

INSTRUCTIONS FOR USE

Disposable Polyp Snares

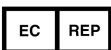
FORESIGHT TECHNOLOGY CO., LTD.

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1. Symbols

The symbols used in the instructions and labels are as follows:

	Single Use Only
	USE BY
	Date of Manufacture
	Batch Code
	Catalogue Number
	Sterilized using Ethylene Oxide
	Caution, avoid of burning when in use.
	Manufacturer
	Authorized Representative in the European Community
	Consult Instructions for Use
	Protection Grade of Electric Shock : BF type
	Symbol for Compliance with MDD93/42/EEC
	Symbol for Recycle of Electronic & Electric products in European market, the used or rejected products should be disposed according to the local law and regulations.
	Indicates a potentially hazardous situation which , if not avoided, could result in minor or moderate injury
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

2. Descriptions of Instrument

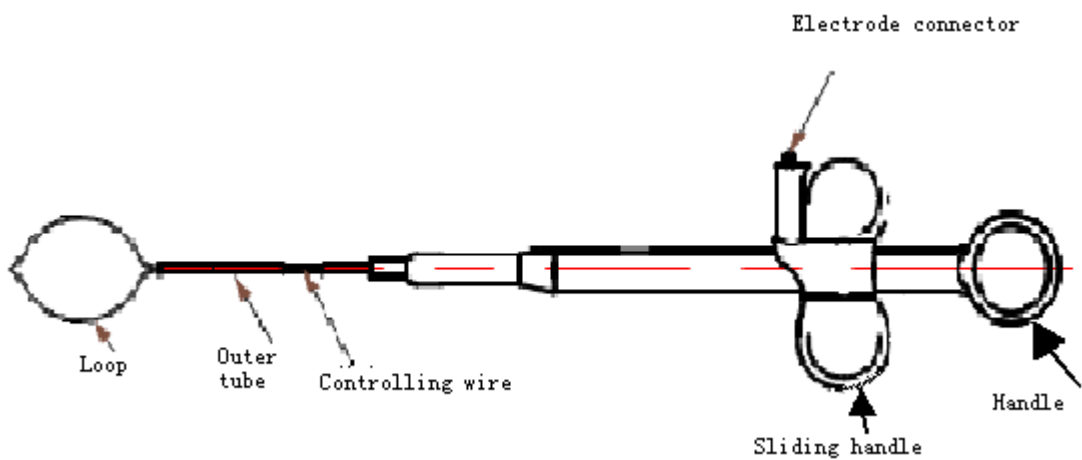
【Name of Instrument】 FST-SD Type Disposable Polypectomy Snares

Note: In the Instructions for Use, “instrument” indicates “FST-SD Type Disposable Polypectomy Snares”.

【Classification of Instrument】 This instrument is classified as BF type application part according to Protection Grade of Electric Shock, standard of IEC60601.1.

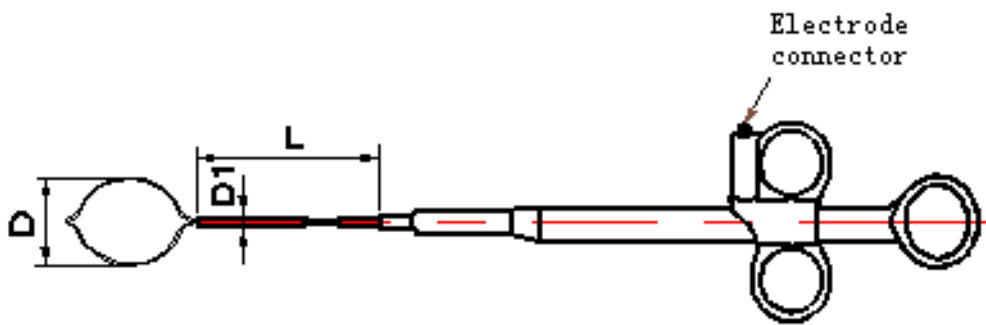
【Configuration】 Main parts: loop, outer tube, controlling wire, handle components, and electrode connector.

