18. OTHER RECORDS AND REPORTS

No additional records and/or reports, other than those previously described in this investigational plan or required for subpart G of 21 CFR 812, will be maintained for this clinical investigation.

APPENDICES

APPENDIX A – INSTRUCTIONS FOR USE

APPENDIX B –DEFINITIONS

MAJOR ADVERSE EVENT DEFINTIONS

All-Cause Mortality:	Death from any cause.
Myocardial Infarction (MI):	Myocardial necrosis as evidenced by ≥ 2 of the following 3 findings: 1. new clinical symptoms suggesting MI 2. changes on ECG consistent with MI 3. elevated CK > 2 times the upper limit of normal (per the institution).
Paraplegia:	Complete loss of motor and/or sensory function in the lower extremities and lower portions of the trunk due to spinal cord injury or disease and occurring intra- or postoperatively and persisting > 1 month.
Renal Failure:	Failure of renal function requiring dialysis or elevation of serum creatinine ≥ 2 times the baseline value.
Cerebrovascular Accident (CVA)/Stroke:	Cerebrovascular ischemia or hemorrhage causing the development of a new neurological deficit that persists > 24 hours, or worsening of previous neurological symptoms that persists > 24 hours.
Left Arm/Hand Ischemia:	Malperfusion of the left arm/hand as a result of an arterial thrombosis/embolus resulting in symptoms of pain, parasthesias, pulselessness, paralysis, pallor, or poikilothermia evidenced on Doppler ultrasound, CTA, or MRA imaging.

SECONDARY OBSERVATIONS DEFINITIONS

All-Cause Mortality:	Death from any cause.
Device, Procedure, and/or Disease (TAA)-Related Adverse Events	Disease-Related: Any adverse event that occurs as a result of the aortic disease treated by the Valiant Mona LSA Thoracic Stent Graft System. Device-Related: Any adverse event that occurs as a result of any defect, malfunction, or failure of the Valiant Mona LSA Thoracic Stent Graft System. Procedure-Related: Any adverse event that occurs within 30 days of a procedure to treat the aneurysm or a stent graft device malfunction/failure unless specifically shown not to be related to that procedure.
Serious Adverse Events (SAEs)	A serious adverse event is an adverse event that: •Led to a death. •Led to a serious deterioration in the health of the subject that resulted in: a. a life threatening illness or injury, or b. a permanent impairment of a body structure or a body function, or c. in-patient hospitalization or prolongation of existing hospitalization d. medical or surgical intervention to prevent life-threatening illness or 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. * Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without serious deterioration in health, is not considered a serious adverse event. * An observational, overnight hospital admission < 24 hours in duration does not qualify an adverse event as a serious adverse event.

Secondary Index Procedures	An additional procedure required to achieve successful treatment of the subject during the index procedure including placement or use of additional component: • Deployment of secondary endoluminal prosthesis within the primary prosthesis. • Balloon dilatation of anchor zones.
Secondary Endovascular Procedure	A secondary endovascular procedure is defined as any endovascular procedure performed during the relevant time period which involves the targeted vascular segment treated by the Valiant Mona LSA Thoracic Stent Graft System in which there is either manipulation of the existing Valiant Mona LSA devices or implantation of any additional stent graft devices.
Conversion to (Open) Surgical Repair:	**Primary Conversion:** Conversion from endovascular to open repair required at the time of the index procedure. **Secondary Conversion:** Conversion from endovascular to open repair required at a time beyond the initial index procedure.
Surgical Revascularization of the LSA	Open surgical bypass to restore blood flow through the LSA.
Endoleak	Defined by the presence of contrast outside the lumen of the endoluminal graft but within the aneurysm sac
Exclusion of aneurysm	Defined as the absence of type I or III endoleak associated with the absence of growth > 5 mm of the maximum measurable aneurysm diameter; reference diameter is the diameter measured at first post-operative imaging exam.
Exclusion of penetrating aortic ulcer (PAU)	Defined as the absence of type I or III endoleak associated with the absence of growth > 5 mm of the maximum measurable aortic diameter at the level of PAU; reference diameter is the diameter measured at first post-operative imaging exam.
Exclusion of false lumen (dissection)	Defined as the coverage of the primary entry tear of dissection associated with the thrombosis of false lumen at the level of stent graft.

Primary intimal tear false lumen perfusion (PIT FLP)	Defined as flow from a proximal aortic source through the primary intimal tear (PIT), into the aortic false lumen (similar to a Type IA endoleak after treatment of aneurysms).
Proximal aorta false lumen perfusion (PA FLP)	Defined as flow from an aortic source proximal to the endovascular stent-graft, through an entry tear proximal to the PIT, into the aortic false lumen.
Distal aorta false lumen perfusion (DA FLP)	Defined as flow from an aortic source distal to the endovascular stent-graft, through fenestrations in the dissection septum, secondary aortic tears, or re-entry points, into the aortic false lumen.
Proximal branch false lumen perfusion (PB FLP)	Defined as flow into the aortic false lumen via retrograde flow from aortic arch branch vessels.
Distal branch false lumen perfusion (DB FLP)	Defined as flow into the aortic false lumen via retrograde flow from distal branch vessels in the chest (intercostals), abdomen (e.g., mesenteric, renal), or pelvis (iliac).

APPENDIX C – ADVERSE EVENT DEFINITIONS

ADVERSE EVENT DEFINITIONS

In addition to the definitions provided in Appendix B – Major Adverse Event Definitions, the following definitions apply to expected adverse events that may occur and must be reported throughout this clinical study. Events reported should represent a new onset or increase in the severity of the condition from the time of enrollment (the subject is considered to be enrolled at the time of arterial access with the intent to implant the Valiant Mona LSA Stent Graft).

A. PULMONARY COMPLICATIONS	DEFINITION
Pneumonia	Lung inflammation and/or infection as determined by physical, radiographic, and laboratory findings requiring treatment with antibiotics, inhalation therapy, intubation, or suctioning.
Atelectasis	Complete or partial collapse of lung tissue as determined by physical, radiographic, and laboratory findings requiring treatment with respiratory therapy, incentive spirometry, oxygen, medications, inhalation therapy, or bronchoscopy.
Pulmonary Embolism	Blockage of an artery in the lungs by a blood clot or other material moving through the venous bloodstream as evidenced by sudden onset of pleuritic chest pain, cough, hemoptysis, hypoxia, tachycardia, and a positive ventilation/perfusion scan.
Pulmonary Edema	Abnormal accumulation of fluid in the lungs.
Other Pulmonary Complications	Any other significant pulmonary complication that causes clinically relevant changes in the subject's health, e.g., wheezing, pleural effusion, pneumothorax, chronic obstructive pulmonary disease.

