Ensure™ Single-Use Coagulation Forceps

User Manual

Micro-Tech (Nanjing) Co., Ltd.

℞ only 

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

These instruments have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

CONTRAINDICATIONS

Contraindications include but are not limited to: coagulopathy. And those specific to the primary endoscopic procedure.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: transmural burns, thermal injury to the patient or explosion.

WARNING:

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
4. The instrument is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principals, clinical applications, and associated risks is expected before usage.
5. DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

6. The product is intended for adult populations.
7. This device is not made with natural rubber latex.
8. When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during the operation may affect the heart.
9. When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgery unit. Needle monitoring electrodes should not be used. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
10. When endoscopes are used with the device, the patient leakage currents may be additive.
11. Prepare monitoring equipment and rescue equipment to control unpredictable risks.
12. No modification of this equipment is allowed.
13. DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.When using this product with active electrosurgical current, do not touch the wire as shown in picture a.
14. When using this product with active electrosurgical current, do not touch the wire with any metal part, as shown in picture b.

picture a

picture b

15. The PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided.
    When not using, place ACTIVE ELECTRODES in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
16. The intensity should be set as low as is necessary to achieve the desired effect.
17. ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
18. DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.
19. The instrument is monopolar. The high-frequency electrosurgical unit should be used with a neutral electrode to prevent burns/injury to the patient.

20. To ensure the correct use of applicable electrosurgical units and neutral electrodes, please refer to the electrosurgical unit and neutral electrode user manuals for additional instructions.
21. DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
22. Please check if the compatible generator has a CQM. If it does not have a CQM, please be noted that the loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode is used.

【Product Name】 EnsureTM Single-Use Coagulation Forceps
【Packaging】 Packed in Tyvek pouch
【Production Date】 See packing
【Sterilization】 Sterilized by EO (ethylene oxide) gas
【Period of Validity】 Two years
【Compatible Working Channel】 ≥ø2.8 mm
【Applicable Electrosurgical Unit】
High-frequency electrosurgical unit which is legal listing in USA is recommended such as ConMed Electrosurgery 60-8200-230, Erbe electrosurgical system VIO® 200 D.
【Neutral Electrode】
1. Legally listed in USA.
2. For adults use.
【Rated High-Frequency Voltage】
COAG: 2300 Vp (4600 Vp-p)
DO NOT use higher repeated peak voltage than the Coag -2300 Vp (4600 Vp-p)
【Applicable Endoscopes】 Endoscope which is legal listing in USA is recommended such as Olympus.

STRUCTURE

The Ensure™ Single-Use Coagulation Forceps consists of jaws, spring sheath, HF connector-plug and handle (See Figure 1).

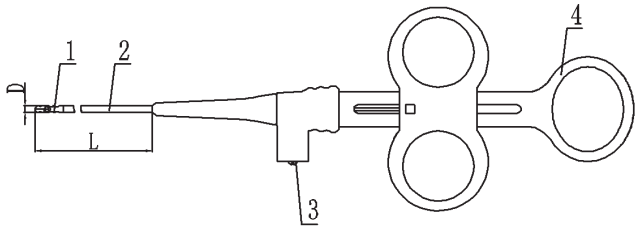

Figure 1 Structural drawing of EnsureTM Single-Use Coagulation Forceps
1.Jaws 2. Spring Sheath 3. HF Connector-Plug 4. Handle

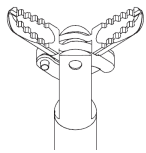	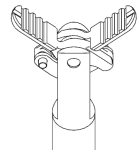	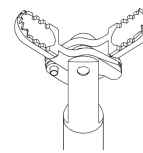
Type A Jaws	Type B Jaws	Type C Jaws

Figure 1

Specification

Unit: mm

REF	Working length (L)	Maximum diameter (D)	Jaws type	Applicable channel diameter
CF165-A	1650	≤2.7	Type A	≥2.8
CF165-B	1650	≤2.7	Type B	≥2.8
CF165-C	1650	≤2.7	Type C	≥2.8
CF230-A	2300	≤2.7	Type A	≥2.8
CF230-B	2300	≤2.7	Type B	≥2.8
CF230-C	2300	≤2.7	Type C	≥2.8

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. Before use, please check the device to ensure that there are no sharp edge.
6. INSPECT instruments and cables for damage prior to each use, especially the insulation of endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
7. Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
8. Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode. Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout the procedure.

9. Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.

INSTRUCTIONS FOR USE

1. Endoscopically visualize area to cauterize and coagulate or to perform hemostasis.
2. With cups closed, insert forceps into accessory channel of endoscope.
3. Advance forceps in 1-2 cm increments until it is visualized exiting endoscope.
   Note: Keep end of forceps that is extending from accessory channel straight at all times. Allowing forceps to hang from accessory channel may cause damage to device.
4. Advance forceps to desired hemostasis site, then open the jaws.
5. Turn the handle to orient the jaws in the optimum direction (see Figure 2).
6. Advance into tissue to cauterize and coagulate or to perform hemostasis.
7. Using slight pressure on handle, close jaws around tissue.
8. Following electrosurgical unit manufacturer's instructions for settings, verify desired settings and activate electrosurgical unit.
   Caution:
   1) DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
   2) When applying current, ensure metal tip of jaws does not come in contact with endoscope. Contact of forceps tip with endoscope may result in grounding, injury to patient and/or operator, as well as damage to endoscope and/or forceps.
   Note:
   1) The recommended settings in the table refer to the output levels of Erbe and ConMed electrosurgical equipment.

