Protocol Number: Pro00058006

Protocol Title:
Pilot Study of the Endolumik Gastric Calibration Tube for Bariatric Surgery

Sponsoring Company: Endolumik Inc.

Study Site: Duke University
Principal Investigator:
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Study Site: West Virginia University
Principal Investigator:
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Associate Professor
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Lay Summary:
Endolumik Inc. has developed a fluorescence-guided calibration device, the Endolumik Gastric Calibration Tube, to improve visualization during bariatric operations. The present pilot study will be a First In Human Investigational Device Exemption (IDE) Clinical Trial to evaluate the Endolumik Gastric Calibration Tube and associated methods in a human clinical cohort of 20-30 bariatric patients at two high-volume bariatric programs. During this clinical study, the single-use, disposable Endolumik Gastric Calibration Tube will be used during twenty sleeve gastrectomy operations and gastric bypass operations. The goal of the present study is to confirm that the Endolumik Gastric Calibration Tube performs similar to predicate devices currently on the market, as well as to get end-user feedback prior to submitting a 510(k) application to the U.S. Food and Drug Administration (FDA).

In this multicenter trial, both study sites are certified as Bariatric Centers of Excellence through the American Society of Metabolic and Bariatric Surgery. The first clinical site is Ruby Memorial Hospital, part of West Virginia University; the second clinical site is Durham Regional Hospital, part of Duke University.

To date, using funding from a West Virginia Clinical & Translational Science Institute Launch Pilot Grant, our team has validated the device and associated methods of

fluorescence-guided sleeve gastrectomy and fluorescence-guided gastric bypass in ex-vivo and in-vivo porcine models, as well as human cadaveric tissue models. Based on FDA criteria, this investigational device meets the definition of a Non-Significant Risk (NSR) device; the risk classification document is included with submission materials.

The study will be performed with an Investigational Device Exemption (IDE). The investigational device provided will have met design controls per FDA code of federal regulation (CFR): 21 CFR 820.30. Endolumik Inc. will serve as the industry sponsor for this study and will donate the devices being used for the protocol to the two participating study sites. Development of the technology in this research is supported by the West Virginia University Department of Surgery.

Scientific rational with References:

Background on Morbid Obesity, Bariatric Surgery & Sleeve Gastrectomy
More than one-third of U.S. adults (42%) and 17% of U.S. children and adolescents have obesity. The CDC projects that an even larger proportion of the population will suffer from obesity by 2030, and if current trends continue, >57% of today's youth will have obesity at age 35 [1]. In addition, the World Health Organization has reported that global obesity rates have nearly tripled since 1975. Currently 39% of adults worldwide have an overweight body size and 13% have obesity [2]. The estimated annual medical cost of obesity in the U.S. was $270 billion in 2011. Medical costs for individuals with obesity were $1,429 higher than those with normal weight.

Bariatric surgery has emerged as the most effective treatment for obesity and obesity-related comorbidities. The use of bariatric surgery in the United States has increased from 150,000 operations in 2011 to 252,000 in 2018 [3]. However, less than 1% of patients who are eligible for bariatric surgery receive this care. Since 2013, the laparoscopic sleeve gastrectomy (LSG) has overtaken gastric bypass (RNY) as the most widely performed procedure in both community and academic practices [4].

The poor visualization and inconsistent methodologies used today in bariatric operations contribute to a costly number of complications. The most common complications of sleeve gastrectomy include leak (1-2%), bleeding (1-2%), and venous thromboembolism (0.25%). However, another described complication is bougie-related injury (also known as calibration tube related injury). A bougie is a thin cylinder, made of silicone, rubber, or plastic, that a physician inserts into a body passageway, such as the esophagus or stomach, to diagnose or treat a condition. A bougie is used in bariatric operations as a calibration device to ensure esophagogastric patency during specific portions of the operation. Bougie-related injury is defined as an injury to the patient that occurs as a result of bougie/calibration tube placement. Typical bougie-related injuries can include, proximal, mid, or distal esophageal perforation; proximal, mid or distal gastric perforation, as well as stapling the bougie into the stomach, necessitating immediate revision/reconstruction, or stapling across the bougie and leaving a foreign body behind inside the patient. The Emergency Care Research Institute (ECRI), an independent nonprofit notes that injuries and death from misuse of surgical staplers

ranked the number one health technology hazard of 2020, and was often caused by clamping on or firing over another instrument, such as a bougie. Within the bariatric literature the incidence of bougie-related injury is 0.1-1.2%, however there is concern that these injuries are under-reported due to the growing number of non-certified general surgeons performing bariatric operations [5,6]. Complications associated with bougie placement cost US hospitals $630 million annually in sleeve gastrectomy procedures alone [7]. Developing improved techniques to decrease the rate of these injuries is a priority.

