

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I (we) voluntarily request Dr. _____ as my physician, and such associates as he/she may deem necessary (for example anesthesia providers, educational assistants, and other health care providers who are identified and their professional role explained to me) to treat my condition. My condition has been explained to me as:

(Condition to be treated)

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedure(s):

(Procedures)

I (we) understand that my physician may discover other or different conditions which require additional procedures than those planned. I (we) authorize my physician, and any associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

I (we) understand that these qualified medical practitioners may be performing significant tasks related to the surgery such as opening or closing incisions, harvesting or dissecting tissue, altering tissue, implanting devices, tissue removal or photography during procedures.

☐ Initial

I (we) Do ☐ Do Not ☐ consent to the use of blood and blood products as considered necessary. *Benefits, risks, alternatives and the risks and benefits of alternatives have been discussed and I (we) have been given the opportunity to ask questions.*

TEXAS MEDICAL DISCLOSURE
Hematic and lymphatic system

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1. Transfusion of blood and blood components.

1. Fever.
2. Transfusion reaction which may include failure or anemia
3. Heart failure
4. Hepatitis
5. AIDS (Acquired Immune Deficiency Syndrome)
6. Other infections



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★ T R E A T ★

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Initial

Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me, such as the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions and even death. I (we) also realize that the following specific risks and hazards may occur in connection with this particular procedure(s):

Initial

I (we) Do ☐ Do Not ☐ consent to have one or more manufacturer's technical representatives, as requested by my physician, in the room during the procedure. I understand that one or more representatives from the equipment and/or supply company for the products that the physician will use during my procedure, may be present for the procedure but will not perform any portion of the procedure. I further understand that all manufacturer's technical representatives present have confidentiality agreements and that none of the my personal health information will be disclosed to anyone other than my caregivers within this hospital.

I (we) consent to the disposal by hospital authorities of any tissue or parts which may be removed.

I (we) have been given the opportunity to ask questions about my current condition(s), the proposed procedure(s), the benefits, the likelihood of success, the possible problems related to recovery, the possible risks of nontreatment of my condition, and other alternative forms of treatment, and the risks and benefits of alternatives involved. I (we) understand that no warranty or guarantee has been made to me as to result or cure. Any professional/business relationship between my health care providers, the hospital and educational institutions has been explained to me.

I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me (us), that the blank spaces have been filled in, and that I (we) understand its contents. I (we) believe that I (we) have sufficient information to give this informed consent and I (we) request the procedure(s) to be done.

Patient's Signature _____ Date _____ Time _____

Other Legally Responsible Person's Signature _____ Relationship _____ Date _____ Time _____

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☐ Other:

Witness Signature/Title/Position _____ Date _____ Time _____

Witness Work Address _____

Interpreter _____

Reason: _____

I have provided the patient/parent/guardian with information on risks, benefits, and alternatives to treatment as outlined in the above within my area of expertise.

Physician Signature _____ Date _____ Time _____
Responsible for Procedure



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**DISCLOSURE AND CONSENT -
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Anesthesia Consent

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended anesthesia/analgesia to be used so that you may make the decision whether or not to receive the anesthesia/analgesia after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to the anesthesia/analgesia.

I (we) understand that anesthesia involves additional risks and hazards, but I (we) request the use of anesthetics for the relief and protection from pain during the planned and additional procedures. I (we) realize the anesthesia may have to be changed possibly without explanation to me (us).

I (we) understand that serious but rare complications may result from the use of any anesthetic including respiratory problems, drug reactions, paralysis, brain damage or even death.

I (we) voluntarily request that anesthesia and/or perioperative pain management care (analgesia) as indicated below be administered to me (the patient). I understand it will be administered by an anesthesia provider and/or the operating practitioner, and such other health care providers are necessary. Perioperative means the period shortly before, during or shortly after the procedure. I also understand that other complications may occur. Those complications include but are not limited to:

Check planned anesthesia/analgesia method(s) and have the patient/other legally responsible person initial.

