

ColonRing™ with BioDynamix™ Anastomosis Technology

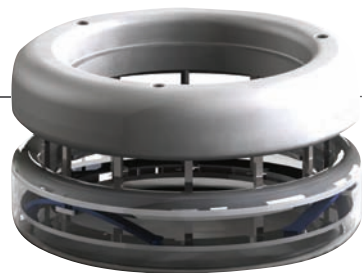
A Guide for Health Care Institutions



What is BioDynamix™ Anastomosis?

BioDynamix™ Anastomosis, the next generation of closure technology for colorectal surgery, involves applying consistent compression to sections of the intestine after surgery in order to promote complete and natural healing. Used in the ColonRing™, BioDynamix™ Anastomosis satisfies several important clinical goals: creating a large patent lumen, minimizing strictures and adhesions, leaving no permanent foreign body behind, and preserving the natural tissue structure.

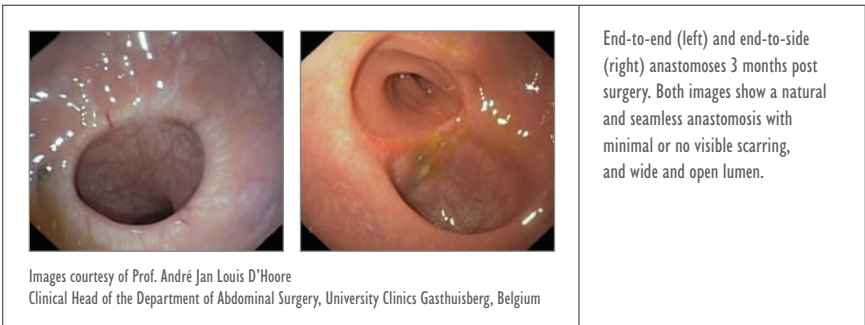
**ColonRing™ with
BioDynamix™ Anastomosis**



How does ColonRing™ improve on existing surgical standards?

The current surgical standard for reconnecting the resected bowel involves surgical staples and stapling devices, which can crush and puncture tissue and cause adhesions. Stapling hinders the natural healing process and the natural structure of the resected bowel, potentially resulting in a number of adverse effects including leakage, inflammation, infection, and bleeding. Surgical staples, being permanent implants, leave a foreign material within the body. The bowel is often left with a reduced lumen size. Further, multiple circular stapler sizes must be stocked to address specific sizing issues.

ColonRing™ with BioDynamix™ Anastomosis technology addresses each of these drawbacks. The ring creates no through bowel wall punctures, allowing natural healing to occur in an aseptic environment and potentially minimizing strictures. It has the potential to reduce adverse events such as leakage, inflammation, infection, and bleeding. It leaves no permanent foreign material in the body. Studies have demonstrated that ColonRing™ preserves full lumen size. Only one size is needed for anastomosis of the intestine, so stocking of multiple sizes is unnecessary. Unlike stapling devices, the ColonRing™ applicator is not withdrawn from the body through the newly created anastomosis. This eliminates the potential for trauma to the anastomosis site.



How did NiTi overcome the engineering challenges found in previous anastomosis devices?

Early anastomosis devices used steel, other non-elastic metals, or biodegradable materials that did not effectively accommodate variations in tissue thickness. This led to peripheral ischemia and an uneven necrotic process.

The ColonRing™ incorporates Nitinol, an advanced metal alloy that exhibits “shape memory,” the ability to return to its original shape after being deformed. In addition, it applies a consistent force range as it returns to its original shape. In the ColonRing™, Nitinol leaf springs stretch to open the ring. After the ring is set during surgery, it gradually returns to its original closed position, adapting to variations in tissue thickness and accommodating compressed tissue. The Nitinol leaf springs apply a constant force range of pressure around the full circumference of the anastomosis. The result is a full circumferential, hemostatic sealed anastomosis.