B. BLEEDING COMPLICATIONS	DEFINITION
Bleeding, Post-Procedural	Post-procedural bleeding > 750 cc after the subject leaves the operating room.

Coagulopathy	An abnormality of blood clotting function (e.g., disseminated intravascular coagulopathy or thrombocytopenia) documented by appropriate laboratory studies and requiring therapy with medication or transfusion.
Hematoma	An abnormal localized collection of blood (clotted or partially clotted) situated within an organ or a soft tissue space, requiring surgical intervention, evacuation, transfusion or prolonged hospitalization.
Seroma	A mass caused by the localized accumulation of serum within a tissue or organ.
Gastrointestinal bleeding	Bleeding of the gastrointestinal tract as evidenced by hematemesis, hematochezia, melena, or occult blood in the stool and confirmed by laboratory and/ or endoscopic findings.
Retroperitoneal Bleed	Bleeding into the retroperitoneal space due to trauma, surgery, or percutaneous puncture of an artery or vein.
Other Bleeding Complications	Any other significant bleeding complication that causes clinically relevant changes in the subject's health, e.g., intracranial hemorrhage, hemothorax, visceral hemorrhage, or intraperitoneal hemorrhage.

C. CARDIAC COMPLICATIONS	**DEFINITION**
Angina	Chest, neck, arm, back, or other pain related to decreased coronary blood flow.
Unstable Angina	Changes in previously reported chest pain type (e.g. chest pain at rest, more frequent, or more severe), unrelieved by anti-anginal medications in a subject with known coronary artery disease without significant elevations in cardiac enzymes.
Arrhythmia	The development of a new atrial and/or ventricular arrhythmia, significant increase in the severity of a preexisting arrhythmia, or any episode of cardiac arrest.
Congestive Heart Failure	Failure of the heart to pump blood with normal efficiency. Development of an acute episode of or exacerbation of existing low cardiac output or fluid overload accompanied by peripheral and/or pulmonary edema.
Other Cardiac Complications	Any other significant cardiac complication that causes clinically relevant changes in the subject's health, e.g., cardiac tamponade, pericarditis.

D. RENAL FUNCTION COMPLICATIONS	DEFINITION
Renal Insufficiency	Decrease in and inadequacy of the filtration function of the kidney resulting from disease (e.g., diabetes, cancer, hypertension, or glomerulonephritis). If creatinine levels are available, an increase of > 25% above the pre-procedure creatinine level, excluding cases in which regardless of the 25% increase, the creatinine levels are still within the normal ranges.
Other Renal Complications	Any other significant renal complication that causes clinically relevant changes in the subject's health, e.g., infarct of kidney, kidney stones/tumors.

E. WOUND COMPLICATIONS	DEFINITION
Dehiscence	Surgical complication in which the sutured wound separates along the incisional line.
Lower Limb Edema	Abnormal accumulation of fluid in a lower extremity, defined in this study by a circumference of the affected limb that is 2 cm greater than that of the contralateral extremity more than 2 weeks following treatment.
Lymphocele/ Lymph Fistula	Cystic mass containing lymph occurring at the incision or puncture site > 3 days after surgery.
Wound Infection	Infection and inflammation of the incision or puncture site requiring drainage and/or debridement in addition to antibiotic therapy, e.g., cellulitis.
Other Wound Complications	Any other significant wound complication that causes clinically relevant changes in the subject's health, e.g., tissue necrosis, false aneurysm.

F. GASTRO-INTESTINAL COMPLICATIONS	DEFINITION
Bowel Obstruction	The clinical picture of mechanical bowel obstruction, in which the transit of products of digestion is blocked, confirmed by abdominal x-ray studies,

	requiring nasogastric or long tube decompression (with or without laparotomy for adhesiolysis).
Bowel Necrosis	Death of part of the intestine after its blood supply is interrupted.
Ileus	Intestinal paralysis that may lead to obstruction.
Other Gastrointestinal Complications	Any other significant gastrointestinal complication that causes clinically relevant changes in the subject's health, e.g., pancreatitis, cholecystitis, gall stones, biliary tract stones, appendicitis, gastric ulcer (not bleeding), gastritis, positive stool culture, nausea and vomiting (not related to medications), gastroenteritis, hemorrhoids, constipation, diarrhea, esophageal hernia.

G. VASCULAR COMPLICATIONS	**DEFINITION**
Aortic Dissection	Acute (< 2 weeks) or chronic (> 2 weeks) intimal tear resulting in propagation of blood within the aortic media, usually distally, but sometimes retrograde, with numerous reentry sites.
Aortic Rupture	The tearing apart of the aortic tissue. Signs of aortic rupture include hemothorax, unrelenting chest or back pain, or hypotension refractory to medical management for a period > 2 days.
Aneurysm Rupture	Rupture or perforation of the targeted aneurysmal sac as detected by angiography, CT scan, and/or direct observation at surgery or autopsy. Aneurysm rupture should be reported as either procedure-related aneurysm rupture, i.e., perforation of the aneurysm during the course of the implantation procedure, or as a late aneurysm rupture that follows device deployment. For purposes of this study, Aneurysm Rupture only applies to the aneurysm which was the target treatment of the Mona LSA Thoracic Stent Graft System. Other aneurysm ruptures, which were not treated by the Mona LSA Thoracic Stent Graft System, should be captured in the "Vascular, Other" section of the eCRF.
Arterial or Venous Occlusion	Vessel lumen narrowing by atherosclerotic plaque, thrombus, or embolism causing occlusion of blood supply to the extremities.
Arteriovenous Fistula	Formation of an abnormal connection between the lumens of an artery and a vein as documented by CT, ultrasound, angiography, or direct observation.

