

Instruction for Use

Trade Name: Radiolucent Multi-purpose Head Frame Up Grade Kit

Warning

Please read these instructions carefully prior to using this product. Product should be used according to these instructions, and pay close attention to the safety of patients. Failure to follow manufacturer's recommendations may cause harm or injury to the patient.

For the US market

Do not reuse the device when it is used on a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) or variant CJD (vCJD).

For markets outside the US

When the device is used on a patient with, or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Be cautious of the possibility of secondary infection. Refer to www.a-k-i.org or AAMI Standard ST79 for more information related to cleaning and sterilization.

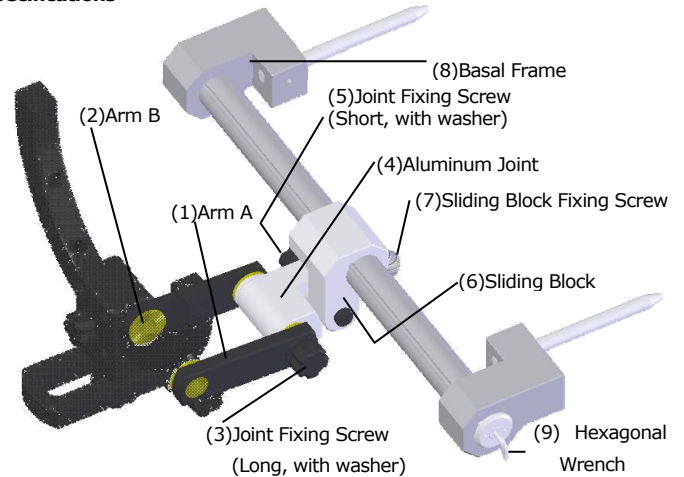
Contraindication/Prohibition

- Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
- Use with specified products only
Use this product only with products specified by Manufacturer. Other products than those specified by Manufacturer could be incompatible with this product due to differences in design and development policies.
- Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
- Prohibition of secondary processing of this product
Do not apply any secondary processing to this product. For example, do not apply impacts or vibration markings to the surface of this product. Doing so could break this product.
- Handle with care
Handle this product with care, as it can be deformed or damaged. Rough handling could significantly reduce the service life of devices and appliances.
- Prohibition of use of polishing powder and wire wool
When cleaning this product, do not attempt to polish its surfaces with rough polishing powder or wire wool. This could cause scratches on the surface of this product and result in rust or corrosion.
- Prohibition of use of acid and household detergents
Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any acid and household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
- Do not use low temperature hydrogen peroxide gas plasma sterilization. This product is not suitable for sterilization with hydrogen peroxide low temperature gas plasma. It may discolor the surface of the product or affect the feature of the product.

Symbol mark for labeling

: Medical Device

Specifications



Code No.	Product Description
07-986-50	Head Arm Base, Up Grade Kit for Intraoperative CT

No.	Component name	Unit
(1)	Arm A	1 pc
(2)	Arm B	1 pc
(3)	Joint Fixing Screw (Long, with washer)	1 pc
(4)	Aluminum Joint	1 pc
(5)	Joint Fixing Screw (Short, with washer)	1 pc
(6)	Sliding Block	1 pc
(7)	Sliding Block Fixing Screw	1 pc
(8)	Basal Frame	1 pc
(9)	Hexagonal Wrench	1 pc

Materials : carbon fiber reinforced resin, resin, aluminum alloy, and stainless steel

Specified optional products:

- Radiolucent Multi-purpose Head Frame
- Operating tables of MIZUHO Corporation

Intended purpose

This product is a surgery device to hold the skull in order to fix the head and neck at the specific position during operation. It is usually used for neurosurgical procedures.

