

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

Instructions for Use

Trade Name: Clip Applier (SUGITA AVM MICROCLIP APPLYING FORCEPS)

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 the market outside the US

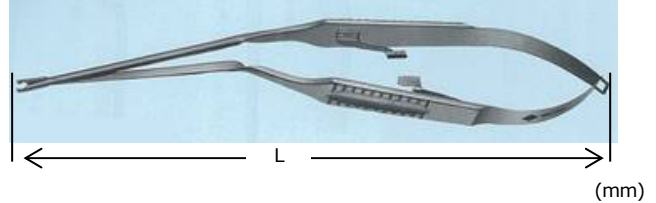
When the device is used on a patient with or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse. Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for more information related to cleaning and sterilization.

2. Use with Sugita AVM Clips only.
Use with any other style clip may damage the aneurysm clip.
3. When removing the proximal section of the spring handle for cleaning, handle it carefully so that its shape is not altered. If its shape is altered from the original, the clip applier may no longer release clips properly due to a decreased opening of jaws.

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. 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 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.
7. Do not sterilize with the ratchets in the locked position.
It may damage the return spring and the device.

Shape / Structure



	Code No.	Product Description	L
1)	07-935-10	Sugita AVM Micro Clip Applier	212
2)	07-935-20	Sugita AVM Micro Clip Applier	193
3)	07-935-22-MA	Sugita AVM Microclip Applier short	165

Material: 1),3) Jaws: Co-Cr alloy, Other parts: Stainless steel
2) Stainless steel

Intended Purpose

This device is exclusively designed to place Sugita AVM Microclips in surgeries.

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.

1. Outline of use:

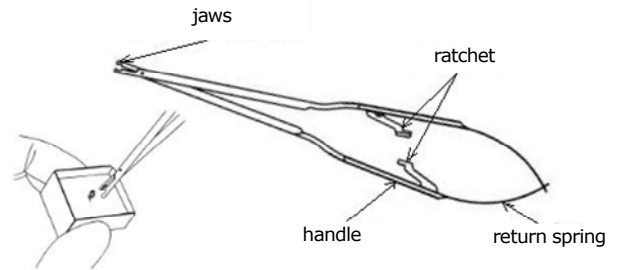
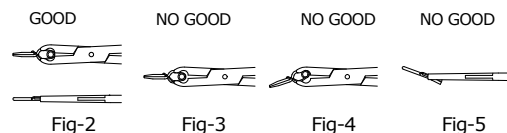


Fig-1

- (1) By squeezing the Applier handles, the ratchet may be locked. Further squeezing of the handles will release the locked ratchet. (Fig-1)
- (2) Set a clip between the Applier 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 loosening of the handles will open the jaws and release the clip while closing the clip blades.

Warning/Caution

1. Important fundamental cautions:



- (1) 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) Please confirm that the clip is held securely in the slot of the gripping part of the forceps. (Fig-2)
- (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. (Fig-3, Fig-4, Fig-5)
- (4) Do not hold the clip at a bent angle. (Fig-4, Fig-5)
- (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) This product is designed specifically for Sugita AVM Clips. Do not use this product with clips made by other manufacturers or conventional cobalt alloy clips. They must NOT be used with clips from other manufacturers or for conventional cobalt alloy clips.

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 the specified maintenance, inspection and proper storage)

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 to ensure proper functioning.
2. Check after each use
 - (1) Immerse and clean microsurgery and delicate instruments manually. If disassembly is possible, disassemble and clean the entire surface of the instrument. Device shall be placed and fixed in holders to avoid breakage when 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.
 - (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 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.
 - (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, 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) Use distilled water or reverse osmosis water
Use distilled water or reverse osmosis water to wash and sterilize 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 that are regulated 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 / 270°F*	4 min
	134°C / 273°F*	3 min

*According to the Guideline for Disinfection and Sterilization in Healthcare Facilities ,2008 (Update:May 2019)

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 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.

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 damage on purpose. 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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