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1. GENERAL OVERVIEW

SMART[™] diode laser is the latest laser device used for cutting, coagulation and tissue vaporization. High-end optical system and the availability of different light sources (405nm, 635nm, 980nm, 1470nm or 1940nm) as well as flexible fiber optic with a variety of handpieces provides a unique application scope in contact microsurgery, phlebology (EVLT and vascular therapy), proctology and Pain Management.

High power parameters of laser radiation provide unparalleled efficiency of treatments. Unique versatility of diode lasers makes them indispensable tools in every modern medical practice.

1.1. BASIC FEATURES

VERSALITY

- The device is designed to be used in many medical fields. Available In many versions, differing in power and wavelength, it can be used in a small practice as well as in a large clinic.

UNIVERSAL

- A wide variety of accessories: fibers, optical systems, handpieces, etc. provides means for treatment of a substantial number of illnesses.

PRECISION

- Choice of different work modes and their easy interchangeability along with a clearly visible pilot beam (optional green pilot beam available) are the secret behind high precision of treatments.

DURABILITY

- The most modern diode modules from renown suppliers provide years worry-free work.

1.2. APPLICATIONS

Proctology

- In proctology lasers are used commonly for the precise excision or vaporization of the hemorrhoids, polyps, fistula, fissure and pilonidal sinus. The result of the laser surgery is less discomfort, less medication, and faster healing. A hospital stay is generally not required. The laser is inherently therapeutic, sealing off nerves and tiny blood vessels. By sealing superficial nerve endings patients have a minimum of postoperative discomfort. With the closing of tiny blood vessels, the proctologist is able to operate in a controlled and bloodless environment. Laser can be use alone or in combination with other modalities.

○ Hemorrhoids

Under LA/GA, laser energy is delivered by conical fiber directly to hemorrhoidal nodes and they will obliterate from inside and this will help to preserve mucosa and sphincter structure to an extremely high precision. Laser energy is used to close off the blood supply nourishing the abnormal growth. The laser energy induces destruction of the venous epithelium and simultaneous obliteration of the hemorrhoidal pile by a shrinkage effect.

Advantage of using laser compare to conventional surgery, fibrotic reconstruction generates new connective tissue, which ensures that the mucosa adheres to the underlying tissue. This also prevents the occurrence or recurrence of prolapsed hemorrhoids. The laser procedure can be executed in only a few minutes.

○ Fistulas

Under LA/GA, laser energy is delivered, via diffuse emission fiber, into the anal fistula tract and is used to ablate thermally and close off the abnormal pathway. The laser energy induces destruction of the fistula epithelium and simultaneous obliteration of the remaining fistula tract by a shrinkage effect. The epithelialized tissue is being destroyed in a controlled way and the fistula tract collapses to a very high degree. This also supports and accelerates the healing process.

Advantage of using diode laser using diffuse emission fibre compare to conventional surgery is, it gives a good control to operator, also allows to use in convoluted tract, no excision or splitting independent on the length of the tract. This laser procedure can be executed in only a few minutes.

Phlebology (EVLT)

- Endovascular surgery is a form of minimally invasive surgery that was designed to access many regions of the body via blood vessels. Laser endovascular treatment is a one-hour procedure that replaces the surgical stripping and binding commonly associated with varicose vein treatment. Unlike the traditional method, which many patients found very painful and required up to

six weeks recovery time, laser vein ablation involves minimal discomfort and immediate recovery for most patients. This procedure is often ideal for treating greater saphenous vein incompetence, which causes varicose veins. The laser used in the procedure destroys the greater saphenous vein, relieving the backflow pressure and allows the blood to flow in the right direction. This eliminates the varicose vein and the pain caused by it.

Within this method is possible:

- treatment of the vascular changes in the transdermal mode (with skin cooling), EVLT treatment of the saphenous vein and varicose veins
- removal of the dilated blood vessels
- removal of the spider veins

Contact Microsurgery – excision of warts, fibromas, yellow tufts

○ **Anal Fissure**

Anal Fissure is a small cut or a tear in the skin that lines the anus. Anal fissures are caused as a result of passing large or hard stool during bowel movement. The condition is not life-threatening or serious and can easily be treated with medication or laser therapy.