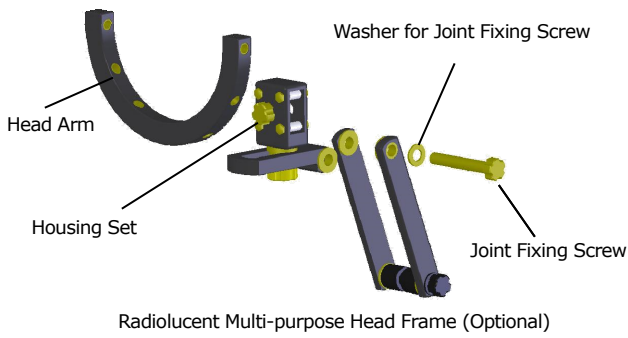
Intended user

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

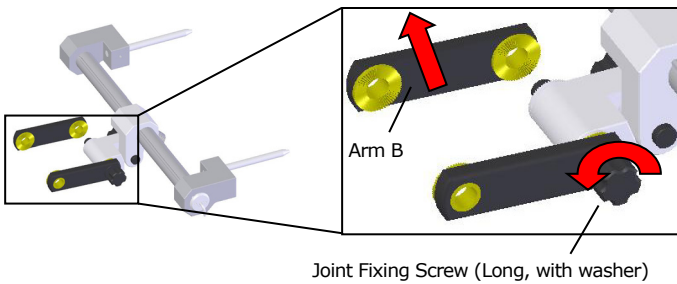
Instructions for use

1. Attachment of the Radiolucent Multi-purpose Head Frame

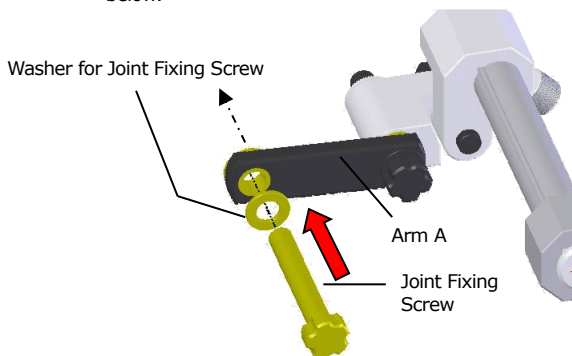
1.1 Detach the Head Arm, Housing Set, Joint Fixing Screw, and Washer for Joint Fixing Screw from the Radiolucent Multi-purpose Head Frame (optional).



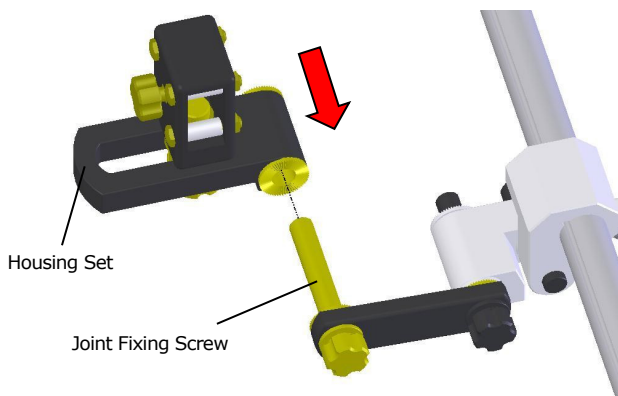
1.2 Loosen the Joint Fixing Screw (Long, with washer) and detach Arm B.



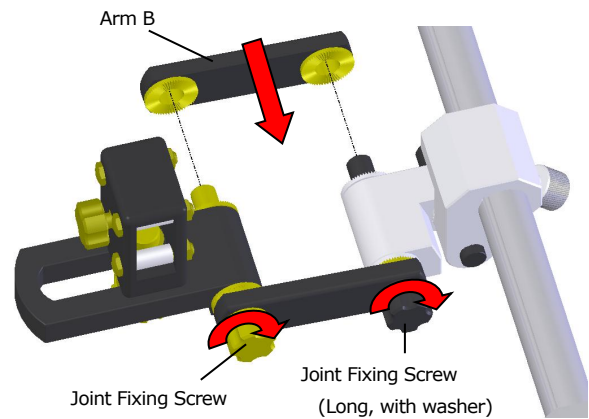
1.3 Insert the Joint Fixing Screw and Washer for Joint Fixing Screw detached in Step 1.1 into the hole of the Arm A as shown below.



