52000025

Disposable Coagulation Electrode

1. STANDARD SET LIST

This package includes the following items:

- Heyinovo Disposable Coagulation Electrode
- Instructions for Use

NOTE:

- *Read this manual before operating.*
- *Failure to read and thoroughly understand the information presented in this manual, as well as those developed for other endoscopic equipment, may result in serious injury to the patient and/or user. Furthermore, failure to follow the instructions in this manual may result in damage to, and/ or malfunction of, this equipment.*
- *It is the responsibility of each medical facility to ensure that only well-educated and appropriately trained personnel, who are competent and knowledgeable about endoscopic equipment, antimicrobial agents/processes, and hospital infection control protocol be involved in the use of these medical devices.*
- *Known risks and/or potential injuries associated with flexible endoscope procedures include, but are not limited to, the following: hemorrhage, burns, electric shock, perforation, sparking, bleeding, abdominal pain, fever, temporary intestinal obstruction, and infection.*

2. INTENDED USE

This device is intended to be used with a flexible endoscope and electrosurgical generator to aid physicians in endoscopic electrocoagulation on the bleeding point with high-frequency current in the digestive tract.

⚠ WARNING:

- *This device has been ETO sterilized for single patient use. Never reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may lead to device failure, patient injury, and/ or illness. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection. Contamination of the device may lead to injury and/or illness of the patient.*
- *Never attempt to repair or modify this device. The use of a repaired or modified device may result in patient injury.*

⚠ CAUTION:

Never use this device for any purpose other than that for which it has been designed. Since endoscopic accessories are designed to be used in conjunction with other medical devices, the effectiveness of an accessory is dependent upon a number of factors, including the condition of the endoscope and electrosurgical generator.

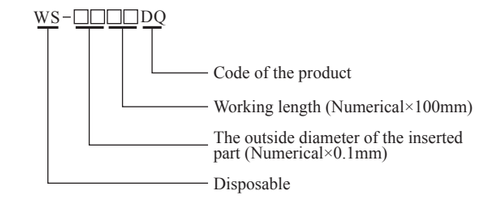
3. CONTRAINDICATIONS

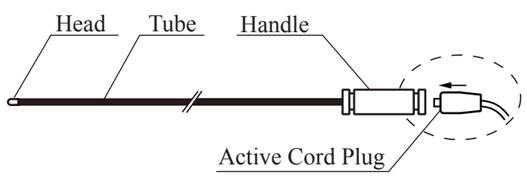
Do not use the device or cord onto patients who are implanted with cardiac pacemakers.

4. PRODUCT DESCRIPTION

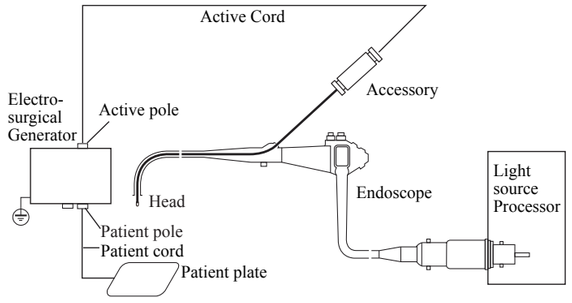
- *This device consists of distal portion (the head), insertion section (which consists of conductive wire enclosed in insulated tube), and handle.*
- *The insertion portion is being fixed to the handle.*
- *The head, tube, and handle are in an all-in-one integrated design.*

5. NOMENCLATURE





6. SYSTEM CONFIGRATION



⚠ WARNING:

To avoid burns to the patient and user, use only a floating type electrosurgical generator. Do not use non-floating (B type) electrosurgical systems.

Use of the correct active cord is required to connect different brands of electrosurgical generators (such as: ERBE® brand generator) to this device. For details, please consult the electrosurgical generator manufacturer.

7. PREPARATION AND INSPECTION BEFORE USE

⚠ CAUTION:

Wear sterile surgical gloves when performing the pre-use inspection.

1) Prior to use, the endoscope with which this device will be used must be carefully and thoroughly inspected for cleanliness and proper function to determine that it is appropriate for patient use. Please refer to the manual supplied with the endoscope.
2) Select an appropriate device to satisfy the technical characteristics as well as the intended application of the endoscopic accessory.

Disposable Coagulation Electrode Application Table

Model \ (mm)	Max. Insertion Portion Width	Working Length	Compatible Endoscope	
			Minimum Channel Width	Working Length
WS-1810DQ	ϕ1.9	1000	ϕ2.0	700 or less
WS-1816DQ		1600		1300 or less
WS-2416DQ	ϕ2.5	1600	ϕ2.8	1300 or less
WS-2423DQ		2300		2000 or less

* The above product specifications are only partial, just for reference.
* There is no guarantee that instruments selected solely using this minimum Instrument channel width will be compatible in combination.

