## INTENDED APPLICATION

- Intended Application

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DESCRIPTION

The Transcutaneous Implant Evacuation System (TIES®) is a complete method for providing a continent ileostomy for the treatment of inflammatory, autoimmune or tumour intestinal diseases. The TIES® system intends to provide a permanent, patient-controlled continent stoma that obviates the need to wear a bag after removal of the large intestine.

INTENDED APPLICATION

INDICATIONS

Patients with diseases such as ulcerative colitis, familial polyposis, multiple colonic cancers, Crohn’s disease or other requiring elective colectomy followed by a permanent ileostomy. Patients with a failing conventional ileostomy, continent ileostomy, ileo rectal anastomosis or ileal pouch-anal anastomosis. Male or female, 18 years or older.

CONTRAINDICATIONS

Any clinically significant anatomical deviation, abnormal, baseline laboratory result which affects the patient’s suitability or puts the patient at risk. Severe illness which may put the patient at risk or may influence the result or affect the patient’s ability to take care of the implant. Patients with a diagnosis of undetermined colitis, recurrent parastomal hernia or recurrent incisional hernia. Patients under immuno-suppressive/depressive or anti-coagulation treatments. Condition associated with the risk of poor compliance, e.g. dementia, self-destructive personality disorder, excessive use of alcohol or drug abuse.
WARNINGS

Follow all warnings and caution statements. If the system is to function as intended, the healing time and associated instructions must be complied with.

WARNING! The implant needs time to heal as it grows firmly into the correct position. Avoid continuous and sudden loads that could affect the implant and the surrounding skin. This includes pulling, pressing, twisting and bending. Take particular care when cleaning the implant and the surrounding skin, and when using the accessories.

WARNING! Avoid the use of a catheter. If a catheter needs to be inserted, always use a soft catheter and water soluble gel. Be careful not to touch the inside of the implant cylinder and be very gentle when feeding the catheter into the intestine to avoid irritating the ileum tissue or disturbing the implant-tissue integration.

WARNING! If the implant is subjected to extreme mechanical forces (accidents, physical abuse, misuse, forceful catheterization, or similar), ask your physician to gently verify that the implant-tissue integration has not been damaged.
TIES® (Transcutaneous Implant Evacuation System) is intended to create a continent stoma using an implant, the TIES® Port, and associated lid, the TIES® Lid.

**DESCRIPTION OF THE PRODUCTS**

**TERMINOLOGY**

TIES® (Transcutaneous Implant Evacuation System) is intended to create a continent stoma using an implant, the TIES® Port, and associated lid, the TIES® Lid.

**IMPLANT, TIES® PORT**

The round section protruding through the skin provides stable attachment for the Lid and is easy to keep clean.

The implanted section (not shown), is in the form of a mesh, providing strong tissue ingrowth.

**ILEUM SECURING DEVICE, TURNBULL ADAPTOR**

Used during the first weeks to provide optimum ingrowth conditions by securing the ileum above the Port.

**STABILIZER KIT, STABILIZER KIT**

The Stabilizer secures the implant and provides support above skin level during the ingrowth period. The Stabilizer consists of a Spacer pair and a Locking Ring.

All Stabilizer components can be re-used several times and withstand boiling water. They can also be cleaned in 70% alcohol or 2% room-tempered Clorox solution (household bleach). Rinse carefully afterwards. Replace the Stabilizer every week.
DESCRIPTION OF THE PRODUCTS

**SPACER, SPACER**
Comes as a pair and is used together with a Locking Ring.

**LOCKING RING, LOCKING RING**
Used to lock the Spacer pair in place around the implant.

**LID, TIES® LID**
The Lid is used to achieve a continent stoma after the intestine has grown into the implant and healed completely.

The Lid is re-usable and can be cleaned in the same way as the Stabilizer. Replace the Lid every week.

