MIZUHO

MES-CK09-228-10EN-0
PREPARED: (2018-01-15) (Version 1)

Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

Instruction for Use

Trade Name: Arm for Abdominal Lifting with Clamp

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. 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. Use with specified products only
   Use this product with only 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 surface of this product and result in rust or corrosion
7. Prohibition of use of household detergents
   Use only medical detergents to clean this product. Do not use any household detergent. Washing this product with an improper detergent could result in discoloration or corrosion.

Shape/ Structure

Code No.	Product Description
09-228-10	Arm for Abdominal Lifting with clamp, dia.18mm

Code No.	Product Description
09-228-12	Side Rail Clamp (18mm)

Material: Stainless Steel

Intended purpose

A device that creates a space in the abdominal cavity for laparoscopic procedures by mechanically lifting the abdominal wall. This method of lifting the abdominal wall includes inserting a retractor, sling, or subcutaneous wires and then providing lift with an external lifting mechanism, e.g. a manual traction device, a support arm clamped to the operating table, or a winch and framework. This device requires no, or minimal, gas insufflation.

Instructions for use

This is an accessory to be used with Wire Spooler.
Remove the stopper screw from the underside of Arm for Abdominal Lifting, and then set up Wire Spooler to it. Once finished, return the stopper screw to the original position and make sure to fasten it firmly. Wire Spooler could fall off from Arm for Abdominal Lifting if the dislocation of Wire Spooler occurs due to vibration during the operation.

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

Caution

1. Warning
   Device must be sterilized by users under the standard sterilization conditions or the validated sterilization conditions which validity is proven by medical organizations in each country or region.
2. Defect/Adverse event
   -Prohibition of use of chemicals
   Avoid exposing this product to chemicals. Doing so could damage this product and cause corrosion.

Storage/Life

1. Storage

   Do not store the device in high temperature or in areas with high humidity with drastic temperature or humidity variations.

2. Service life of this product: 7 years

   (Subject to the specified maintenance, inspection, and proper storage)

Maintenance / Inspection

1. Operational and functional checks

   Conduct daily and pre-operation checks of this product to make sure that it works properly.

2. Immediate washing with clean water

   2-1Wash and rinse with clean water immediately in case the device is exposed to bleach or antiseptic solution, which may contain chlorine or iodine.

   2-2 Remove any remaining contamination with a brush.

   2-3 Select a proper detergent for each decontamination method and maintain appropriate density and handling. Use of a neutral detergent is recommended.

   2-4 Use a soft towel, a plastic brush, or a water gun for cleaning.

   2-5 Do not use a metal brush, coarse polishing agents, nor apply excessive force when handling the device.

   2-6 Use distilled water or deionized water to wash this product.

   2-7 Use fully demineralized water (reverse osmosis) for final rinse.

   2-8 Using an ultrasonic washing machine for this device simultaneously is recommended.

3. Dry this product immediately after washing it.

   3.1 Please rinse the frame fully, for more than 5 minutes, by warm or cold water without additives after cleaning.

   3-2 Dry this product immediately after washing it. Do not leave it wet for a longer time than necessary.

4. Use distilled or deionized water

   Use distilled or deionized water to wash this product.

   Residual chlorine and organic matters in tap water could cause stains and rust.

5. Use a water-based anticorrosive lubricant

   Lubricating oil is completely removed by washing. Do not use without lubricant oil to sliding part, or galling could occur. After washing this product, apply a water-based anticorrosive lubricant prior to sterilization.

6. 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.

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

ISO/TS17665-2	
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

Temp.	Minimum exposure time
134°C / 273.2°F	18 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 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.

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

MIZUHO Corporation
3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
http://www.mizuho.co.jp