**Study Title: Is the Gastro™ LMA® a feasible alternative to the use of a native airway for endoscopic retrograde cholangiopancreatography (ERCP) cases?**
**Principal Investigator: Katherine Hagan, MD**

**Co-Investigator(s): Carin Hagberg, MD,**

**Collaborator(s): Richard Carlson III, MD, Benjamin Arnold, MD, Linh Nguyen, MD, Jeffrey Lee, MD, Brian Weston, MD**

**Statistician: Mike Hernandez**

**Sponsor Name: Teleflex**

## SUMMARY TABLE

| ***Title*** | **Is the Gastro™ LMA® a feasible alternative to the use of a native airway for endoscopic retrograde cholangiopancreatography (ERCP) cases?** |
|---|---|
| *Study Size (# of patients)* | 30 |
| *Study Design* | This is a prospective feasibility study. |
| *Primary Objective* | To evaluate the successful completion of ERCP with the LMA® Gastro™ |
| *Secondary Objectives* | To evaluate the following:<br>1) Gastroenterologist satisfaction<br>2) Anesthesiologist satisfaction<br>3) Rate of successful placement of LMA® Gastro™<br>4) To determine the ability of the LMA® Gastro™ to provide adequate oxygenation and ventilation throughout the procedure<br>5) To determine and describe the rate of adverse events |
| *Inclusion Criteria* | Adult patients (≥ 18 years old) undergoing elective ERCP requiring general anesthesia |
| *Exclusion Criteria* | Patients with propofol allergy<br>Patients at increased aspiration risk<br>Patients with abnormal head/neck pathology making LMA® Gastro™ placement difficult<br>Patients with surgical or radiation treatment to the head/neck making LMA® Gastro™ placement difficult |

| | |
|---|---|
| | Esophagectomy patients<br>Patients already intubated upon arrival to endoscopy suite<br>Patients undergoing Endoscopic Ultrasound (EUS)<br>Patients with BMI ≥ 35 kg/$m^2$<br>Non-English speaking patients |
| ***Study Procedures*** | |
| *Pretreatment Evaluation* | Eligible subjects will be identified from within the patient population of the study site. There will be no advertisements for study subjects. |
| *On-Study Visits* | All patients meeting study criteria will have anesthesia induced with propofol<br><br># of attempts to place LMA® Gastro™ will be recorded<br><br>Upon completion of the procedure, the gastroenterologist and anesthesiologist will complete a device satisfaction survey. |
| *Follow-up Visits* | None |
| *End of Study Visit* | None |
| *Primary Endpoint* | Successful completion of ERCP with the LMA® Gastro™ is defined as the ability to place LMA gastro within 3 attempts where completion of the procedure occurs with the LMA® Gastro™ in place. |
| *Feasibility Definition* | The study will be deemed feasible if the study can be completed without crossing any of the stopping boundaries associated with study failure provided by the Bayesian monitoring rule requiring suspension of patient accrual. |
| ***Brief Analysis Plan*** | The success rate will be estimated using an exact 95% confidence interval. Assuming a success rate of 90% (27/30), the limits of an exact 95% confidence interval are (0.73, 0.98). Descriptive statistics will be used to summarize all study data. Study failure, defined as inability to place the LMA gastro after 3 attempts or removal of the LMA gastro prior to the completion of the procedure for any reason, will be monitored using the following Bayesian rule: $Pr(p(F) > 0.10 \mid data) > 0.90$, where the probability of failure is denoted by p(F). Therefore, we will suspend accrual if at any time there is a greater than 90% chance that the failure rate exceeds 10%. |

## 1. OBJECTIVES

Primary Objective: To assess the successful completion of ERCP with the LMA® Gastro™

Secondary Objectives:

1) To determine gastroenterologist satisfaction with the LMA® Gastro™
2) To determine anesthesia provider satisfaction with the LMA® Gastro™
3) To determine the rate of unsuccessful LMA® Gastro™ placement
4) To determine the ability of LMA® Gastro™ to provide adequate oxygenation and ventilation throughout the procedure.
5) To determine and describe the rate of adverse events

