**Official title: The VivaSight Double Lumen Tube versus Conventional Double Lumen Tube in Thoracic Surgical Patients**

**NCT number: NCT03690284**

**Document date: 06-18-2019**

**Form A**

| IRB # | STU-2018-0098 |
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**PROTOCOL FORM / RESEARCH DESCRIPTION**

If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

**Click once on the highlighted entry in each box to provide your response.** Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

**1. Purpose and objectives.** *List the purpose and objectives:*

Specific Aim 1: To assess if intubation without flexible fiberoptic bronchoscopy is possible in conventional double lumen tube (DLT) vs VivaSight DLT.

Primary Hypothesis: Cases utilizing the VivaSight will need fiberoptic bronchoscopy in 30% of cases versus 100% of cases with a conventional DLT.

Specific Aim 2: To assess the time to successful placement of the VivaSight DLT vs conventional DLT and compare the incidence of tube malposition in the two types of DLTs.

Secondary Hypothesis: The VivaSight DLT will take significantly less time to place compared with the conventional DLT. Additionally, the incidence of malposition will be significantly less with the VivaSight.

Specific Aim 3: To determine the reduction in cost associated with using VivaSight DLTs compared to conventional DLT.

Tertiary Hypothesis: Use of the VivaSight DLT will reduce the cost of fiberoptic bronchoscopy purchasing and maintenance by 50%.

**2. Background.**

- Describe past experimental and/or clinical findings leading to the formulation of your study.
- For research involving investigational drugs, describe the previously conducted animal and human studies.
- For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.
- Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (section number and/or title) or if none, ensure background includes references.

Please respond to all components of this item, or clearly indicate which components are not applicable.

**a. Background**

Thoracic surgery frequently involves single lung ventilation, which is most commonly achieved with a double lumen endotracheal tube (DLT). Double lumen tubes are more difficult to insert than single lumen tubes because they are much larger and stiffer. Malposition can lead to problems with lung deflation, difficulty with oxygenation and ventilation, or cause airway injury [1]. As auscultation alone is unreliable, the use of a flexible fiberoptic bronchoscope remains the gold standard for confirming correct placement of DLTs [2]. In one study, 35% of blindly inserted DLTs that were thought to be in correct position were found to be malpositioned upon fiberoptic bronchoscopic confirmation [3]. However, fiberoptic bronchoscopes can be costly to acquire and maintain and may not be available in all hospitals or surgical centers. The VivaSight DLT is a FDA-approved device that is indicated for use in thoracic surgical patients to provide single lung ventilation. The VivaSight DLT has an integrated camera on the distal tip of the tracheal lumen, which is attached to a screen and permits continuous visualization of its position in the trachea. In many cases, this may obviate the need to use flexible fiberoptic bronchoscopy to

confirm correct tube placement. Previous studies have shown that time to placement for the VivaSight is significantly decreased compared to conventional DLTs [4].

Placement of the VivaSight is significantly faster than traditional DLTs because continuous visualization during insertion eliminates the need for fiberoptic confirmation in the majority of cases. Due to the continuous visualization of its position, displacement from repositioning or surgical manipulation can be detected more quickly and therefore able to be rectified faster with VivaSight DLTs. Many patients who are undergoing thoracic procedures have preexisting pulmonary disease. This compounded with the need for single lung ventilation makes these patients very intolerant to malpositioned tubes or inadequate ventilation. Being able to continuously visualize the position of the DLT may thus allow earlier identification and rectification of tube malposition for this vulnerable population of patients.

Both conventional DLT and the VivaSight DLT are made of polyvinylchloride and have similar size bronchial and tracheal cuffs. A disadvantage of the VivaSight is that if secretions or blood cover the lens, it can be difficult to dislodge and therefore the view may become obscured. It is easier to clean the tip of a fiberoptic bronchoscope since it can be removed from the airway. Based on 6 months of clinical practice at Parkland Hospital, the necessity of fiberoptic bronchoscopy use with VivaSight DLT is around 20% [unpublished data].

**b. Current practice**

The current clinical practice is to use either a conventional Mallinkrodt double lumen tube or a VivaSight DLT for thoracic cases. This is usually up to the discretion of the anesthesia faculty, as both types of tubes are readily available.

