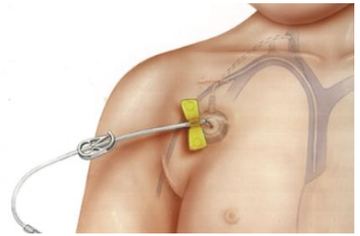


Example of a port puncture with a SFN® port needle

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

Patients with this implanted TITAN-PORT P-N get into contact with following materials (tested for biocompatibility):

- approx. 6.12 g titanium alloy TiAL4V6,
- 0.48 g Nusil-Med 4750 silicone (septum)
- 0.43 g polyurethane (depending on the implanted length of the catheter), incl. small amounts of barium sulphate (BaSO4)
- Printing ink

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

MR-SAFETY INFORMATION

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 (venous/ vena cephalica right):

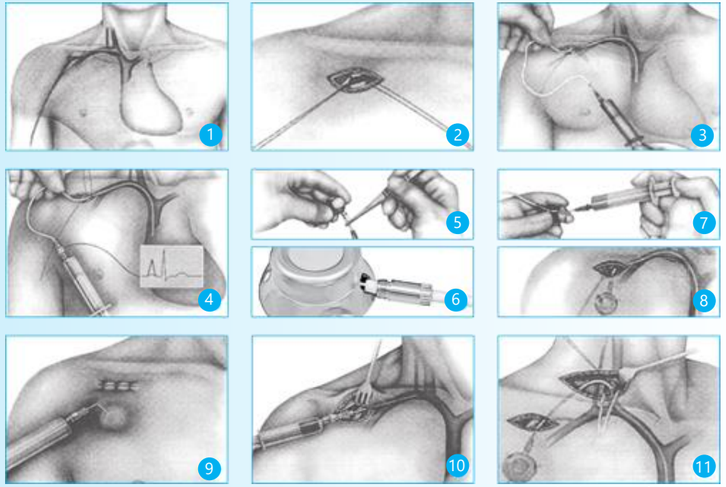


Fig.1: After preparation and draping of the surgical field, a 5 cm transverse subclavicular incision over the deltoideopectoral sulcus is made under local anesthesia.

Fig.2: The cephalic vein is exposed between the deltoid and pectoralis major muscles (sulcus deltoideopectoralis). The cephalic vein is ligated proximal and a transverse venotomy is then made.

Fig.3: The 0.9% saline-filled catheter is advanced approx. 10-14 cm into the vena cava superior.

Fig.4: The position of the catheter tip is confirmed by means of image intensification or intra-atrial ECG electrode tracing.

Fig.5 and 6: The portal chamber is filled. Surplus catheter is trimmed off distally.

The catheter is then connected to the portal chamber by advancing the sleeve over the catheter. Push the catheter up to 2/3 onto the outlet tube and fix it with the screw.

Fig.7: Patency of the system is tested with 10 ml 0.9% saline.

Fig.8: The port chamber is then placed into a subcutaneous pocket away from the skin incision and secured to the surrounding tissue with 3 sutures (alternative placement in a small subcutaneous pocket without fixation sutures is possible).

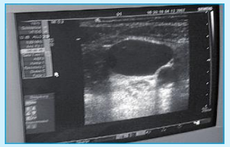
Fig.9: Closure of the wound with subcutaneous and skin sutures.

Fig.10: If the cephalic vein is unsuitable or difficulties arise, the application of the Seldinger technique is recommended for placement of the catheter into the subclavian vein.

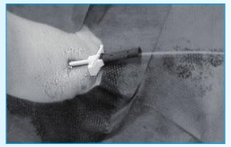
In general, placement of the catheter should be performed on the right side. The right subclavian vein is usually of greater diameter. The topographical relationship of the left subclavian vein with the thoracic duct, the brachiocephalic trunk, and common carotid artery, can potentially pose a problem when left venipuncture is performed. Primary puncture of the left subclavian vein is not recommended due to the higher complication rate.
Cave: "Pinch-off"-syndrome
Nowadays Duplex-sonografic controlled puncture is the standard method (see figure below).

Fig.11: Supraclavicular exposures of internal and external jugular veins are alternatives, especially when cephalic vein exposure fails.

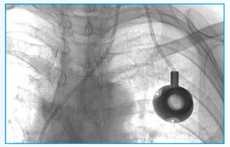
Alternative:



Ultrasonic scan of the jugular vein.



Puncture of the jugular vein and advance of guide wire, dilatation and insertion of the catheter up to the V. cava sup.



X-ray control

PakuMed® medical products gmbh

Im Löwental 79 · 45239 Essen · Germany
Tel.: +49 201-43 70 97-0
Fax: +49 201-43 70 97-29
E-Mail: info@pakumed.de
Internet: www.pakumed.de

TITAN-PORT P-N

Product code: 111244 P-N

Instruction for use
please read carefully!

TITAN-PORT A/V D P®
F G S PD PC APH AS/P1 UA DR

revision: 3 (01/2022)

TITAN-PORT P-N
(LOW PROFILE)

PRODUCT DESCRIPTION

The TITAN-PORT P-N is a fully implantable venous port catheter system. It consists of a titanium port chamber with a twist and screw closure mechanism and a self-sealing silicone membrane and a polyurethane catheter. Each system comes with a 20 G puncture needle, a refill needle, a vein lifter, a special puncture needle SFN 0720 S, an introducer set, these instructions for use and an implant card.
The introducer set consists of a 0.46 mm guide wire, an 18 G introducer needle, a 20 G introducer needle and a 5.5 F dilator.

