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A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 2D Versus 3D Laparoscopic Bariatric Surgery

The "Black Box" Study

CLINICAL INVESTIGATION PLAN

Olympus Protocol Number: 2015-SE-01

Sponsored By

Olympus Corporation of the Americas
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Contact Information

Role	Contact
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Coordinating Principal Investigator	Teodor Grantcharov, MD, PhD, FACS Professor of Surgery, University of Toronto, Canada Research Chair in Simulation and Surgical Safety Division of General Surgery St. Michael's Hospital 30 Bond Street Room 16-056, Cardinal Carter Wing Toronto, Ontario M5B 1W8 Canada Tel: 416.864.5748 Email: grantcharovt@smh.ca

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Original Release: [Month, Day, Year]

Current Version: 2.0

Revision History

Version Number	Release Date	Section	Change	Reason for Change
2.0		N/A	N/A	Initial release of protocol

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Sponsor Protocol Approval Page

Alexander Milstein, MD Chief Medical Officer	Date: 11 OCTOBER 2017
Alexis James Manager, Clinical Affairs	Date: 12-OCT-2017

STUDY TITLE:	**A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 2D Versus 3D Laparoscopic Bariatric Surgery** **The "Black Box" Study**
PROTOCOL NUMBER:	**2015-SE-01**
VERSION NUMBER:	**2.0**

We, the undersigned, have read and approve the protocol specified above and agree on its content.

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Investigator Protocol Approval Page

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 2D Versus 3D Laparoscopic Bariatric Surgery

The "Black Box" Study

2015-SE-01

Protocol Version 2.0

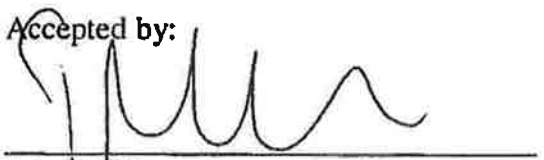
I hereby agree to participate in in the above named study Sponsored by Olympus. (here in after "Study Sponsor"). I agree to conduct this investigation according to the requirements of the protocol provided by the Study Sponsor in accordance with applicable local regulations, and in accordance with the conditions imposed by the reviewing Institutional Review Board (IRB) or Ethics Committee (EC). I agree to supervise all use of the study devices and to ensure appropriate informed consent is obtained from all subjects prior to inclusion in this study.

I understand that this investigation will be monitored by the Study Sponsor and/or a designee employed by the Study Sponsor. This monitoring will involve periodic inspection of my investigational site and ongoing review of the data that are submitted by me to the Study Sponsor.

I am aware that the Study Sponsor reserves the right to discontinue this investigation at any time.

I understand this study protocol and trial results are confidential, and I agree not to disclose any such information to any person other than a representative of the Study Sponsor, the IRB/EC, or regulatory authorities without the prior written consent of the Study Sponsor.

Accepted by:



Principal Investigator

Oct 4, 2017

Date

T. Glenn Mahoney

Printed Name

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Protocol Synopsis

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 3D Versus 2D Laparoscopic Bariatric Surgery - The "Black Box" Study	
Study Objective	This is a hypothesis generating pilot study to compare the impact of 2D versus 3D visualization on surgical performance, as measured by the OR BlackBox® platform, during laparoscopic bariatric surgery.
Study Device	The Olympus HD 2D Laparoscopic Surgical Video System, which is comprised of the following components: • CV-190 Processor • CLV-190 Light Source • 3DV-190 3D Visualization Unit • LMD-X310ST • IMH-20 Image Capture System • UHI-4 Insufflator • K10021611 Cart • OL-0015-08 Tall Rollstand • LTF-S190-10 Endoeye Flex 2D • MAJ-172 tray for 2D scope • MAJ-2016 8.5M 3G cable • MAJ-2015 3M 3G cable The Olympus HD 3D Laparoscopic Surgical Video System, which is comprised of the following components: • CV-190 Processor • CLV-190 Light Source • 3DV-190 3D Visualization Unit • LMD-2451MT/2G4 sonly 24" 3D Monitor • IMH-20 Image Capture System • UHI-4 Insufflator

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 3D Versus 2D Laparoscopic Bariatric Surgery - The "Black Box" Study	
	• K10021611 Cart • OL-0015-08 Tall Rollstand • LTF-190-10-3D ENDOEYE FLEX 3D Videoscope • 3D Glasses (Regular and Clip-on Styles)
Other Device(s)	OR BlackBox® Platform
Indications for Use	The Olympus HD 2D Laparoscopic Surgical Video System is cleared for use in Canada within the thoracic and abdominal cavities including female reproductive organs. The Olympus HD 3D Laparoscopic Surgical Video System is cleared for use in Canada within the thoracic and abdominal cavities including female reproductive organs.
Study Design	Prospective, post-market, hypothesis generating, pilot study
Planned Number of Subjects	N=50 25 subjects will undergo 2 dimensional (2D) laparoscopic surgery 25 subjects will undergo 3 dimentional (3D) laparoscopic surgery
Planned Number of Investigational Sites / Countries	1 site in Canada
Primary Endpoint	There is no primary endpoint for this study as it is a hypothesis generating pilot study. • This pilot study will quantify opeartive performance and intraoperative errors after the introduction of the 2D and 3D technology using the following tools: o Generic Error Rating Tool (GERT) o Objective Structured Assessment of Technical Skill (OSATS)
Secondary Endpoints	1. Clinically significant adverse events related to the device(s) and/or procedure. a. Clinically significant is defined as any deviation from the

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 3D Versus 2D Laparoscopic Bariatric Surgery - The "Black Box" Study	
	normal surgical or post operative course that requires special treatment or action. 2. Operating room (OR) team's perception of human factors and teamwork following each procedure using the Modified Surgical Team Assessment Record (STAR) questionnaire. 3. NASA Task Load Index to assess mental workload and frustration 4. Visualization and Physical Symptoms Questionnaire 5. Surgical Team Demographic Questionnaire
Follow-up Schedule	1. Screening/Baseline (Clinic Visit): a. Eligibility criteria b. Informed consent c. Demographics d. Medical history 2. Procedure (Hospital Visit): a. Laparoscopic 2D or 3D Roux-en-Y gastric bypass surgery b. Adverse events (Including Clavien Classficiation of Surgical Complications (CCSC)) c. Device Deficiencies d. Completion of STAR Questionnaire by each OR team member e. NASA Task Load Index to assess mental workload and frustration f. Visualization and Physical Symptoms Questionnaire g. Surgical Team Demographic Questionnaire 3. <u>Post-Procedure OSATS and GERT</u> a. Post-Procedure is not a subject follow-up visit, it is the point at which the video and audio feed of each surgical procedure will be reviewed by an Expert Surgical Analyst (ESA) to complete the OSATS and GERT tools. b. The ESA must review video feed within 30 days following each procedure.

