



THD SphinKeeper & **THD** GateKeeper

Minimally invasive treatments for faecal incontinence

Document intended for Health Care Professionals only.



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Minimally invasive treatments 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)



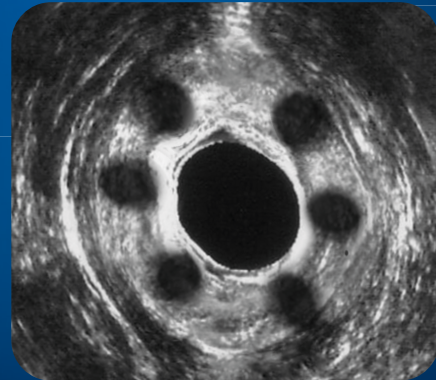
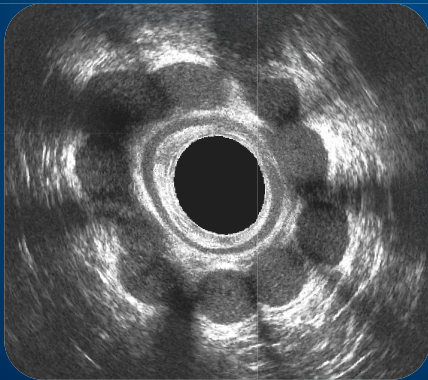
WHY THD:

THD SphinKeeper® and THD GateKeeper® were 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.



THD SphinKeeper & THD GateKeeper



BENEFITS

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 40 minutes or less for THD SphinKeeper® and in 30 minutes or less for THD GateKeeper®.

COST-EFFECTIVE

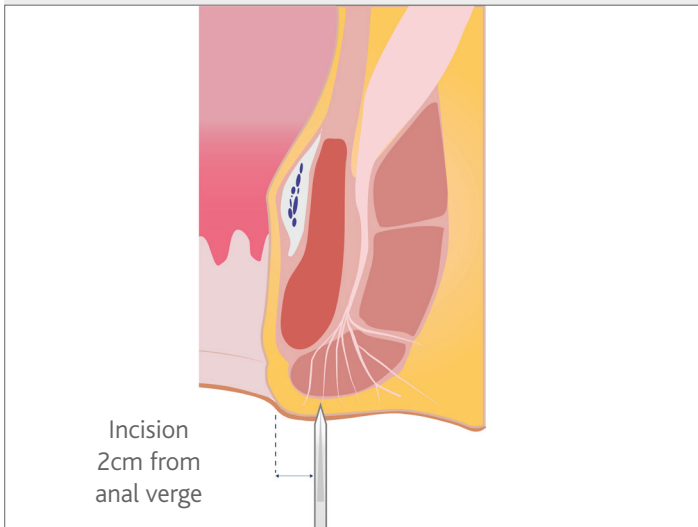
This procedure is cost effective with low material expenditure combined with short hospital stays and limited pain medication.

THE BASIC STEPS

1

Incision

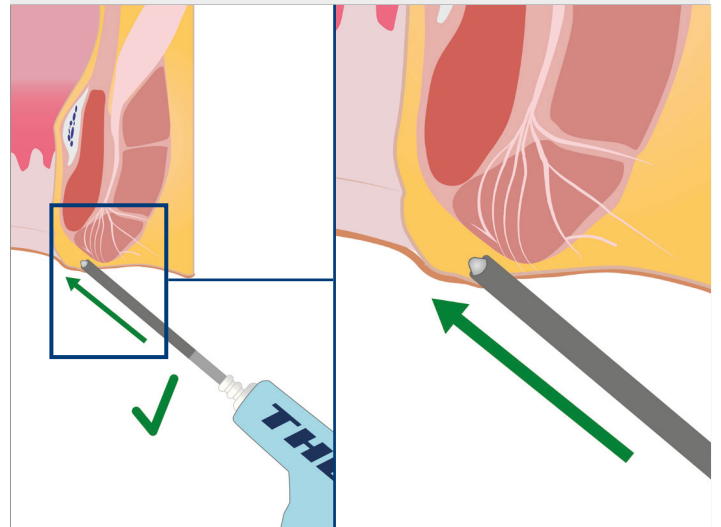
THD SphinKeeper® and THD GateKeeper® implant procedure should be performed in local anesthesia (however, it is suitable also for general). The starting point of the procedure is generally the patient's left side. In this standard example the first implant is located at 3 o'clock.



