MIZUHO

MES-CK07-157-01EN-0

PREPARED: (2023-07-21) (Version 7)

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

CE

Instruction for Use

Trade Name: TAPERED SELF-RETAINING RETRACTOR

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 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. Use with specified products only
   Use this product only with 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 surfaces of this product and result in rust or corrosion.
7. 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.
8. 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.

Symbol mark for labeling

MD :Medical Device

Specifications

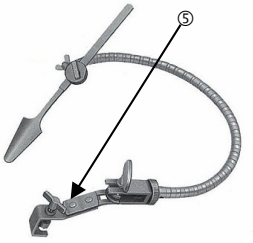
	Code No.	Product Description
①	07-174-24	TAPERED SELF-RETAINING RETRACTOR 42cm Without Clamp
②	07-174-25	TAPERED SELF-RETAINING RETRACTOR 37cm Without Clamp

Material: Titanium alloy, stainless steel

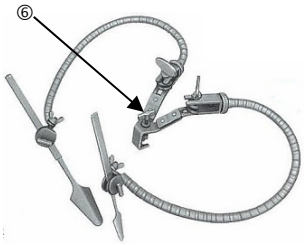
	Code No.	Product Description
③	07-157-11	TAPERED SELF-RETAINING RETRACTOR 5mm 37cm (HADEISHI version)
④	07-157-12	TAPERED SELF-RETAINING RETRACTOR 6mm 37cm (HADEISHI version)

Note: The cerebral spatulas having the thickness over 2mm cannot be attached to the TAPERED SELF-RETAINING RETRACTOR (HADEISHI version).

Material: Titanium alloy, stainless steel, resin



⑤ Combination with SELF-RETAINING RETRACTOR Clamp Single（Code No.: 07-174-31）



⑥ Combination with SELF-RETAINING RETRACTOR Clamp Double（Code No.: 07-174-32）

Code No.	Product Description	Composition
*07-157-01	TAPERED SELF-RETAINING RETRACTOR 42cm	① : 1 piece ⑤ : 1 piece
*07-157-02	TAPERED SELF-RETAINING RETRACTOR 37cm	② : 1 piece ⑤ : 1 piece
*07-158-01	TAPERED SELF-RETAINING RETRACTOR 42cm W	① : 2 piece ⑥ : 1 piece
*07-158-02	TAPERED SELF-RETAINING RETRACTOR 37cm W	② : 2 piece ⑥ : 1 piece
*CE Not applicable		

Material: Titanium alloy, stainless steel

	Code No.	Product Description
⑤	*07-174-31	SELF-RETAINING RETRACTOR Clamp Single
⑥	*07-174-32	SELF-RETAINING RETRACTOR Clamp Double
*CE Not applicable		

Material: Stainless steel

Intended purpose

This device is a surgical instrument to hold a spatula and secure its position during a surgery. This is a reusable device.

Intended user

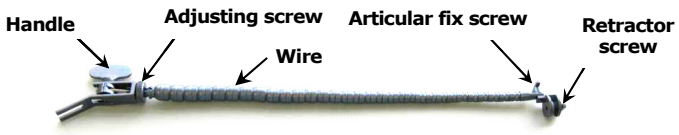
This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

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

To secure the Self-Retaining Retractor in a desirable position, 1) rotate the Handle to a locking position of the Self-Retaining Retractor's Wire.

2) If after the Handle is rotated to a locking position and the tension does not hold the Wire to your desired position, unlock the Handle and rotate the Adjusting Screw and repeat steps 1) and 2) until the desired position is maintained on the Self-Retaining Retractor.
To attach a spatula to the Self-Retaining Retractor, place the spatula into the clamp's receptacle and tighten the Retractor Screw. To provide additional positions after locking the spatula, loosen the Articular Fix Screw, adjust and tighten.



Warning/Caution

1. WARNING
   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 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
   (1) 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. Use of a neutral detergent is recommended.
   (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.
   (1)-8 It is recommended to use a washer-disinfector for this device.
   (2) After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.
   (2)-1 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 at least
   Use distilled water or reverse osmosis water to wash and sterilize this product at least. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.
   (4) 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, or galling could occur.
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.
   Do not use hydrogen peroxide gas plasma sterilization.
   - Sterilization of the device may be accomplished by steam. 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 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

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

EMERGO EUROPE
Westervoortsedijk 60, 6827 AT Arnhem
The Netherlands