MES-CK08-115-01EN-0

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



PREPARED: (2023-07-26) (Version 8)

Instruction for Use

Trade Name: Leg Traction Device

- 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 $\ensuremath{\mathsf{I}}$ 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.

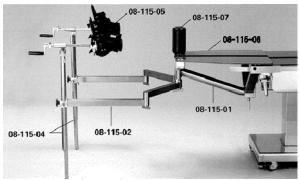
Contraindication/Prohibition

This product is only validated for use with Mizuho operating tables.

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
2	08-115-02	Extension Arm, Right/Left Stainless ste	
3	08-115-04	Traction Device Right/Left	Stainless steel
4	08-115-05	Traction Shoe Right/Left	Artificial leather
5	08-115-06	Wide Pelvic Support	Thermosetting resin and polyurethane
6*	08-115-07	Inner Thigh Column with Pad	Carbon fiber reinforced resin and polyurethane
	08-115-36	Inner Thigh Column	Carbon fiber reinforced resin
	08-115-37	Pad for Inner Thigh Column	Polyurethane
7★	08-115-08	Pelvic Support for Pediatric	Polycarbonate
8	08-115-09	L-Shaped Knee Rest with Pad	Stainless steel

No.	Code No.	Product Description	Material
9	08-115-10	Lower Limb Support, Right/Left	Stainless steel
	08-115-38	Lower Limb Support Clamp	Aluminum alloy
	08-115-73	Lower Limb Support without Fixing Bracket	Stainless steel
10	08-115-11	Inner Thigh Support with Pad for Traction in Lateral Posture	Stainless steel and polyurethane
11	08-115-12	Lower Thigh Support for Traction in Lateral Posture	Stainless steel
12★	08-115-13	Radiolucent Head Rest	Thermosetting resin and polyurethane
13★	08-115-14	Face Rest	Aluminum alloy and polyurethane
	08-115-15	Arm for Head Rest & Face Rest	Aluminum alloy
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
16★	08-115-18	Direct Traction Device	Stainless steel
17★	08-115-19	Direct Traction Hook Attachment	Stainless steel
18★	08-115-20	Movable Pelvic Support	Thermosetting resin and polyurethane
	08-115-26	Pelvic Support Board	Thermosetting
19☆	08-115-26-R1	Pelvic Support Board (R1)	resin and
	08-115-26-R2	Pelvic Support Board (R2)	polyurethane
20☆	08-115-27	Support Rods	Stainless steel
21★	08-115-43	Carbon Fiber Lshaped Knee Rest with Pad	Carbon fiber reinforced resin
22★	08-115-45	Direct Traction Device for Borshards	Stainless steel
23★	08-115-76	Wide Pelvic Support II	Thermosetting resin and polyurethane
24★	08-115-77	Transfer Board II (Pin Fixation Type)	Stainless steel and polyurethane
			Carbon fiber

^{★:} Optional item

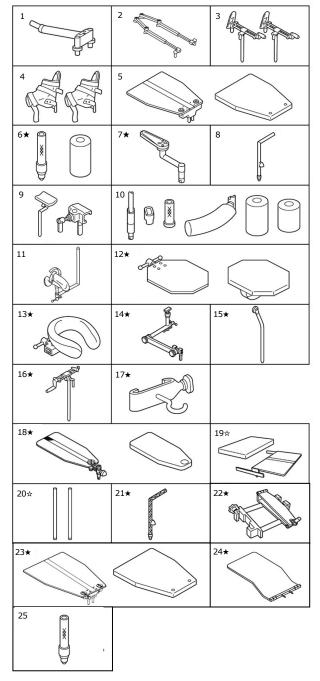
Attachment for Traction Device.

Code No.	Product Description	Components
08-052-01	Traction Device	1234589101192025
08-052-01-R1	Traction Device (R1)	123458911192025
08-052-01-R2	Traction Device (R2)	123458911192025

Note: The numbers correspond to those in the No. $\mbox{\sc column}$ in

1. Components and material.

2. Shape



★: Optional item

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

1. Components and material.

Intended purpose

This is an accessory for an operating table.

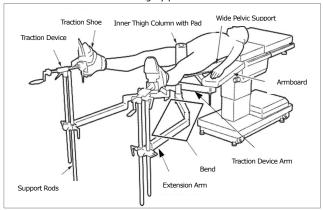
This product is designed for setting the position of the patient in a traction operation.

Intended user

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

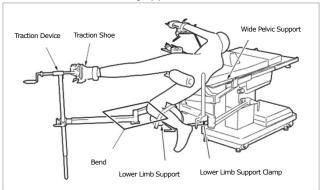
Instructions for use

- 1. Attachment
 - 1-1. Detach the leg section from the operating table.
 - 1-2. Align the position of the insertion shaft of the Traction Device Arm with the reception hole of the operating table.
 - 1-3. Attach the insertion shaft to the reception hole and tighten the fixing handle.
 - 1-4. Set the position by rotating or sliding the Extension Arm, $\label{eq:Right} \mbox{Right/Left}.$
 - 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 the Lower Limb Traction Device
 - 2-1. Femoral neck fracture surgery position

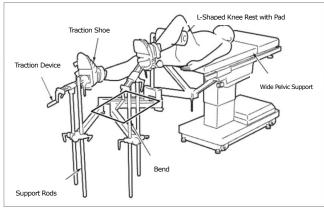


Note: Armboard is not included.

2-2. Femoral shaft fracture surgery position



2-3. Lower thigh bone fracture surgery position



3. 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. 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.
 - 2-2. For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.
 - 2-3. Do not pull on the belt of Traction Shoe Right/Left (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 Shoe Right/Left (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.

Note: The numbers correspond to those in the No. column in 1.

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

List of products using pad

List of products using pad				
No.	Product name			
5	Wide Pelvic Support			
6	Inner Thigh Column with Pad			
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			
23	Wide Pelvic Support II			

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. Check before and after use
 - 1-1. Check that this product is not damaged or broken before and after each use.
 - 1-2. Make sure that the belts of Traction Shoe Right/Left (No.4) and Lower Thigh Support for Traction in Lateral Posture (No.11) are not damaged and do not come off from the main body when the belts are pulled.
- 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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