Advancing BioDynamix™ Anastomosis Technology

Connecting sections of the intestine after the surgical removal of a diseased portion has been the subject of research and invention since the 19th century. Today, BioDynamix™ Anastomosis technology is bringing the goal of natural, biologic healing and durable, stricture-free anastomosis closer to reality.

BIODYNAMIX™
Anastomosis

Natural Healing, Right from the Start™

Setting the Standard for Effective Anastomosis

The ideal anastomosis creates a large patent lumen using a method that facilitates the natural healing process, reduces strictures and adhesions, leaves no permanent foreign elements behind, and preserves the natural tissue structure. Stapling falls short of this ideal because it involves puncturing and crushing tissue, which can lead to excessive inflammation, infection, and leakage. Compression anastomosis – pressing bowel ends together until natural healing creates an anastomosis – represents a closer approach to the ideal. However, it has taken many generations of technology to develop a consistent, effective, easy to use device.

Early Compression Anastomosis Devices

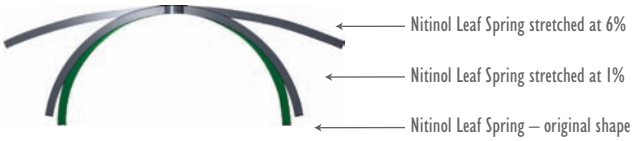
Perhaps the best known early anastomotic device was the Murphy button, developed by John Benjamin Murphy in 1892. The steel Murphy button had two rounded heads mounted on hollow shafts. After the intestinal ends were tied on the shafts, the heads were screwed together to compress the tissue. The Murphy button was believed to result in too tight compression that led to peripheral ischemia and premature necrosis.[1] Further, the central lumen in the device was narrow, which sometimes caused impaction of intestinal content.[2] It could not accommodate different tissue thicknesses and other variations in tissue anatomy and therefore could not ensure a uniform necrotic process.

One hundred years after the Murphy button, the BAR, biofragmentable anastomotic ring, (Sherwood-Davis & Geck, St. Louis, MO) attempted to address the issue of tissue necrosis at the anastomotic site. Its two identical rings have a scalloped shape similar to the Murphy button, but with a 1.5 to 2.5 mm gap between the rings in the closed position to prevent tissue ischemia.[3] As can be surmised by its name, the BAR fragments after a period of time and is expelled from the body. However, the biofragmentation process has been problematic and can cause other postprocedural morbidities, such as bowel obstruction or strictures.[1] Also, the rings cannot accommodate different tissue thicknesses and must be adjusted manually within a range of widths.

Other compression technologies include a magnetic compression device and the AKA-2, a transanal compression ring device for proximal rectal anastomosis, which has limited clinical experience.[1]

The Nitinol Breakthrough

Nitinol, an advanced metal alloy of nickel and titanium, is paving the way for a new generation of anastomosis device. Nitinol exhibits "shape memory," the ability to return to its original shape after being deformed. Nitinol can be elastically deformed far more (up to 8%) than any regular metal (up to 0.5%), and applies a consistent force range as it returns to its original shape.



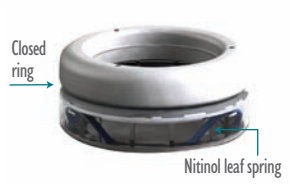
Nitinol's superelasticity allows it to be stretched up to 6% whereas steel can only be stretched up to 0.4%. As a shape memory material, Nitinol also "memorizes" its original shape and can return to it after stretching up to 6%.

NiTi ColonRing™ with BioDynamix™ Anastomosis Technology

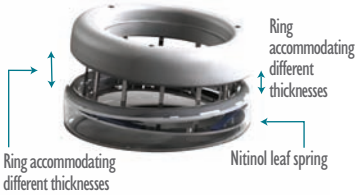
NiTi™ Surgical Solutions has leveraged the features of Nitinol in the ColonRing™ with BioDynamix™ Anastomosis technology. In the ColonRing™, the Nitinol leaf springs stretch to open the ring for placement in the bowel, then gradually return to their original closed position, adapting to variations in tissue thickness and accommodating compressed tissue. The Nitinol leaf springs apply constant force range of pressure around the full circumference of the anastomosis. As the compression progresses over several days, the tissue trapped within the ring becomes necrotic, while healthy tissue is generated along the ring's outer perimeter.