2

Subcutaneous tunneling

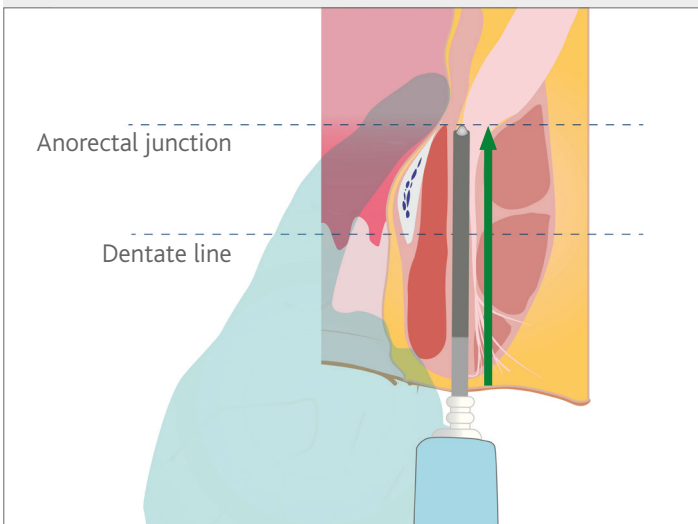
The implant must be inserted via a subcutaneous tunnel under the skin. NOTE: while inserting the cannula avoid going vertically through the external sphincter. Follow the natural path to the intersphincteric groove.



5

Device insertion up to the anorectal ring

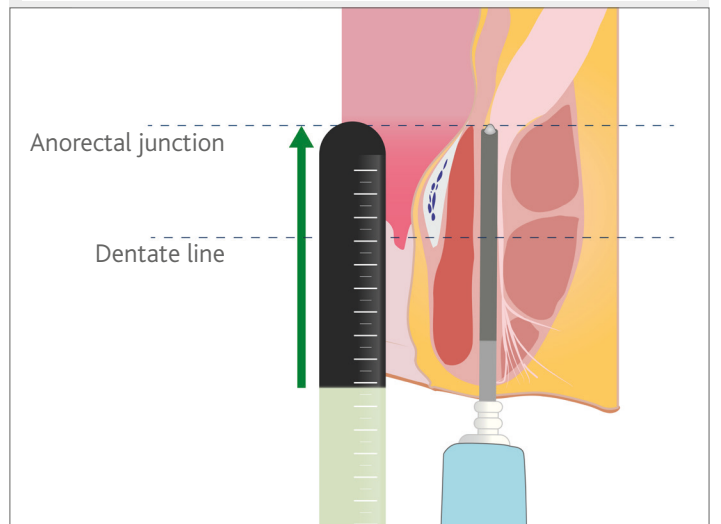
The insertion of the Delivery System cannula needs to be followed by digital palpation. Continue inserting safely the cannula into the intersphincteric space up to reach the anorectal junction: your finger can locate there the tip of cannula, avoiding injuries to the tissues.



6

Check with endoanal ultrasound (EAUS)

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.

