

MES-CK08-110-11-EN-0

PREPARED: (2017-09-05) (Version 2)\*  
(2016-06-29) (Version 1)

## Instruction for Use

Trade Name: Multi clamp

### Warning

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.

### 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 alkaline, acid, and household detergents  
Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any alkaline, acid, or household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
8. 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



Code No.	Product Description
08-110-11	Multi clamp

Material: stainless steel, plastic

### Intended purpose

This tool is used for fixing operating table accessories to an operating table.

### Instructions for use

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. Defect/Adverse event
  - 2.1 Defect  
·Corrosion or pitting caused by use of chemicals

### 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: 7 years  
(Subject to the specified maintenance, inspection and proper storage)

### Maintenance/Inspection

<Maintenance and checks conducted by users>

1. Checking matters before use
  - 1.1 Operational and functional checks  
Conduct daily and pre-operation checks of this product to make sure that it works properly.
2. Checking matters after use
  - 2.1 Immediate washing with clean water
    - 2.1.1 Wash and rinse with clean water immediately and immerse in neutral enzyme detergent in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine. Then remove all the contaminated matter by hand or an ultrasonic-cleaner.
    - 2.1.2 Remove any remaining contamination with a brush.
    - 2.1.3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.
    - 2.1.4 Use a soft towel, a plastic brush or a water jet for cleaning.
    - 2.1.5 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
    - 2.1.6 Use distilled water or deionized water to wash this product.
    - 2.1.7 Use fully demineralized water (reverse osmosis) for final rinse.
    - 2.1.8 Using an ultrasonic washing machine simultaneously for this device is recommended.
  - 2.2 Dry this product immediately after washing it.
    - 2.2.1 After cleaning, please rinse the frame fully, for more than 5 minutes, with warm or cold water without additives.
    - 2.2.2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.
  - 2.3 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.
  - 2.4 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.

### 3. 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.

<Maintenance and check by agents >

For safety use of this instrument, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact your local distributor or the manufacturer.

#### 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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