

TRILOGY

Soft Anal Band

Comfort Drain

FiXcision



Solutions for **Coloproctology**

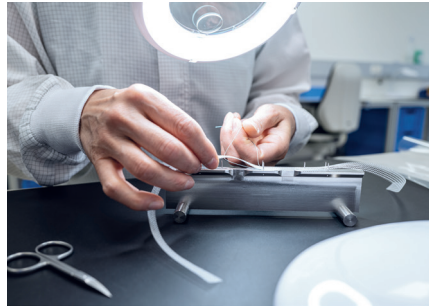
Less pain and discomfort as well as higher safety for the patients, through innovative surgical techniques in the fields of Coloproctology, Urology and Urogynecology: As a leading-edge technology company, A.M.I. Agency for Medical Innovations GmbH develops and manufactures high-quality medical products for surgeons and hospitals around the world.

To assure the highest standards, our team collaborates with internationally recognized experts and surgeons. In this way, we will continue significant progress in the field of minimally invasive surgery.

Innovative solutions

for improved quality of life.





Precision from Austria

Made in Europe.



A.M.I. offers various solutions for Coloproctology:

Treatment of Hemorrhoids

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Our company

- Leading manufacturer of medical technology with headquarter in Austria/Europe
- Over 20 years of experience in the fields of Coloproctology, Urology and Urogynecology
- High quality manufacturing in Europe
- Subsidiaries in Germany, France and USA
- Worldwide distribution network
- Development and manufacturing partner for medical technology companies with core competencies in precision mechanics as well as plastics and silicone processing

Our vision

- Development of innovative products for pain-reducing, minimally invasive surgical methods
- Meeting the highest quality requirements of surgeons and patients
- Creating and implementing innovative ideas through close cooperation with experts, surgeons, technicians and scientists
- Constructive exchange and consultation of users through our specially trained on site sales team
- Constant optimization of all processes related to development, production and service



Hemorrhoids

TRILOGY.

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



Locate. Ligate. Lift.

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

For surgeons, TRILOGY gives you the benefit of Doppler-ultrasound technology with no cables attached. Literally, with a Bluetooth connection between the unit and speaker, you can hear the system's signals for precise, individual detection of hemorrhoidal arteries while enjoying absolute freedom to maneuver 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.

Facts

- The Wi-3 HAL-RAR System enables precise detection of vessels (e.g. hemorrhoidal arteries) by means of Doppler ultrasound technology
- The Wi-3 HAL-RAR System is a wireless system (battery-driven) and has a Bluetooth technology
- Bright illumination of surgical area of interest inside the probes (due to three white LEDs)
- The Wi-3 Arm supports ergonomic handling of the Wi-3 HAL-RAR Unit in the rectum

Benefits [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16]

- Improved Quality of Life and patients' satisfaction
- Low risk of peri-operative (short- and long-term postoperative) pain
- Less post-operative pain compared to hemorrhoidectomy
- Shorter recovery time compared to hemorrhoidectomy
- A minimally invasive surgery with a low risk of intra-operative complications which is suitable for ambulatory surgery
- The ligation window in the probe is adequate and enables a proper manual ligation of detected arteries
- An effective surgical method after failure of previous treatments