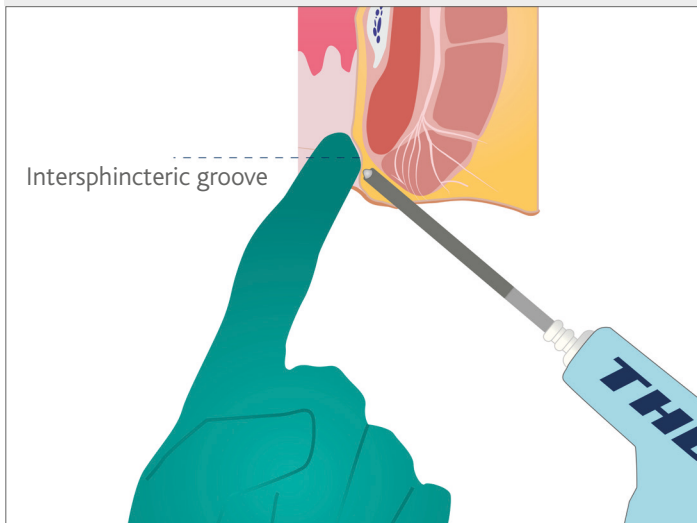


THE BASIC STEPS

3

Tunneling up to the intersphincteric groove

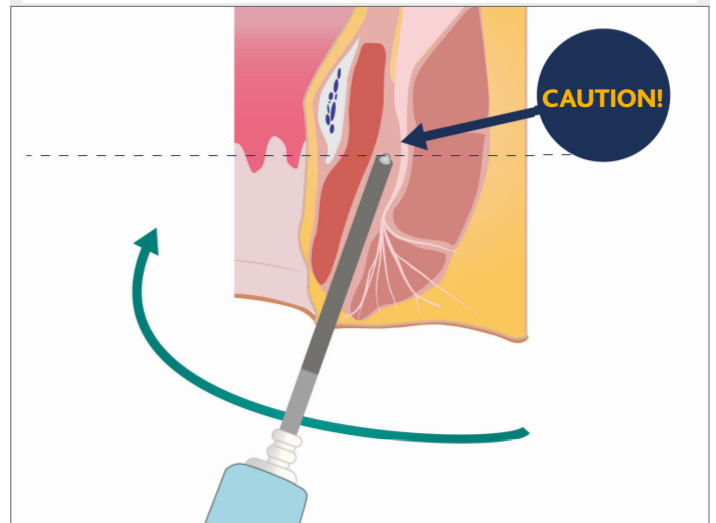
Locate the intersphincteric groove with your finger and use it as a direction for the device insertion. Push the cannula of the device until you reach the finger placed at the intersphincteric groove.



4

Insertion of the delivery system into the intersphincteric space

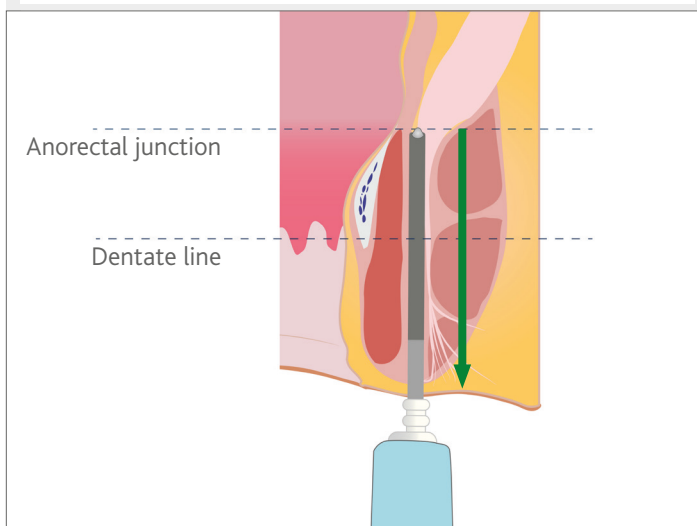
When the intersphincter groove has been reached, change the cannula orientation until it's parallel to the longitudinal axis of the anal canal. Gradually insert the cannula in the intersphincteric space. Close to the dentate line, there is a point of higher resistance: pay attention when pushing the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



