# ZEUS-400/300/200



#### **UPGRADE VERSION**

The upgrade version provide safety flexibility and convenience by powerful and stable technology.

10 storages are available by using user storage function. Bipolar cut function is available.

· Main Frequency: 400, 500KHz

· Power Source: AC120V or AC230V, 50Hz / 60Hz

· Protection class : Class 1, Type CF

· Dimension(WxDxH mm) 330x455x150

· Weight: 13.0Kg

# pplication

- · General Surgery
- · Dermatology
- · Vascular Surgery
- · Gynecology
- · ORL/ENT
- · Pediatric Surgery
- · Urology
- · Orthopedics
- · Oral Surgery
- · Plastic Surgery
- · Endoscopy

# **utput Specification**

	Mada	ZEUS series UPGRADED VER.			
	Mode	ZEUS-400	<b>ZEUS-</b> 300	ZEUS-	
•	Pure cut	400W / 300Ω	300W / 300Ω	200W / :	
	Blend 1	250W / 300Ω	230W / 300Ω	150W / 3	
	Blend 2	200W / 300Ω	180W / 300Ω	120W / 3	
	Blend 3	150W / 300Ω	120W / 300Ω	100W / 3	
	Contact Coag.	120W / 300Ω	100W / 300Ω	100W / 3	
	Spray Coag.	100W / 300Ω	80W / 300Ω	80W / 3	
	Bipolar Coag.	100W / 100Ω	80W / 100Ω	80W / 1	
	Bipolar Cut	100W / 200Ω	80W / 200Ω	80W / 2	

# Standard Accessories

Code No.	Name of Item
FS02-01R	Double Foot Switch
FS01-01R	Single Foot Switch
HD02-01D	Disposable Twin Button Handle
HD01-01R	Monopolar Handle & Cable
PL02-04R	Silicon Patient Plate(240X150mm)
PL03-02D	Disposable Patient Plate (2ea)
CA02-03R	Patient Return Plate Cable
CA03-01R	Ground Cable
CA01-01R	Bipolar Forceps Cable
BF01-01R	Bipolar Forceps(Bayonet 17.8cm 1.0 Tip)
EL01-02D	Electrode(Knife 2.4*70mm)
EL02-02D	Electrode(Ball 5mm)
EL03-02D	Electrode(Loop 6mm)
EL04-02D	Electrode(Needle 2.4*70mm)
EL04-04D	Electrode(Needle Angled 2.4*70mm)

# **E**eature

- A display window allows you to easily check output value, indicated as digits.
- Unit provides various functions that are required to perform an operation as functional cut mode (Pure cut, Blend1, Blend2, Blend3)Coagulation mode(Spray coag., Contact coag.), Bipolar coag. mode by hand or foot, Bipolar cut(upgrade version only).
- Each working condition can be checked by sound and indication lamp.
- Hand bipolar(Auto bipolar)can be checked only by contacting Forceps.
- Unit output strong and stable power by micro-processor.
- Input power frequency is automatically detected.

# ZEUS-400/300/200



S-200	ZEUS-400	<b>ZEUS-</b> 300	ZEUS-200
/ 300Ω	400W / 300Ω	300W / 300Ω	200W / 300Ω
/ 300Ω	250W / 300Ω	230W / 300Ω	150W / 300Ω
/ 300Ω	200W / 300Ω	180W / 300Ω	120W / 300Ω
/ 300Ω	150W / 300Ω	120W / 300Ω	100W / 300Ω
/ 300Ω	120W / 300Ω	100W / 300Ω	100W / 300Ω
/ 300Ω	100W / 300Ω	80W / 300Ω	80W / 300Ω
/ 100Ω	99W / 100Ω	80W / 100Ω	80W / 100Ω
/ 200Ω			





\* In case of Zeus-200, receptacle part is little different than Zeus-400/300, When customer buys Zeus-200, please check.

The ZEUS series provide safety flexibility and convenience by powerful and stable technology.

