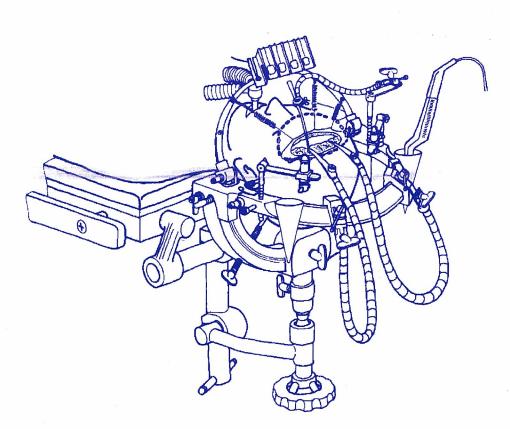
Directions for Attachment of Multipurpose Head Frame Handling Instructions





Directions for Attachment of Multipurpose



Precaution when handling

This equipment is a medical device used to support a patient's head when performing neurosurgical procedures.

If failure or breakdown of this device occurs during the surgical procedure, it may cause damage to the patient's head or neck, or failure to maintain the respiratory airway under anesthesia with possible serious consequences. To prevent this, it is very important to understand the device fully and observe the rules of proper setting and handling of the device. Check before and after use, routinely inspect the device and replace the parts or whole unit in a timely mannar. Those who may handle this device should read this manual carefully and understand the contents fully before using the device.

Caution in general.

- OCaution specific to material used.
- Made of an aluminum alloy, this device may break upon sudden impact. Do not hit the device against an operating table or drop it during use.
- Olmportance of checking before use.
- During installation check all joints and connections to be sure they are secure. Check the unit for any abnormality such as cracks or misshapen areas. After prolonged use the joints can wear and connections can become loose. Do not use the device if any problem has been detected. Contact your distributor with any questions.

INSTALLATION AND HANDLING

1 Installation of Table Attachment

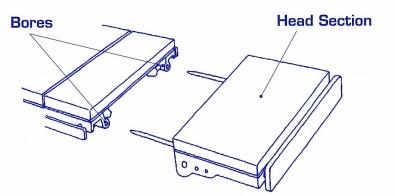
First, detach the head section from the table.

You will find two bores underneath the tabletop on both sides. (Fig. 1)

Caution!

To install this device on the table, the head section must be removed first. No installation is possible with the head section in place.

1.Remove the hexagon key attached to the end of the table attachment by turning it counterclockwise. By using the hexagon key, loosen the set screw of the inserting pin on the right side to allow free sliding on the bar. Align the inserting pins with the bores on the table by adjusting the right pin. (the left pin is fixed).(Fig.2) \$\times\$Do not misplace the key.



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Fig.1

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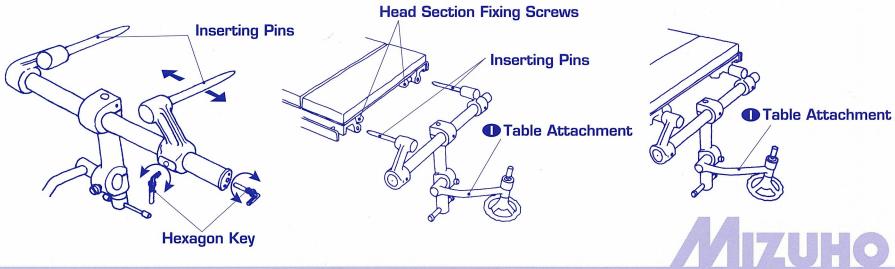
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2.Insert both inserting pins into the bores and tighten "Head section fixing screws"
on the Table. (Fig. 3-1, 3-2)

*Note: Never tighten down the table attachment without the handwheel arm in place. This may severely damage the unit.



2 Attachment of Head Holder

Fix the Table Attachment temporarily by turning the angle-adjusting lever and the handwheel (Fig.4).

- 3. After inserting the Head Holder 1 into the end of the Table Attachment

 , the Head Holder

 is securely fixed by turning the slide-adjusting screw and wing screw. (Position of the Head Holder may be adjusted by loosening the slideadjusting screw.)
- ★ When attaching the Head Holder to the Table Attachment , face the V-shape groove of the Head Holder and the slide-adjusting screw towards the surgeon (or away from the table). (fig.5)

Table Attachment

Head Holder (1)

Wing Screw

Hand Wheel

Slide-Adjusting Screw

3 Fixing of the patient's head

4. While the patient's head is being supported by an attendant, the head is fixed in place on the Head Holder with four(4) head pins • or • inserted at desired positions.



