

Fistura[®]

Radiofrequency treatment of anal fistulas

Fistura®

A new radiofrequency procedure for the treatment of anal fistulas

Fistura® is a minimally invasive technique that seals the fistula tract without having to open the anal sphincter.

The procedure is based on the method of thermocoagulation – utilising the emission of electromagnetic waves at a very high frequency (4MHz). The technique is safe, efficient and does not damage surrounding tissue.

This new treatment for anal fistulas is performed in a day-case or outpatient setting. The procedure takes only a few minutes to fulfil with minimal discomfort for the patient, allowing an immediate return to daily activities.



The 4 phases of thermocoagulation



Ionic agitation



Vaporisation and dehydration of the tissue



Denaturation of proteins



Coagulation by thermal destruction



Advantages



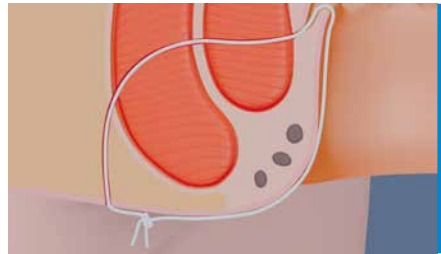
For the patient

- + Minimally invasive (no incision)
- + Quick procedure
- + Comparatively little or no pain
- + Minimal post-operative care
- + Immediate return to daily activities

For the practitioner

- + Alternative to more invasive techniques
- + Sphincter-saving technique:
no faecal incontinence
- + Simple to perform
- + Quick and efficient procedure
- + Safe control of energy, avoiding damage
to surrounding tissue and muscles
- + Suitable for patients with Crohn's disease
- + Minimal post-operative care

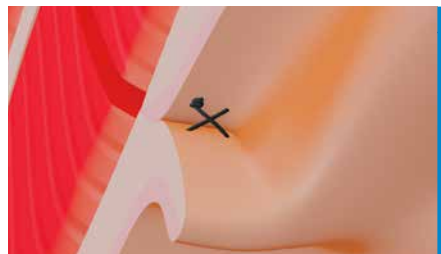
The Fistura[®] procedure



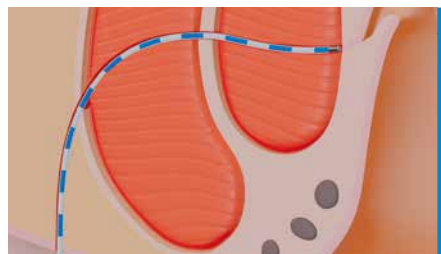
1 The fistula should be drained prior to surgery using a seton to clean the tract and prevent infection.



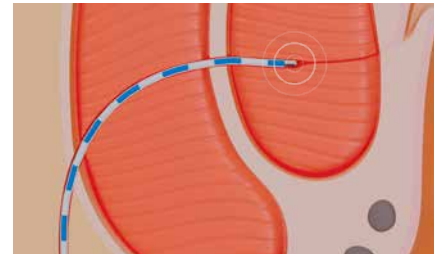
2 The tract is cleaned using a fistula brush prior to inserting the catheter.



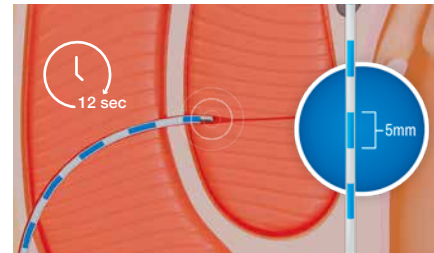
3 The internal opening of the anal fistula is closed with a cross suture.



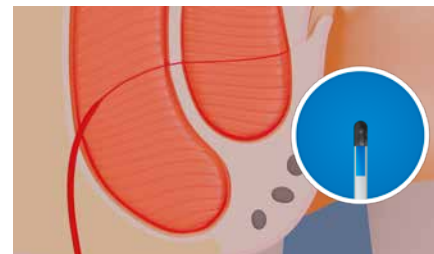
4 Choose the appropriate sized catheter (6F to 9F) that suits the diameter of the fistula. The catheter is inserted into the anal fistula from the external opening until it reaches the closed internal end.



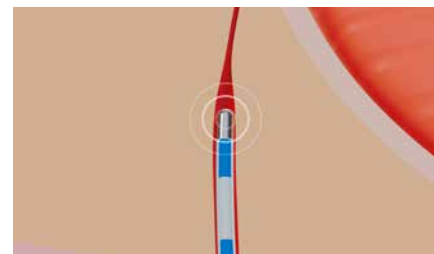
5 Ensure the correct settings on the device and then press the generator pedal to deliver the power.



6 Gradually withdraw the catheter, half a centimetre at a time, according to the beeps generated by the device. ± 5 mm (= 1 marking) every 12 seconds



7 During the procedure, regularly clean the catheter tip. Reinsert and proceed.



8 Work from end to end. Occasionally check that the tract is closed by pushing the catheter back to see if it re-advances. Generally, the tract will seal immediately and the catheter will not be able to re-advance.

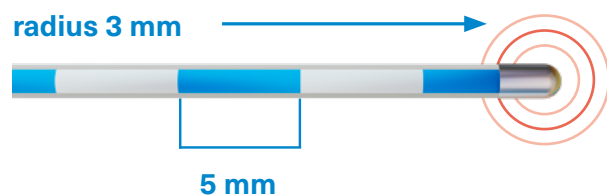
Equipment

1. Catheters

The flexibility of the Fistura® catheters is a key advantage that allows you to easily follow the path of the anal fistula – it will allow you to close the fistula along its entire length.

Depending on the diameter of the anal fistula, a range of different catheter sizes is available (from 6F to 9F).

The thermal effect around the catheter tip has a 3 mm radius, thus avoiding damage to surrounding tissue or muscle.



Technical specifications

French size	6F	7F	8F	9F
Catheter diameter	2 mm	2.33 mm	2.66 mm	3 mm
Catheter weight	40 g	41 g	42 g	43 g
Catheter length	350mm			
Marking	every 5 mm			
Insulating material	PFTE			
Tip length	4 mm			
Tip material	stainless steel AISI316L			
Extension cable length	2.5 m			
Medical device	class IIb			
Product reference	05FIS6F	05FIS7F	05FIS8F	05FIS9F

Equipment

2. Radiofrequency generators

Depending on your medical discipline, you can choose to use either the Rafaelo® or MedRF4000® generator.

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

The MedRF4000® can be used for multiple treatments with radiofrequency energy. It's a smart all-in-one generator to which you can connect all sorts of disposables. Adding a treatment to the device takes a simple software installation.

Both devices are monopolar and generate 4MHz radiofrequency waves which are transmitted to the tip of the connected utensil. The energy application is controlled by a foot pedal.

The generators are easy to use and have pre-set parameters for each treatment. They do not require any special/regular maintenance other than the standard annual PAT testing.

Rafaelo® generator



CE 1304


MedRF4000® generator



CE 1304




For treatment of

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



For treatment of

- Anal fistulas
 - Haemorrhoids
 - Saphenous veins
 - Collateral and perforating veins
 - Telangiectasia
- 
- Plug & play device
 - Touchscreen operated
 - User-friendly interface
 - Time and energy display on tilted screen
 - Foot switch energy control
 - Export of individual procedure settings via USB key



Technical specifications

Rafaelo® generator	
Technology	monopolar RF generator
Output Frequency	4 MHz
Dimensions	W 360mm x D 280mm x H 120mm
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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