PAJUNK®

Disposable Valve Mounting for TrocaPort Trocar Sleeves

Laparoscopy

Instructions for use

These instructions for use were translated into the following languages: DE, EN, FR, IT, ES, PT, NL, DA, SV, EL, BG, ET, HR, LV, LT, PL, RO, SK, SL, CS, HU. The translations can be downloaded from our website: eifu.pajunk.com.

Special notice

Please read the following information and operating instructions carefully.

Caution: Federal law restricts this device to sale by or on the order of a physician. The device may only be used by qualified medical staff in accordance with these user instructions.

PAJUNK® does not recommend any particular treatment method. Professional medical staff are responsible for the way in which the device is used and for patient selection. In addition to these instruction for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge. Failure to comply with the instructions for use invalidates the warranty and puts patient safety at risk.
If used in combination with other devices, it is essential that the compatibility information and user instructions for these other devices are taken into account. A decision regarding the combined use of devices from different manufacturers (where they do not constitute treatment units) is the responsibility of the user.

The device must not be used under any circumstances if there are good reasons to suspect incompleteness, damage or loss of sterility.

Only devices in perfect condition, which are within the sterile expiry date marked on the label, in undamaged packaging, may be used.

Device description / compatibility

The disposable valve mountings are accessories which are intended to be used with TrocaPort trocar sleeves. They are available with and without reducing system.

Model	Size Ø	Figure
REF 1287-63-xx series The disposable valve mounting for TrocaPort system	5.5 mm 5.8 mm 11 mm	
REF 1287-64-xx series The disposable valve mounting with reducing system for TrocaPort system	11 / 5.8 mm	

Please see the current declaration of conformity for a detailed product list.

In addition to these instructions for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.

Users must provide patients with information.

Intended use

Ensuring the tightness of trocar systems; regulation of the gas flow.
The reducing system permits the gastight introduction of instruments with a smaller shaft diameter by shifting of the reducer.

Target user group

Medical specialist statt only; surgeon

Target patient population

Adults and children

Indication

For use with trocar sleeves in laparoscopy, in general surgery, gynaecology and urology.

Contraindications

Device specific contraindications

Under no circumstances is the device to be used in the event of known material incompatibilities and/ or known interactions.

Clinical contraindications

Contraindications depend primarily on the laparoscopic procedure being performed.

Complications

Device specific complications
Insecure pneumoperitoneum, leakage, gas problem, vascular/visceral injuries, bleeding/haematomas, intestinal lesions, organ injury, hernia, scars/ adhesions, infection at the insertion site.

Clinical complications
Complications depend primarily on the laparoscopic procedure being performed.

Users must inform patients of complications typically associated with the procedure.

If complications occur while using the device, follow the protocols of your organisation. If this does not resolve the complications, or if they are regarded as serious or untreatable, carefully stop the procedure and remove invasive device components from the patient.

Warnings

for sterile product:

This is a disposable medical device for use with only one patient.

This device must not be re-used under any circumstances.

This device must not be resterilised under any circumstances.

The materials used in the manufacture of this device are not suitable for reprocessing or resterilisation.
This device is not designed to be reprocessed or resterilised.

Unauthorised re-use or reprocessing
- can cause the device to lose the essential performance properties intended by the manufacturer.
- leads to a significant risk of cross-infection / contamination as a result of potentially inadequate processing methods.
- may cause the device to lose functional properties.
- may cause materials to break down and lead to endotoxic reactions caused by the residues.

further warning indications:

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. You must routinely take general precautions for handling blood and bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.
3. Please note that the continued use of a device of the same type must be assessed cumulatively as described in the legislation on medical devices, even after the device has been exchanged or replaced.

Sequence of use

1. Take the disposable valve mounting from the sterile packing.
2. Screw the disposable valve mounting into the TrocaPort – trocar sleeve in clockwise direction.
3. After use, unscrew the disposable valve mounting in counter clockwise direction and discard it properly.

Assembly / dismantling

The instruments can be dismantled and assembled without tools and can be mounted on the valve housing by means of a quick-lock (1.5 turns).

Use and storage conditions

Temperature range from +10 °C to +30 °C

Air humidity 20 % to 65 %

Keep away from sunlight

Keep away from rain

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

Non-pyrogenic

Any serious incident that has occurred while using the device should be reported to the manufacturer and the corresponding authorities of the country the user and/or patient are residing in.

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling


Manufacturer

Use-by date


Catalogue number


Sterilized using ethylene oxide


Do not resterilize


Do not use if package is damaged


Keep dry


Single Sterile Barrier system with protective packaging outside


Humidity limitation


Do not re-use


Caution


Date of manufacture


Batch code


Keep away from sunlight


Temperature limit


Consult instructions for use


Non-pyrogenic


Caution: Federal law restricts this device to sale by or on the order of a physician


MR unsafe


Advice


Information


„CE marking of conformity“ or „CE marking“ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Medical Device Regulation and other applicable Union harmonisation legislation providing for its affixing.


Does not contain Phthalates


Does not contain natural rubber latex


Quantity


Translation


Medical device


Unique Device Identifier


Single Sterile Barrier system

CE 0124

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