**3. Study Design.**
Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

This prospective, randomized, comparative study is intended to enroll a total of 50 patients undergoing thoracic surgery that necessitates single lung ventilation. The efficacy and performance of the VivaSight DLT will be compared to the conventional double lumen tube. Use of fiberoptic bronchoscopy for initial tube positioning and subsequently during the case will be recorded. The attending thoracic surgeon will judge the quality of lung deflation. The occurrence of any malposition and subsequent maneuvers will be recorded. A standardized anesthetic protocol that is usual and customary for the type of operation the patient is having will be provided to the anesthesia teams of enrolled subjects. The remainder of the anesthetic care of the subject will not deviate from the standard of care.

**4. Research Plan / Description of the Research Methods:**

**4.a.** Provide a **comprehensive narrative** describing the **research methods**.

1) Provide the **order in which tests/procedures will be performed**,
2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.
3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Please respond to all components of this item, or clearly indicate which components are not applicable.

**1) Order in which tests/procedures will be performed**

*Screening and Informed Consent*

A member of the research team will use a screening form to look for surgical patients that meet all the inclusion and exclusion criteria. He/she will approach potential subjects in the preoperative area and the study will be explained in detail in a private room. Patients will be informed that they will receive no compensation for participating in the study and there will be no adverse consequences if they choose not to participate. If the subjects agree to participate,

informed written consent will be obtained prior to any study procedures and this document will be sent to pmhresearchparticipants@phhs.org, for inclusion in the patient's medical record, per Parkland regulations. The study duration will be from the beginning of anesthesia care to postoperative (POD) 1.

*Anesthetic Protocol*
The anesthesia team that will be caring for the subject during surgery will be given the protocol for the study, which standardizes the general anesthetic technique.

*Subject Group Assignment*
A randomization schedule will be created by a member of the research team that is not involved in clinical care (i.e., statistician). Subjects will be randomized 1:1 to receive either a standard double lumen endotracheal tube or a VivaSight double lumen endotracheal tube. ETT size will be selected based on gender and height-

- A woman shorter than 5'3" should be intubated with a 35-Fr tube
- A woman taller than 5'3" should be intubated with a 37-Fr tube
- A man shorter than 5'5" should be intubated with a 35-Fr tube
- A man taller than 5'5" but shorter than 5'10" should be intubated with a 39-Fr tube
- A man taller than 5'10" should be intubated with a 41-Fr tube

Once the patient is in the operating room, they will be positioned on the operating room table and standard ASA monitors will be applied. All patients will undergo a standard anesthetic induction, which includes neuromuscular blockade.

Following induction of anesthesia, the anesthesia provider will use a direct laryngoscopy with a Mac 3 or 4 blade to visualize the glottis. Patients who have a difficult airway or who require more than 3 attempts for intubation will be excluded from the study. In the conventional DLT group, the provider will be asked to stop insertion of the tube after the tracheal lumen has passed the vocal cords. The fiberoptic bronchoscope will then be inserted into the bronchial lumen to guide the tube into the left mainstem bronchus. In the Vivasight DLT group, the tube will be connected to a monitor prior to laryngoscopy and direct visualization of the tube's position will be used to guide it into the correct position. The time that the facemask is taken off the patient's face will be recorded as the 'start time' for laryngoscopy, and the 'end time' will be when the double lumen tube is verified to be in the correct position.

Successful DLT placement will be defined as chest rise during ventilation, a square capnography waveform, bilateral breath sounds, and no air leakage. Details regarding tube placement including Cormack-Lehane grade, number of attempts, number of operations, and use of any adjunct airway devices will be recorded. An independent investigator will evaluate and record all measurements and times. The intubator will be asked to assess the procedural difficulty of intubation on a scale of 1-5- 1: very easy; 2: easy; 3: some difficulty; 4: significant difficulty; 5: impossible.

When single lung ventilation becomes necessary, the anesthesia provider will inflate the bronchial cuff and clamp the respective lumen of DLT to provide single lung ventilation. After the pleura is opened, the surgeon will be asked to rate the quality of lung collapse- 1: excellent; 2: fair; 3: poor. At the conclusion of surgery, patients who meet extubation criteria will be extubated and taken to the PACU or ICU. The duration of intubation will be recorded.

If the lens of the VivaSight becomes obscured, the anesthesia provider will be asked to take the following steps:

1. Inject 20mL air into red injection port
2. Connect 10mL syringe filled with 2 mL saline and inject (twice- total 4mL)
3. Connect 10mL syringe filled with 5-10mL of air and inject (twice)
4. Connect empty 10mL syringe and suck the saline injected (twice)
5. Confirm correct tube position with FOB.

