

THD Slide One FAST

Minimally invasive surgical treatment for haemorrhoids

Document intended for Health Care Professionals only.



THD Doppler

Why the Doppler?

The THD® Doppler Method was born with the aim to enable accurate identification of the terminal branches of the superior rectal artery and ligate them.

The THD® Doppler procedure offers reliable efficacy in achieving haemorrhoidal dearterialization, thanks to effective ligation of the arteries leading to successful reduction in arterial hyperflow.*

** Haemorrhoidal haemodynamic changes in patients with haemorrhoids treated using Doppler-guided dearterialization - BJS Online - C. Ratto - 2021*

This study has elucidated the haemodynamic effects of arterial ligation and justifies the use of this approach to treat haemorrhoidal engorgement and bleeding, leaving the haemorrhoidal piles fully viable with intact anatomy and physiology.

The use of Doppler ultrasonography has been justified by the understanding that ligating all SRA terminal branches is essential for the resolution of haemorrhoids. The positions of these branches have been found to be relatively constant at odd hours but in a non-negligible number of cases this is not true.*

** Is Doppler ultrasonography essential for haemorrhoidal artery ligation? - Tech Coloproctol. - S. Avital et al. - 2012*

If, for the patients included in this study, surgeons had ligated arteries without using Doppler ultrasonography, they would have located all the arteries in only 71 % of patients.



BENEFITS

ANATOMICAL ACCURACY

The ultrasound Doppler probe allows accurate localization of arteries supplying the haemorrhoids, which are individually ligated as needed. The venous outflow is not affected, but the inflow to outflow ratio drops significantly. The connective tissue in the collapsed haemorrhoid slowly regenerates with resolution of the prolapse.

SAFETY

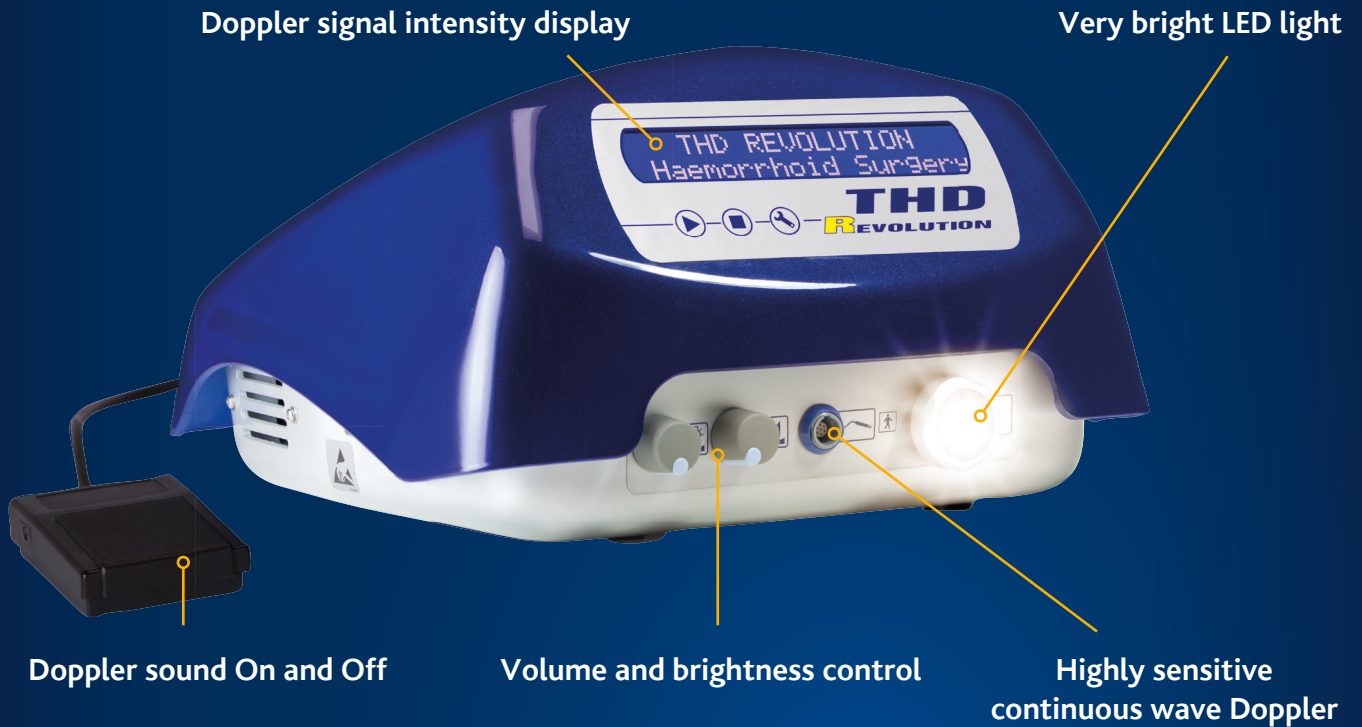
The safety of the THD® Doppler dearterialization procedure, proven in several publications, is guaranteed by an accurate localization of arteries supplying the haemorrhoids and by the pivot controlling the depth of the needle in the submucosa without the risk of serious adverse events (none reported by NICE, FDA or any other regulatory organism, at the moment).

