instruments are suitable for conventional bipolar coagulation.

The ligature instruments are intended to be used with the bipolar ligation operating mode.

They are intended to be used in connection with the ligation program of BOWA ARC generators,

The NIghtKNIFE ligation instrument can also be used to cut tissue.

Any other use of the ligation instruments is neither intended nor proper and must be effectively prevented.

In the COMFORT version, item 770-000, the connecting cable is solidly connected to the handle.
Generators with Plug'n Cut COMFORT can recognise BOWA COMFORT instruments and automatically select the appropriate parameters.

It is not necessary to use a neutral electrode with bipolar ligation instruments.

2.2. General safety instructions

The HF device may be used only by trained medical staff. The surgeon and medical staff must be trained in the fundamental principles, rules for use and risks of HF surgery and must be familiar with them.

- Read the operating manual carefully and thoroughly before using the device.

In connection with your responsibility for the sterility of the ligation instruments, observe the following when using them:

- Clean and sterilize the ligation instrument before using it for the first time. It is not sterile as delivered.
- Clean and sterilize the ligation instrument before each subsequent use.
- Use only cleaning, disinfection and sterilization methods that have been adequately validated for the specific devices and products concerned.
- Comply with the validated parameters for each cycle.
- Observe the applicable legal requirements in your country and the hygiene regulations of the hospital.

In case of cleaning in an ultrasound bath or manual precleaning, there is a risk of infection due to water spray and vapors.

- Wear a face mask and protective clothing.

Adequate ventilation is recommended.

There is a risk of injury due to the sharp blade:

- Be careful with the blade during assembly and disassembly.
- Remove the replaceable blade before cleaning the jaw insert.
- To avoid punctures and lacerations, always use the insertion aid for assembly and dismantling.

2.2.1. HF device

- Use only approved HF devices and programs (see section 8, page 51).
- Observe the operating instructions of the HF device and the general instructions for electrosurgical operations.

Improper use of HF current can lead to endogenous and exogenous burns and explosions:

- Carry out electrosurgical operations only with insufflation using a non-flammable gas (CO_2).
- Avoid direct skin contact with HF cables.
- Avoid contact with flammable gases and liquids.

2.2.2. HF cable

Improper use of HF cables can lead to patient injuries:

- Never lay the HF cable on the patient's skin.
- Connect the ligation instrument for coagulation before switching on the HF generator.
- When plugging or unplugging the HF cable, always grasp the connector directly.
- Use only HF cables that are in perfect condition. Never use a defective HF cable.

The HF cable may cause interference to imagery on monitors.

- Never route the HF cable alongside a camera cable.
- Do not lay the HF cable in loops.

2.2.3. Active electrodes

Defective or worn electrodes can cause burns on patients.

- Never use or repair worn or defective jaw components or electrode surfaces. Dispose of them.

Hot electrode surfaces may cause patient injuries.

- Maintain sufficient distance between the tips of the instrument and sensitive tissue structures, such as the pancreas or intestine.
- Ensure that hot instruments are not used for preparation.

Inadvertent activation of the ligation instrument may cause patient injuries.

- Do not lay the ligation instrument on the patient.

Dirty electrodes may cause a short circuit, thereby resulting in functional failure of the ligation instrument.

- Clean the jaw electrodes regularly with a moist cloth.
- Replace the jaw insert if the electrodes are damaged.

2.2.4. Replaceable blade with insertion aid (only for NightKNIFE with replaceable blade)

Do not recondition the replaceable blade and insertion aid.

- Replace or discard used blades and insertion aids.

2.2.5. Repairs and servicing

Do not repair or service defective devices.

- Discard or replace defective devices.

2.3. Personal safety instructions

Incorrect HF generator configuration settings and limited visibility can lead to patient injuries.

- Select the HF generator and the HF cable according to the requirements of the ligation instrument.
- Carry out operations only with adequate visibility.
- Never operate ligation instruments in Autostart mode.

2.3.1. Patients with pacemakers

Malfunctions or destruction of the pacemaker can endanger the life of the patient or result in irreversible injuries to the patient.

- Never perform ambulant operations on patients with pacemakers.
- In cases of patients with pacemakers, consult the cardiologist before carrying out HF surgery.
- Set the demand pacemaker to a fixed frequency.
- Ensure that the pacemaker does not come into contact with the HF electrode.
- Keep a fully operational defibrillator within reach
- Carry out a postoperative pacemaker check.

3. Functionality

In bipolar HF surgery, tissue coagulation is achieved by applying a high-frequency AC current, which generates heat.

The NightKNIFE and LIGATOR ligation instruments are invasive surgical instruments for use in laproscopic or open surgery. They are used through surgically generated access openings in conjunction with products for endoscopic use, such as trocars and optics.

The active electrodes (branches) are the non-insulated areas of the jaws.

The HF current flows from one branch of the instrument through the biological tissue to the other branch to produce the desired localized coagulation effect.

With this method, sealing of a vessel or tissue segment carrying blood is achieved by HF current in combination with supplementary pressure.

The sealed location is hemostatically tight with respect to systolic blood pressure and permanently closed.

The integrated cutting function of the NightKNIFE allows the tissue under treatment to be separated immediately after sealing without first changing instruments.

The jaws of the jaw insert can be opened or closed by actuating the handle, and they can be locked in place with the ratchet lever.

The jaw insert can be turned and locked using the fluted knob on the shank tube (8x 45°).

4. Assembly

⚠ WARNING

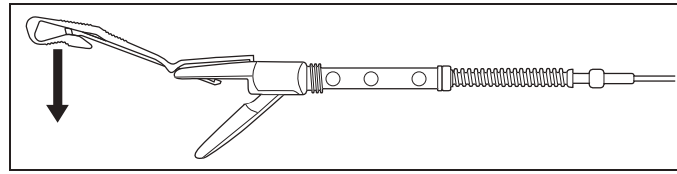
Risk of patient injury from non-sterile ligation instruments!

▶ The ligation instrument is not sterile as delivered. Clean and sterilize the instrument before using it.

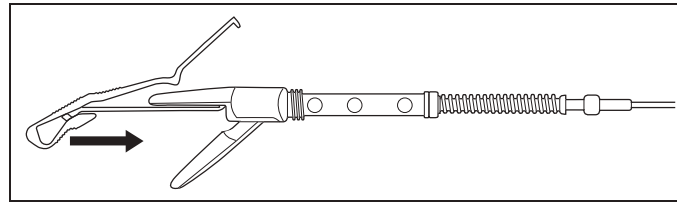
4.1. Attaching the replaceable blade with the insertion aid (only for NightKNIFE with replaceable blade)

☑ The blade and insertion aid have been cleaned and disinfected (see section 7.5, page 42).

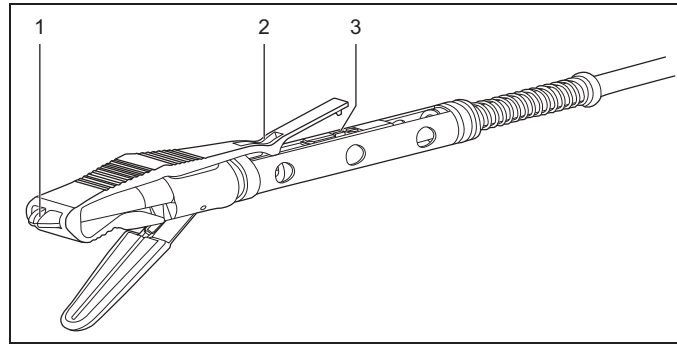
1. Remove the blade and insertion aid **E** from the sterile package.



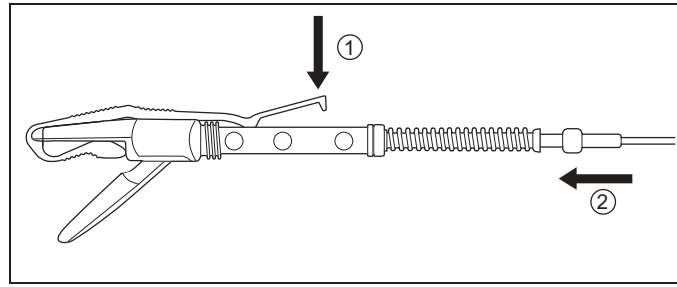
2. Rotate the jaw insert **A** with the fixed jaw **A1** facing upward to open the jaws.
3. Insert the fixed jaw **A1** between the blade **E2** and the insertion aid **E1** and press the insertion aid **E1** downward in the arrow direction to release the blade.



4. Slide the insertion aid **E** with the blade along the fixed jaw **A1** in the arrow direction until it reaches the stop.

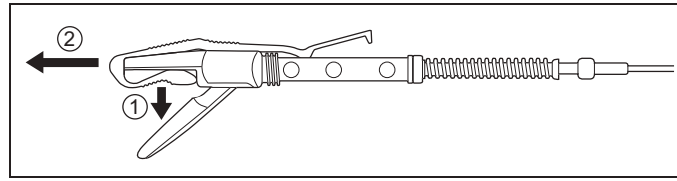


5. Ensure that the blade with insertion aid **E** is positioned in the middle at the marked position.
6. If necessary, use your fingers to position the insertion aid **E1** in the middle.



7. Hold the insertion aid **E1** firmly and press it lightly downward in the direction of arrow **1**.
8. Move the sliding tube **A3** in the direction of arrow **2** until you see and hear the blade **E2** click into place.

↳ The spring remains compressed.



9. Pull the short arm of the insertion aid **E1** downward (arrow **1**) to return the blade to its initial position.
10. Remove the insertion aid **E1** from the fixed jaw in the direction of arrow **2**.

▶ Keep the insertion aid in a safe place. You will need it to remove the blade.

4.2. Assembling the ligation instrument

1. Screw the jaw insert **A** fully into the shank tube **B**.
2. Check that there is no gap between the jaw insert **A** and the shank tube **B**.
3. Close the jaws **A1** with your fingers and insert the shank tube **B** in the handle **C**:
   - With NightKNIFE: ensure that the alignment spring **B4** and the alignment groove **C5** line up with each other.
   - Let the shank tube **B** click into the handle **C**.
4. Check the ligation instrument for proper gripping operation by actuating the handle **C**.
5. Using the ratchet lever **C1**, open the jaws **A1**.
6. With NightKNIFE: check the initial position and ease of motion of the blade by actuating the trigger **B3**.
7. Check that the fluted knob **B2** can be turned.

5. Operation

5.1. Before use

☑ The ligation instrument is assembled (see section 4, page 18) and prepared (see section 7, page 31).

⚠ WARNING

Risk of patient injury!

- ▶ Use only approved BOWA ARC generators with ligation capability (see section 8, page 51).
- ▶ Use only suitable products and accessories as described in the system overview.
- ▶ Use only intact, sterilized products.

⚠ WARNING

Risk of patient injuries from the combustion or explosion of flammable liquids and gases!

- ▶ Carry out electrosurgical operations only with insufflation using a non-flammable gas (CO_2).
- ▶ Avoid contact with flammable gases and liquids, such skin cleaners, disinfectants and anesthetic gases.

1. Connect the HF cable **C3** to the HF device and switch on the HF device.
2. Set the output power of the HF device.
3. Perform a thorough visual inspection and functional test each time before using the ligation instrument (see section 7.6, page 44).

The jaws **A1** are open in the initial state.

4. Using the handle **C**, close the jaws **A1**.
5. Insert the jaw insert **A** in the trocar sleeve.

5.2. During the operation

⚠ WARNING

Risk of patient injury due to incorrect device settings and limited visibility!

- ▶ Set the output power of the HF device to the value necessary for the operation.
- ▶ Use only approved programs (see section 8, page 51).
- ▶ Carry out operations only with adequate visibility.

⚠ WARNING

Risk of patient injury due to hot electrode surfaces and vapor emission!

- ▶ Maintain sufficient distance between the tips of the instrument and sensitive tissue structures, such as the pancreas or intestine.
- ▶ Ensure that hot ligation instruments are not used for preparation.
- ▶ Do not lay the ligation instrument on the patient.

- ▶ Using visual control, insert the ligation instrument into the patient’s body.

Grasping, clamping and sealing tissue

⚠ WARNING

Risk of patient injury due to inadvertent activation of the ligation instrument!

- ▶ Never use the AUTOSTART function.
- ▶ Do not switch on the HF current before the active electrodes are in contact with the tissue to be coagulated.

1. Place the jaw insert **A** on the operation site.

The jaw insert **A** can be rotated and locked in steps of 45°.

2. Turn the fluted knob **B2** to set the angle of the jaw insert **A**.
3. Place the tissue to be sealed between the electrodes of the jaws **A1**.
4. Close the jaws **A1** to grasp the tissue.

↳ The tissue is grasped.

5. Use the three-position ratchet of the handle **C** to adjust the pressure on the tissue to best match the amount of grasped tissue.

↳ The tissue is clamped.

6. Using the foot switch of the HF device, activate the HF current for coagulation:
   - A continuous acoustic signal sounds during the entire sealing process to indicate that power is being supplied.
   - An alternating acoustic signal indicates the end of the sealing process.
7. Release the foot switch to stop the supply of power.
8. Using the ratchet lever **C1**, open the jaws **A1**.

↳ The tissue is coagulated.

Cutting tissue (only with NightKNIFE)

⚠ **WARNING**

Strong bleeding may occur if the grasped tissue is cut before coagulation or ligation!

- ▶ With blood vessels, place at least two seals to the left and right of the cutting site.
- ▶ Before cutting, ensure that the tissue has been reliably sealed.
- ▶ Cut only in the sealed area.

☑ The tissue is grasped by the jaws and is coagulated.

1. To cut, pull the trigger **B3** and then release it.

↳ The tissue is cut.

2. Using the ratchet lever **C1**, open the jaws **A1**.

Changing the output power of the HF device

▶ Before increasing the output power of the HF device, check that:

- all HF cables and connectors are properly connected;
- the ligation instrument is properly connected (see the operating instructions of the HF device);
- the foot switch works properly;
- the insulation of the HF cable **C3**, the jaws **A1**, the shank tube **B** and the trocar sleeve is in good condition;
- the active electrodes of the jaws **A1** are clean and not worn out.

5.3. Withdrawal

⚠ WARNING

Risk of patient injury due to damaged or broken-off parts!

▶ Check the jaw insert after each withdrawal. All parts must be present.

1. Close the jaws **A1**.
2. Withdraw the ligation instrument from the trocar sleeve.

5.4. After use

⚠ WARNING

Dirty electrodes may lead to functional failure of the ligation instrument!

- ▶ Clean the electrodes of the jaws **A1** regularly with a moist cloth.
- ▶ Replace the jaw insert **A** if the electrodes are damaged.
- ▶ For NightKNIFE with exchangeable blade: replace the blade **E2** after every operation.

1. Prepare the ligation instrument after use (see section 7, page 31).

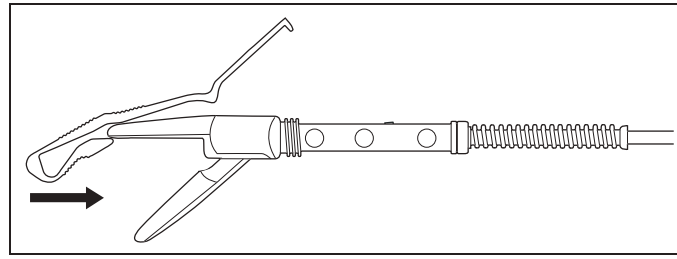
6. Dismantling

6.1. Dismantling the ligation instrument

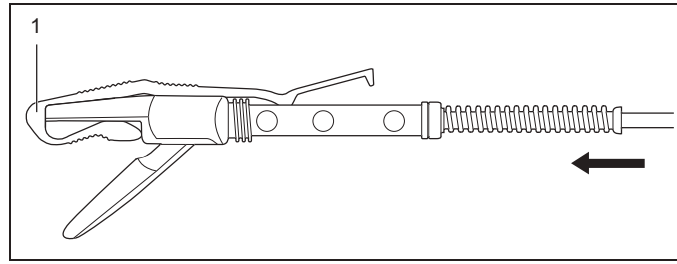
1. Press and hold the buttons **C4** and the locking lever **C2** on the handle **C**, then pull the handle off the shank tube **B**.
2. Unscrew the jaw insert **A** from the shank tube **B**.
3. For NightKNIFE with exchangeable blade: Using the insertion aid **E**, remove the blade (see section 6.1, page 28).

6.2. Removing the blade with the insertion aid (only for NightKNIFE with exchangeable blade)

1. Rotate the jaw insert **A** with the fixed jaw **A1** facing upward to open the jaws.

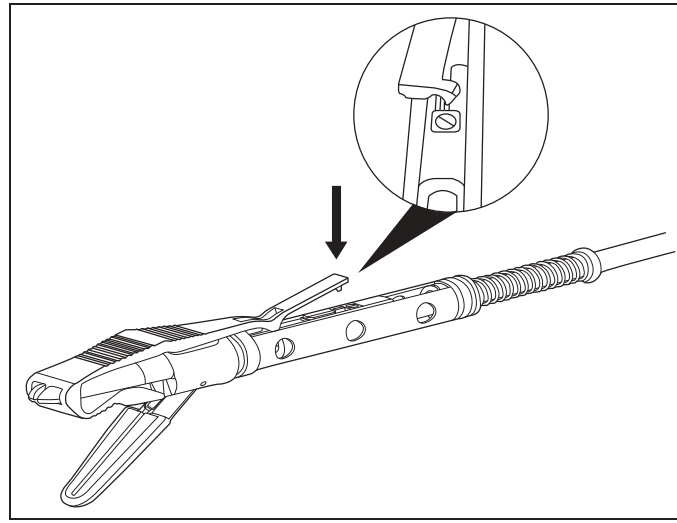


2. Grasp the insertion aid **E1** firmly by the sides and slide it onto the fixed jaw **A1** in the arrow direction until it reaches the stop.



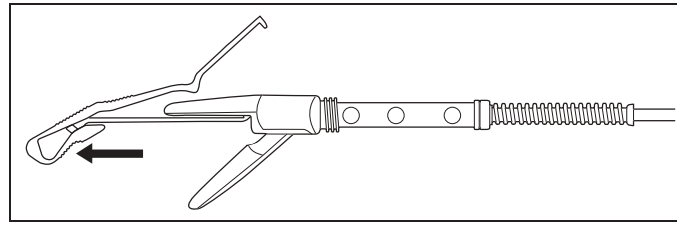
3. Ensure that the blade with insertion aid **E** is aligned to the middle of the fixed jaw **A1** at position **1**.
4. If necessary, use your fingers to align insertion aid **E1** in the middle.
5. Hold the insertion aid **E1** by the sides in position **1** and move the sliding tube slowly in the arrow direction until the blade **E2** distinctly clicks in place.

With the blade attached, the spring remains compressed.



6. Using the wedge on the insertion aid **E1**, release the blade **E2** from the latch.

The spring relaxes and the sliding tube snaps back.



7. Pull out the insertion aid and blade **E** in the arrow direction and dispose of the blade and insertion aid **E**.

Reconditioning the blade and insertion aid is prohibited.

7. Preparation

Ligation instruments must always be cleaned, disinfected and sterilized before use. Effective cleaning and disinfection are essential for effective subsequent sterilization of the ligation instruments.

1. Ensure that only adequately validated device- and product-specific methods are used for cleaning, disinfection and sterilization and that the validated parameters are complied with in each cycle.
2. Observe the applicable national legal regulations and the hygiene regulations of the hospital or clinic.

The following information on the possible number of preparation cycles should be regarded as a guideline. The actual number may vary depending on the stress level.

With a sterilization time of 20 minutes and a sterilization temperature of 134 °C, the number of preparation cycles of the individual instrument components is:

- Jaw insert **A**: 20,
- Shank tube **B:** up to 200,
- Handle **C**: up to 100.

Preparation of the ligation instrument comprises the following steps:

- Soaking
- Dismantling
- Pretreatment in an ultrasonic bath
- Manual removal of contamination
- Automatic preparation in a CDM
- Inspection
- Packing
- Autoclaving
- Storage
- Functional test in the operating room

7.1. Soaking

⚠ CAUTION

Risk of infection due to water spray and vapors from the ultrasonic bath or with manual cleaning!

- ▶ Wear a face mask and protective clothing.
- ▶ Adequate ventilation is recommended.

⚠ CAUTION

With NightKNIFE: risk of injury due to the sharp blade!

- ▶ Be careful with the blade during cleaning.
- ▶ For NightKNIFE with exchangeable blade: remove the blade from the jaw insert before cleaning.

NOTE

Risk of material damage to the jaw insert by scouring products and metal brushes!

- ▶ Never use scouring products to clean the jaw insert.

- If necessary, first use a nonwoven cloth to remove residual dirt.
- Soak the ligation instrument immediately after use, or no later than 2 hours after use.
- Use only aldehyde-free disinfectants suitable for disinfecting ligation instruments, such DGHM- or FDA-approved products or products with the CE mark.

The disinfectant used for soaking is intended solely for personal protection and does not replace subsequent disinfection.

7.2. Dismantling

1. Dismantle the ligation instrument (see section 6.1, page 28).
2. For NightKNIFE with exchangeable blade: remove the blade from the ligation instrument and dispose of the blade (see section 6.2, page 28).

7.3. Pretreatment in an ultrasonic bath

⚠ CAUTION

Risk of infection due to water spray and vapors from the ultrasonic bath!

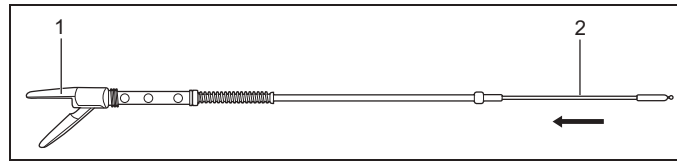
- ▶ Wear a face mask and protective clothing.
- ▶ Adequate ventilation is recommended.

1. Place the jaw insert **A**, shank tube **B** and handle **C** in the ultrasound bath for at least 5 minutes. Position instrument parts with large surface areas in the ultrasonic bath such that they will not be damaged by the ultrasonic energy.
2. Use suitable cleaning and disinfection products for ultrasonic cleaning (see section 7.4, page 36).
3. Follow the manufacturer's instructions with regard to the concentration and exposure time of the cleaning and disinfection products.

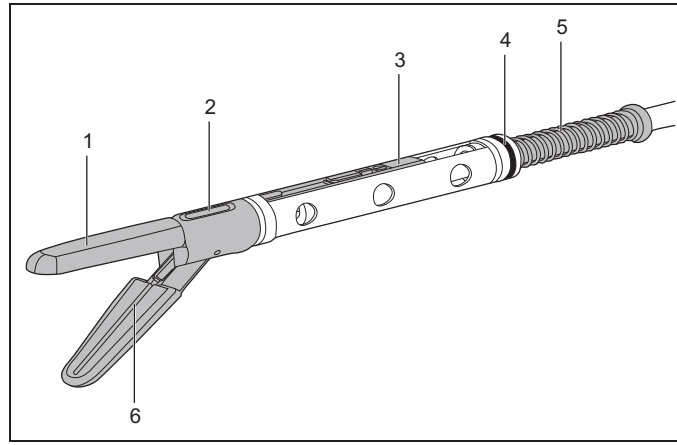
7.4. Manual removal of contamination

The NightKNIFE ligation instrument is described as an example in this section.

Jaw insert



1. Slide the drawrod **2** in the arrow direction to open the jaws **1**.



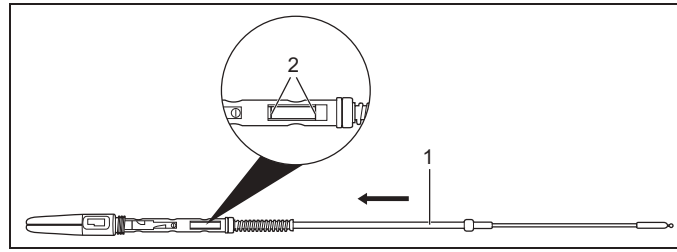
NOTE

Risk of material damage to the jaw insert from metal brushes!

▶ Use only plastic brushes to clean the jaw insert.

2. Using a plastic brush and a steam sprayer, remove contamination from the areas shaded in grey.
   - Jaws **1**: exterior surfaces top and bottom; electrode surfaces
   - Mechanism **2**: openings top and bottom
   - With NightKNIFE: ratchet mechanism **3**
   - With NightKNIFE: spring **5**
3. With NightKNIFE: using a sharp object, clean the inner edges of both grooves **6**.

4. With NightKNIFE: using a sharp object, remove contamination under seal ring **4**. Avoid damaging the ring in the process.



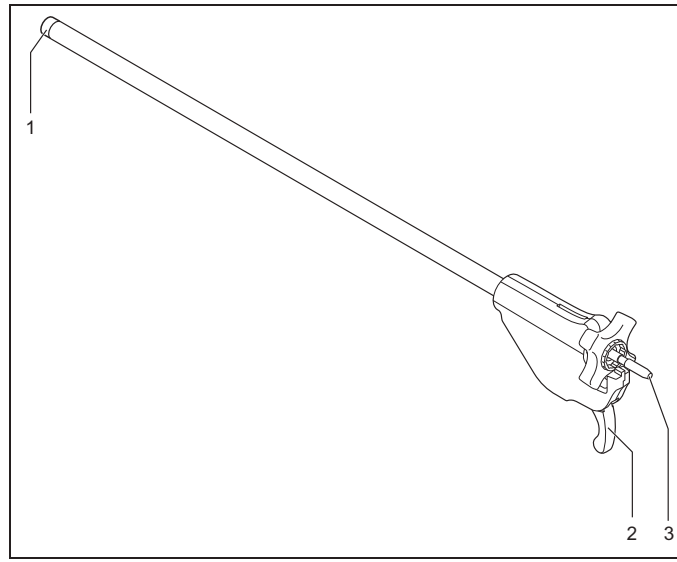
5. Move the sliding tube **1** in the arrow direction and use a steam sprayer to clean the exposed contact surfaces **2**.

Shank tube

NOTE

Risk of material damage to shank tube from metal brushes!

- ▶ Use only the plastic brushes supplied with the instrument to clean the shank tube.
- ▶ If necessary, use a steam sprayer for cleaning.



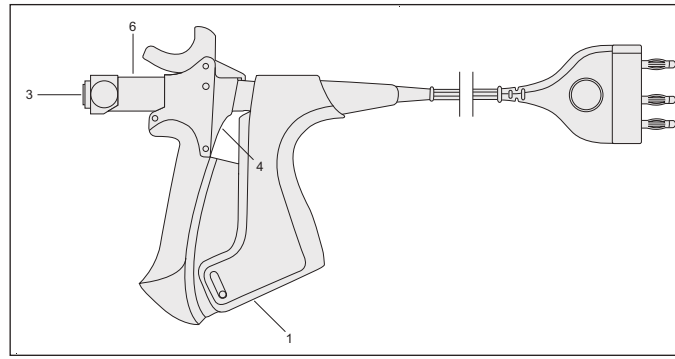
1. Use the small cleaning brush to clean the inside of the proximal end **3** of the shank tube.
2. Use the large cleaning brush to clean the inside of the distal end **1** of the shank tube.
3. Rinse the distal end of the shank tube B with fully demineralized water or distilled water to clean the inside of the housing. At the same time, actuate the trigger **2** to clean the actuation mechanism inside the housing.

Handle

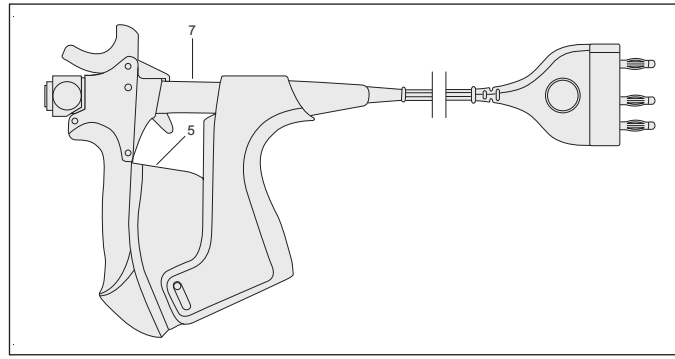
NOTE

Risk of material damage to the handle from metal brushes!

- ▶ Use only the plastic brushes supplied with the instrument to clean the shank tube.
- ▶ If necessary, use a steam sprayer for cleaning.



1. Actuate the handle until it latches, and use the cleaning brush to clean the guide rails **6**.
2. Using the cleaning brush, clean all of the marked positions on the handle from the inside.



3. Release the handle ratchet.
4. Using the cleaning brush, clean the ratchet teeth and guide rails **7** at the rear of the handle.
5. Using the cleaning brush, clean the marked positions **5** on the handle from the inside.

Rinsing

▶ After pre-cleaning, rinse all parts of the instrument thoroughly with fully demineralized or distilled water.

7.5. Automatic preparation in a CDM

Suitable cleaning and disinfection methods

▶ Use a cleaning and disinfection machine (CDM) to clean and disinfect the ligation instruments.

Manual methods are not recommend due to their significantly lower effectiveness.

▶ Ensure that the selected CDM fulfils the following requirements:

- (as shown by DGHM or FDA approval or a CE mark in accordance with EN ISO 15883).
- A proven program for thermal disinfection (at least 5 minutes at 90 °C or an A_0 factor greater than 3000). With chemical disinfection, there is a risk that disinfectant residues may be present on the instrument components.
- A program suitable for the instrument, with adequate rinse cycles, is selected.
- Sterile water or water with a low microorganism count (max. 10 germs/ml) and low endotoxin count (max. 0.25 endotoxin units per ml) is used for rinsing.
- Drying air is filtered.
- The CDM is serviced and tested at regular intervals.

Suitable cleaning agents

▶ Ensure that the selected cleaning agent system fulfils the following requirements:

- The cleaning agent is suitable for the ligation instrument.
- If thermal disinfection is not used, a suitable disinfection agent with proven effectiveness (e.g. DGHM or FDA approval or CE mark) and compatible with the cleaning agents is also used.
- The chemicals that are used are compatible with the instrument components (see section 7.4, page 36).

▶ Follow the manufacturer's instructions with regard to the concentration and exposure time of the cleaning and disinfection products.

Cleaning and disinfection

NOTE

Risk of damage to the HF cable due to incorrect placement in the CDM!

▶ Ensure that the HF cable is not kinked or pinched.

1. Place the instrument components in the CDM. Ensure that:
   - the instrument components are positioned to allow exposure to the rinsing media;
   - the distal ends of the shank tube and jaw insert are inserted in the rinsing sleeve;
   - the drawrod of the jaw insert is slid in so the jaws are opened as far as possible in the rinsing tube;
   - the handle is cleaned in the latched position;

- the HF cable is located in a sieve tray with a cover.

2. For NightKNIFE with exchangeable blade: remove a new blade with insertion aid from its package and place the blade and insertion aid in a sieve tray with a cover.
3. Restart the program.
4. After the program is finished, remove the instrument components from the CDM.

NOTE

Risk of handle damage due to compressed air!

▶ Restrict compressed air pressure to 3 bar or less for handle drying.

5. Use filtered compressed air to dry the instrument components.

7.6. Inspection

These products are subject to wear when used as intended, depending on the intensity of use. This wear arises from the design and construction of the instruments and is unavoidable.

Replace the product if it shows externally visible defects or does not function as described in this manual. Please advise the manufacturer or the manufacturer's authorized representative in such cases.

▶ After cleaning, visually inspect each of the instruments and test them for proper operation.

▶ Replace any damaged parts.

7.6.1. NightKNIFE inspection

⚠ DANGER

Risk of patient burns with brittle or defective insulation!

▶ Replace instrument components with damaged insulation.

Jaw insert

1. For NightKNIFE with exchangeable blade: install a new blade (see section 4.1, page 18).
2. Check the jaws **A1** for proper opening and closing.
3. Visually inspect the ball on drawrod **A4** for damage.
4. Move the sliding tube **A3** on the jaw insert **A** to check for ease of motion and the initial position of the blade **E2**.
5. Visually inspect the blade **E2** for damage.
6. Check the insulation of drawrod **A4** for damage.
7. Check the coating of jaw insert **A** for damage.
8. Check the seal ring **A2** for damage.
9. Check whether the drawrod **A4** or sliding tube **A3** is bent.

Shank tube

1. Visually inspect the insulation for damage.
2. Check whether the shank tube is bent.
3. Check that the fluted knob **B2** can be turned easily.
4. Check the trigger **B3** for proper operation.

Handle

1. Check the ratchet lever **C1**, locking lever **C2** and buttons **C4** for ease of motion.

HF cable

1. Check the connector for damage and corrosion.
2. Visually inspect the insulation for damage.

7.6.2. LIGATOR inspection

⚠ DANGER

Risk of patient burns with brittle or defective insulation!

▶ Replace instrument components with damaged insulation.

Jaw insert

1. Check the jaws **A1** for proper opening and closing.
2. Visually inspect the ball on drawrod **A4** for damage.
3. Check the insulation of drawrod **A4** for damage.
4. Check whether the shank tube **A4** is bent.

Shank tube

1. Visually inspect the insulation for damage.
2. Check whether the shank tube **B** is bent.

Handle

1. Check the ratchet lever **C1**, locking lever **C2** and buttons **C4** for ease of motion.

HF cable

1. Check the connector for damage and corrosion.
2. Visually inspect the insulation for damage.

7.7. Packing

The packaging must meet the following requirements:

- EN (ANSI AAMI) ISO 11607/
  EN 868-2...10 (formerly EN 868/
  ANSI AAMI ISO 11607)
- Suitable for steam sterilization
  (resistant to temperatures up to 137 °C, with sufficient steam permeability)
- Serviced at regular intervals (sterilization container)

▶ Pack the ligation instrument in a suitable disposable sterilization package and/or a suitable sterilization container.

Sterilization in the transportation packaging is not allowed.

7.8. Autoclaving

▶ Always dismantle the ligation instrument for sterilization.

NOTE

Risk of destruction of the ligation instrument from hot-air sterilization

▶ Use a suitable sterilization method.

Use only steam sterilization with the following specifications:

- Fractional vacuum method (with adequate device drying)
- Compliant with EN 13060 or EN 285
- Validation in accordance with EN ISO / ANSI AAMI ISO 17665 (formerly EN 554 / ANSI AAMI ISO 11134) (with applicable IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Maximum sterilization temperature 134 °C plus tolerance in accordance with EN ISO / ANSI AAMI ISO 17665 (formerly EN 554 / ANSI AAMI ISO 11134)
- Minimum sterilization time 20 minutes at 121 °C or 5 minutes at 132 or 134 °C

Using the less effective gravitation method must be secured by means of additional validation (longer sterilization times may be necessary).

The manufacturer accepts no responsibility whatsoever for the use of other sterilization methods, such as sterilization using ethylene oxide, formaldehyde, radiation or low-temperature plasma.

1. Observe the following if such methods are used:
   - EN ISO 14937 / ANSI AAMI ISO 14937;
   - standards relevant to the method.
2. Demonstrate the suitability and effectiveness of the method, taking into account the specific product geometry in the context of validation (including investigation of sterilization medium residues if appropriate).

7.9. Storage

1. Store the ligation instrument in a location where it is protected against:
   - strong mechanical stresses such as shocks, falling or blows;
   - direct exposure to sunlight;
   - X-ray radiation.
2. Store the ligation instrument in a dry place at room temperature.

The storage life of the sterilized ligation instrument depends on the type of packaging and the storage conditions.