## 2. BACKGROUND

There is ongoing debate within the anesthesia community concerning the best way to sedate patients for ERCP. Traditionally, anesthesiologists have intubated these patients. However, many ERCP patients are now receiving propofol sedation for ERCP with a native airway. Unfortunately, it has been demonstrated in other patient populations that moderate propofol sedation frequently progresses to deep anesthesia which encompasses all the inherent airway and cardiopulmonary risks associated with propofol anesthesia.(1-5) This type of anesthetic requires constant vigilance on the part of the anesthesia provider and, at times, frequent interventions (chin lift/jaw thrusts or placement of an oral airway or nasal trumpet). Furthermore, 28% of patients experience oxygen saturations of < 90% and a small percentage (0.2%) experience aspiration pneumonia which may lead to significant morbidity and mortality.(6)

Management of a native airway for overweight or obese individuals or for longer procedures is particularly challenging.(7,8) The alternative to propofol sedation with a native airway is either endotracheal intubation (which is more invasive for the patient, increases anesthesia time, and is not without its own risks, such as prolonged muscle paralysis and dental damage) or moderate sedation by the endoscopist (which requires significant attention from the endoscopist to do safely and effectively, perhaps making completion of their therapeutic procedure more difficult). Osborn et al. demonstrated that it was feasible to perform ERCP with a laryngeal mask airway by displacing the LMA tube to the lower left side of the mouth.(9) LMAs are generally placed easily by trained practitioners, with a maximum of 3 attempts allowable, as described by the Difficult Airway Society.(10)

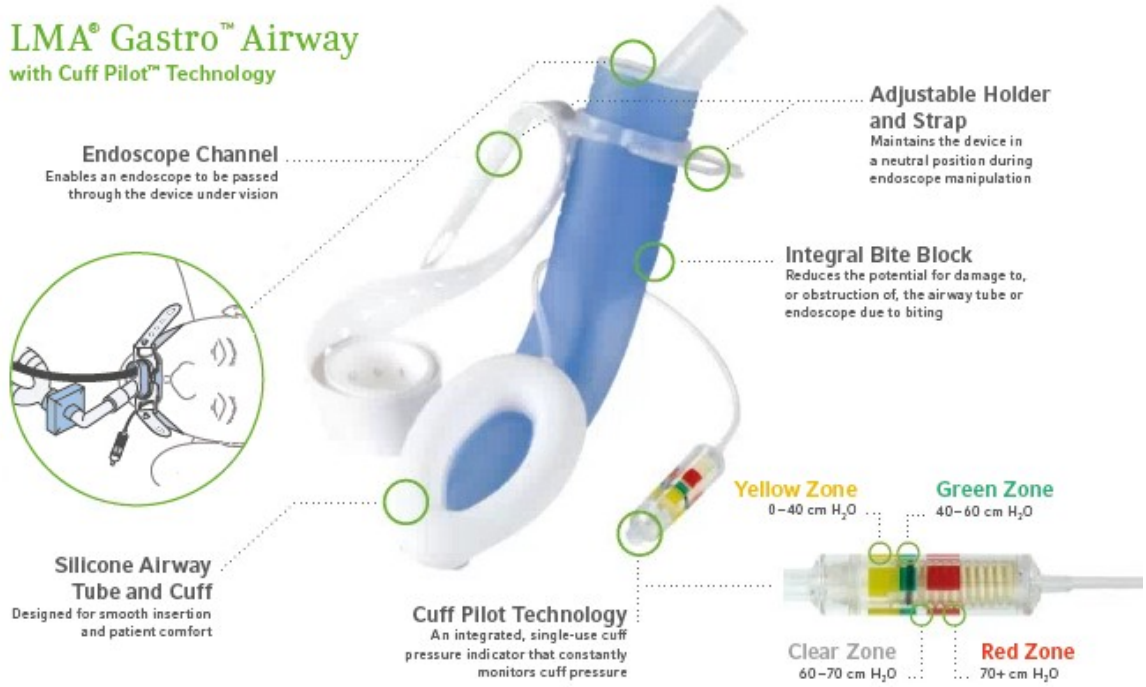
The LMA® Gastro™ represents a novel device with the ability to facilitate direct endoscopic access via the integrated endoscopic channel. Although the utility for esophagogastroduodenoscopy has been demonstrated(11), a similar feasibility study has not been conducted for ERCP procedures. The utility of the LMA® Gastro™ may be less for ERCPs, as ERCP procedures require multiple small movements to enable cannulation of the bile duct and frequent advancement or retraction of the endoscope in order to successfully complete the procedure. It is possible that the presence of the LMA tube will make these maneuvers more challenging. The goal of this study is to determine the feasibility of the LMA® Gastro™ for ERCP.

