* MIZUHO

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

* MES-CK07-096-55EN

PREPARED: (2014-01-01) (Version 2)*
(2017-04-13) (Version 3)**

Instruction for Use

Trade Name: Anastomosis Clips and Instruments Case

** **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).

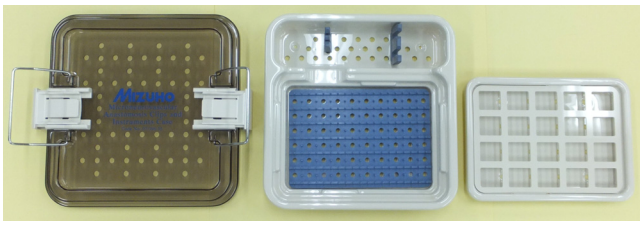
For markets outside the US

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.

** **Contraindication / Prohibition**

1. Use for intended purpose only
   Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. 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.
3. 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.
4. 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.
5. 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.
6. Do not use low temperature 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



Material: plastic, stainless steel

Code No.	Product Description
07-096-55	Anastomosis Clips and Instruments Case

** **Intended Purpose**

This product is intended for the protection, organization, and delivery to the surgical field of the Anastomosis Clips and Instruments.

** **Instructions for Use**

When using this product for sterilization:

1. Remove plastic bag packaging to inspect Anastomosis Clip aluminum containers prior to use. **Do Not** break the taped seal on the Anastomosis Clip aluminum container.
2. Anastomosis Clips are to be sterilized in its original sealed aluminum case in this product as shown in Fig-1. The Clips can also be sterilized without this product; however, it must be used in conjunction with an appropriate wrapping method.

CAUTION

The aluminum container for the Anastomosis Clip is only a container to store and protect the device during transit and Does Not Provide a Protective Sterile Barrier. 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.

3. Set appliers securely into instrument holders and Clip containers into the case as shown in Fig-1.

Fig-1

4. Double wrap the case containing Anastomosis Clips and Instruments in accordance with local procedures, using standard wrapping techniques such as those described in the current revision of ANSI/AAMI ST79. The manufacturer's instructions for use for the sterilization wrap, pouches are to be followed.

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

5. Please refer to "Sterilization" for the recommended sterilization method, cautions and parameters for further guidelines.

CAUTION

1. Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions which validity is proven by medical organizations in each country or region. Do not use hydrogen peroxide gas plasma sterilization or flash sterilization.
2. This product is not designed to maintain sterility by itself. It is designed to facilitate the sterilization process when used in conjunction with an appropriate wrapping material. In the US, use an FDA approved wrap.

3. **DO NOT CLEAN ANASTOMISIS CLIPS.** The **CLIPS** are **NOT** intended to be subjected to cleaning.

** **Storage and Shelf Life**

Do not store the device in high temperatures, or in areas with high humidity (greater than 90%RH) and/or where the temperature varies more than +/- 30° Degrees Centigrade.

** **Inspection / Maintenance**

1. Operational and functional checks

Conduct daily and pre-operation checks of this product to make sure that it works properly.

If not functioning properly, do not use and contact your sales representative for additional support.

2. Use distilled or deionized water

Use distilled or deionized water to wash or rinse the instruments or clip/instrument case assemblies. Residual chlorine and organic matters from standard tap water may cause stains and may cause rusting.

3. Immediate washing with clean water

3.1 If exposed to bleach or antiseptic solutions, immediately wash: Wash and rinse with clear water immediately in case of exposure to solutions that may contain chlorine or iodine.

3.2 Remove all contaminated matters manually or using an ultrasonic-cleaner.

3.3 To manually remove contamination gently scrub with a soft plastic brush. **Do Not** use a metal brush, coarse polishing agents, or apply excessive force when handling the device.

3.4 Select a proper detergent for each decontamination method and maintain appropriate density and handling. To extend the life of your instrument, use of a neutral pH detergent is recommended.

3.5 Use a soft towel, a plastic brush, or a water jet for final cleaning and use distilled water or deionized water (reverse osmosis) to wash this product.

3.6 Use fully deionized water (reverse osmosis) for the final rinse.

3.7 Using an ultrasonic washing machine simultaneously for this device is also recommended.

4. Fully dry this product immediately after washing.

4.1 After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.

4.2 **Do Not** leave instruments or trays wet.

** **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. The recommended sterilization parameters for autoclave sterilization is as follows:

Method	Temp.	Minimum exposure time
Pre-vacuum (Wrapped)	134℃	3 Min

- Instruments and case/ tray configurations should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized reusable instruments should be suitable for steam sterilization and the appropriate grade for the weight of the instruments. Additionally, the blue wrap should be compliant to the following requirements: •AAMI ST79 •ISO 11607 •CE mark •FDA 510(k) clearance. The process parameters are validated and recommended for sterilization. Steam autoclave (moist heat) sterilization using a pre-vacuum cycle is recommended as noted above. Autoclaves should comply with the requirements of, and be validated and maintained in accordance with, EN285, EN13060, EN ISO17655 and ANSI/AAMI ST79.

  And after sterilization, reusable instruments should be stored the in the sterilization wrap in a dry and dust- free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions, and handling. A maximum shelf life for sterilized reusable instruments should be defined by each health care facility based on the recommendations of the wrap manufacturers.
- Mizuho does not recommend the use of 'flash' sterilization for this product.
- Do not use low-temperature hydrogen peroxide gas plasma sterilization. It may cause discoloration on the surface and affect performance.

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 markets 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.

Packaging

1 piece per package

* **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
Contact : Mizuho Medical Co., Ltd.
TEL: 81-3-3815-7101 FAX: 81-3-3818-1705