MIZUHO

MES-CK07-797-01EN-0

PREPARED: (2022-02-28) (Version 3)

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

Instruction for Use

Trade Name: Flexible Forceps

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 use of chemicals

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

3. 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.

4. Handle with care

Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of tools and appliances.

5. 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 surfaces of this product and result in rust or corrosion.

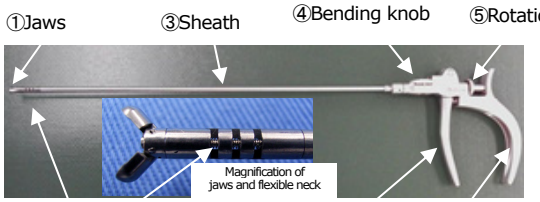
6. Prohibition of use of household detergents

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.

7. Do not use low temperature hydrogen peroxide gas plasma sterilization.

This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.

Specifications



Code No.	Product Description
07-797-01	Flexible Curette Forceps Φ3.0

Material: stainless steel, Ni-Ti Alloy

Intended purpose

This device is an instrument used together with a dedicated endoscope during endoscopic treatment. It is used for mechanical work such as tissue or foreign matter grasping, collecting, ablation, clipping, ligation, medical solution administration, suctioning, lumen dilation, and probing. It operates without the use of electricity (high frequency, electromagnetic waves, ultrasonic waves, laser energy, etc.). This device can be reused.

This product is a brain endoscopic surgical instrument, especially for the pituitary gland surgery, used to hold the soft tissue.

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

Refer to the Specifications picture for each part name.

Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Instruction

1. In brain endoscopic surgery, this product holds and separates the diseased tissue or soft tissue and holds the foreign materials.
2. The flexible neck bends right and left when rotating the bending knob (④). Jaws rotate and hold an object when rotating the top of rotation knob (⑤).

Warning/Caution

1. Important fundamental cautions

(1) Prior to use the device must be sterilized under the standard sterilization conditions or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

(2) Operation with excessive force (200g and more) in endoscopic surgery or lack of observing the endoscope image may give rise to serious problems or adverse events.

(3) Use tools for their intended purposes only.

(4) In case the device is dropped on the floor or hard surface, use only after confirming that there are no problems with the jaws, flexible neck, sheath, and all other parts.

(5) Follow these instructions with caution or problems or adverse events may occur.

・Do not use for holding and cutting a bone or hard tissue.

・Do not rotate when a flexible neck is bending and jaws are closing or holding any tissue.

・When operating flexibility of flexible neck, prevent any tissue from being caught in a gap of the flexible neck.

(6) Do not use iodine disinfectant for the device.

2. Defect/Adverse event

Defect

・Corrosion or pitting caused by use of chemicals

・Damage or breakage caused by the corrosion or pitting

・Breaks or malfunction caused by irrational operation

Adverse event

・Damage or perforation in a body cavity

・Broken pieces or damaged pieces left in the patient's body.

Storage/Life

1. Storage

・Do not store the device in high temperature areas. Do not store in areas of high humidity where the temperature may vary wildly causing condensation.

・Do not store this product in areas where chemicals are stored or gas is being produced.

・Be careful not to impact or vibrate (including while transporting) this product.

2. Service life of this product: 3 years

(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

1. Check prior to each use

1.1 Operational and functional checks

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

1.2 Perform maintenance check-ups every 6 months.

1.3 Content inspection

1.3.1 Jaws rotate while opened when rotating the rotation knob.

1.3.2 The flexible neck bends right and left when rotating the bending knob.

1.3.3 Jaws open and close when gripping the lever.

1.3.4 No damage in the flexible neck part.

2. Check after each use

2.1 Immediately wash with clean water

Wash and rinse with clean water immediately and immerse in neutral enzyme detergent in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine. After use, spray the preliminary wash detergent, including rust and dry inhibitors, in case the device is exposed to organic matters (blood, body fluid, etc.) and contacted suspected contamination. Then, remove all the contaminated matter by hand or an ultrasonic-cleaner.

2.2 Further remove any remaining contamination with a plastic brush.

2.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

2.4 Use a soft towel, a plastic brush, or a water gun for cleaning.

2.5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

2.6 Reverse osmosis water is recommended to wash this product.

2.7 Only use reverse osmosis water for the final rinse.

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)

2.8 Fully dry this product immediately after washing it.

Do not leave it wet for a longer time than necessary as residual water may damage the instrument.

2.9 Use distilled water or reverse osmosis water

Use distilled water or reverse osmosis water to wash and sterilize this product. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

2.10 Use a water-based anticorrosive lubricant

Lubricating oil is completely removed by washing. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization. Do not use without lubricant oil to sliding part, or galling could occur.

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.

When sterilizing the item, the flexible neck section must be straight and jaws must be open.

Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows;

ISO/TS 17665-2	
Temp.	Minimum exposure time
121°C / 250°F*	15 Min
126°C / 259°F*	10 Min
134°C / 273°F*	3 Min

*According to the Guideline for Disinfection and Sterilization in Healthcare Facilities,2008 (Update: May 2019)

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.

Maintenance and check by agents

For safety use of this instrument, 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.

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