

ENDOLUMENAL SURGERY

DEFINING A NEW ERA IN DIGESTIVE DISEASE CARE

— **NewYork-Presbyterian**
— Weill Cornell Medical Center

Minimally Invasive
New Technologies Program



Weill Cornell Medical College

Defining a New Era in Digestive Disease Care.

endolumenal surgery [en" dō-loo'mīn-əl sərj(ə)rē] *noun*:

performing surgery INSIDE the intestine.

The goals?

- dramatically improve patient outcomes
- improve safety

AND

- lower costs

Introduction

Throughout the past few centuries, medical discoveries have led to dramatic improvements in patient care, from the introduction of smallpox vaccination to the discovery of penicillin. Surgical breakthroughs have also led to quantum leaps in medical care, with major advances like antiseptic techniques and general anesthesia. Open heart procedures and heart-lung machines have recently transformed heart disease treatment. And today, many patients with coronary heart disease are treated using endovascular methods and drug-eluting stents, reducing a week-long hospital stay to one day.

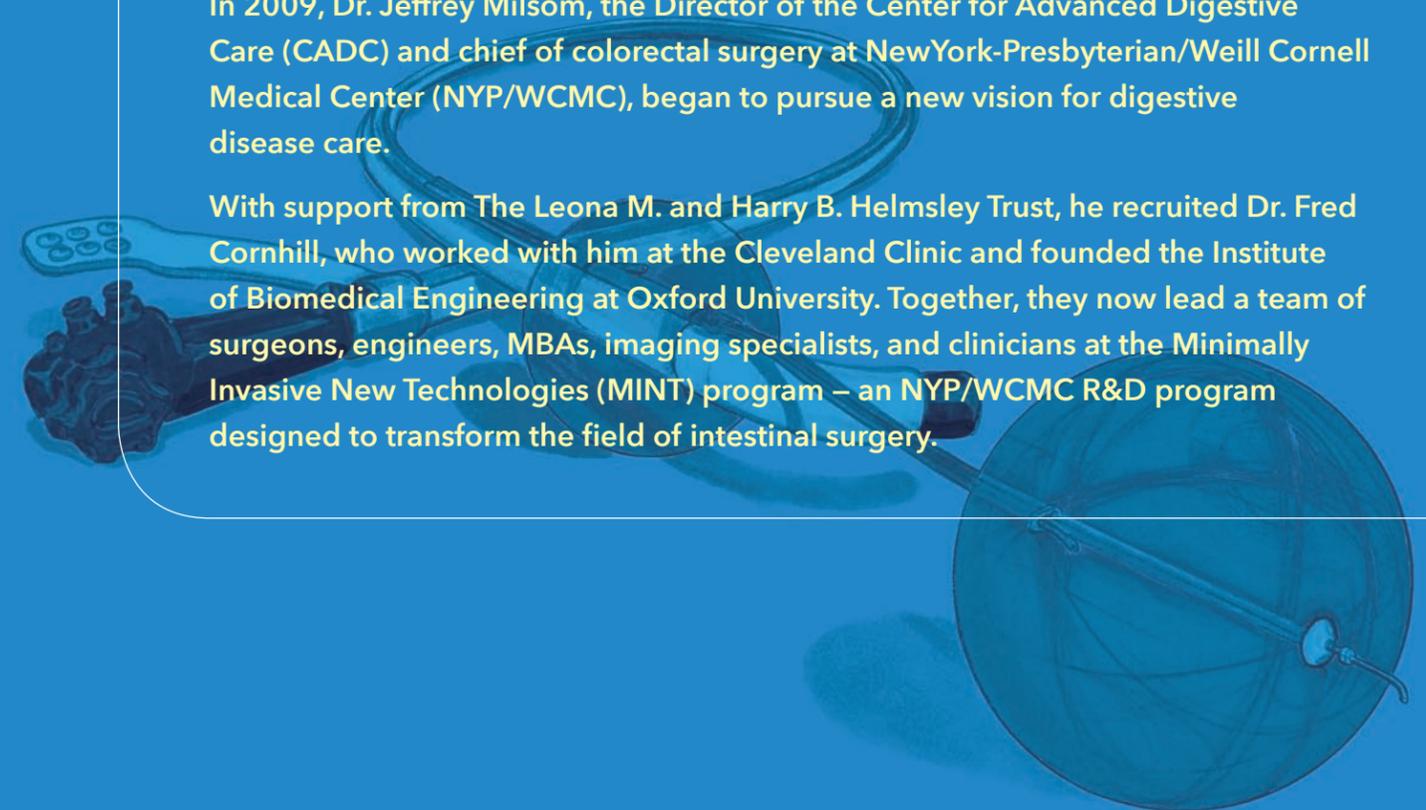
Digestive disease surgery has not progressed as dramatically as other surgical fields. Gastrointestinal surgeons still use a "cut out a piece of intestine and sew it back together" approach to eradicating disease. The use of flexible endoscopes and laparoscopic procedures are major technical advances, but the field thus far has been defined by open surgical procedures.

