

PREPARED: (2023-07-20) (Version 7)

Instruction for Use

Trade Name: Knee Rests



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

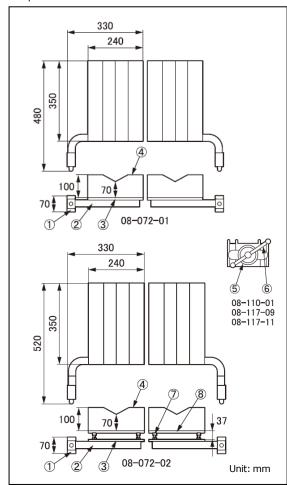
- 1. This product is only validated for use with Mizuho operating tables.
- The Knee Rests is designed to support the patient's knees and legs as shown in Fig. 1-1, Fig.2-1, Fig.3-1 and Fig.4-1 of **Instructions** for use. Any other positioning may damage the knee rest, clamp or table, and may injure the patient.
- Do not ride or sit on the edge of the board (shown in Fig.1-2, Fig. 2-2, Fig.3-2 and Fig. 4-2 of **Instructions for use**). Doing so may cause damage to the product and injury to patient or staff.
- Do not exceed weight capacity specified in **Specifications**, 3.
 Allowable load. Otherwise the product could break.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



Code No.	Product Description	Components
08-072-01	Knee Rests	1234
08-072-02	Radiographic Tops for Knee Rests	123478
08-072-03	70mm Pads for Knee Rests	4
08-110-01	Clamp for Round Bar *3	56
08-117-09	Clamp for Round Bar (R1) *4	56
08-117-11	Clamp for Round Bar (R2) *5	56

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

*2: 1 set (1 each for right and left)

*3,*4 and *5: The size of mountable side rail is different.

2. Weight (per piece)

Main unit: 2.5 kg/4.4 kg (08-072-02)

Pad: 0.5 kg

Rail clamp (including R1, R2): 0.9 kg

3. Allowable load

Unit: 20 kg (per board)

Maximum patient weight: 135 kg

4. Material

Insertion rod : Stainless steel
 Frame : Stainless steel
 Board : Thermosetting resin

4 Pad: Polyurethane

Radiographic top leg : Carbon steel Radiographic top : Thermosetting resin

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

Intended purpose

This is an accessory for the operating table. This product is an operating table attachment used for supporting patients in prone kneeling position* and extending leg section's length. This is horizontally attached onto a leg section that is lowered 90° to support the patient's knee. Or, this is horizontally attached onto the tip of the leg section to support the patient's leg.

*Note: Refer to **Instructions for use**, Fig.1-1 and Fig.3-1.

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. To support patient's knee.

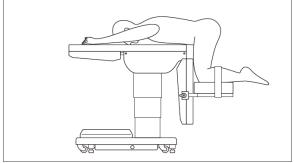


Fig.1-1

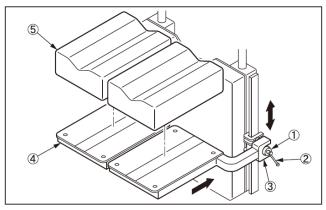


Fig.1-2

- 1-1. Articulate the leg section of the operating table down 90°.
- 1-2. Attach the rail clamp① to the side rail of the leg section.
- 1-3. Insert the insertion rod③ into the rail clamp①, and tighten the fixing handle② to fix the insertion rod③.
- 1-4. Attach the pad⑤ to the board④.
- 2. To support patient's leg

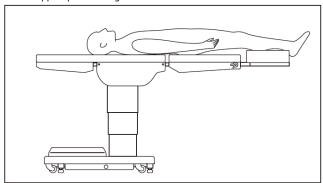
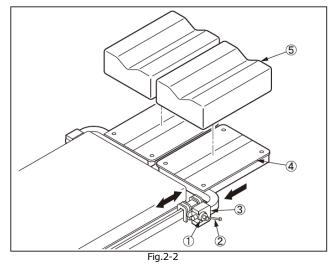


Fig.2-1



- 2-1. Check the leg section of the operating table is in the horizontal position.
- 2-2. Attach the rail $\mathsf{clamp} \ensuremath{\mathfrak{T}}$ to the side rail of the leg section.
- 2-3. Insert the insertion rod into the rail clamp①, and tighten the fixing handle② to fix the insertion rod③.
- 2-4. Attach the pad⑤ to the board④.

3. To support patient's knee. (Radiographic Tops)

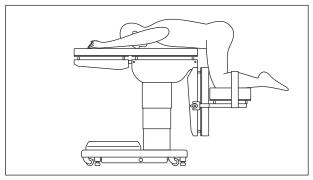


Fig.3-1

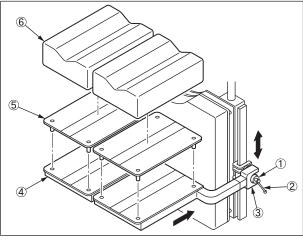


Fig.3-2

- 3-1. Articulate the leg section of the operating table down 90°.
- 3-2. Attach the rail clamp① to the side rail of the leg section.
- 3-3. Insert the insertion rod③ into the rail clamp①, and tighten the fixing handle② to fix the insertion rod③.
- 3-4. Attach the radiographic top® to the board.
- 3-5. Attach the pad⑥ to the radiographic top⑤.
- 4. To support patient's leg (Radiographic Tops)

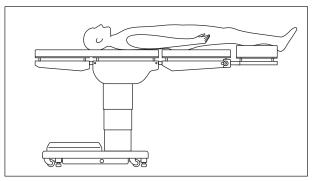


Fig.4-1

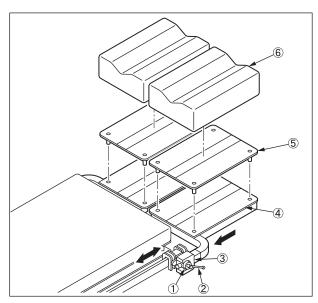


Fig.4-2

- 4-1. Check the leg section of operating table is in the horizontal position.
- 4-2. Attach the rail clamp① to the side rail of the leg section.
- 4-3. Insert the insertion rod③ into the rail clamp①, and tighten the fixing handle② to fix the insertion rod③.
- 4-4. Attach the radiographic top^⑤ to the board^⑥.
- 4-5. Attach the pad[®] to the radiographic top[®].

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. Use a pair of Knee rests (right and left) to support the patient.
- 2-3. When using this product to support patient's leg (Fig.2-1 and Fig.4-1), read instructions for use of operating table carefully and pay close attention to the patient and devices. Patient could fall down by the condition or position of the devices.
- 2-4. For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.
- 3. Interaction
- 3-1. Combination contraindicated

Do not use the Knee Rests (08-072-01) which are incompatible with the cassette board attached to the operating table. When the board is flexed upwards, the board will bump into the cassette board, and it may get damaged.

Storage/Life

- 1. 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: 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 set 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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