

Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

Instructions for Use

Trade Name: Anastomosis 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. 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).
3. 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.

Contraindication / Prohibition

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Use with specified products only
Use this product only with products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
3. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
4. 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.
5. 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 and appliances.
6. 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 surface of this product and result in rust or corrosion.
7. Prohibition of use of household detergents
Use only medical detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.

Shape / Structure



Code No.	Product Description
07-097-00	Anastomosis Clip Applier
07-097-01	Anastomosis Clip Applier Straight S

Material: stainless steel

Intended Purpose

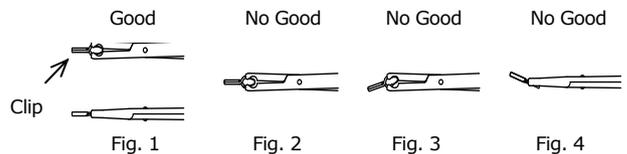
This device is to be used to place Anastomosis Clips.

Instructions for use

Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Caution

1. Warning
 - 1.1 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.
2. Precautions concerning method of use
 - 2.1 To set a clip in the Applier jaws, make sure that the clip is correctly placed in the recesses of the jaws. (Fig.1)
 - 2.2 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. (Fig.2, 3, 4)
 - 2.3 Do not hold the clip in an angled position. (Fig.3, 4)
 - 2.4 Wash the Applier and remove adhered debris after each use. Make sure NOT to leave any deposits in the Applier's joint.
 - 2.5 This device is exclusively designed and constructed for use with Anastomosis Clip only. They must NOT be used with clips from other manufacturers.



3. Defect/Adverse event

- 3.1 Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product and cause corrosion.

Storage/Life

1. Do not store the device in high temperature areas. Do not store in areas of high humidity where the temperature may vary wildly causing condensation. Do not store on or near chemicals.
2. Service life of this product: 5 years
(Subject to the specified maintenance, inspection and proper storage)

Maintenance / Inspection

1. Operational and functional checks
Conduct daily and pre-operation checks of this product to make sure that it works properly.
2. Immediate washing with clean water
Wash and rinse with clean water immediately in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine
3. Dry this product immediately after washing it.
Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.
4. Use distilled or deionized water.
Use distilled or deionized water to wash this product. Residual chlorine and organic matters in tap water could cause stains and rust.
5. Use a water-based anticorrosive lubricant
Lubricating oil is completely removed by washing. Do not use without lubricant oil to sliding part, or galling could occur. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.
6. Sterilization
Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows,

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

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 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.

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



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