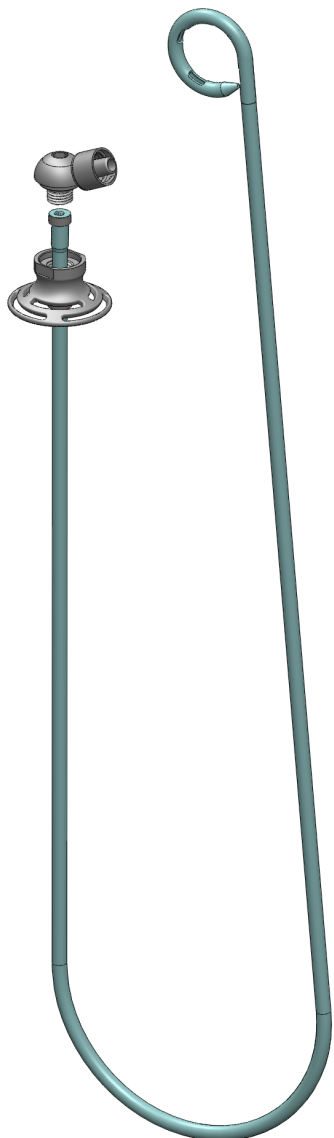

T-Port™ Enteral Access System



Instructions for Use

T-Port™ Enteral Access Implant Kit

T-Port™ Enteral Access Replacement Kit

T-Port™ Tools Kit















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Symbol definition

The following symbols may appear on the device packaging or in this Instruction For Use (IFU)

Symbol	Definition
	Caution
	Manufacturer
	Production batch code
	Reference number
	Use by date, , provided as year and month according the format YYYY-MM
	Do not reuse
	Do not resterilize
	Sterilized using ethylene oxide
	Consult instruction for use
	Keep dry
	Do not use if package is damaged
	Indication of conformity with essential health and safety requirements set out in European Directives

TransCutan T-Port™ Enteral Access Kit User's Manual

1. DESCRIPTION

The T-Port™ Enteral Access System offers safe, aesthetic, and well functioning transcutaneous, gastrointestinal access. The system consist of a port made of medical grade titanium and stainless steel and a polyurethane enteral catheter. The design allows easy and rapid placement, and if needed, exchange of catheter. The top of the port, which penetrates the skin, is fitted with a Male Luer-Lock connector allowing easy connection to external devices. The system should be positioned by skilled, and for the purpose, well trained physicians (e.g. interventional radiologist). It is supplied as a sterile device and is intended for single patient use only.

2. INTENDED USE

The T-port™ Enteral Access System is indicated when patient therapy requires repeated and/or long term access to the gastrointestinal tract. The system can be used for enteral delivery of medications, nutritional supplementation, and fluids.

3. CONTRAINDICATIONS

- Patients with very thin skin
- Liver disease with portal hypertension
- Ascites
- Coagulopathy disorders
- Inflammatory small intestinal disease (Chron's Disease)

4. WARNINGS AND PRECAUTIONS

General

- Read the User's Manual carefully. Failure to properly follow the instructions, warning and precautions may lead to serious consequences or injury to the patient.
- The TransCutan 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.
- TransCutan T-Port™ Enteral Access System is supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, call your TransCutan representative.
- TransCutan T-Port™ Enteral Access System is intended for single use only. Do not reuse, reprocess, or resterilize the device. Reuse, reprocessing, or resterilization may compromise the structural integrity and/or create a risk of contamination of the device which, in turn may lead to injury of the patient.
- The T-Port™ Enteral Access System must be used with the supplied Enteral Access Catheter.
- Extreme 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 can pressurize the skin and cause necrosis of the overlying skin.

- Do not use the T-Port™ Enteral Access System beyond the expiration date printed on the package.
- The T-Port™ Enteral Access System consist of chemically stable materials. Nevertheless compatibility all possible medications can not be guaranteed.

