ACCESSORIES

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

Article no.	Size specification	PZN
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

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

Recommendation: www.sfn-portneedles.de

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

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

- 19.33 g titanium alloy TiAL4V6
- 2.13 g Nusil-Med 4750 silicone (septum)
- 5,90 g silicone (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
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)

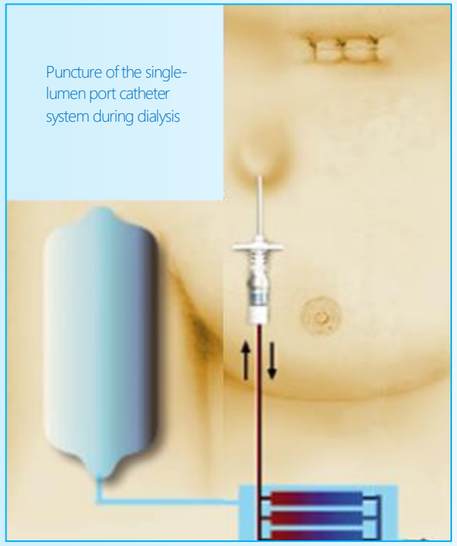
Under the scan conditions defined above, the "Titan Chamber" is expected to produce a maximum temperature rise of less than **2.3 °C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of · 1.4 °C (2 W/kg, 1.5 Tesla)** **3.9 °C (2 W/kg, 3 Tesla) RF-related temperature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

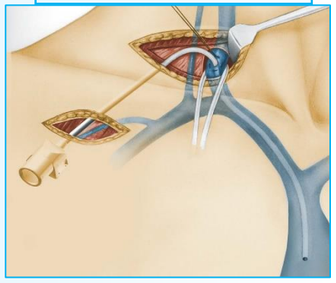
Notice to users and patients: Please report all serious incidents related to this product to the manufacturer, as well as to the competent authority of the member state in which you are established.

Product training is available on request!

EXAMPLE OF IMPLANTATION (schematic):



Puncture of the single-lumen port catheter system during dialysis



Implantation of the single-lumen port catheter system

Example of using the entire surface of the membrane for puncture

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

	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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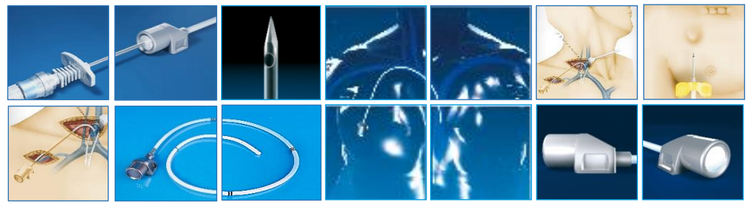

TITAN PORT D
for single lumen dialysis

Product code:
111255 D

Instruction for use
please read carefully!

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

revision: 3 (01/2022)

TITAN-PORT D (single lumen dialysis)

PRODUCT DESCRIPTION

Titanium Port D (Dialysis) is a fully implantable venous port catheter system as an access option for performing veno-venous dialysis. The set includes a titanium port chamber with a self-sealing silicone membrane and a screw to fix the catheter to the outflow tube and a single lumen silicone catheter with an inflow and outflow connection to the port chamber. Each system is also supplied with a special puncture cannula SFN 1835 B, a puncture cannula SFN 0930 G, an introducer set (consisting of an 18 G introducer cannula, a 13 F introducer peel-away and a 0.89 mm guide wire), a tunnelizer, these instructions for use and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium.
The chamber has the following dimensions: width: 24 mm, length: 36.3 mm, height: 19.9 mm, weight: approx. 21.46 g and internal volume: 0.66 ml. There are suture holes in the base plate to fix the system to the muscle fascia. The port chamber and catheter are each connectable and are connected to each other via a screw mechanism with a sleeve over the outflow tube.

The silicone membrane in the port chamber (11.5 mm diameter) can be punctured many times with the associated non-coring special puncture cannula. It is characterised by high pressure stability. The membrane holds the needle in position.

The single lumen silicone catheter (12 French with an outer diameter of 4.0 mm, an inner diameter of 2.5 mm, a total length of 60 cm and an inner volume of 0.49 ml/10cm) has side holes at the proximal end, a round shaped tip and can be shortened at the distal end (non-perforated) if necessary before connection to the corresponding port chamber (recommendation to document accordingly in the implant card).
The proximal, round shaped tip prevents flotation of the catheter tip at the dwelling site after implantation due to suction or pulsation in the blood vessel and reduces adherence to the vessel wall, which also improves the flow rate. The catheter is length-marked over 50 cm from the distal end (one line corresponds to 10 cm each) and is radiopaque

Only special non-coring port needles should be used to puncture the port membrane. In order to achieve the blood volume necessary for dialysis purposes, correspondingly large-volume special port needles are required, e.g. **SFN 1835 B** or **DPK 2035**.
The needles exhibit a unique bevel and angle at the tip. This prevents punch defects at the membrane when the needle is inserted. Two suitable cannulas are included with each system. Appropriate accessories can be ordered separately if required.

The flow rate **("gravity flow")** is 223ml/min when puncturing with DPK 2035 and 164 ml/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 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 D allows repeated access to the central venous blood vessel system for the following applications, for example:

- veno-venous dialysis for renal insufficiency requiring dialysis
- primarily
- as an alternative in case of failure of other access routes for long-term dialysis e.g. Cimino shunt

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 APH:	for extracorporeal apheresis
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 D 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 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

- 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.

Implantation must only be carried out by experienced medical personnel.

Possible implantation sites are mainly the internal jugular vein, but alternative locations are also possible. The following implantation recommendation is only an example of the possible or usual surgical procedure. Alternatives are possible. Postoperative X-ray control is essential.

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

Implantation of a TITAN-PORTS D is usually possible under local anaesthesia.

1. Expose the internal jugular vein (Supraclavicular incision)
2. Apply distal and proximal loop ligatures
3. Subclavicular incision
4. Subcutaneous tunnel between the two incisions
5. Subcutaneous preparation of a recess
6. Move the catheter tip from the subclavicular incision to the supraclavicular incision via the subcutaneous tunnel.
7. Small phlebotomy (caution air embolism!). Insert catheter tip up to the right atrium (positional check by intraatrial ECG tracing or by x-ray fluoroscopy)
8. Purse-string suture at the phlebotomy.
9. Length of the catheter can be shortened if required
10. Slide the catheter end onto the port outlet tube and secure with the screw.
11. Position the port chamber subcutaneously as far as possible from the cutaneous incision, and secure if necessary.
12. Cutaneous suture

Alternative: Seldinger technique

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

The system could be used immediately, but recommended after complete healing of wound (approx. one week).

The concentrations mentioned and the entire procedure are recommendations and 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.

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.

INSTRUCTIONS FOR USE FOR THE PUNCTURE

1. Skin disinfection, sterile gloves, mask (patient and user)
2. have patient in supine position if possible
3. Puncture the port membrane with a special puncture needle (supplied), until the tip of the needle touches the bottom plate, caution air embolism!
4. Unblock the system
5. Check for occlusion with saline solution and connect to the relevant inlet and outlet parts of the dialysis machine.
6. At the end of dialysis, flush the port chambers with at least 20 ml saline solution 0.9 %
7. block the system with e.g. heparin, taurolidine or citrate respectively
8. Remove the puncture needle using gentle positive pressure
9. Disinfect the skin; apply dry dressing
10. 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 (previous: x-ray control)

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
- 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.

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 illustration on the last page of these instructions for use.).
Puncture with a special cannula allows for a corresponding length of implantation 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.

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 implantation certificate.