

** Trade Name : Clip Applier

【Warning】

1. The use with improper clip is prohibited.
[Wrong use may damage an aneurysm clip.]
2. Make it sure, when the part of return spring is removed and cleaned, so that its shape can not be modified.
Once it happens, an applier may not release clip due to less opening of jaws.
3. Make sure to follow updated restriction available in each country and region, when the device used for the patient with Creutzfeldt-Jakob disease (CJD) or having its suspicious is re-used. [Be cautious about secondary infection.]
4. Make sure to understand before use and pay attention on patient's safety carefully, follow these instructions.
[It may cause huge and adverse event.]

【Contraindication · Prohibition】

1. 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.
2. Use prohibitions other than purpose.
The device to be used for proper purpose.
[Wrong usage may damage the device.]
3. Taboo of using with tools by other manufacturers.
Do not use it together excluding the product designated by us.
[The design and the development policy may be different, it is likely not to suit.]
4. No use with chemical substances.
Avoiding exposing the device to chemicals.
[It causes damage due to corrosion.]
5. Secondary processing prohibition.
Do not do the secondary elaboration such as carving the sign by using the impact and the vibration on the surface of this item.
[It causes breakage.]
6. No rough handling.
Do not handle the device in a rough manner that may deform or scratch it [This may reduce the product's life-span]
7. No sterilization with forceps ratcheted.
[It may damage return spring]
8. No scouring powder or steel wool.
When cleaning, do not scrub the surface with coarse powder or steel wool. [This may spoil the device surface, possibly causing rust or corrosion.]
9. No alkaline / acid and domestic-use detergent.
*Ensure use of "medical" detergent only. Do not use domestic-use detergent.
*Ensure use of neutral detergent (pH 6~8), not use alkaline or acid detergent. [It may cause discoloration or corrosion.]
10. Do not use a method of low-temperature hydrogen peroxide gas plasma sterilization.
This method is not good for the device.
[It may cause discoloration on surface and affect its property.]

*** 【Shape/ Structure or principle】**

Shape & Structure

(1) Sugita Titanium Clip Applier

Code No	Production description
07-941-31	Sugita Titanium Clip Applier (Straight) for Standard
07-941-32	Sugita Titanium Clip Applier (15° Angled) for Standard
07-941-33	Sugita Titanium Clip Applier (30° Angled) for Standard
07-941-34	Sugita Titanium Clip Applier (Sideward Angled) for Standard
07-941-41	Sugita Titanium Clip Applier (Straight) for Fenestrated
07-941-42	Sugita Titanium Clip Applier (15° Angled) for Fenestrated
07-941-43	Sugita Titanium Clip Applier (30° Angled) for Fenestrated
07-942-31	Sugita Titanium Clip Applier (Straight) for Mini
07-942-32	Sugita Titanium Clip Applier (30° Angled) for Mini
07-942-33	Sugita Titanium Clip Applier (Sideward Angled) for Mini

* (2) Sugita Titanium Clip II Applier

Code No	Product description
17-012-51	Sugita Titanium Clip II Applier Standard, Straight 70mm
17-012-52	Sugita Titanium Clip II Applier Standard, Straight 90mm
17-012-53	Sugita Titanium Clip II Applier Standard, Straight 110mm
17-012-54	Sugita Titanium Clip II Applier Standard, 15° Angled
17-012-55	Sugita Titanium Clip II Applier Standard, 30° Angled
17-012-58	Sugita Titanium Clip II Applier Standard, Sideward Angled
17-013-51	Sugita Titanium Clip II Applier Mini, Straight 70mm
17-013-52	Sugita Titanium Clip II Applier Mini, Straight 90mm
17-013-53	Sugita Titanium Clip II Applier Mini, Straight 110mm
17-013-54	Sugita Titanium Clip II Applier Mini, 15° Angled
17-013-55	Sugita Titanium Clip II Applier Mini, 30° Angled
17-013-58	Sugita Titanium Clip II Applier Mini, Sideward Angled
17-014-52	Sugita Titanium Clip II Applier Straight 90mm, For Long Clips
17-014-54	Sugita Titanium Clip II Applier 15° Angled, For Long Clips

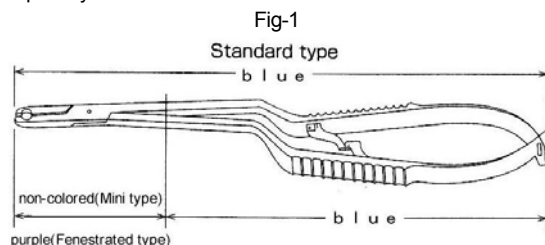
Material: Titanium alloy Stainless Steel

【Intended purpose / Potency or Effect】

This device is to be used when clips are placed on in a surgery.

(1) Sugita Titanium Clip Applier

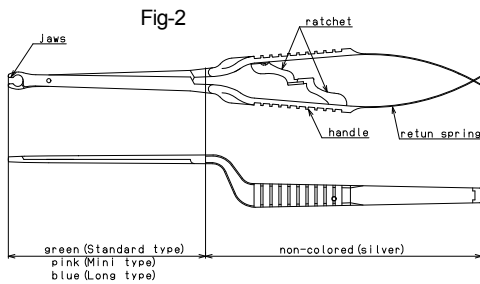
- ① Instrument is exclusively designed for Sugita Titanium Aneurysm Clip.
- ② Three types of forceps are available for Standard, Mini and Fenestrated clip each.
Forceps are color-coded on the applicable clips as follows, (Fig-1)
○Forceps for Standard type : Forceps body colored blue.
○Forceps for Mini type: Distal part of forceps left non-colored, while the rest of the forceps body colored blue.
○Forceps for Fenestrated type: Distal part of forceps colored purple, while the rest of the forceps colored blue.
- ③ Applicable clip types are imprinted on the return spring of the forceps for your verification before use.



