GE Healthcare

Clinical Study Protocol:

Clinical Evaluation of the OEC Elite MD for Vascular Procedures

(Study # 104-2017-GES-0005)

Version: 1.0; 20/Oct/2017

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Investigational Device/Product: OEC Elite™ CFD Mobile Fluoroscopy System--Motorized Configuration

Modality: Surgery

FOR QUALIFIED INVESTIGATORS, STUDY STAFF, AND THEIR ETHICS COMMITTEE(S) ONLY

1. BACKGROUND AND JUSTIFICATION

1.1 Mobile Fluoroscopy and Vascular Procedures

Over the past 25 years, fluoroscopically guided interventional procedures have rapidly increased worldwide. [2, 3] Fluoroscopy guidance provides surgeons and interventional specialists with the improved ability to assess anatomy and implant materials, [4] as well as guide catheters, guidewires, and stents through small vessels and pathways throughout the human body. [2]

In modern angiography, fluoroscopy provides necessary imaging guidance during dynamic vascular procedures, such as aortic aneurysm repairs, percutaneous artery angioplasty, and angiographic examinations. [5] Preoperative fluoroscopy may also be necessary for arteriography of the aorta and other vessels to determine precise anatomical relations when the proximal landing zone of a stent graft cannot be determined by non-invasive imaging. [6] Furthermore, peripheral angiography is regarded as the most accurate imaging tool for definitive diagnostics and preoperative planning of surgical and endovascular interventions in patients with advanced arterial disease. [7]

Gastrointestinal imaging has significantly evolved since the 1950s and fluoroscopy maintains a critical role in GI radiology. Mobile fluoroscopy is accepted as safe and effective for use during intraoperative cholangiography and external percutaneous biliary drainage procedures, and fluoroscopic imaging of upper gastrointestinal series has demonstrated better tumor localization when compared to endoscopic examination.

In contemporary clinical practice, complicated urologic procedures, including endourologic procedures such as retrograde cholangiopancreatography and upper urinary tract procedures are increasingly being performed using mobile C-arm fluoroscopy. With the advent of more complex fluoroscopically guided procedures, new interventional techniques and devices, such as the device under investigation in this study, are being developed and introduced to the market.

This prospective clinical study is being conducted to acquire image guidance adequacy data from physicians conducting clinically-indicated vascular, gastrointestinal (GI), urology and pain management procedures for engineering use, as deemed appropriate by the Sponsor, for the investigational OEC Elite™ CFD Mobile Fluoroscopy System –Motorized Configuration (OEC Elite) in the vascular configuration. Clinical procedures included in this study will involve three (3) anatomical regions of interest – extremities and neck, thorax, and abdomen and pelvis. These regions are being targeted because they represent the range of clinical applications and anatomical regions intended for OEC Elite in the vascular configuration.

1.2 Pre-Clinical Trials and Previous Clinical (human) Experience

GE Healthcare (GEHC), the study Sponsor, is a manufacturer of mobile fluoroscopy equipment and has extensive experience in conducting clinical trials.

A GEHC-sponsored study of human cadaveric tissue was conducted as part of feasibility and optimization of the investigational device's predicate, the OEC 9900 Elite (Study Title: A Diagnostic Capability Bench Study of An SSXI Mobile Fluoroscopy System and the OEC® 9900 Elite Mobile Fluoroscopy System; GEHC Study Number: 104-2014-GES-0003). A preclinical study using the swine animal model was recently conducted by the Sponsor for software optimization of the vascular configuration prior to implementing investigational OEC Elite in the vascular configuration in the clinical setting (Study Title: A Preclinical Imaging Study of the OEC Elite Vascular System; GEHC Study Number 104-GES-2016-0001).

In addition, the Sponsor has conducted research on previous non-motorized CFD (flat panel detector) systems. Imaging Evaluation of the OEC Elite Mobile Fluoroscopy System (GEHC Study Number 104-GES-2015-0003) was conducted to gather image data for a regulatory submission on the OEC Elite CFD. Two other studies, Clinical Evaluation of the OEC Elite Vascular Mobile Fluoroscopy System (GEHC Study Number 104-2016-PTHS-0005) and Evaluation of the OEC Elite Vascular Mobile Fluoroscopy System (GEHC Study Number 104-2017-GES-0001) were conducted to gather workflow and survey data.

