

Shoulder Positioner 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. Intended purpose

This is an accessory for the operating table. This product is used with Pad for Shoulder Positioner for supporting the patient's head and back when shoulder operations are being performed. Swap the head section and the back section 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

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.



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

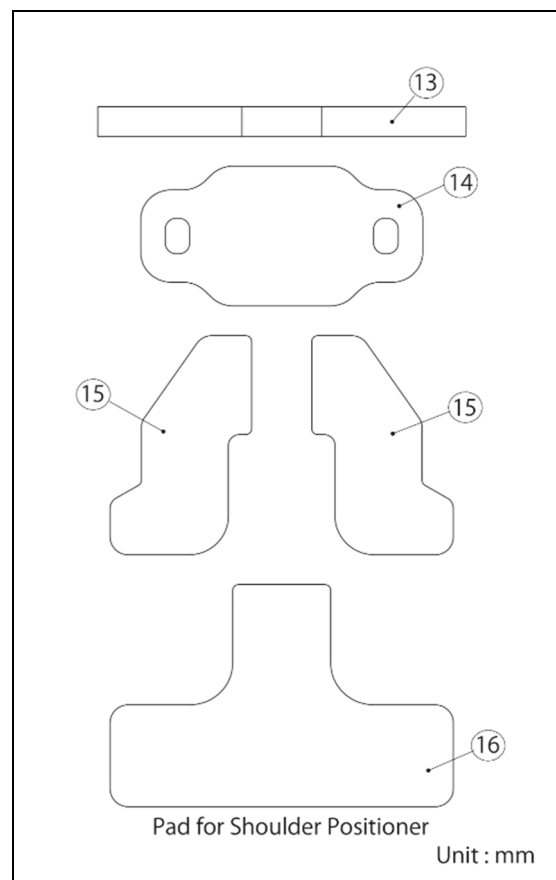
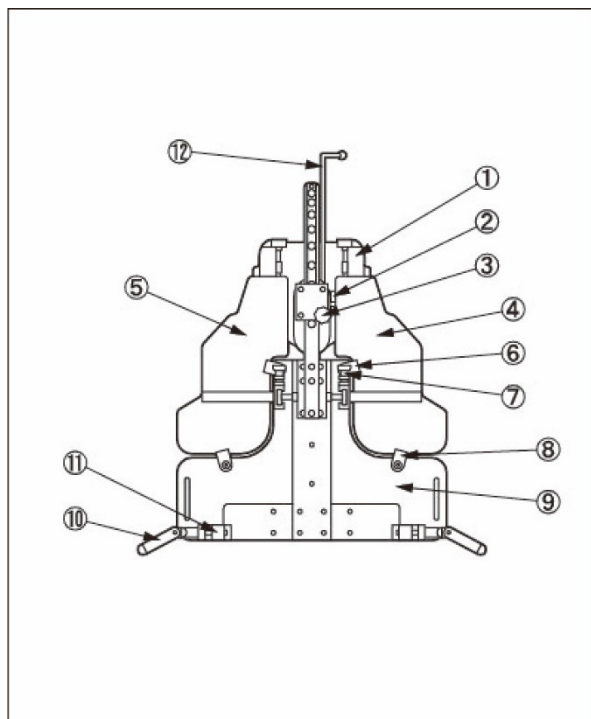
- This product is only validated for use with Mizuho operating tables.
 - Do not exceed the allowable load specified in 5.Specifications, "Allowable load". Otherwise the product could break.
 - Before attaching this product to the operating table, check that the tabletop is in the center position by using the sliding function.
 - Do not use the sliding function after this product is attached to the operating table.
 - Make sure that this product is fully inserted into the operating table.
 - 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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1-4. Symbol mark for labeling

MD : Medical Device

2. Component

The components of this product are as follow.



