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SafeHeal starts CE-mark clinical study to replace ostomy

29 January 2018 | News

The study will evaluate safety and efficacy of the Colovac bypass device for ostomy-free anastomosis protection following colorectal surgery

SafeHeal, a leading innovator in the field of digestive surgery and developer of the Colovac device, announces that it has enrolled the first five patients in its CE mark study.

The Colovac device is a unique endoluminal bypass sheath placed in the colon following rectal resection, aimed at significantly improving the recovery of patients after colorectal surgery without the need for an ostomy.

This prospective, single-arm, 15-patient study, was approved at the end of 2017 by the French health authority ANSM.

It aims to evaluate the safety and efficacy of Colovac for the protection of colorectal anastomosis in adult patients initially scheduled to receive a diverting ostomy as per standard of care, following colorectal surgery.

In the study, patients receive a Colovac device in lieu of the ostomy. The study is currently enrolling more patients at two hospitals in France (Strasbourg and Paris).

Based on this early experience, the trial confirms the good usability of the device, its placement and retrieval, in line with preclinical experiments. Colovac was well tolerated by patients.