In addition, minimally invasive surgery, especially robotic surgery, provides decreased tactile feedback to the surgeon, which is associated with increased risk of iatrogenic esophageal and gastric injury with bougie/calibration tube use. These types of injuries can result in serious morbidity and even mortality if they go undetected until after the procedure, and even when detected immediately, they can require lengthy and costly procedural modifications that result in increased morbidity and longer hospital stay. Furthermore, with the growing use of robotic bariatric surgery, where the surgeon is remote from the patient with even more limited tactile sensation, the need for additional techniques/tools to improve intraoperative visualization and safely perform minimally invasive surgical procedures is necessary.

The Growth of Fluorescence-Guided Surgery

The use of near infrared imaging and fluorescence-guided surgery (FGS) is a rapidly growing modality, allowing surgeons to see more intraoperatively, enhancing surgical precision, and improving surgical decision-making and patient outcomes. Fluorescence-guided surgery is defined as a medical imaging technique that uses a fluorescent dye or a near-infrared emitting light source to identify anatomic structures during surgical procedures[8]. In 2020 alone, over 1200 academic articles were published on the topic of fluorescence guidance and surgery [9].

Description of the Endolumik Gastric Calibration Tube & Device Clinical Uses

The fluorescence-guided device in the present study, called the Endolumik Gastric Calibration Tube, is a surgical instrument designed for use in minimally-invasive bariatric operations. The intellectual property (IP) for the device was developed using funding from a West Virginia Clinical and Translational Science Institute Launch Pilot Grant in 2020. Endolumik Inc. obtained an exclusive license to the aforementioned IP, which facilitated development of the Endolumik Gastric Calibration Tube. The novel integration of near-infrared lighting with the intra-gastric calibration tube is designed to improve visualization and situational awareness, team confidence, gastric conduit size consistency, and safety of minimally-invasive sleeve gastrectomy and gastric bypass operations.

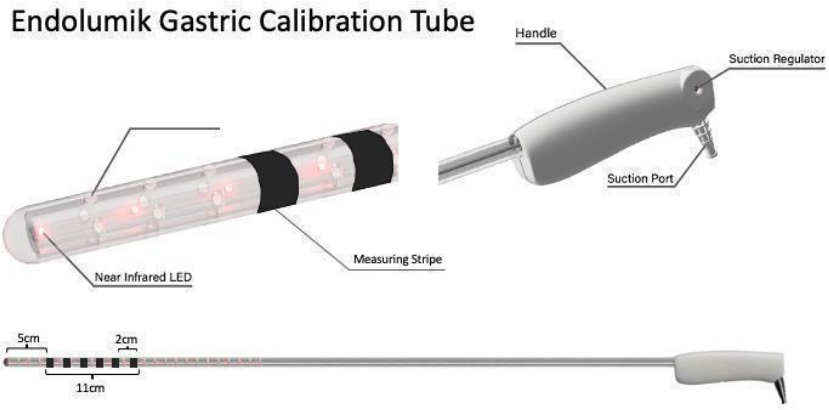

Figure 1: Computer-Aided Design Image of the Endolumik Gastric Calibration Tube

This disposable, single-use device consists of a body and a handle (Figure 1). The body is a LED lighted stent/tube that has suction capability and the handle contains the battery power source, a suction regulator, and a suction adaptor. The device body is size 40 French.

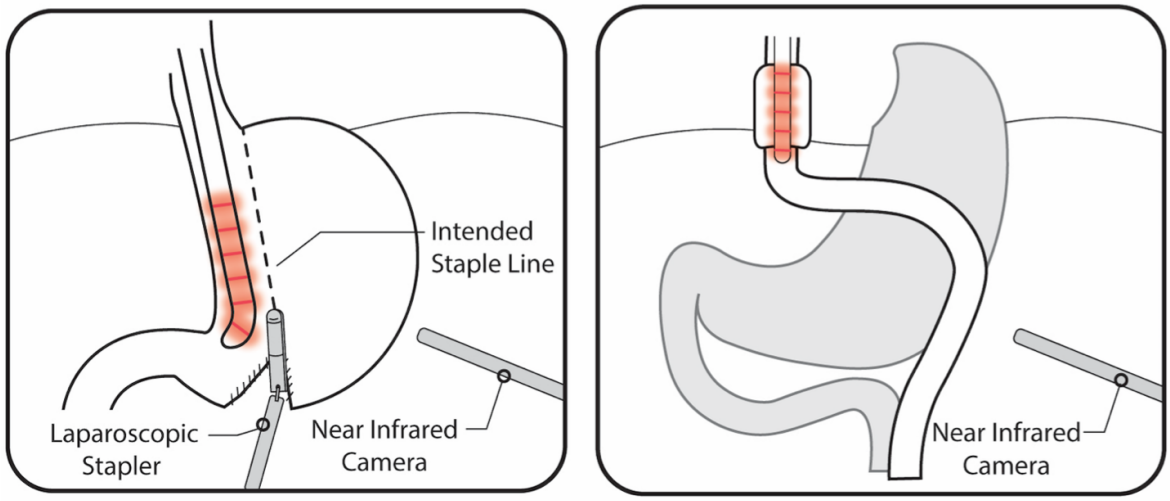

Figure 2: Surgical Applications of the Endolumik Gastric Calibration Tube. (a) Use during Sleeve Gastrectomy and (b) Gastric Bypass.