- ☐ _____ **General Anesthesia** - injury to vocal cords, teeth, lips, eyes; awareness during the procedure; memory dysfunction/memory loss; permanent organ damage; brain damage.
- ☐ _____ **Regional Block Anesthesia/Analgesia** - nerve damage; persistent pain; bleeding/hematoma; infection; medical necessity to convert to general anesthesia; brain damage.
- ☐ _____ **Spinal Anesthesia/Analgesia** - nerve damage; persistent back pain; headache; infection; bleeding/epidural hematoma; chronic pain; medical necessity to convert to general anesthesia; brain damage.
- ☐ _____ **Epidural Anesthesia/Analgesia** - nerve damage; persistent back pain; headache; infection; bleeding/epidural hematoma; chronic pain; medical necessity to convert to general anesthesia; brain damage.
- ☐ _____ **Monitored Anesthesia Care** - memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.
- ☐ _____ **Deep Sedation** - memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.
- ☐ _____ **Moderate Sedation** - memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.
- ☐ _____ **OTHER** - Including possible complications (required): _____

ADDITIONAL COMMENTS/RISKS:

- ☐ _____ **PRENATAL/EARLY CHILDHOOD ANESTHESIA** - potential long-term negative effects on memory, behavior, and learning with prolonged or repeated exposure to general anesthesia/moderate sedation during pregnancy and in early childhood.

Additional Comments/Risks: _____

I (we) have been given an opportunity to ask questions about my condition, benefits, risks, alternatives and the risks and benefits of alternative forms of anesthesia and treatment, risks and benefits of non-treatment, the procedures to be used, and the risks and hazards involved. I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me, that the blank spaces have been filled in, and that I (we) understand the contents.

I (we) understand that no promises have been made to me as to the result of anesthesia/analgesia methods.

Patient's Signature _____ Date _____ Time _____

Other Legally Responsible Person's Signature _____ Relationship _____ Date _____ Time _____

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☐ Other: _____

Witness Signature/Title/Position _____ Date _____ Time _____

Witness Work Address _____

Reason: _____

Interpreter _____

The risks, benefits, and alternatives have been explained and the patient/family understand(s) and agree(s) to the procedure.

Signature of Physician / Proceduralist responsible for Anesthesia: _____ Date: _____ Time: _____



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DISCLOSURE AND CONSENT - MEDICAL AND SURGICAL



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LIST A TEXAS MEDICAL DISCLOSURE

(Rev. 2022)

Procedures requiring full disclosure (List A). The following treatments and procedures require full disclosure by the physician or health care provider to the patient or person authorized to consent for the patient.

Patient to initial appropriate square.

CARDIOVASCULAR SYSTEM

1. Cardiac.

☐

(A) Coronary artery bypass.

- (i) Acute myocardial infarction.
- (ii) Hemorrhage (severe bleeding).
- (iii) Kidney failure.
- (iv) Stroke.
- (v) Sudden death.
- (vi) Infection of chest wall/chest cavity.

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(B) Heart valve replacement by open surgery, structural heart surgery.

- (i) Acute myocardial infarction (heart attack).
- (ii) Hemorrhage (severe bleeding).
- (iii) Kidney failure.
- (iv) Stroke.
- (v) Sudden death.
- (vi) Infection of chest wall/chest cavity.
- (vii) Valve related delayed onset infection.
- (viii) Malfunction of new valve.
- (ix) Persistence of problem for which surgery was performed, including need for repeat surgery.

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(C) Heart transplant.

- (i) Infection.
- (ii) Rejection.
- (iii) Death.

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(D) Coronary angiography (Injection of contrast material into arteries of the heart), coronary angioplasty (opening narrowing in heart vessel), and coronary stent insertion (placement of permanent tube into heart blood vessel to open it).

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the

contrast agent used during the procedure).

(ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

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(E) Percutaneous (through the skin) or minimally invasive heart valve insertion/replacement.

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Malfunction of new valve.
- (xi) Need for permanent pacemaker implantation.

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(F) Left atrial appendage closure (closing of small pouch on left side of heart) - percutaneous (through the skin) or minimally invasive.

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Device embolization (device moves from intended location).
- (xi) Pericardial effusion (development of fluid in the sack around the heart) and cardiac tamponade (fluid around heart causing too much pressure for heart to pump properly).

☐

(G) Patent foramen ovale/atrial septal defect/ventricular septal defect closure by percutaneous (through the skin) or minimally invasive procedure (closing of abnormal hole between the chambers of the heart).

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).



