PAJUNK®

# Eco Balloons
# Eco Balloon Kits

Minimally Invasive Surgery

# Instructions for Use

**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 user instructions invalidates the warranty and puts patient safety at risk.
If used in combination with other products, it is essential that the compatibility information and user instructions for these other products 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**

REF *Please see the current declaration of conformity for product numbers and the scope of these instructions for use.*

These instructions for use cover PAJUNK® Eco Balloons and Eco Double Balloon Sets.

Pajunk® Eco Balloons are used in combination with a trocar valve (TrocaTec or TrocaPort) and a reusable obturator. These can be purchased separately.
Compatible valves are listed in XS190260, compatible obturators in XS190259.

Connection: LUER

REF 1285-xx-xx Eco Balloons

– Space-creating, dilating balloons DIL, DIL-XL, DIL-BI

| Name | Diameter | Length | Filling volume | Ball pump |
|---|---|---|---|---|
| DIL | 11 mm | 105 mm | approx. 300 ml | press up to 15 times; max. internal pressure 120 mmHg ≙ 160 mbar |
| DIL-XL | 11 mm | 105 mm | approx. 470 ml | press up to 25 times; max. internal pressure 120 mmHg ≙ 160 mbar |
| | 12.5 mm | 105 mm | approx. 470 ml | press up to 25 times; max. internal pressure 120 mmHg ≙ 160 mbar |
| DIL-BI | 11 mm | 105 mm | approx. 300 ml | press up to 15 times; max. internal pressure 120 mmHg ≙ 160 mbar |

*Balloons to secure access:*

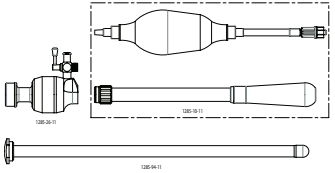
- Structural balloon systems: SB
- Ring-anchor balloon systems: RA, RA-S
- URO ring-anchor balloon systems: URO, URO-S
- SlimLine ring-anchor balloon systems: SL, SL-S

| Name | Diameter | Length | Filling volume | Syringe |
|---|---|---|---|---|
| SB | 11 mm | 105 mm | approx. 75 ml | press ball pump 3-4 times; max. internal pressure 150 mmHg ≙ 200 mbar |
| RA | 11 mm | 105 mm | approx. 30 ml | 30 ml |
| | 5.8 mm | 105 mm | approx. 10 ml | 10 ml |
| RA-S | 11 mm | 80 mm | approx. 30 ml | 30 ml |
| URO | 11 mm | 105 mm | approx. 30 ml | 30 ml |
| | 5.8 mm | 105 mm | approx. 20 ml | 20 ml |
| URO-S | 11 mm | 80 mm | approx. 30 ml | 30 ml |
| SL | 11 mm | 105 mm | approx. 12 ml | 12 ml |
| SL-S | 11 mm | 80 mm | approx. 12 ml | 12 ml |

REF 1285-xx-xx Eco Double Balloon Sets

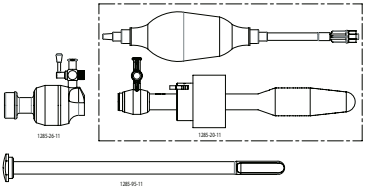
- EcoBalloonDuo DIL-XL + RA
- EcoBalloonDuo DIL-XL + SB
- EcoBalloonDuo DIL-XL + URO
- EcoBalloonDuo DIL-XL + SL
- EcoBalloonDuo DIL-BI + RA
- EcoBalloonDuo DIL-BI + SB
- EcoBalloonDuo DIL-BI + URO
- EcoBalloonDuo DIL-BI + SL

A space-creating balloon system consists of a disposable Eco Balloon and a reusable TrocaTec or TrocaPort valve (see XS190260) and obturator (see XS190259).
The system uses a balloon to separate tissue layers (dissection) and to create a connected work area in the extraperitoneal space under sight. After separating the tissue, a second sleeve with a balloon anchor (PAJUNK® structural or ring-anchor balloon system or other suitable instrument) is introduced into the work area and $CO_2$ gas is insufflated in the extraperitoneal space.