The method is the technique of using a near-infrared camera while introducing the fluorescence-guided calibration device into the patient's stomach and forming the gastric sleeve during a sleeve gastrectomy operation or forming the gastric pouch during a gastric bypass operation (Figure 2). Additional functionality of the device includes ability to make near-infrared guided measurements of the stomach & esophagus. The above intellectual property is described further in a utility patent

published October 1, 2020 entitled, “Improved Surgical Devices for Bariatric and Gastroesophageal Surgery” Application No.: 16/836,396.

To date our team has validated the device using an ex-vivo porcine model in Spring 2020, an in-vivo porcine model in November 2020, and two human cadaveric models in December 2020 and April 2021 (Figures 3 & 4).

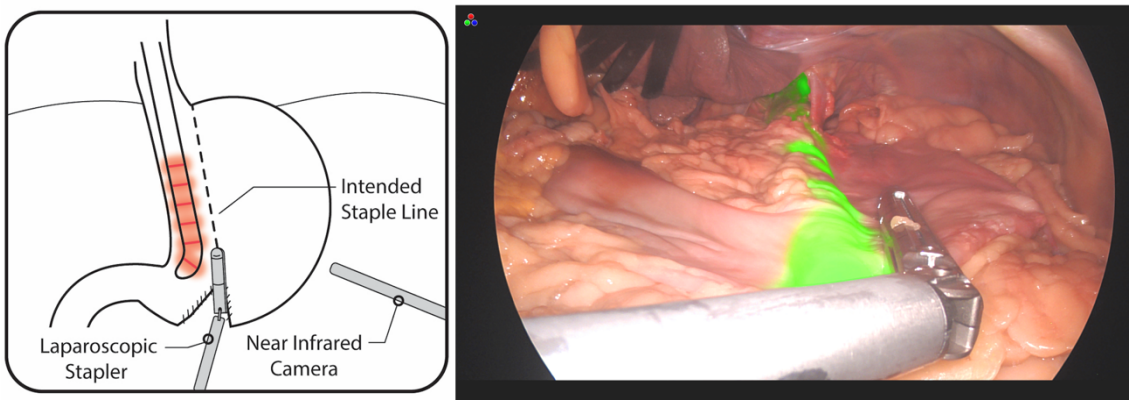

Figure 3. Fluorescence-Guided Sleeve Gastrectomy: Endolumik Gastric Calibration Tube testing in human cadaver model, April 2021.

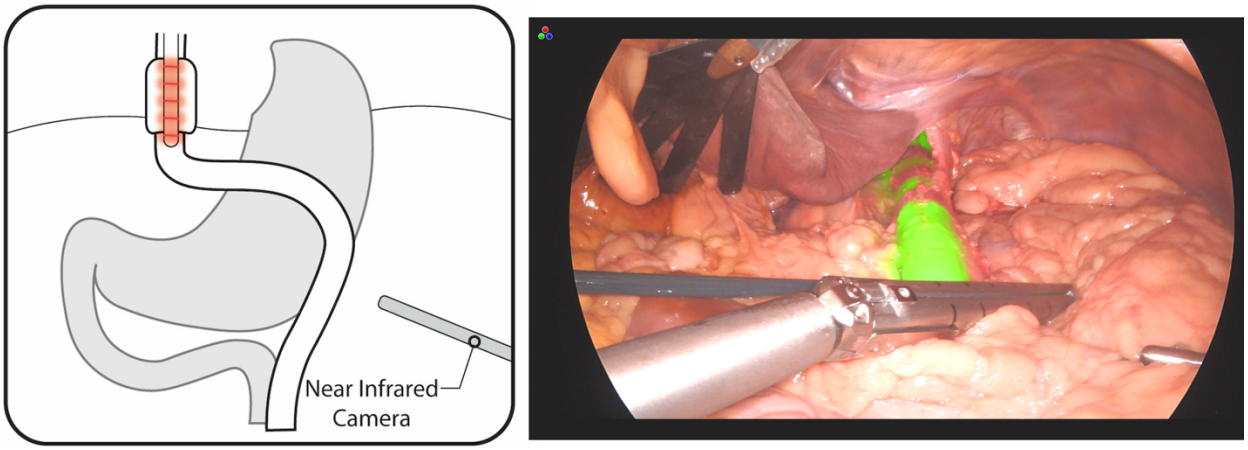

Figure 4. Fluorescence-Guided Gastric Bypass: Endolumik Gastric Calibration Tube testing in human cadaver model, April 2021.

