ACCESSORIES

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

Article no.	Size specification	PZN
SFN 1535 B	Ø 1.5 mm, Length: 35 mm, 17 G	12363624
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!

Further recommended **SFN® - port needles** are the following:

Article no.	Size specification	PZN
SFN 0930 B	Ø 0.9 mm, Length: 30 mm, 20 G	13837567
SFN 0930 G	Ø 0.9 mm, Length: 30 mm, 20 G	01060286

Table 2: SFN® - port needles

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

Recommendation: www.sfn-portneedles.de

By using SFN® port needles straight (Tab. 2) the period of application should not exceed 24 hours.

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

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

- approx. 12.69 g titanium alloy TiAL4V6
- 2.02 g Nusil-Med 750 silicone (septum)
- 4.86 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 (schematic):

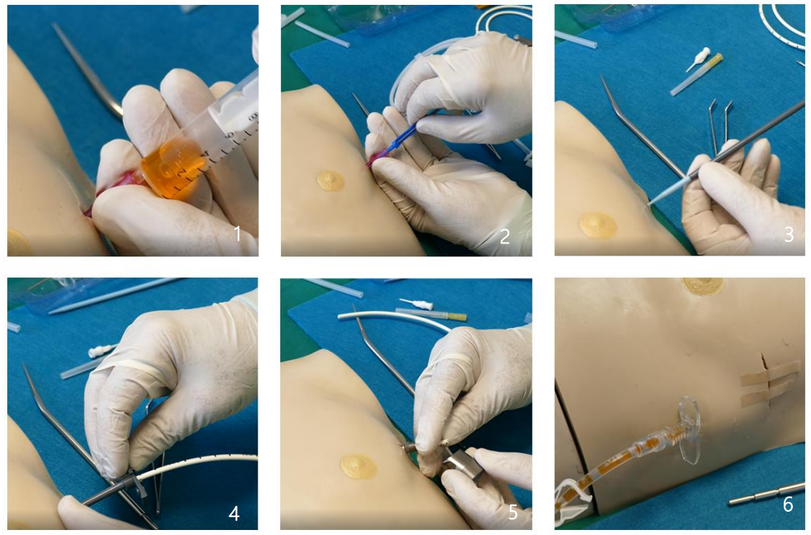

Fig. 1: Checking the ideal implantation location via a puncture.
Fig. 2: Insertion of the guide wire via the puncture cannula
Fig. 3: Insertion of the peel-away sheet over the guide wire
Fig. 4: Insertion of the catheter through the peel-away sheet
Fig. 5: Connecting catheter with port chamber
Fig.6: Port puncture after implantation

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

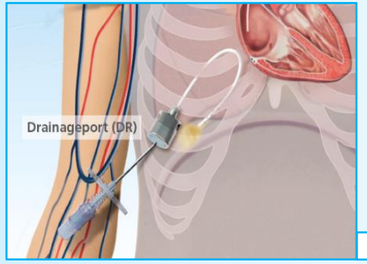

Fig. 7 Thorax with port implant and puncture

Fig. 8 Example of using the entire surface of the membrane for puncture

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TITAN PORT DR
Drainage

Product code:
111262 DR

Instruction for use
please read carefully!

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

revision: 3 (01/2022)

TITAN-PORT DR (Drainage)

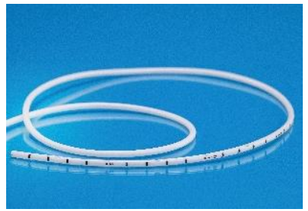
PRODUCT DESCRIPTION

The TITAN-PORT DR (drainage) is a fully implantable port catheter system providing an access facility to the pleura cavity. The set contains a titanium port chamber with a self-sealing silicone membrane and a single-lumen polyurethane catheter for connection to the port chamber and fixing to the outlet tube with a screw. Each system also includes a port cannulae SFN 0930 G, a special puncture needle SFN 1835 B, an introducer set (consisting of an 18 G introducer, an 11 F introducer peel-away and a 0.89 mm guidewire), a tunnelizer, a vein lifter, a rinsing needle, user instructions and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber dimensions are: width 20.6 mm, height 16.7 mm, length 25.5 mm, weight approx. 14.71 g, priming volume 1.42 ml. The base plate has suture openings for securing the system to the fascia. Port chamber and catheter can be disconnected and are connected via a screw with the outlet tube.

