

Rafaelo[®]

Radiofrequency treatment of haemorrhoids
under local anaesthesia

Rafaello®

A safe and reliable treatment with lasting results

The Rafaello® procedure uses the principle of radiofrequency thermocoagulation to treat haemorrhoids. A minimally invasive technique based on the emission of high frequency electromagnetic waves (4MHz).

The sharp needle-like probe is introduced into the haemorrhoid and the energy is administered. This causes tissue dehydration, coagulation, fibrosis, necrosis and finally exfoliation of the haemorrhoid.

Besides having the advantage of being safe and reliable, the method is simple, effective and shows long-lasting results. The procedure can be performed under local anaesthesia on an outpatient basis. The intervention only takes a few minutes with minimal discomfort for the patient, allowing a speedy return to daily activities.



The 4 phases of thermocoagulation



Ionic agitation



Dehydration of the tissue



Denaturation of proteins



Coagulation by thermal destruction



Advantages



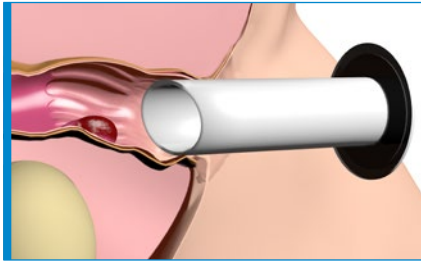
For the patient

- + Minimally invasive procedure:
no incision = no risk of faecal incontinence
- + Quick procedure: estimated outpatient
treatment time of 15 minutes
- + Can be carried out under local anaesthetic
- + Low pain scores
- + No post-operative wound care
- + Low risk of recurrence
- + Speedy return to daily activities

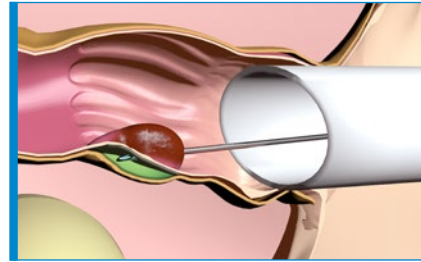
For the practitioner

- + Suitable for grade II to III and some
grade IV haemorrhoids
- + Minimally invasive procedure perfectly
suited for outpatient use
- + Safe energy control, avoiding damage
to surrounding tissue or muscles
- + Less complications
- + Very effective in treating bleeding
and prolapse symptoms
- + Minimal post-operative care required
- + High patient satisfaction rate

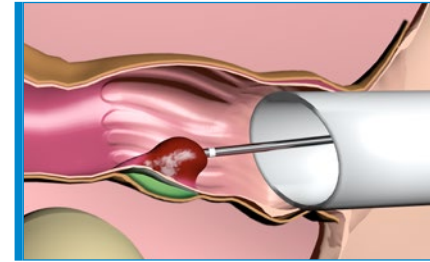
The Rafaelo[®] procedure



- 1 Insert the anoscope into the patient's rectum to locate the haemorrhoid to be treated.

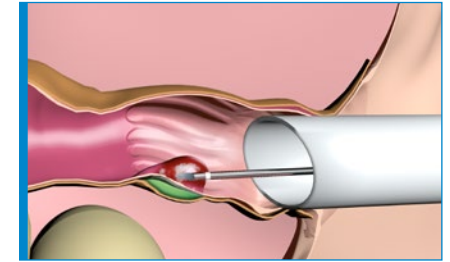


- 2 Inject a local anaesthetic with a syringe into the submucosal layer of the haemorrhoid. It forms a barrier that protects the muscle below the haemorrhoid.



- 3 Insert the HPR45i probe into the haemorrhoid above the dentate line and, using the foot pedal, apply the radiofrequency energy. The haemorrhoid will react by contracting and by whitening. It will also harden.

For larger piles, manoeuvre the probe to spread the heat internally.



- 4 Then apply the radiofrequency energy to the surface of the haemorrhoid, scarring it. Cool the haemorrhoid with a compress soaked in cold saline to halt the heating process.

Equipment

1. Probe

Probe length: 210 mm

Tip length: 10 mm

Needle diameter: 2 mm

Handle diameter: 19.5 mm

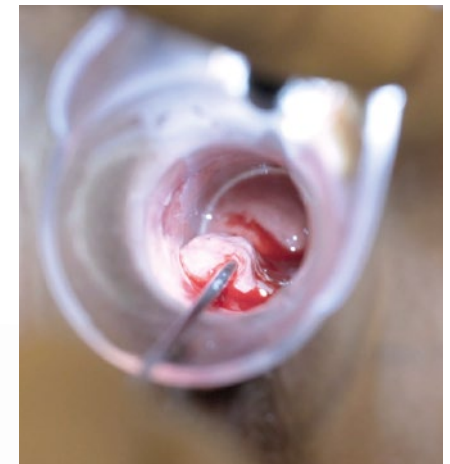
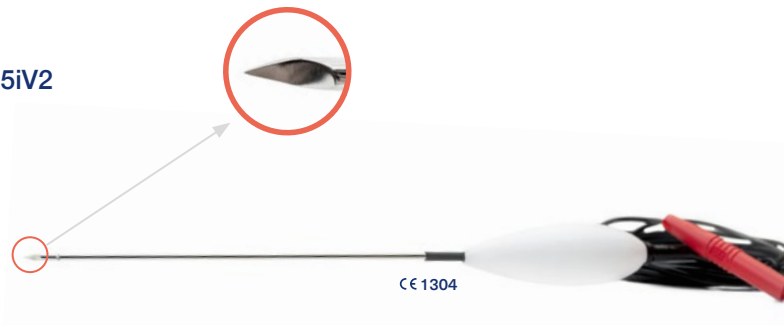
Extension cable: 2.5 m

