QUALITATIVE / QUANTITATIVE INFORMATION ON THE IMPLANT

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

- approx. 6.22 g titanium alloy TiAL4V6,
- 0.48 g Nusil-Med 4750 silicone (septum)
- 0.05 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.

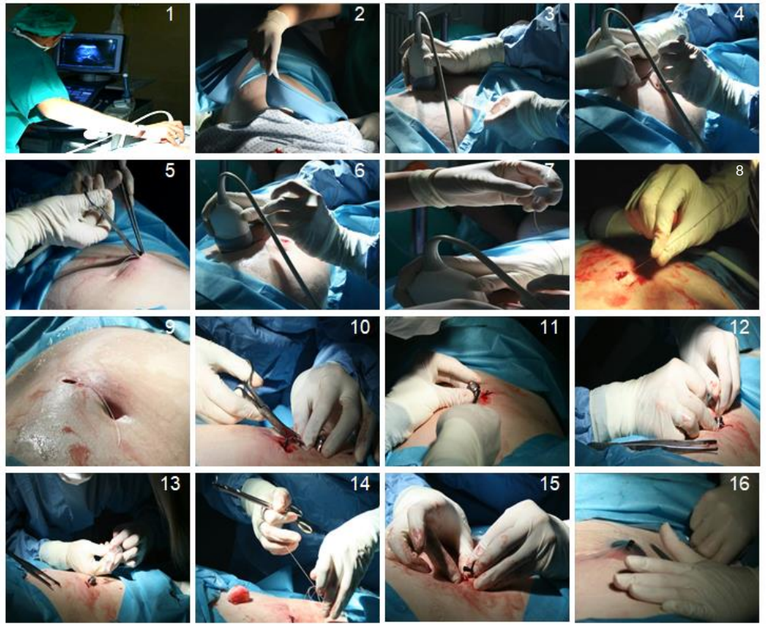
Notes:

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		

IMPLANTATION EXAMPLE:



Step 1: Preparation
It is recommended to use tocolysis from 12 hours before to 12 hours after the procedure to avoid uterine contractions (e.g. intravenous 2 g / hour Mg infusion + 100 mg indomethacin supp. rectally).

Step 2: Determination of the appropriate site for placement of the port catheter system.
The appropriate site for puncture and incision should be selected by ultrasound. Ultrasonographic determination of the position of the foetus, placenta and position of the umbilical cord. This and the vitality of the fetus should be documented.

a) For amnioinfusion
transplacental puncture should be avoided. In case of loose insertion into the uterine cavity, an area without placental or fetal parts should be carefully located and chosen for insertion (Fig. 1). A fluid depot via amnioinfusion (approx. 300-400 ml) facilitates site finding and intrauterine placement of the catheter.

b) In case of intravascular application, the area with the best access to the umbilical vein should be chosen in case of an anterior wall placenta.

Step 3: Creation of a port pocket
After extensive disinfection of the surgical area and careful hand disinfection, the surgical field is sterilely covered (Fig. 2). After local anaesthesia has been administered, a 2-3 cm long incision is made along the skin cleft lines (fig. 3). After the skin and the subcutis have been cut, a subcutaneous pocket is prepared, partly bluntly and partly with fine scissors (fig. 4 and 5).

Step 4: Insertion of the catheter

a) Amnioinfusion
An 18 gauge puncture cannula (with stylet) is inserted through the pre-prepared pocket into the fluid depot under constant ultrasound control (Fig. 6).

b) Into the umbilical vein
Puncture of the umbilical vein with an 18 gauge puncture cannula (with stylet) under constant ultrasound control (Fig. 6).

Remove the stylet and insert the radiopaque catheter with guide wire through the cannula into the uterine cavity (option A) or into the umbilical vein (option B) (Fig. 7). Carefully remove the guide wire with the cannula without moving the catheter out of position.

For this purpose, the catheter should be fixed close to the skin at the external part with an instrument or finger (Fig. 8 and 9).

Step 5: implantation of the port chamber
After placement, the catheter is shortened at the proximal end with the scissors and connected to the port chamber (Fig. 10). The sleeve is screwed onto the outflow tube of the port chamber and the catheter is fixed with it (Fig. 11). Flush the port catheter system with saline under colour Doppler ultrasound control using the enclosed punch-free port cannula to check the correct position of the catheter (Fig. 12 and 13). Fixation of the port chamber in the skin pocket using single button sutures and skin suture (Fig. 14).

Step 6: Completion of the procedure
Puncture of the port chamber through the skin with a non-coring port cannula (Fig. 15) and covering of the implantation site with a semi-permeable foil dressing. Finally, a sonographic control and documentation of the correct position of the catheter and the vitality of the foetus is carried out.

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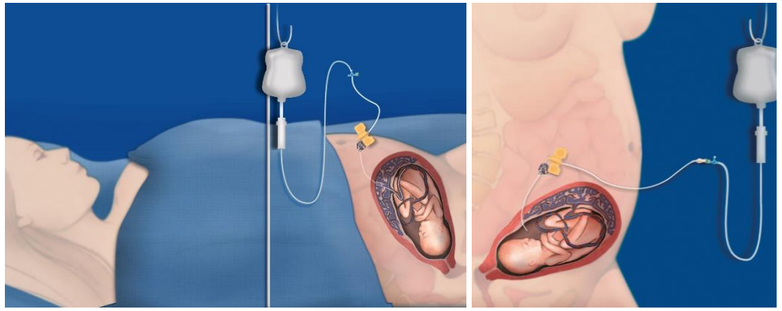

TITAN-PORT F
Fetal-Port (Prenatal port)

Art.-No.: 111243 F

Instruction for use
please read carefully!