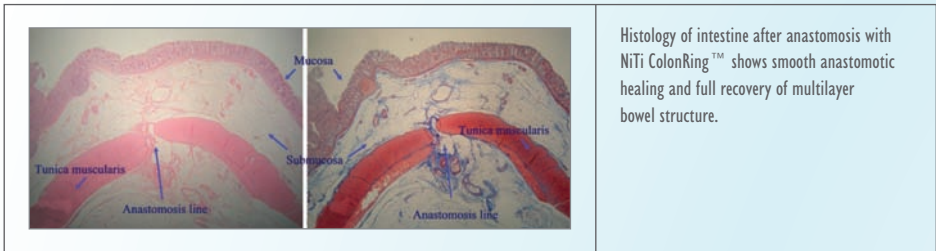
What clinical data is available for ColonRing™?

The safety and efficacy of the ColonRing™ have been demonstrated in pre-clinical and clinical trials and in commercial use, including a meta-analysis of over 1,200 cases in North America, Europe, South Africa, and Israel. This analysis showed that successful anastomosis was independent of distance from the anal verge, as well as patient age, sex, and BMI, and concluded that the ColonRing™ has the potential to provide durable, stricture-free anastomosis with minimal complications for a broad range of patients.

ColonRing™ was shown to be efficacious even in the most challenging low and chemo-radiated cases. In the meta-analysis, 30% of procedures (n=147) were performed at 10 cm or less from the anal verge. Of these 40 involved chemo-radiated patients. Efficacy in these cases was equal to that seen in higher cases.

Pre-clinical and clinical data also show that ColonRing™ provides:

- 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



Is ColonRing™ easy for the surgeon to learn?

ColonRing™ is deployed with a device very similar to that used for circular staplers, designed to minimize the surgeon's learning curve. It is intuitive to use and easy to teach. In the meta-analysis, 75% of surgeons rated the device very easy or easy to use.

EASE OF USE	
Very Easy	33%
Easy	42%
Fairly Easy	25%
Difficult	0%
Very Difficult	0%

How will ColonRing™ benefit patients?

ColonRing™ has the potential to reduce post-operative leaks and strictures while eliminating staple line bleeding. This may contribute to a shorter hospital stay, earlier return to natural body function, and overall cost savings. Use of the device provides the patient with the largest end-to-end anastomosis lumen possible and maintains the natural lumen size of the bowel. Once the natural healing process is complete, the ColonRing™ is expelled, leaving behind no permanent foreign material.

Can my institution benefit from highlighting this new technology to the patients and community we serve?

Many institutions have begun or are beginning targeted public relations efforts to make the public aware that they are offering this advanced technology. NiTi has also prepared press releases, fact sheets, product and procedure B-roll, and photography for use by your institution in highlighting this important advancement. In addition, NiTi has created a patient brochure that assists the surgeon in explaining the procedure to the patient. Finally, NiTi maintains an archive of institutions' public relations efforts available for your review.

What are the economics of ColonRing™ with BioDynamix™ Anastomosis?

ColonRing™ is designed to minimize the high costs associated with the complications of circular staplers, including leakage, inflammation, infection, and bleeding. However, the institutional cost remains only slightly advanced over current circular staplers. Long-term economic impact studies have not been conducted.

NiTi ColonRing™ and Applier



FEATURES

POTENTIAL BENEFITS

Promotes natural healing	Recovery of natural multi-layer bowel structure
Circumferential, hemostatic seal	Aseptic healing environment, seamless anastomosis
Exclusive Nitinol leaf springs	Accommodate varying tissue thicknesses
No staples	No through bowel wall puncture or staple line bleeding
No permanent foreign body	No foreign body reaction, largest end-to-end lumen attainable
Standard surgical technique	Easy to use
Perfect anastomotic index	Full lumen capacity within 8-12 weeks
Open and laparoscopic procedure	End-to-end and end-to-side anastomosis
One size	Reduced inventory by replacing up to 7 competitive sizes

ORDERING INFORMATION: CAR™ 27 (ColonRing™) Box of 3

U.S Customer Service:
866-295-7125

International Customer Service:
+972-9-860-3030
cs-int@nitisurgical.com

NiTi Surgical Solutions
17295 Chesterfield Airport Rd.
Suite 200
Chesterfield, MO 63005
Fax: 636-532-4049
Office: 636-532-4048
Email: cs-us@nitisurgical.com



www.nitisurgical.com



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