MICRO-TECH™
ENDOSCOPY

Single Use Electrosurgical Knife
Instructions for Use

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 and electrosurgical units for dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.

CONTRAINDICATIONS

Contraindications include but are not limited to: coagulopathy, and those specific to the primary endoscopic procedure, endoscopic submucosal dissection (ESD) and endoscopic mucosal resection (EMR).

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to:

- ◆ Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
- ◆ Infection, septicemia;
- ◆ Complications which are not currently known or observed may be present.

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. This instrument is intended for use by physicians or medical personnel who have received appropriate training, in accordance with the applicable laws.
4. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
5. The product is only intended for adult.
6. This device is not made with natural rubber latex.
7. Patients should be informed of the potential risks and complications, which may lead to injury,illness or death of the patient.
8. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
9. This device is not intended to be used in the presence of Flammable liquids, in an Oxygen Enriched Atmosphere or in the presence of explosive gases. Any electrosurgical device constitutes a potential electrical hazard to the patient and/or operator.
10. Avoid High Frequency output settings where maximum output voltage exceeds rated accessory voltage.
11. Use this instrument in an environment equipped to accommodate open surgery and have a hospitalization plan prepared in case a problem occurs that cannot be resolved endoscopically.
12. Do not force the cutting knife against tissue with excessive force while activating output. Otherwise,unintended resection, perforation, bleeding and cutting knife crack may occur. When resecting tissue, always confirm the direction of resection and use the instrument without excessive force.
13. **If the instrument is used on a patient with an implanted pacemaker,serious harm to the patient may occur. This instrument may cause an implanted pacemaker to malfunction.Before proceeding,always confirm with a cardiologist or the manufacturer of the pacemaker that is safe.**
14. **When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output.Spark discharge during operation may affect the heart.**
15. When using an electrocardiograph or other physiological monitoring

equipment simultaneously with the instrument on a patient,any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgical unit.Needle monitoring electrodes should not be used,as they may cause patient burns.Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.

16. If using this instrument to perform endoscopic submucosal dissection (ESD), inject an appropriate solution, such as saline, in submucosal layer to elevate the tissue prior to starting the cut. If necessary, add injection of an appropriate solution such as saline during dissection. If electrosurgical dissection is performed while there is minimal space from the muscle layer, perforations may occur.
17. Do not resect tissue too deeply. Deep resection of tissue may cause bleeding, perforation, pneumomediastinum and/or aerodermectasia during or after the procedure. When resecting tissue, confirm that there is no irregularity in resected area and monitor the patient's condition all the time.
18. Check the output mode and power setting of the electrosurgical unit before use. Using output modes and settings above the recommended levels may result in patient injury, damage to the endoscope and or instrument.
19. Endogenous gases (e.g. methane) can ignite through the HF flow if this product is used in the gastrointestinal track. It must therefore be ensured, prior to use of the product that endogenous gases are present in the gastrointestinal track.
20. Temporarily unused instruments should be stored in a location that is isolated from the PATIENT.
21. A warning addressing the RISKS resulting from neuromuscular stimulation which can occur especially with modes which produce electrical arcs between the ELECTRODE and tissue.
22. Portable RF communications equipment should be used no closer than 30cm.
23. Since supporting the use of Olympus endoscopic system, Olympus endoscopic system's light source may affect Single Use Electrosurgical Knife's temperature to exceed 41℃, to minimize the risk of injury, please ensure the correct use of it according to Olympus endoscopic system and the manufacturer' s instructions.

PRECAUTIONS:

Failure to observe these precautions could result in patient injury, such as perforations, bleeding or mucous membrane damage. Endoscope and or

instrument damage may also occur.
1. This instrument does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it.
2. If excessive resistance is encountered during insertion, do not force the instrument. Straighten the endoscope when possible, and reduce the angle of the insertion portion, at the biopsy valve to reduce resistance.
3. Do not angulate the endoscope's bending section abruptly while the instruments distal end is extended out of the endoscope.
4. If the cutting knife is too long for the application, do not use this instrument.
5. When not in use, do not place the device on the patient. Store on a non-conductive surface.
6. Please read the instructions for use entirely before use.