Smart M Laser Sphincterotomy or LASER treatment is opted when a patient suffers from chronic fissure. During the treatment process, the surgeon uses laser to create an incision. This helps to relax the tight anal sphincter muscles thereby helping in healing of the fissure.

○ **Pilonidal Sinus/Cyst**

A pilonidal cyst is an abnormal pocket in the skin that usually contains hair and skin debris. A pilonidal cyst is almost located near the tailbone at the top of the cleft of the buttocks.

These pilonidal cysts typically occur when hair punctures the skin and then becomes embedded. If a pilonidal cyst becomes infected, the resulting abscess is often extremely painful. The cyst can be drained through a small incision or removed surgically.

Pilonidal cysts most commonly occur in young men, and the problem has a tendency to recur. People who sit for prolonged periods of time, such as truck drivers, are at higher risk of developing a pilonidal cyst.

This is a minimally invasive procedure done using the Smart M 1470nm diode laser. In Laser Pilonidal sinus surgery, a small cut is made on the skin and all the pus is drained out. The entire sinus tract is then sealed with the laser diffuse emission fiber.

○ Anal Warts

Anal warts, also known as condyloma, are growths found on the skin around the anus (rectal opening) and sometimes in the anal canal.

Smart M Laser surgery uses an intense beam of light, or laser, to burn and destroy the wart tissue. It is usually done in a doctor's office or clinic. Local or general anesthetic may be used, depending on the number of warts to be removed or the size of the area to be treated.

Pain Management (LLLT, Biomodulation with 635nm)

- Treatment of open ulcers, wound, diabetic foot, bedsores, stimulation of wound healing, reducing the inflammatory, process swelling and pain

Smart M 635nm laser is invaluable therapeutic modality for treating most wounds. Wound healing entails a) the process of inflammation during which the hematoma formed in and around the wound site is resolved; b) cellularity and protein synthesis, i.e., two processes that culminate in the formation of granulation tissue; and c) wound remodeling, a process that may continue long after the wound may be said to be well healed. The evidence today is that laser Biostimulation:

- Accelerates the inflammatory phase of wound healing by altering the levels of those prostaglandins that influence the process.
- Quickens protein synthesis by quickening DNA and RNA synthesis, and augments fibroplasia thereby promoting cell proliferation and formation of granulation tissue
- Increases ATP synthesis by enhancing electron transfer in the inner membrane of mitochondria, thus providing the extra energy required for protein synthesis and cell proliferation.
- Enhances the ability of immune cells to combat pathogens; thus minimizing the impact of infection. Hence, chronic wounds such as those of decubitus ulcers and burns may heal faster when stimulated with laser.

DIAGNOSTICS WITH 405nm

- Detection of inflammation zone and bacterial infection with 405nm

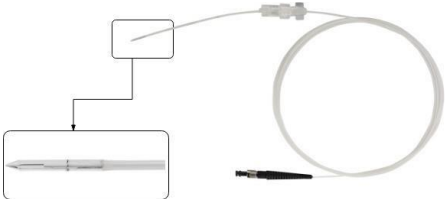
2. TECHNICAL PARAMETERS

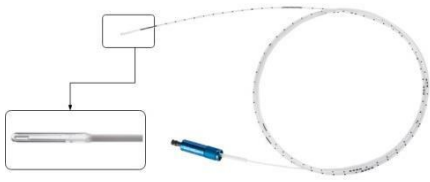
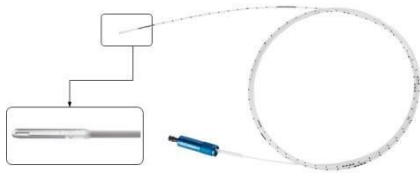
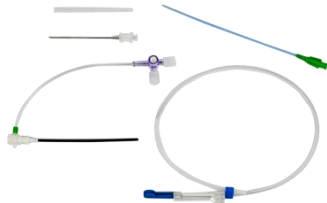
Laser type:	diode, semiconductor	
Operation mode:	continuous or pulsed	
Wavelength:	405nm, 635nm, 980nm, 1470nm or 1940nm	
Max power:	up to 30W (for 980nm)	
Pulse time:	0.05 - 10 000ms	
Frequency:	0.05 - 10 000Hz	
Controller:	microprocessor	
Display:	TFT with touch panel	
Beam delivery:	fiber optic with SMA 905 connector	
Fiber diameter:	min 200µm	
Fiber length:	3 m	
Pilot beam:	red, 635nm – 0,5mW	
Beam emission initiation:	footswitch	
Power:	(100-240)V / 50-60Hz	
Cooling system:	internal, air and thermoelectric cooling	
Laser dimensions:	270 x 245 x 90mm	
Weight:	2,7kg	
Safety class:	electrical	I type B
	laser	4