Before inserting the head pins into the head, make sure that all joints and connections are securely fastened. Any loose connections may make the puncture hole on the head larger than necessary causing harm to the patient.

With the attendant supporting the Head Holder (1), loosen the angle-adjusting lever and the Head Holder handwheel to place the patient's head in position. Then tighten the lever and the handwheel securely. The head holder can now be draped. (Fig. 5)



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Head Pin(Standerd) or 🕕 Head Pin with short pin tip Head Holder (1) Slide-Adjusting Screw

Table Attachment

Basal Frame

Angle-Ad

Fig.4

Angle-Adjusting Lever

Fig.5

Fig.

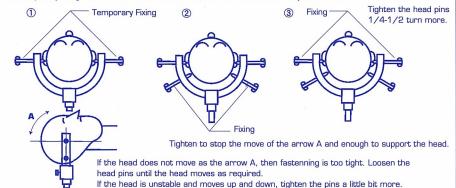
Fix the patient's head according to the following steps

▲ Warning!

Make sure that the Head Holder is rigidly fixed on the Table Attachment when fixing the head. Once the head is fixed, never attempt to detach/attach the head holder and/or the Table Attachment as this is extremely dangerous. Do not fasten the head pins too tightly to hurt the head skin. "Securely enough but not too tight" is the rule.

For a child patient, use short tip head pin(option).

In the temporary fixing, make sure that the head is allowed to move as shown by the arrow A.



5.The Basal Frame (a) is mounted on top of the Head Holder (b) ends perpendicular to the Head Holder (c) (Fig. 6-1)

Before mounting, loosen the Basal Frame fixing screw at the mounting base on both sides to the fullest extent to provide ample space for mounting.

4 Attachment of the Basal Frame

⚠ Caution!

Failure to provide ample space for mounting may cause a malfunction of the basal frame.

⚠ Caution!

Use the handle provided with the unit when fastening all fixing screws of the joint sections. Make sure to tighten the fixing screws of the right and left sides evenly at the same time. Tightening of the fixing screw of one side ahead of the other may cause unstable fixing and/or breakdown of the unit.

6. When performing the craniotomy, the Basal Frame may be angled downwards by loosening the angle-adjusting screw so as not to hinder the surgical operation. (Fig. 6-2)

After the craniotomy, revert the Basal Frame to the horizontal position and fix it securely. (Fig. 6-1)

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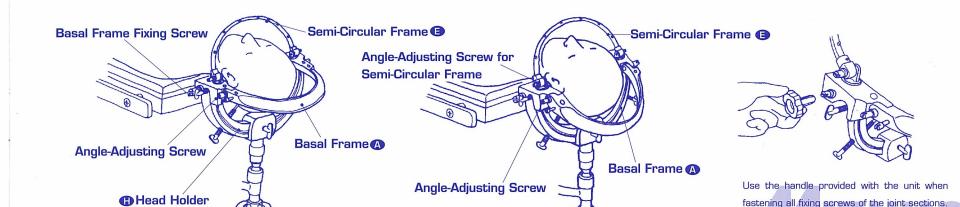


Fig.6-1

Fig.6-2

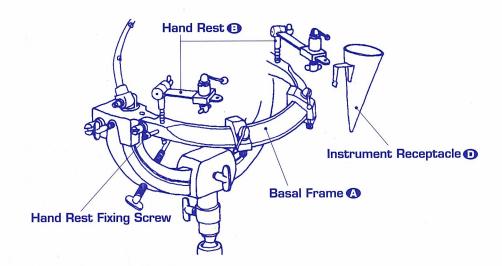
5 Attachment of the Hand Rest

Hand Rest® may be installed on the Basal Frame by inserting the grooves attachment rod into either one of the receiving holes provided near the hinged section and fastening the fixing screw located on the side surface of the Basal Frame (1). (Fig. 7-1)

The Hand Rest/Instrument Receptacle may be easily rotated or moved up and down if the tip of the fixing screw is aligned with an intersection of the circumferential and longitudinal grooves on the attachment rod.

