

Instructions for Use

Trade Name: NV Adaptor

Warning

1. 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 manufacturers recommendations may cause harm or injury to 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).

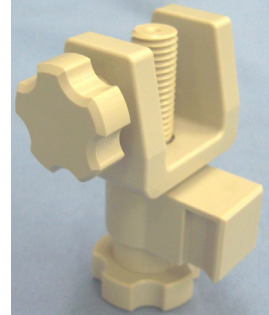
For markets outside the US

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

1. Use for intended purpose only
Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. 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.
3. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
4. 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.
5. 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.
6. 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 surfaces of this product and result in rust or corrosion.
7. Prohibition of use of alkaline, acid, and household detergents
Use only medical neutral detergents (pH 6 to 8) to clean this product. Do not use any alkaline, acid, or household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.
8. 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.

Shape / Structure



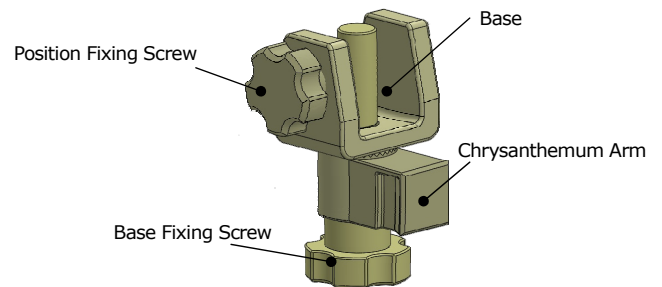
Code No. :07-970-51
Product Description :NV Adaptor, MRI/CT
Material :PEEK resin

Intended Purpose

This product is a surgical tool for cranial and cervical fixation used to maintain a specific fixed cranial position during operative treatment. It is designed for use in neurosurgical procedures.

Instructions for use

Please refer to the following figure for each component name.



Before using this product, inspect, wash, and sterilize in accordance with these instructions.

Usage:

As shown in Figure 1 and Figure 2, attach by screwing the Base Fixing Screw of the NV Adaptor (for MRI/CT) into the screw hole of the Head Pin that is not being used for cranial fixation of the patient. Screw the Position Fixing Screw of the NV Adaptor so that the NV Adaptor fits tightly with the Head Holder.

(Caution) Attach the Base of the NV Adaptor to fit tightly with the Radiolucent Head Frame or MRI Head Holder (optional).

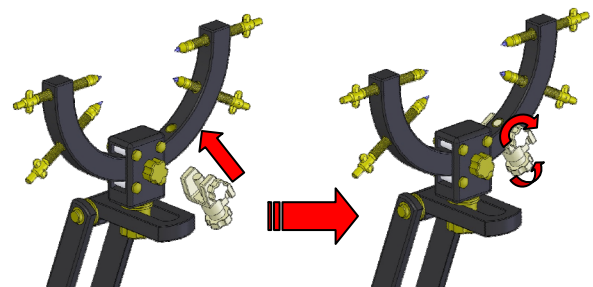


Figure 1 Mizuho Radiolucent Head Frame

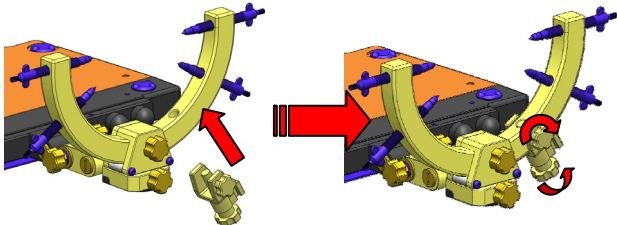


Figure 2 Mizuho MRI Head Frame

CAUTIONS & WARNINGS

1. Warning

Device must be sterilized by users in accordance with our recommended sterilization procedures or the validated sterilization conditions for which validity has been proven by medical organizations in each country or region.

2. Defect/Adverse event

Defect

- Deterioration caused by use of chemicals
- Damage or breakage
- Lowering of holding force
- Rattling

3. Fundamental precautions

- Inspect the appearance before use at all times. Do not use if there are any changes in shape, cracks etc. in the product or there are abnormalities in the sliding portion.
- During an operation, always monitor that there are no problems for the patient.
- Make sure to wash after use.
- Only health professional (doctor, nurse and so on) allowed to use this product.

4. Cautions on use of other tools in combination with this product

- Use with specified products only
Use this product only with the 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.

● Specified optional products

Product name: Radiolucent Multi-Purpose Head Frame

Product name: MRI Head Frame

Storage/Life

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.
2. Be careful not to impact or vibrate (including while transporting) this product.
3. 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) Immediate wash with clean water

(1)-1 If exposed to bleach or antiseptic solutions, immediately wash:

Wash and rinse with clear 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. Use of a neutral detergent is recommended.

(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 Only use distilled water or deionized water (reverse osmosis) to wash this product.

(1)-7 Only use fully deionized water (reverse osmosis) 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) Only use distilled or deionized water.

Use distilled water or deionized water to wash this product.

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.

● Application table of washing, disinfection, and sterilization.

Washing	Neutral	Alkali	Enzyme
	Yes	No	No
Disinfection	Alcohol	Iodine	Chlorine
	Yes	No	No
Sterilization	Steam	EOG	Low temperature hydrogen peroxide gas plasma
		Yes	No

● 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 piece per pack

Matters related to warranty period

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.

Name and address of manufacturer

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