1.3 Controls and Minimization of Bias

All reasonable attempts will be made to control and minimize bias during this study, including the following:

- Subjects will be consecutively enrolled from the patients screened until the accrual quota is filled, with the intent of limiting selection bias;
- Spectrum bias will be limited by using a population expected to be representative of the general population at the investigational site, without regard to race or ethnicity.

2. DEVICE/PRODUCT DESCRIPTION

2.1 Identity, Mechanism, and Function

Name: OEC Elite™ CFD Mobile Fluoroscopy System--Motorized Configuration

Modality/Type: Surgery

Manufacturer: GE OEC Medical Systems, Salt Lake City, UT, USA

Software version: The most current version available will be used.

Regulatory Status: Pre-market

Note: A record of number of devices issued, along with applicable identification numbers (e.g. serial/lot/batch) and components/accessories used in this study will be retained by the Sponsor as part of the clinical history file (CHF), as required by applicable laws and regulations.

The OEC Elite™ CFD Mobile Fluoroscopy System--Motorized Configuration (OEC Elite) is a medical device centrally comprised of a mobile C-arm with flat-panel detector and a mobile workstation that displays resultant images. The device includes hardware and software capable of generating and receiving x-ray signals to produce images of bone and living tissues, and a mobile workstation that includes image display and user interface. As with the predicate device, the investigational device is motorized and uses a tableside Remote User Interface (RUI) to enable the operator to move the C-arm without touching it. The central difference between the predicate OEC 9900 Elite MD device and the investigational system is the replacement of an image intensifier detector with a flat-panel detector.

For this study, the OEC Elite (Figure 1) will be provided to the investigational site in the VAS MTS configuration with a 31-cm flat panel detector.

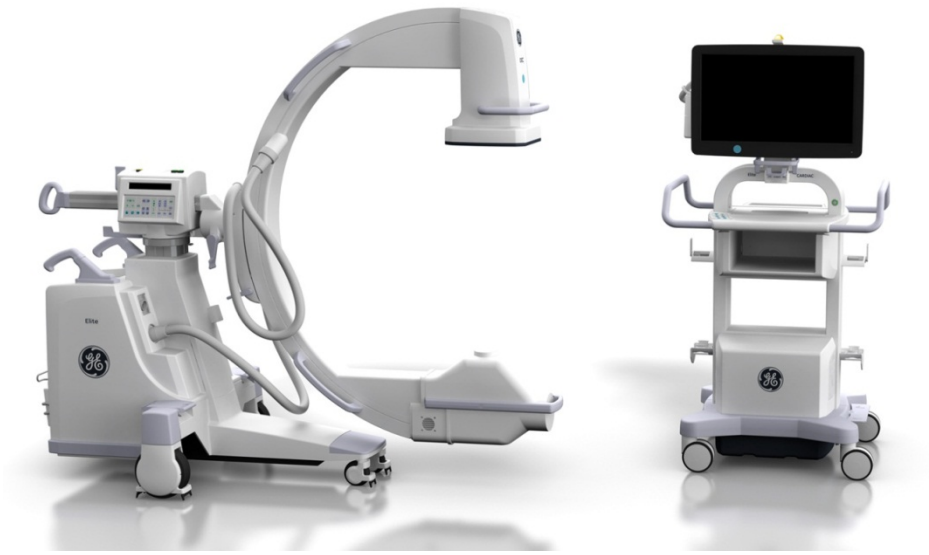

Figure 1 – Investigational OEC Elite Mobile Fluoroscopy System

The research device, instructions for use, or packaging shall indicate that the research device is for use in a research investigation, in accordance with applicable regulations in Canada per Medical Device Regulations (SOR/98-282), Part 3, Sections 79-88 and other applicable laws and regulations.

The investigational device will be exclusively used for research procedures and only as set forth in an Ethics Committee (EC) approved study protocol, in accordance with applicable laws and regulations.

2.2 Intended Use

The OEC Elite Mobile Fluoroscopy System is designed to provide fluoroscopic and digital spot images of adult and pediatric populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, critical care, and emergency procedures.

This study will include vascular, gastrointestinal (GI), urology and pain management procedures in an adult population. Study procedures will be conducted in accordance with the site's standard of care.

2.3 Concomitant/Ancillary Administrations

2.3.1 Medications and Biologic Products

No medications or biologic products will be administered as part of study procedures.

2.3.2 Laboratory Tests and Sample Processing

No laboratory tests or sample processing is planned as part of the study procedures.