G. VASCULAR COMPLICATIONS	DEFINITION
Embolism	The obstruction of a blood vessel by a blood clot or foreign substance, e.g., air, fat, bacteria) that has traveled through the bloodstream from another anatomic location.
Penetrating Atherosclerotic Ulcer (Saccular Aneurysm)	Atherosclerotic aortic intimal erosion resulting in penetration initially into the internal elastic lamina and then through to the media, associated with an intramural hematoma.
Pseudoaneurysm	Enlargement of the aorta, iliac, femoral or arteries, due to vessel injury and a contained leakage of blood. A pseudoaneurysm, unlike a true aneurysm, may contain some or all of the medial layer, the adventitia, and peri vessel tissue and are most commonly associated with operative procedures, trauma, and/or infection.
Stenosis	A reduction in the diameter of the vessel lumen when compared to the reference diameter, as documented by angiography, which requires intervention and is related to the procedure, e.g., access vessel.
Thrombosis	Clotting within a blood vessel which may occlude the vessel, causing infarction of tissues supplied by the vessel, or be attached to the vessel or heart wall without obstructing the lumen.
Transection	Acute (< 2 week) or chronic (> 2 week), partial or full, circumferential tear in the aortic wall.
Tissue Necrosis	Death of body tissue secondary to decreased blood supply.
Gangrene	Tissue necrosis due to obstruction, loss, or diminution of blood supply that may be localized or extensive (involving an entire extremity).
Perforation	Defined as a tear or hole in an access vessel wall or the aorta confirmed by extravasation of contrast under fluoroscopy.
Vessel Disruption	Interruption of the continuity of the vessel wall.

G. VASCULAR COMPLICATIONS	DEFINITION
Vessel Rupture/Dissection	Rupture: Forcible tearing or disruption of tissue. Dissection: Extrusion of blood into the connective tissue framework of a vessel wall, causing separation of the natural vessel layers.
Other Vascular Complications	Other vascular events that cause clinically relevant changes in the subject's health. This will also include ruptures of aneurysms which were not the target lesion of the Mona LSA Stent Graft System.

H. NEUROLOGIC COMPLICATIONS	DEFINITION
Change in Mental Status	The new onset of changes in brain functioning causing defects in memory, alertness, orientation, judgment, emotional control, perception or behavior.
Femoral Neuropathy	Femoral nerve dysfunction as evidenced by pain and/or numbness in the anterior thigh associated with quadriceps muscle weakness and decreased patellar reflex lasting > 1 month after treatment.
Nerve Injury/Peripheral Neuropathy	Direct damage to nerves surrounding the access site, operative field, or implantation site, and the resultant signs and/or symptoms of such damage.
Transient Ischemic Attack	A brief episode of neurological dysfunction caused by focal brain or retinal ischemia with clinical symptoms typically lasting 1 - 24 hours and without evidence of acute infarction.
Other Neurologic Complications	Any other neurologic complication that causes clinically relevant changes in the subject's health, e.g., leg weakness, foot drop, weakness/numbness in hand/fingers, pain (headache, backache), Bell's palsy, spinal stenosis, confusion, vertigo.
Paraparesis	Partial loss of voluntary motor function of lower extremities

I. OTHER EVENTS	DEFINITION
Anesthetic Complications	Reaction or complication caused by administration of an anesthetic.
Loss of Patency of the Stent Graft:	Loss of continued blood flow through the stent graft treated section of the vessel.
Anastomotic False Aneurysm	The development of an anastomotic false aneurysm at the proximal or distal end(s) of the device or surgical graft as determined by CT scan, ultrasound angiography, and/or direct observation at surgery or autopsy.
Aortoenteric Fistula	Formation of an abnormal communication tract between the lumens of the aorta and the gastrointestinal tract or erosion of the prosthetic body into the intestine.
Erectile Dysfunction/Impotence	Subjective report of failure to resume the degree of sexual function documented preoperatively within 6 months of the index procedure.
Post-Implant Syndrome	Self-limiting symptoms of back pain and fever of unknown origin > 101° F (without leukocytosis) lasting longer than 48 hours post index procedure.
Genitourinary	Symptomatic and asymptomatic genitourinary complications with subsequent attendant problems including ischemia, erosion, fistula, incontinence, hematuria, infection (cystitis, urethritis, prostatitis, epididymitis, pyelonephritis).
Sepsis	Systemic infection with confirmed positive blood cultures.
Neoplasm	Any tumor or uncontrolled growth of cells.
Prosthesis Infection	The development of a perigraft infection confirmed by direct examination, CT, and/or perigraft aspiration, and not associated with aortoenteric, fistula, or erosion.
Other Complications	Any event that causes clinically relevant changes in the subject's health, e.g., allergic reaction to dye, anemia.

APPENDIX D – DEVICE-RELATED TECHNICAL OBSERVATIONS

TECHNICAL OBSERVATIONS

If a defect, malfunction, or failure of the Valiant Mona LSA Thoracic Stent Graft System is noted, or the system does not function according to its design intent (including endoleaks), and the event is not related to any untoward medical occurrence in a subject or place the subject at increased risk, then the event will be recorded as a "technical observation" (refer to Section 9.8—Technical Observations). For example, if there is stent graft migration as noted on a follow-up imaging study, but has not resulted in any adverse consequence to the subject, then the migration will be reported as a technical observation. Such observations will be reported separately from device-related adverse events on the **Site Imaging Report Form.** If the technical observation included an adverse event, then the appropriate adverse events forms must be completed as well.

TECHNICAL OBSERVATIONS	DEFINITION
Access Failure	Inability to insert device due to mechanical failure or anatomic conditions of the femoral or iliac arteries.
Aneurysm Expansion	Aneurysm maximum diameter increase of > 5 mm as compared to the discharge contrast enhanced imaging measurements.
Extrusion/Erosion	Extrusion or erosion of the metal frame through the full thickness of the vessel wall as determined by CT, angiography, and/or direct observation at surgery or autopsy.
Stent Graft Fabric Defect	Defect in the fabric of the stent graft.
General Stent Graft Complications	Any device-related technical observation not captured in the other Technical Observation categories.
Lumen Obstruction	Unintentional obstruction of flow through the vascular lumen due to twisting (obstruction in the vertical plane) or kinking (obstruction in the horizontal plane) of the stent graft, oversizing, failure of the implant to fully open, or any other cause.