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- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Atrial fibrillation (irregular heart rhythm).
- (xi) Pulmonary embolus (development of blood clot that travels to blood vessels in lungs).
- (xii) Device embolization (device moves from where it is placed).
- (xiii) Cardiac perforation (creation of hole in wall of heart).

☐ **(H) Electrophysiology studies (exams of heart rhythm), arrhythmia ablation (procedure to control or stop abnormal heart rhythms).**

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Rupture of myocardium/cardiac perforation (hole in wall of heart).
- (xi) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening.
- (xii) Pulmonary vein stenosis (narrowing of blood vessel going from lung to heart).

☐ **(I) Pacemaker insertion, AICD insertion (implanted device to shock the heart out of an abnormal rhythm).**

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

- (x) Rupture of myocardium/cardiac perforation (hole in wall of heart).
- contrast agent used during the procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Rupture of myocardium/cardiac perforation (hole in wall of heart).
- (xi) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening.
- (xii) Device related delayed onset infection (infection related to the device that happens at some time after surgery).

☐ **(J) Electrical cardioversion (shocking the heart out of an abnormal rhythm).**

- (i) Heart arrhythmias (abnormal heart rhythm), possibly life threatening.
- (ii) Skin burns on chest.

☐ **(K) Stress testing.**

- (i) Acute myocardial infarction (heart attack).
- (ii) Heart arrhythmias (abnormal heart rhythm), possibly life threatening.

☐ **(L) Transesophageal echocardiography (ultrasound exam of the heart from inside the throat).**

- (i) Sore throat.
- (ii) Vocal cord damage.
- (iii) Esophageal perforation (hole or tear in tube from mouth to stomach).

☐ **(M) Circulatory assist devices (devices to help heart pump blood).**

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Hemorrhage (severe bleeding) possibly leading to sudden death.
- (xi) Hemolysis (blood cells get broken apart).
- (xii) Right heart failure (poor functioning of the side of heart not assisted by device).
- (xiii) Acquired von Willebrand syndrome (platelets do not work).
- (xiv) Arrhythmia (irregular or abnormal heart rhythm).
- (xv) Cardiac or vascular injury or perforation (hole in heart or blood vessel).



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- (xvi) Limb ischemia (lack of blood flow or oxygen to limb that device placed through).
- (xvii) Device migration or malfunction.
- (xviii) Exposure of device/wound break down with need for surgery to cover/reimplant.



(N) Extracorporeal Membrane Oxygenation (ECMO).

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.
- (ii) Arrhythmia (abnormal heart rhythm), possibly life threatening.
- (iii) Hemorrhage (severe bleeding).
- (iv) Myocardial infarction (heart attack).
- (v) Worsening of the condition for which the procedure is being done.
- (vi) Sudden death.
- (vii) Stroke.
- (viii) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Thrombocytopenia (low platelets) or other coagulopathy (blood thinning).
- (xi) Vascular or cardiac perforation (hole in blood vessel or heart).
- (xii) Seizure.
- (xiii) Device migration or malfunction.
- (xiv) Ischemia to limb (lack of blood flow or oxygen to limb that device placed through).
- (xv) Thromboembolism (blood clots in blood vessels or heart and possibly traveling to blood vessels in lungs).

(2) Vascular.



(A) Open surgical repair of aortic, subclavian, iliac, or other artery aneurysms or occlusions, arterial or venous bypass or other vascular surgery.

- (i) Hemorrhage (severe bleeding).
- (ii) Paraplegia (unable to move limbs) (for surgery involving the aorta or other blood vessels to the spine).
- (iii) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (iv) Worsening of the condition for which the procedure is being done.
- (v) Stroke (for surgery involving blood vessels supplying the neck or head).
- (vi) Kidney damage.
- (vii) Myocardial infarction (heart attack).
- (viii) Infection of graft (material used to repair blood vessel).



(B) Angiography (inclusive of aortography, arteriography, venography) - Injection of contrast material into blood vessels.

- (i) Injury to or occlusion (blocking) of artery which may require immediate surgery or other intervention.

- (ii) Hemorrhage (severe bleeding).
- (iii) Damage to parts of the body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (iv) Worsening of the condition for which the procedure is being done.
- (v) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head).
- (vi) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).
- (vii) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.



(C) Angioplasty (intravascular dilatation technique).