Applicable Electrosurgical Unit	Applied organ	Mode	Effect	Output level
ConMed	Esophagus	/	/	20W-40W
	Stomach			20W-40W
	Colon			15W-40W
Erbe	Esophagus	SOFT COAG	Effect 5	25W-50W
	Stomach			30W-60W
	Colon			20W-50W
	Esophagus	SWIFT COAG	Effect 3	25W-50W
	Stomach			30W-60W
	Colon			20W-50W
	Esophagus	FORCED COAG	Effect 3	25W-50W
	Stomach			30W-60W
	Colon			20W-50W

2) The continuous activation time of Coagulation should not exceed 5 seconds.
3) The recommended settings provided in the table are standard current output levels,which are used in the most common case to the best knowledge of Micro-Tech. When you operate the electrosurgical unit, always set an appropriate out level according to the following conditions:
   - The condition of tissue to be coagulation
   - The type/configuration/rated high-frequency voltage of the device that you use
   - The contact area between the electrode and the tissue
   - Operational conditions like use of injection solution, and so on
   - Your therapeutic strategy (whether you put a priority on the prevention of bleeding or on limiting thermal injury to surrounding tissue)
9. Maintain gentle handle pressure to keep jaws closed and gently withdraw forceps from site.
10. Continue to apply slight pressure on handle and withdraw forceps from channel. While withdrawing forceps from endoscope, wipe excess secretions from cable.

Caution:

1) Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness.
2) Do not activate the instrument while cleaning. Injury to operating room personnel may result.
3) The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

11. Upon completion of procedure, turn electrosurgical unit off, disconnect active cord from handle, then dispose of device per institutional guidelines for biohazardous medical waste.

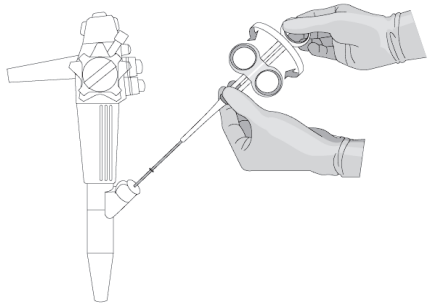

Figure 2

EMC CONDITIONAL

Guidance and manufacturer's declaration - electromagnetic emissions - for all ME EQUIPMENT and ME SYSTEM.

Table 1 - Emission		
Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	
Voltage fluctuations and flicker	IEC 61000-3-3 Complies	

Guidance and manufacturer's declaration - electromagnetic immunity - for all ME EQUIPMENT and ME SYSTEM.

Table 2 - Enclosure Port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Electrical fast transients/bursts	IEC 61000-4-4	±2kV, 100kHz (AC power port) ±1kV, 100kHz (signal input/output parts port)
Surges	IEC 61000-4-5	±0.5kV, ±1kV (line to line); ±0.5kV, ±1kV, ±2kV(line to ground)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz; 6V in ISM band between 0.15MHz and 80MHz
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T; 1cycle at 0° 70% U_T; 25/30 cycles at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Guidance and manufacturer's declaration – electromagnetic immunity for ME EQUIPMENT and ME SYSTEM that are not LIFE-SUPPORTING.

Table 3 – Proximity fields from RF wireless communications equipment		
Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 2 years.

OPERATION ENVIRONMENT

Operation environment	Environment temperature	10-40 °C (50-104 °F)
	Relative humidity	30-85%
	Barometric pressure	700-1060hPa (0.7-1.1Kgf/cm^3) (10.2-15.4psia)

TRANSPORTATION AND STORAGE ENVIRONMENT

Transportation and storage environment	Temperature limitation	-40-+70 °C (-40-+158 °F)
	Humidity humidity	10-95%
	Atmospheric pressure limitation	700-1060hPa (0.7-1.1Kgf/cm3) (10.2-15.4psia)

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

Limited Warranty and Disclaimers:

1. Limited Warranty to Buyer. Micro-Tech warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.
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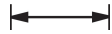
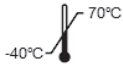
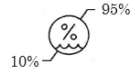
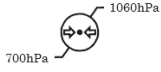
3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.
4. Limitation of Liability. **EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, Micro-Tech's LIABILITY UNDER THIS WARRANTY IS LIMITED TO: (a) THE REPLACEMENT OF THE PRODUCTS OR THE RE-SUPPLY OF EQUIVALENT PRODUCTS; (b) THE REPAIR OF THE PRODUCTS OR PAYMENT OF THE COST OF REPAIRING THE PRODUCTS; or (c) PAYMENT OF THE COST OF REPLACING THE PRODUCTS OR ACQUIRING EQUIVALENT PRODUCTS. Micro-Tech SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY) OR OTHERWISE, FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL, OR INDIRECT DAMAGES, OR FOR LOSS OF USE, LOSS OF REVENUE, LOSS OF BUSINESS, LOST PROFIT, OR OTHER FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH ANY PRODUCT OR OTHER GOODS OR SERVICES FURNISHED BY Micro-Tech, EVEN IF Micro-Tech WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.**

SYMBOLS

	Diameter		Working length
	Compatible working channel		Batch code
	Catalogue Number		Date of Manufacture
	Do not re-use		Manufacturer
	Caution		Sterilized using ethylene oxide
	Keep away from sunlight		Keep dry
	Use-by date		Do not resterilize
	Do not use if package is damaged		Type BF applied part
	This device is not made with natural rubber latex.		Federal law prohibits dispensing without prescription
	Consult instructions for use		Contents
	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		

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