# Informed Consent Form

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| **Sponsor / Study Title:** | **Endolumik Inc. / "Pilot Study of the Endolumik Gastric Calibration Tube for Bariatric Surgery"** |
| **Principal Investigator: (Study Doctor)** | **Lawrence Tabone, MD, MBA, FACS, FASMBS** |
| **Telephone:** | **304-293-1728 (24 Hours)** |
| **Address:** | **Ruby Memorial Hospital<br>One Medical Center Drive<br>Morgantown, WV 26505** |

## Introduction

You are being asked to participate in a research study involving an investigational device, which has been explained to you by your study doctor or study staff. You are being asked to participate because your scheduled bariatric surgery may be enhanced by using the Endolumik Gastric Calibration Device during your sleeve gastrectomy or gastric bypass operation.

## Purpose

***The Endolumik Gastric Calibration Tube is designed to improve visualization during bariatric operations; with improved visualization our team hopes to improve the safety of bariatric surgery.***

The goal of the use of this investigational device study is to test the Endolumik Gastric Calibration Tube and associated method of fluorescence-guided bariatric surgery in a human cohort group of 20-30 bariatric subjects. An investigational device is one that is not approved by the United States Food and Drug Administration (FDA). The new integration of near-infrared lighting with the intra-gastric calibration tube is designed to improve visualization and situational awareness, team confidence, gastric sleeve size consistency, and safety of minimally-invasive sleeve gastrectomy operations. The protocol is designed to treat approximately 30 subjects under investigational use of this device. This is the first time the study device is being used in humans.

## Description of Procedures

WHAT WILL HAPPEN IF I TAKE PART IN THIS IDE USE TREATMENT?

The Endolumik Gastric Calibration Tube in the present study is a fluorescence-guided surgical instrument designed for use in minimally-invasive bariatric operations. The study device replaces the standard gastric calibration tube (also called a bougie) in the operation. The Endolumik Gastric Calibration Tube is designed to improve visualization

during bariatric operations; with improved visualization our team hopes to improve the safety of bariatric surgery.

A. For the sleeve gastrectomy operation, the protocol steps consist of the following:

A laparoscopic or robotic sleeve gastrectomy will be performed, which consists of the following steps: the stomach is mobilized by dividing the short gastric arteries along the greater curvature using a laparoscopic harmonic scalpel device. The Endolumik Gastric Calibration Tube will be inserted through your mouth and into your stomach prior to forming the gastric sleeve to remove stomach contents and guide the surgeon while the gastric sleeve is being formed. Suction will be applied to the device to evacuate the gastric contents. The Endolumik Gastric Calibration Tube will remain positioned in the stomach during sleeve construction. The stomach will be divided with a surgical stapler using minimally-invasive staples. Once the sleeve gastrectomy is completed, the Endolumik Gastric Calibration Tube will be removed. The gastric sleeve operation will be completed in standard fashion.

This procedure will take approximately 60 minutes. The amount of time the Endolumik Gastric Calibration Tube will be inside you is approximately 20 minutes. This is the same amount of time that the standard calibration device would be inside you.

B) For the gastric bypass operation, the steps consist of the following:

A laparoscopic gastric bypass will be performed. The Endolumik Gastric Calibration Tube will be inserted through your mouth and into the your stomach to remove stomach contents and guide the surgeon while the gastric pouch is being formed. The Endolumik Gastric Calibration Tube will be used to calibrate the gastric pouch. Surgical staplers will be used to form the gastric pouch. The gastrojejunostomy will be created connecting the stomach and small intestine. The Endolumik Gastric Calibration Tube will be used to calibrate closure of the gastrojejunal connection and to perform a leak test of the gastrojejunal connection. Once the gastric bypass is completed, the Endolumik Gastric Calibration Tube will be removed. The gastric bypass operation will be completed in standard fashion.

This procedure will take approximately 120 minutes. The amount of time the Endolumik Gastric Calibration Tube will be inside you is approximately 20 minutes. This is the same amount of time that the standard calibration device would be inside you.

**How Long Will I Be Treated**

Although the use of the study device will only take approximately 60 minutes, this study will take 1 month to complete, as the team will monitor your postoperative outcome for 30 days.

**Whom to contact about this study**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00058006.

## Risks and Discomforts

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM PARTICIPATING IN THIS STUDY TREATMENT?