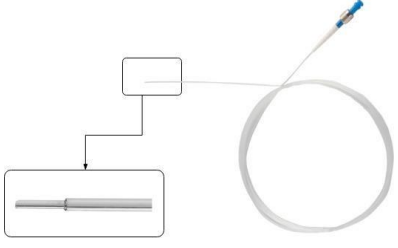
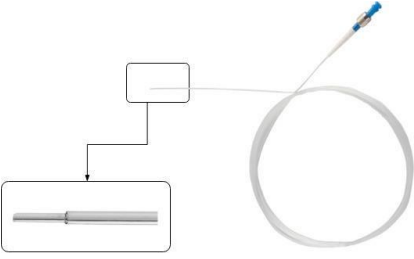
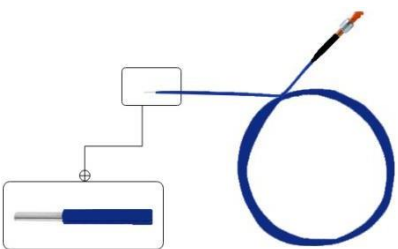
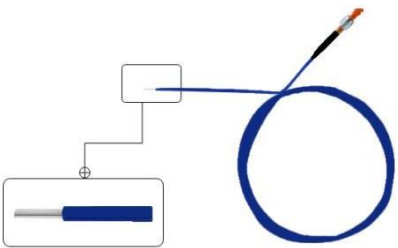
3. LASER EQUIPMENT

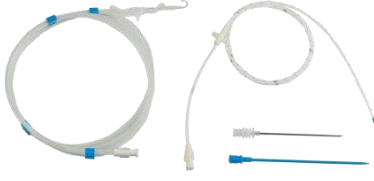
LASER MODEL	SMART TM 1470nm (12W) 980nm (15W)	SMART TM 980nm (15W)	SMART TM 1470nm (15W)	SMART TM 1940nm (7W)	SMART TM 635nm (0.5W)
APPLICATIONS					
Vascular Surgery (EVLT)	●	○	●	●	○
Microsurgery	●	●	○	○	○
Vascular Therapy	●	●	○	○	○
Proctology	●	●	●	○	○
(LLLT) – Biomodulation with 635nm	○	○	○	○	●
Diagnostics with 405nm	○	○	○	○	○
BASIC EQUIPMENT PACKAGE (INCLUDED IN THE LASER PRICE)					
Bare optical fiber (400µm or 600µm fiber core, 3m long, disposable) (12,13)	●	●	●	○	○
Diffuse emission fiber (400µm or 600µm fiber core), EVLT (9,10)	○	○	○	●	○
Catheter set 6F (11)	○	○	○	●	○
Reusable cannulas (5,6)	●	●	●	○	○
Universal surgical handpiece (4)	●	●	●	○	○
Safety glasses 980nm (29)	○	●	○	○	○
Safety glasses universal (405nm / 635nm / 980nm) (30)	○	●	○	○	○
Safety glasses 980nm/1470nm (32)	●	○	○	○	○
Safety glasses 1470nm/1940nm (31)	○	○	●	○	○
Safety glasses 635nm or 405nm (27 or 28)	○	○	○	○	●
Therapeutic laser handpiece 635nm or 405nm (21 or 22)	○	○	○	○	●
Therapeutic tip for BIO (lenticular) ø14mm for 635nm/405nm (24)	○	○	○	○	●
Connection cable for handpiece 635nm/405nm (23)	○	○	○	○	●
SMART^{KEY} - USB, Power cord / AC adapter / Warning labels / Footswitch / Transportation case with accessories.	●	●	●	●	●

