

Soft-tissue Ultrasonic Surgical System Holders/Tips for Single-use

Instruction for use

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Please read the user manual carefully!

All the information contained in this user manual has been confirmed to be correct. This company shall assume no responsibility for any accidental injury or any life-threatening event directly or indirectly caused by improper use or incorrect operation, and all the information contained in this manual is protected by law.

This manual only provides instructions for the use of the product and does not involve surgical technical information.

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Chapter 1 General Description

Product Name:

Soft-tissue ultrasonic surgical system holder/tip, single-use (hereinafter referred to as “ultrasonic cutter head”)

Device Description:

- Intended use

The holder/tip , when used in conjunction with the generator and transducer; which is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels. It is also indicated for general, gynecologic in open and Laparoscopic surgery.

- Intended users:

The device should be performed only by physicians having adequate training by manufacture and familiarity with the operating principles.

- Intended patients:

This product is indicated for pediatric (**Over 3 years old**) and adults who need soft tissue cutting and blood coagulation during surgery.

Indications:

The holder/tip , when used in conjunction with the generator and transducer; which is indicated for general, gynecologic in open and Laparoscopic surgery.

Contraindications:

1. A patient with a systemic hemorrhagic disease;
2. A patient unable to withstand surgery due to serious heart, liver or lung insufficiency;
3. A patient with diabetes or with hypertension whose condition is out of control;
4. A patient taking anticoagulants such as aspirin or warfarin should not be operated on until coagulation function returns to normal 2 weeks after medication withdrawal;
5. A patient complicated by a serious infectious disease whose condition is out of control;
6. Any other patient who may have corresponding surgical contraindications.
7. This instrument is not indicated for bone cutting; not indicated for uterine tube occlusion for contraception; not indicated for nerve closure by coagulation.
8. The instruments are not indicated for incising bone.
9. This product is not intended for use in osteotomy and tubal ligation, as well as neurosurgery.

- Model/manufacturer of combined information
- Device model

Models: ,SE45,SE36,SE23,SE14;

Matching Drive Handle Model: HP1;

Matching Generator Model: SG100;

Product dimensions and Weight:

Model	Dimension (Cannula Length cm)	Weight (g)
SE45	45	285
SE36	36	275
SE23	23	260
SE14	14	251

Operation Environment

Temperature 10 °c – 40 °c, relative humidity ≤ 75%,

pressure range: 700hpa – 1060hpa

Product Performance Requirements

1. Resonant frequency: 55.5kHz±1kHz;
2. Primary tip vibration excursion can be adjusted in 5 steps(i.e levels);
 - The maximum is 75µm with an error of ±10%;
 - The minimum is 45µm with an error of ±10%;
3. Vibration frequency of the tip of cutter head
 - 55.5kHz±1kHz.
4. Grasping force
 - No less than 3N±0.5N.
5. Gripping force
 - No less than 10N.
6. Surface Roughness
 - Surface roughness of the cutting part of cutter bar $R_a \leq 0.8\mu\text{m}$.

7. Sterility

Cutter head shall be bacteria-free after undergoing the sterilization process with ethylene oxide.

8. Ethylene oxide residues

Ethylene oxide residues of cutter head should be no more than 10 μ g/g.

9. Secondary tip vibration excursion tip of cutter head

Less than 10 μ m.

10. Primary acoustic output area

Primary acoustic output area of the tip of cutter head is no more than 3 square millimeters

11. Derived output acoustic power

Model	Output acoustic power				
	1 Gear	2 Gear	3Gear	4 Gear	5 Gear
HP1 transducer+SE45	<2W	<5W	<11W	<21W	<31W
HP1 transducer+SE36	<2W	<5W	<10W	<20W	<30W
HP1 transducer+SE2305	<2W	<5W	<9W	<19W	<29W
HP 1transducer+SE14	<2W	<5W	<9W	<18W	<28W

12. Directivity patterns

Sound pressure at $\theta=0^\circ$ with an error of $\pm 30\%$: 25×10^{-3} MPa

Sound pressure at $\theta=+45^\circ$ with an error of $\pm 30\%$: 20×10^{-3} MPa

Sound pressure at $\theta=+90^\circ$ with an error of $\pm 30\%$: 15×10^{-3} MPa

Sound pressure at $\theta=-45^\circ$ with an error of $\pm 30\%$: 20×10^{-3} MPa

Sound pressure at $\theta=-90^\circ$ with an error of $\pm 30\%$: 15×10^{-3} MPa

13. Secondary acoustic output area

Wide surface secondary acoustic output area should be less than 35mm².

Narrow surface secondary acoustic output area should be less than 25mm².

Safety Requirements

Warnings: Warnings are used to alert users that certain errors in the operation of the instrument may result in injury or death to patients.

Cautions: Cautions are used to remind users of the possibility of patient injury or problems such as malfunction or crash of the instrument, damage to the instrument itself or to any other property, which are caused by operating the instrument correctly or incorrectly.

