




Read this instruction manual
before attempting to use the equipment

Levigator Stirrup Instruction for Use

 Warning

You should read and understand the Levigator Stirrup Instruction Manual before attempting to operate the device.

The Instruction Manual should be kept in a handy place for reference by those who use the Levigator Stirrup.

Levigator Stirrup is designed for use on MIZUHO Corporation operating tables.

Version 1 (2023-10-05)

MES-CK18-070-91EN

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* This Instruction Manual may be subject to change without notice.

* Although we have made done our best to ensure the content of this Instruction Manual is accurate, please let us know if you find anything inadequate or incorrect.

* This Instruction Manual may not be reproduced in whole or part.

* Please note that the specifications in this Instruction Manual may be subject to change for improvement without notice.

* The artwork in the Instruction Manual is just for reference and may be differ from the actual situation.

* The artwork (boots and boot pads) in the Instruction Manual is "Regular" type.

* In this Instruction Manual, the levitator including "Levitator Stirrup II Main Unit, Right Leg" and "Levitator Stirrup II Main Unit, Left Leg" is collectively referred to as "Levitator Stirrup".

*Levitator Stirrup has respective types for left and right legs and the artwork may need to be inverted right and left as necessary.

1. Precautions for Use

1-1 Preface

This Instruction Manual is provided for the purpose of ensuring the safety and correct use of Levitator Stirrup.

Please carefully read and get a full understanding of this Instruction Manual before attempting actual use of the product.

If the Instruction Manual is lost or damaged, please contact your dealer or MIZUHO sales outlet.

1-2 Pictorial indication

This Instruction Manual uses various pictures to ensure safety and correct use of Levitator Stirrup so as to protect the user and patients and prevent damage to property.

The pictorial indication means:



Warning

Indicates that failure to observe this indication when handling the product could result in death or personal injury.



Caution

Indicates that failure to observe this indication when handling the product could result in personal injury or property damage.

Supplement

Indicates supplemental information on the function of the product.

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.

1-3 Levitator Stirrup

Levitator Stirrup is an accessory for operating tables used as a device to support the patient's leg in operations requiring lithotomy position.

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

The followings are the product codes and trade names.

1) Set codes












Product code	Product description	Remarks
18-070-91	Levitator Stirrup II Set, Regular, Right Leg	18-070-21, 18-070-41, 18-070-93
18-070-92	Levitator Stirrup II Set, Regular, Left Leg	18-070-22, 18-070-42, 18-070-94

2) Elemental codes

Product code	Product description
18-070-21	Boot for Levitator Stirrup II, Regular, Right Leg
18-070-22	Boot for Levitator Stirrup II, Regular, Left Leg
18-070-23	Boot for Levitator Stirrup II, Fin Type, Right Leg
18-070-24	Boot for Levitator Stirrup II, Fin Type, Left Leg
18-070-25	Boot for Levitator Stirrup II, Short, Right Leg
18-070-26	Boot for Levitator Stirrup II, Short, Left Leg
18-070-27	Boot for Levitator Stirrup II, Wide, Right Leg
18-070-28	Boot for Levitator Stirrup II, Wide, Left Leg
18-070-41	Boot Pad for Levitator Stirrup II, Regular, Right Leg
18-070-42	Boot Pad for Levitator Stirrup II, Regular, Left Leg
18-070-43	Boot Pad for Levitator Stirrup II, Fin Type, Right Leg
18-070-44	Boot Pad for Levitator Stirrup II, Fin Type, Left Leg
18-070-45	Boot Pad for Levitator Stirrup II, Short, Right Leg
18-070-46	Boot Pad for Levitator Stirrup II, Short, Left Leg
18-070-47	Boot Pad for Levitator Stirrup II, Wide, Right Leg
18-070-48	Boot Pad for Levitator Stirrup II, Wide, Left Leg
18-070-93	Levitator Stirrup II Main Unit, Right Leg
18-070-94	Levitator Stirrup II Main Unit, Left Leg

- The main unit (18-070-93, 18-070-94) does not include the boot and boot pad.

1-4 Symbol

	Warning		General prohibition
	Caution		Refer to the Instruction Manual (Refer to this book)
	Mandatory obligation		Medical Device
	Manufacturer		Catalogue number
	Date of manufacture		Batch code
	European authorized representative		



Warning



- Fixate the product so as not to compress peroneal nerve with the movable portion. External rotation of the lower thigh may cause peroneal nerve disorder.



- Be sure to check the above in the following conditions during surgery. In the case of a surgical procedure requiring an extended period of time, compartment syndrome due to oppression and/or nerve disorder, nerve palsy and/or bed sore due to extension may occur.
 1. When the patient's legs are to be reset
 2. When the surgery takes an extended period of time
 3. When a support rod is elevated



Caution



- Use the product only for the surgical purposes.



- Get a full understanding of this Instruction Manual before attempting to use the product. Pay careful attention to the safety of a patient and use the product in accordance with the Instruction Manual. Failure to do so could result in serious defect or adverse event.