【Product Name】

Single Use Electrosurgical Knife

【Packaging】

Packed in Tyvek package

【Production Date】

See packaging

【Sterilization】

Sterilized by EO (ethylene oxide) gas

【Period of Validity】

3years

【Applicable Endoscopes】

Endoscope which is legal listing in USA is recommended such as Olympus.

【Compatible Working Channel】

≥Φ2.8mm

【Applicable Electrosurgical Unit】

High-frequency electrosurgical unit which is legal listing in USA is recommended such as ERBE Electrosurgery.

【Rated High-Frequency Voltage】

CUT:1200Vp（2400Vp-p）

DO NOT use higher repeated peak voltage than the Cut- 1200Vp（2400Vp-p）.

Power: maximum 80 watts

COAG:1200Vp（2400Vp-p）

DO NOT use higher repeated peak voltage than the Coag- 1200Vp（2400Vp-p）.

Power: maximum 80 watts

STRUCTURE

The Single Use Electrosurgical Knife mainly includes cutting knife assembly, outer tube assembly and handle component (Fig.1).

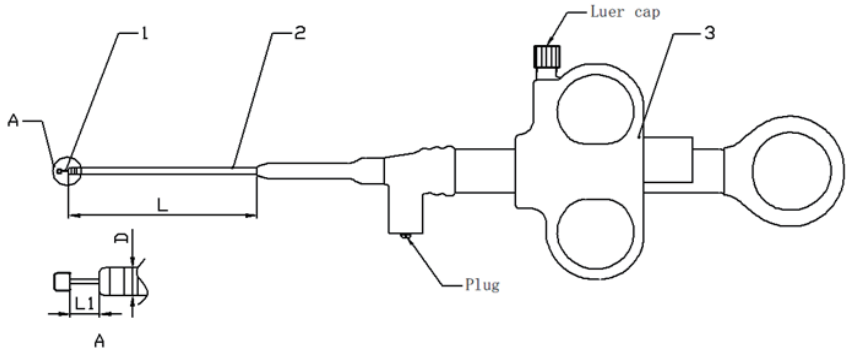

Fig.1 Schematic diagram of Single Use Electrosurgical Knife
1. Cutting knife assembly 2.Outer tube assembly 3.Handle component

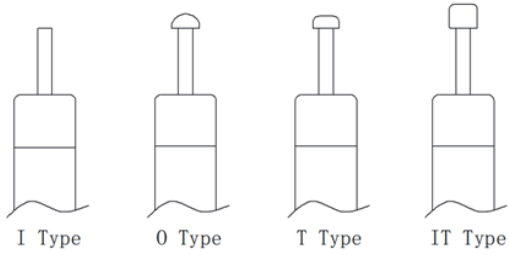

Fig.2 Schematic diagram of cutting knife assembly

SPECIFICATION

Unit:mm

Specification	Cutting Knife Shape	Cutting Knife Length L1	Effective Working Length L	Injection modelor NOT	The maximum diameter of the insertion portion D
MK-I-1-195	I	1.5	1950	Yes	<2.7
MK-I-1-235	I	1.5	2350	Yes	<2.7
MK-I-2-195	I	2	1950	Yes	<2.7
MK-I-2-235	I	2	2350	Yes	<2.7
MK-I-4-195	I	4	1950	Yes	<2.7
MK-I-4-235	I	4	2350	Yes	<2.7
MK-O-1-195	O	1.5	1950	Yes	<2.7
MK-O-1-235	O	1.5	2350	Yes	<2.7
MK-O-2-195	O	2	1950	Yes	<2.7
MK-O-2-235	O	2	2350	Yes	<2.7
MK-O-4-195	O	4	1950	Yes	<2.7
MK-O-4-235	O	4	2350	Yes	<2.7
MK-T-1-195	T	1.5	1950	Yes	<2.7
MK-T-1-235	T	1.5	2350	Yes	<2.7
MK-T-2-195	T	2	1950	Yes	<2.7
MK-T-2-235	T	2	2350	Yes	<2.7
MK-T-4-195	T	4	1950	Yes	<2.7
MK-T-4-235	T	4	2350	Yes	<2.7
MK-IT-4-195	IT	4	1950	Yes	<2.7
MK-IT-4-235	IT	4	2350	Yes	<2.7
MK-IT-4-195-N	IT	4	1950	No	<2.7
MK-IT-4-235-N	IT	4	2350	No	<2.7

PREPARATION

1. Choose the appropriate specification refer to the compatible working channel in package label.
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 period of validity.
4. Before use, remove the distal protection tube and make sure the instrument have no loose or disconnected. Please check the insertion patients body parts, ensure that no sharp edge.