Why?

Because the endolumenal procedures and tools do not exist...yet.

In 2009, Dr. Jeffrey Milsom, the Director of the Center for Advanced Digestive Care (CADC) and chief of colorectal surgery at NewYork-Presbyterian/Weill Cornell Medical Center (NYP/WCMC), began to pursue a new vision for digestive disease care.

With support from The Leona M. and Harry B. Helmsley Trust, he recruited Dr. Fred Cornhill, who worked with him at the Cleveland Clinic and founded the Institute of Biomedical Engineering at Oxford University. Together, they now lead a team of surgeons, engineers, MBAs, imaging specialists, and clinicians at the Minimally Invasive New Technologies (MINT) program – an NYP/WCMC R&D program designed to transform the field of intestinal surgery.



Digestive Disease is a Global Health Challenge.

- Digestive diseases account for 72 million physician visits and 4.6 million hospital admissions in the U.S. annually.
- Colorectal cancer is the leading cause of death from digestive disease, with more than 145,000 new cases detected nationwide and more than a million worldwide each year.
- Each year in the U.S., more than 100,000 patients undergo open surgical procedures to remove complex intestinal polyps.
- Up to 40% of all polyps (precancerous growths) are missed during standard colonoscopies.

Need for a New Approach

Digestive disease becomes prevalent in patients after the age of 50 and increases rapidly in men and women after age 65. As the population ages, the cost of providing good care is also increasing.

Virtually all digestive disease surgery is performed in the hospital and involves incisions. Intestinal surgery requires general anesthesia and a lengthy hospital stay: five to seven days for laparoscopic procedures and seven to 10 days for open surgery.

Surgical implications must also be considered. Many older patients cannot undergo general anesthesia and are at higher risk for complications. Any surgery can result in infections, which can increase medical risk and financial cost for patients and the health care system.

Dr. Milsom and his CADC colleagues have developed a number of surgical procedures that are addressing these issues and leading to a new paradigm of care. But to redefine digestive disease surgery, the entire procedure must be performed within the channel of the intestine.

To accomplish this, Dr. Milsom, Dr. Cornhill, and the MINT team have developed the **Endolumenal Surgical Platform**, a novel medical device for digestive disease therapy.

One Patient's Story - The Potential Benefit

Mrs. P, a patient in her mid-70s, had a benign polyp that was too large for colonoscopy removal. Because polyps often become cancerous, it had to be surgically removed. The surgeon used general anesthesia and a laparoscopic procedure to remove the section of intestine where the polyp was located. Unfortunately, Mrs. P developed an infection and spent four weeks in the hospital. She was discharged with a permanent colostomy (a bag to collect bodily waste).

