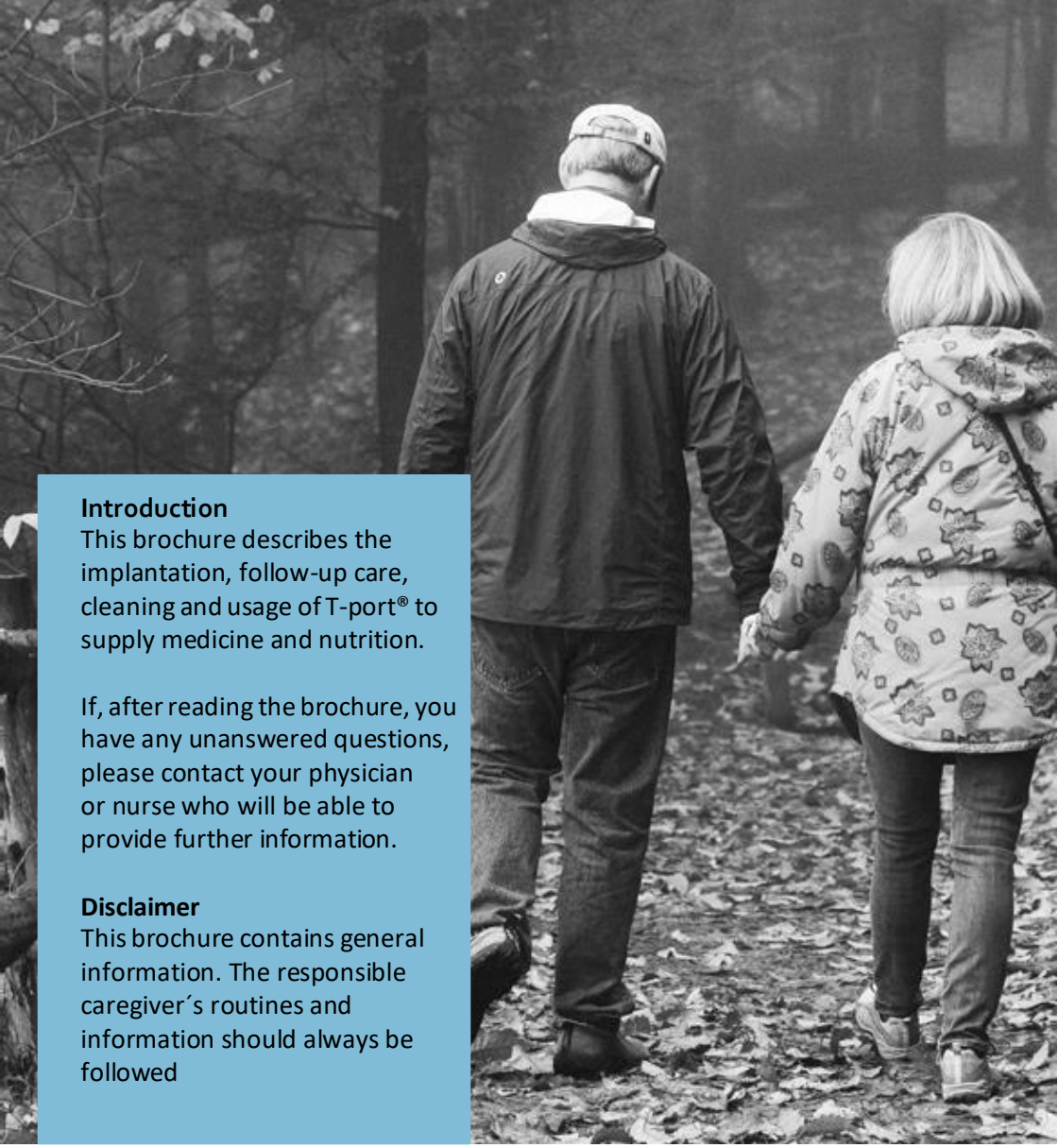
T-port®
Enteral Access System
Patient information

CE 0197

[T-port® Enteral Implant Kit Basic UDI-DI: 0735011572013QT]
[T-port® Enteral Replacement Kit Basic UDI-DI: 0735011572014QV]
[T-port® Tools Kit Basic UDI-DI: 0735011572015QX]

Transcutan



Introduction
This brochure describes the implantation, follow-up care, cleaning and usage of T-port® to supply medicine and nutrition.

