EN

Disposable Sphincterotomes

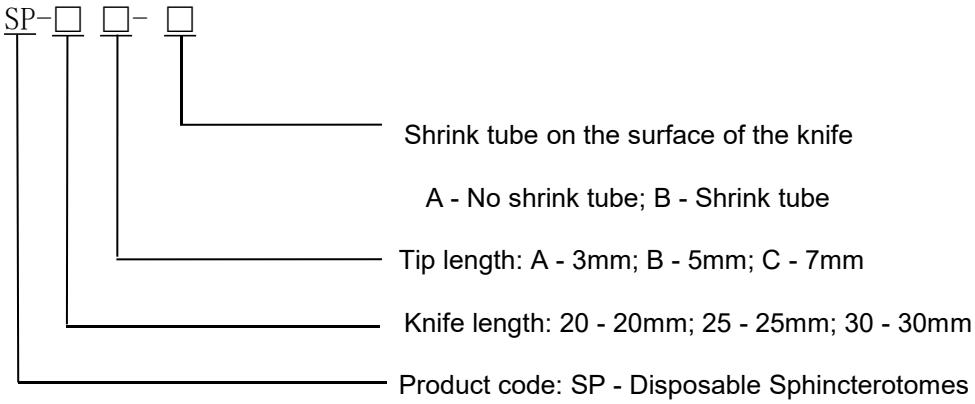
1. Product Name

Disposable Sphincterotomes

2. Product Description

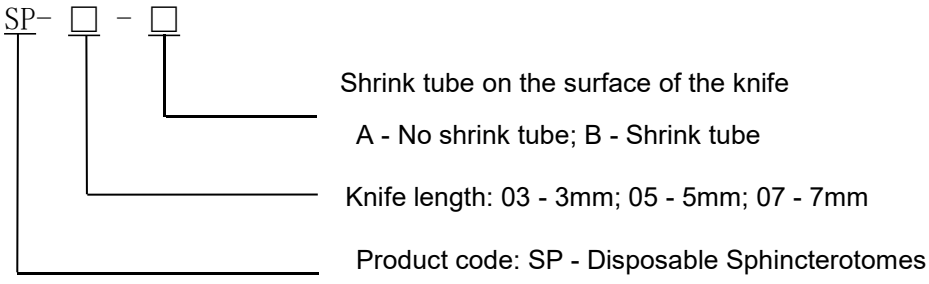
2.1 Naming rule

2.1.1 The model and naming for arch wire type



For example: SP-20A-A means the length of knife of Disposable Sphincterotomes is 20mm, tip length is 3mm, and there is no shrink tube on the surface of the knife , which is triple lumen arch wire type.

2.1.2 The model and naming for needle knife type



For example: SP-05-A means the length of knife of Disposable Sphincterotomes is 5mm, there is no shrink tube on the surface of the knife , which is triple lumen needle knife type.

2.2 Device description

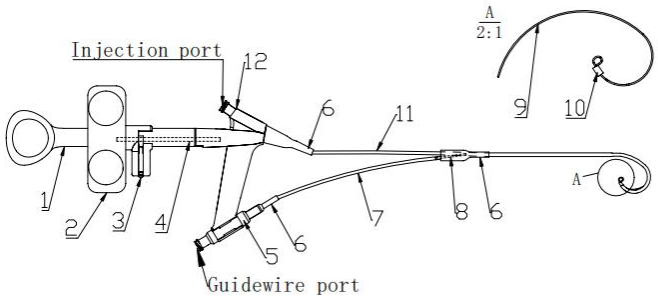
Disposable Sphincterotomes are intended to be used in conjunction with an endoscope and guidewire for papillotomy using high-frequency current.The device consists of the cutting wire section, the sheath section and the handle section. There are two types of structure: the arch wire and needle knife. The cutting wire section of arch wire type consists of cutting wire, shrink tube (optional), connecting tube, silicone tube and mandrel. The cutting wire section of needle knife type consists of round head cutting wire, shrink tube (optional), limit pipe, cutting wire

