

Instructions for Use

Trade Name: Clip Applier

Warning

1. Use with Sugita TII Clips only.
Use with any other style clip may damage the aneurysm clip.
2. 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.
3. When the device is used on a patient where there is a suspicion of Creutzfeldt-Jakob disease (CJD), make sure to follow 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.]
4. Make sure to read and understand the instructions before use, and pay particular attention to the patient's safety in order to prevent a severe and adverse incident.

Contraindication / Prohibition

1. Do not modify or reshape the spring handle.
Appropriate width of the opening for holding clip may be affected by breaking and/or transforming the spring handle. This may come to interfere with the performance of the applier, and eventually the clips may not easily release from the forceps.
2. Do not use the device for anything other than its intended purpose.
Use of the device outside its intended purpose may cause damage.
3. Do not use with devices by other manufacturers.
Do not use with devices other than specified by Mizuho. The design and the development of unauthorized devices may differ from those of the manufacturer and it is likely they will not be suited for the procedure.
4. Do not use with chemical substances.
Avoid exposing the device to chemicals to avoid corrosion damage.
5. Handle with care.
Do not handle the device in a rough manner that may deform or scratch the device. It may significantly alter the life of the device.
6. Do not sterilize with the ratchets in the locked position.
It may damage the return spring and the device.
7. Do not use scouring powder or steel wool.
Do not scrub the surface with coarse powder or steel wool when cleaning. It may result in damage to the device surface, which may result in rust and corrosion.
8. Do not use alkaline / acid and/or household detergents.
Ensure the use of "medical" detergent only. Do not use household detergent/cleaners. The detergent should be neutral, pH 6~8. Do not use alkaline or acid detergent, or it may cause discoloration and/or corrosion.
9. Do not use low-temperature hydrogen peroxide gas plasma sterilization. The device is not designed for such sterilization methods and may cause discoloration on the surface and compromise its utility.

Shape / Structure



Appliers for Standard type:
Green



Appliers for Mini type:
Pink



Accessory : Jig
(Angle Adjustment Handle)



Code No.	Product Description
17-012-60	Sugita Titanium Clip II Applier with the swivel ends, for Standard Clips
17-013-60	Sugita Titanium Clip II Applier with the swivel ends, for Mini Clips

Material: Titanium alloy, Stainless Steel
TII stands for Titanium II Aneurysm Clip

Intended Purpose / Potency or Effect

- This device is to be used to place cerebral aneurysm clips in surgeries.
1. Instrument is exclusively designed for Sugita Titanium II Aneurysm Clips.
 2. Two types of Appliers are available for each of Standard, and Mini clips.
Appliers are color-coded to indicate use with applicable clips as follows; (Fig-1, Table 1)
- Appliers for Standard type: Distal part of forceps: colored Green.
- Appliers for Mini type: Distal part of forceps: colored Pink.
 3. Applicable clip types are imprinted on the return spring of the Appliers for verification before use.
 4. Groove of Applier tip can be turned up to 220 degrees by Jig (Key).

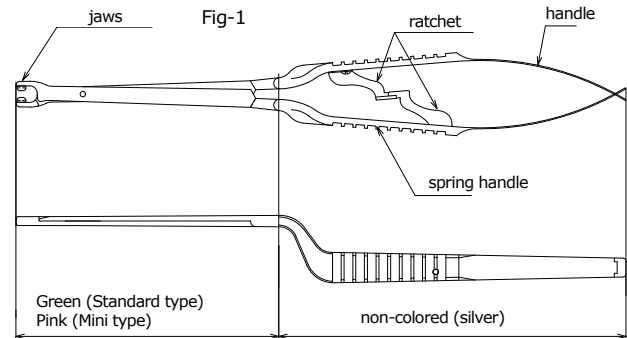


Table 1

Product Description	Color	
	Tip	Jig (Key)
Sugita Titanium Clip II Applier with the swivel ends, for Standard Clips	Green	Green
Sugita Titanium Clip II Applier with the swivel ends, for Mini Clips	Pink	Pink / Color Free

Directions for Use

Make sure to wash and sterilize before each use. Refer to Maintenance / Inspection.

1. Directions for use:

- (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. Groove of Applier tip can be turned up to 220 degrees by Jig (Key). Use only dedicated Jig. (See Table 1)
- (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.

2. Caution:

- (1) Set Jig with Applier like Fig-2 for production of a symmetric appearance and adjustment of angle. (Fig-2)

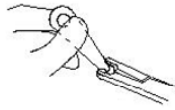


Fig-2

- (2) To set a clip in the Applier jaws, make sure that the clip is correctly placed in the recesses of the jaws.
- (3) Failure to hold the spring of the clip correctly in the recesses of the jaws may cause the clip to slip off or release. Or, the spring section of the clip may be damaged with a risk of fracture.
- (4) Do not hold the clip in an angled position.
- (5) Wash the Applier and remove adhered debris after each use. Make sure NOT to leave any deposits in the Applier's joint.
- (6) Sugita Titanium II Clip Appliers are exclusively designed and constructed for use with Sugita Titanium II Aneurysm Clips only. They must NOT be used with clips from other manufacturers or for conventional cobalt alloy clips.

Caution

1. Warning:

Device has to be sterilized by users, using validated sterilization processes regulated by medical organizations in each country or region. Do not use low-temperature hydrogen peroxide gas plasma sterilization.

2. Harmful/Undesirable matter:

- The use of chemicals

Do not expose the device to chemicals, or damage due to corrosion may result.

Storage and Shelf Life

1. Do not store the device where the temperature or humidity becomes higher or drastically changes.
2. Conduct a specified maintenance check and an appropriate storage check: 5 years (Self-attestation).

Maintenance / Inspection

1. Working / functioning check:

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

2. Make sure to wash in manual soaking device, when device is handled. Device shall be placed and fixed in holders to avoid breakage when ultrasonic cleansing method is used.

3. Immediate washing and rinsing with clear water:

Remove any debris from the device. Wash and rinse with clear water immediately in case the device is exposed to bleach or antiseptic solution which may contain chlorine or iodine.

4. Immediate drying after washing:

Make sure to dry the device immediately after washing. Do not leave the device wet for prolonged periods of time.

5. Use distilled water and de-mineralized water:

Distilled water and de-mineralized water should be used for cleaning and sterilization. The residual chlorine and organic matter contained in tap water may cause bristletail and rust generation.

6. Use aqueous lubricant to prevent rust

Be cautious not to move the sliding portion of the device after washing since the lubricant may be completely removed by washing. It may cause scuffing on the sliding part. After the washing process, use aqueous lubricant before the sterilization process.

7. Do not modify or reshape the return spring.

Breakage or modification on the part of return spring may cause a disturbance in the release of the clip due to less opening of the jaws.

8. Sterilization

The device is non-sterile.

Device must be sterilized by users, using an autoclave method or validated sterilization process regulated by medical organizations in each country or region.

In sterilization, the device is to be stored and kept un-ratcheted. Keeping ratcheted for a long time may cause damage to the return spring.

The recommended sterilization parameters are as follows,

- Sterilization of the device may be accomplished by steam.

ISO17665-2	
Temp.	Minimum exposure time
121°C	15 Min
126°C	10 Min
134°C	3 Min

- Do not use low-temperature hydrogen peroxide gas plasma sterilization. It may cause discoloration on the surface and affect its property.

Packing

1 piece per pack

Matters related to warranty period

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.

* Name and address of manufacturer



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

* Authorized Representative Europe



Emergo Europe B.V.
Prinsessegracht 20, 2514 AP, The Hague
The Netherlands