If, after reading the brochure, you have any unanswered questions, please contact your physician or nurse who will be able to provide further information.

Disclaimer
This brochure contains general information. The responsible caregiver´s routines and information should always be followed

Physician: _____

Nurse: _____

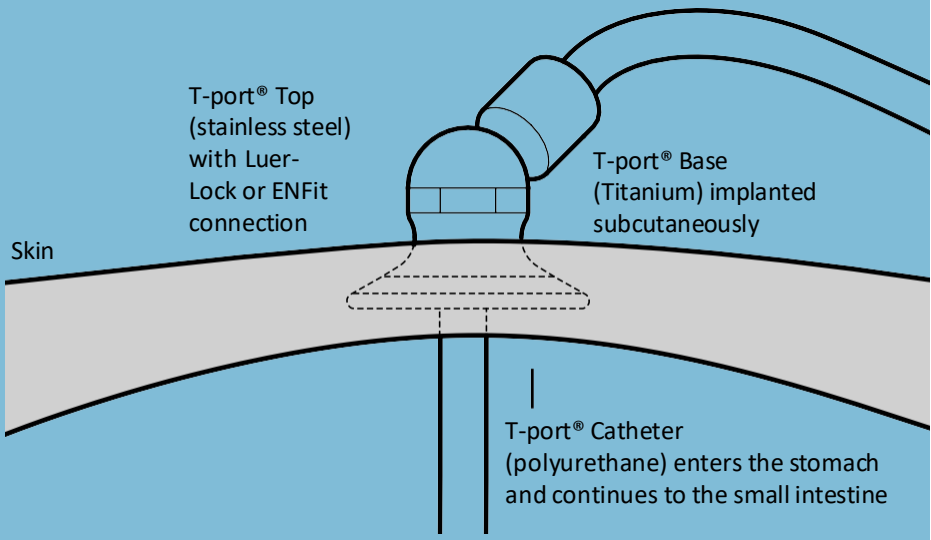
Clinic: _____

T-port® description

The T-port® Base is inserted under the skin and grows into the mucosa.

The T-port® Top is screwed onto the T-port® Base.

The catheter, which is fixed in the T-port® passes into the stomach and continues down to the small intestine.



"The extension tube can be removed when no medicine or nutrition are being supplied. Then only the top of the T-port® is visible"

T-port® Top ENFit

T-port® Top Luer-Lock

T-port® Enteral Catheter

T-port® Base.

T-port® compared to PEG

Design
- A PEG forms a channel (fistula) from the skin to the stomach, through which the PEG passes.
- The T-port® Base is located under the skin, and does not create an open channel from the skin to stomach.

Appearance
- A PEG consists of a tube hanging outside the body
- The tube connected to the T-port® can be removed when medications or nutritional products are infused.

Implantation
The PEG/J system requires a gastroscopy, whilst only an X-ray is required in T-port® implantation.

Complications and problems
Clinical studies have shown that there are fewer complications with T-port® compared to the PEG/J tube system. Above all, the enteral catheter rarely changes position or causes a flow occlusion. Gastric fluid does not normally leak outside on the skin were the T-port® is located

Expected lifespan of the T-port®
On average, a T-port® can be used for 3.6 years, but this varies between 1 and-5 years. The lifespan depends largely on how often and how well the T-port® and the skin around the T-port® inlet are cleaned. Other factors that cannot be controlled also play a role, such as the recepient´s immune system and the structure of the subcutaneous fat and skin in the area where the T-port® is placed.

Replacing the T-port®
If the T-port® becomes loose or is rejected, a new T-port® can usually be inserted in the same place without needing to interrupt the supply of medicine/nutrition. If, for some reason, it is decided to discontinue the use of the T-port®, the T-port® can be replaced with an appropriate system avoiding interruption in treatment.