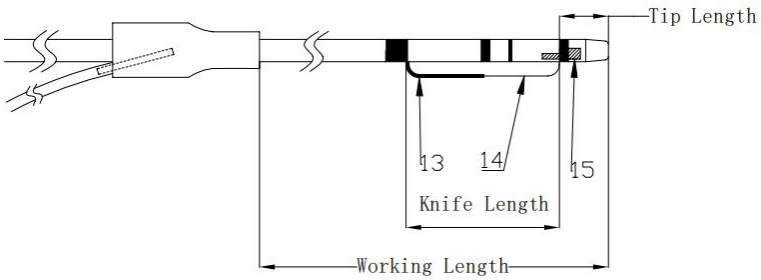
connecting pipe, cutting wire, silicone tube and mandrel. The sheath section consists of printed outer sheath, shrink tube 01, parallel tube, PTFE tube, guidewire luer joint and connecting cap. The handle section consists of slider, core bar,booster tube and conductive plug. The knife lengths for arch wire type are 20mm, 25mm and 30mm; for needle knife type, the lengths of knife are 3mm, 5mm and 7mm. The working length of tube sheath for each device is 1800mm. Outer diameter of maximum insertion part is 2.6mm. The main materials of the subject device are PTFE, SUS304 and ABS.

The device is sterilized using Ethylene Oxide, and shelf life is 3 years. The device is single use.

2.3 Device structure

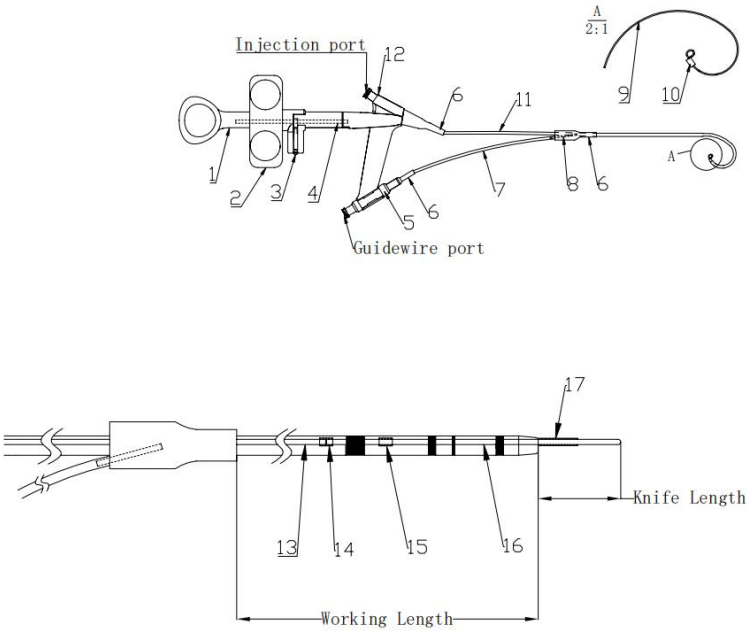
The structural diagram of arch wire type is shown in figure 1; the structural diagram of needle knife type is shown in figure 2.





1.Core bar 2.Slider 3.Conductive plug 4.Booster tube 5.Guidewire luer joint
6.Shrink tube 01 7.PTFE tube 8.Parallel tube 9.Mandrel 10.Silicone tube
11.Printed outer sheath 12.Connecting cap 13.Shrink tube 14.Cutting wire
15.Connecting tube

Figure 1: Structural diagram of Disposable Sphincterotomes (arch wire type)



1.Core bar 2.Slider 3.Conductive plug 4.Booster tube of needle knife
5.Guidewire luer joint 6.Shrink tube 01 7.PTFE tube 8.Parallel tube 9.Mandrel
10.Silicone tube 11.Printed outer sheath 12.Connecting cap 13.Cutting wire
14.Cutting wire connecting pipe 15.Limit pipe 16.Round head cutting wire 17.Shrink tube

Figure 2: Structural diagram of Disposable Sphincterotomes (needle knife type)

2.4 Models and specifications

The knife lengths for arch wire type device are 20mm, 25mm and 30mm; for needle knife type, the knife lengths are 3mm, 5mm and 7mm. The working length of tube sheath for each is 1800mm. Outer diameter of maximum insertion part is 2.6mm.The details of models and specifications are shown in table 1.

