

BIODYNAMIX™
Anastomosis with **ColonRing™**

Natural Healing, Right from the Start



NITI™
Surgical Solutions

The BioDynamix® of Natural Healing

Right from the Start

ColonRing™ with BioDynamix™ Anastomosis, the next generation of closure technology for colorectal surgery, harnesses the body's natural healing properties to improve anastomotic outcomes:

- Staple-free and no intraluminal foreign body left behind
- Produces a seamless anastomotic line
- Accommodates and automatically compensates for varying tissue thickness
- Produces a stented and hemostatic time zero anastomosis

ColonRing™ produces compression with a consistent force range to create a seamless, staple-free anastomosis that preserves the natural tissue structure.



ColonRing™ with BioDynamix™ Anastomosis Technology

Natural Healing

The unique compression characteristics of ColonRing™ with BioDynamix™ Anastomosis facilitate the immediate onset of natural healing.

During the healing period, the tissue that is compressed within the ring becomes necrotic. At the same time, the natural healing process generates healthy tissue along the ring's outer perimeter to provide secure new connections. The necrotic tissue and the ring detach within two weeks, safely pass through the digestive tract and are expelled. The natural lumen size is preserved and anastomosis is seamless.



Efficacy Throughout the Colon, Even in the Lowest Cases

ColonRing™ has been proven effective throughout the colon, from 2 cm to more than 50 cm from the anal verge.



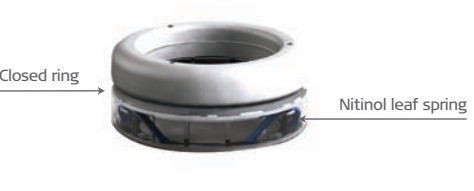
- Used in commercial practice and clinical trials worldwide
- Meta-analysis of data showed anastomosis success was independent of distance from the anal verge, as well as patient age, sex, and BMI
- ColonRing™ has been used at < 10 cm and in chemo-radiated patients with efficacy equal to that in higher cases
- Surgeons overwhelmingly reported that ColonRing™ was easy to use in low cases
 - Unlike stapling devices, the ColonRing™ applicator is not withdrawn through the anastomotic site, eliminating the potential for trauma to the anastomosis

Right from the Start

The Nitinol Advantage

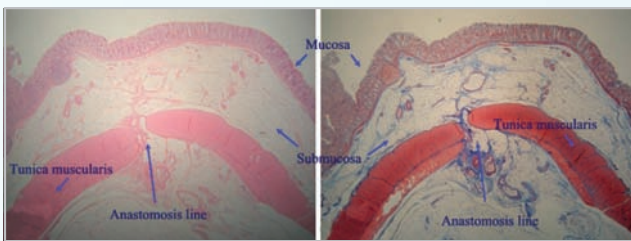
Nitinol, an advanced metal alloy of nickel and titanium, is the technological advance that makes BioDynamix™ Anastomosis possible. Nitinol exhibits “shape memory,” the ability to return to its original shape after being deformed. Nitinol can be elastically deformed far more (up to 6%) than any regular metal (up to 0.5%), and applies a consistent force range as it returns to its original shape.

How ColonRing™ with Nitinol Works

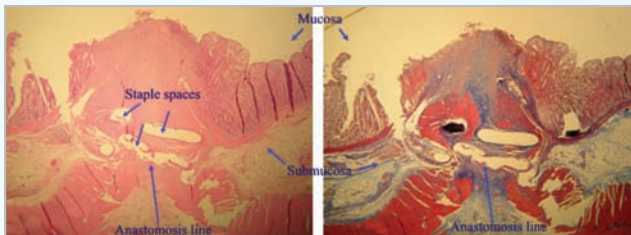
 <p>Open ring</p> <p>Nitinol leaf spring</p>	<p>When placed on the applier, the Nitinol leaf springs in the ColonRing™ flatten to open the ring, accommodating varying thicknesses of tissue.</p>
 <p>Ring accommodating different thicknesses</p> <p>Ring accommodating different thicknesses</p> <p>Nitinol leaf spring</p>	<p>During the healing process, each Nitinol leaf spring gradually returns to its closed position, adapting to variations in tissue thickness while still exerting the same force range.</p>
 <p>Closed ring</p> <p>Nitinol leaf spring</p>	<p>The Nitinol leaf springs continue the process of returning to their original shape and the ring gradually closes. As the compression progresses, the tissue trapped within the ring becomes necrotic, while healthy tissue is generated along the ring's outer perimeter.</p>

Clinical and Preclinical Results

Full Recovery of Multi-layer Bowel Structure



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



B. Histology of surgical staples shows inconsistent anastomotic line

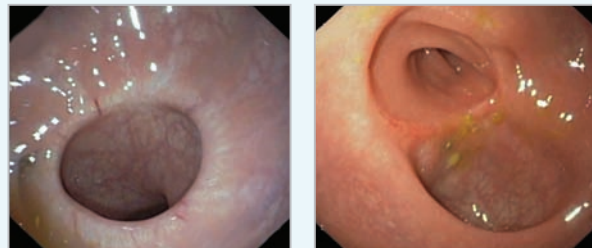
Preservation of Natural Lumen Size

Anastomotic index measurements with intraluminal contrast three weeks post rectal resection and anastomosis using the ColonRing™. Within three weeks after the anastomosis was performed, the index reached nearly one.



Seamless Anastomotic Line

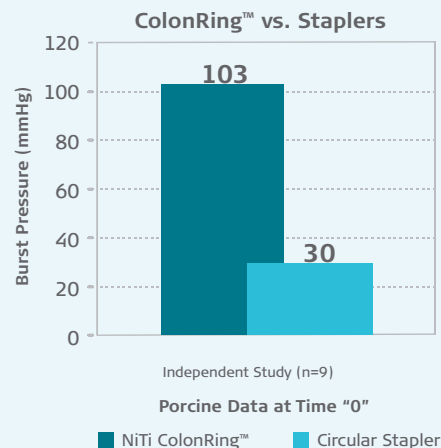
End-to-end (left) and end-to-side (right) anastomoses 3 months post surgery. Both images show a natural and seamless anastomosis with minimal or no visible scarring, and wide and open lumen.



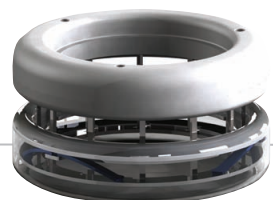
Images courtesy of Prof. André Jan Louis D'Hoore
Clinical Head of the Department of Abdominal Surgery,
University Clinics Gasthuisberg, Belgium

Increased Anastomotic Strength

ColonRing™ provides a time zero burst strength that is up to three times stronger than circular stapled anastomosis.



ColonRing™ with BioDynamix™ Anastomosis Technology



ColonRing™



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	Accommodates 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

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