ACESSORIES

The recommended non-coring port puncture needles are available separately.

Article no.	Size specification	PZN
SFN 1535 B	Ø 1,5 mm, Length: 35 mm, 17 G	12363624
SFN 1835 B	Ø 1,8 mm, Length: 35 mm, 15 G	12363630
DPK 2035	Ø 2,0 mm, Length: 35 mm, 14 G	02429581

Table 1: SFN Special port puncture needles

Further recommended SFN® - port needles are the following:

Artiicle no.	Size specification	PZN
SFN 0930 B	Ø 0,9 mm, Length: 30 mm, 20 G	13837567
SFN 0930 G	Ø 0,9 mm, Length: 30 mm, 20 G	01060286

Table 2: SFN® - port needles

Packaging unit: 25 pieces

Please observe separate instructions for use!

By using SFN® port needles SFN 1320 S and SFN 1325 S the period of application should not exceed **24 hours**.

Recommendation: www.portneedles.de

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

Patients with an implanted TITAN-PORT APH get into contact with following materials (tested for biocompatibility):

- 12.69 g titanium alloy TiAL4V6
- 2.02 g Nusil-Med 4750 silicone (septum)
- 4.97 g polyurethane (depending on the implanted length of the catheter), incl. small amounts of barium sulphate (BaSO4)
- Printing ink

The amount of silicone / polyurethane depends on the implanted length of the catheter.

MR-SAFETY INFORMATION

MR

MR-conditional

Non-clinical testing has demonstrated the "Titan Chamber" is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,900 G/cm (129 T/m)
- **Maximum force product** of 231,000,000 G2/cm (231 T2/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the "Titan Chamber" is expected to produce a maximum temperature rise of less than **2.3 °C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of · 1.4 °C (2 W/kg, 1.5 Tesla)** **3.9 °C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of · 2.0 °C** (2 W/kg, 3 Tesla) after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 34.0 mm from the "Titan Chamber" when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Notes:

Notice to users and patients: Please report all serious incidents related to this product to the manufacturer, as well as to the competent authority of the member state in which you are established.

Product training is available on request!

	Manufacturer		Do not re-use		Do not use if package is damaged
	Date of manufacture		Caution		Consult instruction for use
	Use by date		Temperature limit		Keep away from sunlight
REF	Catalogue number		Keep dry	EC REP	Authorized representative in the European community
LOT	Batch code	MD	Medical Device	STERILE EO	Sterilized using ethylene oxide
	Pyrogen free		Single sterile barrier system with protective packaging inside		

EXAMPLE OF IMPLANTATION (schematic):

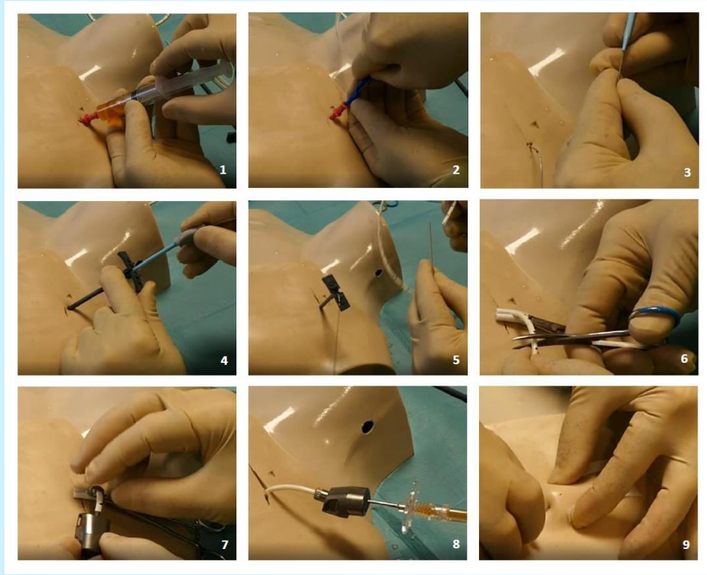

Fig. 1: The subclavian (cephalic/jugular) vein is punctured.
Fig. 2: The guide wire is advanced to the atrium.
Fig. 3: The dilator is inserted over the guide wire with the sheath.
Fig. 4: The dilator is removed.
Fig. 5: The catheter is pushed onto the guide wire up to the atrium. After exact placement of the catheter, the guide wire is removed. (X-ray control). The sheath is removed.
Fig. 6: The catheter is shortened to the desired length at the distal end.
Fig. 7: The catheter is connected to the port via the screw cap.
Fig. 8: The system is checked for patency.
Fig. 9: The port is inserted into the prepared subcutaneous pocket, placed and fixed. Port puncture.

