MIZUHO

MES-CK17-010-06EN

PREPARED: (2025-03-10) (Version 6)

Read these instructions carefully before use.
Keep this instruction leaflet for future reference when necessary.

CE

Instruction for Use

Trade Name: Sugita Titanium Clips II Half Case

Warning

1. 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).

2. 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
   This product is intended to hold Sugita clips and dedicated forceps for sterilization by a high-pressure vapor. The product must be used as intended. [Misuse may cause damage.]
2. Prohibition of use of chemicals
   Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. 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.
4. 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.
5. 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 discoloration or corrosion.
6. 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.

Specifications

Shape

Material: plastic, stainless steel

Code No	Product Description
17-010-06	Sugita Titanium Clips II Half Case
17-010-07	Sugita Titanium Clips II Case EA for Extra A
17-010-08	Sugita Titanium Clips II Case EB for Extra B

A trace plate is attached to each clip tray. The details are described in the attachment, “Trace Plate Instruction Manual”.

Intended purpose

This product is a case that is used for sterilizing the Sugita Titanium Aneurysm Clip II and the Clip Appliers with high-pressure steam.

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 validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.
2. Defect/Adverse event

Defect

- Deterioration, corrosion or pitting caused by use of chemicals
- Damage or breakage caused by the corrosion or pitting

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
   2.1 Immediately wash with clean water
   2.1.1 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.
   2.1.2 Further remove any remaining contamination with a plastic brush.
   2.1.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.
   2.1.4 Use a soft towel, a plastic brush or a water jet for cleaning.
   2.1.5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.
   2.1.6 Reverse osmosis water is recommended to wash this product.
   2.1.7 Only use reverse osmosis water for the final rinse.
   2.1.8 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)

2.2. 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.

2.3. 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.

2.4. 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 validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

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.

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Trace Plate Instruction Manual

<Specification>

The shape of the trace plate is shown in Figure 1.
Size: 230 mm x 335 mm
Thickness: 1.249 mm

Front Back

[Figure 1] Trace Plate"17-010-81"

<Intended purpose>

The trace plate is used for controlling “Sugita Titanium Aneurysm Clip II” (hereafter referred to as the clip) housed in various clip cases.

<Sugita Titanium Aneurysm Clip II Packaging>

- Clip is wrapped every 1 piece.
- Detailed information including a product lot number, closing force is described on the outer box.
- The packing materials shown in Table 1 are placed in the box. Six patient record labels with the clip No. and serial No. are placed in the box [Figure 2].
  For the handling of clip, please refer to the Instruction for use of the clip.

Table 1 Clip packing materials

Packing material	Sugita Titanium Aneurysm Clip II	
	Permanent type	Temporary type
Patient record label	Yes	Yes
Implant card	Yes	No
Patient leaflet	Yes	No
Instruction for use	No *eIFU	Yes

*eIFU, electronic instruction manual.

[Figure 2]

<Control Method>

- Be sure to keep and maintain the Patient record label attached to each individual clip.
- A **Trace Plate** is attached to each style of clip case.
  1. A pocket for a Patient record label is laid out on a **Trace Plate** with the same arrangement as each numbered cell of the case.
  2. Be careful not to put in or take out an incorrect seal.

> Do not sterilize a Trace Plate and Patient record labels.
>
> They cannot be sterilized.

  3. After you applied the clip, make sure to take a Patient record label with the same number applicable to the clip and affix it on the medical record, or input the necessary information into the computer.
  4. Please insert the Patient record label in the proper pocket upon replenishment of the clips.

＜Clip case and Trace Plate＞

- Clip case Code No:17-010-07 • 08 • 81～84
- The diagram of the clip to be housed is printed on the back of the lid of the clip case. The type is linked with the name described on the case body. [Figure 3]
  *No printing was performed on the clip cases for custom.
- The position of the pocket on the trace plate corresponds to the case layout [Figure 4].

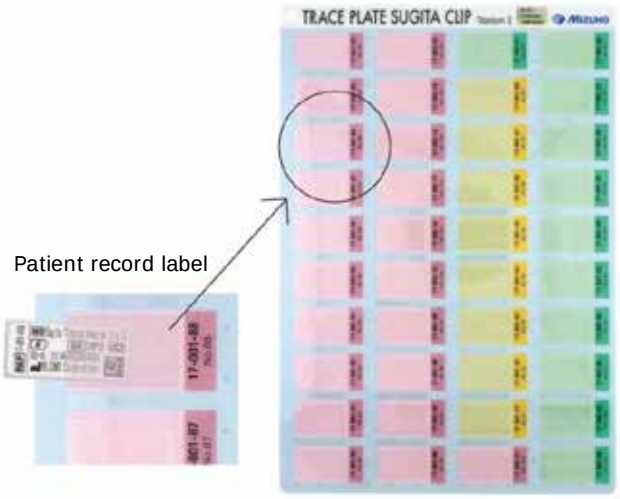
「Clip case」

case

Inside of lid

[Figure 3] Clip case "17-010-81"

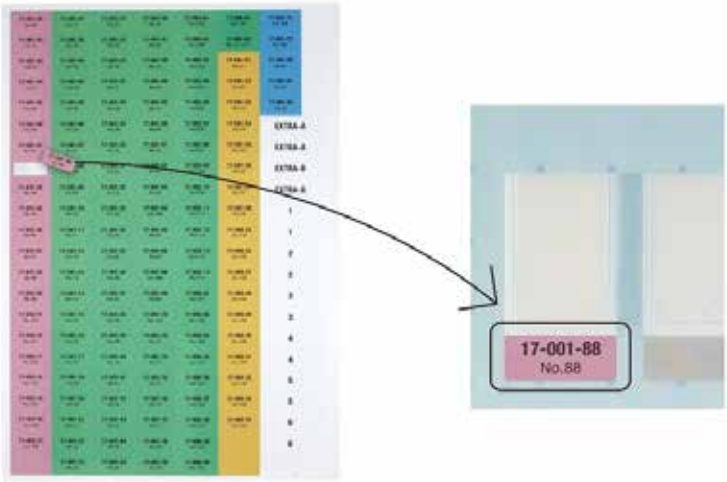
「Trace Plate」



[Figure 4]

＜Number seal＞

- Each slot on the clip case has a corresponding pocket on the trace plate. Common number stickers are available for optimal clip case positioning [Figure 5].



[Figure 5]