



THD SphinKeeper

Minimally invasive treatment for faecal incontinence

Document intended for Health Care Professionals only.



THD SphinKeeper

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:

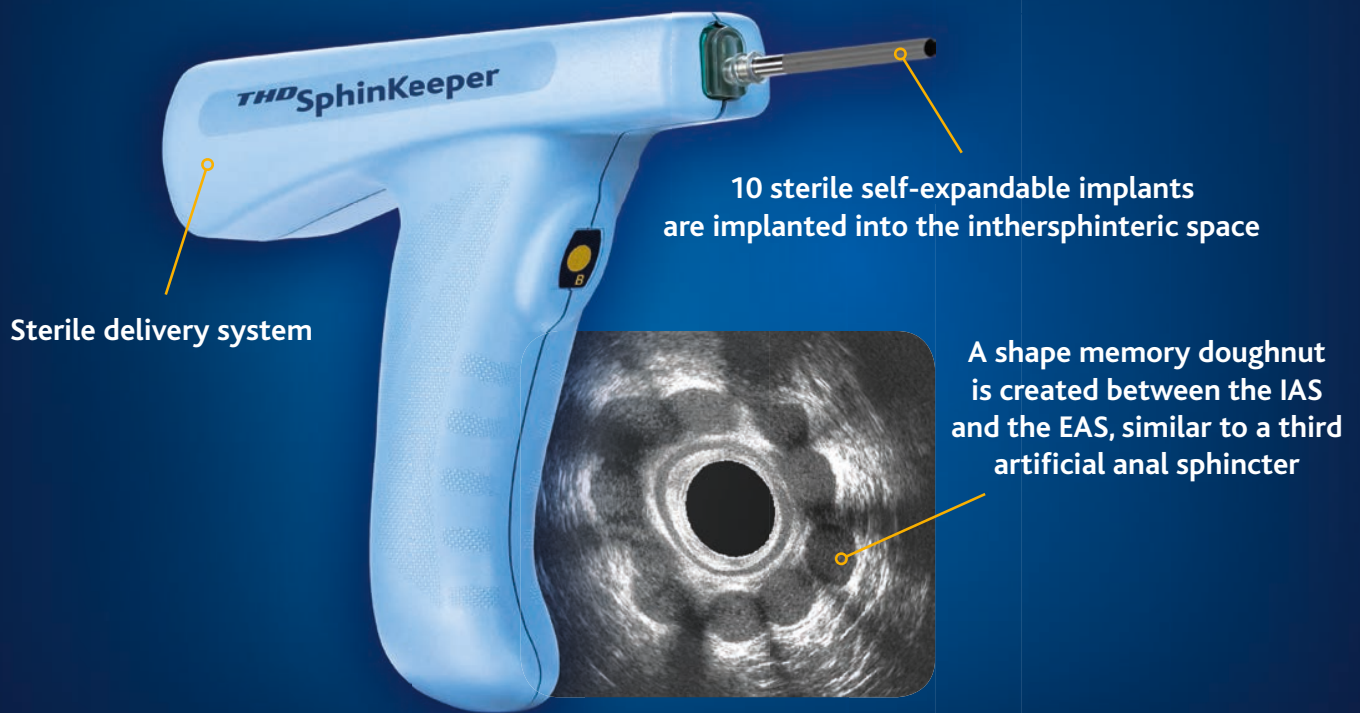
THD SphinKeeper, a new artificial anal sphincter, was devised with the aim to treat faecal incontinence by implanting specifically designed self-expandable prostheses into the intersphincteric space.

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.



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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.