A blinded research assistant will perform all postoperative assessments. As patient-reported outcomes have become increasingly important for hospitals, treatments that have the potential to increase patient satisfaction are being studied closely. The postoperative quality recovery scale (PQRS) is a tool that assesses recovery over time and compares them to baseline values. Some of the advantages of the PQRS are that it is validated, takes less than 5 minutes to administer, has a low patient refusal rate, and is acceptable to patients across a wide range of ages. The PQRS will be administered at baseline in the preoperative area, and after PACU arrival at 45 minutes and on POD 1 (Appendix 1).

**2) Setting**

The study will take place in the pre operative rooms, the operating rooms, and the PACU at Parkland Hospital.

**3) Plan for data analysis**

*Data Sources*

Protected health information including name, medical record number, and date of birth will be recorded and stored securely in a password-protected, secured Excel database.

*Parameters*

1. Protected health information (PHI): name, medical record number, date of birth
2. Demographic information (age, weight, height, BMI, gender), medical and surgical history, ASA)
3. Intraoperative parameters
    - Baseline vital signs upon arrival to operating room
    - Time of induction and intubation
    - Intraoperative vitals (systolic, diastolic, and mean blood pressures, heart rate)
    - Laryngoscopy details (Cormack Lehane view, blade used)
4. Adverse event monitoring
    - Airway injury
    - Patient unable to be intubated (e.g., difficult airway)
    - Prolonged hypoxia (> 1 min at <92%) from anesthesia start to anesthesia stop
    - Respiratory adverse event including bronchospasm, laryngospasm aspiration, reintubation
    - Prolonged PACU stay (> 2 hours)
    - Unplanned hospital admission

*Statistics*

The study is powered to detect a difference in the primary endpoint, the rate of fiberoptic bronchoscopy use, between 30% for the VivaSight versus 100% for the Mallinckrodt DLT. The study will have 90% power (two-sided chi-square test with type I error rate = 0.05). Accounting for patient drop out and protocol deviations, the study will enroll a total of 50 subjects (25 in each group). The continuous data will be summarized as mean and standard deviation or median and inter-quartile range, as appropriate while categorical data will be summarized as frequency and percentages. The incidence of FOB usage in the two groups will be compared using a chi-square test or Fisher's exact test. Statistical significance is set at p=0.05.

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**4.b. List of the study intervention(s) being tested or evaluated under this protocol**

☐ **N/A -** this study does not test or evaluate an intervention. Skip to item 4.d.

| # | Study intervention(s) being tested or evaluated under the protocol<br><br>*Add or delete rows as needed* | Affiliate<br><br>Place a check next to institution(s) where the intervention will be performed | Local Standard Practice?<br>Indicate whether the intervention is considered acceptable practice locally for applicable institutions |
|---|---|---|---|
| 1 | VivaSight DLT | ☐ UTSW | ☐ Yes |
| | | ☐ PHHS | ☐ Yes |
| | | ☐CMC | ☐ Yes |
| | | ☐THR | ☐ Yes |
| | | ☐TSRH | ☐ Yes |
| | | ☐ Other: _____ | ☐ Yes |

**4.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol**

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

*(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)*

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**4.c.**
**Study Intervention #1**
VivaSight DLT

| **List each group exposed to this intervention on a separate line.** (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects | For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none". |
|---|---|
| Experimental Group | Potential faster tube placement/verification of correct tube position |
| | |

**If you are requesting a Waiver of Informed Consent, complete the table below.**

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

| | **Not serious** | **Serious** |
|---|---|---|
| **Likely** These risks are expected to occur in more than **20** out of **100** subjects. | • | • |
| | **Not serious** | **Serious** |
| **Less likely** These risks are expected to occur in **5-20** subjects or less out of **100** subjects. | • | • |
| | | **Serious** |
| **Rare** These risks are expected to occur in less than **5** subjects out of **100** | | • |