The shipping box is not intended for storing the device.

7.10. Functional test in the operating room

1. Assemble the ligation instrument (see section 4, page 18).
2. Test the ligation instrument for proper operation (see section 7.6, page 44).

7.11. Recommended operating supplies

BOWA recommends the use of neutral to slightly alkaline cleaning agents or cleaning and disinfection agents free from potentially harmful ingredients. Alcoholic and/or aldehydic ingredients may be permissible, depending on the concentration.

Pretreatment in an ultrasonic bath

The suitability of the ligation instruments for effective pretreatment in an ultrasonic bath (5 minutes) with the use of an aldehyde-free combined cleaning and disinfection product (Gigasept Instru AF) has been demonstrated by BOWA.

Automatic cleaning

The suitability of the ligation instruments for effective cleaning and/or disinfection with an automated method (90 °C, 5 minutes) and an alkali cleaning product with a surfactant additive (neodic MediCLean forte) has been demonstrated by BOWA.

The manufacturer accepts no responsibility for the use of other cleaning and disinfection products.

8. Technical specifications

8.1. NightKNIFE and LIGATOR

Technical specifications	
HF current	4 A
AC voltage	> 330 kHz
Maximum voltage	200 Vp sinusoidal
Approved HF device	BOWA ARC generators with LIGATION software
Approved programs	LIGATION For BOWA ARC 350L (900-350): LIGATION software V2.6 or later Effect 2 to Effect 4

9. Disposal

Always dispose of medical products, packaging materials and accessories in accordance with applicable national regulations and statutes.

10. System overview

10.1. NightKNIFE

Without replaceable blade:

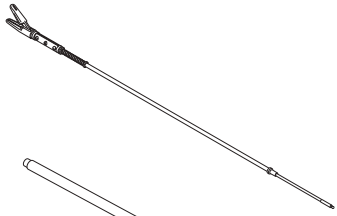
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

With replaceable blade:

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Order from your specialist dealer

▶ 723-020 ☒ 3

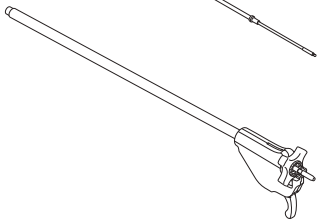


Jaw insert without replaceable blade

- 771-136 ☐ ....
- 771-120 ☐ ....

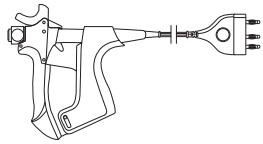
Jaw insert with replaceable blade

- 771-137 ☐ ....
- 771-121 ☐ ....



Shank tube

- 770-336 ☐ ....
- 770-320 ☐ ....

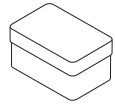


Handle with HF-cable

- 770-000 ☐ ....

Cleaning brush set

- 723-030 ☐ ....



Spare parts for handle

- 723-020 ☐ ....

Replaceable blades (set of 5)

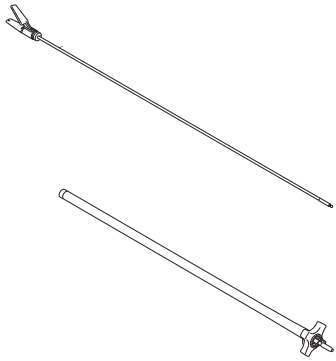
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000 + 770-236 + 723-020)

Order from your specialist dealer

▶ 723-020 ☒ 3

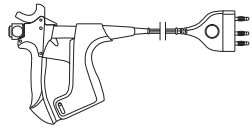


Jaw insert

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Shank tube

- 770-236 ☐ ....
- 770-211 ☐ ....

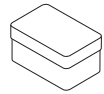


Handle with HF-cable

- 770-000 (new) ☐ ....

Cleaning brush set

- 723-000 ☐ ....



Spare parts for handle

- 723-020 ☐ ....

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BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

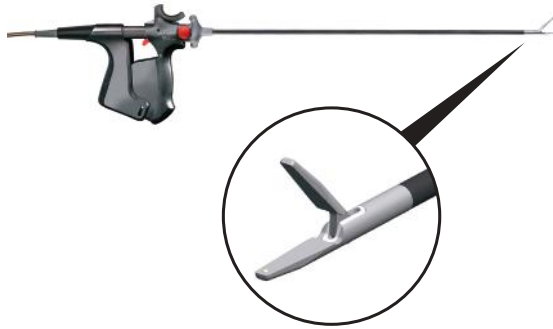
CE 0123

CE marked according to
Medical Device 93/42/EWG

Mode d´emploi

NightKNIFE®

LIGATOR®



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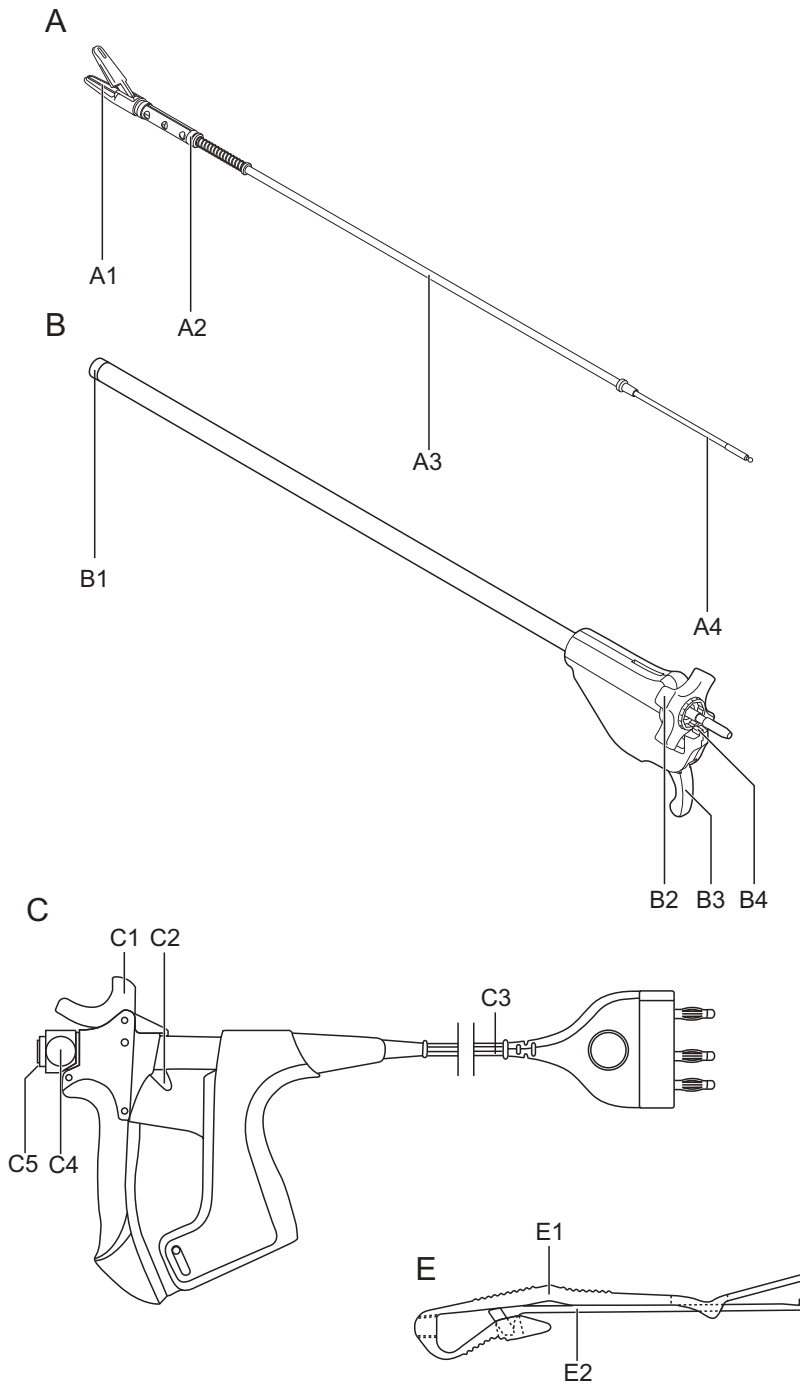
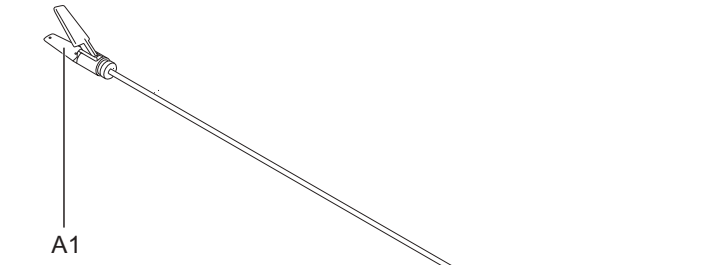
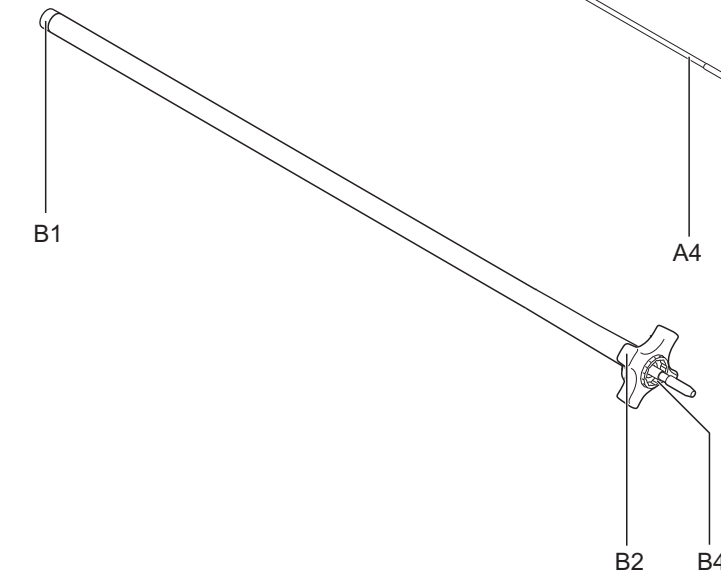

A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

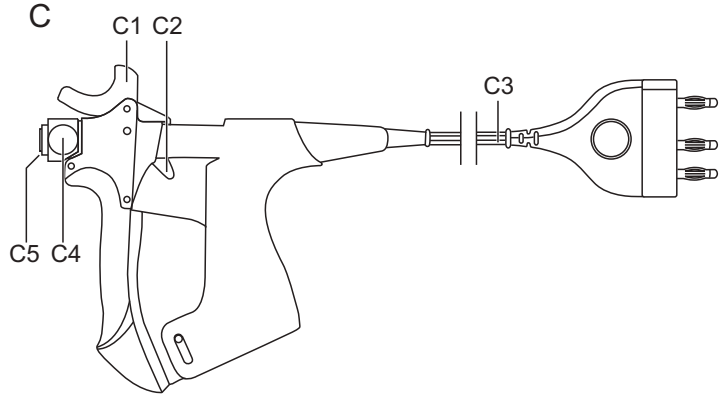
A



B



C



Légende

A	**Mâchoire (sur le NightKNIFE avec lame)**
A1	Mâchoire de pince avec électrode (1x stationnaire, 1x mobile)
A2	Bague d'étanchéité
A3	Tube de poussée
A4	Tige de traction
B	**Conduit**
B1	Douille filetée
B2	Roue-étoile
B3	Gâchette
B4	Ressort d'orientation
C	**Manche**
C1	Levier cranté
C2	Levier de verrouillage
C3	Câble HF
C4	Boutons-poussoirs
C5	Logement pour le conduit avec mâchoire de pince
E	**Lame avec aide à l'introduction**
E1	Aide à l'introduction
E2	Lame

Sommaire

1. Usage de ce mode d’emploi

Ce mode d’emploi fait partie intégrante du produit.

La société BOWA-electronic GmbH & Co. KG décline toute responsabilité et n’assume aucune garantie pour les dommages directs et indirects provoqués par le non-respect du mode d’emploi.

- Lisez attentivement le mode d'emploi, particulièrement le chapitre "sécurité" (voir chapitre 2, page 12 avant toute utilisation.
- Veuillez bien conserver le mode d’emploi pendant toute la durée de vie du produit.
- Veuillez garantir l’accès du personnel du bloc opératoire à ce mode d’emploi.
- Veuillez remettre le mode d’emploi au prochain propriétaire ou au prochain utilisateur du produit.
- Veuillez actualiser le mode d’emploi à chaque ajout effectué par le fabricant.

1.1. Validité

Ce mode d’emploi s'applique exclusivement aux produits désignés sur la page de couverture.

1.2. Symboles et marquages

1.2.1. Mise en évidence des avertissements

⚠ AVERTISSEMENT

Nature, origine et conséquences du danger (dégâts humains) !

▶ Mesure destinée à éviter le danger.

1.2.2. Gradation de danger des avertissements

Symbole	Degré du danger	Probabilité	Conséquences en cas de non-respect
	**DANGER**	Risque de danger imminent	Mort, dommage corporel grave
	**AVERTISSEMENT**	Risque de danger possible	Mort, dommage corporel grave
	**PRUDENCE**	Risque de danger possible	Dommage corporel minime
	**INDICATION**	Risque de danger possible	Dommages matériels

1.2.3. Conseils

Conseils destinés à vous faciliter le travail ou informations complémentaires servant à expliquer une étape de travail.

1.2.4. Autres symboles et marquages

Symbole/Caractérisation	Signification
☑	Condition posée pour effectuer une action
▶	Action à une étape
1. 2. 3.	Action en plusieurs étapes devant respecter une succession déterminée
↳	Résultat d'une action préalable
•	Énumération (premier niveau)
•	Énumération (second niveau)
Mise en valeur	Mise en valeur
..., voir chapitre xxx, page xxx	Renvoi

2. Sécurité

2.1. Conditions prévues d’utilisation

Les instruments de ligature servent au scellement vasculaire des artères et des veines ainsi que des structures tissulaires vascularisées dans le cas d'une utilisation laparoscopique et ouverte en gynécologie urologie, chirurgie générale et autres spécialités chirurgicales faisant appel à un courant HF et une pression mécanique.

Les instruments de ligature sont en outre appropriés pour la coagulation bipolaire classique.

Les instruments de ligature sont destinés au mode de fonctionnement bipolaire "Ligation".

Leur utilisation est liée aux programmes de ligature des générateurs ARC de BOWA.

L'instrument de ligature NightKNIFE sert en outre au sectionnement de tissus.

Toute autre utilisation est considérée comme étant contraire à la destination de l'instrument et doit être exclue !

Pour les articles COMFORT 770-000, le câble de raccordement est rigidement connecté à la manche.
Les générateurs dotés de Plug’n Cut COMFORT reconnaissent les instruments BOWA COMFORT et sélectionnent automatiquement les paramètres correspondants.

Pour les instruments de ligature bipolaires, l'utilisation d'une électrode neutre n'est pas nécessaire.

2.2. Consignes de sécurité générales

L'appareil HF ne doit être utilisé que par un personnel médical spécialisé et qualifié. Le chirurgien et le personnel médical spécialisé doivent impérativement avoir bénéficié d'une formation aux fondements, règles d'utilisation et risques de la chirurgie HF et en connaître les particularités.

- Avant toute utilisation des produits, prenez soins de lire attentivement le mode d'emploi !

Lors de l'utilisation des produits, tenez compte des points suivants dans le cadre de votre responsabilité pour la stérilité des instruments de ligature :

- Nettoyez et stérilisez l'instrument de ligature avant la première utilisation. L'instrument vous est livré non stérile.
- Nettoyez et stérilisez l'instrument de ligature avant chaque utilisation.
- Pour le nettoyage, la désinfection et la stérilisation, ne mettez en application que des méthodes suffisamment validées spécifiquement aux appareils et aux produits.
- Respectez les paramètres validés à chaque cycle.
- Conformez-vous à la législation en vigueur dans votre pays ainsi qu'aux directives d'hygiène de votre établissement hospitalier.

Un risque d'infection existe lors du nettoyage dans un bain à ultrasons et du pré-nettoyage manuel en raison des projections d'eau et des vapeurs :

- Portez un écran de protection du visage et des vêtements de protection.

Une aération suffisante de la salle est recommandée.

Risque de blessure de la lame tranchante :

- Lors du montage et du démontage, faites attention à la lame.
- Avant le nettoyage de la mâchoire de pince, démontez les lames remplaçables.
- Utilisez toujours l'aide à l'introduction pour le Montage et le démontage afin de prévenir les blessures par piqûres ou par coupe.

2.2.1. Appareil HF

- Utilisez exclusivement des appareils HF et des programmes homologués (voir chapitre 8, page 52).
- Respectez le mode d'emploi de l'appareil HF ainsi que les informations générales portant sur les interventions chirurgicales !

L'utilisation incorrecte de courant HF peut provoquer des brûlures endogènes et exogènes ainsi que des explosions :

- N'effectuez les interventions électrochirurgicales que sous insufflation de gaz non combustibles (CO_2).
- Évitez tout contact direct de la peau avec les câbles HF.
- Évitez tout contact avec des gaz et des liquides inflammables.

2.2.2. Câble HF

Tout maniement erroné du câble HF peut provoquer des blessures chez le patient.

- Ne posez jamais le câble HF sur la peau du patient.
- Raccordez l'instrument de ligature pour la coagulation et mettez en route le générateur HF.
- Pour brancher et débrancher le câble HF, ne le tenez que par le connecteur.

- Utilisez exclusivement des câbles HF en parfait état technique. Des câbles HF défectueux ne doivent en aucun cas être utilisés.

Le câble HF est susceptible de provoquer des perturbations de l'image au moniteur :

- Ne posez pas le câble HF à une position rapprochée et parallèle aux câbles de caméra.
- Ne posez pas le câble HF en boucles.

2.2.3. Électrodes actives

Des électrodes défectueuses ou usées peuvent provoquer des blessures chez le patient :

- N'utilisez et ne réparez jamais des éléments de mâchoires ou des surfaces d'électrodes usés ou défectueux. Éliminez ces composants.

Des surfaces d'électrodes chaudes peuvent provoquer des blessures chez le patient :

- Gardez une distance entre les pointes des instruments et les structures tissulaires sensibles (par exemple pancréas, intestin).
- Assurez-vous que vous n'utilisez pas d'instruments brûlants pour la préparation.

Une activation involontaire de l'instrument de ligature peut provoquer des blessures chez le patient :

- Ne déposez aucun instrument de ligature sur le patient.

Des électrodes sales peuvent provoquer un court-circuit et donc une défaillance fonctionnelle de l'instrument de ligature.

- Nettoyez régulièrement les électrodes des éléments de mâchoires de pince à l'aide d'un torchon humide.
- Remplacez la mâchoire de pince si les électrodes sont endommagées.

2.2.4. Lame remplaçable avec aide à l'introduction (seulement sur le NightKNIFE avec lame remplaçable)

Il n'est pas permis de remettre en état la lame remplaçable et l'aide à l'introduction :

- Éliminez ou remplacez les lames et les aides à l'introduction que vous avez utilisées.

2.2.5. Réparation/maintenance

Il n'est pas permis de réparer ou de faire la maintenance de produits défectueux :

- Éliminez ou remplacez tout produit défectueux.

2.3. Consignes de sécurité pour les personnes

Des réglages erronés du générateur HF et une visibilité restreinte peuvent provoquer des blessures chez le patient :

- Sélectionnez le générateur HF et le câble HF en fonction des exigences de l'instrument de ligature.
- N'effectuez les opérations que si la visibilité est suffisante.
- N'utilisez jamais les instruments de ligature en mode Autostart.

2.3.1. Patients porteurs de stimulateur cardiaque

Des fonctions incorrectes ou la destruction du stimulateur cardiaque peuvent entraîner la mort du patient ou des blessures irréversibles.

- N'effectuez jamais des interventions ambulantes chez des patients porteurs d'un stimulateur cardiaque.
- Pour les patients porteurs d'un stimulateur cardiaque, veuillez consulter le cardiologue avant d'avoir recours à la chirurgie HF.
- Réglez le stimulateur à la demande sur la fréquence fixe.
- Assurez-vous que le stimulateur cardiaque n'entre pas en contact avec l'électrode HF.
- Gardez à portée de la main un défibrillateur opérationnel.
- Effectuez un contrôle post-opératoire du stimulateur cardiaque.

3. Fonctionnement

Dans le cas de la chirurgie bipolaire HF, la coagulation du tissu s'effectue par application d'un courant alternatif à haute fréquence, qui génère de la chaleur.

Les instruments de ligature NightKNIFE et LIGATOR sont des instruments chirurgicaux-invasifs destinés à une utilisation laparoscopique et ouverte. Ils s'utilisent en combinaison avec des produits utilisables en endoscopie (par exemple trocarts et optiques) à travers des ouvertures créées par voie chirurgicale.

Les électrodes actives (branches) sont les parties non isolées de l'élément de mâchoire.

Le courant HF circule depuis une branche de l'instrument via le tissu biologique vers la seconde branche et réalise l'effet de coagulation limité localement.

Dans ce procédé, le courant HF, combiné à une pression d'application, permet d'obtenir le scellement d'un vaisseau/d'un segment tissulaire parcouru par du sang.

La zone de scellement est hémostatiquement hermétique par rapport à la pression sanguine systolique et durablement scellée.

Dans le cas du NightKNIFE, grâce à la fonction de sectionnement intégrée, il est possible de sectionner le tissu à traiter immédiatement après le scellement, sans changement préalable de l'instrument.

Par actionnement du manche, il est possible d'ouvrir et de fermer les éléments de mâchoires à la mâchoire et de les bloquer.

La mâchoire de pince peut être tournée et bloquée via la roue-étoile au conduit (8x45°).

4. Montage

⚠ AVERTISSEMENT

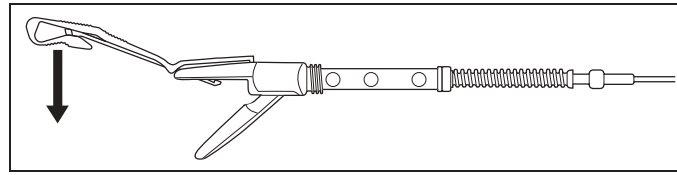
Risque de blessure pour le patient par un instrument de ligature non stérile !

▶ Nettoyez et stérilisez l'instrument de ligature avant l'utilisation, car il vous est livré à l'état non stérile.

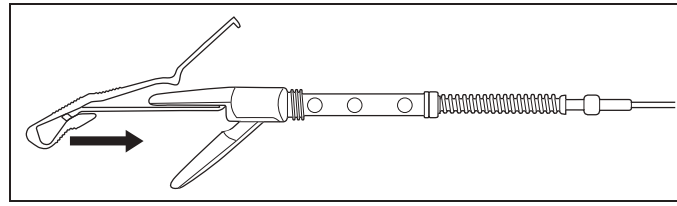
4.1. Monter la lame avec l'aide à l'introduction (seulement sur le NightKNIFE avec lame remplaçable)

☑ La lame avec l'aide à l'introduction est nettoyée et désinfectée (voir chapitre 7.5, page 42).

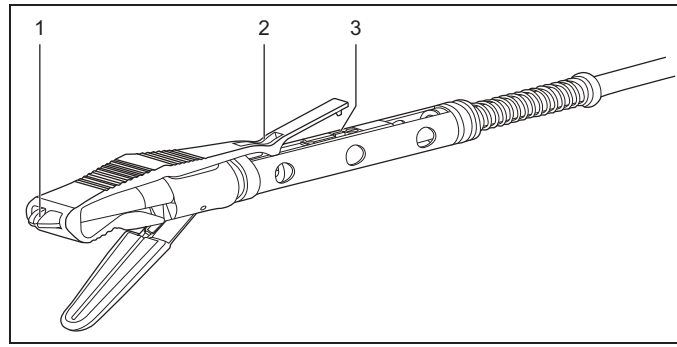
1. Sortez la lame avec aide l'introduction **E** de son emballage stérile.



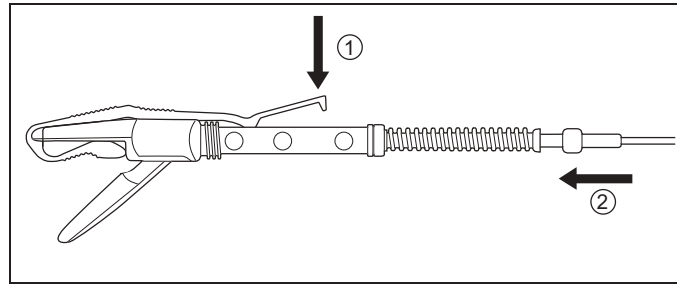
2. Tournez la mâchoire **A** avec l'élément de mâchoire stationnaire **A1** vers le haut pour ouvrir les éléments de mâchoires.
3. Poussez l'élément de mâchoire stationnaire **A1** entre la lame **E2** et l'aide à l'introduction **E1** et appuyez l'aide à l'introduction **E1** dans le sens de la flèche, vers le bas, pour desserrer la lame.



4. Sur l'élément de mâchoire stationnaire **A1,** poussez la lame à fond au moyen de l'aide à l'introduction **E** dans le sens de la flèche.

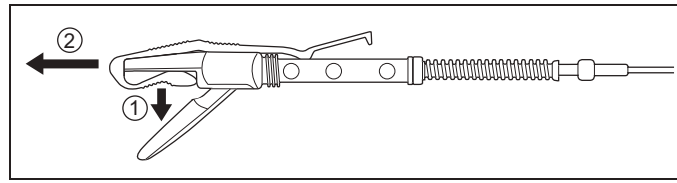


5. Assurez-vous que la lame avec l'aide à l'introduction **E** est bien positionnée au centre aux positions marquées.
6. Le cas échéant, positionnez l'aide à l'introduction **E1** au milieu à l'aide des doigts.



7. Tenez fermement l'aide à l'introduction **E1** et poussez cette dernière légèrement dans le sens de la flèche, vers le bas **1**.
8. Poussez le tube de poussée **A3** dans le sens de la flèche **2** jusqu'à ce que vous entendiez, sentiez et voyiez la lame **E2** s'enclencher.

↳ Le ressort reste à l'état comprimé.



9. Tirez la partie courte de l'aide à l'introduction **E1** vers le bas **1** pour rappeler la lame à sa position initiale.
10. Enlevez l'aide à l'introduction **E1** dans le sens de la flèche **2** depuis l'élément de mâchoire stationnaire.

▶ Conservez l'aide à l'introduction. Elle vous servira pour le démontage de la lame.

4.2. Assembler l'instrument de ligature

1. Vissez totalement la mâchoire **A** dans le conduit **B**.
2. Assurez-vous qu'il n'existe aucune fente entre la mâchoire **A** et le conduit **B**.
3. Fermez les éléments de mâchoire **A1** avec les doigts et introduisez le conduit **B** dans le manche **C** :
   - Pour le NightKNIFE : Faites attention à ce que le ressort d'orientation **B4** et la rainure d'orientation **C5** soient orientés dans le même sens.
   - Faites enclencher le conduit **B** dans le manche **C**.
4. Contrôler la fonction de prise de l'instrument de ligature en actionnant le manche **C**.
5. À l'aide du levier cranté **C1**, ouvrez les éléments de mâchoire **A1**.
6. Pour le NightKNIFE : Contrôler la douceur de fonctionnement et la position de base de la lame en actionnant la gâchette **B3**.
7. Vérifiez s'il est possible de tourner la roue-étoile **B2**.

5. Manipulation

5.1. Avant l'utilisation

☑ L'instrument de ligature est monté (voir chapitre 4, page 19) et conditionné (voir chapitre 7, page 32).

⚠ AVERTISSEMENT

Risque de blessure du patient !

- ▶ Utilisez exclusivement des générateurs ARC BOWA homologués avec fonction de ligature (voir chapitre 8, page 52).
- ▶ Utilisez exclusivement des produits et accessoires appropriés selon la vue d'ensemble du système.
- ▶ Utilisez exclusivement des produits en parfait état et stérilisés.

⚠ AVERTISSEMENT

Risque de blessure pour le patient par des brûlures et des explosions des liquides et gaz inflammables !

- ▶ N'effectuez les interventions électrochirurgicales que sous insufflation de gaz non combustibles (CO_2).
- ▶ Évitez le contact avec les gaz et les liquides inflammables (par exemple les agents de nettoyage corporels et de désinfection et les gaz anesthésiques).

1. Raccordez le câble HF **C3** à l'appareil HF et mettre en marche l'appareil HF.
2. Réglez la puissance de sortie de l'appareil HF.
3. Avant chaque utilisation de l'instrument de ligature, procédez à un contrôle visuel et fonctionnel minutieux (voir chapitre 7.6, page 45).

Les éléments de mâchoire sont ouverts à la position de base **A1**.

4. À l'aide du manche **C**, fermez les éléments de mâchoire **A1**.
5. Introduisez la mâchoire **A** dans la douille de trocart.

5.2. Pendant l'intervention

⚠ AVERTISSEMENT

Risque de blessure pour le patient en raison d'un réglage erroné de l'appareil et d'une visibilité restreinte !

- ▶ Réglez la puissance de sortie de l'appareil HF à la valeur nécessaire pour l'intervention.
- ▶ Utilisez exclusivement des programmes homologués (voir chapitre 8, page 52).
- ▶ N'effectuez les opérations que si la visibilité est suffisante.

⚠ AVERTISSEMENT

Risque de blessure pour le patient aux surfaces d'électrodes brûlantes et en raison du dégagement de vapeur !

- ▶ Gardez une distance entre les pointes de l'appareil et les structures tissulaires sensibles (par exemple pancréas, intestin).
- ▶ Assurez-vous que vous n'utilisez pas d'instruments de ligature brûlants pour la préparation.
- ▶ Ne déposez aucun instrument de ligature sur le patient.

- ▶ Introduisez l'instrument de ligature dans le corps toujours sous contrôle visuel.

Saisir le tissu, le coincer, le sceller

⚠ AVERTISSEMENT

Risque de blessure pour le patient en cas d'activation involontaire de l'instrument de ligature !

- ▶ N'utilisez jamais la fonction AUTOSTART.
- ▶ N'activez le courant HF qu'une fois que les électrodes actives sont en contact avec le tissu devant être coagulé.

1. Positionnez la mâchoire **A** au site opératoire.

La mâchoire **A** est rotative et peut être bloquée à des angles de 45°.

2. Tournez la roue-étoile **B2** pour régler l'angle de la mâchoire **A**.
3. Placez le tissu à sceller entre les électrodes de la mâchoire **A1**.
4. Fermez les éléments de mâchoire **A1** pour saisir le tissu.

↳ Le tissu est saisi.

5. Utilisez la crémaillère à 3 positions du manche **C** pour parfaitement adapter la pression exercée sur le tissu en fonction de la quantité de tissu saisie.

↳ Le tissu est coincé.

6. Activez le courant HF pour la coagulation en utilisant l'interrupteur à pied de l'appareil HF :
   - Une tonalité continue vous signale alors l'injection d'énergie sur toute la durée du scellement.
   - Une tonalité alternative signale la fin du scellement.
7. Relâchez l'interrupteur à pied pour arrêter l'injection d'énergie.
8. À l'aide du levier cranté **C1**, ouvrez les éléments de mâchoire **A1**.

↳ Le tissu est coagulé.

Sectionner le tissu (seulement avec le NightKNIFE)

⚠ AVERTISSEMENT

Fortes hémorragies suite au sectionnement du tissu saisi sans coagulation ou ligature préalable !

- ▶ Pour les vaisseaux, appliquez au moins deux scellements, à gauche et à droite du point de sectionnement.
- ▶ Assurez-vous que le tissu est bien scellé avant l'opération de sectionnement.
- ▶ N'effectuez le sectionnement que dans la zone scellée.

☑ Le tissu est saisi par les éléments de mâchoire et se coagule.

1. Pour effectuer le sectionnement, actionnez la gâchette **B3** et relâchez-la.

↳ Le tissu est sectionné.

2. À l'aide du levier cranté **C1**, ouvrez les éléments de mâchoire **A1**.

Modifier la puissance de sortie de l'appareil HF

▶ Avant d'augmenter la puissance de sortie de l'appareil HF, contrôlez :

- que le contact de tous les câbles HF et connecteurs est correct,
- si l'instrument de ligature est correctement raccordé (voir le mode d'emploi de l'appareil HF),
- le bon fonctionnement de l'interrupteur à pied,
- l'isolation du câble HF **C3**, des éléments de mâchoire **A1**, du conduit **B** et de la douille de trocart,
- l'état de propreté et d'usure des électrodes actives aux éléments de mâchoire **A1**.

5.3. Retrait

⚠ AVERTISSEMENT

Risque de blessure pour le patient par des pièces brisées ou endommagées !

▶ Contrôlez la mâchoire après chaque utilisation. Tous les composants doivent être en place.

1. Fermez les éléments de mâchoire **A1**.
2. Retirer l'instrument de ligature de la douille de trocart.

5.4. Après l'utilisation

⚠ AVERTISSEMENT

Des électrodes sales peuvent provoquer une défaillance fonctionnelle de l'instrument de ligature !

- Nettoyez régulièrement les électrodes des éléments de mâchoires de pince **A1** à l'aide d'un torchon humide.
- Remplacez la mâchoire **A** de pince si les électrodes sont endommagées.
- Pour le NightKNIFE avec lame remplaçable : remplacez la lame **E2** après chaque intervention.

1. Remettez en état l'instrument de ligature après l'utilisation (voir chapitre 7, page 32).

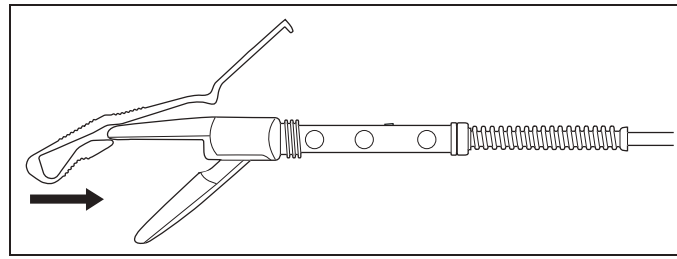
6. Démontage

6.1. Démonter l'instrument de ligature

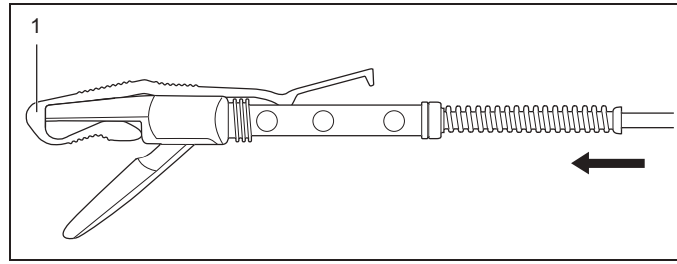
1. Au manche **C,** tenez enfoncés les boutons-poussoirs **C4** et le levier de blocage **C2** et retirez le manche **C** du conduit **B**.
2. Dévissez la mâchoire **A** du conduit **B**.
3. Pour le NightKNIFE avec lame remplaçable : démonter la lame avec l'aide à l'introduction **E** (voir chapitre 6.2, page 29).

6.2. Démonter la lame avec l'aide à l'introduction (seulement sur le NightKNIFE avec lame remplaçable)

1. Tournez la mâchoire **A** avec l'élément de mâchoire stationnaire **A1** vers le haut pour ouvrir les éléments de mâchoires.