- Securely tighten the fixing handle. If not, Levitator Stirrup may move and result in injury to the patient.



- The combined use with an operating table made by another company has not been verified. Do not use on operating tables made by any other manufacturer.



- In order to prevent blood flow obstruction, make sure excessive stress is not applied to the muscles or nerve before and during surgery.



- During use, check for blood flow obstruction through dorsal pedis artery tactile, skin color and the presence or absence of sensation of cold.



- Support portions for both legs must be set symmetrically. Misalignment may cause serious nerve disorder, circulation disorder and/or blood flow obstruction at the hip.



Caution



- Since change in the boot angle changes the pressure in the area of contact between the leg and boot, the boot must always be adjusted with the boot handle while holding the boot. Abrupt movement of a boot may cause serious nerve disorder, circulation disorder and/or blood flow obstruction.



- Since widened angle of split legs may place significant stress on the lateral lower thigh, the height and angle of split legs must be adjusted slowly. Abrupt movement may cause serious nerve disorder, circulation disorder and/or blood flow obstruction.



- Be sure to check that the fastened part is secured. If not, the device may move and injure the patient.



- Observe allowable patient weight (not more than 270 kg). Failure to do so may result in damage to the device or accident such as patient dropping.



- When mounting or dismounting the product, be sure to rotate the fixing handle while holding the leg support rod. If you rotate it without holding the boot, the device may drop, resulting in injury or damage.



- To maintain hygiene, be sure to use a sterilized drape on the contact area (boot pad, etc.) between the patient and Levitator Stirrup



- When adjusting the operating table, be careful of contact/interference with other accessories or top of the operating table.



- For use on a divided operating table, be sure to dismount Levitator Stirrup before detachment/attachment. While mounted, the device cannot be attached or dismounted.



- To maintain hygiene, be sure to use a sterilized drape on the contact area (boot pad, etc.) between the patient and Levitator Stirrup.



- Be sure not to exceed the range of motion of the arm angle. Pushing it beyond the range of motion will lead to part damage.

2. Name and overview of each part

2-1 Names of parts

A summary is provided on the following page.

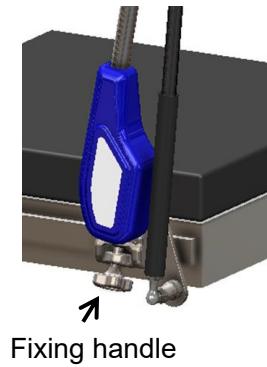


2-2 Overview of each part

1. Fixing handle (fixing clamp)

Mount the Levitator Stirrup on the side rail of the operating table waist plate and fix it.

* Mounting horizontally or diagonally may result in insufficient tightening of the fixing handle, which in turn may result in the part becoming detached from the side rail. (See page 14 for details.)



○: Correct mounting method



×: Incorrect mounting method: a (horizontal)

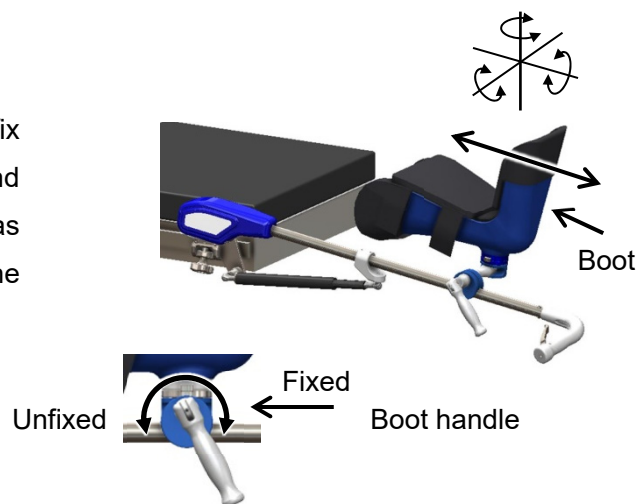


×: Incorrect mounting method: b (diagonal)

2. Boot handle 3. Boot

Adjust the boot position.

Rotate the handle clockwise to fix and counterclockwise to unfix and adjust the position. (orientation as seen from the condition in the illustration on the right)



4. Boot pad

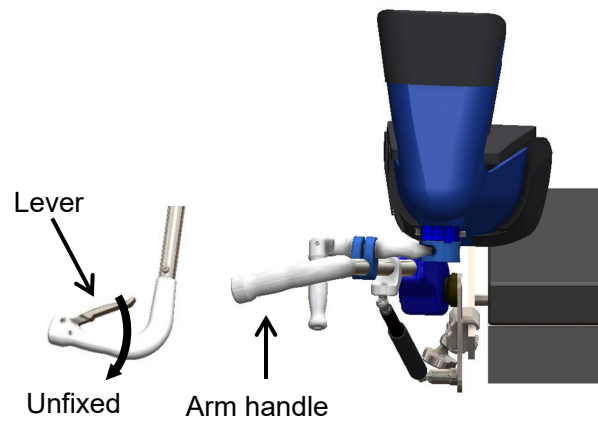
Encases the leg, heel region and lower calf.