RATIONALE

Of all of the non excisional techniques recently developed for the treatment of HD, THD® Doppler Method is the only one addressing all the haemorrhoidal symptoms by accurately reducing the arterial inflow to the haemorrhoids and repositioning haemorrhoidal/mucosal prolapse.

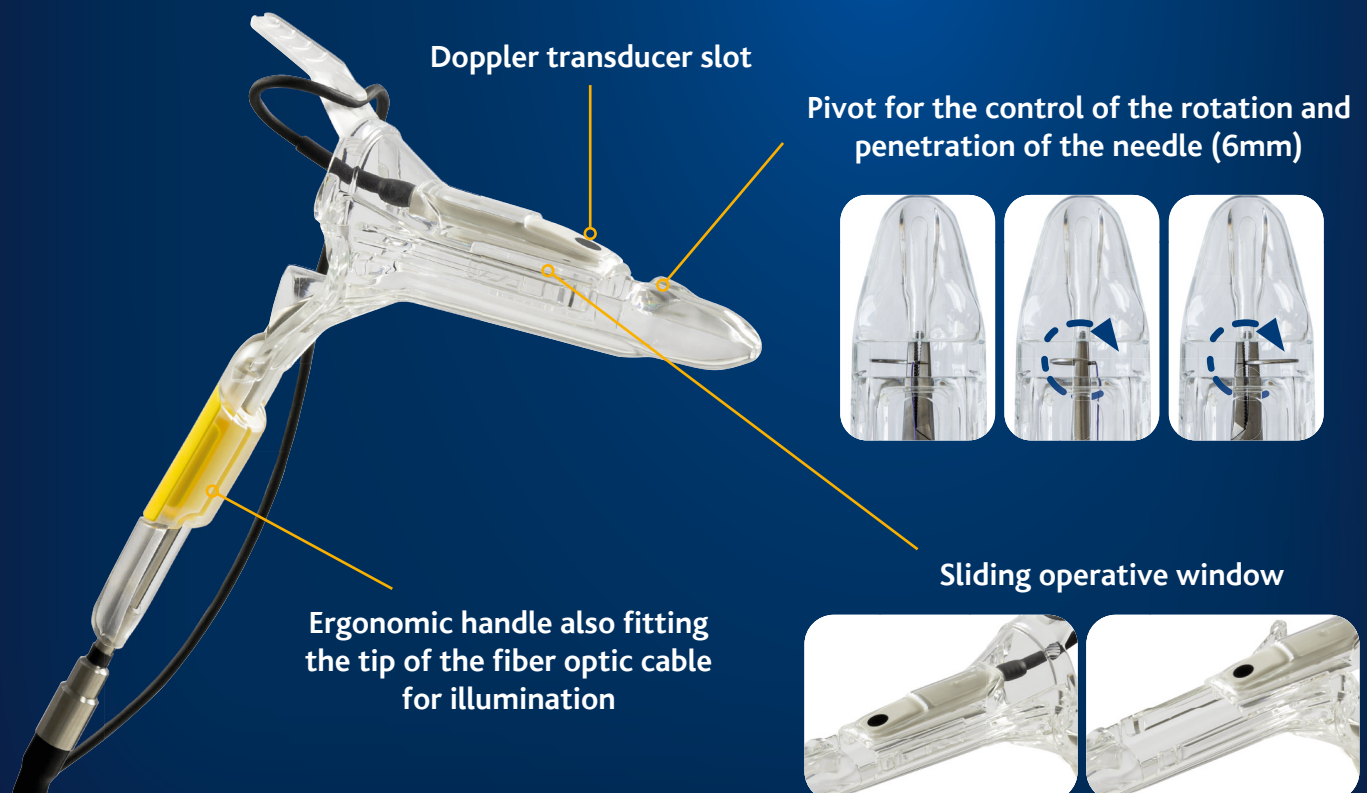
THD Revolution

All-in-one Doppler and LED light generator



