

Instructions for Use

Trade Name: Clip Applier

【Warning】

1. The use with improper clip is prohibited.
[Wrong use may damage an aneurysm clip.]
2. Make sure not to modify return spring. Once the return spring is modified, 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.]
5. Make sure not to use with contact coagulation.
Do not touch the device with the tip of bipolar and/or mono-polar.
[Please refer to 【Caution】 (2) Interaction]

【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

Code #	Description
17-012-09	Sugita Titanium Clip II Applier, Sano Double Action for standard.
17-013-09	Sugita Titanium Clip II Applier, Sano Double Action for Mini.

Accessory : Jig (Angle Adjustment Handle)

Material : Titanium alloy, Stainless Steel

【Intended purpose / Potency or Effect】

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

【Specification】

(1) Sugita Titanium Clip Applier, Sano Double Action for standard

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, Table-1)

○Forceps for Standard type : Distal part of forceps colored blue.

○Forceps for Mini type: Distal part of forceps colored non-colored.

○Forceps for Fenestrated type: Distal part of forceps colored pink.

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

(2) Sugita Titanium Clip II Applier, Sano Double Action for standard.

① Instrument is exclusively designed for Sugita Titanium Aneurysm Clip II.

② Two types of forceps are available for Standard and Mini clip each.

Forceps are color-coded on the applicable clips as follows, (Fig-1)

○Forceps for Standard type : Distal part of forceps colored green.

○Forceps for Mini type : Distal part of forceps :colored pink.

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

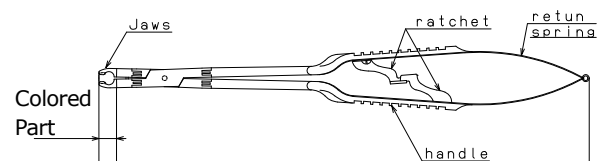


Fig-1

Table-1

Description	Color	
	Applier Tip	Jig (Handle)
Sugita Titanium Clip II Applier, Sano Double Action for standard.	Green	Blue(Common)
Sugita Titanium Clip II Applier, Sano Double Action for Mini.	Pink	

【Direction for use or operation】

1. Make sure to examine, wash and sterilize before use.

(Please refer to 【Maintenance / Inspection】)

2. By squeezing the forceps handles, the ratchet may be locked.

Further squeezing of the handles will release the locked ratchet.

3. 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.
Angle can be adjusted by using Jig
4. 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.

【Cautions】

(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) Cautions:

- ① Use prohibitions other than purpose
The device to be used for proper purpose.
Wrong usage may damage the device
- ② Set a clip into catching part of Applier equally to prevent slipping off a clip. Use a Jig (Handle) for adjustment. (Fig-2)
- ③ When setting a clip in the forceps Jaws, make sure that the clip is correctly placed in the recesses of the jaws. (Fig-3)
- ④ 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)
- ⑤ Do not hold the clip in an angled position. (Fig-5 / Fig-6)
- ⑥ Wash the forceps after use to remove adhered debris. Especially, make sure NOT to leave any deposits on the forceps joint.
- ⑦ Instrument is exclusively designed for Sugita Titanium Aneurysm Clip II, and do not use except the said clips.

Fig-2

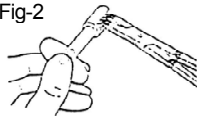


Fig-3



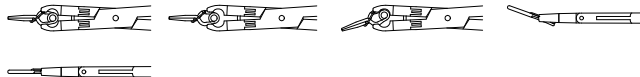
Fig-4



Fig-5



Fig-6



⑧ Cautions for usage of Jig (Handle)

When setting Jig (Handle), insert applier through Jig. Short insertion causes breakage of Jig (Fig-7)

[Good]

[Bad]

Jig (Handle)

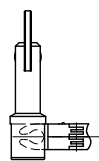
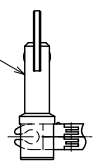


Fig-7

(3) 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.

(4) Harmful/Undesirable matter:

- The use of chemicals
Do not expose the device to chemicals.
Damage due to corrosion may result.

【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

Inspect the device periodically prior to use for ensuring proper functioning. In case of any dysfunctions, contact local distributor.

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 unratcheted in Mizuho rigid sterilization case supplied by us.

Otherwise the return spring will be damaged.

Do not use low-temperature hydrogen peroxide gas plasma sterilization, with the possibility oxide film may be removed.