Illustration:

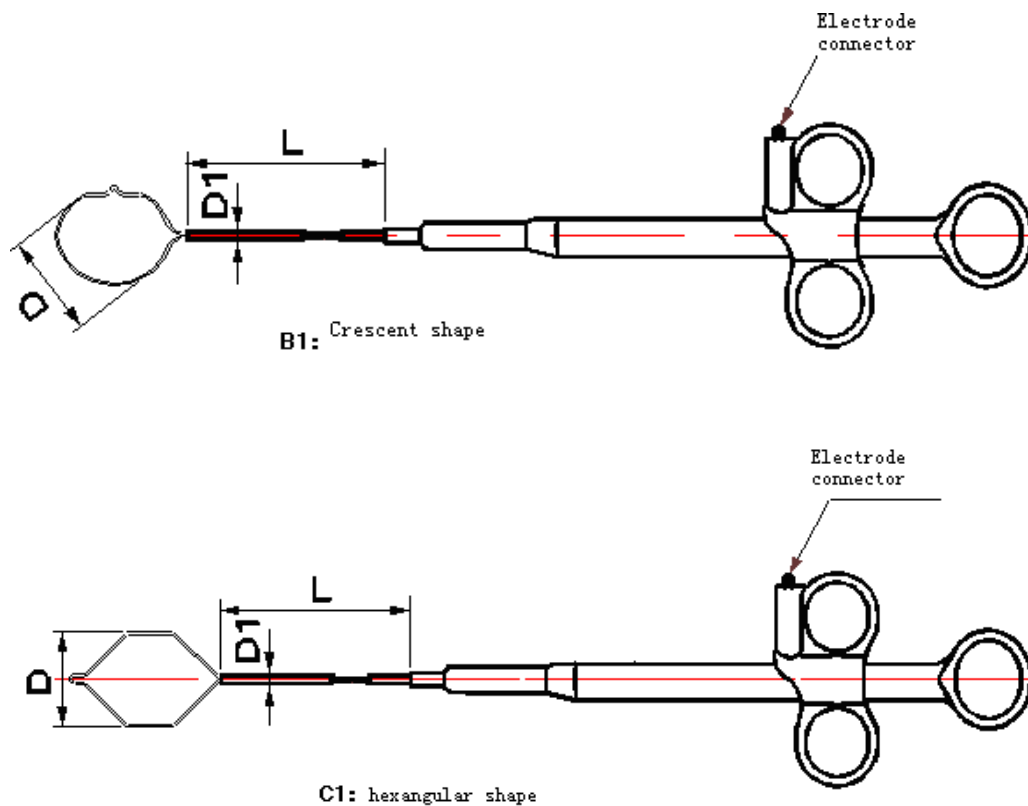


【Specifications】

Outer Tube O.D. (D1) (mm)	Tolerance	Working length (mm)	Tolerance (mm)	Width of Loop D(mm)	Tolerance (mm)	Characteristics of Loop
1.8; 2.3	± 0.2	1200; 1600; 1800; 2000; 2200; 2300; 2400; 2600; 3000	± 15	10; 15; 20; 22; 23; 25; 30; 35; 40; 45; 50	± 4	A1: Oval shape; B1: crescent shape; C1 : hexangular shape A2/B2/C2: Rotatable S: Monofilament HC: Hot&Cold



A1: Oval shape



3. Weight of Instrument

The weight of each instrument is 40g~55g.

4. Application

This instrument is used in electro-surgery, for cutting polyps or other redundant tissues with high-frequency current in digestive tract in combined use with endoscopes.

Warning: Do not use this instrument for any purpose other than its intended use.

5. Contraindications

This instrument is contraindicated for the following:

- The patients who has the contraindications for digestive endoscopic examination.
- Patients with the trend of hemorrhage, time elongated of hemorrhage or cruor, hemoblast reduction, or elongated time of thrombin, cannot recover after medical therapy.
- The patient with deteriorated polyp cancer.
- The place easy for perforation.
- Root of polyp is too large, (with its diameter $>2\text{cm}$), which is confirmed not be able to be resected.
- Others can be judged by professional physicians according to patient's actual conditions.

