

DISCOVER A **NEW PATH** to Intestinal Therapy

The world's newest endolumenal accessory that ensures complete positioning of an endoscope in the large intestine and assists with optical visualization, diagnosis, and endoscopic treatment

DiLumen

Endolumenal Interventional Platform

DEFINING A NEW ERA in Intestinal Therapy

DiLumen™ Endolumenal Interventional Platform



While most screened patients are disease free or may have a minor procedure at the time of screening, others receive a diagnosis that requires additional intervention including surgery. While relatively safe, surgery involves the use of general anesthesia, abdominal incisions and often the removal of a portion of colon. Such interventions generally require a hospital stay of four to six days and over a month of recovery. In addition, potential complications resulting from wound infection or anastomotic leaks can result in much longer hospital stays and recovery times. These factors also may increase the costs of care significantly and result in lost productivity for the patient.

Depending on the diagnosis and the patients access to an appropriately trained clinician, some of these conditions can be treated through endoscopic procedures that may not require general anesthesia or abdominal incisions. However, these procedures can be very difficult to perform and can involve multiple colonoscopies to achieve an acceptable outcome.

DiLumen was designed to address the difficulties of endoscopic therapy procedures by:

- Stabilizing the tip of the endoscope in relation to the intestinal wall.
- Creating a Therapeutic Zone™ inside the intestine that provides improved visualization.
- Manipulating the colon wall to enhance access for treatment

DILUMEN CLINICAL OBJECTIVES

- Improved Patient Outcomes and Satisfaction
- Reduced Complications and Shorter Hospital Stays
- Lower Costs Across to the Healthcare System

SURGICAL TREATMENT	ENDOLUMENAL TREATMENT
Operating Room	Operating Room or GI Suite
Colon Resection	Typically preserves colon
Open or laparoscopic incisions	No incisions
Hospital stay of 4-7 days	Typically go home same day or next day
Recovery of 4-6 weeks	Typical recovery of 1-2 days
Possible stoma	Stoma very unlikely
Potential for complications: <ul style="list-style-type: none"> • Wound infection (5%-30%) • Anastomotic leaks (3%-24%) 	Potential for Complications: <ul style="list-style-type: none"> • Perforation • Infection • Bleeding
Cost of surgery (MS-DRG) <ul style="list-style-type: none"> • \$10,000 with no complications • \$15,000-30,000 with minor to major complications 	Cost of Endolumenal Treatment (MS-DRG) \$1,000-\$8,000



DiLumen™ EIP consists of a soft flexible sheath that fits over standard and small diameter colonoscopes. The platform employs two balloons, one behind the bending section of the colonoscope and the second in front of the tip of the colonoscope. When both balloons are deployed, and inflated the area in between is stabilized. This Therapeutic Zone (TZ) facilitates stabilization, insufflation and manipulation of the tissue thus allowing the clinician to more effectively treat the target area. Once the therapy is completed the balloons are simply deflated and removed along with the colonoscope.

The potential of DiLumen™:

- By holding the scope head in place, slippage and loss of scope position is greatly reduced
- Occlusion of the colon segment by the balloons may reduce the occurrence of effluent migrating into the therapeutic area.
- Insufflation and suctioning is limited to the area of the TZ, therefore reducing the time necessary to reinsufflate.
- The balloons grip the wall of the colon and the pushrods can be advanced or retracted to flatten folds or move tissue closer to scope tip.
- Balloons may be inflated and deflated quickly and independently allowing for a wide variety of potential maneuvers to manipulate tissue or reposition instruments.

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Product Codes & Specifications

DILUMEN™ ENDOLUMENAL INTERVENTIONAL PLATFORM (EIP)

D-1000-5	DiLumen™ EIP 168cm working length (5 units/box)
D-1000-1	DiLumen™ EIP 168cm working length (1 unit/box)
D-1001-5	DiLumen™ EIP 130cm working length (5 units/box)(Short)
D-1001-1	DiLumen™ EIP 130cm working length (1 units/box)(Short)
D-1002-5	DiLumen™ EIP 103cm working length (5 units/box)(X-Short)
D-1002-1	DiLumen™ EIP 103cm working length (1 units/box)(X-Short)



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