ACCESSORIES

The recommended non-coring 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:

Artiicle 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
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® - Port needles

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

Recommendation: www.portneedles.de

By using SFN® port needles SFN 1320 S and SFN 1325 S the period of application should not exceed **24 hours**.

QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

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

- 17.52 g titanium alloy TiAL4V6
- 2.3 g Nusil-Med 4750 silicone (septum)
- 2.3 g silicone (depending on the implanted length of the catheter), incl. small amounts of barium sulphate ($BaSO_4$)
- 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):

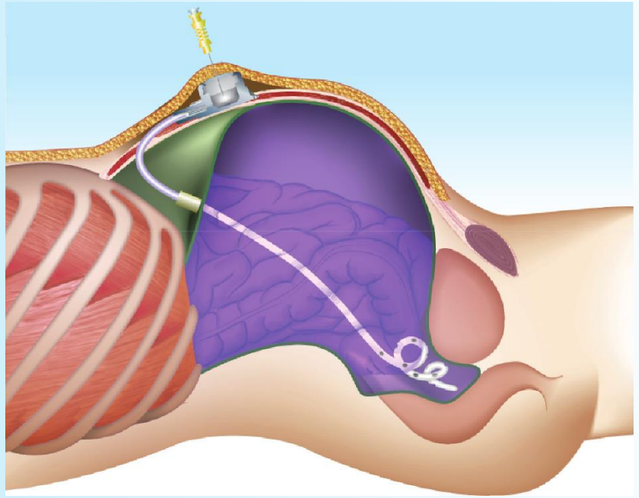

Figure 1 Abdominal cavity with port implant and puncture

	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 AS/PT
Ascites- and peritoneal therapy

Product code:
111259 AS/PT

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 AS/PT

(Ascites and peritoneal therapy)

PRODUCT DESCRIPTION

The TITAN-PORT AS/PT (ascites/ peritoneal therapy) is a fully implantable port catheter system providing an access facility to the peritoneal space. The set contains a titanium port chamber with a self-sealing silicone membrane and a silicone catheter for connection to the port chamber and fixing to the outlet tube with a screw. Each system also includes a port cannula, a SFN 0930 G, a special puncture needle DPK 2035, an introducer set (consisting of an 18 G introducer, an 11 F introducer peel-away and a 0.89 mm guidewire), a tunnelizer, this user instructions and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber dimensions are: width 28.8 mm, height 15.5 mm, weight approx. 19.82 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 (diameter of puncture area: 14 mm) in the port chamber can be punctured frequently with a suitable non-coring puncture needle. The membrane is highly resistant to pressure and holds the inserted needle reliably in place.

The silicone catheter 14.5 F has lateral holes and is rolled about approx. 12 cm at the distal end. At the proximal (non-perforated) end, the catheter can be shortened as required (before connection to the corresponding port chamber) and connected to the outflow tube of the port chamber via a screw. The outer diameter is 4.9 mm with a length of 600 mm. The priming volume of the catheter is 0.59 ml/10 cm. The catheter is radiopaque.

Example of the silicone catheter of the TITAN Port AS/ PT

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® safety port needles in various sizes, e. g. SFN 1320 S and SFN 1325 S. 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 268 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 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 AS/PT allows repeated access to the peritoneal cavity if necessary while minimizing the rate of infection with external peritoneal catheters. Indications may be:

- ascites puncture
- peritoneal therapy (e. g. peritoneal chemotherapy or peritoneal dialysis)

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-termaccess to the peritoneal 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 APH:	for extracorporeal apheresis
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 AS/ PT 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
- 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
- Injuries to abdominal organs

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.

Implantation is normally performed under anesthesia.

Possible implantation sites are according to the preferred puncture procedure.

Implantation is performed similar to that used with the Tenckhoff catheter. Various implantation techniques can be employed.

After successful placing of the catheter in the abdominal cavity it is particularly important to provide a water-tight purse-string suture at the entry point of the catheter in the peritoneum!

- Tunneling to the port in a port recess in the abdominal wall
- Shorten the catheter as required and secure it close to the skin with the screw at the port chamber
- Cutaneous sutures

With optimum implantation, the system can be used after approx. 3 days if the peritoneum is tightly closed at the catheter entrance.

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

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.

Deposits in the system generally indicate one of the following

- leakage of the system
- defective septum
- faulty handling

INSTRUCTIONS FOR USE FOR THE PUNCTURE

1. Skin desinfection, sterile gloves, mask (patient and operator)
2. Puncture the port septum with a special puncture needle with a mandrin (supplied) (until the tip of the needle touches the base plate)
3. Remove the mandrin, check for occlusion with physiological saline solution and especially pay attention to possible extravasation
4. At the end of treatment, gently withdraw the puncture needle (exerting opposite pressure at the port)
5. Disinfect the skin; apply dry dressing

Always insert the needle carefully into the silicone membrane perpendicular to the base plate and with the mandrin in the exact position (for DPK 2035).

For lower flow rates other recommended SFN® port needles without mandrin may be sufficient (see further down).

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.

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. 500 punctures with DPK 2035** allocated on the entire membrane.
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.

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 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.