COST-EFFECTIVE

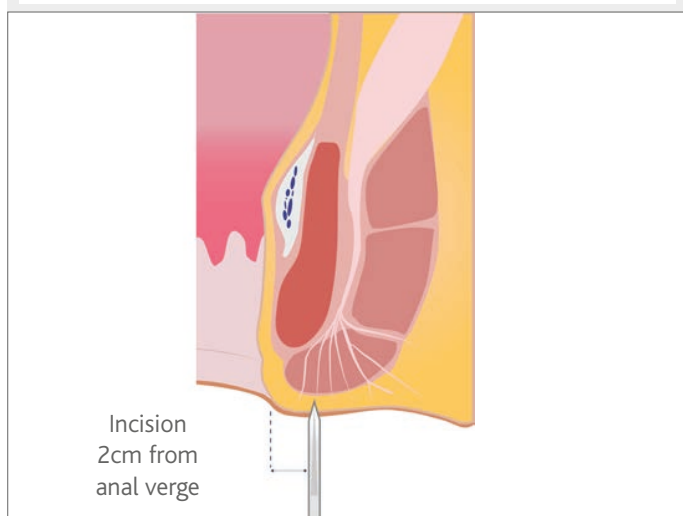
This procedure is cost effective with low material expenditure combined with short hospital stays and limited pain medication.

THD SphinKeeper

1

Incision

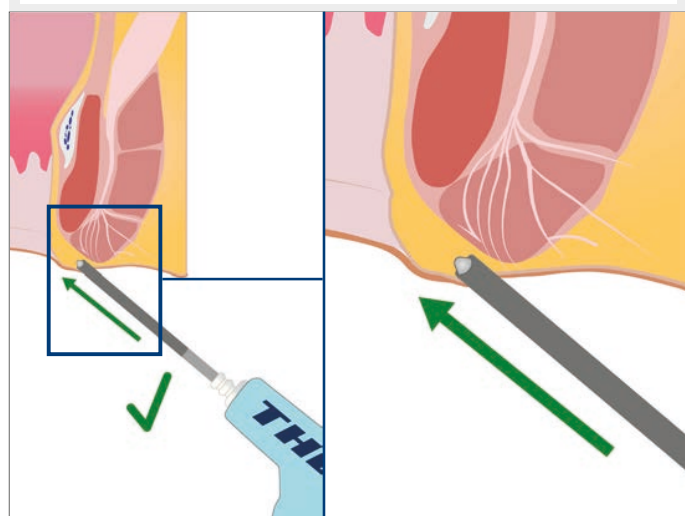
THD SphinKeeper® implant procedure should be performed in local anesthesia (however, it is suitable also for general). The starting point of the procedure is generally the patient's left side. In this standard example the first implant is located at 3 o'clock.



2

Subcutaneous tunneling

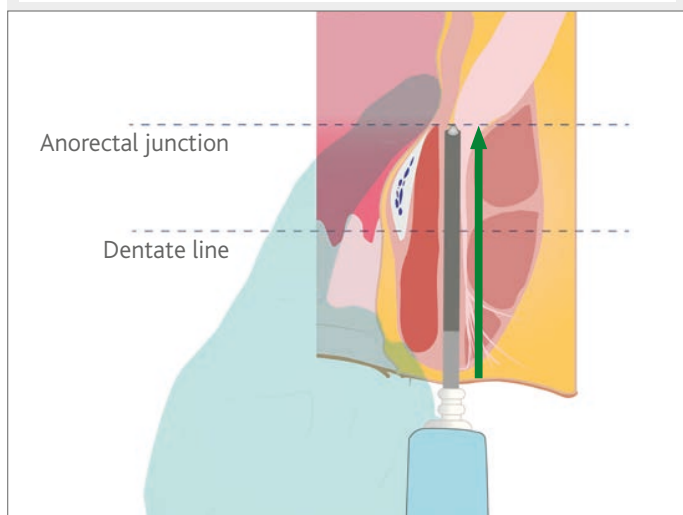
THD® SphinKeeper must be inserted via a subcutaneous tunnel under the skin. NOTE: while inserting the cannula avoid going vertically through the external sphincter. Follow the natural path to the intersphincteric groove.



