TRILOGY

Product Group Coloproctology | Issue **09/2015**

Locate. Ligate. Lift.

All with no cables.

The new wireless way to treat haemorrhoids.

The third generation of HAL-RAR equipment combines all the advantages of these procedures with the world's first wireless technology for Doppler-guided treatment of haemorrhoids.

A.M.I.®

TRILOGY Locate. Ligate. Lift.

HAL-RAR with TRILOGY

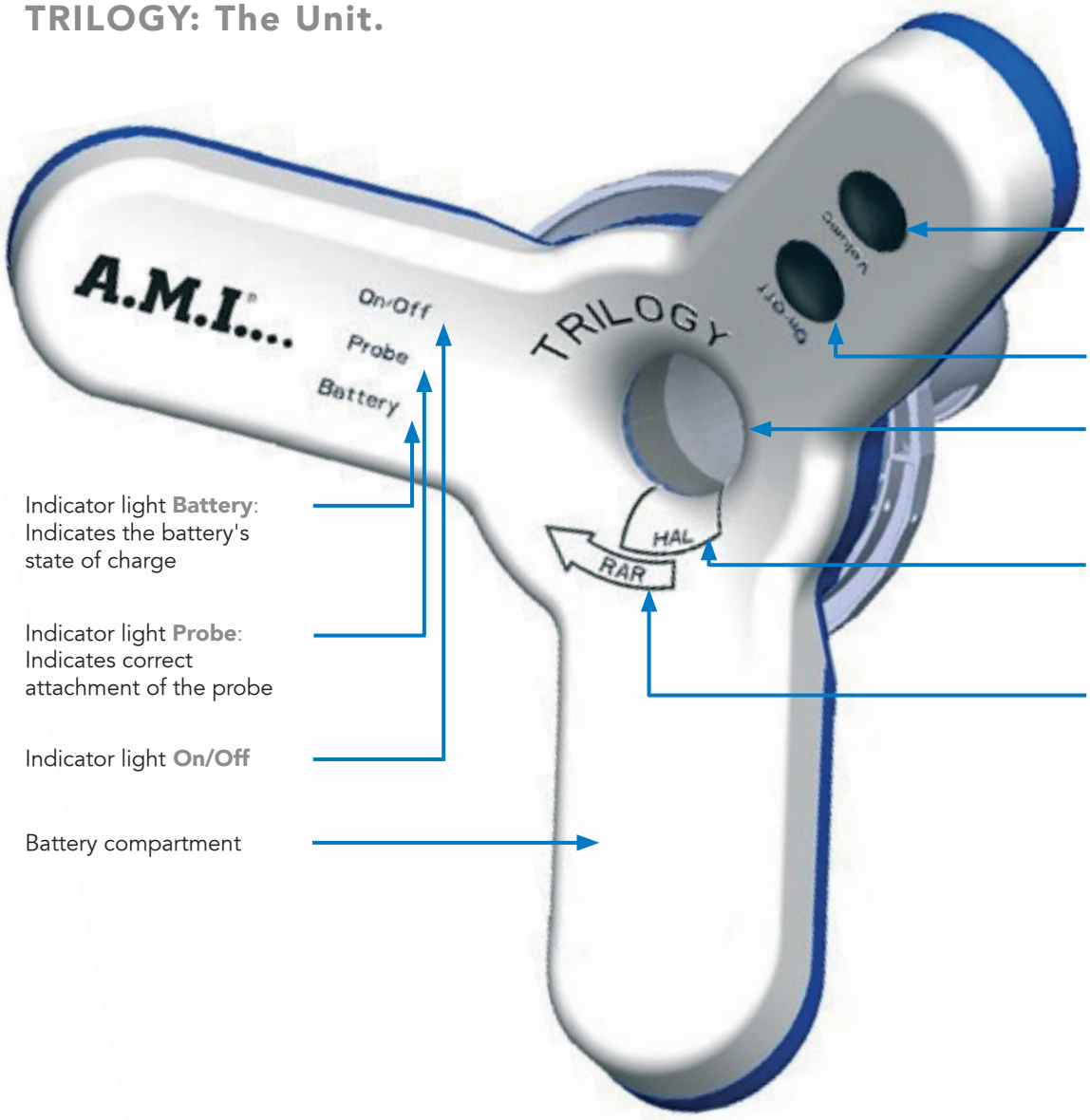
Comfort and convenience for the patient.
Comfort and convenience for the surgeon.