5. Arm handle


Adjust the height and angle of split legs.

Grip the lever of the arm handle to unfix and adjust the position. Release the lever of the arm handle to fix.




3. Operation method

3-1 Mounting the boot and boot pad



Caution



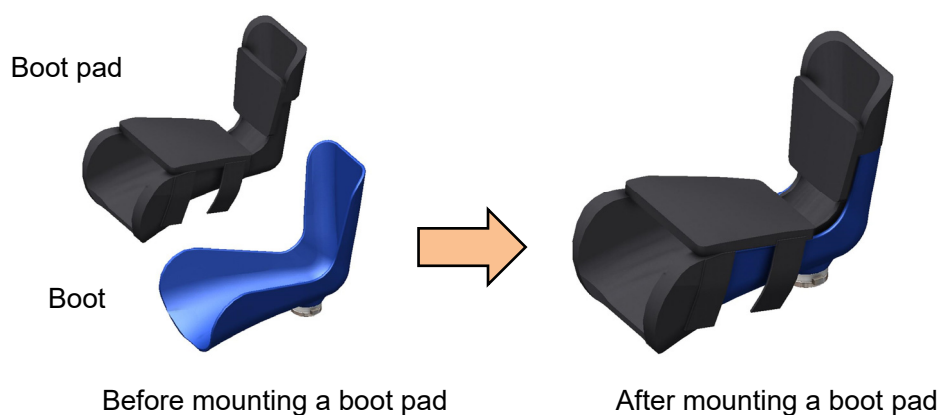
- Use a boot pad compatible with the boot to be used.

1) Mounting a boot pad compatible with the boot.

Overlay the boot pad over the boot in line with the boot shape.

Fix it using Velcro fastener.

To remove, perform the mounting procedure in reverse.



Matching List of Boots and Boot Pads

Product code and Product description		Product code and Product description
18-070-21 Boot for Levitator Stirrup II, Regular, Right Leg	↔	18-070-41 Boot Pad for Levitator Stirrup II, Regular, Right Leg
18-070-22 Boot for Levitator Stirrup II, Regular, Left Leg	↔	18-070-42 Boot Pad for Levitator Stirrup II, Regular, Left Leg
18-070-23 Boot for Levitator Stirrup II, Fin Type, Right Leg	↔	18-070-43 Boot Pad for Levitator Stirrup II, Fin Type, Right Leg
18-070-24 Boot for Levitator Stirrup II, Fin Type, Left Leg	↔	18-070-44 Boot Pad for Levitator Stirrup II, Fin Type, Left Leg

Product code and Product description		Product code and Product description
18-070-25 Boot for Levitator Stirrup II, Short, Right Leg	↔	18-070-45 Boot Pad for Levitator Stirrup II, Short, Right Leg
18-070-26 Boot for Levitator Stirrup II, Short, Left Leg	↔	18-070-46 Boot Pad for Levitator Stirrup II, Short, Left Leg
18-070-27 Boot for Levitator Stirrup II, Wide, Right Leg	↔	18-070-47 Boot Pad for Levitator Stirrup II, Wide, Right Leg
18-070-28 Boot for Levitator Stirrup II, Wide, Left Leg	↔	18-070-48 Boot Pad for Levitator Stirrup II, Wide, Left Leg

⚠ Caution



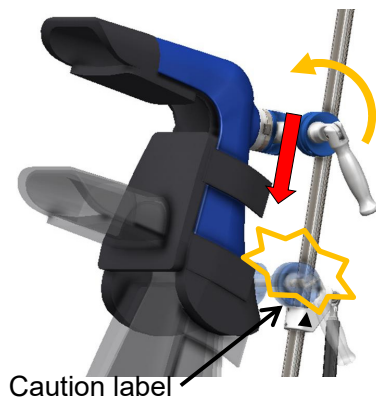
- Note that there are respective types for right and left legs.



- Hold the boot firmly when adjusting.
If the boot handle is loosened without holding it firmly, the boot may fall and pinch fingers or damage the parts. (Potential health hazard.)



