

Instructions for Use

Trade Name: Sugita Titanium Clip Single Shaft Applier

Warning

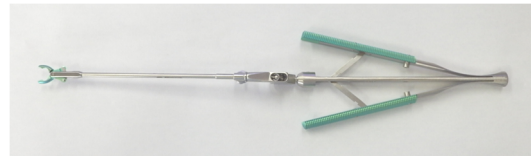
1. Please read these instructions carefully prior to using this product. Product should be used according to these instructions and pay close attention to the safety of patients. Not doing so may give rise to serious problems or adverse events.
2. Use this product only with the products that are intended to be used with this product. Use this product only with the Sugita Titanium Clip II. [Failure to do so might damage the clip.]
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 acid and household detergents
Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any 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



Standard (green)



Mini (pink)

Code No	Product Description
17-012-71	Sugita Titanium Clip II Single Shaft Applier Standard, 50mm
17-012-72	Sugita Titanium Clip II Single Shaft Applier Standard, 90mm
17-012-73	Sugita Titanium Clip II Single Shaft Applier Standard, 110mm
17-012-74	Sugita Titanium Clip II Single Shaft Applier Standard, 50mm 30deg.
17-012-75	Sugita Titanium Clip II Single Shaft Applier Standard, 90mm 30deg.
17-012-76	Sugita Titanium Clip II Single Shaft Applier Standard, 110mm 30deg.
17-013-71	Sugita Titanium Clip II Single Shaft Applier Mini, 50mm
17-013-72	Sugita Titanium Clip II Single Shaft Applier Mini, 90mm
17-013-73	Sugita Titanium Clip II Single Shaft Applier Mini, 110mm
17-013-74	Sugita Titanium Clip II Single Shaft Applier Mini, 50mm 30deg.
17-013-75	Sugita Titanium Clip II Single Shaft Applier Mini, 90mm 30deg.
17-013-76	Sugita Titanium Clip II Single Shaft Applier Mini, 110mm 30deg.

Material: Titanium alloy, Stainless steel

Intended Purpose

This device is a surgical tool designed to apply a Sugita aneurysm surgical clip.

Instructions for use

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

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

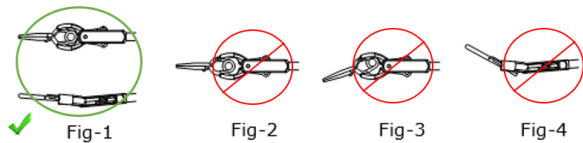
- Corrosion and pitting caused by use of chemicals
- Damage or breakage caused by the corrosion or pitting

Adverse event

- Broken pieces of metal from the damaged instrument falling into the patient.

3. Important fundamental cautions

- (1) Please confirm that the clip is held securely in the slot of the gripping part of the forceps. (Fig-1)
- (2) If the clip is not held properly, the clip may slip or come loose from the forceps. This may also damage the spring part of the clip, and may break the spring. (Figs. 2, 3, and 4)
- (3) Do not hold the clip in angled position. (Figs. 3, 4)



- (4) Please clean the product to remove the attached materials (dirt). Take extra care to clean the moving part (e.g. the joint) thoroughly.
- (5) This product is designed specifically for the Sugita Titanium Clip II.
Do not use this product with clips made by other manufacturers or conventional cobalt alloy clips.
- (6) This product does not include a locking mechanism. After installation of clip ensure the clip does not fall off from the forceps.

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

<Maintenance and checks conducted by users>

1. Checking matters before use

Operational and functional checks

Conduct daily and pre-operation checks of this product to make sure that it works properly.

2. Checking matters after 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.

- (1)-8 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 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) 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.

- (5)-3 Confirm that moving parts operate smoothly without binding, excessive force or moving parts appear to be loose and are rattling.

<Mizuyo 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

This product should be cleaned in the sequence of <Manual Procedure > and <Automated Procedure > as described below. Not doing so may result in insufficient 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 a 0.5% detergent solution.

- 4) 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.

<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 (AO 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.

1. Sterilization

- 3.1 Remove the port cap before sterilizing the product because it is specially used to protect the port only during transportation
- 3.2 Device must be sterilized by users in accordance with our recommended sterilization procedures or using packaging materials for sterile products and the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

The recommended sterilization parameters are as follows,

Sterilization method	Pre-vacuum steam sterilization (Autoclave sterilization)	
	Sterilization temp.	Retention time
Sterilization conditions	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.

Matters related to warranty period

The guarantee period for this product is 1 year from the delivery date or installation date. However, damage caused by repair by any other party, natural disasters or inappropriate use, or damage caused intentionally are excluded from the guarantee. Other conditions of the guarantee depend on the regulations stipulated by Mizuho.

Name and address of manufacturer



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