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

CE

MES-CK07-941-31EN-0
PREPARED: (2020-09-17) (Version 3)

Instruction for Use

Trade Name: Clip 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. Failure to follow manufacturer's recommendations may cause harm or injury to the 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.
2. The use with improper clip is prohibited.
   [Wrong use may damage an aneurysm clip.]

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 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 devices 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 surface of this product and result in rust or corrosion.
6. 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.
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.
8. Do not modify or reshape the return spring.
   Appropriate width of the opening at holding clip is ruined by breaking and transforming the return spring and the clip might come to interfere, and eventually not come off easily with forceps.
9. No sterilization with forceps ratcheted.
   [It may damage return spring]

Symbol mark for labeling

MD : Medical Device

Specifications

(1) Sugita Titanium Clip Applier

Standard type

Mini type

Fenestrated type

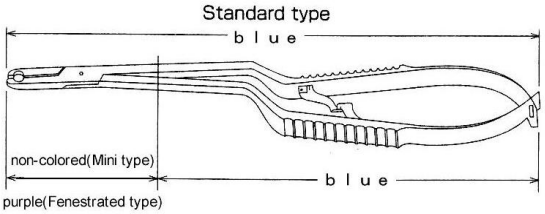
Code No.	Product Description
07-941-31	Sugita Titanium Clip Applier, Straight for Standard Clips
07-941-32	Sugita Titanium Clip Applier, 15°Angled for Standard Clips
07-941-33	Sugita Titanium Clip Applier, 30°Angled for Standard Clips
07-941-34	Sugita Titanium Clip Applier, Sideward Angled for Standard Clips
07-941-41	Sugita Titanium Clip Applier, Straight for Fenestrated Clips
07-941-42	Sugita Titanium Clip Applier, 15°Angled for Fenestrated Clips
07-941-43	Sugita Titanium Clip Applier, 30°Angled for Fenestrated Clips
07-942-31	Sugita Titanium Clip Applier, Straight for Mini Clips
07-942-32	Sugita Titanium Clip Applier, 30°Angled for Mini Clips
07-942-33	Sugita Titanium Clip Applier, Sideward Angled for Mini Clips

Material: Titanium alloy, stainless steel

Three types of forceps are available for Standard, Mini and Fenestrated clip each.

Forceps are color-coded on the applicable clips as follows,

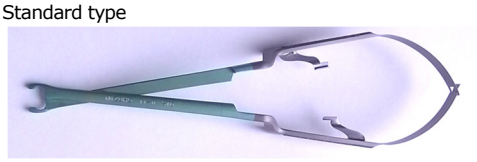
- ○Forceps for Standard type : Forceps body colored blue.
- ○Forceps for Mini type: Distal part of forceps left non-colored, while the rest of the forceps body colored blue.
- ○Forceps for Fenestrated type: Distal part of forceps colored purple, while the rest of the forceps colored blue.



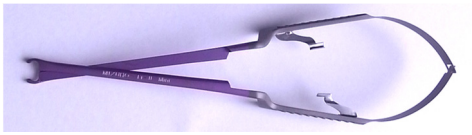
Applicable clip types are imprinted on the return spring of the forceps for your verification before use.

(2) Sugita Titanium Clip Ⅱ Applier

Standard type



Mini type



Long type

Code No.	Product Description
17-012-51	Sugita Titanium Clip Ⅱ Applier, Straight 70mm for Standard Clips
17-012-52	Sugita Titanium Clip Ⅱ Applier, Straight 90mm for Standard Clips
17-012-53	Sugita Titanium Clip Ⅱ Applier, Straight 110mm for Standard Clips
17-012-54	Sugita Titanium Clip Ⅱ Applier, 15°Angled for Standard Clips
17-012-55	Sugita Titanium Clip Ⅱ Applier, 30°Angled for Standard Clips
17-012-58	Sugita Titanium Clip Ⅱ Applier, Sideward Angled for Standard Clips
17-013-51	Sugita Titanium Clip Ⅱ Applier, Straight 70mm for Mini Clips
17-013-52	Sugita Titanium Clip Ⅱ Applier, Straight 90mm for Mini Clips
17-013-53	Sugita Titanium Clip Ⅱ Applier, Straight 110mm for Mini Clips
17-013-54	Sugita Titanium Clip Ⅱ Applier, 15°Angled for Mini Clips
17-013-55	Sugita Titanium Clip Ⅱ Applier, 30°Angled for Mini Clips
17-013-58	Sugita Titanium Clip Ⅱ Applier, Sideward Angled for Mini Clips
17-014-52	Sugita Titanium Clip Ⅱ Applier, Straight 90mm for Long Clips
17-014-54	Sugita Titanium Clip Ⅱ Applier, 15°Angled for Long Clips