Main unit: Shoulder Positioner

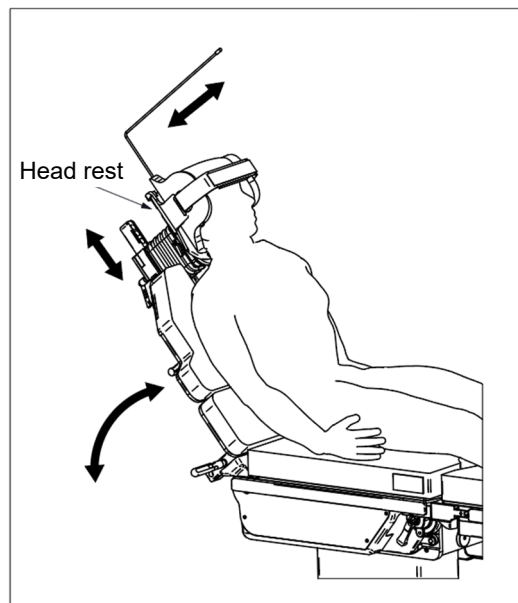
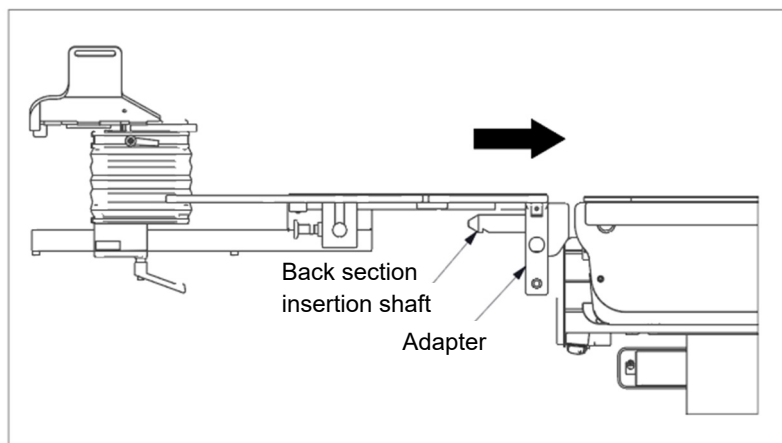
Component		Material
①	Head rest	Thermosetting resin
②	Flexion positioning lever	Synthetic resin
③	Head rest sliding adjustment lever	Synthetic resin
④	Right shoulder panel	Thermosetting resin
⑤	Left shoulder panel	Thermosetting resin
⑥	Upper rotation lock	Polyacetal resin
⑦	Plunger	Synthetic resin
⑧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

Option: Pad for Shoulder Positioner

Component		Material
⑬ to ⑯	Pad for Shoulder Positioner	Polyurethane
⑬	Shoulder Positioner Replacement Strap for Head Support	Polyurethane
⑭	Shoulder Positioner Replacement Pad, Head Section	Polyurethane
⑮	Shoulder Positioner Replacement Pad, Shoulder Section	Polyurethane
⑯	Shoulder Positioner Replacement Pad, Back Section	Polyurethane

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 automatic returning to level function of the operating table.
2. Check that the tabletop is in the center position by using the sliding function of the operating table.
3. Detach the head section and the back section from the operating table.
4. Attach the adapter part of the Shoulder Positioner to the back section attaching pin of the operating table and fix the Shoulder Positioner.
5. Attach the Pad for Shoulder Positioner to the Shoulder Positioner.
6. Transfer and set the patient to the Shoulder Positioner.
7. Operate the back section bending up function of the operating table to adjust the angle of the back section.
8. Use the flexion positioning lever and the head rest sliding adjustment lever of the head rest to adjust the head position.
9. After use, return the head rest position and the back section angle to level, detach the Shoulder Positioner adapter from the back section attaching pin of the operating table, and then attach the head section and the back section to the operating table.

4. Maintenance/Inspection

4-1. Check 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 pads 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 pads.
 - d) As with step c), disinfect the surface of this product.
 - e) Wipe off this product with a clean dry cloth within 15 minutes after disinfecting it.
- Make sure to use Mizuho authorized disinfectants. The disinfectants are as shown below.
 - 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)

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.