Replacing the enteral catheter
If the enteral catheter needs to be replaced, this can be done painlessly without local anaesthetic by opening the top of the T-port® and replacing the enteral catheter using an X-ray. Antibiotics should also be administered before and after the intervention, in order to minimise the risk of infection.

Implantation of T-port®

Common procedure, please consult your physician for further information.

Preparation

Fast for 6 hours prior to the implantation, but you can drink until 4 hours before the implantation. Necessary medication may be taken with small amounts of water until the time of the operation. A contrast medium containing barium will be administered 8-12 hours prior to the operation to make the bowels visible on X-ray.

Implantation

The implantation takes 1-2 hours and is performed using X-ray. The radiation dose is low. A local anaesthetic is provided, and you remain awake during the operation. An IV drip with antibiotics is given during the procedure.

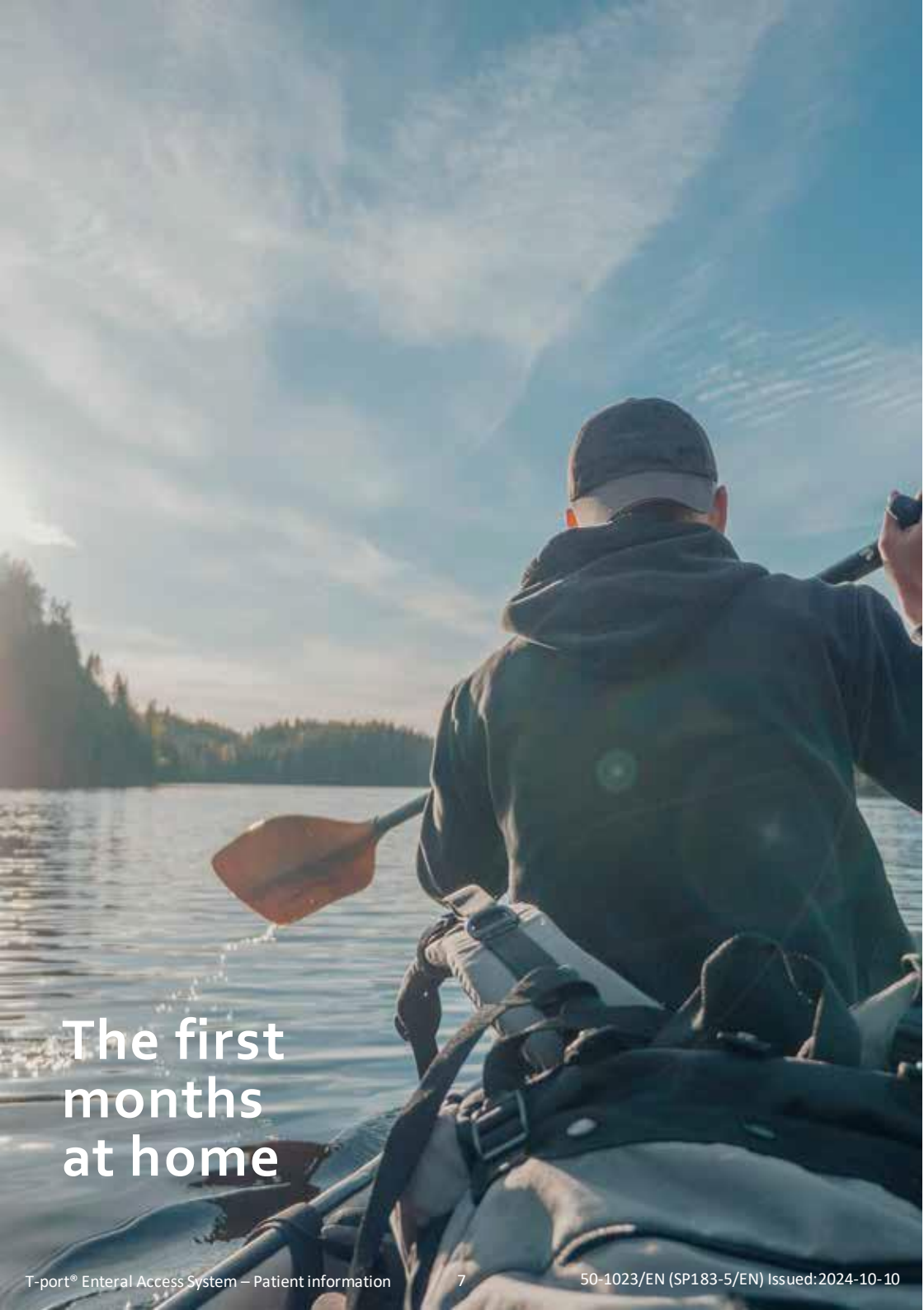
A thin tube is inserted through the nose to the stomach. The tube is used during the operation to inflate the stomach with air and to ensure a safe procedure.