Nitinol Leaf Spring at 6% (Thick Tissue)

Nitinol Leaf Spring at 3% (Thin Tissue)



Nitinol Leaf Spring at 1% (Necrosed Tissue)



During the healing process, each Nitinol Leaf Spring adapts to variances in tissue thickness while still exerting the same force range.

Constancy of Force – The exclusive Nitinol leaf springs within the ring provide the means to constant force regardless of extent to which the alloy is stretched.

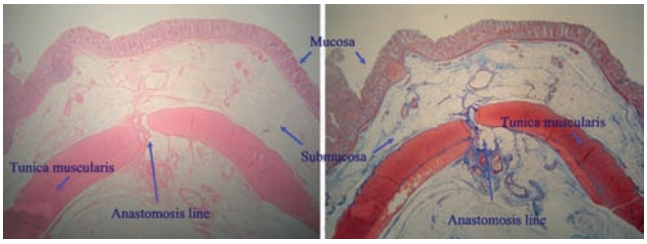
Optimal Anastomotic Outcomes

ColonRing™ with BioDynamix™ Anastomosis technology has resulted in optimal anastomotic outcomes:

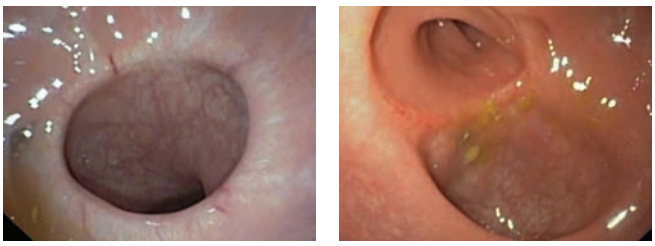
- Full recovery of multi-layer bowel structure
- Full circumferential, hemostatic sealed anastomosis
- Time zero anastomotic burst strength up to three times stronger than circular staplers
- Preservation of natural lumen size
- Creation of a seamless anastomotic line with no anastomotic lip

In human trials and clinical practice, BioDynamix™ Anastomosis technology has shown the potential to provide durable, stricture-free anastomosis with minimal complications. In animal studies, histologic examination of resected anastomoses showed early reepithelialization of the mucosa and a uniform anastomosis showing full recovery to the natural multi-layer tissue structure without scar formation.[4] Colonoscopic examination at six months demonstrated a satisfactory anastomosis.[5]

NiTi™ Surgical Solutions is committed to advancing BioDynamix™ Anastomosis to provide surgeons with a safer, more effective, and easier method of addressing the challenges of gastrointestinal surgery.



Histology of anastomosis with ColonRing™ shows smooth anastomotic healing and full recovery of the multi-layer bowel structure



End-to-end (left) and end-to-side (right) anastomoses 3 months post surgery.
Images courtesy of Prof. André Jan Louis D'Hoore Clinical Head of the Department of Abdominal Surgery, University Clinics Gasthuisberg, Belgium

BIODYNAMIX™ Anastomosis

Natural Healing, Right from the Start™

REFERENCES

1. Kopelman, D. Compression anastomosis, the optimal hollow viscus anastomosis: are we there yet? Expert Rev Med Devices. 2007. 4(4):423-425.

2. Zederfeldt B, Jiborn H, Ekelund G. Sutureless colonic anastomoses. Langenbecks Arch Chir.1990. 375:181-185.

3. Aggarwal, R and Darzi, A. Compression Anastomosis Revisited. J Am Coll Surg. 2005. 201(6):965-971.

4. Nudelman, IL, et al. Gastrointestinal anastomosis with the nickel-titanium double ring. World J Surg. 2000. 24:874-877.

5. Nudelman, IL, et al. A nickel-titanium memory-shaped device for colonic anastomosis in laparoscopic surgery. Surg Endosc. 2004. 18:1085-1089.

NiTi™ Surgical Solutions

The BioDynamix™ of Natural Healing

www.nitisurgical.com

CE