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 3D Versus 2D Laparoscopic Bariatric Surgery - The "Black Box" Study	
	4. <u>30 Day Post Procedure Follow-up (Telephone Call) / End of Study</u> a. Adverse events (Including CCSC) b. End of study will be reached after completion of the 30 Day Post Procedure Follow-up Telephone Call, subject withdrawal, or lost to follow-up, whichever occurs first.
Study Duration	This study is anticipated to take 9 months to complete following IRB approval. Eight months of enrollment and 1 month of follow-up.
Key Inclusion Criteria	1. ≥ 18 years of age 2. Scheduled to undergo elective, primary roux-en-y gastric bypass surgery 3. BMI of 35 to 54.9 4. Willing and able to provide informed consent
Key Exclusion Criteria	1. Previous open abdominal surgery 2. Previous open or laparoscopic upper GI surgery 3. Contraindicated for laparoscopic bariatric surgery 4. Unable or unwilling to provide informed consent
Statistical Methods	
Primary Statistical Hypothesis	N/A – This is a hypothesis generating pilot study. As a result no statistical hypothesis will be tested as part of this study.
Statistical Test Method	Outcomes will be assessed using descriptive statistics and comparative analysis.
Sample Size Parameters	N/A – This is a hypothesis generating pilot study. As a result a sample size calculation is not required. Fifty roux-en-y gastric bypass surgeries will be performed as part of this study; 25 consecutive surgeries will be performed using a 2D laparoscopic camera and 25 consecutive cases will be performed using a 3D laparoscopic camera.

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Table of Contents

1 Introduction

Data published in 2008 estimated the global number of surgical procedures performed annually as 234 million with a rate of major perioperative complications reported between 3% and 17% in industrialized countries.[1-3] As a derivative of these figures, it is estimated that approximately 7 to 40 million major complications occur worldwide each year. Studies have shown that between 39.6% and 54.2% of surgical complications occur in the operating room (OR); furthermore, it has been suggested that one third to half of all surgical errors are potentially avoidable.[2-5] These findings have brought considerable attention to quality improvement in the technically demanding field of laparoscopic surgery wherein the risk of intraoperative error is increased by the sociotechnical complexity of the operative environment. In particular, there has been growing interest in evaluating surgical processes from a human factors point of view, as human factors, such as fatigue and mental workload, have become increasingly recognized as root causes of adverse surgical events and outcomes.[6]

Among the most commonly reported errors in conventional laparoscopic surgery are technical errors associated with impaired depth perception; laparoscopic surgeons rely on two-dimensional (2D) video displays to guide their work in a three-dimensional (3D) space, resulting in the loss of depth perception and spatial orientation, as well as the experience of increased visual and cognitive load.[7,8] Technical errors can be defined as manual errors of the surgeon (e.g. damage to adjacent structures) and procedural errors due to a lack of surgeon proficiency or experience. These errors are frequently described, especially when evaluating closed malpractice cases.[2,6,10] These factors have been extensively examined but still remain controversial. A major limitation of error analyses of closed malpractice cases and root cause analyses of complications is the hindsight bias introduced through the knowledge of patient outcome.

Laparoscopic cameras with 3D display functionality were first developed in the early 1990s.[7] The poor image quality produced by early cameras resulted in pronounced physical side effects, including dizziness, headache, and nausea; however, a significant technological advancement in the field of 3D laparoscopy has dramatically improved the usability of these systems.[9] Despite these improvements and the potential for improved surgical safety, the use of 3D laparoscopic equipment remains limited in modern surgical centers. Outdated and conflicting research findings regarding the effectiveness of these systems and the physical side effects associated with their use may be contributing to slow adoption into clinical practice.[7] Furthermore, investigations assessing the impact of 3D laparoscopy on surgical performance in the clinical setting are notably lacking.[7] Thus, robust comparative evaluations of modern 2D and 3D laparoscopic surgical display systems in clinical settings are required to clearly elucidate the impact of 3D laparoscopy on surgical performance and safety with an aim to establish best practices in laparoscopic surgery.

The restoration of stereoscopic vision in laparoscopic surgery has the potential to mitigate these challenges and, to this end, the introduction of 3D stereoscopic displays in laparoscopic surgery may be beneficial to improving surgical safety. The purpose of this study is to compare the impact of 2D versus 3D visualization on surgical performance, as measured by the OR BlackBox® Platform, during laparoscopic Roux-en-Y gastric bypass surgery.

2 Device Descriptions

2.1 Olympus HD 2D Laparoscopic Surgical Video System

The Olympus HD 2D Laparascopic Surgical Video System is cleared for use in Canada within the thoracic and abdominal cavities including female reproductive organs and is comprised of the following components:

- CV-190 Processor
- CLV-190 Light Source
- 3DV-190 3D Visualization Unit
- LMD-X310ST
- IMH-20 Image Capture System
- UHI-4 Insufflator
- K10021611 Cart
- OL-0015-08 Tall Rollstand
- LTF-S190-10 Endoeye Flex 2D
- MAJ-172 tray for 2D scope
- MAJ-2016 8.5M 3G cable
- MAJ-2015 3M 3G Cable

2.2 Olympus HD 3D Laparoscopic Surgical Video System

The Olympus HD 3D Laparoscopic Surgical Video System is cleared for use in Canada within the thoracic and abdominal cavities including female reproductive organs and is comprised of the following components:

- CV-190 Processor
- CLV-190 Light Source
- 3DV-190 3D Visualization Unit
- LMD-2451MT/2G4 sonly 24" 3D Monitor
- IMH-20 Image Capture System
- UHI-4 Insufflator
- K10021611 Cart
- OL-0015-08 Tall Rollstand
- LTF-190-10-3D ENDOEYE FLEX 3D Videoscope
- 3D Glasses (Regular and Clip-on Styles)

The Olympus HD 2D and 3D Imaging System is lightweight and ergonomically designed with the intention to lessen surgeon fatigue and maximize ease of use. The ENDOEYE FLEX 3D Videoscope allows for 100° of articulation in all directions while maintaining a level visual horizon regardless of viewing angle. Additionally, the system allows for focus free visualization with the ability to toggle back in forth between 2D and 3D imaging.