2.4 Accountability

Accurate and adequate records will be maintained for all devices, from time of shipment to the site until return or disposal of all devices issued by the Sponsor as part of this study, as required by applicable

laws and regulations. The Principal Investigator will be ultimately responsible for the security and integrity of research devices at the investigational site during the study.

2.4.1 Issuance

The Sponsor will provide the site with devices, including necessary hardware and software components of the device. The Sponsor will provide necessary maintenance for the investigational device(s) installed at the sites. GE technical support will be available, as needed, to maintain integrity of study data.

2.4.2 Disposition

Upon completion of the study, Sponsor-provided devices at the investigational site will be de-installed by Sponsor-authorized engineers and returned to the Sponsor, or otherwise dispositioned, in accordance with applicable laws and regulations. Identifiable subject information will be removed from the device(s) prior to dispositioning devices.

2.5 Anticipated Risks and Benefits

The device under study has undergone risk assessment, in accordance with International Standards Organization (ISO) 14971:2012, and risks have been mitigated to levels as low as reasonably practicable (ALARP).

The investigational OEC Elite is expected to present similar potential risks to patients, operators, or others in this study as the predicate commercial device, OEC 9900 Elite, when used under similar clinical indications for use. The risks of study participation are not expected to be different than those of non-study procedures. Because basic image guided fluoroscopy will be used for conventional procedure applications, there will be no post-trial care or follow-up required by this study.

As with all x-ray devices, OEC Elite uses the minimum possible ionizing x-ray radiation dose, which is within acceptable limits set forth by applicable local laws and regulations necessary to complete a procedure. Because the radiation dose and procedural duration widely vary for the procedures included in this study, there is no prospective per-procedure maximum radiation dose or duration prescribed by this protocol. All procedures will be conducted per the clinical standards of the site and the medical discretion of physicians performing the clinically indicated study procedures.

In the unlikely event that a device error prevents or impairs image acquisition, it is possible that a subject may require alternative or additional imaging to complete an intervention or exam. If imaging is not adequate or diagnostic-quality images cannot be obtained using the investigational device, the subject will not undergo additional investigational imaging. Necessary medical care will be provided by the sites, and equivalent, site-provided commercial fluoroscopy systems (e.g. the predicate device or equivalent) will be readily available throughout the study.

Subjects who undergo additional or elongated imaging procedures may be at a small increased risk because of additional x-ray exposure and possible additional procedure time, which may also impact the duration and/or dosages of anesthesia and contrast administration.

Subjects are not expected to benefit directly from study participation; however, the results may benefit future patients by helping to better understand the device under study.

2.5.1 Risk Category and Rationale

In Canada, the OEC Elite™ CFD Mobile Fluoroscopy System—Motorized Configuration is a Class III medical device, as defined by Schedule 1, Part 1, Rule 8 of the Medical Devices Regulations (SOR/98-

282). Use of OEC Elite is not expected to pose significant risk to human subjects in accordance with the standards of Health Canada's Medical Device Regulations, Part 3 – Medical Devices for Investigational Testing Involving Human Subjects (SOR/98-282, §79-88).

3. PURPOSE OF THE STUDY

The purpose of the study is to collect survey data on the use of the OEC Elite based on the routine clinical use of the device.

3.1 Study Objectives:

3.1.1 Primary Objective:

The primary objective is to collect investigator feedback on imaging guidance adequacy of the OEC Elite during clinical procedures.

3.1.2 Secondary Objective(s):

The secondary objectives of this study are to collect image data acquired during clinical procedures and to collect investigator feedback via surveys on the use of the system during clinical procedures.

3.2 Study Endpoints

3.2.1 Primary Endpoints:

The primary endpoint is the per-subject investigator report of imaging guidance adequacy to complete the procedure (Y/N).

3.2.2 Secondary Endpoints:

The secondary endpoints are the total number of surveys reflecting the investigator opinion of procedures performed and the image data collected.

4. STUDY DESIGN

4.1 Summary of Study Design

This is a pre-market, Clinical, open label, prospective, non-randomized research study conducted at one (1) site in Canada.

4.2 Study Population

The study population will be adults undergoing vascular, gastrointestinal (GI), urology or pain management procedures for which use of the OEC Elite system in the vascular configuration would be prescribed. This population is expected to be representative of the general population that would require mobile fluoroscopic imaging with C-arm devices, such as OEC Elite. Pediatric patients (i.e. patients younger than 18 years old) will not be enrolled in this study.

