

PREPARED: (2023-07-20) (Version 4)

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

Instructions for Use

Trade Name: IVR Armboard

Warning

When using operating table accessories, always pay close attention to the patient. Patients left in the same posture for an extended period of time are at risk for developing nerve paralysis and/or bedsores.

Contraindication/Prohibition

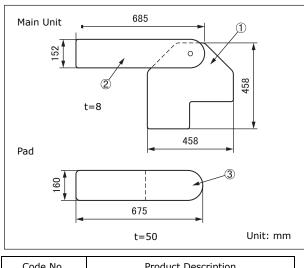
This product is only validated for use with Mizuho operating tables.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



08-065-72	IVR Armboard

2. Weight

08-065-72: 3.5 kg

Material

12 Board: Thermosetting resin

③ Pad: Polyurethane

Note: The number corresponds to those used in 1. Shape.

4. Board bending angle

360°

Intended purpose

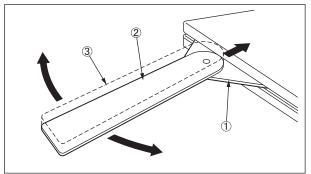
This is an accessory for the operating table. This is the armboard capable of fluoroscopy at the time of catheter insertion from the arm in IVR.*1

*1 IVR: Interventional radiology (IR). Treatment of inserting the needle into the interior of the catheter and the body while looking at the X-ray fluoroscopy, ultrasound images or CT.

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



- 1. Insert the board ① between the tabletop and the pad of the operating table.
- 2. Attach the pad³ to the board².
- 3. Adjust the position of the board⁽²⁾ where the X-ray is conducted.

Warning/Caution

Important caution

- When working with an operating table, take care not to allow this product to make contact or interfere with the tabletop or with other tools and appliances used in combination with this product. Otherwise the product could break.
- For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.

Storage/Life

- Do not store the device in high temperatures or in areas with high humidity where the temperature had drastic variations.
- Service life of this product: 7 years (Subject to the specified maintenance and inspection and is stored properly.)

Maintenance/Inspection <By the user>

- Check before and after use Check that this product is not damaged or broken before and after each use.
- 2. Cleaning and disinfection

Wipe off blood, chemicals, contaminants, and other stains with water, and clean the device with gauze or other materials soaked in disinfectants. In addition, use the same disinfectants as the authorized disinfectants on Mizuho's operating table described in the operating table operator's manual. 3. In case of a malfunction

When this product is broken, clearly label the device as "Broken", "Do not use", "Need repair", etc., and contact your local distributor or Mizuho.

<By agents>

Maintenance and inspection can only be carried out by certified agents of Mizuho.

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, acts 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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