Patient selection treatment and follow-up

- The T-Port™ Enteral Access System is not recommended in patients with known sensitivities to allergies to titanium, stainless steel, or silicone.
- Patients with a systemic infection may be at increased risk of T-Port™ infection.
- Patients with signs of local infection near the site of implantation may be at increased risk of T-Port™ 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 unable to undergo, or who will not be compliant with the necessary postoperative and long term care
- In skinny patients there is increased risk that the edge of the subcutaneously placed flange can pressurize the skin and cause necrosis of the overlying skin.
- Avoid placing the T-Port™ in a skinfold. Check implantation site with the patient both in supine sitting position.
- Any skin disease at the site of implantation may cause an increased risk of T-Port™ infection

5. (UNDESIRABLE EFFECTS) ADVERSE EVENTS

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

Adverse Event	Possible Cause
Slight skin irritation and debris formation with risk for stained clothes	leakage from the T-Port™ (Top not tightened enough or tightened to hard causing Top to break, wrong catheter, catheter used without Catheter Cone), poor hygiene, forgetting to cap the Luer-Lock port when not used, deep implantation causing 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 sterile condition during implantation, implantation in a skin fold, T-Port™ not sterile at delivery, catheter replacement under poor hygienic conditions, re-sterilization 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, hit on 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,
Explant 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 hygienic, poor condition of the patient, uncooperative patient
Wrong dose of medication or supplied nutrition	leakage from the T-Port™, kink on the catheter, clotting of the catheter
Wrong delivery location of medication or supplied nutrition	dislocation of catheter, rupture on catheter, breakage of catheter
Leaving a broken section of the catheter in the stomach or the small intestines	use of the catheter too long 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

6. SUMMARY OF CLINICAL STUDIES

A soft-tissue anchored percutaneous device for long-term intracorporeal access was first developed by Lundgren et. al 1989 (1). Its first intended use was for insulin delivery to the peritoneum. It was shown that the device was well incorporated and fixated in the subcutaneous tissue and that an epidermal seal was obtained. The device was further developed and connected to a catheter that could be exchanged. In 2001 a clinical study in 11 patients with malignant obstruction of the bile ducts was performed (2). The study was approved by the research ethical committee of Uppsala. It was shown that the device was well tolerated by all the patients and healed in uneventfully without any major adverse events. The mean implantation time was 9 months. A cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, varying from that of the surrounding tissue to a slight or moderate redness sometimes with slight oedema. No serous exudation or pus formation was observed. This is a type of reaction seen around most titanium implants (3-9).

Shortly thereafter a collaboration with Neopharma AB started around drug delivery access in Parkinson's Disease. Neopharma was developing a new formulation of L-dopa (DUODOPA®), a gel to be delivered in the small intestines in patients with advanced Parkinson's Disease where oral treatment is no longer effective (10-13). They were using normal Gastrostomy (PEG and J-tube) to create an artificial external opening into the stomach for nutritional support or gastrointestinal decompression, but were in need of a better access technology. The major drawbacks of the PEG-system were complications related to the tube (kinking, blockage) and connectors (leakages) together with leakage and infection around the stoma (14-25). In addition, patients have been reluctant to try DUODOPA®, due to the discomfort and unattractiveness of the tube protruding from the abdomen. A case series study approved by the research ethical committee of Uppsala was performed (26). The first T-Port™ replacing the need for normal Gastrostomy, named T-Port™ Enteral Access System was inserted in January 2003. Totally 15 patients had a T-Port™ implanted for 34.5 years (mean 2.3 years/patient with a maximum duration of 4.9 years). All percutaneous procedures were performed in local anaesthesia without any major discomfort for the patients. The patients have been followed and all events with the procedure have been carefully registered using a specially designed protocol. The patients tolerated the procedure and the device well. There was no problem with blockage, kinking or dislocation of the tube or leakage of gastric juice. The same observation with cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, varying from that of the surrounding tissue to a slight or moderate redness sometimes with slight oedema with hypergranulation tissue was encountered. Two major problems were encountered with penetration of the skin of the flange and leakage of DUODOPA® at connection site. This led to redesign of the port with a vault flange and a more secure connection between the dome and the T-Port™ base (generation III T-Port), which substantially reduced these problems. All explantations of the T-Port™ were performed in local anaesthesia and the wounds in the explanted area healed uneventfully.