4.3 Number Subjects/Cases

Up to 40 subjects may be enrolled the site. Enrollment may be discontinued at any time prior to reaching 40 subjects at the discretion of the sponsor.

4.4 Protection of Vulnerable Subjects

Vulnerable subjects are individuals whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate.

The Sponsor shall avoid improper influence on, or inducement of, the subject, monitor, any investigator(s), or other parties participating in, or contributing to, the clinical investigation.

All investigators shall avoid improper influence on, or inducement of, the subject, Sponsor, monitor, other investigator(s), or other parties participating in, or contributing to, the clinical investigation.

This study does not examine any groups of subjects who are vulnerable subjects in the country in which the study is being conducted.

4.5 Eligibility Criteria

4.5.1 Inclusion Criteria

Subjects who meet all the following inclusion criteria may be included:

1) Male or female between the ages of 18 and 85 years (≥18 and ≤85 years old);
2) Clinical indication for procedures including vascular, gastrointestinal (GI), urology or pain management for which mobile fluoroscopy has been prescribed for image guidance;
3) Able and willing to comply with study procedures; and
4) Able and willing to provide written informed consent to participate.

4.5.2 Exclusion Criteria

Subjects who meet any of the following exclusion criteria will be excluded:

1) Pregnant or suspected to be pregnant based on the opinion of and as documented by a medically qualified physician investigator;
2) Expected to be at increased risk due to study participation (e.g. due to allergies, sensitivities), in the medical opinion of an investigator; or
3) Previously participated in this study, or enrolled in another active GEHC study or other research study that could be expected to interfere with participation in study procedures, in the opinion of the investigator.

4.6 Recruiting and Screening

Subjects will be recruited for potential enrollment at the site from an adult population scheduled for a clinical procedure with mobile fluoroscopy. Subjects will be screened for enrollment against the inclusion and exclusion criteria, and enrollment determinations will be made by the site investigator. Recruitment, screening, and enrollment will be conducted per the standard procedures of the investigational site. All participation will be voluntary.

Following recruitment, a subject will be considered enrolled (the point of enrollment) once he/she signs and dates the informed consent form (ICF). Once enrolled, the subject will be assigned a unique subject number, which will not contain information that could identify him/her (e.g. subject name or date of birth). The unique subject number will be used to label case report form (CRF) data for the subject throughout his/her participation in the study.

4.7 Criteria for Withdrawal/Discontinuation

A subject may withdraw from study participation at any time, for any reason. The investigator may withdraw a subject at any time, for any reason. The reasons for withdrawal and discontinuation for any subject shall be recorded and reported to the Sponsor. The EC should be notified per their notification of subject withdrawal policy.

If a subject withdraws or is withdrawn, all efforts will be made to complete and report study data up to the time of withdrawal. A complete final evaluation at the time of the subject's withdrawal shall be made and recorded on a CRF. If the reason for withdrawal is related to an adverse event (AE) or serious adverse event (SAE), monitoring of the subject will continue until the outcome is evident.

Any data collected for the subject, up until the time of withdrawal or discontinuation, may still be included in the study results and provided to the Sponsor, unless the subject requests that their data not be used. The site shall document all requests by subjects regarding their data use.

5. STUDY PROCEDURES

5.1 Subject Preparation

Study staff will confirm that each subject is eligible and willing to comply with applicable site requirements prior to starting study procedures. No preparation beyond that required by the investigational site is required before procedures.

5.2 Description of Study Procedures

Each subject will undergo his/her clinically indicated vascular, gastrointestinal (GI), urology and pain management procedure with fluoroscopic imaging conducted using the investigational OEC Elite device. Prescribed treatments (e.g. contrasts, anesthesia) will be administered according to the standard of care.

5.3 Follow-up

No follow-up will be conducted as part of this study. Subjects will be followed for AEs from the time they enter the procedural room containing the investigational device until the study procedure ends and they exit the procedural room.

5.4 Malfunction/Error Handling

The site should report the occurrence and resolution of any procedures terminated due to non-recoverable malfunctions (i.e. malfunctions or errors with OEC Elite that prevent image collection and are not able to be immediately resolved by the device operator). The site should also report recoverable errors (i.e. issues with the device that do not prevent image collection and are able to be resolved immediately by the device operator) and operator errors. The occurrence of any recoverable error, operator error, or non-recoverable malfunction will be reported on the subject's CRF.