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| | | **4.d**. List ALL other research procedures or components not listed in table 4.b.<br>***The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.***<br><br>Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments) | | |
| | | | | |
| **#** | **Research component**<br>• **individual procedures**<br>*example:*<br>**Eligibility Assessments**<br>• History and physical<br>• Questionnaire<br>• Laboratory tests<br>*Add or delete rows as needed* | **Column A**<br>**Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the study.** | **Column B**<br>**Research Only**<br>Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if they were not participating in the study)* | **Column D**<br>**Risks**<br>**If you are requesting a Waiver of Informed Consent, complete the table below.**<br><br>List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate:<br>• Serious and likely;<br>• Serious and less likely;<br>• Serious and rare;<br>• Not serious and likely;<br>• Not serious and less likely |
| **1** | **Research component** | | | |

| | | | |
|---|---|---|---|
| Intubation | The anesthesia provider will use a direct laryngoscopy with a Mac 3 or 4 blade to visualize the glottis. Patients who have a difficult airway or who require more than 3 attempts for intubation will be excluded from the study. In the conventional DLT group, the provider will be asked to stop insertion of the tube after the tracheal lumen has passed the vocal cords. The fiberoptic bronchoscope will then be inserted into the bronchial lumen to guide the tube into the left mainstem bronchus. | In the Vivasight DLT group, the tube will be connected to a monitor prior to laryngoscopy and direct visualization of the tube's position will be used to guide it into the correct position. The time that the facemask is taken off the patient's face will be recorded as the 'start time' for laryngoscopy, and the 'end time' will be when the double lumen tube is verified to be in the correct position. | If the lens of the VivaSight becomes obscured (a risk that is not serious and less likely), the anesthesia provider will be asked to take the following steps:<br>1. Inject 20mL air into red injection port<br>2. Connect 10mL syringe filled with 2 mL saline and inject (twice- total 4mL)<br>3. Connect 10mL syringe filled with 5-10mL of air and inject (twice)<br>4. Connect empty 10mL syringe and suck the saline injected (twice)<br>5. Confirm correct tube position with FOB. |
| DLT Placement | Successful DLT placement will be defined as chest rise during ventilation, a square capnography waveform, bilateral breath sounds, and no air leakage. Details regarding tube placement including Cormack-Lehane grade, number of attempts, number of operations, and use of any adjunct airway devices will be recorded. An independent investigator will evaluate and record all measurements and times. The intubator will be asked to assess the procedural difficulty of intubation on a scale of 1-5- 1: very easy; 2: easy; 3: some difficulty; 4: significant difficulty; 5: impossible. | | |

| | | | | |
|---|---|---|---|---|
| | Single Lung Ventiliation | When single lung ventilation becomes necessary, the anesthesia provider will inflate the bronchial cuff and clamp the respective lumen of DLT to provide single lung ventilation. After the pleura is opened, the surgeon will be asked to rate the quality of lung collapse- 1: excellent; 2: fair; 3: poor. | | |
| **2** | **Eligibility Assessments** | | | |
| | Screening | A member of the research team will use a screening form to look for surgical patients that meet all the inclusion and exclusion criteria. He/she will approach potential subjects in the preoperative area and the study will be explained in detail in a private room. Patients will be informed that they will receive no compensation for participating in the study and there will be no adverse consequences if they choose not to participate. If the subjects agree to participate, informed written consent will be obtained prior to any study procedures and this document will be sent to pmhresearchparticipants@phhs.org, for inclusion in the patient's medical record, per Parkland regulations. | | |
| | Post-operative assessments: PQRS | A blinded research assistant will perform all postoperative assessments. The postoperative quality recovery scale (PQRS) is a tool that assesses recovery over time and compares them to baseline values. The PQRS will be administered at baseline in the preoperative area, and after PACU arrival at 45 minutes and on POD 1. | | |

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**5. Safety Precautions.** *(Describe safeguards to address the serious risks listed above.)*

**a.** Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

All study procedures will be explained to the patient in layman's terms. Patients will be informed that they will receive no compensation for participating in the study and there will be no adverse consequences if they choose not to participate.

A non-identifiable code will be assigned to the data collection sheet so that there is not a direct link to specific names. Patient IDs will be standardized in chronological order as patient 1, patient 2, etc. A key to the coding system will be maintained in a locked storage cabinet with limited access until all the data is collected and analyzed. Access to study data will be restricted to authorized study personnel only. Following the completion of the analysis and the project, the key to the coding system or subject identifiers themselves will be destroyed by shredding the documents so that there is no direct or indirect link to subject identifiers and information.

All data from the study will be kept on encrypted computers belonging to the University, which are stored in secured areas. All electronic study data will be password protected and passwords will be changed on a regular basis.