Indication of TRILOGY

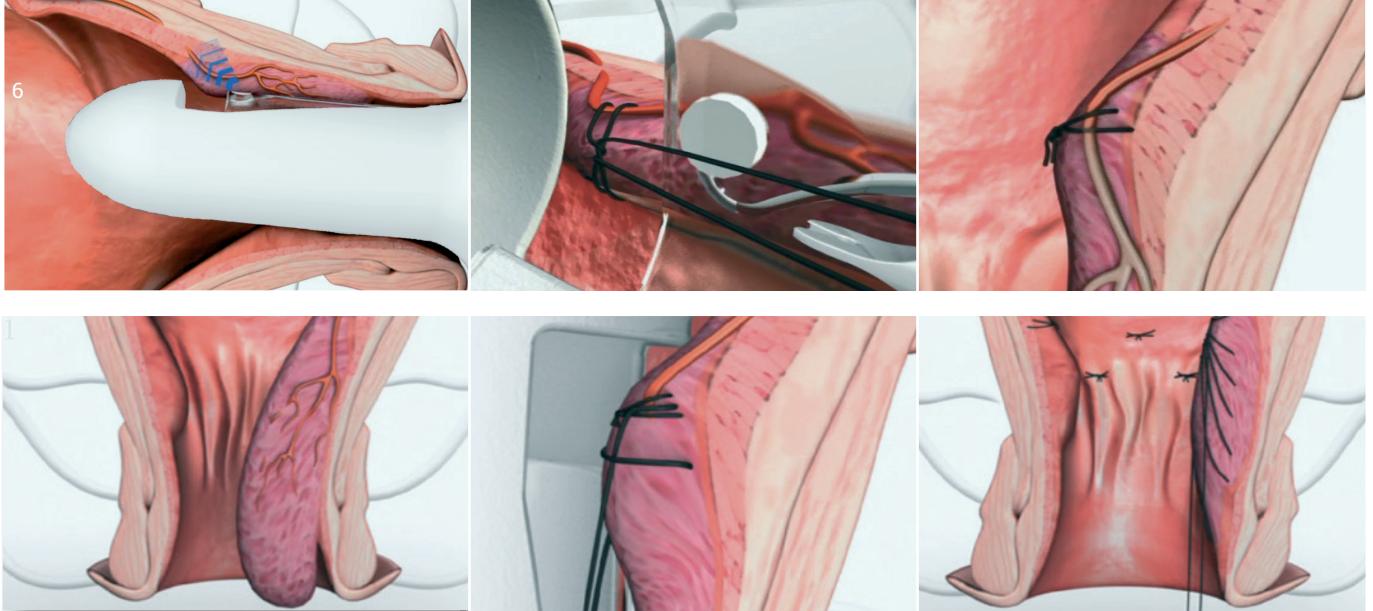
Surgical treatment of hemorrhoidal disease.



Animation video



Surgery video



HAL-RAR with TRILOGY

TRILOGY. **One device. All kinds of advantages.**

HAL (Hemorrhoidal Artery Ligation)

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

- 01** 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.
- 02** Once the first artery has been found, it is ligated using an A.M.I. Suture with 5/8 needle.
- 03** The unit is then turned again to locate further arteries. Once found, each artery is ligated as described in step 2.

"Modern surgical treatment of hemorrhoids 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..."

[11, p. 1255]

RAR (Recto Anal Repair)

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

- 01** 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.
- 02** An initial stitch is made as far proximal as possible. The unit and probe are then turned slightly to reveal more mucosa distally.
- 03** 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.

"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..."

[17, p. 92]



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.

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 incorporates 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 maneuver the unit into whatever position you require before suturing through the ligation window, all with the convenience of no bothersome cables.



