MIZUHO

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

MES-CK07-797-01EN-0
PREPARED: (2017-04-21) (Version 2)
(2016-03-29) (Version 1)

Instructions for Use

Trade Name: Flexible Forceps

Warning

1. 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).

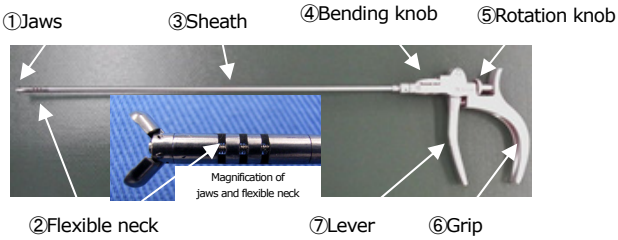
2. For the market outside the US

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. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
2. 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.
3. 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.
4. Prohibition of use of household detergents
Use only medical neutral detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
5. 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.

Shape / Structure



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

Material: Stainless Steel, Ni-Ti Alloy

Intended Purpose

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

Instructions for use

Refer to the Shape/ Structure 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).

Caution

1. Warning
(1) Device must be sterilized by users under the standard sterilization conditions or the validated sterilization conditions which validity is 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.
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
・ Serious health damage
・ Damage or perforation in a body cavity
3. Important fundamental cautions
(1) Use tools for their intended purposes only.
(2) 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.
(3) 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.
(4) Do not use iodine disinfectant for the device.

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. Life
・Service life of this product: 3 years
(Subject to the specified maintenance, inspection, and proper storage)

Maintenance / Inspection

1. Checking matters before use
(1) Operational and functional checks
Conduct daily and pre-operation checks of this product to make sure that it works properly.
(2) Perform maintenance check-ups every 6 months.

(3) Content inspection

(3)-1 Jaws rotate while opened when rotating the rotation knob .

(3)-2 The flexible neck bends right and left when rotating the bending knob.

(3)-3 Jaws open and close when gripping the lever.

(3)-4 No damage in the flexible neck part.

2. Checking matters after use

(1) Immediate washing with clean water

(1)-1 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.

(1)-2 Remove any remaining contamination with a brush.

(1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.

(1)-4 Use a soft towel, plastic brush, or water jet for cleaning.

(1)-5 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

(1)-6 Use distilled water or deionized water to wash this product.

(1)-7 Use fully demineralized water (Reverse Osmosis) for final rinse.

(1)-8 Using an ultrasonic washing machine simultaneously for this device is recommended.

(2) Dry this product immediately after washing it.

(2)-1 After cleaning, please rinse the device fully, for more than 5 minutes, with warm or cold water without additives.

(2)-2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.

(3) Use distilled or deionized water.

Use distilled or deionized water to wash this product.
Residual chlorine and organic matters in tap water could cause stains and rust.

(4) 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/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 the market 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.

Matters related to warranty period

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

Name and address of manufacturer

MIZUHO Corporation
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
Contact : Mizuho Medical Co., Ltd.
TEL: 81-3-3815-7101 FAX: 81-3-3818-1705