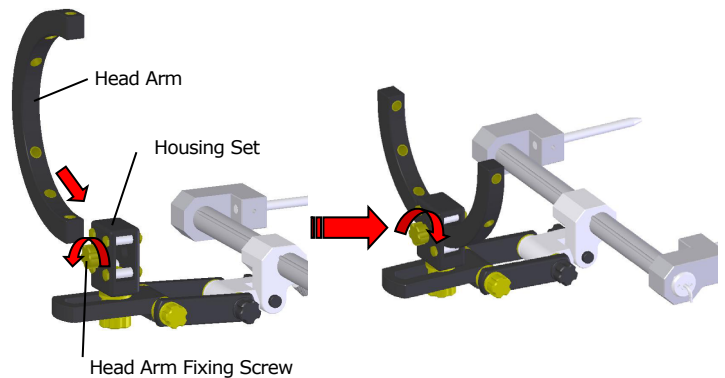
1.4 Attach the Housing Set to the Joint Fixing Screw as shown below.



1.5 Fix the Arm B detached in Step 1.2 by turning the Joint Fixing Screw and the Joint Fixing Screw (Long, with washer) clockwise alternately. Note: It may cause damage to Arm B and other parts if you keep turning only either the Joint Fixing Screw or the Joint Fixing Screw (Long, with washer) when attaching the Arm B. Upon attaching the Arm B, be sure to turn the Joint Fixing Screw and Joint Fixing Screw (Long, with washer) alternately.



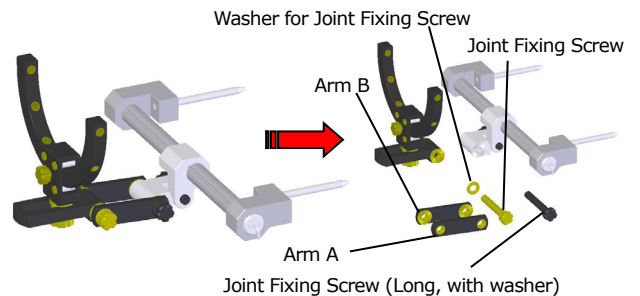
1.6 Loosen the Head Arm Fixing Screw of the Housing Set and attach the Head Arm to the Housing Set. Fix the Head Arm by tightening the Head Arm Fixing Screw.



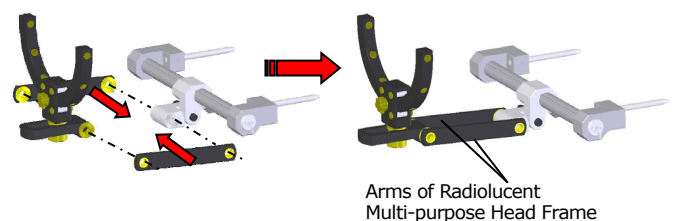
2. Change of the Arms

To extend the length of the Arms of this product, change the Arm B and Arm A to the Arms of the Radiolucent Multi-purpose Head Frame (optional) as shown in the following figures, and you may extend the length of the Arms by 100 mm.

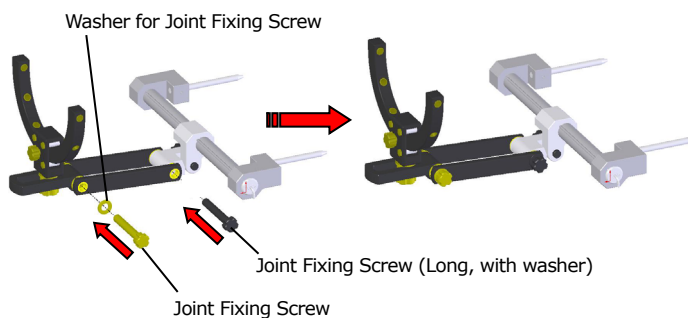
2.1 Detach the Joint Fixing Screw, Washer for Joint Fixing Screw, Joint Fixing Screw (Long, with washer), Arm B, and Arm A.