Aftercare

Look out for the following signs:

- pain and leakage of gastric juice at the operation site
- bleeding
- leakage of medicine or nutrition in the system (if used)

If pain occurs, pain-relieving medication may be given. It is usually fine to drink water 6 hours after the operation. Food can be taken the following morning. The staff will notify you when you can start to drink and eat. The infusion of medicine into the small intestine can normally be started when you return to the ward. The physician gives approval when the T-port® can start to be used.



The first months at home

The first 3 weeks

1	2	3									

For 3 weeks after surgery, the following advice should be given:

- Do not remove the dressing.
- The extension tube must be fixed in place with tape.
- Avoid pulling or rotating the extension tube to the T-port®.
- If the bandage becomes wet or comes off, contact healthcare personnell to change the dressing.
- Avoid wetting the dressing. Wash in some other way and keep the dressing dry. The nurse can explain the best way to do this.
- When the medicine pump or nutrition pump is disconnected, the extension must be closed with a cap.

It is normal to feel some pain/aching for the first few days. Pain can be controlled/managed using over-the-counter painkiller medications.

Contact your healthcare clinic:

- If painkillers do not relieve the pain.
- If you have a fever.
- If the medicine/nutrition leaks outside of the T-port®.
- If the dressing becomes bloody or wet.

3 weeks after implantation

- Return visit to the clinic after about 3 weeks.
- Remove dressing.
- Inspect the stoma and T-port®.
- Remove sutures and anchor threads.
- The anchoring threads have been fixed in place with a cushion on the skin. The threads are cut close to the skin just below the cushion. The anchor becomes loose in the stomach, and is expelled together with faeces.

4 weeks after implantation

1	2	3	4	5	6	7	8	9	10	11	12

After suture removal, the following advice should be followed:

If the wound looks dry and normal, you can shower without the dressing.

- Note that the T-port® is still not entirely fixed in place, and it is important to avoid the T-port® being exposed to pulling or twisting.
- It is therefore important to continue to use the extension tube, and to secure it in place with tape.
- If the extension tube needs to be replaced, this must be performed without pulling or twisting the T-port®.
- If medicine/nutrition is leaking from the connection close to or in the wound, wash the wound immediately.

The skin around the T-port® can be washed daily using soap and water.

- Use a sponge and a sprinkling of water.
- Wax-like formations next to the port can be carefully removed using a wet cotton bud. Dry the area around the T-port® carefully. It is important to keep the skin clean and dry.

After the first and the third months

After one month, the wound should have healed, even if the T-port® is not entirely fixed in place. Clean in the morning and evening using soap and water.
It is important to remember to dry the area around the T-port® thoroughly after cleaning.
See the information regarding recommended daily cleaning on page 13.

After implantation:

The first 3 weeks

4 weeks after implantation

1	2	3	4	5	6	7	8	9	10	11	12

- Healing process.
- Covered with dressing (keep dry).
- Securing the extension tube with tape
- No pulling or twisting of the T-port®.

- Securing the extension tube.
- No pulling or twisting the T-port®
- Daily cleaning.
- Shower without dressings if the wound has healed.
- The skin around the T-port® should be kept clean and dry.

