

Instruction for Use

Trade Name: Carbon Fiber Extension

Warning

1. 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.
2. Avoid sudden impacts or excessive vibrations to the device. Otherwise, the device may unintentionally rebound and vibrate that may harm the patient.

Contraindication/Prohibition

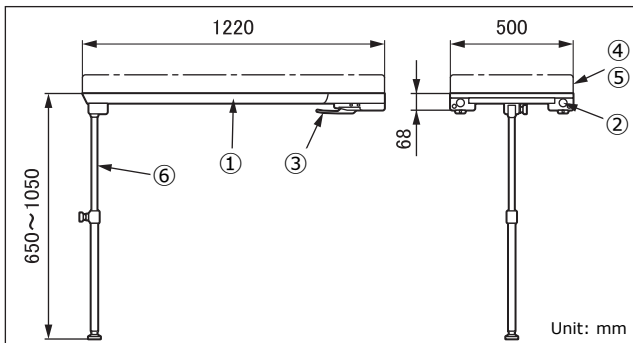
1. This product is only validated for use with Mizuho operating tables.
2. Use only on the models listed in **Instructions for use**, 2. Applicable operating tables.
3. Do not exceed the allowable load specified in **Specifications**, 3. Allowable load. Otherwise the product could break.
4. Use the board 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



122cm Carbon Fiber Extension

Code No.	Product Description	Components
08-070-35	122cm Carbon Fiber Extension	①②③⑥
08-070-36	50mm Pad for 122cm Carbon Fiber Extension	④
08-070-37	70mm Pad for 122cm Carbon Fiber Extension	④
08-070-38	90mm Pad for 122cm Carbon Fiber Extension	④
08-070-39	110mm Pad for 122cm Carbon Fiber Extension	④
08-083-67	70mm Mizuho Original Pad for 122cm Carbon Fiber Extension	⑤
08-083-68	110mm Mizuho Original Pad for 122cm Carbon Fiber Extension	⑤

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

2. Weight
122cm Carbon Fiber Extension: 14 kg
3. Allowable load
135 kg
4. Material
 - ① Carbon Fiber Extension: Carbon fiber reinforced resin
 - ② Reception holes: Aluminum alloy
 - ③ Handle: Carbon steel
 - ④ Pad: Polyurethane
 - ⑤ Pad: Polyurethane
 - ⑥ Support pole: Aluminum alloy

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

Intended purpose

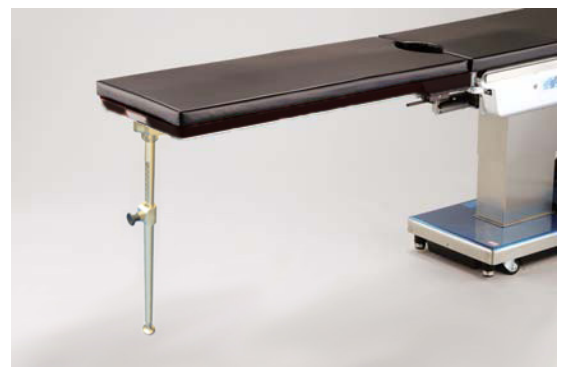
This is an accessory for the operating table. This product is used for supporting the back or head of a patient. It is made of a carbon-fiber reinforced resin material with a high degree of radiolucency.

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 from the operating table.
 - 1-2. With the back section insertion shafts of the operating table in the horizontal position, insert the Carbon Fiber Extension (main body) completely.
 - 1-3. Pull the Carbon Fiber Extension (main body) toward you to check that it is fully inserted.
 - 1-4. Set the support pole.
 - 1-5. Attach the dedicated pad.



122cm Carbon Fiber Extension

2. Applicable operating tables
Refer to the brochure "OPERATING TABLE ACCESSORIES" of Mizuho.

Warning/Caution

Important Caution

1. Regardless of the model, adjust the height of the operating table to be within the Carbon Fiber Extension's movable range (650 to 1050 mm).
2. When setting the support pole, make sure that the support pole is vertically to the floor.
3. Do not operate the operating table with the support pole making contact with the ground. The Carbon Fiber Extension may get overloaded, which might lead to damage and/or serious accidents.
4. Make sure that the Carbon Fiber Extension is fully inserted into the operating table.
5. 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.
6. The attachment brackets of the device are made of a metallic material. Take the radiopaque brackets into consideration when using this product for X-ray photography.
7. Do not pull the Carbon Fiber Extension that is attached to the operating table to move the operating table. Otherwise it may fall down, get damaged or the operators get injured.
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

1. Do not store the device in high temperatures or in areas with high humidity where the temperature has drastic variations.
2. 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 devices 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 body: 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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