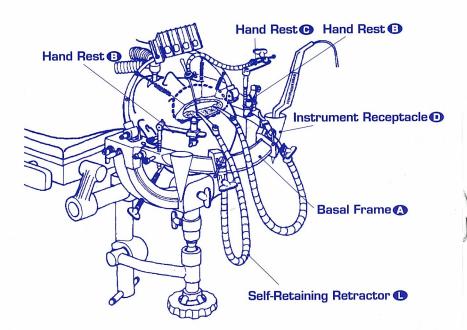
A Caution!

Fasten the Hand Rest fixing screw securely with the handle provided.



6 Attachment of Instrument Receptacle

The Instrument Receptacle (Funnel-shaped) may also be installed on the Basal Frame (A) in the same fashion as the Hand Rest. (Fig. 7-2)



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Attachment of Self-Retaining Retractor

- **a.** Place the Slide Adjuster **o** on the Basal Frame **o** and fasten the fixing screw **o** . The position of the Slide Adjuster may be adjusted over the Basal Frame.
- **b.** Loosen the Dome Screw **6** and insert the U-shaped end of the Self-Retaining Retractor under the Dome Screw **6** and fasten the dome screw again. (Fig. 8-2)

Caution!

When installing the Slide Adjuster • make sure to loosen the fixing screw • fully. To slide the adjuster • over the Basal Frame during the procedure, loosen the fixing screw • by 1/2 turn.

A Caution!

Improper or incomplete tightening of the fixing screw may cause the Slide Adjuster to drop off from the Basal Frame. Be careful!

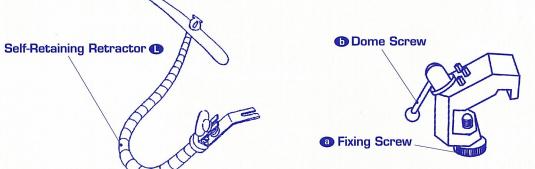
C. Fix the Flexible Brain Spatula to the **Screw Clamp** of the Self-Retaining Retractor.

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The position of the Slide Adjuster may be adjusted over the Basal Frame.





MIZUHO

Fig.8-2

8 Attachment of Other Fittings

The cotton plate \odot and L-shaped bracket for the Spring Scalp Hooks \odot are attached to the semi-circular frame \odot with a fixing screw . (Fig. 9-3)

The spring tension of the Spring Scalp Hooks may be adjusted by changing the length of the beaded chain at the bracket. (Fig.9-3)

Attach the Cotton Plate by using the U-shaped slit. At this time, make sure to direct the U-shaped slit upwards as illustrated. (Fig.9-1/9-2)

A Caution!

If attached with the U-shaped slit heading downwards, the fixing screw tends to be loosened easily with possible dropping of the Cotton Plate. Make sure of the direction of the U-shaped slit when attaching.

• If the length of the beaded chain is made too short at the bracket, the spring tension of the Spring Scalp Hooks may become too strong with possible harm to the patient.

A Warning!

Do not apply the Spring Scalp Hooks to critical areas such as nerves, major blood vessels, etc.

● When tugging the scalp with the Spring Scalp Hooks attached to the Semi-Circular Frame → make sure to position the Semi-Circular Frame → at an angle of more than 45° with respect to the Basal Frame →.

A Warning!

Do not position the Semi-circular Frame at an angle of less than 45°∆when using the spring scalp hooks. Otherwise, sequelae such as nerve injury may result.

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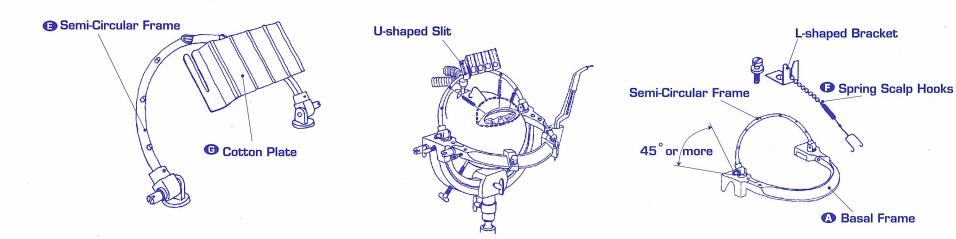


Fig.9-1 Fig.9-2 Fig.9-3

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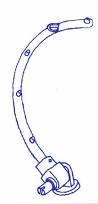
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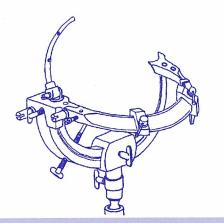
Quarter Frame, Right/Left use (Optional)

• In the craniotomy through lateral sub-occipital approach, use of the regular Semi-Circular Frame ⊕ may at times hinder the surgeon's access to the operative field. In such a case, use of the Quarter Frame allows for effective tugging of the scalp with providing a sufficient working space for the surgeon.