During the present study, a near-infrared laparoscopic camera system will be used to provide near-infrared fluorescence-imaging for laparoscopic surgeries and the Da Vinci Firefly System will be used to provide fluorescence-imaging for robotic surgeries. Current near-infrared enabled camera systems have the ability to create an overlay mode which combines white light and near-infrared (NIR) views into one image (Figure 5).

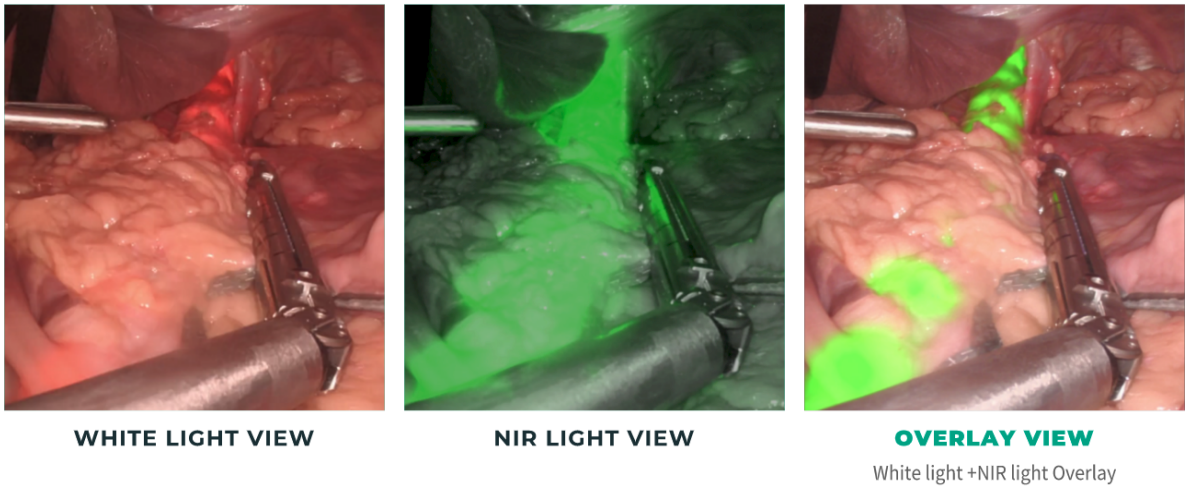

Figure 5. Camera modes of the Stryker 1688 camera system include (from left to right) a white light mode, a near-infrared light mode, and an overlay mode that combines both white light and near infrared views.

The IDE devices used in this study will be donated by Endolumik Inc. to the respective study site at no cost. Neither the study participant nor their insurance provider will be responsible for the cost of the investigational device.

Predicate Device
The FDA approved predicate device for the Endolumik Gastric Calibration Tube is the VISIGI 3D Sleeve Calibration System With Bulb. Please see attached forms “Predicate Device Information” and “Visigi 3D 510k” for more information.

Device Risk Determination
Based on a careful review of FDA document “Investigational Device Exemptions” 21 CFR 812.3, the relevant guidance documents, and information sheets, it is our determination that the 40F Calibration System does not meet the definition for a Significant Risk (SR) device study [10].

In reviewing the four criteria for a significant risk device, it is determined that:

- The device is NOT intended as an implant
- The device is NOT purported or represented to be for use supporting or sustaining human life
- The device is NOT for a use of substantial importance in preventing impairment of human health
- The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject

Additionally, the Information Sheet provides in Section X.A several examples of NSR Devices. Among the NSR examples are Conventional Gastroenterology and Urology

Endoscopes and/or Accessories, which are very similar devices to the study device in terms of typical usage and risk.

Given that the device study does not meet the definition of a SR study, it is very similar to example NSR devices, and the proposed use of the device does not introduce significant risk, it is our determination that it is best categorized as a Nonsignificant Risk (NSR) Device Study.

For further information see attached risk determination document.

Relevant Research Team Experience
Dr. Keri Seymour DO, FACS, FASMBS, principal investigator of the Duke arm of the study, is an Assistant Professor and Bariatric Surgeon at the Duke Center for Metabolic and Weight Loss Surgery. She completed her general surgery residency at SUNY Upstate Medical University in 2014, and a minimally-invasive/bariatric surgery fellowship at Duke University in 2015. She has performed over 1,000 bariatric operations, and helps run the Duke Bariatric Surgery Program, an accredited MBSAQIP Center of Excellence.

Dr. Lawrence Tabone, MD, FACS, FASMBS, MBA, principal investigator of the West Virginia University arm of the study, is an Associate Professor and Bariatric Surgeon in the West Virginia University Department of Surgery. He completed his general surgery residency at Loyola University Medical Center in 2012, a postdoctoral research fellowship at Duke University in 2013, and a minimally-invasive/bariatric surgery fellowship at Duke University in 2014. He has performed over 1,000 bariatric operations, and is the Director of the WVU Bariatric Program, an accredited MBSAQIP Center of Excellence.

