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

Table 2: SFN® safety port 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 A get into contact with following materials (tested for biocompatibility):

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

The quantity of 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		

IMPLANTATION (arterial) on the example of the liver:

- after indication, preoperative imaging of the arterial liver supply. (mesenterico-zoeliacography, atypical vascular supply to the liver).
- laparatomy and visualisation of the arterial liver system (hepatica propria and communis, A. gastroduodenalis, if necessary A. hepartica dextra from mesenterica superior, An hepatica sinistra from A. Gastrica sinistra etc.)
- ligature of the gastrica dextra or gastroduodenal artery.
- implantation of the port catheter system (by means of vascular ligation or tabac pouch vascular suture)
- caution with accessory or atyopic originating hepatic arteries.
- followed by intraoperative fluorescein monitoring or methylene blue to record of the complete liver supply.
- connection of the port chamber and fixation in the subcutaneous pocket using fascia sutures.
- filling of the port system with heparinised saline.

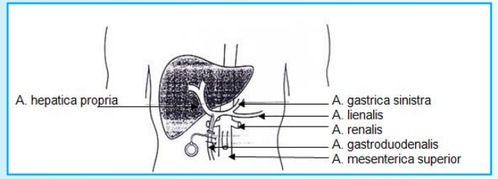
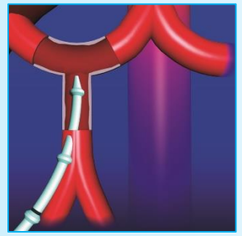


Fig. 1 body with an implanted port catheter system



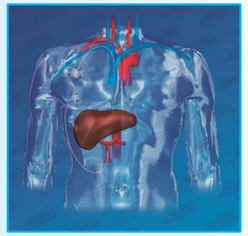


Fig. 2 & 3 Graphical representation of the implanted port catheter system

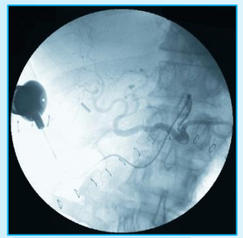


Fig. 4 X-ray image of an upper abdominal perfusion

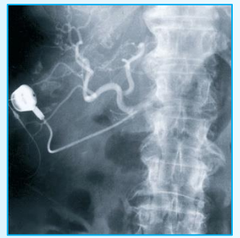


Fig. 5 X-ray image of a liver perfusion

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TITAN-PORT A
Arterial

Article number:
111251 A

Instruction for use
please read carefully!

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

revision: 3 (03/2022)

TITAN-PORT A (ARTERIAL)

PRODUCT DESCRIPTION

TITAN-PORT A is a totally implantable port catheter systems for arterial 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 catheter.
Each system includes a 20 G access needle, a rinsing needle, a vein lifter, this instruction for use and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber dimensions are: diameter base plate: 21 mm, height: 9.8 mm, weight: 6.60 g, priming volume: 0.27 ml. The base plate has suture holes 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 non-coring puncture needle. The membrane is highly resistant to pressure and holds the inserted needle reliably in place.

The polyurethane catheter (5 French, with an outer diameter 1.7 mm, an inner diameter 0.9 mm, total length 70 cm and internal volume of 0.06 ml per 10 cm) 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 is provided with length markings in the range up to 35 cm and at 50 cm (seen from proximal) at intervals of five centimetres each (a dot stands for five 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 tip is tapered and there is an additional hole on the side. The catheter is radiopaque and has two fixation rings distally.

Example of an arterial catheter

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. The SFN 0720 S 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 6 ml/min when puncturing with SFN 0925 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 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 system A ensures the repeated access for regional intra-arterial chemotherapy for the following applications, for example:

- Primary malignant liver tumours
- Liver metastases of gastrointestinal malignancies
- Pancreatic carcinoma
- Head and neck tumours

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.

Please note that blood sampling is **NOT** possible via an arterial port catheter system!

Patient group: Patients in need of long-term access to the arterial blood vessel system.

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

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

TITAN-PORT APH:	for apheresis
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 A 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 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 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 following complications can also occur with arterial port catheter systems:

- Liver abscesses with infected port catheter systems
- Occurrence of ventricular ulcers with arterial gastric port systems
- Bile duct / arterial fistula

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!

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

Various options are available for implanting the port chamber and catheter (see implantation example). Postoperative X-ray control is essential.

Implantation of a TITAN-PORT A is usually possible under local anaesthesia.

- the decision and procedure are in the operators' authority
- 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 thrombosis is suspected, a radiological or Doppler sonographic check is necessary!
- if the system is not in use, it should be flushed with 20 ml 0.9% saline solution once every 8 to 12 weeks
- 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 formation can be reduced in those at risk by inhibiting platelet aggregation (e.g. with acetylsalicylic acid).

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

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. With regard to all medicines and liquids used, reference is always made to the package inserts of the respective pharmaceutical manufacturers.

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 in the artery/blood vessel 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
- 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.

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 cycle of chemotherapy, an imaging of the port catheter system (port angiography) must be performed. This serves to exclude arterial dissections or extravasations.

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.