## 3. BACKGROUND DEVICE INFORMATION

The LMA® Gastro™ has separate gastric and airway access. Respiratory depression from sedative drugs and airway obstruction requiring intervention are known risks associated with endoscopic

procedures, with studies demonstrating that hypoxemia can occur in 11-50% of cases. The LMA® Gastro™Airway with Cuff Pilot™ Technology from Teleflex is the only laryngeal mask specifically designed to give clinicians control of their patients' airways while facilitating direct endoscopic access via the integrated endoscopic channel. With the airway in place, clinicians can monitor end tidal $CO_2$ for patient safety. The LMA® Gastro™Airway is indicated for airway management in adult patients.

The LMA® Gastro™Airway is a single-use laryngeal mask with a di(2-ethylhexyl)phthalate (DEHP)-free silicone cuff and airway tube. The silicone cuff is soft and flexible, and conforms to patient anatomy to create an effective oropharyngeal seal. The LMA® Gastro™Airway also features Cuff Pilot Technology – an integrated, cuff pressure indicator that constantly monitors cuff pressure detecting changes resulting from fluctuations in temperature, nitrous oxide levels and movements within the airway. It provides at-a-glance feedback, highlighting changes that could affect patient safety so that adjustments can be made when necessary.




## 4. STUDY DESIGN

This is a prospective single arm feasibility study.

## 5. DISCUSSION OF STUDY POPULATION

### 5.1 Study Characteristics

a) **Number of Subjects:** This study will enroll 30 patients. We anticipate a screen failure rate of

30-50%.

### 5.2 Inclusion and Exclusion Criteria

a) Inclusion Criteria

- Adult patients (≥ 18 years old) undergoing elective ERCP with general anesthesia.

b) Exclusion Criteria

- Patients with propofol allergy
- Patients at increased aspiration risk
- Patients with abnormal head/neck pathology preventing LMA® Gastro™ placement
- Patients with surgical or radiation treatment to the head/neck making LMA® Gastro™ placement difficult
- Esophagectomy patients
- Patients already intubated upon arrival to endoscopy suite
- Patients undergoing Endoscopic Ultrasound (EUS)
- Patients with BMI ≥ 35 kg/$m^2$
- Non-English speaking patients

## 6. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

### 6.1 Method of Subject Identification and Recruitment

Eligible subjects will be identified from within the patient population of the study site by a member of the research team. Advertisements for study subjects are not anticipated.

### 6.2 Consent Process

Subjects deemed eligible to participate in the study will be explained in detail the purpose, nature and procedures of the study, as well as the potential risks, benefits and alternatives. They will be given a consent form to read and if they so choose, to discuss with friends, family, and other clinicians. They will be invited to ask questions and, after all questions are answered to their satisfaction, invited to sign the consent form. The Principal Investigator or another member of the research team will participate in the consenting process to ensure the subject has full understanding of the procedure and risks. No study-specific procedure will be performed before the consent form is signed.

All consents will be signed electronically within the medical record on a MD Anderson password protected computer.

### 6.3 Costs to the Subject

None

### 6.4 Payment for Participation

There will be no payments for participation in the study.

### 6.5 Return of Individual Research Results

Individual research results will not be provided back to the subject.

## 7. METHODS AND STUDY PROCEDURES

### 7.1 Pretreatment Evaluation

The PI/Co-PI/research coordinator of the study will evaluate the inclusion/exclusion criteria. Patients will be approached while in the preoperative area to discuss participation in the study. The PI/Co-PI/research coordinator will ensure that patients are properly informed about the study. All study related data will only be collected after the PI or Co-PI approves patient enrollment in the study and the patient has signed the consent.