* (2) Sugita Titanium Clip II Applier

- ① Instrument is exclusively designed for Sugita Titanium Aneurysm Clip II.
- ② Three types of forceps are available for Standard, Mini and Long clip each.
Forceps are color-coded on the applicable clips as follows, (Fig-2)
○Forceps for Standard type: Distal part of forceps colored green.
○Forceps for Mini type: Distal part of forceps: colored pink.
○Forceps for Long type: Distal part of forceps: colored blue.

- ③ Applicable clip types are imprinted on the return spring of the forceps for your verification before use.



【Specification】

Appearance : Make sure to examine the overall surface condition of the forceps, not find a crack scratch which may affect its property before use.

【Direction for use or operation】

Make sure to examine, wash and sterilize before use.

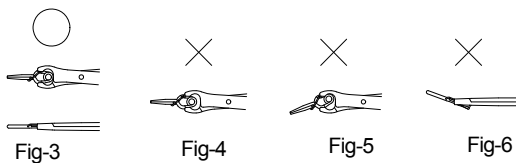
(Please refer to **【Maintenance / Inspection】**)

(1) Direction for Use:

- ① By squeezing the forceps handles, the ratchet may be locked. Further squeezing of the handles will release the locked ratchet. (Fig-1, Fig-2)
- 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.
- 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.

(2) Cautions:

- ① When setting a clip in the forceps Jaws, make sure that the clip is correctly placed in the recesses of the jaws. (Fig-3)
- ② Failure to hold the spring of the clip correctly in the recesses of the jaws may cause to Slip off or sprung out. Or, the spring section of the clip may be damaged with a risk of fracture. (Fig-4 / Fig-5 / Fig-6)
- ③ Do not hold the clip in an angled position. (Fig-5 / Fig-6)
- ④ Wash the forceps after use to remove adhered debris. Especially, make sure NOT to leave any deposits on the forceps joint.
- ⑤ Sugita Titanium Clip Applier is exclusively designed and constructed for use with Sugita Titanium Aneurysm Clips only, thus it must NOT be used for clips of other manufacturers or conventional cobalt alloy clips.



*** 【Caution】**

(1) Warning:

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

(2) Interaction:

- Do not use with contact coagulation.
- Do NOT touch the device with the tip of bipolar and/or mono-polar. It may cause the electric shock and the burn.

【Storage and Shelf Life】

Do not store the device at places where the temperature or humidity gets higher or changes drastically.

【Maintenance / Inspection】

1. Working / functioning check

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

2. Make sure to wash in manual soaking device, when device is handled.

Device shall be fixed with holder to avoid breakage before it, when the ultrasonic cleansing method is used.

3. Immediate washing and rinsing with clear water.
Wash and rinse with clear water, in the case that device is exposed to bleach, and content of chlorine and the iodine such as antiseptic solution.
4. Immediate drying after washing
Make sure to dry the device immediately after washing. Do not leave wet device as it is for a prolonged period of time.
5. Use distilled water and de-mineralized water.
Distilled water and de-mineralized water shall be used for cleaning and sterilization.
The residual chlorine and the organic matter contained in tap water may cause the bristletail and the rust generation.
6. Use water lubrication to prevent rust.
Lubricant may be completely removed after washing, thus be cautious not to move the sliding area if there is before being treated by water lubricant, otherwise it may bite each.
7. Do not modify or reshape the return spring.
Breakage or modification on the part of return spring may not release clip due to less opening of jaws.
8. Sterilization

The device is non-sterile.

Device has to be sterilized by users, using autoclave method or validated sterilization processes regulated by Medical organization in each country or region.

In sterilization, the device is to be stored and left unclamped in Mizuho rigid sterilization case supplied by us.

Otherwise the return spring will be damaged.

In addition, be advised to use applicable Sugita titanium clip forceps sterilization case shown below (Table-1).

Each forceps shall be stored and fixed at designated position inside case, otherwise forceps will be damaged.

Table-1

Code No	Product description	Applicable sterilization case
17-012-53	Sugita Titanium Clip II Applier Standard, Straight 110mm	17-010-50
17-012-58	Sugita Titanium Clip II Applier Standard, Sideward Angled	
17-013-53	Sugita Titanium Clip II Applier Mini, Straight 110mm	
17-013-58	Sugita Titanium Clip II Applier Mini, Sideward Angled	

The recommended sterilization parameters are as follows,

- Sterilization of the device may be accomplished by steam.

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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 peace per pack

**** 【Name and address of manufacturer】**

 Manufacturer and distributor
Mizuho Ikakogyo Co., Ltd.
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
TEL: 81-3-3815-7101 FAX: 81-3-3818-1705

 European Representative
Emergo Europe
Molenstraat 15, 2513 BH, The Hague
The Netherlands