The new generation TRILOGY combines all the proven advantages of the HAL-RAR procedures with the flexibility of wireless technology.

For patients, HAL-RAR offers a safe and gentle alternative to conventional treatment methods that provides effective relief from all the symptoms of haemorrhoids, even in the more advanced stages. Artery ligation and mucopexy of prolapsing mucosa can be carried out in one procedure under local anaesthetic, depending on the individual patient and the prevailing healthcare system.

For surgeons, TRILOGY gives you the benefit of Doppler-ultrasound technology with no strings attached. Literally. With a Bluetooth® connection between the unit and speaker, you can hear the system's signals for precise, customised detection of haemorrhoidal arteries while enjoying absolute freedom to manoeuvre the unit and attached probe as required. In addition, the absence of a cable - which acts as an antenna for surrounding electromagnetic radiation - means the equipment is less sensitive to interference and the arteries can be heard more clearly than ever before.

TRILOGY: The Unit.



Indicator light **Battery**: Indicates the battery's state of charge

Indicator light **Probe**: Indicates correct attachment of the probe

Indicator light **On/Off**

Battery compartment

Volume button: Multi-level volume adjustment

On/Off button

Enlarged opening for better visibility and easier suturing

HAL: Unit in position for artery ligation

RAR: Unit in start position for mucopexy; arrow indicates direction of rotation

TRILOGY Locate. Ligate. Lift.

Why TRILOGY?

Comfort and convenience for the surgeon.

First came HAL, then there was RAR. Now there is **TRILOGY.**

The new generation of HAL-RAR equipment incoporates state-of-the-art technology in a small, easy-to-handle device to give you the highest level of operating comfort. Trilogy offers the ultimate in flexibility: the Bluetooth® connection allows you to rotate and manoeuvre the unit into whatever position you require before suturing through the ligation window, all with the convenience of no bothersome cables. In addition, you can choose between two different probes depending on your own individual preference.

Just two AA-batteries are required to power the small, handy Trilogy Unit. After surgery, the batteries are removed before the unit is steam-autoclaved ready for the next use.

The probe fits onto the unit and is secured with the fixation nut before being covered by the accompanying sleeve.

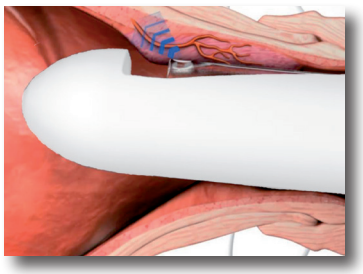
The unit is Bluetooth® paired with the speaker for transmittal of the acoustic Doppler signals. Once paired, the devices only need to be switched on and will subsequently connect automatically.

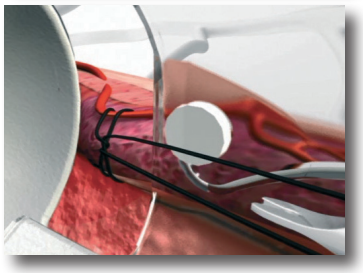
During surgery, high-performance LEDs provide optimal illumination and a clear view of the site.

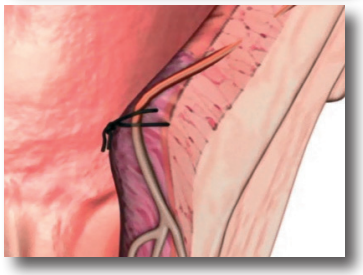
TRILOGY Locate. Ligate. Lift.

HAL-RAR with TRILOGY

One device. All grades of haemorrhoids.







HAL (Haemorrhoidal Artery Ligation)

The HAL method is suitable for treating low to medium grade haemorrhoids, and is extremely effective in addressing the symptoms of haemorrhoidal disease. The ligations serve to reduce the arterial blood supply, causing the haemorrhoidal cushions to shrink back to normal size. This method can be carried out with ease using the Trilogy Probe.

1. Attached to the Trilogy Unit, the probe is introduced into the rectum and the unit with attached probe then rotated slowly to search for arteries. The loudest Doppler signal indicates the centre of the artery.

2. Once the first artery has been found, it is ligated using an A.M.I. Suture with 5/8 needle.

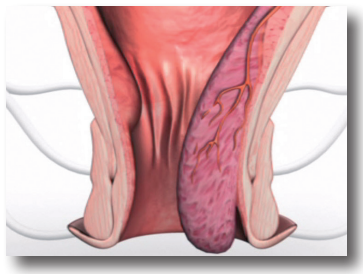
3. The unit is then turned again to locate further arteries. Once found, each artery is ligated as described in step 2.

