MIZUHO

MES-CK07-793-56EN-0

PREPARED: (2023-11-22) (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: Malleable 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. Failure to follow manufacturer's recommendations may cause harm or injury to the 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.
2. Do not bend the shaft between the printed line on the shaft and the shaft base.
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.

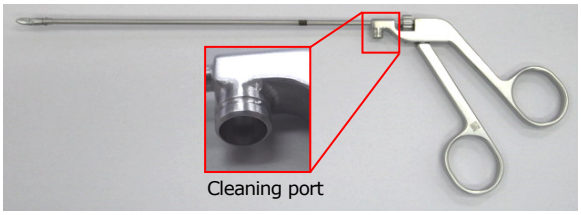
Contraindication/Prohibition

1. Use for intended purpose only

   Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. 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.

Specifications



Code No.	Product Description
07-793-56	Malleable Cup Forceps Rotation Type

Material: Stainless steel

Intended purpose

This product is a surgical instrument with atraumatic design to grip, connect, press, or support an organ, tissue, or blood vessel under the direction of a qualified surgeon. This instrument is reusable provided the cleaning, maintenance, and sterilization steps below are followed.

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

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

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. Defect/Adverse event

   Defect

   · Corrosion or pitting caused by use of chemicals

   · Damage or breakage caused by the corrosion or pitting

   Adverse event

   · 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, immediately wash:

   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 plastic brush.

   (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

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

   (1)-5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.

   (1)-6 Reverse osmosis water is recommended to wash this product.

   (1)-7 Only use reverse osmosis water 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/194.0-199.4°F, 5-10 minutes (A0 value: 3000-12000) (reference EN ISO 15883-1)

   (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) 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.

(4) Use a water-based lubricating agent and a water-based rust-prevention agent

Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization. Do not use this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

<Mizuho recommends the following procedures>

(1) Cleaning preparation

1) When handling devices contaminated with blood or bodily fluids, wear appropriate protective equipment such as masks, gloves, eye protection, and waterproof aprons.
2) Do not allow blood or bodily fluids on devices to dry.
3) The instrument is fragile so handle carefully throughout the cleaning and sterilization process so that the instrument and its tips are not damaged.

(2) Cleaning

This product should be cleaned in the sequence of <Manual Procedure> and <Automated Procedure> as described below. Not doing so may result in insufficient cleaning.

<Manual Procedure>

1) Use a syringe to inject 10 ml of a 1v% solution of neutral enzyme cleaner (40°C) into the cleaning port, and then submerge the entire instrument into the same solution for 15 minutes.
2) Brush the tip with a medical-grade brush until all foreign material such as blood has been removed.
3) Rinse off the entire instrument with running water, and then rinse out the inside of the cleaning port with a water jet.

<Automated Procedure>

Set the washer-disinfector with the conditions in the following table. Clean the device with the forceps closed.

Stage	Procedure	Temperature [°C (°F)]	Time [min]	Quality of water	Remarks
I	Preclean	10 (50)	3	Distilled water Reverse osmosis water	For 10°C, ambient temperature is also allowed
II	Washing	50 (122)	10		0.5v% neutral enzyme cleaner
III	Rinsing	10 (50)	1		For 10°C, ambient temperature is also allowed
IV	Rinsing	10 (50)	1		For 10°C, ambient temperature is also allowed
V	Hot water disinfection	90 (194)	5		
VI	Drying	110 (230)	40	—	

(3) Only use a water-based, anticorrosive lubricant

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

3. Sterilization

The device must be sterilized in accordance with the manufacturer's recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

The recommended sterilization parameters are as follows,

Sterilization method	Pre-vacuum steam sterilization (Autoclave sterilization)	
Sterilization conditions	Sterilization temp.	Retention time
	132°C / 270°F*	4 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 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.

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