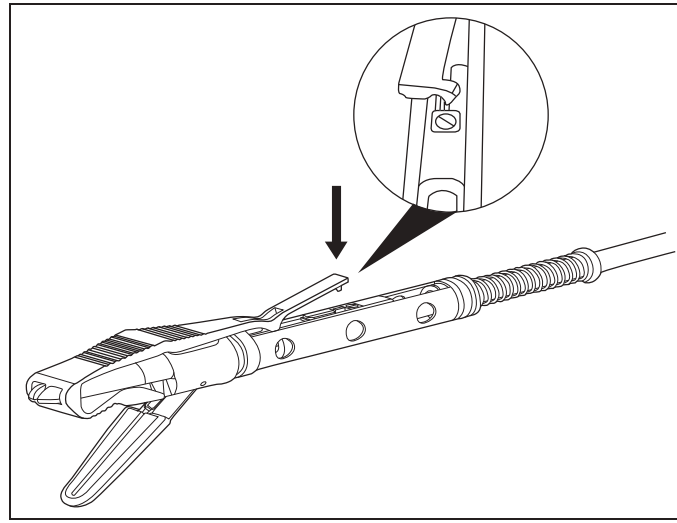


2. Tenez fermement l'aide à l'introduction **E1** sur le côté et poussez l'aide à l'introduction **E1** sur l'élément de mâchoire stationnaire **A1** à fond dans le sens de la flèche.



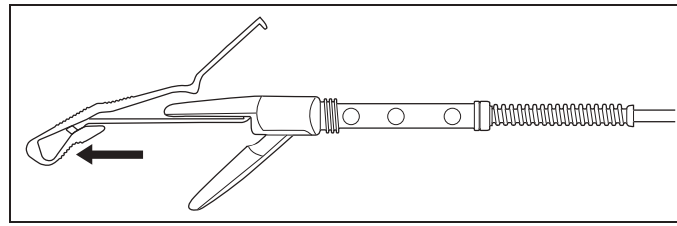
3. Assurez-vous que la lame avec l'aide à l'introduction **E** est positionnée au milieu de l'élément de mâchoire **A1** à la position **1**.
4. Le cas échéant, positionnez l'aide à l'introduction **E1** au milieu à l'aide des doigts.
5. Tenez fermement, sur le côté, l'aide à l'introduction **E1** à la position **1** et poussez le tube de poussée lentement dans le sens de la flèche, jusqu'à ce vous sentiez la lame **E2** s'enclencher.

↳ Lorsque la lame est coincée, le ressort reste à l'état comprimé.



6. À l'aide de la clavette à l'aide à l'introduction **E1**, débloquer la lame **E2** de son enclenchement.

↳ Le ressort se détend et le tube de poussée recule.



7. Retirez l'aide à l'introduction avec la lame **E** dans le sens de la flèche et éliminez la lame avec l'aide à l'introduction **E**.

La remise à neuf de la lame et de l'aide à l'introduction n'est pas permise.

7. Préparation

Les instruments de ligature ne doivent en aucun cas être utilisés sans nettoyage, désinfection et stérilisation préalables. Un nettoyage et une désinfection efficaces sont la condition préalable pour une stérilisation effective des instruments de ligature.

1. Notez que pour le nettoyage, la désinfection et la stérilisation, vous ne devez utiliser que des méthodes suffisamment validées spécifiquement aux appareils et aux produits et que les paramètres validés doivent être respectés à chaque cycle.
2. Conformez-vous à la législation en vigueur dans votre pays et aux directives d'hygiène de votre établissement hospitalier/clinique.

Les indications suivantes sur le nombre possible de cycles de remise à neuf ne sont que des valeurs indicatives. Le nombre peut varier selon la sollicitation.

Le nombre de cycles de remise à neuf des différents composants de l'instrument s'élève aux chiffres suivants pour une durée de stérilisation de 20 minutes et une température de stérilisation de 134 °C :

- mâchoire de pince **A** : 20 fois,
- conduit **B** : 200 fois max,
- manche **C** : 100 fois max.

La remise à neuf de l'instrument de ligature comprend les étapes suivantes :

- Trempage
- Démontage
- Prétraitement dans un bain à ultrasons
- Élimination manuelle des saletés
- Remise à neuf mécanique dans l'appareil de nettoyage et de désinfection
- Contrôle
- Emballage
- Autoclavage
- Stockage
- Essai fonctionnel en salle opératoire

7.1. Trempage

⚠ PRUDENCE

Risque d'infection en raison de projections d'eau et de vapeurs depuis le bain à ultrasons et lors du pré-nettoyage manuel !

- ▶ Portez un écran de protection du visage et des vêtements de protection.
- ▶ Une aération suffisante de la salle est recommandée.

⚠ PRUDENCE

Pour le NightKNIFE : risque de blessure à la lame tranchante :

- ▶ Lors du nettoyage, faites attention à la lame.
- ▶ Pour le NightKNIFE avec lame remplaçable : avant le nettoyage, démonter la lame de la mâchoire de pince.

INDICATION

Dégâts matériels à la mâchoire de pince par l'agent à récurer !

- Ne nettoyez jamais la mâchoire de pince au moyen d'agents à récurer.

- Si cela est nécessaire, commencer le nettoyage en éliminant les dépôts de saletés au moyen d'une toison.
- Trempez immédiatement l'instrument de ligature, au plus tard 2 heures après l'utilisation.
- Utilisez exclusivement des désinfectants exempts d'aldéhyde (par exemple avec homologation DGHM, FDA ou marquage CE).

Le désinfectant utilisé pour le trempage sert exclusivement à la protection des personnes et ne remplace pas les étapes de désinfection ultérieures.

7.2. Démontage

1. Démontez l'instrument de ligature (voir chapitre 6.1, page 29).
2. Pour le NightKNIFE avec lame remplaçable : Démonter la lame de l'instrument de ligature et éliminez la lame (voir chapitre 6.2, page 29).

7.3. Prétraitement dans un bain à ultrasons

⚠ PRUDENCE

Risque d'infection par les projections d'eau et les vapeurs provenant du bain à ultrasons !

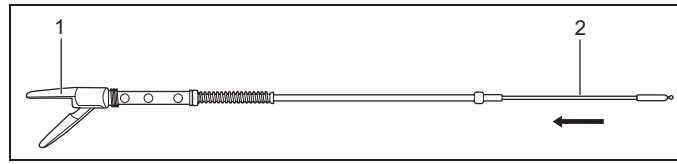
- ▶ Portez un écran de protection du visage et des vêtements de protection.
- ▶ Une aération suffisante de la salle est recommandée.

1. Immergez la mâchoire de pince **A**, le conduit **B** et le manche **C** dans un bain à ultrasons pendant au moins 5 minutes. Positionnez les composants d'instrument à grande surface dans le bain à ultrasons de telle manière qu'il ne se forme pas d'ombres acoustiques .
2. Pour le nettoyage aux ultrasons, utilisez des agents de nettoyage et de désinfection appropriés (voir chapitre 7.4, page 36).
3. Respectez les concentrations et durées d'action indiquées par le fabricant de l'agent de nettoyage et de désinfection.

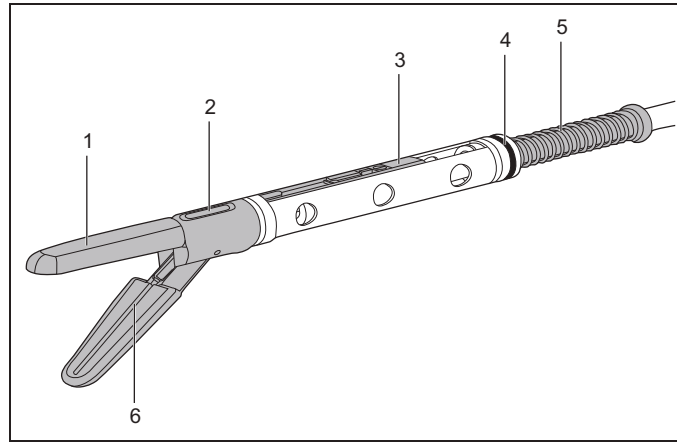
7.4. Élimination manuelle des saletés

Dans ce chapitre, l'exemple présenté sera celui de l'instrument de ligature NightKNIFE.

Mâchoire de pince



1. poussez la tige de traction **2** dans le sens de la flèche pour ouvrir les éléments de mâchoire **1**.



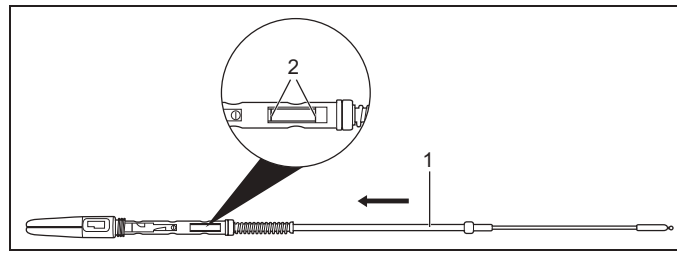
INDICATION

Dégâts matériels à la mâchoire par une brosse métallique !

▶ Utilisez exclusivement une brosse en matière plastique pour le nettoyage de la mâchoire.

2. Éliminez les saletés existant aux zones marquées en gris à l'aide d'une brosse en matière plastique ou d'un nettoyeur à vapeur :
   - Éléments de mâchoire **1** : surfaces extérieures en haut et en bas, surfaces d'électrodes
   - Articulation **2** : ouvertures en haut et en bas
   - Pour le NightKNIFE : mécanisme à encliquetage **3**
   - Pour le NightKNIFE : ressort **5**
3. Pour le NightKNIFE : nettoyez les arêtes intérieures des deux rainures en utilisant un objet pointu **6**.

4. Pour le NightKNIFE : Éliminez les saletés existant sous la bague d'étanchéité **4** en utilisant un objet pointu. Faites attention de ne pas endommager la bague d'étanchéité.



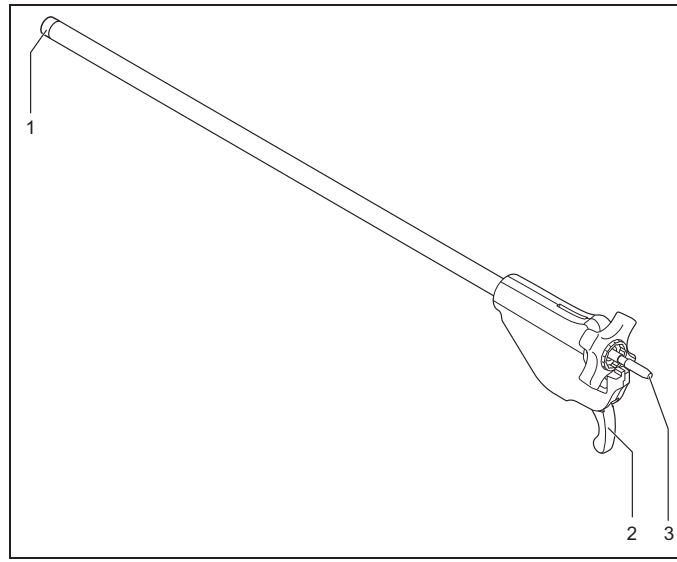
5. Poussez le tube de poussée **1** dans le sens de la flèche et nettoyez les surfaces d'appui dégagées **2** en utilisant un nettoyeur à vapeur.

Conduit

INDICATION

Dégâts matériels au conduit par une brosse métallique !

- ▶ Nettoyez le conduit seulement avec les brosses en matière plastique fournies.
- ▶ Utilisez au besoin un nettoyeur à vapeur pour le nettoyage.



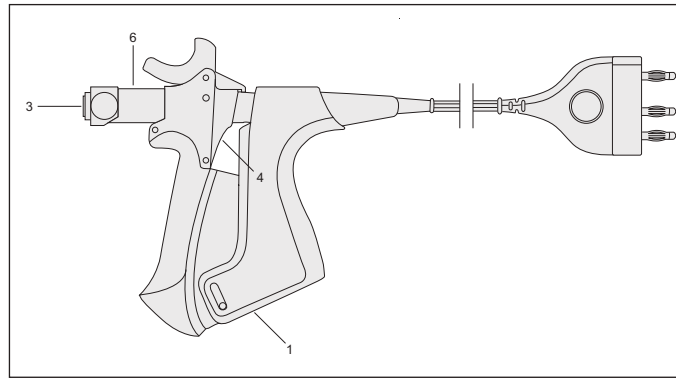
1. Nettoyez le conduit en utilisant la petite brosse de nettoyage à l'extrémité proximale **3**, par l'intérieur.
2. Nettoyez le conduit en utilisant la grande brosse de nettoyage à l'extrémité distale **1**, par l'intérieur.
3. Rincez le conduit **B** à l'extrémité distale en utilisant de l'eau entièrement déminéralisée ou distillée afin de nettoyage l'intérieur du boîtier. Ce faisant, actionnez la gâchette 2 pour nettoyer le mécanisme d'actionnement dans le boitier.

Manche

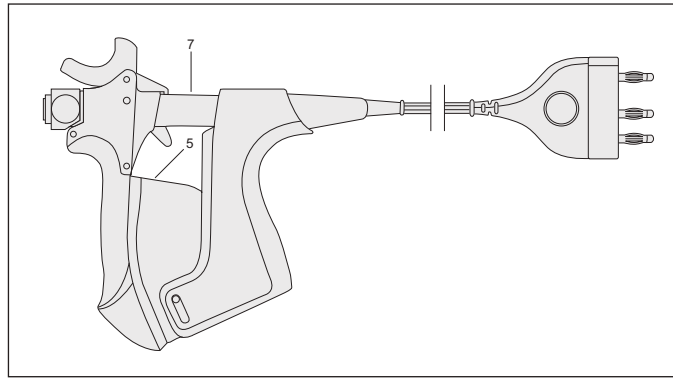
INDICATION

Dégâts matériels au manche par une brosse métallique !

- ▶ Nettoyez le manche en utilisant les brosses en matière plastique fournies.
- ▶ Utilisez au besoin un nettoyeur à vapeur pour le nettoyage.



1. Actionnez le manche jusqu'à ce qu'il s'enclenche et nettoyez les rails de guidage **6** avec la brosse de nettoyage.
2. Avec la brosse de nettoyage, nettoyez par l'intérieur toutes les positions marquées du manche.



3. Débloquer l'enclenchement au manche.
4. Avec la brosse de nettoyage, nettoyez les dents d'arrêt et les rails de guidage 7 dans la partie arrière du manche.
5. Avec la brosse de nettoyage, nettoyez par l'intérieur la position marquée **5** du manche.

Rincer

▶ Après le pré-nettoyage, rincer abondamment tous les composants de l'instrument en utilisant de l'eau entièrement déminéralisée ou distillée.

7.5. Remise à neuf mécanique dans l'appareil de nettoyage et de désinfection

Procédés de nettoyage et de désinfection appropriés

▶ Pour le nettoyage et la désinfection de l'instrument de ligature, utilisez un appareil de nettoyage et de désinfection.

Un nettoyage manuel est déconseillé en raison de son efficacité nettement plus basse.

▶ Pour le choix de l'appareil de nettoyage et de désinfection, veillez à ce que :

- l'appareil offre une efficacité certifiée (par exemple homologation DGHM, FDA ou marquage CE selon DIN EN ISO 15883).
- la désinfection utilise un programme certifié pour la désinfection thermique (5 minutes au moins à 90 °C ou valeur A_0 > 3000). La désinfection chimique présente le risque de dépôts de désinfectant sur les composants de l'instrument.
- la désinfection utilise un choix de programme adapté à l'instrument, avec un nombre de cycles de nettoyage suffisant.
- soit utilisée une eau stérile/à faible teneur en germes (10 germes/ml max.) et à faible teneur en endotoxine (0,25 unité d'endotoxine/ml) pour rinçage ultérieur.
- l'air de séchage soit filtré.
- l'appareil de nettoyage et de désinfection soit soumis à une maintenance et à des essais réguliers.

Agent de nettoyage approprié

▶ Pour le choix du système d'agent de nettoyage, veillez à ce que :

- l'agent de nettoyage soit approprié à l'instrument de ligature.
- si la désinfection n'est pas thermique, soit utilisé un agent de désinfection approprié supplémentaire présentant une efficacité certifiée (par exemple homologation DGHM ou FDA ou marquage CE), qui est compatible avec les agents de nettoyage.
- les substances chimiques utilisées soient compatibles avec les composants de l'instrument (voir chapitre 7.4, page 36).

▶ Respectez les concentrations et durées d'action indiquées par le fabricant de l'agent de nettoyage et de désinfection.

Nettoyer et désinfecter

INDICATION

Dommages au câble HF par un entreposage incorrect dans l'appareil de nettoyage et de désinfection !

▶ Veiller à ne pas plier ou écraser le câble HF.

1. Placez les composants de l'instrument dans l'appareil de nettoyage et de désinfection. Tenez compte de ce qui suit :
   - Positionnez les composants de l'instrument de telle manière qu'il ne forme pas de zones d'ombre.
   - Introduisez le conduit et la mâchoire de pince dans la douille de rinçage par l'extrémité distale

- Introduisez la tige de traction dans la mâchoire de pince pour ouvrir autant que possible les éléments de mâchoire dans la douille de rinçage.
- Nettoyer le manche à l'état enclenché.
- Positionnez le câble HF séparément dans un panier avec couvercle.

2. Pour le NightKNIFE avec lame remplaçable : Sortez une nouvelle lame avec aide à l'introduction de l'emballage et placez la lame avec aide à l'introduction dans un panier avec couvercle.
3. Démarrer le programme.
4. Sortez les composants de l'instrument de l'appareil de nettoyage et de désinfection après la fin du programme.

INDICATION

Dommages au manche par l'air comprimé !

▶ Utilisez de l'air comprimé à une pression maximale de 3 bars pour sécher le manche.

5. Utilisez de l'air comprimé filtré pour sécher les composants de l'instrument.

7.6. Contrôle

Ces produits sont soumis à l'usure dans le cas d'une utilisation conforme à la destination et selon l'intensité de l'utilisation. Cette usure à des causes techniques et elle est inévitable.

Ce produit doit être remplacé s'il fait apparaitre des défauts apparents ou s'il ne fonctionne pas de la manière décrite dans le présent mode d'emploi. Dans ce cas, informez-en le fabricant ou ses représentants compétents.

- ▶ Après le nettoyage, procédez à un contrôle visuel et fonctionnel des différents composants de l'instrument.
- ▶ Remplacez tout composant défectueux.

7.6.1. Contrôle pour le NightKNIFE

⚠ DANGER

Risque de brûlure pour le patient dans le cas d'une isolation fragile ou défectueuse !

- ▶ Remplacez les composants de l'instrument si l'isolation est endommagée.

Mâchoire de pince

1. Pour le NightKNIFE avec lame remplaçable : Montez une nouvelle lame **E2**, voir chapitre **4.1**, page 19.
2. Contrôlez que les éléments de mâchoire **A1** exécutent correctement les fonctions Ouvrir/Fermer.
3. Contrôler visuellement la présence éventuelle de dommages aux billes de la tige de traction **A4**.
4. Bougez le tube de poussée **A3** dans la mâchoire **A** pour contrôler la douceur de marche et la position de base de la lame **E2**.
5. Contrôler la présence éventuelle de dommages à la lame **E2**.

6. Contrôlez la présence éventuelle de dommage à l'isolation de la tige de traction **A4**.
7. Contrôlez la présence éventuelle de dommages au revêtement de la mâchoire **A**.
8. Contrôlez la présence éventuelle de dommages à la bague d'étanchéité **A2**.
9. Contrôlez si la tige de traction **A4** et le conduit **A3** sont déformés.

Conduit

1. Contrôler la présence éventuelle de dommages sur l'isolation.
2. Contrôlez si le conduit est déformé.
3. Vérifiez s'il est possible de tourner facilement la roue-étoile **B2**.
4. Vérifiez que la gâchette **B3** fonctionne

Manche

1. Contrôlez la douceur de marche du levier cranté **C1**, du levier de blocage **C2** et des boutons-poussoirs **C4**.

Câble HF

1. Contrôlez la présence éventuelle de dommages et de corrosion sur le raccord.
2. Contrôler la présence éventuelle de dommages sur l'isolation.

7.6.2. Contrôle pour le LIGATOR

⚠ DANGER

Risque de brûlure pour le patient dans le cas d'une isolation fragile ou défectueuse !

▶ Remplacez les composants de l'instrument si l'isolation est endommagée.

Mâchoire de pince

1. Contrôlez que les éléments de mâchoire **A1** exécutent correctement les fonctions Ouvrir/Fermer.
2. Contrôler la présence éventuelle de dommages aux billes de la tige de traction **A4**.
3. Contrôlez la présence éventuelle de dommage à l'isolation de la tige de traction **A4**.
4. Contrôlez si la tige de traction **A4** est déformée.

Conduit

1. Contrôler la présence éventuelle de dommages sur l'isolation.
2. Contrôlez si le conduit **B** est déformé.

Manche

1. Contrôlez la douceur de marche du levier cranté **C1**, du levier de blocage **C2** et des boutons-poussoirs **C4**.

Câble HF

1. Contrôlez la présence éventuelle de dommages et de corrosion sur le raccord.
2. Contrôler la présence éventuelle de dommages sur l'isolation.

7.7. Emballage

L'emballage doit répondre aux exigences suivantes :

- DIN EN (ANSI AAMI) ISO 11607/
  DIN EN 868-2...10 (précédemment DIN EN 868/
  ANSI AAMI ISO 11607)
- adaptée à la stérilisation à la vapeur
  (constance thermique jusqu'à 137 °C, perméabilité à la vapeur suffisante)
- soumis à une maintenance régulière (enceinte de stérilisation)

▶ Emballez l'instrument de ligature dans un emballage de stérilisation à usage unique et/ou une enceinte de stérilisation appropriée.

La stérilisation n'est pas autorisée dans l'emballage de transport.

7.8. Autoclavage

▶ Stérilisez l'instrument de ligature seulement à l'état démonté.

INDICATION

Destruction de l'instrument de ligature par les procédés de stérilisation à l'air chaud !

▶ Veillez à un procédé de stérilisation approprié.

Pour la stérilisation, utilisez exclusivement la stérilisation à la vapeur avec les spécifications suivantes :

- Procédé par vide fractionné (avec séchage suffisant du produit)
- répond à la norme DIN EN 13060 ou DIN EN 285
- Validation selon DIN EN ISO/ ANSI AAMI ISO 17665 (précédemment DIN EN 554/ ANSI AAMI ISO 11134) (IQ/OQ (préparation des commandes) et qualification des performances spécifique au produit (PQ) valables)
- température de stérilisation max. 134 °C (plus la tolérance selon DIN EN ISO/ ANSI AAMI ISO 17665 (précédemment DIN EN 554/ ANSI AAMI ISO 11134))
- Durée de stérilisation minimale 20 minutes à 121 °C ou 5 minutes à 132/134 °C.

L'utilisation du procédé à déplacement de gravitation, moins efficace, doit être assurée par une validation supplémentaire (le cas échéant, des durées de stérilisation plus longues seront nécessaires).

L'utilisation d'autres procédés de stérilisation (par exemple stérilisation à l'oxyde d'éthylène et au formaldéhyde, la radiostérilisation et la stérilisation au plasma à basse température) s'effectue hors du domaine de responsabilité du fabricant.

1. En cas d'utilisation, notez ce qui suit :
   - DIN EN ISO 14937/ANSI AAMI ISO 14937,
   - Normes spécifiques aux procédés.
2. Prouvez l'adéquation et l'efficacité du procédé en tant compte de la géométrie spécifique du produit dans le cadre de la validation (le cas échéant, y compris l'analyse des dépôts de l'agent de stérilisation).

7.9. Stockage

1. Stockez l'instrument de ligature à un endroit où il est protégé contre :
   - les effets mécaniques forts tels que les chocs, la chute ou les coups,
   - le rayonnement solaire direct,
   - les rayons X.
2. Stockez l'instrument de ligature à un endroit sec, à la température ambiante.

La durée de stockage de l'instrument de ligature stérilisé dépend du type d'emballage et des conditions de stockage.

Le carton d'expédition n'est pas prévu pour la conservation du produit.

7.10. Essai fonctionnel en salle opératoire

1. Assemblez l'instrument de ligature (voir chapitre 4, page 19).
2. Contrôlez les fonctions de l'instrument de ligature (voir chapitre 7.6, page 45).

7.11. Ressources de service recommandées

BOWA recommande d'utiliser des agents de nettoyage légers à légèrement alcalins ou des agents de nettoyage et de désinfection ne contenant pas de composants critiques. Les composants alcooliques et/ou aldéhydiques sont autorisés selon leur concentration.

Prétraitement dans un bain à ultrasons

L'aptitude des instruments de ligature pour un prétraitement efficace dans un bain à ultrasons (5 min) a été prouvée par BOWA à l'aide d'un agent de nettoyage et de désinfection combiné exempt d'aldéhyde (Gigasept Instru AF).

Nettoyage mécanique

L'aptitude des instruments de ligature pour un nettoyage/une désinfection efficace par le procédé mécanique (90 °C, 5 min) a été prouvée par BOWA au moyen d'un agent de nettoyage alcalin contenant des additifs d'agents tensioactifs (neodisher MediClean forte).

L'utilisation d'autres agents de nettoyage et de désinfection s'effectue hors de la responsabilité du fabricant.

8. Données techniques

8.1. NightKNIFE et LIGATOR

Données techniques	
Courant HF	4 A
Tension alternative	> 330 kHz
Tension max.	200 Vp sinusoïdale
Appareil HF homologué	Générateurs de la série ARC de BOWA avec logiciel LIGATION
Logiciels homologués	Pour le BOWA ARC 350L (900-350): LIGATION à partir de la version de logiciel V2.6 Effet 2 jusqu'à effet 4

9. Mise au rebut

L'élimination des produits médicaux, du matériel d'emballage ainsi que des accessoires doit être effectuées conformément à la législation et aux règlements spécifiques en vigueur dans le pays d'utilisation.

10. Vue d'ensemble du système

10.1. NightKNIFE

Sans lame remplaçable :

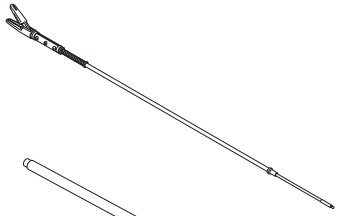
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

Avec lame remplaçable :

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Commande auprès d'un distributeur spécialisé

▶ 723-020 ☒ 3

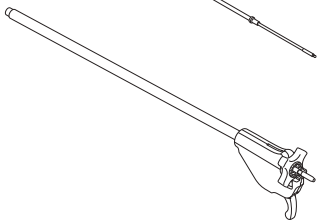


Mâchoire de pince sans lame remplaçable

- 771-136 ☐ ....
- 771-120 ☐ ....

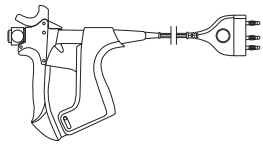
Mâchoire de pince avec lame remplaçable

- 771-137 ☐ ....
- 771-121 ☐ ....



Conduit

- 770-336 ☐ ....
- 770-320 ☐ ....

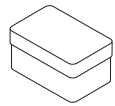


Manche avec câble HF

- 770-000 ☐ ....

Lot de brosses de nettoyage

- 723-030 ☐ ....



Pièces de rechange de manche

- 723-020 ☐ ....

Lame remplaçable (lot de 5)

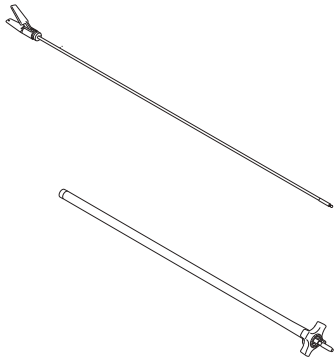
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000+770-236+723-020)

Commande auprès d'un distributeur spécialisé

▶ 723-020 ☒ 3

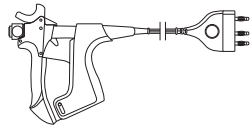


Mâchoire de pince

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Conduit

- 770-236 ☐ ....
- 770-211 ☐ ....

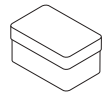


Manche avec câble HF

- 770-000 (nouveau) ☐ ....

Lot de brosses de nettoyage

- 723-000 ☐ ....



Pièces de rechange de manche

- 723-020 ☐ ....

BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

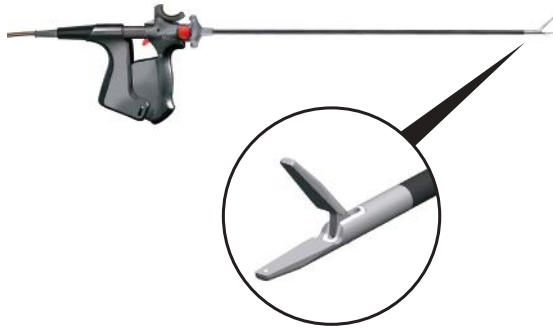
CE 0123

Marquage CE conforme aux directives 93/42/CEE

Manual de instrucciones

NightKNIFE®

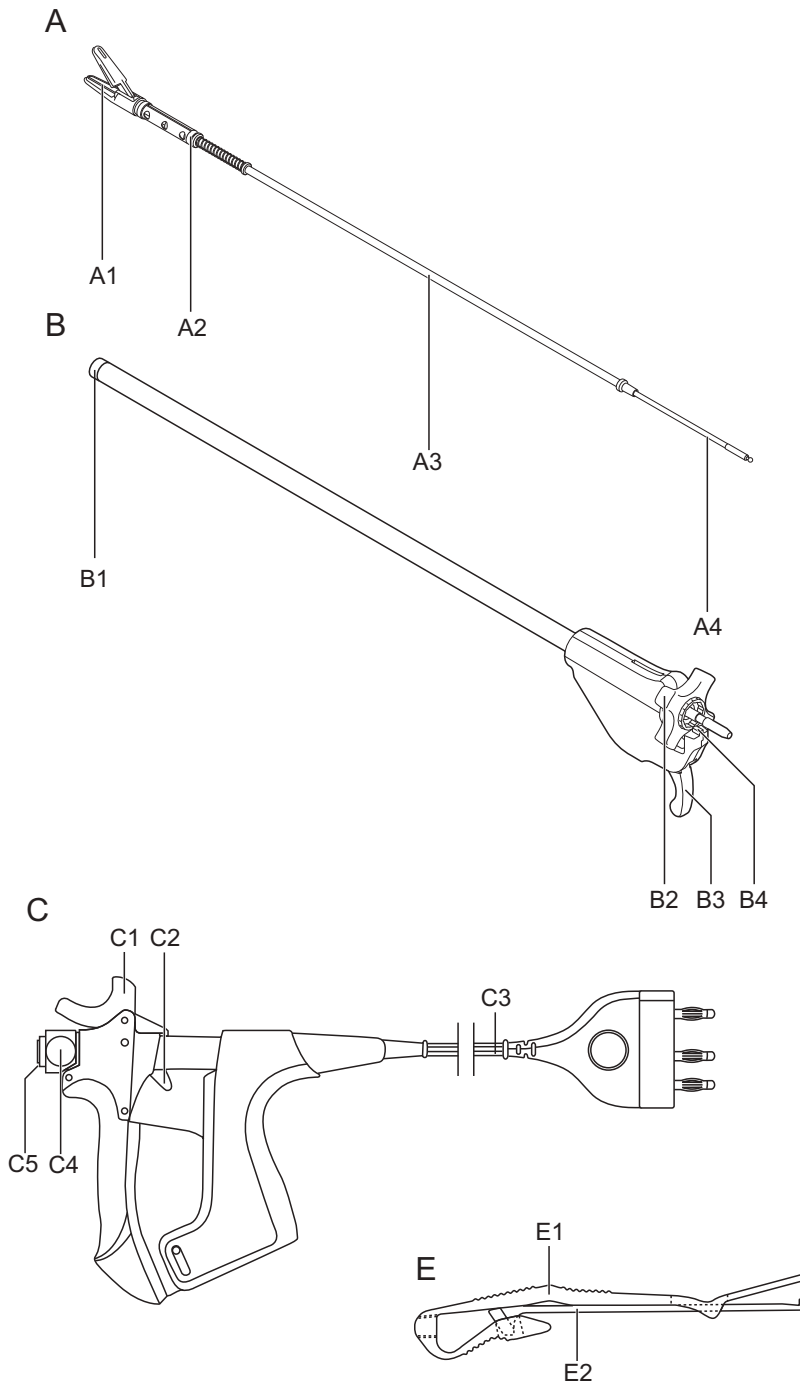
LIGATOR®



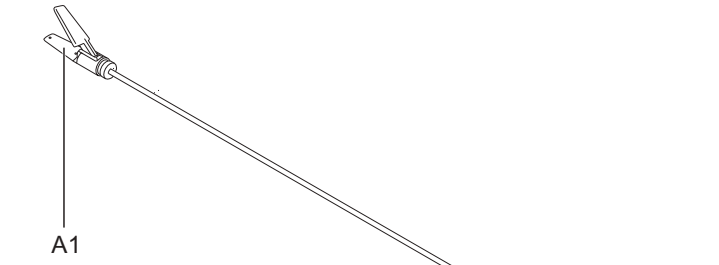
BOWA

EINFACH SICHER

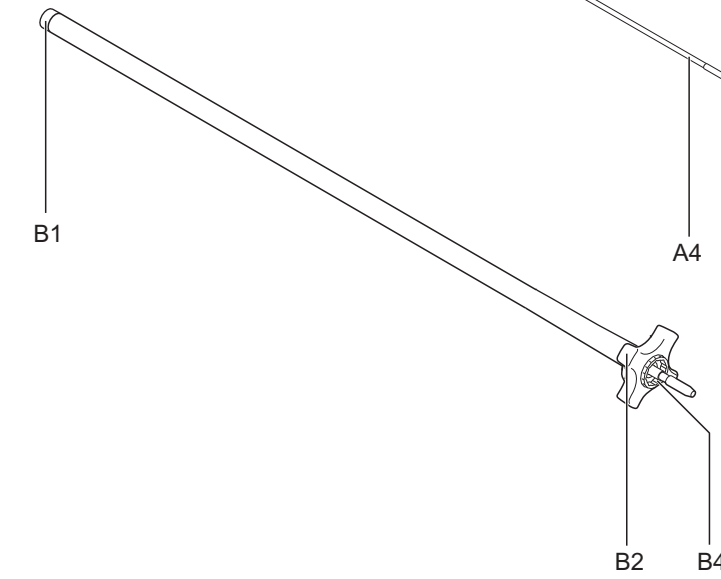
ES


A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

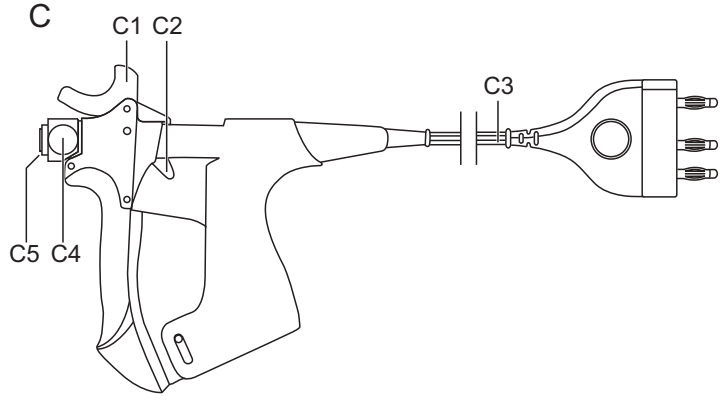
A



B



C



Leyenda

A	**Pinza prensora (de NightKNIFE con cuchilla)**
A1	Mandíbula con electrodo (1x fija, 1x móvil)
A2	Junta de sellado
A3	Tubo de empuje
A4	Barra de tracción
B	**Tubo**
B1	Casquillo roscado
B2	Rueda en estrella
B3	Gatillo
B4	Muelle de ajuste
C	**Mango**
C1	Palanca de parada
C2	Palanca de bloqueo
C3	Cable HF
C4	Pulsador
C5	Toma para tubo con pinza prensora
E	**Cuchilla con asistente de inserción**
E1	Asistente de inserción
E2	Cuchilla

índice página

1. Modo de emplear estas instrucciones

Este manual forma parte del aparato.