5. If this device shows any signs of damage and suspicious problems, do not use.Do not attempt to repair nonfunctional or damaged device.
6. Holding the instrument form a loop in the insertion portion of approximately 20cm in diameter.Operate the slider and confirm that the cutting knife extends and retracts smoothly. If the cutting knife does not operate smoothly and as intended, do not use the instrument; use a spare instead.
7. If appropriate solution such as saline will be injected through the injection lumen, remove the luer cap and attach a syringe ⩽10mL (10cc) to the luer taper and inject some saline to check the injection lumen and eliminate the air in the injection lumen.

INSTRUCTIONS FOR USE

1. Attach the patient plate.
2. Pull the slider to retract the cutting knife into the outer sheath.With the cutting knife retracted,carefully insert the instrumentin to the biopsy value of the endoscope.Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.

Note:

When inserting the instrument into the endoscope,hold it close to the biopsy valve and keep it as straight as possible relative to the biopsy valve.Otherwise,the instrument could be damaged.

3. Insert the plug of knife into the electrosurgical unit's plug until it clicks.
4. Push the slider to extend the cutting knife.
5. Set the power switch of the electrosurgical unit to ON and set an appropriate outer power.

Warning:

1) Do not bundle the cord with cables from other medical equipment(electrocardiograph,endoscopic video system, electrosurgical unit,etc.) High-frequency signals and spark discharge noise during cauterization may cause malfunctions in other medical equipment that could have an adverse effect on the patient.Another possibility is that output from the electrosurgical unit will be abnormal and could cause patient injury,such as perforation,bleeding or mucous membrane damage

2) When an irregularity is detected during the use of this instrument,do not continue to use the electrosurgical knife anymore.Otherwise perforation,bleeding or mucous membrane damage may occur.

3) Make sure that electrosurgical unit is supplied to the instrument when making an incision.Incision without electricity may result in patient injury, such as perforation,bleeding or mucous membrane damage

Caution:

1) To avoid burning healthy tissue, do not activate output if the electrode and the cutting knife are in contact with non-target tissue.

2) Do not activate output when the distal end of the endoscope is too close to or in contact with body cavity tissue.This could burn the tissue and/or damage the endoscope.

3) Do not activate output if any of the patient's skin surfaces are touching each other (a bare arm and the side of the chest,for example). This could burn the patient.

4) Do not activate output when patient is in contact with metal parts of operating table or other units.This could burn the patient,operator or assistant.

6. Hold the electrode and the cutting knife against the tissue,and activate the high-frequency current for mark, dissection and preparation of the tissue layers.

Caution:

1) Aspirate fluids such as mucus that adhere to the electrode and/or the cutting knife, outer sheath and body cavity tissues. Patient injury such as perforations, bleeding, mucous membrane damage and thermal injury of tissue could result if output is activated when in contact with these adhering fluids. When current is discharged while the cutting knife is being separated from the mucosa under wet situation, it may break the cutting knife or crack the distal end.

2) If the cutting knife shape is IT type. Only cauterize tissue after confirming that the electrode and cutting knife are in contact with the tissue. Tissue might be cauterized by not only the cutting knife but also the electrode.

3) To clean the instrument, be careful not to use excessive force when removing tissue attached to the cutting knife. Needle on the luer cap can be used to remove tissue attached to the cutting knife. When the electrode is subjected to excessive force, for example, when scraping with excessive force the cutting knife by tweezers, etc. or when extending and retracting the cutting knife abruptly and continuously, it may break the cutting knife or crack the distal end.

NOTE:

1) Reference current output levels in combination with ERBE electrosurgical unit.

Operative technique method	Applied organ	Mode	Effect	Output level
Marking	Esophagus, Stomach	SOFT COAG	Effect 5	20-50W
	Colon	SOFT COAG	Effect 5	20W
Incision/ Dissection	Esophagus, Stomach	ENDO CUT Q Cutting Duration 2 Cutting Interval 2	Effect 3	-
	Colon	ENDO CUT Q Cutting Duration 3 Cutting Interval 3	Effect 2	-
Coagulation	Esophagus, Stomach	FORCED COAG	Effect 2	40-60 W
	Colon	FORCED COAG	Effect 2	40 W

2) 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 cut or coagulation

- The type/configuration/rated high-frequency voltage of the device that you use

- The contact area (length) 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).