Notes: Include some important and easily overlooked information for users to better understand and apply the instrument.

Warnings:

- Product accessories not manufactured by this company may not be compatible with this system. Use of any product not manufactured by this company may cause unintended consequences or harm to users or to patients.
- Minimally invasive procedures are only intended for medical personnel who have been professionally trained and proficient in minimally invasive techniques. It is known from relevant medical literature and related techniques that the use of any minimally invasive procedure may produce complications .
- It is very necessary to master the theories of operations and techniques for laser, electrosurgery and ultrasonic procedures. Such things can be avoided as electric shock, burn hazard to both patients and medical personnel , and damage to the device or to any other instrument or equipment. Make sure that electrical insulation and grounding are good. The electrosurgical instrument can not be immersed in liquid unless the instrument is designed to be immersed in liquid and its label indicates that it can be immersed in liquid.
- Safety and effectiveness of ultrasonic surgical equipment depend not only on the equipment design, but also on many factors like the system control by the operator. In order to improve the safety and effectiveness of the system, the user manual must be read and understood before use.
- Equipment can not be used in any place where flammable anesthetics formed by air or oxygen mixing with carbon monoxide. Hitting a metal instrument may produce sparks, which may ignite such flammable gases as xenon.
- It is prohibited to use this instrument in an environment with flammable anesthetic gases.
- It is prohibited to use this instrument in the course of nuclear magnetic resonance imaging (MRI) examination or in the course of computed tomography(CT)examination.
- It is prohibited to use this instrument in an environment with any high frequency.

Chapter 2 Instrument Brief Introduction

Soft-tissue ultrasonic surgical system holder/tip, single-use(hereinafter referred to as “cutter head”) is used together with Ultrasonic surgical system generator model SG100 by this company (hereinafter referred as “system”).

2.1 Theory of Operation

The metal cutter head mechanically vibrates at an ultrasonic frequency of 55.5KHz to vaporize water molecules in tissues, break protein hydrogen bonds, disintegrate cells, cut or to solidify tissues and close blood vessels so as to achieve the purpose of tissue cutting and hemostasis

Ultrasonic surgical system generator uses ultrasonic energy to achieve hemostatic cutting and/or coagulation of soft tissues to control bleeding and reduce thermal injury.

2.2 Product Appearance

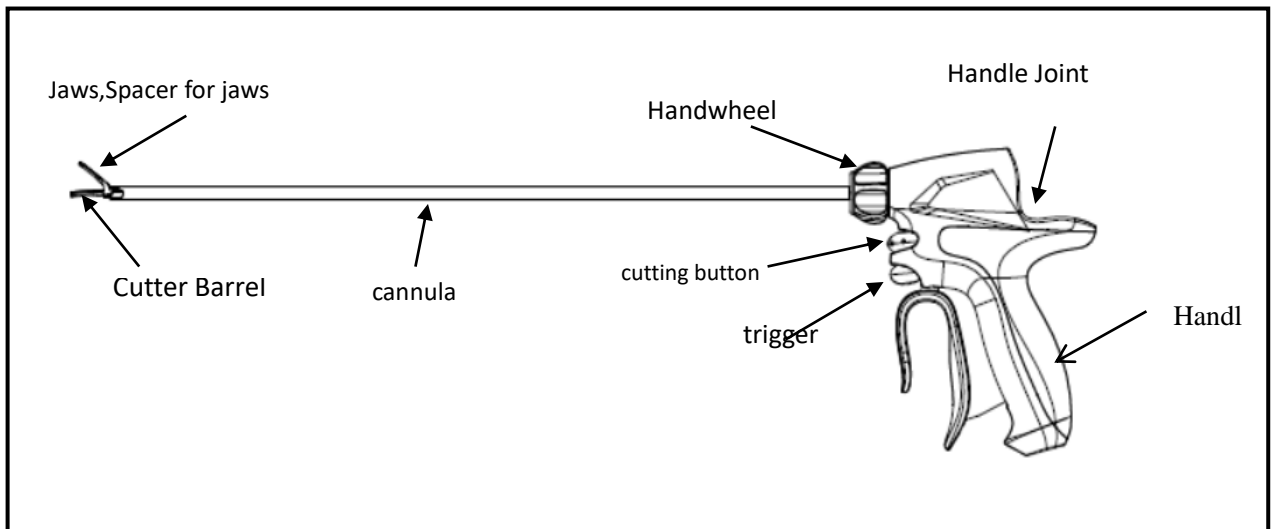


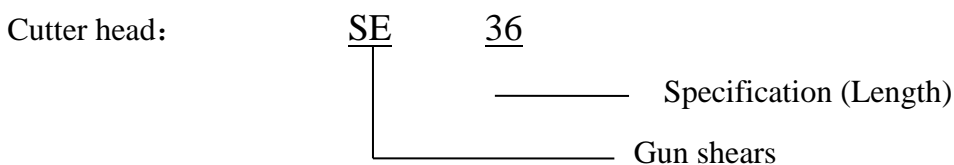
Fig 2-1

2.3 Basic Parameters

2.3.1 Cutter head parameters(take Model SE36 as an example):

- a) Length 36cm, diameter 5.5mm, curved cutter head, gun handle.