4. FULL LIST OF LASER ACCESSORIES:

NO.	NAME AND SPECIFICATION	PRODUCT NAME
1.	Proctology handpiece (including adapter luer slip (LS) internal diameter 2.5mm for proctology) Part no.: 170042	
2.	Conical Fiber (600µm fiber core, 3m long, standard SMA 905 connector with knurl nut, disposable) Part no.: 250026	
3.	Proctology cannula 14Gx6cm Part no.: 170032	
4.	Handpiece for microsurgery applications Part no.: 170027.02	
5.	Proctology cannula L50 straight (length 50 mm) (reusable) Part no.: 170040	
6.	Proctology cannula L50R110 curved (length 50 mm) (reusable) Part no.: 170040.01	

7.	Adapter luer slip (LS) internal diameter 1mm for proctology compatible with handpiece for microsurgery applications Part no.: 560074	
8.	Adapter luer slip (LS) internal diameter 2,5mm for proctology compatible with handpiece for microsurgery applications Part no.: 560074.01	
9.	Diffuse emission fiber (400µm fiber core, 2.6m long, SMA905 connector, disposable) Part no.: 250045	
10.	Diffuse emission fiber (600µm fiber core, 2.6m long, SMA905 connector, disposable) Part no.: 250046	
11.	Catheter set for diffuse emission fibers 6F (sheath introducer, dilator, guidewire, puncture needle) Part no.: 250042	

12.	Bare optical fiber (400µm fiber core, 3m long, SMA905 connector/ open-ended, disposable) Part no.: 250016	
13.	Bare optical fiber (600µm fiber core, 3m long, SMA905 connector/ open-ended, disposable) Part no.: 250017	
14.	Bare optical fiber (400µm fiber core, 3m long, SMA905 connector/ open-ended, reusable - up to 10 sterilizations) Part no.: 250018	
15.	Bare optical fiber (600µm fiber core, 3m long, SMA905 connector/ open-ended, reusable - up to 10 sterilizations) Part no.: 250019	
16.	Handpiece for dermatology with fiber optic cable 320µm diameter (grey), beam spot diameter regulated: 0.5mm, 1.0mm, 1.5mm for 980nm laser (1 wavelength) Part no.: 170044	

17.	EVLT Catheter 14G for bare fiber, 70cm long, Seldinger Puncture needle 18 G – 7 cm, Dilator 7 F – 10 cm, Guide wire 0.035" - 150cm J-tip Part no.: 250020 (70cm long)	
18.	Lock Adapter for EVLT Catheter Part no.: 250022	
19.	Stripper for optical fibers Part no.: 690012	
20.	Carbide fiber optic scribe Part no.: 690002.01	
21.	Therapeutic laser handpiece 635nm Part no.: 170043.01	
22.	Therapeutic laser handpiece 405nm Part no.: 170043.02	

23.	Connection cable (between diode laser housing and therapeutic handpiece) Part no.: 170031	
24.	Therapeutic tip for biostimulation (lenticular) ø14mm for 635nm/405nm Part no.: 170020	
25.	Adaptor for fiber therapeutic biomodulation and diagnostics tips (635nm/405nm) Part no.: 170024	
26.	Therapeutic tip for biomodulation and diagnostics (fiber) 8mm/8mm diameter (405nm) Part no.: 170025	
27.	Safety glasses for 635nm Part no.: 260001	
28.	Safety glasses for 405nm Part no.: 260006	
29.	Safety glasses for 980nm Part no.: 260010	

30.	Safety glasses universal for 405nm, 635nm and 980nm Part no.: 260005	
31.	Safety glasses for 1470nm/1940nm Part no.: 260008	
32.	Safety glasses for 980nm/1470nm Part no.: 260016	
33.	SMART^{KEY} USB with manual and personal patient database Part no.: 470001.01	
34.	Foot switch Part no.: 120051	

35.

