

Instructions for Use

Trade Name: Anastomosis Clip

DO NOT REUSE

*** 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. Advantages and disadvantages of Anastomosis Clips and related surgery must be fully explained to each patient.
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 devices.
5. Do not clean, product is provided clean and ready for sterilization. Cleaning may damage the product and may cause harm to the patient.

*** Contraindication / Prohibition**

1. Do not reuse. Anastomosis Clips are for single use only. Once a clip has been held by clip applying forceps or has come into contact with the patient's blood or tissue, it must be discarded because of breakage/risk of transferring communicable diseases.
2. Handle with care
Handle this product with care, as it can be deformed or damaged.
3. Use for intended purpose only
Anastomosis Clips are contraindicated for uses other than temporary occlusion of peripheral blood vessels during cerebrovascular anastomosis. Do not use for permanent occlusion or insertion.
4. Use the Anastomosis Clips applying forceps designed exclusively for the product so that the closing force of the clip or its mechanical characteristics does not change. Do not use applying forceps made by other manufacturers.
5. Do not compress and open the Anastomosis Clips with fingers. Open the clip only when it is correctly positioned in the appropriate place of the applying forceps.
6. Do not bend or modify the product.
7. Do not use concomitantly with implants made by other manufacturers or implants made of different materials.
8. Do not use in patients with a serious allergy to metals or foreign bodies.
9. Do not use hydrogen peroxide gas plasma sterilization. This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.

*** Shape / Structure**

1. Form and Structure

Product Code	Product Description	Closing Force
07-096-11	Anastomosis Clip Straight 2mm LP	30g ±10g
07-096-12	Anastomosis Clip Straight 3mm LP	
07-096-13	Anastomosis Clip Straight 4mm LP	
07-096-14	Anastomosis Clip Straight 5mm LP	
07-096-15	Anastomosis Clip Bent 3mm LP	
07-096-16	Anastomosis Clip Bent 4mm LP	
07-096-17	Anastomosis Clip Sideward Bent 3mm LP	

Product Code	Product Description	Closing Force
07-096-21	Anastomosis Clip Straight 2mm HP	60g ±10g
07-096-22	Anastomosis Clip Straight 3mm HP	
07-096-23	Anastomosis Clip Straight 4mm HP	
07-096-24	Anastomosis Clip Straight 5mm HP	
07-096-25	Anastomosis Clip Bent 3mm HP	
07-096-26	Anastomosis Clip Bent 4mm HP	
07-096-27	Anastomosis Clip Sideward Bent 3mm HP	

2. Material:

cobalt-chromium alloy/ASTM F1058G2 (ISO5832/7)

3. Principle of Action

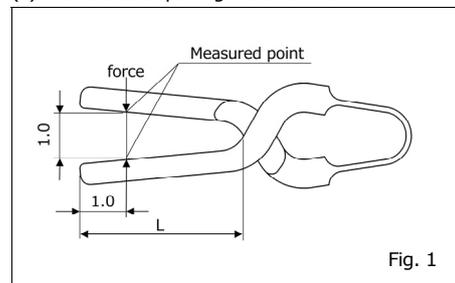
- 1) Spring Type: INTEGRAL SINGLE BEND
- 2) Action Mechanism: ALLIGATOR ACTION

4. Performance

- Anastomosis Clips are made of non-ferromagnetic material (ASTM F1058/ISO 5832-7). It has been confirmed by the ASTM-defined test method that they may be used without being affected by MRI up to 3T, which is currently in clinical use.

ASTM: American Society for Testing and Materials
ISO: International Organization for Standardization

The closing force of each clip is measured in the final quality assurance stage with a computerized electronic scale at a measuring point located 1.0mm from the distal end of the clip blade (L) with a blade opening width of 1.0mm.



5. Packaging

- Anastomosis Clip is placed in color-coded aluminum container (gold for low pressure clip, blue for high pressure clip) with cushioning material (silicone sponge), and the container is sealed with a product label (Fig.2).
- For additional information, please find product information description, size, closing force, lot and serial numbers on the packaging label.

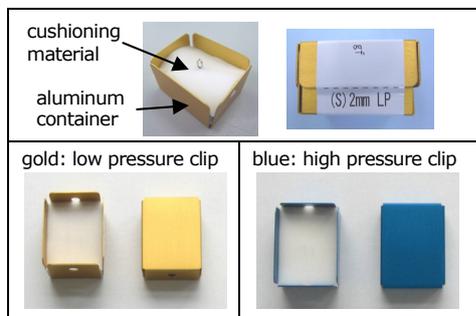


Fig. 2

Intended Purpose

Anastomosis Clips are indicated for temporary occlusion of peripheral blood vessels during cerebrovascular anastomosis.