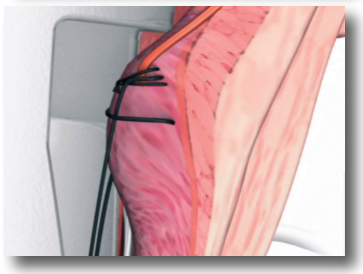
As a rule, between five and eight arteries will be found during the procedure. However this number can vary from patient to patient, and will also depend on the severity of the haemorrhoids in each case.

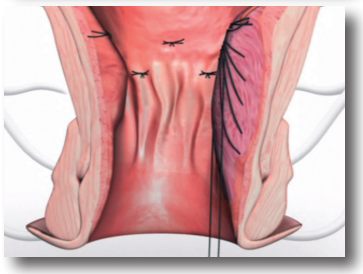
TRILOGY

One device. All kinds of advantages.

- New Bluetooth® technology
- Improved light sources for better visibility
- Clearer Doppler signal for easier artery detection
- Greater working space







RAR (Recto Anal Repair)

The RAR method is used to treat the prolapsing haemorrhoids that occur during more advanced stages of the disease. RAR involves one or more mucopexies of prolapsing mucosa, carried out after the haemorrhoidal arteries have been ligated.

1. The Trilogy Unit with attached probe is placed in the starting position as for ligation. The ligation window points towards the prolapse position requiring treatment.

2. First, an initial stitch is made as far proximal as possible. The unit and probe are then turned slightly to reveal more mucosa distally.

3. Now a running suture is started, and then continued with gradual turning of the unit, leaving 7 to 10 mm between each stitch. After the last stitch, which ends proximal of the Linea Dentata, the needle is cut off and the suture material knotted up near the initial stitch. This causes the prolapsing tissue to be pulled up towards the initial stitch, where it is then secured in place with a sliding knot.

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Why HAL-RAR?

Comfort and convenience for the patient.

Since the introduction of these minimally-invasive methods, over 100,000 patients have been treated with them worldwide. The operation can be tailored to suit each individual patient and achieves excellent results in terms of effectiveness, patient-friendliness and safety, which are reflected in the consistently high rates of patient satisfaction shown in the literature.

Considering the large number of procedures, the safety record to date is quite remarkable with not one major complication reported as having been caused by HAL-RAR.

Effective

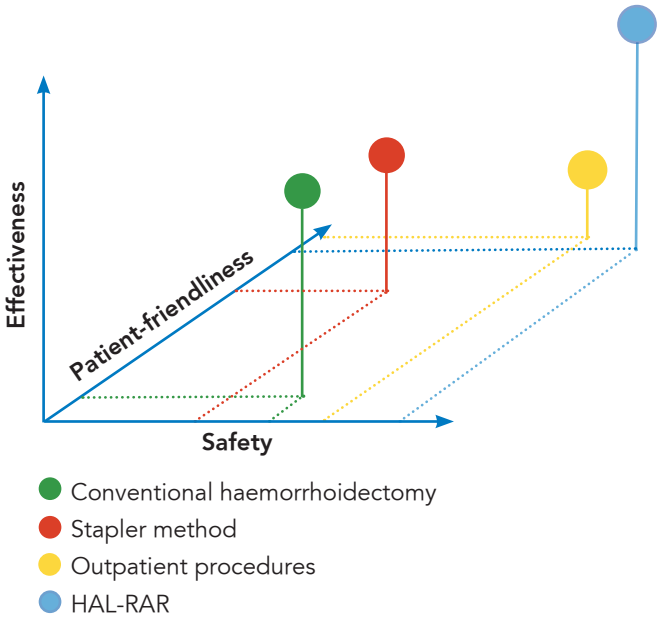
- Treatment with HAL of the three main symptoms - bleeding, itching and pain
- Treatment of the prolapse with RAR

Patient-friendly

- Minimal pain
- No cutting and no open wounds
- Quick recovery and return to work
- Local anaesthesia sufficient in many cases

Safe

- Fewer intra-operative complications
- Fewer post-operative complications



This diagram represents an assessment made by A.M.I. based partly on published data and partly on evaluations by surgeons who have experience with the HAL and RAR methods.