The silicone membrane in the port (118 mm^2) can be punctured frequently with a suitable non-coring puncture needle. The membrane is highly resistant to pressure and keeps the inserted needle reliably in place.

The polyurethane catheter (10 French, with an outer diameter 3.4 mm, an inner diameter 2.0 mm, total length 72 cm and internal volume of 0.31 ml per 10 cm) has at the distal end a fish mouth tip and ten side holes. If necessary the catheter can be shortened at the proximal (non-perforated) end. The catheter is marked, every centimetre, with length marker until 40 cm (line means 1 cm, points means 5 cm). The catheter is radiopaque.



Example of the catheter with length markings

Only special non-coring port needles should be used to puncture the port membrane.
Depending on indication and flow rate different special puncture needles can be used. These may be the DPK 2035, SFN 1835 B and SFN 1535 B, as well as the smaller SFN® port needles in various sizes, e. g. SFN 0930B and SFN 0930 G. The needles exhibit a unique bevel and angle at the tip. This prevents punch defects at the membrane when the needle is inserted. Each system contains a suitable needle. Appropriate accessories can be ordered separately if required.

The **flow rate ("gravity flow")** is 134 ml/min when puncturing with DPK 2035. The flow rates depend on the type of application, device and cannula used (these measurements are according to DIN EN ISO 10555-1).

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

The TITAN-PORT DR allows repeated access to the pleura cavity if necessary especially for drainage of blood, secretions and gases within the following indications

- Pleural effusion
- Pleural empyema
- Chylo-, haemato- or pneumothorax
- Abcess
- Installation of therapeutics e.g. antibiotics, cytostatics or rinsing fluids

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. In particular, this significantly improves the patient's quality of life and minimises the infection rate during access with pleural catheters.

Patient group: Patients with the need for long-term access to the pleura cavity.

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 UA:	as side port e.g. for implantation in the arm
TITAN-PORT APH:	for apheresis
TITAN-PORT G:	suitable for all needles

Intended purpose

The port catheter system is only used to pass liquids and medication into or out of the patient's thoracic cavity. The product itself thus fulfils a physical property and has no medical, therapeutic effect.

CONTRAINDICATION

Relative contraindications are:
Coagulation disorders, emphysema, skin infections or adhesions of the lung with the thoracic wall after surgical interventions.

The TITAN-PORT DR 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
- torsion of chamber or catheter
- membrane and catheter dislocation, catheter rupture
- extravasation due to improper handling of the system
- damage to neighbouring tissues by the pharmaceutical agents (in the event of leakage of portal components)
- leakage from chamber, septum, connection

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 suitable 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 is normally performed under insufflation anesthesia according to Seldinger technique.

Possible implantation sites are according to the preferred puncture procedure (e.g. see Fig. 7). Various implantation techniques can be employed.

Example:

- placement of the catheter in the desired position
- tunneling to the port chamber in a port recess
- shorten the catheter as required and secure it to the port chamber with the screw
- cutaneous sutures
- control of the catheter position by X-ray, CT or ultrasound is indispensable.
- with optimum implantation, the system can be used directly.

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

The recommendations mentioned 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.

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.

After a long implantation period or system use, check the membrane for leakage resulting from frequent punctures. When there are no complications a puncture frequency of **up to approx. 1000 punctures with SFN 1835 B** (by using a special port needle) allows a corresponding period of application. If possible, the silicone membrane should be punctured at different sites (see Fig. 8). It is possible to exchange the port chamber if the silicone membrane leaks under local anesthesia.

INSTRUCTIONS FOR USE FOR THE PUNCTURE

1. skin disinfection, sterile gloves, mask (patient and operator)
2. puncture the port septum with a special puncture needle (until the tip of the needle touches the base plate)
3. unblock the system
4. check for occlusion with saline 0,9% and especially pay attention to possible extravasation.
5. at end of treatment, gently withdraw the puncture needle (exerting opposite pressure at the port).
6. disinfect the skin; apply dry dressing

For lower flow-rates other recommended SFN® port needles may be sufficient (see Tab.2)

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.

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.