A case series study approved by research ethical committee at UMCG, Groningen, Netherlands was performed between September 2007 and December 2008 (27). The patients were carefully followed and the data registered in a special designed protocol during 6 months. Totally 15 patients (8 former PEG and 7 non-PEG) with advanced Parkinson's disease were included and had T-Port™ generation III implanted. There were no technical problems with the implantation and the wounds healed uneventfully. There were no major adverse events and seven out of eight former-PEG patients considered the T-Port™ system as good to very good. The total lack of obstructions, kinking, retractions, or leakage was an important improvements compared to the former PEG-systems. So within the first 6 months, the tolerability of the T-Port™ was considered 100%.

Totally 24 patients have had implanted generation III T-Ports and have been continuously followed-up both in Uppsala (9 patients) and Groningen (15 patients) following the designed protocol. Total implantation time at 2012-07-31 was 79.3 years with an average time/patient of 3.3 years. Ten T-Ports have been explanted under local anaesthesia without any wound healing problems. Two were explanted after 1 year, 2 after 2 years, 1 after 3.5 years, 3 after 4 years and 2 after 5 years. The reason for explantation was loosening and migration of the port in 7 cases, infection in 2 and on patient request in one. All 10 T-Ports could be explanted under local anaesthesia without any wound healing problems. Two patients have deceased with T-Port™ for reasons not related to the T-Port. Twelve patients still have working T-Ports with a mean implantation time of 3.5 years (range 2-4.5 years). The long-term results also demonstrate total lack of obstructions, kinking and retractions of the tubes. The same observation with cyclic variation in the colour of the skin surface immediately adjacent to the implant was also noted in all patients, varying from that of the surrounding tissue to a slight or moderate redness sometimes with slight oedema with more or less hypergranulation tissue. Most patients were somewhat bothered with more or less secretion of a brownish debris material around the port. This local inflammatory reaction could in most cases be controlled with local cleaning, cortisone ointment and lapis of the hypergranulation tissue. If this could not be controlled over time it unavoidable led to loosening and rejection of the port. No leakage of DUODOPA® or gastric juice was observed.

The main problem with the device relates to in the interface between the penetrating part of the T-Port™ and the skin edge, where a small sinus or pocket appears by nature and where dead tissue debris (a brownish wax-like material) is assembled. This sinus might be a possible locus for the development of superficial infection/inflammation with slight secretion, debris and sometimes wild meat formation. This problem can most likely be reduced with strict optimised implantation technique, choose of optimal sites for implantation, and strict hygienic routines, all important factors for success.

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7. DEVICE DESCRIPTION

The T-Port™ Enteral Access System is made up of the following components:

- T-Port™ Base (1)
- T-Port™ Top (2)
- T-Port™ Catheter Cone (3)
- T-Port™ Enteral Catheter with Catheter Cone Mounted (4)
- T-Port™ Catheter Holder (5)
- T-Port™ Base Holder (6)
- T-Port™ Top Wrench (7)

The Base, the Top, the Cone, and the Enteral Catheter (1-4) forms the actual access, while the remaining items are tools needed during implant or catheter replacement (5-7).



- ① **The T-Port™ Base (1)** is made up of a ring-shaped flange that is placed subcutaneously and a tower that penetrates the skin. The flange contains two rows of circumferential perforations allowing ingrowth of connective soft tissue that will safely anchor the Base (1). At the center there is conically shaped pass-through allowing insertion of the Enteral Catheter.

Material: non-alloyed, medical grade 2, titanium



- ② **The T-Port™ Top (2)** is made up of a Luer-Lock male connector welded to a Dome. In the Dome a freely rotating threaded "Center piece" fits into the pass-through of the Base (1). The "Center piece" is hollow and forms a connection from the Luer-Lock male connector to the Enteral Catheter (4) fitted in the Base (1). At the top level of the Dome the "Center piece" is formed into a hex socket allowing tightening of the T-Port™ with the Top Wrench (7). Since the "Center piece" rotates freely inside the Dome, the tightening can be done without rotating the Luer-Lock connector. When the Top is fully screwed down in the Base (1), the "Center piece" of the Top presses the Enteral Catheter fitted with the Catheter Cone (4) against the conically shaped pass-through in the Base (1) forming a tight seal. Sealing rings on the "Center piece" further assure tightness. The flat plane of the Dome contains three sharp points that will grab into the tower of the Base when the Dome is screwed into the Base (1), thus eliminating the problem of gradual unscrewing over time. To assure the integrity of the sharp points the Top should always be changed together with a Catheter exchange.