Forrest et al.
"Modern surgical treatment of haemorrhoids should be guided by patient symptoms. It should treat these symptoms to the patient's satisfaction with low impact on the individual.
DGHAL-RAR is safe, effective and well-tolerated. It reduces the need for potentially dangerous excisional procedures. Overall patient satisfaction following DGHAL–RAR was high..."

Int J Colorectal Dis DOI 10.1007/s00384-010-0951-4

Scheyer et al.
"91.25% of patients would again ask for HAL treatment if necessary and 93.75% of patients would recommend HAL to a friend.
The HAL procedure is synonymous with a high level of patient comfort...."

Am J Surg 191 (2006) 89-93

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HAL-RAR

The evidence.

Roka et al.
"For the first time in a study concerning DG-HAL/RAR, a multi-variate analysis was carried out to demonstrate the statistically significant influence of various factors on parameters of efficacy. The number of PRSs [RAR, prolapse-reduction sutures] and in particular the number of ligations [HAL] were shown to influence the recurrence of symptoms, whereas the only factor affecting the recurrence of prolapse was the grade of disease. It is interesting to note that the only factor significantly influencing patient satisfaction was the number of ligations [HAL]."
"...centres contributing to this study have chosen HAL-RAR as their first-line treatment for high-grade haemorrhoids owing to the perioperative benefits, very low number of complications, good symptom control and acceptably low prolapse recurrence rate."
Eur Surg 2013; DOI 10.1007/s10353-012-0182-8

Zagriadskiy et al.
"Patients undergoing HAL-RAR derive greater short-term benefits, while being subject to less pain and a much lower risk of severe complications. Furthermore, they are hospitalized for a shorter length of time and may return to work earlier."
*Pelviperineology 2011; **30**: 107-112*

Faucheron et al.
"One of the advantages of the HAL-RAR procedure is that it can be tailored to best treat each individual case, because the number of arterial ligations depends on the blood pulsations detected, and the number of mucopexies depends on the number of prolapses identified. Particularly in this respect, the HAL-RAR technique would appear to be more suitable than many other methods."
*Dis Colon Rectum 2011; **54:** 226-231*

Theodoropoulos et al.
"DG-HAL with the selective application of RAR is a safe and effective technique for advanced grade haemorrhoids."
*Colorectal Dis 2010; **12:** 125-134*

Satzinger et al.
"The present study confirms that the RAR procedure is a very effective technique for treatment of high-grade hemorrhoids. RAR offers a variety of advantages including improved treatment of symptoms, lower pain levels, shorter hospital stays, less time off work and high patient satisfaction levels."
*Pelviperineology 2009; **28:** 37-42*

Wilkerson et al.
"Given the low complication rates and therefore the low risk, it may well be reasonable to offer DGHAL as a first line treatment".
"With the advent of HAL-RAR (Recto-Anal Repair), outcomes for prolapse may improve and the place of PPH may also be questioned."
*Colorectal Dis 2009; **11:** 394 - 400*

Dorn et al.
"HAL is superior to sclerotherapy in stage I and more effective than rubber band ligation in stage II regarding the success rate as well as the relapse rate."
Coloproctology 2007;29:205–10

Bursics et al.
"In conclusion, both the closed scissors hemorrhoidectomy and the DG-HAL procedure proved effective in treating hemorrhoids in both the short and the long term."
*Int J Colorectal Dis 2004; **19:** 176-80*

NHS National Institute for Health and Clinical Excellence (UK)

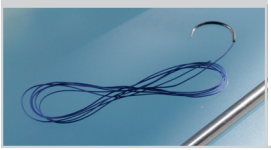
Guidance: "Current evidence on haemorrhoidal artery ligation shows that this procedure is an efficacious alternative to conventional haemorrhoidectomy or stapled haemorrhoidopexy in the short and medium term, and that there are no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit."