Risks from participation include the risks of elective surgery which are:

- Bleeding
- Infection
- Damage to surrounding structures
- Need for further operations
- Venous thromboembolism (blood clots)
- Stroke
- Heart attack
- Death

The possible complications associated with the use of the Endolumik Gastric Calibration Tube are expected to be those typically associated with calibration systems. All surgical calibration tubes have the following known adverse reactions and potential complications associated with their use:

- Esophageal/gastric perforation (hole or tear of the esophagus or stomach)
- Bleeding/hemorrhage
- Fistula (abnormal connection between two different organs)
- Improper disinfection/infection
- Accidental stapling of tube

In addition, potential adverse events associated with bariatric surgeries may include:

- Leaks

- Strictures (abnormal narrowing of a body passage)
- Ischemia (reduced blood flow)
- Gastroesophageal reflux disease
- Chronic pain
- Dysphagia (difficulty swallowing)
- Excess weight loss

This device should not be used with the following medical conditions:

- Esophageal stricture
- Esophageal varices
- Zenker's Diverticulum
- Any conditions that preclude a sleeve gastrectomy or gastric bypass operation

Please notify the study doctor if anyone has told you that you have any of these conditions.

Since the study device is investigational, there may be other risks that are unknown.

## Alternatives

You do not have to participate in the study to have your bariatric surgery done. Alternatives that could be considered in your case include standard of care treatment without participation in this study.

## Benefits

Participation in the study may or may not lower your risk related to visualization during the surgery. Information learned from the study may help other people in the future.

## Financial Considerations

### Cost

The Sponsor will provide the study device at no charge. However, you or your insurance company will still be responsible for the cost of the surgery.

### Compensation

You will not receive any monetary compensation for your participation in this study.

### Compensation for Injury

No compensation is available as the result of injury associated with this device. Treatment of side effects or injury associated with the study device will be billed to you or your insurance company as part of your medical treatment. By signing and dating this

document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

### Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities, such as the US Food and Drug Administration (FDA), without your additional consent.

In any publications that result from this treatment, neither your name nor any information from which you might be identified will be published without your consent.

### Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate at any time and there will be no penalty to you. The study doctor or the sponsor can stop your participation at any time without your consent.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

## HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign and date or not to sign and date this authorization section. However, if you choose not to sign and date this authorization, you will not be able to take part in the study. Whatever choice you make about this study will not have an effect on your access to medical care.

### Persons/Organizations Providing the Information

Subject/West Virginia University (WVU) Hospitals/ WVU Medicine/ West Virginia United Health System (WVUHS)/ Duke University

### Persons/Organizations Receiving the Information

- The study site(s) carrying out the study. This includes West Virginia University and Duke University. It also includes each site's study staff and medical staff.
- Laboratories and other people and groups that look into your health information as part of your study treatment in agreement with the study plan.

- The members and staff of any institutional review board that oversees the use of investigational devices.
- The West Virginia University Human Research Protection Program and/or Compliance and the Office of Sponsored Programs.
- WVU School of Medicine/ Department of Surgery.

## The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as:

- Medical Record Number
- Age
- Sex
- Race
- Height
- Weight
- Body Mass Index (BMI)
- Medications
- Post medical history
- Past surgical history
- Operative time
- Intraoperative adverse events
- 30-day morbidity

## The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes.
- Publication of treatment results (without identifying you).
- Other research purposes such as developing a better understanding of disease; improving the design of future clinical trials.

## You May Cancel This Authorization at Any Time by Writing to the Principal Investigator at the address listed on page 1 of this form.

Only written cancelation of Authorization is permissible.

If you cancel this authorization, any information that was collected already for this procedure cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the procedure until the sponsor has completed all work related to the study. At that time, you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is incorrect.

This authorization will expire at the end of the study unless you cancel it before that time.

## Signatures

You have been given the opportunity to ask questions about the study plan and you have received answers concerning areas you did not understand. Upon signing and dating this form, you will receive a copy.

### Subject Signature

I willingly consent to participate in this research.

Signature of Subject

Printed Name Date

### Consenting Individual Signature

The subject has had the opportunity to have questions addressed. The subject willingly agrees to participate in the study of this investigational device.

Signature of Person Obtaining Informed Consent

Printed Name Date