

Instructions for Use

Trade Name: Clip Applier

(SANO Double Action 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. Not doing so may give rise to serious problems or adverse events.

2. The use with improper clip is prohibited.

[Wrong use may damage an aneurysm clip.]

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.

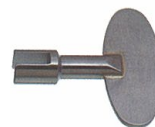
8. Do not modify or reshape the return spring.

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.

Shape/Structure



Code No.	Product Description
07-946-00	Sugita Clip Applier, Sano Type Double Action for Standard / Large Clips
07-950-12	Sugita Clip Applier, Sano Type Double Action for Mini Clips



Accessory: Angle-Adjustment Wrench

Contraindication/Prohibition

1. Use for intended purpose only

Use tools for their intended purposes only. Incorrect use could cause breakage of this product.

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 tools 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 surfaces of this product and result in rust or corrosion.

6. 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.

7. Do not sterile the applier with ratchet locked.

[It may damage return spring]

Material: Stainless steel, Co-Cr alloy

Intended Purpose

This device is a surgical tool designed to apply a Sugita surgical aneurysm clip.

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 (Fig-1). 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 (Fig-2).

By using attached angle-adjustment wrench, the tip of the clip applier can be adjusted to the various angles and shapes.

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 close the clip blades with opening of the jaws to release the clip.

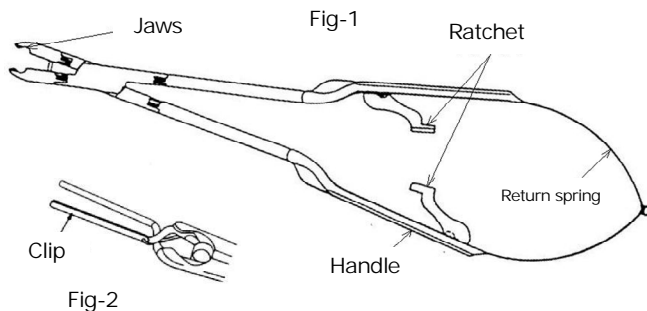


Fig-2

How to use the attached angle-adjustment wrench

- (1) Set the angle-adjustment wrench on the tip of the clip applier
- (2) Adjust the tip of the clip applier to an appropriate angle.

Cautions / Warnings

1. Warning

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. Defect/Adverse event

Defect

- Corrosion and 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. Important fundamental cautions

- (1) Please confirm that the clip is held securely in the slot of the gripping part of the forceps. (Fig-3)
- (2) If the clip is not held properly, the clip may slip or come loose from the forceps. This may also damage the spring part of the clip, and may break the spring. (Figs. 4, 5, and 6)
- (3) Do not hold the clip in angled position. (Figs. 5, 6)
- (4) Please clean the product to remove the attached materials (dirt). Take extra care to clean the moving part (e.g. the joint) thoroughly.
- (5) This product is exclusively designed and constructed for use with Sugita Aneurysm Clips only, thus it must NOT be used for clips of other manufacturers.

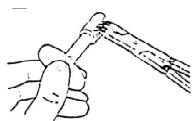


Fig-3

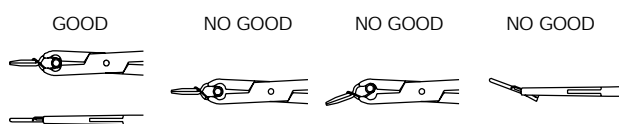


Fig-4

Fig-5

Fig-6

Fig-7

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

<Maintenance and checks conducted by users>

1. Checking matters before use

Operational and functional checks

Before using this product, inspect appearance and construction. Do not use in case there are any deformation, crack or anything wrong in sliding motion.

2. Checking matters after 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, 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 soft nylon brush.

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

- (2)-4 Use a soft towel, a soft nylon 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 Only use distilled water or deionized water (reverse osmosis) to wash this product.

- (2)-7 Only use fully deionized water (reverse osmosis) for the final rinse.

- (2)-8 It is recommended to use a washer-disinfector for this device

- (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.

- (3)-1 After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.

- (3)-2 Do not leave this product wet for a longer time than necessary as residual water may damage the instrument.

- (4) Only use distilled or deionized water

Use distilled or deionized 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 our recommended sterilization procedures or using packaging materials for sterile products and the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

The minimum 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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