6. Potential Contraindications

Potential contraindications of snare operation includes(but not limited to):
Hemorrhage, perforation, burning, blood poisoning, infection, hypotension.

7. Cautions

Caution

- This instrument is sterilized, for single use only. Destroy it after use, reuse is prohibited.
- Check the sterilization validity period on the package before use, and use the instrument within the stated period.
- This instrument doesn't include the parts that can be maintained by user himself.

Disassembly, refit, or attempt to repair is not allowed, otherwise, patient or operator injury, or instrument damage may result.
- Before the endoscope and its accessory's inserting into patient's body, it is a must for the inspection of the endoscope and the bare electrode, where if any roughness, sharp angle, or extruding is found, the immediate exchange or pause of use is a must, otherwise, it would result in damage to patient.
- Do not attempt to sterilize it, otherwise, it could pose an an infection control risk, cause tissue irritation or equipment damage or malfunction.
- Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Do not use the instrument, use the spare instrument instead.
- Remember not to use this instrument in the patient who has been equipped with the heart pacemaker. Otherwise, the high-frequency signals and spark electricity from this instrument, high-frequency equipment, and cable, may cause discharge interference, and would cause ventricle tremble or damage to electronic components of pacemaker, then may result in death injury.
- In operation, the meeting between electrode and combustible gas should be prevented. Do not use nitrous oxide and oxygen as the anaesthesia gas. The electrode is also be prevented to meet combustibility material.(i.e. Cotton, gauze, wood, alcohol), it may cause burning in the oxygen.
- The damage to insulation of electrode cable should be prevented when the instrument is used in combination with endoscope.

8. Preparations and Inspections

【Preparations】

Prepare all the devices and personal protective equipments that used with this instrument according to the corresponding instructions for use. Appropriate personal protective equipments include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves.

Always have a spare instrument available.

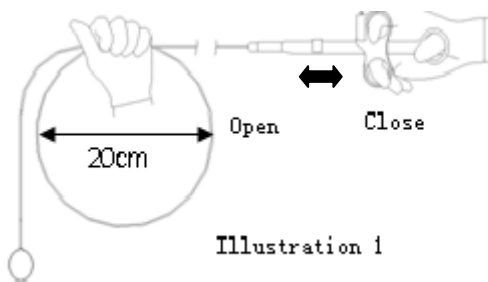
【Inspection】

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Do not use the instrument, use the spare instrument instead.

Make sure the connection part of this instrument has no breaking off or being loosen.
Gently run your gloved fingertips over the entire length of the insertion portion to check for any crushed areas, excessive bends, broken areas or other damage.

Confirm no protuberance, edge, or other defects of the tip of the insertion portion.

As per illustration 1, hold this instrument and its handle, make the insertion portion form a circle with approximate diameter of 20cm. Push and pull the sliding part in the handle, to confirm the ferrule is of the right shape, and pull the sliding handle to confirm the tip of ferrule could be completely retracted to its outer tube.



Confirm no cracking of handle parts.

Confirm no breaking of high-frequency connection cable or no bare part of leading cable.

9. Inspection and Cautions of connection between the instrument and high-frequency equipment

【The connection between this instrument's electrode and high-frequency equipment】

- 1) According to Instructions for Use of the high-frequency equipment, insert the high-frequency connection cable into the electrode connector of this instrument, until the clatter sound can be heard.
- 2) Confirm the electrode plug of this instrument is in the right position of the socket.
- 3) Insert the plug on the other end of high-frequency connection cable into the socket CUT/COAG of the high-frequency equipment.
- 4) Confirm the clatter sound is heard and the plug is in the right close position in the socket.
- 5) Remove the plug of high-frequency connection cable.
- 6) If any irregularities found in the above steps, check the cause or use the spare instrument instead.

Caution

- Choose the high-frequency equipment and high-frequency connection cable.

The high-frequency equipment of ERBE、 MARTIN、 STORZ and OLYMPUS is appropriate, And the high-frequency connection cable is also available by these companies. But make sure the appropriate matching with the connection part of this instrument before use.

