



Biovision Investor Conference 13-14 APRIL 2016



BIOVISION The World Life Sciences Forum



One line pitch:

SafeHeal develops a digestive anastomosis protection device, designed to reduce complications & obviate the need for ostomies for colectomy patients.

Market Analysis:

About 250000 colectomy patients receive a temporary ostomy every year in Europe and the USA, representing an initial market for SafeHeal of 1 billion €, considering the device could be marketed at an average selling price of 3-5k€. (Colonic stents are sold at 2-3K€ and limited to palliation whereas the SafeHeal device saves an entire 2nd surgery, with associated cost of 5-15K€, while reducing complications, and benefitting from higher patient preference). Moreover, clinician feedback suggested that the device could be applied to other indications, such as esophageal anastomosis, diabetes and obesity, creating growth relays for the company.

Business Proposition:

The device consists of a bypass sleeve, which is designed to isolate the anastomosis from the feces in order to let it heal post-surgery. The device is placed in the digestive tract with its anchoring system proximal to the anastomosis at the time of the colectomy. The anchor, which represents the disruptive innovation in the product, is made of a double-stent which delineates a depression chamber in which a permanent vacuum is pulled, enabling a perfectly safe, non invasive and reversible implantation. A flexible sleeve covers the anastomosis down to the anus. The device is removed manually after 2 weeks during an outpatient visit.

Competitive Advantage:

Many colectomy patients have a temporary ostomy in order to let the anastomosis heal. When the patient is fit again, another surgical operation is performed to takedown the ostomy. The process is debilitating, costly, and prone to frequent complications. The SafeHeal device is meant to enable patients to resume a normal life after surgery, without the need for an ostomy pouch, thereby eliminating incomfort, complications and unnecessary costs compared to the standard of care. Other bypass products have not been adopted in clinical practice due to technical limitations (inefficient or dangerous anchoring, impractical delivery and retrieval).

Investment Attractiveness:

SafeHeal fits an ambitious strategy. It is a breakthrough therapy which addresses one of the if not the largest unmet medical needs in GI surgery. Patients, physicians and payers are searching for better solutions than temporary ostomies. With little technical development and strong IP protection, the company plans to achieve first-in-man in 2016, CE Mark in 2017 and subsequent commercial launch. The product is in perfect strategic alignment with large medtech players, with repeat interest for SafeHeal from major players in the field, including Medtronic, and the potential for a strategic deal or acquisition soon after first-in-man.

IP Situation:

The SafeHeal device is protected by 2 separate patents, one for the whole device and one for the anchoring system. Both patents have been delivered in EU & Japan, are being examined in the USA and are pending in additional geographies: Surgical device for the temporary protection of anastomosis (US20110295288 A1;PCT/FR2010/050210), & Surgical device for controlled anchoring in the intestine (US20140222039 A1;PCT/FR2012/051576). Preliminary analysis by Knobbe Martens is very encouraging from both a Freedom to Operate and patentability standpoints. The inventor is designated as the sole inventor, and the patents have been assigned to SafeHeal.

COMPANY PROFILE

- **Website:**
http://mdstart.eu/pages/portfolio_d/5/safeheal
- **Activity:** MedTech
- **Contact:**
OSDOIT Anne
anne@mdstart.eu
- **Location:**
9 rue du 4 Septembre
75009
France
- **Founded in:** 01/07/2015
- **Employees:** 1
- **Management:**
Hascoët Gérard
Chairman
Osdoit Anne
CEO
- **Financial information (€):**
 - **Company stage:**
Preparing First-In-Man clinical study
 - **Capital raised to date:**
1.7M€
 - **Monthly burn rate:**
70000€
 - **Capital seeking and date:**
4M€, Q4 2016
- **Investors:**
MD Start
- **Referred by:**
Gérard Hascoët