- These accessories comply with IEC60601-1, IEC60601-2-2, IEC60601-2-18.
- Degree of protection against electric shock: type BF
- Ingress Protection Rating/Waterproof Rating: IPX0

⚠ CAUTION:

Use of this device with an incompatible endoscope can result in endoscope and/or accessory damage/failure.

⚠ WARNING:

This device should only be used in an endoscope with forward viewing optics. Never use this device with an endoscope with oblique or side viewing optics.

3) Check the sterilization expiration date printed on the package/ labeling and confirm that the product has not expired. Make sure that there are no signs of abnormalities such as stains, wetness, tears, or any other indications that the packaging has previously been opened or compromised.

⚠ WARNING:

Do not use this device if it is expired or if the sterilization package is opened, damaged, or displays any abnormalities. In such cases, sterility can't be guaranteed, and clinical use of the device can result in patient infection or allergic reaction.

4) Remove the device from the packaging.
5) With the gloves on, 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.

⚠ WARNING:

If the abnormal conditions of the insertion portion are noticed, do not use the device as it may cause the damage of the mucosal or burn of the non-target tissue of the patient. It may also cause the damage and burn of the user.

⚠ CAUTION:

Avoid tight coiling or bending of the insertion portion into a diameter less than 15cm. Doing so can damage the insertion portion of the device.

6) The device should be slowly inserted through the channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to advance the device further, as the endoscope channel may be damaged. Remove the endoscope from service for inspection and repair.
7) After the device exits the distal tip of the endoscope, connect the device and electrosurgical generator.
8) Connect the active cord securely to the active cord plug of the device. Confirm that it has been clicked into the place and is seated. Avoid leaving any metal parts of the active cord and active cord plug exposed. Insert the other end of the active cord into generator. Always operate the device in compliance with the generator manufacturer's instructions so as to avoid injury to operators and/or patients.
9) Ensure that related equipment functions properly (according to the operating manuals supplied with each device).
10) Turn off the electrosurgical generator.
11) After the device exits the distal tip of the endoscope, withdraw it from the endoscope.

⚠ CAUTION:

As a precaution, always have an extra device available for use in the event that the original device becomes inoperable and/or unsafe for patient use. If a spare device is used, the above preparation and inspection steps should be followed.

⚠ WARNING:

Do not use a device that shows any signs of damage or operational difficulty. Any malfunction of the device during a patient procedure can result in serious injury to the patient.

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8. OPERATION

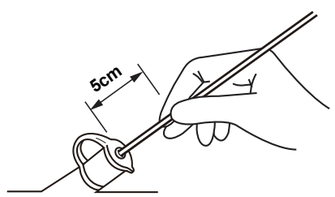
⚠ WARNING:

- *The user must carefully read and follow all instructions in the operating manuals supplied with all related equipment. The equipment should be carefully and thoroughly inspected to determine that it is appropriate for patient use.*
- *NEVER use this device in the presence of a high concentration of oxygen, flammable explosive gases, or chemicals.*
- *To avoid burns to the patient and user, use only a floating type electrosurgical generator. Do not use a non-floating (B type) electrosurgical generator.*
- *Technical criteria, clinical applications, and accompanying risks must be well understood before using this device.*
- *Physicians and assistants should wear personal protective equipment such as gloves, gowns, face masks, goggles, etc. to minimize the risk of cross contamination.*
- *A rubber eye-shield should be placed on the eyepiece of a fiberscope to avoid burns.*
- *When an electrosurgical generator and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the device. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.*
- *DO NOT use the device on patients who have implanted cardiac pacemakers. High-frequency signals or spark discharge may cause ventricular fibrillation or damage electronic components of pacemakers.*
- *To avoid damaging the device when inserting or withdrawing it through the instrument channel inlet of an endoscope, keep the endoscope in a straight position and slowly insert, advance, or withdraw the device. Never apply excessive force.*

1) Slowly insert the endoscope under direct vision.
2) The device should already be appropriately connected with an active cord to a suitable electrosurgical generator.
3) A patient plate should already be appropriately positioned under the patient.
4) Insert the device through the slit in the rubber inlet seal with the endoscope in a straight position.

NOTE:

- *When the distal end of the device is first passed through the rubber inlet seal, temporary resistance will be encountered. Overcome this resistance by holding the tube tightly at about 5cm from the distal end and pushing it past the area of resistance.*
- *During insertion, if the device becomes difficult to advance, decrease the deflection of the bending section to a level suitable for smooth insertion, and insert the device again. Alternately, withdraw the device, and then attempt to insert it again.*



⚠ CAUTION:

Never apply excessive pressure when introducing any device, since the instrument channel or the device may be damaged.

5) When an endoscope with a device elevator is used (such as a duodenoscope), the previously raised elevator mechanism will stop advancement of the device before it exists the distal tip of the endoscope. Once the device reaches the elevator, the mechanism should be lowered to allow the device to advance approximately 1cm. The elevator may then be maneuvered as needed to bring the device into view and to aid in the application of the device.
6) When the head of the device becomes visible in the viewing field, always slowly and carefully advance it into the target area.