- The recommended high-frequency equipment is with frequency 300~500KHz,the peak voltage less than 1000V. When cutting polyps with high-frequency electricity, appropriate electricity wave and different output power (generally 15—35W for

electrocoagulation and electro-cutting) should be selected according to different conditions of polyps.

- A limited output power of high-frequency equipment should be set up, to ensure patient's safety, and to prevent unconscious heat injury to human body tissue, and in the meantime to prevent the damage caused by the too high frequency electrical current during the meeting between the electrode and other metal instruments, in the condition that this instrument and the high-frequency equipment have already started up.
- When the high-frequency equipment is turned on, do not connect with any equipments or inspect any connections, otherwise, it may cause the burning to hands of the operator or assistant.
- If the high-frequency is equipped with the monitor circuit, please refer to the Instructions for Use of the high-frequency equipment to confirm if they are compatible with each other.
- When in normal use, the output power of high-frequency equipment should be turned as down as possible. If need to turn it up, the inspection of the correct connection between each part is a must.
- Do not drag the connection cable when pull out the electrode plug or high-frequency connection cable, otherwise, it may result in the damage to high-frequency connection cable.
- When not in use, the electrode should be placed isolated from patients.

Warning

- Do not knot the high-frequency connection cable, or bind with the cables of other medical equipments (such as: electrocardiograph, endoscope system, etc.) Otherwise, the working high-frequency signals and spark discharge may cause interference and malfunction of other medical instruments, then may result in injury to patient.
- The output voltage adjusted by the high frequency generator should not exceed the maximum voltage which is indicated in the Instructions for Use.
- It is prohibited to use the explosive gas in the operation area when this instrument is used.
- The users should take notice and try to avoid of the potential risk when using this instrument and the equipped endoscope.
- If with malfunction of high-frequency equipment, it may cause the unexpected increase of the output power.
- The unsafe contact between this instrument and patient would not have the alarm, which may have the potential risk, until equipped with electrode monitor circuit.

10. Operation and Cautions

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

- 1) According to the Instructions for Use of high-frequency equipment, connect the neutral electrode plug to the equipment.
- 2) Cautiously place the neutral electrode with its maximum area on patient's upper arm or thigh in the same side of the body where the operation needed.

Caution

- The neutral electrode can not be used in the following parts:
wound area
skin with inflammation

area of bone extruding
the surface under which is the metal
the surface under which is the thick hypodermic fat

- The contact between skin and skin is prevented.
- When in use, the loop caused by this electrode with others should be prevented.
- Patient cannot hold metal stuff on body, or to contact other metals.

3) Inserting into the endoscope

Caution

- When inserting this instrument into the endoscope, hold it close to the endoscope channel portal, and try to hold it straight. Otherwise, the insertion portion may be damaged.
- Slowly insert this instrument, abrupt insertion would cause damage to endoscope or this instrument.
- Do not force this instrument if resistance to insertion is encountered. Reduce the endoscope's angulation (or lower the forceps elevator if applicable) until the instrument passes smoothly. Attempting to force this instrument could cause damage to endoscope and this instrument.
- When this instrument has been completely drawn out from the endoscope channel tip, the inspection of system can be executed. Otherwise, it may result in damage to endoscope and this instrument.
- When the loop contacts with the endoscope tip, don't allow the output, otherwise, it may result in damage to endoscope and this instrument.
- When inserting this instrument into the endoscope channel, the sliding handle should be kept immovable, otherwise, it may result in damage to endoscope or this instrument.
- When the loop is not completely retracted into the outer tube, do not insert or withdraw this instrument, otherwise, it may result in damage to the endoscope or this instrument.
- When this instrument is used in combination with endoscope with double channels, do not use other instruments at the same time, otherwise, it may result in burning to hands of patient, operator or assistant.

- 4) According to the Instructions for Use of the high-frequency equipment, insert one end of high-frequency connection cable into the high-frequency equipment, and another end into the electrode connector of this instrument.
- 5) Pull the sliding handle to open the ferrule.
- 6) Adjust the angle of endoscope insertion portion according to requirement, and advance this device or rotate the loop, until the target tissue is trapped.
- 7) Enclose the target tissue with the ferrule.
- 8) Pull the sliding handle to enclose the target tissue.

Caution

- Do not make an abrupt push to the sliding handle, otherwise, it would make the loop reach out abruptly, this would result in perforation, hemorrhage or mucous membrane damage.
- Do not use too much power when attempt to enclose the target tissue, otherwise, it may result

in patient hemorrhage or mucous membrane damage.

- Confirm the high-frequency equipment is turned off when attempt to connect this instrument with the equipment, otherwise, it may result in burning to the hands of the operator or assistant.

9) Pull the sliding handle, start the output, first for electrocoagulation, then for electrical cutting, (alternation for 3~4 seconds/each time), and repeatedly, gradually, and smoothly cut the redundant tissue.

Warning

- Aspirate the liquids that adhered to the loop and body duct tissues (such as mucilage). If electrical cutting is executed when these liquids are adhered, it would result in patient perforation, hemorrhage, mucous membrane damage or burning to tissue.
- When operating the high-frequency equipment, try to use the minimum output and time needed by the operation. Excessive output would result in patient perforation, hemorrhage or mucous membrane damage.
- When in cutting, make sure this instrument is connected with electricity. It may result in patient hemorrhage or mucous membrane damage if to execute cutting when this instrument is disconnected with electricity.

Caution

- When this instrument is connected with high-frequency electricity currency, don't start the output when this instrument is in contact with the normal duct tissue, otherwise, the non-target tissue will be burned.
- If swelling air formed in intestines duct, change it with unflammable air (such as CO₂), otherwise, the swelling air could result in burning or Explosion, then cause burning to patient's tissue.
- To avoid of burning healthy tissue, do not start up output when the ferrule is in contact with the non-target tissue.
- When any part of the target tissue (i.e. the head end of polypus) is in contact with non-target tissue, do not start up output, otherwise, the non-target tissue will be burned.
- When the tip portion of endoscope is too close to duct tissue or they are in contact, do not start up output, Otherwise, it could result in burning to tissue or endoscope damage.
- When the metal part in the tip portion of endoscope is too close to loop part, or they are in contact, do not start up output.
- When patient's skins are in contact (i.e. bare arm are in contact with chest side), do not start up output, otherwise, it may result in burning to patient.
- When patient's clothing is wet, do not start up output, otherwise, it may result in burning to patient.
- When patient is in contact with the operation platform or the metal part of other equipments, do not start up output, otherwise, it may result in burning to the hands of patient, operator or assistant.
- When in output status, do not contact the connection cable or other person, otherwise, it

may result in burning to the hands of patient, operator or assistant.

- 10) Turn off the high-frequency equipment, remove the high-frequency connection cable from the electrode plug connector.
- 11) Withdraw the instrument from the endoscope.

Caution

- **Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucus or other patient debris and pose an infection control risk.**
- **When the loop is not completely retracted to its outer tube, do not withdraw the instrument from the endoscope, otherwise, it may result in damage to endoscope or the instrument.**

11. Transport, Packaging and Storage**Caution**

- The single packaging is paper-plastic bag, middle is the box, and out is the carton. When in transport, it should be kept clean, dry and sealed. The transport condition should be: the temperature should be of $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$, and the humidity of $10\% \sim 90\%$, it could not be transported together with sand, metal fragments, glasses, or keen-edged stuff, nor can with the poisonous, corrosive or flammable stuff. During transport, sling of packages, insolation under the sun or drenching in rain are all prohibited.
- This instrument is sterilized product, for single use only. Store the sterile package at the temperature of $-20^{\circ}\text{C} \sim 50^{\circ}\text{C}$ and at the humidity of $10\% \sim 90\%$. Store the instrument at the dry room of good ventilation. Do not store it in direct sunlight.

Warning

- Do not store the sterile package containing the instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could pose an infection control risk or cause tissue irritation.

【Sterilization style】EO sterilization

【Sterilization valid period】two years



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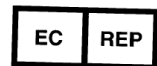
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