

MES-CK17-012-71EN-0

PREPARED: (2017-08-10) (Version 3) \*  
(2016-11-29) (Version 2)

## Instructions for Use

Trade Name: Sugita Titanium Clip Single Shaft Applier

### Warning

1. 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.]
2. **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).
3. **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. Be cautious of the possibility of secondary infection. Refer to [www.a-k-i.org](http://www.a-k-i.org) or AAMI Standard ST79 for more information related to cleaning and sterilization.

### Contraindication/Prohibition

1. Prohibition of use of chemicals  
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
2. 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.
3. 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.
4. 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.
5. 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
17-013-71	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

Material: Titanium alloy, Stainless steel

### Intended Purpose

This product is a surgical tool to apply other medical devices such as a surgical clip on human tissue.

### Instructions for use

Before using this product, inspect, wash, and sterilize in accordance with these instructions (See the requirements relating to maintenance and inspection).

### Caution

1. Warning  
Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions which validity is 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.
3. Fundamental precautions  
(1) Please confirm that the clip is held securely in the slot of the gripping part of the forceps.  
(2) If the clip is not held securely, the clip may slip or come loose from the forceps.  
(3) Please clean the product to remove the attached materials (dirt). Take extra care to clean the moving part (e.g. the joint) thoroughly.  
(4) 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.  
(5) This product does not have a ratchet. Make sure the clip does not fall off from the forceps.

### Storage/Life

1. Do not store the device in high temperature areas. Do not store in areas of high humidity where the temperature may vary wildly causing condensation. Do not store on or near chemicals.

2. Service life of this product: 5 years  
(Subject to the specified maintenance, inspection and proper storage)

### 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) Immediate washing with clean water.
    - (1)-1 Wash and rinse with clean water immediately and immerse in neutral enzyme detergent in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine. Then remove all the contaminated matter by hand or an ultrasonic-cleaner.
    - (1)-2 Remove any remaining contamination with a 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 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
    - (1)-6 Use distilled water or deionized water (reverse osmosis) to wash this product.
    - (1)-7 Use fully deionized water (reverse osmosis) for the final rinse.
    - (1)-8 Using an ultrasonic washing machine simultaneously for this device is recommended.
    - (1)-9 Our recommended cleaning procedures are as follows:
      - a. Use enzyme cleaning immersion (neutral) detergent. Immerse the product in the detergent at 37°C to 43°C for 30 minutes.
      - b. Wash the product with your hands in the immersion bath.
      - c. Flush the product with detergent from the cleaning port to the tubes (20 ml x 3 times).
      - d. Rinse the product with hot or cold additive-free water and simultaneously flush the product (20 ml x 1 time).
      - e. Wash the product using the ultrasonic cleaner with neutral ultrasonic detergent for 10 minutes.
      - f. Rinse the product with hot or cold additive-free water and simultaneously flush the product (20 ml x 1 time).
  - (2) Fully dry this product immediately after washing.
    - (2)-1 After cleaning, fully for more than 5 minutes, with warm or cold water without any additives.
    - (2)-2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.
  - (3) Use distilled or deionized water
    - Use distilled or deionized water to wash this product. Residual chlorine and organic matters from standard tap water may cause stains and may cause rusting.
  - (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.]
3. Sterilization
  - (1) Discard the port cap before sterilizing the product because it is specifically used to protect the port only during transportation.
  - (2) Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions which validity is proven by medical organizations in each country or region.

Our 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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