Always check the outside of the packaging for any damage. If the packaging has been damaged the product must not be used. Contact your clinic or OstomyCure if any item is missing or damaged.
DESCRIPTION OF THE PRODUCTS

QUANTITIES AND SIZES

TIES® Port system is summarised in the table below.

<table>
<thead>
<tr>
<th>IMPLANT</th>
<th>INNER DIAMETER</th>
<th>OUTER DIAMETER</th>
<th>STABILIZER KIT CONTAINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>D24</td>
<td>23,2 mm</td>
<td>28,4 mm</td>
<td>5 Spacer pairs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 Locking Rings</td>
</tr>
</tbody>
</table>

RECOMMENDED STANDARD ACCESSORIES

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>RECOMMENDED SIZE</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ostomy skin barrier</td>
<td>70 mm</td>
<td>Matching the ostomy bag</td>
</tr>
<tr>
<td>Ostomy bag</td>
<td>70 mm</td>
<td>Matching the ostomy skin barrier</td>
</tr>
<tr>
<td>Adhesive remover</td>
<td>-</td>
<td>Spray or wipes</td>
</tr>
<tr>
<td>Irrigation sleeve</td>
<td>-</td>
<td>Disposable or Flushable Drainage Sleeve</td>
</tr>
</tbody>
</table>
Cut a 40 mm hole and centre the skin barrier around the implant.

Assemble the Stabilizer with a Spacer pair around the implant and use the Locking Ring.

The ostomy bag fits over the Stabilizer.

Bathe gently with tap water when cleaning, do not rub. Dry carefully.

Use the Lid only when the implant is completely healed.

*Never twist, push, bend or pull the implant or the surrounding skin!*
AVOID THE FOLLOWING

Never twist, push, bend or pull the implant or the surrounding skin! This is very important to prevent disturbing the ingrowth.

SKIN BARRIER USE

- The ostomy skin barrier must be affixed to clean and dry skin.
- The protruding end of the intestine has been turned inside out on the Turnbull Adaptor on top of the implant and secured with a few sutures.
- Cut out a 40 mm diameter hole in the ostomy skin barrier. Best is to use a pair of curved scissors, following the guiding pattern on the skin barrier.
- Accurately centre the ostomy skin barrier with the cut-out hole over and around the implant and fix it gently to the clean, dry skin.
ASSEMBLING THE STABILIZER

- Place two Spacers on the skin barrier around the implant. Align an arrow on the Spacer pair to an arrow on the Turnbull Adaptor and gently press the Spacer pair together, locking into the groove on the implant just below the Turnbull Adaptor.

Be very careful not to put any stress to the implant and do not rotate the Turnbull Adaptor! Also, be careful not to insert the Spacers between the skin and the base of the cylinder top.

- Hold the Spacer pair firmly with one hand. Put on the Locking Ring (line up the positioning indexes) and carefully turn it clockwise with the other hand until the bayonet locks in place.
- Do not rotate, pull or push on the Spacer pair!
- Place an ostomy bag over the implant and Stabilizer. Gently seal the bag to the skin barrier fixing flange in the usual manner. Take great care not to push against the skin and work only against the fixing flange on the skin barrier.
PHASE ONE | INITIAL HEALING PERIOD

EMPTYING THE OSTOMY BAG

- The length of time between draining or replacing the ostomy bag varies from person to person, but it normally needs to be emptied 2-5 times a day. When removing and replacing the bag, take great care and work only against the fixing flange on the skin barrier.
- Avoid pulling or pressing on the skin barrier itself.
- When replacing the bag, clean the area around the implant and the outside of the implant with lukewarm water as necessary. Avoid the use of disinfectants.