A Warning!

Make sure to apply the Spring Scalp Hooks only after confirming that the frame is securely fastened.





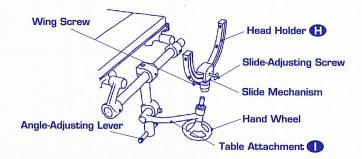


After-Use Care

- Disassemble the device after use and wash the parts with running water to wash off stains of chemical, blood, etc. When cleaning, use neutral detergents so as not to have an adverse effect on the head frame. Do not use the blood dissolving agents as they may corrode the head frame.
 - When sterilizing the device after use with a sterilizing solution for infectious cases, soaking in the solution must be limited to time specified for the solution. Prolonged soaking may cause corrosion of the head frame.
- When using a full-automatic washing machine, make sure to wipe off blood that may adhere to head frame, drying thoroughly before putting the device into the machine.
- Make sure to dry the device quickly after washing to prevent rusting.

Sterilization

- Use autoclaving or ETO sterilization technique when sterilizing the basal frame assembly, head pins and other fittings attached to the basal frame. Make sure to wash them thoroughly before sterilizing.
- Do not sterilize the head holder assembly and the table attachment. Sterilization may cause Teflon pads and rollers used in the head holder slide mechanism to shrink with possible wobbling of the head holder.



Product Warranty

Every surgical instrument bearing the Mizuho brand name is guaranteed to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose and life. Any Mizuho brand name instrument delivered from Mizuho proving to be defective will be replaced or repaired, at Mizuho's discretion, at no charge.

Mizuho Ikakogyo Co., Ltd. assumes no responsibilities whatsoever for any and all damage, accidental or consequential, resulting from improper use or handling of the device, disassembling or modification of the device by persons other than authorized by Mizuho, or negligence of the following instructions.

- Make sure to perform a final safety check at all times when using the device.
- Use only Mizuho products in combination with the Mizuho Head Frame. However, Mayfield base unit may be used in combination with Mizuho Mayfield Adapter provided that the safety is verified by Mizuho staff or authorized Mizuho dealers.
- Do not use optional accessories such as Self-Retaining Retractors, etc., of manufacturers other than Mizuho in combination with the Mizuho unit, this may cause wobbling or breakdown of the head frame assembly.

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purpose Head Frame Handling Instructions

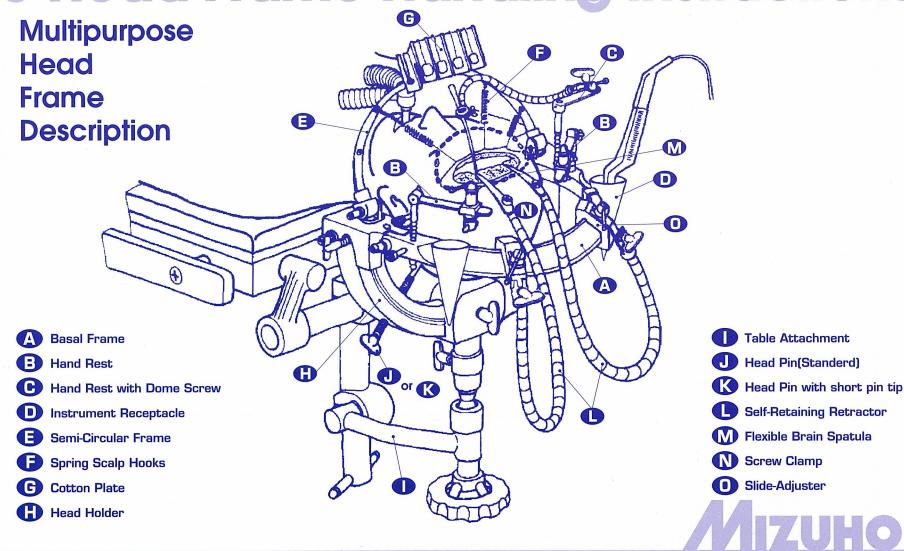
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