All data will be de-identified when exported from the REDCap database. Patient data will be analyzed without patient identifiers by assigning study ID subject numbers that are de-linked from patient identifiers. Signed consent forms, HIPAA forms, and study questionnaires will remain in a locked cabinet in the PI's office.

**b.** Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

If the lens of the VivaSight becomes obscured, the anesthesia provider will be asked to take the following steps:

1. Inject 20mL air into red injection port
2. Connect 10mL syringe filled with 2 mL saline and inject (twice- total 4mL)
3. Connect 10mL syringe filled with 5-10mL of air and inject (twice)
4. Connect empty 10mL syringe and suck the saline injected (twice)
5. Confirm correct tube position with FOB.

The PI will monitor all subjects for adverse events or unanticipated problems involving subjects

**c.** Will the safeguards be different between/among groups?

☐ ☐ No

If yes, describe here

**Title of Study: The VivaSight Double Lumen Tube versus Conventional Double Lumen Tube in Thoracic Surgical Patients**

**CONSENT TO BE PART OF A RESEARCH STUDY**
**TO BE CONDUCTED AT**

Parkland Health & Hospital System
Clements University Hospital

## Information About This Form

You may be eligible to take part in a research study. This form provides important information about the study.

Please take the time to review this information carefully. You should talk to the researchers about the study and ask them any questions that you may have. You may also want to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

### Voluntary Participation

You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

## General Information – "Who is conducting this research?"

### Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Tiffany Moon MD., Department of Anesthesiology and Pain Management at UT Southwestern Medical Center and Parkland Health Hospital System.

## Purpose – "Why is this study being done?"

When patients have surgery on one of their lungs, the anesthesiologist needs to insert a special kind of breathing tube called a double lumen endotracheal tube (DLT). This special tube allows the anesthesiologist to breathe for one of your lungs (the lung that is not being operated on) while the surgeon fixes the other. A traditional DLT does not have any sort of camera attachment, so we have to insert a separate camera called a "fiberoptic bronchoscope" to confirm the correct placement of the DLT. Recently, a new kind of tube called the VivaSight has come on the market. The VivaSight has a camera on the end that is connected to a monitor. The Vivasight's camera may decrease the time to

place the tube as well as provide the anesthesiologist with a better idea of where exactly the tube is at all times.

This study will help find out what effects, good and/or bad, this device has. This device has previously been studied in research subjects as well as used as part of standard care in other patients undergoing lung surgery. However, some side effects may not yet be known. The researchers hope to learn if one of the double lumen tubes is superior to the other.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are scheduled to undergo thoracic (lung) surgery and you will be getting a double lumen tube.

**How many people are expected to take part in this study?**
This study will enroll a total of 50 study participants.

## Information about Study Procedures – "What will be done if you decide to be in the research?"

**Assignment to Study Groups** –
If the researchers believe you can take part in this study, you will be assigned randomly (like drawing straws) to receive one of the two types of double lumen tubes. The group you will be in is decided by a randomization number in a sealed envelope.

Neither you nor the researchers will be allowed to choose which group you are assigned to.

**Study Procedures - as a participant, you will undergo the following procedure:**
Placement of a double lumen endotracheal tube which is standard and would have been done even if you were not in the study (in the same timing and frequency**).**
Confirmation of correct tube placement either through fiberoptic bronchoscopy (if you get a standard double lumen tube) versus embedded camera (if you get a VivaSight double lumen tube)
Occasional rechecking of tube position throughout surgery, either with a fiberoptic bronchoscope or through the camera of the VivaSight.
If the camera of the VivaSight becomes obscured, we may inject air or saline down the tube to try to un-obscure the view.
In the recovery room, you will be asked a serious of questions pertaining to your pain level, nausea, anxiousness, sadness, and quality of recovery.

## Risks – "What are the risks of participation in the research?"

There is minimal risk to participating in this study, since the type of surgery you are going to have necessitates a double lumen tube. There are standard risks associated with placement of a double lumen endotracheal tube such as sore throat, hoarseness, dental damage, and displacement but these

are present even if you do not participate in the study since either way you will be having a double lumen tube.

The VivaSight tube is the same size as the traditional DLT. The only difference is the embedded camera at the tip of the tube.