NICE interventional procedure guidance 342; Issue date: May 2010 http://guidance.nice.org.uk/IPG342

No.	Author Procedure Date	Title	Number of patients	Grade I	Grade II	Grade III	Grade IV	Follow-up
1	Roka et al. HAL-RAR Published 2013	DG-RAR for the treatment of symptomatic grade III and grade IV haemorrhoids: a 12-month, multi-centre, prospective observational study	184			58%	42%	12 months
2	Zagriadskiy et al. HAL-RAR vs. CH Published 2011	Transanal Doppler-guided Hemorrhoidal Artery Ligation and Recto Anal Repair vs Closed Hemorrhoidectomy for treatment of grade III-IV hemorrhoids. A randomized trial	135			Grades III - IV*		15 months (mean)
3	Faucheron et al. HAL-RAR Published 2011	Doppler-Guided Hemorrhoidal Artery Ligation and Rectoanal Repair (HAL-RAR) for the Treatment of Grade IV Hemorrhoids: Long-Term Results in 100 Consecutive Patients	100				100%	34 months (mean)
4	Forrest et al. HAL-RAR Published 2010	Doppler-guided haemorrhoidal artery ligation with recto anal repair: a new technique for the treatment of symptomatic haemorrhoids	77		16%	84%		13 months (mean)
5	Theodoropoulos et al. HAL-RAR Published 2010	Doppler-Guided Haemorrhoidal Artery Ligation (DGHAL), Rectoanal Repair (RAR), Sutured Haemor-rhoidopexy (SHP) and Minimal Mucocutaneous Excision (MMCE) for Grade III-IV Haemorrhoids: A Multicenter Prospective Study of Safety and Efficacy	147			65%	35%	15 months
6	Satzinger et al. HAL-RAR Published 2009	Recto Anal Repair (RAR): a viable new treatment option for high-grade hemorrhoids. One year results of a prospective study.	83			90%	10%	12 months
7	Wilkerson et al. HAL Published 2009	Doppler-guided haemorrhoidal artery ligation: long-term outcome and patient satisfaction	113	Grades I - III*				30 months
8	Walega et al. HAL Published 2008	Two-center experience in the treatment of hemorrhoidal disease using Doppler-guided hemorrhoidal artery ligation: functional results after 1-year follow-up	507		28%	63%	9%	12 months
9	Faucheron et al. HAL Published 2008	Doppler-Guided Hemorrhoidal Artery Ligation for the Treatment of Symptomatic Hemorrhoids: Early and Three-Year Follow-up Results in 100 Consecutive Patients	100		1%	78%	21%	3 years
10	Dorn et al. HAL Published 2007	5 Years of HAL: Experience and Long-Term Results. A Prospective Study	200	42%	38%	20%		5 years
11	Scheyer et al. HAL Published 2006	Doppler-guided hemorrhoidal artery ligation	308		29%	62%	9%	18 months
12	Bursics et al. HAL Published 2004	Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study	60	1%	22%	32%	45%	12 months

* No differentiation made between grades for the purposes of the study

TRILOGY Locate. Ligate. Lift.

Order Code	Product	Technical Details
TRI2010	**TRILOGY** **Wi-3 HAL-RAR Unit** System for performing HAL-RAR procedures with integrated Bluetooth® technology Set consists of: - Doppler-ultrasound electronic unit with integrated Bluetooth® transmitter - TRI2020 Wi-3 Battery Cap - TRI2030 Wi-3 Fixation Nut - TRI2040 Wi-3 Battery Set	- High-performance LEDs for excellent visibility - New Doppler-ultrasound technology for quick, precise artery detection - New Bluetooth® technology for cable-free surgery Multi-use (50 applications) Delivered non-sterile, steam autoclavable Batteries: AA NiMH, 2100 mAh
TRI2050	**TRILOGY** **Wi-3 Speaker** Bluetooth® loudspeaker for optimal acoustic replay of signals from the Trilogy Unit (TRI2010) during HAL-RAR procedures	1 speaker with power cable
RAR2081	**RAR Flexi Probe** Disposable probe and sleeve set for performing HAL and RAR procedures Probe with asymmetric design for the gradual release of mucosa	5 sets / box Delivered sterile
RAR2091	**RAR Precision Probe** Disposable probe and sleeve set for performing HAL and RAR procedures Comb-shaped probe for holding back mucosa	5 sets / box Delivered sterile
AHN 006	**A.M.I. HAL Needleholder** Stainless steel needleholder designed specially to fit the ligation groove inside the probes	1 instrument Delivered non-sterile, steam autoclavable
AHK 007	**A.M.I. HAL Knotpusher** Stainless steel knotpusher to facilitate knot tying inside the probes	1 instrument Delivered non-sterile, steam autoclavable
AHAL 70 	**A.M.I. HAL Suture** Suture material for HAL and RAR procedures	36 sutures / box 5/8 circle needle Synthetic, absorbable, 2/0 75 cm long

International patent filed / pending / granted

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