Insulation material: PTFE

Material tip: stainless steel

Weight: 34 g

Product REF: 05HPR45iV2



2. Rafaelo® Pack

Content*

1x sterile perineal drape
1x anoscope with LED (96 x Ø23 mm)
1x lubricating gel
1x sterile needle 21G

1x sterile probe HPR45i
3x sterile compresses
1x sterile forceps

Product REF: 06RAFAELOPACK

*Availability and content may vary from region to region



Clinical studies

“Radiofrequency ablation for internal haemorrhoids is safe, reliable, easy to perform and associated with minimal pain and early return to work/normal activities. In addition, we have seen no evidence of functional deterioration or anal incontinence following RFA, but rather a significant improvement in patients’ quality of life.”

Radiofrequency ablation for the treatment of haemorrhoidal disease: a minimally invasive and effective treatment modality;
M.M.R. Eddama, M. Everson, S. Renshaw, T. Taj, R. Boulton, J. Crosbie, C. Richard Cohen; Techniques in Coloproctology, July 24, 2019

“Our results support this new technique. It is ideally suited to outpatient treatment, resulting in little or no post-operative work disability, and thus offering a new, effective and less aggressive tool for the management of internal haemorrhoids.”

Radiofrequency thermocoagulation of haemorrhoidal bundles, an alternative technique for the management of internal haemorrhoids;
J.-M. Didelot, R. Didelot; International Journal of Colorectal Disease 2020

“RFT, although imperfect, leads to a significant improvement in hemorrhoidal symptoms and a lasting increase in QoL with minimal pain and downtime, high acceptance, and low complication and recurrence rates.”

What can patients expect in the long term from radiofrequency thermocoagulation of hemorrhoids on bleeding, prolapse, quality of life, and recurrence: “no pain, no gain” or “no pain but a gain”?
J.-M. Didelot, B. Raux, R. Didelot, F. Rudler, A. Mulliez, A. Buisson, A. Abergel, P. Blanc; Annals of Coloproctology, October 11, 2022

“RFA is safe and effective for treatment of third-degree haemorrhoids. The main advantages of this new method are its use on an outpatient basis under local anaesthesia, a very low level of postoperative pain and significant control of haemorrhoid symptoms over 2 years.”

Early and midterm results of radiofrequency ablation (Rafaelo® procedure) for third-degree haemorrhoids: a prospective, two-centre study;
Dr. S. Tolksdorf, D. Tübergen, C. Vivaldi, M. Pisek, F. Klug, M. Kemmerling, H. Schäfer; Techniques in Coloproctology, March 2022

Use of painkillers after the procedure



3. Radiofrequency generators

Haemorrhoids can be treated with the Rafaelo® generator or with the new MedRF4000®. The choice depends on the range of treatment options you require in addition to the haemorrhoid therapy. Both utilise the same radiofrequency technology.

The Rafaelo® generator is suitable for proctology applications. Both haemorrhoids and anal fistulas can be treated with this device.

The MedRF4000® can be used for multiple radiofrequency treatments. It is an all-in-one smart generator with many applications, including haemorrhoids, fistulas, and veins but is upgradable as new applications are introduced (simply using a USB fob).

Both devices are monopolar and generate 4MHz radiofrequency waves through whichever probe or catheter that is attached. The application of energy is controlled by a foot pedal.

The generators are easy to use and have preset parameters for each treatment.


Rafaelo® generator



CE 1304



For treatment of

- Haemorrhoids
 - Anal fistulas
- 
- Plug & play device
 - Touchscreen operated
 - Display of time and energy (joules)
 - Foot switch energy control


MedRF4000® generator



CE 1304



For treatment of

- Haemorrhoids
 - Anal fistulas
 - Saphenous veins
 - Collateral and perforating veins
 - Telangiectasia
- 
- Plug & play device
 - Tilted touchscreen with user-friendly interface
 - Display of time, energy (joules), hemorrhoidal grade and position
 - Foot switch energy control
 - Export of individual procedure settings via USB fob



Technical specifications

Rafaelo® generator	
Technology	monopolar RF generator
Output Frequency	4 MHz
Dimensions	W 360 mm x D 280 mm x H 120 mm
Supply voltage	110-230 V / 50-60 Hz
Max. input power	125 VA
Output setting	25 W
Applied parts classification	type BF
Weight	± 4 kg
Product REF	00RAFAELO



MedRF4000® generator	
Technology	monopolar RF generator
Output Frequency	4 MHz
Dimensions	W 252 mm x D 245 mm x H 185 mm
Supply voltage	110-230 V / 50-60 Hz
Max. input power	125 VA
Output setting	100% (25 W)
Applied parts classification	type BF
Weight	± 5 kg
Product REF	00MEDRF4000



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