· Main Frequency: 400, 500KHz

Power Source : AC120V or AC230V, 50Hz or 60Hz
Protection class : Class 1, Type CF · Dimension(WxDxH mm) 330x455x150

· Weight: 13.0Kg



- · General Surgery
- · Dermatology
- · Vascular Surgery
- · Gynecology
- · ORL/ENT
- · Pediatric Surgery
- · Urology
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- · Oral Surgery
- · Plastic Surgery · Endoscopy

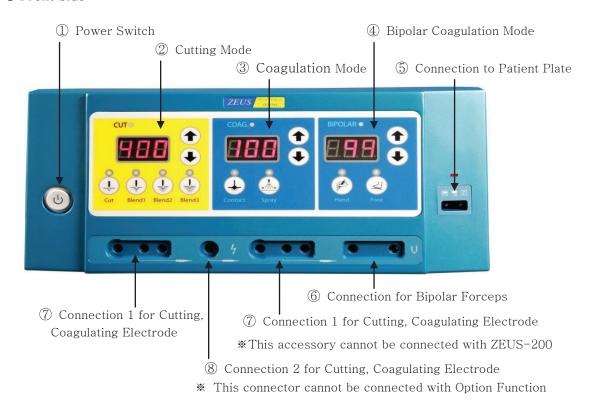
# S afety Function

- A fuse which is built in a power circuit board prevents over current from flowing through the equipment
- When the plate attached to the patient is disconnected from the unit, red alarm light begins flickering. If press any button of the twin button handle or press any pedal of double foot switch, alarm sound is made but the unit doesn't work.
- REM(Return Electrode Monitoring) function monitors the size of contacting area between a patient and the pad.
- If size is inappropriate, it automatically blocks the high-frequency current to minimize the danger of burning incident.
- To protect a patient, the case is fully grounded so that a leakage current can flow into the earth.

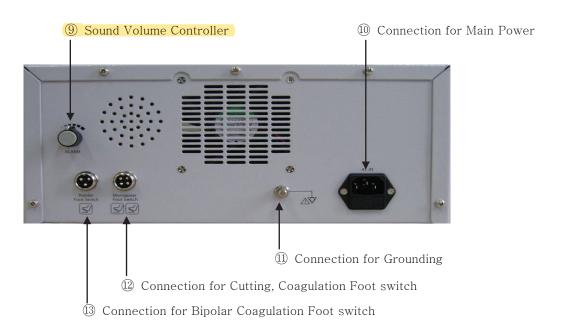
ZEUS-400/300/200 ZO-OM-001

#### 5.5 Name and Function of Each Part

#### • Front Side



#### Back Side



REV: 08 16 ZERONE

# **Accessories**

Accessory	Code No.	Name of Item	Specification
<b>O</b> :-	FS01-01R	Single Foot Switch	3pin Plug Cable 4m
0=	FS02-01R	Double Foot Switch	4pin Plug Cable 4m
0	PL02-01R	Silicon Patient Plate	240mm x 150mm 6.3Pie Plug Cable 3m
0	PL02-02R	Silicon Patient Plate	165mm x 90mm 6.3Pie Plug Cable 2m
0	PL02-03R	Silicon Patient Plate	110mm x 80mm 6.3Pie Plug Cable 2m
0	PL02-04R	Silicon Patient Plate	240mm x 150mm ValleyLab Type Plug Cable 3m
0_	PL02-05R	Silicon Patient Plate	165mm x 90mm ValleyLab Type Plug Cable 2m
0_	PL02-06R	Silicon Patient Plate	110mm x 80mm ValleyLab Type Plug Cable 2m
* * (X, W)	PL03-02D	Disposable Patient Plate	Adult Dual (120㎡ )
	PL03-03D	Disposable Patient Plate	Pediatric Dual (66cm²)
	HD01-01R	Monopolar Handle & Cable	Silicon Cable 4ø 3m
	HD01-02R	Monopolar Handle & Cable	Silicon Cable 4ø 3m
	HD02-01D	Disposable Twin Button Handle	3pin Plug Cable 3m
	CA01-01R	Bipolar Forcep Cable	2pin Plug Cable 3m EN Type Connector
	CA01-02R	Bipolar Forcep Cable	2pin Plug Silicon Cable 3m EN Type Connector
0	CA01-03R	Bipolar Forcep Cable	2pin Plug Silicon Cable 3m EU Type Connector
	CA01-04R	Laparoscopy Bipolar Connecting Cable	Silicon Cable, 3m
	CA01-06R	Bipolar Sealer Cable	Silicon Cable 4Ø, 3m
0	CA01-07R	Vessel Sealing Cable	2pin Plug Silicon, Cable 3m, EU Type connector
0-	CA03-01R	Ground Cable	Cable 4ø, 3m

