

Shoulder Positioner Operator's Manual

Table of Contents

1. Introduction.....	2
2. Component.....	3
3. Instructions for use	4
4. Maintenance / Inspection	5
5. Specifications	6

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

1. Introduction

1-1. Intended purpose

This product is used with Ultra shoulder positioner® patient care kit with rehab sling for supporting the patient's head and back when shoulder operations are being performed. Swap the head plate and the back plate of the applicable Mizuho operating tables with this product to use it.

1-2. Intended user

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

1-3. Warning/Caution

To ensure safe operation and proper functionality, please read the following instructions thoroughly before use and follow them carefully. Failure to follow these instructions could lead to serious injury of the patient or the user or damage to this product.



If these indications are ignored and the product is incorrectly used, death and/or serious injury may result.

- Do not use this product for any purposes other than the intended use. This product is designed for shoulder operations and cannot be used for other purposes.
 - 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.
 - Ensure all fixing handles are tight. Loose condition can cause the product to come off or move, which may result in a patient injury.
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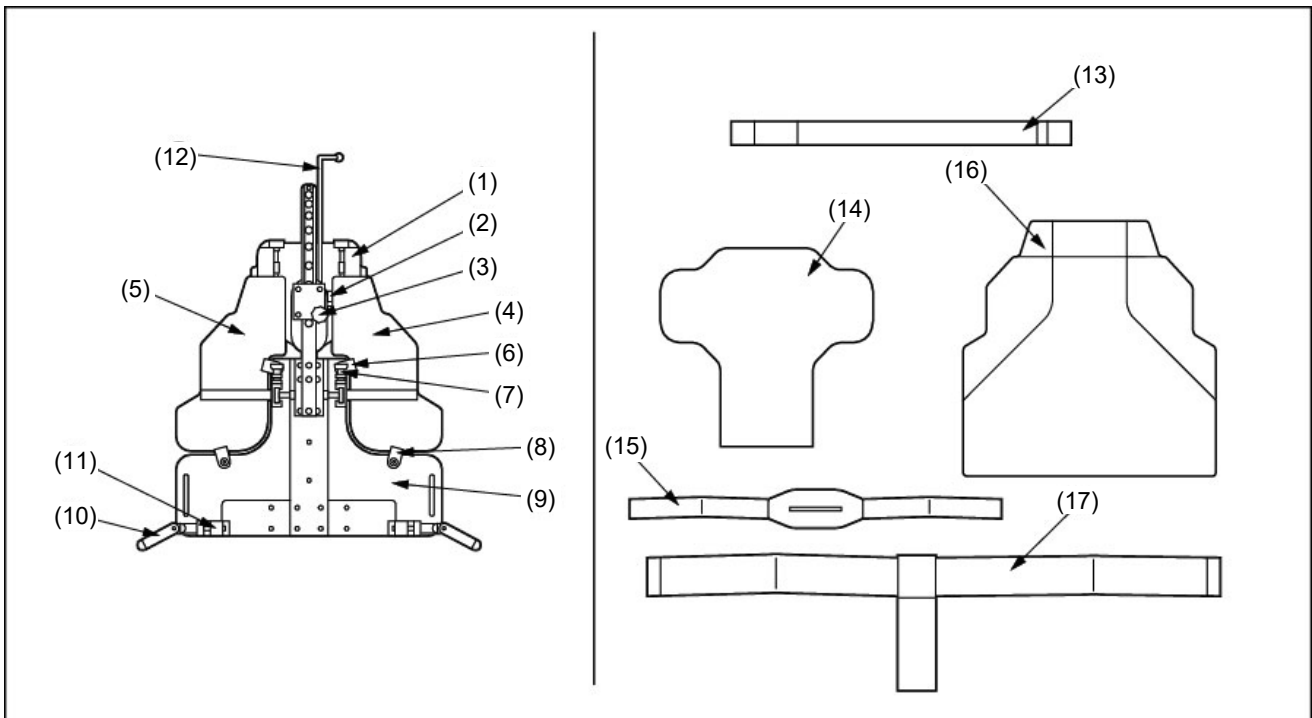
If these indications are ignored and the product is incorrectly used, injury and/or damage to property may result.

- Do not use this product with other company's operating table. This product is only validated for use with Mizuho operating tables. Do not use this product beyond the allowable load. Doing so may damage this product. (See the section "Specifications" for the allowable load.) Before attaching this product to the operating table, check that the tabletop is in the midpoint by using the sliding function.
 - Do not use the sliding function after this product is attached to the operating table.
 - Check that this product has been completely inserted to the operating table body.
 - 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.
 - 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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1-4. Symbol mark for labeling

MD : Medical Device

2. Component



Main body: Shoulder Positioner

Component	Material
(1) Head rest	Thermosetting resin laminated board
(2) Flexion positioning lever	Plastic
(3) Head rest sliding adjustment knob	Plastic
(4) Right shoulder panel	Thermosetting resin laminated board
(5) Left shoulder panel	Thermosetting resin laminated board
(6) Upper rotation lock	Plastic
(7) Plunger	Plastic
(8) Lower rotation lock	Plastic
(9) Back panel	Thermosetting resin laminated board
(10) Mounting handle	Aluminum alloy
(11) Adapter	Aluminum alloy
(12) Drape support rod	Stainless steel

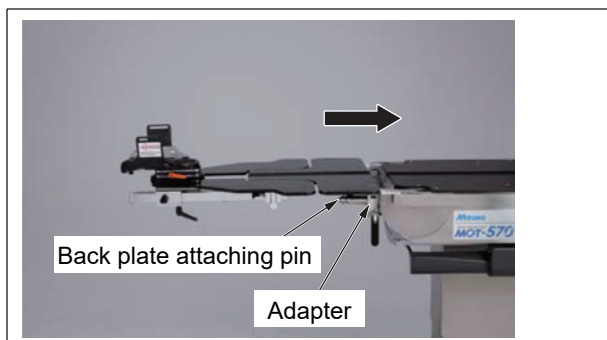
Option: Ultra shoulder positioner® patient care kit with rehab sling (3/case)

Component	Material
(13) Forehead strap	Plastic
(14) Head pad	Urethane foam
(15) Jaw strap	Plastic
(16) Back pad	Urethane foam
(17) Arm fixing strap	Plastic

Note: Ultra shoulder positioner® patient care kit with rehab sling (3/case) is the product of Mizuho OSI.

3. Instructions for use

The following describes how to attach, detach and operate this product.



1. Check that the tabletop is in the horizontal position by using the operating table's automatic re-leveling function.
2. Check that the tabletop is in the center position by using the sliding function of the operating table.
3. Remove the head plate and the back plate from the operating table.
4. Attach the Adapter part of the Shoulder Positioner to the back plate attaching pin on the operating table.
5. Attach the disposable patient care kit to the Shoulder Positioner.
6. Transfer and set the patient to the Shoulder Positioner.
7. Operate the back plate up function of the operating table to adjust the angle of the Back panel.
8. Use the Flexion positioning lever and Headrest sliding adjustment knob of the Head rest to adjust the head position.
9. After use, put the position and angle of the Head rest back to in place, detach the Adapter part of the Shoulder Positioner from the back plate attaching pin on the operating table, and then attach the head plate and the back plate to the operating table.

Note: Ultra shoulder positioner® patient care kit with rehab sling is disposable. Do not reuse this product.

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 this product, make sure to follow the steps below to clean up and disinfect this product.
 - a) Detach this product from the operating table.
 - b) Detach all the Ultra shoulder positioner® patient care kit with rehab sling (3/case) from this product.
 - c) Use a lint-free cloth soaked with proper volume of disinfectant to wipe off the upper, side, and back side of the surface of the product.
 - d) Wipe this product dry with a clean cloth within 15 minutes after disinfecting.
- Make sure to use Mizuho authorized disinfectants listed below.

Disinfectants

 - a) Sodium hypochlorite 0.1% (halogen containing compound)
 - b) Hypo Alcohol (iodine decolorant color removing agent)
 - c) Chlorhexidine (chlorhexidine gluconate 0.5%)
 - d) Benzalkonium chloride (invert soap 10%)
 - e) Povidone iodine
 - f) Ethanol 80%
 - g) Oxydol (hydrogen peroxide)
 - h) Saline
 - i) Isopropyl alcohol (IPA)

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 dealer 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.

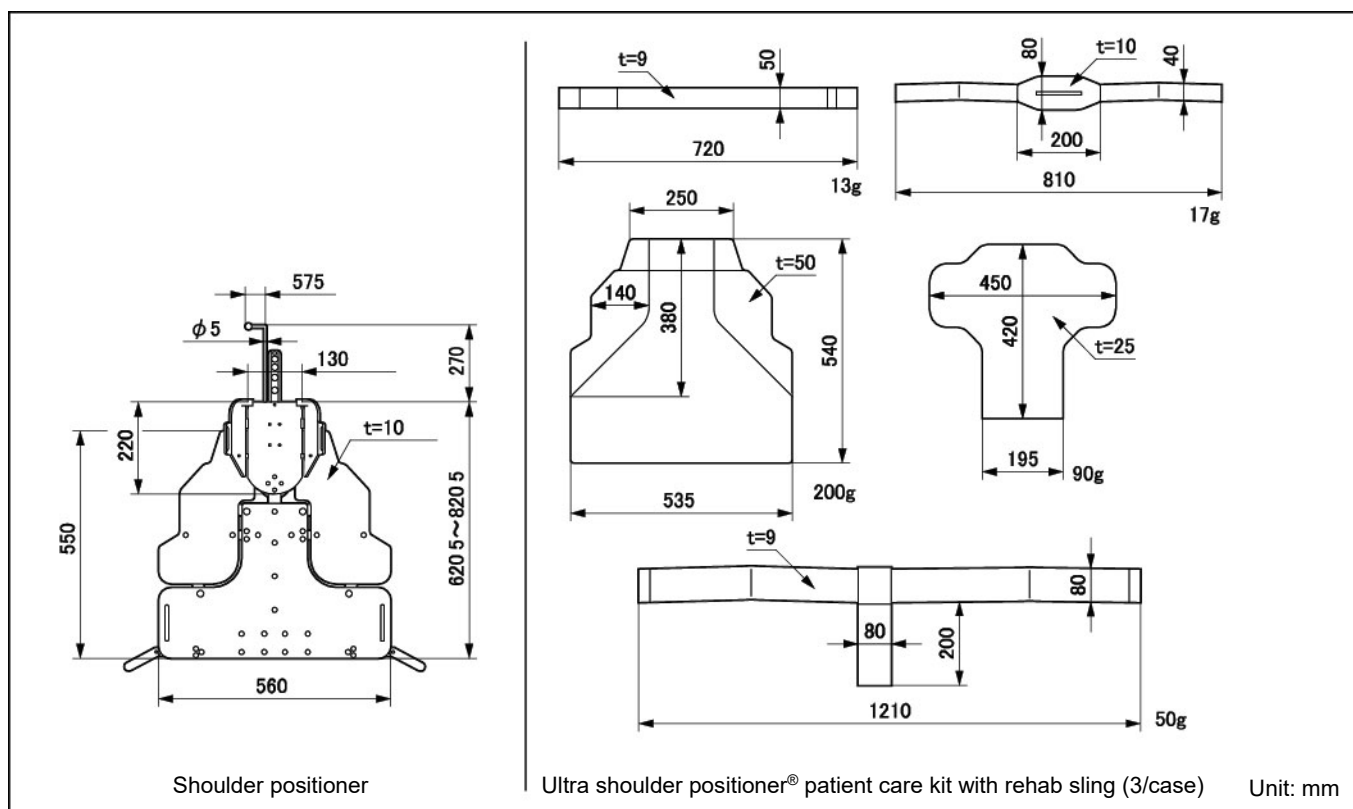
4-5. Disposal

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



Code No.	Product description	Weight (kg)	Component
08-068-22	Shoulder Positioner without Pad	9	(1) to (12)
5348	Ultra shoulder positioner® patient care kit with rehab sling (3/case)	-	(13) to (17)


Note: Ultra shoulder positioner® patient care kit with rehab sling (3/case) is the product of Mizuho OSI.

Head rest Specifications	Slide range	Max. 200 mm
	Lift range	Max. 115 mm
	Side adjustment angle	Max. 30° on each right and left
Allowable load	120kg: Amount of weights of the patient and devices used together.	
Operating environment	Temperature	10 to 40 °C
	Relative humidity	30 to 75 %
	Atmospheric pressure	700 to 1060 hPa
Transportation and storage environment	Temperature	-10 to 50 °C
	Relative humidity	10 to 85 %
	Atmospheric pressure	700 to 1060 hPa
Service life	7 years (Subject to the specified maintenance and inspection and is stored properly.)	





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Manufacturer:



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