2.3.2 Explanation for Model Classification



2.3.3 Main raw materials of the cutter head are shown in table 1 below.

Table 1 Product Main Raw Materials

Part Name	Material Grade	Standard No.
Cutting Barrel	TI 6AL 4V ELI	ISO 5832-3
Jaws	17-4PH	AMS 5643
Spacer for Jaws	PTFE	GB/T7370-2015
Inner and outer casings	06Cr19Ni10 (304)	GBT20878-2007

Chapter 3 System Installation

3.1 Preparation and Checkout

Warnings:

- Prepare and check this product according to the following instructions before each time use. Other pieces of equipment to be used together with this product shall be checked in accordance with their respective user manuals. Please do not use this product even if any slight abnormality is found, and refer to the content of “troubleshooting” in chapter 7. If there is still any abnormality after referring to chapter 7, please contact our company. Damage or abnormality to the equipment may endanger the safety of patients or of operators, and may lead to more serious damage to the equipment.
- If any crack or scratch is found on the cutter bar, Cutter head tuning failed, please do not use it. Otherwise abnormal output or broken cutter bar may occur.
- Check the pressure mouth for wear, tooth deformation or for other damage. These conditions can result in abnormal output or broken cutter bar.
- Do not use a cutter with exposed metal of its pressure mouth. Otherwise, fall-off of the cutter bar or of the pressure mouth may occur.
- When checking or using this product, be sure to wear appropriate personal protective equipment, such as goggles, masks, waterproof protective clothing, and chemical protective gloves of appropriate size and length that will not expose skin. Otherwise, blood, mucus and other potentially infectious substances from patients may cause infection risk.
- Do not use a cutter if any gap is found between its pressure mouth (white part) and its metal part.

Cautions:

- Do not exert excessive force when installing or disassembling this product. If the equipment is difficult to install, do not bend or hit any parts by force, but should disassemble and reinstall them. If it is still difficult to install, thoroughly check the equipment and its components for abnormalities. If you observe or suspect that there is something wrong with the equipment or its components, please do not use it and contact our company.
- Do not use any component if it is out of shape. Even the original shape is restored, the durability of the component will be weakened. Its continued use will result in more serious instrument damage or inability to remove the instrument from the trocar cannula.
- Do not use a cutter if its clamping spacer (white part) is visibly worn. Too thin a clamping

spacer will reduce grasping force and solidification ability. The clamping spacer(white part) will wear away gradually.

- Do not touch any plug contact or socket contact when checking or connecting drive handle and the cutter. The electrostatic charge accumulated by high temperature and high pressure sterilization can cause electric shocks.
- When used in combination with energized endoscopes , patient leakage currents may be additive. Please check whether the applied part of the cutter is leakage, ensure the cutter is keep no leaking during the endoscopic surgery procedure.
- Before each use, please check the compatibility of the endoscopic equipment with the cutter, if it's not compatible, stop use the cutter.
- Before each use , please check the outer surface of the portion of the cutter , ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.

3.1.1 Checkout for the Drive Handle, Connection Cable, and the Cutter

Damage to the cutter's pressure mouth can lead to abnormal output, aggravated damage to equipment or injury to patients. Do not use any damaged cutter.

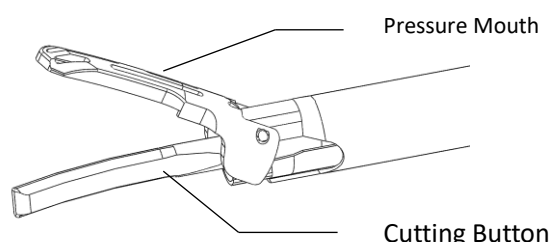


Fig 3-1

1. Confirm the cutter is marked with a clear serial number
2. Confirm the cutter is free of dust, dislocation, cracks, looseness, dents or bending
3. Check the entire insulation part of the cannula for peeling, loosening, breakage or crease.
4. Verify the pressure mouth of the cutter is not damaged. Special care shall be taken in the following cases:
 - 1) If the teeth of the pressure mouth are bent or too far apart from each other, insufficient grasping or improper cutting will arise; Please do not use this cutter, replace it with a new one.
 - 2) Make sure stop using the cutter immediately as long as its clamping spacer(white part) is too thin or worn, and replace the cutter with a new one. Failure to do so will result in abnormal output, broken cutter bar or damaged tissues.
 - 3) Do not use a cutter if there is any gap between its clamping spacer (white part) and its metal part.