**Loss of Confidentiality**
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

**Other Risks**
There may possibly be other side effects that are unknown at this time. If you are concerned about other unknown side effects, please discuss this with the researchers.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors are not aware of all the side effects that you may experience. Be sure to tell your study doctor immediately about any side effect(s) that you have while taking part in the study.
For more information about risks and side effects, ask one of the researchers or study staff.
There may be unforeseeable side effects, but given all previous studies and knowledge of this device, the study investigators feel there is minimal risk above what would already be there by participating in this study.

**Are there Risks related to withdrawing from the study?**

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes assessments of pain, nausea, anxiousness, and recovery up until the time of study withdrawal. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

**Are there risks if you also participate in other research studies?**
Being in more than one research study at the same time, or even at different times, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

**What if a research-related injury occurs?**
The researchers have taken steps to minimize any known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section “Contact Information” for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured as a result of taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

**Benefits – "How could you or others benefit from your taking part in this study?"**

You may not receive any personal benefit from being in this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

**Alternative procedures or course of treatment – "What other options are there to participation in this study?"**

There are other options available to you. Your other choices may include: traditional double lumen endotracheal tube without a camera.

**Costs – Will taking part in this study cost anything?**

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you take part in this study, such as surgery, general anesthesia, and the cost of the double lumen endotracheal tube. You will be charged the standard rate for a double lumen tube (you will not be charged more regardless of which group you are in). It is important to understand that some insurance companies do not cover some costs. If your insurance company does not cover these treatments or procedures, you will be required to pay for them. Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

**Confidentiality – How will your records be kept confidential?**

The information that we learn about you in this study will be handled in a confidential manner within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

**HIPAA Section:**
Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

**What is Protected Health Information (PHI)?**
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

1. Protected health information (PHI): name, medical record number, date of birth
2. Demographic information (age, weight, height, BMI, gender), medical and surgical history, ASA)
3. Intraoperative parameters

- Baseline vital signs upon arrival to operating room
- Time of induction and intubation
- Intraoperative vitals (systolic, diastolic, and mean blood pressures, heart rate)
- Laryngoscopy details (Cormack Lehane view, blade used)

4. Adverse event monitoring
   - Airway injury
   - Patient unable to be intubated (e.g., difficult airway)
   - Prolonged hypoxia (> 1 min at <92%) from anesthesia start to anesthesia stop
   - Respiratory adverse event including bronchospasm, laryngospasm aspiration, reintubation
   - Prolonged PACU stay (> 2 hours)
   - Unplanned hospital admission

Your medical history and blood work, information that we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to the study, information that is created or collected during your participation in the study including medical and treatment history, information you give us during your participation in the study such as during interviews.

We will get this information by asking your doctor, and looking at your chart at the (Parkland Health Hospital System).

**How will your PHI be shared?**

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The following collaborators at other institutions that are involved with the study: Parkland Health Hospital System
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at: The University of Texas Southwestern Medical Center, Parkland Health and Hospital System.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

**How will your PHI be protected?**

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information for review. If the results of this study are reported in medical journals or at meetings, you will not be identified.

**Do you have to allow the use of your health information?**
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to **Tiffany Moon, MD**. with the Department of Anesthesiology and Pain Management at UT Southwestern Medical Center (5323 Harry Hines Blvd, Dallas, TX, 75390-9068). If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

**Can you ask to see the PHI that is collected about you for this study?**
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

**How long will your PHI be used?**
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

**Contact Information – Who can you contact if you have questions, concerns, comments or complaints?**

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact: Tiffany Moon, MD at (469)419-5790 during regular business hours and by pager at (214)768-2038 after hours and on weekends and holidays.

To use the pager, you need to have a touch tone (push button) telephone. Dial the pager number as you would any phone number. When you hear 3 short high pitched beeps, dial in the number where you want the doctor to call you back. Push the # button, hang up and wait for the doctor to return your call.

**Primary Contact:**
Tiffany Moon, MD. can be reached at (469) 419-5790 during regular business hours and by pager at (214)768-2038 after hours and on weekends and holidays.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will

answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at (214)648-3060.

**Research Consent & Authorization Signature Section**

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

**Adult Signature Section**

| | | | |
|---|---|---|---|
| | | | AM PM |
| Printed Name of Participant | Signature of Participant | Date | Time |
| | | | AM PM |
| Printed Name of Person Obtaining Consent | Signature of Person Obtaining Consent | Date | Time |

**Blind or Illiterate Signature Section** *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

**Declaration of witness:**
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

| Printed Name of Witness | Signature of Witness | Date | Time AM PM |
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