Table 1: Models and specifications

Model	Type	Knife length (mm)	Tip length (mm)	The surface of the knife contains shrink tube (Yes/No)	Compatible endoscope channel inner diameter (mm)	Compatible guide wire diameter (mm)
SP-20A-A	arch wire	20	3	No	≥2.8	≤0.89
SP-20B-A	arch wire	20	5	No	≥2.8	≤0.89
SP-20C-A	arch wire	20	7	No	≥2.8	≤0.89
SP-20A-B	arch wire	20	3	Yes	≥2.8	≤0.89
SP-20B-B	arch wire	20	5	Yes	≥2.8	≤0.89
SP-20C-B	arch wire	20	7	Yes	≥2.8	≤0.89
SP-25A-A	arch wire	25	3	No	≥2.8	≤0.89
SP-25B-A	arch wire	25	5	No	≥2.8	≤0.89
SP-25C-A	arch wire	25	7	No	≥2.8	≤0.89
SP-25A-B	arch wire	25	3	Yes	≥2.8	≤0.89

SP-25B-B	arch wire	25	5	Yes	≥2.8	≤0.89
SP-25C-B	arch wire	25	7	Yes	≥2.8	≤0.89
SP-30A-A	arch wire	30	3	No	≥2.8	≤0.89
SP-30B-A	arch wire	30	5	No	≥2.8	≤0.89
SP-30C-A	arch wire	30	7	No	≥2.8	≤0.89
SP-30A-B	arch wire	30	3	Yes	≥2.8	≤0.89
SP-30B-B	arch wire	30	5	Yes	≥2.8	≤0.89
SP-30C-B	arch wire	30	7	Yes	≥2.8	≤0.89
SP-03-A	needle knife	3	--	No	≥2.8	≤0.89
SP-03-B	needle knife	3	--	Yes	≥2.8	≤0.89
SP-05-A	needle knife	5	--	No	≥2.8	≤0.89
SP-05-B	needle knife	5	--	Yes	≥2.8	≤0.89
SP-07-A	needle knife	7	--	No	≥2.8	≤0.89
SP-07-B	needle knife	7	--	Yes	≥2.8	≤0.89

3. Intended use

The instruments are intended to be used in conjunction with endoscope and guidewire for papillotomy using high-frequency current.

4. Indications for Use

Suitable for biliary system diseases.The instruments are intended to use in conjunction with endoscope and guidewire for papillotomy using high-frequency current.

5. Intended users

The trained medical professionals.

6. User qualification

1) Medical personnel with medical qualifications/qualifications.
2) A doctor who has sufficient language ability to understand/read the operating instructions of the instruction for use and the accompanying documents.
3) Users who are familiar with the operation process of this product, have been trained in product use, and can operate in strict accordance with the instruction for use.

7. Intended target groups

Patients are between 18 and 75 years old.

8. Performance characteristics

1) The device has a channel that can be matched with the guidewire, and the guidewire can be inserted and retracted freely in the cavity. (Maximum diameter of matching guide wire ≤0.89mm).
2) The device instrument can be matched with ≥φ2.8mm endoscope channel and can pass through the channel smoothly.
3) The front end of the device has X-ray detectability, which can be detected under the normal operation of the X-ray equipment.
4) The device is sterilized using ethylene oxide, and the device is shipped in sterilized state.

9. Contraindications

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy.

10. Potential clinical side-effects

- Post-ERCP pancreatitis (PEP),
- Bleeding,
- Cholangistis,
- Perforation.