With endolumenal surgery, Mrs. P's polyp could be removed without any incisions, greatly reducing the risk of infection. Sedation could be used, her intestine would remain intact, and she would be able to return home after a short hospital stay, with no colostomy or quality of life issues. The cost to hospitals, patients, and insurers would be much lower.

Endolumenal Surgical Platform

The intestine is a winding, contracting channel filled with body fluids and solids. Endoscopes and colonoscopes enable simple diagnostic procedures and the snaring of non-complex polyps. But they are free-floating inside the intestine and do not allow advanced therapies or surgical procedures. The ability to visualize polyps around flexures and behind folds in the colon is also limited with endoscopes. According to a recent study, up to 40% of all polyps in the intestine are not detected during standard colonoscopies.

The Endolumenal Surgical Platform (ESP) solves these challenges. ESP is mounted like a sleeve on a conventional endoscope and permits clinicians to:

- **Stabilize the endoscope tip in relation to the intestinal wall**
- **Create a therapeutic zone with improved visualization inside the intestine**
- **Manipulate the colon wall to provide better access for treatment**

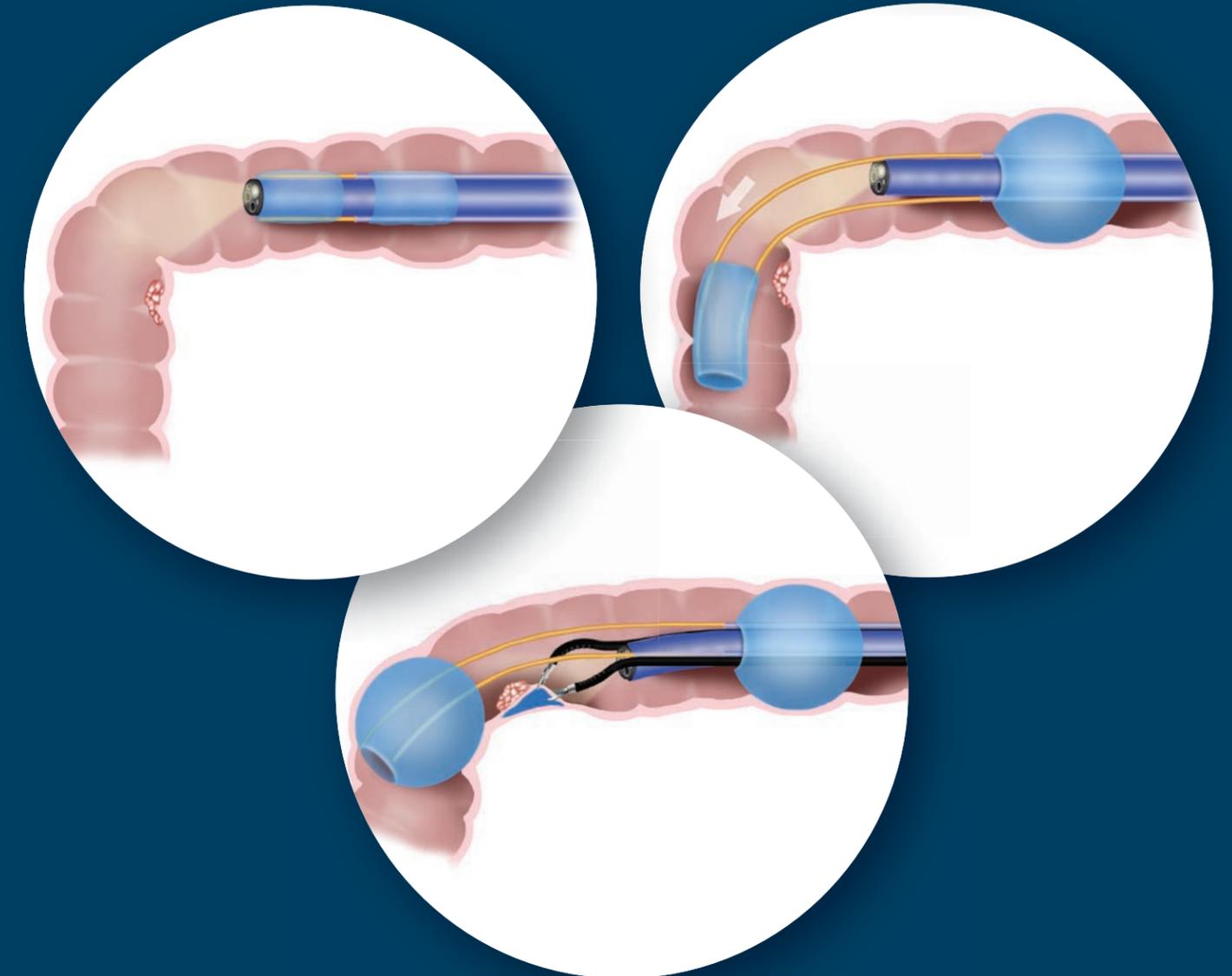
When used as a diagnostic tool, ESP will increase the polyp detection rate and make colonoscopy a more effective screening tool. It will also permit clinicians to perform simple surgical procedures with endoscopes, so that treatments can be done with no incisions, improved safety, and a faster recovery.