Subjects:
Details of the population to be included in the study:
- English speaking
- Adult (age 18 to 65)
- Male or female bariatric patients
- Body mass index (BMI) between 35 and 65.99 kg/m^2

Inclusion Criteria:
Individuals included in this pilot study are:
- English speaking
- Adults (between age of 18 and 65 years old)
- Have body mass index (BMI) between 35 and 65.99 kg/m^2
- Male or female bariatric patients undergoing bariatric surgery at one of the two sites included in the protocol.

Exclusion Criteria are:
Individuals excluded from this study include:

- Nonbariatric patients
- Patients who have conditions that preclude a sleeve gastrectomy or gastric bypass operation
- Patients with esophageal stricture
- Patients with esophageal varices
- Patients with a Zenker's diverticulum
- Patients aged 66 and older
- Patients with a BMI of 66 kg/m^2 or greater
- Pregnant Women
- Lactating Women
- Other vulnerable patient populations: pregnant and lactating women, prisoners, cognitively impaired and critically ill subjects.

Sample Size:

- The sample size (n) will be 20-30 Bariatric patients.
  - Twenty participants will undergo laparoscopic or robotic sleeve gastrectomy using the Endolumik Gastric Calibration Tube instead of the standard bougie calibration tube.
  - Ten participants will undergo laparoscopic gastric bypass using the Endolumik Gastric Calibration Tube instead of the standard calibration tube.

Sample Size Justification:
The current pilot protocol is a qualitative, not quantitative, study design, thus no power calculation is indicated. The goal of the present pilot study is to serve as the First In Human IDE trial and confirm that the Endolumik Gastric Calibration Tube performs similar to predicate devices currently on the market, as well as to get end-user feedback prior to 510(k) application to the FDA. The sample size was chosen because 20 to 30 uses will allow the development team to appropriately evaluate device performance.

Study Design and Procedures

1. The study type is prospective and non-randomized.

2. The sample size will be 20-30 Bariatric patients (total between both testing sites) who meet the inclusion criteria listed above.

    a. Twenty participants meeting inclusion criteria will undergo laparoscopic or robotic sleeve gastrectomy using the Endolumik Gastric Calibration Tube instead of the standard bougie calibration tube. This bariatric operation will take approximately 60 minutes. The amount of time the Endolumik Gastric Calibration Tube will be inside the patient is approximately 20 minutes. The device is removed prior to the conclusion of the operation, while the patient is under anesthesia.

The portions of the sleeve gastrectomy operation where the Endolumik Gastric Calibration Tube will be used include:

- ***To evacuate gastric contents***
- ***During construction of the gastric sleeve***
- ***To perform the leak test of the gastric sleeve***

b. Ten participants meeting inclusion criteria will undergo laparoscopic gastric bypass using the Endolumik Gastric Calibration Tube instead of the standard calibration tube. This bariatric operation will take approximately 120 minutes. The amount of time the Endolumik Gastric Calibration Tube will be inside the patient is approximately 20 minutes. The device is removed prior to the conclusion of the operation, while the patient is under anesthesia.

The portions of the gastric bypass operation where the Endolumik Gastric Calibration Tube will be used include:

- ***To evacuate gastric contents***
- ***During construction of the gastric pouch***
- ***To calibrate closure of the gastrojejunal anastomosis***
- ***To perform a leak test of the gastrojejunal anastomosis***

3. Eligible participants will undergo informed consent.

4. The operative steps for use of the Endolumik Gastric Calibration Tube during the sleeve gastrectomy operation are as follows:

a. Informed consent will be obtained at the preoperative clinic appointment. All patient questions will be answered.

b. Participants will undergo general endotracheal anesthesia in standard fashion.

c. Once under anesthesia, jelly lubrication will be applied to the Endolumik Gastric Calibration Tube, and it will be gently introduced by the anesthesia provider through the patient's mouth and oral pharynx and into the esophagus to a distance of 40cm or once gastric content/fluid is visible within tube.

d. A Veress insufflation needle will be inserted into the peritoneum the left upper quadrant abdominal region, confirmation of location will be achieved using a water drop test, (instilling 3ml of water into the needle and confirming a positive meniscus test).

e. Carbon dioxide insufflation will be connected to the Verress needle and pneumoperitoneum (laparoscopic working space) will be created.

f. Prior to placing ports, a skin incision will be made with a scalpel for each port site. Access to the peritoneum will be gained using an optical trocar in the left upper quadrant.

g. The remaining ports will be placed under direct laparoscopic visualization: a 12mm port in the left supraumbilical area, one 5mm port in the right upper quadrant, and one 15mm port in the right supraumbilical area.