In uncommon cases, the research procedures using the investigational device may need to be terminated unexpectedly. If the investigator suspects that a subject would be at increased risk, or that the subject's clinical procedure will not be able to be completed using the investigational device in this study, the investigator may terminate the procedure at any time and for any reason. In some cases, it may not be feasible to end a procedure; in which case, equivalent, site-provided commercial fluoroscopy equipment (such as the predicate device or equivalent) may be used. The site will ensure that access to alternative commercial fluoroscopy equipment is maintained during all procedures. All patient care and management

decisions for terminated procedures will be made outside of this study according to the sites' standard clinical practices and the subject's regular physician's or investigator's medical judgment.

6. STUDY DATA COLLECTION AND ASSESSMENTS

6.1 Operating Physicians

At the completion of a procedure, the physician (e.g. interventional specialist or surgeon) conducting the procedure will provide feedback on the capability of the system by completing a User Survey. Survey data will be recorded on case report forms (CRFs).

7. QUALIFICATION AND TRAINING PLAN

7.1 Staff Qualifications

All members of the study staff participating in the conduct of the Clinical investigation shall be qualified by education, training, and/or experience to perform their tasks. Qualifications shall be documented appropriately, as per ISO 14155:2011.

7.2 Training Plan for the Protocol and Research Device/Product

Before starting the study, the study staff will be trained on the clinical investigation requirements set forth in this study protocol, including completion of Informed Consent Forms (ICFs), CRFs, and other study documentation. Training will also be provided to ensure appropriate storage and handling of data, and all study staff will be required to be trained on Good Clinical Practice (GCP) guidelines per ISO 14155: 2011.

A record of all formal training will be stored in the Site Regulatory Binder and provided to the Sponsor for inclusion in the Sponsor's CHF. Documentation of training will include:

- Title of Training
- Training objectives
- Training logistics (trainer and training methods)
- Documentation of trainees
- Training content (e.g. device operation, protocol review and CRF completion)

Study staff directly operating or maintaining the research device will be trained based on device operation and safety. A copy of the device operator manual will be provided to the site along with Sponsor-provided training.

The PI will be ultimately responsible for execution of this study, in accordance with the protocol, and for device use in this study by members of the study staff.

7.3 Case Report Form

The study procedure CRF will report the following:

- Basic demographic
- Type of procedure or technique being performed
- Anatomical region being imaged
- Contrast information

- User Evaluation Survey
- Guidance Adequacy

8. SAFETY

8.1 Anticipated Adverse Events

The study design is not expected to pose additional risk to patients above that required by routine diagnostic, surgical, or interventional procedures that are clinically indicated for the patient and related to use of the OEC Elite.

All subjects included in this study will require imaging during a diagnostic exam or surgery per their clinically indicated procedure. Intraoperative imaging with OEC Elite and similar commercial mobile C-arm devices produce ionizing radiation at levels generally considered safe, but in extremely rare cases, may pose risks of deterministic tissue effects (e.g. skin reddening, cataracts, and hair loss) and very small increases in lifetime cancer risk. These side effects would be risks whether or not patients participate in this study, and they are extremely rare when a mobile C-arm is used for procedures similar to the proposed study procedures. These risks generally occur only in patients exposed to excessive amounts of x-ray radiation in a short time or excessive amounts over a long period of time concentrated to a single region. These events are unusual for mobile C-arms.

Subjects may also require prescribed medications, such as contrast (“dye”), anesthesia, and other medicines that are not expected to change as a result from participation in this study. These medications have widely recognized side effects that include allergic reactions, itching, swelling, burning, bleeding, mental confusion, lung infection, stroke, heart attack, and other potentially serious metabolic complications. Patients would be at risk for these side effects whether or not they participate in this study. Patients will receive consultation on possible benefits and risks specific to their recommended procedures according to the standard of care outside of this study, and the procedures for this study will not influence these discussions.

Patient participation in this study is not expected to increase risks for side effects from imaging, contrast, anesthesia, or other medication administration or to negatively impact the results of the procedure compared to equivalent procedures performed outside of this study, using commercially available devices.