TECHNICAL OBSERVATIONS	DEFINITION
Deployment Failure	Deployment failure due to patient anatomy or mechanical failure. This specifically refers to deployment of the stent graft from the delivery system.
Bare Stent Fracture	Fracture or breakage of the bare stent.
Stent Graft Wireform Fracture	Fracture or breakage in stent graft wireform.
Branch Stent Graft Occlusion	A **complete** blockage of the lumen of the stent graft as evidenced by CT, angiography, ultrasound, or other appropriate imaging modality, and/or pathological analysis.
Stent Graft Stenosis	Reduction in the diameter of the stent graft lumen as compared to the reference diameter.
Stent Graft Thrombosis	Hemodynamically significant thrombus formation within the lumen of the device or surgical graft material as determined by ultrasound, CT scan, angiography, and/or pathological examination. Classify as to the location of the thrombosis: branch stent graft or main stent graft.
Stent Graft Migration	Evidence of movement of the stent graft relative to fixed anatomic landmarks, which is not due to remodeling of the subject's vasculature. Proximal migration of the main stent graft is observed when the main stent graft movement is > 10 mm antegrade. Distal migration of the main stent graft is observed when the main stent graft moves > 10 mm caudal, relative to fixed anatomic landmarks. Proximal migration of the branch stent graft is observed when branch stent graft movement is > 10 mm into/towards the aorta. Distal migration of the branch stent graft is observed when movement is > 10 mm away from the aorta relative to fixed anatomical landmarks.

ENDOLEAKS	DEFINITION
Endoleak – Type I	Blood flow into the aneurysm sac from the proximal anchoring site (proximal endoleak) or the distal anchoring site (distal endoleak) of the device.
Endoleak – Type II	Retrograde flow into the aneurysmal sac from patent branch arteries.

ENDOLEAKS	DEFINITION
Endoleak – Type III	Leak from the mid-graft region due to the defect of fabric or between the segments of the modular graft (junctional endoleak).
Endoleak – Type IV	Transgraft leak due to fabric porosity.
Endoleak – Type V	Aneurysm enlargement in the absence of any demonstrable perfusion of the aneurysmal sac.

APPENDIX E – INFORMED CONSENT TEMPLATE

APPENDIX F – LABELING

APPENDIX G – ASSESSMENTS AND GUIDELINES

- ASA Anesthesia Classification
- NIH Stroke Scale
- The Folstein Mini-Mental Status Examination (MMSE)
- The Modified Rankin Scale (mRS)
- TAA Anatomical Characteristics and Dimensions Diagram
- Modified SVS/AAVS Medical Comorbidity Grading System
- Imaging Recommendations

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PHYSICAL STATUS CLASSIFICATION SYSTEM**********

Class	Description
I	A normal healthy patient.
II	A patient with mild systemic disease.
III	A patient with severe systemic disease.
IV	A patient with severe systemic disease that is a constant threat to life.
V	A moribund patient who is not expected to survive without the operation.
VI	A declared brain-dead patient whose organs are being removed for donor purposes.

********** Per American Society of Anesthesiologists website: www.asahq.org/clinical/physicalstatus.htm.

MODIFIED SVS/AAVS MEDICAL COMORBIDITY GRADING SYSTEM

SVS RISK FACTORS

Components	0 (Absent)	1 (Mild)	2 (Moderate)	3 (Severe)
Age (years)	< 55	55-69	70-85	> 85
Hypertension	None Cut-off point: diastolic pressure usually lower than 90 mmHg	Controlled Cut-off point: diastolic pressure usually lower than 90 mmHg) with single drug	Controlled with 2 or more drugs	Uncontrolled hypertension ††††††††††††††††††
Cardiac	Asymptomatic, with normal ECG	Asymptomatic, but with either remote MI by history (6 months), occult MI by ECG, or fixed deficit on dipyridamole thallium or similar scan	Any one of the following: • Stable angina • No angina but significant reversible perfusion deficit on dipyridamole thallium scan • Significant silent ischemia (1% of time) on Holter monitoring • EF = 25-45% • Controlled ectopy or	Any one of the following: • Unstable angina • Symptomatic or poorly controlled ectopy or arrhythmia (chronic or recurrent) • Poorly compensated or recurrent CHF • EF < 25% • MI within 6 months with no intervention

†††††††††††††††††† Physicians generally use the full armamentarium of drugs available to them. As such the key issue with respect to risk classification is whether the hypertension is controlled and not necessarily how many drugs were used to establish effective control.

Components	0 (Absent)	1 (Mild)	2 (Moderate)	3 (Severe)
			asymptomatic arrhythmia • History of CHF that is now well compensated	(CABG, angioplasty or stenting)
Pulmonary	Asymptomatic, normal chest X-ray, pulmonary function tests within 20% of predicted	Asymptomatic or mild dyspnea on exertion, mild chronic parenchymal radiograph changes, pulmonary function tests 65-80% of predicted	Between 1 and 3	Vital capacity <1.85L, FEV1 <1.2L or <35% of predicted, maximal voluntary ventilation <50% of predicted, PCO_2 >45 mmHg, supplemental O_2 medically necessary, or pulmonary hypertension
Renal	No known disease, normal creatinine	Moderately elevated creatinine level, as high as 2.4 mg/dL	Creatinine level 2.5-5.9 mg/dL	Creatinine level >6.0 mg/dL, or on dialysis, or with kidney transplant

Note: ECG = electrocardiography; MI = myocardial infarction; CHF = congestive heart failure; VC = vital capacity; FEV1 = forced expiratory volume in 1 second; PCO2 = partial pressure of carbon dioxide.

NIH STROKE SCALE SCORING SYSTEM

Score	Description
0	No stroke.
1-4	Minor stroke.
5-15	Moderate stroke.
15-20	Moderate/severe stroke.

Score	Description
21-42	Severe stroke.

Per NIH Stroke Scale Training, Part 2. Basic Instruction. Department of Health and Human Services, National Institute of Neurological Disorders and Stroke. The National Institute of Neurological Disorders and Stroke (NINDS) Version 2.0

THE FOLSTEIN MINI-MENTAL STATUS EXAMINATION (MMSE)

Score	Description
27-30	Normal cognition.
21-26	Mild cognitive impairment.
10-20	Moderate cognitive impairment.
<10	Severe cognitive impairment.

The Mini-Mental State Examination score and the clinical diagnosis of dementia. J Clin Epidemiol. 1994 Sep ;47(9):1061-7.

