PAJUNK®

# VPC
# (Visual Pressure Control)

Regional Anesthesia

# 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.*

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.*

VPC is an instrument for displaying a change in pressure.

VPC for single use.

Hub connectivity: LUER

**Intended use**

Identification of the epidural space by loss of resistance (by means of saline).

**Indications**

Epidural anaesthesia/analgesia
VPC is only used in combination with an epidural cannula.

**Contraindications**

Using VPC for injections and aspirations.

Fluid entering the capillary when drawing in saline solution (changing the pressure display)

**Complication**

No further complications in addition to those encountered in epidural applications.

*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:*

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.

**Sequence of use**

*Preparing the VPC (Visual Pressure Control)*

1. VPC is delivered with 2 ml of air.

There must be no fluid in the capilary before application.

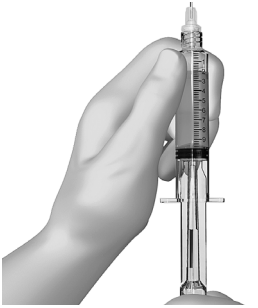
2. Prepare the VPC by filling it with saline. Use a suitable drawing-up cannula or filter cannula for this purpose. Leave the plunger at the preset 2 ml position and draw approx. 8 ml of saline solution into the VPC so that the VPC plunger stops at a filling volume of 10 ml.

When filling the VPC, make sure that the 2 ml air chamber is always in the area of the VPC plunger, or that the VPC Luer connector always points downward.

*The plunder of the VPC must be dry, otherwise the pressure column will not be built up.*

3. Now evacuate the air from the VPC by holding it with the Luer connector pointing upward so that the 2-ml air chamber is near the Luer connector.

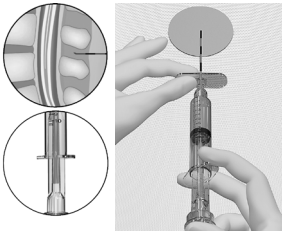
Then apply pressure to the VPC plunger to remove the air from the VPC. The plunger must stop at the 8 ml position.



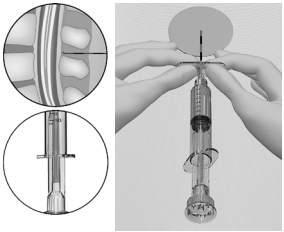
*Placement of the epidural cannula*

1. Perform skin disinfection and cover the puncture area with a sterile fenestrated drape.
2. Administer a local anesthetic.
3. If necessary, perform a perforating incision of the area to be punctured (lancet, or similar).
4. With the stylet inserted, advance the cannula into the muscle tissue, beyond the subcutaneous tissue (2-3 cm).
5. Remove the stylet from the cannula.
6. Connect the VPC (Visual Pressure Control) to the cannula.

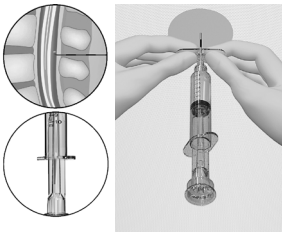
7. Build up pressure in the VPC by applying pressure to the VPC's plunger and advancing the plunger in the cylinder until the column of saline solution reaches the magnifying glass of the capillary.



8. With the help of bimanual cannula guidance, advance the cannula with the connected VPC deeper into the muscle tissue or interspinous ligaments. While doing so, keep a close eye on the pressure column in the capillary of the plunger.



9. The entry of the needle into the epidural space is identified by a characteristic loss of resistance, shown by a clear pressure drop in the column, which you can see when looking through the magnifying glass of the capillary.



10. Recheck the cannula position by building up pressure once again. Another pressure drop confirms correct placement of the cannula tip in the epidural space.

If the pressure column does not fall off, it can be assumed that the cannula tip is in a compartment instead of the epidural space.

11. After positive identification of the epidural space, remove the VPC and inject the anaesthetic (depending on age and weight of the patient, as well as on the type of the intervention and the composition of the anaesthetic) or continue with "Placement of the epidural catheter" if a continuous technique should be used.

*Placement of the epidural catheter*

1. Remove the VPC and place the insertion aid on the cannula hub.
2. Push the catheter with the marked end into the epidural space until reaching the required depth. Do not advance the catheter forward any further, if you feel clear resistance.
3. After successful positioning, remove the cannula over the catheter. Hold the catheter tightly with the other hand, if necessary.
4. After removing the cannula, connect the catheter to the ClampingAdapter.
5. Fill the filter with the anaesthetic solution to be used at the beginning of the epidural anaesthesia/analgesia to compensate for the dead volume (the filling volume of the filter is approximately 0.8 ml).
6. Connect the catheter adapter to the hub of the filter.
7. Fill a VPC with the selected anaesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
8. Fix the catheter at the outlet site with the optionally provided FixoCath.
9. Optionally fix the catheter and filter with FixoLong close to the outlet site.

*Recalibration of the VPC*

If any fluid should have entered accidentally the capillary tube, it can be removed again by recalibration. To do so, proceed as follows:

1. Drain the VPC as completely as possible.
2. Fill the VPC with at least 2 ml of air.
3. Screw a locking cap on the Luer connection of the VPC.
4. Now point the Luer connection of the VPC downwards und retract the plunger as far as possible.

5. Remove the locking cap before releasing the plunger again.
6. Now no more fluid should be present in the capillary tube. Otherwise, repeat the recalibration procedure.

**Operating 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.*

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## 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 purpose.)


Advice


Information

Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body

Does not contain phthalates (acc. to section 7.5 of Appendix I 93/42/EEC)

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

Quantity


Translation

Medical device

CE 0124

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