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

CE

MES-CK08-115-01EN-0

PREPARED: (2020-10-16) (Version 5)

Instruction for Use

Trade Name: Leg Traction Device

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. Ensure all 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. Components and material

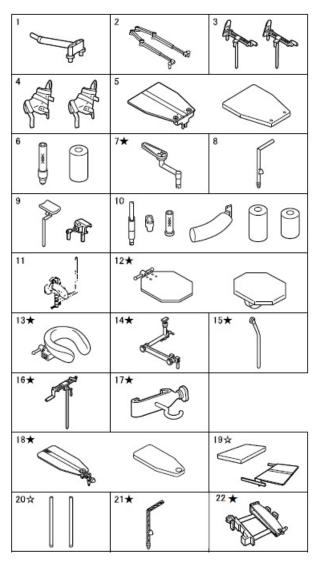
No.	Code No.	Product Description	Material
1	08-115-01	Traction Device Arm	Stainless steel bar
2	08-115-02	Extension Arm, Right/Left	Stainless steel bar
3	08-115-04	Traction Device Right/Left	Stainless steel bar
4	08-115-05	Traction Shoe Right/Left	Artificial leather
5	08-115-06	Wide Pelvis Support	Thermosetting resin laminated plate and urethane
6*	08-115-07	Inner Thigh Column with Pad	Carbon fiber reinforced plastic and urethane
	08-115-36	Inner Thigh Column	Carbon fiber reinforced plastic
	08-115-37	Pad for Inner Thigh Column	urethane
7★	08-115-08	Pelvic Support for Pediatric	Polycarbonate
8	08-115-09	L-shaped Knee Rest with Pad	Stainless steel bar

No.	Code No.	Product Description	Material
9	08-115-10	Lower Limb Support, Right/Left	Stainless steel bar
	08-115-38	Lower Limb Support Clamp	Aluminum alloy casting
9	08-115-73	Lower Limb Support without Fixing Bracket	Stainless steel bar
10	08-115-11	Inner Thigh Support with Pad for Traction in Lateral Posture	Stainless bar and urethane
11	08-115-12	Lower Thigh Support for Traction in Lateral Posture	Stainless steel bar
12★	08-115-13	Radiolucent Head Rest	Thermosetting resin laminated plate and urethane
13★	08-115-14	Face Rest	Aluminum alloy casting and urethane
	08-115-15	Arm for Head rest & Face Rest	Aluminum alloy casting
14★	08-115-15-R1	Arm for Head Rest & Face Rest(R1)	
	08-115-15-R2	Arm for Head Rest & Face Rest(R2)	
15★	08-115-17	Traction Pulley	Stainless steel bar
16★	08-115-18	Direct Traction Device	Stainless steel bar
17★	08-115-19	Direct traction Hook Attachment	Stainless steel bar
18★	08-115-20	Movable Pelvic Support	Thermosetting resin laminated plate and urethane
	08-115-26	Pelvic Support Board	Thermosetting resin laminated plate and urethane
19☆	08-115-26-R1	Pelvic Support Board(R1)	
	08-115-26-R2	Pelvic Support Board(R2)	
20☆	08-115-27	Support Rods	Stainless steel bar
21★	08-115-43	Carbon Fiber L Shaped Knee Rest with Pad	Carbon fiber reinforced plastic
22★	08-115-45	Direct Traction Device for Borshards	Stainless steel bar

 $[\]star$: Optional item

^{☆:} Standard model using V attachment for traction device

2. Shape



Note: The numbers correspond to those in the No. column in

- 1. Components and material.
- Applicable operating tables
 Refer to the brochure "OPERATING TABLE ACCESSORIES" of Mizuho.

Intended purpose

This is an accessory to an operating table.

The device is designed for setting the position of the patient in a traction operation.

Intended user

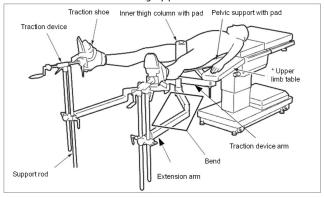
This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

- 1. How to attach the lower limb traction device
 - 1-1. Remove the leg plate from the surgery table.
 - 1-2. Align the position of the insertion shaft of the traction device arm with the insertion hole of the surgery table.
 - 1-3. Mount the insertion shaft to the insertion hole and tighten the lock handle.
 - 1-4. Set the position by rotating or sliding the extension arm.
 - 1-5. Attach the components according to the requirements of surgery.
 - 1-6. Put the patient on the table and set the position.

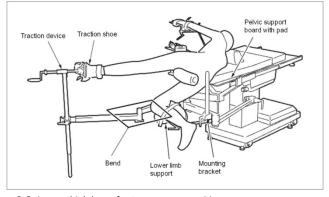
2. Examples of combination of lower limb traction device

2-1. Femoral neck fracture surgery position

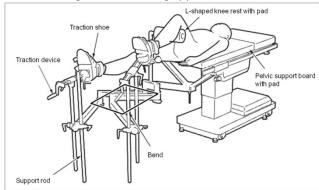


Upper limb table is not included.

2-2. Femoral shaft fracture surgery position



2-3. Lower thigh bone fracture surgery position



Warning / Caution

1. Warning

Check always if tightening sections are fixed securely. Otherwise the apparatus may be disengaged or moved, causing hazards on the patient.

2. Important precautions

- 2-1. For hygiene, be sure to use sterile drapes on this product where the patient comes into contact with it.
- 2-2. When operating the surgery table, be aware of the contact and interference with other accessories and tabletop.
- 2-3. Do not pull on the belt of traction shoes (No. 4) and lower thigh support for traction in lateral posture (No. 11) with excessive force. They may be damaged.
- 2-4. For products using pad (refer to the table below), do not expose the sharp products to the pad part. They may be damaged.
- 2-5. For traction shoes (No. 4), lower thigh support for traction in lateral posture (No. 11) and products using pad (refer to the table below), depending on the type of disinfectant to be used, it may cause deterioration to the material. Ensure to check the display and/or description in the manual before using the disinfectant.
- 2-6. For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.

Note: The numbers correspond to those in the No. column in

1. Components and material in the **Specifications** section.

List of products using pad

No.	Product name		
5	Wide pelvis support		
9	Lower Limb support, right/left (1 piece)		
10	Inner thigh support with pad for traction in lateral posture		
12	Radiolucent head rest		
13	Face rest		
18	Movable pelvic support		
19	Pelvic support board		

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. Inspection before and after use

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 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.

Manufacturer



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