

PRINTER FEATURE IN HAL II

A.M.I. HAL-Doppler II

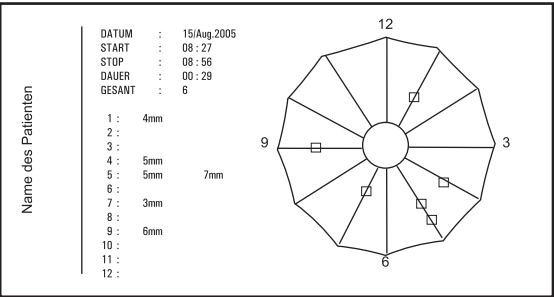
The system has a new feature: a built in printer!

How does it work?

The front of the HAL-Electronic Unit shows a clock-like field, representing the possible positions of ligations set. When ligating an artery, the assistant / nurse simply presses the button on the "clock", which represents where the ligature has been placed.

The protocol is printed automatically when the

- The date of the procedure
- The duration of the procedure
- The number of ligations
- The depth of ligatures
- space for the patient's name
- Graphical design showing the depth and positions of the ligated arteries.



Additional customer benefit:

- Print out allows perfect patient documentation and follow up.
- Surgeon can show patients how many stitches he placed and how deep
- Tool to make patient feel important
- Patient marketing tool for surgeons!

From left to right: Pre-op, post-op and 21-day post-op images of a 76-year old patient with prolapsing fourth degree haemorrhoids. The result after six ligations and six mucopexies speaks for itself.



Pre-op

Post-op

Post-op 21 Days

Order Code	Product	Technical Details
AHD 204	<b>A.M.I. HAL-Doppler II System</b> Set consists of: -AHE 203 A.M.I. HAL-II Electronic System, Incl. rechargeable battery -AHH 001 A.M.I. HAL Handle -AHK 007 A.M.I. HAL Knotpusher -AHN 006 A.M.I. HAL Needleholder -RAR2081 RAR Flexi Probe -AHAL 70 A.M.I. HAL Suture -AHA 00x A.M.I. HAL-II Adapter (x = 1,2,3,4,5) -Instructions for Use and patient guide	230 V Adapter or battery operation 1 unit (385 mm x 140 mm x 260 mm) 2 handles 2 instruments 2 instruments 1 box 1 box 2 adaptors
AHH 001	<b>A.M.I. HAL Handle</b> Reusable aluminium handle for use with the A.M.I. HAL – II Electronic System and probes	1 handle Delivered non-sterile, steam autoclavable
RAR2081	<b>RAR Flexi Probe</b> 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	<b>RAR Precision Probe*</b> 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	<b>A.M.I. HAL Needleholder</b> Stainless steel needleholder designed specially to fit the ligation groove inside the A.M.I. probes	1 instrument Delivered non-sterile, steam autoclavable
AHK 007	<b>A.M.I. HAL Knotpusher</b> Stainless steel knotpusher to facilitate knot tying inside the A.M.I. probes	1 instruments Delivered non-sterile, steam autoclavable
AHAL 70	<b>A.M.I. HAL Suture</b> Suture material for HAL and RAR procedures	36 sutures/box 5/8 circle needle Synthetic, absorbable, 2/0 75 cm long

\*The RAR Precision Probe is a new product concept currently being tested by A.M.I. and is not yet commercially available.

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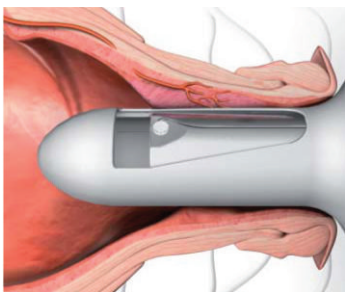
- Safe, gentle and effective treatment for all grades of haemorrhoids in one procedure.
- Doppler ultrasound technology for the precise, customised detection of haemorrhoidal areries in each patient.
- Handle with high-performance LED's for bright, even illumination and clear view.



The A.M.I. HAL and RAR methods

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 RAR Flexi Probe.