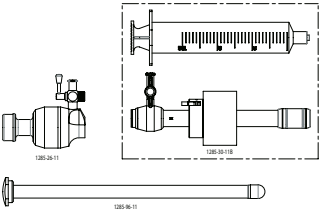

The space-creating balloon is filled via the TrocaTec/TrocaPort valve and the corresponding ball pump.
To empty the space-creating balloon, open the valve on the metal trocar valve.

A structural balloon system consists of a disposable Eco Balloon and a reusable TrocaTec or TrocaPort valve (see XS190260) and obturator (see XS190259).
The system uses a structural balloon for gas-tight anchoring and mechanical support of the extraperitoneal space. In case of a peritoneum rupture, collapse of the extraperitoneal space is avoided and tissue kept away from the distal end of the instrument channel.



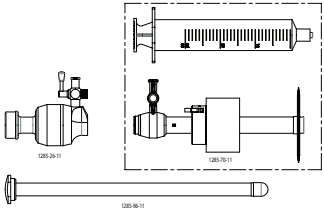

The structural balloon is filled via a valve by means of the corresponding ball pump.
To empty the structural balloon, open the plastic valve. The valve must remain open after emptying.

A ring-anchor balloon system consists of a disposable ring-anchor Eco Balloon and a reusable TrocaTec or TrocaPort valve (see XS190260) and obturator (see XS190259).
The system uses a small ring balloon for gas-tight anchoring of an instrument channel in the extraperitoneal space.



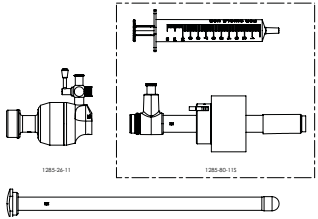
The ring balloon is filled via a valve by means of the corresponding syringe. The air is kept in the balloon by locking the valve. To empty the ring balloon, open the valve. The valve must remain open after emptying.

A URO ring-anchor balloon system consists of a disposable ring-anchor Eco Balloon and a reusable TrocaTec or TrocaPort valve (see XS190260) and obturator (see XS190259).
The system uses a small ring balloon for gas-tight anchoring of an instrument channel in the extraperitoneal space.




The ring balloon is filled via a valve by means of the corresponding syringe. The air is kept in the balloon by locking the valve.
To empty the ring balloon, open the valve. The valve must remain open after emptying.

A SlimLine ring-anchor balloon system consists of a disposable ring-anchor Eco Balloon and a reusable
TrocaTec or TrocaPort valve (see XS190260) and obturator (see XS190259). The system uses a ring balloon for gas-tight anchoring of an instrument channel in the extraperitoneal space.
The ring balloon is filled via a check valve and the corresponding syringe.
Keep the syringe pressed to remove it from the valve so that the check valve closes and the filling volume is locked in the balloon.
To empty the ring balloon, draw up the filling volume through the check valve using the syringe provided.




**Intended use**

PAJUNK® balloon systems for extraperitoneal dilatation and fixation (structural balloon system and ring-anchor balloon system).

**Indications**

*The space-creating, dilating balloon system by* PAJUNK® is indicated for minimally invasive procedures, in particular in extraperitoneal surgery, when tissue separation in the extraperitoneal space under sight is required.

*The structural and ring-anchor balloon system by* PAJUNK® is indicated for minimally invasive procedures, in particular in extraperitoneal surgery, when a well-anchored, gas-tight access with instrument channel (structural balloon system: mechanical support of the extraperitoneal space) is required.

- Hernioplasty
- Spinal surgery
- Lymphatic gland removal
- 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.*

⚠ PAJUNK® *balloon systems must be handled with care. Damage to the balloons by instruments used for introducing and during surgical interventions may cause product failure. The use of sharp hooks together with balloon systems is contraindicated.*

*Clinical contraindications*

*Absolute contraindications:*

- Treatment with anticoagulants

*Relative contraindications:*

- Clinically manifest coagulation disorders
- Limited cardiopulmonary function
- Ileus
- Earlier surgical interventions in the abdomen / suspected adhesions
- Unfavourable anatomy
- Large hernias

**Complication**

*Device-specific complications*

Excessive balloon insufflation may cause leaks or bursting.

*Clinical complications*

*Intraoperative:*

Bleeding, damage to organs, damage to blood vessels, general anaesthesia risks

*Postoperative:*

Bleeding, seroma, wound healing disorders, infections, recurrent hernia, long-term pain, adhesions

*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.

