MIZUHO

MES-CK07-959-21EN-0

PREPARED: (2023-04-12) (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: SPATULA

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. Failure to follow manufacturer's recommendations may cause harm or injury to 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.

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

Spatula 210 mm x 5 mm, Stainless

Spatula 140 mm x 10 mm, Stainless

Color : Black (Oxidation coloring)

Code No.	Product Description
07-959-21	Spatula 210 mm x 5 mm, Stainless
07-959-22	Spatula 210 mm x 10 mm, Stainless
07-959-23	Spatula 210 mm x 15 mm, Stainless
07-959-24	Spatula 210 mm x 20 mm, Stainless
07-959-25	Spatula 210 mm x 30 mm, Stainless
07-959-26	Spatula 140 mm x 10 mm, Stainless
07-959-27	Spatula 140 mm x 15 mm, Stainless
07-959-28	Spatula 140 mm x 20 mm, Stainless

Material: stainless steel

JIS (Japanese Industrial Standards)	ISO 15510	
	ISO Name	ISO Designation
SUS316L	4404-316-03-I	X2CrNiMo17-12-2
	4432-316-03-I	X2CrNiMo17-12-3
	4435-316-91-I	X2CrNiMo18-14-3

Intended purpose

This product is a surgical instrument used to separate tissue or other anatomical parts. It exposes or accesses an organ or tissue to allow examination or treatment. This device can be reused.

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
   Prior to use the device must be sterilized under the standard sterilization conditions 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 or damaged pieces left in the patient's body.

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. Number of bends in the case of specified maintenance and inspection and proper storage: 100 times
   (Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

1. Check prior to each use
   (1) Operational and functional checks
   Conduct daily and pre-operation checks of this product to make sure that it functions properly.
   (2) Discontinue use it if a crack like the one shown in the figure is observed.

(Fig.)

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

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

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

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 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 this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

(5) 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.

3. Sterilization

(1) 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.

Sterilization of the device may be accomplished by steam. 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.

(2) 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.

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

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.

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