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



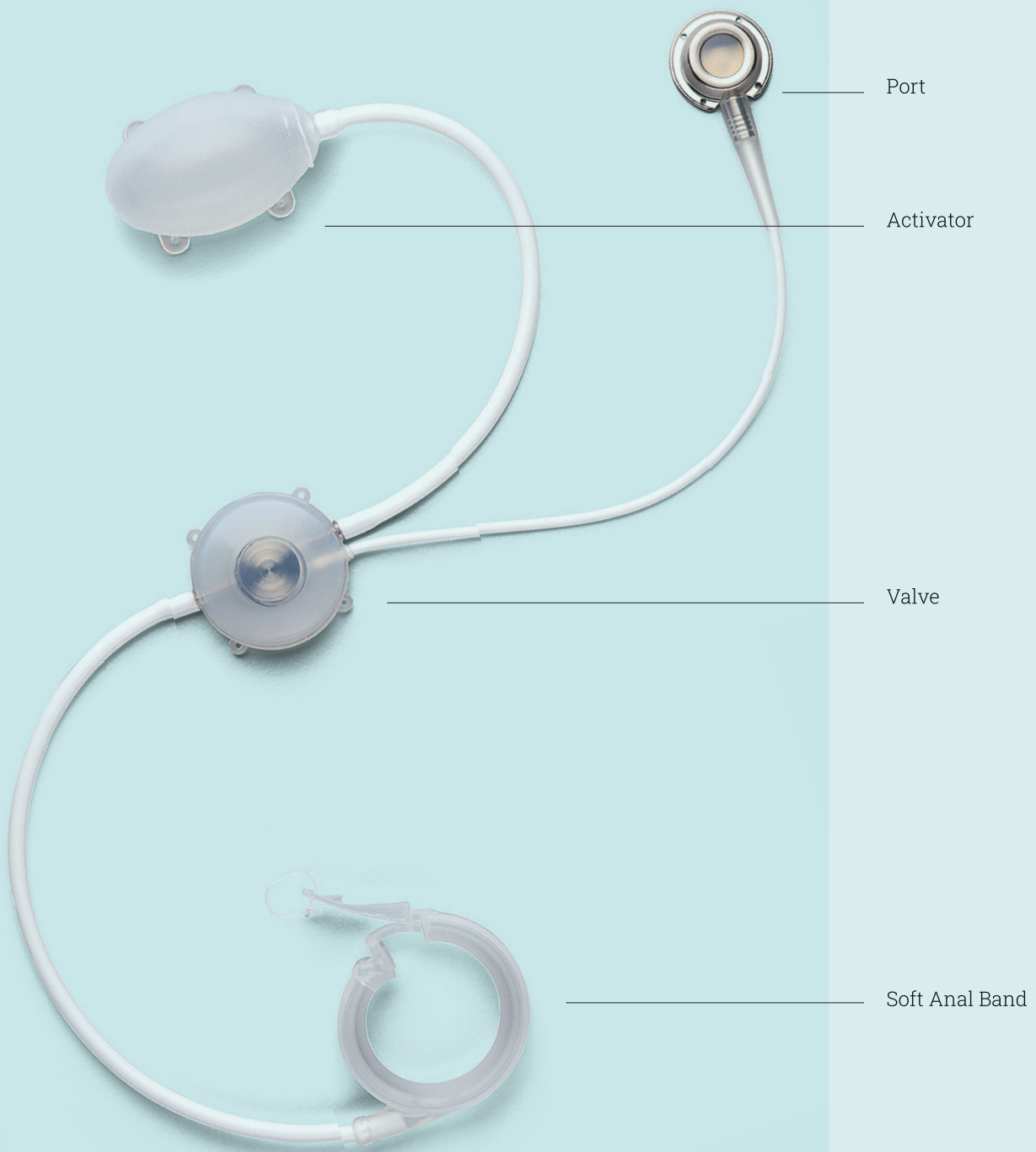
The unit is Bluetooth paired with the speaker for transmittal of the acoustic Doppler signals. Once paired, the devices only need to be switched on and will subsequently connect automatically.



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

Fecal Incontinence

Soft Anal Band





Fecal Incontinence

Soft Anal Band. Long-term implant for the treatment of fecal incontinence in adults.

The Soft Anal Band is a long-term subcutaneous implant to control the sphincter function for the treatment of fecal incontinence in adults. The ring is placed inside the surgically created circular pocket around the non-functioning anal sphincter. The ring and the activator are available in two different sizes (M and L).

Function and the procedure

- A soft, inflatable ring of silicone (**Anal Band**), which is implanted around the anal canal and can be adjusted in size
- A mechanism for closing the silicone ring – the **activator**
- A **valve** to open the band and the valve is typically implanted under the skin in the region of the pubic bone, sternum or abdominal wall
- An access **port**, which is used to adjust the amount of liquid in the system and thereby the necessary pressure to close the sphincter
- Tubing, which is radiopaque and connects all the system's components – band, port, activator and valve – lying under the skin