THD Slide One

Customized surgical anoscope



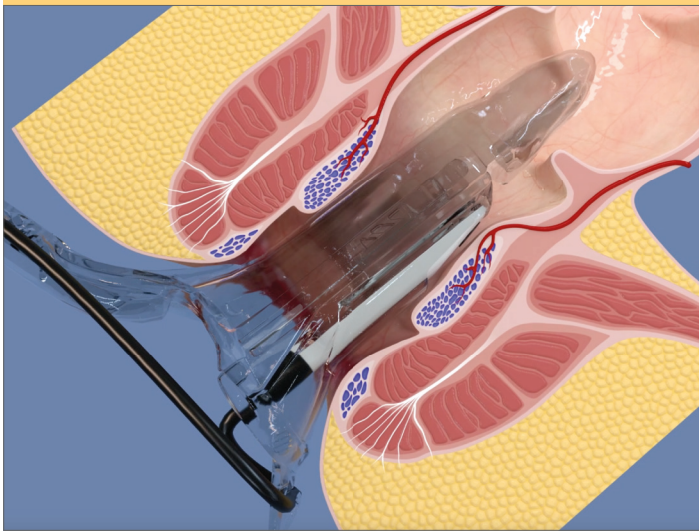
THD[®] DOPPLER METHOD

Phase 1: Dearterialization

1.1

Dilation and full device insertion

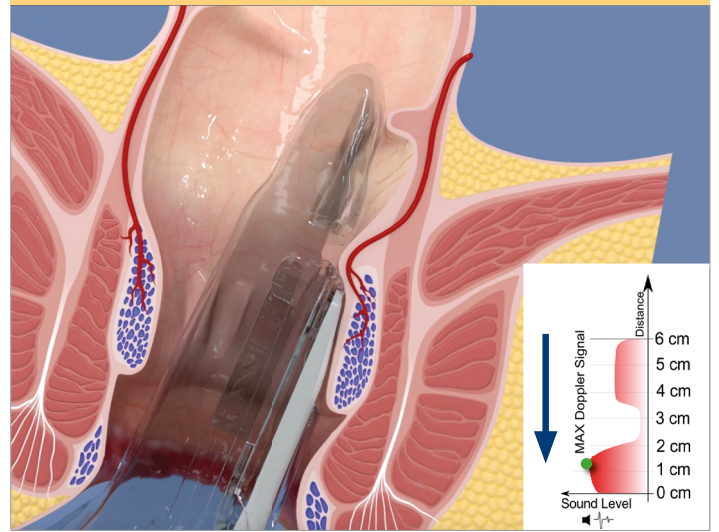
Activate the doppler, dilate the anus avoiding pushing the prolapse back inside, introduce the proctoscope gently and continually until the handle is flush with the buttock.



