# CONTENTS

1. SUMMARY .................................................................................................................... 3
2. DESCRIPTION ............................................................................................................... 4
   2.1 Intended Application ................................................................................................. 4
3. WARNINGS .................................................................................................................. 4
4. DESCRIPTION OF THE PRODUCTS ......................................................................... 5
   4.1 Quantities and sizes ................................................................................................. 7
   4.2 Recommended standard accessories ...................................................................... 7
5. PHASE I – INITIAL HEALING PERIOD .................................................................. 8
   5.1 Skin barrier use ....................................................................................................... 8
   5.2 Assembling the Stabilizer ...................................................................................... 10
   5.3 Emptying the stoma bag ....................................................................................... 12
   5.4 Replacing the skin barrier .................................................................................... 13
6. REMOVING THE TURNBULL ADAPTOR .............................................................. 16
   6.1 Turnbull Adaptor Removal .................................................................................... 16
   6.2 Ileum Trimming ..................................................................................................... 16
7. PHASE II – FINAL HEALING .................................................................................. 17
   7.1 Ileum healing ......................................................................................................... 17
   7.2 Temporary Lid use ................................................................................................. 17
8. PHASE III – USING THE LID ............................................................................... 18
   8.1 Lid acclimatisation ................................................................................................. 18
   8.2 Emptying the intestine .......................................................................................... 19
   8.3 Cleaning .................................................................................................................. 20
   8.4 Schedule for using the Lid .................................................................................... 20
9. DISCOMFORTS AND RISKS .................................................................................. 21
   9.1 Surgical and device risks ...................................................................................... 21
   9.2 Functional risks .................................................................................................... 21
10. MANUFACTURER ................................................................................................... 22
    10.1 Address ............................................................................................................... 22
    10.2 Declaration of Conformity ................................................................................... 22
    10.2 Patents and Trademarks ....................................................................................... 22

NB! – READ THE LIST OF WARNINGS ON PAGE 4 CAREFULLY
1. SUMMARY

Cut a 40 mm hole and center the skin barrier around the implant.

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

Bathe delicately 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!
2. DESCRIPTION

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

2.1 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 of age.

CONTRAINDICATIONS
Any clinically significant, 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. Condition associated with the risk of poor compliance, e.g. excessive use of alcohol or drug abuse.

3. 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 be very delicate 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), a clinical investigation shall be conducted to verify that the implant-tissue integration has not been damaged.
4. DESCRIPTION OF THE PRODUCTS

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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 in-growth.  
Available in two inner diameters to fit varying intestinal thicknesses. |
| **Ileum securing device, Turnbull Adaptor** | Used during the first weeks to provide optimum in-growth conditions by securing the ileum above the Port.  
Available in two sizes to fit the implant. |
| **Spacer, Spacer** | Comes as a pair and is used together with a Locking Ring. Together they form a Stabilizer that secures the implant and provides support above skin level during the in-growing period.  
One size fits all implants. |
| **Locking ring, Locking Ring** | Used to lock the Spacer pair in place around the implant.  
One size fits all implants. |
<table>
<thead>
<tr>
<th><strong>Stabilizer kit, Stabilizer Kit</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Spacer and Locking Ring are supplied together as a kit.</td>
<td></td>
</tr>
<tr>
<td>All components can be re-used several times and withstand boiling water. They can also be cleaned in alcohol or 2 % room-tempered Clorox solution (household bleach). Rinse carefully afterwards. Replace the Stabilizer every week.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lid, TIES® Lid</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The Lid is used to achieve a continent stoma after the intestine has grown into the implant and healed completely.</td>
<td></td>
</tr>
<tr>
<td>The Lid is re-usable and can be cleaned in the same way as the Stabilizer. Replace the Lid after two weeks.</td>
<td></td>
</tr>
</tbody>
</table>

One size fits all implants.

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.
## 4.1 QUANTITIES AND SIZES

<table>
<thead>
<tr>
<th>Stabilizer kit contains</th>
<th>Implant</th>
<th>Diameter [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Inner</td>
</tr>
<tr>
<td>5 pairs Spacers</td>
<td></td>
<td>D22</td>
</tr>
<tr>
<td>5 pcs Locking Rings</td>
<td></td>
<td>D24</td>
</tr>
</tbody>
</table>

## 4.2 RECOMMENDED STANDARD ACCESSORIES

<table>
<thead>
<tr>
<th>Product</th>
<th>Recommended manufacturer</th>
<th>Article no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stoma skin barrier</td>
<td>Hollister Conform 2</td>
<td>37500 or 27200</td>
</tr>
<tr>
<td>Closed stoma bag</td>
<td>Hollister Conform 2</td>
<td>27420 (skin) or 27520 (clear)</td>
</tr>
<tr>
<td>Drainable stoma bag</td>
<td>Hollister Conform 2</td>
<td>27760 (skin) or 27860 (clear)</td>
</tr>
<tr>
<td>Adhesive remover spray</td>
<td>Hollister</td>
<td>7731</td>
</tr>
<tr>
<td>Irrigation bag</td>
<td>Convatec Iridess</td>
<td>175612</td>
</tr>
<tr>
<td></td>
<td>GP Medical Devices ApS</td>
<td>EasyDrainer Flushable Drainage Sleeve</td>
</tr>
<tr>
<td>Nonwoven swabs</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Scissors</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
5. PHASE I – INITIAL HEALING PERIOD

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

Fig 1. Avoid twisting, pushing, bending or pulling the implant.