5

Device insertion up to the anorectal ring

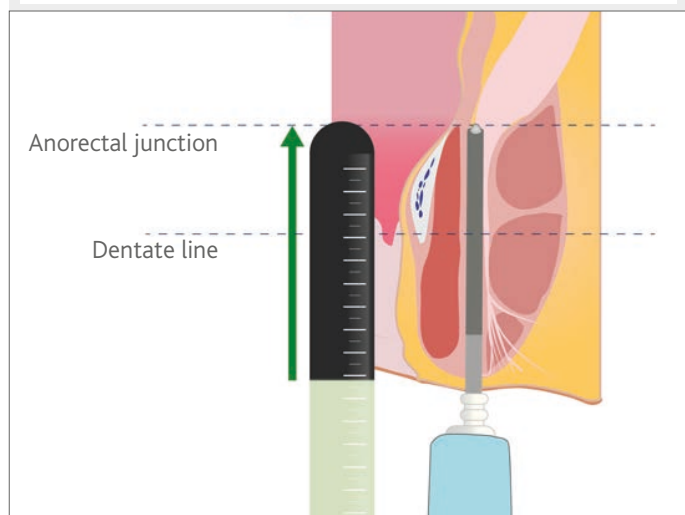
The insertion of the Delivery System cannula needs to be followed by digital palpation. Continue inserting safely the cannula into the intersphincteric space up to reach the anorectal junction: your finger can locate there the tip of cannula, avoiding injuries to the tissues.



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.

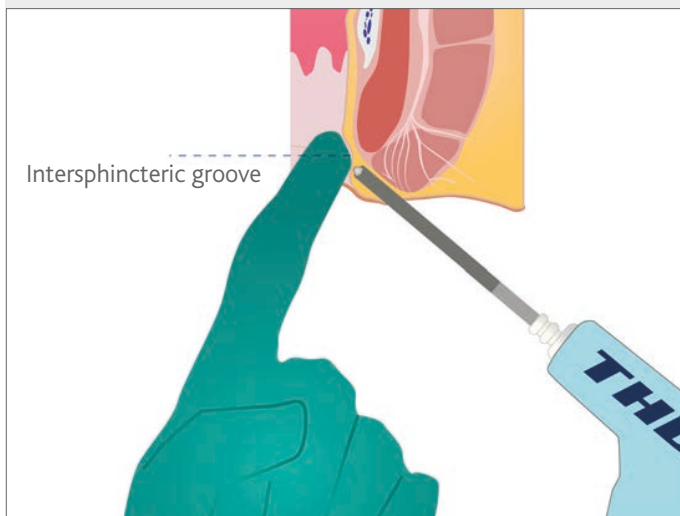


THE BASIC STEPS

3

Tunneling up to the intersphincteric groove

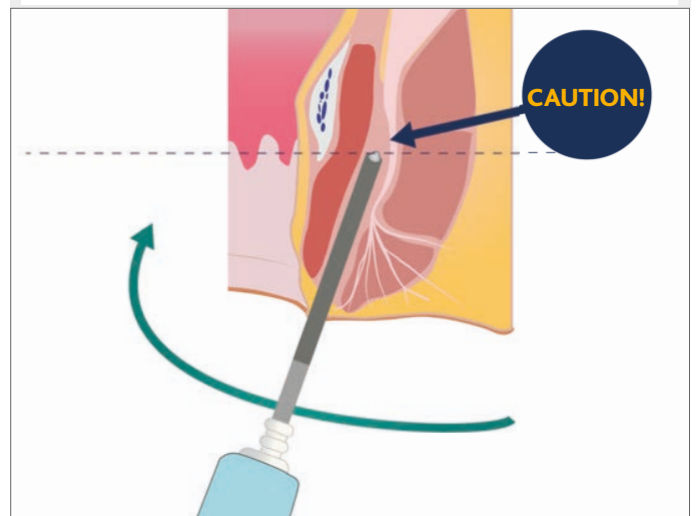
Locate the intersphincteric groove with your finger and use it as a direction for the device insertion. Push the cannula of the device until you reach the finger placed at the intersphincteric groove.



