MIZUHO

MES-CK07-868-01CEEN-0

PREPARED: (2018-04-03) (Version 1)

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

CE

Instructions for Use

Trade Name: Micro Dilator 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. 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 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
   Incorrect use can cause breakage of this product. Never use as a lever or twist the unit with force. Doing so may cause failure of the internal mechanism or otherwise damage the instrument.
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 devices 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 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 rust or corrosion.

Shape/Structure

Code No.	Product Description
07-868-01CE	Micro Dilator Forceps 15cm, 0.2mm Tip, Str. RH CE
07-868-03CE	Micro Dilator Forceps 18cm, 0.2mm Tip, Str. RH CE
07-868-05CE	Micro Dilator Forceps 21cm, 0.2mm Tip, Str. RH CE

Material: Stainless steel

Code No.	Product Description
07-868-02CE	Micro Dilator Forceps 15cm, 0.2mm Tip, 45deg. RH CE
07-868-04CE	Micro Dilator Forceps 18cm, 0.2mm Tip, 45deg. RH CE
07-868-06CE	Micro Dilator Forceps 21cm, 0.2mm Tip, 45deg. RH CE

Material: Stainless steel

Intended Purpose

This device is a surgical instrument to grasp an object with the 2 blades placed symmetrically.

Instructions for use

Before using this product, inspect, wash, and sterilize in accordance with these instructions (See the requirements relating to maintenance and inspection).

Cautions/Warnings

1. Warning
   Device must be sterilized by users in accordance with sterilization procedures or the validated sterilization conditions which validity is 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
   -Scissors may not cut properly due to damaged tip of the blades.
   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: 7 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.
   It is recommended to use a washer-disinfector for this device.
   Thermal Disinfection can be used by following the manufacture'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) 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 staining 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 our recommended sterilization procedures or the validated sterilization conditions which validity is proven by medical organizations in each country or region.

Our recommended sterilization parameters are as follows.

Sterilization method	Pre-vacuum steam sterilization (Autoclave sterilization)	
Sterilization conditions	Sterilization temp.	Retention time
	132°C / 269.6°F	4 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 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

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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