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 implant card.

ACCESSORIES

The recommended non-coring SFN® port puncture needles with safety system 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
SFN 1320 S*	Ø 1,3 mm, length: 20 mm, 18 G	07746257
SFN 1325 S*	Ø 1,3 mm, length: 25 mm, 18 G	11094033

Table 2: SFN® safety port needles

Packaging unit: 25 pieces

Please observe separate instructions for use!

*Suitable for high pressure injections with contrast media

Recommendation: www.portneedles.de

QUALITATIVE/ QUANTITATIVE INFORMATION ON THE IMPLANT

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

- Titanium alloy TiAL4V6: 11.70 g (111246 V/V-PU), 14.94 g (111248 V/V-PU), 14.78 g (111257 V-PU).
- Nusil-Med 4750 silicones (septum): 1.30 g
- Silicones: 3.51 g (7.58 F silicone catheter), incl. small amounts of barium sulphate (BaSO4)
- Polyurethanes: 3.37 g (7.5 F PU catheter), 4.56 g (9 F PU catheter), incl. small amounts of barium sulphate (BaSO4)
- Small amounts of ink

The quantity 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!

EXAMPLE OF IMPLANTATION (venous/ vena cephalica right):

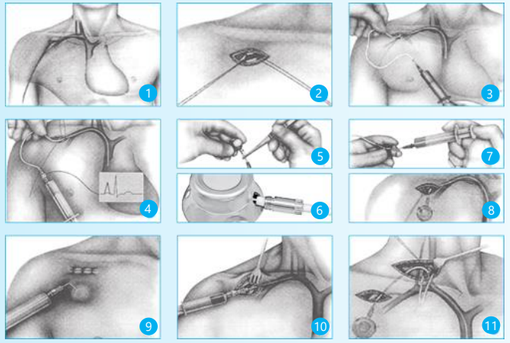


Fig.1: After preparation and draping of the surgical field, a 5 cm transverse subclavicular incision over the deltoideopectoral sulcus is made under local anesthesia.

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 port chamber is filled with 0.9% saline. The 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.

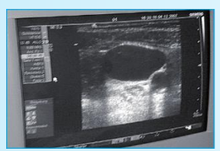
Fig.8: The port chamber is then placed into a subcutaneous pocket at distance from the skin incision and secured to the surrounding tissue with 3 sutures (alternative placement in a small subcutaneous pocket without fixation sutures is possible).

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

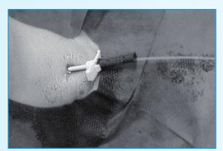
Fig.10: If the cephalic vein is unsuitable or difficulties arise, the application of the Seldinger technique is recommended for placement of the catheter into the subclavian vein. In general, placement of the catheter should be performed on the right side. The right subclavian vein is usually of greater 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.

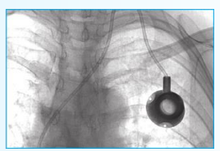
Alternative:



Ultrasonic scan of the internal 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

	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		

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 V

Product codes:
111246 V
111246 V-PU
111246 V-SET
111246 V-PU-SET
111248 V
111248 V-PU
111248 V-SET
111248 V-PU-SET
111257 V-PU-SET

Instruction for use
Please read carefully!

APPROPRIATE TO HIGH PRESSURE RADIO. PAQUE MATERIAL INJECTION
300 psi/21 bar
to 5,2 ml/sec

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

revision: 3.1 (03/2022)

TITAN-PORT V

PRODUCT DESCRIPTION

TITAN-PORT V are totally implantable port catheter systems for venous implantation consisting of a titan chamber (port) with a self-sealing silicone membrane and a screw dosure mechanism which enables the connection with the respective catheter.
Each system includes a 20 G access needle, a rinsing needle, a vein lifter, this instruction for use, a patient care guide and an implant card. If the port catheter system is a complete set (recognisable by the suffix "SET" at the end of the article number), it also includes a special port puncture needle SFN 0925 S, a tunnelizer and a matching introducer set (e.g., for implantation using the Seldinger technique).
The port catheter systems summarised in this instruction of use are placed on market as a procedure pack with difference in size of the port chamber, material and size of the catheter and associated introducer set. The corresponding configurations can be found in the table below:

Art. No.	port chamber	catheter	profile
111246 V	diameter (Ø): 24.9 mm, height: 13 mm, weight: 13 g, filling volume: 0.84 ml	**Silicone**, 7.58 French (F), outer diameter: 2.5 mm, inner diameter: 1.2 mm, total length 70 cm, internal volume: 0.11 ml / 10 cm	M (LOW PROFILE)
111246 V-SET including introducer and tunnelizer			
111246 V-PU		**Polyurethane**, 7.5 F, outer diameter: 2.5 mm, inner diameter: 1.2 mm, total length 72 cm, internal volume: 0.11 ml / 10 cm	
111246 V-PU-SET including introducer and tunnelizer			
111248 V	Ø: 28 mm, height: 13.45 mm, weight: 16.24 g, filling volume: 0.84 ml	**Silicone**, 7.58 F outer diameter: 2.5 mm, inner diameter: 1.2 mm, total length 70 cm, internal volume: 0.11 ml / 10 cm	L
111248 V-SET including introducer and tunnelizer			
111248 V-PU		**Polyurethane**, 7.5 F, outer diameter: 2.5 mm, inner diameter: 1.2 mm, total length 72 cm, internal volume: 0.11 ml / 10 cm	
111248 V-PU-SET including introducer and tunnelizer			
111257 V-PU-SET including introducer and tunnelizer	Ø: 28 mm, height: 13.45 mm, weight: 16.08 g, filling volume: 0.85 ml	**Polyurethane**, 9 F, outer diameter: 3.0 mm, inner diameter: 1.5 mm, total length 72 cm, internal volume: 0.18 ml / 10 cm	

Table 1: product configurations

The port chamber is made of hypoallergenic, biocompatible titanium. 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: each 12mm) can be punctured frequently (up to 3000 times) with a suitable special non-coring needle. The membrane is highly resistant to pressure and keeps the inserted needle reliably in place.
The catheter can be shortened at the distal end to the individual length required before it is connected with the port chamber. The catheter is radiopaque. The catheter tip is tapered and has an additional hole on the side (especially for easier blood sampling).
The **silicone catheter** (seen from proximal) is marked with length markings at intervals of 1 cm in the area between 5 and 40 cm (one line represents 1 cm, from 5 to 25 cm each five cm are marked with a line, two lines, three lines, etc., above 25 cm these are shown with black bars).
The **polyurethane catheters** (seen from proximal) have length markings in the area up to 35 cm and at 50 cm at intervals of 5 cm each (a dot means 5 cm and a dash 10 cm each). In addition, the area between 10 and 20 cm is divided into centimetre sections by dots.

Example of the catheter with length markings

Only special non-coring port access 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.
Puncturing with a 20 G port needle, the systems achieves the following **flow rates („gravity flow"):**

111246 V, 111246 V-SET:	14 ml/min
111246 V-PU, 111246 V-PU-SET:	13 ml/min
111248 V, 111248 V-SET:	13 ml/min
111248 V-PU, 111248 V-PU-SET:	13 ml/min
111257 V-PU-SET:	15 ml/min

The flow rates depend on the type of application, device and needle used (these measurements are according to DIN EN ISO 10555-1).

The introducer sets consist of a 0.89 mm guide wire, a 10 ml syringe, a 18 G introducer needle, an 8 F or 9 F (see Table. 1) introducer sheath (peelable) and a disposable scalpel. Please observe the enclosed separate instructions for use!

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

The implant card is filled out by the doctor who performed the implantation and is given to the patient who should always carry this 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

TITAN port catheter systems ensure 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
- for venous blood sampling
- for blood transfusions (*see note blood transfusion)
- for high-pressure injection (systems marked accordingly are also suitable for high-pressure injection, see note high-pressure injection)

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 P:	for paediatrics
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 V 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 to the base plate.

- if the situation is unclear or thrombotic obstruction is suspected a radiographic or duplex sonographic control is necessary.
- if the system is not in use a venous implant should be flushed with 20 ml 0.9% saline solution once every 8 to 12 weeks
- 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 e.g. 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

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.

*Blood Transfusion

For blood transfusions, use 18 or 19 gauge needles if possible! Afterwards, the system **must** be rinsed immediately with at least 20 - 50 ml of 0.9 % saline. Thereby, the needle should be rotated to ensure an even rinsing of the chambers.

HIGH-PRESSURE INJECTIONS

The port catheter systems described are **appropriate for power injections with contrast media** and are designed to be able to achieve a flow rate of 5.2 ml/s at a maximum pressure of 21 bar (300 PSI).

For the connection to the power injection, large lumen port needles are recommended e.g.:

SFN 1320 S: Ø 1.3 mm, length: 20 mm, 18 G (PZN 07746257)
SFN 1325 S: Ø 1.3 mm, length: 25 mm, 18 G (PZN 11094033)

The present port catheter systems, in combination with these needles, allow power infusion of contrast media into the central vascular system.

In addition to the general precautions and contraindications of port catheter systems, the following should be observed during power injection:

- Injections / infusions may only be carried out if the attending physician has confirmed himself (by means of aspiration or manual injection) of the perfect patency of the system. If there is any doubt about the patency of the system, the injection / infusion must be omitted!
- The contrast medium must be prepared according to the manufacturer's instructions.
- Before and after infusion, the system should be rinsed with 10 ml each of 0.9 % saline.
- Do not use the system if an infection, bacteraemia or septicaemia is present or suspected.
- Please also pay particular attention to the instructions for use for the high-pressure infusion system used.
- Carrying out the power injection on patients is only under the physician's responsibility.

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.