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.
- (ii) Hemorrhage (severe bleeding).
- (iii) Damage to parts of the body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (iv) Worsening of the condition for which the procedure is being done.
- (v) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head).
- (vi) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).
- (vii) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Failure of procedure or injury to blood vessel requiring stent (small, permanent tube placed in blood vessel to keep it open) placement or open surgery.



(D) Endovascular stenting (placement of permanent tube into blood vessel to open it) of any portion of the aorta, iliac or carotid artery or other (peripheral) arteries or veins.

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.
- (ii) Hemorrhage (severe bleeding).
- (iii) Damage to parts of the body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (iv) Worsening of the condition for which the procedure is being done.
- (v) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head).
- (vi) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).
- (vii) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).
- (viii) Contrast nephropathy (kidney damage due to the being done).



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- (ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (x) Failure of procedure or injury to blood vessel requiring stent (small, permanent tube placed in blood vessel to keep it open) placement or open surgery.
- (xi) Change in procedure to open surgical procedure.
- (xii) Failure to place stent/endoluminal graft (stent with fabric covering it).
- (xiii) Stent migration (stent moves from location in which it was placed).
- (xiv) Impotence (difficulty with or inability to obtain penile erection) (for abdominal aorta and iliac artery procedures).

☐ **(E) Vascular thrombolysis (removal or dissolving of blood clots) - percutaneous (through the skin) (mechanical or chemical).**

- (i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.
- (ii) Hemorrhage (severe bleeding).
- (iii) Damage to parts of the body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (iv) Worsening of the condition for which the procedure is being done.
- (v) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head).
- (vi) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).
- (vii) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).
- (viii) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (ix) Kidney injury or failure which may be temporary or permanent (for procedures using certain mechanical thrombectomy devices).
- (x) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (xi) Increased risk of bleeding at or away from site of treatment (when using medications to dissolve clots).
- (xii) For arterial procedures: distal embolus (fragments of blood clot may travel and block other blood vessels with possible injury to the supplied tissue).
- (xiii) For venous procedures: pulmonary embolus (fragments of blood clot may travel to the blood vessels in the lungs and cause breathing problems or if severe could be life threatening).
- (xiv) Need for emergency surgery.

☐ **(F) Angiography with occlusion techniques (including embolization and sclerosis) - therapeutic.**

- (i) For all embolizations/sclerosis:
 - (I) Injury to or occlusion (blocking) of blood vessel other than the one intended which may require immediate surgery or other intervention.
 - (II) Hemorrhage (severe bleeding).
 - (III) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).

- (IV) Worsening of the condition for which the procedure is being done.
- (V) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (VI) Unintended thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (VII) Loss or injury to body parts with potential need for surgery, including death of overlying skin for sclerotherapy/treatment of superficial lesions/vessels and nerve injury with associated pain, numbness or tingling or paralysis (inability to move).
- (VIII) Infection in the form of abscess (infected fluid collection) or septicemia (infection of blood stream).
- (IX) Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues supplied by those vessels.

(ii) For procedures involving the thoracic aorta and/or vessels supplying the brain, spinal cord, head, neck or arms, these risks in addition to those under clause (i) of this subparagraph:

- (I) Stroke.
- (II) Seizure.
- (III) Paralysis (inability to move).
- (IV) Inflammation or other injury of nerves (for procedures involving blood vessels supplying the spine).
- (V) For studies of the blood vessels of the brain: contrast-related, temporary blindness or memory loss.

(iii) For female pelvic arterial embolizations including uterine fibroid embolization, these risks in addition to those under clause (i) of this subparagraph:

- (I) Premature menopause with resulting sterility.
- (II) Injury to or infection involving the uterus which might necessitate hysterectomy (removal of the uterus) with resulting sterility.
- (III) After fibroid embolization: prolonged vaginal discharge.
- (IV) After fibroid embolization: expulsion/delayed expulsion of fibroid tissue possibly requiring a procedure to deliver/remove the tissue.

(iv) For male pelvic arterial embolizations, in addition to the risks under clause (i) of this subparagraph: impotence (difficulty with or inability to obtain penile erection).

(v) For embolizations of pulmonary arteriovenous fistulae/malformations, these risks in addition to those under clause (i) of this subparagraph:

- (I) New or worsening pulmonary hypertension (high blood pressure in the lung blood vessels).
- (II) Paradoxical embolization (passage of air or an occluding device beyond the fistula/malformation and into the arterial circulation) causing blockage of blood flow to tissues supplied by the receiving artery and damage to tissues served (for example the blood vessels supplying the heart (which could cause chest pain and/or heart attack) or brain (which could cause stroke, paralysis (inability to move) or other neurological injury).