ESP will be introduced at leading academic medical centers in a “first in human” clinical study in 2017 - the first step to widespread use at hospitals worldwide. Based on preclinical studies, ESP will have a major impact on digestive disease care.

ESP System Diagram



ESP in Action.



New Paradigm of Care

The MINT team’s process for developing this new paradigm of care has included:

- Filing patents to protect intellectual property
- Identifying the regulatory pathway for FDA clearance (510K)
- Creating a business plan to turn ESP into a commercial product
- Licensing the intellectual property to Lumendi, a startup company with investors who have extensive experience in medical device development and distribution

Lumendi, Ltd. holds an exclusive worldwide license from Cornell University for the ESP platform and related ancillary products. Lumendi has a vision to revolutionize digestive surgery by developing and making available tools and devices that enable minimally invasive gastrointestinal interventions. The collaboration between MINT and Lumendi has opened up countless possibilities to transform digestive care for patients around the world. For more information, visit www.lumendi.com.



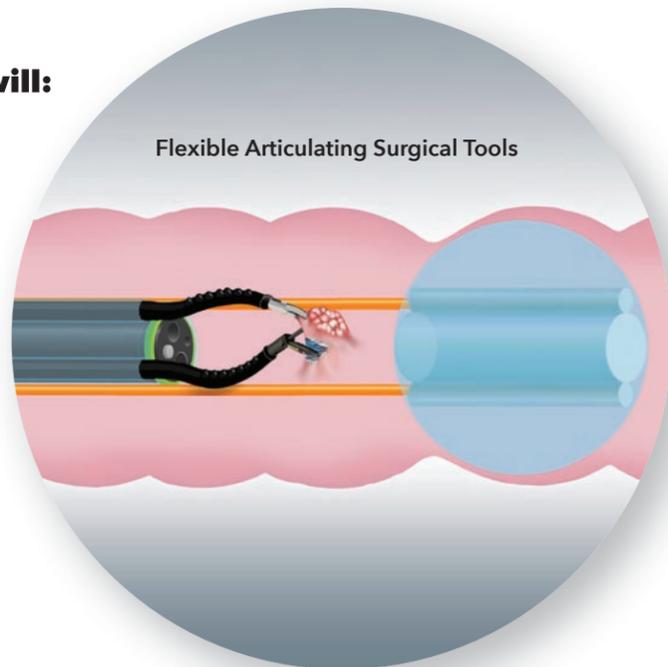
MINT is also developing a second-generation ESP platform (ESP+) that will permit specialists to perform more sophisticated procedures within the channel of the intestine. With ESP+, external channels are fitted along the endoscope sleeve to enable multiple surgical tools to be deployed at treatment locations.