* Instructions for Use

Precautions concerning method of use

- Only users with a thorough knowledge of using surgical instruments and adequate training should use Anastomosis Clips. Incorrect choice of a clip and inappropriate surgical techniques may result in serious health injury and/or complications
- Decline in Closing Force
If opening/closing of the clip is repeated more than 10 times, the claimed closing force may decrease by more than 5%.
- The closing force written on the label is warrantable only at the initial time when the clip is held by the clip-applying forceps designed exclusively for the product. The closing force decreases if opening and closing of the clip is repeated by the forceps or fingers.
- Anastomosis Clips are indicated for temporary occlusion of peripheral blood vessels during cerebrovascular anastomosis.
- Anastomosis Clips are for single-use only with the clip-applying forceps designed exclusively for the product.
- DO NOT CLEAN ANASTOMOSIS CLIPS. The CLIPS are provided clean and **NOT** intended to be subjected to cleaning.
- Anastomosis Clips are supplied non-sterile. Prior to use the sealed Anastomosis Clip aluminum container must be removed from the outer packaging, and sterilized with an appropriate method (double-wrapped or peel-pouch). The device must be sterilized by users under the standard sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
Do not use low temperature hydrogen peroxide gas plasma sterilization.

Sterilization of the device may be accomplished by steam.

ISO/TS 17665-2	
Temp.	Minimum Exposure Time
121°C / 249.8°F	15 Min
126°C / 258.8°F	10 Min
134°C / 273.2°F	3 Min

For the US market: Only legally marketed, FDA-cleared sterilization barriers should be used for packaging terminally sterilized devices.

Caution

1. Use carefully in the following patients:
 - Patients with neurological or mental disorders or alcohol addiction, as these patients may be difficult to follow up after surgery. Prolonged treatment and development of malfunctions are highly likely to occur because they have difficulty following the physician's instructions; therefore, post-surgical care may be compromised.
 - Patients with a lifestyle-related disease such as diabetes or chronic rheumatism. Development of malfunctions is possible due to complications.

- Epileptic patients. Development of malfunctions is possible because they have difficulty following the physician's instructions; therefore, post-surgical care may be compromised.
- Patients with infectious disease It may cause transposition of infection focus or concurrence of sepsis.

2. Important Precautions

- 1) Always use the exclusive Anastomosis Clip applying forceps. Do not use clip-applying forceps from any other manufacturer.
- 2) Most importantly, the clip should be correctly held using the clip-applying forceps designed exclusively for this product so that the spring portion of the clip is entirely wrapped in the jaw of the Anastomosis Clip applying forceps. (Figure 3) Holding the clip incorrectly in the jaw or holding the clip using forceps with mismatched size other than the clip applying forceps designed exclusively for this product, may damage or break the clip. The clip damaged by such improper holding may cause a significant reduction in the closing force, an offset at the tip of clip blades, and/or inversion; thus, the officially claimed closing force cannot be guaranteed in such cases.

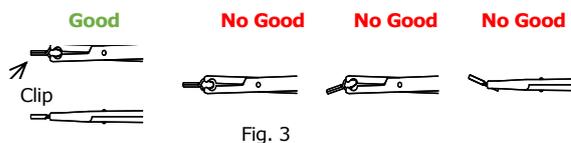


Fig. 3

- 3) It has been confirmed with the testing defined by ASTM F2052 that Anastomosis Clips may be used without influence in magnetic field up to 3.0 tesla, therefore, patients with this clip can be MRI scanned in field up to 3.0 tesla. However, artifacts may occur under certain MRI scanning-conditions.
MRI scan in strong magnetic field over 3.0 tesla can lead to displacement of the clip.
- 4) Do not use Anastomosis Clips for purposes other than temporary occlusion of peripheral blood vessels during cerebrovascular anastomosis.
- 5) Do not open a clip until it is ready to use. Repeated opening of a clip may reduce the closing force of the clip.
- 6) Inspect each clip carefully before use.
- 7) If the clip is found to be damaged in any way before use, do not use the clip.
- 8) The container is sealed to ensure the safety of product. Once the product has been processed (e.g. seal is broken, or product is sterilized even if the container is still sealed), the product cannot be returned to the manufacturer.
- 9) This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.
- 10) Only if unused, and/or undamaged, and/or not removed from its container, and/or not exposed to the surgical field, the Anastomosis Clips may be re-sterilized.
- 11) If the sterilization barrier is opened in the surgical field exposing the clip to possible contaminants, the clip must be discarded.

3. Interactions

Contraindications/prohibitions for concomitant use. This product should not be used with the following medical devices:

Medical Devices	Clinical Symptoms/Action to be Taken	Mechanism/Risk Factors
Forceps incompatible with the size of the clip	The clip fails to open and close properly	Breakage of the clip. Poor performance of the clip
Use of applying forceps from other manufacturers	The clip fails to open and close properly	Breakage of the clip. Poor performance of the clip
Clips made of different metal, or clips and applying forceps from other manufacturers	Risk of development of malfunctions due to corrosion	Electrochemical corrosion due to contact between different kinds of metals

4. Malfunctions/Adverse Events

1) Clinically significant adverse events

- Displacement of clip (clip slippage)
- Ejection of clip from applying forceps
- Breakage of clip
- Cerebrovascular accident
- Hemorrhage
- Death

2) Other adverse events

- Infection of surgical wound
- Common surgical complications
- Occlusion of adjacent blood vessels
- Foreign body reaction

5. Other Precautions

- Discard used implants properly in accordance with the regulations concerning waste management and public cleaning.

Storage and Shelf Life

1. Storage Conditions

- Store and transport this product in a cool and dry place protecting it from condensation and direct sunlight.

Packing

One sealed outer box contains one clip inside a metal case.

* Name and address of manufacturer



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