h. A liver retractor will be placed through a 5mm epigastric incision.

i. Under laparoscopic visualization with the laparoscopic camera in NIR mode the Endolumik Gastric Calibration Tube, which will be sitting at 30cm in the esophagus, will be advanced by the head of bed provider under direct visualization of all team members (anesthesia team at head of bed and surgical team in sterile field) into the stomach and connected to suction to evacuate gastric air and contents. Once the gastric contents are removed, the Endolumik Gastric Calibration Tube will be taken off suction, visualized using NIR camera mode, and withdrawn to the top gastroesophageal junction.

j. A sleeve gastrectomy operation will then be performed via the following steps: the stomach is mobilized by dividing the short gastric arteries along the greater curvature using an energy device.

k. With the surgical camera in NIR mode, the Endolumik Gastric Calibration Tube is advanced into the patient’s stomach prior to forming the gastric sleeve.

l. Suction will be applied to the device to evacuate any additional gastric contents.

m. The Endolumik Gastric Calibration Tube will remain positioned in the stomach during gastric sleeve construction. During sleeve construction, the laparoscopic camera will be changed from white-light mode to NIR mode.

n. The stomach is divided with a laparoscopic stapler using minimally-invasive staple loads, starting 6cm from the pylorus, taking care not to narrow the stomach at the incisura or the angle of His.

o. Once the sleeve gastrectomy is completed the the Endolumik Gastric Calibration Tube will be used to perform a leak test. The accessory bulb will be connected to the the Endolumik Gastric Calibration Tube and inflated to the pressure of approximately 35mm Hg. The gastric sleeve will be submerged in saline and evaluate for any leak

p. The Endolumik Gastric Calibration Tube will be removed under direct visualization.
q. The surgeon will perform an intraoperative upper endoscopy to examine the gastric sleeve mucosa.
r. The gastric sleeve operation will be completed in standard fashion.

s. After completion of the operation the surgeon, surgical assistant, anesthesia providers, and OR nurse will complete a web-based Device Evaluation Form which asks each provider relevant questions regarding their experience with this novel device. (See attached Device Evaluation Form for Gastric Sleeve)

5. The operative steps for use of the Endolumik Gastric Calibration Tube during the gastric bypass operation are as follows:

a. Informed consent will be obtained at the preoperative clinic appointment. All patient questions will be answered.

b. Participant will undergo general endotracheal anesthesia in standard fashion.

c. Once under anesthesia, jelly lubrication will be applied to the Endolumik Gastric Calibration Tube, and it will be gently introduced by the head of be provider through the patient's mouth and oral pharynx and into the esophagus to a distance of 40cm or once gastric content/fluid is visible within tube

d. A Verress insufflation needle will be inserted into the peritoneum the left upper quadrant abdominal region, confirmation of location will be achieve using a water drop test, (instilling 3ml of water into the needle and confirming a positive meniscus test).

e. Carbon dioxide insufflation will be connected to the Verress needle and pneumoperitoneum (laparoscopic working space) will be created.

f. Prior to placing ports, a skin incision will be made with a scalpel for each port site. Access to the peritoneum will be gained using an optical trocar in the left upper quadrant.

g. The remaining ports will be placed under direct laparoscopic visualization: a 12mm port in the left supraumbilical area, one 5mm port in the right upper quadrant, and one 15mm port in the right supraumbilical area.

h. A liver retractor will be placed through a 5mm epigastric incision.

i. Under laparoscopic visualization with the laparoscopic camera in NIR mode the Endolumik Gastric Calibration Tube, which will be sitting at 30cm in the esophagus, will be advanced by the head of bed provider under direct visualization of all team members (anesthesia team at head of bed and surgical team in sterile field) into the stomach and connected to suction to evacuate gastric air and contents. Once the gastric contents are removed, the Endolumik Gastric Calibration Tube will be taken off suction, visualized using NIR camera mode, and withdrawn to the top gastroesophageal junction.

j. During creation of the gastric pouch, with the surgical camera in NIR mode, the Endolumik Gastric Calibration Tube will be advanced into the stomach to assist with pouch size calibration and pouch size measurement.

k. During creation of the gastrojejunostomy, the Endolumik Gastric Calibration Tube will be advanced through the gastrojejunal anastomosis calibrate closure and prevent narrowing of said anastomosis.

l. Once the gastrojejunostomy is completed the the Endolumik Gastric Calibration Tube will be used to perform a leak test. The accessory bulb will be connected to the the Endolumik Gastric Calibration Tube and inflated to the pressure of 35mm Hg. A bowel clamp will be placed on the roux limb distal to the gastrojejunostomy. The gastrojejunostomy will be submerged in saline and evaluated for any leak.

m. The Endolumik Gastric Calibration Tube will be removed under direct visualization.

n. The surgeon will perform an intraoperative upper endoscopy to examine the gastric pouch mucosa and the gastrojejunostomy anastomosis.

o. The gastric bypass operation will be completed in standard fashion.

p. After completion of the operation the surgeon, surgical assistant, anesthesia providers, and OR nurse will complete a web-based Device Evaluation Form which asks each provider relevant questions regarding their experience with this novel device and monitors for any adverse events. (See attached “Device Evaluation Form for Gastric Bypass”)

6. The follow-up period for the study will be 30 days from the date of the bariatric operation.

    a. Within the postoperative period the patient will follow the standard of care post surgical protocol of each respective site’s bariatric program.