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

【Packing】

1 peace 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



Instructions for Use

Trade Name: Clip Applier

【Warning】

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[Wrong use may damage an aneurysm clip.]
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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.]
5. Make sure not to use with contact coagulation.
Do not touch the device with the tip of bipolar and/or mono-polar.
[Please refer to 【Caution】 (2) Interaction]

【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

Code #	Description
07-946-10	Sugita Titanium Clip Applier, Sano Double Action for standard.
07-946-11	Sugita Titanium Clip Applier, Sano Double Action for Mini.
07-946-12	Sugita Titanium Clip Applier, Sano Double Action for Fenestrated.

Accessory : Jig (Angle Adjustment Handle)

Material : Titanium alloy、Stainless Steel

【Intended purpose / Potency or Effect】

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

【Specification】

(1) Sugita Titanium Clip Applier, Sano Double Action for standard

① Instrument is exclusively designed for Sugita Titanium Aneurysm Clip.

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Forceps are color-coded on the applicable clips as follows, (Fig-1, Table-1)

- Forceps for Standard type : Distal part of forceps colored blue.
- Forceps for Mini type: Distal part of forceps colored non-colored.
- Forceps for Fenestrated type: Distal part of forceps colored pink.

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

(2) Sugita Titanium Clip II Applier, Sano Double Action for standard.

① Instrument is exclusively designed for Sugita Titanium Aneurysm Clip II.

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- Forceps for Standard type : Distal part of forceps colored green.
- Forceps for Mini type : Distal part of forceps :colored pink.

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

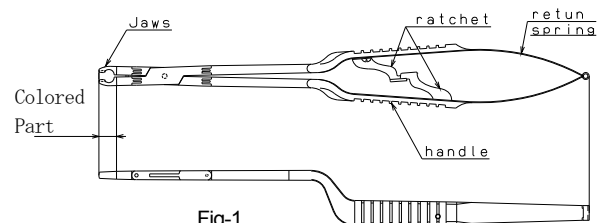


Fig-1

Table-1

Description	Color	
	Applier Tip	Jig (Handle)
Sugita Titanium Clip Applier, Sano Double Action for standard.	Blue	Blue(Common)
Sugita Titanium Clip Applier, Sano Double Action for Mini.	Color Free	
Sugita Titanium Clip Applier, Sano Double Action for Fenestrated.	Pink	

【Direction for use or operation】

1. Make sure to examine, wash and sterilize before use.
(Please refer to 【Maintenance / Inspection】)

- By squeezing the forceps handles, the ratchet may be locked.
Further squeezing of the handles will release the locked ratchet.
- 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.
Angle can be adjusted by using Jig
- 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.

【Cautions】

(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) Cautions:

① Use prohibitions other than purpose

The device to be used for proper purpose.

Wrong usage may damage the device

② Set a clip into catching part of Applier equally to prevent slipping off a clip. Use a Jig (Handle) for adjustment. (Fig-2)

③ When setting a clip in the forceps Jaws, make sure that the clip is correctly placed in the recesses of the jaws. (Fig-3)

④ 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)

⑤ Do not hold the clip in an angled position. (Fig-5 / Fig-6)

⑥ Wash the forceps after use to remove adhered debris. Especially, make sure NOT to leave any deposits on the forceps joint.

⑦ Instrument is exclusively designed for Sugita Titanium Aneurysm Clip II, and do not use except the said clips.

Fig-2

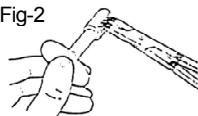


Fig-3

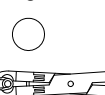


Fig-4

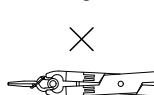


Fig-5

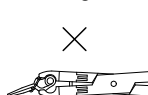
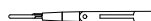
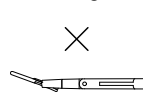


Fig-6

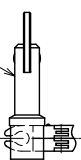


⑧ Cautions for usage of Jig (Handle)

When setting Jig (Handle), insert applier through Jig. Short insertion causes breakage of Jig (Fig-7)

[Good]

Jig (Handle)



[Bad]

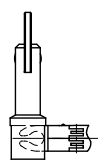


Fig-7

(3) Interaction:

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- The use of chemicals

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Damage due to corrosion may result.

【Storage and Shelf Life】

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【Maintenance / Inspection】

1. Working / functioning check

Inspect the device periodically prior to use for ensuring proper functioning. In case of any dysfunctions, contact local distributor.

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.

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【Packing】

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【Name and address of manufacturer】



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