11. Warnings and precautions

1) The device is a single use product and shall not be reused, retreated or re-sterilized. Repeated use, repeated treat, and repeated sterilization may affect the device structure and lead to device failure, which may lead to patient injury, illness, or death. There is also a risk of device contamination and patient infection or cross-infection, including but not limited to the transmission of infectious diseases from one patient to another. Contamination of the device may result in injury, illness or death.
2) With the electronic duodenoscope imaging system, verify that the cutting wire has been withdrawn through the endoscope channel. If the above step is not performed, which may result in contact between the cutting wire and the endoscope during power-up. This can cause grounding, which could lead to injury to the patient and the damage to the cutting wire, and/or damage to the endoscope.
3) The instrument may affect medical electrical equipment, and the purchaser or user must install and use it according to the information on EMC compliance (IEC 60601-1-2:2014) provided in the document instruction for use.
4) Because the instrument is used in conjunction with the high-frequency surgical equipment, there is an output of radio frequency energy during use. It is recommended that other equipment should be kept away from the instrument as much as possible.
5) The basic performance of the device when detecting electromagnetic compatibility is: the deviation of the output power of the instrument is less than ±20%.
6) Do not entangle the device with other devices such as high-frequency electrocautery devices, electrocardiograms, and cables of the endoscopic system, which may cause

abnormal functions of other equipment, thereby causing adverse effects on patients.

7) In addition to the cables sold by the company as spare parts for internal components, the use of unspecified accessories and cables may lead to an increase in the emission of the instrument or a decrease in immunity.
8) The device shall not be used in the presence of flammable liquids, explosive gases or oxygen-enriched environments.
9) Any fluid or flammable solutions pooled under the patient or in body depressions,and in body cavities should be mopped up before HF surgical equipment is used.
10) The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth, it is recommended to use an operating table supports.
11) Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
12) The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
13) The output power selected should be as low as possible for the intended purpose. However, if the power setting is too low, it will affect the cutting efficiency, so it is necessary to set the appropriate power.
14) It is strictly forbidden to use the instrument for surgery on patients with cardiac pacemakers and metal implants. High-frequency signals generated during use can cause cardiac fibrillation, damage pacemakers, or produce electrical shocks, resulting in serious patient injury or even death.
15) When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
16) The device has been sterilized by ethylene oxide. Do not use it if the package is damaged.
17) After use, the products and packaging shall be handled in accordance with the rules and policies of the hospital, administrative and/or local government.

12. Attention

1) Please check and operate follow the instruction for use, if not, it may endanger the safety of patients or users, and cause the risk of infection, perforation, bleeding, mucosal damage, etc.
2) If the package is damaged, use is strictly prohibited. Check the expiry date on the package label, beyond the expiry date, it is strictly prohibited to use.
3) Before use, the parts of the endoscope and the instrument inserted into the human body must be inspected for rough surfaces, sharp edges or protrusions that could pose a safety hazard.
4) Flush the catheter lumen with sterile water or normal saline to remove all air in the lumen.
5) If the liquid is injected through the injection port, please use a syringe ≤20mL and connect

the syringe to the proximal injection port.

6) It is not recommended to bend the distal end of the instrument or draw the bow more than 90° to avoid damaging or breaking the cutting wire. Make sure that the cutting wire of the instrument has protruded out of the endoscope before power-on cutting.
7) Using multiple short 2-3 cm movements, carefully push the device through the endoscope to avoid accidental damage to outer tube.
8) This is a sterile device, sterilized by ethylene oxide and single use. After use, disposal of the device shall be in accordance with the applicable local regulations and laws. Repeated use is strictly prohibited.
9) It must be operated by physicians trained in digestive endoscopy techniques.
10) The maximum rated input voltage of the device is 1200Vp. Do not use parameter settings that could cause the high frequency device to output a voltage that exceeds the maximum voltage rating of the device.
11) The handle part of the instrument is used in conjunction with a high-frequency surgical equipment. After connecting with the high-frequency surgical equipment, it is used as the application part, the degree of protection against electric shock is determined by the high-frequency surgical equipment.
12) The recommended cutting power of high-frequency surgical equipment is ≤80W.
13) This instrument cannot be used for other purposes beyond the scope of application.
14) Do not let the small needle electrodes or small metal objects touch the conductive plug when the device is energized.