The implantation procedure as a demo is available as a video via the QR code.

The implantation procedure on humans is available as a video via the QR code.

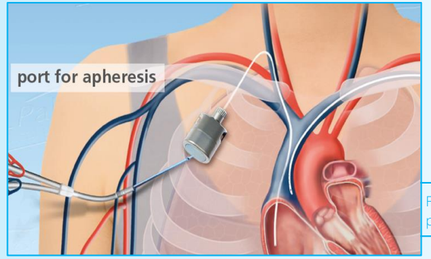

Figure 2 Example of using the entire surface of the port membrane for the puncture

Figure 1 Upper body with port implant and puncture, e.g. via the vena jugularis

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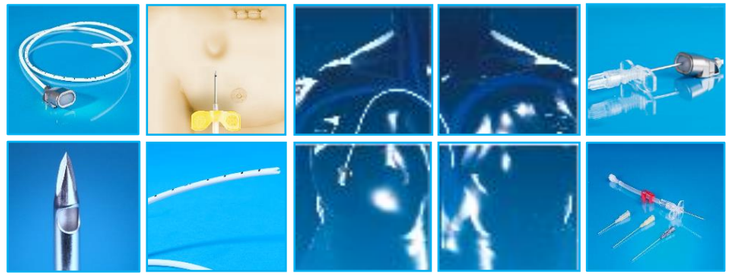


TITAN PORT APH
for extracorporeal apheresis

Product code:
111263 APH

Instruction for use
please read carefully!

TITAN-PORT A/V D P®
F G S PD PC APH AS/PT UA DR

revision: 3.1 (03/2022)

TITAN-PORT APH (Apheresis)

PRODUCT DESCRIPTION

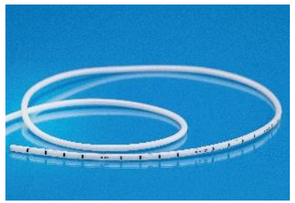
TITAN-PORT APH (exctracorporeal apheresis) is a fully implantable port catheter system providing an access facility for performing extracorporeal apheresis. The set contains a titanium port chamber with a self-sealing silicone membrane and a single-lumen polyurethane catheter for connection to the port chamber and fixing to the outlet tube with a screw. Each system also includes a special puncture needle SFN 1535 B, an introducer set (consisting of an 18 G introducer, an 11 F introducer peel-away and a 0.89 mm guidewire), a tunnelizer, a vein lifter, a rinsing needle, a port cannulae SFN 0930 G, this user instruction and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber dimensions are: width: 20.6 mm, height: 16.7 mm, length: 25.5 mm, weight: 14.71 g, priming volume: 1.42 ml. The base plate has suture openings for securing the system to the fascia. Port chamber and catheter can be disconnected and are connected via a screw with the outlet tube.

The silicone membrane in the port (118 mm^2) can be punctured frequently with a suitable non-coring puncture needle. The membrane is highly resistant to pressure and holds the inserted needle reliably in place.

The single-lumen polyurethane catheter (10 French, with an outer diameter 3.35 mm, an inner diameter 2 mm, total length 72 cm and internal volume of 0.31 ml per 10 cm) has at the distal end a special catheter tip (fishmouth tip). If necessary the catheter can be shortened at the proximal end. The fishmouth tip reduces adsorption at the vessel wall, thereby also improving the flow rate.

The catheter is marked, every centimetre, with length marker until 40 cm (lines stand for 1 cm, points stand for 5 cm). The catheter is radiopaque.



Example of the catheter with length markings

Only special non-coring port needles should be used to puncture the port membrane.
Depending on indication and flow rate different special puncture needles can be used, e.g. the DPK 2035, SFN 1835 B and SFN 1535 B as well as the smaller SFN® safety port needles, e. g. SFN 0930 B and SFN 0930 G.

The needles exhibit a unique bevel and angle at the tip. This prevents punch defects at the membrane when the needle is inserted. Each system contains a suitable needle. Appropriate accessories can be ordered separately if required.

The flow rate **("gravity flow")** is 137 ml/min when puncturing with DPK 2035 and 123ml/min with the SFN 1835 B. The flow rates depend on the type of application, device and cannula used (these measurements are according to DIN EN ISO 10555-1).