### 7.2 Procedure

Prior to patient induction, the appropriate size LMA® Gastro™ will be chosen based upon manufacturer recommendations. The LMA® Gastro™ will be fully deflated and the posterior aspect will be lubricated with KY jelly as per manufacturer instructions prior to insertion.

Upon arrival to the procedure room, all standard of care monitoring will be performed, including pulse oximetry, noninvasive blood pressure monitoring, EKG, and capnography. The patient will be preoxygenated with 100% oxygen via full face mask in the supine position prior to induction of general anesthesia. Pre-oxygenation will be administered for 3 minutes of normal tidal volume breathing or for 8 deep breaths over one minute, or until end expiratory oxygen reaches 90%.

Once pre-oxygenation is complete, patients will be induced with 1mg/kg 1% lidocaine and 1-4 mg/kg propofol. Upon loss of the patients lash reflex, the LMA® Gastro™ will be placed in the patient's oropharynx. The cuff should be inflated until the cuff pilot indicator line is within the green zone. Appropriate placement will be confirmed with end tidal $CO_2$ and adequate tidal volumes of at least 4-5 cc/kg. The LMA® Gastro™ will be secured using the manufacturer provided adjustable holder and strap. Following placement confirmation, sedation will be titrated to achieve deep to general anesthesia using a propofol infusion at 50-300 mcg/kg/min. Insufficient sedation with propofol may be supplemented with inhalational anesthetics or opioids.

After securing the airway, the patient will be positioned on the fluoroscopy table in the prone position with head facing to the right (although occasionally patient may be repositioned in the left lateral decubitus or supine position) to facilitate the ERCP. Positioning is at the discretion of the gastroenterologist. After the patient is positioned, the anesthesiologist will again confirm that the LMA® Gastro™ is positioned properly before allowing the procedure to begin. During the procedure, the patient may receive positive pressure ventilation keeping airway pressures $\leq$20 mmHg or the patient may maintain spontaneous ventilation with or without ventilator support, as

long as adequate minute ventilation (≥5 L/min) and appropriate end tidal $CO_2$ (< 45 mmHg) is maintained.

A standard sideviewing duodenoscope measuring 11.3mm in maximum diameter will be lubricated with KY jelly by the gastroenterologist, coating the full length of the endoscope that will be inserted into the LMA® Gastro™.

Should the LMA® Gastro™ impede completion of the procedure, the anesthesiologist will remove the LMA® Gastro™ and either proceed with a native airway or place an endotracheal tube. This decision will be at the discretion of the anesthesiologist.

### 7.3 Data Collected from EMR

- Demographics (e.g. BMI, age, gender)
- Comorbidities
- Indication for procedure
- Dosing of medications
- Information regarding anesthetic management
- Information about the ERCP procedure

### 7.4 Additional Data Collected by Research Coordinator

- Number of attempts required to place the LMA® Gastro™ (See Appendix 2)
- Removal of the LMA® Gastro™ prior to completion of the procedure (See Appendix 2)
- Any adverse events (See Appendix 2)
- Gastroenterologist device satisfaction survey (See Appendix 3)
- Anesthesiologist device satisfaction survey (See Appendix 3)

### 7.5 Special Instructions and Definitions of Events

- LMA® Gastro™ placement attempt is defined as passage of the LMA® Gastro™ into the oropharynx
- The gastroenterologist and anesthesiologist device satisfaction surveys will be filled out independently and privately

## 8. SUBJECT WITHDRAWALS

Subjects may be withdrawn from the study for the following reasons:

1). Subject non-compliance with study procedures
2). Unacceptable adverse events (safety or tolerability)
3). The subject may withdraw from the study at any time and for any reason
4). Clinician decision that it is in the best interest of the subject to withdraw from the study

## 9. SAFETY AND REPORTABLE EVENTS

### 9.1 Adverse Event Definition

An adverse event is any symptom, sign, illness, or experience which develops or worsens during the course of the study, whether or not the event is considered related to investigational product. This includes a change in a subject's condition or laboratory results, which has or could have a deleterious effect on the subject's health or well-being. An Adverse Event that is related to the investigational device may be referred to as an Adverse Device Effect (ADE).

