

Instruction for Use

Trade Name: Knee Crutches

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 compartment syndrome, neuropathy, nerve paralysis, bedsores and/or redness.
- Set this product symmetrically for both legs. If it is displaced at one side, a serious neuropathy, circulatory disturbance or interruption in the blood circulation could occur on the hip joint of patient.
- When adjusting the position of the Thigh rest, always operate the Thigh rest fixing handle while holding the patient's leg. Otherwise the Thigh rest may move suddenly, causing a serious neuropathy, circulatory disturbance or interruption in the blood circulation.
- Adjust the height and the angle of open legs slowly. Abrupt movement could cause a serious neuropathy, circulatory disturbance or interruption in the blood circulation.
- Avoid compression of the lateral aspect of the peroneal nerve. Failure to do so could cause paralysis.

Contraindication/Prohibition

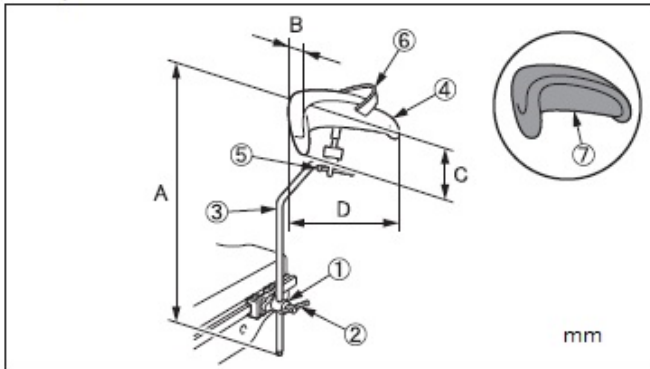
- This product is only validated for use with Mizuho operating tables.
- Do not place the patient's leg directly on the device. Doing so could result in a burn due to a contact with an electrosurgical knife or nerve paralysis.

Symbol mark for labeling

MD : Medical Device

Specifications

1. Shape



2. Dimension (A x B x C x D)

770 x 170 x 160 x 220 (mm): 08-070-00
970 x 170 x 160 x 220 (mm): 08-070-00-UE
700 x 120 x 110 x 150 (mm): 08-070-01
350 x 170 x 160 x 220 (mm): 08-070-30

3. Weight (per piece)

Code No.	Product Description	Weight Kg/piece
08-070-00	Knee Crutches with Clamps *1	3.0
08-070-00-UE	Knee Crutches (UE)	2.4
08-070-13	Urethane Pad for Knee Crutches	—
08-110-01	Clamp for Round Bar *2	0.9
08-117-09	Clamp for Round Bar (R1) *3	0.9
08-117-11	Clamp for Round Bar (R2) *4	0.9

*1: *2 is included.

*2, *3, and *4: The size of mountable side rail is different.

3. Material

- Rail clamp: Stainless cast steel
- Fixing handle: Stainless steel rod
- Support pole: Stainless steel rod
- Thigh rest: Cold-rolled stainless steel plate
- Thigh rest fixing handle: Stainless steel rod
- Thigh strap: Nylon resin
- Pad: Urethane

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

Intended purpose

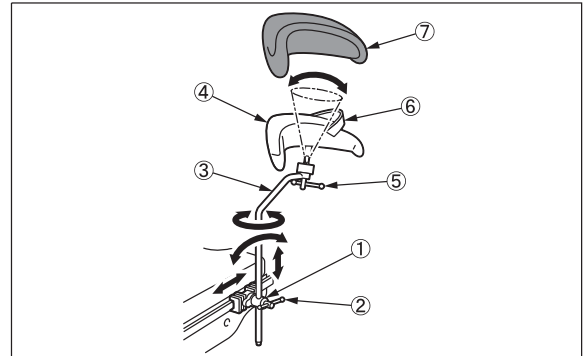
This is an accessory to an operating table.