2.3 OR BlackBox® Platform

The OR BlackBox® "Black Box" Platform is a multi-channel data recorder that records multiple synchronized feeds during a surgical procedures including:

- Panoramic views of the operating room
- View of the laparoscopic camera
- Intraoperative audio
- Room temperature

Video feeds of the room are sent to the Black Box from surveillance cameras that are affixed to the walls inside the OR, and audio feeds are captured using microphones placed at critical locations throughout the room. The Black Box subsequently integrates these recordings into a single interface to provide a comprehensive overview of the operation. The various video perspectives are displayed side-by-side with synchronized audio and a juxtaposed timeline that allows observers to flag any observable errors. This interface allows researchers to study the state of the entire OR for the period of time leading up to, during, and after a flagged error, which is critical for performing root-cause analyses of technical errors.

3 Study Objectives

This is a hypothesis generating pilot study to compare the impact of 2D versus 3D visualization on surgical performance, as measured by the OR BlackBox® platform, during laparoscopic bariatric surgery.

4 Study Endpoints

4.1 Primary Endpoint

There is no primary endpoint for this study as it is a hypothesis generating pilot study. This pilot study will quantify opeartive performance and intraoperative errors after the introduction of the 2D and 3D technology using the following tools:

- Generic Error Rating Tool (GERT)
- Objective Structured Assessment of Technical Skill (OSATS)

4.2 Secondary Endpoints

1. Clinically significant adverse events related to the device(s) and/or procedure.
    - Clinically significant is defined as any deviation from the normal surgical or post operative course that requires special treatment or action.

2. Operating room (OR) team's perception of human factors and teamwork following each procedure using the Modified Surgical Team Assessment Record (STAR) questionnaire.
3. NASA Task Load Index to assess mental workload and frustration
4. Visualization and Physical Symptoms Questionnaire
5. Surgical Team Demographic Questionnaire

5 Study Design

Prospective, post-market, hypothesis generating, pilot study

5.1 Scale and Duration

A total of 50 subjects, 25 undergoing 2D laparoscopic surgery and 25 undergoing 3D laparacopic surgery, will be enrolled and treated at 1 study site in Canada. Each subject will be followed for approximately 30 days following the study procedure. It is anticipated for the entire study to last 9 months.

5.2 Treatment Assignment

A total of 50 laparoscopic roux-en-y gastric bypass surgeries will be assessed as part of this study. Twenty-five consecutive 2D laparoscopic surgeries and 25 consecutive 3D laparoscopic surgeries.

5.3 Justification for the Study Design

This study was designed as a pilot study to compare the impact of 2D versus 3D visualization on surgical performance, as measured by the OR BlackBox® Platform, during laparoscopic bariatric surgery. Data from this study will be used to potentially generate a hypothesis for a larger, pivotal study.

6 Subject Selection

6.1 Study Population and Eligibility

Patients who meet all of the inclusion criteria and none of the exclusion criteria will be considered for enrollment in this study.

6.2 Inclusion Criteria

1. ≥ 18 years of age
2. Scheduled to undergo elective, primary roux-en-y gastric bypass surgery
3. BMI of 35 to 54.9
4. Willing and able to provide informed consent

6.3 Exclusion Criteria

1. Previous open abdominal surgery
2. Previous open or laparoscopic upper GI surgery
3. Contraindicated for laparoscopic bariatric surgery
4. Unable or unwilling to provide informed consent

6.4 Recruitment of nursing, anesthesia and surgical staff

Prior to start of the study, approval will be obtained from the clinical manager of perioperative services. Nursing staff as well as a technical assistant will be identified through the roster and addressed by the clinical Leader Managers of Perioperative Services, via their St Michaels. Nursing staff as well as a technical coordinator will then obtain written informed consent.
Occasionally, anesthesia residents will be scheduled for the unit's OR. After approval by the anesthesiology program director, anesthesiology residents will be contacted and informed of the study.

Dr. Teodor Grnatcharov as well as the participating staff surgeon in the Department of General Surgery at St Michael's Hospital will be study subjects in the observed procedures, and will also sign the written informed consent prior to the procedure. Fellows will be informed of the study prior to their rotation. Surgical residents who are undergoing 2 or 3 month rotations will be contacted by the General Surgery Program director, and then approached by the research coordinator, and the informed consent will be obtained.

Since all OR team members including nursing, anesthesia and surgical team will be recorded, they are all required to provide the informed consent. However it should be clarified that only the surgical team will be evaluated.

7 Subject Accountability

7.1 Point of Enrollment

A subject will be considered enrolled in the study if they meet all eligibility criteria specified in Section 6 of this protocol and after the subject signs and dates the Research Ethics Committee (REC) approved informed consent form (ICF). No study-related procedures can take place until the ICF is signed.

7.2 Withdrawal

All subjects enrolled in the clinical study (including those withdrawn from the clinical study or lost to follow-up) shall be accounted for and documented. If a subject withdraws from the clinical study, the reason(s) shall be reported. Reasons for withdrawal include:

- Physician discretion

- Subject choice to withdraw consent
- Lost to follow-up
- If the subject dies due to any cause
- Termination of the study by Sponsor, IRB/EC or regulatory authority

The reason for a subject's failure to return for the necessary follow-up visits or for a subject's discontinuance from the study must be determined and recorded in the Case Report Forms (CRFs).