Flexible Articulating Surgical Tools (FAST)

will traverse the winding pathway inside the colon and permit doctors to treat conditions that currently still require open or laparoscopic surgery with new endolumenal therapies and procedures. These conditions include early colon cancers, large and complex polyps, diverticulitis, Crohn’s disease, ulcerative colitis, bleeding lesions, strictures, and infections.

The new endolumenal approach will:

- Increase patient safety
- Reduce the need for general anesthesia
- Increase the number of patients eligible for treatment
- Shorten hospital stays
- Reduce financial costs
- Dramatically improve patient outcomes



Cost Savings

Improved patient outcomes and safety is the main motivation for endolumenal surgery, but cost savings is a close second:

- The average cost of an open GI surgical procedure is \$19,000, and the main cost driver is the average hospital stay of eight days.
- For laparoscopic GI surgery, these figures are \$15,300 and five days.
- An ESP-based endolumenal surgery will have an average hospital stay of two days, with an average cost of \$3,900.

As endolumenal surgery becomes as accepted as endovascular care, hospital stays of one day will eventually become the norm.

When the ESP family of products is implemented broadly, over \$1.7 billion in cost savings will accrue to U.S. patients, hospitals, and insurers annually. Worldwide, the costs savings are estimated at more than \$3.5 billion annually.

Table 1 - ESP Cost Savings (U.S.)*

Target Applications	Cases Where ESP Would Be Used	Annual U.S. Cost Savings (\$M)**
Complex Polyps	52,000	\$690
Anastomosis Leaks	25,600	\$340
Volvulus	20,800	\$276
Strictures	14,700	\$195
Diverticular Disease	13,700	\$182
Fistulae	2,800	\$37
Total Annual Savings		(U.S.) \$1.7B

* Based on HCUP Data (Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality (AHRQ), Nationwide Inpatient Sample, 2011) and Medical Literature

** Assumes cost savings per procedure of \$13,270 (averaging cost savings from open and from laparoscopic surgeries)

The Innovation Imperative

Revolutions in health care do not happen overnight. It costs money to develop and test new tools and procedures. Philanthropic support is needed for continuing medical education. These activities require an innovation ecosystem that draws on the talents of experts in many disciplines.

The MINT and CADC teams believe that convergence is the driving force of innovation. Our work involves surgeons, physicians, and medical educators from the departments of Surgery, Medicine, and Radiology at Weill Cornell; and MBAs, engineers, life scientists, and physical scientists at MINT. Together, they are pushing the boundaries of medicine, surgery, and patient care.

In the future:

- Instead of removing a piece of intestine to treat **Crohn's disease**, we will work within the intestine to insert a bio-absorbable stent with medicinal properties that widens the channel and cures inflammation.
- Instead of resecting a length of intestine for **diverticulitis**, we will seal off the weakness with a new biomaterial, curing the disease and avoiding major surgery.
- Instead of removing a major section of intestine for early **colon cancer**, we will locally resect the tumor, use advanced imaging techniques to stage it, and treat the cancer without the need for hospitalization.

This transformation is needed because the aging population, the growing incidence of digestive disease, and spiraling healthcare costs require it.

We are blazing a new trail of healing and discovery. We are pursuing innovation because patients deserve it.

Please join us in this effort.

To learn more or to discuss ways to contribute to the groundbreaking work of MINT, contact Matthew Baird at 212-746-2008 or mab9327@nyp.org.

Innovation Imperative: Only the Beginning.

MINT
MINIMALLY INVASIVE NEW TECHNOLOGIES

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The Minimally Invasive New Technologies (MINT) Program is an innovative collaboration between NewYork-Presbyterian Hospital (NYPH) and the Weill Cornell Medical College (WCMC). Through the MINT program, clinicians, engineers, and experts from a range of disciplines develop technologies that advance minimally invasive surgery at NewYork-Presbyterian and beyond.

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