7. The following participant outcomes will be recorded:

    A. Operative time
    B. Intraoperative adverse events
    C. 30-day morbidity, specifically any 30-day Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Occurrences (See attached document “MBSAQIP Occurrences”)
    D. Video recording of the operation.
        a. Video storage will be via one of the following: an encrypted harddrive or Epiqar, a HIPAA-compliant system with instant cloud-based surgical video archiving and web-based video conferencing. The Epiqar system interfaces with existing camera equipment in the operating room[11].

8. The following device performance will be gathered:

    A. Device performance data will be collected using de-identified, web based surveys given to surgical team members, anesthesia provider(s), and the operating room team member who unpackages the device.
        a. The following surveys are included in supplementary materials:
            i. Device Evaluation Form for Sleeve Gastrectomy
            ii. Device Evaluation Form for Gastric Bypass

Storage, Handling and Accountability for Investigational Device

The storage plan for the investigational device is as follows: the devices used in the current protocol will be stored in locked, temperature controlled rooms at each study site. At the West Virginia University protocol site this will be the locked, temperature controlled office of the Principal Investigator (PI). At the Duke University protocol site this will be the locked, temperature controlled office of Principal Investigator (PI) Keri Seymour, DO.

The handling plan for the investigational device is as follows: the device will be transported to the operating room on the day of the planned bariatric operation by the PI. Once the device is in the operation room, it will be handled and unwrapped by the operating room circulating nurse or the anesthesia provider. Once the bariatric operation is complete, the device will be disposed of in the operating room trash.

In order to ensure accountability of device use, the device will be labeled as investigational use only. Specifically, the device will be labeled in accordance with the labeling provisions of the FDA IDE regulations (§812.5) and will bear the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use."

Scientific / medical knowledge:
This study will demonstrate the feasibility of using a fluorescence-guided calibration device to improve visualization during minimally-invasive bariatric operations and further knowledge regarding the use of fluorescence-guided surgery to improve patient outcomes.

Data Collection

1. Participant data will be collected and stored in a HIPPA Compliant REDCap Database at West Virginia University that will be maintained by the Principle Investigator. (See attached REDCap Form “Pilot Study of Endolumik Device: Participant Registry)
    - Each consented participant will be assigned a participant ID that will serve as their unique identifier for the duration of the study. The participant ID will be a number from 1 to 30, and will be assigned in chronological order based on the order which subjects are consented for the study (i.e. the first participant enrolled will be assigned Participant ID 1, the final participant enrolled will be assigned Participant ID 30).
2. Device performance data will be collected using a de-identified REDCap Survey (See attached device evaluation forms) that will use the Participant ID as the unique identifier to connect device performance with individual participants.
    - Clinical providers (surgical team, anesthesia team, operating room staff/nurse) will complete a de-identified web-based questionnaire (Device Evaluation Form) after each operation. The device evaluation form asks each provider relevant questions regarding their experience with this novel device. (See attached Device Evaluation Forms)
    - The Device Evaluation Forms will be stored in the REDCap participant registry for each corresponding Participant ID.
3. Participant Demographic Data
    - Participant ID (assigned as described above)
    - Study Site
    - Date of Operation
    - Surgeon

- Operation Type
- Patient Name
- Medical Record Number
- Age
- Sex
- Height
- Preoperative Weight
- Preoperative Body Mass Index (BMI)
- Past Medical History (hypertension, hyperlipidemia, diabetes, asthma, obstructive sleep apnea, emphysema/COPD, gastroesophageal reflux disease, chronic kidney disease, heart disease, liver disease, venous thromboembolism)
- Past Surgical History

4. Outcome Data
    - Operative time (minutes)
    - Intraoperative adverse events
    - 30-day morbidity/MBSAQIP Occurrences
    - Device Evaluation Form(s)
    - Video file of operation

How will the results be analyzed?
Descriptive statistics will be calculated for the patient cohort.

Data Monitoring Committee & Data Monitoring Plan
The plan for monitoring data to ensure subject safety (e.g. serious adverse event and unanticipated problem reporting) includes the creation of the following: a formal multidisciplinary Data Monitoring Committee (DMC), a schedule for the DMC to meet, as well as a list of device-related complications that will be monitored for during and after each use of the device.