THE MODIFIED RANKIN SCALE (MRS)

Score	Description
0	No symptoms.
1	No significant disability. Able to carry out all usual activities, despite some symptoms.
2	Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.
3	Moderate disability. Requires some help, but able to walk unassisted.
4	Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.
5	Severe disability. Requires constant nursing care and attention, bedridden, incontinent.

6	Dead.

PDF of Modified Rankin Scale Score. http://www.strokecenter.org/wp-content/uploads/2011/08/modified_rankin.pdf.

CLASSIFICATION OF AORTIC ATHEROMA

Grade	Description
I	Normal to mild intimal thickening
II	Severe intimal thickening
III	Atheroma protruding < 5mm into lumen
IV	Atheroma protruding ≥ 5mm into lumen
V	Atheroma with a mobile component

Katz ES, Tunick PA, Rusinek H, et al: Protruding aortic atheromas predict stroke in elderly patients undergoing cardiopulmonary bypass: Experience with intraoperative transesophageal echocardiography. *JACC* 1992;20 (1):70–77.

ANATOMICAL CHARACTERISTICS AND DIMENSIONS DIAGRAM

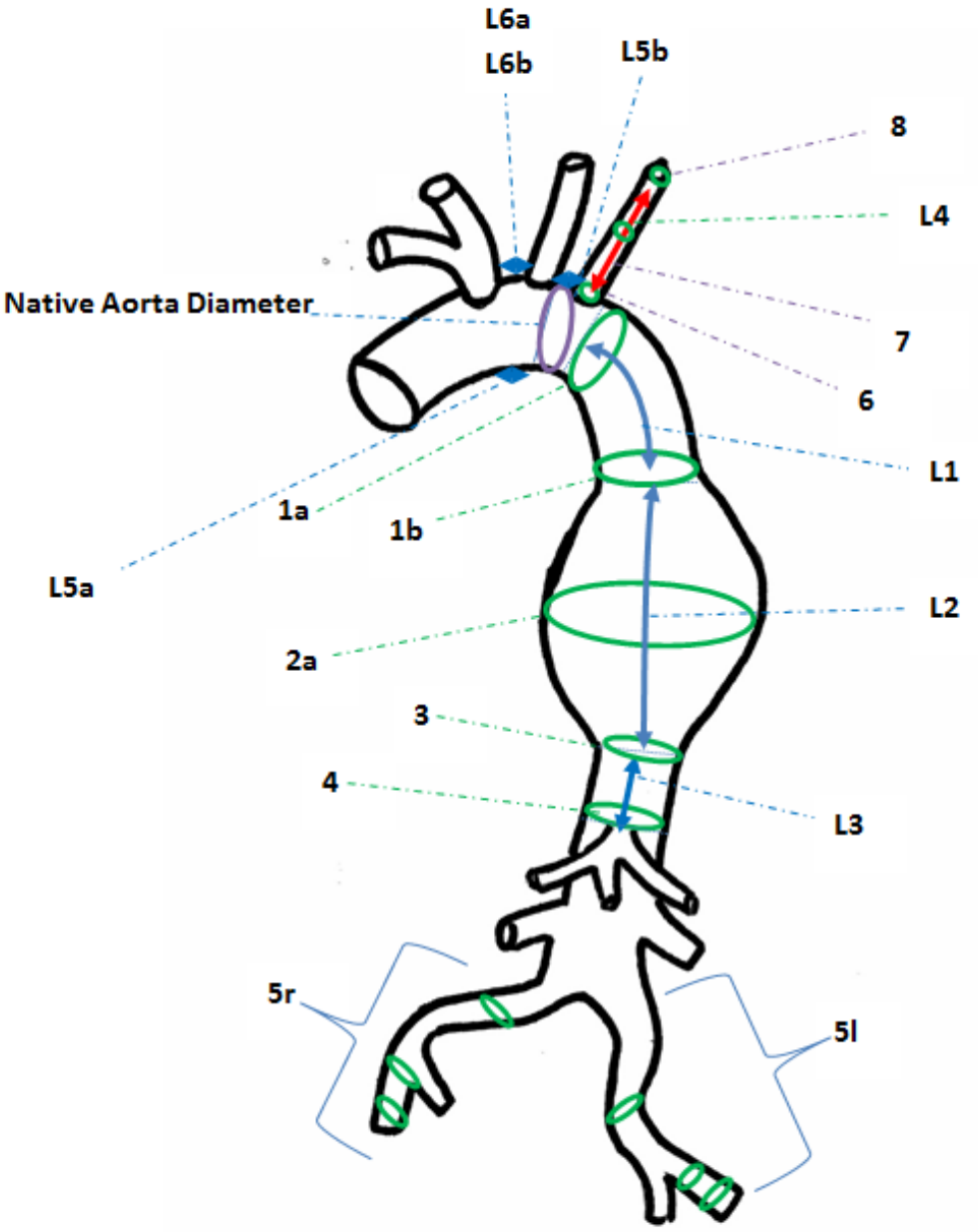


Figure 5: Anatomical characteristics and dimensions diagram

THORACIC DISSECTION MEASUREMENTS

Information pertaining to the measurements for chronic dissection, maximum thoracic aortic diameter and true and false lumen diameters should be recorded on the eCRFs. Refer to **Figure 6 and 7** below for an overview of these measurements.

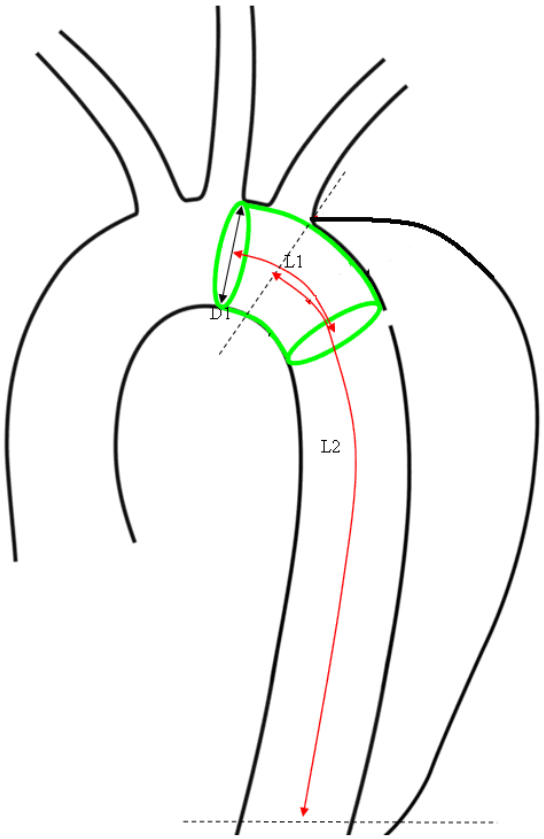


Figure 6: Thoracic Dissection Measurements

- D1: Diameter at distal margin of left CCA (long axis of ellipse).
- D2 (not shown): Diameter at proximal landing zone if different from D1.
- L1: Distance from distal margin of left CCA to start of most proximal tear. (Inclusion criteria: ≥20mm.)
- L2: Total length of aortic (thoracic and abdominal) dissection.
- L3 (not shown): Total thoracic aortic length (left CCA to celiac).