S= small

This product is marked as a low profile port.
Low profile port catheter systems have a low profile of the port chamber and are identified by corresponding stickers on the outer folding boxes.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber has the following dimensions: Diameter (base plate): 21 mm, height: 9.8 mm, weight: 6.65 g, filling volume: 0.26 ml.
There are suture holes in the base plate to fix the system to the muscle fascia. Port chamber and catheter are connectable.

The silicone membrane (diameter: 8 mm) can be punctured frequently (up to 3000 times) with a suitable special port needle (such as the SFN 0720 S). The membrane is highly resistant to pressure and keeps the inserted needle reliably in place.

The polyurethane catheter (3 French with an outer diameter of 0.95 mm, an inner diameter of 0.46 mm, a total length of 70 cm and an inner volume of 0.02 ml/10 cm) can be individually shortened at the distal end to the required length before connection to the corresponding port chamber.

The catheter is provided with length markings in the range up to 30 cm (seen from proximal) at intervals of 2 centimetres each (a line stands for 2 cm and two line for 10 cm each). In addition, the area between 10 and 20 cm is divided into centimetre sections by dots. The tip is tapered and there is an additional hole on the side. The catheter is radiopaque.

Example of catheter length markings

Only special non-coring port puncture needles (e.g., **SFN® port needles** or other suitable port needles) should be used to puncture the port membrane. These needles exhibit a unique bevel at the tip. 20 Gauge is recommended for standard use.

The use of special port needle prevents that holes or silicone particle are punched out, which could proceed into the bloodstream or plug the system. Each system contains a suitable needle.

The **flow rate ("gravity flow")** is 1 ml/min when puncturing with the SFN 0720 S. The flow rates depend on the type of application, device and needle used (these measurements are according to DIN EN ISO 10555-1).

The implant card is filled out by the doctor who performed the document with her/him.

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

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

INDICATION

The TITAN port catheter systems P-N ensures the repeated access to the central venous vascular system for the following applications, e.g.:

- for long-term treatment of cytostatics agents and other "aggressive" medications
- patients with poor peripheral veins requiring frequent intravenous injections
- for infusion therapy
- for parenteral nutrition
- for HIV patients

Note: Because of the very small diameter of the catheter, blood drawing from the system may be difficult.

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

Patient group: Patients with the need for long-term central venous access to the vascular system. Due to the size of the port chamber and the catheter, this port catheter system is particularly suitable for small paediatric patients.

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 APH:	for apheresis
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 system 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 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
- breakage of the catheter between the clavicle and first rib (so-called pinch-off syndrome)
- breakage of catheter or damage to catheter
- torsion of chamber or catheter
- perforation of catheter
- drug extravasation due to improper handling of the system
- damage to neighbouring tissues by the pharmaceutical agents (in the event of leakage of portal components)
- 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

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 needle is provided for this purpose.

INSTRUCTION FOR THE PORT IMPLANTATION

Caution: During implantation a sterile handling is absolutely mandatory!

Various techniques are available for implantation of port and catheter, including the Seldinger technique or open surgery.

The decision and procedure are in the operators' authority.

- The implantation of TITAN-PORT P-N is usually possible under local anaesthesia.
- recommended sites for venous catheter placement are the cephalic vein, subclavian vein, or internal and external jugular veins.
- do not use syringes < 10 ml (danger of overload pressure) and only special non-coring needles for puncturing the septum. The needles are intended for single use only.
- the needle should be inserted into the silicone membrane carefully and vertical.

- if the situation is unclear or thrombotic obstruction is suspected a radiographic or duplex sonographic control is necessary.
- a venous implantation should be flushed with 20 ml 0.9% saline solution once every 8 to 12 weeks if the system is not in use.
- When blood sampling 3 ml of blood should initially be aspirated and discarded. At least a 20 G needle should be used and the required quantity of blood aspirated slowly (to avoid falsification of the results)
- to avoid interactions between various drugs (in particular cytostatic agents or aliphatic solutions) the system must be flushed with at least 10 ml 0.9% saline in between.
- When using needles with tubing always ensure beforehand that the needle/tubing is vented and the clamp is closed so that no blood can enter the system.
- the system must be flushed after each use. The port needle is removed with gentle force against the port chamber.
- catheter obstruction due to a thrombus can usually be cleared by injecting Streptokinasis / Urokinasis (with 10 ml syringe, small amounts should be injected at intervals, allowed time to take effect and patency check).
- The complication of thrombus can be reduced in those at risk by prophylactic "low-dose" heparinization.

The above mentioned recommendations must always be adapted to patient's status as monitored by a physician. The product description of all pharmaceuticals used should always be consulted.

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.
- 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

When not in use, the system should be monitored regularly. Flushing every 8-12 weeks is recommended. After completion of treatment or end of necessity the system should be removed.

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
- massive 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** is enclosed with the documents of the product.

WARNINGS

- the port chamber should be secured to the muscle fascia/subcutaneous tissue by sutures or placed in the smallest of portal pockets 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.

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 needles, 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 implantation certificate.

ACCESSORIES

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

Art. No.	Size specification	PZN
SFN 0720 S	Ø 0.7 mm, length: 20 mm, 22 G	07781615
SFN 0916 S	Ø 0.9 mm, length: 16 mm, 20 G	07781590
SFN 0920 S	Ø 0.9 mm, length: 20 mm, 20 G	06910275
SFN 0925 S	Ø 0.9 mm, length: 25 mm, 20 G	07746286
SFN 0930 S	Ø 0.9 mm, length: 30 mm, 20 G	07746300
SFN 1120 S	Ø 1.1 mm, length: 20 mm, 19 G	07781621
SFN 1125 S	Ø 1.1 mm, length: 25 mm, 19 G	07781609

Table 1 SFN® Safety port needles

Packaging unit: 25 pieces

Please observe separate instructions for use!

Recommendation: www.sfn-portneedles.de