3.2 System Connection and Installation

3.2.1 Connection and Installation of the Cutter and the Drive Handle

As shown in Fig 3-2

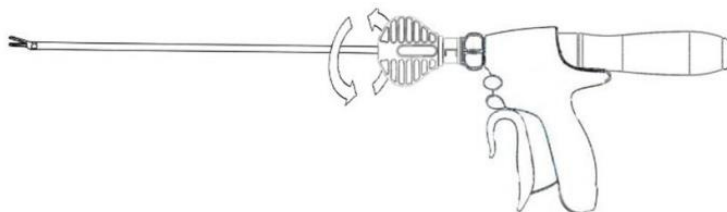


Fig 3-2

Cautions:

- Confirm the cutter and its drive handle are firmly connected. Hand-tightened cutter may lead to unsafely transmitted ultrasonic output, damaged cutter bar, or hot surface of the drive handle.
- Only use a torque wrench to loosen/tighten the cutter. Please do not use other equipment to tighten the cutter. Otherwise, the equipment or the drive handle will be damaged.
- If the cutter does not rotate smoothly, disassemble itself and its matching parts and reinstall, and then screw them together. Excessive screwing force can cause damage to the cutter or to its drive handle.
- Tighten with the torque wrench until a click is heard, which indicates tightness has been achieved.
- Connection of Multiple Time Use Cutter:
 1. Insert the drive handle's screw part into the cutter bar's joint. Then rotate the drive handle with your fingers until it is tightened.
 2. Install the torque wrench into the cannula's groove and tightly hold both the torque wrench and the drive handle. Then rotate the cutter clockwise with the torque wrench until the torque wrench clicks.
 3. When a drive handle has to be replaced during use, check the new drive handle according to "Checkout for the Drive Handle, Connection Cable, and the Cutter and the Cutter Bar", Perform step 1 and step 2 above to connect the new drive handle to the cutter.
- Connection and Installation of Single time use Cutter
 1. Remove the disposable cutter from the package.
 2. Insert the drive handle's screw part into the cutter bar's joint. Then rotate the drive handle with your fingers until it is tightened.
 3. Install the torque wrench into the cannula's groove and tightly hold both the torque wrench

and the drive handle. Then rotate the cutter clockwise with the torque wrench until the torque wrench clicks.

4. When a drive handle has to be replaced during use, check the new drive handle according to “Checkout for the Drive Handle, Connection Cable, and the Cutter and the Cutter Bar”, Perform step 1 and step 2 above to connect the new drive handle to the cutter.

Chapter 4 System Checkout

4.1 System Checkout

Cautions

- Do not carry out ultrasonic output while closing the pressure mouth. Otherwise, the abnormal heat caused by the friction between the pressure mouth and the cutter bar may cause damage to the both or cause their fall-off
- Please do not carry out ultrasonic output when the cutter bar is in contact with other objects. Otherwise, the equipment will be damaged, the head of the cutter bar may fall off, or the metal noise may be caused by friction.
- Please do not touch the cutter bar while output is being carried out. Otherwise, burns will occur.
- The main machine enters “PLEASE TUNE” state after its initialization is successfully completed. Click the “TUNE” button, a few seconds later, if the main machine does not prompt “STANDBY”, but prompts “TUNING FAILED”, it is highly possible that the drive handle or the cutter is not working properly. In such a case, immediately replace the drive handle or the cutter with a spare drive handle or with a spare cutter respectively.

4.2 Ultrasonic Output Checkout

Warnings:

- Abnormal noise made during output process may indicate that the equipment or the drive handle has been damaged. The continued use of the damaged equipment will result in the damage or fall-off of the cutter bar. In such a case, it should be replaced with standby equipment.
1. During the checkout, confirm that the cutter bar of the instrument does not touch any other object, and that the pressure mouth is in an open state.
 2. Step down the output pedal of the foot switch (maximum value) for about 5 seconds. During this time, confirm that ultrasonic output sound is heard, and that output music is played at the same time. Please refer to “Troubleshooting” in chapter 7 if the ultrasonic output is abnormal.

4.3 Trocar Compatibility Checkout

Warnings:

- The outer diameter of this product’s cannula is 5.5 mm. Use a right sized trocar. It is recommended that these pieces of equipment be confirmed to be compatible with each other

before the trocar is used in combination with this product.

- Please do not fall this product off. Excessive force on the pressure mouth or on the head of the cutter bar will result in a broken cutter or failure to open or failure to close the cutter bar. Do not use any broken cutter, which may be stuck in the sheathing cannula in the course of pulling out or extraction even if it is available to insert the product into the trocar's sheathing cannula.
 - When installing a trocar with sharp edges and corners of the opening part, hard contact can cause the fall-off of or other damage of the insulation skin of the cannula. Before use, install this product on the trocar, and verify its insulation skin is not damaged.
 - Please do not open the cutter's pressure mouth when inserting the pressure mouth into the trocar, otherwise, mechanical damage to the cutter, trocar or to the interior of the cutter may occur. This product will be unable to grasp tissues correctly if its cutter or pressure mouth is damaged.
 - Hold the cutter firmly when extracting this product out of the trocar. Please do not hold its cannula; Otherwise the pressure mouth will get stuck in the trocar, causing damage to the cutter.
1. Close the pressure mouth of the cutter, and carefully insert the instrument cannula into the trocar.
 2. Verify that both the cutter and the cutter bar's pressure mouth protrude from the head of the trocar.
 3. Make sure the cannula moves smoothly within the trocar.
 4. After confirming compatibility, carefully remove the cannula from the trocar.

