

# 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 – utilizing the emission of electromagnetic waves at a 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**



**Dehydration of the tissue**



**Denaturation of proteins**



**Coagulation by thermal destruction**



## Advantages

---



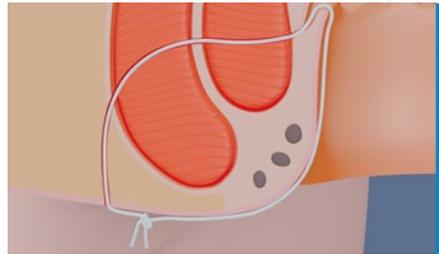
### For the patient

- + 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 risk of fecal 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

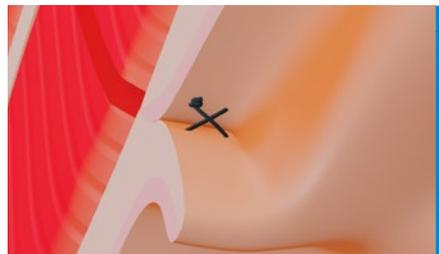
## The Fistura<sup>®</sup> procedure



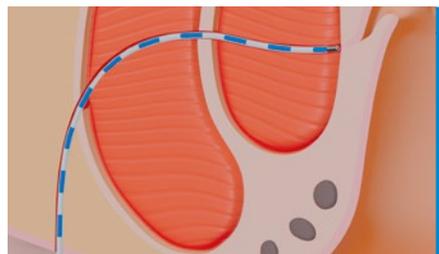
**1** The fistula should be drained prior to surgery using a seton to clean the tract and prevent infection.



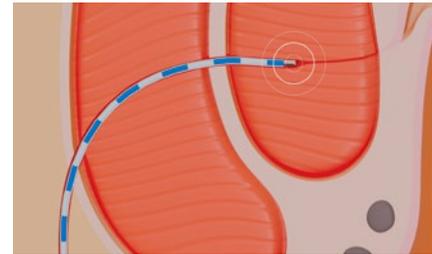
**2** The tract is cleaned using a fistula brush prior to inserting the catheter.



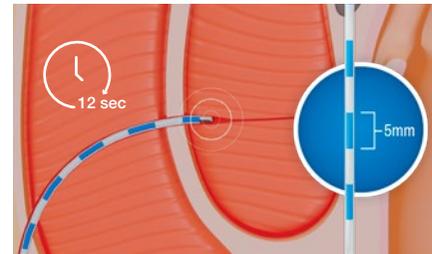
**3** The internal opening of the anal fistula is closed with a cross suture.



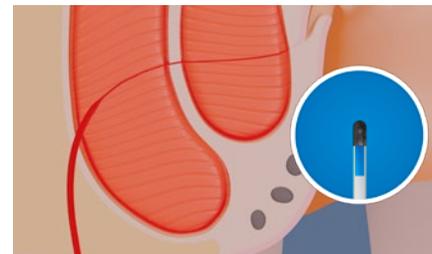
**4** Choose the appropriate sized catheter (6F to 9F) that suits the diameter of the fistula. The catheter is inserted into the anal fistula from the external opening until it reaches the closed internal end.



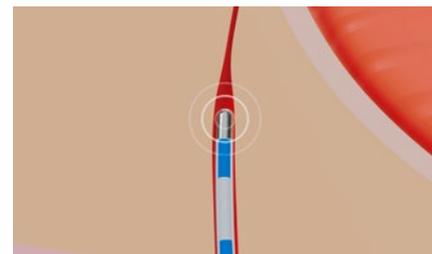
**5** Ensure the correct settings on the device and then press the generator pedal to deliver the power.



**6** Gradually withdraw the catheter, half a centimeter at a time, according to the beeps generated by the device.  $\pm 5$  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.

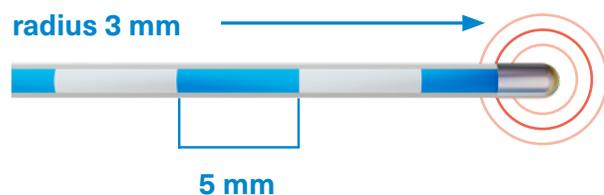
# Equipment

## 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	350 mm			
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 hemorrhoids 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.

Rafaelo® generator



CE 1304

MedRF4000® generator



CE 1304



### For treatment of

- Anal fistulas
- Hemorrhoids



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



### For treatment of

- Anal fistulas
- Hemorrhoids
- 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 fob



## Technical specifications

Rafaello® 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
Classification applied parts	BF type
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)
Classification applied parts	BF type
Weight	± 5 kg
Product REF	00MEDRF4000



**F Care Systems NV (HQ)**

Uitbreidingstraat 42-46  
2600 Antwerp  
BELGIUM

Tel +32 3 451 51 45  
Fax +32 3 451 51 39

**F Care Systems France SARL**

13 bis Av. de La Motte-Picquet  
75007 Paris  
FRANCE

Tel +33 1 78 90 04 93  
Fax +33 1 76 21 90 98  
Mob +33 6 61 07 75 75

**F Care Systems Germany GmbH**

Oberstraße 3  
47829 Krefeld  
GERMANY

Tel +49 2151 4799420  
Fax +49 2151 4799425

**F Care Systems USA LLC**

11098 Biscayne Blvd, Suite 301  
Miami, FL, 33161  
UNITED STATES

Tel +1 786 288 0740  
Mob +1 305 987 1822