There are potential risks to subjects participating in this study that are associated with unexpected device issues or procedural complications. These risks include:

- Longer duration of patient procedures, which are expected to be minimal (accounting for time to transfer patient to alternative, commercial device and/or mitigate any other procedural or device issues) and are not expected to significantly increase the total duration of the procedure.
- Additional imaging, which could involve using an alternative, commercial system available at the site.
- Extension or interruption of regular medical care or medication administration, including prolongation; re-administration of medicines, including contrast, anesthesia, and other medicinal agents; or delay of ending anesthesia or other medications.

These events are expected to be rare, but the risks for side effects normally related to surgery, imaging, contrast, anesthesia, or other medication administration may be increased for affected patients. To minimize the impact of these risks, alternative, commercially available mobile fluoroscopy systems

available at the sites will be placed in an accessible location during all procedures that use investigational devices.

There is always a chance of unexpected risks. Throughout the study, the Sponsor will evaluate and update safety information in study documents.

8.2 Adverse Event Definitions

Adverse Event (AE): any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device [ISO 14155:2011 3.2]. This includes events related to the investigational device or the comparator and to the procedures involved. For users or other persons, this is restricted to events related to the investigational medical device.

Serious Adverse Event (SAE): an adverse event that led to death; led to a serious deterioration in the health of the subject, that either resulted in a life-threatening illness or injury, a permanent impairment of a body structure or a body function, or in-patient or prolonged hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function; or led to fetal distress, fetal death or a congenital abnormality or birth defect. Planned hospitalization for a pre-existing condition, or a procedure required by the protocol without serious deterioration in health, is not considered a SAE [ISO 14155:2011 3.37].

Adverse Device Effect (ADE): an adverse event related to the use of an investigational medical device [ISO 14155:2011 3.1]. This includes any adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This includes any event that is a result of a user error or intentional misuse of the investigational device [ISO 14155:2011 3.43].

Serious Adverse Device Effect (SADE): an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event [ISO 14155:2011 3.36].

Device deficiency: an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance, such as malfunctions, use errors, and inadequate labelling [ISO 14155:2011 3.15].

Unanticipated serious adverse device effect (USADE): a 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 [ISO 14155:2011 3.42]. In the United States, 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 study documents, will be reported in accordance with 21 CFR §812.3 and applicable laws and regulations.

8.3 Documentation of Safety Events

All adverse events (AE), including all serious adverse events (SAE), are required to be collected, investigated, and documented during the study reporting period, as defined in the study procedure set forth in this protocol. Documentation will include:

- Description of Event
- Date of onset and resolution
- Severity (mild, moderate, or severe)
    - *Mild*: Symptom(s) barely noticeable to the subject or does not make the subject uncomfortable. The AE does not influence performance or functioning. Prescription drugs are not ordinarily needed for relief of symptom(s).

- *Moderate*: Symptom(s) of a sufficient severity to make the subject uncomfortable. Performance of daily activities is influenced. Treatment of symptom(s) may be needed.
- *Severe*: Symptom(s) of a sufficient severity to cause the subject severe discomfort. Treatment for symptom(s) may be given.

- Serious (yes/no)
- Causal relationship to investigational medical device? (not related, possibly related, or related)
  - *Not related*: The adverse event is reasonably expected to be related to (or caused by) a concurrent illness, effect of another device/drug or other cause, and is unlikely related to the investigational product.
  - *Possibly related*: The adverse event is reasonably expected to be related to the investigational product, and an alternative etiology is equally or less likely compared to the potential relationship to investigational product.
  - *Related*: There is a strong relationship to investigational product or recurs on re-challenge, and another etiology is unlikely or there is no other reasonable medical explanation for the event.
- Treatment given and/or action taken (procedure stopped, withdrawn from study, or no action)
- Anticipated (yes/no)

8.4 Reporting of Safety Events and Device Deficiencies/Complaints

The following events are to be reported to the Sponsor within 72 hours of the event occurrence and to the EC per their policy:

- All SAEs and USADEs
- All device issues that could possible lead to an SAE

Additional follow-up information may be requested by the Sponsor. In addition, safety information may be shared with regulatory agencies and other participating sites, as required by applicable law and regulation.

8.5 Device Deficiencies

Device deficiencies should be reported to the study Sponsor contact identified on the cover page of this protocol. All device deficiencies will to be collected, fully investigated, and documented in the source document and appropriate Sponsor document during the study reporting period. The PI is responsible for notifying the Sponsor in the event that there is any device issue that could potentially lead to a SAE.