4

Insertion of the delivery system into the intersphincteric space

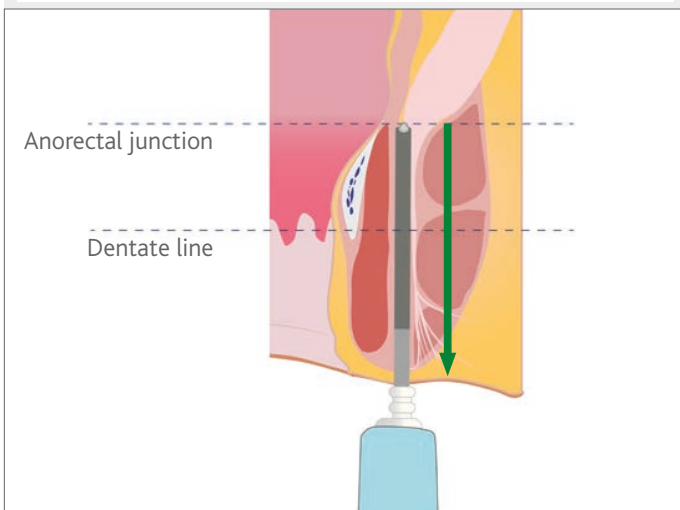
When the intersphincter groove has been reached, change the cannula orientation until it's parallel to the longitudinal axis of the anal canal. Gradually insert the cannula in the intersphincteric space. Close to the dentate line, there is a point of higher resistance: pay attention when pushing the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



7

Release of prosthesis

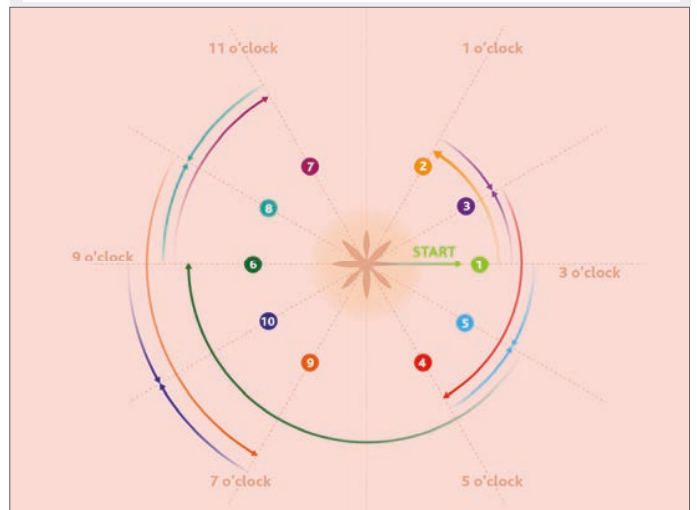
"Press the button located on the Delivery System handle (named "B") to release the prosthesis. When the LED on the back of Delivery System is flashing orange, extract it from the site of implant.



8

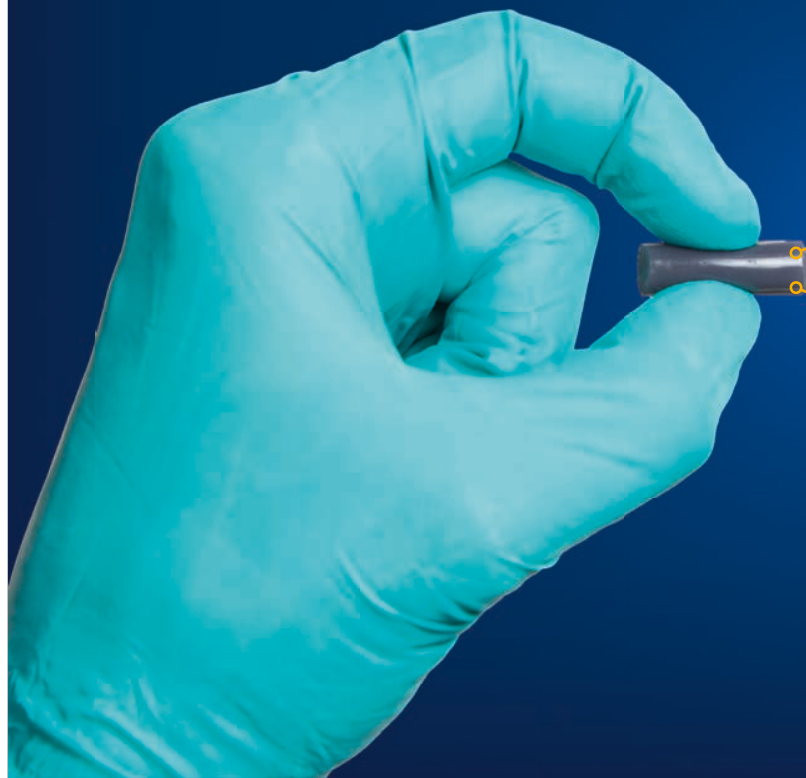
Suture and repetition of steps

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




THD® SphinKeeper 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.