BOWA-electronic GmbH & Co. KG no asume ningún tipo de responsabilidad o garantía por los daños y consecuencias causados por el incumplimiento de estas instrucciones.

- Lea atentamente las instrucciones de uso antes de utilizar el aparato, especialmente el capítulo "Seguridad" (ver capítulo 2, pág 12).
- Conserve el manual de instrucciones en un lugar seguro durante toda la vida del producto.
- Conserve el manual de instrucciones en un lugar accesible para el personal.
- Entregue el manual de instrucciones al siguiente propietario o usuario del aparato.
- Actualice el manual de instrucciones con cada suplemento que reciba del fabricante.

1.1. Validez

Este manual de instrucciones es válido únicamente para los productos indicados en la portada.

1.2. Símbolos y marcas

1.2.1. Estructura de las indicaciones de aviso

⚠ AVISO

"Tipo, causa y consecuencia del peligro" (daños personales)

▶ Medidas para evitar el peligro.

1.2.2. Grados de peligro en las indicaciones de aviso

Símbolo	Grado de peligro	Probabilidad de ocurrencia	Consecuencias por incumplimiento
	**PELIGRO**	Peligro inminente	Muerte, lesiones corporales graves
	**AVISO**	Peligro posible	Muerte, lesiones corporales graves
	**CUIDADO**	Peligro posible	Lesiones corporales leves
	**NOTA**	Peligro posible	Daños materiales

1.2.3. Consejos

Consejos para facilitar el trabajo o informaciones complementarias para aclarar pasos del trabajo.

1.2.4. Otros símbolos y marcas

Símbolo / Marca	Significado
☑	Condición para una operación
▶	Operación con un paso
1. 2. 3.	Operación con varios pasos con un orden de ejecución obligatorio
⇳	Resultado de la operación precedente.
•	Enumeración (primer nivel)
•	Enumeración (segundo nivel)
Subrayado	Subrayado
..., ver capítulo xxx, pág. xxx	Referencia a un capítulo concreto

2. Seguridad

2.1. Uso correcto

Los instrumentos de ligado sirven para el sellado vascular de arterias y venas así como de estructuras de tejidos vascularizadas por aplicación laparoscópica y abierta en la ginecología, urología, cirugía general y otras disciplinas quirúrgicas con aplicación de corriente HF y presión mecánica.

Los instrumentos de ligado además son aptos para la coagulación bipolar clásica.

Los instrumentos de ligado están destinados a la operación de "ligado" bipolar.

El uso está ligado a los programas de ligado de los generadores BOWA ARC.

El instrumento de ligado NightKNIFE sirve adicionalmente para el corte de tejidos.

Cualquier otro uso de los instrumentos de ligado será considerado como indebido y deberá ser evitado.

En los artículos COMFORT 770-000 el cable de conexión está conectado de modo fijo con el mango.

Los generadores con Plug'n Cut COMFORT reconocen los instrumentos BOWA COMFORT y seleccionan automáticamente los parámetros adecuados.

En instrumentos de ligado bipolar no es necesaria la utilización de un electrodo neutro.

2.2. Indicaciones generales de seguridad

El aparato HF solo debe ser utilizado por especialistas médicos con formación. El cirujano y el personal especializado médico deben capacitarse en los fundamentos, reglas de utilización y riesgos de la cirugía HF y responsabilizarse de ello.

- ¡Lea atentamente las instrucciones de uso antes de utilizar el aparato!

En cuanto a su responsabilidad por la esterilidad de los instrumentos de ligado, deberá prestar atención en su utilización a lo siguiente:

- Limpie y esterilice el instrumento de ligado antes del primer uso. Se suministrará no estéril.
- Limpie y esterilice el instrumento de ligado antes de cada uso.
- Emplee suficientes aparatos y procedimientos validados específicos del producto para la limpieza, desinfección y esterilización.
- Mantenga los parámetros validados en cada ciclo.
- Cumpla con las disposiciones legales de aplicación en su país así como con las disposiciones de higiene del hospital.

En limpieza con baños de ultrasonidos y en limpieza preliminar manual existe riesgo de infección por salpicaduras de agua y vapores:

- Lleve puesta una máscara de seguridad y ropa protectora.

Se recomienda bastante ventilación.

Riesgo de lesiones por la cuchilla afilada:

- Preste atención a la cuchilla durante el montaje/desmontaje.
- Saque la cuchilla recambiable antes de la limpieza de la pinza prensora.
- Realice el montaje y desmontaje solo con el asistente de inserción para evitar daños por pinchazos o cortes.

2.2.1. Instalación del aparato HF

- Utilice únicamente los aparatos HF y programas autorizados (ver capítulo 8, pág. 52).
- ¡Consulte el manual de instrucciones del aparato HF así como las notas generales para intervenciones electroquirúrgicas!

El empleo inadecuado de corriente HF puede dar lugar a quemaduras endógenas y exógenas así como a explosiones:

- Realice intervenciones electroquirúrgicas solo por insuflación de gases no combustibles (CO_2).
- Evite el contacto directo de la piel con los cables HF.
- Evite el contacto con gases y líquidos inflamables.

2.2.2. Cable HF

Una utilización errónea del cable HF puede dar lugar a lesiones del paciente.

- No coloque nunca el cable HF sobre la piel del paciente.
- Conecte el instrumento de ligado para la coagulación y encienda el aparato HF.
- Para enchufar y desenchufar tome el cable HF solo por el conector.
- Utilice únicamente electrodos en perfecto estado técnico. No deberán utilizarse cables HF defectuosos.

El cable HF puede provocar interferencias en la imagen del monitor:

- No ponga el cable HF directamente en paralelo con el cable de la cámara.
- No disponga el cable HF formando lazos.

2.2.3. Electrodos activos

Los electrodos defectuosos o desgastados pueden dar lugar a quemaduras en los pacientes:

- Nunca utilice o repare mandíbulas o superficies de electrodos desgastadas o defectuosas. Elimínelos.

Las superficies de electrodos calientes pueden dar lugar a quemaduras de los pacientes:

- Mantenga distancia entre las puntas de los instrumentos y las estructuras de tejidos delicadas (p.ej. páncreas, intestino).
- Asegúrese de que no se utilicen instrumentos calientes para la preparación.

La activación por descuido del instrumento de ligado puede ocasionar lesiones en el paciente:

- No deposite ningún instrumento de ligado sobre el paciente.

Los electrodos sucios pueden producir cortocircuito y con ello un fallo de funcionamiento del instrumento de ligado.

- Limpie los electrodos de las mandíbulas regularmente con un paño húmedo.
- Reemplace la pinza prensora cuando los electrodos estén deteriorados.

2.2.4. Cuchilla recambiable con asistente de inserción (solo en NightKNIFE con cuchilla recambiable)

La cuchilla recambiable y el asistente de inserción no deben reciclarse:

- ▶ Eliminar o sustituir cuchillas y asistentes de inserción usados.

2.2.5. Reparación/Mantenimiento

No deben repararse o mantenerse productos defectuosos: Eliminar o sustituir productos defectuosos.

- ▶ Indicaciones de seguridad sobre las personas

2.3. Indicaciones de seguridad sobre las personas

Las configuraciones erróneas del generador de HF y una visibilidad restringida pueden provocar lesiones en el paciente:

- ▶ Seleccione el generador HF y el cable HF según los requisitos del instrumento de ligado.
- ▶ Opere únicamente con suficiente visibilidad.
- ▶ No use nunca el instrumento de ligado en modo Autostart.

2.3.1. Pacientes con marcapasos cardiaco

El malfuncionamiento o el fallo total del marcapasos puede implicar riesgo de muerte o de lesiones irreversibles para el paciente.

- No realice nunca intervenciones ambulatorias en pacientes con marcapasos cardiaco.
- En el caso de pacientes con marcapasos cardiaco consulte previamente al cardiólogo antes de aplicar la cirugía HF.
- Ajuste el marcapasos a demanda a frecuencia fija.
- Asegúrese de que el marcapasos cardiaco no está en contacto con el electrodo HF.
- Prepare un desfibrilador operativo para tenerlo a mano.
- Efectúe un control postoperatorio del marcapasos cardiaco.

3. Modo de funcionamiento

En la cirugía HF bipolar se efectúa la coagulación del tejido mediante la aplicación de una corriente alterna de alta frecuencia que genera calor.

Los instrumentos de ligado NightKNIFE y LIGATOR son instrumentos quirúrgicos invasivos para intervenciones laparoscópicas y abiertas. Se aplican en combinación con productos endoscópicos utilizables (p.ej. trócares y ópticos) por medio de accesos manufacturados quirúrgicos.

Los electrodos activos (sectores) son aquellas zonas no aisladas de la mandíbula.

La corriente HF va de una zona del instrumento a través del tejido biológico a la segunda zona y logra a nivel local el efecto de coagulación deseado.

En este procedimiento se consigue por medio de la corriente HF con presión adicional un sellado de un segmento de tejido/vasos inundado de sangre.

El punto de sellado se cierra ante la presión sistólica de forma hemostática hermética y permanente.

Mediante la función de corte integrada con NightKNIFE puede separarse el tejido tratado directamente en contacto con la zona sellada sin cambio previo de instrumental.

Pulsando el mango puede abrirse o cerrarse la mandíbula en la pinza prensora y con la palanca de parada se puede bloquear.

La pinza prensora se puede girar a través de la rueda de estrella en el tubo y bloquear (8x45°).

4. Montaje

⚠ AVISO

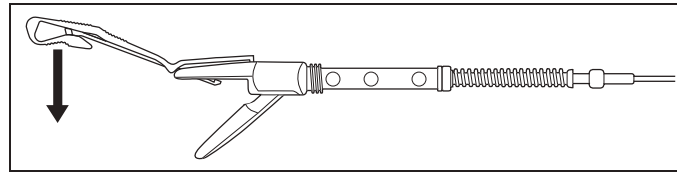
¡Riesgo de provocar lesiones al paciente por instrumento de ligado no estéril!

▶ Limpie y esterilice el instrumento de ligado antes del primer uso ya que se suministra no estéril.

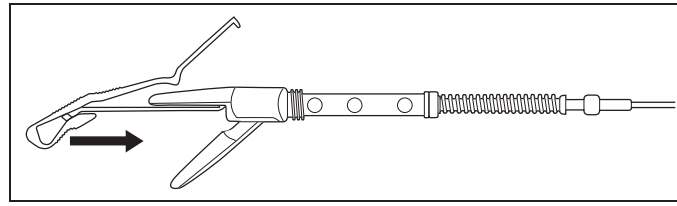
4.1. Montar cuchilla con asistente de inserción (solo en NightKNIFE con cuchilla recambiable)

☑ La cuchilla con asistente de inserción está limpia y desinfectada (ver capítulo 7.5, pág. 42)

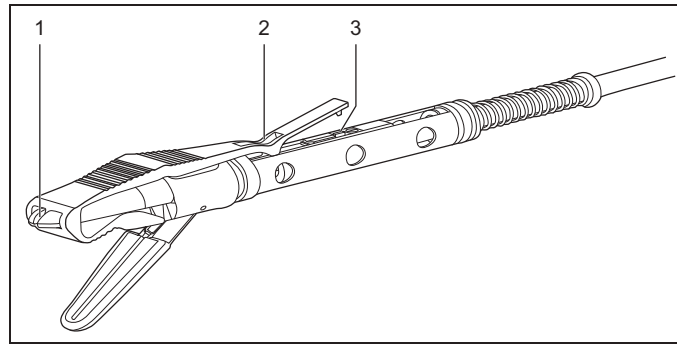
1. Saque la cuchilla con asistente de inserción **E** del envase estéril.



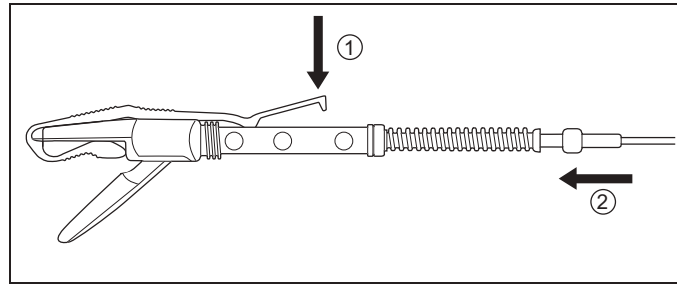
2. Gire la pinza prensora **A** con la mandíbula fija **A1** hacia arriba, para abrirla.
3. Para sacar la cuchilla, introduzca la mandíbula fija **A1** entre cuchilla **E2** y asistente de inserción **E1**, y apriete el asistente de inserción **E1** hacia abajo en el sentido de la flecha.



4. Empuje sobre la mandíbula fija **A1** la cuchilla con el asistente de inserción **E** en el sentido de la flecha hasta el tope.

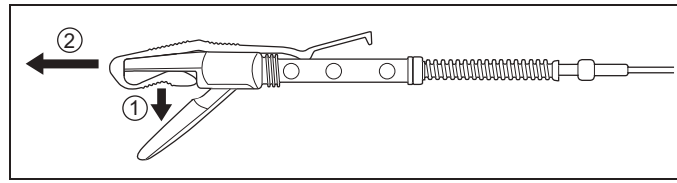


5. Asegúrese de que la cuchilla con asistente de inserción **E** están centrados en las posiciones marcadas.
6. Coloque el asistente de inserción **E1** en posición centrada con los dedos en caso necesario.



7. Sujete el asistente de inserción **E1** y presione ligeramente el asistente de inserción **E1** hacia abajo en el sentido de la flecha **1**.
8. Desplace el tubo de empuje **A3** en el sentido de la flecha 2 hasta que la cuchilla **E2** encaje de forma audible/perceptible y visible.

↳ Los muelles permanecen comprimidos.



9. Retire la parte corta del asistente de inserción **E1** hacia abajo **1**, para volver a poner la cuchilla en su posición original.
10. Retire el asistente de inserción **E1** en el sentido de la flecha **2** de la mandíbula fija.

▶ Conserve el asistente de inserción. Será necesario para el desmontaje de la cuchilla.

4.2. Montaje de instrumento de ligado

1. Enrosque la pinza prensora **A** completamente en el tubo **B**.
2. Asegúrese de que no exista ninguna hendidura entre la pinza prensora **A** y el tubo **B**.
3. Cierre la mandíbula **A1** con los dedos e introduzca el tubo **B** en el mango **C**:
   - En NightKNIFE: Procure que el muelle de ajuste **B4** y la ranura de ajuste **C5** estén alineados.
   - Encaje el tubo **B** en el mango **C**.
4. Compruebe la función de agarre del instrumento de ligado pulsando el mango **C**.
5. Con ayuda de la palanca de parada **C1**, abra la mandíbula **A1**.
6. En NightKNIFE: Compruebe la suavidad y la posición inicial de la cuchilla pulsando el gatillo **B3**.
7. Compruebe que la rueda de estrella **B2** pueda girar.

5. Manejo

5.1. Antes de la utilización

☑ Se monta el instrumento de ligado (ver capítulo 4, pág. 19) y se prepara (ver capítulo 7, pág. 32).

⚠ AVISO

¡Riesgo de lesiones para el paciente!

- ▶ Utilice únicamente los generadores BOWA ARC con función de ligado autorizados (ver capítulo 8, pág. 52).
- ▶ Utilice únicamente productos y accesorios apropiados de acuerdo a la descripción general del sistema.
- ▶ Utilice únicamente productos en perfecto estado y esterilizados.

⚠ AVISO

¡Riesgo de lesiones para el paciente por quemaduras y explosiones de líquidos y gases inflamables!

- ▶ Realice intervenciones electroquirúrgicas solo por insuflación de gases no combustibles (CO_2).
- ▶ Evite el contacto con gases y líquidos inflamables (p.ej. de limpieza de la piel, desinfectantes y gases para anestesia).

---

1. Conecte el cable HF **C3** en el aparato HF y encienda dicho aparato.
2. Ajuste la potencia de salida del aparato HF.

3. Antes de cada uso del instrumento de ligado, realice una inspección visual y funcional básica (ver capítulo 7.6, pág. 45).

En su posición inicial la mandíbula **A1** está abierta.

4. Con ayuda del mango **C1**, cierre la mandíbula **A1**.
5. Introduzca la pinza prensora **A** en el manguito del trocar.

5.2. Durante la intervención

⚠ AVISO

¡Riesgo de lesiones del paciente por ajustes erróneos del aparato y por visibilidad restringida!

- ▶ Ajuste la potencia de salida del aparato HF al valor preciso para la intervención.
- ▶ Utilice únicamente los programas autorizados (ver capítulo 8, pág. 52).
- ▶ Opere únicamente con suficiente visibilidad.

⚠ AVISO

¡Riesgo de lesiones al paciente por superficies de electrodo calientes y emisión de vapores!

- ▶ Mantenga distancia entre las puntas de los aparatos y las estructuras de tejidos delicadas (p.ej. páncreas, intestino).
- ▶ Asegúrese de que no se utilicen instrumentos de ligado calientes para la preparación.
- ▶ No deposite ningún instrumento de ligado sobre el paciente.

- ▶ Introduzca el instrumento de ligado en el cuerpo bajo control visual.

Tomar, sujetar, sellar tejidos

⚠ AVISO

¡Riesgo de provocar lesiones al paciente por activación no intencionada del instrumento de ligado!

- ▶ No utilice nunca la función AUTOSTART.
- ▶ Solo encienda la corriente HF cuando los electrodos activos estén en contacto con el tejido a coagular.

1. Sitúe la pinza prensora **A** en el campo de operación.

La pinza prensora **A** es giratoria y bloqueable en ángulos de 45°.

2. Gire la rueda en estrella **B2**, para ajustar el ángulo de la pinza prensora **A**.
3. Sitúe el tejido a sellar entre los electrodos de la mandíbula **A1**.
4. Cierre la mandíbula **A1** para agarrar el tejido.

↳ Se agarra el tejido.

5. Utilice la muesca fijadora de tres etapas del mango **C**, para adecuar la presión sobre el tejido de forma óptima a la cantidad de tejido agarrado.

↳ Se aprieta el tejido.

6. Active la corriente HF con el interruptor de pedal del aparato HF para la coagulación:
   - E con sonido continuo indica el aporte de energía durante la duración completa del sellado.
   - Un sonido intermitente indica el fin del sellado.
7. Suelte el interruptor de pedal para parar el abastecimiento de energía.
8. Con ayuda de la palanca de parada **C1**, abra la mandíbula **A1**.

↳ Se coagula el tejido.

Corte de tejidos (solo en NightKNIFE)

⚠ AVISO

Sangrado abundante por corte del tejido tomado sin coagulación o ligado previo!

- ▶ Haga al menos dos sellados en los tejidos a la izquierda y a la derecha de la posición de corte.
- ▶ Asegúrese de que el tejido esté sellado con certeza antes del proceso de corte.
- ▶ Corte solo en la zona sellada.

☑ El tejido será tomado por la mandíbula y coagulado.

1. Para cortar pulse el gatillo **B3** y suéltelo.

↳ Se corta el tejido.

2. Con ayuda de la palanca de parada **C1**, abra la mandíbula **A1**.

Modificar potencia de salida del aparato HF

▶ Antes del aumento, compruebe la potencia de salida del aparato HF:

- el contacto en perfecto estado de todos los cables HF y enchufe,
- si el instrumento de ligado está conectado correctamente (ver el manual de instrucciones del aparato HF),
- la función del interruptor de pedal,
- el aislamiento del cable HF **C3**, de la mandíbula **A1**, del tubo **B** y del manguito del trocar,
- la limpieza y desgaste de los electrodos activos en la mandíbula **A1**.

5.3. Extracción

⚠ AVISO

Riesgo de provocar lesiones al paciente por componentes rotos o dañados!

▶ Compruebe la pinza prensora tras cada extracción. Todos los componentes deben estar presentes.

1. Cierre la mandíbula **A1**.
2. Extraiga el instrumento de ligado del manguito del trocar.

5.4. Tras la utilización

⚠ AVISO

¡Los electrodos sucios pueden producir un fallo funcional del instrumento de ligado!

- ▶ Limpie los electrodos de la mandíbula **A1** regularmente con un paño húmedo.
- ▶ Reemplace la pinza prensora **A** cuando los electrodos estén deteriorados.
- ▶ En NightKNIFE con cuchilla recambiable: Sustituya la cuchilla **E2** después de cada intervención.

1. Trate el instrumento de ligado después de cada utilización (ver capítulo 7, pág. 32).

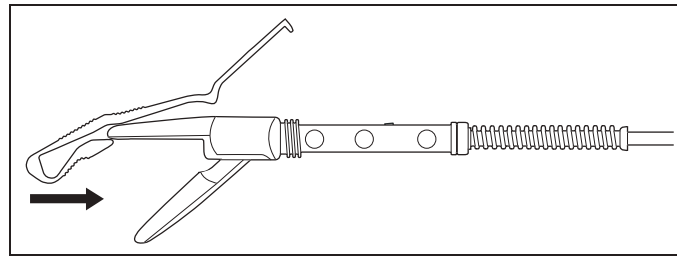
6. Desmontaje

6.1. Desmontar instrumento de ligado

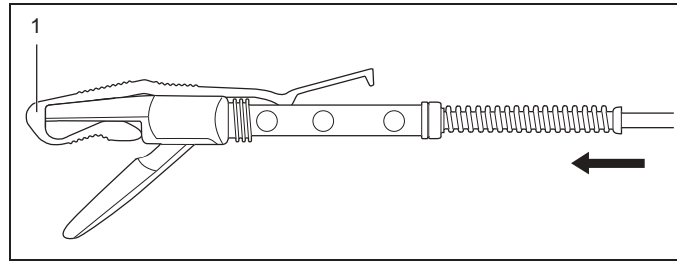
1. Mantenga apretado en el mango **C** el pulsador **C4** y la palanca de bloqueo **C2** y separe el mango **C** del tubo **B**.
2. Desenrosque la pinza prensora **A** del tubo **B**.
3. En NightKNIFE con cuchilla recambiable: Retire la cuchilla con asistente de inserción **E** (ver capítulo 6.2, pág. 29).

6.2. Retirar cuchilla con asistente de inserción (solo en NightKNIFE con cuchilla recambiable)

1. Gire la pinza prensora **A** con la mandíbula fija **A1** hacia arriba, para abrirla.

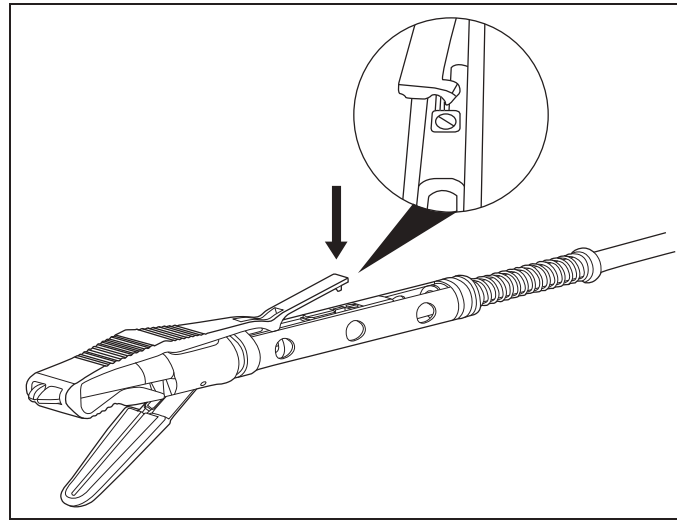


2. Sujete lateralmente el asistente de inserción **E1** e introduzca el asistente de inserción **E1** en la mandíbula fija **A1** en el sentido de la flecha hasta el tope.



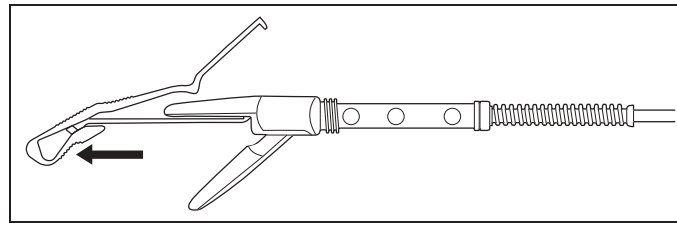
3. Asegúrese de que la cuchilla con asistente de inserción **E** en la mandíbula fija **A1** está centrada en la posición **1**.
4. Ponga el asistente de inserción **E1** en posición centrada con los dedos en caso necesario.
5. Sujete lateralmente el asistente de inserción **E1** en posición **1** y empuje el tubo despacio en el sentido de la flecha, hasta que la cuchilla **E2** encaje de forma perceptible.

↳ Con la cuchilla fija los muelles permanecen comprimidos.



6. Con ayuda de la cuña en el asistente de inserción **E1** separe la cuchilla **E2** de la muesca fijadora.

↳ Los muelles se aflojan y el tubo vuelve a encajar.



7. Saque el asistente de inserción con la cuchilla **E** en el sentido de la flecha y elimine la cuchilla con asistente de inserción **E**.

No está permitido el reciclaje de cuchilla ni del asistente de inserción.

7. Tratamiento

Los instrumentos de ligado no deben utilizarse sin limpieza, desinfección y esterilización previas. Una limpieza y desinfección eficaces son condición previa para una esterilización efectiva del instrumento de ligado.

1. Observe que solo se emplearán los métodos de limpieza, desinfección y esterilización específicos para los aparatos y el producto suficientemente validados, y que se respetarán los parámetros validados en cada ciclo.
2. Cumpla con las disposiciones legales aplicables en el país, así como con disposiciones de higiene del hospital/clínica.

Los siguientes detalles sobre el número de ciclos de tratamiento son indicativos. El número puede variar con el uso.

El número de ciclos de tratamiento de los componentes individuales del instrumento se encuentra en un tiempo de esterilización de 20 y en una temperatura de esterilización de 134 C:

- Pinza prensora **A**: 20 veces,
- Tubo **B**: hasta 200 veces,
- Mango **C**: hasta 100 veces.

El tratamiento del instrumento de ligado comprende los siguientes pasos:

- Poner a remojo
- Desmontaje
- Tratamiento previo en baño de ultrasonidos
- Eliminación manual de suciedad
- Tratamiento a máquina en ALD
- Inspección
- Envase
- Esterilización en autoclave
- Almacenamiento
- Test funcional en operación

7.1. Poner a remojo

⚠ CUIDADO

Peligro de infección por salpicaduras de agua y vapores del baño de ultrasonidos y en limpieza manual previa!

- ▶ Lleve puesta una máscara de seguridad y ropa protectora.
- ▶ Se recomienda bastante ventilación.

⚠ CUIDADO

En NightKNIFE: ¡Riesgo de lesiones por cuchilla afilada!

- ▶ Preste atención a la cuchilla durante la limpieza.
- ▶ En NightKNIFE con cuchilla recambiable: Saque la cuchilla de la pinza prensora antes de la limpieza.

NOTA

¡Daños materiales en la pinza prensora por productos de limpieza y cepillos de metal!

- ▶ Nunca limpie la pinza prensora con productos de limpieza.

- ▶ Elimine de antemano si es necesario los restos de suciedad con una gasa.
- ▶ Ponga inmediatamente el instrumento de ligado en remojo, como máximo hasta 2 horas después de su utilización.
- ▶ Utilice únicamente desinfectantes libres de aldehídos, que son aptos para la desinfección de instrumentos de ligado (p.ej. autorización de la DGHM o de la FDA, o etiquetado CE).

El desinfectante aplicado en la puesta a remojo solo sirve para la protección personal y no reemplaza pasos de desinfección posteriores.

7.2. Desmontaje

1. Desmonte el instrumento de ligado (ver capítulo 6.1, pág. 29).
2. En NightKNIFE con cuchilla recambiable: Retire la cuchilla del instrumento de ligado y elimínela (ver capítulo 6.2, pág. 29).

7.3. Tratamiento previo en baño de ultrasonidos

⚠ CUIDADO

¡Peligro de infección por salpicaduras de agua y vapores del baño de ultrasonidos!

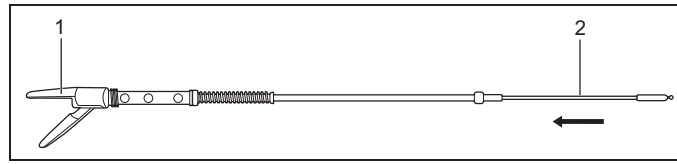
- ▶ Lleve puesta una máscara de seguridad y ropa protectora.
- ▶ Se recomienda bastante ventilación.

1. Deposite la pinza prensora **A**, tubo **B** y mango **C** al menos 5 minutos en el baño de ultrasonidos. Coloque las partes grandes de tal manera en el baño de ultrasonido que no generen sombras sónicas.
2. Utilice productos de limpieza y desinfección adecuados para la limpieza con ultrasonidos (ver capítulo 7.4, pág. 36).
3. Respete los tiempos de actuación y concentraciones indicadas por el fabricante del detergente y desinfectante.

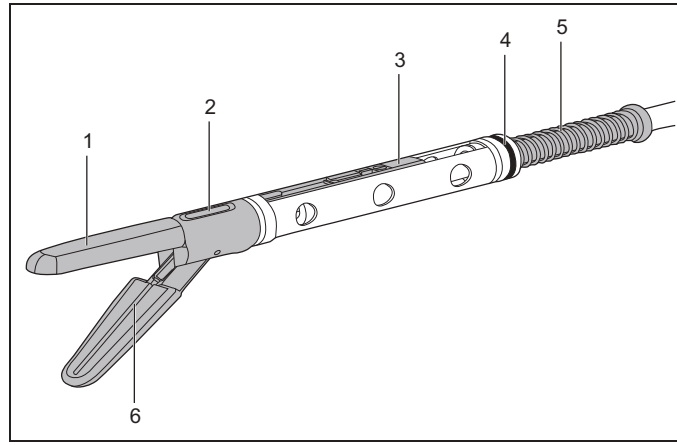
7.4. Eliminación manual de suciedad

En este capítulo se muestra a modo de ejemplo el instrumento de ligado NightKNIFE.

Pinza prensora:



1. Empuje las barras de tracción **2** en el sentido de la flecha, para abrir la mandíbula **1**.



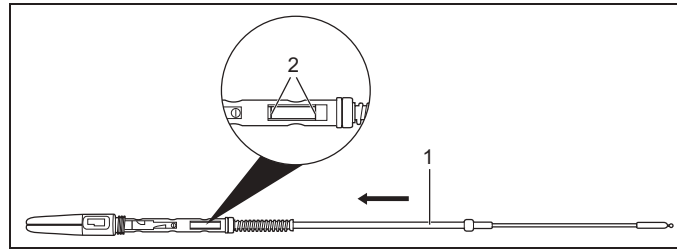
NOTA

¡Daños materiales en la pinza prensora por cepillos de metal!

▶ Limpie solo la pinza prensora con un cepillo de plástico.

2. Elimine la suciedad con un cepillo de plástico y un limpiador a vapor en las zonas marcadas en gris:
   - Mandíbula **1**: Superficies exteriores arriba y abajo, superficies de electrodos
   - Articulación **2**: Aperturas arriba y abajo
   - En NightKNIFE: Mecanismo de parada **3**
   - En NightKNIFE: Muelles **5**
3. En NightKNIFE: Limpie con un objeto punzante los lados interiores de ambas ranuras **6**.

4. En NightKNIFE: Elimine la suciedad con un objeto punzante bajo la junta de sellado **4**. Procure que la junta no resulte dañada con ello.



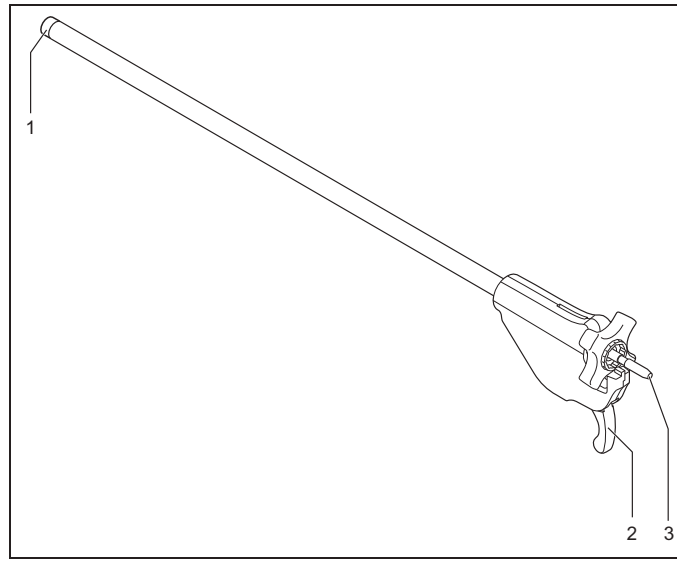
5. Empuje el tubo **1** en el sentido de la flecha y limpie las bases de apoyo independientes **2** con un limpiador a vapor.

Tubo

NOTA

¡Daños materiales en el tubo por cepillos de metal!

- ▶ Limpie el tubo solo con el cepillo de plástico suministrado.
- ▶ Utilice un limpiador a vapor en caso necesario para la limpieza.



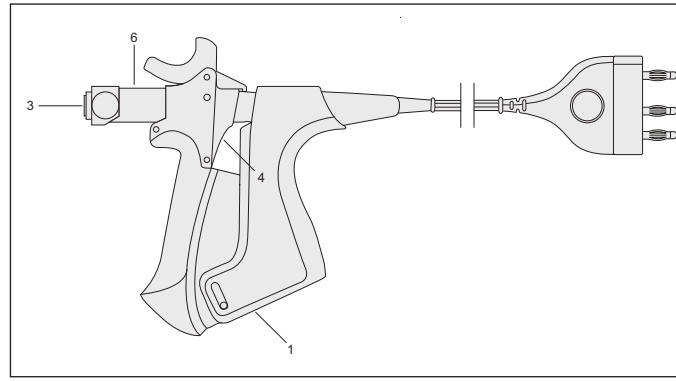
1. Limpie el tubo con el cepillo pequeño de limpieza en su extremo proximal **3** desde el interior.
2. Limpie el tubo con el cepillo grande de limpieza en su extremo distal **1** desde el interior.
3. Lave el tubo **B** en el extremo distal con agua completamente desalinizada o destilada, para limpiar la cubierta desde el interior. Pulse el gatillo **2**, para limpiar el mecanismo accionador en la cubierta.

