

Instruction for Use

Trade Name : Four-point Spinal Frame

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 manufacturer's recommendations may cause harm or injury to the patient.
2. 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).
3. For the market 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. Prohibition of use of chemicals
Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
3. 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.
4. 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.
5. 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.
6. Prohibition of sterilization
Do not sterilize this product. Sterilization could affect the properties of this product.

Symbol mark for labeling

:Medical Device

Specifications

1. Shape/Structure



Code No.	Product Description	Component
02-121-10	Radiolucent Carbon Fiber Four Point Spinal Frame	A+B

2. Material

*	Material
A	Plastic, Cloth material
B	Carbon fiber reinforced plastic, Plastic, Cloth material

* "A" and "B" correspond to those used in 1. Shape/Structure.

Intended purpose

This is an accessory to an operating table, and is used for supporting a patient to keep the prone position.

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

Before using this product, be sure to inspect, wash it under proper conditions and disinfect.

For hygiene, be sure to use sterilized drapes on the areas on this product where the patient comes into contact with it.

Warning/Caution

1. Prohibition of sterilization
Do not sterilize this product. Sterilization could affect the properties of this product
2. Defect/Adverse event
 - Corrosion or pitting caused by use of chemicals
 - Damage or breakage caused by the corrosion or pitting
 - Decrease in function due to deterioration of sliding parts over time
3. Allowable Load
Do not add load more than 60 kg.

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. Service life of this product: 7 years
(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance/Inspection

<By the user>

1. Check before and after use
Check that this product is not damaged or broken before and after use.
2. Cleaning and disinfection
Wipe off blood, chemicals, contaminants, and other stains with water, and clean the device with gauze or other material moistened with alcohol to disinfect.

Cleaning	Disinfection*1	Sterilization		
Wipe with medical neutral detergents	Clean with alcohol	EOG	high-pressure steam	hydrogen peroxide gas plasma
OK	OK	NG	NG	NG

*1: Iodine-based disinfectant, is not available for any parts

3. In case of a malfunction
If you need to have this product repaired, clearly label the device as "Broken", "Need repair" etc. and contact your local dealer or Mizuho.

<By suppliers>

Maintenance and inspection can only be carried out certified suppliers of MIZUHO.

Maintenance and check by agents

For safety use of this device, 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

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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