Minimally invasive treatment for faecal incontinence
Faecal incontinence is the inability to control bowel movements, causing stool (feces) to leak unexpectedly from the anus. Also called bowel incontinence, faecal incontinence ranges from an occasional leakage of stool while passing gas to a complete loss of bowel control.

Some data:
- 1-7.4% general population
- 25-30% of institutionalized & geriatrics
- Average cost per patient USD$17 000
- Clinical categories:
  - Urge
  - Passive
  - Soiling
  - Faecal seepage

Treating faecal incontinence may require these surgical principles:
- Repair (e.g. sphincteroplasty)
- Replace (e.g. dynamic graciloplasty)
- Re-route (e.g. colostomy)
- Re-innervate (e.g. SNS)

**WHY THD:**

THD® GateKeeper was devised with the aim to treat faecal incontinence by implanting specifically designed self-expandable prostheses into the intersphincteric space.

Solid agents in the inter-sphincteric space produce longer and stable results and ultrasound check in the long term reveals no migration of the prostheses in almost all cases.
**SAFE**
Minimum discomfort, no major complications, no infection, minimum rate of implant extrusion (assuring patient compliance in observing bed rest or slowly moving out of bed to chair for 48 hours after the procedure to minimize early prosthesis dislocation).

**FAST**
Cases are typically performed in 30 minutes or less.

**COST-EFFECTIVE**
This procedure is cost effective with low material expenditure combined with short hospital stays and limited pain medication.
The insertion of the Delivery System cannula needs to be followed by digital palpation. Continue inserting safely the cannula into the intersphincteric space up to reach the anorectal junction: your finger can locate there the tip of cannula, avoiding injuries to the tissues.

THD® GateKeeper implant procedure should be performed in local anesthesia (however, it is suitable also for general). The starting point of the procedure is generally the patient’s left side. In this standard example the first implant is located at 3 o’clock.

THD® GateKeeper must be inserted via a subcutaneous tunnel under the skin. NOTE: while inserting the cannula avoid going vertically through the external sphincter. Follow the natural path to the intersphincteric groove.

Remove your finger and insert the EAUS probe in order to correctly place the prosthesis into the intersphincteric space. EAUS is used to check the correct position of the tip of the cannula into the intersphincteric space.
THE BASIC STEPS

3  **Tunneling up to the intersphincteric groove**
Locate the intersphincteric groove with your finger and use it as a direction for the device insertion. Push the cannula of the device until you reach the finger placed at the intersphincteric groove.

4  **Insertion of the delivery system into the intersphincteric space**
When the intersphincteric groove has been reached, change the cannula orientation until it’s parallel to the longitudinal axis of the anal canal. Gradually insert the cannula in the intersphincteric space. Close to the dentate line, there is a point of higher resistance: pay attention when pushing the cannula through this level.

7  **Release of prosthesis**
“Press the button located on the Delivery System handle (named “B”) to release the prosthesis. When the LED on the back of Delivery System is flashing orange, extract it from the site of implant.

8  **Suture and repetition of steps**
Suture the incision and repeat the steps following the order in the illustration to deliver the other prostheses.
The material is able to grow in volume through the absorption of body fluids up to 550% the original dimension.

Thanks to its shape memory effect, the material reverts to the initial shape following the sphincters movement.

### FEATURES

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>1.8 mm (+0.2/-0.4)</td>
<td>6 mm (+0.5/-1.0)</td>
</tr>
<tr>
<td>Length</td>
<td>20 mm (±2,0)</td>
<td>10 mm - 15 mm</td>
</tr>
<tr>
<td>Single volume</td>
<td>51 mm³</td>
<td>282 mm³</td>
</tr>
<tr>
<td>Total volume</td>
<td>306 mm³ = 0.3ml</td>
<td>1692 mm³ = 1.7ml</td>
</tr>
</tbody>
</table>

THD® GateKeeper implants are made with a patented self expandable material with shape memory.

The self expandable material is biocompatible, non-allergenic, non-immunogenic, non-carcinogenic.
**CLINICAL STUDIES**

**Gatekeeper Improves Voluntary Contractility in Patients With Faecal Incontinence**  
Ugo Grossi, MD, Veronica De Simone, MD, Angelo Parello, MD, Francesco Litta, MD, Lorenza Donisi, MD, Gian Luca Di Tanna, PhD, Marta Goglia, MD, and Carlo Ratto, MD - 2018

**Outcomes of Gatekeeper™ prosthesis implantation for the treatment of faecal incontinence: a multicenter observational study**  
Biondo S., Trenti L., Noguerales F., Nomdedeu J. et al - 2017

**Multicentre observational study of the Gatekeeper™ for faecal incontinence**  

**Treatment for Faecal Incontinence Results of sphincter augmentation with Hyexpan implants in a pilot study**  
Bouassida S., Krüger K., Adam U. - 2015

**Simultaneous Delorme’s procedure and inter-sphincteric prosthetic implant for the treatment of rectal prolapse and faecal incontinence: Preliminary experience and literature review**  

**Anal Gatekeeper a new bulking agent for faecal incontinence**  

**Gatekeeper in faecal incontinence: prospective European multicentre study**  

**Novel bulking agent for faecal incontinence**  
Ratto C., Parello A., Donisi L., Litta F., De Simone V., Spazzafumo L. & Giordano P. - 2011
SPECIFICATIONS

THD GateKeeper

Part No. 820005
Includes
• THD® GateKeeper delivery system (sterile)
• 6 THD® GateKeeper self expandable implants

THD S.p.A.
Via Industria 1, 42015, Correggio (RE), Italy
Tel +39 0522 634 311 Fax +39 0522 634 371
www.thdlab.com