Chapter 5 Instructions for Operation

Warnings:

- Wearing personal protective equipment can protect operators from dangerous chemicals and potentially infectious substances. Appropriate personal protective equipment, such as goggles, masks, waterproof clothing and chemical gloves, shall be worn during operations. Personal protective equipment should be of the right size and long enough to avoid skin exposure
- To ensure that surgery is successfully completed without being affected by malfunction, standby equipment or appropriate emergency handling should be well prepared.
- In the course of use, if this product has any abnormality or malfunction, stop using and replacing it with standby equipment, and contact our company.
- Ensure that neither the pressure mouth nor the cutter bar is in contact with surrounding tissues before output is activated, otherwise, ultrasonic output can lead to perforation, bleeding, burns or tissue damage
- Whenever possible, try to avoid the cutter's cannula in contact with tissues. If ultrasonic output is carried out for a long time, the temperature of the cannula's surface will rise, resulting in burns at the tissues in contact with the cannula.

- When ultrasonic output is activated, do not touch the cutter bar with any hard objects (such as metal clips or other equipment), please do not grab the cutter bar.
- Accidental contact with the cutter bar should also be avoided. Otherwise, the cutter bar may be overworn or damaged due to ultrasonic vibration.
- Please do not activate ultrasonic output when twisting the cannula to grab hard or thick tissues, or when rotating the rotatable knobs. Otherwise, the cutter bar may come into contact with internal components, resulting in its damage or its head's fall-off.
- Do not output ultrasound at no load. Otherwise, the result may be patients' injury or reduced durability of the equipment.
- In the course of use, if ultrasonic output stops, the cannula connected with the drive handle and with the connection cable should be immediately extracted from the patient's body, and then be checked according to the instructions for "when ultrasonic output malfunctions". Otherwise, the patient will get injured.
- If the pressure mouth or the cutter bar falls off, please stop using the equipment immediately and take an appropriate method to take out the fallen part.
- When the cutter bar is contaminated by carbonized tissues, wet soft gauze should be used to remove tissue debris. Do not scrape with sharp objects such as a scalpel. Otherwise, the cutter bar can be scratched or broken, and very likely to fall into the body cavity during the ultrasonic output process.
- Do not activate the output when no object is grabbed between the pressure mouth and the cutter bar, or when it is not certain that the tissues to be grabbed have been completely removed. Otherwise, the friction between the pressure mouth and the cutter bar will produce abnormal heat, causing damage to the both or causing their fall-off.
- Continuous ultrasonic output can make the cutter bar hot. Do not come into contact with any tissue other than targeted issues, otherwise the issue will be burned. The output shall be stopped immediately after tissues are removed. Otherwise, the pressure mouth and the cutter bar's head can be worn out. Extra care should be taken when using the instrument at a higher output.
- Do not use this product unless clear endoscopic images are obtained. Otherwise, the patient may be injured.
- The cutter bar's head of this product is relatively sharp, so the trocar should be inserted and operated carefully.
- Please do not attempt to remove tissues when the pressure mouth cannot be opened smoothly. Excessive force on the cannula can lead to cutter damage. When the pressure mouth is unable to be opened/closed, the equipment shall be stopped immediately and be extracted from the patient's body to avoid injury.
- When replacing the drive handle, be sure to extract the cutter from the patient's body. After its extraction, remove the plug from the drive handle socket. If the drive handle is being replaced while the cannula is in the patient, the force used for removal can cause the cutter head to press against tissues, causing damage to the equipment or injury to the patient.
- Do not activate ultrasonic output if blood or saline solution is found inside the plug or inside the socket. Otherwise, the equipment will be short-circuited, resulting in damage to the main machine.
- If the connection point inside the drive handle's plug or inside the connection cable's socket blackens, replace the drive handle and the connection cable. Otherwise, the equipment will be short-circuited and cause damage to the main machine.

Cautions:

- Gently hold the control cutter and ensure that the pressure mouth is closed when inserting this product into the trocar, or removing this product from the trocar. If the pressure mouth is open when the product is inserted or removed, the cutter bar will be likely to be damaged, or the product will be unlikely to be removed from the trocar.
- Do not apply excessive force when inserting this product into the trocar or removing the product from the trocar. If insertion is difficult to do, withdraw the product from the trocar

and make sure it is not damaged. Insertion or extraction of this product by excessive force may result in damage to the equipment or inability to remove the product from the trocar.