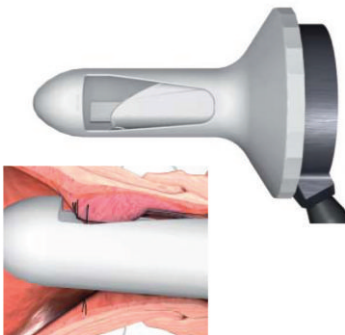


- 1. The handle with the RAR Flexi Probe is introduced into the rectum, then rotated slowly to search for arteries. The loudest Doppler signal indicates the centre of the artery .
- 2. Once the first artery has been found, it is ligated using an A.M.I. Suture with 5/8 needle.
- 3. The handle is then 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.

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.



RAR Flexi Probe

- 1. The handle is placed in the starting position as for ligation. The ligation window - and hence the handle - point towards the prolapse position requiring treatment .
- 2. First, an initial stitch is made as far proximal as possible. The handle is then turned slightly to reveal more mucosa distally.
- 3. Now a running suture is started, and then continued with gradual turning of the handle, 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.

RAR Precision Probe\*

The RAR Precision Probe differs from the RAR Flexi Probe by virtue of its comb-shaped teeth, which serve to standardise the mucopexy.

- 1. The comb-shaped part of the RAR Precision Probe sits directly under the outer sleeve's window and points towards the prolapse .
- 2. The initial proximal stitch is followed by the continuous running suture placed distally. The comb-shaped part of the probe serves to keep the mucosa in place, whi le the surgeon places stitches in the gaps between the comb's teeth.
- 3. After the last stitch, which ends above the Linea Dentata, the handle is turned in a clockwise direction to release the suture material. Subsequently the prolapsing mucosa is pulled up towards the initial stitch and secured in place with a sliding knot.

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Advantages of HAL and RAR

Since the introduction of these minimally-invasive methods, many tens of thousands of patients have been treated with them and excellent results achieved in terms of effectiveness, patient-friendliness and safety

Effective

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

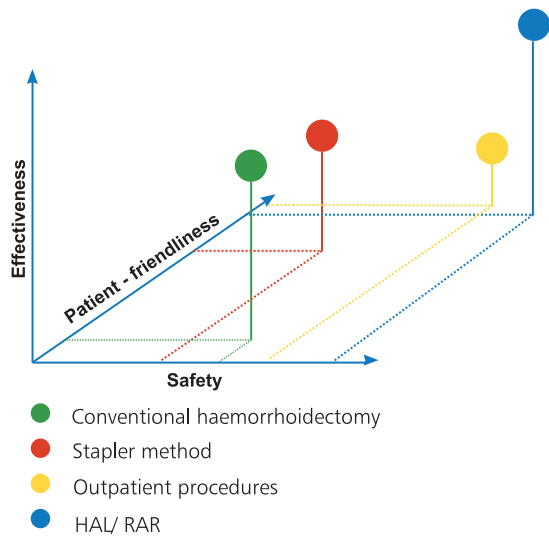
Patient-friendly

- Minimal pain
- Quick recovery

Safety

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

Furthermore, the operation can be tailored to suit each individual patient.

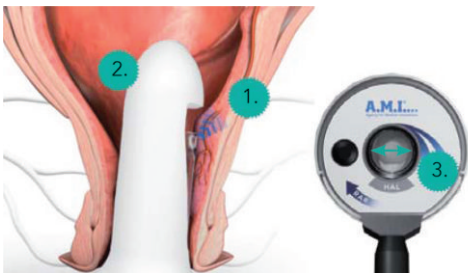


This diagram represents an assessment made by A.M.I, based partly on published data and partly on evaluations by surgeons who have experience with the HAL and RAR methods.

Publications with long-term results

Over the last few years, many interesting publications have appeared showing long-term results achieved with HAL and RAR. The literature currently available covers several thousands of patients.  
Satzinger 2009 - 83 RAR operations - prospective study with 1-year follow-up  
"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 ..."  
Zagriadskiy 2008 - 85 RAR operations for high-grade hemorrhoids  
"The use of RAR will lower or eliminate invasive operations, it is a painless and minimally invasive procedure that offers an excellent alternative to hemorrhoidectomy."  
Theodoropoulos - RAR with 15-month follow-up  
"DG-HAL with the selective application of RAR is a safe and effective technique for advanced grade hemorrhoids."  
Dorn 2007 - 5-year results after HAL  
"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."  
Wilkerson 2008 - Long-term results and patient satisfaction after HAL  
"Given the low complication rates and therefore the low risk, it may well be reasonable to offer DGHAL as a first line treatment."