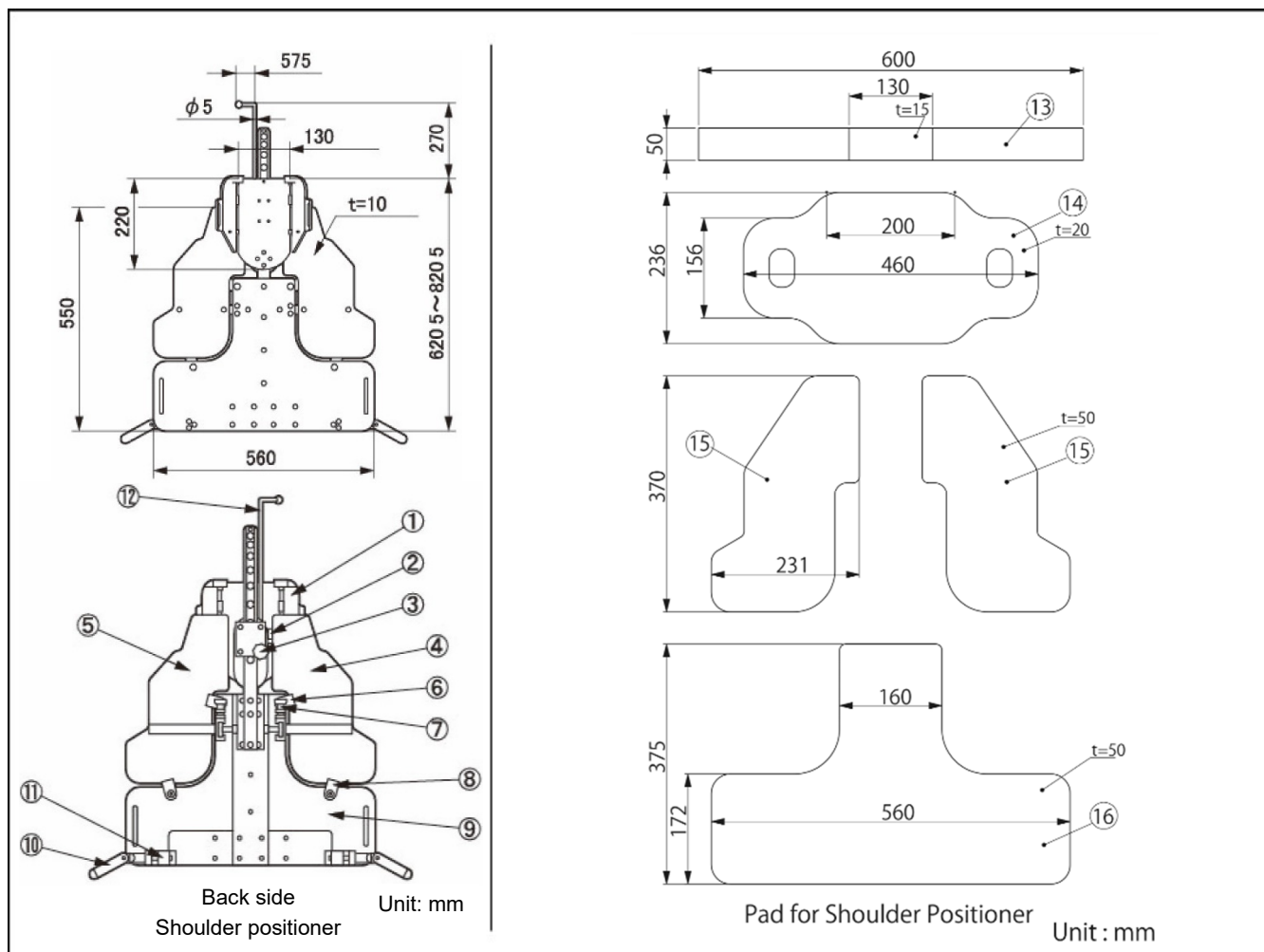
4-5. Disposal

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



Code No.	Product Description	Components
08-068-22	Shoulder Positioner without Pad	① to ⑫
08-068-23	Pad for Shoulder Positioner	⑬ to ⑯
08-068-24	Shoulder Positioner Replacement Strap for Head Support	⑬
08-068-25	Shoulder Positioner Replacement Pad, Head Section	⑭
08-068-26	Shoulder Positioner Replacement Pad, Shoulder Section	⑮
08-068-27	Shoulder Positioner Replacement Pad, Back Section	⑯

Dimensions	As shown above	
Weight	9.5 kg (excluding pad)	
Head rest Specifications	Slide range	Max. 200 mm
	Lift range	Max. 115 mm
	Bending angle	Max. 30° on each right and left
Allowable load	120 kg: Amount of weights of the patient and devices used together.	
Operating environment	Temperature	10 to 40 °C (50 to 104 °F)
	Humidity	30 to 75 %
	Atmospheric pressure	700 to 1060 hPa
Transportation and storage environment	Temperature	-10 to 50 °C (14 to 122 °F)
	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.)	



Sales Agent



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