

MES-CK08-080-11EN-0

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

Instruction for Use

Trade Name: Adjustable Body Support

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

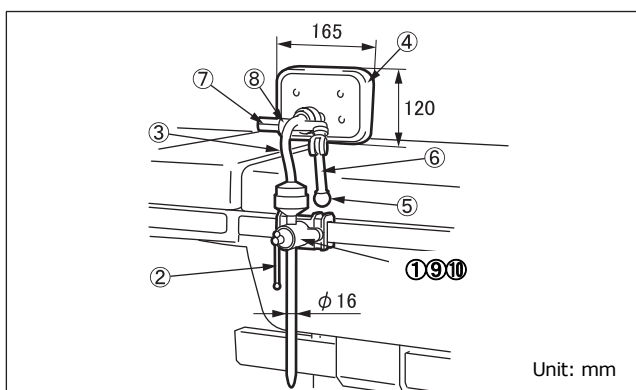
This product is only validated for use with Mizuho operating tables.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



Code No.	Product Description	Components
08-080-11	Adjustable body support with clamp	①②③④⑤⑥⑦⑧
08-080-11-NC	Adjustable body support (NC)	③④⑤⑥⑦⑧
08-110-01	Clamp for Round Bar *1	①②
08-117-09	Clamp for Round Bar (R1) *2	②⑨
08-117-11	Clamp for Round Bar (R2) *3	②⑩

*1, *2 and *3: The size of mountable side rail is different.

2. Weight

Main unit: 2.5 kg

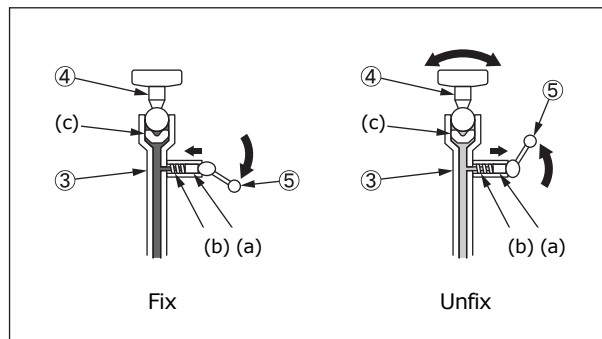
Rail clamp: 0.9 kg

3. Material

- ①⑨⑩ Rail clamp: Stainless steel
- ② Fixing handle: Stainless steel
- ③ Arm: Stainless steel
- ④ Pad: Polyurethane
- ⑤ Stopper lever: Stainless steel
- ⑥ Stopper collar: Stainless steel
- ⑦ Adjustable screw: Stainless steel
- ⑧ Nut: Stainless steel

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

4. Operating principle



The arm③ has a piston(c) which is contacting with the ball part of the pad④. Also, it has a plunger(a) and a spring(b) which re contacting with the stopper lever⑤. Hydraulically operated piston(c) inside the arm③ moves up and down to make the pad④ and stopper lever⑤ move.

4-1. How to fix

Pushing the stopper lever⑤ downward, a spherically shaped part at the bottom of the stopper lever⑤ will push back the plunger(a) to the other side. This movement makes the piston(c) to hydraulically moves up to the ball part of the pad④.

Then the pad④ will be hydraulically fixed at the arm③.

4-2. How to unfix

Pushing the stopper lever⑤ upward, a spherically shaped part at the bottom of the stopper lever⑤ will apply the tension to the spring(b) and the plunger(a) will move back to the stopper lever⑤ side. This movement makes the hydraulic pressure applied to piston(c) to be relieved and the pad④ will be unfix.

Thus the pad④ and the arm③ will be free.

Intended purpose

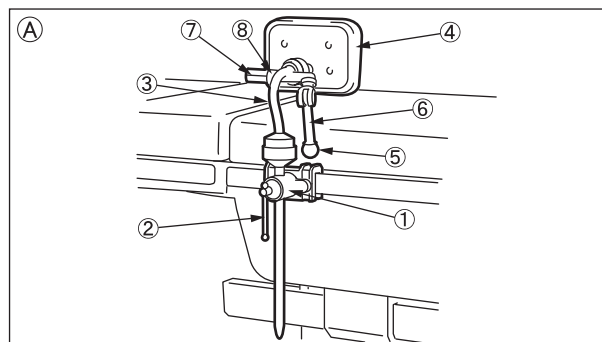
This is an accessory for the operating table.