After 3 months

13	14	15	16	17	18

- The wound should normally have healed and the T-port® should now be well-anchored in the soft tissue.
- Daily cleaning.
- General caution.
- Avoid pulling and twisting.
- The skin around the T-port® should be kept clean and dry.

Daily activities

Activities
After three months, when the T-port® is fixed in place, there are no problems with normal daily activities. A cap should always be on the T-port® when not in use.

Shower and bathe as usual.

The T-port® is fixed to the abdominal wall. Any tension or impact to the T-port® may cause discomfort or pain. There is a low risk of injury, and the wound will usually heal without any problems.

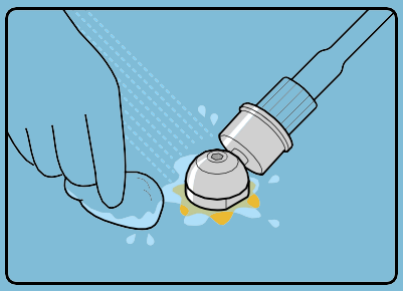
Recommended daily cleaning
- Clean the skin around the T-port® every day
- Rinse the enteral catheter after use with 20-40ml of drinking water (cold or lukewarm)

Even if the wound has completely healed, there will always be a small pocket between the T-port® and the skin.

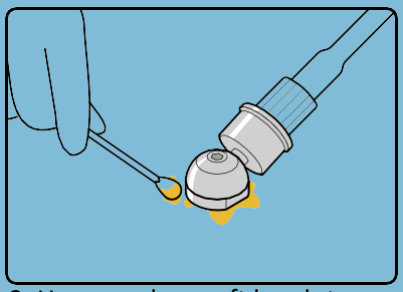
The pocket resembles the natural pockets that occur in the gums around the teeth. In order to prevent inflammation, it is important to keep the pocket clean of debris. (See figures on page 13)

Make it a habit to clean the skin and pocket around the T-port® every morning and evening.

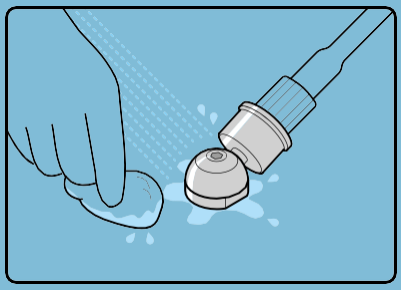
It is easiest to clean the pocket with soap and water.
Cleaning and rinsing extends the life of the T-port®. Healthcare personnel can show you how to perform this.



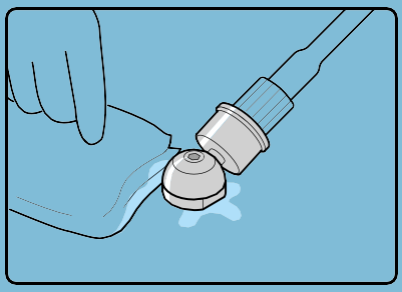
1. Wet the area with water



2. Use a swab or soft brush to remove debris



3. Flush with water



4. Dry gently and thoroughly

"Make it a habit to clean the skin and pocket around the T-port® every morning and evening."

Possible skin problems

If skin problems develop
Regardless of how well you clean the T-port® and the skin around it, there may be periods when you develop minor skin problems.

These problems are manageable and are not normally disruptive. Care should always be taken to inspect the problem and if there is a major inflammation, it can lead to rejection and the T-port® will have to be removed. It is therefore important to take care of any problems carefully.

Redness and mild soreness are signs of an inflammatory reaction around the T-port®. This should be a reminder that there is a certain amount of debris remaining in the pocket, and cleaning needs to be more thorough.

As soon as you feel that the skin problems are becoming more permanent (the skin continues to be red and irritated, and fluid is excreting around the T-port®), you should ask for advice from your nurse or get more intensive treatment for the skin.

In this case, it may be recommended to clean the skin with chlorhexidine for 10-14 days, and sometimes to treat the area locally with a cortisone ointment. This can help to reduce the inflammation. If there is intense redness, swelling, pus or pain, there is likely to be an infection, and your physician/nurse should be contacted immediately. It may be necessary for the T-port® to be removed if you are not taking proper care of an infection or taking the correct actions.