- Please do not bend the cannula hard when this product is used in conjunction with the trocar. If the equipment comes into contact with the opening of the trocar cannula, the insulation part of the equipment's cannula can be peeled off or the equipment can be damaged.
- Do not drop or strike this product. In that case, even if the equipment does not appear to be damaged, its durability will be weakened. Please do not use this product and contact our company if the product falls or is struck.
- This product is a precision instrument. Be careful when doing checks, preparations and operations.
- Use this product in an environment specified in "Operation Environment".
- This product can only be used in soft tissues, not in cartilages, bones or hard objects. Failure to do so may result in damage to the equipment or inability to remove this product from the trocar.
- During surgery, if any body fluid or tissue debris is found on the surface of the pressure mouth, the cutter bar or of the cannula, it should immediately be wiped with sterile gauze or immediately be soaked in saline solution. If saline solution or blood is found between the cutter bar and the cannula, it should be wiped with sterile dry gauze. Otherwise these substances attached will solidify and affect the pressure mouth's operation, or cause damage to the equipment.
- Do not rotate the pressure mouth unless necessary. Otherwise, the cutter cable can be twisted, resulting in equipment malfunction.

5.1 Procedure for Operation

1. Correctly install and check the system as described in chapters 3 and 4, and then activate the main machine in accordance with the steps in the main machine user manual;
2. After the system's successful activation, the words "PLEASE TUNE" appear on the system state column;
3. Press the manual switch of MAX button, the system will tune, while the state column prompting "TUNING IN PROCESS, PLEASE WAIT A MOMENT..."

TUNING IN PROCESS, PLEASE WAIT A MOMENT.....

Fig 5-2

If tuning fails, the words "TUNING FAILED" will appear in the system state column and the voice prompt "TUNING FAILED" will sound.

TUNING FAILED

Fig 5-3

If tuning succeeds, the word "STANDBY" will appear in the system state column and a voice prompt will sound.

STANDBY

Fig 5-4

5. In the STANDBY mode, the equipment is in a suspended state, and the manual switch does not work. Press the "READY" button, the equipment enters the ready state, the

word "READY" appears in the system state column.

6. Press the manual buttons to do cutting and blood coagulation.

Warnings:

- During cutting and blood coagulation, the front half of the pressure mouth shall be used to grab tissues. If only the rear half of the pressure mouth is used to grab tissues, the temperature of the part between the pressure mouth and the cutter bar will rise, leading to damage or fall-off of the cutter bar.
1. When this product is used in conjunction with the endoscope, close the pressure mouth and slowly insert the equipment into the trocar.
 2. Operate the cutter to grab the tissues to be cut or to be solidified. Make sure the cutter bar is not contact with any non-targeted tissue.

5.2 System Operation After Use

Cautions:

- When extracting this product from the trocar, be careful not let mucous membranes or other substances from patients fall into the gap between the trocar and this product.
 - Please do not pull the trocar and this product at the same time. Otherwise, the pressure mouth or the cutter bar may damage surrounding tissues, or the equipment itself may be damaged.
 - Do not use any other tool other than a torque wrench to remove the cutter head.
 - When sliding the torque wrench to the handwheel or removing the wrench from the handwheel, operate carefully so as not to damage the tip of the cutter head.
1. Power off the main machine.
 2. Close the accessories according to the contents of the user manual for the accessories used in conjunction with this product.
 3. While holding the trocar, close the equipment's pressure mouth, and pull it out of the cannula.
 4. Close the pressure mouth, put the torque wrench onto the outer cannula through the pressure mouth's end and cooperate with the outer cannula at the handwheel, turn the torque wrench counterclockwise with one hand, and hold the drive hand with the other hand, rotate the torque wrench repeatedly until the cutter's head is separated from the drive handle.
 5. All applicable national and local laws and regulations shall be followed when discarding this product and its components.

5.3 Emergency treatment

There is no emergency start/off button, if need to emergency breaking, please press the stop button or turn off power of generator which connect with the holder/tip.

Chapter 6 Storage and Disposal

6.1 Storage Conditions and Validity Period

Cautions:

- Please do not store the instrument in direct sunlight or in hot and humid places. Failure to do so may cause equipment damage or risk of infection.
- Please do not store this product in the shipping box. Otherwise there will be risk of infection
- Please do not store the equipment in a places with x-rays, radiation energy or strong electromagnetic waves (such as somewhere close to microwave diagnosis and treatment equipment, short-wave diagnosis and treatment equipment, or close to MRI, radio devices, etc.). Otherwise, the result will be the damage to the equipment or risk of infection.
- Any strong impact of this product should be avoided during storage, otherwise the equipment may be damaged.
- The equipment storage conditions: temperature -40°C — $+50^{\circ}\text{C}$; Humidity $\leq 90\%$; Pressure range 500hPa — 1060hPa . And shall be stored in clean, dry and well ventilated places.
- Sterilization validity period: Valid for 5 years from the date of sterilization completion.

6.2 Discard Disposal

All applicable national and local laws and regulations shall be followed when discarding this product and its components.