Mango

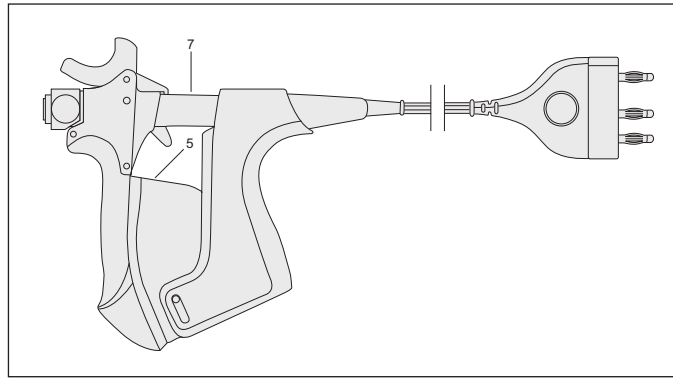
NOTA

¡Daños materiales en el mango por cepillos de metal!

- ▶ Limpie el mango solo con el cepillo de plástico suministrado.
- ▶ Utilice un limpiador a vapor en caso necesario para la limpieza.



1. Pulse el mango hasta que encaje y limpie con el cepillo las guías **6**.
2. Limpie todas las posiciones marcadas del mango con el cepillo desde el interior.



3. Separe el encaje en el mango.
4. Limpie con el cepillo los dientes de bloqueo y las guías **7** en la parte posterior del mango.
5. Limpie con el cepillo la posición marcada **5** del mango desde el interior.

Lavar

▶ Tras la limpieza preliminar lave a fondo todos los componentes del instrumento con agua completamente desalinizada o destilada.

7.5. Tratamiento a máquina en ALD

Métodos de limpieza y desinfección apropiados

▶ Emplee un Aparato de Limpieza y Desinfección (ALD) para la limpieza y desinfección del instrumento de ligado.

No se recomienda un procedimiento manual, debido a su eficacia claramente inferior.

▶ En la selección del ALD, preste atención a que:

- presente una eficacia probada (p.ej. autorización de la DGHM o de la FDA, o etiquetado CE conforme DIN EN ISO 15883).
- se utilice un programa probado para la desinfección térmica (al menos 5 minutos a 90 °C o valor-A_0 > 3000). En la desinfección química existe el riesgo de residuos de desinfectante en los componentes del instrumento.
- se utilizará una selección de programa apropiada para el instrumental con suficientes ciclos de lavado.
- se emplee agua estéril/pobre en gérmenes (máx. gérmenes/ml) y pobre en endotoxinas (máx. unidades de endotoxinas/ml) para aclarar.
- se realice un filtrado del aire seco.
- se realice un mantenimiento y comprobación regulares del ALD.

Detergente apropiado

▶ En la selección del sistema de limpieza adecuado, preste atención a que:

- el detergente para el instrumento de ligado sea el adecuado.
- en tanto que no se desinfecte térmicamente, se emplee además un desinfectante apropiado con eficacia probada (p.ej. autorización de la DGHM o de la FDA, o etiquetado CE) que sea compatible con el detergente.
- las sustancias químicas sean compatibles con los componentes del instrumento (ver capítulo 7.4, pág. 36).

▶ Respete los tiempos de actuación y concentraciones indicadas por el fabricante del detergente y desinfectante.

Limpieza y desinfección

NOTA

¡Daños del cable HF por incorrecta disposición en el ALD!

▶ Preste atención a que el cable HF no se encuentre doblado o enganchado.

1. Ponga los componentes del instrumento en el ALD. Observe lo siguiente:
   - Colocar los componentes de tal forma que no se originen zonas inaccesibles al lavado.
   - Meter tubo y pinza prensora con los extremos distales en la cabina de lavado

- Barras de tracción entremetidas en pinza prensora, para abrir la mandíbula lo más que se pueda en la cabina de lavado
- Limpiar mango encajado
- Colocar suelto el cable HF en una bandeja de esterilización de instrumental con tapa

2. En NightKNIFE con cuchilla recambiable: Saque una nueva cuchilla del envase con el asistente de inserción y ponga la cuchilla con asistente de inserción en una bandeja de esterilización de instrumental con tapa.
3. Inicie el programa.
4. Saque del ALD los componentes del instrumento tras la finalización del programa.

NOTA

¡Daños del mango por aire comprimido!

▶ Seque el mango a un máximo de 3 bar de aire comprimido.

5. Seque los componentes con aire comprimido filtrado.

7.6. Inspección

En un uso conforme al destinado, Estos productos están sujetos a desgaste según la intensidad del uso. Este desgaste está condicionado técnicamente y es inevitable.

Cuando el producto muestre externamente defectos reconocibles o no trabaje según lo descrito en este manual, deberá reemplazarse. En este caso, comuníqueselo por favor al fabricante o a sus representantes competentes.

- ▶ Tras la limpieza, realice una inspección visual y funcional de los componentes individuales.
- ▶ Sustituya las piezas dañadas.

7.6.1. Inspección en NightKNIFE:

⚠ PELIGRO

¡Riesgo de quemar al paciente en aislamiento frágil o defectuoso!

- ▶ Sustituya los componentes con aislamiento defectuoso.

Pinza prensora:

1. En NightKNIFE con cuchilla recambiable: Introduzca una nueva cuchilla **E2** (ver capítulo 4.1, pág. 19).
2. Compruebe la función abrir/cerrar de la mandíbula **A1**.
3. Compruebe visualmente si hay daños en la bola en la barra de tracción **A4**.
4. Mueva el tubo de empuje **A3** en la pinza prensora **A**, para comprobar la suavidad y posición básica de la cuchilla **E2**.
5. Compruebe visualmente los daños de la cuchilla **E2**.
6. Compruebe los daños en el aislamiento de la barra de tracción **A4**.

7. Compruebe los daños en el recubrimiento de la pinza prensora **A**.
8. Compruebe la junta de sellado **A2**.
9. Compruebe si la barra de tracción **A4** y el tubo de empuje **A3** están doblados.

Tubo

1. Compruebe visualmente los daños en el aislamiento.
2. Compruebe si el tubo está torcido.
3. Compruebe si la rueda de estrella **B2** puede girarse con facilidad.
4. Compruebe el funcionamiento del gatillo **B3**.

Mango

1. Compruebe la suavidad de la palanca de parada **C1**, la palanca de bloqueo **C2** y el pulsador **C4**.

Cable HF

1. Compruebe los daños y la corrosión en la conexión del cable.
2. Compruebe visualmente los daños en el aislamiento.

7.6.2. Inspección en LIGATOR

⚠ PELIGRO

¡Riesgo de quemar al paciente en aislamiento frágil o defectuoso!

▶ Sustituya los componentes con aislamiento defectuoso.

Pinza prensora:

1. Compruebe la función abrir/cerrar de la mandíbula **A1**.
2. Compruebe si hay daños en la bola en la barra de tracción **A4**.
3. Compruebe los daños en el aislamiento de la barra de tracción **A4**.
4. Compruebe si la barra de tracción **A4** está torcida.

Tubo

1. Compruebe visualmente los daños en el aislamiento.
2. Compruebe si el tubo **B** está torcido.

Mango

1. Compruebe la suavidad de la palanca de parada **C1**, la palanca de bloqueo **C2** y el pulsador **C4**.

Cable HF

1. Compruebe los daños y la corrosión en la conexión del cable.
2. Compruebe visualmente los daños en el aislamiento.

7.7. Envase

El envase debe satisfacer los criterios siguientes:

- DIN EN (ANSI AAMI) ISO 11607/
  DIN EN 868-2...10 (anteriormente DIN EN 868/
  ANSI AAMI ISO 11607)
- apropiado para esterilización por vapor
  (resistencia térmica hasta 137 °C, suficiente
  permeabilidad al vapor)
- mantenido regularmente (contenedor de esterilización)

▶ Empaquete el instrumento de ligado en un envase de esterilización desechable y/o un contenedor de esterilización apropiado.

No está permitida una esterilización en el envase para el transporte.

7.8. Esterilización en autoclave

▶ Esterilice el instrumento de ligado solo cuando esté desmontado.

NOTA

¡Fallo total del instrumento de ligado por esterilización con aire caliente!

▶ Preste atención a un método de esterilización apropiado.

Para la esterilización aplique solo la esterilización por vapor con las especificaciones siguientes:

- proceso de vacío fraccionado (con suficiente secado de producto)
- conforme a DIN EN 13060 o DIN EN 285
- Validación conforme a DIN EN ISO/ ANSI AAMI ISO 17665 (hasta ahora DIN EN 554/ ANSI AAMI ISO 11134) (IQ/OQ en vigor (Comision) y evaluación de rendimiento específica de producto (PQ))
- temperatura máxima de esterilización 134 °C (más tolerancia según DIN EN ISO/ ANSI AAMI ISO 17665 (previamente DIN EN 554/ ANSI AAMI ISO 11134))
- tiempo de esterilización de al menos 20 minutos a 121 °C o 5 minutos a 132/134 °C

El empleo del método de la gravedad, menos eficaz, deberá asegurarse mediante una validación adicional (si es el caso, serán necesarios tiempos de esterilización más largos).

Si se emplea otro método de esterilización (p. ej. esterilización con óxido de etileno, con formaldehído, por radiación y con plasma de baja temperatura), no tendrá vigencia la responsabilidad del fabricante.

1. Observe en el caso de uso:
   - DIN EN ISO 14937/ANSI AAMI ISO 14937,
   - Normas específicas del método.
2. Demuestre la idoneidad y eficiencia del método bajo consideración de la geometría específica del producto en el marco de la validación (si es el caso, incluyendo examen de residuos del producto de esterilización)

7.9. Almacenamiento

1. Almacene el instrumento de ligado en un sitio protegido de:
   - acciones mecánicas fuertes como choque, caída o impacto,
   - irradiación directa del sol,
   - rayos-X.
2. Almacene el instrumento de ligado en seco y a temperatura ambiente.

El período de almacenamiento del instrumento de ligado depende del tipo de envase y de las condiciones del almacenamiento.

El material de expedición no está previsto para la conservación del producto.

7.10. Test funcional en operación

1. Ensamble el instrumento de ligado (ver capítulo 4, pág. 19).
2. Compruebe las funciones del instrumento de ligado (ver capítulo 7.6, pág. 45).

7.11. Materiales de trabajo recomendados

BOWA recomienda la utilización desde productos de limpieza neutros hasta ligeramente alcalinos, o productos de limpieza y desinfección sin ingredientes críticos. Dependiendo de la concentración, están permitidos ingredientes alcohólicos y/o aldehídicos.

Tratamiento previo en baño de ultrasonidos

La idoneidad de los instrumentos de ligado para un tratamiento previo eficaz en baño de ultrasonidos (5 min) fue demostrada por BOWA empleando un producto combinado detergente y desinfectante, libre de aldehídos.

Limpieza a máquina

La idoneidad de los instrumentos de ligado para una limpieza/desinfección eficaz a máquina (90 ºC, 5 min) fue demostrada por BOWA empleando un detergente alcalino con ingrediente Tensid (neodisher MediClean forte).

Si se emplean otros productos de limpieza y desinfección, no tendrá vigencia la responsabilidad del fabricante.

8. Datos técnicos

8.1. NightKNIFE y LIGATOR

Datos técnicos	
Corriente HF	4 A
Tensión alterna	> 330 kHz
Tensión máxima	200 Vp sinusoidal
Aparato HF autorizado	Generadores ARC BOWA con software de LIGATION
Programas autorizados	LIGATION En BOWA ARC 350L (900-350): LIGATION a partir del software V2.6 Efecto 2 hasta efecto 4

9. Eliminación

La eliminación de productos médicos, de materiales de envasado y de accesorios deben cumplir la normativa y leyes específicas vigentes en el país.

10. Descripción general del sistema

10.1. NightKNIFE

Sin cuchilla recambiable:

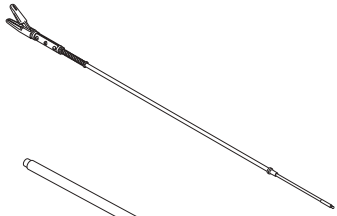
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

Con cuchilla recambiable:

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Solicitud en distribuidor

▶ 723-020 ☒ 3.

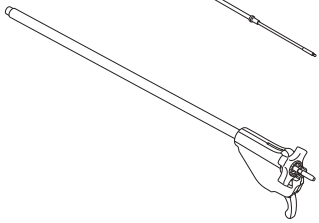


Pinza prensora sin cuchilla recambiable:

- 771-136 ☐ ....
- 771-120 ☐ ....

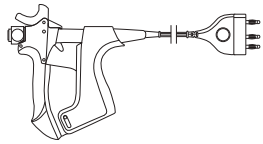
Pinza prensora con cuchilla recambiable:

- 771-137 ☐ ....
- 771-121 ☐ ....



Tubo

- 770-336 ☐ ....
- 770-320 ☐ ....

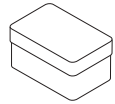


Mango con cable HF

- 770-000 ☐ ....

Juego de cepillos de limpieza

- 723-030 ☐ ....



Piezas de repuesto del mango

- 723-020 ☐ ....

Cuchillas recambiables (5 piezas)

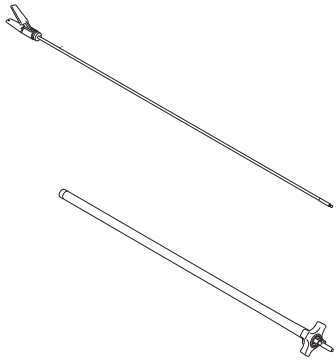
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000+770-236+723-020)

Solicitud en distribuidor

▶ 723-020 ☒ 3

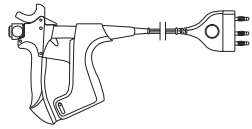


Pinza prensora:

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Tubo

- 770-236 ☐ ....
- 770-211 ☐ ....

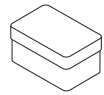


Mango con cable HF

- 770-000 (nuevo) ☐ ....

Juego de cepillos de limpieza

- 723-000 ☐ ....



Piezas de repuesto del mango

- 723-020 ☐ ....

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BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

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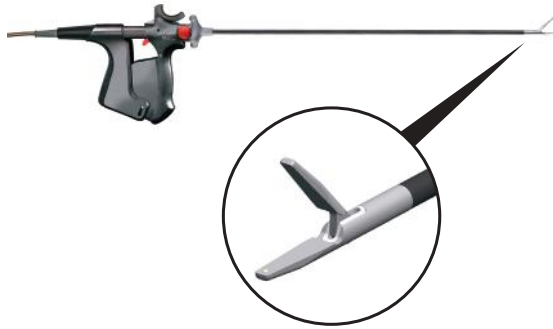
Istruziono d´uso

NightKNIFE®

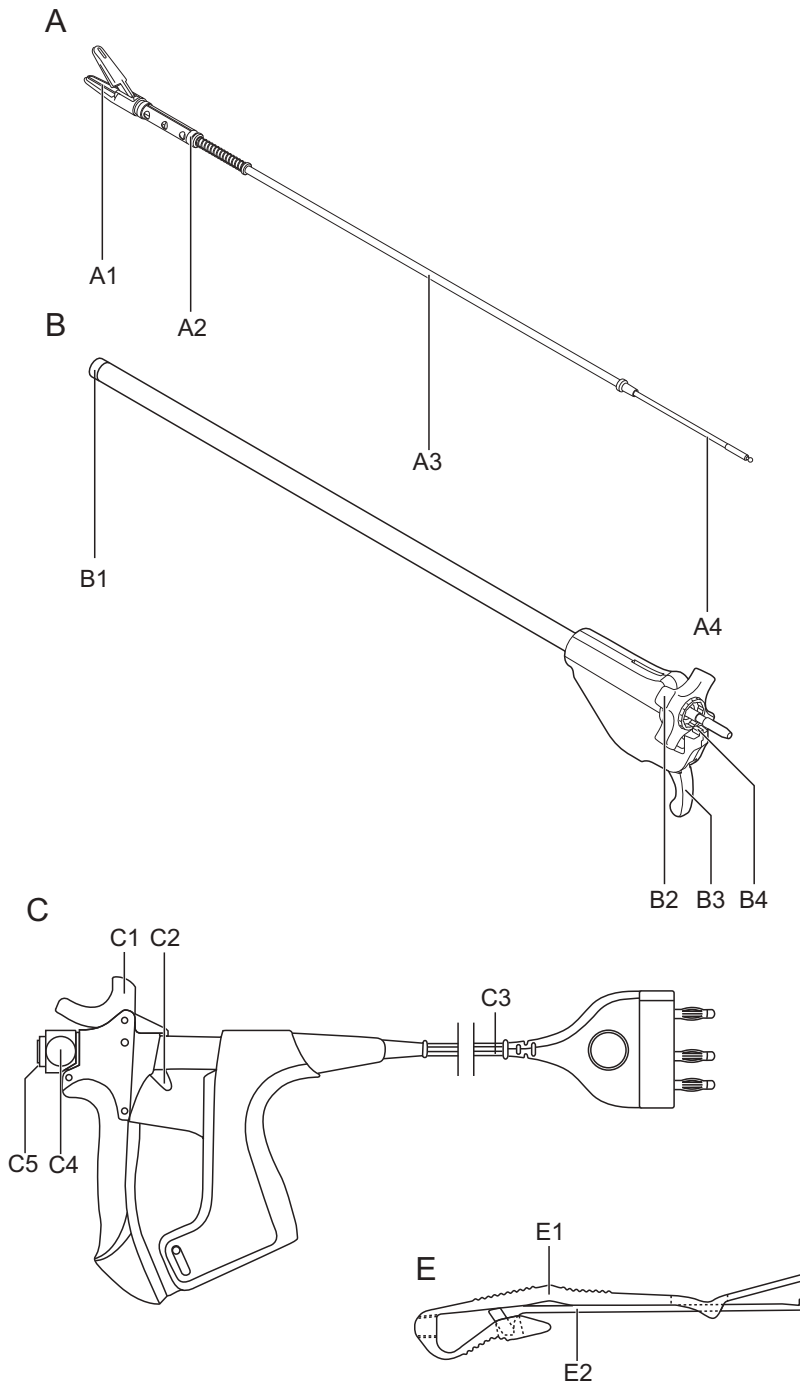
LIGATOR®



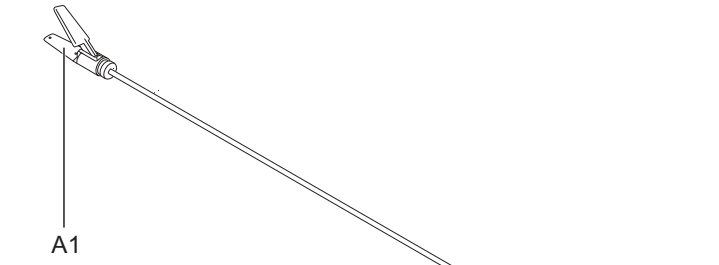
BOWA

EINFACH SICHER

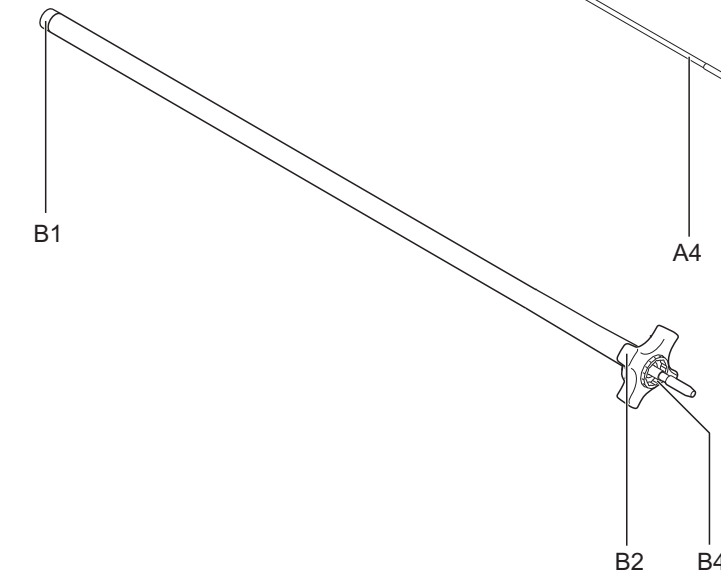
IT


A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

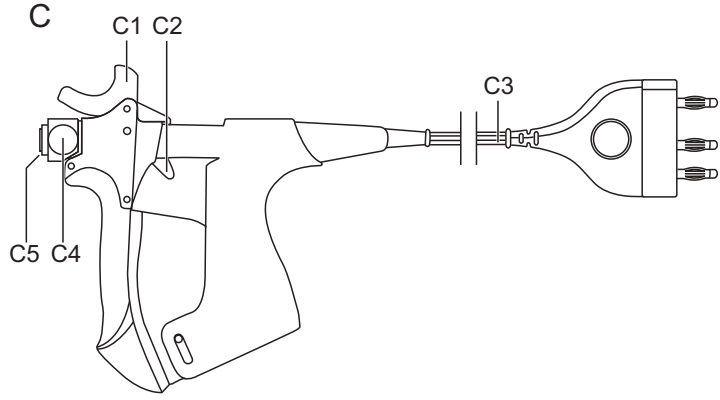
A



B



C



Legenda

A	**Branche della pinza (NightKnife con lama)**
A1	Branche della pinza con elettrodo (1x fisso, 1x mobile)
A2	Anello di guarnizione
A3	Tubo di spinta
A4	Asta di trazione
B	**Asta tubolare**
B1	Inserto filettato
B2	Ruota stellare
B3	Grilletto
B4	Molla di regolazione
C	**Manipolo**
C1	Leva d'arresto
C2	Leva di bloccaggio
C3	Cavo HF
C4	Pulsanti
C5	Sede asta tubolare con gruppo pinza
E	**Lama con introduttore**
E1	Introduttore
E2	Lama

Indice pagina

1. Utilizzo delle presenti istruzioni d’uso

Le presenti istruzioni d’uso sono parte integrante del prodotto.

BOWA-electronic GmbH & Co. KG, non si assume alcuna responsabilità, né offre garanzie
di alcun tipo, per i danni diretti e indiretti provocati dalla mancata osservanza delle istruzioni d’uso.

- ▶ Prima dell'utilizzo leggere attentamente le istruzioni per l'uso, in particolare il capitolo "Sicurezza" (vedere capitolo 2, pagina 12).
- ▶ Conservare al sicuro le istruzioni d’uso per l’intera durata del prodotto.
- ▶ Conservare le istruzioni d’uso in un luogo accessibile per il personale della sala operatoria.
- ▶ Trasmettere le istruzioni d’uso a tutti i successivi proprietari o utenti del prodotto.
- ▶ Aggiornare le istruzioni d’uso con ogni integrazione ricevuta dal produttore.

1.1. Validità

Le presenti istruzioni d'uso sono valide solo per i prodotti definiti nella pagina iniziale.

1.2. Simboli e contrassegni

1.2.1. Struttura delle avvertenze

⚠ AVVERTIMENTO

Tipo, origine e conseguenze del pericolo (danni alle persone)!

▶ Misura per prevenire il pericolo

1.2.2. Livelli di pericolo nelle avvertenze

Simbolo	Livello di pericolo	Probabilità dell'occorrenza	Conseguenze in caso di mancata osservanza delle prescrizioni
	**PERICOLO**	Pericolo incombente	Morte, gravi lesioni fisiche
	**AVVERTIMENTO**	Pericolo possibile	Morte, gravi lesioni fisiche
	**PRUDENZA**	Pericolo possibile	Lievi lesioni fisiche
	**AVVISO**	Pericolo possibile	Danni materiali

1.2.3. Suggerimenti

Suggerimenti per facilitare l'uso oppure informazioni supplementari a spiegazione di una fase di lavoro.

1.2.4. Ulteriori simboli e contrassegni

Simbolo/Contrassegno	Significato
☑	Presupposto per un’azione
▶	Azione con un passaggio
1. 2. 3.	Azione con più passaggi in sequenza vincolante
⇳	Risultato di un’azione precedente
•	Enumerazione (primo livello)
•	Enumerazione (secondo livello)
Rilievo	Rilievo
..., vedere capitolo xxx, pagina xxx	Riferimento incrociato

2. Sicurezza

2.1. Utilizzo corretto

Gli strumenti di ligazione servono per la sigillatura dei vasi di vene e arterie nonché su tessuti a struttura vascolarizzata nelle applicazioni laparoscopiche e aperte in ginecologia, urologia, chirurgia generale e altre discipline chirurgiche con l'utilizzo di corrente HF e pressione meccanica.

Inoltre gli strumenti di ligazione sono adatti per l'utilizzo nella coagulazione bipolare classica.

Gli strumenti di ligazione sono concepiti per la modalità di utilizzo bipolare "Ligation".

L'utilizzo è collegato al programma di ligazione dei generatori BOWA ARC.

Lo strumento di ligazione NightKNIFE serve inoltre per il taglio dei tessuti.

Qualsiasi altro utilizzo dello strumento di ligazione viene considerato non conforme alle disposizioni ed è pertanto da escludere!

Negli articoli COMFORT 770-000 il cavo di collegamento è saldamente collegato all'manipolo.

I generatori forniti di Plug'n Cut COMFORT rilevano gli strumenti BOWA COMFORT e selezionano automaticamente i parametri appropriati.

Con l'utilizzo degli strumenti di ligazione bipolari l'utilizzo di un elettrodo neutro non è necessario.

2.2. Avvertenze generali di sicurezza

L'apparecchio HF può essere utilizzato solo da personale tecnico sanitario qualificato. Il chirurgo ed il personale tecnico sanitario devono avere ricevuto una specifica formazione e informazione nei fondamenti e regole applicative nonché nei rischi della chirurgia HF ed averne familiarità.

- Prima di utilizzare il prodotto leggere con attenzione le istruzioni per l'uso.

Nell'ambito della vostra responsabilità di garantire la sterilità degli strumenti di ligazione nell'utilizzo è necessario osservare quanto segue:

- Pulire e sterilizzare lo strumento di ligazione prima del primo uso. Lo strumento viene consegnato non sterilizzato.
- Pulire e sterilizzare lo strumento di ligazione prima di ogni utilizzo successivo.
- Adottare solo procedure sufficientemente convalidate specifiche per il prodotto e per le apparecchiature per la pulizia, disinfezione e sterilizzazione.
- Rispettare i parametri convalidati per ogni ciclo.
- Osservare la normativa specifica del proprio paese nonché le regole relative all'igiene del proprio presidio sanitario.

Con la pulizia in bagno ad ultrasuoni e nella prepulitura manuale esiste il pericolo di infezione a causa di schizzi di acqua e vapori:

- Indossare sempre una protezione per il viso e indumenti protettivi.

Si raccomanda di impiegare sempre una ventilazione adeguata.

Pericolo di ferite provocate dalla lama affilata:

- Fare molta attenzione durante il montaggio e lo smontaggio della lama.
- Rimuovere sempre la lama intercambiabile prima di procedere con la pulizia del gruppo pinza.
- Eseguire il montaggio e lo smontaggio solo utilizzando l'introduttore per evitare di procurarsi punture o tagli.

2.2.1. Apparecchio HF

- Utilizzare solo gli apparecchi HF e i programmi approvati (vedere capitolo 8, pagina 51).
- Osservare le istruzioni per l'uso dell'apparecchio HF nonché i suggerimenti generali relativi agli interventi elettrochirurgici!

L'uso non conforme della corrente HF può provocare ustioni endogene ed esogene nonché esplosioni:

- Eseguire interventi elettrochirurgici solo con insufflazione di gas non infiammabili (CO_2).
- Evitare il contatto cutaneo diretto con i cavi HF.
- Evitare il contatto con gas e liquidi infiammabili.

2.2.2. Cavo HF

Un utilizzo errato dei cavi HF può provocare ferite al paziente.

- Non toccare mai la pelle del paziente con i cavi HF.
- Collegare lo strumento di ligazione per la coagulazione e accendere il generatore HF.
- Per inserire e staccare afferrare il cavo HF solo dal connettore.
- Utilizzare solo cavi HF in condizioni tecnicamente perfette. È proibito usare cavi HF difettosi.

Il cavo HF può provocare disturbi di immagine sul monitor:

- Non far passare il cavo HF in parallelo vicino ai cavi del monitor.
- Posare il cavo HF solo disteso.

2.2.3. Elettrodi attivi

Elettrodi difettosi o usurati possono provocare ustioni al paziente.

- Non utilizzare o riparare mai branche della pinza o superfici di elettrodo usurate o difettose. Smaltirle.

Le superfici scottanti degli elettrodi possono ferire il paziente:

- Mantenere la distanza tra la punta dello strumento e le strutture di tessuto sensibili (es. pancreas, intestino).
- Assicurarsi che per la preparazione non vengano utilizzati strumenti scottanti.

L'attivazione involontaria dello strumento di ligazione può provocare ferite al paziente:

- Non posare strumenti di ligazione sul paziente.

Elettrodi sporchi possono provocare cortocircuiti e quindi pregiudicare il funzionamento dello strumento di ligazione.

- Pulire gli elettrodi delle branche della pinza con un panno umido.
- In caso di elettrodi danneggiati sostituire il gruppo pinza.

2.2.4. Lama intercambiabile con introduttore (solo nel modello NightKNIFE fornito di lama intercambiabile)

La lama intercambiabile con introduttore non può essere riutilizzata:

- Smaltire e sostituire le lame usate con i supporti per l'inserimento.

2.2.5. Riparazioni/Manutenzione

I prodotti difettosi non devono essere riparati o sottoposti a manutenzione:

- Smaltire e sostituire i prodotti difettosi.

2.3. Avvertenze di sicurezza per danni a persone

Impostazioni errate del generatore HF e un campo di visione limitato possono provocare lesioni al paziente:

- Selezionare generatore HF e cavo HF in conformità ai requisiti dello strumento di ligazione.
- Operare solo quando il campo visivo è soddisfacente.
- Non azionare lo strumento di ligazione in modalità Autostart.

2.3.1. Pazienti con pacemaker cardiaci

Anomalie di funzionamento o rottura del pacemaker cardiaco possono mettere a repentaglio la vita del paziente oppure causargli lesioni irreversibili.

- Non eseguire mai interventi ambulanti su pazienti portatori di pace-maker cardiaci.
- In caso di pazienti con pace-maker cardiaci, prima dell'utilizzo della chirurgia HF consultare il cardiologo.
- Impostare il pacemaker a domanda sulla frequenza fissa.
- Assicurarsi che il pacemaker cardiaco non entri in contatto con l'elettrodo HF.
- Tenere a portata di mano un defibrillatore pronto all'uso.
- Eseguire un controllo post-operatorio del pacemaker.

3. Modalità di funzionamento

Nella chirurgia HF la coagulazione del tessuto si ottiene tramite l'applicazione di una corrente alternata ad alta frequenza che crea calore.

Gli strumenti di ligazione NightKNIFE e LIGATOR sono strumenti chirurgici invasivi per l'utilizzo sia per l'intervento in laparoscopia che in quello chirurgico aperto. Vengono utilizzati congiuntamente a prodotti utilizzabili endoscopicamente (es. trocar e ottica) attraverso accessi creati chirurgicamente.

Gli elettrodi attivi (branche) sono i settori non isolati delle branche della pinza.

La corrente HF scorre da una branca dello strumento attraverso il biotessuto alla seconda branca e ottiene, localmente, l'effetto di coagulazione desiderato.

Con questo processo si ottiene una sigillatura dei vasi/segmento di tessuto irrorati da sangue tramite la corrente HF e una pressione aggiuntiva.

Il punto di sigillatura viene sigillato emostaticamente in modo duraturo rispetto alla pressione sanguigna sistolica.

Con NightKNIFE grazie alla funzione di taglio integrata è possibile separare, direttamente dopo la sigillatura, il tessuto da trattare senza necessità di sostituire precedentemente lo strumento.

Con l'azionamento del manipolo le branche del gruppo pinza possono essere aperte e chiuse e bloccate con la leva di arresto.

Il gruppo pinza può essere ruotato e bloccato tramite la ruota stellare sull'asta tubolare (8x45°).

4. Montaggio

⚠ AVVERTIMENTO

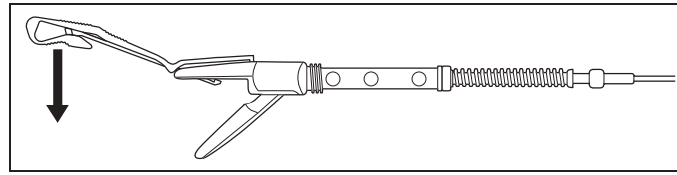
Pericolo di lesioni per il paziente provocate da strumento di ligazione non sterile!

▶ Pulire e sterilizzare lo strumento di ligazione prima dell'utilizzo, poiché lo stesso viene consegnato in stato non sterile.

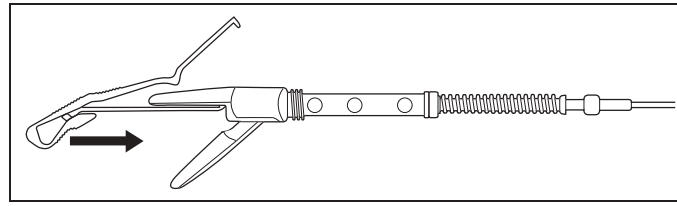
4.1. Montare la lama intercambiabile con l'introduttore (solo nel modello NightKNIFE fornito di lama intercambiabile)

☑ La lama con l'introduttore è pulita e disinfettata (vedere capitolo 7.5, pagina 41)

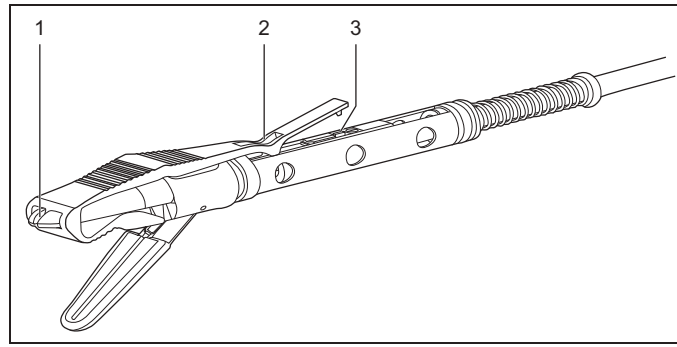
1. Rimuovere la lama completa di introduttore **E** dalla confezione sterile.



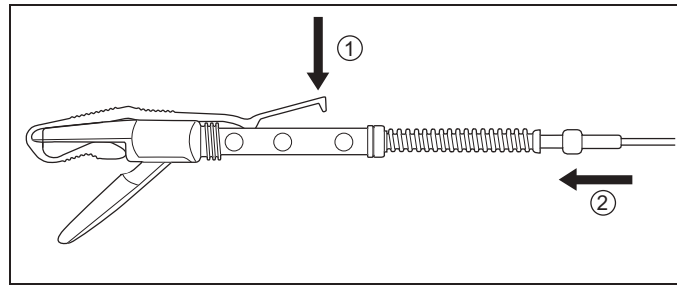
2. Ruotare il gruppo pinza **A** con l'elemento pinza fisso **A1** volto verso l'alto per aprire le branche.
3. Inserire la branche della pinza fissa **A1** tra lama **E2** e introduttore **E1**e premere l'introduttore **E1** in direzione della freccia verso il basso, per liberare la lama.



4. Inserire sull'elemento fisso delle branche della pinza **A1** la lama con l'introduttore **E** in direzione della freccia fino alla battuta.