The trocar is used for subcutaneous guidance and placement of the catheter if necessary.

The instructions for use should also be available to nurses and doctors responsible for follow-up care.

The implant card is filled out by the doctor who performed the document with her/him and is given to the patient who should always carry this document with her/him.

The contents of the product are stated on the label of the double-sterile individual packaging.

INDICATION

The TITAN-PORT APH allows repeated vascular access for therapeutical apheresis.

The advantage is a low risk of infection, simplified access and considerably improved quality of life for the patient as provided by a closed system.

Patient group: Patients in need of long-term central venous access to the vascular system.

Operators: Medical professionals (doctors, nurses) with appropriate qualifications.

In addition, there are PakuMed port systems for the following applications:

TITAN-PORT A (arterial):	for direct arterial perfusion of organs
TITAN-PORT D:	for dialysis venous ↔ venous
TITAN-PORT V:	for venous application
TITAN-PORT P-N:	for neonatology
TITAN-PORT F:	for fetal/ prenatal application
TITAN-PORT P:	for paediatrics
TITAN-PORT AS/PT:	for ascites- and peritoneal therapy
TITAN-PORT UA:	as side port e.g. for implantation in the arm
TITAN-PORT DR:	for drainage in the thoracic cavity
TITAN-PORT G	suitable for all needles

Intended purpose: The port catheter system is only used to pass blood and medication into or out of the patient's vascular system. The product itself thus fulfils a physical property and has no medical, therapeutic effect.

CONTRAINDICATION

The TITAN-PORT APH systems should not be used in case of:

- extremely rare but possible hypersensitivity to silicone, polyurethane or titanium (all port chambers contain titanium and silicones)
- suspected bacteraemia / sepsis
- disseminated intravascular coagulation (DIC)
- poor patient compliance

and it is always dependent on the clinical patient situation.

COMPLICATIONS AND POTENTIAL ADVERSE REACTIONS

The following complications or adverse reactions can occur:

- intraoperative complications
- tissue incompatibility
- local reactions (inflammation, edema, hematoma)
- infection
- disconnection or dislocation
- thrombosis / thromboembolism
- torsion of chamber or catheter
- membrane and catheter dislocation, catheter rupture drug extravasation due to improper handling of the systemdamage to neighbouring tissues by the pharmaceutical agents (in the event of leakage of portal components)
- leakage from chamber, septum, connection
- air embolism
- Cardiac arrhythmia and heart wall damage

The application must not be carried out by doctors / medical staff who are not familiar with the product and / or possible complications. Complications may occur at any time during and after the procedure.

PREPARATION

- Before implantation, discuss and mark the ideal implantation site with the patient.
- The catheter is filled with 0.9% saline solution before implantation.
- The port chamber is also filled and deflated.
- The outlet tube of the port chamber is hold upwards in order to let the remaining air escapes. A puncture cannula is provided for this purpose.

INSTRUCTION FOR THE PORT IMPLANTATION

Caution: During implantation a sterile handling is absolutely mandatory!

Selection, decision-making and technique are the responsibility of the physician performing implantation.

Possible implantation sites are the Vena jugularis interna, Vena jugularis externa or Vena subclavia with alternative locations also possible (Fig. 1). Implantation can be performed in local anesthesia.

The following represents an example of the possible / standard surgical implantation technique. Other surgical procedures, alternatives are possible. Postoperative X-Ray control is indispensable.

Various surgical options are available for implanting the port chamber and catheter (including open surgery or the Seldinger technique).

1. Exposure of the internal jugular vein (supraclavicular incision).

2. subclavicular incision

3. subcutaneous tunnel between both incisions

4. subcutaneous dissection of a pocket

5. advance catheter tip subcutaneously from subclavicular incision to supraclavicular incision under tunnelling

6. Small venotomy (caution air embolism!). Insertion of the catheter tip into the right atrium (check position by intra-atrial ECG section or X-ray fluoroscopy)

7. tabac suture at the venotomy

8. shorten catheter end if necessary

9. Push the catheter end onto the outflow tube of the port chamber and fix it with the screw.

10. place the port chamber subcutaneously as far as possible from the skin incision, fix if necessary

11. skin sutures

Alternative: Seldinger technique

When using the introducer sheath, make sure that the catheter is not withdrawn through the introducer sheath!

