

# Fistura® Procedure for the Treatment of Complex Anal Fistulas

NCT06113068

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Status	RECRUITING
Phase	Not Applicable
Sponsor	F Care Systems NV
Enrollment	50 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Patients with complex fistulas
  - Complex fistulas include trans-sphincteric fistulas involving more than 30% of the external sphincter, supra-sphincteric fistulas, extra-sphincteric fistulas, horseshoe fistulas, fistulas involving multiple tracts (according to the ASCRS) and fistulas with a curved tract or a tract presenting diverticula, for which:
  - Suppuration is described by the patient and/or visible by an opening in the anal margin or by anoscopy Clinical symptoms led to an MRI demonstrating the path Fistula path demonstrated in the acute phase during drainage of an abscess
  - Patient e 18 years at study entry
  - Patients with a previously drained fistula, without diverticula  $\gt 10$  mm, without T2 hyperintensity (assessed by MRI). Drainage is achieved by placing a seton, usually from 10 weeks to 12 months prior to the procedure
- ... and 1 more (see full listing online)

### Exclusion (9)

- Patient  $\lt 18$  years at study entry
  - Patient has a known contraindication to treatment using radiofrequency (infectious anal pathologies, anal fissures, residual Longo anterior treatment staples)
  - Patient has a known contraindication to MRI
  - Simple fistulas defined as inter-sphincteric or trans-sphincteric, involving less than 30% of the total height of the sphincter apparatus (attested by MRI, ASCRS classification)
  - Patient has a fistula associated with radiation and inflammatory bowel disease
- ... and 4 more (see full listing online)

## Locations (1 total)

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CHIREC site Braine l'Alleud-Waterloo, Braine-l'Alleud, Belgium