# **Accessories**

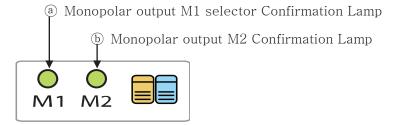


Accessory	Code No.	Name of Item	Specification
0	CA08-01R	Monopolar Connecting Cable	3Ø Connector, 4m
0	CA08-02R	Monopolar Connecting Cable	4Ø Connector, 4m
0	CA08-03R	Monopolar Connecting Cable	4.2Ø Connector, 4m
	CA02-02R	Patient Return Plate Cable	6.3Pie Plug Silicon Cable 3m
0-	CA02-03R	Patient Return Plate Cable	ValleyLab Type Plug Silicon Cable 3m
	BF01-01R	Bipolar Forceps	Bayonet 17.8cm 1.0 Tip
~	BF01-02R	Bipolar Forceps	Bayonet 15.2cm 1.0 Tip
	BF02-01R	Bipolar Forceps	Straight 9.0cm 0.5 Tip
-	BF02-02R	Bipolar Forceps	Straight 12.1cm 1.0 Tip
	BF02-03R	Bipolar Forceps	Straight 17.8 cm 1.0 Tip
====	BF03-01R	Bipolar Forceps	Angled 9,0cm 0,5 Tip
<del></del>	BF03-02R	Bipolar Forceps	Angled 17.8cm 1.0 Tip
	EL01-02D	Electrode	Knife 2.4 * 70mm Black
9 H	EL02-02D	Electrode	Ball 5mm Black
<del></del>	EL03-02D	Electrode	Loop 6mm Black
-	EL04-02D	Electrode	Needle 2.4 * 70mm Black
	EL04-04D	Electrode	Needle Angled 45° 2.4 * 70mm Black
I	CT01-01R	CART	W390xD480xH850
	HD03-02D	Sens Probe	3 Pin Plug Cable 3m
	HD03-01D	Sens Probe	2 Pin Plug Cable 3m

ZEUS-400/300/200 ZO-OM-001

- Select Coagulation Mode (Contact, Spray) and set a wanted output (W) level by using UP and DOWN buttons.

- Select Bipolar Coagulation Mode (Bipolar Cut, Foot, Hand) and set a wanted output (W) level by using UP and DOWN buttons.
- press the memory button longer to save.
- ③ Monopolar output selector Indicator



- (a) Monopolar output M1 selector Confirmation Lamp Choose the monopolar output selector switch on the rear side as M1, the light is turned on. When the Foot switch is pressed, output comes from the connection part of cutting and coagulation electrode.
- (b) Monopolar output M2 Confirmation Lamp Choose the monopolar output selector switch on the rear side as M2, the light is turned on. When the Foot switch is pressed, output comes from the connection part of cutting and coagulation electrode.
- 4 Monopolar output selector switch



Select the output part 1, 2 of cutting and coagulation electrode and use them.

M1 and M2 selected on the monopolar output selector mark area is ON.

#### Accessories

① Double Foot Switch



Connect it to 4pin Connector on the back side of the product. The yellow pedal is for Cutting and the blue one is for Coagulation.

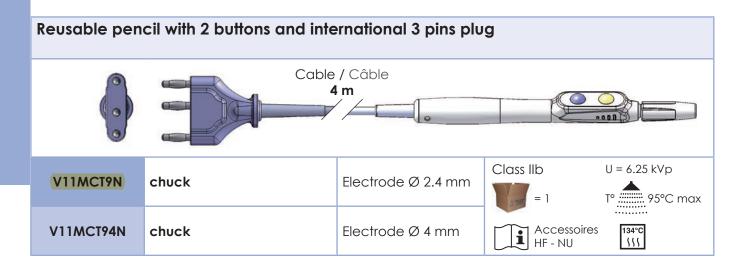
4pin plug, Cable 4m

#### ② Single Foot Switch



Connect it to 3pin Connector on the back side of the product during an operation of Bipolar function. 3pin plug, Cable 4m

# TACTILEC: Reusable pencil with control buttons





# EC CERTIFICATE Full Quality Assurance System

Certificate No.: 10731-2017-CE-KOR-NA-PS Rev. 2.0

Project No.: PRJC-40529-2007-MSL-KOR

Valid Until: 27 May 2024

This is to certify that the quality system of:

Zerone Co., Ltd.

