

Lumendi Redefining Intestinal Therapy

For Mrs. Jefferson, life was moving at a brisk pace. A retired schoolteacher, she was enjoying her life by traveling to exotic landscapes and climbing rocky mountains. However, her life came to a sudden standstill when she was diagnosed with a large polyp during a routine colonoscopy. The clinicians informed her that surgery was necessary to remove a section of her colon that included the polyp, and being an outdoor person, she didn't like the prospect of a surgical intervention. The energetic Mrs. Jefferson was concerned that the projected recovery from surgery would prevent her from enjoying a good portion of the summer. And this started her endeavor to find an alternative. After a relentless pursuit, she found a solution: a clinician in a nearby city could remove the polyp while preserving her colon without surgery—an endoluminal interventional therapy using Lumendi's DiLumen, an accessory to an endoscope, which ensures the accurate positioning of an endoscope in the large intestine and enhances optical visualization. The procedure enabled the treatment of intestinal diseases through the anus rather than through surgical incisions and resulted in an overnight stay and a return to normal activity for Mrs. Jefferson after a couple of days.



Eric Coolidge



Lucky for Mrs. Jefferson, she found a better alternative; but for the estimated 50,000 patients who are diagnosed with benign polyps in the U.S. every year, surgery is their only option. Over the last 15 years, the issue of removing large and complex polyps has plagued the industry. It is difficult to remove them during colonoscopy screening, and clinicians have to schedule advanced procedural surgeries to do so. Moreover, these large polyps occur in a place where it is difficult to access them due to the location or size. Over the years, many tools have been developed and used through the working channels of the colonoscope, but they have not addressed the issue of stability within the colon. Through its DiLumen Endoluminal Interventional Platform (EIP) device, Lumendi is changing this paradigm. Offered as a novel and innovative accessory to an endoscope, this device can facilitate endoluminal therapeutic procedures that otherwise require laparoscopic or open surgery of the colon. "Endolumenal treatment allows patients to leave the hospital either the same day or after a one night stay and immediately return to normal activity, rather than six to eight days and a month recovery. The associated complications generally are also much less," says Eric Coolidge, VP, Marketing, Lumendi.

Stabilizing Scopes. Avoiding Surgeries.

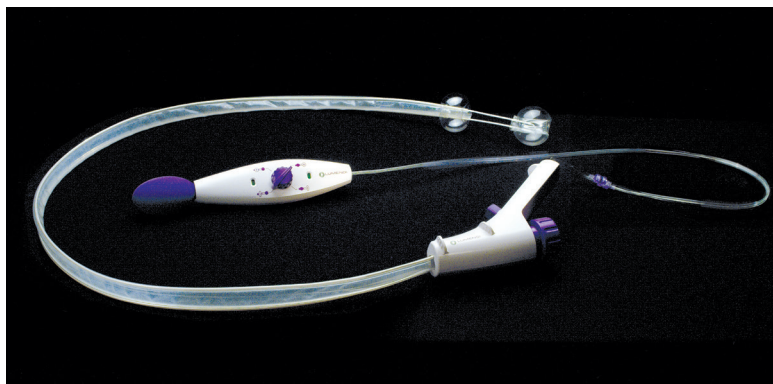
The DiLumen Endolumenal Interventional Platform is a one-time-use accessory that fits over traditional endoscopes and assists with various endoscopic procedures of the large intestine. The product provides stability when visualizing, diagnosing, and treating conditions within the large intestine. It consists of a soft, flexible sheath that fits over standard and small diameter colonoscopes. Coolidge explains that DiLumen works by inflating two balloons

that have the capability to anchor themselves in the lumen of the large intestine. While one of the balloons is positioned ahead of the distal tip of the endoscope, the other part is located behind the tip of the endoscope. Furthermore, the two balloons are attached to each other through two flexible rods, which do not inhibit the endoscope's tip and are still free to move around mostly unimpeded.

This Therapeutic Zone (TZ) facilitates the stabilization, insufflation, and the manipulation of the tissue thus allowing the clinician to treat the target area more effectively. Once the therapy is completed, the balloons are simply deflated and removed along with the colonoscope.

Innovation is the Name of the Game

The central idea behind the development and the delivery of the DiLumen device is to provide endoscopic stability such that it becomes a possibility for clinicians to avoid certain GI surgeries. "The DiLumen device transitions the procedure from the operating room into the endo-lab where it can be performed by an advanced endoscopist," mentions Coolidge. "We have also developed enhancements to the DiLumen, such as attaching suture loops to the fore balloon assembly that can then be attached to the polyp via homeostasis clips. The fore balloon assembly can then be pushed forward to lift the edge of the polyp and provide greater access during dissection."



The other product that Lumendi is working on is DiLumen C². The device, much like its predecessor, consists of a soft, flexible sheath that fits over standard- and small-diameter colonoscopes and employs two balloons, one behind the bending section of the endoscope and the second in front of the tip. When both balloons are deployed and inflated, the area in between is stabilized. In addition, DiLumen C² employs two 6mm working channels at the 3 and 9 o'clock position of the endoscope. These working channels accommodate the DiLumen Ig grasper, and the DiLumen Is scissor. The DiLumen C² is designed to improve stability and manipulation of the tissue in the rectum and colon during complex procedures, such as Endoscopic Submucosal Dissection (ESD). "ESD continues to be a challenging procedure to learn and adapt for clinicians.

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However, many of the current limitations of ESD can be overcome with DiLumen C² and instruments," says Coolidge. "We are planning to launch the DiLumen C² in 2019."

A Stable Future

The main reason behind the relentless success that Lumendi has achieved since its inception in December 2014 is that the company is backed by years of experience and expertise in the GI therapy arena. Further, Lumendi also holds a worldwide exclusive license to certain intellectual property developed by Minimally Invasive New Technologies (MINT), a joint program of the Weill Cornell Medical College and the NewYork-Presbyterian Hospital.

In addition, the company partners with leaders in healthcare to understand their needs and that of their patients, and works to develop new solutions that will improve their lives, and moving forward builds on the same vision. "We recently received our CE mark, which allows us to market the DiLumen EIP in the EU, and have also started performing procedures there," informs Coolidge. "We have representatives in several of the largest EU countries and will soon add Germany and Spain, which will put us in a stronger position in 2019 to conquer the global turf." 