*in the application:*

1. In case of adhesions, small pelvic size or previous surgery, insufflate slowly and carefully and adjust the inflation volume to anatomical conditions.
2. Avoid forced introduction of the dilation balloon or introduction below the pubic bone as this may result in injury to organs and structures in the extraperitoneal space.
3. Mineral-based lubricants are not allowed in combination with PAJUNK® balloon systems.
4. Caution: PAJUNK® balloon systems may only be used in combination with PAJUNK® modular trocar sleeves and obturators.

*further warning indications:*

1. Caution: Sharp object warning. The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. The most relevant ones in practice are the human immunodeficiency virus (HIV), the hepatitis B virus (HBV) and the hepatitis C virus (HCV).

2. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
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.
4. You must routinely take general precautions for handling blood and body fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.

**Sequence of use**

Using total extraperitoneal hernioplasty as an example
*Dilatation*

1. Remove the disposable balloon system from its sterile packaging and screw it into the housing of the trocar sleeve instead of the guide tube. Slide the blunt obturator carefully into the trocar sleeve until the stop. Keep it in this position. If necessary, put sterile lubricant onto the distal end and introduce it between the tissue layers to be separated using an open method. While introducing the balloon system and during the surgical intervention, make sure that the balloon is not damaged by other instruments (see fig. 1). Alternatively, you may replace the blunt obturator of the (bilateral) PAJUNK® dilating balloon system by an endoscope at the beginning of the procedure in order to introduce it under sight. Make sure not to apply too much pressure when introducing the endoscope to avoid damage to the balloon.

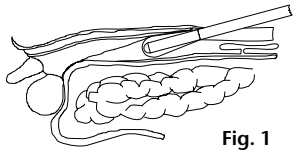


**Fig. 1**

2. Push the (bilateral) dilating balloon system forward until reaching a suitable position in the extraperitoneal space (see fig. 2). In no case should you introduce the instrument too deeply and apply too much pressure onto the balloon to avoid injury to adjacent organs and structures, e.g. the bladder. (Fig. 3). Place the balloon system with the green mark at its base (only 1285-50-11) facing up, i.e. pointing away from the abdominal wall. This is the only way to make sure that the balloon unrolls laterally from bottom to top.

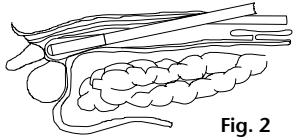


**Fig. 2**

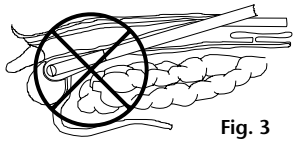


**Fig. 3**

3. After having positioned the instrument, connect the insufflation ball pump with its transparent connector to the open insufflation valve of the trocar sleeve. Then remove the obturator and replace it by an endoscope, unless already done (see point 2). Now the balloon is carefully insufflated through the upward-pointing insufflation valve by means of the insufflation ball pump. To insufflate the (bilateral) PAJUNK® distension balloon system, actuate the ball pump max. 15 times (extra large: 25 times), taking into account the anatomical conditions; monitor the process continuously via an endoscope. Insufflation of the balloon results in a progressing dissection, which is monitored via the endoscope (see fig. 4).

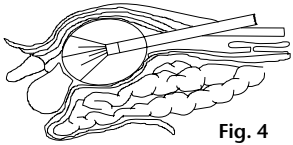


**Fig. 4**

4. If the extraperitoneal space is adequately prepared, air is discharged from the distension balloon by removing the endoscope and opening the insufflation valve. If required, you may use the black suction port of the ball pump to evacuate the air. Carefully remove the (bilateral) PAJUNK® distension balloon system and replace it by a PAJUNK® trocar system, a PAJUNK® structural or ring-anchor balloon system or another suitable instrument (see fig 5).

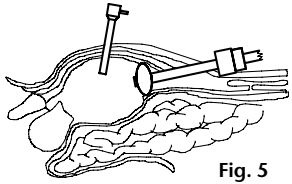


**Fig. 5**

5. Then the extraperitoneal space is insufflated with low pressure. Further trocars may be placed and other work instruments may be introduced into them.

