

Imaging Armboard Operator's Manual

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This product is designed for medical operations. Using this product for any other purpose other than this intended use may cause serious injury.

The operator and the person in charge of the maintenance of this product must read this operator's manual thoroughly and understand the contents before operating, inspecting, adjusting and maintaining it.

Keep this manual for reference in a place where is readily accessible.

1. Introduction

1-1. This manual

This manual contains information for safely and effectively using this product. Before operating this product, read this manual thoroughly to understand how to operate and inspect the product. Failure to follow these instructions could lead to serious injury.

The safety information is categorized as per the following so that the contents of warnings and cautions, and the details of warnings and cautions which are labeled on the product may be comprehended.



If this indication is ignored and the product is incorrectly used, serious injury or death may result.



If this indication is ignored and the product is incorrectly used, injury and/or damage to property may result.

NOTE

This notice notes additional information on the product's functions.

The warning and caution notices on this manual relating to operating and inspecting, apply to the intended use (surgical operations) of this product. If the product is used for purposes other than surgery, the user is responsible in regard to safety for performing operations and inspections which are not contained in this manual.

1-2. Intended purpose

This product is an accessory which is attached on the operating table, and it is a surgical instrument for hand surgeries.



When using this product, 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.



- This product is only validated for use with Mizuho operating tables.
 - 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.
 - For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.
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1-3. Intended user

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

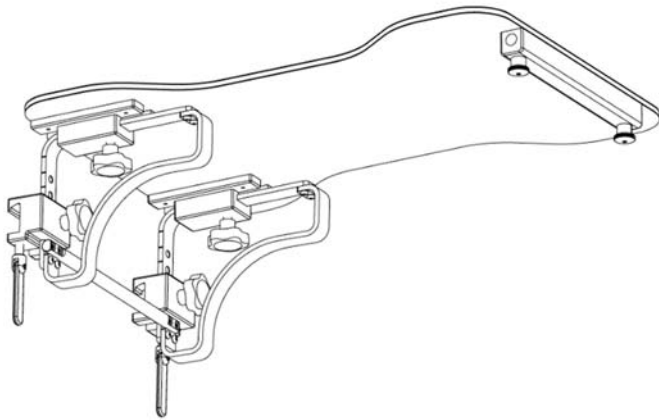
1-4. Symbol mark for labeling

MD : Medical Device

2. Component

The components of this product are as follow.

■ Standard components

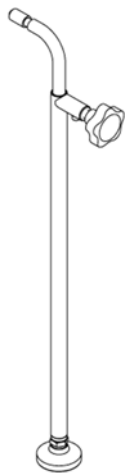


Imaging Armboard II

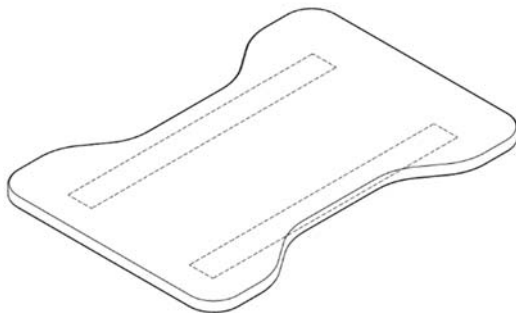


Operator's Manual

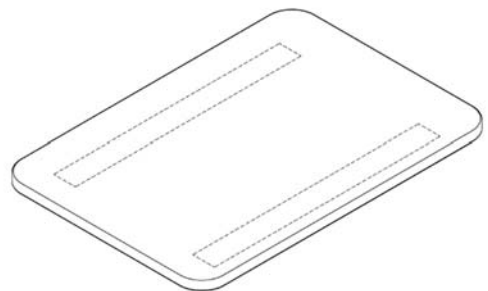
■ Optional parts



Support Rod for Imaging Armboard II



Pad for Imaging Armboard II, Hourglass



Pad for Imaging Armboard II, Rectangle

3. Instruction for use

The operation methods for this product are as per the following.



Ensure all fixing sections are tight. Loose condition can cause the product to come off or move, which may result in a patient injury.