Chapter 7 Troubleshooting and Warranty

If the equipment is found to be obviously damaged and unable to function normally, or if other abnormalities are found during the check according to the method described in chapter 4 “system checkout”, please do not use this product, and contact our company. The non-fault problems found can be corrected by referring to section 7.1 “troubleshooting guidelines”. If these problems can not be solved in accordance with the methods described, please stop using the product and send it to our company for repair.

Warning

- If an instrument is found to be abnormal, do not use the instrument on the patient.

7.1 Troubleshooting Guidelines

Table 3 Troubleshooting Guidelines

Fault Phenomenon	Possible Cause	Solution
Tuning Failed	Damage to drive handle or to cutter bar	Replace the drive handle or the cutter with a spare drive handle or with a spare cutter respectively
Ultrasonic output cannot be activated. (with ultrasonic working tone)	Damage to cutter bar (such as cracks)	Replace the cutter with a spare one
	Incorrect connection between drive handle and cutter	Remove and re-install both the cutter and the drive handle with a torque wrench
	Excessive force on cutter bar	Reduce the force on the cutter bar (do not use it on hard tissues or on hard objects)
	A foreign matter or liquid inside plug or socket	If liquid is found, dry the liquid with dry gauze. If a foreign matter is found, use a sterile cleaning brush to clean the connection point as well as the inside of the socket.
Ultrasonic output cannot be activated. (without ultrasonic working tone)	Poor pedal contact of foot switch	Replace the foot switch with a spare one
	Poor contact of manual switch	Replace the cutter with a spare one
	Machine is in a state of standby	Press the "READY" button to deactivate the standby state

Chapter 8 Electromagnetic Compatibility

This chapter is a reminder of electromagnetic compatibility. Soft-tissue ultrasonic surgical system holder/tip SE series shall be installed and used according to the electromagnetic compatibility information in this chapter.

A portable or mobile radio frequency communication device may affect the use of soft-tissue ultrasonic surgical system holder/tip SE series. it is recommended to stay away from portable or mobile radio frequency communication devices or keep them in an off state when using soft-tissue ultrasonic surgical system holder/tip SE series in a normal way,.

Warning: The use of any accessory other than the accessories provided by this company may lead to the increase of emission or to the decrease of immunity of soft-tissue ultrasonic surgical system holder/tip SE series.

Soft-tissue ultrasonic surgical system holder/tip SE series should not be close to or be superimposed with other equipment with the same or similar frequency. If the stapler is required to do so, it should be observed and verified to be able to operate normally under its used configuration.

Please choose the connection cables and their related accessories provided by this company in order to ensure that the normal use of soft-tissue ultrasonic surgical system holder/tip SE series and that no increase of its emission or no decrease of its immunity

The use of non-specified accessories, transducers or cables in conjunction with soft-tissue ultrasonic surgical system holder/tip SE series may result in increased emission or reduced immunity of the equipment or the system.

Refer to below Table 5 to table 9 for detailed guideline and declaration.

Table 5 Guidelines and Manufacturer's Statement-Electromagnetic Emission-Electromagnetic radiation guidelines		
Soft-tissue ultrasonic surgical system holder/tip SE series is expected to be used in the following specific electromagnetic environments. Users and buyers of Soft-tissue ultrasonic surgical system holder/tip SE series the must ensure that this product is used in such an environment.		
Radiation Test	Conformity	Electromagnetic environment-guidelines
IEC 61000-3-2 Harmonic emission	Not applicable	Used in professional healthcare environment only and don't connected to AC mains.
IEC 61000-3-3 Voltage fluctuation/Flicker emission	Not applicable	
CISPR 11 Radio-frequency radiation	Complies Class A	

Table 6 Guidelines and manufacturer's statement-electromagnetic immunity guidelines


Soft-tissue ultrasonic surgical system holder/tip SE series is expected to be used in the following specific electromagnetic environments. Users and buyers of Soft-tissue ultrasonic surgical system holder/tip SE series must ensure that this product is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidelines
Electrostatic Discharge(ESD) IEC 61000-4-2	±6kV Contact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	±6kV Contact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical Fast Transient Burst IEC 61000-4-4	±2kV 100kHz Repetition frequency	Not applicable	The product doesn't connected to AC mains.
Surge IEC 61000-4-5 Line to line Line to Ground	±0.5kV ±1kV ±2kV	Not applicable	The product doesn't connected to AC mains.
Voltage Sag on Power Input Line, short interruption and voltage change IEC 61000-4-11	0% UT;0.5 cycle g) 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° q) 0% UT;1 cycle and 70% UT;25/30 cycles h) Single-phase: on° 0% UT;250/300 cycles h)	Not applicable	The product doesn't connected to AC mains.
Power frequency magnetic field IEC 61000-4-8	30A/mg) (50/60Hz)	30A/m (50/60Hz)	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field in typical places in a typical commercial or hospital environment.

Note: Ut refers to the AC network voltage before voltage is applied.

