

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

Instructions for Use

Trade Name: CEA Shunt Clamp

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. Prohibition of use during contact coagulation
Never allow the tip of an electrosurgical knife to make contact with this product during contact coagulation or a similar procedure.
3. **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 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.

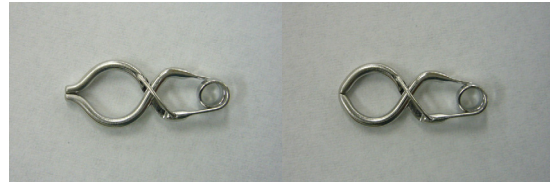
Contraindication / Prohibition

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

07-500-41/-44

07-500-42/-43



07-500-45/-46/-47/-48

07-501-45/-46/-47/-48



Code No.	Product Description
07-500-41	IC Shunt Clamp I.D. 3.5mm
07-500-42	IC Shunt Clamp I.D. 4.0mm
07-500-43	IC Shunt Clamp I.D. 4.5mm
07-500-44	IC Shunt Clamp I.D. 5.0mm
07-500-45	IC Shunt Clamp Curved I.D. 3.5mm
07-500-46	IC Shunt Clamp Curved I.D. 4.0mm
07-500-47	IC Shunt Clamp Curved I.D. 4.5mm
07-500-48	IC Shunt Clamp Curved I.D. 5.0mm
07-501-45	IC Shunt Clamp Curved I.D. 3.5mm with Blade
07-501-46	IC Shunt Clamp Curved I.D. 4.0mm with Blade
07-501-47	IC Shunt Clamp Curved I.D. 4.5mm with Blade
07-501-48	IC Shunt Clamp Curved I.D. 5.0mm with Blade

Material: Cobalt-chromium alloy

Intended Purpose

A surgical instrument used to compress tubing. This device is reusable after sterilization.

Instructions for use

- This product shall be used only using a dedicated clip forceps.
- Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Caution

1. Warning
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. Cautions on use of other tools in combination with this product
 - Prohibition of use during contact coagulation
Never allow the tip of an electrosurgical knife to make contact with this product during contact coagulation or a similar procedure.
3. Defect/Adverse event
 - Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product and cause corrosion.

Storage/Life

1. Storage
Do not store the device in high temperature or in areas with high humidity with drastic temperature or humidity variations.

2. Service life of this product: 2 years
(Subject to the specified maintenance, inspection, and proper storage)

Maintenance / Inspection

- Operational and functional checks
Conduct daily and pre-operation checks of this product to make sure that it works properly.
- 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.
- 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.
- 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.
- 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.
- 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/TS17665-2	
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

Temp.	Minimum exposure time
134°C / 273.2°F	18 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 intentional damage. 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>