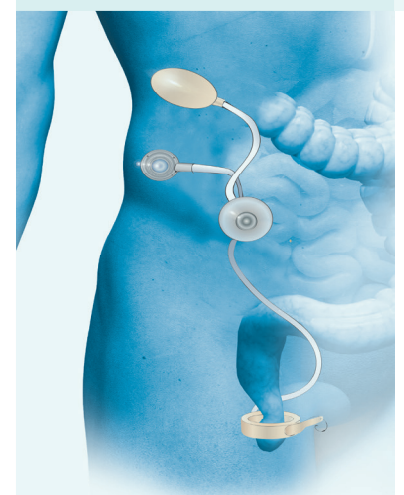
Benefits [18], [19], [20], [21], [22], [23]

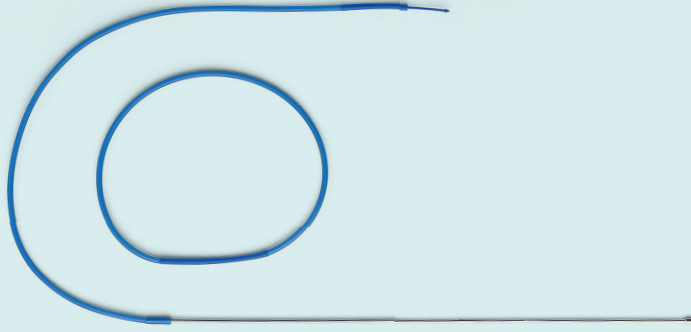
- Postoperative adjustment of the artificial anal sphincter is easy to accomplish
- Patients are able to activate the Soft Anal Band system independently without assistance by another person
- Soft Anal Band prevents episodes of incontinence without creating obstruction
- Soft Anal Band improves the patient's Quality of Life
- Adjustment of the ring pressure by the patient according to his/her individual needs (e.g. physical activity, stool consistency etc.)



Indication of Soft Anal Band

Surgical treatment of chronic fecal incontinence after failed conservative treatment.





Anal Abscesses and Fistulas

Comfort Drain. Long-term drainage for anal fistulas.

The Comfort Drain is a flexible, silicone, elastic drain with knotless closure that facilitates drainage of perianal fistulas. The Comfort Drain consists of a fistula probe, a silicone drain and a closure thread. The fistula probe is a flexible stainless-steel wire with a ball shaped tip. The fistula probe may be bent to meet the fistula's run. The fistula probe is pre-attached to the drain. After pulling the drain through the perianal fistula, the pre-attached fistula probe is cut off the drain at the length appropriate to the individual patient. After disconnecting the drain from the fistula probe, the closure thread from one end is fed into the drain's other end, thus connecting both ends of the drain, creating a knotless closure.

To facilitate the closure of the Comfort Drain, the **Comfort Drain Grasper** can be used to connect the end of the drain with the closure thread, to the other cut / trimmed end of the drain.

Facts

- Knotless drain
- Implementation of the beneficial concept of loose setons (e.g., possible treatment of high and complex anal fistulas / sphincter sparing procedure)

Benefits [24], [25]

- Improvement of the patient's Quality of Life due to increased comfort
- Low rates of post-operative complications (e.g., skin irritation, burning sensation, pruritus)
- Low complication rate during the insertion of Comfort Drain
- The Comfort Drain Grasper enables a time sparing and secure closure of the Comfort Drain

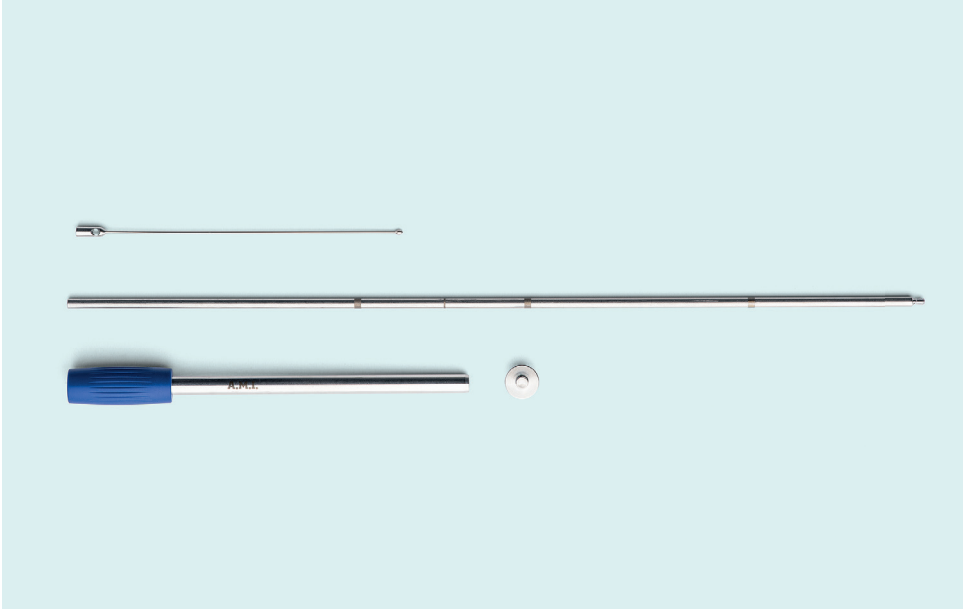


Indication of Comfort Drain

Treatment of inter-, trans-, and suprasphincteric fistulas.



Animation video



Anal Abscesses and Fistulas

FiXcision. Precise excision of anal fistulas.

FiXcision is a surgical invasive multi-part cutting instrument for anal fistula treatment in coloproctology. The device is delivered in sterile condition (EO sterilisation) and is intended for single use only. FiXcision consists of the following components:

- Probe
- Guide
- Base Plate
- Circular Cutter

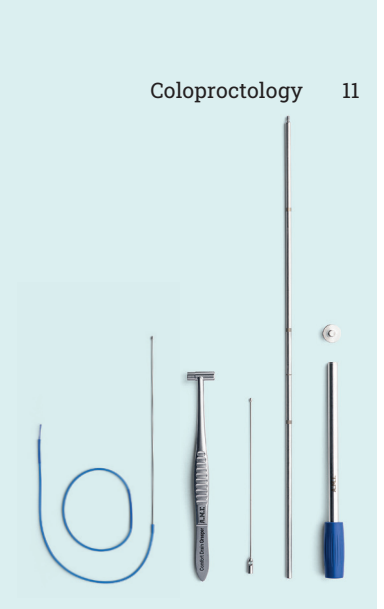
The probe and the base plate can be connected to the guide. The guide features a marking (indicator) to check whether the complete length of the anal fistula channel can be covered and cut by the circular cutter.

Facts

- Feasible and uncomplicated application of FiXcision for the surgeon

Benefits [26], [27], [28], [29]

- Minimally invasive treatment
- Low rates of post-operative pain
- Low rates of peri-operative complications



Indication of FiXcision

FiXcision is indicated for the surgical treatment of anal fistulas.