*b) Fixation*

1. Remove the balloon system from its sterile packaging and screw it into the housing of the trocar sleeve instead of the guide tube. *Structural balloon system:* Slide the blunt obturator with two lateral fillets at the distal end carefully into the trocar sleeve until the stop. Turn it so that the folded balloon cover in its plastic hood may be accommodated in the fillets. *Ring-anchor balloon system:* Slide the blunt obturator carefully into the trocar sleeve until the stop. Keep it in this position.
2. If necessary, put sterile lubricant onto the distal end of the balloon system and introduce it through an existing access port into the prepared extraperitoneal space. While introducing the balloon system and during the surgical intervention, please make sure that the balloon is not damaged by other instruments (see fig. 6).

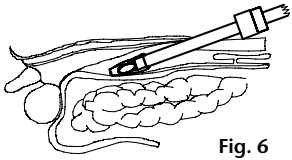


**Fig. 6**

3. Move the balloon system forward until the first third of the guide tube is positioned in the extraperitoneal space. In no case should you introduce the instrument too deeply to avoid injuries to adjacent organs and structures, e.g. the bladder.
4. *Structural balloon system:* Place the balloon system with the valve and the black mark on the tube of the balloon system facing up, i.e. pointing away from the abdominal wall. This is the only way to make sure that the structural balloon is correctly positioned for mechanical support of the extraperitoneal space. After having positioned the instrument, connect the insufflation ball pump with its transparent connector to the open plastic valve on the plastic tip of the guide tube. Now the balloon is carefully insufflated through the upward-pointing insufflation valve by means of the insufflation ball pump. To insufflate the PAJUNK® structural balloon system, actuate the ball pump max. 3-4 times as required, taking into account the anatomical conditions; monitor the process continuously via an endoscope. Insufflation of the balloon results in a progressing dissection and anchoring in the extraperitoneal space (see fig. 7).
   *Ring-anchor balloon system:* After having positioned the instrument, connect the air-filled syringe (syringe see table above) to the plastic valve/check valve on the plastic base of the guide tube. Then fill the ring-anchor balloon carefully by slowly pressing the air-filled piston down (max. filling volume, see table above). After completing the filling process, close the plastic valve at the plastic tip (if any) of the guide tube and remove the syringe from the plastic valve/check valve keeping the syringe piston pressed. While filling the balloon, the ring-anchor expands (see fig. 7).

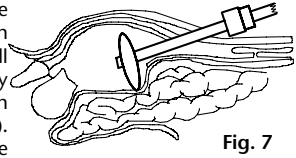


**Fig. 7**

5. Then pull the complete instrument slightly backwards so that the balloon is tightly pressed against the inside of the access opening. In this position, unlock the lock using the clamping lever, move it distally until it reaches the skin and lock it again in its end position using the clamping lever (see fig. 8).

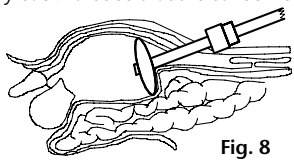


**Fig. 8**

6. Now remove the blunt obturator carefully and insufflate the extraperitoneal space via the metal insufflation valve on the trocar sleeve body.
7. You can now introduce instruments with a diameter of 5.8 mm/11 mm through the instrument channel of the system.
8. At the end, empty the balloon with the provided syringe by sucking out the entire filling volume via the plastic valve/check valve. If there is a valve, you may discharge the air from the balloon by opening the valve at the tip of the guide tube. Let the valve open so that the air can escape completely. If

required, you may use the black suction port of the ball pump to evacuate the air. Then you can remove the PAJUNK® structural or ring-anchor balloon system carefully and dispose of properly.

**Use and storage conditions**

| | | |
|---|---|---|
|  | Temperature limit | +10 °C to +30 °C |
|  | Humidity limitation | 20 % to 65 % |
|  | Keep away from sunlight | |
|  | Keep dry | |

**General information**

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

*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


Humidity limitation


Do not re-use


Caution


Date of manufacture

Batch code


Keep away from sunlight


Temperature limit


Consult instructions for use

Dispensing with prescription only (the product may only be used by qualified medical staff for the intended use.)

MR unsafe


Advice


Information

P"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.


Sharp object warning

Does not contain Phthalates

Natural rubber has not been used as a component in the manufacture of this product

Quantity


Translation

Medical device

CE 0124

XS190101K_Englisch 2020-11-25

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