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.

Artiicle no.	Size specification	PZN
SFN 0750 G	Ø 0.7 mm, length: 50 mm, 22 G	00560673
SFN 0930 G	Ø 0.9 mm, length 30 mm, 20 G	01060286
SFN 0930 B	Ø 0.9 mm, length: 30 mm, 20 G	13837567

Table 1: SFN Special Port puncture needles

Packaging unit: 25 pieces
Please observe separate instructions for use!

Recommendation: www.portneedles.de

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

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

- approx. 4.88 g titanium alloy TiAL4V6
- 0.57 g Nusil-Med 4720 silicone (septum)
- 1.38 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)

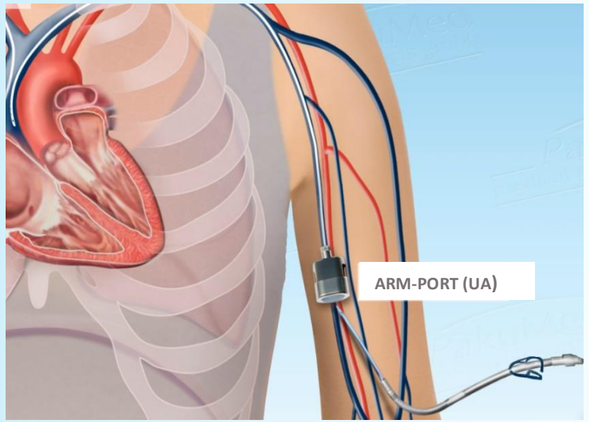
Under the scan conditions defined above, the "Titan Chamber" is expected to produce a maximum temperature rise of less than
2.3 °C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of · 1.4 °C (2 W/kg, 1.5 Tesla)
3.9 °C (2 W/kg, 3 Tesla) RF-related temperature 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!

Example of the implantation site with placement of the catheter via the v. basilica
Alternative design with lateral access route



The graphic shows the exemplary implantation of the ARM-PORT

	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		

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TITAN PORT V-UA (ARM-PORT)

Product code:
111258 V-UA

Instruction for use
please read carefully!

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

revision: 3 (01/2022)

TITAN-PORT V-UA (Arm-Port)

PRODUCT DESCRIPTION

TITAN-PORT V-UA is a totally implantable port catheter system for venous implantation consisting of a titan chamber (port) with a self-sealing silicone membrane and a screw closure mechanism which enables the connection with the respective polyurethane catheter.
Each system also includes a special puncture cannula SFN 0930 G, a refill cannula, a vein lifter, an introducer set, this instruction for use and an implant card.
The introducer set consists of a 0.46 mm guide wire, an introducer syringe, a 20 G introducer cannula, a 6 F dilator and a disposable scalpel. Please observe the enclosed separate instructions for use.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber has the following dimensions: Width: 14.6 mm, Length: 23 mm, Height: 10.3 mm, Weight: 5.45 g, Volume: 0.16 ml. There are suture holes in the base plate for fixation of the system to the muscle fascia. Port housing and catheter are connectable.

The silicone membrane (puncture area 71 mm²) can be punctured frequently (up to 3000 times) with a suitable special port needle. The membrane is highly resistant to pressure and keeps the inserted needle reliably in place.

The polyurethane catheter (5.15 French), with an outer diameter of 1.7 mm, an inner diameter of 0.9 mm, a length of 70 cm and an inner volume of 0.06 ml/10cm, can be individually shortened to the required length at the distal end before connection to the corresponding port chamber.

The catheter is provided with length markings in the range up to 35 cm and at 50 cm (seen from proximal) at intervals of 5 centimetres each (a dot stands for 5 centimetres and a line for 10 centimetres each). In addition, the area between 10 and 20 centimetres is divided into centimetre sections by dots. The catheter tip is tapered and has an additional hole on the side (especially for easier blood sampling).

Example of the catheter with length markings

Only special non-coring port needles should be used to puncture the port membrane.
These needles exhibit a unique bevel at the tip. This prevents punch defects at the membrane when the needle is inserted. For standard applications, the SFN 0750 G, SFN 0930 G and SFN 0930 B and are recommended. Each system contains a suitable needle.

The flow rate **("gravity flow")** is 9.1 ml/min when puncturing with the SFN 0930 G. The flow rates depend on the type of application, device and cannula used (these measurements are according to DIN EN ISO 10555-1).

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

The TITAN PORT V-UA 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
- for venous blood sampling
- for blood transfusions (*see note blood transfusion)

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 with the need for 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 APH:	for apheresis
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 V-UA 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
- breakage of the catheter
- 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 cannula is provided for this purpose.

INSTRUCTION FOR THE PORT IMPLANTATION

Caution: During implantation a sterile handling is absolutely mandatory!

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

Selection, decision and execution are the responsibility of the implanting physician.

- After visualisation of the vein, it is blocked distally. Through a small venotomy, the catheter is inserted up to the superior vena cava. The catheter is then shortened to the desired
- length. Fill the catheter with heparin or saline solution and connect it to the port chamber.

Alternative: Seldinger technique

- When using the introducer, care must be taken not to withdraw the catheter through the introducer cannula.
- Venous backflow, patency and exclusion of a puncture error must be checked without fail before the application of a drug or connection to an infusion system.
- Puncture is carried out in the same way as venipuncture, but only with a suitable straight special puncture cannula (e.g. SFN 0930 G).

This port system is designed to allow the flattest possible implantation, e.g. on an extremity, preferably the upper arm, forearm (however, in the case of the forearm, note the increased movement of the catheter and slightly increased risk of thrombosis and catheter rupture because it lies further peripherally) or with relatively little subcutaneous tissue. Implantation is also possible via the subclavian vein.

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.

INSTRUCTION FOR THE PORT PUNCTURE

After palpation and the usual disinfection, the silicone membrane of the port chamber is punctured laterally with the straight port cannula and the cannula is advanced until a metallic resistance is supposed.

Since the silicone membrane of this ARM-PORT is very small, special attention must be paid to the exact positioning of the cannula in the membrane during lateral puncture!

- only use special non-coring straight needles for puncturing the septum.
- the needle should be inserted into the silicone membrane carefully and vertical to the base plate. The puncture method/ direction is similar to a common venipuncture.
- do not use syringes < 10 ml (danger of overload pressure)
- 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.

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

*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 % NaCl solution. Thereby, the needle should be rotated to ensure an even rinsing of the chambers.

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.

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** (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!