



Radio Frequency Treatment of Haemorrhoids Under Local Anaesthesia

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The Rafaelo Procedure*

treats all grades of internal haemorrhoids in a walk in walk out setting, requiring only local anaesthetic, **which benefits both the patient and the hospital.**

This safe and reliable treatment is now available and utilises established radio frequency technology.

The Rafaelo Procedure is generally concluded with - in a few minutes, with minimal discomfort for the patient which enables immediate return to normal daily activities.



HPR45i probe

The Rafaelo[®] Procedure:

A safe and reliable haemorrhoid treatment with lasting results

4 step procedure

1. Insert the anoscope in the rectum of the patient to see the haemorrhoid.



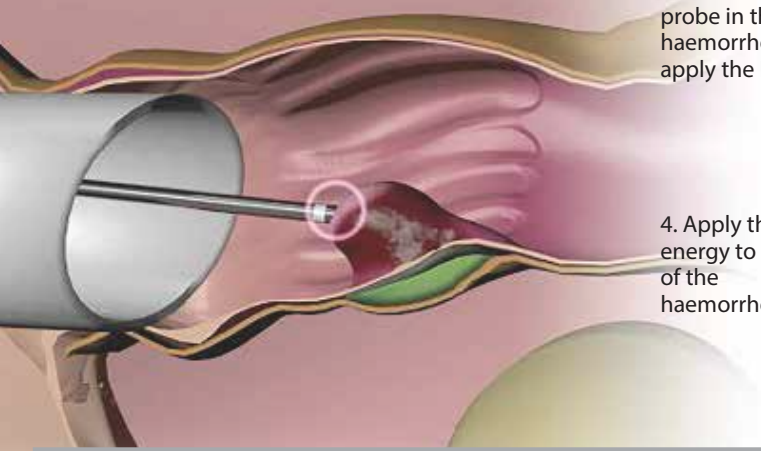
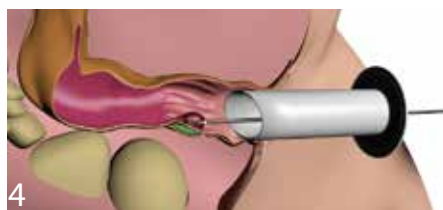
2. Apply local anaesthesia (Lidocaine 1%, 3-6 ml) in the muscle layer under the haemorrhoid, NOT in the haemorrhoidal tissue.



3. Insert the HPR45i probe in the haemorrhoid and apply the RF energy.



4. Apply the RF energy to the surface of the haemorrhoid.



- Radiofrequency thermocoagulation of haemorrhoidal bundles, an alternative technique for the management of internal haemorrhoids; J. M. Didelot ; International Journal of Colorectal Disease, (), 1-4 29 Oct 2020 <http://link.springer.com/article/10.1007/s00384-020-03789-3>
- Radio frequency ablation (Rafaelo procedure) for the treatment of prolapsing stage III haemorrhoids -technique and initial results ., H. Schäfer, S.Tolksdorf, C.Vivaldi ; Coloproctology 2018: 40:204-210 online published 9Mai2018 <https://doi.org/10.1007/s00053-018-0250-z>
- 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 24 July 2019 , <https://doi.org/10.1007/s10151-019-02054-2>



*In addition to the Rafaelo RF Generator, the clinician requires only a disposable anoscope and our proprietary HPR45i single use probe, both of which are supplied in the Rafaelo Procedure Pack.



Radio Frequency Treatment of Anal Fistulas

A New Monopolar Radio Frequency **treatment for anal fistulas**

Fistura®, is a safe and minimally invasive RF procedure to treat anal fistulas.

The flexible Fistura® catheter is inserted from the external opening and follows the tract of the anal fistula easily. The blunt 4mm stainless-steel active tip facilitates the push through of the marked catheter without causing extra damage to the fistula wall.



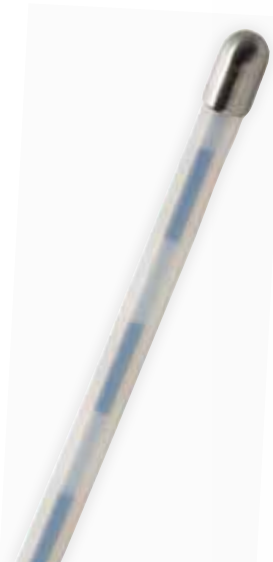
9 French Fistura® Catheter



Appearance of the fistula after completion of the RF

A 4 MHz radiofrequency wave delivers a controlled level of energy to the epithelialized tissue. This tissue will be destroyed in a controlled way and causes the fistula tract to collapse. The internal orifice of the fistula can easily be closed by a direct suture to keep tensions low in the mucous membrane.

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The flexibility of the catheters is a key advantage and enables you to follow the tortuous tract of the anal fistula allowing to work end-to-end. According to the diameter of the anal fistula, a set of different sized catheters maximizes the energy penetration to a high degree, emitting radio energy in a 3mm radius avoiding unnecessary tissue or muscle damage.

The advantages

Rafaelo RF Generator

For the patient

- 15 Minute walk in walk out procedure
- Local anaesthesia
- Minimal post-operative pain and care
- Can be used to treat all grades of internal haemorrhoids
- Immediate return to daily activities

For the surgeon

- Quick safe and effective procedure
- Minimal post procedure care
- Increased patient throughput
- Cost effective

Fistura

- Safe control of energy
- No limitation of the fistula length
- Different sizes of flexible marked catheter
- Treatment can be done in a few minutes

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Technical specifications

HPR45i

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- | | |
|--------------------------|-----------------|
| • Tip length | 10 mm |
| • Probe length | 210 mm |
| • Diameter tip | 2 mm |
| • Diameter handle | 19,5 mm |
| • Insulation material | PTFE |
| • Tip material | Stainless steel |
| • Length extension cable | 2,5 m |
| • Class | IIb |
| • CE | 1304 |
| • Shelf life | 3 years |



Fistura®

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• Product	6F	7F	8F	9F
• Tip length	4mm	4mm	4mm	4mm
• Catheter length	350mm	350mm	350mm	350mm
• Diameter	2mm	2,33mm	2,66mm	3mm
• Insulation material	PTFE			
• Tip material	Stainless steel AISI316L			
• Length extension cable	2,5m			
• Markings	5mm	5mm	5mm	5mm
• Weight	40gr	41gr	42gr	43gr
• Class	IIb			