

Instructions for Use

Trade Name: Air Pump for Tourniquet

Warning

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.

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 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 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. 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. Do not sterilize
Do not sterilize this product. [Doing so may affect the capabilities of the product.]

Shape / Structure



Code No.	Product Description
01-440-07	Air Pump for Tourniquet

Material: Stainless Steel, Rubber, Resin

Intended Purpose

A unit intended to deliver air to a reusable tourniquet to set, control and maintain pressure of the tourniquet during surgery.

Instructions for use

- Inspect this product before use. Under appropriate conditions, clean and disinfect before use. (Refer to items related to maintenance and inspection.)

CAUTIONS

1. Defect/Adverse event
Defect
 - Deterioration, corrosion and pitting caused by use of chemicals
 - Damage or breakage caused by the corrosion or pitting
 - Degradation of functionality due to deformation.
 - Degradation of functionality due to poor sliding of moving parts
2. Pressure decrease
Pressure may decrease due to a change in the patient's posture. In such cases, apply pressure again.

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: 5 years
(Subject to following manufacturer's specified maintenance, inspection and proper storage requirements.)

Maintenance / Inspection

1. Check prior to each use
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
 - Cleaning and disinfecting
Remove blood, medicine, or dirt with water, and disinfect product with alcohol or gauze.

Packing

1 piece per pack

Maintenance and check by agents

For safe use of this instrument, inspect device prior to and after each use. Alternative or no review and/or inspection may cause injury to the patient and/or healthcare worker and may decrease the performance and function of this device. Additionally, it is recommended to schedule a periodic inspection through your local distributor or the manufacturer.

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>