9. ETHICAL CONDUCT OF THE STUDY

The study will be carried out in accordance with the protocol and with principles enunciated in the current version of the Declaration of Helsinki; the guidelines of Good Clinical Practice (GCP) for medical devices, as set forth by ISO 14155:2011 and ISO 14971:2012; applicable requirements of Health Canada's Medical Device Regulations (SOR/98-282); and other applicable regulatory authority requirements of Canada, as necessary.

The study will be conducted and reported in accordance with applicable policies of the local Ethics Committee (EC) and governing regulatory authorities.

If national or regional EC requirements are less strict than the requirements of GCP, such as ISO 14155:2011 for medical devices, the Sponsor shall apply the requirements of this International Standard to the greatest extent possible, irrespective of any lesser requirements, and shall record such efforts.

9.1 Ethics Committee

The responsible site PI will ensure that approval from an appropriately constituted EC is attained for the clinical study prior to enrolling subjects. The PI will also ensure that documentation of approval is maintained for the duration of the study.

The PI will ensure that the Sponsor is notified of any withdrawal of EC approval within 5 working days of such occurrence. If approval is terminated or suspended, the PI will promptly notify the Sponsor and provide written explanation.

9.2 Regulatory Agencies and Competent Authority

The Sponsor will obtain approval from the local regulatory agency or competent authority (CA), Health Canada, before the start of the clinical trial, if necessary, per applicable local laws and regulations. Any additional requirements imposed by the EC or CA shall be followed, when applicable.

9.3 Management of Protocol Modifications and Amendments

Substantial amendments will only be implemented after EC approval.

A deviation is any instance(s) of failure to follow, intentionally or unintentionally, the requirements of the protocol. Under emergency circumstances, deviations from the protocol to protect the rights, safety, and wellbeing of human subjects may proceed without prior approval of the Sponsor and the EC/CA. Such deviations shall be documented and reported to the Sponsor and the EC as soon as possible. Deviations will be reported as:

- **Critical Deviations:** Deviations that significantly affect the safety, efficacy, integrity, or conduct of the study. These deviations must be reported to the Sponsor no later than 5 working days from awareness of occurrence and reported to the EC per the deviation reporting policy.
- **Non-Critical Deviations:** Protocol deviations that do not significantly affect the safety, efficacy, integrity, or conduct of the trial. These deviations must be documented on the CRF Protocol Deviation page and will be reviewed by the study monitor.

Non-substantial modifications may be made during the normal course of device optimization, maintenance, and feasibility testing. Non-substantial modifications will be communicated to the CA as soon as possible, if applicable, and to the EC per their policy.

9.4 Participant Information and Informed Consent

The investigator will explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration of exposure to the investigational device, the potential risks and benefits, and any potential discomforts. Each participant will be informed that participation in the study is voluntary, that he/she may withdraw from the study at any time, and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment. The participant must be informed that his/her medical records may be examined by authorized individuals other than their treating physician.

All participants for the study will be provided with an ICF, describing the study and providing sufficient information to allow the participant to make an informed decision about his/her participation in the study. Informed consent documents will be subject to approval by the EC prior to enrolling subjects in the study.

The participant should read and consider the statement before signing and dating the ICF, and shall be given a copy of the signed document. The ICF must also be signed and dated by the investigator (or his/her designee), and it shall be retained as part of the study records.

9.5 Early Termination of the Study

The Sponsor may terminate the study prematurely according to certain circumstances. Examples of such circumstances include ethical concerns, insufficient participant recruitment, participant safety concerns, alterations in accepted clinical practice that make the continuation of a clinical trial unwise, early evidence of benefit or harm of the research product, or for any other reason.

10. STATISTICAL METHODS

10.1 Statistical Hypothesis

No statistical hypothesis is being tested in this study.

10.2 Sample Size Determination

The sample size is based on the Sponsor's previous clinical experience and the expectation that enough procedures using the OEC Elite will be performed to demonstrate clinical performance.

10.3 Statistical Analysis

No statistical analysis is prospectively planned.

10.3.1 Interim Analysis

No interim analyses are intended to be conducted as part of this study.

10.4 Handling of Missing Data

Analysis will be based on collected data, and no imputation will be done for missing data.

10.5 Deviation(s) from the Original Statistical Plan

Any changes or deviations from the original statistical plan specified in this protocol will be described and justified in study final report, per ISO 14155:2011.