1.2

Highest Doppler signal and dearterialization-point finding

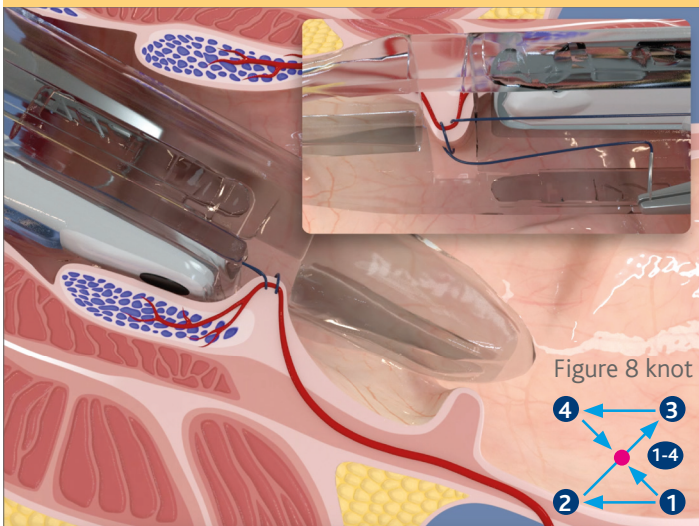
Once a Doppler sound is heard retract and move distally the device searching for the maximum Doppler signal, usually from 1 to 2 cm above the anorectal junction. This is the dearterialization point.



1.3

Dearterialization by artery transfixion

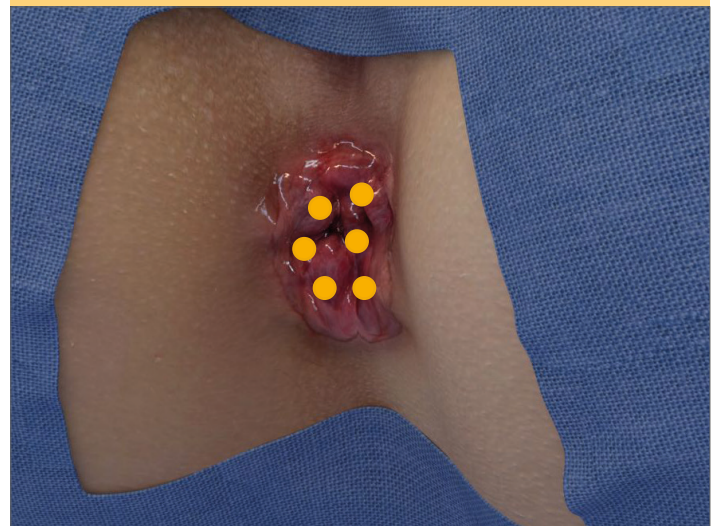
On the dearterialization point the artery is transfixed, by inserting the tip of the needle holder in the pivot, with a figure 8 knot to interrupt the arterial blood flow. Use the 5/8 needle vycril sutures provided.



1.4

Repetition of dearterialization

Repeat the procedure at point 1.1,1.2,1.3 moving the proctoscope in the same direction (clockwise or anti-clockwise) up to 6 times (typically 6 arteries are found and ligated).