The Data Monitoring Committee will consist of the following four members: Alice Race MD, Dr. Pavithra Ellison MD, and Mara McFadden MBA. The multidisciplinary Data Monitoring Committee (DMC) will meet at regular intervals to ensure no serious adverse events or unanticipated problems arise during device testing, specifically the DMC will meet to review intraoperative outcomes after every 5 patients, and immediately after any adverse events.

Data Monitoring Committee Members

1. **Dr. Pavithra Ellison MD, MMM, FASA** is an anesthesiologist and the medical director of Perioperative services for WVU Medicine Children's Hospital. She has more than 30 publications, with several funded studies. She was part of WVU Health Sciences Office of Research Integrity and Subject protection- Institutional Review Board from 2014-2021 and has been a part of numerous study approvals and its review including medical devices. She is also an integral part of the

Children's Hospital Research Consortium which will oversee all research and quality projects at WVU Medicine Children's Hospital.

2. **Dr. Alice Race MD** obtained her medical degree at Indiana University School of Medicine and completed surgical residency at Ascension Providence Hospital / Michigan State University in Southfield, Michigan. She then completed a Minimally Invasive Surgery Fellowship at the University of California San Diego. Her research interests include clinical outcomes and global health.

3. **Mara McFadden MBA** is the Chief Executive Officer of Endolumik Inc. She is a mechanical engineer and seasoned medical device executive, with experience launching medical devices for Johnson & Johnson and Philips Healthcare.

Collection, Assessment and Reporting of Adverse Events

The most important goal of our team during this pilot study is to ensure the safety of the device being tested.

The two adverse events which will signal an immediate end to the study are: (i) if the device leads to an intraoperative perforation of the esophagus or stomach or (ii) if the device is stapled across. If these events were to occur, the study would be ended and a root cause analysis would be performed.

The protocol for recording, reporting and remediating adverse events will be as follows: Following each device use, the clinical providers (surgical team, anesthesia team, operating room staff/nurse) will complete a de-identified web-based questionnaire (Device Evaluation Form). Included in this questionnaire is an area to report any adverse event occurrence. Furthermore, if an intraoperative adverse event occurs, the operating surgeon will notify the study PI immediately following the operation; the PI will arrange for a meeting of the Data Monitoring Committee so that the adverse event can be discussed and a remediation plan can be developed.

Risk to participants:

The risks to participants include the risks of elective surgery which are bleeding, infection, damage to surrounding structures, need for further operations, venous thromboembolism, stroke, heart attack, or death. Furthermore, the potential adverse events associated with bariatric surgeries may include leaks, strictures, ischemia, gastroesophageal reflux disease, chronic pain, dysphagia, and excess weight loss.

In addition, participant risks include the potential complications associated with all intragastric calibration systems. All surgical calibration tubes have the following known adverse reactions and potential complications associated with their use: esophageal / gastric perforation, bleeding / hemorrhage, fistula, improper disinfection / infection, and/or accidental stapling of the tube. The possible complications associated with the use of the Endolumik Gastric Calibration Tube are those typically associated with all gastric tube and calibration systems.

Subject Privacy and Confidentiality

Any information about participants that is obtained as a result of participation in this research will be kept as confidential as legally possible. Records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities without additional participant consent. In any publications that result from this treatment, neither participant name nor any information from which the participant might be identified will be published.

All identifiable data will be stored in a secure, encrypted REDCap Database hosted at each study site. The PHI (Name, MRN) will be entered into a REDCap Spreadsheet (see attached document "PilotStudyEndolumikDeviceParticipantRegistry". Once the data is collected and saved on the spreadsheet, the MRN and Name variables will be removed and only the Participant ID number will remain. The key will be kept in a separate file and destroyed after all data has been collected.

Operative Video Storage: The surgical video of each operation will be stored on an encrypted drive in the locked office of the PI at each study site.

Describe the potential benefit(s) to Participants, society and scientific / medical knowledge of your study:

I. Benefits to Participants:

The Endolumik Gastric Calibration Tube will have improved visibility during bariatric operations compared to the standard device, thus use of this novel device should decrease participant risk of bougie-related injury or other adverse outcomes stemming from poor intraoperative visualization.

II. Benefit to Society:

The Endolumik Gastric Calibration Tube should have improved visibility during bariatric operations compared to the standard device, thus may decrease participant risk of bougie-related injury, as well as may decrease healthcare costs related to complications of bariatric surgery.

Informed Consent Process

See attached informed consent form & recruitment document/patient facing material

References:

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[5] Mahawar KK. Bougie-Related Oesophageal Injury with Bariatric Surgery: An Unrecognised Problem. Obes Surg. 2016 Aug;26(8):1935-6. doi: 10.1007/s11695-016-2213-1. PMID: 27129804.

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[8] https://isfgs.org/what-is-fluorescence-guided-surgery/

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[10]https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812

[11] https://epiqar.com