Animation video



Surgery video

References

TRILOGY

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Comfort Drain

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FiXcision

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Overview


Treatment of Hemorrhoids

Order Code		Product description	Included in delivery
TRI2010		<p>Wi-3 HAL-RAR Unit System for HAL-RAR surgery with integrated bluetooth technology.</p> <p>1 system consists of:</p> <ul style="list-style-type: none"> • Doppler-ultrasound electronic unit with integrated bluetooth submitter • TRI2020 Wi-3 Battery Cap • TRI2030 Wi-3 Fixation nut • TRI2040 Wi-3 Battery Set 	Delivered non-sterile, steam autoclavable Multi-use (50 applications) Batteries: 2 units, AA NiMH, 2100 mAh
TRI2110		<p>Speaker for TRILOGY Bluetooth speaker for the optimal reproduction of the TRILOGY Unit's signal (TRI2010) during HAL-RAR surgery</p>	1 unit, supplied with USB cable
TRI2210		<p>Adaptor for Speaker USB adaptor for connecting the speaker Manufacturer Frimo FOX12-X11-USB</p>	1 unit, delivered non-sterile
TRI2220		<p>Connector Europe Replaceable connector for connection to adaptor, Manufacturer Frimo</p>	1 unit, delivered non-sterile
TRI2020		<p>Wi-3 Battery Cap Reusable battery cap for the TRILOGY Unit (TRI2010)</p>	1 unit, delivered non-sterile, steam autoclavable
TRI2030		<p>Wi-3 Fixation Nut Reusable fixation nut for the fixation of probes onto the TRILOGY Unit (TRI2010)</p>	1 unit, delivered non-sterile, steam autoclavable
TRI2040		<p>Wi-3 Battery Set 1 package consisting of 2 rechargeable batteries (AA, NiMH, 2100 mAh)</p>	2 pieces, delivered non-sterile
TRI2070		<p>Wi-3 Arm Reusable holding wheel to enhance holding position for the assistance during surgery</p>	1 unit, delivered non-sterile, steam autoclavable
RAR2081		<p>RAR Flexi Probe Disposable probe and sleeve set for performing HAL and RAR procedures. Probe with asymmetric design for the gradual release of mucosa</p>	1 box, delivered sterile 5 x RAR Flexi probe and sleeve
RAR2181		<p>HAL-RAR Procedure Kit – Flexi</p>	1 kit, delivered sterile 1 x RAR Flexi probe and sleeve 8 x A.M.I. HAL Suture 1 x Single-use knotpusher designed especially to fit the A.M.I. probes
AHAL 70		<p>A.M.I. HAL Suture Suture material for HAL and RAR procedures.</p>	1 box, delivered sterile 36 x sutures, 5/8 needle absorbable, 2/0, 75cm

<p>AHN 006</p>		<p>A.M.I. HAL Needleholder Stainless steel needleholder designed especially to fit the A.M.I. probes</p>	<p>1 instrument, delivered non-sterile, steam autoclavable</p>
<p>AHK 007</p>		<p>A.M.I. HAL Knotpusher Stainless steel knotpusher to facilitate knot-tying inside the A.M.I. probes</p>	<p>1 instrument, delivered non-sterile, steam autoclavable</p>




Overview

Fecal Incontinence

Order Code	Product description	Included in delivery
<p>AAB 300</p> 	<p>Soft Anal Band System for treatment of fecal incontinence.</p>	<p>1 system, delivered sterile 1 x Soft Anal Band Ring M/L 1 x Soft Anal Band Activator M/L 1 x Soft Anal Band Valve 1 x Soft Anal Band Port 1 x Soft Anal Band Port Connector 1 x Soft Anal Band Ring Connector</p>

Overview

Anal Abscesses & Fistulas

Order Code	Product description	Included in delivery
<p>CDS2001</p> 	<p>Comfort Drain System consisting of a flexible stainless steel probe for the location of fistula passages and a unique knotless 360° lockable silicone drain with a polypropylene connector. System suitable for long-term drainage of anal fistulas.</p>	<p>1 box, delivered sterile 10 x set</p>
<p>CDS2010</p> 	<p>Comfort Drain Grasper Reusable instrument to facilitate the closure of the Comfort Drain CDS2001.</p>	<p>1 box, non-sterile, steam autoclavable 1 x Comfort Drain Grasper</p>
<p>FIX2001</p> 	<p>FiXcision Enables the circumferential tissue removal to treat simple anal fistulas.</p> <p>Set consisting of probe to discover the fistula tract, guide for tissue compression around the fistula tract, base plate and circular blade for precise excision of the fistula tract.</p>	<p>1 box, delivered sterile 10 x set</p>



The products contained in this brochure meet the requirements of the Medical Device Directive 93/42/EEC and are accordingly marked with the CE mark: TRI2010, TRI2070, RAR2081, AHN 006, AHK 007, AAB 300, CDS2001, CDS2010, FIX2001

The following products are FDA-cleared (USA):

- Wi-3 HAL-RAR System (TRI2010, TRI2020, TRI2030, TRI2040, TRI2050, TRI2060, TRI2070), 510(k) number: K150718
- Fixcision (FIX2001), 510(k) number: K182664
- RAR Flexi Probe (RAR2081), 510(k) number: K061831

The following products are FDA-listed (USA):

- A.M.I. HAL Knotpusher (AHK 007) and A.M.I. HAL Needleholder (AHN 006)
- Comfort Drain (CDS2001) and Comfort Drain Grasper (CDS2010)

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