Material: Medical Grade Stainless Steel and medical grade silicone



- ③ **The Catheter Cone (3)** is a 10 Fr cone with a central lumen containing push-on hose barbs for a tight fit into the end of the Enteral Catheter (4), allowing the catheter to be tightly fixated against the conically shaped pass-through in the center of the Base (1).

Material: medical grade stainless steel



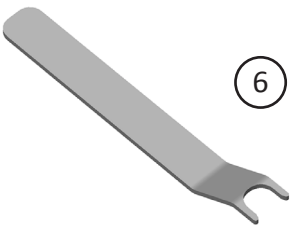
- ④ **The T-Port™ Enteral Catheter (4)** is a single lumen radiopaque 10 Fr pigtail catheter with a working length (with the pigtail) of 550 mm. The diameter of the pigtail, which contains 4 oval holes, is around 21 mm. The catheter has a forward hole to allow for passage of a 0.97 mm (0.038') guidewire. At the proximal end of the Enteral Catheter the Catheter Cone (3) is pre-mounted.

Material: medical grade biocompatible Polyurethane and medical grade stainless steel (Catheter Cone)



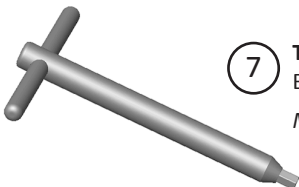
- ⑤ **The Catheter Holder (5)** is used when inserting or retracting the Enteral Catheter (4) into the Base (1). It contains a threaded tip fitting the inside threads of the Catheter Cone (3). A central lumen allows passage of a 0.97 mm (0.038') guidewire.

Material: medical grade stainless steel



- ⑥ **The Base Holder (6)** is used to fixate the Base (1) during implant. It fits into two parallel chamfers in the tower of the Base (1).

Material: medical grade stainless steel



- ⑦ **The Top Wrench (7)** is used to screw and unscrew the Top (2) into the Base (1) at implant and catheter exchange.

Material: medical grade stainless steel

8. HOW SUPPLIED

The T-Port™ Enteral Access System is provided in three variants:

T-Port™ Enteral Access Implant Kit

Art. Number: 1010-1

T-Port™ Enteral Access Replacement Kit

Art. Number: 1010-2

T-Port™ Enteral Access Tools Kit

Art. Number: 1010-3

KITS

A cardboard box containing STERILE double peel open pouches (PACKS) according to below:

The T-Port™ Enteral Access Implant Kit

Items needed for a new implant

- T-Port™ Base Pack
- T-Port™ Top Pack
- T-Port™ Tools Pack
- T-Port™ Enteral Catheter Pack

The T-Port™ Enteral Access Replacement Kit

Items needed for a catheter replacement:

- T-Port™ Top Pack
- T-Port™ Tools Pack
- T-Port™ Enteral Catheter Pack

The T-Port™ Enteral Access Tools Kit

Tools needed for the implant and replacement procedure:

- T-Port™ Tools Pack

PACKS

STERILE double peel open pouches

T-Port™ Base Pack

- T-Port™ Base (1)

T-Port™ Top Pack

- T-Port™ Top (2)
- T-Port™ Catheter Cone (3)

T-Port™ Tools Pack

- T-Port™ Catheter Holder (5)
- T-Port™ Base Holder (6)
- T-Port™ Top Wrench (7)

T-Port™ Enteral Catheter Pack

- T-Port™ Enteral Catheter with pre-mounted Catheter Cone (4)

9. DEVICE PARTICULARS

Shelf life

Expiration date is printed on the carton box label and outer pouch label of each pack in the format year-month (YYYY-MM). Do not use the items beyond the expiration date.