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

Revision: 3 (05/2022)

TITAN-PORT F

PRODUCT DESCRIPTION

The TITAN-PORT F System is a totally implantable port catheter system consisting of injection titan chamber (port) with a screw closure mechanism and a self-sealing silicone membrane as well as a polyurethane catheter.

Each system also includes a special puncture cannula SFN 0720 S, a 20 G puncture cannula, a rinsing needle, an introducer cannula (18 F), this instructions for use and an implant card.

The port chamber is made of hypoallergenic, biocompatible titanium. The chamber has the following dimensions: Diameter (base plate): 21 mm, height: 9.8 mm, weight: 6.70 g. Filling volume: 0.26 ml. The base plate has holes for securing the system to the fascia with sutures. The port chamber and the catheter can be connected.

The silicone membrane (diameter: 8 mm) can be punctured frequently (up to 3000 times) with a suitable special port needle (such as the SFN 0720 S). The membrane is highly resistant to pressure and keeps the inserted needle reliably in place.

The polyurethane catheter (1.92 French with an outer diameter of 0.64 mm, an inner diameter of 0.42 mm, a total length of 40 cm with an internal guide wire) can be individually shortened at the distal end to the required length before connection to the corresponding port chamber.

The catheter is provided with length markings in the range up to 25 cm. The tip is tapered and there is an additional hole on the side. Five centimetres from the proximal end of the catheter, a small fixation ring (lock) is attached to counteract dislocation from the uterus.

example of a catheter

Only special **non-coring port puncture 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. 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 0.4 ml/min when puncturing with the 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

The TITAN-PORT F ensures the repeated access to:

A: Cavum uteri (Amnion)

B: to the vascular system of the umbilical cord for e.g. the following applications:

A: Continuous amnioinfusion in preterm premature rupture of membranes (PPROM) with oligo-/anhydramnios

B: Infusion therapy and intrauterine nutrition in growth-restricted fetuses due to placental insufficiency (IUGR - intrauterine growth restriction)

The advantage is low risk of infection, simplified access and considerably improved quality of life for the patient as provided by a closed system.

Patient group:

A: PPROM: Patients between the 22nd and 30th week of pregnancy until delivery with the corresponding indication.

B: IUGR: Patients from the 24th to the 32nd week of pregnancy until birth with an appropriate indication with an estimated fetal weight of less than 1/10th of a percentile.

Operators: Implantation should only be carried out by experienced operators (with appropriate qualifications), usually neonatologists or gynaecologists at appropriate centres.

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 P:	for paediatric
TITAN-PORT APH:	for apheresis
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 fluids 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 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 is always dependent on the clinical patient situation.

In particular, the prenatal port must not be used in the case of:

- infections such as peritonitis, septicaemia, HIV or hepatitis
- severe abdominal skin infections
- intrauterine amniotic death
- amnioinfectious syndrome

A: Further contraindications for the indication PPROM:

- Malformation of the foetus or placenta
- choramnionitis
- Contractions at diagnosis

B: Further contraindications for the indication of IUGR:

- posterior wall placenta

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
- thrombosis / thromboembolism
- breakage of catheter or damage to 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)
- Bleeding
- Premature rupture of membranes
- Premature labour
- Intrauterine amniotic death
- Miscarriage

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 needle is provided for this purpose.

INSTRUCTION FOR THE PORT IMPLANTATION

Caution: During implantation a sterile handling is absolutely mandatory!

The decision and procedure are in the operators' authority.

- The implantation of TITAN-PORT F is usually possible under local anaesthesia.

  A: Loose insertion of the catheter into the uterine cavity.

  B: The recommended implantation site for the catheter is the umbilical vein at the placental attachment. Before implanting a fetal port catheter system into the umbilical vein, it is recommended to use tocolysis to avoid uterine contractions. In addition, a suitable site for puncture and incision should be selected beforehand using ultrasound. This should be the area with the best access to the umbilical vein in the case of an anterior wall placenta.
- 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.

- if the situation is unclear or thrombotic obstruction is suspected a radiographic or duplex sonographic control is necessary.
- 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.
- the system **must** be flushed after each use. The port needle is removed with gentle force against the port chamber.

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.

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

LIFETIME AND CONSEQUENTIAL MEASURES

The prenatal port should be removed after the end of therapy or delivery.

AFTERCARE / MONITORING

Regular treatment sessions and associated care of the port system are coincidental with monitoring of the system. This is done under visual control and, if necessary, ultrasound control. Training of the patients by the attending physicians is also recommended for self-monitoring.

WARNINGS

- the port chamber should be secured to the subcutaneous tissue by sutures or placed in the smallest of portal pockets in order to prevent the port to migrate.
- the safe connection of the catheter to the port must be confirmed.

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!
- Regular dressing changes when using a transparent, semi-permeable film dressing that allows constant visual control. The dressing change should always be accompanied by a change of the port cannula. If a compress dressing is used, the puncture site should be checked regularly for signs of inflammation.

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.

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 1: SFN® Safety port needles

Packaging unit: 25 pieces

Please observe separate instructions for use!

Recommendation: www.sfn-portneedles.de