2.2 Attach the Arms of Radiolucent Multi-purpose Head Frame instead of the Arm B and Arm A detached in Step 2.1.

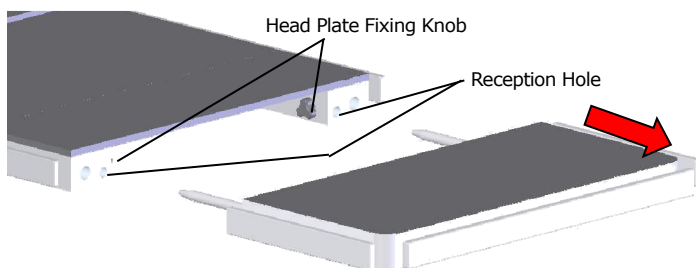


- 2.3 Fix the Arms by tightening the Joint Fixing Screw, Washer for Joint Fixing Screw, and Joint Fixing Screw (Long, with washer).



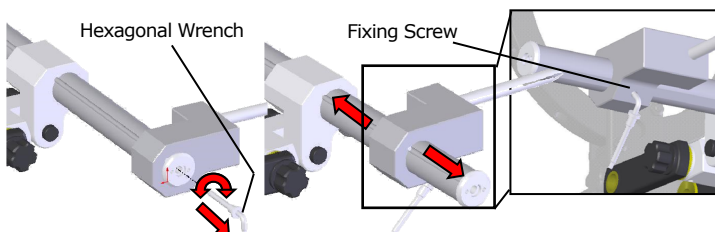
3. Attachment to the operating table

- 3.1 Loosen the Head Plate Fixing Knobs and then detach the Head Plate from the operating table.

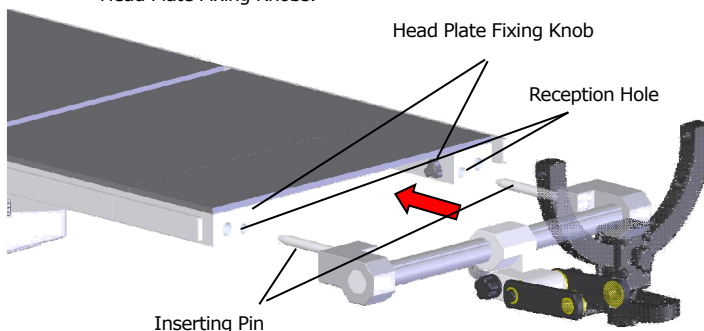


- 3.2 Turn the Hexagonal Wrench counterclockwise to detach. Loosen the Fixing Screw behind the right bracket with the Hexagonal Wrench so that the right bracket can slide right and left. Adjust the width between the right and left Inserting Pins to fit to the Reception Holes of the operating table, and tighten the Fixing Screw with the Hexagonal Wrench again to fix the position of the right Inserting Pin.

Note) Put the Hexagonal Wrench back to the original place after use.



- 3.3 Insert the Inserting Pins of this product into the Reception Holes of the operating table, and fix them by tightening the Head Plate Fixing Knobs.



- 3.4 Adjust each joint to make the Housing Set horizontal to the floor.

Warning/Caution

1. WARNING

Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

2. Defect/Adverse event

- Defect
- Lowering of holding force
 - Rattling
 - Breakage
 - Crack
 - Deformation

Adverse event

- Contamination

3. Important fundamental cautions

3.1 Fixing the head and neck

Confirm that there is sufficient airway and no twisting of the patient's carotid when setting a head position for fixing cranium.

3.2 Cleaning

To remove dried organic dirt, we recommend to do hand washing using medical neutral detergent. Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary. Please refer to the manual provided with each detergent for more details about how to use it.

3.3 Application to elderly people

When the device is applied to an elderly person, any load or movement during the operation may cause fractures, especially if the elderly person has osteoporosis. Make sure to use the device with utmost care.

4. Other cautions

- 4.1 Before fixing the skull, make sure that all the joints are securely fixed.
- 4.2 During an operation, always monitor that there are no problems for the patient.

Storage/Life

1. Storage

- 1.1 Please store the device in normal ambient temperature areas. Do not store in areas of high humidity where the temperature may dramatically vary causing condensation. Do not store on or near chemicals as the chemicals may cause damage to the device. Do not store this product in areas where gas is being produced.
- 1.2 Be careful not to impact or vibrate (including while transporting) this product.

2. Life

Service life of this product: 5 years
(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

1. Check prior to each use

- (1) Operational and functional checks
Conduct daily and pre-operation checks of this product to make sure that it functions properly.