Table 7 Guidelines and manufacturer's statement - electromagnetic immunity guidelines

Soft-tissue ultrasonic surgical system holder/tip SE series is expected to be used in the following specific electromagnetic environments. Users and buyers of Soft-tissue ultrasonic surgical system holder/tip SE series must ensure that this product is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidelines
<p>Radio-frequency Conduction IEC 61000-4-6</p> <p>Radio-frequency Radiation IEC 61000-4-3</p>	<p>3V 150kHz~80MHz 6V in ISM band</p> <p>3V/m 80MHz-2.7GHz 80%AM,1kHz c)</p>	<p>3V 150kHz~80MHz 6V in ISM band</p> <p>3V/m</p>	<p>A portable or mobile radio frequency communication device shall be at a distance from any part of Soft-tissue ultrasonic surgical system holder/tip SE series (cables included) no shorter than the recommended isolation distance for the device. The specific distance shall be calculated by a formula corresponding to the transmitter frequency</p> <p>Recommended isolation distance</p> <p>d=1.2 错误!未找到引用源。 80MHz~800MHz</p> <p>d=1.2 错误!未找到引用源。 800MHz~2.7GHz</p> <p>where, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts(W); and d is the recommended isolation distance, in meters(m).^b The field strength of the fixed RF transmitter is determined by the electromagnetic field site survey^a, and should be lower in each frequency range^b than the coincident level. Interference may occur near devices marked with the following symbol.</p> 

Note 1: The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz.

Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.

“a” field strengths of fixed transmitters, such as: wireless (cellular/cordless) telephones and base stations for ground mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasting and television broadcasting, etc., These field strengths above cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of a fixed RF transmitter, the survey of electromagnetic field site should be considered. If the field strength in the place where Soft-tissue ultrasonic surgical system holder/tip SE series is located is measured to be higher than the RF coincident level for the above application, the device shall be observed and verified to be able to operate normally. If any abnormal performance is observed, supplementary measures, such as redirection or repositioning of the device, may be necessary.

“b” In the whole frequency range of 150kHz-80kHz, the field strength should be less than 3V/m.

Table 8 Recommended isolation distance between a portable or mobile radio frequency communication device and the SG100

Soft-tissue ultrasonic surgical system holder/tip SE series is expected to be used in an electromagnetic environment where RF harassment is controlled. According to the maximum output power of the communication device, buyers and users of Soft-tissue ultrasonic surgical system holder/tip SE series can prevent electromagnetic interference by maintaining the minimum distance recommended below between a portable or mobile radio frequency communication device (transmitter) and Soft-tissue ultrasonic surgical system holder/tip SE series.

Rated maximum Output power of the transmitter W	Isolation distances for different frequencies of the transmitter (m)		
	150kHz~80MHz ISM Frequency Band d=1.2 错误!未找到引用源。	80MHz~800MHz d=1.2 错误!未找到引用源。	800MHz~2.7GHz d=2.4 错误!未找到引用源。
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For any rated maximum output power of the transmitter not listed in the table above, the recommended isolation distance d , in meters(m), can be determined by the formula in the corresponding transmitter frequency column, where p is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (w).

Note 1: The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz.















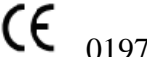
Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.

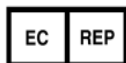
Table 9 Test Specifications for Immunity of Surgical Ports to RF Wireless Communication Devices						
Test Frequency (MHz)	Frequency Range a) (MHz)	Service a)	Modulation b)	Max Power (W)	Separation Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA	Pulse Modulation b) 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM c) Deviation ±5 kHz Sine 1 kHz	2	0.3	28
710	704-787	LTE Frequency Band 13,17	Pulse Modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Frequency Band 5	Pulse Modulation b) 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Frequency Band 1,3,4,25, UMTS	Pulse Modulation b) 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Frequency Band 7	Pulse Modulation b) 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation b) 217 Hz	0.2	0.3	9
5500						
5785						
Note: The distance between the transmitting antenna and the device or the system can be reduced to 1 meter if the immunity test level requires to be reached. IEC 61000-4-3 allows a test distance of 1 meter.						
a) For some services, only uplink frequencies are included.						
b) The carrier shall be modulated using a square wave signal with a 50% duty cycle						
c) As an alternative to FM modulation, 50% pulse modulation at 18Hz can be used. Because while it does not represent actual modulation, this would be the worst case scenario.						

Chapter 9 Symbols and Meanings

Go to <http://111.204.46.40:8180/lddsm/sh/bsOfu5uR> get for latest revision of service manual.

Table 8 Drawing Marks Interpretation

Drawing Mark	Meaning	Drawing Mark	Meaning
	Sterile		Sterilized with ethylene oxide
	Batch code		Type CF Applied part Can be directly used in the heart
	Storage temperature and humidity		Do not use when the package is broken
	Manufacture date		Manufacturer information
	Guard against rain		Attention! Consult Accompanying Documents
	Electrical and electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in EU countries. Please follow decontamination instructions before returning waste.		Do not reuse
			Do not resterilize
	Authorized representative in the European Community		Notified body
Basic UDI-DI	69392824SUSSH10007D		



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