All applicable CRFs up to the point of subject withdrawal must be completed. Subjects who are lost to follow-up should have documented attempts to contact them prior to being deemed lost.

Additional data may no longer be collected after the point at which a subject has been withdrawn from the study or withdraws his/her consent, for whatever reason. Data collected up to the point of subject withdrawal may be used for study analysis.

7.3 Enrollment Controls

Enrollment figures will be regularly communicated to Olympus. Enrollment should not exceed 50 subjects as specified in Section 5.1 of this protocol.

8 Study Methods

8.1 Data Collection

The schedule of data collection is illustrated in Table 1.

8.2 Informed Consent

All subjects taking part in this clinical study must undergo the informed consent process. Subjects must be allowed adequate time to review the consent, raise questions, and make a voluntary decision to participate in the clinical study. Each subject must sign and date the REC approved ICF before any clinical study-related procedures are performed. A copy of signed ICF will be provided to the subject for his/her records. A subject's participation in the clinical study begins with the signing and dating of the ICF.

9 Visit Schedule

9.1 Screening/Baseline (Clinic Visit)

- Eligibility criteria
- Informed consent
- Demographics
  - Age
  - Gender
  - BMI
- Medical history
  - Alcohol use
  - Tobacco use
  - Co-morbidities
  - Previous surgeries (ensure previous surgeries do not meet exclusion criteria)

9.2 Procedure (Hospital Visit)

- Laparoscopic 2D or 3D roux-en-y gastric bypass surgery
  - All study procedures will be video and audio recorded using 2 mounted cameras and auxilliary microphones. One camera will be focused on the surgical field and the second focusing on the OR door.
  - The laparoscopic video (internal subject view) will be recorded according to standard of practice.
  - All video and audio recordings will begin after the subject has been intubated and will end at skin closure prior to extubation.
- Procedure time (minutes) (skin-to-skin)
  - The Principal Investigator will perform the gastrojejunostomy (GJ) anastamosis
  - A surgical fellow will perform the jejunojejunostomy (JJ) anastamosis
- Adverse events (Including Clavien Classficiation of Surgical Complications (CCSC))
- Device deficiencies
- STAR Questionnaire will be completed by each surgical team member within 24 hours of surgical procedure

Table 1: Data Collection Schedule

Procedure/Assessment	Screening/Baseline (Clinic Visit)	Procedure (Hospital Visit)	Post-Procedure OSATS and GERT	Follow-up Visits	
				30 Day Follow-up[4] (Telephone Call)	Unscheduled Visit[3] (Clinic Visit)
Visit Window	*N/A*	*N/A*	*Within 30 Days After the Procedure*	*+/- 10 Days*	*N/A*
Eligibility Criteria	X				
Informed Consent Form	X				
Demographics	X				
Medical History	X				
Laparoscopic 2D or 3D Roux-en-Y Gastric Bypass Surgery		X			
STAR Questionnaire (Immediately following procedure in OR)		X[1]			
NASA Task Load Index		X			
Visualization and Physical Symptoms Questionnaire		X			
Surgical Team Demographic Questionnaire		X			
ESA Video Feed Review (Completion of OSATS & GERT Tools)			X[2]		
Device Deficiencies		X			
Adverse Events		X		X	X

[1] Immediately following the procedure, the STAR Questionnaire will be completed by each member of the OR team who participated in or attended the surgical procedure.
[2] Post-Procedure is not a subject follow-up visit, it is the point at which the video and audio feed of each surgical procedure will be reviewed by an ESA to complete the OSATS and GERT tools.
[3] Unscheduled Visits for subjects may be performed between protocol specified visits as deemed appropriate by the Investigator.
[4] End of study will be reached after completion of the 30 Day Follow-up Telephone Call, subject withdrawal, or lost to follow-up, whichever occurs first.

- Only the role of the surgical team member will be captured on this form, no names.

- NASA Task Load Index will be completed by each surgical team member within 24 hours of surgical procedure
- Visualization and Physical Symptoms Questionnaire will be completed by each surgical team member withn 24 hours of surgical procedure
- Surgical Team Demographic Questionnaire

9.3 Post-Procedure (Within 30 Days of Surgical Procedure – No Subject Follow-up)

- Two ESAs will perform surgical video and audio review and completion of OSATS and GERT
  - ESAs are surgeons in the Investigator's research group with comprehensive knowledge OF SURGICAL PERFORMANCE ASSESSMENT as well as formal training and experience using the tools utilized in this study.
  - ESAs will not have access to the OR during study surgical procedures to ensure unbiased completion of OSATS and GERT.
- ESA 1 will review the video and audio recordings for all subjects
- ESA 2 will review the video and audio recordings for 20% of subjects to ensure objectivity during analysis. Cases for review with be randomly selected

9.4 30 Day Post Procedure Follow-up (Telephone Call) (+/- 10 Days)

- Adverse events (Including CCSC)

9.5 Unscheduled Visit

Unscheduled visits may be performed between visits required by the protocol as deemed necessary by the Investigator. Unscheduled visits will be captured on the adverse event (AE) CRF.

9.6 End of Study

End of study will be reached after completion of the 30 Day Post Procedure Follow-up Telephone Call, subject withdrawal ,or lost to follow-up, whichever occurs first.

10 Video and Audio Recordings

All data records, documentation or information containing patient data will be de-identified with study numbers to ensure that persons outside of the study will not be able to identify the participating patients. The code will be kept on a password protected hard drive that will only be accessible to the Research Coordinator. The researchers will however be given access to the data sheets as required to enter additional information such as follow-up data. The video recordings will only capture the details of the operative procedures while patients will be

protected from the camera view by sterile drapes. All staff participants will be wearing surgical hoods and masks as per standard operating procedure and OR hygiene regulations.

Recorded, de-identified video files will be retained until completion of patient follow-up (30 days). If a complication occurs within this follow-up period, the material will undergo a second review by the same team of observers as in the first review. First and second review will then be compared. After 30 days the video and audio files will be permanently and securely deleted.

10.1 Educational Library

Educational library is a collection of anonymized and de-identified video materials created for the purpose of future education and training of the operating room team members.

