Be sure to read this instruction manual before using this product. Keep this manual available for reference when needed.

MES-CK08-070-55EN-0
PREPARED: (2023-07-21) (Version 3)



# Instruction for Use

# Trade Name: Carbon Fiber 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.
- Avoid sudden impacts or excessive vibrations to the device.Otherwise, the device may unintendedly rebounds and vibrates that may harm the patient.

# Contraindication/Prohibition

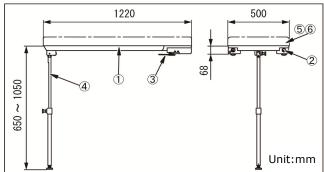
- This product is only validated for use with Mizuho operating tables.
- Do not exceed the allowable load specified in **Specifications**,
   Allowable load. Otherwise the product could break.
- Do not apply any unbalanced loads on the tips of the board. [Doing so may cause the board and the operating table to tip over or to get damaged.]
- 4. Use the board and the operating table in a level position. Also, do not use it whereas the support pole's height exceeds the height adjustment range. Otherwise, it cannot be safely fixed and the patients may get injured.

# Symbol mark for labeling

MD : Medical Device

# **Specifications**

1. Shape



Code No.	Product Description	Components
08-070-55	122 cm Carbon Fiber Extension II	1234
08-070-36	50 mm Pad for 122 cm Carbon Fiber Extension	(5)
08-070-37	70 mm Pad for 122 cm Carbon Fiber Extension	(5)
08-070-38	90 mm Pad for 122 cm Carbon Fiber Extension	(5)
08-070-39	110 mm Pad for 122 cm Carbon Fiber Extension	(5)
08-083-67	70 mm Mizuho Original Pad for 122 cm Carbon Fiber Extension	6
08-083-68	110 mm Mizuho Original Pad for 122 cm Carbon Fiber Extension	6

# 2. Weight

122 cm Carbon Fiber Extension II: 14.0 kg

3. Allowable load: 135 kg

# 4. Material

- ① Board: Carbon fiber reinforced resin
- ② Reception hole: Aluminum alloy
- ③ Handle: Carbon steel, carbon fiber reinforced resin
- Support pole: Aluminum alloy
- ⑤ Pad: Polyurethane

6 Pad: Polyurethane

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

## **Intended purpose**

This is an accessory for the operating table. This tool is used for supporting the back and head or legs of a patient. It is made of a carbon-fiber reinforced resin material with a high degree of radiolucency.

### 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

- 1-1. Detach the head section and the back section, or the leg section from the operating table.
- 1-2. Make sure that the insertion shafts of the operating table or the operating table accessory to the level position.
- 1-3. Hold both sides of the board① securely, align the reception holes② to the insertion shafts, and insert them until they click
- 1-4. Pull the board  $\ensuremath{\mathfrak{D}}$  toward you to check that it is fully inserted.
- 1-5. Adjust the height of the support pole ④ so that the height of the board① is level with the tabletop of the operating table.
- 1-6. Attach the dedicated pad(5) (or (6)).

# 2. Detachment

- 2-1. Detach the dedicated pad(s) (or (6)).
- 2-2. Fold the support pole 4 to the board 1 side.
- 2-3. Pull the board① straight out towards you while simultaneously holding the handles③ on both left and right.
- 2-4. Attach the head section and the back section, or the leg section to the operating table.

3. Applicable operating tables

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

# Warning/Caution

1. Warning

Ensure all attaching parts are fixed. Loose condition can cause the product to come off or move, which may result in a patient injury.

- 2. Important Caution
  - 2-1. Adjust the height of the operating table to be within the support pole's height adjustment range (650 to 1050 mm).
  - 2-2. Set the support rod perpendicular to the floor.
  - 2-3. Do not operate the operating table with the support pole making contact with the ground. This product may get overloaded, which might lead to damage and/or serious accidents.
  - 2-4. Make sure that this product is fully inserted into the operating table.
  - 2-5. 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. Otherwise the product could break.
  - 2-6. The attachment brackets of the device are made of metallic material. Take the radiopaque brackets into consideration when using this product for X-ray photography.
  - 2-7. Do not pull this product that is attached to the operating table to move the operating table. Otherwise it may fall down, get damaged or the operators get injured.
  - 2-8. For hygiene, be sure to use sterilized 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.
- Serve 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**

Main unit: 1 piece per pack Pad: 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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