

MES-CK08-078-20EN-0

PREPARED: (2023-07-21) (Version 5)

Instruction for Use

Trade Name: Leg Plate

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

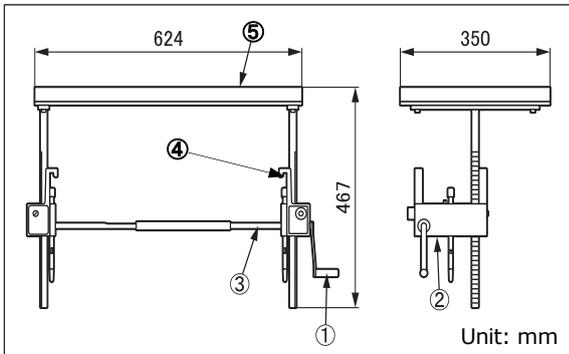
This product is only validated for use with Mizuho operating tables.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



Code No.	Product Description
08-078-20	Leg Plate *1
08-078-20-R1	Leg Plate (R1) *2
08-078-20-R2	Leg Plate (R2) *3

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

2. Material

- ① Handle: Stainless steel
- ② Gear case: Stainless steel
- ③ Motion axis: Stainless steel
- ④ Clamp: Stainless steel
- ⑤ Leg plate: Polyurethane

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

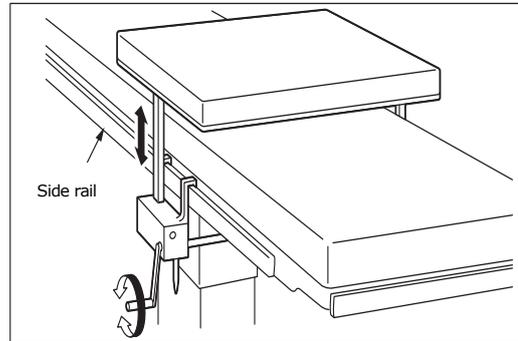
Intended purpose

This is an accessory for the operating table. This product is used to set the surgical positions for the lateral recumbent position.

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. Attach this product to the side rail of the operating table.
2. Use the handle to adjust the Leg plate up or down.

Maximum elevation height of the Leg plate: 270 mm

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. 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 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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