Unanticipated Adverse Device Effect (UADE): Any device related adverse event, the nature or severity of which is not consistent with or listed in the applicable product information (e.g., instructions for use, subject informed consent document, subject information brochure [if applicable], promotional literature) or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

**Expected Adverse Events**
Abrasion to lips, tongue, or oral mucosa
Conversion to endotracheal intubation or native airway
Small amount of blood tinged sputum
Sore throat

### 9.2 Serious Adverse Event

A serious adverse event is defined as any adverse medical experience that results in any of the following outcomes:

- Death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Requires medical or surgical intervention to prevent permanent impairment or damage

### 9.3 Recording Adverse Events

The site study staff will assess adverse events by recording all voluntary complaints of the subject and by assessment of clinical and laboratory features.

All adverse events, whether observed by the investigator, elicited from or volunteered by the subject, should be documented. Each adverse event will include a brief description of the experience, the date of onset, the date of resolution, the duration and type of experience, the severity, the relationship to investigational product (i.e. the device), contributing factors, and any action taken with respect to the study device.

### 9.4 Responsibilities for Reporting Serious Adverse Events

The Investigator should record all serious adverse experiences that occur during the study period in the appropriate source documents and/or AE log as applicable. The study period for

reporting serious adverse events (e.g. from the time of signing consent to final study visit) should be indicated, who needs to be notified and the time frame for notification. If there are any specific reporting forms to be completed, this should be indicated here. The Investigator will comply with regulations and IRB policy regarding the reporting of adverse events.

## 10. RISK/BENEFIT ASSESSMENT

### 10.1 Potential Risks

- Minor trauma to the lips of oropharynx
- Difficulty ventilating through the LMA® Gastro™
- Possibility that device will need to be removed prior to procedure completion, necessitating intubation

### 10.2 Protection Against Risks

- Appropriate patient selection, avoiding patients with oropharyngeal abnormalities

### 10.3 Potential Benefits to Subjects

- More secure airway with reduced risk of respiratory compromise and aspiration than treatment with a native airway
- Less likely to have a sore throat than with endotracheal intubation

### 10.4 Alternatives to Participation

- Management of the airway with an endotracheal tube or with a native airway at the discretion of the anesthesiologist

## 11. CONFIDENTIALITY OF DATA AND INFORMATION STORAGE

All study participants will be assigned a study number. The PI will maintain the key to the study number and medical record number in a password locked MD Anderson computer. Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Patient data will be entered into a password protected electronic spreadsheet and online database (i.e. REDCap). Only the investigators, who have been invited to participate in the study and who are registered with the IRB, as well as have documented completion of all IRB and HIPAA regulations will have access to patient data, but not the medical record key.

Electronic records will be stored for 5 years after study conclusion on the institution's password protected computer, after which time they will be deleted. If there is a breach in confidentiality or violation of IRB and HIPAA regulations, the IRB will be notified in a timely manner (within 7 days) and appropriate actions taken thereafter. All data used in the analysis and reporting of this investigation will be de-identified. Any photography shall be done in a discrete manner. Should images run the risk of enabling patient identification, identifying characteristics will be obscured electronically prior to publication.

In order to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA), all subjects enrolled in the study will be required to provide authorization to disclose Protected Health Information (PHI). This authorization will be included in the informed consent document as required by the IRB. In all study reports and in any resulting publications, subjects will not be referred to by their initials and/or study identification number.

## 12. SAMPLE SIZE DETERMINATION AND DATA ANALYSIS

### 12.1 Sample Size Determination

- This feasibility study will enroll 30 patients.
- Study success is defined as the ability to place LMA gastro within 3 attempts where completion of the procedure occurs with the LMA® Gastro™ in place.
- The success rate will be estimated using an exact 95% confidence interval.
- Assuming a success rate of 90% (27/30), the limits of an exact 95% confidence interval are (0.73, 0.98).
- The study will be deemed feasible if the study can be completed without crossing any of the stopping boundaries associated with study failure provided by the Bayesian monitoring rule (described below) requiring suspension of patient accrual.

Monitoring of the Failure Rate

- Study failure is defined as inability to place the LMA gastro after 3 attempts or removal of the LMA gastro prior to the completion of the procedure for any reason.
- It will be monitored using the following Bayesian rule: $Pr(p(F) > 0.10|data) > 0.90$, where the probability of failure is denoted by p(F).
- A uniform prior for study failure, $p(F) \sim beta(1, 1)$, is assumed.