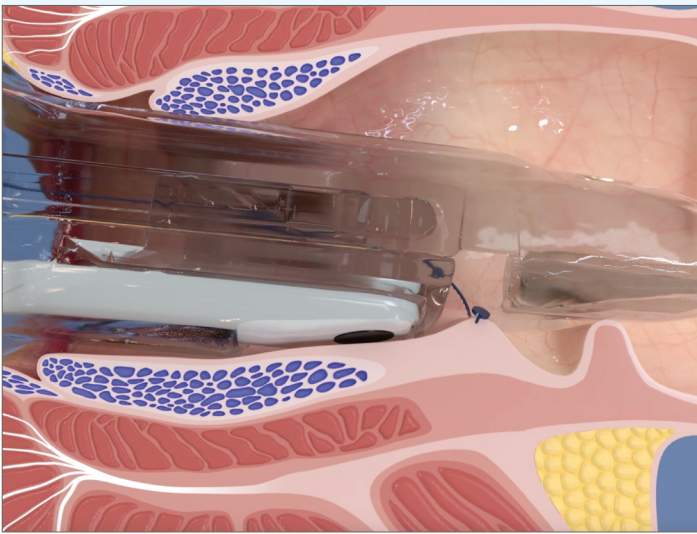
THD® DOPPLER METHOD

Phase 2: Mucopexy

2.1

THD® Block suture: anchor point

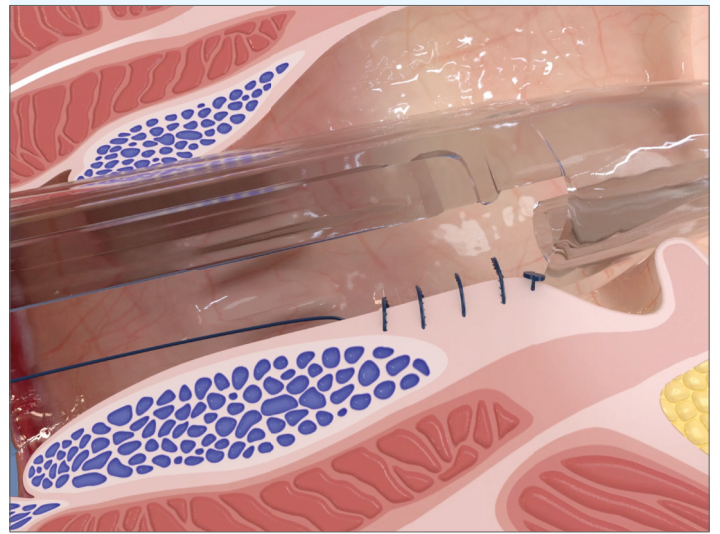
Upon completion of the dearterialization phase, the next step is to target the prolapsed tissue (an average of 3 sites). Using the THD® Block suture (1/2 circle, 30mm needle, barbed self locking suture) start from the most proximal point of the prolapse and transfix the mucosa using the "button" as an anchoring point for the mucopexy.



2.2

Running suture

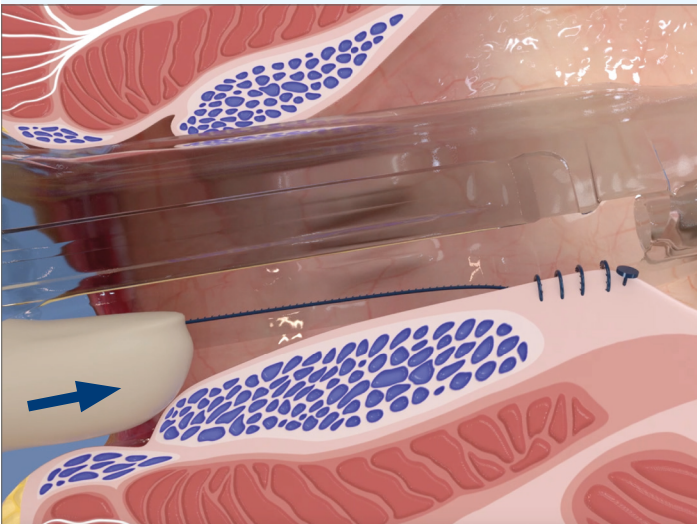
Pull back the sliding part of the proctoscope to perform a continuous suture (5 mm between each bite) reaching the anorectal junction. The higher the start and the lower the finish, the better the lift but stay above the anorectal junction.



2.3

Anolift: prolapse lifting

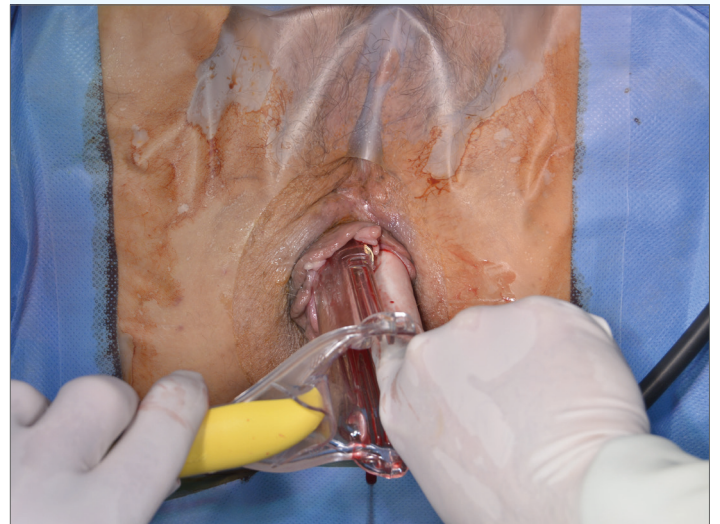
While gently pulling on the free end of the suture, push the prolapsed mucosa proximally along the rectal wall and the barbed suture will lock the prolapsed tissue in its lifted position, restoring the anatomical condition.



