

MES-CK02-121-10EN-0

PREPARED: (2017-09-05) (Version 3)** (2016-08-03) (Version 2)*

Keep this manual available for reference when needed.



Instruction for Use

Trade Name: Radiolucent carbon fiber 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. Not doing so may give rise to serious problems or adverse events..
- 2. When the device is used on a patient where there is a suspicion of Creutzfeldt-Jakob Disease (CJD), 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.1

Contraindication/Prohibition

- 1. Use for intended purpose only
 - Use tools for their intended purposes only. Incorrect use could cause breakage of this product.
- 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 tools and
- 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.

Shape/ Structure

1. Shape/Structure



Code No.	Product Description	Component
02-121-10	Radiolucent carbon fiber four point spinal frame	A+B

2. Material

	Material			
Α	Plastic, Cloth material			
В	Carbon fiber reinforced plastic, Plastic, Cloth material			

Intended purpose

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

Directions for Use

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

Precautions before use

- 1. Prohibition of sterilization
 - Do not sterilize this product. Sterilization could affect the properties of this product
- 2. A fault or an adverse event
 - -Prohibition of use of chemicals
 - Avoid exposing this product to chemicals. Doing so could damage this product due to corrosion.
- * 3. Allowable Load
 - Do not add load more than 60kg.

Storage/Life

- 1. Do not store the device in high temperatures or in areas with high humidity where the temperature has drastic variations.
- 2. Service life of this product: 7 years (subject to the specified maintenance and inspection and is stored properly)

Handling instructions

- Use this product for its intended purpose only. Incorrect use could cause damage to this product and the operating table to which this product is attached.
- · Cleaning and disinfection

Wipe off blood, chemicals, contaminants, and other stains with water, and clean the product with gauze or other material moistened with alcohol to disinfect it.

Maintenance/Inspection

- *<Bv 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	Clean with	EOG	high-pres	hydrogen			
medical neutral	alcohol		sure	peroxide gas			
detergents			steam	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.

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 damage on purpose. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

** Name and address of manufacturer



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