⚠ CAUTION:

Always maintain a view of the device during its advancement beyond the scope tip.

⚠ WARNING:

To avoid patient and user burnt, follow the instructions below before electro-surgical-energy is delivered.

1) The position of the target area, the tube and the head of the device should be visible.
2) The head of the device should not touch the metallic distal portion of the endoscope or any hemostasis clips directly or via fluids.
3) The metallic portion of the endoscope should not touch the surrounding tissue directly or via fluids.
4) The head should not make contact with any body tissues other than the area intended to be treated, either directly or indirectly through body fluids.
5) According to the medical literature, the typical power shall be set at 40~50W. If you are not aware of the proper setting for the generator, set the device below the recommended power range, and increase the power carefully until you get the desired effect.
6) During performance of the high-frequency surgical operation, the injection of excessive air or inert gas may cause a gas embolism, which is a potential safety hazards.
7) The head of any lesion such as a polyp should not touch the surrounding tissue directly or via fluids.
8) Physicians and assisting personnel should avoid contact with the patient while high frequency energy is delivered.
9) Electro-surgical energy should be delivered for as short a time period as necessary to accomplish the desired clinical effect.
10) When repeating delivery of electro-surgical energy, ensure that coagulated tissue and/or blood is not attached to the head to avoid conductivity failure of the cups.
11) Select a high frequency output power setting suitable for the particular intended procedure in order to avoid thermal invasion of the tissue, or insufficient coagulation, each of which can result in excessive bleeding.
12) When using a two-channel endoscope, never simultaneously use a diathermic device in one channel and another accessory (e.g. retrieval device) in the other channel unless both accessories are insulated.
13) Use with adequate ventilation. Surgical smoke might be generated during electro-surgical procedures.
14) Do not use a patient return electrode in surgery that utilizes a bipolar electrode endoscopic accessory.

7) While the head reaching the bleeding point (ensuring no other contact of the head with the patient and/or scope tip), apply desired current to the device. Use proper technique. Carefully squeeze the handle.

	Coagulation mode
Maximum Rated Voltage	2900VP (5800Vp-p)

⚠ WARNING:

Peak voltages exceeding those identified in the chart above should never be applied during electrosurgical procedures with the equipment.

⚠ WARNING:

If the device exhibits unusual performance characteristics or if the patient experiences difficulty during a procedure, stop immediately and withdraw the scope carefully from the patient.

8) During prolonged endoscopic examinations involving this device, patient fluids and/or blood may dry/harden and potentially interfere with device performance. Never deliver electrosurgical energy when patient tissue adheres to the head.
9) After the procedure has been completed, hold the head away from the target area and turn off the electrosurgical generator before unplugging the active cord from this device.
10) Withdraw the device from the endoscope slowly with the elevator mechanism lowered.

⚠ WARNING:

Do Not turn off the electrosurgical generator while the active portion touches the target area. The active portion may stick to the target area and separation from the target area may damage the tissue.

⚠ WARNING:

Do Not withdraw the device quickly. This can result in potential cross-contamination due to the possible scattering of patient debris.

9. CARE AFTER USE

⚠ WARNING:

This device is for single patient use. Never reuse or resterilize the device. For disposal, follow the applicable protocol at your medical facility, as well as local or national regulations.

	Operation Environment	Storage Environment
Ambient temperature	10℃ ~ 40℃	-40℃ ~ 70℃
Relative humidity	30% ~ 85%	10% ~ 95%
Atmospheric pressure	700hPa ~ 1060hPa (0.7atm ~ 1.05atm)	700hPa ~ 1060hPa (0.7atm ~ 1.05atm)

⚠ WARNING:

Store the packaged device in a clean and dry place. Avoid storage areas with high humidity, high temperature, and exposure to direct sunlight.

Heyinovo

Wilson Instruments (SHA) Co., Ltd.
25D, He Yi Business Plaza, No. 420, Jiang Ning Rd., Shanghai 200041, P.R.China
Tel: 0086-21-66311471
Fax: 0086-21-66311472

EC REP Lotus Global Co., Ltd.
1 Four Seasons Terrace, West Drayton, Middlesex, London, UB79GG, United Kingdom
15 Alexandra Road, London, NW80DP, United Kingdom
Tel: 0044-20-75868010
Fax: 0044-20-79006187

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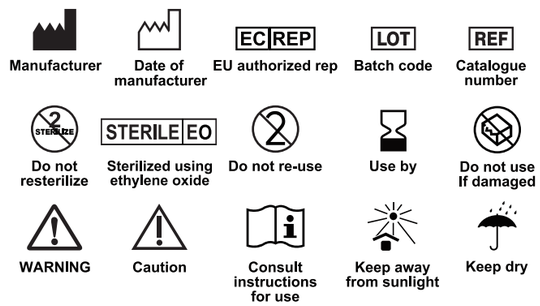

USA
Federal (USA) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.