7

Release of prosthesis

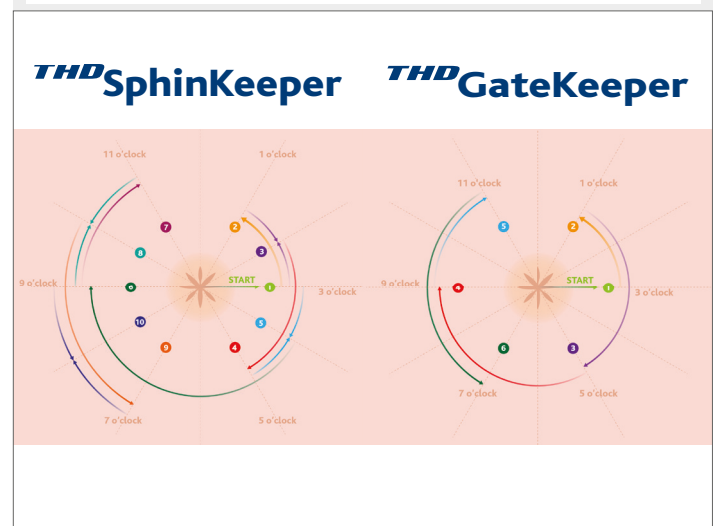
"Press the button located on the Delivery System handle (named "B") to release the prosthesis. When the LED on the back of Delivery System is flashing orange, extract it from the site of implant.



8

Suture and repetition of steps

Suture the incision and repeat the steps following the order in the illustration to delivery the other prostheses.



SELF EXPANDABLE MATERIAL

Patented material with shape memory





Implants are made with a patented self expandable material with shape memory

The self expandable material is biocompatible, non-allergenic, non-immunogenic, non-carcenogenic

FEATURES

The material is able to grow in volume through the absorption of body fluids up to 730% the original dimension for THD SphinKeeper® and up to 550% for THD GateKeeper®.

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

			
		Pre	Post
Diameter		3 mm (+0,2/-0,4)	8,5 (±1,0)
Length		22,5 mm (±1,0)	18,5 mm (±2,0)
Single volume		143 mm ³	1049 mm ³
Total volume		1430 mm ³ = 1,4ml	10490 mm ³ = 10,5ml
			
		Pre	Post
Diameter		1,8 mm (+0,2/-0,4)	6 mm (+0,5/-1,0)
Length		20 mm (±2,0)	10 mm - 15 mm
Single volume		51 mm ³	282 mm ³
Total volume		306 mm ³ = 0,3ml	1692 mm ³ = 1,7ml

CLINICAL STUDIES

Efficacy of Sphinkeeper™ implant in treating faecal incontinence

Litta F., Parello A., De Simone V. et al. - 2020

Initial experience with SphinKeeper™ intersphincteric implants for faecal incontinence in the United Kingdom: a two-centre retrospective clinical audit

Leo C.A., Leeuwenburgh M., Orlando A., Corr A., Scott M. et al – 2020

Sphinkeeper™ for faecal incontinence: a preliminary report

La Torre M., Lisi G., Milito G., Campanelli M., Clementi I. – 2019

Anal Injectable and Implantable Bulking Agents for Faecal Incontinence

Camilleri-Brennan J. – 2020

Outcomes of Gatekeeper™ prosthesis implantation for the treatment of faecal incontinence: a multicenter observational study

Biondo S., Trenti L. et al. – 2017

Middle-term Outcomes of Gatekeeper Implantation for Fecal Incontinence

Brusciano L., Tolone S., Del Genio G. et al. – 2020

Gatekeeper improves voluntary contractility in patients with fecal incontinence

Grossi U., Ratto C., De Simone V. et al. – 2019

Implantable Agents for Fecal Incontinence: An Age-Matched Retrospective Cohort Analysis of GateKeeper versus SphinKeeper

Grossi U., Brusciano L., Tolone S. et al. – 2020

Multicentre observational study of the Gatekeeper™ for faecal incontinence

Ratto C., Buntzen S., Aigner F. et al. – 2016

Implantation of Sphinkeeper™: a new artificial anal sphincter

Ratto C., Campenni P., Papeo F. et al. – 2016

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

Cavazzoni E., Rosati E., Zavagno V., Graziosi L. & Donini A. – 2015

Treatment for Faecal Incontinence Results of sphincter augmentation with Hyexpan implants in a pilot study

Bouassida S., Krüger K., Adam U. – 2015

SPECIFICATIONS

THD SphinKeeper

Part No. 820011

- Includes
- THD SphinKeeper® delivery system (sterile)
 - 10 THD SphinKeeper® self expandable implants



THD GateKeeper

Part No. 820005

- Includes
- THD® GateKeeper® delivery system (sterile)
 - 6 THD® GateKeeper® self expandable implants

