INFORMED CONSENT FORM

Observational clinical study

Efficacy and safety of the Luso-Cor esophageal stent compared to other endoscopic techniques in the management of fistulas and anastomotic dehiscences after upper digestive tract surgery (ES-LCCE-UDFM)

5th March 2025

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Fistulas developing after surgery of the upper digestive tract are associated with high morbidity and a risk of mortality. Although covered or partially covered metallic stents in combination or not with other endoscopic devices are associated with a high success rate in fistula closure, this minimally invasive therapeutic approach is resource-intensive and is not free from adverse events such as stent migration, gastro-esophageal reflux, perforation and aorto-esophageal fistula.

The Luso-Cor® esophgeal stent was designed taking into account the difficulties in the management of digestive fistulas after surgery of the upper digestive tract and the preliminary results with regard to efficacy and reduction of the risk of migration have been very positive.

Several studies have been published highlighting the usefulness of endoscopic vacuum therapy, which high success rate in closing fistulas with a reduction in the rate of adverse events. However, this technique is resource-intensive and sometimes requires prolonged hospitalisation and naso-enteral or parenteral nutrition during the treatment period.

We plan to analyze and compare the efficacy and safety of these main therapeutic approaches to manage fistulas developing after surgery on the upper digestive tract in a national and international observational study.

The decision to participate in this study will depend on the will of the patient and the treating physician as there are no firm recommendations on which type of approach is the most appropriate. The study has a duration of two years. The privacy of the patient and clinical data will always be safeguarded, and there is no possibility of individual identification of patients.

Dr. _____ explained to me the purpose and procedures of the study in which I was invited to participate.

I have read and understood the patient information and informed consent document, and I have been informed about the benefits I may have, and the possible side effects. I also understand that there may be other risks or discomforts that are not yet known.

I grant Dr. _____ permission to inform my general practitioner or other healthcare professional about my participation in this study.

I have had the opportunity to ask questions and to take into account the answers given. I understand that my participation in the program is voluntary and that I can leave the program at any time of my own volition, and if I do, it will not affect the future care and attention I will receive from my doctors.

I know that my consent does not relieve the investigators of their responsibilities and that my legal rights are guaranteed.

I agree to consult my doctor whenever I plan to take other medications, whether or not they are prescribed.

I have received a copy of this informed consent.

_____	_____	_____
Patient's Name	Signature	Date (DD/MM/YYYY)

_____	_____	_____
Doctor's Name	Signature	Date (DD/MM/YYYY)