

## Instruction for Use

### Trade Name: Cervical Spine Frame

#### 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

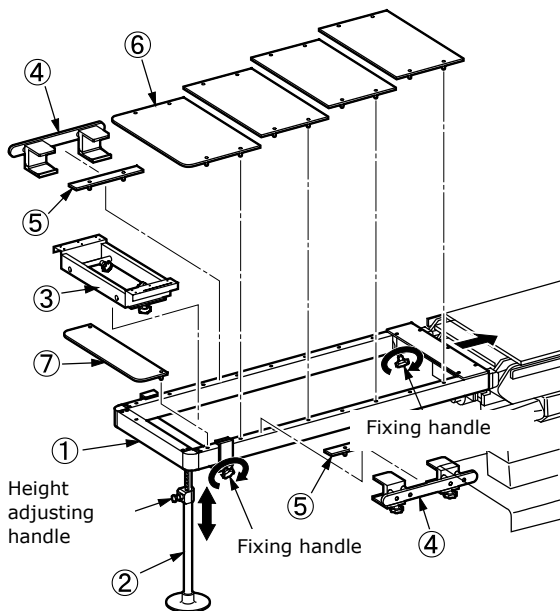
1. This product is only validated for use with Mizuho operating tables.
2. Do not use the product with the insertion shaft of the tabletop or the auxiliary tabletop broken. [If the tabletop or the auxiliary tabletop moves during use, the patient may get injured.]
3. Do not place anything sharp on the tabletop or the auxiliary tabletop as it may compromise the surface, may cause damage and/or harm.
4. When using this product, set the tabletop of the operating table in a horizontal position while making its height within the adjustable range of the support pole. Otherwise this product may not be fixed securely, which may result in a patient injury.

#### Symbol mark for labeling

**MD** : Medical Device

#### Specifications

1. Shape



Code No.	Product Description
08-007-22	Cervical Spine Frame
08-007-22-R1	Cervical Spine Frame (R1)
08-007-22-R2	Cervical Spine Frame (R2)

2. Weight: 23 kg

#### 3. Material

- ① Frame: Carbon fiber reinforced resin, synthetic resin
  - ② Support pole: Aluminum alloy, synthetic resin
  - ③ Head fixing adapter: Stainless steel, synthetic resin
  - ④ Side rail attachment: Stainless steel, synthetic resin
  - ⑤ Spacer: Thermosetting resin, stainless steel
  - ⑥ Tabletop: Thermosetting resin, polyacetal
  - ⑦ Auxiliary tabletop: Thermosetting resin, polyacetal
- Note: The number corresponds to those used in 1. Shape.

4. Allowable load: 135 kg

#### Intended purpose

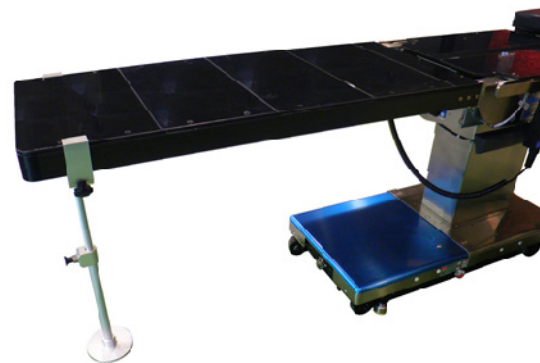
This is an accessory for the operating table and is designed to support patient's cervical spine during surgery. The head fixing adapter③, the side rail attachment④, the spacer⑤, etc. should be attached according to the surgical procedure.

#### 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. Prior to attaching the frame①, ensure the back section insertion shaft of the table is horizontal. Carefully slide the frame① onto the shafts and firmly tighten the fixing handle.
  - 1-3. Attach the tabletop⑥ or the auxiliary tabletop⑦ on the tip of the frame① and attach the support pole②.
  - 1-4. Operate the fixing handle and the height adjusting handle of the support pole② to determine the position.
  - 1-5. Attach the head fixing adapter③, the side rail attachment④ and the spacer⑤ according to the surgical procedure.



Cervical Spine Frame

2. 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 the frame① is fully inserted into the operating table.
- 2-2. Make sure to use this product with the support pole② attached.
- 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. 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

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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