

Instruction for Use

Trade Name: Head Supporter

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.
- Do not use the Head Supporter alone to support a patient in the Trendelenburg position or another position where the Head supporter is subject to the load of the body (chest, abdomen, arms and legs).
Doing so may put the patient in an unstable position and result in injury.
- When using the Head Supporter, also use the Shoulder Supports, the Adjustable body support, the Levitator stirrups and other accessories that provide strong support and secure the chest, waist, legs and upper body of the patient.
Not doing so may result in the patient being put into an unstable position and falling down.

Contraindication/Prohibition

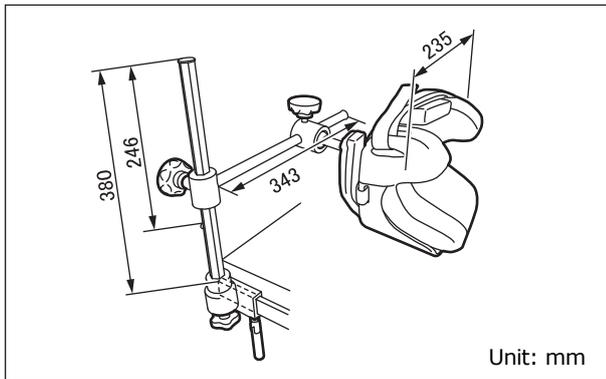
- This product is only validated for use with Mizuho operating tables.
- Do not use this product on an operating table tilted at an angle of more than 25 degrees in the Trendelenburg or reverse Trendelenburg position or more than 45 degrees laterally.
Doing so will decrease the load bearing capacity of the product.

Symbol mark for labeling

MD : Medical Device

Specifications

- Shape



Code No.	Product Description	Weight
08-075-06	Head supporter *1	4.5kg
08-075-06-R1	Head supporter (R1) *2	4.5kg
08-075-06-R2	Head supporter (R2) *3	4.5kg

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

- Material

Stainless steel, Polyurethane

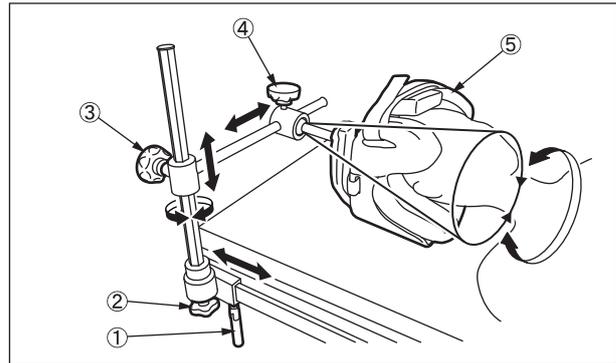
Intended purpose

This is an accessory for the operating table. This tool is used for supporting a patient's head during an endoscopic operation.

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



- Attach this product to the side rail of the operating table, and adjust and fix the position by using the fixing handle①.
- Adjust and fix the arm position by using the arm rotation handle② and the arm adjustment handle③.
- Adjust the position of the supporter⑤ by using the supporter bending handle④.
- Hold the head of a patient with the supporter⑤.
- After supporting the patient's head, fix the position by using the supporter bending handle④.
- Check that each of the fixing handle①, the arm rotation handle②, the arm adjustment handle③, and the supporter bending handle④ are fixed securely.

Warning/Caution

- 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.
- Important caution
 - 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.
 - 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.
- 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 by certified agents of Mizuho.

Packing

1 piece per package

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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