(Shinil IT UTO Bldg., Dangjeong-dong) #810, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Electrosurgical and Ultrasonic Surgical Units, Infusion Pumps, Suction-irrigation pumps, Electrocardiograph and Endoscopic electrosurgical electrode.

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date: Høvik, 29 April 2021 For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Mariann Jeremiassen Principal Assessor



Certificate No.: 10731-2017-CE-KOR-NA-PS Rev. 2.0 Place and date: Høvik, 29 April 2021

#### **Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

#### Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	03 July 2017
1.0	Extension in scope - new products added (INFU-Z 2000)	24 September 2018
2.0	Recertification	29 April 2021

#### Products covered by this Certificate:

Product Description	Product Name	Class
	- ZEUS PRIME	J
	<ul><li>ZEUS VISION</li></ul>	
	DOCTANZ TOUCH	
	- ACE VISION	7
	■ ZEUS-400	7
10-1	- DOCTANZ400	
	- ACE-400	
	■ ZEUS-300	
	- DOCTANZ300	
	• ACE-300	
	■ ZEUS-200S	
	<ul><li>DOCTANZ200S</li></ul>	
Electrosurgical Unit	• ACE-200S	IIb
	■ ZEUS-200	
	DOCTANZ200	
	• ACE-200	
	■ ZEUS-150	
	DOCTANZ150	
	• ACE-150	
	■ ZEUS-100	
	DOCTANZ100	
	• ACE-100	
	• ZEUS-80	
	DOCTANZ80	
	• ACE-80	

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



Certificate No.: 10731-2017-CE-KOR-NA-PS Rev. 2.0 Place and date: Høvik, 29 April 2021

	<ul><li>ZERO50</li><li>SENS-Z</li><li>ARGON-Z</li></ul>	
Ultrasonic Surgical Unit	• ULTRA-Z	IIb
• INFU-Z 1000 • INFU-Z 2000 • INFU-Z 4000		IIb
SYRINGE PUMP	• SYRIN-Z 4000	
Endoscopic electrosurgical electrode, bipolar, reusable	<ul><li>VS01-01R</li><li>VS01-02R</li><li>VS02-01R</li><li>VS02-02R</li></ul>	IIb
SUCTION-IRRIGATION PUMP	■ ZP-1000	Ila
ECG (electrocardiographs)	rdiographs) - CZ-800 - CZ-430	

The complete list of devices is filed with the Notified Body

#### Sites covered by this certificate

Site Name	Address 4064
	(Shinil IT UTO Bldg., Dangjeong-dong) #810, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea

#### **EU Representative**

CMC Medical Devices & Drugs S.L. C/Horacio Lengo N° 18, CP 29006, Málaga, Spain



Certificate No.: 10731-2017-CE-KOR-NA-PS Rev. 2.0

Place and date: Høvik, 29 April 2021

#### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a
  defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning
  liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies
  the quality system. the Notified Body reserves the right, on a spot basis or based on
  suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

#### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate



# Management System Certificate

Certificate No.: 10865-2017-AQ-KOR-NA-PS Rev. 3.0

Initial Certification Date: 05 July 2006

Valid Until: 05 July 2024

This is to certify that the quality system of:

# Zerone Co., Ltd.

(Shinil IT UTO Bldg., Dangjeong-dong) #810, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

Design and Manufacture, Sales and Distribution of Electrosurgical and Ultrasonic Surgical Units, Disposable Sterile Laparoscopy Trocars, Infusion Pumps, Syringe Pumps, Suction-irrigation pumps, Electrocardiograph and Endoscopic electrosurgical electrode.

Place and date: Høvik, 09 June 2021



For the issuing office: DNV Product Assurance AS

Tone Elise Kolpus Lead Auditor



MSYS 018

ficate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.