

MES-CK08-075-20EN-0

PREPARED: (2023-07-26) (Version 6)

Instruction for Use

Trade Name: Head Extension

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

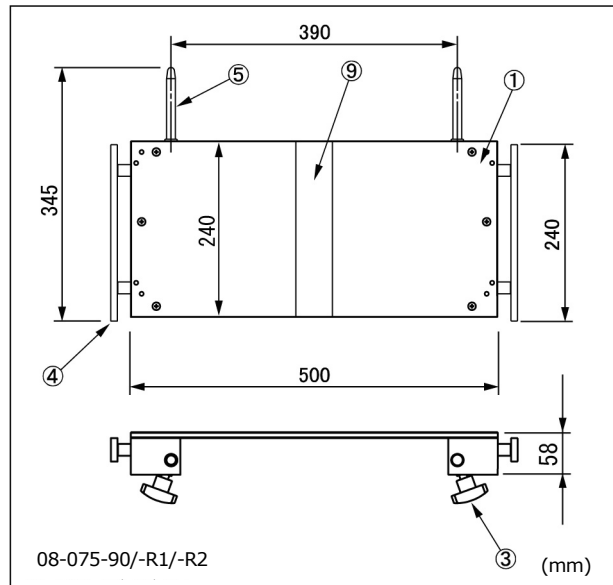
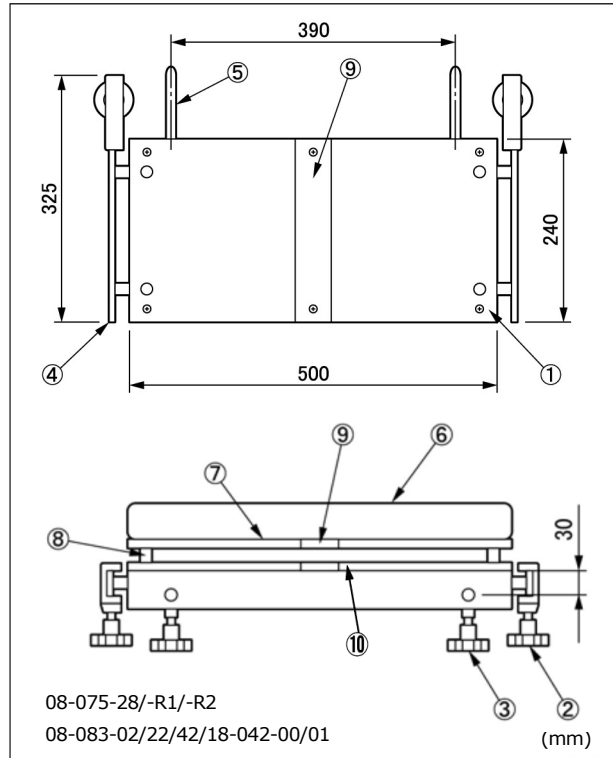
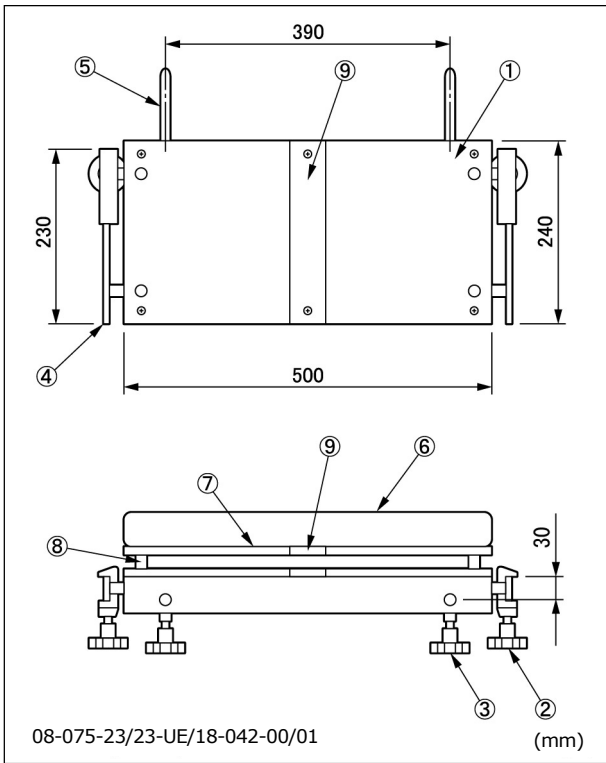
This product is only validated for use with Mizuho operating tables.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



Code No.	Product Description	Compon ents	Wei ght
08-075-23	Radiographic Top for Head Extension *1	⑦⑧⑨	1.3 kg
08-075-23-UE	Radiographic Top for Head Extension (UE) *2	⑦⑧⑨	1.3 kg
08-075-28	Head Extension for 5701 *3	①②③④ ⑤⑨	7.0 kg
08-075-28-R1	Head Extension (R1) *4	①②③④ ⑤⑨	7.0 kg
08-075-28-R2	Head Extension (R2) *5	①②③④ ⑤⑨	7.0 kg