New Probe Technology



The RAR Flexi Probe offers surgeons several key advantages for both the HAL and RAR procedures:

- 1. New Doppler ultrasound technology: quicker, more precise detection of arteries
- 2. White sleeve: highly improved illumination
- 3. 18% larger inner diameter at the ligation window: easy, quick suturing

HAL + RAR Procedure for treatment of Hemorrhoids

The quick, effective and virtually pain-free treatment of hemorrhoids.

HAL – RAR

- No cutting and no open wounds
- Short Operating procedure
- Only one day in Hospital
- Back to work the next day Short Operating procedure
- Very High success rate in India and all over the world

The concept of HAL originally developed in 1995 by Dr. Morinaga in Japan.

The method was enhanced towards the end of 2005 by the addition of RAR ( Recto Anal Repair )

HAL is particularly effective for Grade II and Grade III Hemorrhoids, Coupled with RAR for some Grade III and most Grade IV Hemorrhoids.

Together they form one of the most least invasive treatment methods practiced, With no cutting and virtually no Pain.

The HAL – RAR Procedure takes as little as 20 minutes to complete and can be Performed under various types of Anaesthesia. An ideal one can be opted for.

Most Patients experience only minor discomfort and can return to work within One or Two days of receiving treatment.

The risk of subsequent bleeding is far lower than with other methods, and by any other complications that may arise post – surgery are both minor & quite rare.

The HAL – RAR procedure has now been carried out on thousands of patients Worldwide with excellent results. Statistics show that the treatment of hemorrhoids with HAL – RAR is not only less painful and easier to recover from, than other, more Invasive methods, it is also just as effective.

How Does HAL Work

A miniature Doppler ultrasound device is gently inserted into the anus, and an audible signal allows the surgeon to pinpoint the exact location of the arteries supplying blood to the hemorrhoids

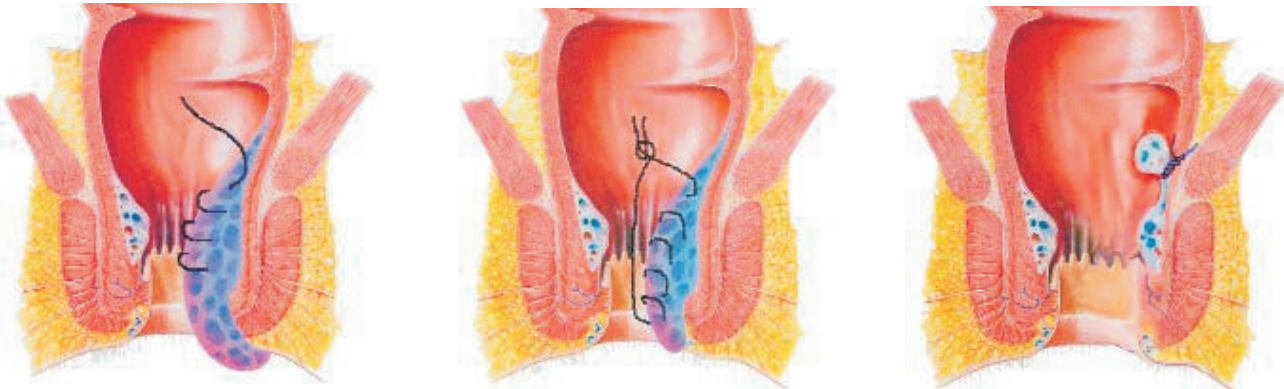
The Surgeon then ties of each artery ( called Ligation ) by placing a stitch around it and knotting the ends. Because the stitch is placed not in the anus but in the lower rectum, where there are almost no pain nerves, the whole procedure is virtually painless.

With the blood supply to the hemorrhoids being obstructed, the pressure in them is reduced almost immediately & they start to shrink. In just a week or two, they are no longer visible & the symptoms resolve.

Where necessary (for example in the case of Grade III or IV hemorrhoids), RAR (Recto Anal Repair) can also be used to reposition the prolapsing hemorrhoids.

How does RAR work?

The principle of RAR is ingeniously simple.



First, a running stitch is made from the top to the bottom. The device is so designed that only the prolapsing tissue is caught by the needle. The ends of the thread are pulled together and knotted at the top. This has the effect of lifting up the hemorrhoids that are hanging down With this “lifting”, the hemorrhoids are back where they belong. The tissue scars over and integrates “seamlessly” back into the anal tissue.