MIZUHO

MES-CK07-935-30EN-0

PREPARED: (2023-12-19) (Version 1)

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

Instruction for Use

Trade Name: Clip Applier

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

1. Use for intended purpose only
   Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. 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.
3. 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 clip applier.
4. Do not sterilize with the ratchets in the locked position
   It may damage the return spring and the device.

Specifications

Code No.	Product Description
07-935-30	Sugita AVM Microclip II Applier 100 mm
07-935-31	Sugita AVM Microclip II Applier 50 mm

Material: Stainless steel and cobalt-chromium-nickelmolybdenum-iron 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>

1. By squeezing the applier handles, the ratchet may be locked. Further squeezing of the handles will release the locked ratchet. [Fig-1]

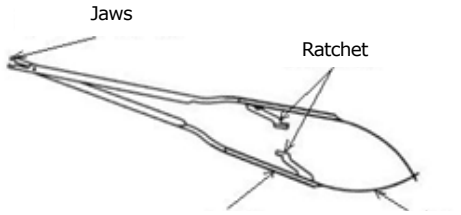
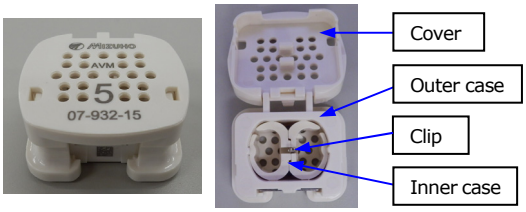


Fig-1

2. 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>.
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.

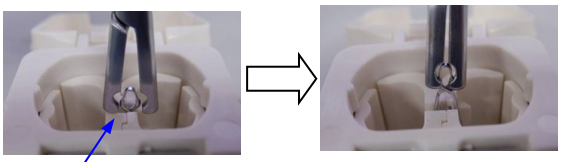
<How to remove the clip>

・ 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.

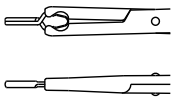


Hold the clip after applying the tip of the clip applier to the inner case.

Warning/Caution

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) 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 applier. [Fig-2]
   (4) If the clip is not held securely, the clip may slip or come loose from the clip applier. This will also damage the spring part of the clip, and may break the spring. [Fig-2 (a), (b), (c) and (d)]
   (5) Do not hold the clip at a bent angle. [Fig-2 (c) and (d)]

<Correct holding method>



<Improper holding method>

(a) The holding of the clip is shallow. (b) The holding of the clip is deep.

(c) Angular misalignment (d) Angular misalignment

Fig-2

   (6) Please clean the product to remove the attached materials (dirt). Take extra care to clean the moving part (e.g. the joint) thoroughly.
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
   Before use, be sure to inspect the surface of the clip applier, and if any functional abnormalities such as deformations, cracks, scratches or loose joints are observed, stop use and inspect, repair, or replace the applier.
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. 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 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.
      (2)-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)
   (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 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.]
   (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
   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 conditions	Sterilization temp.	Retention time
	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.

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.

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