

Instruction for Use

Trade Name: Sugita AVM Microclip II Single Shaft Applier w/o Catches

Warning

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.

Contraindication/Prohibition

- Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
- 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.

Specifications



Code No.	Product Description
07-935-52	Sugita AVM Microclip II Single Shaft Applier 90 mm, Str, w/o Catches
07-935-53	Sugita AVM Microclip II Single Shaft Applier 90 mm, 30 deg, w/o Catches
07-935-54	Sugita AVM Microclip II Single Shaft Applier 110 mm, Str, w/o Catches
07-935-55	Sugita AVM Microclip II Single Shaft Applier 110 mm, 30 deg, w/o Catches
07-935-56	Sugita AVM Microclip II Single Shaft Applier 150 mm, Str, w/o Catches
07-935-57	Sugita AVM Microclip II Single Shaft Applier 150 mm, 30 deg, w/o Catches

Material: Cobalt-chromium-nickel-molybdenum-iron alloy, stainless steel and titanium alloy

Intended purpose

This device is designed exclusively for placing Sugita AVM Microclip II during 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.

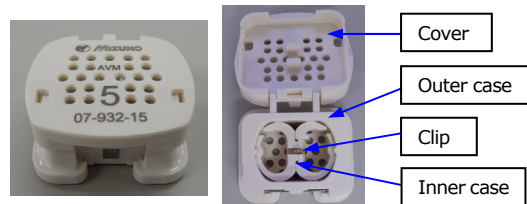
<Method of operation>

- Open and close the clip by opening and closing the handle.
- The clip is set in an individual, dedicated case. Correctly pinch the spring part of the clip with the jaws of the clip applier, and then remove the clip directly.
Refer to <How to remove the clip>.
- 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.



<How to remove the clip>

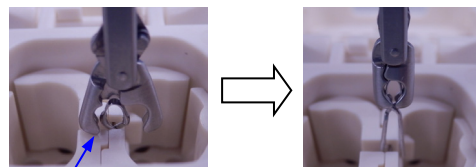
- Individual case and clip set state



- Since the clip is fixed by sandwiching it between plates of the same material as the clip set in the inner case, the clip can be directly held with clip applier and removed.



- Check the clip set in the inner case and correctly pinch it in the groove of the holding jaws of the clip applier to remove it.



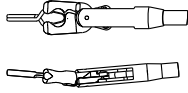
Hold the clip after applying the tip of the clip applier to the inner case.

Warning/Caution

- Important fundamental cautions
 - (1) The device must be sterilized in accordance with the manufacturer's recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

- (2) This product is designed specifically for Sugita AVM Microclip II.
Do not use this product with clips made by other manufacturers.
- (3) Please confirm that the clip is held securely in the groove of the holding jaws of the clip applicator. [Fig-1]
- (4) If the clip is not held securely, the clip may slip or come loose from the clip applicator. This will also damage the spring part of the clip, and may break the spring. [Fig-1 (a), (b) and (c)]
- (5) Do not hold the clip at a bent angle. [Fig-1 (b) and (c)]

<Correct holding method>



<Improper holding method>

- (a) The holding of the clip is shallow. (b) Angular misalignment



- (c) Angular misalignment

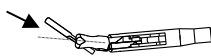
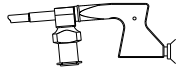


Fig-1

- (6) Please clean the product to remove the attached materials (dirt).
Take extra care to clean the moving part (e.g. the joint) thoroughly.
- (7) This product does not have a ratchet. Make sure the clip does not fall off from the clip applicator.
- (8) This product has a removable cleaning port. The cleaning port is attached to clean the lumen. When cleaning is complete, remove it. [Fig-2]

The cleaning port is attached to the lumen.



The cleaning port is removed from the lumen.

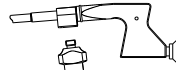


Fig-2

Cleaning port

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
Conduct daily and pre-operation checks of this product to make sure that it functions properly.
2. Check after each use
 - (1) Immediately wash with clean water
 - (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.

- (1)-2 Further remove any remaining contamination with a plastic brush.

- (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

- (1)-4 Use a soft towel, a plastic brush or a water jet for cleaning.

- (1)-5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.

- (1)-6 Reverse osmosis water is recommended to wash this product.

- (1)-7 Only use reverse osmosis water for the final rinse.

- (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) 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) 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.

- (4) Use a water-based lubricating agent and a water-based rust-prevention agent

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) 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.

- (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.

<Mizuho 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.

- 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) Before re-attaching the cleaning port to the product, rinse with tap water and clean with a plastic brush until all visible residue is removed from the surface of the instrument. Be especially careful to clean the connecting part of the cleaning port and the product, upon completion re-attach the cleaning port to the product. Carefully wash hinges, bonded parts, the lumen, and other hard-to-reach areas, spray with cold tap water with a water jet (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 jet (at a maximum of 2 bars of water pressure) for 20 seconds.

<Automated Procedure>

Connect the cavity-cleaning jig of the washer-disinfector to the cleaning port of this device.

- 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 deionized water 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 (A0 value: 3000-12000) (reference EN ISO 15883-1)
- 10) Thoroughly dry prior to use or storage.
- 11) After cleaning, remove the cleaning port and store it until next cleaning procedure.

- (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.

3. Sterilization

- (1) Remove the cleaning port before sterilizing the product.
- (2) The device must be sterilized in accordance with the manufacturer's recommended sterilization procedures or 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 / 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 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.

- (3) 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.

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.



MIZUHO Corporation
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
<https://www.mizuho.co.jp>