Caution label



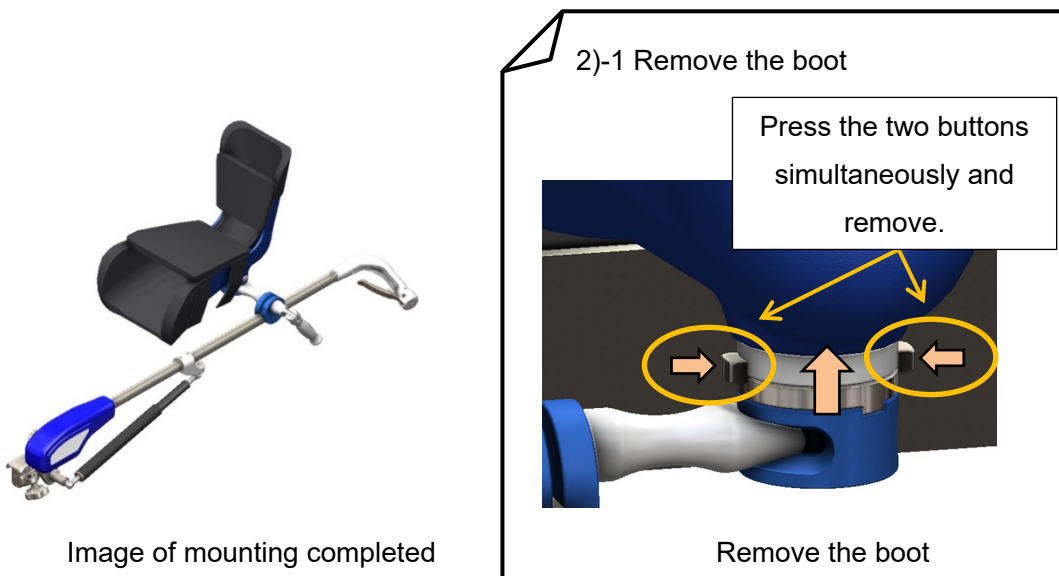
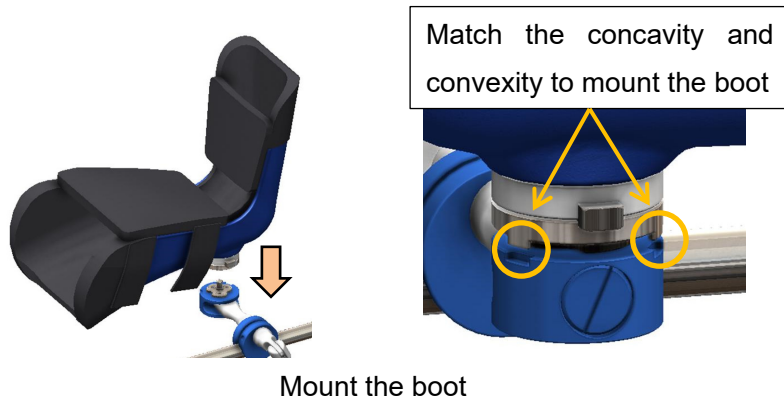
Caution label

2) Mounting a boot.

Match the concavity and convexity at the attaching portion to mount it. When attached, it clicks in place.

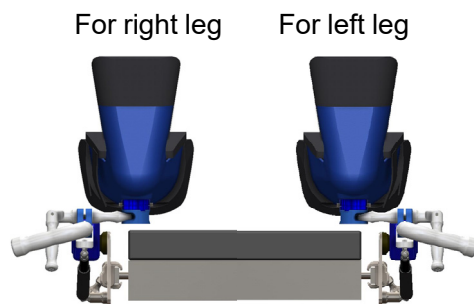
Make sure the boot is secured so it does not come off.

To remove, press the two buttons at the bottom of the boot and the boot will come off.



Supplement

- There are respective boots for right and left legs.
Use the right (left) leg for the patient's right (left) leg.



3-2 Mounting on the operating table

More than two persons should be involved in this operation to prevent injury or damage.

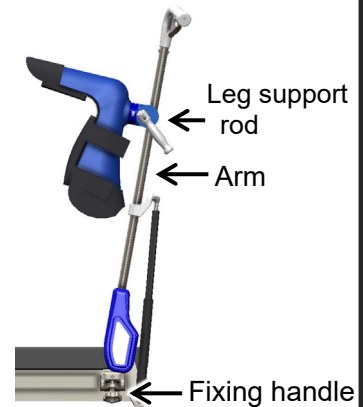
Caution



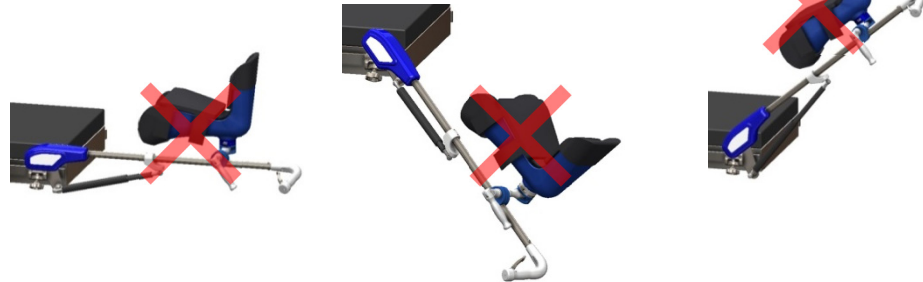
- Securely tighten the fixing handle.
If not, Levitator Stirrup may move and result in injury to the patient.



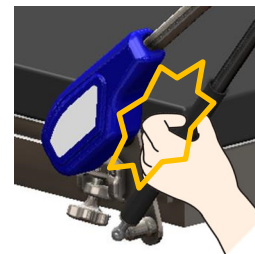
- When mounting the Levitator Stirrup, be sure to turn the fixing handle while holding the arm or leg support. If you turn the fixing handle without holding, the Levitator Stirrup will fall and cause damage. When doing so, be careful not to press the button for boot removal.