The educational video material will be created using video editing software and will contain laparoscopic and panoramic video clips where necessary. All video material will be completely anonymized. Additional video and audio filters will be applied in order to ensure full identity protection of all persons appearing in the recorded materials. Processed educational clips will be rendered completely anonymous by combining video blurring and voice altering technology.

Educational video materials will be available to Operating Room Black Box (ORBB) team members only and will be stored on a secure server as per standard protocol. The materials may be used inside of the St. Michael's Hospital for educational and training purposes only. The responsible custodian of the video materials will be the PI.

11 Statistical Considerations

11.1 Endpoints

11.1.1 *Primary Endpoint*

There is no primary endpoint for this study as it is a hypothesis generating pilot study. This study will quantify opeartive performance and intraoperative errors after the introduction of the 2D and 3D technology using the following tools:

- Generic Error Rating Tool (GERT)
- Objective Structured Assessment of Technical Skill (OSATS)

11.1.2 *Secondary Endpoints*

1. Clinically significant adverse events related to the device(s) and/or procedure.
    - Clinically significant is defined as any deviation from the normal surgical or post operative course that requires special treatment or action.

2. Operating room (OR) team's perception of human factors and teamwork following each procedure using the Modified Surgical Team Assessment Record (STAR) questionnaire.
3. NASA Task Load Index to assess mental workload and frustration
4. Visualization and Physical Symptoms Questionnaire
5. Surgical Team Demographic Questionnaire

11.2 Hypotheses

N/A – This is a hypothesis generating pilot study. As a result no statistical hypothesis will be tested as part of this study.

11.3 Sample Size

This is a hypothesis generating pilot study. As a result a sample size calculation is not required.

Fifty roux-en-y gastric bypass surgeries will be performed as part of this study; 25 consecutive surgeries will be performed using a 2D laparoscopic camera and 25 consecutive cases will be performed using a 3D laparoscopic camera.

11.4 Statistical Methods

Descriptive analysis of data will be performed using the Student's *t*-test and Chi-square test. Association of numerical variables will be performed using Parson's correlation. For determination of whether the 2D or 3D monitor is correlated with intraoperative errors or other factors, binary logistic regressional models will be used.

11.5 Data Analyses

All data will be analyzed using SPSS 22.0 for Windows (SPSS Inc. Chicago, IL, USA) by a professional statistician at St. Michael's hospital.

12 Data Management

12.1 Source documents

Source documents are the subject records maintained at the study site. In most cases, the source documents will be the physician's or hospital's subject chart. In some cases, the source documents may be electronic. In both cases, the information captured in the CRF must match the information in the chart or electronic source document. The Investigator agrees to make source documents (hard copy or electronic) available for monitoring by the Sponsor and/or their representatives.

13 Data Collection, Processing, and Review

Subject data will be recorded in a limited access secure data system.

See Section 10 of this protocol for a description of how video and audio feeds for each surgical procedure will be stored.

Other, non-video and –audio datacollected as part of this study will reside on a production server hosted by an electronic data capture (EDC) System. The Simplified Clinical Data Systems LLC (Simplified) is a provider of fully FDA compliant, responsive clinical data management services, providing a globally accessible hosted platform that meets stringent security and reliability standards.
CDP operates from SSAE16, HIPAA, SOC I/SOC II, compliant data centers in Marlborough, MA, and Tek Park (Allentown), PA. Nightly, offsite backups are mirrored and maintained at Iron Mountain's two underground data centers.
The Network Operations Center (NOC) monitors these systems 7x24x365 with a team of network engineers ensuring system availability and data integrity.
Systems and processes are well documented and have stood up to thorough scrutiny by sponsor and third party audits, for compliance with U.S. and EU standards.
This platform will be maintained by Olympus Corporation.

All changes made to the clinical data will be captured in an electronic audit trail and available for review by the Sponsor or its representative. The associated software and database have been designed to meet regulatory compliance for deployment as part of a validated system compliant with laws and regulations applicable to the conduct of clinical studies pertaining to the use of electronic records and signatures. Database backups are performed regularly

The Investigator provides his/her electronic signature on the appropriate electronic case report forms (eCRFs) in compliance with local regulations. A written signature on printouts of the eCRFs must also be provided if required by local regulation. Changes to data previously submitted to the Sponsor require a new electronic signature by the Investigator acknowledging and approving the changes.

Data entered into the EDC system will be reviewed to identify possible data discrepancies. Manual and/or automatic queries will be created by the Sponsor in the EDC system and will be issued to the site for appropriate response. Site staff will be responsible for resolving all queries in the database.

14 Data Retention

The Principal Investigator or his/her designee or Investigational site will maintain, at the investigative site, all essential study documents and source documentation that support the data collected on the study subjects in compliance with ICH/GCP guidelines. Documents must be retained for at least 2 years have elapsed since the formal discontinuation of the clinical investigation of the product. These documents will be retained for a longer period of time by agreement with Olympus or in compliance with other country/regional/local regulations.

The Principal Investigator or his/her designee will take measures to ensure that these essential documents are not accidentally damaged or destroyed. If for any reason the Principal Investigator or his/her designee withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility and Olympus must receive written notification of this custodial change. Sites

are required to inform Olympus in writing where paper or electronic files are maintained in case files are stored off site and are not readily available.

15 Amendments

If a protocol revision is necessary which affects the rights, safety or welfare of the subject or scientific integrity of the data, an amendment is required. Appropriate approvals (e.g., REB) of the revised protocol must be obtained prior to implementation.

16 Deviations

An Investigator must not make any changes or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency. An Investigator shall notify the Sponsor and the reviewing REC of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, and those deviations which affect the scientific integrity of the clinical investigation. Such notice shall be given as soon as possible, but no later than 5 working days after the emergency occurred, or per prevailing local requirements, if sooner than 5 working days.

All deviations from the investigational plan, with the reason for the deviation and the date of occurrence, must be documented and reported to the Sponsor. Sites may also be required to report deviations to the REC, per local guidelines and government regulations.

Deviations will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective and preventive actions (such as site re-training or site discontinuation/termination) will be put into place by the Sponsor.