- Therefore, accrual will be suspended if at any time there is a greater than 90% chance that the failure rate exceeds 10%. The Bayesian monitoring of the trial will be in place as mechanism to alert the investigative team of any irregularities or unanticipated occurrences that may arise.

Table 1: Stopping Boundaries for Monitoring Study Failure

| No. of Patients | Suspend the Trial with this many Study Failures |
|---|---|
| 5 | 2 to 5 |
| 10 | 2 to 10 |
| 15 | 3 to 15 |
| 20 | 4 to 20 |
| 25 | 5 to 25 |
| 30 | ≥ 5 or max accrual |

- using (http://ibl.mdanderson.org/BTM) MDA Biostatistics Shiny Applications

Table 2: Operating Characteristics for Monitoring Study Failure

| True toxicity rate | Probability of Early Termination | Avg. No. of Patients |
|---|---|---|
| 0.05 | 0.0968 | 28 |
| 0.1 | 0.3221 | 23.6 |
| 0.15 | 0.5725 | 18.7 |
| 0.2 | 0.7717 | 14.5 |
| 0.25 | 0.896 | 11.4 |

- using (http://ibl.mdanderson.org/BTM) MDA Biostatistics Shiny Applications

### 12.2 Planned Statistical Analysis

Descriptive statistics will be used to summarize all study data. Frequencies and percentages will be used to summarize the failure and success rates. Interval estimation of rates will be provided using Clopper-Pearson exact 95% CIs. Visualization techniques (such as bar graphs, line graphs, etc.) will be used to illustrate distribution of the number of LMA® Gastro™ attempts and other select study outcomes. Surveys for gastroenterologist and anesthesiologist satisfaction with the LMA® Gastro™ contain items measured on a 10-point Likert scale with 1 reflecting strong disagreement and 10 strong agreement. Mean scores and standard deviations will be used to provide summaries for each survey item. Summaries will be stratified by gastroenterologist and anesthesiologist. Paired differences in survey items between gastroenterologist and anesthesiologist scores will be summarized using descriptive statistics and 95% CIs. Finally, some patients will have the same anesthesiologist or gastroenterologist who performs the ERCP; therefore, descriptive summaries of study outcomes will be conducted by anesthesiologist and gastroenterologist to explore for the potential of a clustering effect.

## 13. DATA MONITORING

### a. Data and Safety Monitoring

Training of Clinical Site Personnel

The PI will conduct a training session with all anesthesia collaborators. The anesthesia collaborators will view a video demonstrating placement of the LMA® Gastro™ and will practice LMA® Gastro™ placement on a mannequin 10 times prior to being cleared to begin the study.

### b. Data Collection and Management

All study data will either be collected on a paper case report form (CRF) (which will be entered in a computer database) or will be extracted directly from the EMR to the REDCap database. Each subject will be assigned a random number code and the key linking the code and the subject identifier will be stored on an MD Anderson password protected computer. All changes to the CRF will follow Good Clinical Practice guidelines. The Research Manager is responsible for auditing the

consistency of the data transcribed from the paper CRF to the computer. A protocol violation log will be maintained and all protocol violations will be reported to the IRB.

Members of the research team are responsible for transferring the information to the appropriate CRFs. The PI is responsible for ensuring the forms are accurately completed at the time of, or as soon as possible after, the subject procedure or the availability of test results. The PI is required to sign the CRF on the appropriate page(s) to verify that she has reviewed the recorded data. Upon PI approval, CRFs will be entered into the password protected REDCap database for analysis.

Additional clinical monitoring by the sponsor will be at the sponsor's discretion.

## 14. REFERENCES

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## 15. APPENDIX

11.1 Calendar of Events
11.2 RCF for Intraprocedural events
11.3 LMA® Gastro™ satisfaction surveys

## Appendix 1: Calendar of Events

| Visit Window | Screening | Intra-op | Post-op |
|---|---|---|---|
| Subject Recruitment | x | | |
| Enrollment/Pt education | x | | |
| Medical Record Documentation | x | x | x |
| CRF completion | | x | x |