13. Instructions for Use

13.1 Inspection before use

13.1.1 Check the package, do not use if the package is damaged or has been opened.

13.1.2 Check the device, do not use in case of kinking, bending, cutting wire section damage, cutting wire broken or other abnormal conditions.

13.2 Preparation before use

13.2.1 Take the device out of the package.

13.2.2 Take the shaping mandrel out of the catheter (carefully take it out and keep the pre-bent shape of the cutting wire section).

13.2.3 Check the cutting wire section is at a proper deviation to ensure that the catheter is not damaged, such as knots. The catheter knot will cause the injection cavity of the catheter to be blocked and affect the injection function. If the device is found to be damaged, please contact with the relevant personnel for replacement.

13.2.4 Flush the catheter lumen with sterile water or normal saline to remove all air in the lumen.

13.2.5 If the liquid is injected through the injection port, please use a syringe ≤20mL and connect the syringe to the proximal injection port.

13.3 Instruction for use

[Non-wire guidance]

13.3.1 Put the instrument into the endoscope channel in a correct direction, and guide the position of the cutting wire in a desired direction.

13.3.2 After the instrument reaches the expected position in the biliary system, use a contrast

medium for contrast under X-ray fluoroscopy.

[Guide wire guidance]

13.3.3 Put the guide wire into the guide wire catheter of the instrument, and cooperate with the endoscope to perform the intubation operation.

13.3.4 After the successful intubation operation, inject the contrast medium and confirm the position in the common bile duct under X-ray fluoroscopy.

13.3.5 Adjust the position of the instrument cutting wire to make it in the proper position and direction.

13.3.6 Connect the connection cable of the high-frequency surgical device to the conductive plug of the sphincterotomy until the plug of the connection cable cannot be pushed again.Adjust the high-frequency surgical equipment to appropriate parameters, and perform Endoscopic Sphincterotomy (EST) by using high-frequency current.

13.3.7 After use, make sure to release the handle of the instrument, the endoscope lifter shall be put down, and then the device is withdrawn from the endoscope.

13.4 EMC information

Information on EMC compliance (IEC 60601-1-2:2014) (The following Disposable Sphincterotomes applies to all models of Disposable Sphincterotomes manufactured by Xinwell).

Special precautions regarding electromagnetic compatibility (EMC) must be taken for the device, and the EMC information specified in this Instruction for Use must be followed to install and use.

Portable and mobile radio frequency communication equipment may affect the instrument.

With the exception of cables (transducers) sold as spare parts for internal components, the use of non-specified accessories and cables (transducers) may result in increased emission or reduced immunity of equipment or systems.

Equipment or systems shall not be used in close proximity to or in combination with other equipment. If such proximity or combination is necessary, the equipment or system shall be observed to verify that it works properly in the configuration in which it is used.

The basic performance is shown in the following table 2:

Table 2: Basic performance of the device

Performance	Detail Description
Standby mode	No high frequency power output in standby mode.
Automatic cut	In unipolar automatic cut mode, the load impedance is 500Ω, and the deviation between the actual power output and the set power does not exceed ±20%.
Strong electrocoagulation	In the strong coagulation mode, the load impedance is 500Ω, and the deviation between the actual power output and the set power does not exceed ±20%.

The guidance and declaration are shown in table 3, table 4, table 5 and table 6.

Table 3: Guidance and declaration - Electromagnetic emissions

This instrument is intended for use by medical personnel in hospitals and for use in the electromagnetic environment specified below. The customer or the user of this instrument should assure that it is used in such an environment.
WARNING:The use of accessories that are not approved by the manufacturer may result in an increase of

electromagnetic emissions and the compliance with the stipulated limit values are not guaranteed anymore.		
Emissions test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11	Not Apply	This instrument does not have AC power input.
Harmonic emissions IEC 61000-3-2	Same as above	Same as above
Voltage fluctuations/flicker emissions IEC 61000-3-3	Same as above	Same as above