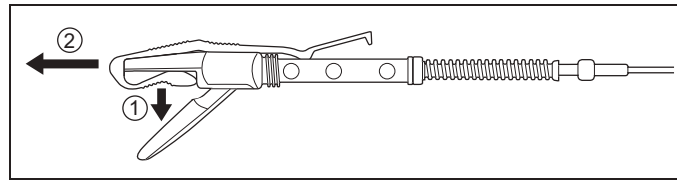


5. Accertarsi che a lama completa di introduttore **E** sia in posizione centrale rispetto alle posizioni indicate.
6. Posizionare l'introduttore **E1** eventualmente in posizione centrale con le dita.



7. Tenere saldamente l'introduttore **E1** e spingere leggermente l'introduttore **E1** in direzione della freccia verso il basso **1**.
8. Scorrere il tubo di spinta **A3** in direzione della freccia **2** fino a quando la lama **E2** non viene inserita in sede in modo udibile/sensibile.

↳ La molla rimane in stato compresso.



9. Tirare verso il basso la sezione più corta dell'introduttore **E1 1**, per tirare nuovamente in posizione la lama.
10. Rimuovere l'introduttore **E1** in direzione della freccia **2** dalle branche della pinza fisse.

▶ Custodire l'introduttore. Sarà necessario per lo smontaggio della lama.

4.2. Assemblaggio dello strumento di ligazione

1. Avvitare completamente il gruppo pinza **A** nell'asta tubolare **B**.
2. Accertarsi che non vi siano spazi tra il gruppo pinza **A** e l'asta tubolare **B**.
3. Chiudere le branche della pinza **A1** con le dita ed inserire l'asta tubolare **B** nel manipolo **C**:
   - Su NightKNIFE: Fare attenzione che la molla di direzione **B4** e la scanalatura di direzione **C5** siano nella stessa direzione.
   - Inserire l'asta tubolare **B** nel manipolo **C**.
4. Verificare la funzione di presa dello strumento di ligazione azionando il manipolo **C**.
5. Aprire aiutandosi con la leva di arresto **C1** le branche della pinza **A1**.
6. Su NightKNIFE: Verificare il funzionamento e la posizione di base della lama tramite l'azionamento del grilletto **B3**.
7. Accertarsi che la Ruota stellare **B2** si possa ruotare.

5. Utilizzo

5.1. Prima dell'uso

☑ Lo strumento di ligazione è montato (vedere capitolo 4, pagina 18) e preparato (vedere capitolo 7, pagina 31).

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente!

- ▶ Utilizzare solo i generatori HF ARC BOWA approvati con funzione di ligazione (vedere capitolo 8, pagina 51).
- ▶ Utilizzare solo i prodotti e accessori adatti conformi alla panoramica del sistema.
- ▶ Utilizzare solo prodotti in condizioni perfette e sterili.

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente provocate da bruciature e esplosioni di liquidi e gas infiammabili.

- ▶ Eseguire interventi elettrochirurgici solo con insufflazione di gas non infiammabili (CO_2).
- ▶ Evitare il contatto con gas e liquidi infiammabili (es. detergenti, disinfettanti e gas narcotici).

1. Collegare il cavo HF **C3** all'apparecchio HF e accendere l'apparecchio HF.
2. Regolare la potenza di uscita dell'apparecchio HF.

3. Prima di ogni utilizzo eseguire sempre un accurato controllo visivo e di funzionamento dello strumento di ligazione (vedere capitolo 7.6, pagina 44).

Nella posizione di base le branche della pinza **A1** sono aperte.

4. Chiudere aiutandosi con il manipolo **C1** le branche della pinza **A1**.
5. Inserire il gruppo pinza **A** nella custodia del trocar.

5.2. Durante l'intervento

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente provocate dalla regolazione errata dell'apparecchio e da un campo visivo limitato!

- ▶ Impostare la potenza di uscita dell'apparecchio HF sui parametri specificati per l'intervento.
- ▶ Utilizzare solo i programmi approvati (vedere capitolo 8, pagina 51).
- ▶ Operare solo quando il campo visivo è soddisfacente.

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente provocato da superfici scottanti degli elettrodi e fuoriuscita di vapore!

- ▶ Mantenere la distanza tra la punta dell'apparecchio e le strutture di tessuto sensibili (es. pancreas, intestino).
- ▶ Assicurarsi che per la preparazione non vengano utilizzati strumenti di ligazione scottanti.
- ▶ Non posare strumenti di ligazione sul paziente.

- ▶ Inserire lo strumento di ligazione nel corpo controllandolo a vista.

Afferrare i tessuti, fissarli e sigillarli.

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente provocate dall'attivazione involontaria dello strumento di ligazione!

- ▶ Non utilizzare mai la funzione AUTOSTART.
- ▶ Attivare la corrente HF solo il momento in cui è stabilito il contatto attivo dell'elettrodo con il tessuto da coagulare.

1. Posizionare il gruppo pinza **A** sul campo operativo.

Il gruppo pinza **A** è girevole e bloccabile ad angoli di 45°.

2. Ruotare la ruota stellare **B2**, per regolare l'angolo delle branche della pinza **A**.
3. Posizionare il tessuto da sigillare tra gli elettrodi delle branche della pinza **A1**.
4. Chiudere le branche della pinza **A1** per afferrare il tessuto.

↳ Il tessuto è stato afferrato.

5. Utilizzare le tre posizioni del manipolo **C** per adattare in modo ottimale la pressione sul tessuto per la quantità di tessuto afferrato.

↳ Il tessuto è serrato.

6. Attivare con il comando a pedale dell'apparecchio HF la corrente HF per la coagulazione:
   - Un segnale acustico fisso segnala la trasmissione di energia per tutta la durata dell'operazione di sigillatura.
   - Un segnale acustico intermittente indica il termine dell'operazione di sigillatura.
7. Lasciare il comando a pedale per interrompere l'alimentazione di energia.
8. Aprire aiutandosi con la leva di arresto **C1** le branche della pinza **A1**.

↳ Il tessuto è coagulato.

Taglio dei tessuti (solo con NightKNIFE)

⚠ AVVERTIMENTO

Forti emorragie provocate dal taglio di tessuto ricco di vasi senza precedente coagulazione o ligazione!

- ▶ Praticare sempre nel caso di vasi due sigillature a sinistra e destra della zona del taglio.
- ▶ Accertarsi, prima del taglio, che il tessuto sia ben sigillato.
- ▶ Tagliare solo nella zona sigillata.

☑ Il tessuto viene afferrato delle branche della pinza e coagulato.

1. Per effettuare il taglio, azionare il grilletto **B3** e rilasciarlo.

↳ Il tessuto è tagliato.

2. Aprire aiutandosi con la leva di arresto **C1** le branche della pinza **A1**.

Modifica della potenza di uscita dell'apparecchio HF.

▶ Prima di aumentare la potenza di uscita dell'apparecchio HFR verificare:

- il contatto perfetto di tutti i cavi HF e connettori,
- il corretto collegamento dello strumento di ligazione (vedere le istruzioni per l'uso dell'apparecchio HF),
- il funzionamento del comando a pedale,
- l'isolamento del cavo HF **C3**, le branche della pinza **A1**, l'asta tubolare **B** e la custodia del trocar,
- la pulizia e lo stato di usura degli elettrodi attivi sulle branche della pinza **A1**.

5.3. Prelievo

⚠ AVVERTIMENTO

Pericolo di lesioni per il paziente provocate da componenti rotti o danneggiati!

▶ Verificare dopo ogni prelievo del gruppo pinza. Tutti i componenti devono essere presenti.

1. Chiudere le branche della pinza **A1**.
2. Estrarre lo strumento di ligazione dalla custodia trocar.

5.4. Dopo l'uso

⚠ AVVERTIMENTO

Gli elettrodi sporchi possono provocare un guasto allo strumento di ligazione!

- Pulire gli elettrodi delle branche della pinza regolarmente **A1** con un panno umido.
- In caso di elettrodi danneggiati sostituire il gruppo pinza **A**.
- Con NightKNIFE dotato di lama intercambiabile: dopo ogni intervento sostituire la lama **E2**.

1. Dopo l'uso trattare lo strumento di ligazione (vedere capitolo 7, pagina 31).

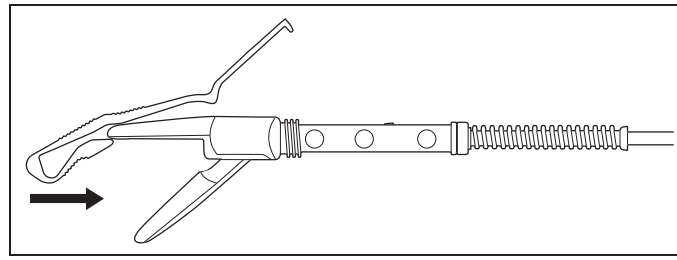
6. Smontaggio

6.1. Scomposizione dello strumento di ligazione

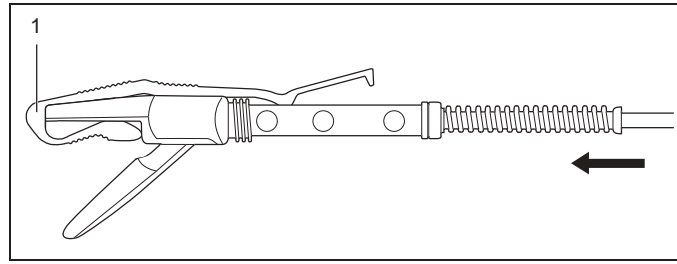
1. Tenere premuti sul manipolo **C** i pulsanti **C4** e la leva di bloccaggio **C2** e rimuovere il manipolo **C** dall'asta tubolare **B**.
2. Svitare completamente il gruppo pinza **A** dall'asta tubolare **B**.
3. Con NightKNIFE dotato di lama intercambiabile: Rimuovere la lama con l'introduttore **E** (vedere capitolo 6.2, pagina 28).

6.2. Rimuovere la lama con l'introduttore (solo nel modello NightKNIFE fornito di lama intercambiabile)

1. Ruotare il gruppo pinza **A** con l'elemento pinza fisso **A1** volto verso l'alto per aprire le branche.

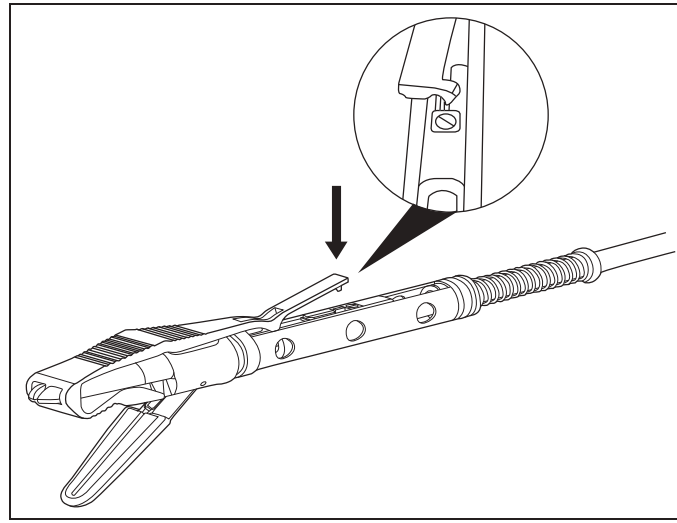


2. Tenere saldo lateralmente l'introduttore **E1** e inserire l'introduttore **E1** sulla branca fissa della pinza **A1** fino alla battuta in direzione della freccia.



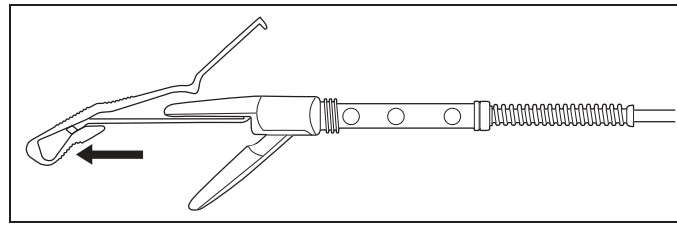
3. Accertarsi che la lama con l'introduttore **E** sulla branca fissa della pinza **A1** sia in posizione in direzione centrale **1**.
4. Posizionare eventualmente in posizione centrale l'introduttore **E1** usando le dita.
5. Tenere l'introduttore **E1** in posizione **1** lateralmente fermo e inserire lentamente il tubo di spinta in direzione della freccia fino a sentire chiaramente la lama **E2** che si inserisce in posizione.

↳ Quando la lama è saldamente inserita la molla rimane in posizione compressa,



6. Staccare con l'aiuto del cuneo sull'introduttore **E1** la lama **E2** dalla sede.

La molla si distende e il tubo di spinta scatta indietro.



7. Estrarre l'introduttore con la lama **E** in direzione della freccia e smaltire la lama insieme all'introduttore **E**.

Un riutilizzo della lama e dell' introduttore è proibito.

7. Preparazione

Gli strumenti di ligazione non possono essere utilizzati senza essere stati prima lavati, disinfettati e sterilizzati. Un lavaggio e una disinfezione efficaci sono la premessa per una sterilizzazione effettiva dello strumento di ligazione.

1. Accertarsi che vengano utilizzati per la pulizia, disinfezione e sterilizzazione solo apparecchi e procedure specifiche per il prodotto, sufficientemente convalidati e che i parametri di convalida siano rispettati per ogni ciclo.
2. Osservare la normativa specifica del proprio paese nonché le regole relative all'igiene dell'ospedale/clinica.

I dati che seguono relativi al numero di possibili cicli di trattamento sono valori indicativi. Il numero può variare in base all'uso.

Il numero di cicli di trattamento dei singoli componenti strumentali ammonta con un tempo di sterilizzazione di 20 minuti e con una temperatura di sterilizzazione di 134 °C:

- Gruppo pinza **A**: 20 volte,
- Asta tubolare **B**: fino a 200 volte,
- Manipolo **C**: fino a 100 volte.

Il trattamento dello strumento di ligazione comprende i seguenti passi:

- Ammollo
- Smontaggio
- Pretrattamento nel bagno di ultrasuoni
- Rimozione manuale dello sporco
- Trattamento a macchina in RDG
- Controllo
- Imballaggio
- Trattamento in autoclave
- Immagazzinaggio
- Test funzionale in OP

7.1. Ammollo

⚠ PRUDENZA

Pericolo di infezione tramite schizzi d'acqua e vapori dal bagno a ultrasuoni e nel prelavaggio!

- ▶ Indossare sempre una protezione per il viso e indumenti protettivi.
- ▶ Si raccomanda di impiegare sempre una ventilazione adeguata.

⚠ PRUDENZA

Su NightKNIFE: Pericolo di lesioni provocate dalla lama affilata!

- ▶ Durante il lavaggio fare molta attenzione alla lama.
- ▶ Con NightKNIFE dotato di lama intercambiabile: Rimuovere la lama dal gruppo pinza prima di procedere con la pulizia.

AVVISO

L'uso di spazzole di metallo e prodotti abrasivi danneggiano il gruppo pinza!

- Non usare mai prodotti abrasivi per la pulizia del gruppo pinza.

- Rimuovere quando necessario in precedenza, i residui di sporcizia con un tessuto non tessuto.
- Mettere lo strumento di ligazione a mollo immediatamente dopo l'uso al più tardi entro 2 ore dall'uso.
- Utilizzare solo detergenti esenti da aldeidi idonei per disinfettare strumenti di ligazione (es. omologazione DHGM, FDA o contrassegno CE).

Il disinfettante utilizzato per ammorbidire serve solo per la protezione personale e non sostituisce le fasi di disinfezione successive.

7.2. Smontaggio

1. Scomporre lo strumento di ligazione (vedere capitolo 6.1, pagina 28).
2. Con NightKNIFE dotato di lama intercambiabile: Rimuovere la lama dallo strumento di ligazione e smaltire la lama (vedere capitolo 6.2, pagina 28).

7.3. Pretrattamento nel bagno di ultrasuoni

⚠ PRUDENZA

Pericolo di infezione tramite schizzi d'acqua e vapori dal bagno a ultrasuoni!

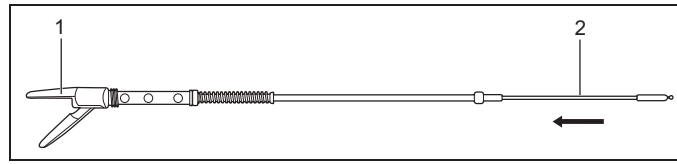
- ▶ Indossare sempre una protezione per il viso e indumenti protettivi.
- ▶ Si raccomanda di impiegare sempre una ventilazione adeguata.

1. Inserire il gruppo pinza **A**, asta tubolare **B** e manipolo **C** per almeno 5 minuti nel bagno ad ultrasuoni. Posizionare i componenti di grandi dimensioni dello strumento nel bagno ad ultrasuoni in modo che vi siano zone di ombra acustica.
2. Utilizzare per la pulizia a ultrasuoni detergenti e disinfettanti idonei (vedere capitolo 7.4, pagina 35).
3. Rispettare sempre le concentrazioni e i tempi di azione forniti dal produttore del detergente e disinfettante.

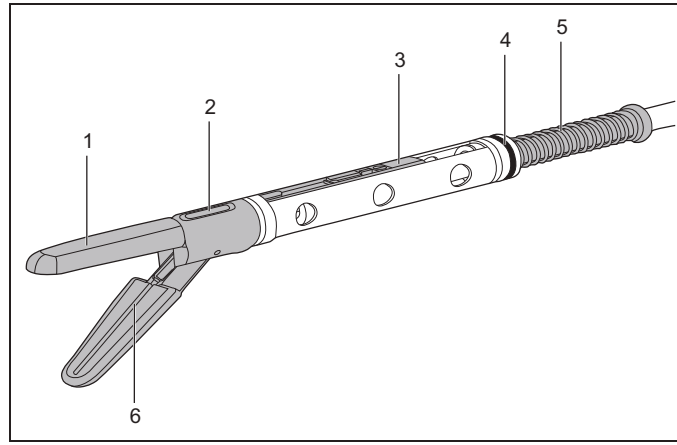
7.4. Rimozione manuale dello sporco

In questo capitolo verrà illustrato come esempio lo strumento di ligazione NightKNIFE.

Branche della pinza



1. Spingere l'asta di trazione **2** in direzione della freccia per aprire le branche della pinza **1**.



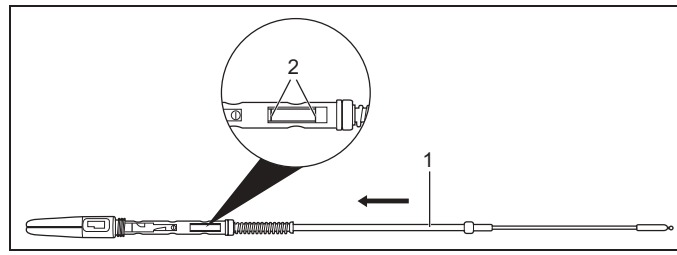
AVVISO

L'uso di spazzole di metallo danneggia il gruppo pinza!

▶ Usare solo spazzole di plastica per la pulizia del gruppo pinza.

2. Rimuovere con una spazzole di plastica e un eiettore a vapore la sporcizia nelle zone contrassegnate in grigio.
   - Branche della pinza **1**: superfici esterne, sopra e sotto, superfici degli elettrodi
   - Articolazione **2**: aperture sopra e sotto
   - Su NightKNIFE: meccanismo di arresto **3**
   - Su NightKNIFE: molla **5**
3. Su NightKNIFE: Pulire con un oggetto a punta i bordi interni di entrambe scanalature **6**.

4. Su NightKNIFE: Rimuovere con un oggetto a punta la sporcizia sotto all'anello di guarnizione **4**. Fare attenzione a non danneggiare l'anello di guarnizione con questa operazione.



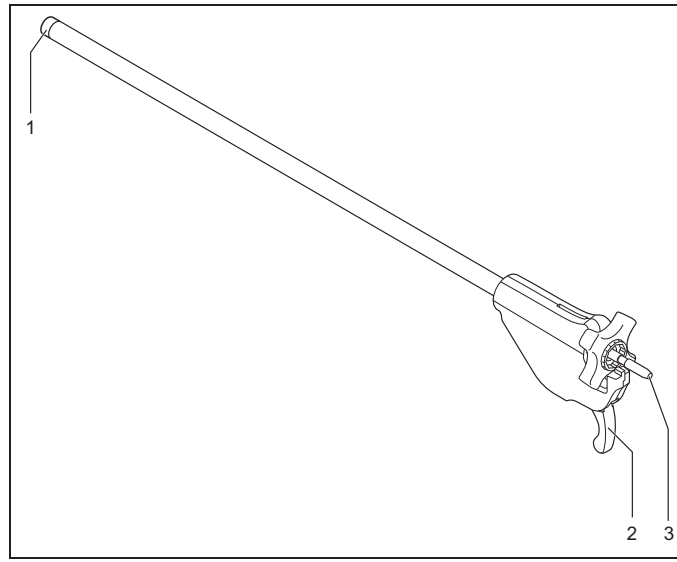
5. Spingere il tubo di spinta **1** in direzione della freccia e pulire con un eiettore a vapore le superfici aperte di rivestimento **2**.

Asta tubolare

AVVISO

L'uso di spazzole di metallo danneggia l'asta tubolare!

- ▶ Pulire l'asta tubolare solo usando le spazzole di plastica fornite in dotazione.
- ▶ Per la pulizia, se necessario, utilizzare un eiettore di vapore.



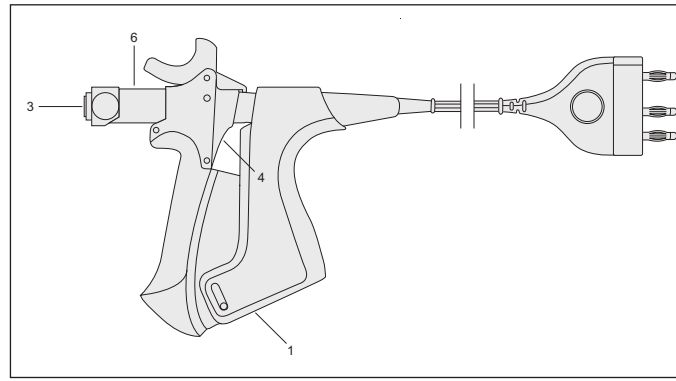
1. Pulire l'asta tubolare dall'interno con la spazzola di pulizia piccola sull'estremità prossimale **3**.
2. Pulire l'asta tubolare dall'interno con la spazzola di pulizia grande sull'estremità distale **1**.
3. Risciacquare l'asta tubolare **B** sull'estremità distale con acqua distillata o completamente demineralizzata, per pulire l'interno della scatola. Azionare il grilletto **2**, per pulire il meccanismo di azionamento nella scatola.

Manipolo

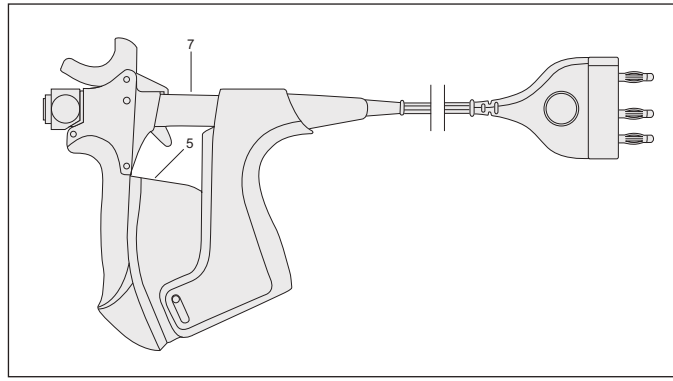
AVVISO

L'uso di spazzole di metallo danneggia il manipolo!

- ▶ Pulire il manipolo solo usando le spazzole di plastica fornite in dotazione.
- ▶ Per la pulizia, se necessario, utilizzare un eiettore di vapore.



1. Azionare il manipolo fino all'innesto e pulire le guide con la spazzola per la pulizia delle guide **6**.
2. Pulire dall'interno con la spazzola per la pulizia tutte le posizioni contrassegnate del manipolo.



3. Allentare il dispositivo di blocco del manipolo.
4. Pulire con la spazzola di pulizia i denti di arresto e guide **7** nella sezione posteriore del manipolo.
5. Pulire con la spazzola di pulizia dall'interno le posizioni contrassegnate **5** del manipolo.

Risciacquo

▶ Risciacquare a fondo dopo la prepulitura tutti i componenti dello strumento con acqua completamente demineralizzata o distillata.

7.5. Trattamento a macchina in RDG

Metodo idoneo di pulizia e disinfezione

▶ Per la pulizia e disinfezione dello strumento di ligazione utilizzare un apparecchio per la pulizia e disinfezione (RDG).

Un procedimento manuale viene sconsigliato a causa dell'evidente minore efficacia.

▶ Quando si sceglie un RDG fare attenzione a:

- la presenza di un'efficacia collaudata (es. omologazione DGHM, FDA o contrassegno CE in conformità alla normativa DIN EN ISO 15883).
- sia impiegato un programma collaudato per la disinfezione termica (minimo 5 minuti a 90 °C oppure un valore A_0> 3000). Con la disinfezione chimica esiste il pericolo che rimangano residui del prodotto disinfettante sugli strumenti.
- vi sia una scelta di programmi adeguata per lo strumento con sufficienti cicli di risciacquo.
- sia utilizzata acqua sterile/quasi sterile (max. 0 germi/ml) e povera di endotossine (max. 0,25 unità di endotossine/ml) per il risciacquo.
- venga eseguito un filtraggio dell'aria asciutta.
- vengano eseguiti una manutenzione e collaudo regolari dell'RDG.

Detergente idoneo

▶ Nella scelta di un sistema di pulizia fare attenzione a :

- il detergente utilizzato sia adatto allo strumento di ligazione.
- a condizione che non venga disinfettato termicamente e che venga utilizzato un disinfettante idoneo di efficacia collaudata (es. omologazione DGHM, FDA o contrassegno CE) compatibile con il detergente.
- I prodotti chimici utilizzati siano compatibili con i componenti dello strumento (vedere capitolo 7.4, pagina 35).

▶ Rispettare sempre le concentrazioni e i tempi di azione forniti dal produttore del detergente e disinfettante.

Pulizia e disinfezione

AVVISO

Danni al cavo HF vengono provocati quando questo è collocato in modo errato nel RDG!

▶ Fare attenzione a non schiacciare o pizzicare il cavo HF.

1. Inserire i componenti dello strumento nel RDG. Fare attenzione a quanto segue:
   - Posizionare i componenti dello strumento in modo tale che non si verifichino ombre di risciacquo
   - Inserire l'asta tubolare e il gruppo pinza nell'estremità distale nella custodia di risciacquo.

- Inserire l'asta di trazione nel gruppo pinza per aprire il più possibile le branche della pinza nella custodia di risciacquo.
- Pulire il manipolo ingranato.
- Posizionare il cavo HF lasco in un setaccio con coperchio.

2. Con NightKNIFE dotato di lama intercambiabile: prendere una nuova lama e introduttore dalla confezione e riporre lama e introduttore in un setaccio con coperchio
3. Avviare il programma.
4. Al termine del programma rimuovere i componenti dello strumento dalla RDG.

AVVISO

Danni al manipolo provocati da aria compressa!

▶ Asciugare il manipolo con aria compressa massimo 3 bar.

5. Asciugare i componenti dello strumento con aria compressa filtrata.

7.6. Controllo

Questi prodotti utilizzati come specificato dalla normativa, in funzione dall'intensità d'uso, sono soggetti a usura. Questa usura è condizionata tecnicamente e non può essere evitata.

Se il prodotto mostra esteriormente difetti evidenti o non lavora come descritto in queste istruzioni deve essere sostituito. In questo caso informare il fabbricante oppure un suo rappresentante responsabile.

- ▶ Dopo la pulizia eseguire un controllo visivo e delle funzioni dei singoli componenti dello strumento.
- ▶ Sostituire i componenti danneggiati.

7.6.1. Controlli con NightKNIFE

⚠ PERICOLO

Pericolo di ustione del paziente in caso di isolamento difettoso o vacillante!

- ▶ In caso di isolamento difettoso sostituire i pezzi dello strumento.

Branche della pinza

1. Con NightKNIFE dotato di lama intercambiabile: montare una lama nuova **E2** (vedere capitolo 4.1, pagina 18).
2. Verificare le branche della pinza **A1** per il corretto azionamento di apertura/chiusura.
3. Verificare visivamente la sfera sull'asta di trazione **A4** per la presenza di eventuali danni.
4. Muovere il tubo di spinta **A3** nel gruppo pinza **A**, per controllare la facilità di azione e la posizione di base della lama **E2**.
5. Verificare visivamente l'eventuale presenza di danni alla lama **E2**.

6. Verificare l'isolamento dell'asta di trazione **A4** per eventuali danni.
7. Verificare l'eventuale presenza di danni al rivestimento della pinza **A4**.
8. Verificare l'eventuale presenza di danni sull'anello di guarnizione **A2**.
9. Controllare se l'asta di trazione **A4** e tubo di spinta **A3** sono piegati.

Asta tubolare

1. Verificare visivamente l'eventuale presenza di danni.
2. Controllare se l'asta tubolare è piegata.
3. Accertarsi che la Ruota stellare **B2** si possa ruotare facilmente.
4. Verificare il corretto funzionamento del grilletto **B3**.

Manipolo

1. Verificare il corretto funzionamento della leva di arresto **C1**, leva di blocco **C2** e dei pulsanti **C4**.

Cavo HF

1. Verificare l'attacco per l'eventuale presenza di danni e corrosione.
2. Verificare visivamente l'eventuale presenza di danni.

7.6.2. Controlli con Ligator

⚠ PERICOLO

Pericolo di ustione del paziente in caso di isolamento difettoso o vacillante!

▶ In caso di isolamento difettoso sostituire i pezzi dello strumento.

Branche della pinza

1. Verificare le branche della pinza **A1** per il corretto azionamento di apertura/chiusura.
2. Verificare la sfera sull'asta di trazione **A4** per la presenza di eventuali danni.
3. Verificare l'isolamento dell'asta di trazione **A4** per eventuali danni.
4. Controllare se l'asta di trazione **A4** tubolare è piegata.

Asta tubolare

1. Verificare visivamente l'eventuale presenza di danni.
2. Controllare se l'asta tubolare **B** è piegata.

Manipolo

1. Verificare il corretto funzionamento della leva di arresto **C1**, leva di blocco **C2** e pulsanti **C4**.

Cavo HF

1. Verificare l'attacco per l'eventuale presenza di danni e corrosione.
2. Verificare visivamente l'eventuale presenza di danni.

7.7. Imballaggio

L'imballaggio deve essere conforme ai seguenti criteri:

- DIN EN (ANSI AAMI) ISO 11607/
  DIN EN 868-2...10 (in precedenza DIN EN 868/
  ANSI AAMI ISO 11607)
- adatto alla sterilizzazione a vapore
  (resistenti a temperatura minima 137 °C, permeabili al vapore)
- manutenzione periodica (contenitore di sterilizzazione)

▶ Imballare lo strumento di ligazione in una confezione di sterilizzazione monouso e/o un container di sterilizzazione adeguato.

Non è consentita la sterilizzazione nell'imballaggio utilizzato per il trasporto.

7.8. Trattamento in autoclave

▶ Sterilizzare lo strumento di ligazione solo quando scomposto.

AVVISO

Distruzione dello strumento di ligazione tramite processo di sterilizzazione con aria calda!

▶ Fare attenzione ad adottare un procedimento di sterilizzazione adeguato.

Per la sterilizzazione utilizzare solo la sterilizzazione a vapore con le seguenti specifiche:

- processo a vuoto frazionato (con sufficiente asciugamento del prodotto)
- conforme a DIN EN 13060 o DIN EN 285
- convalida conforme a DIN EN ISO/ ANSI AAMI ISO 17665 (in precedenza DIN EN 554/ ANSI AAMI ISO 11134) (IQ/OQ validi (commissioning) e valutazione di merito specifica per il prodotto (PQ))
- temperatura di sterilizzazione massima 134 °C (tolleranza ulteriore come da DIN EN ISO/ ANSI AAMI ISO 17665 (in precedenza DIN EN 554/ ANSI AAMI ISO 11134))
- tempo di sterilizzazione minimo 20 minuti a 121 °C o 5 minuti a 132/134 °C

L'utilizzo del meno efficace metodo gravitazionale deve essere garantito tramite una ulteriore convalida (se necessario sono richiesti tempi di sterilizzazione più lunghi).

L'utilizzo di un altro metodo di sterilizzazione (es. a base di ossido di etilene, formaldeide, a raggi al plasma a basse temperature) ricade sotto la responsabilità dell'operatore.

1. Da osservare in caso di applicazione:
   - DIN EN ISO 14937/ANSI AAMI ISO 14937,
   - normative specifiche relative al metodo.
2. Dimostrate l'adeguatezza e l'efficacia del metodo tenendo in considerazione la geometria specifica del prodotto nell'ambito della convalida (eventualmente inclusa l'analisi dei residui del mezzo di sterilizzazione)

7.9. Immagazzinaggio

1. Immagazzinare lo strumento di ligazione in luogo in cui sia protetto da:
   - forti influssi meccanici quali urti, cadute o colpi,
   - l'irradiazione diretta della luce del sole,
   - raggi X.
2. Immagazzinare lo strumento di ligazione in luogo asciutto a temperatura ambiente.

La durata dell'immagazzinaggio dello strumento di ligazione sterilizzato dipende dal tipo di confezione e dalle condizioni di immagazzinaggio.

La scatola utilizzata per la spedizione non è stata concepita per l'utilizzo per l'immagazzinaggio del prodotto.

7.10. Test funzionale in OP

1. Assemblare lo strumento di ligazione (vedere capitolo 4, pagina 18).
2. Verificare il funzionamento dello strumento di ligazione (vedere capitolo 7.6, pagina 44).

7.11. Materiali d'uso consigliati

BOWA consiglia l'utilizzo di prodotti detergenti e prodotti detergenti e disinfettanti da neutri fino a leggermente alcalini che non contengano componenti critici. A seconda della concentrazione è ammesso l'uso di prodotti con componenti di alcol e/o aldeidi.

Pretrattamento nel bagno di ultrasuoni

L'idoneità dello strumento di ligazione ad un pretrattamento efficace in un bagno ad ultrasuoni (5 min) è stato dimostrato da BOWA con l'utilizzo di un prodotto detergente e disinfettante esente da aldeidi (Gigasept Instru AF).

Pulizia a macchina

L'idoneità dello strumento di ligazione per una pulizia/disinfezione efficace tramite un procedimento meccanico (90° C 5 min) è stata dimostrata da BOWA con l'utilizzo di un prodotto detergente alcalino con additivo tensioattivo (neodisher MediCLean forte) .

Il fabbricante non può essere ritenuto responsabile per in caso di utilizzo di prodotti detergenti e disinfettanti diversi da quelli consigliati.

8. Dati tecnici

8.1. NightKNIFE / LIGATOR

Dati tecnici	
Corrente HF	4 A
Tensione alternata	> 330 kHz
Tensione max.	200 Vp sinoidale
Apparecchio HF autorizzato	Generatori BOWA ARC con software di ligazione
Programma autorizzato	LIGATION Da BOWA ARC 350L (900-350): LIGATION dal software V2.6 Effetto 2 fino all'effetto 4

9. Smaltimento

Lo smaltimento di prodotti sanitari, del materiale di confezionamento degli accessori deve essere eseguito in conformità alle normative e leggi in vigore del paese specifico d'uso.

