MIZUHO

MES-CK07-793-51EN-0

PREPARED: (2018-10-16) (Version 2) *
(2018-02-06) (Version 1)

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

Instructions for Use

Trade Name: Forceps

Warning

1. 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. Not doing so may give rise to serious problems or adverse events.

   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 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.

* 2. Do not bend the base of shaft from the printed line. Otherwise, it may damage the shaft.

* 3. Flexion of the shaft should be less than 30 degrees. Otherwise, it may damage the product. It may also decrease the close and open function of the shaft edge as well as its rotation function.

Contraindication / Prohibition

1. Use for intended purpose only
   Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Use with specified products only
   Use this product with only products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
3. Prohibition of use of chemicals
   Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
4. 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.
5. Handle with care
   Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of devices and appliances.
6. 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

* 7. 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.

Shape / Structure

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Code No.	Product Description
07-793-51	Malleable Forceps Rotation Type

Material: Stainless Steel

Intended Purpose

A surgical instrument designed with two blades, which are closed upon the object to be held.

Instructions for use

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

CAUTIONS & WARNINGS

1. **WARNING**
   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. Defect/Adverse event
   Defect
   - Corrosion and pitting caused by use of chemicals
   - Damage or breakage caused by the corrosion or pitting

   Adverse events
   - Broken pieces of metal from the damaged instrument falling into the patient.

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: 2 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.
2. Check after each use
   (1) Immediately wash with clean water
   (1)-1 If exposed to bleach or antiseptic solutions, wash and rinse with clean water immediately and immerse in neutral enzyme detergent to remove any bleach or antiseptic solution, which may contain chlorine or iodine and can damage the instrument. Manually remove contaminated matter by hand or with an ultrasonic-cleaner.
   (1)-2 Further remove any remaining contamination with a soft nylon brush.
   (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

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

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

(1)-6 Only use distilled water or deionized water (reverse osmosis) to wash this product.

(1)-7 Only use fully deionized water (reverse osmosis) for the final rinse.

＊ (1)-8 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, 5-10 minutes (A0 value: 3000-12000)

＊ (2) 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.

＊ (3) Only use distilled or deionized water
Use distilled or deionized water to wash this product.
Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

(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.

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.

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.

Packing

1 piece per pack

Maintenance and check by agents

For safe use of this instrument, inspect device prior to and after each use. Alternative or no review and/or inspection may cause injury to the patient and/or healthcare worker and may decrease the performance and function of this device. Additionally, it is recommended to schedule a periodic inspection through your local distributor or the manufacturer.

Matters related to warranty period

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.

Name and address of manufacturer

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