11. QUALITY ASSURANCE AND CONTROL

11.1 Data Management

Data management processes for handling study data will be maintained by the Sponsor.

11.1.1 Completion of Case Report Forms (CRFs)

The data reported on the CRFs shall be derived from source documents and be consistent with these source documents. Paper CRFs will be used to collect data. The Sponsor will provide CRFs and train study staff on completion of CRFs using Good Documentation Practices (GDP). CRF Completion Guidelines (CCG) may be provided by the Sponsor to help facilitate training.

CRFs are to be completed as information becomes available at the site. CRFs should be signed by indicated parties, in indicated area(s), to certify the contents of the form. The PI is ultimately responsible for ensuring completion of CRFs.

If discrepancies are discovered on paper CRFs during monitoring, the Sponsor's representative will ensure that the study staff makes necessary corrections directly to the CRF(s) prior to collection.

Following CRF collection, the Sponsor will review the data. A Data Clarification Form (DCF) may be provided to the site to correct or clarify discrepancies.

If a site discovers discrepancies after CRF collection, the site may notify the Sponsor and request data modification.

11.1.2 Data Handling and Record Keeping

All documents and data shall be produced and maintained in a manner that assures control and traceability.

11.1.3 Source Data and Documents

Source data includes information in original records, certified copies of original records of clinical findings, observations, or other activities for the study. Source documents for each subject must be retained throughout the investigation, including printed or electronic documents containing source data. Elements should include:

- **Source data and documentation** relevant to data recorded for subject screening and CRF corroboration.
- **Subject records** containing the completed ICFs and CRFs.
- **Regulatory binder** containing the protocol and any subsequent amendments, EC submissions and approvals, blank ICF(s), and site logs.
- **Reference manuals** containing investigator responsibilities, Sponsor, AE/SAE and informed consent guidelines, applicable study aids and training materials, and supplier instructions.

The PI or institution shall provide direct access to source data during and after the clinical investigation for monitoring, audits, EC review, and regulatory authority inspections.

11.1.4 Archiving

All study data must be archived for a minimum of three (3) years after study termination or premature termination of the clinical trial. No source documents or study records will be destroyed without Sponsor notification and approval.

12. MONITORING PLAN

In collaboration with the site, the Sponsor will ensure proper monitoring of the study to confirm that all the research requirements are met. Monitoring visits will oversee the progress of a clinical investigation and ensure that it is conducted, recorded, and reported in accordance with the protocol, written procedures, GCP ISO 14155:2011, and the applicable regulatory requirements.

12.1 Confidentiality and Data Protection

The investigator affirms and upholds the principle of the participant's right to privacy, and the investigator shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing data in scientific journals.

All individual subject medical information obtained as a result of this study will be considered confidential, and disclosure to third parties will be prohibited. Subject confidentiality will be further ensured by utilizing subject identification code numbers. For data verification purposes, authorized representatives of the Sponsor, CA, or EC may require direct access to parts of the medical records relevant to the study, including subject medical history.

12.1.1 Storage of Images and Associated Health Data

Images will be collected or disclosed to the Sponsor as part of this study. No patient information beyond what is captured on the associated Case Report Forms will be collected. Fully de-identified data and images, which have had all personal identifying information removed, may be stored and used by the Sponsor indefinitely. The Sponsor and/or its authorized representatives may use any de-identified data collected in this study for future technology and engineering development, education, marketing, or other possible uses.

12.2 Publication Policy

The results of this study may not be used in future publications.

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APPENDIX A – STUDY SITE AND INVESTIGATOR LIST

The following investigators at each study site will be responsible for the conduct of this study:

Investigator(s):[1]	Investigator Name, *Dr. Theodore Rapanos* *Associate Professor* *Division of Vascular Surgery* *Tel*: *905-521-2100 x44652* *e-mail*: rapanost@mcmaster.ca	Site Name Hamilton General Hospital *Address*: 237 Barton St. East Hamilton, ON L8L 2X2

[1] The role of the ***Principal Investigator*** is to implement and manage the conduct of the investigation as well as ensure data integrity and the rights, safety, and well-being of humans involved in the study [ISO 14155:2011 9.1]. ***Co-Investigators*** share all responsibilities of the ***Principal Investigator***, and ***Sub-investigators*** share only those responsibilities designated by the ***Principal Investigator***.