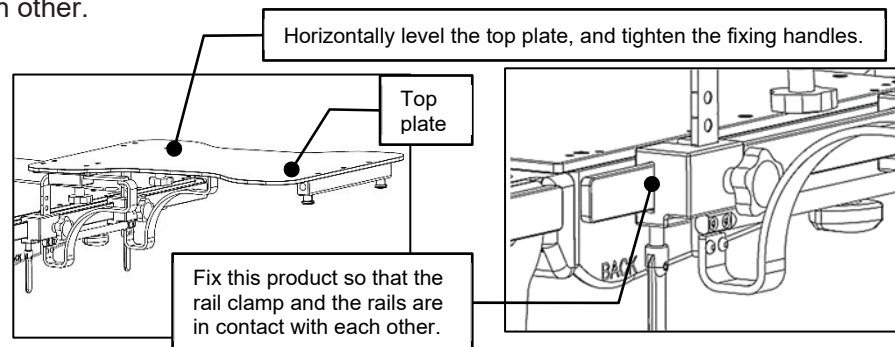
3-1. Operations for the Imaging Armboard II



The Imaging Armboard II weighs 5.5 kg. Pay special attention when handling it. It may drop and cause damage or injury.



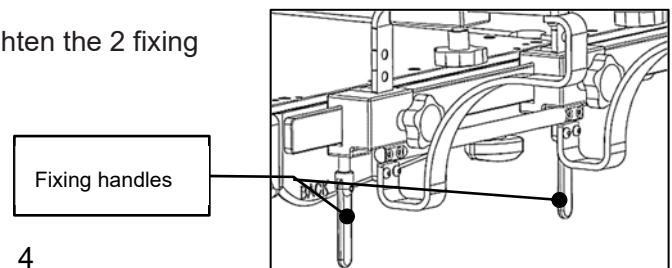
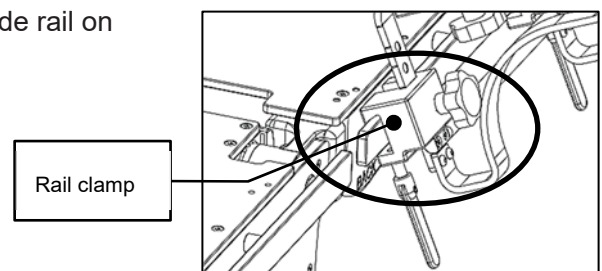
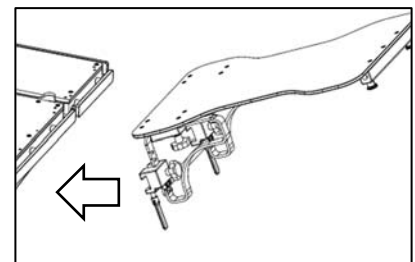
- When attaching the Imaging Armboard II on the operating table, horizontally level the top plate, and fix this product by tightening the fixing handles so that the side rails on the operating table and the rail clamp on this product are in contact with each other.



- After firmly tightening the knob screws and the fixing handles, check that they are fixed.
- When operating the operating table, be careful not to make contact with the operators or devices in the surroundings.

<Attaching the Imaging Armboard II onto the operating table>

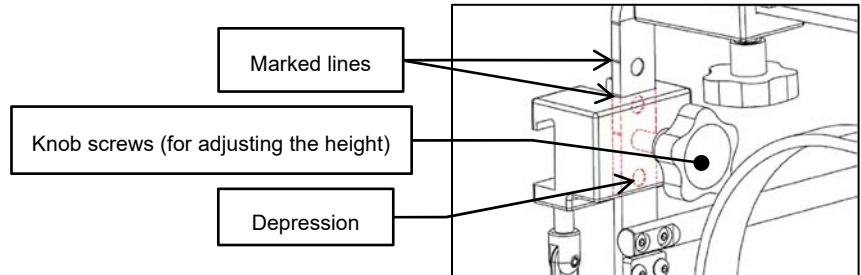
1. Tilt the Imaging Armboard II diagonally.
2. Hook the rail clamp onto the back section side rail on the operating table.
3. Horizontally level the top plate, and tighten the 2 fixing handles to fix it.



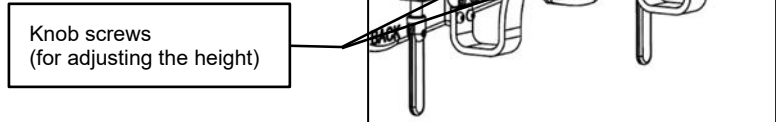
<Adjusting the height of the top plate>



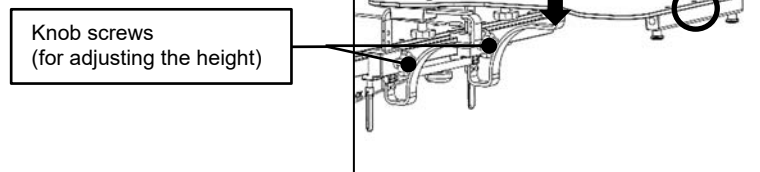
- When adjusting the height of the top plate, make sure to align the top edge of the rail clamp with the marked lines, and tighten the knob screws to fix it.
- If the knob screws are fixed without the top edge of the rail clamp being aligned with the marked lines, the tips of the knob screws will not fit into the depressions, so the top plate may result in dropping due to the loose knob screws.



1. Loosen the 2 height adjustment knob screws.
The height adjustment knob screws can be released by loosening them about one turn.



2. Hold the two places marked with the ○, and manually adjusting the height, then tighten the height adjustment knob screws to fix it.



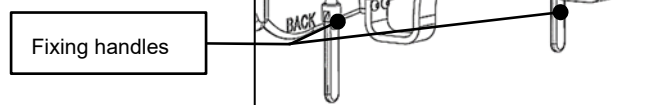
<Adjusting the extending and retracting (slide) of the top plate>

1. Loosen the 2 knob screws for fixing the extending and retracting, and adjust the sliding distance to the desired position, then tighten the knob screws to fix it.

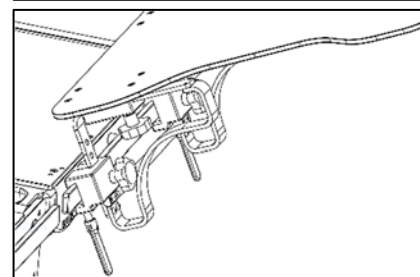


<Detaching the operating table and the Imaging Armboard II>

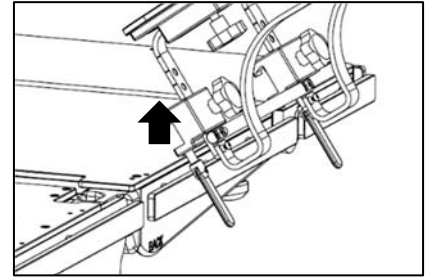
1. Hold the Imaging Armboard II and loosen the 2 fixing handles.



2. Lift the tip of the top plate, and tilt the Imaging Armboard II.



- Lift the Imaging Armboard II straight up, and detach the Imaging Armboard II from the operating table's side rails.



3-2. Operations for the Support Rod for the Imaging Armboard II

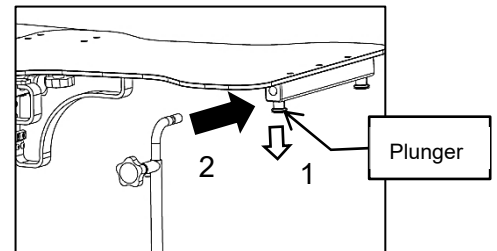
Use it when the top plate's deflection amounts affect the surgeries, such as microsurgeries, etc.



- Do not move down the tabletop of the operating table while the Support Rod for the Imaging Armboard II is attached to the Imaging Armboard II. The Support Rod for the Imaging Armboard II and top plate may get damaged.
- Use the Support Rod for the Imaging Armboard II within the operating table's elevation range, whereby the pole makes contact with the floor.

<Attaching the Support Rod for the Imaging Armboard II>

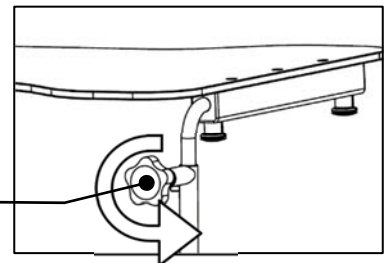
- Attach the Imaging Armboard II onto the operating table.
- Pull the plunger downward.
- Insert the Support Rod for the Imaging Armboard II into any desired mounting hole on the Imaging Armboard II and fix it. (There are 2 mounting holes and 2 plungers.)
- Release your hands from the plunger.



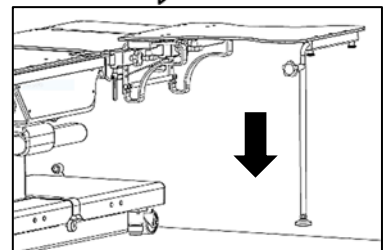
<Adjusting the height of the Support Rod for the Imaging Armboard II>

- Loosen the fixing knob screw of the Support Rod for the Imaging Armboard II.

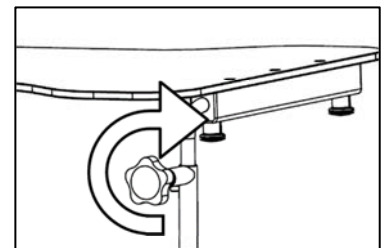
The fixing knob screw of the Support Rod for the Imaging Armboard II



- Extend the pole of the Support Rod for the Imaging Armboard II to the floor.

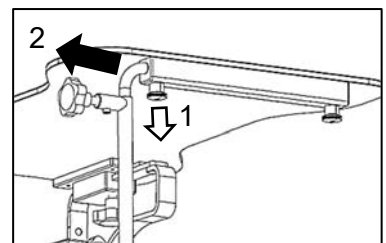


- Tighten the fixing knob screw of the Support Rod for the Imaging Armboard II to fix it.



<Detaching the Support Rod for the Imaging Armboard II>

- Pull the plunger downward.
- Pull the Support Rod for the Imaging Armboard II out of the Imaging Armboard II's mounting hole.
- Release your hands from the plunger.



3-3. Pad for Imaging Armboard II

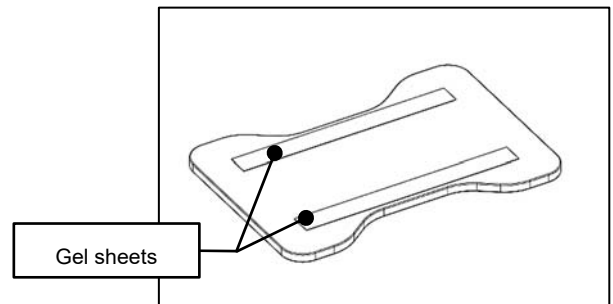
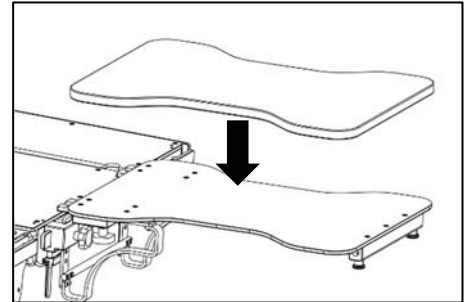
For the first time only, peel off the transparent protective film which is on the surface of the gel sheet before using.



If the gel sheets are dirty, or have liquids on them, then that may decrease their fixing force, and may cause the Pad for Imaging Armboard II to move in unintended directions during surgeries.

<Attaching the Pad for Imaging Armboard II >

1. Place the Pad for Imaging Armboard II on the top plate's surface.
Check that the gel sheets on the back are making contact with the top plate's surface, and that they do not move if the Pad for Imaging Armboard II is pushed on horizontally.

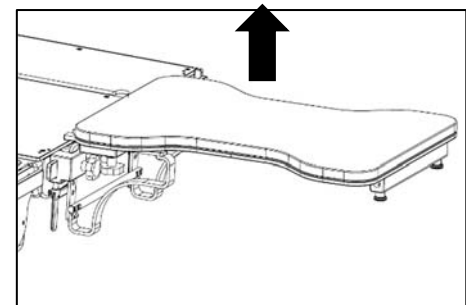


NOTE

Even if the full surface of the gel sheets on the Pad for Imaging Armboard II (rectangle) do not make contact with the top plate, there is not a usage problem.

<Detaching the Pad for Imaging Armboard II >

1. Peel off the Pad for Imaging Armboard II from the top plate's surface.
Peel off the gel sheets of the back along with the Pad for Imaging Armboard II so that they do not remain on the top plate's surface.



4. Maintenance/Inspection

4-1. Inspection before and after Use

Check that this product is not damaged or broken before and after each use.

4-2. Cleaning and Disinfection

- After using the Imaging Armboard II, the Support Rod for the Imaging Armboard II, and Pad for Imaging Armboard II (except for the gel sheets), make sure to follow the steps below to clean up and disinfect this product.
 - a) Detach this product from the operating table.
 - b) Use a lint-free cloth soaked with proper volume of disinfectant to wipe off the upper, side, and back side of the surface of this product.
 - c) Wipe off this product with a clean dry cloth 15 minutes after disinfecting it.Make sure to use Mizuho authorized disinfectants. The disinfectants are as shown below.

Disinfectants

- a) Sodium hypochlorite 0.1% (halogen containing compound)
 - b) Hypo Alcohol (iodine color removing agent)
 - c) Chlorhexidine (chlorhexidine gluconate 0.5%)
 - d) Benzalkonium chloride (invert soap 10%)
 - e) Povidone iodine
 - f) Ethanol 80%
 - g) Hydrogen peroxide
 - h) Isopropyl alcohol (IPA)
- How to clean the Pad for Imaging Armboard II, hourglass and rectangle gel sheets
Peel off only the gel sheets from the Pad for Imaging Armboard II, and wash them with water.
If the povidone iodine is on them for a prolonged time, that may cause discoloration.

4-3. Repair and Maintenance

- When this product is broken, clearly label the device as “Broken”, “Do not use”, “Need repair”, etc., and contact your local distributor or Mizuho.
- Only Mizuho or its certified agents can provide repair and maintenance services of this product. Services by other agents could cause adverse events and/or deterioration of the performance and functions.

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.

4-5. Disposal

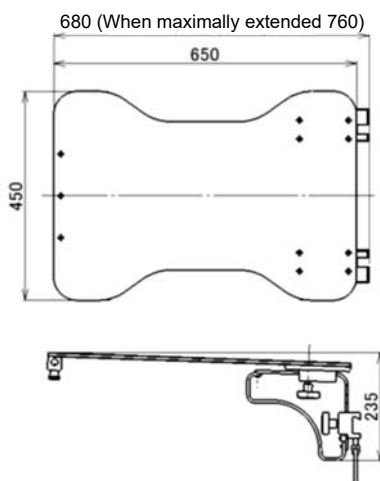
- This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

4-6. Notice

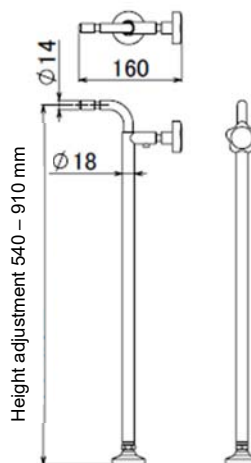
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

5. Specifications

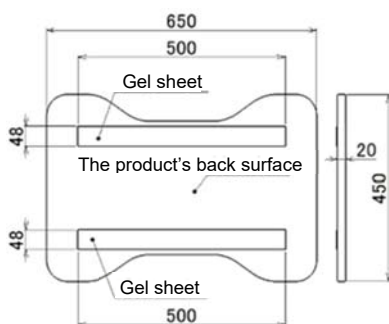
The specifications of this product are as follows.



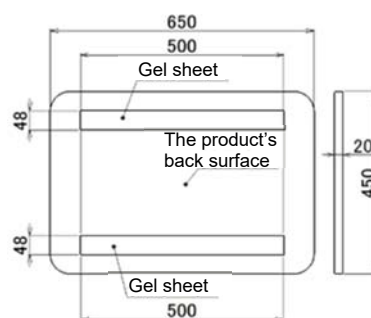
83-000-00 Unit: mm



83-000-01 (Optional) Unit: mm



83-000-02 (Optional) Unit: mm



83-000-03 (Optional) Unit: mm

Code No.	Product description	Weight	Weight capacity
83-000-00	Imaging Armboard II	5.5 kg	225 kg
83-000-01	Support Rod for Imaging Armboard II	1.1 kg	
83-000-02	Pad for Imaging Armboard II, Hourglass	0.4 kg	
83-000-03	Pad for Imaging Armboard II, Rectangle	0.5 kg	

Dimension	Printed in the above diagrams	
Operating environment	Temperature	10 to 40 °C (50 to 104 °F)
	Humidity	30 to 75 %
	Atmospheric pressure	700 to 1060 hPa
Transportation and storage	Temperature	-10 to 50 °C (14 to 122 °F)
	Humidity	10 to 85 % (without moisture condensation)
	Atmospheric pressure	700 to 1060 hPa
Service life	Subject to the specified maintenance and inspection and is stored properly: 7 years	
Replacement parts	Gel sheets: Replacement time 3 years	

NOTE

The replacement time is an estimated time. The replacement time may depend on usage condition and/or usage frequencies.

Revision Record

2023-06-28	Ver.1	New release





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