This is a tool for supporting a patient lying in the lateral recumbent position for a thoracotomy or similar procedure. Move the pad④ and the arm③ to a position (height and angle) appropriate for the patient's posture.

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 Rail clamp
- ② Fixing handle
- ③ Arm
- ④ Pad
- ⑤ Stopper lever
- ⑥ Stopper collar
- ⑦ Adjustable screw
- ⑧ Nut

1. Instructions for use

- 1-1. Attach the rail clamp① to the side rail of the operating table.
- 1-2. Move the rail clamp① to a position appropriate for the patient's posture.
- 1-3. Turn the fixing handle② clockwise to fix the rail clamp①.
- 1-4. Push the stopper lever⑤ downward and pull the stopper collar⑥ toward you.

The pad④ and the arm③ will be unfixed. (Figure B)

- 1-5. Move the pad④ and the arm③ to a position (height and angle) appropriate for the patient's posture.

After the adjustment, push the stopper lever⑤ downward.

The pad④ and the arm③ will be fixed. (Figure C)

2. How to adjust

Use the adjustable screw⑦ to properly adjust (tighten or loosen) the pad④ and the arm③.

- 2-1. Make sure that the pad④ and the arm③ are fixed.

- 2-2. Unscrew the adjustable screw⑦ with the tool. (Figure D)

Turn the nut⑧ clockwise (two turns) while holding the adjustable screw⑦.

Use another tool to hold the adjustable screw⑦ so that the screw will not turn.

- 2-3. Push the stopper collar⑥ downward towards the stopper lever⑤ and pull it toward you. The pad④ and the arm③ will be unfixed. (Figure B)

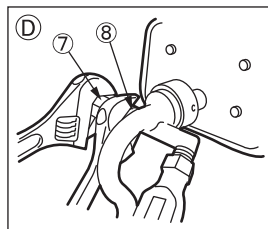
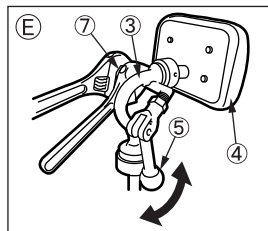
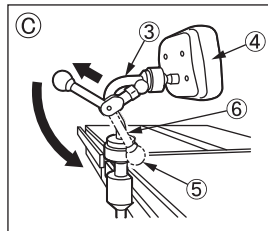
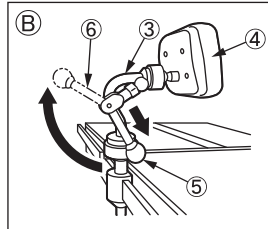
- 2-4. Turn the adjustable screw⑦ to properly adjust (tighten or loosen) the pad④ and the arm③. (Figure E)

- Turn the adjustable screw⑦ clockwise (one quarter) if the pad④ and the arm③ need to be tightened.
- Turn the adjustable screw⑦ counterclockwise (one quarter) if the pad④ and the arm③ need to be loosened.

- 2-5. Repeat the step 2 to 4 until the pad④ and the arm③ are properly fixed.

- 2-6. Pull the stopper lever⑤ upward and push the stopper collar⑥ downward. Make sure that the pad④ and the arm③ are fixed securely. (Figure C)

- 2-7. After checking the fixation, fix the adjustable screw⑦ with the tool. While holding the adjustable screw⑦ with the tool, turn the nut⑧ counterclockwise to tighten until it reaches the adjustable screw⑦. (Figure D)



Warning/Caution

1. Warning

Ensure all fixing handles are tight. Loose condition can cause the product to come off or move, which may result in a patient injury.

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 tabletop or with other tools and appliances used in combination with this product. Otherwise the product could break.
- 2-2. Do not use for the operating table with the radiographic top attached or the built-in radiographic top because the stopper interferes with this product.

- 2-3. For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.

Storage/Life

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

Maintenance/Inspection

<By the user>

1. 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, 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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