2.4

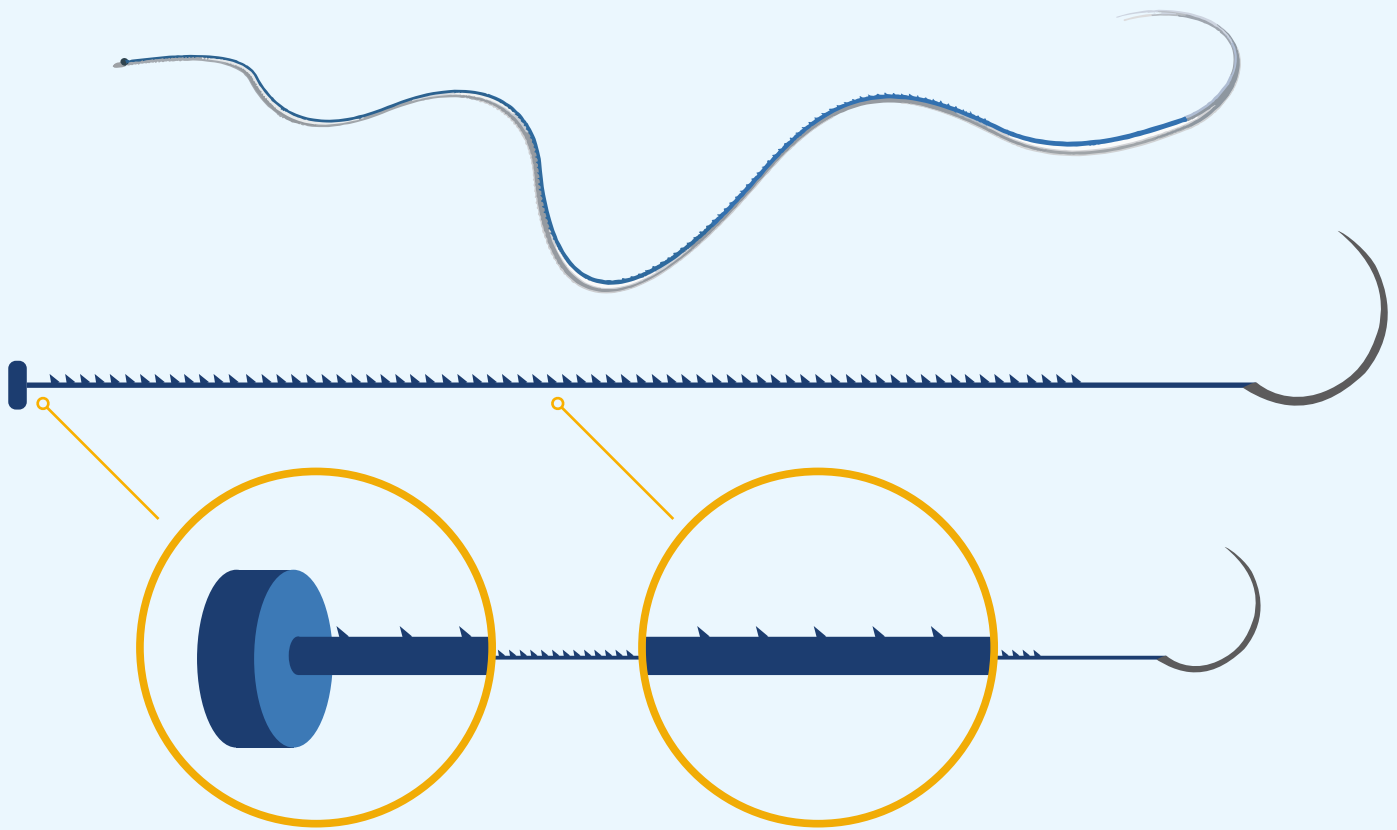
Mucopexy repetition and device extraction

Repeat point 2.1,2.2,2.3 as needed where the prolapsing element is most prominent (an average of 3 sites) and then carefully extract the device. When extracting the device, insert a finger to gently lift the repaired prolapse tissue up as you withdraw the scope.



