MIZUHO

MES-CK09-225-55EN-0

PREPARED: (2020-12-24) (Version 1)

Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

Instruction for Use

Trade Name: Suction Tube with Irrigation

Warning

Please read these instructions carefully prior to using this product. Product should be used according to these instructions, and pay close attention to the safety of patients. Failure to follow manufacturer's recommendations may cause harm or injury to patient.

For the US market

Do not reuse the device when it is used on a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) or variant CJD (vCJD).

For markets outside the US

When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for more information related to cleaning and sterilization.

Contraindication/Prohibition

1. Use for intended purpose only

Use devices for their intended purposes only. Incorrect use could cause this product to break.

2. Prohibition of secondary processing of this product

Do not apply any secondary processing to this product. For example, do not apply impacts or vibration markings to the surface of this product. Doing so could break this product.

3. Prohibition of use of chemicals

Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.

4. Prohibition of use of polishing powder and wire wool

When cleaning this product, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surface of this product and result in rust or corrosion.

6. Prohibition of use of household detergents

Use only medical detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.

Specifications

Code No.	Product Description
09-225-55	Suction Tube with Irrigation (10Φ)

Material: stainless steel, copper, fluororesin

Intended purpose

This device is to be used to coagulate tissues and achieve hemostasis by high-frequency electric current while viewed endoscopically or directly by a doctor.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

1. Instructions for use

Operate the device according to general surgical procedures.

2. Precautions for use

- High-frequency waves are emitted when the output lamp on the main body of the electrosurgical unit is lit and the output sound is produced. When using the device, confirm that the output lamp on the main body of the electrosurgical unit is lit and the output sound is produced. Also, when the device is not in use, ensure that the output lamp on the main body of the electrosurgical unit is not lit and the output sound is not produced.
- If tissues are attached to the device, wipe them away with gauze soaked in physiological saline.

Warning/Caution

1. Important fundamental cautions

Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

2. Cautions on use of other tools in combination with this product

- Prohibition on contact during use

Never allow this device to make contact with other devices while in use. Electric shock or burns could occur.

3. Defect/Adverse event

Defect

- Peeling of coating

Adverse event

- Burns due to contact with peeled areas of the coating
- Burns due to contact with metal parts of devices installed on the operating table
- Electric shock
- Ignition of disinfectants that include alcohol
- Ignition during intubation of the trachea

Storage/Life

1. Please store the device in normal ambient temperature areas. Do not store in areas of high humidity where the temperature may dramatically vary causing condensation. Do not store on or near chemicals as the chemicals may cause damage to the device.
2. Service life of this product: 5 years
(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

1. Check prior to each use

Operational and functional checks

Conduct daily and pre-operation checks of this product to make sure that it functions properly.

Confirm that the coating of the device is not peeling.

(If high-frequency waves are output without sufficient insulation, the patient may be burned, or the operator may experience electric shock.)

2. Check after each use

2.1 If exposed to bleach or antiseptic solutions, immediately wash:

Wash and rinse with clean water immediately.

Use a soft towel or a plastic brush for cleaning.

2.2 Remove contaminants by manually cleaning with a detergent containing enzymes or that does not coagulate or denature proteins.
- If disassembly is possible, disassemble and clean the entire surface of the instrument.
- Select a proper detergent for each decontamination method and maintain appropriate density and handling.
- Reverse osmosis water is recommended to wash this product.

2.3 Only use reverse osmosis water for the final rinse.
Note: It is recommended to use a washer-disinfector for this device. Thermal Disinfection can be used by following the manufacturer's defined parameters;
Thermal Disinfection Band: 90-93 °C/194.0-199.4°F, 5-10 minutes (A0 value: 3000-12000) (reference EN ISO 15883-1)

2.4 If using a washer disinfector (WD), only use a WD process that has been validated according to international standards (ISO 15883), and observe the following.
In addition, in order to ensure an effective cleaning process, correctly load the device in the basket, etc., and ensure that the detergent / disinfectant reaches the entire surface of the device while its joints are kept open.

2.5 If ultrasonic cleaning is performed, observe the following.
- When using a detergent or disinfectant, select the concentration, temperature, ultrasonic cleaning time / exposure time, etc., according to the corresponding instructions for use.
- Fully immerse the device to be washed.
- Use an appropriate tray that does not inhibit ultrasonic cleaning.
- Do not pack the device too tightly, and keep the joint of the device open, if applicable.

3. Sterilization
Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.
Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows;

ISO/TS17665-2	
Temp.	Minimum exposure time
121°C / 249.8°F	15 Min
126°C / 258.8°F	10 Min
134°C / 273.2°F	3 Min

For the US market
FDA has not approved or cleared medical devices, including sterilizers, for the intended use of reducing the infectivity of TSE agents (i.e., prions).

For markets outside the US
When the device is used on a patient with or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

4. Inspection
Check for abnormalities in the coating, the gripping part tip, etc. If an abnormality is found, inspection or repair by MIZUHO Corporation or the agent recognized by MIZUHO Corporation is recommended.

Maintenance and check by agents
For safety use of this device, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact your local distributor or the manufacturer.

Packing
1 piece per pack

Warranty
MIZUHO Corporation will repair defective parts of this product without charge for one year from the date of delivery/installment except for cases of damage caused by a third party's repair, act of nature, improper use or intentional damage. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

Disposal
This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

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

Manufacturer

MIZUHO Corporation
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
http://www.mizuho.co.jp