Primary woundhealing in colorectal anastomoses: the Implican Device.

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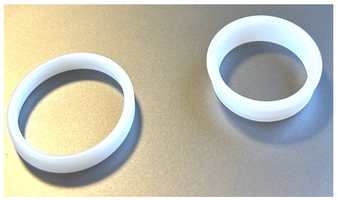
Colorectal surgery continues to struggle with the challenge of anastomotic leakage. In traditional anastomoses, the mucosa is invertedly approximated and perforated multiple times by staples or hand-sewn sutures, often resulting in necrosis and bacterial contamination, leading to secondary wound healing in most cases.

To address this issue, we have developed the Implican Device, a patented technique centered around compression for primary wound healing. The device utilizes two rings—a smaller topring in the afferent colon loop and a larger bottomring in the rectal stump—both in cross section designed in an oval shape. The bowel ends are drawn into a narrow gap between the rings, crushing the bowel wall while leaving only the extracellular collagen fibers of the submucosa intact. A secure snap fit locks the rings, firmly anchoring the strong collagen bowel wall layers. A unique funnel shape at the entry point between the rings facilitates the approximation of uninjured and well-vascularized submucosa and muscularis, promoting primary intent healing.

The device resembles a regular circular stapler and so does the proposed surgical procedure. The bottomring is placed on an applicator that enters the rectal stump, while the topring sits on an 'anvil' that connects to a trocar extending from the applicator. Compression is achieved by turning a wheel on the applicator's base, generating the necessary force through an internal gearbox. After alignment, the anvil is released and pulled inside the applicator, where a circular knife cuts the donut. Once wound healing is complete, the rings naturally disengage from the anastomotic site and exit the bowel after 7 to 10 days.

This device is constructed from stainless steel, making the applicator reusable and therefore sustainable. Preclinical tests in a porcine animal model using the Alpha prototype have demonstrated successful primary wound healing.

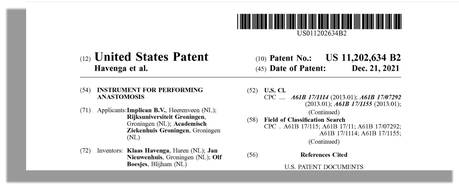
We believe that our approach to primary wound healing in colorectal anastomoses holds significant promise for reducing anastomotic leakage. Moreover, our commitment to sustainability is evident in the reusable design of the device. Anticipating a first-in-human trial next year, we aim to usher in a new era of effective and eco-friendly colorectal surgery.



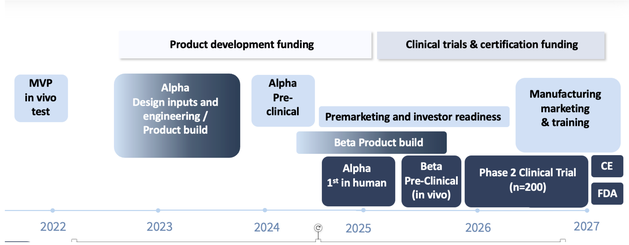
Bottom Ring and Top Ring



Implican Anastomotic Device Alpha Prototype

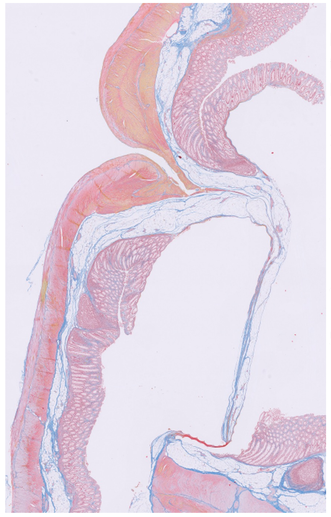


US patent granted



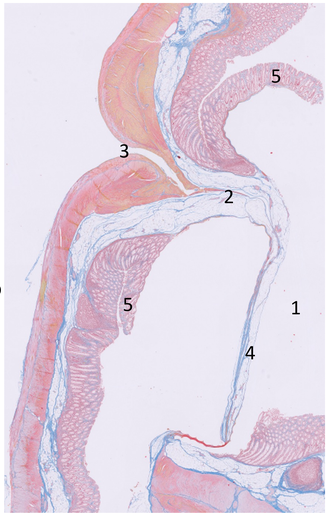


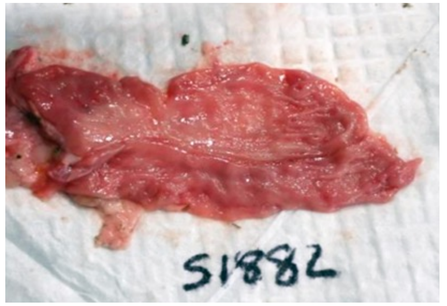
Bowel is approximated | Compression starts, all layers are thinner | Mucosa and muscularis cut by pressure | Only compressed submucosa in space between rings | Rings have clicked, donut is cut



Histological slide after bench testing
MSB (Collagen) staining

1. Lumen of the bowel
2. Approximated layers of submucosa
3. Approximated layers of muscularis (gap is artefact)
4. Collagen fibers held in gap between the rings
5. Stripped off mucosa





Macroscopy of the anastomosis after 16 days



Histologically confirmed primary wound healing



The Implican Team