(vi) For varicocele embolization, these risks in addition to those under clause (i) of this subparagraph:

- (I) Phlebitis/inflammation of veins draining the testicles



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leading to decreased size and possibly decreased function of affected testis and sterility (if both sides performed).

(vi) For varicocele embolization, these risks in addition to those under clause (i) of this subparagraph:

(I) Phlebitis/inflammation of veins draining the testicles leading to decreased size and possibly decreased function of affected testis and sterility (if both sides performed).

(II) Nerve injury (thigh numbness or tingling).

(vii) For ovarian vein embolization/pelvic congestion syndrome embolization: general angiography and embolization risks as listed in clause (i) of this subparagraph.

(viii) For cases utilizing ethanol (alcohol) injection, in addition to the risks under clause (i) of this subparagraph: shock or severe lowering of blood pressure (when more than small volumes are utilized).

(ix) For varicose vein treatments (with angiography) see subparagraph (L) of this paragraph.

(viii) Risk of recurrent pulmonary embolus (continued risk of blood clots going to blood vessels in lungs despite filter).

(ix) Inability to remove filter (for "optional"/retrievable filters).

(I) Pulmonary angiography.

(i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.

(ii) Hemorrhage (severe bleeding).

(iii) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).

(iv) Worsening of the condition for which the procedure is being done.

(v) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).

(vi) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

(vii) Cardiac arrhythmia (irregular heart rhythm) or cardiac arrest (heart stops beating).

(viii) Cardiac injury/perforation (heart injury).

(ix) Death.

(G) Mesenteric angiography with infusional therapy (Vasopressin) for gastrointestinal bleeding.

(i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.

(ii) Hemorrhage (severe bleeding).

(iii) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).

(iv) Worsening of the condition for which the procedure is being done.

(v) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).

(vi) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

(vii) Ischemia/infarction of supplied or distant vascular beds (reduction in blood flow causing lack of oxygen with injury or death of tissues supplied by the treated vessel or tissues supplied by blood vessels away from the treated site including heart, brain, bowel, extremities).

(viii) Antidiuretic hormone side effects of vasopressin (reduced urine output with disturbance of fluid balance in the body, rarely leading to swelling of the brain).

(J) Percutaneous treatment of pseudoaneurysm (percutaneous thrombin injection through the skin versus compression).

(i) Thrombosis (clotting) of supplying vessel or branches in its territory.

(ii) Allergic reaction to thrombin (agent used for direct injection).

(K) Vascular access - nontunneled catheters, tunneled catheters, implanted access.

(i) Pneumothorax (collapsed lung).

(ii) Injury to blood vessel.

(iii) Hemothorax/hemomediastinum (bleeding into the chest around the lungs or around the heart).

(iv) Air embolism (passage of air into blood vessel and possibly to the heart and/or blood vessels entering the lungs).

(v) Vessel thrombosis (clotting of blood vessel).

(L) Varicose vein treatment (percutaneous (through the skin), via laser, radiofrequency ablation (RFA), chemical or other method) without angiography.

(i) Burns.

(ii) Deep vein thrombosis (blood clots in deep veins).

(iii) Hyperpigmentation (darkening of skin).

(iv) Skin wound (ulcer).

(v) Telangiectatic matting (appearance of tiny blood vessels in treated area).

(vi) Paresthesia and dysesthesia (numbness or tingling in the area or limb treated).

(vii) Injury to blood vessel requiring additional procedure to treat.

(H) Inferior vena caval filter insertion and removal.

(i) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.

(ii) Hemorrhage (severe bleeding).

(iii) Worsening of the condition for which the procedure is being done.

(iv) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).

(v) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere including caval thrombosis (clotting of main vein in abdomen and episodes of swelling of legs).

(vi) Injury to the inferior vena cava (main vein in abdomen).

(vii) Filter migration or fracture (filter could break and/or move from where it was placed).



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**DISCLOSURE AND CONSENT
CARDIOVASCULAR SYSTEM**



* T R E A T *

PATIENT IDENTIFICATION