Theoretically, the system can be used immediately, but it is recommended to use it after the wound has healed for about one week.

The recommendations mentioned must always be adapted to the general situation of the patient and are the responsibility of the attending physician. With regard to all medicines and liquids used, reference is always made to the package inserts of the respective pharmaceutical manufacturers. The special features of apheresis must be taken into account.

WARNINGS

- The port chamber should be secured to the muscle fascia/subcutaneous tissue by sutures or placed in the smallest possible port pocket in order to prevent the port to migrate.
- the catheter must be secured to the vein with a firm, but not constricting suture.
- the safe connection of the catheter to the port must be confirmed.

After a long implantation period or system use, check the membrane for leakage resulting from frequent punctures. When there are no complications known a puncture frequency of up to approx. **1000 punctures with SFN 1835 B and 500 punctures with DPK 2035** allocated on the entire membrane (see Fig. 2). Puncture with a special cannula allows for a corresponding length of stay depending on the frequency of puncture if there are no complications. Replacement of the port chamber in case of leakage of the silicone membrane is possible, also under local anaesthesia.

INSTRUCTIONS FOR USE FOR THE PUNCTURE

1. Skin disinfection, sterile gloves, mask (patient and operator)
2. If possible have patient in supine position
3. Puncture the port membrane only with a special puncture needle (supplied) until the tip of the needle touches the base plate **Caution:** air embolism!
4. Unblocking the system
5. Check for occlusion with saline solution and connect up the apheresis system
6. At the end of apheresis, flushing the system with at least 30 ml saline 0.9 %
7. Block the system with e. g. heparin, taurolidine or citrate
8. Remove the puncture needle using gentle positive pressure.
9. Disinfect the skin; apply dry dressing

If system is not used flush every 3-4 weeks with 0.9 % saline and block it afterwards.

Catheter or port thrombotic occlusions can generally be resolved with fibrinolytic agents such as streptokinase / urokinase (e. g. inject 5000 IE/ml 0.9 % saline solution in small solution amounts at intervals, allow time for resolution and check for occlusion. Before: x-ray control.)

Possible causes for an **insufficient or missing "flow"** or an abnormally high puncture resistance could be:

- the needle tip is not correctly placed in the cavity of the port chamber
- bending and kinking of the catheter
- Fibrin deposits or thrombotic occlusion are blocking the catheter or the port chamber.
- The catheter is not correctly positioned in the atrium When blood aspiration is not successful, the port chamber should first be flushed and the patient's position changed slightly.

Blood deposits in the system generally indicate one of the following

- leakage of the system
- defective septum
- faulty handling

LIFETIME AND CONSEQUENTIAL MEASURES

It is possible to leave the system in the patient after the end of therapy. When not in use, the system should be flushed every 8-12 weeks. It is recommended to remove the system 12 months after the end of therapy.

Other indications for explantation might be:

- irreversible occlusion of the port catheter system
- breakage of catheter or damage to catheter
- membrane leakage
- poor patient compliance
- thrombosis of the major vessels (subclavian vein, v. cava, internal or external jugular vein)
- non controllable infection

AFTERCARE / MONITORING

Regular treatment sessions and associated care of the port system are coincidental with monitoring of the system. The implant should be checked at regular intervals by trained medical personnel. This should be done as part of every application, otherwise approx. every 3 months. Patient training by the attending physicians is also recommended for self-monitoring. A **patient care guide** (leaflet) is enclosed with the documents of the product.

RE-USE

The medical device is intended for single use only and is not suitable for reprocessing. Due to biological risk explanted ports must not be implanted again and must be disposed accordingly.

DISPOSAL

Use suitable containers for disposal, e.g. needle drop containers for the cannulas, and observe the applicable legal regulations for the disposal of waste that might be contaminated with blood or bodily fluids.

PRECAUTIONS

Meticulous hygienic and sterile handling technique of the system are mandatory e.g.:

- implantation in sterile OR settings
- hand and skin disinfection, sterile gloves and mouth protection during use
- only use sterile products! If the sterile packaging has already been opened or damaged, DO NOT use the product!

CARE OF THE SYSTEM/ SPECIAL RECOMMENDATIONS

Before each access the correct position of the portal chamber must be checked by palpation. Any signs of wound, haematoma and infection must be excluded.

TRACEABILITY

The LOT number of the product can be found on the labelling, as well as on the included labels, which are also intended for documentation in the implantat card.