



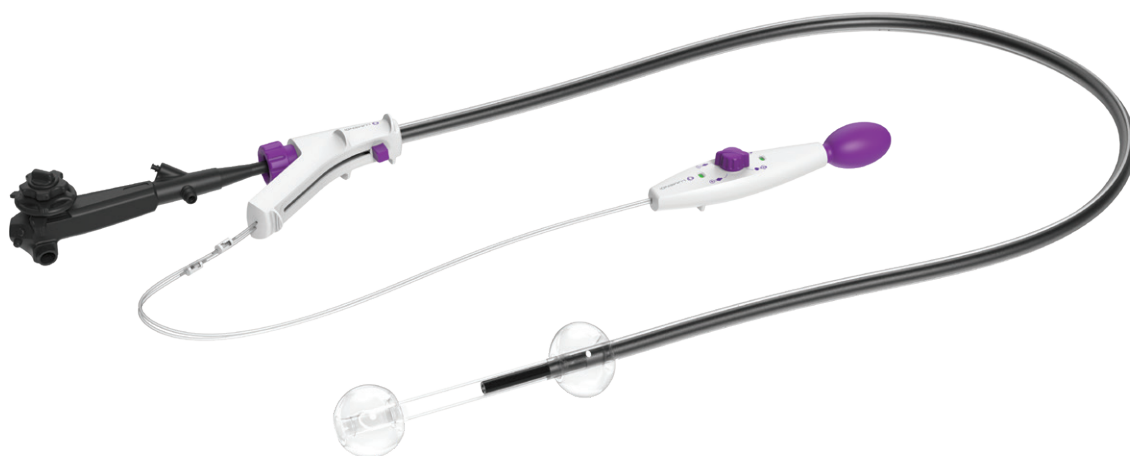
DISCOVER A NEW PATH to Treating Complex Polyps

Getting there is half the battle, and staying in place once you are is the other half. DiLumen™ is a unique endoscopic accessory that assists clinicians during difficult and Complex Polypectomy procedures.

DiLumen[™]
Endolumenal Interventional Platform

DEFINING A NEW ERA in Treatment of Complex Polyps

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. Though 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 may also increase the costs of care significantly and result in loss of productivity for the patient.

With access to an appropriately trained clinician, some of these conditions can be treated through endoscopic procedures rather than surgery. However, patients with difficult anatomy, large polyps on folds, or flexures in the cecum, present challenges that may be difficult to overcome.

Factors like:

- Stability of the endoscope and colon segment can always be a challenge.
- Poor visualization can inhibit progress during the procedure.
- These and other challenges can result in long, arduous procedures and inadequate resections.

**DiLumen™ was designed to address the difficulties
of complex polypectomy procedures**

DiLumen™EIP consists of a soft flexible sheath that fits over standard and small diameter endoscopes. The platform employs two balloons, one behind the bending section of the endoscope and the second in front of the tip of the endoscope. 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 endoscope.



Complex Polypectomy Benefits

Superior manipulation of colon

- Aids in colon straightening and shortening
- Navigate challenging sections of the colon
- Easier access to lesions
- Reduce fatigue from excess torque and manipulation of endoscope

Stabilization of the endoscope tip in relation to the intestinal wall

- Therapeutic Zone™ (TZ) stabilizes colon, endoscope, and tools
- Better control of endoscope, tools, and tissue

Conduit to therapeutic site

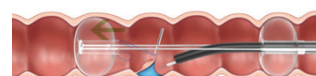
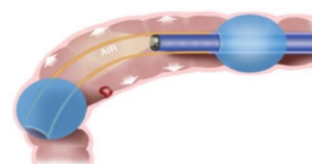
- Scope exchange without loss of position
- Instrument stabilization and exchange, when necessary
- Quick return to the therapeutic site

Visualization is enhanced, especially around flexures and folds

- Manipulation of colon wall and improved positioning of lesions
- Facilitate defect closure
- Expose polyps hidden behind folds

Dynamic retraction of mucosal tissue during procedures

- New suture loops enhance visualization of mucosal planes with Dynamic Retraction +DR™ capabilities



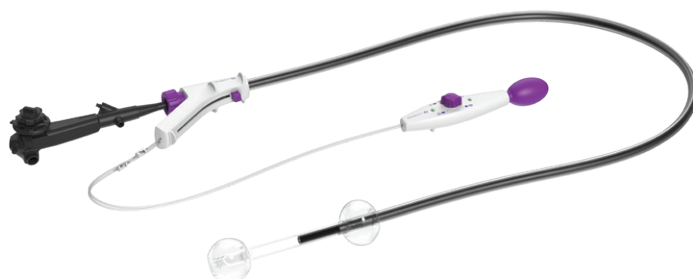
DiLumen™

Endolumenal Interventional Platform

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™ CLINICAL OBJECTIVES

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



Product Codes & Specifications

DILUMEN™ ENDOLUMENAL INTERVENTIONAL PLATFORM (EIP)

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



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