5.1 SKIN BARRIER USE

The stoma skin barrier must be affixed to clean and dry skin.

Fig 2. The protruding end of the intestine has been turned inward 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 stoma skin barrier. Best is to use a pair of curved scissors, following the guiding pattern on the skin barrier.

Fig 3. Follow the guiding pattern on the skin barrier and cut a 40 mm hole.

Accurately center the stoma skin barrier with the cut-out hole over and around the implant and carefully affix it to the clean, dry skin.

Fig 4. Placing the skin barrier around the implant.
5.2 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 carefully 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 absolutely not rotate the Turnbull Adaptor!*

![Fig 5. Two Spacers form a ring around the implant.](image1)

![Fig 6. The Spacer pair in position around the implant.](image2)
Hold the Spacer pair firmly with one hand. Put on the Locking Ring (line up the positioning indexes) and carefully turn it clockwise until the bayonet locks in place.

*Do not rotate, pull or push on the Spacer pair!*

![Fig 7. Turn the Locking Ring carefully onto the Spacer pair](image)

Place a stoma bag over the implant and Stabilizer. Seal the bag carefully to the skin barrier fixing flange in the usual manner. Take great care and work only against the fixing flange on the skin barrier.

![Fig 8. The implant and Stabilizer in place inside the stoma bag](image)
5.3 EMPTYING THE STOMA BAG

The length of time between draining/replacing the stoma 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.

![Fig 9. Replacing the stoma bag](image)
5.4 REPLACING THE SKIN BARRIER

During the first weeks it is advisable to leave the stoma 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 in-growth.*

Hold the Spacer pair firmly with one hand, and turn the Locking Ring counter-clockwise to open the bayonet lock. Gently remove the Locking Ring.

![Unlocking the Locking Ring](image)

**Fig 10. Unlocking the Locking Ring**

Carefully pull the Spacers apart and remove from the implant.

![Removing the two Spacers.](image)

**Fig 11. Removing the two Spacers.**
Carefully lift a corner of the stoma 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 is 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.

---

**Fig 12.** Use adhesive remover spray and dampened swabs.
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.

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

![Image](image1.png)

**Fig 13.** Wash using gentle bathing movements

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.

![Image](image2.png)

**Fig 14.** Dry carefully using bathing movements
6. REMOVING THE TURNBULL ADAPTOR

6.1 TURNBULL ADAPTOR REMOVAL

After two to four weeks the intestine has grown enough into the implant for the Turnbull Adaptor to 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 delicately removed by your physician without surgical intervention. The intestine will reside permanently just at the top of the implant.

6.2 ILEUM TRIMMING

After another two weeks it is time to carefully trim off excess parts of the intestine in a simple 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.
7. PHASE II – FINAL HEALING

The time for final healing varies between individuals but is expected to be in the range of three to four months after Port implantation.

It is recommended to use the Stabilizer also during the final healing period. Use it in the same manner as described for the previous phase above, together with a stoma skin barrier and a stoma bag.

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

7.1 ILEUM HEALING

The ileum will need approximately two weeks for healing and repose after the final trimming. Do not attempt to start using the Lid during this period.

7.2 TEMPORARY LID USE

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

During this period, the Lid may be used once in a while for short periods. 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 a stoma bag.

*Immediately remove the Lid if there is a sensation of intestinal pressure, discomfort or pain connected to the temporary Lid usage.*

Fig 15. Lid removal (reverse steps for application)
8. PHASE III – USING THE LID

When the doctor considers that the intestine has healed completely in and around the implant, you can start using the Lid permanently. This normally occurs three to four months after initial surgery.

8.1 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 stoma nurse or the doctor in charge if the problem persists.

Fig 16. Cross-section of the implant, skin and intestine with reservoir.

The schedule that has been set up by the doctor in charge 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 experiences when acclimatising to the Lid for your follow-up.

Using the Lid means you no longer need to use the stoma skin barrier, Stabilizer and stoma bag.
8.2 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 bag is recommended. Affix the irrigation bag around the implant and position the open end over the toilet. Remove the Lid inside the bag. Use only sufficient force to affix and to remove the Lid.

![Fig 17. Irrigation bag in position over the Lid and implant](image)

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

![Fig 18. Emptying the intestine](image)

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

After each emptying, clean the outside of the implant, the surrounding skin (see Fig 13 and 14 above) and the Lid using lukewarm running water if available. Once the Lid is in continuous use, it should be replaced every second week for hygienic reasons.

Fig 19. Rinsing the Lid in lukewarm tap water

8.4 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 will be drawn up, in collaboration with the doctor in charge, for recommended Lid use during the acclimatisation period. The schedule also contains a diary in which you should note the actual time you use the Lid.

The time for acclimatisation varies from person to person.

The schedule and diary will be supplied separately.
9. DISCOMFORTS AND RISKS

9.1 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, anesthesia or device materials)
- Infection
- Device misplacement or migration
- Entero-cutaneous 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

9.2 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
- Insufficient ingrowth of soft tissue into the device to ensure a leak-free system
10. MANUFACTURER

10.1 ADDRESS

OstomyCure AS
Gaustadalléen 21
0349 OSLO
Norway
www.ostomycure.com
info@ostomycure.com

10.2 DECLARATION OF CONFORMITY

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 including annexes III, V and VII.

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

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

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10.2 PATENTS AND TRADEMARKS

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