7. When it isn't injection model, go to step 8.
   When it is injection model, follow the steps below:
   If need elevation, insert the cutting knife into the desired position and inject the appropriate solution such as saline to elevate mucous membrane, thereby helping to precise cutting.
   If need irrigation, locate the device near the actual or the potential bleeding site, in order to cleanmucous membrane, inject an appropriate solution such as saline to irrigation, thereby helping to get the endoscope field of view.

Warning:

1) Check the position of the cutting knife whether is correct, if inject in the inappropriate position or injection too deep, it could cause patient injury.

2) Take appropriate measures if any fluids attached to this electrosurgical knife come in contact with the eye or skin of the operator. Otherwise, such fluids from the patient could pose an infection control risk and/or cause skin irritation.

Note:

If preferred, a suitable irrigation pump or syringe may be used.

8. Switch the electrosurgical unit OFF.Pull the slider to retract the cutting knife into the outer sheath. With the cutting knife retracted,carefully withdraw the instrument from the endoscope.

Caution:

If the cutting knife is not retracted,it could damage the instrument.

EMC CONDITIONAL

The Single Use Electrosurgical Knife meets emission standards of Class A and Group1.

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

Table 1 – Emission limits per environment		
Phenomenon	Compliance	Electromagnetic environment
Conducted and Radiated 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 – Electromagnetic immunity		
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 fields	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
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz
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 bands between 0,15MHz and 80MHz 80% AM at 1kHz
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycle
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0,15MHz-80MHz; 6V in ISM bands between 0,15MHz and 80MHz 80% AM at 1kHz
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 and 70% U_T; 25/30 cycles Single phase: at 0°

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

Table 3 – Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM[c] ±5kHz deviation 1kHz sine	2	0,3	28
710	704-787	LTE Band 13,17	Pulse modulation[b] 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulatio[b] 18Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25;UMTS	Pulse modulation[b] 217Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217Hz	2	0,3	28

5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT of ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be worst case.						

STORAGE

The product should be stored in a clean, well-ventilated, non-corrosive gas environment. Do not store them in direct sunlight.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 3 years.Prior to use, check the expiry date on the package. If the expiry date has elapsed, do not use.

ENVIRONMENT

Operating environment
Ambient temperature: 10~40℃(50-104 °F)
Relative humidity:30~85%
Atmospheric pressure: 800~1060hPa/0.7-1.1Kgf/cm3/10.2-15.4psia
Transportation and storage environment
Ambient temperature: -40~70℃
Relative humidity: 10~95%
Atmospheric pressure: 800~1060hPa/0.7-1.1Kgf/cm3/ 10.2-15.4psia

PRODUCT DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Limited Warranty and Disclaimers:

1. Limited Warranty to Buyer. Micro-Tech USA 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 USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA'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 USA 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.

2. Disclaimer and Release. **THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER, INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.**
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 USA 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 USA'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 USA 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 USA, EVEN IF MICRO-TECH USA WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.**

SYMBOL INDICATIONS

	Do not reuse		Do not resterilize
	Date of Manufacture		Manufacturer
	Use by		Not made with natural rubber latex.
	Catalogue Number		Batch code
	Sterilization using ethylene oxide		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Type BF applied part		Compatible working channel
	Consult instructions for use		Working length
	Caution, destroy it after using		Diameter
	Temperature limit		Contents
	Atmospheric pressure limitation		Humidity limitation
	Caution：Federal (USA) law restricts this device to sale by or on the order of a physician		Electromagnetic interference

Manufacturer

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, Nanjing 210032 ,Jiangsu Province, PRC
TEL:+ 86 25 58609879, 58646393
FAX:+ 86 25 58744269
Email: info@micro-tech.com.cn
www.micro-tech.com.cn;

Distributed By

Micro-Tech USA Inc.
2855 Boardwalk Drive, Ann Arbor, MI 48104 USA
Tel: 734-259-3768
Toll free: 877-552-4027
info@micro-tech-usa.com

1-0015608 REV.2
2020.05.21