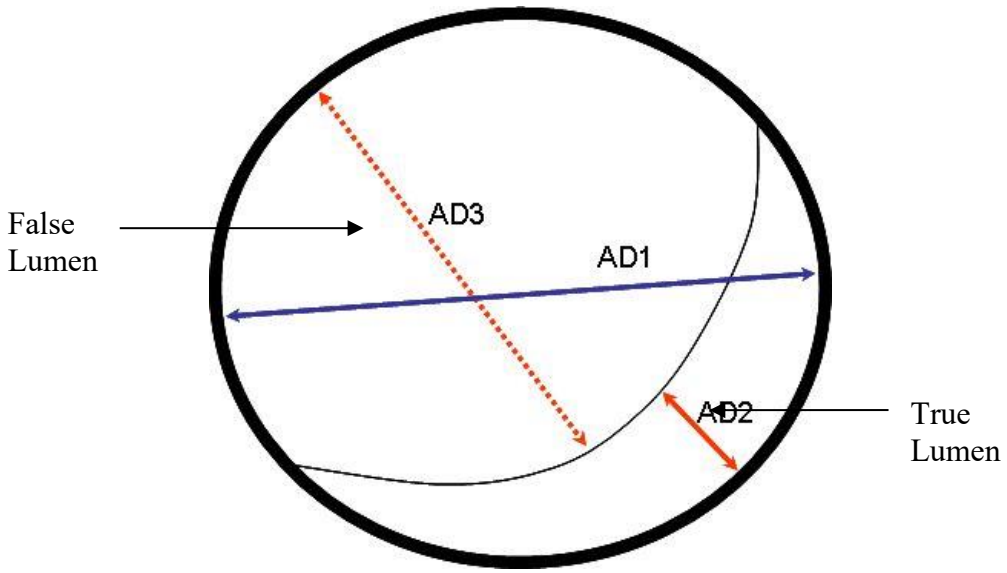


Figure 7: Maximum Thoracic Aortic/True/False Lumen Diameter Measurements

- All measurements should be based on centerline (along the TL) orthogonal 3D reconstructions of contrast CTA scan.
- AD1 (maximum thoracic aortic centerline diameter) = Maximum diameter anywhere along the thoracic aorta defined as distal margin of left CCA origin to proximal margin of celiac trunk (major axis of an ellipse).
- AD2 (maximum TL diameter) = inner wall-to-inner wall length along the minor axis of the TL ellipse. AD2 will be measured at the same location as AD1.
- AD3 (maximum FL diameter) = The maximum distance from the inner point of AD2 to the outer wall. AD3 will be measured at the same location as AD1.
- During follow-up, AD1, AD2, and AD3 should be measured at the point of maximum diameter of the DTA and additionally at the point of maximum diameter over the length of the endografted segment. If the point of maximum diameter for the entire DTA is over the endografted segment, only one set of measurements is needed.
- During follow up, status of FL: patent, partially thrombosed, thrombosed. This must be assessed on the DELAYED phase of a triple-phase CTA.

IMAGING GUIDELINES

ANGIOGRAPHIC IMAGING RECOMMENDATIONS

Current imaging of stent graft patients includes CT scan, with and without contrast medium, and a chest x-ray. If patients cannot tolerate contrast medium, non-contrast CTA should be performed. Additional imaging modalities (i.e., magnetic resonance imaging) should be considered in combination with non-contrast CTA for patients who have impaired renal function or intolerance to contrast media.

Imaging should be scheduled based on the physician's clinical assessment of the patient pre- and post-implantation of the stent graft. Both the type of imaging modality and the frequency of imaging should follow the study time points and guidelines.

CONTRAST ENHANCED SPIRAL CHEST CT SCAN

The accuracy and reproducibility of the CT Angio endpoints of this protocol are dependent upon each Investigator's commitment to rigorous image acquisition techniques. The following guidelines are provided for data acquisition and should be used pre and post procedure. Measurements to be recorded are also described.

CT Angio with 3D reconstructions will be analyzed using the qualitative morphologic criteria and quantitative methods established for the Thoracic Branch Stent Graft System Clinical Study. The entire pre- and post-procedural CT Angio will be reviewed for the documentation of standardized pre- and post-procedural morphologic criteria. Selected frames from the films will be analyzed using computer-assisted automated edge-detection algorithms and these computer-assisted methods are completely dependent on image acquisition quality. CT Angio with 3D reconstructions will be used to assess stent graft. It is important that it captures the entire stent-graft to adequately assess the device appropriately.

The image data should be submitted in DICOM format using any of the following data storage media: CDROM, DVDROM, or an USB flash drive. DICOM data sent to the Medtronic Vascular Clinical Study Team should not utilize "lossy compression". CT's should be obtained at pre-implant, 1 month, 6 months, 12 months and annually for a total of five (5) years post-implant. Images should be submitted to Medtronic Vascular.

DIRECTION OF DATA ACQUISITION

Chest CT examinations will be performed with the direction of data acquisition cephalocaudal.

REGION OF INTEREST

After obtaining anteposterior topogram, the region of interest will be from the cephalic limit to include the origins of the great vessels (brachial-cephalic trunk, left common carotid, left subclavian), and include a minimum of 5mm above the bifurcation of the LSA. The caudal limit will be at the level of the femoral bifurcation for the pre-implant CT and superior mesenteric artery for follow-up CT scans.

RECONSTRUCTION

The spiral acquisition will consist of continuous 360° tube rotations. Examinations could be reconstructed with a slice increment of 1.5 mm, and overlapping reconstructions are recommended. The recommended image reconstruction parameters are a slice increment of 0.8 mm or less, and an axial plane pixel resolution of 0.625mm or less. A zoom factor of 2.8-3.0 or a field of view of 20 to 30 cm centered on the aorta will be used.