Special precautions for storage

Store the package at room temperature in a dry place.

Disposal

Packaging material Dispose of as appropriate

Explanted items Dispose of the items following standard solid biohazard waste procedures

Sterilization

The Packs have been sterilized in ethylene oxide

Compatibility to external devices

External equipment with a Luer-Lock female connector fits

Tightness

The T-Port™ Enteral Access System is completely water tight when properly tightened.

Proper tightening torque

Tightening the T-Port™ Top (2) just to the level where Top's lower surface makes contact with the upper surface of the T-Port™ Base (1) is enough to create a tight seal. This occurs at a torque of around 0.8 Nm. Additional torque will not improve the tightness.

Max tightening torque

The T-Port™ Top will break at at around 2.2 Nm.

Suitable extension tube

If the patient is ambulatory during treatment it is recommended that the external connection tube is fitted with a safety mechanism (weak-link) that breaks if exposed to excessive force (above 15 N).

Compatibility with delivered substances

The T-Port™ Enteral Access system is a tool for repeated channeling of nutritions and/or medications into the intestinal system. Methods of administration (syringe, pump, gravitational force, etc), concentrations, dose, flow rates, and frequency of delivery will depend on the disease and is determined by the

treating physician.

It is thus impracticable for TransCutan to provide a full compatibility list of substances that can or can not be delivered with the system.

It is the responsibility of the treating physician to determine if a specific substance is compatible with the materials in the T-Port™ Enteral Access System.

10. CLINICAL USE INFORMATION

Implanting physician experience

The implanting physician should be experienced in interventional radiological procedures and should have received theoretical background information regarding the T-Port™ Enteral Access System followed by a supervised implantation procedures.

Caregiving staff experience

The caregiving staff should have received theoretical background information regarding the T-Port™ Enteral Access System.

Inspection prior to use

Inspect the device and package to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred or if the sterilization barrier has been damaged or broken, return the items to TransCutan representative.

Materials required

Needed items NOT included in the TransCutan T-Port™ Enteral Access System.

- Nasogastric tube and air pump for insufflation of air to the stomach.
- Sterilized forceps, scissors, tweezers, knife, sterile gauze. Contact your sterilization department and get a special designed tray for this.
- Local anesthetic
- T-fastener (Cope gastrointestinal suture anchor sets, Cook, Denmark)
- Stiff guide wire
- Glide wire
- Angiographic catheter
- Dilators 10 and 12 Fr.
- Skin sutures
- Saline
- Iodine contrast
- Extension Luer-Lock tube between T-Port™ Top and external device.
- Closure for Luer-lock male.
- Female-female adapter in order to be able to fit a Luer-lock syringe.

11. DIRECTIONS FOR USE

Patient preparation

- The doctor who plans to do the implantation should check the implantation site. The T-Port™ Base (1) should be placed in a comfortable area for the patient. Skin folds as implantation sites should be avoided.
- Make sure that the patient is not on warfarin.
- Blood samples: Hb, serum creatinine, APTT, PK.
- Barium contrast can be given orally 8-12 hours before implantation in order to mark the colon.
- Fasting 12 hours before implantation, but the patient can drink water and have oral medicines up to 4 hours before operation.
- Washing of the body.
- Placement of a gastric tube.
- Peripheral venous line with NaCl .

Premedication

Give intravenous antibiotics just before the implantation. Ex. Cefuroxim 1,5 g intravenous as one time dose.

