MIZUHO

MES-CK02-122-00EN-0
PREPARED: (2020-07-17) (Version 3)

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

CE

Instruction for Use

Trade Name: Posterior Lumber Surgery Frame

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. When using this product for a patient in the lateral recumbent position, secure the arm on the lower side onto the Armboard. Failure to secure the arm to the Armboard may lead to a patient injury.

Contraindication/Prohibition

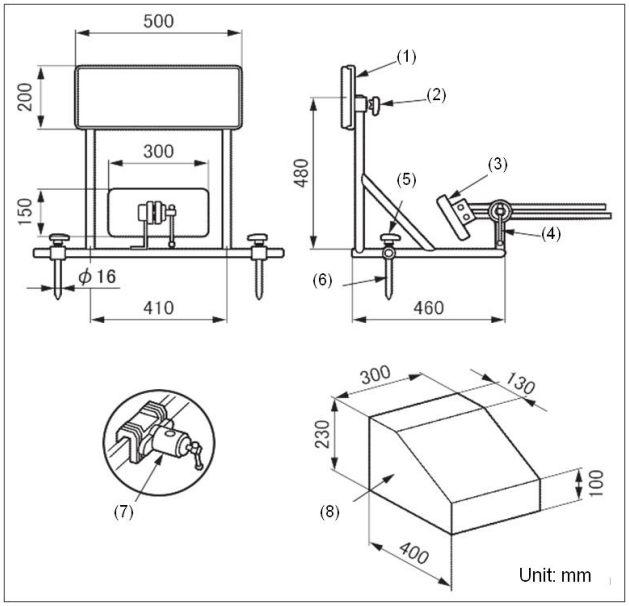
1. This product is only validated for use with Mizuho operating tables.
2. Ensure fixing handles are tight.
   Loose condition can cause the product to come off or move, which may result in a patient injury.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



Code No.	Product Description
02-122-00	Posterior lumbar surgery frame with clamp ✶1
02-122-00-NC	Posterior lumbar surgery frame (NC) ✶2
02-122-02	Posterior lumbar frame pillow
08-110-01	Clamp for round bar ✶3
08-117-09	Clamp for round bar (R1) ✶4
08-117-11	Clamp for round bar (R2) ✶5

For ✶1, ✶3 is included.
For ✶2, select ✶4 or ✶5.
For ✶3, ✶4 and ✶5: The size of mountable side rail is different

2. Weight
   Body: 5kg, mounting bracket: 0.9kg
   Pillow: 1kg
3. Material
(1). Hip support: Urethane
(2). Hip handle: Stainless steel bar
(3). Foot support: Urethane
(4). Foot handle: Stainless steel bar
(5). Insertion shaft handle: Stainless steel bar
(6). Insertion shaft: Stainless steel bar
(7). Mounting bracket: Stainless steel castings
(8). Posterior lumbar frame pillow: Urethane
   Note: The numbers correspond to those in 1. Shape.

Intended purpose

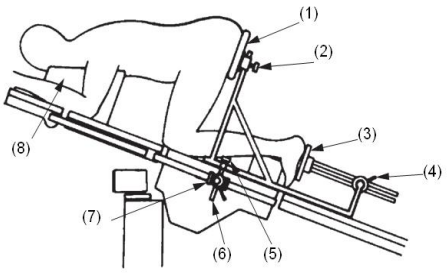
This is an accessory to an operating table.
This frame is designed for a posterior lumbar surgery.

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

■ Usage example



1. Adjust the insertion shaft (6) to the width of the surgery table.
2. Insert the insertion shaft (6) to the Clamp for round bar (7) of the side rail of the surgery table. Fix it with the insertion shaft handle (5).
3. Place the patient on the surgery table as shown. Support the upper body with the posterior lumber pillow (8).
4. If necessary, adjust the position of the hip support (1) and foot support (3). Tighten the hip handle (2) and foot handle (4).

Warning / Caution

Important cautions

1. 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.
2. 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 with gauze or other material moistened with alcohol to disinfect.
3. In case of a malfunction
   If you need to have this product repaired, clearly label the device as "Broken", "Need repair" etc. and contact your local dealer or Mizuho.

<By agents>

Maintenance and inspection can only be carried out 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 adverse 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

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