CONTRAST

Properly timed intravenous injections of contrast media, preferably non-ionic, will be given to visualize arterial structures. It is recommended that the following CT series are submitted: Non-contrast (Native), Contrast (Arterial), and Delay (Venous).

Consider the appropriate site for injection of contrast (i.e., injection of contrast via the right upper extremity will minimize artefacts).

THREE-DIMENSIONAL RECONSTRUCTION

After volumetric data acquisition, 3D reconstruction should be performed with shaded surface rendering and maximum intensity projections and/or multiple-object interactive shaded surface display. Multiple object shaded surface display should include independent display of calcified plaque, contrast enhanced blood flow and thrombus non-calcified plaque.

Multiple image reconstructions will be generated to display relevant anatomic structures for measurement and evaluation. Additional planes of aortic aneurysms, such as coronal, sagittal, or oblique two-dimensional reformations may be generated and displayed.

X-RAY

Chest x-rays (completed per the Investigator's standard of care) may be used to assess stent fracture. It is important that the AP projection captures the entire stent-graft to adequately assess the device for fracture. Lateral projection will be helpful in observing the stent-graft in the proximal segment of the descending thoracic aorta that has anterior/posterior angulation. Bilateral obliques will be helpful in observing the stent graft in the distal segment of the descending thoracic aorta that has lateral angulation or in tortuous anatomy.

Chest x-rays will be obtained per the investigational site's standard of care. Images should be submitted to the Medtronic Vascular Clinical Study Team.

MRI OR MRA

Patients with impaired renal function, i.e. renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess aneurysm size is obtained. Additionally, a complete series of axial reconstructions are requested in order to compare aneurysm measurements taken from CT data. The image reconstruction interval should not exceed 3 mm. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed.

SUPPLEMENTARY IMAGING RECOMMENDATIONS

Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings. The following recommendations may be considered:

If there is evidence of poor position of the stent graft, severe angulation, kinking or migration of the stent graft on chest x-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.

If a new endoleak or increase in descending thoracic aneurysm size is observed by CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm.

APPENDIX H – EXPLANT INSTRUCTIONS

EXPLANT AND AUTOPSY PROCEDURE FOR ENDOVASCULAR PATIENTS

SURGEON AND SITE RESPONSIBILITY

***NOTE**: Priority should be given to patient health and safety at all times during the explant procedure.*

A. If the explant is part of a late conversion to an open-surgical procedure, consideration of the patient is foremost. The surgeon should remove ONLY the endovascular prosthesis, damaging or altering the device as little as possible yet providing optimal surgical care to the patient.

B. If the explant is performed on a cadaver, the surgeon should carefully view the adjacent body organs and excise the intact aorta containing the endovascular prosthesis, including 1cm of tissue adjacent to the proximal and distal fixation sites to facilitate histological assessment.

C. It is important that care be given during the collection, handling and examination of the implant to ensure that it is not damaged or altered.

- Particular care should be taken to avoid applying force, traction, or torsion to the stent graft during the explant.
- Care should be exercised to avoid excessive manipulation with metallic instruments at the proximal and distal fixation sites whenever possible.
- Stent graft or post mortem specimen should be placed in formalin as is. Do not attempt to clean or remove organic debris.

D. Using the Explant Procedure Observation Form (UC200103088EN), the physician should accurately and fully document the explant procedure and the stent graft ex situ. Any possible trauma applied to the device, e.g., clamping, twisting, torsion, or traction should also be documented.

- Physician operation notes may also be used to document the procedure and the characteristics of the stent graft prior to and after explant from the body.

- Mark components that separate during explant. Attach suture or hemoclip to anterior side and on the proximal end for proximal cuffs and distally for distal components.

E. Follow procedures from Explant Return Instructions (UC200103091) included in the explant kit for packaging and return of device to Medtronic.

EXPLANT RETURN INSTRUCTIONS:

1.0 Complete the following forms:

Explant Procedure Observation Form (UC200103088EN). This form is to be completed at the time of explant procedure.

Patient Identification Peel-off Labels (UC200103089EN). Using permanent ink, complete the two labels provided. Place one completed label on the inner plastic container; place the second completed label on the outer metal container

Air bill Fill in shipper information.

2.0 Secure the explant in the explant kit for shipping.

- Place the explanted device and any associated organic tissue into the labeled inner plastic container in a 10% neutral buffered formalin (3.7-4% Formaldehyde) solution to maintain tissue integrity.

Note: Any specimen too large for the provided inner container may be sent in any securely closed container and placed with provided packing in Metal container and box.

- Seal container with red tape (provided in kit). The tape should be stretched clockwise around the cap and the container. Place plastic container in absorbent bag.
- Place the absorbent bag (with plastic container) inside the labeled metal container. Place lid on metal can and seal with locking ring. Place the can in the cardboard box.
- Place the completed **Explant Procedure Observation Form** and implant and explant operative reports, if available, inside the moisture-resistant plastic bag provided. A Record of Disclosure of Health Information for Public Purposes is in included for your convenience and can be placed in the patients file.
- Securely seal the box with clear tape (provided in kit). Affix the Shipping labels to the outside of the box. Arrange for pickup from Shipping Company.

If you have questions about shipping the device, need additional information, or desire additional Explant Kits, please contact the Explant Department, at **(707) 591-7672 or (800)-465-5533.**

Thank you for completing the Explant Forms and returning the device. Medtronic uses this information to meet FDA requirements and track product performance.

EXPLANT PROCEDURE OBSERVATION REPORT

PLEASE COMPLETE THE INFORMATION BELOW:

PATIENT INFORMATION

Patient IDE/ Study ID_____

Name:_____

DOB (Month/Day/Year): _____/_____/_____

IMPLANT INFORMATION

Date of Implant: _____/_____/_____

Implanting Physician: _____

Implanting Hospital Name: _____

City and State:_____

Country: _____

EXPLANT INFORMATION

Date of Explant/Autopsy: _____/_____/_____

Explanting Physician: _____

Name of Hospital: _____

Address: _____

City and State: _____

Country: _____

Telephone: ( )_____

REASON FOR EXPLANT

_____

_____

Planned Surgical Conversion

Emergent Conversion

Autopsy Date of Death: ____/____/____

Remarks about procedure:

_____

Evidence of inflammation Yes No
Comments:_____

Thrombosis present in the seal zones Yes No
Comments:_____

Calcification present in the seal zones Yes No
Comments:_____

How well was the device attached to the patient's tissue?