10. Panoramica del sistema

10.1. NightKNIFE

Senza lama intercambiabile:

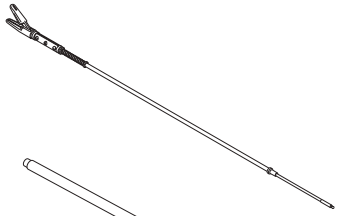
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

Con lama intercambiabile:

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Ordine presso il rivenditore specializzato

▶ 723-020 ☒ 3

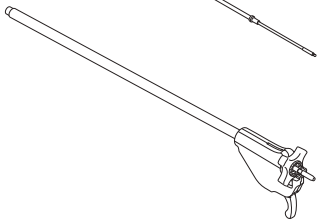


Gruppo pinza senza lama intercambiabile

- 771-136 ☐ ....
- 771-120 ☐ ....

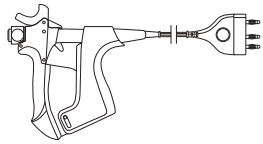
Gruppo pinza con lama intercambiabile

- 771-137 ☐ ....
- 771-121 ☐ ....



Asta tubolare

- 770-336 ☐ ....
- 770-320 ☐ ....

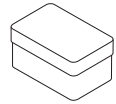


Manipolo con cavo HF

- 770-000 ☐ ....

Reinigungsbürsten-Set

- 723-030 ☐ ....



Handgriff-Ersatzteile

- 723-020 ☐ ....

Auswechselbare Klinge (5 Stück)

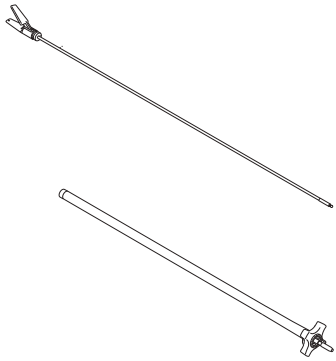
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000+770-236+723-020)

Ordine presso il rivenditore specializzato

▶ 723-020 ☒ 3

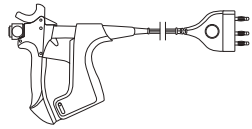


Branche della pinza

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Asta tubolare

- 770-236 ☐ ....
- 770-211 ☐ ....

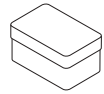


Manipolo con cavo HF

- 770-000 (nuovo) ☐ ....

Reinigungsbürsten-Set

- 723-000 ☐ ....



Handgriff-Ersatzteile

- 723-020 ☐ ....

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BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

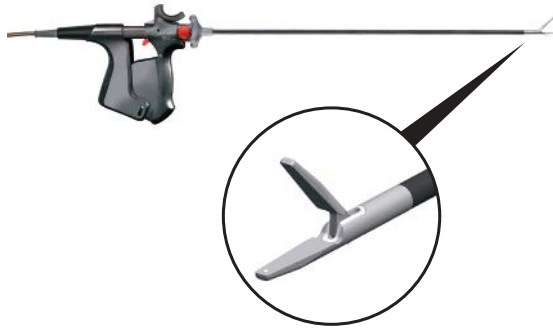
CE 0123

Contrassegno CE secondo
la Direttiva 93/42/CEE

Instrukcja obsługi

NightKNIFE®

LIGATOR®



BOWA

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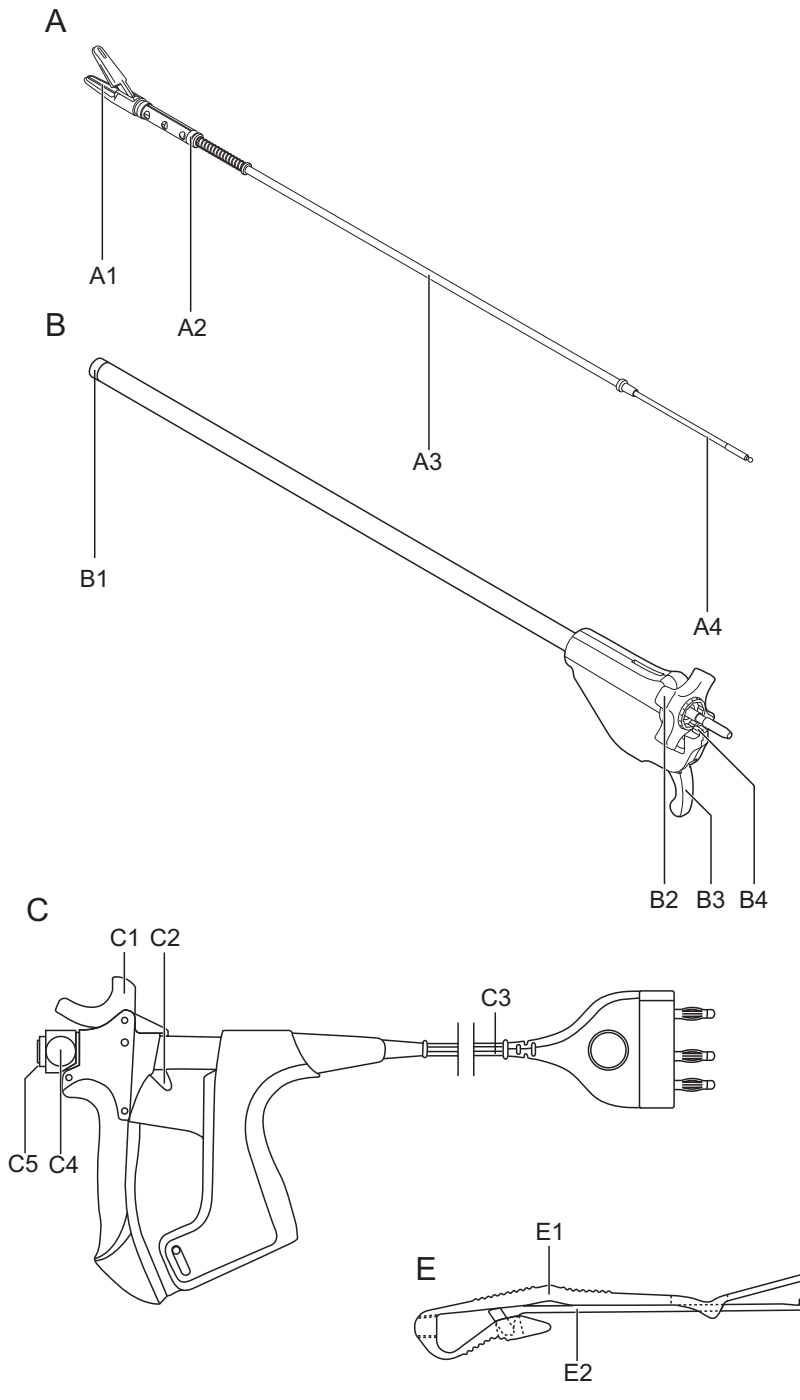
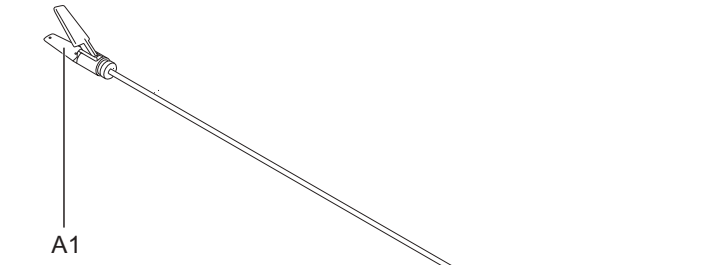
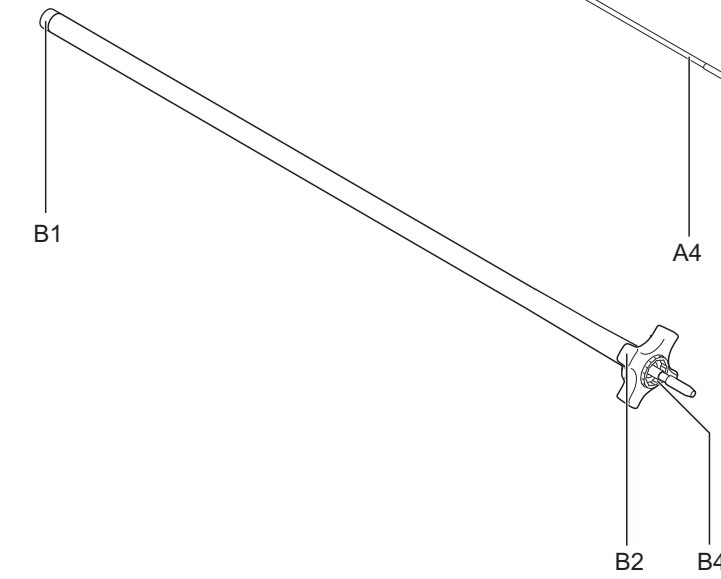
PL


A
A1
A2
A3
B
B1
A4
B2
B3
B4
C
C1
C2
C3
C5
C4
E
E1
E2

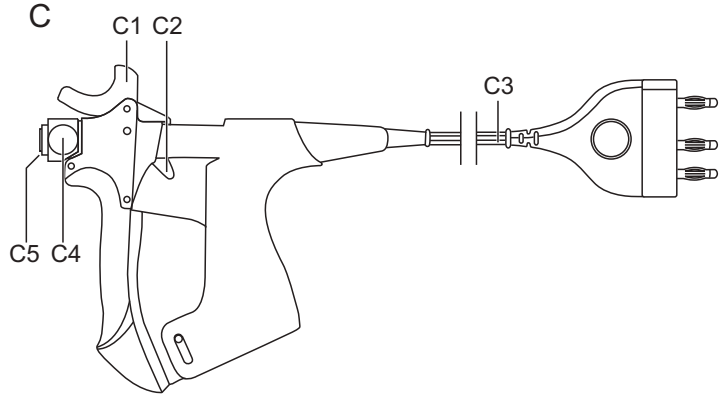
A



B



C



Legenda

A	**Wkład szczękowy (przy NightKNIFE z wymiennym ostrzem)**
A1	Szczęka z elektrodą (1x nieruchoma, 1x ruchoma)
A2	Pierścień uszczelniający
A3	Rurka wsuwna
A4	Cięgło
B	**Tuba**
B1	Tuleja gwintowana
B2	Koło gwiaździste
B3	Spust
B4	Sprężyna
C	**Uchwyt**
C1	Dźwignia zaczepowa
C2	Dźwignia ryglująca
C3	Kabel wysokiej częstotliwości
C4	Przyciski
C5	Zamocowanie dla tuby trzonowej z wkładem szczękowym
E	**Ostrze z ramieniem wprowadzającym**
E1	Ramię wprowadzające
E2	Ostrze

Spis treści

1. Stosowanie instrukcji obsługi

Niniejsza instrukcja obsługi stanowi integralną część produktu.

Firma BOWA-electronic GmbH & Co. KG nie przejmuje żadnej odpowiedzialności ani rękojmi za szkody bezpośrednie i pośrednie powstałe w wyniku nieprzestrzegania niniejszej instrukcji obsługi.

- Przed zastosowaniem urządzenia należy przeczytać uważnie instrukcję obsługi, w szczególności rozdział "Bezpieczeństwo" (patrz rozdział 2, strona 12).
- Instrukcję obsługi należy przechowywać w bezpiecznym miejscu przez cały okres użytkowania produktu.
- Instrukcję obsługi należy przechowywać w miejscu dostępnym dla personelu obsługi.
- Instrukcję obsługi należy przekazać każdemu następnemu właścicielowi lub użytkownikowi produktu.
- Instrukcję obsługi należy zawsze aktualizować w momencie otrzymania uzupełnienia od producenta.

1.1. Zakres obowiązywania instrukcji obsługi

Niniejsza instrukcja obsługi dotyczy jedynie produktów wymienionych na stronie tytułowej.

1.2. Symbole i oznaczenia

1.2.1. Struktura wskazówek ostrzegawczych

⚠ OSTRZEŻENIE

Rodzaj, źródło i skutki zagrożenia (Szkody osobowe)!

▶ Działanie zapobiegające zagrożeniu.

1.2.2. Stopnie zagrożenia podane we wskazówkach ostrzegawczych

Symbol	Stopień zagrożenia	Prawdopodobieństwo wystąpienia	Skutki nieprzestrzegania wskazówek ostrzegawczych
	**NIEBEZPIE-CZEŃSTWO**	Bezpośrednie zagrożenie	Śmierć, ciężkie obrażenia ciała
	**OSTRZEŻENIE**	Możliwe zagrożenie	Śmierć, ciężkie obrażenia ciała
	**UWAGA**	Możliwe zagrożenie	Lekkie obrażenia ciała
	**WSKAZÓWKA**	Możliwe zagrożenie	Szkody rzeczowe

1.2.3. Wskazówki i informacje dodatkowe

Wskazówki mające na celu ułatwienie pracy i dodatkowe informacje wyjaśniające daną czynność.

1.2.4. Pozostałe symbole i oznaczenia

Symbol/ Oznaczenie	Znaczenie
☑	Warunek wykonania czynności
▶	Czynność wykonywana w jednym kroku
1. 2. 3.	Czynność wykonywana w kilku krokach o obowiązującej kolejności
↳	Rezultat wynikający z poprzedniej czynności
•	Wyliczenie (pierwszy poziom)
•	Wyliczenie (drugi poziom)
Wyróżnienie	Wyróżnienie
..., patrz rozdział xxx, strona xxx	Odsyłacz

2. Bezpieczeństwo

2.1. Zastosowanie zgodne z przeznaczeniem

Instrumenty do ligacji służą do zamykania tętnic i żył oraz unaczynionych struktur tkanek w zabiegach laparoskopowych i zabiegach otwartych w ginekologii, urologii, chirurgii ogólnej i innych dyscyplinach chirurgicznych przy zastosowaniu prądu wysokiej częstotliwości i nacisku mechanicznego.

Ponadto instrumenty do ligacji mogą być stosowane w klasycznej koagulacji bipolarnej.

Instrumenty do ligacji są przeznaczone do bipolarnego trybu pracy "Ligacja".

Ich zastosowanie związane jest z programami do ligacji generatorów ARC firmy BOWA.

Instrument do ligacji NightKNIFE służy dodatkowo do cięcia tkanek.

Każde inne użytkowanie instrumentów do ligacji jest niezgodne z przeznaczeniem i należy je wykluczyć!

W przypadku artykułów COMFORT 770-000 kabel podłączeniowy jest trwale połączony z uchwyt.

Generatory z opcją Plug'n Cut COMFORT rozpoznają instrumenty BOWA COMFORT i automatycznie dobierają odpowiednie parametry.

W przypadku bipolarnych instrumentów do ligacji zastosowanie elektrody neutralnej nie jest konieczne.

2.2. Ogólne wskazówki dotyczące bezpieczeństwa

Urządzenie wysokiej częstotliwości może być użytkowane wyłącznie przez fachowy personel medyczny. Chirurg oraz fachowy personel medyczny muszą być przeszkoleni oraz powinni znać podstawowe zasady, reguły stosowania i ryzyko związane z chirurgią wysokich częstotliwości.

- Przed zastosowaniem produktów należy przeczytać uważnie instrukcję obsługi!

W ramach odpowiedzialności użytkownika za jałowość instrumentów do ligacji należy przy ich stosowaniu przestrzegać następujących zasad:

- Instrument do ligacji należy wyczyścić i wysterylizować przed pierwszym zastosowaniem. Dostarczony instrument jest niewyjałowiony.
- Instrument do ligacji należy wyczyścić i wysterylizować przed każdym następnym zastosowaniem.
- Przy czyszczeniu, dezynfekcji i sterylizacji należy stosować wyłącznie zatwierdzone metody wystarczająco odpowiednie dla określonych urządzeń i produktów.
- Przy każdym cyklu czyszczenia, dezynfekcji i sterylizacji należy zachowywać zatwierdzone parametry.
- Należy przestrzegać przepisów prawnych obowiązujących w danym kraju oraz przepisów dotyczących higieny obowiązujących w danym szpitalu.

Podczas czyszczenia w łaźni ultradźwiękowej i podczas wstępnego czyszczenia ręcznego istnieje zagrożenie zakażenia przez rozpryskującą się wodę i opary.

- Należy nosić osłonę twarzy i odzież ochronną.

Zaleca się zapewnienie wystarczającej wentylacji.

Niebezpieczeństwo skaleczenia przez ostrze:

- Podczas montażu/demontażu należy uważać na ostrze.
- Przed czyszczeniem wkładki szczękowej należy zdemontować wymienne ostrze.
- Montaż i demontaż należy wykonywać wyłącznie przy pomocy ramienia wprowadzającego, aby uniknąć spowodowania ran kłutych i ciętych.

2.2.1. Urządzenie wysokiej częstotliwości

- Należy stosować wyłącznie dopuszczone urządzenia wysokich częstotliwości i programy (patrz rozdział 8, strona 51).
- Należy przestrzegać instrukcji obsługi urządzenia wysokich częstotliwości oraz ogólnych wskazówek dotyczących zabiegów elektrochirurgicznych!

Niewłaściwe zastosowanie prądu wysokich częstotliwości może spowodować oparzenia endogenne i egzogenne oraz doprowadzić do wybuchu:

- Zabiegi elektrochirurgiczne należy przeprowadzać wyłącznie przy insuflacji gazów niepalnych (CO_2).
- Należy unikać bezpośredniego kontaktu skóry z kablami wysokiej częstotliwości.
- Należy unikać kontaktu z łatwopalnymi gazami i płynami.

2.2.2. Kabel wysokiej częstotliwości

Niewłaściwe obchodzenie się z kablem wysokiej częstotliwości może spowodować obrażenia ciała pacjenta.

- Zabrania się umieszczania kabla wysokiej częstotliwości na skórze pacjenta.
- Należy podłączyć instrument do ligacji służący do koagulacji i włączyć generator wysokich częstotliwości.
- Podczas podłączania i odłączania kabla wysokiej częstotliwości należy chwytać tylko za wtyczkę.
- Należy stosować wyłącznie całkowicie sprawne technicznie kable wysokiej częstotliwości. Nie należy stosować uszkodzonych kabli wysokiej częstotliwości.

Kabel wysokiej częstotliwości może wywołać zakłócenia obrazu na monitorze:

- Kabla wysokiej częstotliwości nie należy prowadzić bezpośrednio równolegle do kabli kamery.
- Kabla wysokiej częstotliwości nie należy układać w pętle.

2.2.3. Aktywne elektrody

Uszkodzone lub zużyte elektrody mogą spowodować oparzenia u pacjenta:

- Zabrania się używania i naprawiania uszkodzonych lub zużytych szczęk i powierzchni elektrod. Części te należy poddać utylizacji.

Gorące powierzchnie elektrod mogą spowodować obrażenia ciała pacjenta:

- Należy zachować odpowiednią odległość między końcem instrumentu a wrażliwymi strukturami tkanek (np. trzustka, jelito).
- Należy upewnić się, że przy zabiegu nie są używane żadne gorące instrumenty.

Przypadkowa aktywacja instrumentu do ligacji może spowodować obrażenia ciała pacjenta:

- Zabrania się umieszczania instrumentu do ligacji na pacjencie.

Brudne elektrody mogą doprowadzić do zwarcia i awarii instrumentu do ligacji.

- Elektrody szczęk należy czyścić regularnie wilgotną chusteczką.
- W przypadku uszkodzonych elektrod należy wymienić wkład szczękowy.

2.2.4. Wymienne ostrze z ramieniem wprowadzającym (tylko przy NightKNIFE z wymiennym ostrzem)

Nie należy ponownie używać wymiennego ostrza i ramienia wprowadzającego:

- Używane ostrza i ramiona wprowadzające należy poddać utylizacji lub wymienić.

2.2.5. Naprawa i konserwacja

Uszkodzonych produktów nie należy naprawiać ani konserwować:

- Uszkodzone produkty należy poddać utylizacji lub wymienić.

2.3. Wskazówki dotyczące bezpieczeństwa osób

Błędne ustawienia generatora wysokiej częstotliwości i ograniczone pole widzenia mogą spowodować obrażenia ciała pacjenta:

- Generator wysokiej częstotliwości i kabel wysokiej częstotliwości należy dobrać odpowiednio do wymagań instrumentu do ligacji.
- Operację należy przeprowadzić wyłącznie przy wystarczającym polu widzenia.
- Zabrania się używania instrumentów do ligacji w trybie Autostart.

2.3.1. Pacjenci ze sztucznym rozrusznikiem serca

Zaburzenia funkcjonowania lub poważne uszkodzenie sztucznego rozrusznika serca mogą doprowadzić do zagrożenia życia lub nieodwracalnych obrażeń pacjenta.

- Nie należy wykonywać zabiegów ambulatoryjnych u pacjentów ze sztucznym rozrusznikiem serca.
- W przypadku pacjentów ze sztucznym rozrusznikiem serca należy przed zastosowaniem chirurgii wysokich częstotliwości skonsultować się z kardiologiem.
- Rozrusznik serca o zmiennym rytmie (*ang. demand pacemaker*) należy ustawić na stałą częstotliwość.
- Należy się upewnić, że sztuczny rozrusznik serca nie styka się z elektrodą wysokiej częstotliwości.
- W zasięgu ręki powinien znajdować się gotowy do użycia defibrylator.
- Po przeprowadzonej operacji należy sprawdzić sztuczny rozrusznik serca.

3. Sposób funkcjonowania

W przypadku bipolarnej chirurgii wysokich częstotliwości koagulacja tkanki odbywa się przez przyłożenie prądu przemiennego o wysokiej częstotliwości, który wytwarza ciepło.

Instrumenty NightKNIFE i LIGATOR są instrumentami chirurgii inwazyjnej przeznaczonymi do wykonywania zabiegów laparoskopowych i otwartych zabiegów chirurgicznych. Stosowane są one wraz z produktami używanymi endoskopowo (np. trokary i układy optyczne) przez dojścia chirurgiczne.

Elektrody aktywne (odnogi) są nieizolowanymi obszarami szczęk.

Prąd wysokiej częstotliwości płynie od jednej odnogi instrumentu przez biotkankę do drugiej odnogi i uzyskuje ograniczony lokalnie żądany efekt koagulacji.

Podczas tego procesu wskutek działania prądu wysokiej częstotliwości przy dodatkowym nacisku zamykane jest naczynie/odcinek tkanki, przez które przepływa krew.

Miejsce zamknięcia jest zamknięte hemostatycznie, szczelnie i trwale względem skurczowego ciśnienia tętniczego krwi.

W przypadku NightKNIFE można dzięki zintegrowanej funkcji cięcia dokonać cięcia leczonej tkanki bezpośrednio po zamknięciu bez konieczności wcześniejszej zmiany instrumentu.

Szczęki przy wkładzie szczękowym można otwierać i zamykać poruszając uchwytem oraz unieruchomić za pomocą dźwigni zaczepowej.

Wkładkę szczękową można obracać i zablokować (8x45°) za pomocą koła gwiaździstego przy rurze trzonowej.

4. Montaż

⚠ OSTRZEŻENIE

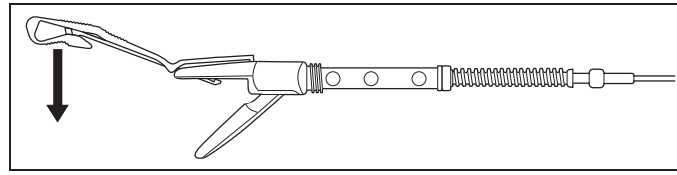
Niebezpieczeństwo uszkodzenia ciała pacjenta przez niewyjałowiony instrument do ligacji!

▶ Przed użyciem instrument do ligacji należy wyczyścić i wysterylizować, ponieważ dostarczony instrument jest niewyjałowiony.

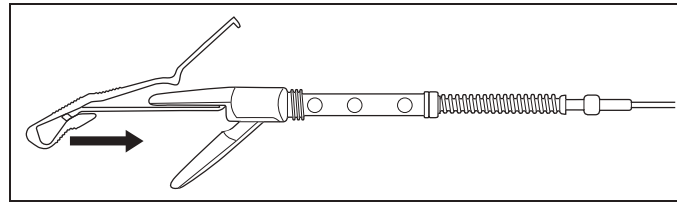
4.1. Ostrze z ramieniem wprowadzającym (tylko przy NightKNIFE z wymiennym ostrzem)

☑ Klinga z ramieniem wprowadzającym jest wyczyszczona i zdezynfekowana (patrz rozdział 7.5, strona 41)

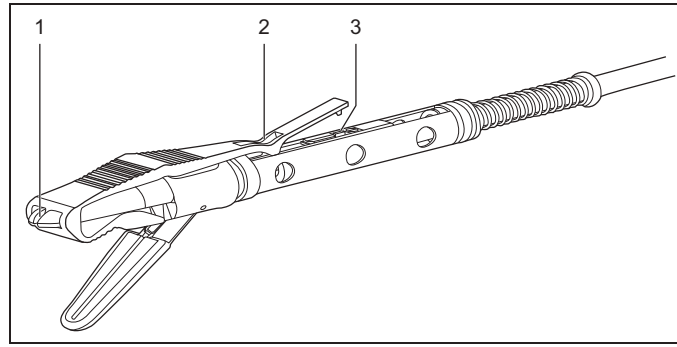
1. Wyjmij klingę z ramieniem wprowadzającym **E** ze sterylnego opakowania.



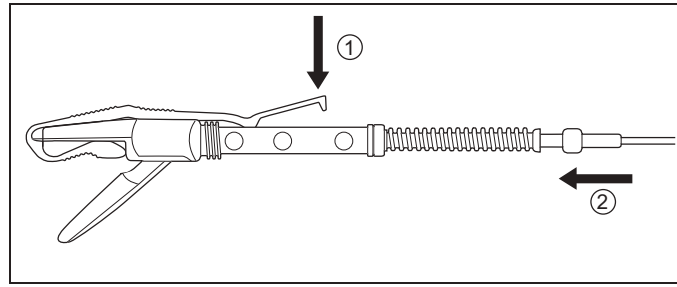
2. Obróć wkład szczękowy **A** nieruchomą szczęką **A1** do góry, aby otworzyć szczęki.
3. Włóż nieruchomą szczękę **A1** między klingę **E2** a ramię wprowadzające **E1** i naciśnij ramię wprowadzające **E1** do dołu zgodnie z kierunkiem strzałki, aby poluzować ostrze.



4. Przesuń ostrze z ramieniem wprowadzającym **E** po nieruchomej szczęce **A1** zgodnie z kierunkiem strzałki aż do momentu zazębienia się.

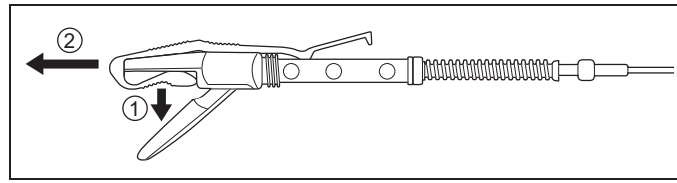


5. Upewnij się, że ostrze z ramieniem wprowadzającym **E** jest ustawione współosiowo w zaznaczonych punktach.
6. W razie potrzeby ustaw palcami współosiowo ramię wprowadzające **E1**.



7. Przytrzymaj ramię wprowadzające **E1** i naciśnij je lekko do dołu w kierunku strzałki **1**.
8. Przesuń rurkę **A3** w kierunku strzałki **2** aż ostrze **E2** zazębi się w sposób słyszalny/odczuwalny i widoczny.

↳ Sprężyna pozostaje w stanie ściśniętym.



9. Pociągnij krótszą część ramienia wprowadzającego **E1** do dołu w kierunku strzałki **1**, aby cofnąć ostrze do pozycji wyjściowej.
10. Usuń ramię wprowadzające **E1** w kierunku strzałki **2** z nieruchomej szczęki.

▶ Ramię wprowadzające należy zachować. Będzie ono potrzebne do demontażu ostrza.

4.2. Złożenie instrumentu do ligacji

1. Wkręć całkowicie wkład szczękowy **A** do tuby **B**.
2. Upewnij się, że między wkładem szczękowym **A** i tubą **B** nie ma żadnej szczeliny.
3. Zamknij palcami szczęki **A1** i włóż tubę **B** do uchwytu **C**:
   - Przy NightKNIFE: Zadbaj o to, aby sprężyna **B4** i wpust **C5** były tak samo ustawione.
   - Tuba **B** powinna zazębić się w uchwycie **C**.
4. Poruszając uchwytem **C**, sprawdź funkcję chwytania instrumentu do ligacji.
5. Otwórz szczęki **A1** za pomocą dźwigni zaczepowej **C1**.
6. Przy NightKNIFE: Sprawdź łatwość poruszania i pozycję wyjściową ostrza poprzez naciśnięcie spustu **B3**.
7. Sprawdź, czy można obracać koło gwiaździste **B2**.

5. Obsługa

5.1. Przed zastosowaniem

☑ Instrument do ligacji jest złożony (patrz rozdział 4, strona 19) i przygotowany do użycia (patrz rozdział 7, strona 32).

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta!

- ▶ Należy używać wyłącznie dopuszczonych generatorów ARC firmy BOWA z funkcją ligacji (patrz rozdział 8, strona 51).
- ▶ Należy używać wyłącznie odpowiednich produktów i akcesoriów zgodnie z wykazem elementów systemu.
- ▶ Należy używać wyłącznie całkowicie sprawnych i wyjałowionych produktów.

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta przez oparzenie i eksplozję łatwopalnych płynów i gazów!

- ▶ Zabiegi elektrochirurgiczne należy przeprowadzać wyłącznie przy insuflacji gazów niepalnych (CO_2).
- ▶ Należy unikać kontaktu z łatwopalnymi gazami i płynami (np. środki dezynfekcyjne do oczyszczania skóry i gazy znieczulające).

1. Podłącz kabel wysokiej częstotliwości **C3** do urządzenia wysokiej częstotliwości i włącz urządzenie wysokiej częstotliwości.
2. Ustaw moc wyjściową urządzenia wysokiej częstotliwości.

3. Przed każdym użyciem instrumentu do ligacji przeprowadź gruntowną kontrolę wizualną i sprawdź jego funkcjonowanie (patrz rozdział 7.6, strona 44).

W pozycji wyjściowej szczęki **A1** są otwarte.

4. Zamknij szczęki **A1** za pomocą uchwytu **C**.
5. Wprowadź wkład szczękowy **A** do tulei trokaru.

5.2. Podczas wykonywania zabiegu

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta przez niewłaściwe ustawienie urządzenia i ograniczone pole widzenia!

- Moc wyjściową urządzenia wysokiej częstotliwości należy ustawić odpowiednio do wartości wymaganej przy danym zabiegu.
- Należy stosować wyłącznie dopuszczone programy (patrz rozdział 8, strona 51).
- Operację należy przeprowadzić wyłącznie przy wystarczającym polu widzenia.

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta przez gorące powierzchnie elektrod i wylatującą parę!

- Należy zachować odpowiednią odległość między końcem urządzenia a wrażliwymi strukturami tkanek (np. trzustka, jelito).
- Należy upewnić się, że przy zabiegu nie są używane żadne gorące instrumenty do ligacji.
- Zabrania się umieszczania instrumentu do ligacji na pacjencie.

▶ Instrument do ligacji należy wprowadzić do ciała pacjenta przy kontroli wizualnej.

Chwytanie, ściskanie i zamykanie tkanek

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta przez niezamierzoną aktywację instrumentu do ligacji!

▶ Zabrania się używania funkcji AUTOSTART.

▶ Prąd wysokiej częstotliwości należy włączyć dopiero wtedy, gdy aktywne elektrody mają kontakt z tkanką przewidzianą do koagulacji.

1. Umieść wkładkę szczękową **A** w polu operacyjnym.

Wkładkę szczękową **A** można obracać i zablokować pod kątem 45°.

2. Obróć koło gwiaździste **B2**, aby ustawić kąt wkładki szczękowej **A**.
3. Umieść tkankę przewidzianą do zamknięcia między elektrodami szczęk **A1**.
4. Zamknij szczęki **A1**, aby chwycić tkankę.

↳ Tkanka została uchwycona.

5. Użyj trzystopniowego systemu zazębiania uchwytu **C**, aby dopasować optymalnie nacisk na tkankę do ilości uchwyconej tkanki.

↳ Tkanka została ściśnięta.

6. Aktywuj prąd wysokiej częstotliwości do koagulacji za pomocą przełącznika nożnego urządzenia wysokiej częstotliwości:
   - Sygnał ciągły sygnalizuje dopływ energii przez cały czas procesu zamykania.
   - Sygnał zmienny sygnalizuje zakończenie procesu zamykania.
7. Zwolnij przełącznik nożny, aby zatrzymać dopływ energii.
8. Otwórz szczęki **A1** za pomocą dźwigni zaczepowej **C1**.

↳ Tkanka została skoagulowana.

Cięcie tkanek (tylko w przypadku NightKNIFE)

⚠ OSTRZEŻENIE

Niebezpieczeństwo silnych krwawień wskutek cięcia uchwyconej tkanki bez poprzedzającej koagulacji lub ligacji!

- ▶ W przypadku naczyń należy wykonać przynajmniej 2 zamknięcia po lewej i prawej stronie od miejsca cięcia.
- ▶ Należy upewnić się, że tkanka jest na pewno zamknięta przed rozpoczęciem procesu cięcia.
- ▶ Cięcie należy wykonywać wyłącznie w obszarze zamkniętym.

☑ Tkanka została uchwycona przez szczęki i dokonano jej koagulacji.

1. W celu wykonania cięcia naciśnij spust **B3** i zwolnij go.

↳ Tkanka została przecięta.

2. Otwórz szczęki **A1** za pomocą dźwigni zaczepowej **C1**.

Zmiana mocy wyjściowej urządzenia wysokiej częstotliwości

▶ Przed zwiększeniem mocy wyjściowej urządzenia wysokiej częstotliwości należy sprawdzić:

- prawidłowy kontakt wszystkich kabli wysokiej częstotliwości i wtyczek,
- czy instrument do ligacji jest prawidłowo podłączony (patrz Instrukcja obsługi urządzenia wysokiej częstotliwości),
- funkcję przełącznika nożnego,
- izolację kabla wysokiej częstotliwości **C3**, szczęk **A1**, rury trzonowej **B** i tulei trokaru,
- czystość i zużycie elektrod aktywnych przy szczękach **A1**.

5.3. Wyjmowanie instrumentu

⚠ OSTRZEŻENIE

Niebezpieczeństwo uszkodzenia ciała pacjenta przez ułamane lub uszkodzone części!

▶ Po każdym wyjęciu instrumentu należy sprawdzić wkładkę szczękową. Wszystkie części powinny być obecne.

1. Zamknij szczęki **A1**.
2. Wyjmij instrument do ligacji z tulei trokaru.

5.4. Po zastosowaniu

⚠ OSTRZEŻENIE

Brudne elektrody mogą doprowadzić do awarii instrumentu do ligacji!

- ▶ Elektrody szczęk **A1** należy czyścić regularnie wilgotną chusteczką.
- ▶ W przypadku uszkodzonych elektrod należy wymienić wkładkę szczękową **A**.
- ▶ W przypadku NightKNIFE z wymiennym ostrzem: Po każdym zabiegu klingę **E2** należy wymienić.