08-075-90	Head Extension II *6	①③④⑤⑨	4.2 kg
08-075-90-R1	Head Extension II (R1) *7	①③④⑤⑨	4.2 kg
08-075-90-R2	Head Extension II (R2) *8	①③④⑤⑨	4.2 kg
18-042-00	Mizuho Original Pad for Head Section Type A *9	⑥	0.6 kg
18-042-01	SUSANO Pad for Head Section Type A *9	⑥	0.5 kg
08-083-02	Radiographic Table Tops Fixed Type for Head Extension (240 mm)	⑦⑧⑨	1.5 kg
08-083-22	Digital Radiographic Table Tops Fixed Type for Head Extension (240 mm)	⑦⑧⑨	1.5 kg
08-083-42	Phenolic Board for Radiographic and Digital Radiographic Table Tops Fixed Type for Head Extension (240 mm)	⑩	1.3 kg

*1: Height: 37 mm

*2: Height: 46 mm

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

*6, *7 and *8: The size of mountable side rail is different.

*9: Accessory (non-medical device)

2. Material

- ① Headrest board: Thermosetting resin
- ② Fixing handle: Carbon steel, nylon
- ③ Head section fixing handle: Carbon steel, nylon
- ④ Side rail: Stainless steel
- ⑤ Insertion shaft: Stainless steel
- ⑥ Pad: Polyurethane
- ⑦ Radiographic top: Thermosetting resin
- ⑧ Support pole: Stainless steel, polycarbonate
- ⑨ Velcro tape: Nylon
- ⑩ Table board: Thermosetting resin

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

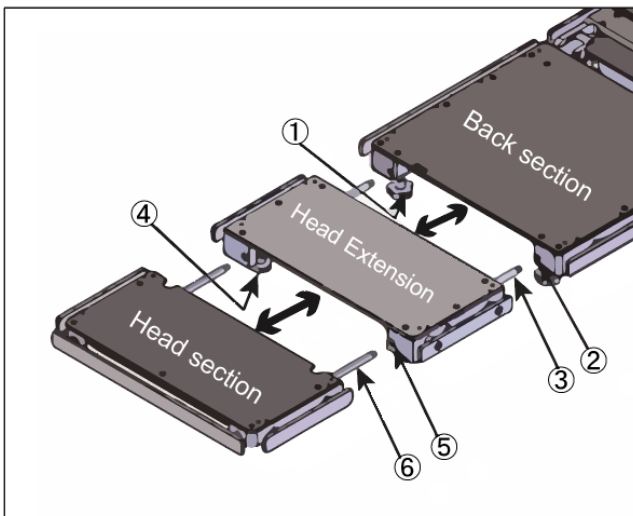
Intended purpose

This is an accessory for the operating table. This product is to be attached to the back section of an operating table to extend the tabletop length.

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. Attachment of the Head Extension (before use)
 - 1-1. Loosen the fixing handles ① of the operating table back section and detach the head section.
 - 1-2. Insert the insertion shafts ③ of the Head Extension into the reception holes ② on the operating table back section.

1-3. Make sure that the Head Extension is fully inserted into the operating table back section.

1-4. Tighten the fixing handles ① of the operating table back section to fix the Head Extension.

2. Attachment of the head section (before use)

If necessary, attach the head section detached from the operating table to the Head Extension.

2-1. Loosen the fixing handles ④ of the Head Extension.

2-2. Insert the insertion shafts ⑥ of the head section into the reception holes ⑤ of the Head Extension.

2-3. Make sure that the head section is fully inserted into the Head Extension.

2-4. Tighten the fixing handles ④ of the Head Extension to fix the head section.

3. Detachment of the head section (after use)

If the head section is attached to the Head Extension, detach the head section first.

3-1. Loosen the fixing handles ④ of the Head Extension.

3-2. Pull the head plate toward you to detach it from the Head Extension.

4. Detachment of the Head Extension (after use)

4-1. Loosen the fixing handles ① of the operating table back section.

4-2. Pull the Head Extension toward you to detach it from the operating table back section.

5. Applicable operating tables

Refer to the brochure "OPERATING TABLE ACCESSORIES" of Mizuho.

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. Make sure that this product or other accessories are fully inserted.

Incomplete insertion may cause the products to come off or move, which may result in a patient injury.

2-2. When performing the head down or the back plate bending down operation with the Head Extension and the head plate attached, be aware that they might come into contact with the floor.

2-3. 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.

2-4. 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 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.



MIZUHO Corporation
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
<https://www.mizuho.co.jp>



EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem, The Netherlands