Exchange of T-port® Top
The T-port® Top is available with a Luer-Lock or ENFit connection. Replacement of the respective connection can be done by the physician who inserted the T-port®. This means that no adapters are needed.

Removing T-port® Enteral Access System
The T-port® can be removed under local anaesthetic, and the wound is sewn together with stitches.
The wound heals quickly, and there are no problems inside the stomach. Scar tissue may, however, develop at the site where the T-port® was placed.

Replacing T-port® Enteral Access System
If the wound is not infected, a new T-port® can be inserted in the same location in conjunction with the removal of the old T-port®, which avoids interruptions in treatment. If the area has become infected, the infection must be allowed to heal before a new T-port® is inserted. During this time, there are other alternatives that can be inserted where the T-port® had been placed in order to supply medicine or nutrition.

Pre- and post- treatment
When replacing the old T-port® with a new T-port®, the same level of care as with implantation is needed before and after inserting the new T-port®.

The card contains important information about the T-port® that was inserted. Ideally, it should always be kept with you, e.g. in your wallet/purse, and it is important that you take it with you when visiting the hospital or when travelling.

The T-port® contains metal, which is important to state for physicians during exams that involve magnetic resonance imaging (MRI). Show the physician your implantation card which includes more information.

Transcutan T-port® Implant Card

Patient name _____

Implant date _____

Health care institution _____

_____

_____

Patient information website www.transcutan.com/t-port

50-1026 (SP181-2)

Device type

EN Gastro-Jejunostomy, tubes and sets / **DE** Gastro-Jejunostomie, Tuben und Sets / **FR** Gastro-Jejunostomy, tubes et ensembles / **NL** Gastro-Jejunostomie, buizen en sets / **SE** Gastro-Jejunostomy, rör och set / **DK** Gastro-Jejunostomi, rør og sæt / **NO** Gastro-Jejunostomi, rør og sett / **FI** Gastro-Jejunostomia, putket ja sarjat

Traceability for the implant

Place device info label here

Information on the degree of magnetic resonance imaging (MRI) compatibility

Transcutan AB
Forskargatan 20J, SE 151 36 Södertälje, Sweden
www.transcutan.com

50-1026 (SP181-2)

Responsible manufacturer of implant

Contraindications

- Patients with thin and fragile skin (e.g. after long-term corticosteroid therapy, cachexia)
- Liver disease with portal hypertension
- Ascites
- Medication and conditions leading to coagulation disorders
- Inflammatory small intestinal disease (Chron's Disease)
- Ongoing local or systemic infection
- Active gastric ulcer/inflammation
- Patients unable to undergo, or who are not compliant with, the necessary postoperative and long-term care

Warnings and precautions

- Read the User Manual carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences for, or injury to, the patient.
- The T-port® Enteral Access System should only be used by physicians and teams trained in T-port® implantation procedure. Specific training expectations are described in section 10.
- The T-port® Enteral Access System is supplied STERILE. Do not use if the sterile barrier is damaged. If damage is found, call your Transcutan representative.
- The T-port® Enteral Access System is intended for single patient and single use only. Do not reuse, reprocess or resterilise the device. Reuse, reprocessing or resterilisation may compromise the structural integrity and/or create a risk of contamination of the device, which, in turn may lead to injury to the patient.
- The T-port® Enteral Access System must be used with the supplied Enteral Access Catheter.
- Do not use the T-port® Enteral Access System beyond the expiration date printed on the packaging.
- The T-port® Enteral Access System consists of chemically stable materials. Compatibility with all possible medications cannot, however, be guaranteed.