THD Block

New generation of barbed suture with final lock system



FEATURES

New generation of barbed suture with self-locking system, absorbable, unidirectional with final lock system.

Functional, fast and safe. It does not require knots, it guarantees a high tightness with a constant stress distribution along the section of approximation of tissues.

COMPOSITION: PGCL (glycolide-co- ϵ -caprolattone).

DESCRIPTION: Synthetic monofilament absorbable surgical suture, "barbed", sterile.

COLOUR: Violet.

SIZES AND NEEDLE: 30 mm, EP 3, Taper 1/2 C. Stainless steel atraumatic.

SUTURE LENGTH: 25 cm.

TENSILE STRENGTH: The progressive loss of the suture tensile strength occurs in consequence of PGCL hydrolysis which allows the absorption and the subsequent metabolization in the body (7 days ~ 50%, 14 days ~ 20%).

ABSORPTION: Complete within 90-120 days.

THD® DOPPLER METHOD - CLINICAL STUDIES

The one and only surgical method, besides haemorrhoidectomy and haemorrhoidopexy, which has been assigned a specific reimbursement code by **AMA** (American Medical Association) and **NICE** (National Institute for Health and Care Excellence).

Safety and Efficacy

- *Transanal Haemorrhoidal Dearterialisation Anolift- prospective assessment of safety and efficacy – Giordano P., Schembari E. – 2021*
- *A cohort study analysing outcomes following transanal haemorrhoidal dearterialisation (THD) – Patel R., Rehman A., Baig M. et al. – 2020*
- *Consensus Statement of the Italian Society of Colorectal Surgery (SICCR): Management and Treatment of Hemorrhoidal Disease – Gallo G., Martellucci J., Sturiale A., Giordano P., et al. – 2020*
- *Ligature des artères hémorroïdaires avec guidage Doppler, suivie d'une mucopexy – Haute Autorité de Santé (HAS) – 2019*
- *Haemorrhoidal artery ligation, IPG 342 - National Institute for Health and Care Excellence (NICE) – 2010*
- *Transanal Haemorrhoidal Dearterialisation and Rectal Mucopexy: Clinical Outcomes and Patient Perspectives – Waterman J., Abdeldayem M. and Haray P. – 2019*
- *Transanal hemorrhoidal dearterialization (THD) for hemorrhoidal disease: a single-center study on 1000 consecutive cases and a review of the literature – Ratto C., Campenni P., Papeo F. et al. – 2017*
- *Transanal dearterialization with targeted mucopexy is effective for advanced haemorrhoids – Giordano P., Tomasi I., Pascariello A. et al. – 2014*

Guidelines and Authorities Recognition

- *Consensus Statement of the Italian Society of Colorectal Surgery (SICCR): Management and Treatment of Hemorrhoidal Disease – Gallo G., Martellucci J., Sturiale A., Giordano P., et al. – 2020*
- *Transanal hemorrhoidal dearterialization – American Medical Association, AMA – 2020*
- *Ligature des artères hémorroïdaires avec guidage Doppler, suivie d'une mucopexy - Haute Autorité de Santé (HAS) – 2019*
- *Haemorrhoidal artery ligation, IPG 342 – National Institute for Health and Care Excellence (NICE) – 2010*

THD vs Other Surgical Techniques

THD VS HAEMORRHOIDECTOMY:

- *Consensus Statement of the Italian Society of Colorectal Surgery (SICCR): Management and Treatment of Hemorrhoidal Disease – Gallo G., Martellucci J., Sturiale A., Giordano P., et al. – 2020*
- *Systematic review and network meta-analysis comparing clinical outcomes and effectiveness of surgical treatments for haemorrhoids – Similis C., Thoukididou S.N., Slessor A.A.P., Rasheed S., Tan E., Tekkis P.P. – 2015*
- *Hemorrhoidal dearterialization with mucopexy versus hemorrhoidectomy: 3-year follow-up assessment of a randomized controlled trial – Denoya P., Tam J., Bergamaschi R. – 2014*
- *A Prospective, Randomized Trial Comparing the Short- and Long-term Results of Doppler-Guided Transanal Hemorrhoid Dearterialization With Mucopexy Versus Excision Hemorrhoidectomy for Grade III Hemorrhoids – De Nardi P., Capretti G., Corsaro A., Staudacher C. - 2014*
- *Short-term Outcomes of Transanal Hemorrhoidal Dearterialization With Mucopexy Versus Vessel-Sealing Device Hemorrhoidectomy for Grade III to IV Hemorrhoids: A Prospective Randomized Multicenter Trial – Trenti L., Biondo S., Moreno E. K., et al. – 2019*

THD VS STAPLED HAEMORRHOIDOPEXY:

- *Consensus Statement of the Italian Society of Colorectal Surgery (SICCR): Management and Treatment of Hemorrhoidal Disease – Gallo G., Martellucci J., Sturiale A., Giordano P., et al. – 2020*
- *Transanal hemorrhoidal dearterialization versus stapled hemorrhoidectomy in the treatment of hemorrhoids A PRISMA-compliant updated meta-analysis of randomized control trials – Song Y., Chen H., Yang F., Zeng Y., He Y., Huang H. – 2018*
- *A systematic review comparing transanal haemorrhoidal de-arterialisation to stapled haemorrhoidopexy in the management of haemorrhoidal disease - Sajid M.S., Parampalli U., Whitehouse P., Sains P., McFall M. R., Baig M. K. – 2011*
- *Doppler-Guided Transanal Hemorrhoidal Dearterialization (DG-THD) Versus Stapled Hemorrhoidopexy (SH) in the Treatment of Third-Degree Hemorrhoids: Clinical Results at Short and Long-Term Follow-Up – Leardi S., Pessia B., Mascio M., Piccione F., Schietroma M., Pietroletti R. - 2016*

For more clinical studies and the complete THD® Doppler literature, visit www.thdlab.com.

SPECIFICATIONS

THD Revolution

Part No. 800133

- Includes
- 1 Generator box
 - 1 Muting pedal
 - 1 Medical grade power cord
 - 2 Reusable fiber optic cords with curved tip
 - 1 Single use Doppler
 - 1 Reusable gold handled needle driver



THD Slide One FAST Kit

Part No. 800280-10

- Includes 800065-10 THD® Slide One:
- 10 THD® Slide One anoscope (Sterile)
 - 10 Single use/disposable Doppler (Sterile)
 - 10 Disposable needle driver (Sterile)
 - 10 Box sutures (6 pieces, sterile)
 - 10 Knot pusher (Sterile)
 - 10 THD® Slide anoscope Sutures Spon (Sterile)
- 880059-10 THD® Block:
- 10 THD® Block - Box Sutures (3 sutures, sterile)



THD Slide FAST Kit

Part No. 800281-10

- Includes 800066-10 THD® Slide Kit:
- 10 THD® Slide anoscope single use (Sterile)
 - 10 Knot pusher (Sterile)
 - 10 Disposable needle driver (Sterile)
 - 10 Suture (env. with 6 pcs each-Sterile)
 - 2 Doppler 5 times use (Not Sterile)
 - 10 Sterile sponge (Sterile)
- 880059-10 THD® Block:
- 10 THD® Block - Box Sutures (3 sutures, Sterile)



Accessories & Spare Parts

Part No. 880059-1	THD® Block	Box Sutures (3 sutures, sterile)
Part No. 880014-1	Rolling Cart	THD® Revolution Rolling Cart
Part No. 880000-1	TrueGlyde Sutures	Box of 6 TrueGlyde Suture
Part No. 880003-1	Gold Handled Needle Driver	Reusable, laser etched needle driver
Part No. 880012-1	Fiber Optic Cord	Fiber optic Cord with curved light tip
Part No. 880006-1	Muting Pedal	THD® Revolution Muting Pedal
Part No. 880050-20	Spon	Anal sponge (Sterile)