MIZUHO

MES-CK07-932-10EN

PREPARED: (2023-10-03) (Version 1)

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

Instruction for Use

Trade Name: SUGITA AVM Microclip II CASE A

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. Failure to follow manufacturer's recommendations may cause harm or injury to the patient.

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).

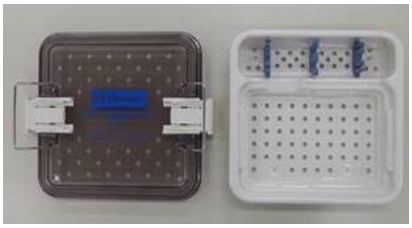
For markets outside the US

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 related to cleaning and sterilization.

Contraindication/Prohibition

1. Use for intended purpose only
   This product is intended to hold Sugita AVM Microclip II and dedicated forceps for sterilization by a high-pressure steam. [Misuse may cause damage.]
2. Prohibition of use of chemicals
   Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. 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.
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.

Specifications



Code No.	Product Description
07-932-10	SUGITA AVM Microclip II CASE A

Material: resin, stainless steel

Intended purpose

This product is a case that is used for sterilizing the Sugita AVM Microclip II and dedicated forceps with high-pressure steam.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

・Before using this product, inspect, wash, and sterilize in accordance with these instructions.

・This product holds "07-932-11: SUGITA AVM Microclip II CASE B" for sterilization by high-pressure steam.

07-932-11: SUGITA AVM Microclip II CASE B

・This product can hold two dedicated forceps.

・How to set "07-935-30: Sugita AVM Microclip II Applier 100 mm" [See Figs. 1 and 2]

Fig. 1

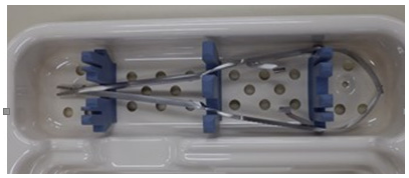
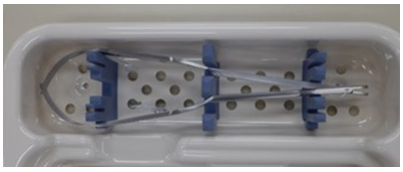


Fig. 2



・How to set "07-935-31: Sugita AVM Microclip II Applier 50 mm" [See Figs. 3 and 4]

Fig. 3

Fig. 4

Warning/Caution

1. Important fundamental cautions
   - Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.
2. Defect/Adverse event

   Defect
   - Deterioration, corrosion or pitting caused by use of chemicals
   - Damage or breakage caused by the corrosion or pitting

Storage/Life

1. Please store the device in normal ambient temperature areas. Do not store in areas of high humidity where the temperature may dramatically vary causing condensation. Do not store on or near chemicals as the chemicals may cause damage to the device.
2. Service life of this product: 5 years

   (Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

1. Check prior to each use

   Operational and functional checks

   Conduct daily and pre-operation checks of this product to make sure that it functions properly.
2. Check after each use

   (1) Immediately wash with clean water

   (1)-1 If exposed to bleach or antiseptic solutions, immediately wash:

   Wash and rinse with clean water immediately and immerse in neutral enzyme detergent to remove any bleach or antiseptic solution, which may contain chlorine or iodine and can damage the instrument. Manually remove contaminated matter by hand or with an ultrasonic-cleaner.

   (1)-2 Further remove any remaining contamination with a plastic brush.

   (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.

   (1)-4 Use a soft towel, a plastic brush or a water jet for cleaning.

   (1)-5 Avoid using metallic brushes or rough polishing agents, applying excessive force, dropping or bumping the device, etc.

   (1)-6 Reverse osmosis water is recommended to wash this product.

   (1)-7 Only use reverse osmosis water for the final rinse.

   (1)-8 It is recommended to use a washer-disinfector for this device. Thermal Disinfection can be used by following the manufacturer's defined parameters.

   Thermal Disinfection Band: 90-93°C/194.0-199.4°F, 5-10 minutes (A0 value: 3000-12000) (reference EN ISO 15883-1)

   (2) Fully dry this product immediately after washing it

   Do not leave it wet for a longer time than necessary as residual water may damage the instrument.

   (3) Use distilled water or reverse osmosis water

   Use distilled water or reverse osmosis water to wash and sterilize this product. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

   (4) Use a water-based lubricating agent and a water-based rust-prevention agent

   Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization.

   (5) 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.
3. Sterilization

   (1) 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.

   (2) 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.

Maintenance and check by agents

For safety use of this device, 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.

Packing

1 piece per pack

Warranty

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.

Disposal

This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

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