1. Po użyciu instrument do ligacji należy wyczyścić (patrz rozdział 7, strona 32).

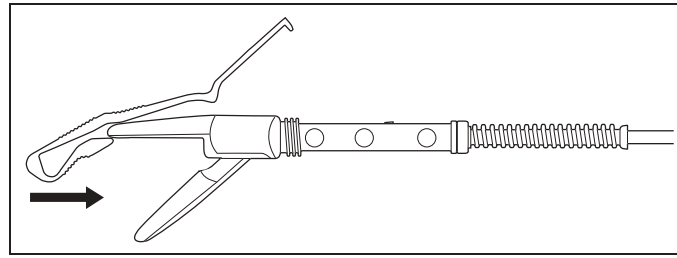
6. Demontaż

6.1. Demontaż instrumentu do ligacji

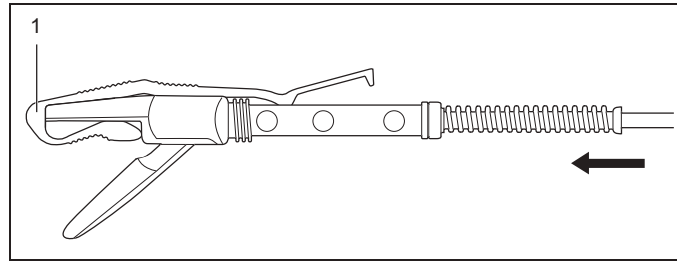
1. Przyciśnij przyciski **C4** znajdujące się przy uchwycie **C** oraz dźwignię ryglującą **C2** i odłącz uchwyt **C** od tuby **B**.
2. Odkręć wkład szczękowy **A** od tuby **B**.
3. W przypadku NightKNIFE z wymiennym ostrzem: Usuń ostrze z ramieniem wprowadzającym E (patrz rozdział 6.2, strona 29).

6.2. Demontaż ostrza z ramieniem wprowadzającym (tylko przy NightKNIFE z wymiennym ostrzem)

1. Obróć wkładkę szczękową **A** nieruchomą szczęką **A1** do góry, aby otworzyć szczęki.

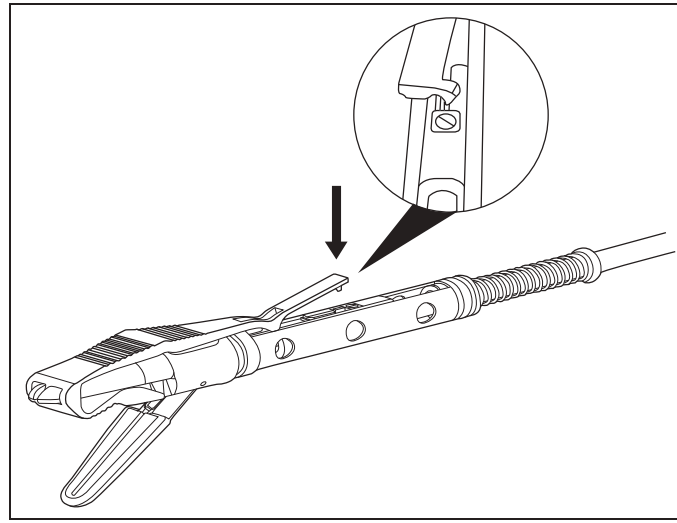


2. Przytrzymaj z boku ramię wprowadzające **E1** i przesuń je po nieruchomej szczęce **A1** aż do momentu zazębienia się w kierunku strzałki.



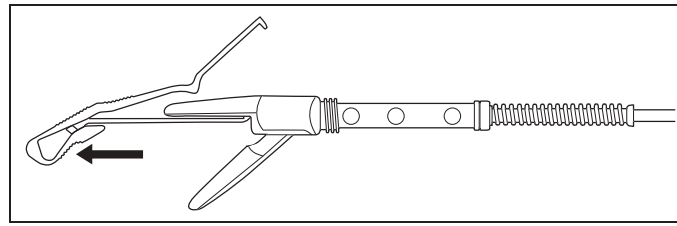
3. Upewnij się, że ostrze z ramieniem wprowadzającym **E** jest ustawione współosiowo na nieruchomej szczęce **A1** w punkcie **1**.
4. W razie potrzeby ustaw palcami współosiowo ramię wprowadzające **E1**.
5. Przytrzymaj z boku ramię wprowadzające **E1** w punkcie **1** i wsuń powoli rurkę wsuwną w kierunku strzałki aż ostrze **E2** zazębi się w sposób odczuwalny.

↳ Przy dobrze zamocowanym ostrzu sprężyna pozostaje w stanie ściśniętym.



6. Za pomocą klina przy ramieniu wprowadzającym **E1** zwolnij ostrze **E2** z zamocowania.

↳ Sprężyna rozluźnia się i rurka wsuwana cofa się.



7. Wyciągnij ramię wprowadzające z ostrzem **E** w kierunku strzałki i poddaj utylizacji ostrze z ramieniem wprowadzającym E.

Przygotowanie ostrza i ramienia wprowadzającego do ponownego użycia jest niedozwolone.

7. Przygotowanie instrumentu do użycia

Instrumentów do ligacji nie można używać bez wcześniejszego wyczyszczenia, dezynfekcji i sterylizacji. Skuteczne czyszczenie i dezynfekcja stanowią warunek skutecznej sterylizacji instrumentów do ligacji.

1. Przy czyszczeniu, dezynfekcji i sterylizacji należy stosować wyłącznie zatwierdzone metody wystarczająco odpowiednie dla określonych urządzeń i produktów. Przy każdym cyklu czyszczenia, dezynfekcji i sterylizacji należy zachować zatwierdzone parametry.
2. Należy przestrzegać przepisów prawnych obowiązujących w danym kraju oraz przepisów dotyczących higieny obowiązujących w danym szpitalu/klinice.

Podane poniżej dane dotyczące ilości możliwych cykli przygotowawczych są wartościami orientacyjnymi. Ilość cykli przygotowawczych może ulec zmianie w zależności od stopnia zużycia.

Poniżej podano ilość cykli przygotowawczych dla poszczególnych instrumentów przy czasie sterylizacji 20 minut i temperaturze sterylizacji 134 °C:

- Wkład szczękowy **A**: 20 razy,
- Tuba **B**: do 200 razy,
- Uchwyt **C**: do 100 razy.

Przygotowanie instrumentu do użycia obejmuje następujące czynności:

- Moczenie instrumentu
- Demontaż
- Wstępne czyszczenie w łaźni ultradźwiękowej
- Ręczne usunięcie zanieczyszczeń
- Czyszczenie maszynowe w urządzeniu do mycia i dezynfekcji
- Kontrola
- Zapakowanie instrumentu
- Sterylizacja w autoklawie
- Przechowywanie
- Test funkcji na sali operacyjnej

7.1. Moczenie instrumentu

⚠ UWAGA

Zagrożenie zakażenia przez rozpryskującą się wodę i opary z łaźni ultradźwiękowej i podczas wstępnego czyszczenia ręcznego!

- ▶ Należy nosić osłonę twarzy i odzież ochronną.
- ▶ Zaleca się zapewnienie wystarczającej wentylacji.

⚠ UWAGA

W przypadku NightKNIFE: Niebezpieczeństwo skaleczenia przez ostrze!

- ▶ Podczas czyszczenia należy uważać na ostrze.
- ▶ W przypadku NightKNIFE z wymiennym ostrzem: Przed czyszczeniem należy usunąć ostrze z wkładu szczękowego.

WSKAZÓWKA

Niebezpieczeństwo uszkodzenia wkładu szczękowego przez środki do szorowania i metalowe szczotki!

- Zabrania się czyszczenia wkładu szczękowego za pomocą środków do szorowania.

- W razie potrzeby należy najpierw usunąć pozostałe zabrudzenia za pomocą szmatki z włókniny.
- Instrument do ligacji należy namoczyć natychmiast, najpóźniej jednak 2 godziny po jego użyciu.
- Należy stosować wyłącznie środki dezynfekcyjne niezawierające aldehydów, które nadają się do dezynfekcji instrumentów do ligacji (np. posiadają certyfikat DGHM, certyfikat FDA lub oznaczenie CE).

Stosowany podczas moczenia instrumentu środek dezynfekcyjny służy jedynie do ochrony osobistej i nie zastępuje późniejszej dezynfekcji.

7.2. Demontaż

1. Dokonaj demontażu instrumentu do ligacji (patrz rozdział 6.1, strona 29).
2. W przypadku NightKNIFE z wymiennym ostrzem: Usuń ostrze z instrumentu do ligacji i poddaj je utylizacji (patrz rozdział 6.2, strona 29).

7.3. Wstępne czyszczenie w łaźni ultradźwiękowej

⚠ UWAGA

Zagrożenie zakażenia przez rozpryskującą się wodę i opary z łaźni ultradźwiękowej!

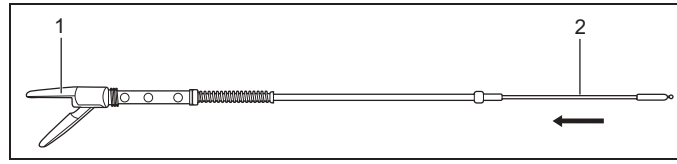
- ▶ Należy nosić osłonę twarzy i odzież ochronną.
- ▶ Zaleca się zapewnienie wystarczającej wentylacji.

1. Wkład szczękowy **A,** tubę **B** i uchwyt **C** należy umieścić w łaźni ultradźwiękowej na co najmniej 5 minut. Części o większej powierzchni należy umieścić w łaźni dźwiękowej w takiej pozycji, aby nie tworzyły się cienie akustyczne.
2. Należy stosować środki czyszczące i dezynfekcyjne nadające się do czyszczenia ultradźwiękowego (patrz rozdział 7.4, strona 36).
3. Należy przestrzegać stężenia i czasu działania podanego przez producenta środków czyszczących i dezynfekcyjnych.

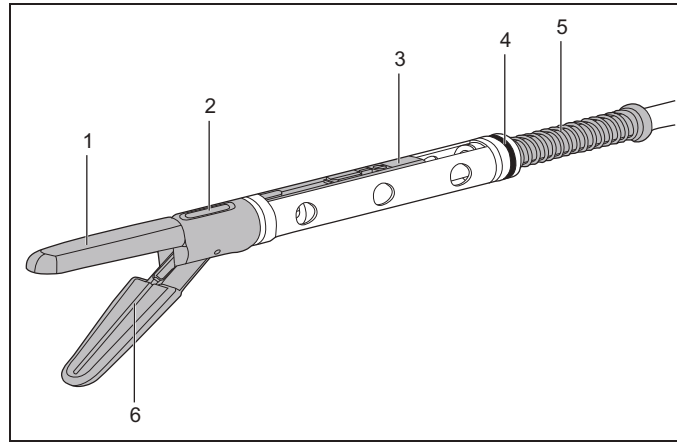
7.4. Ręczne usunięcie zanieczyszczeń

W tym rozdziale zostanie przykładowo przedstawiony instrument do ligacji NightKNIFE.

Wkładka szczękowa



1. Przesuń cięgło **2** zgodnie z kierunkiem strzałki, aby otworzyć szczęki **1**.

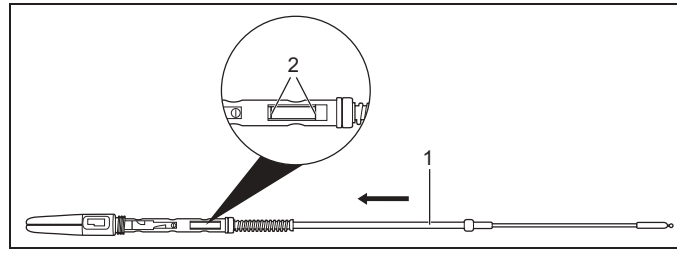


WSKAZÓWKA

Niebezpieczeństwo uszkodzenia wkładki szczękowej przez metalową szczotkę!

▶ Wkładkę szczękową należy czyścić wyłącznie przy użyciu szczotki z tworzywa sztucznego.

2. Usuń zabrudzenia z miejsc zaznaczonych na szaro za pomocą szczotki z tworzywa sztucznego i oczyszczacza parowego:
   - Szczęki **1**: górne i dolne powierzchnie zewnętrzne, powierzchnie elektrod
   - Przegub **2**: otwory górne i dolne
   - W przypadku NightKNIFE: mechanizm ryglowy **3**
   - W przypadku NightKNIFE: sprężyna **5**
3. W przypadku NightKNIFE: Za pomocą ostrego przedmiotu wyczyścić wewnętrzne krawędzie obu wpustów **6**.
4. W przypadku NightKNIFE: Za pomocą ostrego przedmiotu usuń zabrudzenia spod pierścienia uszczelniającego **4**. Uważaj, aby nie uszkodzić przy tym pierścienia uszczelniającego.



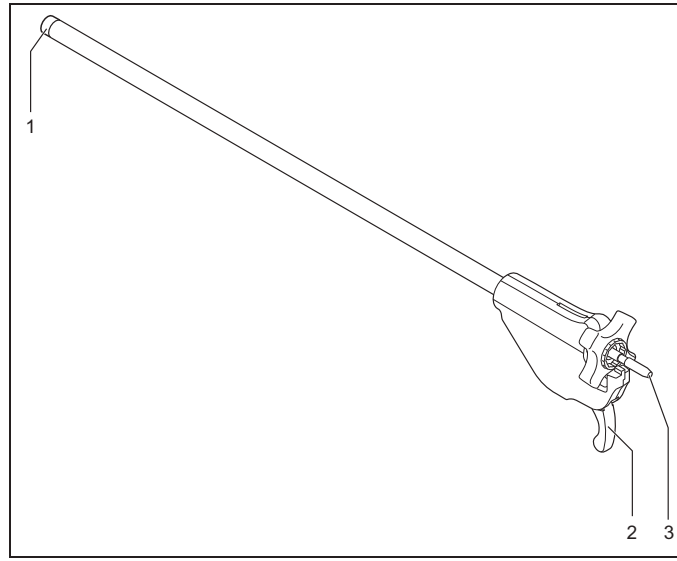
5. Przesuń rurkę wsuwną **1** w kierunku strzałki i wyczyść odkryte powierzchnie **2** przy użyciu oczyszczacza parowego.

Tuba

WSKAZÓWKA

Niebezpieczeństwo uszkodzenia tuby przez metalową szczotkę!

- ▶ Tubę należy czyścić wyłącznie przy użyciu dostarczonych szczotek z tworzywa sztucznego.
- ▶ W razie potrzeby do czyszczenia należy użyć oczyszczacza parowego.



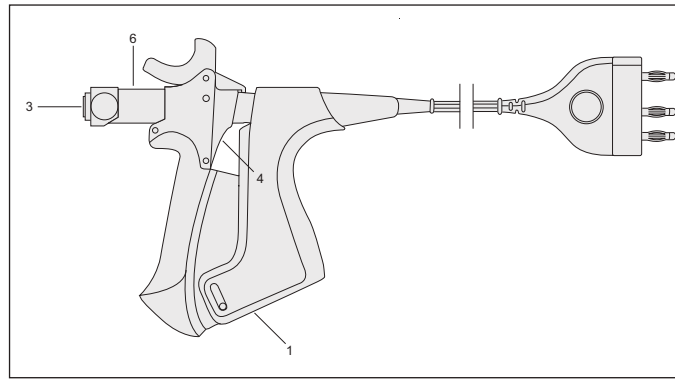
1. Wyczyść tubę od środka przy bliższym końcu **3** za pomocą małej szczotki.
2. Wyczyść tubę od środka przy dalszym końcu **1** za pomocą dużej szczotki.
3. Przepłucz tubę **B** przy dalszym końcu wodą całkowicie demineralizowaną lub destylowaną, aby oczyścić od środka obudowę. Naciśnij spust **2**, aby oczyścić mechanizm uruchamiania w obudowie.

Uchwyt

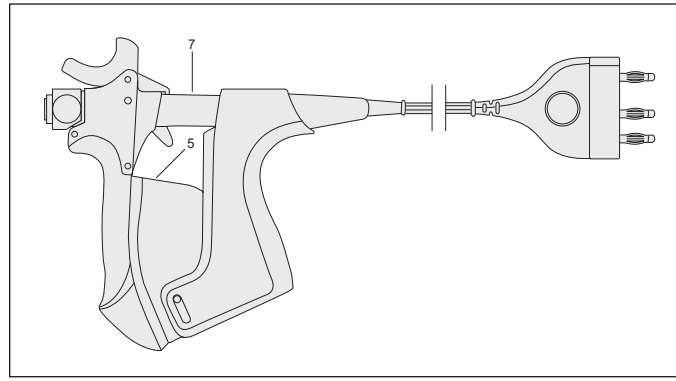
WSKAZÓWKA

Niebezpieczeństwo uszkodzenia uchwytu przez metalową szczotkę!

- ▶ Uchwyt należy czyścić wyłącznie przy użyciu dostarczonych szczotek z tworzywa sztucznego.
- ▶ W razie potrzeby do czyszczenia należy użyć oczyszczacza parowego.



1. Naciśnij uchwyt aż się zazębi i wyczyść szyny prowadzące **6** za pomocą szczotki.
2. Wyczyść od środka wszystkie zaznaczone miejsca uchwytu za pomocą szczotki.



3. Zwolnij zazębienie uchwytu.
4. Wyczyść zęby zazębienia i szyny prowadzące **7** w tylnym obszarze uchwytu za pomocą szczotki.
5. Wyczyść od środka zaznaczone miejsce uchwytu **5** za pomocą szczotki.

Przepłukanie

▶ Po zakończeniu wstępnego czyszczenia wszystkie części instrumentu należy przepłukać gruntownie wodą całkowicie demineralizowaną lub destylowaną.

7.5. Czyszczenie maszynowe w urządzeniu do mycia i dezynfekcji

Odpowiednia metoda mycia i dezynfekcji

▶ Czyszczenie ręczne nie jest zalecane ze względu na wyraźnie niewielką skuteczność.

Ein manuelles Verfahren wird aufgrund der deutlich geringeren Wirksamkeit nicht empfohlen.

▶ Przy wyborze myjni-dezynfektora należy zwrócić uwagę na to, aby:

- była udokumentowana jego skuteczność (np. przez certyfikat DGHM, certyfikat FDA lub oznaczenie CE zgodnie z normą DIN EN ISO 15883).
- posiadał program dezynfekcji termicznej (min. 5 minut przy 90 °C lub wartość A_0 > 3000). Przy dezynfekcji chemicznej istnieje niebezpieczeństwo, że resztki środków dezynfekcyjnych pozostaną na częściach instrumentu.
- posiadał odpowiedni wybór programów z wystarczającymi cyklami płukania, który jest odpowiedni dla instrumentów do ligacji.
- do płukania używana była woda jałowa/o małej ilości bakterii (max. 10 zarazków/ml) i woda o małej ilości endotoksyn (max. 0,25 jednostek endotoksycznych/ml).
- przeprowadzana była filtracja suchego powietrza.
- przeprowadzana była regularna kontrola i konserwacja myjni-dezynfektora.

Odpowiednie środki myjące

▶ Przy wyborze środków myjących należy zwrócić uwagę na to, aby:

- środek myjący był odpowiedni dla instrumentu do ligacji.
- stosowany był dodatkowo odpowiedni środek dezynfekcyjny o sprawdzonej skuteczności (np. posiadający certyfikat DGHM, certyfikat FDA lub oznaczenie CE), który jest kompatybilny ze środkiem myjącym, o ile nie jest przeprowadzana dezynfekcja termiczna.
- stosowane środki chemiczne były kompatybilne z częściami instrumentu (patrz rozdział 7.4, strona 36).

▶ Należy przestrzegać stężenia i czasu działania podanego przez producenta środków myjących i dezynfekcyjnych.

Mycie i dezynfekcja

WSKAZÓWKA

Niebezpieczeństwo uszkodzenia kabla wysokiej częstotliwości wskutek niewłaściwego ułożenia w myjni-dezynfektorze!

▶ Kabel wysokiej częstotliwości należy ułożyć tak, aby nie doszło do jego zgięcia lub przygniecenia.

1. Części instrumentu należy włożyć do myjni-dezynfektora. Należy zadbać o spełnienie następujących warunków:
   - Części instrumentu należy umieścić tak, aby nie powstał cień przeszkadzający w czyszczeniu innych elementów.

- Tubę i wkład szczękowy należy włożyć dalszym końcem do tulei.
- Cięgło przy wkładce szczękowej należy wsunąć, aby móc jak najszerzej otworzyć szczęki w tulei.
- Uchwyt należy myć w stanie zaryglowanym.
- Kabel wysokiej częstotliwości należy umieścić luźno w koszu z pokrywą.

2. W przypadku NightKNIFE z wymiennym ostrzem: Nowe ostrze z ramieniem wprowadzającym należy wyjąć z opakowania i położyć ją wraz z tym ramieniem w koszu z pokrywą.
3. Należy uruchomić program.
4. Po zakończeniu programu należy wyjąć części instrumentu z myjni-dezynfektora.

WSKAZÓWKA

Niebezpieczeństwo uszkodzenia uchwytu przez sprężone powietrze!

▶ Uchwyt należy osuszyć używając powietrza sprężonego o maksymalnej wartości 3 bar.

5. Części instrumentu należy osuszyć za pomocą przefiltrowanego sprężonego powietrza.

7.6. Kontrola

Podczas stosowania zgodnego z przeznaczeniem produkty ulegają zużyciu. Stopień zużycia zależy od intensywności użytkowania. Zużycie jest uwarunkowane technicznie i jest nieuniknione.

W przypadku, gdy produkt wykazuje zewnętrznie widoczne braki lub nie pracuje w sposób opisany w niniejszej instrukcji obsługi, należy go wymienić. W takim przypadku należy powiadomić producenta lub jego odpowiedniego przedstawiciela.

- ▶ Po zakończeniu procesu czyszczenia należy przeprowadzić kontrolę wizualną poszczególnych części instrumentu i sprawdzić ich funkcjonowanie.
- ▶ Uszkodzone części należy wymienić.

7.6.1. Kontrola instrumentu NightKNIFE

⚠ NIEBEZPIECZEŃSTWO

Niebezpieczeństwo oparzenia pacjenta w przypadku popękanej lub uszkodzonej izolacji!

- ▶ W przypadku uszkodzonej izolacji należy wymienić części instrumentu.

Wkład szczękowy

1. W przypadku NightKNIFE z wymiennym ostrzem: Załóż nowe ostrze **E2** (patrz rozdział 4.1, strona 19).
2. Sprawdź szczęki **A1** pod kątem poprawności otwierania/zamykania.
3. Sprawdź wizualnie kulkę przy cięgle **A4** pod kątem uszkodzenia.

4. Poruszaj rurką wsuwną **A3** we wkładzie szczękowym **A**, aby sprawdzić łatwość poruszania i pozycję wyjściową ostrza **E2**.
5. Sprawdź wizualnie ostrze **E2** pod kątem uszkodzenia.
6. Sprawdź izolację cięgła **A4** pod kątem uszkodzenia.
7. Sprawdź powłokę wkładu szczękowego **A** pod kątem uszkodzenia.
8. Sprawdź pierścień uszczelniający **A2** pod kątem uszkodzenia.
9. Sprawdź, czy cięgło **A4** i rurka wsuwna **A3** są skrzywione.

Tuba

1. Sprawdź wizualnie izolację pod kątem uszkodzenia.
2. Sprawdź, czy tuba jest skrzywiona.
3. Sprawdź, czy koło gwiaździste **B2** daje się łatwo obracać.
4. Sprawdź spust **B3**, czy prawidłowo funkcjonuje.

Uchwyt

1. Sprawdź dźwignię zaczepową **C1**, dźwignię ryglującą **C2** i przyciski **C4** pod kątem łatwości poruszania.

Kabel wysokiej częstotliwości

1. Sprawdź przyłącze pod kątem uszkodzenia i korozji.
2. Sprawdź wizualnie izolację pod kątem uszkodzenia.

7.6.2. Kontrola instrumentu LIGATOR

⚠ NIEBEZPIECZEŃSTWO

Niebezpieczeństwo oparzenia pacjenta w przypadku popękanej lub uszkodzonej izolacji!

▶ W przypadku uszkodzonej izolacji należy wymienić części instrumentu.

Wkład szczękowy

1. Sprawdź szczęki **A1** pod kątem poprawności otwierania/zamykania.
2. Sprawdź kulkę przy cięgle **A4** pod kątem uszkodzenia.
3. Sprawdź izolację cięgła **A4** pod kątem uszkodzenia.
4. Sprawdź, czy cięgło **A4** jest skrzywione.

Tuba

1. Sprawdź wizualnie izolację pod kątem uszkodzenia.
2. Sprawdź, czy tuba **B** jest skrzywiona.

Uchwyt

1. Sprawdź dźwignię zaczepową **C1**, dźwignię ryglującą **C2** i przyciski **C4** pod kątem łatwości poruszania.

Kabel wysokiej częstotliwości

1. Sprawdź przyłącze pod kątem uszkodzenia i korozji.
2. Sprawdź wizualnie izolację pod kątem uszkodzenia.

7.7. Zapakowanie instrumentu

Opakowanie powinno spełniać następujące kryteria:

- DIN EN (ANSI AAMI) ISO 11607/ DIN EN 868-2...10 (dotychczas DIN EN 868/ ANSI AAMI ISO 11607)
- powinno nadawać się do sterylizacji parą (odporność termiczna do 137 °C, wystarczająca przepuszczalność dla pary wodnej)
- powinno być regularnie konserwowane (kontener sterylizacyjny)

▶ Instrument do ligacji należy włożyć do jednorazowego opakowania do sterylizacji i/lub odpowiedniego kontenera sterylizacyjnego.

Sterylizacja w opakowaniu transportowym jest zabroniona.

7.8. Sterylizacja w autoklawie

▶ Instrument do ligacji należy sterylizować tylko w rozmontowanym stanie.

WSKAZÓWKA

Niebezpieczeństwo uszkodzenia instrumentu do ligacji przez sterylizację gorącym powietrzem!

▶ Należy zastosować odpowiednią metodę sterylizacji.

Należy stosować wyłącznie sterylizację parą spełniającą poniższe wymagania:

- frakcjonowany proces próżniowy (z wystarczającym osuszeniem produktu)

- zgodność z normą DIN EN 13060 lub DIN EN 285
- walidacja zgodnie z normą DIN EN ISO/ ANSI AAMI ISO 17665 (dotychczas DIN EN 554/ ANSI AAMI ISO 11134) (obowiązująca dokumentacja kwalifikacyjna IQ/OQ (kompletacja) i ocena sprawności funkcjonowania charakterystyczna dla produktu (PQ))
- maksymalna temperatura sterylizacji 134 °C (plus tolerancja zgodnie z DIN EN ISO/ ANSI AAMI ISO 17665 (dotychczas DIN EN 554/ ANSI AAMI ISO 11134))
- minimalny czas sterylizacji 20 minut przy 121 °C lub 5 minut przy 132/134 °C

Zastosowanie mniej skutecznej metody grawitacyjnej powinno być zabezpieczone przez dodatkową walidację (w razie potrzeby może być wymagany dłuższy czas sterylizacji).

Producent nie ponosi odpowiedzialności za zastosowanie innych metod sterylizacji (np. sterylizacja tlenkiem etylenu, sterylizacja formaldehydem, sterylizacja promieniami i sterylizacja plazmowa niskotemperaturowa).

1. Podczas stosowania należy przestrzegać:
   - norm DIN EN ISO 14937/ANSI AAMI ISO 14937,
   - norm obowiązujących dla danej metody.
2. Należy wykazać odpowiedniość i skuteczność metody przy uwzględnieniu specyficznej geometrii produktu w ramach walidacji (w razie potrzeby należy przeprowadzić badanie pozostałości środka sterylizującego).

7.9. Przechowywanie

1. Urządzenie do ligacji należy przechowywać w miejscu, w którym chronione jest przed:
   - silnymi, mechanicznymi oddziaływaniami, takimi jak potrącenie, upadek i uderzenie,
   - bezpośrednim promieniowaniem słonecznym,
   - promieniami rentgenowskimi.
2. Instrument do ligacji należy przechowywać w suchym miejscu w temperaturze pokojowej.

Okres przechowywania wysterylizowanego instrumentu do ligacji zależy od rodzaju opakowania i warunków przechowywania.

Karton wysyłkowy nie nadaje się do przechowywania produktu.

7.10. Test funkcji na sali operacyjnej

1. Złóż instrument do ligacji (patrz rozdział 4, strona 19).
2. Sprawdź poprawność funkcjonowania instrumentu do ligacji (patrz rozdział 7.6, strona 44).

7.11. Zalecane środki myjące i dezynfekcyjne

Firma BOWA zaleca stosowanie neutralnych i lekko alkalicznych środków czyszczących lub środków myjących i dezynfekcyjnych bez krytycznych składników. W zależności od stężenia dopuszczalne są składniki alkoholowe i/lub aldehydowe.

Wstępne czyszczenie w łaźni ultradźwiękowej

Firma BOWA wykazała, że instrumenty do ligacji nadają się do skutecznego wstępnego czyszczenia w łaźni ultradźwiękowej (5 min) przy zastosowaniu złożonego środka czyszczącego i dezynfekującego niezawierającego aldehydu (Gigasept Instru AF).

Czyszczenie mechaniczne

Firma BOWA wykazała, że instrumenty do ligacji nadają się do skutecznego mycia/dezynfekcji metodą maszynową (90 °C, 5 min) przy zastosowaniu alkalicznego środka myjącego zawierającego związki powierzchniowo-czynne (neodisher MediClean forte).

Producent nie ponosi odpowiedzialności za zastosowanie innych środków myjących i dezynfekcyjnych.

8. Dane techniczne

8.1. NightKNIFE / LIGATOR

Dane techniczne	
Prąd wysokiej częstotliwości	4 A
Napięcie przemienne	> 330 kHz
Max. napięcie	200 Vp sinusoidalne
Dopuszczone urządzenie wysokiej częstotliwości	Generatory ARC firmy BOWA z oprogramowaniem do ligacji
Dopuszczone programy	LIGATION Przy ARC 350L firmy BOWA (900-350): Ligacja od wersji oprogramowania V2.6 Efekt 2 do Efektu 4

9. Utylizacja

Utylizację produktów medycznych, materiału opakowaniowego oraz akcesoriów należy przeprowadzić zgodnie z przepisami i ustawami obowiązującymi w danym kraju.

10. Wykaz elementów systemu

10.1. NightKNIFE

Bez wymiennego ostrza:

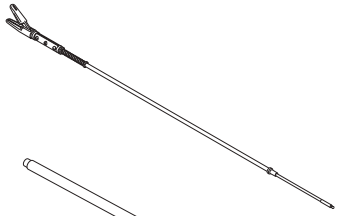
- **770-300** = 360 mm
  (770-000+770-336+771-136+723-030+723-020)
- **770-200** = 200 mm
  (770-000+770-320+771-120+723-030+723-020)

Z wymiennym ostrzem:

- **770-201** = 200 mm
  (770-000+770-336+771-121+723-030+723-020)
- **770-301** = 360 mm
  (770-000+770-336+771-137+723-030+723-020)

Zamówienie należy składać u dystrybutora

▶ 723-020 ☒ 3

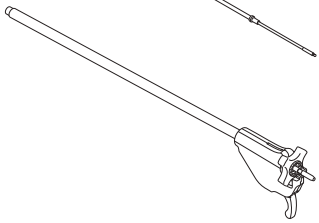


Wkładka szczękowa bez wymiennego ostrza

- 771-136 ☐ ....
- 771-120 ☐ ....

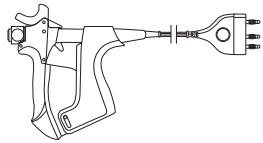
Wkładka szczękowa z wymiennym ostrzem

- 771-137 ☐ ....
- 771-121 ☐ ....



Tuba

- 770-336 ☐ ....
- 770-320 ☐ ....

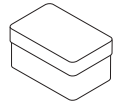


Uchwyt z kabel wysokiej częstotliwości

- 770-000 ☐ ....

Zestaw szczotek czyszczących

- 723-030 ☐ ....



Części zamienne uchwytu

- 723-020 ☐ ....

Ostrze wymienne (5 sztuk)

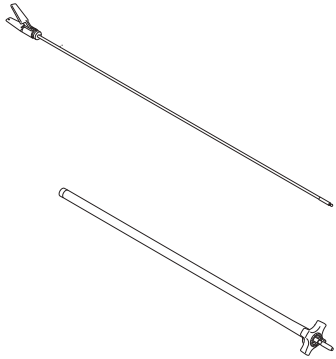
- 770-999 ☐ ....

10.2. LIGATOR

- **770-036** = 360 mm (770-000+770-236+723-020)

Zamówienie należy składać u dystrybutora r

▶ 723-020 ☒ 3.

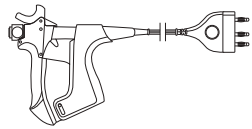


Wkład szczękowy

- 771-036 ☐ ....
- 772-036 ☐ ....
- 771-011 ☐ ....
- 772-011 ☐ ....

Tuba

- 770-236 ☐ ....
- 770-211 ☐ ....

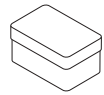


Uchwyt z kabel wysokiej częstotliwości

- 770-000 (neu) ☐ ....

Zestaw szczotek czyszczących

- 723-000 ☐ ....



Części zamienne uchwytu

- 723-020 ☐ ....

BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4–10
D-72810 Gomaringen | Germany

Phone: +49 (0) 7072-6002-0
Fax: +49 (0) 7072-6002-33
info@bowa-medical.com | www.bowa-medical.com

CE 0123

Oznaczenie CE zgodnie z normą 93/42/EWG dla urządzeń medycznych

Declaration of Conformity (DoC)

We

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4-10
72810 Gomaringen / Germany
SRN manufacturer: DE-MF-000007801

declare in sole responsibility that the medical device(s)

Basic UDI-DI UDI	4250350186085E 4250350105566
CND	**Z120109** ELECTROSURGERY INSTRUMENTS
Product code / REF	**900-400**
Device name	**Electrosurgical unit ARC 400**
Product group(s)	PG14-3
Intended purpose	Electrosurgical equipment for cutting and coagulation of tissue

to which this declaration relates is classified as **risk class IIb**, according to the rules as set out in **Annex VIII,** is in conformity with the following relevant European Union harmonization legislation:

Regulation (EU) 2017/745 relating to medical devices,

and that the device(s) is/are in conformity with the following standards and/or other normative documents

EN ISO 14971 / EN ISO 60601-1 / EN ISO 60601-2-2 / EN ISO 10993-1 / EN ISO 13485 / DIN EN ISO 20417

and that the following Notified Body performed the intervention as described and issued the certificate

Notified Body name	TUEV-SUED Product Service GmbH
Address	Ridlerstr. 65, 80339 München
Country	Germany
Identification number	0123
Description of intervention	Conformity assessment to **Annex IX**
Number certificate	**G10 016316 0022 Rev. 00**
Date certificate	2020-08-10
Duration and conditions of validity of the examination certificate	2025-08-09

Gomaringen, 2023-05-12

Head of Quality Management /
Regulatory Affairs

Wolf-Rüdiger Fritz

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany

Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa-medical.de | bowa-medical.de

Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich