MIZUHO

MES-CK07-821-05EN-0

PREPARED: (2023-07-21) (Version 4)

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: Tumor Probe

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 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. Use for intended purpose only
   Use tools for their intended purposes only. Incorrect use could cause breakage of this product.
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 alkaline, acid, and household detergents
   Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any alkaline, acid, or 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.

Shape / Structure

Code No.	Product Description
07-821-05	CP ANGLED SUPER MICRO-DISSECTORS CP-5 3.0mm Tumor Probe 90 Deg. Angled

Material: Stainless Steel, Gold Plating

Intended Purpose

This device is a slender, rod like surgical instrument made of metal of flexible material and used for exploring sinuses, fistulas or other cavities or wounds.

Instructions for use

Before using this product, inspect, wash under proper conditions and sterilize.

Cautions / Warnings

1. Warning
   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 and pitting caused by use of chemicals
   - Damage or breakage caused by the corrosion or pitting
   - Plating adhesion failure

   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: 5 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
   (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 stains 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.

(5) Maintenance

(5)-1 After cleaning, visually inspect under ambient lighting and confirm all dirt and debris has been removed.

(5)-2 If any dirt or debris is visible, repeat cleaning and lubrication steps.

<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 on instrument.
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

<Manual Procedure>

1) Soak the product in cold tap water for 5 minutes, covering all surfaces, and confirm that the lumen is filled with water.
2) Rinse with tap water and clean with a soft nylon brush until all visible residue is removed from the surface of the instrument. Carefully wash hinges, bonded parts, the lumen, and other hard-to-reach areas, spray with cold tap water with a water gun (at a maximum of 2 bars of water pressure) for 20 seconds.
3) Place the product into its washing basket and ultrasonically clean at room temperature for 10 minutes in deionized water with a neutral enzyme detergent dissolved to establish an 0.5% detergent solution.

<Automated Procedure>

Use a washer rack intended for cleaning the lumen.

1) Perform pre-cleaning for 2 minutes using tap water.
2) Drain the water.
3) Clean for 5 minutes in 55°C tap water with 0.3% alkaline detergent solution.
4) Drain the water.
5) Rinse for 3 minutes with distilled or deionized water.
6) Drain the water.
7) Rinse for 2 minutes with distilled or fully deionized water (reverse osmosis) for the final rinse.
8) Drain the water.
9) 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)
10) Thoroughly dry prior to use or storage.

(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

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 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 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.

Packing

1 peace 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.

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