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

CLINICAL STUDIES

Implantation of SphinKeeper™: a new artificial anal sphincter

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INTRODUCTION

A new artificial anal sphincter, SphinKeeper™, was devised with the aim to treat faecal incontinence (FI) by implanting specifically designed self-expandable prostheses into the intersphincteric space. Preliminary data concerning the procedure feasibility and prosthesis localization at 3 months are presented

METHODS

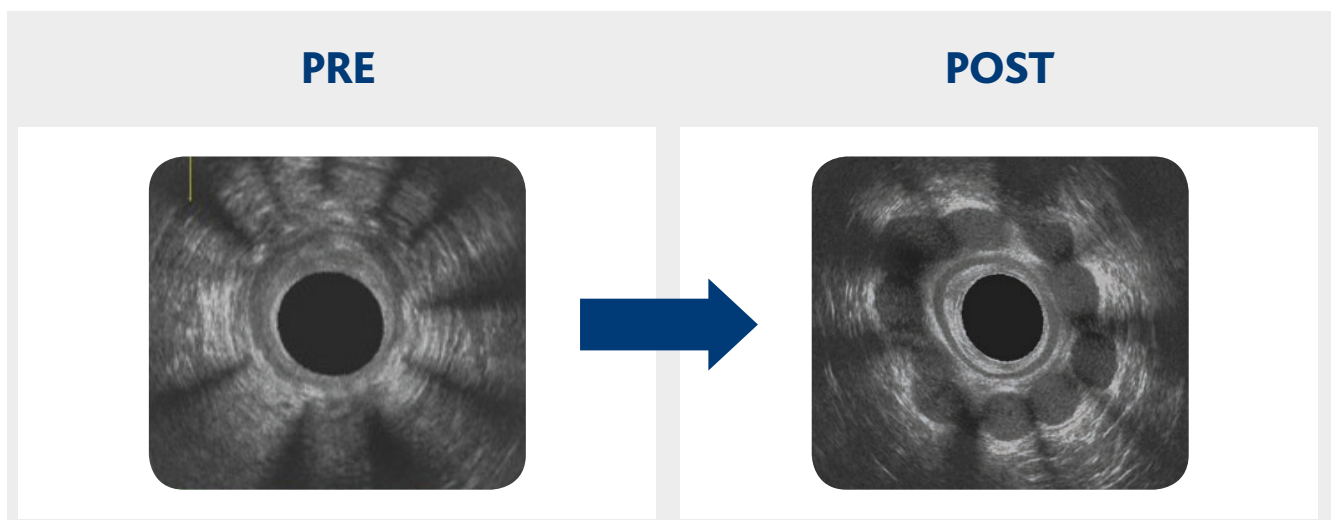
SphinKeeper™ prostheses in the native state are dehydrated, thin, solid cylinders, changing their state, shorter thicker and softer, with shape memory, within 48 h of contact with fluids. In this study, 10 prostheses were implanted in each patient with FI under local anesthesia and under endoanal ultrasound (EAUS) guidance, into the upper-middle intersphincteric space of the anal canal by a specifically designed delivery system. EAUS was used postoperatively to assess prostheses dislocation.

RESULTS

Ten patients (5 females; median age 58 years, range 20–75) were enrolled and treated with SphinKeeper™ implantation. Median duration of procedure (performed by endoanal ultrasound guidance) was 40 min (range 30–45). Neither intraoperative nor postoperative complications were reported after a 3-month follow-up. In one patient, a partial dislocation of a single prosthesis was documented by EAUS, causing anal discomfort which resolved after 1 week.

CONCLUSION

SphinKeeper™ can be safely implanted in patients with FI of different etiology. Implantation was well tolerated with no dislodgment of implants at 3-month follow-up was documented.



SPECIFICATIONS

THDSphinKeeper

Part No. 820011

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



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