SMARTTM diode
laser workstation
Laser device position
adjustable
Shelf for all optical
accessories
Basket for footswitch
and protective glasses
Cable and power
supply management
system.
Well balance and
movable trolley

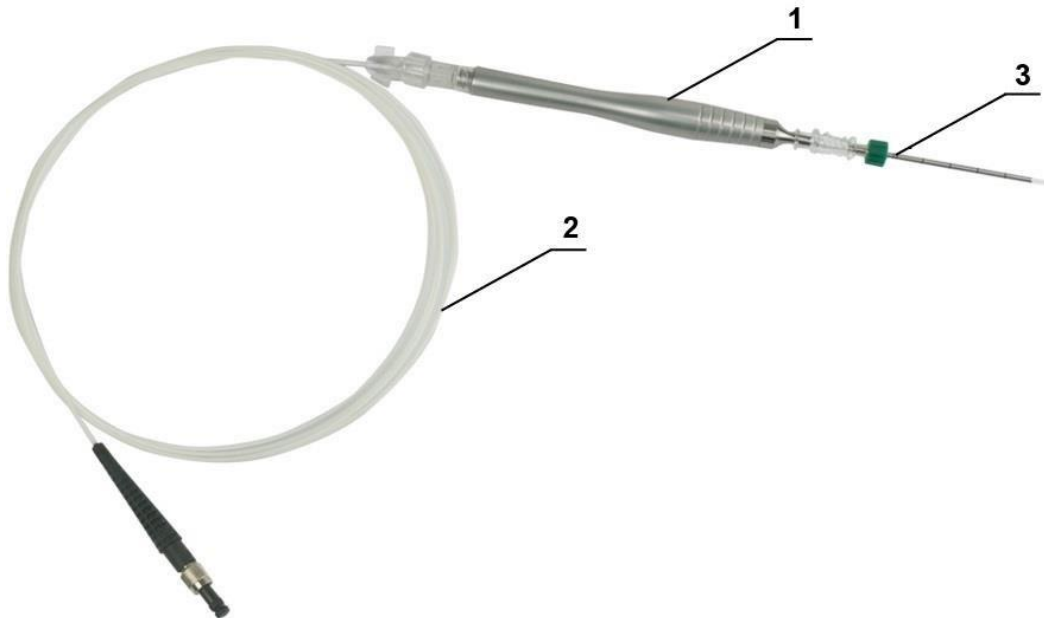
Part no.: 180006.24
24V



Exemplary sets for:

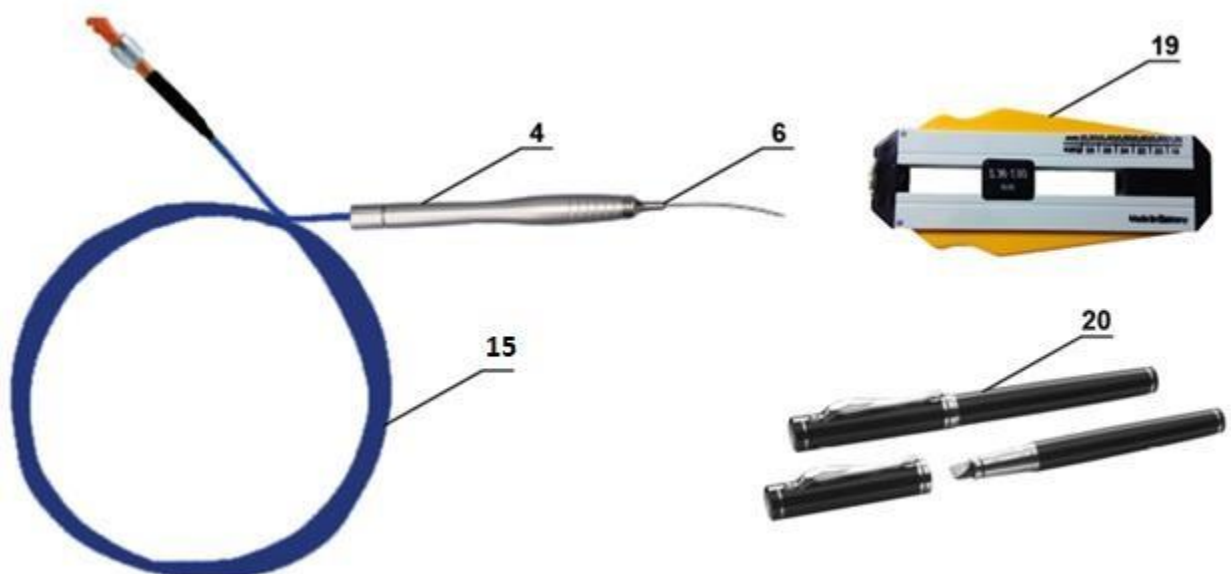
1. HEMORRHOIDS WITH CONICAL FIBER

p. 1, p. 2 and p.3



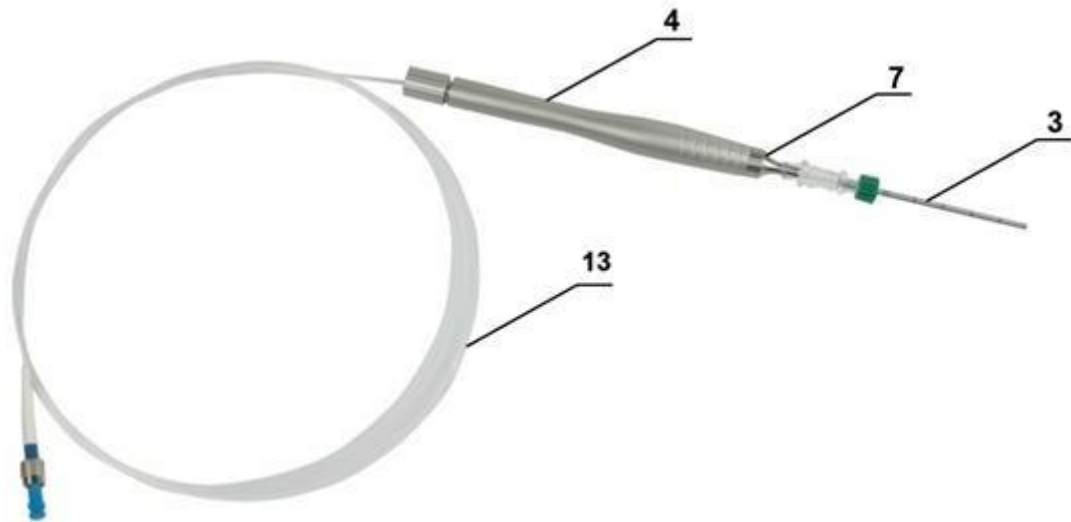
2. HEMORRHOIDS, ANAL FISSURES, SOFT TISSUE CUTTING AND COAGULATION WITH REUSABLE BARE FIBER AND REUSABLE CANNULA

p. 15, p. 4, p. 6 and p. 19, p. 20



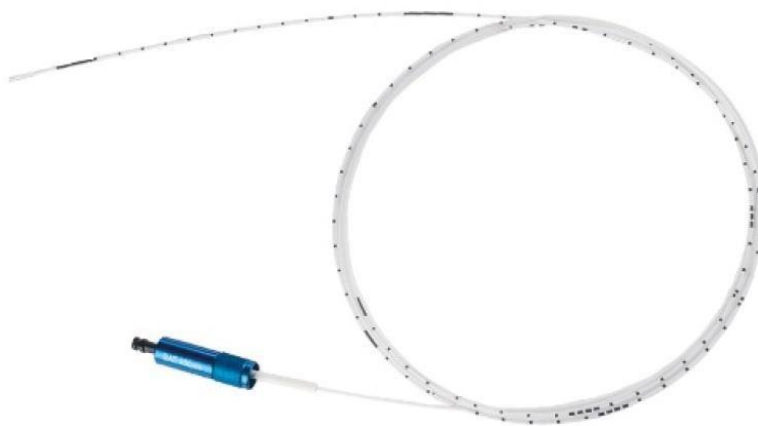
3. HEMORRHOIDS, ANAL FISSURES, SOFT TISSUE CUTTING AND COAGULATION WITH DISPOSABLE BARE FIBER AND DISPOSABLE CANNULA

