

## Instruction for Use

Trade Name: Sugita Titanium Clip II Case

### Warning

When the device is used on a patient where there is a risk of Creutzfeldt-Jakob disease (CJD), make sure to follow the most recent and updated restrictions available in each country and/or region for its reuse. [Be cautious of the possibility of secondary infection.]

### Contraindication / Prohibition

1. Do not use the device for anything other than its intended purpose.  
Use of the device outside its intended purpose may cause damage.
2. Do not modify the device.  
Do not make any modifications to the device such as engraving.  
Engraving a mark by making an impact on the surface of the device may cause damage.
3. Handle with care.  
Do not handle the device in a rough manner that may deform or scratch the device. It may significantly alter the life of the device.
4. Do not use scouring powder or steel wool.  
Do not scrub the surface with coarse powder or steel wool when cleaning. It may result in damage to the device surface, which may result in rust and corrosion.
5. Do not use household detergents.  
Ensure the use of "medical" detergents only. Do not use household detergents/cleaners, as they may cause discoloration and/or corrosion.
6. Do not use low-temperature hydrogen peroxide gas plasma sterilization. The device is not designed for such sterilization methods and may cause surface discoloration or damage the device's functional ability.

### Shape / Structure



Material: plastic, stainless steel

Code No	Product Description
17-010-70	Sugita Titanium Clip II Case for Appliers
17-010-71	Sugita Titanium Clip II Case for Mini, Temporary and Standard Clips
17-010-72	Sugita Titanium Clip II Case for Standard Clips
17-010-73	Sugita Titanium Clip II Case for Fenestrated Clips
17-010-74	Sugita Titanium Clip II Case for Deflected Fenestrated Clips
17-010-75	Sugita Titanium Clip II Case for Clips and Appliers

### Intended Purpose

This product is for sterilizing the SUGITA Titanium II Clips and the Clip Appliers with high-pressure steam.

### Caution

Device must be sterilized by users. See "Maintenance/Inspection 5. Sterilization". Do not use low-temperature hydrogen peroxide gas plasma sterilization.

### Storage and Shelf Life

Do not store the device in high temperatures, or in areas with high humidity where the temperature has drastic variations.

### Maintenance / Inspection

1. Working / functioning check:  
Make sure to inspect the device periodically as well as prior to use to ensure proper functioning.
2. Immediately wash and rinse with clear water:
  - 2.1 Remove any debris from the device. Wash and rinse with clear water immediately in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine. Then remove all the contaminated matters by hand or an ultrasonic-cleaner.
  - 2.2 Remove any remaining contamination with a brush.
  - 2.3 When using a detergent and an antiseptic, follow the manufacturer's instructions.  
(Dilution concentration, humidity, immersion time, etc.)
  - 2.4 Use a soft towel, a plastic brush, or a water gun for cleaning.
  - 2.5 Do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
  - 2.6 Wash with fully demineralized water (Reverse Osmosis) if possible.
  - 2.7 Use fully demineralized water (Reverse Osmosis) for final rinse.
  - 2.8 Using a washer-disinfector for this device simultaneously is recommended.
3. Dry the device immediately after washing:
  - 3.1 Please rinse the frame fully (for more than 5 minutes) by warm or cold water without additives after cleaning.
  - 3.2 Make sure to dry the device immediately after washing. Do not leave the device wet for prolonged periods of time.
4. Use distilled water and de-mineralized water.  
Distilled water and de-mineralized water should be used for cleaning and sterilization. The residual chlorine and organic matter contained in tap water may cause rust generation.
5. 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,
  - Sterilization of the device may be accomplished by steam.

Method	Temp.	Minimum exposure time	
		Wrapped	In a sterile container
Pre-vacuum	134°C	5 Min	5 Min
Gravity	134°C	10 Min	30 Min

  - Do not use low-temperature hydrogen peroxide gas plasma sterilization. It may cause discoloration on the surface and affect its property.

### 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



MIZUHO Corporation  
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan  
<http://www.mizuho.co.jp>

### \*\* Authorized Representative Europe



Emergo Europe B.V.  
Prinsessegracht 20, 2514 AP, The Hague  
The Netherlands