17 Device/Equipment Accountability

The study devices/equipment supplied by the Sponsor for this study shall be securely maintained, controlled, and used only in this clinical study.

The Sponsor shall keep records to document the physical location of all study devices/equipment from study device/equipment shipment until use, return, or disposal.

The Principal Investigator or an authorized designee shall keep records documenting the receipt, use, return and disposal of the study devices/equipment, which shall include the following

- Date of receipt
- Identification of each study device/piece of equipment (serial number or unique code)
- Expiry date, as applicable
- Date or dates of use
- Unique subject identification number
- Date of return (and number) of unused, expired, or malfunctioning study devices/equipment, as applicable.

18 Compliance

18.1 Statement of Compliance

This study will be conducted in accordance with ICH Guidelines, Good Clinical Practices, ISO 14155, ethical principles that have their origins in the Declaration of Helsinki, and pertinent individual country laws and regulations. The study shall not begin until the required approval/favorable opinion from the REC has been obtained. Any additional requirements imposed by the REC shall be followed, if appropriate.

19 Investigator Responsibilities

The Principal Investigator of an investigational site is responsible for ensuring that the study is conducted in accordance with the Clinical Trial Agreement, the clinical investigation plan, ISO 14155, ethical principles that have their origins in the Declaration of Helsinki, any conditions of approval imposed by the reviewing IRB/EC, and prevailing local and/or country laws and/or regulations, whichever affords the greater protection to the subject.

The Principal Investigator's responsibilities include, but are not limited to, the following.

- Prior to beginning the study, sign the Clinical Trial Agreement and comply with the Investigator responsibilities as described in such Agreement.
- Prior to beginning the study, sign the Protocol Signature page documenting his/her agreement to conduct the study in accordance with the protocol.
- Provide his/her qualifications and experience to assume responsibility for the proper conduct of the study and that of key members of the site team through up-to-date curriculum vitae or other relevant documentation and disclose potential conflicts of interest, including financial, that may interfere with the conduct of the clinical study or interpretation of results.
- Make no changes in or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency; document and explain any deviation from the approved protocol that occurred during the course of the clinical investigation.
- Create and maintain source documents throughout the clinical study and ensure their availability with direct access during monitoring visits or audits; ensure that all clinical-investigation-related records are retained per requirements.
- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the CRFs and in all required reports.
- Record, report (to Sponsor, and IRB as applicable), and assess every adverse event as applicable per the protocol and observed device deficiency.
- Report to the REC and regulatory authorities any SAEs and device deficiencies that could have led to a SADE and potential/USADE or UADE, if required by the national regulations or this protocol or by the IRB/EC, and supply Olympus with any additional requested information related to the safety reporting of a particular event.

- Maintain the device accountability records and control of the device, ensuring that the study device is used only by authorized/designated users and in accordance with this protocol and instructions/directions for use.
- Allow the Sponsor to perform monitoring and auditing activities, and be accessible to the clinical research monitor or auditor and respond to questions during monitoring visits or audit(s).
- Allow and support regulatory authorities and the REC when performing auditing activities.
- Ensure that informed consent is obtained in accordance with applicable laws, this protocol and local IRB/EC requirements.
- Provide adequate medical care to a subject during and after a subject's participation in a clinical study in the case of adverse events, as described in the ICF.
- Inform the subject of the nature and possible cause of any adverse events experienced.
- As applicable, provide the subject with necessary instructions on proper use, handling, storage, and return of the study device when it is used/operated by the subject.
- Inform the subject of any new significant findings occurring during the clinical investigation, including the need for additional medical care that may be required.
- Provide the subject with well-defined procedures for possible emergency situations related to the clinical study, and make the necessary arrangements for emergency treatment, including decoding procedures for blinded/masked clinical investigations, as needed.
- Ensure that clinical medical records are clearly marked to indicate that the subject is enrolled in this clinical study.
- Ensure that, if appropriate, subjects enrolled in the clinical investigation are provided with some means of showing their participation in the clinical investigation, together with identification and compliance information for concomitant treatment measures (contact address and telephone numbers shall be provided).
- Inform, with the subject's approval or when required by national regulations, the subject's personal physician about the subject's participation in the clinical investigation.
- Make all reasonable efforts to ascertain the reason(s) for a subject's premature withdrawal from clinical investigation while fully respecting the subject's rights.
- Ensure that an adequate investigation site team and facilities exist and are maintained and documented during the clinical investigation.
- Ensure that maintenance and calibration of the equipment relevant for the assessment of the clinical investigation is appropriately performed and documented, where applicable.

20 Delegation of Authority

The Principal Investigator is responsible for providing appropriate training and adequate supervision of those to whom tasks are delegated. The Principal Investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

21 Research Ethics Committee

The protocol and informed consent document must have the approval of a properly constituted committee (REC) responsible for approving clinical trials. The signed REC approval letter must identify the documents approved (i.e., list the Investigator's name, the protocol title, and date of approval, and informed consent document). A copy of the approval of the protocol (or permission to conduct the study) and ICF, must be received by the Sponsor before recruitment of subjects into the study and shipment of investigational product/equipment. Prior approval must also be obtained for other materials related to subject recruitment or which will be provided to the subject.

Annual REC approval and renewals will be obtained throughout the duration of the study as or as locally required. Copies of the Investigator's reports and the IRB/EC continuance of approval must be provided to the Sponsor.

22 Sponsor Responsibilities

All information and data sent to Olympus concerning subjects or their participation in this study will be considered confidential by Olympus. Only authorized Olympus personnel or an Olympus representative including, but not limited to Contract Research Organization (CRO) will have access to these confidential records. Authorized regulatory personnel have the right to inspect and copy all records pertinent to this study. Study data collected during this study may be used by Olympus for the purposes of this study, publication, and to support future research and/or other business purposes. All data used in the analysis and reporting of this study will be without identifiable reference to specific subject name.

Olympus will keep subjects' identifiable health information confidential in accordance with all applicable laws and regulations. Olympus may use subjects' health information to conduct this research, as well as for additional purposes, such as overseeing and improving the performance of its device, new medical research and proposals for developing new medical products or procedures, and other business purposes. Information received during the study will not be used to market to subjects; subject names will not be placed on any mailing lists or sold to anyone for marketing purposes.

