

## 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

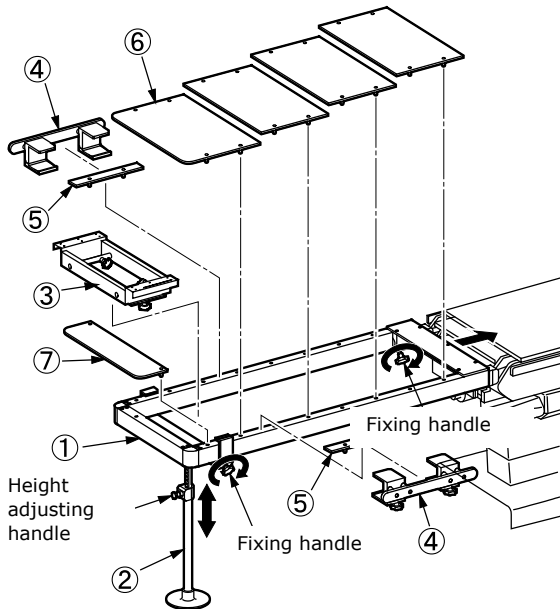
1. This product is only validated for use with Mizuho operating tables.
2. Do not use the product with the Support pole of Tabletop or Auxiliary tabletop broken. [If the Tabletop or Auxiliary tabletop moves during use, the patient may get injured.]
3. Do not place anything sharp on the Tabletop or Auxiliary tabletop as it may compromise the surface, may cause damage and/or harm.
4. When using this product, set the table top 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: 23kg

### 3. Material

- ① Frame: Carbon-fiber reinforced plastic, synthetic resin
- ② Support pole: Aluminum alloy rod, synthetic resin
- ③ Head fixing adapter: Cold-rolling austenitic stainless steel plate, synthetic resin
- ④ Side rail attachment: Cold-rolling austenitic stainless steel plate, stainless steel rod, synthetic resin
- ⑤ Spacer: Thermosetting resin laminated board, stainless steel rod
- ⑥ Tabletop: Thermosetting resin laminated board, polyacetal
- ⑦ Auxiliary tabletop: Thermosetting resin laminated board, polyacetal

### 4. Applicable operating tables

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

5. Allowable load: 135 kg

### Intended purpose

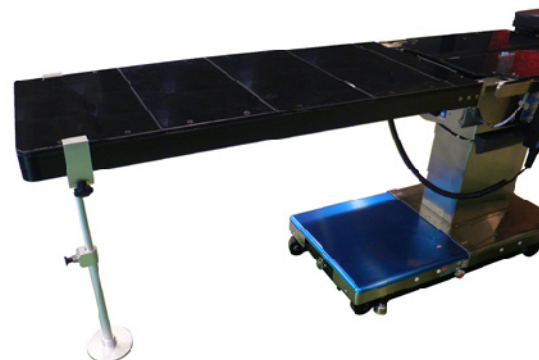
This is an accessory to the operating tables and is designed to support patient's cervical spine during surgery. The Head fixing adapter ③, Side rail attachment ④, Spacer ⑤, etc. should be attached according to the surgical procedure.

### 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. Remove the head plate and back plate from your Mizuho operating table.
2. Prior to attaching the Frame ①, ensure the back plate insertion shaft of the table is horizontal. Carefully slide the Frame ① onto the shafts and firmly tighten the Fixing handle.
3. Attach the Tabletop ⑥ or Auxiliary tabletop ⑦ on the top of the Frame ① and attach the Support pole ②.
4. Operate the Fixing handle and Height adjusting handle of the Support pole ② to determine the position.
5. Attach the Head fixing adapter ③, Side rail attachment ④, and/or Spacer ⑤ according to the surgical procedure.



Cervical Spine Frame

## 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. Be sure to check that the Frame ① is surely inserted into the operating table unit.
- 2-2. Be sure to use the product with the Support pole ② attached.
- 2-3. 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.
- 2-4. 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 that this product is not damaged or broken before and after use.
2. Cleaning and disinfection  
Wipe off blood, chemicals, contaminants, and other stains with water, and clean the device and pad with gauze or other material moistened with alcohol to disinfect it.
3. If you need to have this product repaired, consult your local dealer or Mizuho.

<By agents>

Maintenance and inspection can only be carried out by certified agents of Mizuho.

## Packing

Main body: 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.

## Manufacturer



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

## European authorized representative



Emergo Europe B.V.  
Prinsessegracht 20, 2514 AP, The Hague  
The Netherlands