

CE

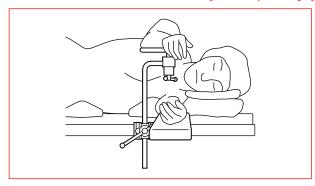
Instruction for Use

Trade Name: Double Axis Armboard

Warning

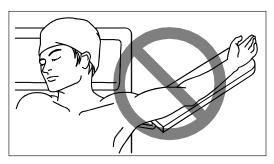
- 1. When using operating table accessories, always pay close attention to the patient. Patients left in the same posture for an extended period of time are at risk for developing bedsores.
- When using this product for a patient in the lateral recumbent position, secure the arm on the lower side onto the Armboard.

Failure to secure the arm to the Armboard may lead to a patient injury.

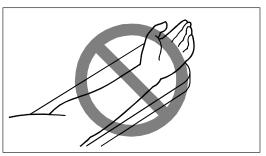


Contraindication/Prohibition

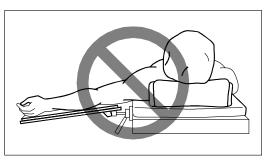
- 1. This product is only validated for use with Mizuho operating tables.
- 2. Avoid putting a patient's arm in any of the positions shown below, in order to prevent nerve paralysis in the arm.



Do not allow the arm to be positioned at an angle of more than 90 degrees with respect to the longitudinal direction of the operating table.



Do not turn up the inside of the arm (except for patients in the lateral recumbent position).

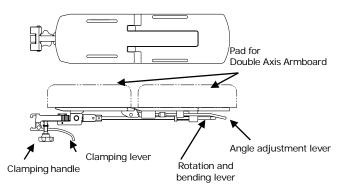


Do not use this product if its upper surface is lower than the surface of the operating table.

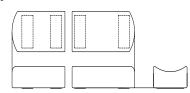
Symbol mark for labeling

MD : Medical Device

Specifications



Accessory: Pad for Double Axis Armboard



| Code No. | Product Description |
|-----------|-------------------------------------|
| 08-065-51 | Double Axis Armboard |
| 08-065-52 | 60 mm Pad for Double Axis Armboard |
| 08-065-53 | 100 mm Pad for Double Axis Armboard |

Material: Stainless steel, Aluminum alloy, Synthetic resin

Intended purpose

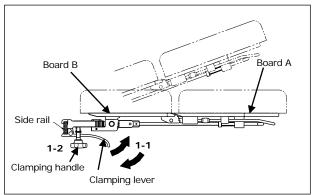
This is an accessory to an operating table and is used to support the arm of a patient.

Intended user

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

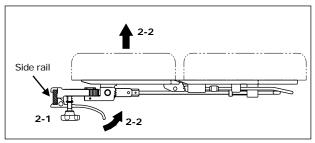
Instructions for use

1. Attached and fixed



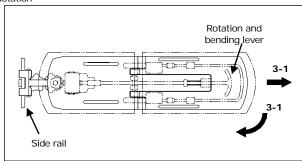
- 1-1 While engaging the clamping lever, elevate the distal end and place the clamp onto the side rail. Lower the Armboard to level and release the clamping lever.
- 1-2 Tighten the clamping handle to secure the Armboard.
 Make sure the Armboard is fixed well and does not sideslip.

2. To Remove



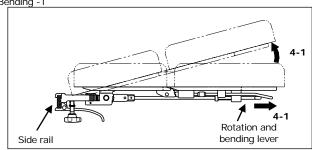
- 2-1 Loosen the Clamping handle until it stops.
- 2-2 While pulling the clamping lever toward you, lift the distal end of the board B. Remove the Armboard from the side rail.

3. Rotation



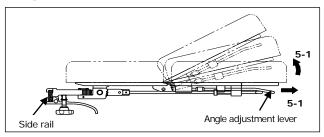
3-1 Pull the rotation and bending lever to rotate the Armboard up to 90 degrees.

4. Bending -1



4-1 Pull the rotation and bending lever to reflect the Armboard up to 15 degrees.

5. Bending -2 (Board A)



5-1 Pull the rotation and bending lever to flex the board A 15 or 30 degrees.

Warning/Caution

1. Warning

Make sure that the clamping lever is fixed to the side rail. Failure to properly secure to rail may lead to damage to Armboard or injury to patient.

2. Important caution

- 2.1 When working with an operating table, take care not to allow this product to make contact or interfere with the table top or with other tools and appliances used in combination with this product.
- 2.2 After adjusting the rotation angle, be sure to check that the catch at the end of the rotation and bending lever fully engages with the gear below the board.
- 2.3 When using the operating table at the vertical change position, Armboards may slip. Pay close attention to the patient
- 2.4 Do not add load more than 15kg
- 3. Defect/Adverse event
 - 3.1 Adverse event
 - -Bedsore
- For hygiene, be sure to use sterile 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 has drastic variations.
- Service life of this product: Seven (7) years
 (subject to the specified maintenance and inspection and is stored properly)

Maintenance/Inspection

<Maintenance and checks conducted by users>

1. Check before and after use

Check that this product is not damaged or broken before and after use.

2. Cleaning and disinfection

Wipe off blood, chemicals, contaminants, and other stains with water, and clean the device with gauze or other material moistened with alcohol to disinfect

3. In case of a malfunction

If you need to have this product repaired, clearly label the device as "Broken", "Need repair" etc. and contact your local dealer or Mizuho..

<Maintenance and check by suppliers>

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

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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