This tool is used for supporting the patient's legs mainly in the lithotomy position for a urological, gynecological or similar operation or examination.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

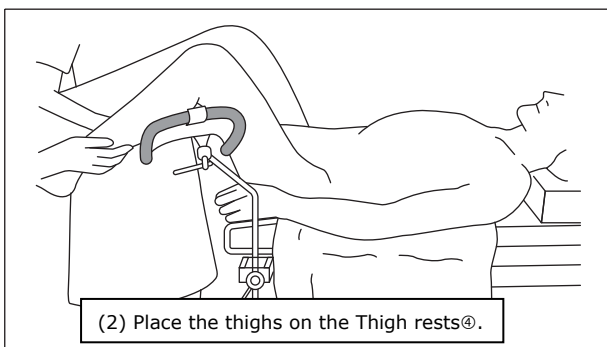
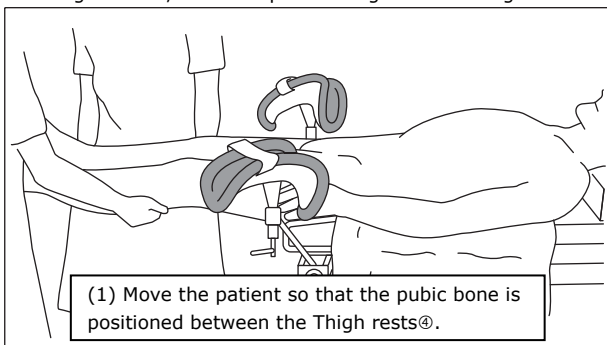
Instructions for use



- Rail clamp
- Fixing handle
- Support pole
- Thigh rest
- Thigh rest fixing handle
- Thigh strap
- Pad

- Attach this product in bilaterally symmetrical positions.
 - 1-1. Attach the Pads⑦ to the Thigh rests④.
 - 1-2. Attach the Rail clamps① to the side rails of an operating table.
 - 1-3. Insert the Support poles③ into the Rail clamps① and tighten the Fixing handles② to temporarily secure the Support poles③.
 - 1-4. Move the Support poles③ to the position appropriate for the patient's posture.
 - 1-5. After the adjustment, rotate the Fixing handles② to secure the Rail clamps① and the Support poles③.

2. Move the patient so that the pubic bone is positioned between the Thigh rests④, and then put the thighs on the Thigh rests④.



- 2-1. Put the thighs on the Thigh rests④ with Pads⑦ specifically designed for this product or appropriate padding.
- 2-2. Loosen the Thigh rest fixing handles⑤ and adjust the angles of the Thigh rests④ as required.
- 2-3. After the adjustment, tighten the Thigh rest fixing handles⑤ to secure the Thigh rests④.
- 2-4. Secure the patient's legs with the Thigh straps⑥.

Warning/Caution

1. Important fundamental cautions
 - 1-1. 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. Otherwise the product could break.
 - 1-2. Ensure all fixing handles are tight. Loose condition can cause the product to come off or move, which may result in a patient injury.
 - 1-3. Protect the legs by covering the Thigh rests with Pads specifically designed for this product or appropriate padding.
 - 1-4. For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.

2. Defect/Adverse event

Defect

- Malfunction
- Failure
- Damage

Adverse event

- Injury
- Redness
- Neuro paralysis or neuropathy
- Peroneal nerve paralysis
- Compartment syndrome
- Muscle crush syndrome
- Crush syndrome
- Circulatory disturbance
- Interruption in the blood circulation
- Bedsore

3. Important cautions

- 3-1. Users should be trained to get used to the usage of the product before using it to the patient.
- 3-2. The patient may inform the medical staff of the postural limits before being anesthetized. Confirm the posture with the patient before fixing.
- 3-3. When using this product, palpate the dorsalis pedis artery, check the skin color and temperature of the legs to see if there is no impaired blood flow.

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. Inspection 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 material moistened with alcohol to disinfect.
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 dealer or Mizuho.

<By agents>

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

Packing

1 pair 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.

Manufacturer



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European authorized representative



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