- If the Levitator Stirrup is mounted horizontally or diagonally on the side rails, the fixing handle may not be sufficiently tightened, resulting in the device becoming detached from the side rails.



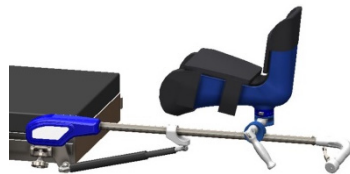
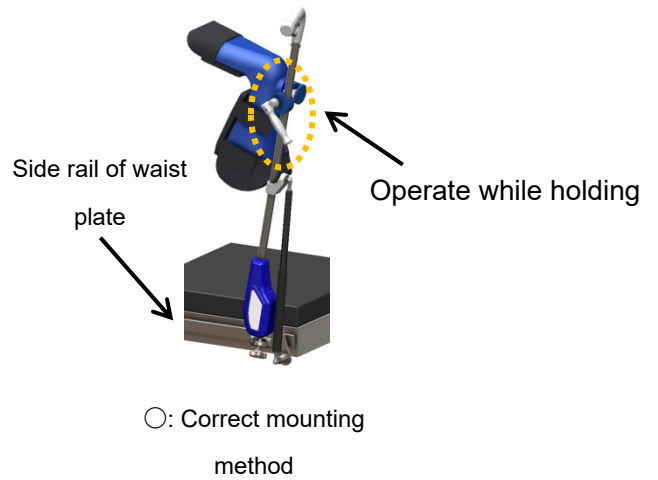
- When standing the arm of the Levitator Stirrup, be careful not to pinch your fingers in the position shown.
(Potential health hazard.)



1) Mount the Levitator Stirrup while holding the arm and leg support with the arm upright against the side rail of the operating table waist plate (right figure: correct mounting method).

If the Levitator Stirrup is mounted horizontally or diagonally on the side rails (Incorrect mounting method: a and b in the figure), the fixing handle may not be tightened enough and may come off the side rails.

* The operating table (side rail) manufactured by our company is the only one for which fixation has been verified. Do not use on operating tables manufactured by any other company.

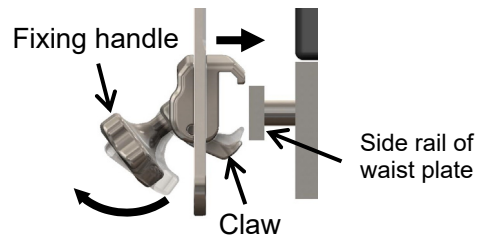


×: Incorrect mounting method: a (horizontal)



×: Incorrect mounting method: b (diagonal)

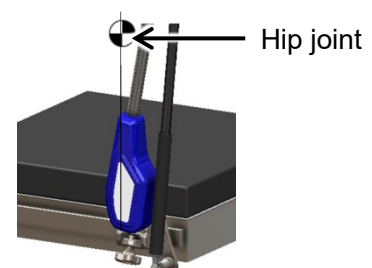
1)-1 Lift the fixing handle to open the claw. Hook the Levitator Stirrup on the side rail of the waist plate.



1)-2 Make sure the Levitator Stirrup is hooked and tighten the fixing handle. Be sure that it is properly fixed to the side rail of the waist plate.



2) Position the patient's hip joint as shown and tighten the fixing handle. Make sure the Levitator Stirrup is properly fixed to the side rail of the waist plate before attempting to use.



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3-3 Removing Levitator Stirrup from the operating table

Two or more persons should be involved in this operation to prevent injury or damage.

Caution

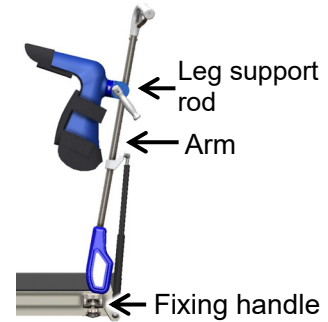
- When removing the Levitator Stirrup, keep the arm upright as shown in the figure.



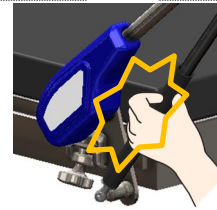
- When removing the Levitator Stirrup, be sure to turn the fixing handle while holding the arm or leg support. When doing so, do not press the button for boot removal.



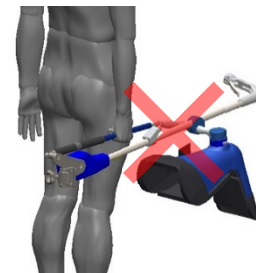
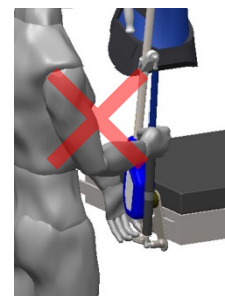
If you turn the fixing handle without holding the arm or leg support, the Levitator Stirrup will fall and cause damage.



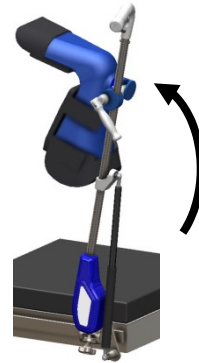
- When standing the arm of the Levitator Stirrup, be careful not to pinch your fingers in the position shown. (Potential health hazard.)



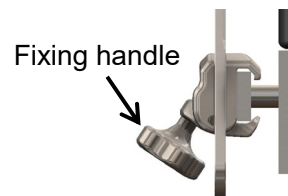
- Do not grab the gas cylinder (including the cover) and remove it from the operating table or move it while holding it. Excessive load may be applied to the gas cylinder, leading to deformation or damage.



- 1) Put the arm of Levitator Stirrup in the upright position as shown in the figure on the right.



- 2) Loosen and remove the fixing handle while holding the arm and leg support of Levitator Stirrup.



3-4 Setting the patient leg

Warning

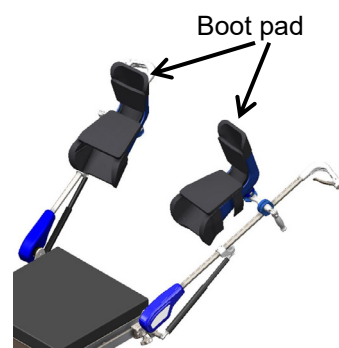


- Support portions for both legs must be set symmetrically.
Misalignment may cause serious nerve disorder, circulation disorder and/or blood flow obstruction at the patient's hip.

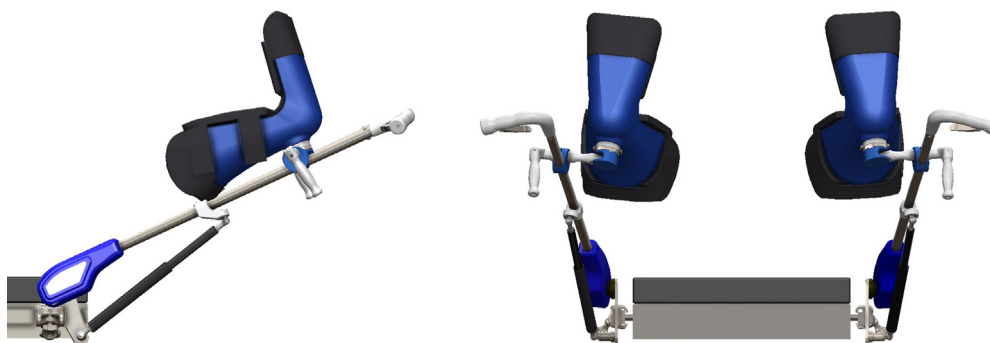
Caution



- In order to prevent blood flow obstruction and perceptual disorder caused by oppressing the patient leg, use a boot pad.



- 1) Placing the leg support rods at the same length and height, put the patient legs into the boots (boot pads).



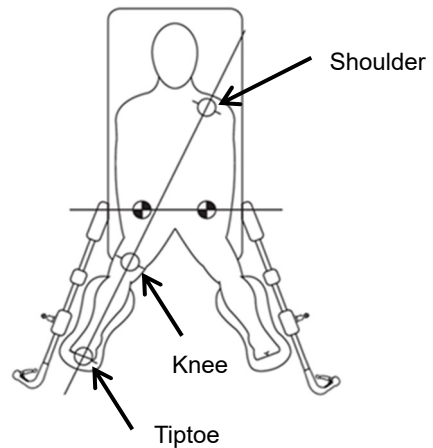


Warning



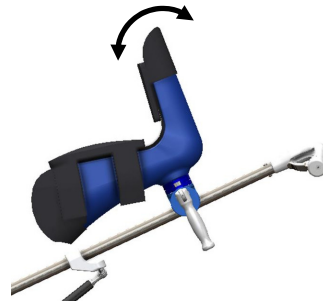
- A boot must always be adjusted with the boot handle while holding the boot. Change in the boot angle also changes the pressure in the area of contact between the leg and boot. Abrupt movement of the boot may result in injury to the patient.

- 2) Adjust the boot so that the tiptoe, knee and the opposite shoulder are aligned as shown in the right sketch.



Supplement

- The boot can move in the direction of the arrow even with the boot handle is fixed to prevent injury to the patient's tendons.





Warning

- Slowly adjust the height and angle of split legs.



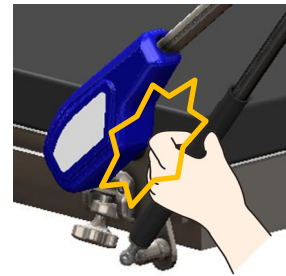
Widening the angle of split legs may place significant stress on the lateral lower thigh.

Abrupt movement may result in injury to the patient.



Caution

- When standing the arm of the Levitator Stirrup, be careful not to pinch your fingers in the position shown.
(Potential health hazard.)



- When adjusting an operating table, be careful of contact between Levitator Stirrup and the table top.

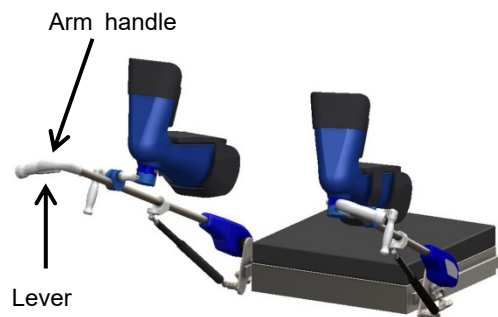


- For use on a divided operating table, move Levitator Stirrup for detachment so that it does not come into contact with the stretcher rail receiving part.

3) Pull the lever, move the arm handle and adjust the height and angle of split legs.

* In an actual situation, a patient would be on the device.

* During position alignment, be careful not to entangle or tuck the patient, drape, etc., as the device would be covered with a sterilized drape in an actual situation.



3-5 Checks before and during surgery



Warning



- Check the patient condition and for any oppressed region, before and during surgery, in order to prevent compartment syndrome, nerve disorder, nerve palsy and/or bedsore.

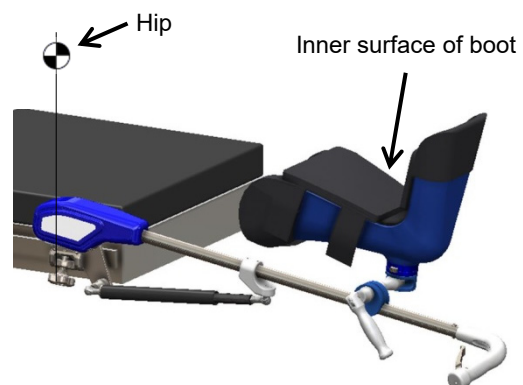


- Be sure to check the above items in the following conditions during surgery.
 - 1) When the patient's legs are to be reset
 - 2) When the surgery takes an extended period of timeEspecially in a long surgical procedure, nerve disorder may occur due to extension.

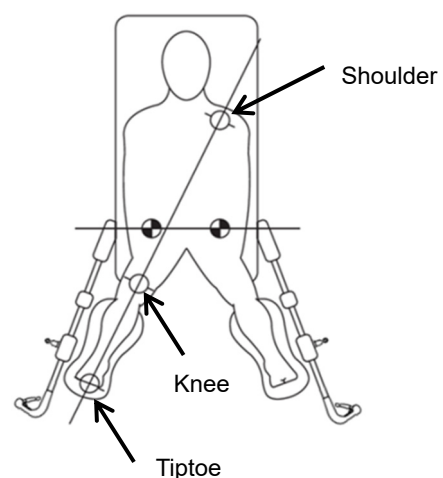
Place your hand between the boot and leg and/or conduct visual observation to check the following:

- 1) Is there any area where the leg subjected to excessive pressure by the inner surface of the boot?

* In an actual situation, this would be checked while a patient is on the device.



- 2) Does the body position produce excessive physiological strain?



4. Maintenance check



Caution

Cleaning and disinfection



- Follow the instruction manual for the disinfectant used for cleaning; do not use any product that has a negative impact on metal or resin. Observe the content of the label and Instruction Manual of the disinfectant to be used.

Adjustment, replacement and repair



- Adjustment, replacement and repair require professional knowledge. Be sure to contact your dealer or MIZUHO for adjustment, replacement or repair, if required. Adjustment, replacement or repair by a person without professional knowledge may not only result in incorrect execution, but may also result in injury.

In case of faulty equipment



- Identify any faulty Levitator Stirrup as “Out of Order” or “Do not use” to avoid use.

4-1 Check before and after use

- 1) Can the fixing handle be fixed in a secure manner?
- 2) Can the boot handle be fixed/unfixed in a secure manner?
- 3) Is the boot adjustable?
- 4) Can the arm handle be fixed/unfixed, and the height and angle of split legs be adjusted in a secure manner?
- 5) Is there any broken part of Levitator Stirrup as a whole (main unit, boot, boot pad, etc.)?
If you find anything out of the ordinary, please contact your dealer or MIZUHO for repair.

4-2 Cleaning and disinfection

Wipe off blood, chemicals, waste, etc. with water and clean with alcohol gauze for disinfection.

4-3 Servicing

If you have any question about servicing such as repair, please consult with your dealer or MIZUHO.

4-4 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.

Requests to customers

A. Disinfection, etc., of a medical device

Before and after making a request for maintenance check or repair, please clean and disinfect the medical device. Your cooperation would be appreciated to prevent infection to persons involved in maintenance check or repair and patients.

B. Disposition of medical waste

Medical waste with infectious substances attached is called "infectious waste" under the Wastes Disposal and Public Cleansing Act and classified as "specially controlled waste."

When disposing of "infectious waste;" please dispose of it properly.

C. Disposal of this product

This device must be disposed of in accordance with local regulations.

Please contact your local distributor for proper disposal.

5. Specifications

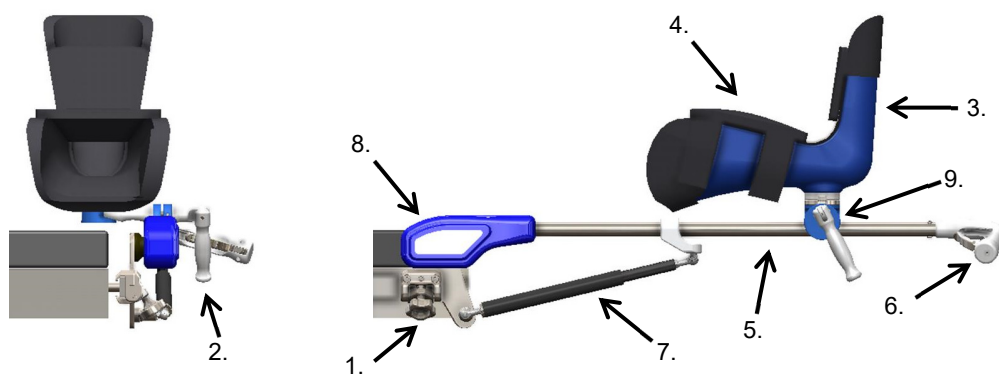
5-1 Specifications

Trade name	Levigator Stirrup
Arm angle (on the basis of a horizontal position)	Up: 80°, Down: 35°, Inward rotation: 10°, Outward rotation: 30°
Boot range of motion (on the basis of a horizontal position)	Back and forth: 360°, Up and down: 360°, Left and right total: 50°
Boot slide volume	340 mm
Mass	Regular set (One leg): Approx. 6.5 kg
Allowable patient weight	Not more than 270 kg
Storage environment	Ambient temperature range: 10 °C – 40 °C Relative humidity range: 30 % - 70 % Pressure range: 700 hPa - 1060 hPa
Durable period [as per self-authentication]: Note	Boot pad: 2 years Other than boot pad: 5 years

Note: In the case of proper maintenance check and proper storage.

In the case of unexpected failure, significant consumption, deterioration, damage, etc., the part in question must be replaced even during the durable period depending on the use conditions or frequency of use.

5-2 External view

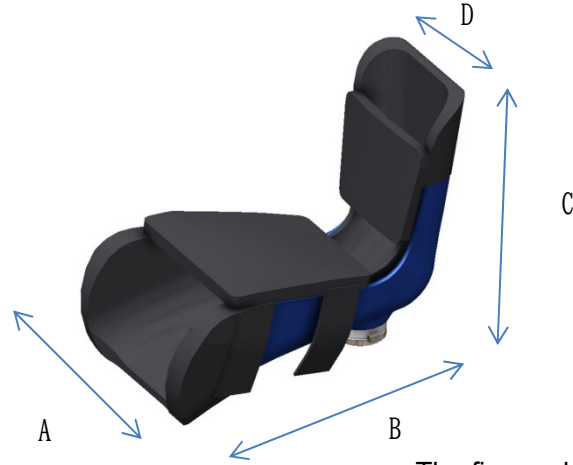


The above indicates the product for right leg and regular boot and boot pad.

- | | | |
|---------------------------------|----------------|--------------------|
| 1. Fixing handle (fixing clamp) | 2. Boot handle | 3. Boot |
| 4. Boot pad | 5. Arm | 6. Arm handle |
| 7. Gas cylinder | 8. Joint | 9. Leg support rod |

5-3 Guideline for outer dimensions of boot pad

This is a guideline for the outer dimensions of the product with the boot pad mounted on the boot.



The figure shows a regular type.

Type	A (mm)	B (mm)	C (mm)	D (mm)	Remarks
Regular	250	400	330	185	a, b
Fin Type	265	555 (no fins: 400)	330	185	c, d
Short	170	285	270	150	e, f
Wide	275	475	330	185	g, h

	Product code	Product description
a	18-070-21 18-070-41	Boot for Levitator Stirrup II, Regular, Right Leg Boot Pad for Levitator Stirrup II, Regular, Right Leg
b	18-070-22 18-070-42	Boot for Levitator Stirrup II, Regular, Left Leg Boot Pad for Levitator Stirrup II, Regular, Left Leg
c	18-070-23 18-070-43	Boot for Levitator Stirrup II, Fin Type, Right Leg Boot Pad for Levitator Stirrup II, Fin Type, Right Leg
d	18-070-24 18-070-44	Boot for Levitator Stirrup II, Fin Type, Left Leg Boot Pad for Levitator Stirrup II, Fin Type, Left Leg
e	18-070-25 18-070-45	Boot for Levitator Stirrup II, Short, Right Leg Boot Pad for Levitator Stirrup II, Short, Right Leg
f	18-070-26 18-070-46	Boot for Levitator Stirrup II, Short, Left Leg Boot Pad for Levitator Stirrup II, Short, Left Leg
g	18-070-27 18-070-47	Boot for Levitator Stirrup II, Wide, Right Leg Boot Pad for Levitator Stirrup II, Wide, Right Leg
h	18-070-28 18-070-48	Boot for Levitator Stirrup II, Wide, Left Leg Boot Pad for Levitator Stirrup II, Wide, Left Leg



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