23 Insurance

Where required by local/country regulation, proof and type of insurance coverage, by Olympus for subjects in the study will be obtained.

24 Monitoring

On site and/or remote monitoring will be performed during the study to assess continued compliance with the protocol and applicable regulations. In addition, the clinical research monitor verifies that study records are adequately maintained, that data are reported in a satisfactory manner with respect to timeliness, adequacy, and accuracy, and that the Principal Investigator continues to have sufficient staff and facilities to conduct the study safely and effectively. The Principal Investigator/institution guarantees direct access to original source documents by Olympus personnel, their designees, and appropriate regulatory authorities.

The study may also be subject to a quality assurance audit by Olympus or its designees, as well as inspection by appropriate regulatory authorities. It is important that the Principal Investigator and relevant study personnel are available during on-site monitoring visits or audits and that sufficient time is devoted to the process.

25 Potential Risks and Benefits

25.1 Anticipated Adverse Events

The following anticipated AEs have been identified for this study.

25.2 Risks Associated with the Study Device(s)

Incremental risks that are associated with the study device and are above those of market available products are listed below.

25.3 Anticipated Benefits

There are no direct benefits from participation in this study. This study will not give you any improved treatment of any kind. There is however a potential benefit for future patients and operating room teams since the purpose of this study is to improve the training of the entire operating room team with the overall intention to improve patient safety in surgery. Results from this study may further medical or scientific knowledge.

26 Safety Reporting

26.1 Reportable Events by Investigational Site to Olympus

It is the responsibility of the Investigator to assess and report to Olympus any event which occurs in any of following categories:

- Clinically significant adverse events related to the device(s) and/or procedure.
    - Clinically significant is defined as any deviation from the normal surgical or post operative course that requires special treatment or action
- Device Deficiencies
- Unanticipated Adverse Device Effects/Unanticipated Serious Adverse Device Effects
- New findings/updates in relation to already reported adverse events

When possible, the medical diagnosis should be reported as the Event Term instead of individual symptoms.

If it is unclear whether or not an event fits one of the above categories, or if the event cannot be isolated from the device or procedure, it should be submitted as an AE and/or device deficiency.

Any AE experienced by a study subject during the study procedure through completion of the study must be recorded in the CRF.

Underlying diseases are not reported as AEs unless there is an increase in severity of frequency during the course of the investigation

26.2 Definitions and Classification

Adverse event definitions are provided in Table 2.

Table 2: Adverse Event Definitions

Term	Definition
Adverse Event (AE) *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	Any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational medical device. NOTE 1: This includes events related to the investigational medical device or comparator. NOTE 2: This definition includes events related to the procedures involved. NOTE 3: For users or other persons, this definition is restricted to events related to the investigational medical device.
Adverse Device Effect (ADE) *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	Adverse event related to the use of an investigational medical device • NOTE 1: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device. • NOTE 2: This definition includes any event resulting from use error or intentional abnormal use of the investigational medical device.
Serious Adverse Event (SAE) *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	Note: This definition meets the reporting objectives and requirements of ISO 14155 and MEDDEV 2.7/3. Adverse event that: • Led to death, • Led to serious deterioration in the health of the subject as defined by either: o a life-threatening illness or injury, or o a permanent impairment of a body structure or a body function, or o in-subject hospitalization or prolongation of existing hospitalization , or o in medical or surgical intervention to prevent life-threatening

Table 2: Adverse Event Definitions

Term	Definition
	illness o injury or permanent impairment to a body structure or a body function • Led to fetal distress, fetal death, or a congenital abnormality or birth defect. **NOTE 1:** This includes device deficiencies that might have led to a serious adverse event if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate. These are handled under the SAE reporting system. **NOTE 2:** A planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health, is not considered to be a serious adverse event.
Serious Adverse Device Effect (SADE) *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Unanticipated Adverse Device Effect (UADE) *Ref: 21 CFR Part 812*	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Unanticipated Serious Adverse Device Effect (USADE) *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report. **NOTE 1**: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.
Device Deficiency *Ref: ISO 14155* *Ref: MEDDEV 2.7/3*	An inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer.

26.3 Clavien Classification of Surgical Complications

All AEs that occur intra-operatively or within the 30 Day Follow-up period will be assessed using the CCSC:

Grade I: Any deviation from the normal post-operative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions.

Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at bedside.

Grade II: Requiring pharmacological treatment with drugs other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition are also included.

Grade III: Requiring surgical, endoscopic or radiological intervention.

Grade IIIa: Intervention not under general anesthesia

Grade IIIb: Intervention under general anesthesia

Grade IV: Life-threatening complication (including CNS complications) requiring IC/ICU management.

Grade IVa: Single organ dysfunction (including dialysis)

Grade IVb: Multi-organ dysfunction

Grade V: Death of a patient

Suffix "d": If the patient suffers from a complication at the time of discharge the suffix "d" (for disability) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

26.4 Relationship to Study Device

The Investigator must assess the relationsip of an AE to the study devicd and procedure. Relationship classification criteria is defined in Table 3.

Table 3: Adverse Event Relationship Classification Criteria

Classification	Description
Not Related	Relationship to the device or procedures can be excluded when: - the event is not a known side effect of the product category the device belongs to or of similar devices and procedures; - the event has no temporal relationship with the use of the study device or the procedures; - the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), has no impact on the serious event;

	- the event involves a body-site or an organ not expected to be affected by the device or procedure; the serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors); - the event does not depend on a false result given by the study device used for diagnosis, when applicable; harms to the subject are not clearly due to use error; - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
Unlikely	The relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
Possible	The relationship with the use of the study device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probable	The relationship with the use of the study device seems relevant and/or the event cannot reasonably be explained by another cause, but additional information may be obtained.
Definite	The serious event is associated with the study device or with procedures beyond reasonable doubt when: - the event is a known side effect of the product category the device belongs to or of similar devices and procedures; - the event has a temporal relationship with study device use/application or procedures; - the event involves a body-site or organ that o the study device or procedures are applied to; o the study device or procedures have an effect on; - the serious event follows a known response pattern to the medical device (if the response pattern is previously known); - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible); - other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; - harm to the subject is due to error in use; - the event depends on a false result given by the study device used for diagnosis, when applicable; - In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

26.5 Investigator Reporting Requirements

The communication requirements for event reporting to Olympus are as follows:

- **Adverse events** related to the device or procedure must be reported to Olympus within 30 business days of the study site becoming aware of the event.