REPLACING THE SKIN BARRIER

- During the first weeks, it is advisable to leave the ostomy skin barrier in place as long as possible, normally up to 7 days. Use a protective skin cream or ointment to prevent skin irritation.
- Early or frequent replacement of the skin barrier may disturb the ingrowth (implant – tissue integration).
- Hold the Spacer pair firmly with one hand, and turn the Locking Ring counter-clockwise with the other hand to open the bayonet lock. Gently remove the Locking Ring.
- Carefully pull the Spacers apart and remove from the implant.
• Carefully lift a corner of the ostomy skin barrier. Hold a dampened, nonwoven swab gently against the skin right next to the skin barrier.

• Do not pull or stretch the skin near the implant, as this may affect healing.

• An adhesive remover spray or wipes are recommended to help loosen the skin barrier. This will reduce the stress on the skin and minimise the effect on healing. Gently lift away the skin barrier, and spray again as required on the skin under the skin barrier.

• Carefully clean the area around the implant and the outside of the implant each time the skin barrier is replaced. Use lukewarm water and mild soap as needed. Ordinary tap water is sufficient. Avoid the use of disinfectants.

• Never rub or press on the skin surrounding the implant.

• Dry completely using soft, bathing movements. Leave for a short time to dry in the air and then apply a new skin barrier and Stabilizer.
REMOVING THE TURNBULL ADAPTOR

TURNBULL ADAPTOR REMOVAL

After three to four weeks the intestine has grown enough into the implant and the Turnbull Adaptor may be removed. The very end of the intestine protruding outside the implant has now started to wizen and the sutures are coming loose. Normally the Turnbull Adaptor can be gently removed by your physician without surgical intervention. The intestine will reside permanently just at the top of the implant.

ILEUM TRIMMING

After another two weeks, it is time to carefully trim off excess parts of the intestine in a simple daycare surgical procedure.

Alternatively, your surgeon may choose not to actively trim off excess parts, but rather wait a few more weeks for the wizening process to complete, thus achieving a “natural trimming” of excess parts of the intestine.
PHASE TWO | FINAL HEALING

The time for final healing varies between individuals but is expected to be in the range of two to three weeks after trimming (two to three months after Port implantation).

It is recommended to use an ostomy skin barrier and an ostomy bag during this time.

*The Lid must not be used permanently before final healing is completed!*

ILEUM HEALING

After the final trimming, the ileum will need approximately two weeks for healing and rest. Do not attempt to start using the Lid during this period.

TEMPORARY LID USE

After ileum recovery and per judgement of your doctor, it is possible to start using the Lid momentarily.

During this period, the Lid may be used occasionally for short periods (up to an hour). Before final healing is accomplished, it is important to avoid any build-up of intestinal pressure. This is merely a training and habituation phase. Be very observant in avoiding intestinal pressures or discomfort and swiftly remove the Lid in such cases. Never use the Lid at night or when risk of falling asleep or not being in full control.

Normal procedure during this phase shall be the use of an ostomy bag.

*Immediately remove the Lid if there is a sensation of intestinal pressure, discomfort or pain connected to the temporary Lid usage.*
When your physician considers that the intestine has healed completely inside and around the implant, you can start using the Lid permanently. This normally occurs two to three months after initial surgery.

**LID ACCLIMATISATION**

In the beginning, the Lid should still only be used for a few hours at a time to prepare the intestine and to allow it to expand gently behind the implant. The length of time the Lid is used is gradually increased causing increased pressure on the intestine. Gradually the intestine develops a natural reservoir behind the implant. This reservoir means that the intestinal contents do not need to be emptied as often. Expect several months for this process to be fully completed.

Lid acclimatisation can progress much faster for patients who already have a reservoir when the TIES® Port is implanted.

When starting to use the Lid for extended periods, a certain amount of discomfort can occur around the implant and in the abdomen. This is fully normal and only shows that the intestine is adjusting and expanding. *If you experience pain in the abdomen, the lid should be removed. Contact the ostomy nurse or your physician if the problem persists.*

![Cross-section of the implant, skin and intestine with reservoir.](image)

The schedule that has been set up by your physician must be followed when acclimatising to use of the Lid. How quickly the intestine acclimatises to the Lid varies from person to person. If you experience discomfort, the length of time the Lid is used should be shortened. Keep a record of your experience when acclimatising to the Lid for your follow-up.

