

Instructions for Use

Trade Name: Suction Tube A

Warning

1. 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).

2. 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 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.
2. 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 surfaces of this product and result in rust or corrosion.
3. 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.
4. 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.

1 Shape / Structure



Mandrin (attachment)



| Code No. | Product Description |
|-----------|---|
| 07-960-10 | SUGITA Balanced Interchangeable Suction A Set |
| 07-960-20 | Suction Tube A Short 1.0mm |
| 07-960-21 | Suction Tube A Short 1.5mm |
| 07-960-22 | Suction Tube A Short 2.0mm |
| 07-960-23 | Suction Tube A Short 2.5mm |
| 07-960-24 | Suction Tube A Long 1.0mm |
| 07-960-25 | Suction Tube A Long 1.5mm |
| 07-960-26 | Suction Tube A Long 2.0mm |
| 07-960-27 | Suction Tube A Long 2.5mm |
| 07-960-28 | Suction Tube A Base |
| 07-960-29 | Hand Grip for Suction Tube A |

| Attachment |
|------------|
| Mandrin A |
| Mandrin B |

Material: Stainless Steel, Aluminum Alloy, Copper Alloy, Chrome-plating, Nickel-plating

2 Checks

The medical devices must be checked for proper function prior to use. Damages on the surface such as scratches, cracks, notches, nicks etc. as well as twisted parts, indicate that the medical devices have to be repaired and cannot be reused.

3 Application range

The medical devices are manufactured as standard medical devices for surgical use. However, a medical doctor attending is responsible for selection of the medical devices for certain applications or surgical application. The medical doctor is also responsible for adequate training and sufficient information for the surgical staff and for sufficient experience in handling of the medical devices.

4 Handling

The medical devices must not be overstrained to the twisting or levering, as this may break parts or lead to damage of the medical device.

5 Storage notes

The medical devices are partially very delicate. Therefore, they should be stored individually packed or in a protective container with individual compartments. In order to avoid corrosion, make sure that no chemicals are kept within reach. Keep the medical devices in a dry place.

6 Sterilization, cleaning and maintenance

Medical devices are shipped non-sterile from the factory and must be cleaned and sterilized prior to the first use. After each use, it is imperative that the medical device is manually cleaned. Remove blood and other remains with a soft brush and a mild cleaning agent. If cleaning the medical devices in an automatic washer or ultrasonic cleaning device, assure that the medical device is stored safely in order to avoid damage. For machine cleaning, follow the instructions of the cleaning unit manufacturer in detail. Overdosing of cleaning agents must also be avoided. Clean, examine, and test every medical device thoroughly. During cleaning, special care should be taken for areas that are not easily accessible. If a medical device can be dismantled, it should be cleaned when it is taken apart. Sterilize all medical devices prior to use. Maintenance of surgical instruments means also lubricating with a physiologically safe instrument oil or water-based anticorrosive lubricant paying particular attention to the joints. Make it a basic rule to thoroughly lubricate surgical instruments prior to checking for function. All movable parts (joints) and cutting blades of scissors must be lubricated. This avoids metal abrasion when checking for function.

Lubricants used must guarantee that even after repeated use, a "sticking" of joints through lubricant "build-up" is avoided.

- 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.

7 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