- **The stainless-steel parts of the device are manufactured with alloys containing a CMR substance i.e. Cobalt (CAS no.: 7440-48-4) in concentrations above 0.1% w/w. The residual risk for the patient or user is found to be acceptable, and no precautionary measures are needed.**

Patient selection, treatment and follow-up

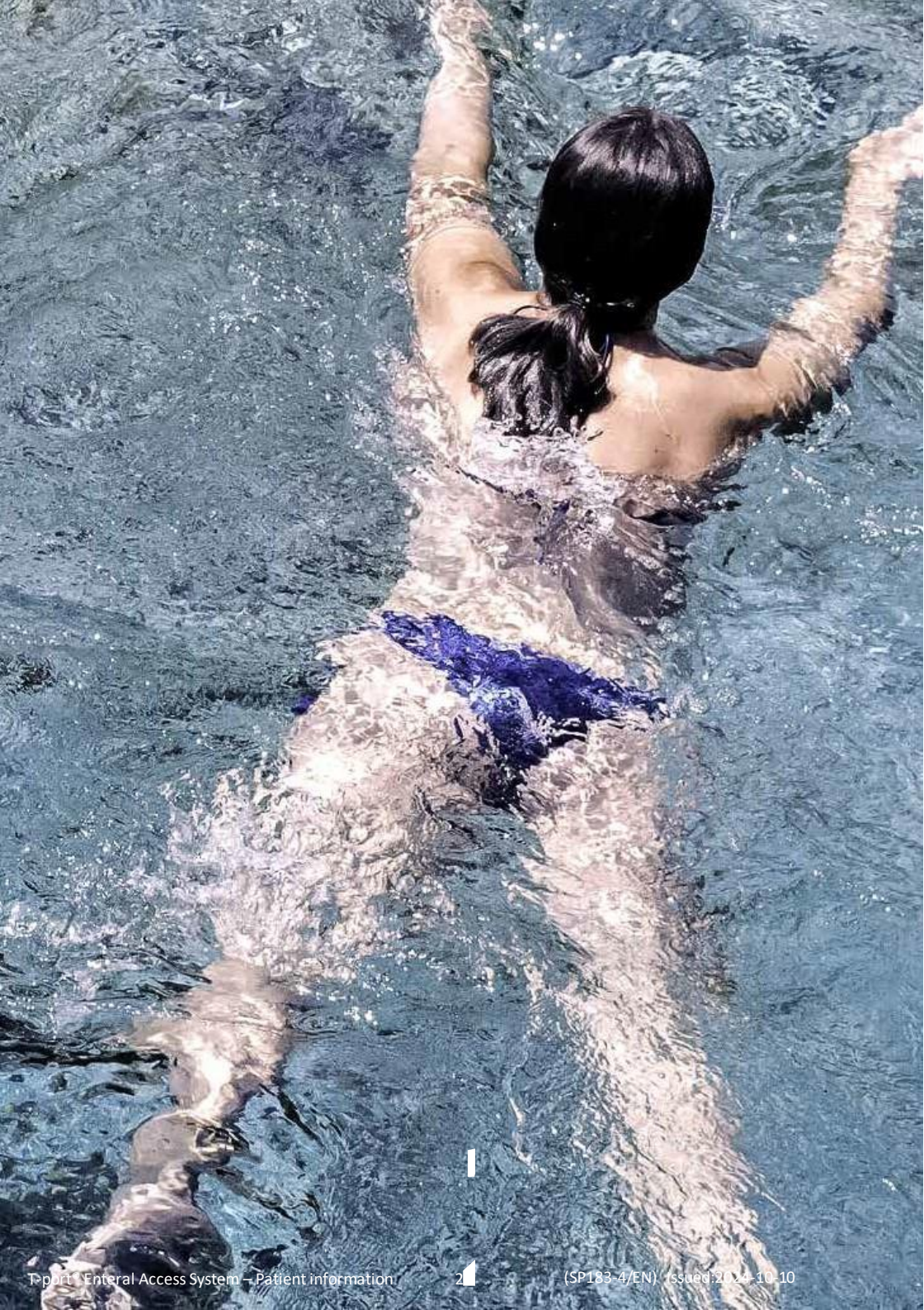
- **The T-port® Enteral Access System is not recommended for patients with known sensitivities or allergies to titanium, stainless steel, polyurethane or silicone.**
- **Patients with a systemic infection are at increased risk of stoma infection.**
- **Patients with signs of local infection near the site of implantation are at increased risk of stoma infection.**
- **Avoid placing the T-port® in an area with significant scar tissue.**
- **Avoid placing the T-port® in areas with substantial movements.**
- **The T-port® Enteral Access System is not recommended in patients who are unable to undergo, or who will not be compliant with, the necessary postoperative and long-term care.**
- **In patients with thin and fragile skin (e.g. after long-term corticosteroid therapy, cachexia), there is an increased risk that the edge of the subcutaneously placed flange may pressurise the skin and cause necrosis of the overlying skin.**
- **Avoid placing the T-port® in a skin-fold. Check the implantation site with the patient both in supine and sitting positions.**
- **Avoid placing the T-port® close to the costal arch to avoid the risk of causing pain.**
- **Any skin disease at the site of implantation may increase the risk of stoma infection.**
- **An extremely oblique implantation position of the port should be avoided. With a T-port® implanted in a very oblique position, there is a risk that the edge of the subcutaneously placed flange may pressurise the skin and cause necrosis of the overlying skin.**

(Undesirable Effects) Adverse Events

Long-term transcutaneous access devices should be implanted by physicians familiar with catheter introductions, checked regularly by caregiving staff, and regularly cleaned by the patient. Complications that may be associated with the use of transcutaneous access products include, but are not limited to, the following:

Adverse Events	Possible Cause
Slight skin irritation and debris formation with risk for staining of clothes	Leakage from the T-port® (Top inadequately tightened or tightened too hard causing Top to break, wrong catheter, catheter used without Catheter Cone), poor hygiene, forgetting to cap the ENFit or Luer-Lock port when not used, deep implantation causing ENFit or Luer-Lock to rub against the skin
Pocket inflammation leading to irritation, secretion and proud flesh formation	Continuous micro-movement and leakage from the T-port® Base in the pocket
Pocket infection	Poor hygiene, poor sterility condition during implantation, implantation in a skin-fold, T-port® not sterile at delivery, catheter replacement under poor hygienic conditions, re-sterilisation and re-use of T-port® parts, uncooperative patient
Pocket wound, pocket bleeding	Excessive force on externally connected device when not using a weak-link connection tube
Pain around pocket	Inflammation, infection, impact on or disturbance of T-port®, excessive force on externally connected device when not using a weak-link connection tube
Skin penetration by the subcutaneous flange	Oblique implantation, chronic pocket inflammation, severe infection, skin disease, wrong implant site, thin skin

Explantation of the system	Non-treatable pocket infection, chronic pocket inflammation, severe ulcer caused by catheter, oblique implantation, chronic pain
Irritation, ulcer and possible penetration of the intestinal wall by the catheter	Using wrong catheter, catheter stiffening due to incompatible substance delivered over a long period of time, intestinal disease
Peritonitis	Dislocation of catheter to the peritoneum, poor fistula between pocket and the stomach allowing leakage of gastric juice into the peritoneum, leakage from the T-port® into the peritoneum
Systemic infection with sepsis	Severe pocket infection due to non-sterile condition at implantation, poor hygiene, poor condition of the patient, uncooperative patient
Wrong dose of medication or supplied nutrition	Leakage from the T-port®, kink in the catheter, clotting of the catheter
Wrong delivery location of medication or supplied nutrition	Dislocation of catheter, rupture of catheter, breakage of catheter
Leaving a broken section of the catheter in the stomach or the small intestine	Use of the catheter for too long time without exchange, use of wrong catheter, very active patient causing much strain on the catheter, catheter becoming fragile or weakened due to incompatible substance delivered over a long period of time



Closing remarks

Where can I find more information?
Note that this brochure only contains information about T-port®.
The Parkinson team will provide information about pharmaceutical treatment, and the nutrition team will provide more information regarding how to take nutrition.
If you have any additional questions or concerns, please contact your nurse or physician.

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Transcutan

The most recently updated product information is available on Transcutan's website
http://www.transcutan.com/T-port