p. 13, p. 4, p. 7 and p. 3



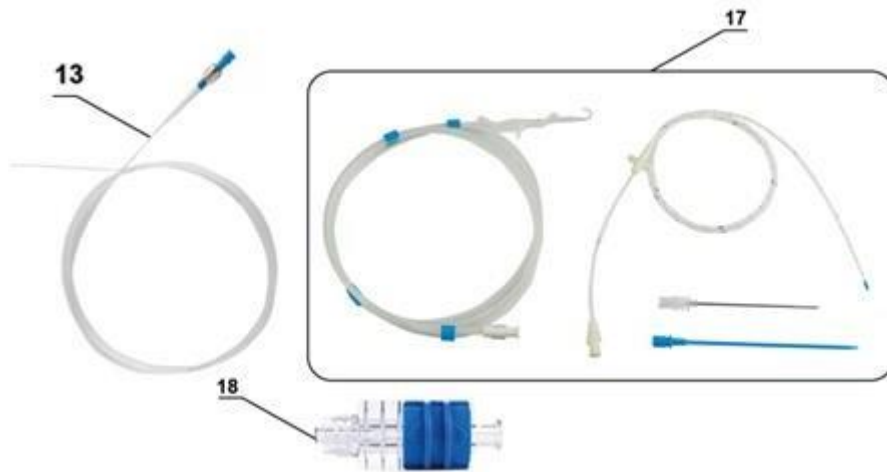
4. FISTULAS AND PILONIDAL SINUS (diffuse emission fibers)

p. 9 or p. 10



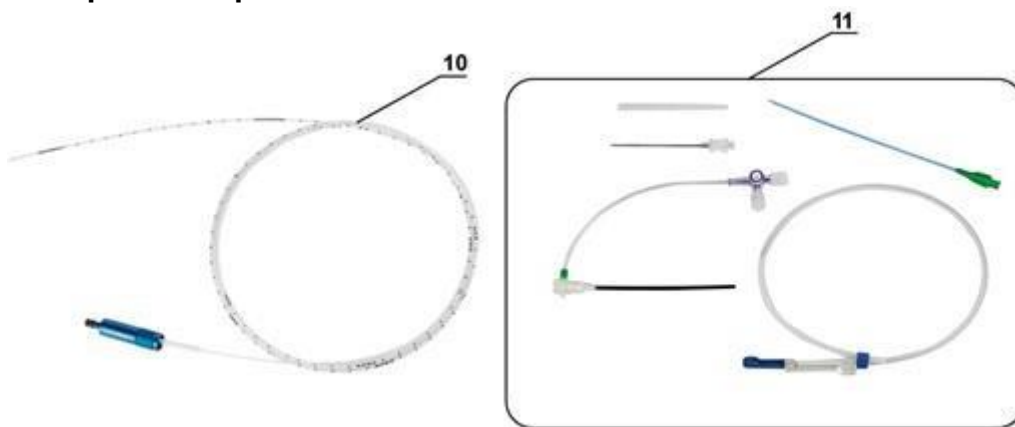
5. EVLT WITH DISPOSABLE BARE FIBER AND CATHETER SET

p. 13, p. 17 and p. 18



6. EVLT WITH DIFFUSE EMISSION FIBER AND CATHETER SET

p. 10 and p. 11



7. BIOMODULATION 635nm

p. 27, p. 24, p. 21 and p. 23



8. DIAGNOSTICS 405nm

p. 22, p. 25, p. 26 and p. 28



5. WARRANTY AND SERVICE

Diode lasers are covered by a 24-month warranty which can be extended up to 5 years. Basic warranty conditions:

1. The warranty covers possible material, production and design errors provided that the device is installed and used according to its purpose.
2. Any damage caused by inappropriate use, (against the rules stated in the operation manual), mechanical damage caused by fall, etc. is not covered by the warranty.
3. Any unauthorized repair or attempt of repair or removing seals voids the warranty.
4. Glass elements (fiber optics, lenses, etc.) are not covered by the warranty.

Further details concerning warranty service and after warranty service are described in the Warranty Card.