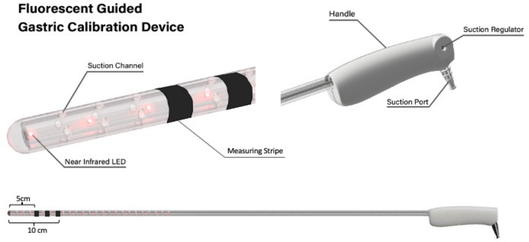
# Fluorescence-Guided Gastric Calibration Device With Measuring Functionality For Bariatric Surgery

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## Introduction

Fluorescence-guided surgery (FGS) is a medical imaging technique that uses fluorescent dye or a near-infrared emitting light source to identify anatomic structures during surgical procedures. FGS is a rapidly growing field that provides visual cues to improve surgical precision and improve surgical decision making. Our team has developed a fluorescence-guided gastric calibration device for use in bariatric surgery to allow for improved visualization and increased size consistency when constructing the gastric sleeve and gastric pouch during sleeve gastrectomy and gastric bypass operations.




## Device Specifications

- Disposable, single-use device consisting of LED lighted body and handle
- Size 40 French
- Body with included suction capability
- Handle contains battery power source, suction regulator, and suction adaptor
- Additional Functionality: near-infrared guided measurement capabilities

## Fluorescence-guided Laparoscopic Sleeve Gastrectomy

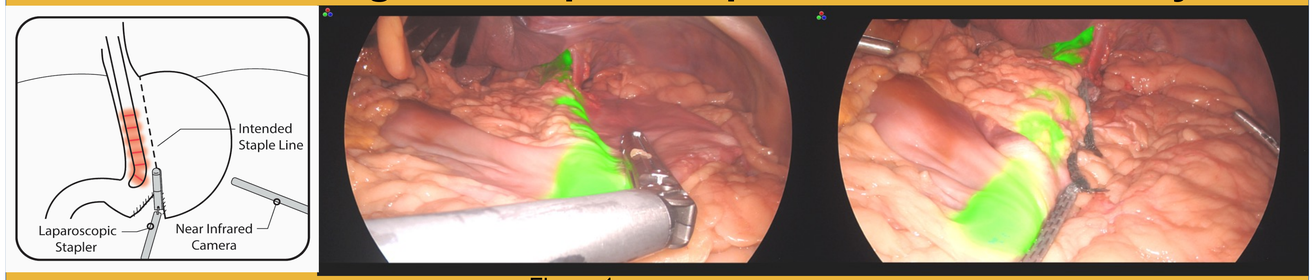



Figure 1

## Fluorescence-guided Laparoscopic Gastric Pouch Construction

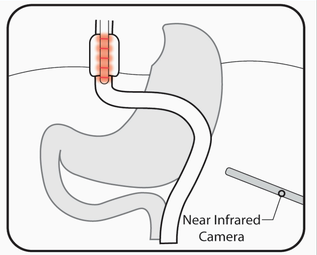



Figure 2

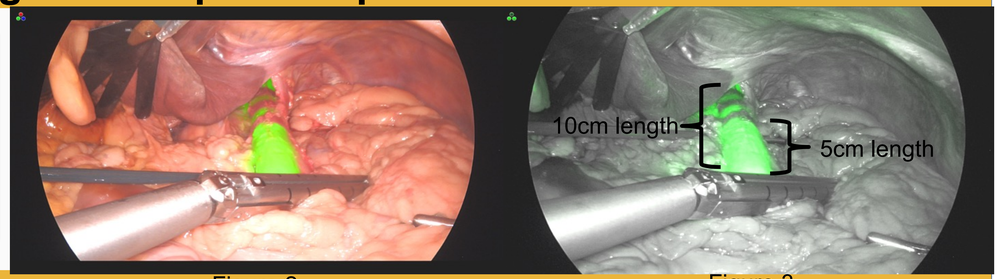



Figure 3

## Technique

A laparoscopic camera with white light/ near-infrared overlay mode is used to introduce the fluorescence-guided calibration device into the patient's stomach and form the gastric sleeve during a sleeve gastrectomy (Figure 1) or the gastric pouch during gastric bypass (Figure 2). The markings on the device allow for measurements up to 10cm in length(Figure 3).

## Results

- FGS technology and associated techniques - validated in ex-vivo and in-vivo porcine models and human cadaveric tissue model.
- Preliminary testing - improved visualization of the calibration tube for surgical team members during introduction of the device for gastric sleeve and pouch formation
- Device allows measurement of gastric pouch length

## Next Steps

- 510K FDA submission
- Clinical trial for in-human testing of device & associated methods