2. Check after each use

- (1) Immediately wash with clean water
(1)-1 If exposed to bleach or antiseptic solutions, immediately wash:
Wash and rinse with clean water immediately and immerse in neutral enzyme detergent to remove any bleach or antiseptic solution, which may contain chlorine or iodine

and can damage the instrument. Manually remove contaminated matter by hand or with an ultrasonic-cleaner.

- (1)-2 Further remove any remaining contamination with a plastic brush.
- (1)-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling.
- (1)-4 Use a soft towel, a plastic brush or a water jet for cleaning.
- (1)-5 To avoid damage, do not use a metal brush, coarse polishing agents, or apply excessive force when handling the device.
- (1)-6 Reverse osmosis water is recommended to wash this product.
- (1)-7 Only use reverse osmosis water for the final rinse.
- (1)-8 It is recommended to use a washer-disinfector for this device.

(2) After cleaning, fully rinse for more than 5 minutes, with warm or cold water without any additives.

(2)-1 Fully dry this product immediately after washing it. Do not leave it wet for a longer time than necessary as residual water may damage the instrument.

(3) Use distilled water or reverse osmosis water at least Use distilled water or reverse osmosis water to wash and sterilize this product at least. Residual chlorine and organic matters in tap water may cause stainings and/or rust and may damage the instrument.

(4) Use a water-based anticorrosive lubricant Lubricating oil is completely removed by washing. After washing this product, apply a water-based, anticorrosive lubricant prior to sterilization. Do not use this product without applying anticorrosive lubricant on its sliding part. [Galling could occur.]

3. Sterilization

Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

Table 1: Applicable detergent

No.	Component name	Detergent	
		Neutral	Alkaline
(1)	Arm A	Yes	No
(2)	Arm B	Yes	No
(3)	Joint Fixing Screw (Long, with washer)	Yes	No
(4)	Aluminum Joint	Yes	No
(5)	Joint Fixing Screw (Short, with washer)	Yes	No
(6)	Sliding Block	Yes	No
(7)	Sliding Block Fixing Screw	Yes	Yes
(8)	Basal Frame	Yes	No
(9)	Hexagonal Wrench	Yes	Yes

Table 2: Applicable disinfectant

No.	Component name	Detergent	
		Iodine	Alcohol
(1)	Arm A	No	Yes
(2)	Arm B	No	Yes
(3)	Joint Fixing Screw (Long, with washer)	No	Yes
(4)	Aluminum Joint	No	Yes
(5)	Joint Fixing Screw (Short, with washer)	No	Yes
(6)	Sliding Block	No	Yes
(7)	Sliding Block Fixing Screw	No	Yes
(8)	Basal Frame	No	Yes
(9)	Hexagonal Wrench	No	Yes

Table 3: Applicable sterilization method

No.	Component name	sterilization		
		Steam	EOG	Plasma *
(1)	Arm A	Yes	Yes	Yes
(2)	Arm B	Yes	Yes	Yes
(3)	Joint Fixing Screw (Long, with washer)	Yes	Yes	No
(4)	Aluminum Joint	Yes	Yes	No
(5)	Joint Fixing Screw (Short, with washer)	Yes	Yes	No
(6)	Sliding Block	Yes	Yes	No
(7)	Sliding Block Fixing Screw	Yes	Yes	Yes
(8)	Basal Frame	Yes	Yes	No
(9)	Hexagonal Wrench	Yes	Yes	Yes

Yes: Applicable No: Not applicable

*Low temperature hydrogen peroxide gas plasma

Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows;

ISO/TS 17665-2	
Temp.	Minimum exposure time
121°C / 249.8°F	15 Min
126°C / 258.8°F	10 Min
134°C / 273.2°F	3 Min

For the US market

FDA has not approved or cleared medical devices, including sterilizers, for the intended use of reducing the infectivity of TSE agents (i.e., prions).

For markets outside the US

When the device is used on a patient with or suspected of having CJD or vCJD, make sure to adhere to the most recent and updated restrictions available in each country and/or region for its reuse.

Maintenance and check by agents

For safety use of this instrument, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact your local distributor or the manufacturer.

Packing

1 set 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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