Implantation

- Check all parts of the T-Port™ Enteral Access System. The implantation should be aseptic with disinfection of the skin. The operator must use sterile clothes and instruments.
- Air is insufflated through a nasogastric tube into the stomach and the puncture site is chosen preferably over the antrum of the stomach as high as possible and avoid skinfolds. Also think of where the patient have its waist-lining. Local anesthetics is injected into the puncture canal and the stomach is punctured with the needle in the T-fastener set. Angle the needle slightly towards the pylorus, but avoid too oblique puncture canal. After verification of the needle position within the stomach, using iodine contrast, the T-fastener is inserted. The T-fastener allows having control of the stomach wall during the procedure (in order to further secure the stomach wall to the abdominal wall 2 or 3 more T-fastener can be placed with a distance of at least 1 cm from the puncture site). A guide wire is placed through the needle into the stomach and the needle is then taken out over the wire and replaced by a 4-5 Fr catheter. The string to the T-fastener is secured on the skin with a forceps. The pylorus is catheterized and the tip of the catheter is placed at the ligament of Treitz.
- After infiltration of the skin around the puncture site with local anesthetics, a 2 cm long incision is made in the skin through the puncture site. Blunt subcutaneous dissection is made to allow room for the perforated flange of the T-Port™ Base (1). Make sure that the dissection is deep enough and in the same plane as the skin surface to allow the flange to be covered with fatty tissue and to avoid oblique position. Do careful hemostasis to prevent hematoma and be careful not to cut the catheter or the line to the T-fastener. Check the dissection pocket by using the T-Port™ Base (1).
- A stiff guide wire is placed with the tip passed to the ligament of Treitz through the catheter, which is taken out. The puncture track is dilated to 10-12 Fr using a dilator or a peel away introducer. The T-Port™ Base (1) is then placed over the guide wire. The Enteral Catheter with the pre-mounted metal

Catheter Cone (4) is pulled over the wire and through the T-Port™ Base (1). The tip of the Enteral Catheter (4) should be beyond the ligament of Treitz. The port is closed and the catheter fixated by screwing the T-Port™ Top (2) onto the T-Port™ Base using the Top Wrench (7) and the Base Holder (6). The direction of the Luer-Lock can be individually chosen. Make sure that there is no space left between the T-Port™ Top (2) and the T-Port™ Base (1) after tightening (do not use excessive force a torque of 0.8 Nm to 1 Nm is suitable). Use the needle of the T-fastener line and puncture the skin to the side of the dissection and pull out the line. Flush the wound carefully with saline and then place the perforated flange of the t-Port™ Base (1) in the subcutaneous pocket. Make sure that the stomach wall is in contact with the abdominal wall and that there is no bending force on the tube before fixating the T-fastener line. Suture the T-fastener line with such a tension to avoid space between the stomach and the abdominal wall. Suture the skin around the tower and make sure that the Luer-Lock connector is positioned in the most optimal direction for the patient. If the catheter is found to long it can be cut and a new catheter cone (the spare Catheter Cone enclosed in the T-Port™ Top Pack) mounted on the cut end of the catheter. For this purpose mount the cone on the catheter holder and do the mounting over a stiff guide wire. In order to be able to press the cone into the cut end of the catheter it can be helpful to pre-dilate the catheter end with a pair of forceps

- A suitable connection tube (with a Weak-Link) is connected to the Luer-Lock on the T-Port™ Top (2). Apply a bandage with slight pressure over the wound. The bandage and the connection tube must be fixated in such a way to avoid that the port lean in any direction and to prevent any rotation force that can effect the port during the healing period.



Do not over-tight the T-Port™ Top



Use external connection tube with Weak-Link incorporated



T-Port™ Access should only be used with the supplied Enteral Catheter



If shortening of Enteral Catheter do not forget to insert the Catheter Cone



Avoid oblique position and position in skinfold



The Enteral Catheter can dislocate up into the stomach or even out into the peritoneum if the T-fastener is too loosely fixated

- Treatment can be initiated at this time by connecting the external device to the connection tube leading to the Luer-Lock connector on the T-Port™.

Post-operative care

- Four hours bed rest and then careful mobilization.
- Bleeding control.

- Flush the tube with 20 cc saline. Check for signs of leakage.
- Suitable pain relief.
- Check hemoglobin.
- Fasting until next day when liquid foods can be started. If no pain or other problems solid food can be tried. Pain could be a sign of leakage and slops or solid food should be stopped and doctor contacted.
- Change bandage if signs of bleeding through the dressing becomes apparent. Keep the bandage dry. Trained nursing staff should do the change of the bandage.
- Avoid rotation or angled force on the T-Port™ during healing.
- If necessary check the position of the Enteral Catheter with a plain x-ray of the abdomen.
- Cutting of sutures and T-fastener line are done after 14 days and the wound can then be left open if no signs of infection. The patient can then shower with the T-Port™. After 1 month there should be no need for any bandage.
- The patient should be informed to avoid any traction or rotation force to the T-Port™ especially during the first month of healing.
- If any sign of infection, take culture, give antibiotics and regular treatment of wound.

