Post Shark Tank Milestones: Bariatric Applications of Novel Near-Infrared Calibration Tube

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Objective of Technology

After participating and winning SAGES Shark Tank in 2021, Endolumik Inc. has commercialized a fluorescence guided calibration tube (FGCT) which uses a near infrared (NIR) light source to increase intraoperative visual cues and improve visualization in bariatric operations. The FDA awarded the device with a Safer Technology Program (STeP) designation, which means the device is reasonably expected by the FDA reviewers to significantly improve the safety and benefit-risk profile of currently available treatments through substantial safety innovations over predicate, non-lit calibration tubes.

Description of Technology

The FGCT is a single-use device, which comes in sizes 36 and 40 French, consisting of an 80cm body lit with NIR spectrum LEDs and a handle that contains the battery power source, suction regulator, and suction adapter. It can be visualized by surgical cameras with near infrared capability. The device has suction and irrigation capability via small side holes. For leak testing, an additional squeeze bulb with a pressure gauge can be attached. Three black stripes at the distal end of the tube, combined with the spacing of the LED lights, enable fluorescence-guided measurements of up to 10cm.

The FGCT enables fluorescence guided dissection and measuring techniques by providing transillumination through esophagogastric tissues. It can be used to enhance intraoperative visualization and prevent the following adverse events related to poor visualization: stapling the calibration tube, perforating the esophagus or stomach, narrowing the incisura or gastroesophageal junction while constructing a gastric sleeve and can be used to form and measure the gastric pouch. The device can enhance visualization in revisional operations by helping the surgeon distinguish esophagus from other hiatal structures (crura, hernia sac, scar tissue).

Results

Since FDA Approval and STeP designation in March 2023, the device has been used in nearly 5000 procedures by 75 surgeons across 50 hospitals. No device related adverse events have occurred.

Surgeon feedback has been encouraging, with comments including that the device “allows me to perform safer surgeries by defining anatomy with exceptional accuracy" and “ensures consistent and perfect sleeve gastrectomy creation every time, while eliminating the common pitfalls of narrowed incisura or leaving retained fundus.” Another surgeon commented that “for gastric bypass, the lights give me a precise 5cm measurement of my gastric pouch. The FGCT was also helpful in a complex hiatal case where the lights allowed me to see the esophagus more clearly.”

Surgeons also report the device is helpful in revisional bariatric operations, one user used the FGCT to identify a gastric fistula that was not detected prior. Anesthesia providers also report increased confidence introducing the device, as they can see it coming into the stomach, and no longer rely on the surgical team feeling the tube.

Finally, patients have expressed support for this technology and are enthusiastic for their surgeon to use a device that can improve intraoperative visualization during their surgery.



Image 1. The Endolumik Fluorescence Guided Calibration Tube

Future Directions

- The FGCT improves visualization during bariatric surgery, however further study is warranted to determine if it can improve surgical outcomes.

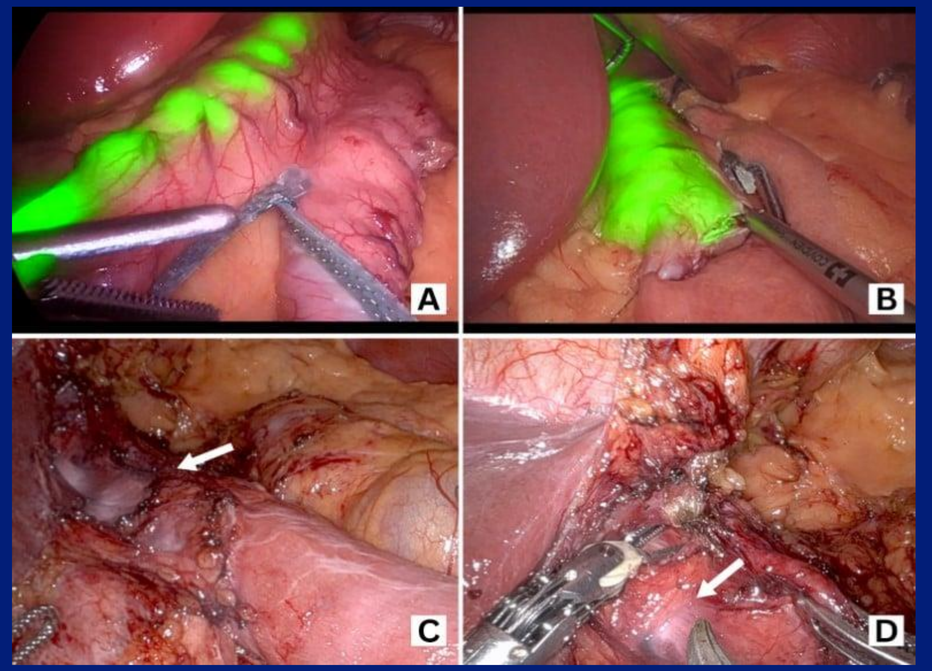


Image 2. The fluorescence guided calibration tube within the stomach during (A) laparoscopic sleeve gastrectomy (visible in green), (B) laparoscopic gastric bypass (visible in green), and (C&D) robotic revisional bariatric operation (visible in white)

Disclosures:
Szoka, Founder Endolumik Inc., Consultant CSATS