Using the Lid means you no longer need to use the ostomy skin barrier, Stabilizer and ostomy bag.
PHASE THREE | USING THE LID

EMPTYING THE INTESTINE

The length of time between emptying the intestine varies from person to person, but it normally needs to be emptied two to ten times a day.

For quick procedures, an irrigation sleeve is recommended. Affix the irrigation sleeve around the implant and position the open end over the toilet. Remove the Lid inside the sleeve. Operate the Lid from the outside of the sleeve to avoid soiling of your hands. Use only sufficient force to affix and to remove the Lid.

When the Lid has been removed, the intestine can be emptied. Bend slightly forward to empty all the contents and drain through the irrigation sleeve.

Should the emptying procedure require more time, a standard ostomy bag could be temporarily used, instead of the irrigation sleeve.
CLEANING

After each emptying, clean the outside of the implant, the surrounding skin (see PHASE ONE / REPLACING THE SKIN BARRIER) and the Lid using lukewarm running water if available. Avoid the use of disinfectants.

Once the Lid is in continuous use, it should be replaced every week for hygienic reasons.

SCHEDULE FOR USING THE LID

In the beginning, the Lid should be used for a limited time and a limited number of times during the day. A personalised schedule for recommended Lid use shall be drawn up in collaboration with your physician. During the acclimatisation period, it is recommended to keep a diary in which you note the actual times and durations of Lid use.

The time for acclimatisation varies from person to person.
**DISCOMFORTS AND RISKS**

**SURGICAL AND DEVICE RISKS**

Potential discomforts and risks, originating from the surgical procedure or the TIES device itself.

- Redness at the operation site
- Pain
- Allergic reaction (including to medications, anaesthesia or device materials)
- Infection
- Device misplacement or migration
- Enterocutaneous fistula
- Perforation of the intestine during insertion of ileum through implant
- Contamination of implant with intestinal content during surgery
- Narrow passage or constipation caused by irritated or swollen intestine
- External violence - skin or body injuries caused by the protruding part of the implant getting caught or by violent accidents
- In patients with Crohn’s disease or determined colitis, there is a risk of recurrence. However, this risk is in line with the one patients with conventional ileostomies face. A recurrence may cause a partial or complete obstruction of the implant. The implant may have to be removed. Should a recurrence of Crohn’s disease occur it is not advised to replace the implant. It should be removed and a conventional ileostomy should be done.

**FUNCTIONAL RISKS**

Potential discomforts and risks regarding the functional performance of the device related to the embedding of the implant into the soft tissue of the abdomen during the healing period after surgery.

- Leakage of intestinal liquid between the device and the skin due to
  - Ileum retraction
  - Too early use of Lid
  - Trauma
  - Other factors
- Insufficient ingrowth of soft tissue into the device to ensure a leak-free system

**REMEDIES IN CASE OF LEAKAGE**

Should the system show incomplete ingrowth inside or outside or being harmed in a way or another over time, it should be “put to rest”. The usage of the Lid should be stopped for a few weeks to give the biological system time to adjust to the situation and come to a new balance; the ingrowth of the skin and the intestine tends to adjust by itself.
OstomyCure AS certifies the compliance with the EC Directive 93/42/EEC (Medical Device Directive, MDD) of June 14, 1993. We declare that the compliance of the TIES® system conforms to the essential requirements of the MDD regarding medical devices per annex II.

Any modification to the device, not authorized by us, will invalidate this declaration.

Benedict Brönnimann, MD
CEO OstomyCure AS
Oslo 2016-06-17

TIES® is a brand name registered to OstomyCure AS, Norway.
The TIES® system is internationally protected by several patents and design registrations.