Care after Healing Period

- Avoid severe traction or rotation of the T-Port™.
- Keep the area around the port clean and dry. Clean every day 1-2 times around the T-Port™ with soap and water. Preferably do this with a shower and use wet Tops. The brownish material produced around the port is cell debris from the skin edges and should be cleaned away everyday to prevent infection.
- It is not unusual with a cyclic recurrent slight redness of the skin edges around the T-Port™, which usually needs no further treatment than daily cleaning. If more pronounced it can be treated with saline and covering with Skin-X (ErgoNordic, Sweden) or Duoderm (ConvaTec, USA).
- If signs of more pronounced redness, secretion and wild meat around the T-Port™ use the same hygienic principals as above and add cortisone ointment grade 3 two times a day for 14 days. This can be combined with local antibiotics if superficial bacterial infection is suspected. Lunar caustic (Iapis) 2 times a week can be used as an alternative for treatment of the wild meat. A trained nurse should do this as it can cause erosion of the skin.
- If severe redness, signs of pus and general effects a bacterial culture should be taken. Wash with chlorhexidine solution and cover with sterile dressing such as Allevyn (Med Net.se, Smith and Nephew) once a day. Per oral antibiotics should be considered and chosen after the culture answer. If infection cannot be controlled the T-Port™ can be explanted and the wound sutured using local anesthetics. After 1 month of healing a re-implantation of T-Port™ Enteral Access System can be performed.

Exchange of Enteral Catheter and T-Port™ Top

- The T-Port™ (2) and the Enteral Catheter (4) are exposed to long term mechanical stress. It is recommended that they are exchanged every third year.

- Enteral Catheter exchange is a risk for infection and should be done with careful aseptic rules with disinfections of the wound around the skin by a specially trained doctor.
- Use the T-Port™ Top Wrench (7) and the Base Holder (6) to remove the T-Port™ Top (2). Screw the Catheter Holder into the Catheter Cone (3) at the end of the Enteral Catheter (4) and pull out over a stiff guide wire. Replace with a new Enteral Catheter (4). Make sure that the tip is beyond the ligament of Treitz.
- A new T-Port™ Top (2) is screwed onto the T-Port™ Base (1). Make sure that there is no space left between the T-Port™ Top (2) and the T-Port™ Base (1) after tightening (do not use excessive force a torque of 0.8 Nm to 1 Nm is suitable)



Do not re-use the T-Port™ Top (2)



Be careful to avoid traction or rotation force to the T-Port™ Base (1). Use the Base Holder (6).



Do not over-tight the T-Port™ Top

Explantation of T-port

- The area around the T-Port™ Base is infiltrated with local anesthetics. If possible unscrew the T-Port™ Top (2) and remove the Enteral Catheter (4) according to the instructions in Exchange of Enteral Catheter and T-Port™ Top. Cut around the T-Port™ Base (1) and dissect underneath the flange. This usually has to be done sharp with scissor and/or knife. If the catheter was not removed it might be accidentally cut, which should be avoided. After the system is removed the skin can usually be closed with sutures. If uneventful healing a reimplantation can be performed after 1 month.

12. INFORMATION AND INSTRUCTIONS TO THE PATIENT

- Avoid traction, bending or rotation of the T-Port™.
- Use extension tube between the port and the pump. If possible the extension tube should be fixated with a tape to avoid movements of the port.
- Keep the area around the port clean and dry.
- Clean every day 1-2 times around the T-Port™ with soap and water. Preferably do this with a shower and use wet Tops.
- The brownish material produced around the port is cell debris from the skin edges and should be cleaned away everyday to prevent infection. Give special attention to the sinus around the port.
- Make sure that there is no leakage of medication at the couplings.



Improper cleaning increase the risk for discharge, low grade inflammation which in turn may lead into pocket infection