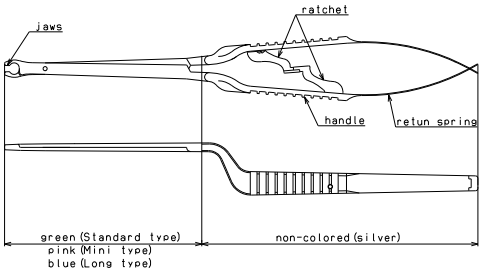
Material: Titanium alloy, stainless steel

Three types of forceps are available for Standard、Mini and Long clip each. Forceps are color-coded on the applicable clips as follows,

○Forceps for Standard type: Distal part of forceps colored green.

○Forceps for Mini type: Distal part of forceps: colored pink.

○Forceps for Long type: Distal part of forceps: colored blue.



Applicable clip types are imprinted on the return spring of the forceps for your verification before use.

Intended purpose

This device is to be used when clips are placed on in a surgery.

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.

Direction for Use:

1. By squeezing the forceps handles, the ratchet may be locked. Further squeezing of the handles will release the locked ratchet.
2. Set a clip between the forceps jaws by placing the clip correctly in the holding recesses of the jaws while the ratchet is released, then lock the ratchet. The clip will be held firmly between the jaws.
3. When the handles are further squeezed with the clip in the jaws, the ratchet will be released to open the clip blade to the maximum width. At this point, gradual loosing of the handles will close the clip blades with opening of the jaws to release the clip.

Warning/Caution

1. Important fundamental cautions
   (1) 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) Please confirm that the clip is held securely in the slot of the gripping part of the forceps. (Fig-1)
   (3) If the clip is not held securely, the clip may slip or come loose from the forceps. This will also damage the spring part of the clip, and may break the spring. (Figs. 2, 3, and 4)
   (4) Do not hold the clip at a bent angle. (Figs. 3, 4)
   (5) Please clean the product to remove the attached materials (dirt). Take extra care to clean the moving part (e.g. the joint) thoroughly.
   (6) Sugita Titanium Clip Applier is exclusively designed and constructed for use with Sugita Titanium Aneurysm Clips only. Sugita Titanium Clip Ⅱ Applier is exclusively designed and constructed for use with Sugita Titanium Aneurysm Clips Ⅱ only. Thus it must NOT be used for clips of other manufacturers or conventional cobalt alloy clips.

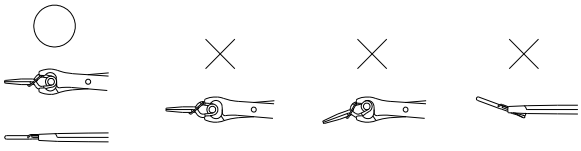


Fig-1 Fig-2 Fig-3 Fig-4

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: 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

Make sure to inspect the device periodically as well as prior to use for ensuring proper functioning.

2. Check after each use

(1) Make sure to wash in manual soaking device, when device is handled.

Device shall be fixed with holder to avoid breakage before it, when the ultrasonic cleansing method is used.

(2) Immediately wash with clean water

(2)-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)-2 Further remove any remaining contamination with a plastic brush.

(2)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

(2)-4 Use a soft towel, a plastic brush, or a water jet for cleaning.

(2)-5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

(2)-6 Reverse osmosis water is recommended to wash this product.

(2)-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)

(3) 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.

(4) Only use distilled or reverse osmosis water

Use distilled or reverse osmosis water to wash this product.

Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

(5) 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.]

(6) Maintenance

(6)-1 After cleaning, visually inspect under ambient lighting and confirm all dirt and debris has been removed.

(6)-2 If any dirt or debris is visible, repeat cleaning and lubrication steps.

(6)-3 Confirm that moving parts operate smoothly without binding, excessive force or moving parts appear to be loose and are rattling.

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.

In sterilization, the device is to be stored and left unratcheted in Mizuho rigid sterilization case supplied by us. (Table-1)
Otherwise the return spring will be damaged.

Table-1

Code No.	Product Description
17-010-80	Sugita Titanium Clip II Case A for Appliers
17-010-06	Sugita Titanium Clips II Half Case

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.

Manufacturer

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