Proximally: Comes out easily from aortic vessel

Appears firmly attached to aortic vessel

Mid body: Comes out easily from aneurysm contents

Appears firmly attached to aneurysm contents

Comments _____

Successful Surgical Conversion: Yes No

Patient Outcome: Alive Expired

DEVICE	CATALOG NUMBER	LOT NUMBER

FORM COMPLETED BY: _____ **TITLE**_____

Additional Comments

RECORD OF DISCLOSURE OF HEALTH INFORMATION FOR PUBLIC HEALTH PURPOSES

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require providers to record and, upon patient request, account for disclosures of patient information for public health purposes (except where disclosed pursuant to patient authorization or as part of a limited data set) (45 C.F.R. § 164.528(a)). This Record of Disclosure may be appended to the medical record to facilitate an accounting of disclosures.

The information you are providing to Medtronic Vascular as described below, is necessary for Medtronic Vascular to meet our government obligations regarding safety, effectiveness and quality, and is a public health disclosure under Section 164.512(b)(1)(iii) of the HIPAA Privacy Rule.

Date of Disclosure:

Recipient and Contact Information:

Medtronic Vascular, Inc.

Quality Assurance Department

3576 Unocal Place

Santa Rosa, California 95403

707-591-7672

Description of Patient Information Disclosed:

Examples of descriptions to be written here include:

- *Information regarding the functioning of the patient's Valiant Stent Graft*
- Implant Operative Report, the Explant Operative Report, and surveillance radiology reports

Purpose of Disclosure:

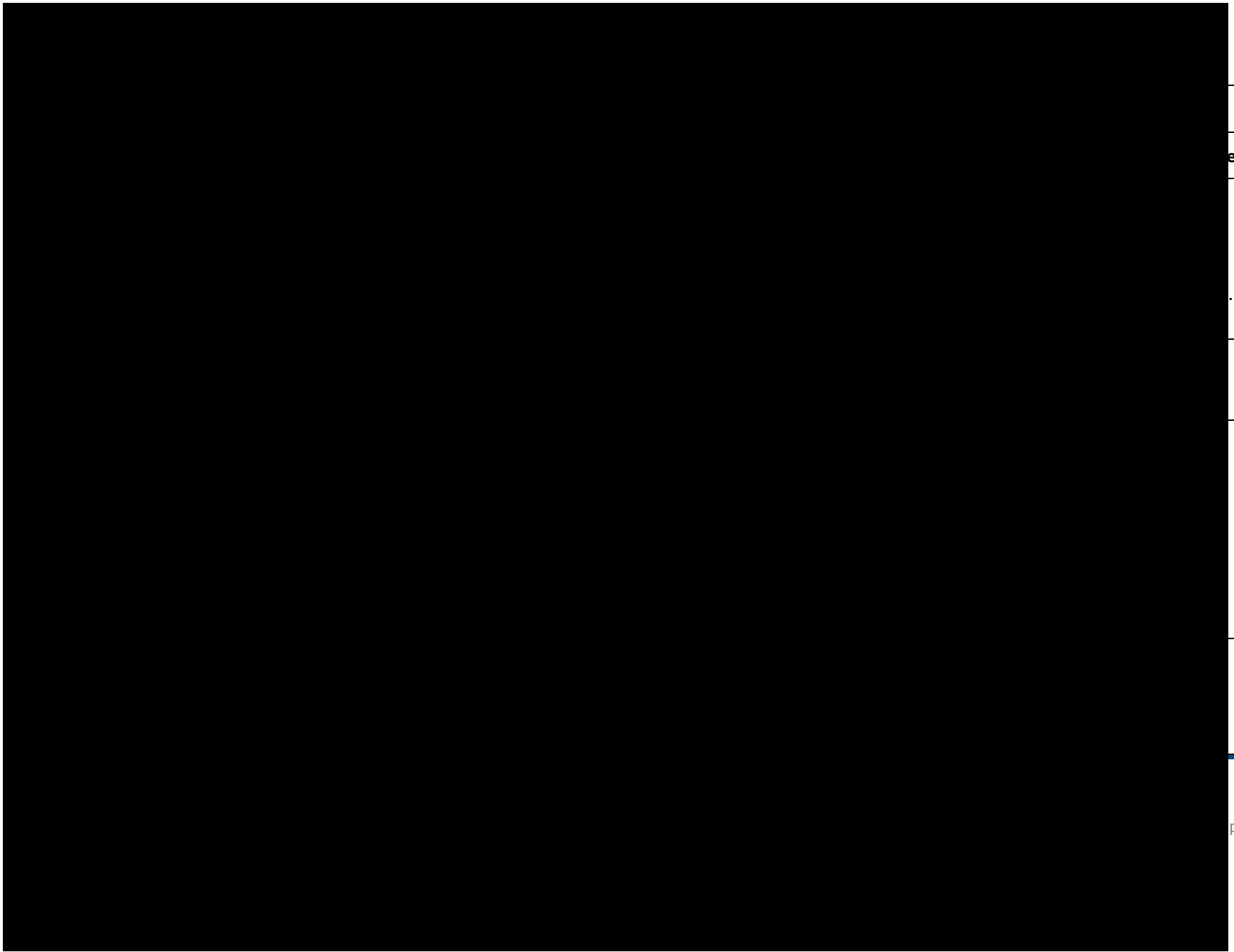
The following language can be used on all Records of Disclosures:

"For public health activities and purposes under Section 164.512(b)(1)(iii) of the HIPAA Privacy Rule, i.e. activities related to the quality, safety or effectiveness of FDA-regulated products or activities for which [Medtronic/Medtronic business unit] is responsible."

APPENDIX I - CMS STUDY CRITERIA

Medicare beneficiaries may be affected by the device because in 2013 more than 63% of TEVAR cases were performed in Medicare beneficiaries, and 59% of claims with principal TAA diagnoses involve patients age 65 or older. Study results are expected to be generalizable within the Medicare beneficiary population based on the prevalence of TAA in patients age 65 and older.

All IRBs should comply with 45 CFR part 46.



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