ENDOFIS, a new medical device for the endoscopic treatment of post-surgical fistulas

DESCRIPTION OF THE TECHNOLOGY

The appearance of a fistula through dehiscence or leakage of the post-surgical anastomosis is one of the most serious complications, which can occur in up to 7% of cases depending on the type of surgery or indication, and is also the main cause of postoperative mortality.

Endoscopic treatment is the first choice in the management of these post-surgical complications, as it is a less invasive and more cost-effective technique than surgical re-intervention. The endoscopic techniques available today are based on mechanical methods, such as clips, covered expandable prostheses, vacuum therapies, vacuum systems or tissue sealants, whose clinical efficacy is low, less than 50%, as technical success is not always achieved for various reasons (poor manoeuvrability, failure in anchorage or migration of the sealing fluid, etc.).

For this reason, a new medical device has been developed as we have a clear unmet need in this field, therefore there is a strong niche market for our biomedical device.

EndoFIS is a class III medical device, biocompatible and biodegradable, which allows a novel combined therapeutic approach, both mechanical and bioactive through a mechanical closure system using a double porous biodegradable balloon, made with a combination of different materials, which allows the closure of the post-surgical fistula by means of a system of approximation and fixation to the wall of the digestive tract around the fistulous orifice (EndoFIS balloon); and another bioactive by release of sealing hydrogels through the pores of the balloon, which can also function as a platform for the release of specific drugs for each patient (EndoFIS gel).

The advantages of this product are unquestionable, as we believe that it will substantially increase the clinical efficacy of the systems currently available, considerably reducing morbidity and mortality and the costs associated with this complication, the incidence of which is increasing given the large increase in surgical procedures, promoting an efficient health and healthcare model by stimulating private investment based on innovation and experimentation.

MARKET APPLICATION SECTORS

The expected sector or area of application for this device is digestive endoscopy for the treatment of post-surgical complications.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

- Easy to use
- It allows a combined mechanical and bioactive therapeutic approach.
- It uses and releases degradable biomaterials.
- The device supports endoscopic closure of post-surgical fistulas.
- It offers a short learning curve.
- It avoids reoperation by sealing the fistulous cavity.

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CURRENT STATE OF DEVELOPMENT

The invention is in TRL 4. The next step will be to generate an industrializable and marketable product when collaboration with other companies and/or entities is established.

INTELLECTUAL PROPERTY RIGHTS

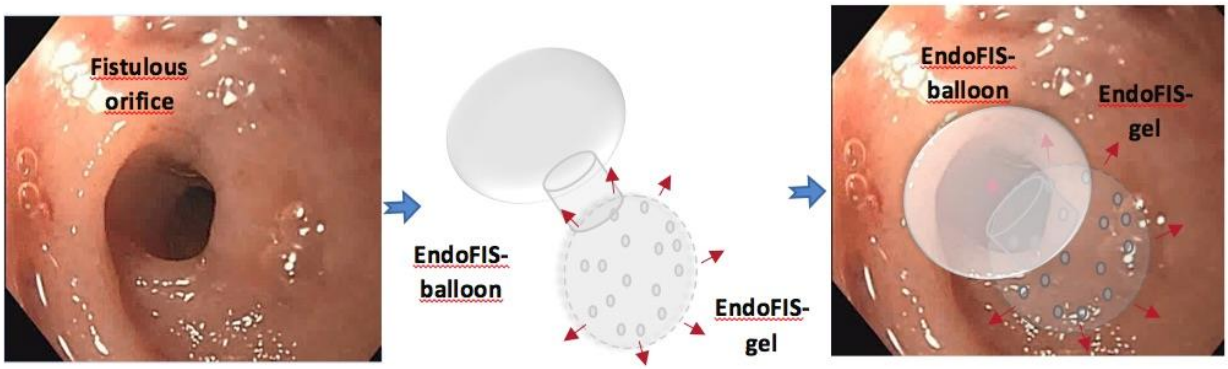
The product, co-owned by IIS La Fe and UPV-CBIT, has been registered as a European Patent with application number EP22382100, and application date February 7, 2022.

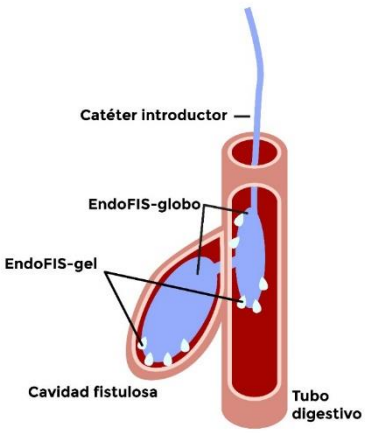
Patent title: "Fistula sealings".

COLABORATION SOUGHT

Companies that manufacture instruments for endoscopic procedures and healthcare institutions to reduce the costs associated with this complication.

RELATED IMAGES





Images 1 and 2. System for endoscopic treatment of post-surgical fistulas.

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