Table 4: Guidance and declaration - Electromagnetic immunity (IEC60601-1-2:2014)

This instrument is intended for use by medical personnel in hospitals and for use in the electromagnetic environment specified below. The customer or the user of this instrument should assure that it is used in such an environment. WARNING:Portable RF communications equipment(including peripherals such as antenna cables and external antennas)should be used no closer than 30 cm(12inches) to any part of the video system center,including cables specified by Xinwell.Otherwise,degradation of the performance of this equipment could result.			
Immunity test	IEC60601-1-2:2014 Test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC61000-4-2	Contact: ±8 kV Air. ±2, ±4, ±8, ±15 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not apply	This instrument does not have AC power input.
Surge IEC61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as above	Same as above
Voltage dips, short	0% U_T (100% dip in U_T) for 0.5 cycle /1 cycle	Same as above	Same as above

interruptions, and voltage variations on power supply input lines IEC61000-4-11	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/30 cycle (60 Hz) Phase angle causing voltage dips: 0º		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/300 cycle (60 Hz)		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Definition: U_T is the a.c. mains voltage prior to application of the test level.			

Table 5: Guidance and declaration - Electromagnetic immunity (IEC60601-1-2:2014)

This instrument is intended for use by medical personnel in hospitals and for use in the electromagnetic environment specified below. The customer or the user of this instrument should assure that it is used in such an environment.			
Immunity test	IEC60601-1-2:2014 Test level	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz - 80 MHz)	Same as left	Refer to the guidance in the left column.
	6V (ISM brand of 150 kHz - 80 MHz)	Same as left	Refer to the guidance in the left column.
	ISM (industry, science, and medical care) band of 6.765 MHz - 6.795 MHz, 13.553 MHz - 13.567 MHz, 26.957 MHz - 27.283 MHz, and 40.66 MHz - 40.70 MHz between 0.15 MHz and 80 MHz		
Radiated RF IEC 61000-4-3	3V/m (80 MHz - 2.7 GHz)	Same as left	Refer to the guidance in the left column.
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the next table	Same as left	Refer to the guidance in the left column.

Table 6: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band[a](MHz)	Service	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity test levels (V/m)
385	380-390	TETRA 400	Pulse Modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460,	FM[c]	2	0.3	28

		FRS 460	±5 kHz deviation 1 kHz sine			
710 745 780	704-787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL , the distance between the transmitting antenna and the ME EQUIPMENT or 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 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

14. Compatibility

Disposable Sphincterotomes are used in conjunction with HF equipment, active cords and endoscope and compatible with HF generators.

The parameters of compatibility HF generator are shown in below:

- Rated Working Voltage: 1200Vp;
- Max Working Power: 80W;
- Working Frequency Scope: 350KHz±20%.

The inner diameter of the endoscope channel of the connection device Video Duodenoscopes should be ≥2.8mm.

15. Environment

Storage environment: Ambient temperature -10°C ~ 40°C; Relative humidity ≤80%.
Working environment: Ambient temperature 10°C ~ 35°C; Relative humidity 30% ~ 75%.

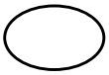
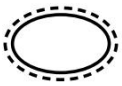
16. Shelf Life

Sterilized using Ethylene Oxide. Shelf life is 3 years. Manufacture date and expiration date are on the product label.

17. Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

18. Symbols

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community/ European Union
	Date of manufacture; Country of manufacture: CHINA		Use-by date
	Batch code		Catalogue number
	Model number		Sterilized using ethylene oxide
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
	Do not resterilize		Do not re-use
	Do not use if package is dam- aged and consult instructions for use		Keep away from sunlight
	Keep dry		Temperature limit
	Humidity limitation		Non-pyrogenic

	Does not contain natural rubber latex		Caution
	Medical device		Unique device identifier
	Follow instructions for use		Non-ionizing electromagnetic radiation
	Indicates separate collection for waste of electrical and electronic equipment (WEEE)		

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Document No.:IFU300000264, Version A/2, Issued Date:2023-09-14.