- **Serious Adverse Events** must be reported to Olympus within 2 business days of the study site becoming aware of the event.
- **Device Malfunctions** must be reported to Olympus within 2 business days of the study site becoming aware of the event.
- **Unanticipated Adverse Device Effect / Unanticipated Serious Adverse Device Effect** must be reported to Olympus within 1 business day of the study site becoming aware of the event.

26.6 Olympus Device Deficiencies

All device deficiencies (including but not limited to failures, malfunctions, use errors, product nonconformities, and inadequacy in the information supplied by the manufacturer) will be documented and reported to Olympus. If possible, the device(s) should be returned to Olympus for analysis. Instructions for returning the study device(s) will be provided. If it is not possible to return the device, the Investigator should document why the device was not returned and the final disposition of the device. Device failures and malfunctions should also be documented in the subject's medical record.

Device deficiencies (including but not limited to failures, malfunctions, and product nonconformities) are not adverse events. However, an adverse event that results from a device failure or malfunction, would be recorded as an adverse event on the appropriate eCRF.

Any Device Deficiency that might have led to a serious adverse event if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate is considered a reportable event.

26.7 Reporting to REC

The Principal Investigator is responsible for informing the REC of study events according to local regulation.

27 Suspension or Termination

27.1 Premature Termination of the Study

Olympus reserves the right to terminate the study at any stage but intends to exercise this right only for valid scientific or administrative reasons and reasons related to protection of subjects. The Investigator, REC, and regulatory authorities, as applicable, will be notified in writing in the event of study termination.

27.1.1 *Criteria for Premature Termination of the Study*

Possible reasons for premature study termination include, but are not limited to, the following.

- The occurrence of unanticipated adverse device effects that present a significant or unreasonable risk to subjects enrolled in the study.
- An enrollment rate far below expectation that prejudices the conclusion of the study.

- A decision on the part of Olympus to suspend or discontinue development of the device.

27.2 Termination of Study Participation by the Investigator or Withdrawal of Research Ethics Committee (REC) Approval

Any Investigator, or REC in this Study may discontinue participation in the study or withdrawal approval of the study, respectively, with suitable written notice to Olympus. Investigators, the REC, and regulatory authorities, as applicable, will be notified in writing in the event of these occurrences.

27.3 Requirements for Documentation and Subject Follow-up

In the event of premature study termination by Olympus a written statement as to why the premature termination has occurred will be provided to all participating sites by Olympus. The REC and regulatory authorities, as applicable, will be notified. Detailed information on how enrolled subjects will be managed thereafter will be provided.

In the event a Principal Investigator terminates participation in the study, study responsibility will be transferred to another Investigator, if possible. In the event there are no opportunities to transfer Principal Investigator responsibility; detailed information on how enrolled subjects will be managed thereafter will be provided by Olympus.

The Principal Investigator or his/her designee must return all study-related documents and investigational product to Olympus, unless this action would jeopardize the rights, safety, or welfare of the subjects.

28 Publication Policy

Olympus requires disclosure of its involvement as a Sponsor or financial supporter in any publication or presentation relating to a Olympus study or its results. Olympus and the study investigative team will submit study results for publication (regardless of study outcome) following the conclusion or termination of the study. Olympus adheres to the Contributorship Criteria set forth in the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE; http://www.icmje.org). In order to ensure the public disclosure of study results in a timely manner, while maintaining an unbiased presentation of study outcomes, Olympus personnel may assist authors and Investigators in publication preparation provided the following guidelines are followed.

- All authorship and contributorship requirements as described above must be followed.
- Olympus involvement in publication preparation should be discussed with the Coordinating Principal Investigator(s) at the onset of the project.

29 Conflict of interest

Dual roles

There is a conflict of interest due to the dual roles of Dr. Grantcharov as study subject and P.I. as well as with respect to his involvement in the development of recording and analytic technology. However, Dr. Grantcharov will not participate in the evaluation of any recorded procedures. Our analysts will be using objective, closely defined rating, and inter-rater

agreement with a second, blinded rater will continuously be monitored to ensure objectivity of evaluation.The data will be de-identified for the duration of the follow-up period during which the outcome measures will be assessed (30 days), after this period the link code to the data set will be destroyed and the data will be anonymous. The PI will have access to the data content of the de-identified and anonymized dataset. The linking code, however, will not be made available to minimize the risk of bias being introduced by the PI. The PI will know the clinical outcome of each patient but will not have access to the technical and non-technical data until the treatment phase has been completed at 30 days.

The technology used in the study is provided by Surgical Safety Technologies (SST, Toronto, Canada), a company owned by Dr. Grantcharov and in which St. Michaels' Hospital has shares. The company is physically located at St. Michael's Hospital.

The aggregate non-identifiable, data will be analyzed using technology provided by the SST and in that form the data will be shared with the company.

30 Bibliography

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31 Abbreviations

Abbreviation	Definition
2D	Two-dimensional
3D	Three-dimensional
AE	Adverse Event
ADE	Adverse Device Effect
CRF / eCRF	Case Report Form / Electronic Case Report Form
CCSC	Clavien Classficiation of Surgical Complications
EC	Ethics Committee
EDC	Electronic Data Capture
ESA	Expert Surgical Analyst
GERT	Generic Error Rating Tool
GJ	Gastrojejunostomy
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonization
ICMJE	International Committee of Medical Journal Editors
IFU	Instructions for Use
IRB	Institutional Review Board
JJ	Jejunojejunostomy
ORBB	Operating Room Black Box
OSATS	Objective Structured Assessment of Technical Skill
OR	Operating room
REC	Research Ethics Committee
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
STAR	Surgical Team Assessment Record
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect