

1. Page 2 is the “consent” form
 - a. At the top of the page ask the patient if his/her physician or healthcare provider performing the procedure explained the proposed procedure and the risks involved to his/her satisfaction. Circle yes or no. Have the patient initial their answer. **If the patient answers “NO”, the nurse stops the process and contacts the physician or healthcare provider.**
 - b. Line 1- fill in the patient’s name and the operating physician’s or healthcare provider performing the procedure’s full name.
 - c. Ask the patient to answer in his own words what the physician or healthcare provider performing the procedure has told him/her, what their condition is and write their answer in the blank (if the patient’s response does not match the proposed procedure, notify the physician or healthcare provider performing the procedure).
 - d. Line 2- write in the ordered procedure (no abbreviations).
 - e. Lines 3, 4 & 5- have the patient read statements and ask if they understand. No signature is necessary.
 - f. Line 6- have the patient read the statement, make a selection of yes or no, and initial.
 - g. Line 7- only needs to be filled in if the physician or healthcare provider performing the procedure has indicated ordered risks for the proposed procedure. If none ordered, leave blank.
 - h. Line 8- have the patient read and acknowledge understanding.
2. Page 4 Panels
 - a. Top box is only for patients having surgery that will require tissue other than his/her own. Leave this box blank if it does not apply.
 - b. Box 2 is only to be checked if the proposed procedure does not have a risk panel assigned. Leave blank if the procedure does have a panel.
 - c. Box 3 is the risk panel for blood and should be checked for all patients and each section should be initialed by the patient.
3. Pages 4-14 contain the risk panels for the proposed procedure. Check the corresponding panel to the procedure, ordered by the physician or healthcare provider performing the procedure, and have the patient initial in the appropriate blank.
4. Signing the consent:
 - a. After the patient has read the entire consent, fill in the date and time, have the patient sign the consent (the patient must sign as long as he/she is competent. If the patient is not competent, the appropriate legal representative may sign for the patient (System PC/PS23 for the complete list). If a translator is being used, he or she must sign the consent if he or she is physically present. If a video-conference or tele-conference is used, such that he or she is not physically present, it is sufficient to write the translator’s name and/or ID number on the consent form in lieu of having the translator sign the consent form.
 - b. The individual witnessing the patient’s signature must then sign as the witness.
5. **If the nurse is unable to fill in any of the blanks on this form, the reason for the blank should be explained during the handoff, (i.e. laterality unknown, physician or healthcare provider performing the procedure unknown, patient needs to talk to physician or healthcare provider performing the procedure prior to the procedure.)**



HM2227



Medical Care and Surgical Procedures

Please check or otherwise indicate the name of the facility where the procedure or other type of medical treatment is to take place.

- Houston Methodist Hospital - 6565 Fannin St, Houston, TX 77030
- Houston Methodist Baytown Hospital - 4401 Garth Rd, Baytown, TX 77521
- Houston Methodist Clear Lake Hospital - 18300 Houston Methodist Dr, Houston, TX 77058
- Houston Methodist Continuing Care Hospital - 701 S Fry Rd, Katy, TX 77450
- Houston Methodist Cypress Hospital - 24510 Northwest Fwy, Cypress, TX 77429
- Houston Methodist Sugar Land Hospital - 16655 Southwest Fwy, Sugar Land, TX 77479
- Houston Methodist The Woodlands Hospital - 17201 Interstate 45 S, The Woodlands, TX 77385
- Houston Methodist West Hospital - 18500 Katy Fwy, Houston, TX 77094
- Houston Methodist Willowbrook Hospital - 18220 Tomball Pkwy, Houston, TX 77070
- Houston Methodist Surgery Center - Bellaire - 4460 Bissonnet St, Ste 300, Bellaire, TX 77401



TO THE PATIENT: You have the right to be informed about 1) your condition, 2) the recommended medical care or surgical procedure, and 3) the risks related to this care/procedure. This disclosure is designed to provide you this information, so that you can decide whether to consent to receive this care/procedure. Please ask your physician or healthcare provider performing the procedure any remaining questions you have before signing this form.

Has your physician or healthcare provider performing the procedure informed you about the medical, surgical, or invasive procedure(s) proposed for you, along with the risks, benefits, alternatives and side effects of the procedure involved to your satisfaction? Y / N _____(Pt. Initials)

1. I, _____ [Patient's Name] voluntarily request my physician/health care provider [name/credentials] _____ and other health care providers, to treat my condition which is _____

2. I, understand that the following care/procedures are planned for me:

3. I understand that during my care/procedure(s) my physician/health care provider may discover other conditions which require additional or different care/ procedure(s) than originally planned.

I authorize my physicians/health care providers to use their professional judgment to perform the additional or different care/procedure(s) they believe are needed.

4. Just as there may be risks and hazards to my health without treatment, there are also risks and hazards related to the care/procedure(s) planned for me.

I understand that all care/procedure(s) involve some risks, ranging from minor to severe. These risks include infection, blood clots in the veins, lungs or other organs, hemorrhage (severe bleeding), allergic reactions, poor wound healing, and death.

The chances of these occurring may be different for each patient based on the care/procedure(s) and the patient's current health.



5. I understand that in addition to my physician or health care provider, residents, medical students, advanced practice provider students (such as nurse practitioners or physician assistants), and other applicable students, may be performing important, medically necessary tasks related to my surgery, or examinations or invasive procedures for educational and training purposes, in accordance with the hospital's policies and under the supervision of my physician or health care provider. Important surgical tasks include, but not limited to: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices, and placing invasive lines.

6. Y / N **(Pt. Initials)** I consent to students, including, but not limited to, residents, medical students, advanced practice provider students (such as nurse practitioners or physician assistants), and other applicable students, conducting examinations outside the medically necessary procedure for educational and training purposes. These examinations include, but are not limited to, breast, pelvic, prostate, and rectal examinations.

7. ADDITIONAL RISKS OR COMMENTS (line through if none) _____

8. Granting of Consent for this Care/Procedure(s)

In signing below, I consent to the care/procedure(s) described below. I acknowledge the following:

- I understand this care/procedure(s) does not guarantee a result or a cure to my condition.
- I have been given an opportunity to ask questions I may have about:
 1. Alternative forms of treatment,
 2. Risks of non-treatment,
 3. Steps that will occur during my care/procedure(s), and
 4. Risks and hazards involved in the care/procedure(s)
 5. Recovery time, pain management and restrictions immediately following my procedure.
- I believe I have enough information to give this informed consent.
- I certify this form has been fully explained to me and the blank spaces have been filled in.
- I have read this form or had it read to me.
- I understand the information on this form.

If any of those statements are not true for you, please talk to your physician/health care provider before continuing.

Patient/Other Legally Authorized Representative (signature required)

Print Name: _____ Signature: _____

If Legally Authorized Representative, list relationship to Patient: _____

Date: _____ Time: _____ AM/PM (circle one)

Witness:

Print Name: _____ Signature: _____ Date: _____ Time: _____

Name and/or ID number of the qualified interpreter (if applicable): _____

Signature of qualified interpreter: (if applicable) _____

Date: _____ Time: _____

Medical Care and Surgical

Procedures

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OR Council



RISKS AND HAZARDS

<p><input type="checkbox"/> Tissue: I understand that my physician or healthcare provider may use tissue other than my own, and the following are possible risks from the use of that tissue: (1) The transmission of infectious diseases, including bacterial infection. (2) Allergic reaction and other immunological responses, including rejection of the tissue. (3) Other: _____</p> <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (B) Heart valve replacement by open surgery, structural heart surgery. (1) Acute myocardial infarction (heart attack). (2) Hemorrhage (severe bleeding). (3) Kidney failure. (4) Stroke. (5) Sudden death. (6) Infection of chest wall/chest cavity. (7) Valve related delayed onset infection. (8) Malfunction of new valve. (9) Persistence of problem for which surgery was performed, including need for repeat surgery.</p> <p style="text-align: right;">PT INITIALS</p>
<p>The following are the risks and hazards associated by the Texas Medical Disclosure Panel with treatments and procedures.</p>	
<p><input type="checkbox"/> The Texas Medical Disclosure Panel has not established a risk disclosure standard for the proposed procedure(s). My physician or healthcare provider performing the procedure has discussed with me the risks of the procedure(s) such that I am able to give my informed consent.</p> <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (C) Heart transplant. (1) Infection. (2) Rejection. (3) Death.</p> <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (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). (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.</p> <p style="text-align: right;">PT INITIALS</p>	
<p><input type="checkbox"/> (E) Percutaneous (through the skin) or minimally invasive heart valve insertion/replacement. (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Malfunction of new valve. (11) Need for permanent pacemaker implantation.</p> <p style="text-align: right;">PT INITIALS</p>	
<p><input type="checkbox"/> (F) Left atrial appendage closure (closing of small pouch on left side of heart) - percutaneous (through the skin) or minimally invasive. (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Device embolization (device moves from intended location). (11) 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).</p> <p style="text-align: right;">PT INITIALS</p>	

1. CARDIOVASCULAR SYSTEM

I. Cardiac

<p><input type="checkbox"/> (A) Coronary artery bypass. (1) Acute myocardial infarction (heart attack). (2) Hemorrhage (severe bleeding). (3) Kidney failure. (4) Stroke. (5) Sudden death. (6) Infection of chest wall/chest cavity.</p> <p style="text-align: right;">PT INITIALS</p>	<p>↑ ADHERE PATIENT LABEL WITHIN THIS AREA ↓</p>
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<input type="checkbox"/> 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). <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Atrial fibrillation (irregular heart rhythm). (11) Pulmonary embolus (development of blood clot that travels to blood vessels in lungs). (12) Device embolization. (13) Cardiac perforation (creation of hole in wall of heart). 	
PT INITIALS	
<input type="checkbox"/> (H) Electrophysiology studies (exam of heart rhythm), arrhythmia ablation (procedure to control or stop abnormal heart rhythms). <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Rupture of myocardium/cardiac perforation (hole in wall of heart). (11) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening. (12) Pulmonary vein stenosis (narrowing of blood vessel going from lung to heart). 	
PT INITIALS	
<input type="checkbox"/> (I) Pacemaker insertion, AICD insertion (implanted device to shock the heart out of an abnormal rhythm). <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy (kidney damage due to the contrast agent used during the procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Rupture of myocardium/cardiac perforation (hole in wall of heart). (11) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening. (12) Device related delayed onset infection (infection related to the device that happens at some time after surgery). 	
PT INITIALS	
<input type="checkbox"/> (J) Electrical cardioversion (shocking the heart out of an abnormal rhythm). <ol style="list-style-type: none"> (1) Heart arrhythmias (abnormal heart rhythm), possibly life threatening. (2) Skin burns on chest. 	
PT INITIALS	
<input type="checkbox"/> (K) Stress testing. <ol style="list-style-type: none"> (1) Acute myocardial infarction (heart attack). (2) Heart arrhythmias (abnormal heart rhythm), possibly life threatening. 	
PT INITIALS	
<input type="checkbox"/> (L) Transesophageal echocardiography (ultrasound exam of the heart from inside the throat). <ol style="list-style-type: none"> (1) Sore throat. (2) Vocal cord damage. (3) Esophageal perforation (hole or tear in tube from mouth to stomach). 	
PT INITIALS	

<input type="checkbox"/> (M) Circulatory assist devices (devices to help heart pump blood). <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Hemorrhage (severe bleeding) possibly leading to sudden death. (11) Hemolysis (blood cells get broken apart). (12) Right heart failure (poor functioning of the side of heart not assisted by device). (13) Acquired von Willebrand syndrome (platelets do not work). (14) Arrhythmia (irregular or abnormal heart rhythm). (15) Cardiac or vascular injury or perforation (hole in heart or blood vessel). (16) Limb ischemia (lack of blood flow or oxygen to limb that device placed through.) (17) Device migration or malfunction. (18) Exposure of device/wound break down with need for surgery to cover/reimplant. 	
PT INITIALS	

<input type="checkbox"/> (N) Extracorporeal Membrane Oxygenation (ECMO). <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery. (2) Arrhythmia (abnormal heart rhythm), possibly life threatening. (3) Hemorrhage (severe bleeding). (4) Myocardial infarction (heart attack). (5) Worsening of the condition for which the procedure is being done. (6) Sudden death. (7) Stroke. (8) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (10) Thrombocytopenia (low platelets) or other coagulopathy (blood thinning). (11) Vascular or cardiac perforation (hole in blood vessel or heart). (12) Seizure. (13) Device migration or malfunction. (14) Ischemia to limb (lack of blood flow or oxygen to limb that device placed through). (15) Thromboembolism (blood clots in blood vessels or heart and possibly traveling to blood vessels in lungs). 	
PT INITIALS	

2. VASCULAR

<input type="checkbox"/> (A) Open surgical repair of aortic, subclavian, iliac, or other artery aneurysms or occlusions, arterial or venous bypass or other vascular surgery. <ol style="list-style-type: none"> (1) Hemorrhage (severe bleeding). (2) Paraplegia (unable to move limbs) (for surgery involving the aorta or other blood vessels to the spine). (3) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part). (4) Worsening of the condition for which the procedure is being done. (5) Stroke (for surgery involving blood vessels supplying the neck or head). (6) Kidney damage. (7) Myocardial infarction (heart attack). (8) Infection of graft (material used to repair blood vessel). 	
PT INITIALS	



<p><input type="checkbox"/> (B) Angiography (inclusive of aortography, arteriography, venography) - Injection of contrast material into blood vessels.</p> <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of artery which may require immediate surgery or other intervention. (2) Hemorrhage (severe bleeding). (3) Damage to parts of body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part). (4) Worsening of the condition for which the procedure is being done. (5) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head). (6) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain). (7) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine). (8) Contrast nephropathy (kidney damage due to the contrast agent used during procedure). (9) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. 	PT INITIALS
<p><input type="checkbox"/> (C) Angioplasty (intravascular dilatation technique).</p> <ol style="list-style-type: none"> (1) All associated risks listed under paragraph 2 (B) of this subsection. (2) 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. 	PT INITIALS
<p><input type="checkbox"/> (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.</p> <ol style="list-style-type: none"> (1) All associated risks listed under paragraph 2 (B) and (C) of this subsection. (2) Change in procedure to open surgical procedure. (3) Failure to place stent/endoluminal graft (stent with fabric covering it). (4) Stent migration (stent moves from location in which it was placed). (5) Impotence (difficulty with or inability to obtain penile erection) (for abdominal aorta and iliac artery procedures). 	PT INITIALS
<p><input type="checkbox"/> (E) Vascular thrombolysis (removal or dissolving of blood clots) - percutaneous (through the skin) (mechanical or chemical).</p> <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of artery which may require immediate surgery or other intervention. (2) Hemorrhage (severe bleeding). (3) Damage to parts of body supplied by the artery or drained by the vessel with resulting loss of use or amputation (removal of body part). (4) Worsening of the condition for which the procedure is being done. (5) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head). (6) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain). (7) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine). (8) Contrast nephropathy (kidney damage due to the contrast agent used during procedure). (9) Kidney injury or failure which may be temporary or permanent (for procedures using certain mechanical thrombectomy devices). (10) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (11) Increased risk of bleeding at or away from site of treatment (when using medications to dissolve clots). (12) For arterial procedures: distal embolus (fragments of blood clot may travel and block other blood vessels with possible injury to the supplied tissue). (13) 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). (14) Need for emergency surgery. 	PT INITIALS
<p><input type="checkbox"/> (F) Angiography with occlusion techniques (including embolization and sclerosis) - therapeutic.</p> <ol style="list-style-type: none"> (1) For all embolizations/sclerosis: <ol style="list-style-type: none"> (a) Injury to or occlusion (blocking) of blood vessel other than the one intended which may require immediate surgery or other intervention. (b) Hemorrhage (severe bleeding). (c) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part). (d) Worsening of the condition for which the procedure is being done. (e) Contrast nephropathy (kidney damage due to the contrast agent used during procedure). (f) Unintended thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (g) 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.) (h) Infection in the form of abscess (infected fluid collection) or septicemia (infection of blood stream). (i) Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues supplied by those vessels. 	PT INITIALS

<ol style="list-style-type: none"> (2) 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 (1) of this subparagraph: <ol style="list-style-type: none"> (a) Stroke. (b) Seizure. (c) Paralysis (inability to move). (d) Inflammation or other injury of nerves (for procedures involving blood vessels supplying the spine). (e) For studies of the blood vessels of the brain: contrast-related, temporary blindness or memory loss. (3) For female pelvic arterial embolizations including uterine fibroid embolization, these risks in addition to those under clause (1) of this subparagraph: <ol style="list-style-type: none"> (a) Premature menopause with resulting sterility. (b) Injury to or infection involving the uterus which might necessitate hysterectomy (removal of the uterus) with resulting sterility. (c) After fibroid embolization: prolonged vaginal discharge. (d) After fibroid embolization: expulsion/delayed expulsion of fibroid tissue possibly requiring a procedure to deliver/remove the tissue. (4) For male pelvic arterial embolizations, in addition to the risks under clause (1) of this subparagraph: impotence (difficulty with or inability to obtain penile erection). (5) For embolizations of pulmonary arteriovenous fistulae/malformations, these risks in addition to those under clause (1) of this subparagraph: <ol style="list-style-type: none"> (a) New or worsening pulmonary hypertension (high blood pressure in the lung blood vessels). (b) Paradoxical embolization (passage of air or an occluding device beyond the fistula/malformation and into 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)). (6) For varicocele embolization, these risks in addition to those under clause (1) of this subparagraph: <ol style="list-style-type: none"> (a) Phlebitis/inflammation of veins draining the testicles leading to decreased size and possibly decreased function of affected testis and sterility (if both sides performed). (b) Nerve injury (thigh numbness or tingling). (7) For ovarian vein embolization/pelvic congestion syndrome embolization: general angiography and embolization risks as listed in clause (1) of this subparagraph. (8) For cases utilizing ethanol (alcohol) injection, in addition to the risks under clause (1) of this subparagraph: shock or severe lowering of blood pressure (when more than small volumes are utilized). (9) For varicose vein treatments (with angiography) see subparagraph (L) of this paragraph. 	PT INITIALS
<p><input type="checkbox"/> (G) Mesenteric angiography with infusional therapy (Vasopressin) for gastrointestinal bleeding.</p> <ol style="list-style-type: none"> (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention. (2) Hemorrhage (severe bleeding). (3) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part). (4) Worsening of the condition for which the procedure is being done. (5) Contrast nephropathy (kidney damage due to the contrast agent used during procedure). (6) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (7) 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). (8) Antidiuretic hormone side effects of vasopressin (reduced urine output with disturbance of fluid balance in the body, rarely leading to swelling of the brain). 	PT INITIALS



(H) **Inferior vena caval filter insertion and removal.**

- (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.
- (2) Hemorrhage (severe bleeding).
- (3) Worsening of the condition for which the procedure is being done.
- (4) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (5) 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).
- (6) Injury to the inferior vena cava (main vein in abdomen).
- (7) Filter migration or fracture (filter could break and/or move from where it was placed).
- (8) Risk of recurrent pulmonary embolus (continued risk of blood clots going to blood vessels in lung despite filter).
- (9) Inability to remove filter (for "optional"/retrievable filters).

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(I) **Pulmonary angiography.**

- (1) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.
- (2) Hemorrhage (severe bleeding).
- (3) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).
- (4) Worsening of the condition for which the procedure is being done.
- (5) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).
- (6) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.
- (7) Cardiac arrhythmia (irregular heart rhythm) or cardiac arrest (heart stops beating).
- (8) Cardiac injury/perforation (heart injury).
- (9) Death.

PT INITIALS

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

- (1) Thrombosis (clotting) of supplying vessel or branches in its territory.
- (2) Allergic reaction to thrombin (agent used for direct injection).

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

- (1) Pneumothorax (collapsed lung).
- (2) Injury to blood vessel.
- (3) Hemothorax/hemomediastinum (bleeding into the chest around the lungs or around the heart).
- (4) Air embolism (passage of air into blood vessel and possibly to the heart and/or blood vessels entering the lungs).
- (5) Vessel thrombosis (clotting of blood vessel).

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

- (1) Burns.
- (2) Deep vein thrombosis (blood clots in deep veins).
- (3) Hyperpigmentation (darkening of skin).
- (4) Skin wound (ulcer).
- (5) Telangiectatic matting (appearance of tiny blood vessels in treated area).
- (6) Paresthesia and dysesthesia (numbness or tingling in the area or limb treated).
- (7) Injury to blood vessel requiring additional procedure to treat.

PT INITIALS

3. DIGESTIVE SYSTEM TREATMENTS AND PROCEDURES.

(A) **Cholecystectomy with or without common bile duct exploration.**

- (1) Pancreatitis (inflammation of the pancreas.)
- (2) Bile duct injury (injury to the tube between the liver and the bowel).
- (3) Retained bile duct stones (stones remaining in the tube between the liver and the bowel).
- (4) Bile duct stenosis or occlusion (narrowing or obstruction of the tube between the liver and the bowel).
- (5) Injury to the bowel and/or intestinal obstruction.
- (6) Bile leak (leak of bile from end of gallbladder duct or variant duct from the liver).

PT INITIALS

(B) **Bariatric surgery (including gastric bypass (Roux-En-Y), biliopancreatic diversion with duodenal switch, sleeve gastrectomy, gastric banding).**

- (1) Failure of wound to heal or wound dehiscence (separation of wound).
- (2) Injury to organs.
- (3) Failure of device, including slippage or erosion requiring additional surgical procedure (for surgeries with implanted devices such as gastric banding).
- (4) Obstructive symptoms requiring additional surgical procedure.
- (5) Development of gallstones (Roux-En-Y).
- (6) Development of metabolic and vitamin disorders (Roux-En-Y, biliopancreatic diversion with duodenal switch).
- (7) Dumping syndrome causing nausea, vomiting, diarrhea, dizziness, sweating (Roux-En-Y, biliopancreatic diversion with duodenal switch).

PT INITIALS

(C) **Pancreatectomy (subtotal or total and including Whipple Procedure (pancreaticoduodenectomy)).**

- (1) Pancreatitis (inflammation of the pancreas) (subtotal).
- (2) Diabetes (total).
- (3) Lifelong requirement of enzyme and digestive medication.
- (4) Anastomotic leaks (leak of bile or intestinal fluids at surgical site where ducts and intestines are joined).

PT INITIALS

(D) **Colectomy - total or subtotal.**

- (1) Permanent ileostomy.
- (2) Injury to organs.
- (3) Infection.
- (4) Anastomotic leaks (leak of bowel contents at site where intestines reattached).
- (5) Need for colostomy, permanent or temporary (subtotal colectomy).
- (6) Incontinence (if ileoanal anastomosis) (unable to control bowel if small bowel attached directly to anus).

PT INITIALS

(E) **Hepatobiliary drainage/intervention including percutaneous transhepatic cholangiography, percutaneous biliary drainage, percutaneous cholecystostomy, biliary stent placement (temporary or permanent), biliary stone removal/therapy (bile duct, gallbladder, and gallstone related procedures).**

- (1) Leakage of bile at the skin site or into the abdomen with possible peritonitis (inflammation of the abdominal lining and pain or if severe can be life threatening).
- (2) Pancreatitis (inflammation of the pancreas).
- (3) Hemobilia (bleeding into the bile ducts).
- (4) Cholangitis, cholecystitis, sepsis (inflammation/infection of the bile ducts, gallbladder, or blood).
- (5) Pneumothorax (collapsed lung) or other pleural complications (complications involving the chest cavity).

PT INITIALS

(F) **Gastrointestinal tract stenting**

- (1) Stent migration (stent moves from location in which it was placed).
- (2) Esophageal/bowel perforation (creation of a hole or tear in the tube from the throat to the stomach or in the intestines).
- (3) Tumor ingrowth or other obstruction of stent.
- (4) For stent placement in the esophagus (tube from the throat to the stomach).
 - (a) Tracheal compression (narrowing of windpipe) with resulting or worsening of shortness of breath.
 - (b) Reflux (stomach contents passing up into the esophagus or higher).
 - (c) Aspiration pneumonia (pneumonia from fluid getting in lungs) (if stent in lower part of the esophagus).
 - (d) Foreign body sensation (feeling like there is something in the throat) (for stent placement in the upper esophagus).
 - (e) Tracheoesophageal fistula (formation of hole and connection between the windpipe and tube between mouth and stomach).

PT INITIALS



<p><input type="checkbox"/> (G) Anti reflux procedures (surgical, endoscopic, including hiatal hernia repair).</p> <ol style="list-style-type: none"> (1) Dysphagia (difficulty swallowing). (2) Stomach bloating, difficulty belching or vomiting. (3) Esophageal perforation (hole in tube from mouth to stomach). (4) Mediastinal abscess (infected collection in central portion of chest). (5) Pneumothorax (collapsed lung). (6) Device erosion into esophagus/surrounding tissues (procedures with implanted devices). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (P) Pyloromyotomy (cutting of the muscle at the end of the stomach to treat blockage of the stomach outlet).</p> <ol style="list-style-type: none"> (1) Perforation (creation of a hole from the mucosa (inside of the stomach) to the outside of the stomach) possibly requiring additional procedures or surgeries. (2) Incomplete myotomy (incomplete cutting of the muscle) possibly requiring repeat procedure/surgery. (3) Delayed gastric emptying (food takes longer to leave the stomach than normal). <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (H) Endoscopy simple (diagnostic endoscopy).</p> <ol style="list-style-type: none"> (1) Perforation (hole) of the esophagus (tube from mouth to stomach), stomach, small intestine (with leakage of contents into chest or abdomen), possibly requiring additional procedures including open surgery. (2) Need for inclusion of or conversion to advanced endoscopy procedures with those risks (see subsection (I) of this section). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (Q) Colonoscopy. Perforation (creation of a hole in the intestine) possibly requiring additional procedures or open surgery.</p> <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (I) Advanced upper endoscopic procedures (anything more than simple, diagnostic endoscopy) (ERCP, POEM, ESD, pancreatic fluid collection drainage/necrosectomy).</p> <ol style="list-style-type: none"> (1) Perforation (hole) of the esophagus, stomach, small intestine (with leakage of contents into chest or abdomen). (2) Pancreatitis (inflammation of the pancreas) (for any procedures involving pancreas/pancreatic duct). (3) Hemorrhage (severe bleeding). (4) Adjacent organ injury for transluminal procedures (e.g. liver biopsy, fluid drainage). (5) Biliary peritonitis (bile leakage causing inflammation of the abdominal cavity). (6) Sepsis (severe infection). 	<p><input type="checkbox"/> The following shall be in addition to risks and hazards of the same surgery when done as an open procedure.</p> <ol style="list-style-type: none"> (1) Damage during introduction of trocar to adjacent intra-abdominal structures (e.g., organs, blood vessels, or other vital tissues) and potential need for additional surgery. (2) Trocar site complications (e.g., hematoma/bleeding, leakage of fluid, or hernia formation). (3) Air embolus (bubble causing heart failure or stroke). (4) Postoperative pneumothorax (collapsed lung). (5) Subcutaneous emphysema (air in between skin layers). (6) Change during the procedure to an open procedure. (7) If cancer is present, may increase the risk of the spread of cancer. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (J) Appendectomy.</p> <ol style="list-style-type: none"> (1) Injury to nearby organs. (2) Infectious collection of fluid (abscess) requiring additional procedure(s). (3) Normal appendix. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (A) Stapedectomy.</p> <ol style="list-style-type: none"> (1) Diminished or bad taste. (2) Total or partial loss of hearing in the operated ear. (3) Brief or long-standing dizziness. (4) Eardrum hole requiring more surgery. (5) Ringing in the ear. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (K) Hemorrhoidectomy with/without fistulectomy or fissurectomy.</p> <ol style="list-style-type: none"> (1) Fecal incontinence (unable to control bowel). (2) Anal stenosis (narrowing of the anus). (3) Damage to bowel. (4) Recurrent or new hemorrhoid(s). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (B) Reconstruction of auricle of ear for congenital deformity or trauma.</p> <ol style="list-style-type: none"> (1) Less satisfactory appearance compared to possible alternative artificial ear. (2) Exposure of implanted material. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (L) Repair and plastic operations on anus and rectum (anal fistula repair, rectovaginal fistula repair, rectal prolapse repair, anal sphincter repair, perineal reconstruction).</p> <ol style="list-style-type: none"> (1) Fecal incontinence (unable to control bowel). (2) Anal stenosis (narrowing of the anus). (3) Damage to bowel. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (C) Tympanoplasty with mastoidectomy.</p> <ol style="list-style-type: none"> (1) Facial nerve paralysis. (2) Altered or loss of taste. (3) Recurrence of original disease process. (4) Total loss of hearing in operated ear. (5) Dizziness. (6) Ringing in the ear. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (M) Hernia repair (for example inguinal or ventral) (for hiatal hernia repair see subsection (G) of this section).</p> <ol style="list-style-type: none"> (1) Injury to adjacent structures (bowel, bladder, blood vessels, nerves). (2) Seroma (fluid) or hematoma (blood) collection at surgical site. (3) Chronic pain. (4) Testicular injury (for those of male sex). (5) If mesh used, infection, failure, migration, or rejection of the mesh. (6) Recurrence. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (A) Thyroidectomy (standard).</p> <ol style="list-style-type: none"> (1) Acute airway obstruction requiring temporary tracheostomy (creation of hole in neck to breathe). (2) Injury to nerves resulting in hoarseness or impairment of speech. (3) Injury to parathyroid glands resulting in low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness, and muscle irritability. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (N) Esophageal dilatation (opening a narrowing of the tube between the mouth and the stomach).</p> <ol style="list-style-type: none"> (1) Perforation of the esophagus (creation of hole in tube from mouth to stomach), with possible need for additional procedures including open surgery. (2) Recurrent stenosis (return of narrowing of the tube from the mouth to the stomach). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (B) Patient Label Area.</p> <p style="text-align: center;">ADHERE PATIENT LABEL WITHIN THIS AREA</p>
<p><input type="checkbox"/> (O) Gastrostomy/gastrojejunostomy open, percutaneous, or endoscopic (placement of tube directly between the skin and the stomach with surgical incision, puncture from the skin into the stomach, or puncture from the stomach out towards the skin with endoscopy (camera)).</p> <ol style="list-style-type: none"> (1) Damage to surrounding organs. (2) Hemorrhage (severe bleeding). (3) Peritonitis (irritation of the abdominal compartment). <p style="text-align: right;">PT INITIALS</p>	

<p><input type="checkbox"/> (B) For scarless/minimally invasive thyroidectomy.</p> <p>(1) All risks of standard thyroidectomy.</p> <p>(2) For axillary approach.</p> <p>(a) Injury to brachial plexus (nerves in shoulder/neck) which can affect function of muscles and sensation in the affected extremity.</p> <p>(b) Tract seeding of thyroid tissue (thyroid tissue can deposit and grow along the surgical tract).</p> <p>(c) Postoperative seroma (fluid collection in the area of the surgery).</p> <p>(d) Great vessel injury (injury to large blood vessels of the upper chest and neck).</p> <p>(3) Transoral/transoral vestibular approach (TOETVA).</p> <p>(a) CO2 embolism (gas bubbles enter bloodstream) (TOETVA).</p> <p>(b) Mental nerve injury (nerve injury causing paresthesias (pins and needles sensation) of the lower lip and/or chin (TOETVA).</p> <p>(c) Skin perforation (hole in skin) (TOETVA).</p> <p>(d) Burns (TOETVA).</p>	PT INITIALS
<p><input type="checkbox"/> (C) Parathyroidectomy.</p> <p>(1) Acute airway obstruction requiring temporary tracheostomy (creation of hole in neck to breathe).</p> <p>(2) Injury to nerves resulting in hoarseness or impairment of speech.</p> <p>(3) Low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness, and muscle irritability.</p> <p>(4) Persistent high calcium level with need for additional treatment/surgery.</p>	PT INITIALS
<p><input type="checkbox"/> (D) Adrenalectomy.</p> <p>(1) Loss of endocrine functions (lifelong requirement for hormone replacement therapy and steroid medication).</p> <p>(2) Damage to kidneys.</p>	PT INITIALS

7. EYE TREATMENTS AND PROCEDURES.

<p><input type="checkbox"/> (A) Eye muscle surgery.</p> <p>(1) Additional treatment and/or surgery.</p> <p>(2) Double vision.</p> <p>(3) Partial or total blindness.</p>	PT INITIALS
<p><input type="checkbox"/> (B) Surgery for cataract with or without implantation of intraocular lens.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Need for glasses or contact lenses.</p> <p>(3) Complications requiring the removal of implanted lens.</p> <p>(4) Partial or total blindness.</p>	PT INITIALS
<p><input type="checkbox"/> (C) Retinal or vitreous surgery.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Recurrence or spread of disease.</p> <p>(3) Partial or total blindness.</p>	PT INITIALS
<p><input type="checkbox"/> (D) Reconstructive and/or plastic surgical procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma.</p> <p>(1) Blindness.</p> <p>(2) Nerve damage with loss of use and/or feeling to eye or other areas of face.</p> <p>(3) Painful or unattractive scarring.</p> <p>(4) Worsening or unsatisfactory appearance.</p> <p>(5) Dry eye</p>	PT INITIALS
<p><input type="checkbox"/> (E) Photocoagulation and/or cryotherapy.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Pain.</p> <p>(3) Partial or total blindness.</p>	PT INITIALS
<p><input type="checkbox"/> (F) Corneal surgery, such as corneal transplant, refractive surgery and pterygium.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Pain.</p> <p>(3) Need for glasses or contact lenses.</p> <p>(4) Partial or total blindness.</p>	PT INITIALS
<p><input type="checkbox"/> (G) Glaucoma surgery by any method.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Worsening of the glaucoma.</p> <p>(3) Pain.</p> <p>(4) Partial or total blindness.</p>	PT INITIALS

<p><input type="checkbox"/> (H) Removal of the eye or its contents (enucleation or evisceration).</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Worsening or unsatisfactory appearance.</p> <p>(3) Recurrence or spread of disease.</p>	PT INITIALS
<p><input type="checkbox"/> (I) Surgery for penetrating ocular injury, including intraocular foreign body.</p> <p>(1) Complications requiring additional treatment and/or surgery.</p> <p>(2) Possible removal of the eye.</p> <p>(3) Pain.</p> <p>(4) Partial or total blindness.</p>	PT INITIALS

8. FEMALE GENITAL SYSTEM TREATMENTS AND PROCEDURES.

<p><input type="checkbox"/> (A) All fallopian tube and ovarian surgery with or without hysterectomy, including removal and lysis of adhesions.</p> <p>(1) Injury to the bowel and/or bladder.</p> <p>(2) Sterility.</p> <p>(3) Failure to obtain fertility (if applicable).</p> <p>(4) Failure to obtain sterility (if applicable).</p> <p>(5) Loss of ovarian functions or hormone production from ovary(ies).</p>	PT INITIALS
<p><input type="checkbox"/> (B) Removing fibroids (uterine myomectomy).</p> <p>(1) Injury to bladder.</p> <p>(2) Sterility.</p> <p>(3) Injury to the tube (ureter) between the kidney and the bladder.</p> <p>(4) Injury to the bowel and/or intestinal obstruction.</p> <p>(5) May need to convert to hysterectomy.</p> <p>(6) If laparoscopic surgery is utilized, include the following risks:</p> <p>(a) Damage during introduction of trocar to adjacent intra-abdominal structures and organs (e.g., bowel, bladder, blood vessels, or nerves) and potential need for additional surgery.</p> <p>(b) Trocar site complications (e.g., hematoma, bleeding, leakage of fluid, or hernia formation).</p> <p>(c) Air embolus (bubble causing heart failure or stroke).</p> <p>(d) Change during the procedure to an open procedure.</p> <p>(e) If cancer is present, may increase the risk of the spread of cancer.</p>	PT INITIALS

<p><input type="checkbox"/> (C) Uterine suspension.</p> <p>(1) Uncontrolled leakage of urine.</p> <p>(2) Injury to bladder.</p> <p>(3) Injury to the tube (ureter) between the kidney and the bladder.</p> <p>(4) Injury to the bowel and/or intestinal obstruction.</p>	PT INITIALS
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<p><input type="checkbox"/> (D) Removal of the nerves to the uterus (presacral neurectomy).</p> <p>(1) Uncontrolled leakage of urine.</p> <p>(2) Injury to bladder.</p> <p>(3) Injury to the tube (ureter) between the kidney and the bladder.</p> <p>(4) Injury to the bowel and/or intestinal obstruction.</p> <p>(5) Hemorrhage (severe bleeding)</p>	PT INITIALS
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<p><input type="checkbox"/> (E) Removal of the cervix.</p> <p>(1) Uncontrollable leakage of urine.</p> <p>(2) Injury to bladder.</p> <p>(3) Sterility.</p> <p>(4) Injury to the tube (ureter) between the kidney and the bladder.</p> <p>(5) Injury to the bowel and/or intestinal obstruction.</p> <p>(6) Need to convert to abdominal incision.</p>	PT INITIALS
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<input type="checkbox"/> (F) Repair of vaginal hernia (anterior and/or posterior colporrhaphy and/or enterocoele repair). <ul style="list-style-type: none"> (1) Uncontrollable leakage of urine. (2) Injury to bladder. (3) Sterility. (4) Injury to the tube (ureter) between the kidney and the bladder. (5) Injury to the bowel and/or intestinal obstruction. (6) Mesh erosion (with damage to the vagina and adjacent tissue) 	
PT INITIALS	
<input type="checkbox"/> (G) Abdominal suspension of the bladder (retropubic urethropexy). <ul style="list-style-type: none"> (1) Uncontrollable leakage of urine. (2) Injury to bladder. (3) Injury to the tube (ureter) between the kidney and the bladder. (4) Injury to the bowel and/or intestinal obstruction. 	
PT INITIALS	
<input type="checkbox"/> (H) Conization of cervix. <ul style="list-style-type: none"> (1) Hemorrhage (severe bleeding) which may result in hysterectomy. (2) Sterility. (3) Injury to bladder. (4) Injury to rectum. 	
PT INITIALS	
<input type="checkbox"/> (I) Dilation and curettage of uterus (diagnostic/therapeutic). <ul style="list-style-type: none"> (1) Possible hysterectomy. (2) Perforation (hole) created in the uterus. (3) Sterility. (4) Injury to the bowel and/or bladder. (5) Abdominal incision and operation to correct injury. 	
PT INITIALS	
<input type="checkbox"/> (J) Surgical Abortion/dilatation and curettage/dilation and evacuation <ul style="list-style-type: none"> (1) Possible hysterectomy. (2) Perforation (hole) created in the uterus. (3) Sterility. (4) Injury to the bowel and/or bladder. (5) Abdominal incision and operation to correct injury. (6) Failure to remove all products of conception. 	
PT INITIALS	
<input type="checkbox"/> (K) Medical Abortion/non-surgical <ul style="list-style-type: none"> (1) Hemorrhage with possible need for surgical intervention. (2) Failure to remove all products of conception. (3) Sterility. 	
PT INITIALS	
<input type="checkbox"/> (L) Selective salpingography and tubal reconstruction. <ul style="list-style-type: none"> (1) Perforation (hole) created in the uterus or Fallopian tube. (2) Future ectopic pregnancy (pregnancy outside of the uterus). (3) Pelvic infection. 	
PT INITIALS	
<input type="checkbox"/> (M) Fallopian tube occlusion (for sterilization with or without hysterectomy) <ul style="list-style-type: none"> (1) Perforation (hole) created in the uterus or Fallopian tube. (2) Future ectopic pregnancy (pregnancy outside of the uterus) (3) Pelvic infection. (4) Failure to obtain sterility 	
PT INITIALS	
<input type="checkbox"/> (N) Hysteroscopy <ul style="list-style-type: none"> (1) Perforation (hole) created in the uterus. (2) Fluid overload/electrolyte imbalance. (3) Possible hysterectomy. (4) Abdominal incision to correct injury. 	
PT INITIALS	

9. HEMATIC AND LYMPHATIC SYSTEM.

<input type="checkbox"/> (A) Transfusion of blood and blood components. <ul style="list-style-type: none"> (1) Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment. (2) Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system. (3) Severe allergic reaction, potentially fatal. 	
PT INITIALS	

<input type="checkbox"/> (B) Splenectomy. <ul style="list-style-type: none"> (1) Susceptibility to infections and increased severity of infections. (2) Increased immunization requirements. 	
PT INITIALS	

10. BREAST SURGERY (NON-COSMETIC)

<input type="checkbox"/> (A) Radical or modified radical mastectomy (removal of the breast, possible removal of other chest wall tissues, and possible removal of lymph nodes in the chest and/or under the arm). <ul style="list-style-type: none"> (1) Limitation of movement of shoulder and arm. (2) Permanent swelling of the arm. (3) Loss of the skin of the chest requiring skin graft. (4) Residual or recurrent malignancy, if present (cancer remaining or comes back after the surgery, if cancer present before the surgery). (5) Decreased sensation or numbness of the inner aspect of the arm and chest wall. 	
PT INITIALS	
<input type="checkbox"/> (B) Simple mastectomy (removal of the breast). <ul style="list-style-type: none"> (1) Loss of skin of the chest requiring skin graft. (2) Residual or recurrent malignancy, if present (cancer remaining or comes back after the surgery, if cancer present before the surgery). (3) Decreased sensation or numbness of the nipple. 	
PT INITIALS	
<input type="checkbox"/> (C) Lumpectomy (removal of a portion of the breast). <ul style="list-style-type: none"> (1) Loss of skin of the chest requiring skin graft. (2) Residual or recurrent malignancy, if present (cancer remaining or comes back after the surgery, if cancer present before the surgery). (3) Decreased sensation or numbness of the nipple. 	
PT INITIALS	
<input type="checkbox"/> (D) Open biopsy of the breast. <ul style="list-style-type: none"> (1) Loss of skin of the chest requiring skin graft. (2) Residual or recurrent malignancy, if present (cancer remaining or comes back after the surgery, if cancer present before the surgery). (3) Decreased sensation or numbness of the nipple. 	
PT INITIALS	

11. MALE GENITAL SYSTEM.

<input type="checkbox"/> (A) Orchidopexy [reposition of testis(es)]. <ul style="list-style-type: none"> (1) Removal of testicle. (2) Atrophy (shriveling) of the testicle with loss of function. 	
PT INITIALS	
<input type="checkbox"/> (B) Orchiectomy [removal of the testis(es)]. <ul style="list-style-type: none"> (1) Decreased sexual desire. (2) Difficulties with penile erection. (3) Permanent sterility (inability to father children) if both testes are removed. 	
PT INITIALS	
<input type="checkbox"/> (C) Vasectomy. <ul style="list-style-type: none"> (1) Loss of testicle. (2) Failure to produce permanent sterility (inability to father children). 	
PT INITIALS	
<input type="checkbox"/> (D) Circumcision. <ul style="list-style-type: none"> (1) Injury to penis. (2) Need for further surgery. 	
PT INITIALS	



12. MATERNITY AND RELATED CASES.

(A) Delivery (vaginal).

- (1) Injury to bladder and/or rectum including a fistula (hole) between bladder and vagina and/or rectum and vagina.
- (2) Hemorrhage (severe bleeding) possibly requiring blood administration and/or hysterectomy (removal of uterus) and/or artery ligation (tying off) to control.
- (3) Sterility (inability to get pregnant).
- (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or vaginal delivery whether or not cause is known.

PT INITIALS

(B) Delivery (cesarean section).

- (1) Injury to bowel and/or bladder.
- (2) Sterility (inability to get pregnant).
- (3) Injury to ureter (tube between kidney and bladder).
- (4) Brain damage, injury or even death occurring to the fetus before or during labor and/or cesarean delivery whether or not the cause is known.

(5) Uterine disease or injury requiring hysterectomy (removal of uterus).

PT INITIALS

(C) Cerclage

- (1) Premature labor.
- (2) Injury to bowel and/or bladder.
- (3) Rupture to membranes and possible infection.

PT INITIALS

13. MUSCULOSKELETAL SYSTEM TREATMENTS AND PROCEDURES

(A) Arthroplasty of any joints with mechanical device.

- (1) Impaired function, such as stiffness, limp, or change in limb length.
- (2) Blood vessel or nerve injury.
- (3) Pain.
- (4) Blood clot in limb or lung.
- (5) Failure of bone to heal.
- (6) Infection.
- (7) Removal or replacement of any implanted device or material.
- (8) Dislocation or loosening requiring additional surgery.
- (9) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

(B) Arthroscopy of any joint.

- (1) Blood vessel or nerve injury.
- (2) Continued pain.
- (3) Stiffness of joint.
- (4) Blood clot in limb or lung.
- (5) Joint infection.
- (6) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

(C) Open reduction with internal fixation.

- (1) Impaired function, such as stiffness, limp, or change in limb length.
- (2) Blood vessel or nerve injury.
- (3) Pain.
- (4) Blood clot in limb or lung.
- (5) Failure of bone to heal.
- (6) Infection.
- (7) Removal or replacement of any implanted device or material.
- (8) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

(D) Osteotomy.

- (1) Impaired function, such as stiffness, limp, or change in limb length.
- (2) Blood vessel or nerve injury.
- (3) Pain.
- (4) Blood clot in limb or lung.
- (5) Failure of bone to heal.
- (6) Infection.
- (7) Removal or replacement of any implanted device or material.
- (8) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery

PT INITIALS

(E) Ligamentous reconstruction of joints.

- (1) Continued instability of the joint.
- (2) Arthritis.
- (3) Continued pain.
- (4) Stiffness of joint.
- (5) Blood vessel or nerve injury.
- (6) Impaired function and/or scarring.
- (7) Blood clot in limb or lung.
- (8) If performed on a child age 12 or under, include the following risks: problems with appearance, use, or growth requiring additional surgery.

PT INITIALS

(F) Vertebroplasty/Kyphoplasty

- (1) Nerve/spinal cord injury.
- (2) Need for emergency surgery.
- (3) Embolization of cement (cement used passes into blood vessels and possibly all the way to the lungs).
- (4) Collapse of adjacent vertebrae (bones in spine).
- (5) Leak of cerebrospinal fluid (fluid around the brain and spinal cord).
- (6) Pneumothorax (collapsed lung).
- (7) Failure to relieve pain.
- (8) Rib fracture.

PT INITIALS

(G) If the following procedures are performed on a child age 12 or under, problems with appearance, use, or growth requiring additional surgery should be disclosed.

- (1) Arthrotomy (opening of joint).
- (2) Closed reduction with or without pin or external fixation.
- (3) Surgical management of open wound.
- (4) Partial excision or removal of bone.
- (5) Removal of external fixation device.
- (6) Traction or casting with or without manipulation for reduction.

PT INITIALS

(H) Amputation of limb.

- (1) Pain and/or phantom sensation in removed limb.
- (2) Need for further surgery.
- (3) Infection.
- (4) Hemorrhage (severe bleeding).
- (5) Difficulty with prosthesis fitting.

PT INITIALS

14. NERVOUS SYSTEM TREATMENTS AND PROCEDURES.

(A) Craniotomy, Cranectomy or Cranioplasty

- (1) Loss of brain function, such as memory and/or ability to speak.
- (2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).
- (3) Stroke (damage to brain resulting in loss of one or more functions).
- (4) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
- (5) Weakness, paralysis, loss of coordination.
- (6) Cerebrospinal fluid leak with potential for severe headaches.
- (7) Meningitis (infection of coverings of brain and spinal cord).
- (8) Brain abscess.
- (9) Persistent vegetative state (not able to communicate or interact with others).
- (10) Hydrocephalus (abnormal fluid buildup causing pressure in the brain).
- (11) Seizures (uncontrolled nerve activity).
- (12) Need for permanent breathing tube and/or permanent feeding tube.

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<p><input type="checkbox"/> (B) Cranial nerve operations.</p> <ol style="list-style-type: none"> (1) Weakness, numbness, impaired muscle function or paralysis. (2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). (3) Seizures (uncontrolled nerve activity). (4) New or different pain. (5) Stroke (damage to brain resulting in loss of one or more functions). (6) Persistent vegetative state (not able to communicate or interact with others). (7) Loss of senses (blindness, double vision, deafness, smell, numbness, taste). (8) Cerebrospinal fluid leak with potential for severe headaches. (9) Meningitis (infection of coverings of brain and spinal cord). (10) Need for prolonged nursing care. (11) Need for permanent breathing tube and/or permanent feeding tube. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (G) Elevation of depressed skull fracture.</p> <ol style="list-style-type: none"> (1) Loss of brain function such as memory and/or ability to speak. (2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). (3) Loss of senses (blindness, double vision, deafness, smell, numbness, taste). (4) Weakness, paralysis, loss of coordination. (5) Cerebrospinal fluid leak with potential for severe headaches. (6) Meningitis (infection of coverings of brain and spinal cord). (7) Brain abscess (8) Persistent vegetative state (not able to communicate or interact with others). (9) Seizures (uncontrolled nerve activity). (10) Need for permanent breathing tube and/or permanent feeding tube. <p style="text-align: right;">PT INITIALS</p>
<p>15. RADIOLOGY</p>	
<p><input type="checkbox"/> (C) Spine operation, including laminectomy, decompression, fusion, internal fixation or procedures for nerve root or spinal cord compression; diagnosis; pain; deformity; mechanical instability; injury; removal of tumor, abscess or hematoma (excluding coccygeal operations).</p> <ol style="list-style-type: none"> (1) Weakness, pain, numbness or clumsiness. (2) Impaired muscle function or paralysis. (3) Incontinence, impotence or impaired bowel function (loss of bowel/bladder control and/or sexual function). (4) Migration of implants (movement of implanted devices). (5) Failure of implants (breaking of implanted devices). (6) Adjacent level degeneration (breakdown of spine above and/or below the level treated). (7) Cerebrospinal fluid leak with potential for severe headaches. (8) Meningitis (infection of coverings of brain and spinal cord). (9) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse). (10) Unstable spine (abnormal movement between bones and/or soft tissues of the spine). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (A) Splenoportography (needle injection of contrast media into the spleen)</p> <ol style="list-style-type: none"> (1) All associated risks as listed under subsection 2 (B) of this section. (2) Injury to the spleen requiring blood transfusion and/or removal of the spleen. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (D) Peripheral nerve operation: nerve grafts, decompression, transposition or tumor removal; neurorrhaphy, neurectomy or neurolysis.</p> <ol style="list-style-type: none"> (1) Numbness. (2) Impaired muscle function. (3) Recurrence, continuation, or worsening of the condition that required the operation (no improvement or symptoms made worse). (4) Continued, increased or different pain. (5) Weakness <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (B) Chemoembolization</p> <ol style="list-style-type: none"> (1) All associated risks as listed under subsection 2 (B) of this section. (2) Tumor lysis syndrome (rapid death of tumor cells releasing their contents which can be harmful). (3) Injury to or failure of liver (or other organ in which tumor is located). (4) Risk of the chemotherapeutic agent(s) utilized. (5) Cholecystitis (inflammation of the gall bladder) (for liver or other upper GI embolizations). (6) Abscess (infected fluid collection) in the liver or other embolized organ requiring further intervention. (7) Biloma (collection of bile in or near the liver requiring drainage) (for liver embolizations). <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (E) Transphenoidal hypophysectomy or other pituitary gland operation.</p> <ol style="list-style-type: none"> (1) Cerebrospinal fluid leak with potential for severe headaches. (2) Necessity for hormone replacement. (3) Recurrence, continuation, or worsening of the condition that required the operation (no improvement or symptoms made worse). (4) Deformity or perforation of nasal septum (hole in wall between the right and left halves of the nose). (5) Facial nerve injury resulting in disfigurement (loss of nerve function controlling muscles in face). (6) Loss of senses (blindness, double vision, deafness, smell, numbness, taste). (7) Stroke (damage to brain resulting in loss of one or more functions). (8) Persistent vegetative state (not able to communicate or interact with others). (9) Headaches. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (C) Radioembolization</p> <ol style="list-style-type: none"> (1) All associated risks as listed under subsection 2 (B) of this section. (2) Tumor lysis syndrome (rapid death of tumor cells releasing their contents which can be harmful). (3) Injury to or failure of liver (or other organ in which tumor is located). (4) Radiation complications: pneumonitis (inflammation of lung) which is potentially fatal; inflammation of stomach, intestines, gallbladder, pancreas, stomach or intestinal ulcer; scarring of liver. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (F) Cerebrospinal fluid shunting procedure or revision.</p> <ol style="list-style-type: none"> (1) Shunt obstruction (blockage of shunt/tubing causing it to stop draining adequately). (2) Malposition or migration of shunt/tubing (improper positioning or later movement of shunt/tubing causing it to stop draining adequately). (3) Seizures (uncontrolled nerve activity). (4) Recurrence or continuation of brain dysfunction. (5) Injury to internal organs of the chest or abdomen. (6) Brain injury. (7) Stroke (damage to brain resulting in loss of one or more functions). (8) Persistent vegetative state (not able to communicate or interact with others). (9) Loss of senses (blindness, double vision, deafness, smell, numbness, taste). (10) Cerebrospinal fluid leak with potential for severe headaches. (11) Meningitis (infection of coverings of brain and spinal cord). (12) Need for prolonged nursing care. (13) Need for permanent breathing tube and/or permanent feeding tube. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (D) Thermal and other ablative techniques for treatment of tumors (for curative intent or palliation) including radiofrequency ablation, microwave ablation, cryoablation, and high intensity focused ultrasound (HIFU)</p> <ol style="list-style-type: none"> (1) Injury to tumor-containing organ or adjacent organ/structures. (2) Injury to nearby nerves potentially resulting in temporary or chronic (continuing) pain and/or loss of use and/or feeling. (3) Failure to completely treat tumor. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (E) TIPS (Transjugular Intrahepatic Portosystemic Shunt) and its variants such as DIPS (Direct Intrahepatic Portacaval Shunt)</p> <ol style="list-style-type: none"> (1) All associated risks as listed under subsection 2 (B)–(D) of this section. (2) Hepatic encephalopathy (confusion/decreased ability to think). (3) Liver failure or injury. (4) Gallbladder injury. (5) Hemorrhage (severe bleeding). (6) Recurrent ascites (fluid building up in abdomen) and/or bleeding. (7) Kidney failure. (8) Heart failure. (9) Death. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (F) Myelography</p> <ol style="list-style-type: none"> (1) Chronic continuing pain. (2) Nerve injury with loss of use and/or feeling. (3) Transient (temporary) headache, nausea, and/or vomiting. (4) Numbness. (5) Seizures. <p style="text-align: right;">PT INITIALS</p>



<p><input type="checkbox"/> (G) Percutaneous abscess/fluid collection drainage (percutaneous abscess/seroma/lymphocele drainage and/or sclerosis (inclusive of percutaneous, transgluteal, transrectal and transvaginal routes))</p> <p>(1) Sepsis (infection in the blood stream), possibly resulting in shock (severe decrease in blood pressure).</p> <p>(2) Injury to nearby organs.</p> <p>(3) Hemorrhage (severe bleeding).</p> <p>(4) Infection of collection which was not previously infected, or additional infection of abscess.</p>	PT INITIALS
<p><input type="checkbox"/> (H) Procedures utilizing prolonged Fluoroscopy</p> <p>(1) Skin injury (such as epilation (hair loss), burns or ulcers).</p> <p>(2) Cataracts (for procedures in the region of the head).</p>	PT INITIALS
16. RESPIRATORY SYSTEM TREATMENTS AND PROCEDURES.	
<p><input type="checkbox"/> (A) Biopsy and/or excision (removal) of lesion of larynx, vocal cords, trachea.</p> <p>(1) Loss or change of voice.</p> <p>(2) Swallowing or breathing difficulties.</p> <p>(3) Perforation (hole) or fistula (connection) in esophagus (tube from throat to stomach).</p>	PT INITIALS
<p><input type="checkbox"/> (B) Rhinoplasty (surgery to change the shape of the nose) or nasal reconstruction with or without septoplasty (surgical procedure to remove blockage in or straighten the bone and cartilage dividing the space between the two nostrils).</p> <p>(1) Deformity of skin, bone or cartilage.</p> <p>(2) Creation of new problems, such as perforation of the nasal septum (hole in wall between the right and left halves of the nose) or breathing difficulty.</p>	PT INITIALS
<p><input type="checkbox"/> (C) Submucous resection of nasal septum or nasal septoplasty (surgery to remove blockage in or straighten the bone and cartilage dividing the space between the two nostrils).</p> <p>(1) Persistence, recurrence or worsening of the obstruction.</p> <p>(2) Perforation of nasal septum (hole in the bone and/or cartilage dividing the space between the right and left halves of the nose) with dryness and crusting.</p> <p>(3) External deformity of the nose.</p>	PT INITIALS
<p><input type="checkbox"/> (D) Sinus surgery/endoscopic sinus surgery.</p> <p>(1) Spinal fluid leak.</p> <p>(2) Visual loss or other eye injury.</p> <p>(3) Numbness in front teeth and palate (top of mouth).</p> <p>(4) Loss or reduction in sense of taste or smell.</p> <p>(5) Recurrence of disease.</p> <p>(6) Empty Nose Syndrome (sensation of nasal congestion, sensation of not being able to take in adequate air through nose).</p> <p>(7) Injury to tear duct causing drainage of tears down the cheek.</p> <p>(8) Brain injury and/or infection.</p> <p>(9) Injury to nasal septum (the bone and cartilage dividing the space between the two nostrils).</p> <p>(10) nasal obstruction.</p>	PT INITIALS
<p><input type="checkbox"/> (E) Lung biopsy (removal of small piece of tissue from inside of lung).</p> <p>(1) Air leak with pneumothorax (leak of air from lung to inside of chest causing the lung to collapse) with need for insertion of chest tube or repeat surgery.</p> <p>(2) Hemothorax (blood in the chest around the lung) possibly requiring additional procedures.</p> <p>(3) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).</p>	PT INITIALS
<p><input type="checkbox"/> (F) Segmental resection of lung (removal of a portion of a lung).</p> <p>(1) Hemothorax (blood in the chest around the lung).</p> <p>(2) Abscess (infected fluid collection) in chest.</p> <p>(3) Air leak with pneumothorax (leak of air from lung inside of chest causing the lung to collapse) with need for insertion of chest drainage tube into space between lung and chest wall or repeat surgery.</p> <p>(4) Need for additional surgery.</p>	PT INITIALS
<p><input type="checkbox"/> (G) Thoracotomy (surgery to reach the inside of the chest).</p> <p>(1) All associated risks as listed under paragraph (F) of this subsection.</p>	PT INITIALS
<p><input type="checkbox"/> (H) VATS — video-assisted thoracoscopic surgery (camera-assisted surgery to reach the inside of the chest through small incisions).</p> <p>(1) All associated risks as listed under paragraph (F) of this subsection.</p> <p>(2) Need to convert to open surgery.</p>	PT INITIALS
<p><input type="checkbox"/> (I) Percutaneous (puncture through the skin instead of incision) or open (surgical incision) tracheostomy.</p> <p>(1) Loss of voice.</p> <p>(2) Breathing difficulties.</p> <p>(3) Pneumothorax (collapsed lung) with the need for insertion of chest tube.</p> <p>(4) Hemothorax (blood in the chest around the lung).</p> <p>(5) Scarring in trachea (windpipe).</p> <p>(6) Fistula (connection) between trachea into esophagus (tube from throat to stomach) or great vessels.</p> <p>(7) Bronchospasm (constriction of the airways leading to trouble breathing).</p> <p>(8) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).</p>	PT INITIALS
<p><input type="checkbox"/> (J) Bronchoscopy (insertion of a camera into the airways of the neck and chest).</p> <p>(1) Mucosal injury (damage to lining of airways) including perforation (hole in the airway).</p> <p>(2) Pneumothorax (collapsed lung) with need for insertion of chest tube.</p> <p>(3) Pneumomediastinum (air enters the space around the airways including the space around the heart).</p> <p>(4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords).</p> <p>(5) Bronchospasm (constriction of the airways leading to trouble breathing).</p> <p>(6) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).</p>	PT INITIALS
<p><input type="checkbox"/> (K) Endobronchial valve replacement (device inserted into airways in the lung that controls air movement into and out of abnormal portions of a lung).</p> <p>(1) Mucosal injury (damage to lining of airways) including perforation (hole in the airway).</p> <p>(2) Pneumothorax (collapsed lung) with need for insertion of chest tube.</p> <p>(3) Pneumomediastinum (air enters the space around the airways including the space around the heart).</p> <p>(4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords).</p> <p>(5) Migration (movement) of the stent from its original position.</p> <p>(6) Airway blockage, potentially life threatening.</p> <p>(7) Stent blockage.</p> <p>(8) Worsening of chronic obstructive pulmonary disease (worsening of emphysema).</p> <p>(9) Respiratory failure (need for breathing tube placement with ventilator support).</p> <p>(10) Bronchospasm (constriction of the airways leading to trouble breathing).</p> <p>(11) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).</p> <p>(12) Recurrent infections.</p>	PT INITIALS



<p><input type="checkbox"/> (L) Endobronchial balloon dilatation with or without stent placement (placement of tube to keep airway open).</p> <ol style="list-style-type: none"> (1) Bronchial rupture (tearing of the airway) with need for additional surgery. (2) Pneumothorax (collapsed lung) with need for insertion of chest tube. (3) Pneumomediastinum (air enters the space around the airways including the space around the heart). (4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords). (5) Migration (movement) of the stent from its original position. (6) Airway blockage, potentially life threatening. (7) Stent blockage. (8) Stent fracture. (9) Recurrent infections. (10) Stent erosion into adjacent structures (stent wears a hole through the airway and injures nearby tissues). (11) Hemoptysis (coughing up blood which can result in respiratory distress and the need to be placed on a ventilator or breathing machine and oxygen). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (E) Ureterectomy (partial/complete removal of ureter (tube that carries urine from kidney to bladder), Ureterolysis (partial/complete removal of ureter (tube that carries urine from kidney to bladder) from adjacent tissue).</p> <ol style="list-style-type: none"> (1) Leakage of urine at surgical site. (2) Incomplete removal of stone (if stone present). (3) Blockage of urine. (4) Damage to organs next to ureter. (5) Damage to or loss of ureter (ureterolysis). <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (M) Mediastinoscopy (insertion of a camera into the space behind the breastbone and between the lungs) with or without biopsy (removal of tissue).</p> <ol style="list-style-type: none"> (1) Hemorrhage (severe bleeding) requiring open surgery. (2) Nerve injury causing vocal cord paralysis or poor function. (3) Pneumothorax (collapsed lung). (4) Tracheal injury (damage to the airway/windpipe). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (F) Ureteral reimplantation (reinserting ureter (tube between the kidney and bladder) into the bladder)</p> <ol style="list-style-type: none"> (1) Leakage of urine at surgical site. (2) Blockage of urine. (3) Damage to organs next to the ureter. (4) Damage to or loss of the ureter. (5) Backward flow of urine from bladder into ureter. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (N) Pleurodesis (procedure to prevent fluid build-up in space between the lung and chest wall).</p> <ol style="list-style-type: none"> (1) Respiratory failure (need for breathing tube placement). (2) Empyema (infection/pus in the space around the lung). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (G) Prostatectomy (partial or total removal of prostate)</p> <ol style="list-style-type: none"> (1) Leakage of urine at surgical site. (2) Blockage of urine. (3) Incontinence (difficulty with control of urine flow). (4) Semen passing backward into bladder. (5) Difficulty with penile erection (possible with partial and probable with total prostatectomy). <p style="text-align: right;">PT INITIALS</p>
<p>17. URINARY SYSTEM</p> <p><input type="checkbox"/> (A) Nephrectomy (removal of part or all of the kidney).</p> <ol style="list-style-type: none"> (1) Incomplete removal of stone(s) or tumor, if present. (2) Blockage of urine (risk of partial nephrectomy). (3) Leakage of urine at surgical site. (4) Injury to or loss of the entire kidney (risk of partial nephrectomy, intentional for total or radical nephrectomy). (5) Loss of the adrenal gland (gland on top of the kidney that makes certain hormones/chemicals the body needs) - intentional in the case of radical nephrectomy. (6) Damage to organs next to kidney. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (H) Total cystectomy (removal of bladder).</p> <ol style="list-style-type: none"> (1) Probable loss of penile erection and ejaculation in the male. (2) Damage to organs next to bladder. (3) This procedure will require an alternate method of urinary drainage (urine will need a new place to collect or empty from the body). <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (B) Nephrolithotomy and Pyelolithotomy (removal of kidney stone(s)).</p> <ol style="list-style-type: none"> (1) Incomplete removal of stone(s). (2) Blockage of urine. (3) Leakage of urine at surgical site. (4) Injury or loss of kidney. (5) Damage to organs next to the kidney. <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (I) Radical cystectomy.</p> <ol style="list-style-type: none"> (1) Probable loss of penile erection and ejaculation in the male. (2) Damage to organs next to bladder. (3) This procedure will require an alternate method of urinary drainage (urine will need a new place to collect or empty from the body). (4) Chronic (continuing) swelling of thighs, legs, and feet. (5) Recurrence or spread of cancer if present. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (C) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system). Ureteroplasty (reconstruction of ureter (tube between kidney and bladder)).</p> <ol style="list-style-type: none"> (1) Blockage of urine. (2) Leakage of urine at surgical site. (3) Injury to or loss of the kidney (pyeloureteroplasty) or ureter (ureterolithotomy). (4) Damage to organs next to kidney. (5) Incomplete removal of the stone or tumor (when applicable). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (J) Partial cystectomy (removal of a portion of the bladder).</p> <ol style="list-style-type: none"> (1) Leakage of urine at surgical site. (2) Incontinence (difficulty with control of urine flow). (3) Backward flow of urine from bladder into ureter (tube between kidney and bladder). (4) Blockage of urine. (5) Damage to organs next to bladder. <p style="text-align: right;">PT INITIALS</p>
<p><input type="checkbox"/> (D) Ureterolithotomy (surgical removal of stone(s) from ureter (tube between kidney and bladder)).</p> <ol style="list-style-type: none"> (1) Leakage of urine at surgical site. (2) Incomplete removal of stone. (3) Blockage of urine. (4) Damage to organs next to ureter (tube that carries urine from kidney to bladder). (5) Damage to or loss of ureter (tube that carries urine from kidney to bladder). <p style="text-align: right;">PT INITIALS</p>	<p><input type="checkbox"/> (K) Cystolithotomy (surgical removal of stone(s) from the bladder).</p> <ol style="list-style-type: none"> (1) Injury to bladder or surrounding organs. (2) Urinary incontinence (inability to control release of urine from bladder). <p style="text-align: right;">PT INITIALS</p> <p><input type="checkbox"/> (L) Cystolitholapaxy (cystoscopic crushing and removal of bladder stone(s)).</p> <ol style="list-style-type: none"> (1) Injury to bladder. (2) Scarring/injury of urethra (tube from bladder to outside). <p style="text-align: right;">PT INITIALS</p> <p><input type="checkbox"/> (M) Cystostomy (placement of tube into the bladder). Injury to bladder or surrounding organs.</p> <p style="text-align: right;">PT INITIALS</p> <p><input type="checkbox"/> (N) Diverticulectomy of the bladder (removal of outpouching of the bladder).</p> <ol style="list-style-type: none"> (1) Injury to bladder or surrounding organs. (2) Urinary incontinence (inability to control release of urine from bladder). <p style="text-align: right;">PT INITIALS</p>

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<p><input type="checkbox"/> (O) Urinary diversion (ileal conduit, colon conduit).</p> <p>(1) Blood chemistry abnormalities requiring medication.</p> <p>(2) Development of stones, strictures (scars or narrowings) or infection in the kidneys, ureter or bowel (intestine).</p> <p>(3) Leakage of urine at surgical site.</p> <p>(4) This procedure will require an alternate method of urinary drainage (urine will need a new place to collect or empty from the body).</p>	
PT INITIALS	
<p><input type="checkbox"/> (P) Ureterosigmoidostomy (attachment of ureters (tubes between kidney and bladder) to the colon (large intestine)).</p> <p>(1) Blood chemistry abnormalities requiring medication.</p> <p>(2) Development of stones, strictures or infection in the kidneys, ureter or bowel (intestine).</p> <p>(3) Leakage of urine at surgical site.</p> <p>(4) Difficulty in holding urine in the rectum.</p>	
PT INITIALS	
<p><input type="checkbox"/> (Q) Urethroplasty (construction/reconstruction/dilation of drainage tube from bladder to the outside).</p> <p>(1) Leakage of urine at surgical site.</p> <p>(2) Stricture formation (narrowing of urethra (tube from bladder to outside)).</p> <p>(3) Need for additional surgery.</p>	
PT INITIALS	
<p><input type="checkbox"/> (R) Diverticulectomy or diverticulotomy of the urethra (repair or drainage of outpouching of the urethra).</p> <p>(1) Injury to urethra (tube from bladder to outside) with leak of urine or narrowing of urethra.</p> <p>(2) Fistula formation (connection between urethra and other pelvic structure).</p> <p>(3) Sexual dysfunction (pain with sexual intercourse, change in sensation with sex).</p>	
PT INITIALS	
<p><input type="checkbox"/> (S) Percutaneous nephrostomy/stenting/stone removal</p> <p>(1) Pneumothorax or other pleural complication (collapsed lung or filling of chest cavity on the same side with fluid).</p> <p>(2) Septic shock/bacteremia (infection of the blood stream with possible shock/severe lowering of blood pressure) when pyonephrosis (infected urine in the kidney) present.</p> <p>(3) Bowel (intestinal) injury.</p> <p>(4) Blood vessel injury with or without significant bleeding.</p>	
PT INITIALS	
<p><input type="checkbox"/> (T) Lithotripsy ("Shockwave Lithotripsy") (sound wave removal of stones from kidney and ureter).</p> <p>(1) Injury to kidney, ureter (tube between kidney and bladder), or other nearby organs.</p> <p>(2) Stone fragments blocking ureter.</p> <p>(3) Bleeding in or around kidney or ureter.</p>	
PT INITIALS	
<p><input type="checkbox"/> (U) Dialysis (technique to replace function of the kidney and clean blood of toxins)</p> <p>(1) Hemodialysis</p> <p>(a) Hypotension (low blood pressure).</p> <p>(b) Hypertension (High blood pressure).</p> <p>(c) Air embolism (air bubble in blood vessel) resulting in possible death or paralysis.</p> <p>(d) Cardiac arrhythmias (irregular heart rhythms).</p> <p>(e) Infections of blood stream, access site, or blood borne (for example: Hepatitis B, C or HIV).</p> <p>(f) Hemorrhage (severe bleeding as a result of clotting problems or due to disconnection of the blood line).</p> <p>(g) Nausea, vomiting, cramps, headache and mild confusion during and/or temporarily after dialysis.</p> <p>(h) Allergic reaction.</p> <p>(i) Chemical imbalances and metabolic disorders (unintended change in blood minerals).</p> <p>(j) Pyrogenic reactions (fever).</p> <p>(k) Hemolysis (rupture of red blood cells).</p> <p>(l) Graft/fistula damage including bleeding, aneurysm formation (ballooning of vessels), clotting (closure) of graft/fistula.</p> <p>(2) Peritoneal dialysis</p> <p>(a) Infection, including peritonitis (inflammation or irritation of the tissue lining the inside wall of abdomen and covering organs), catheter infection, and catheter exit site infection.</p> <p>(b) Development of hernias of umbilicus (weakening of abdominal wall or muscle).</p> <p>(c) Hypertension (high blood pressure).</p> <p>(d) Hypotension (low blood pressure).</p> <p>(e) Hydrothorax (fluid in chest cavity).</p>	

- (f) Arrhythmia (irregular heart rhythm).
- (g) Perforation of the bowel (hole in intestine).
- (h) Sclerosis or scarring of the peritoneum (lining of the abdomen) with loss of dialysis function.
- (i) Weight gain leading to obesity.
- (j) Abdominal discomfort/distension.
- (k) Heart burn or reflux.
- (l) Increase in need for anti-diabetic medication.
- (m) Muscle weakness.
- (n) Dehydration (extreme loss of body fluid).
- (o) Chemical imbalances and metabolic disorders (unintended change in blood minerals).
- (p) Allergic reactions.
- (q) Nausea, vomiting, cramps, headache, and mild confusion during and/or temporarily after dialysis.

PT INITIALS

18. PAIN MANAGEMENT PROCEDURES

- (A) **Neuroaxial procedures (injections into or around spine)**
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Nerve damage including paralysis (inability to move).
 - (3) Epidural hematoma (bleeding in or around spinal canal).
 - (4) Infection.
 - (5) Seizure.
 - (6) Persistent leak of spinal fluid which may require surgery.
 - (7) Breathing and/or heart problems including cardiac arrest (heart stops beating).
 - (8) Loss of vision.
 - (9) Stroke.
- (B) **Peripheral and visceral nerve blocks and/or ablations**
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Bleeding.
 - (3) Nerve damage including paralysis (inability to move).
 - (4) Infection.
 - (5) Damage to nearby organ or structure.
 - (6) Seizure.
- (C) **Implantation of pain control devices**
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Nerve damage including paralysis (inability to move).
 - (3) Epidural hematoma (bleeding in or around spinal canal).
 - (4) Infection.
 - (5) Persistent leak of spinal fluid which may require surgery.

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19. DENTAL SURGERY PROCEDURES

- (1) **Oral surgery.**
 - (A) Extraction (removing teeth).
 - (i) Dry socket (inflammation in the socket of a tooth).
 - (ii) Permanent or temporary numbness or altered sensation.
 - (iii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iv) Fracture of alveolus and/or mandible (upper and/or lower jaw).
 - (B) Surgical exposure of tooth in order to facilitate orthodontics.
 - (i) Injury to tooth or to adjacent teeth and structures.
 - (ii) Failure to get proper attachment to tooth requiring additional procedure.
- (2) **Endodontics (deals with diseases of the dental pulp).**
 - (A) Apicoectomy (surgical removal of root tip or end of the tooth, with or without sealing it).
 - (i) Shrinkage of the gums and crown margin exposure.
 - (ii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iii) Displacement of teeth or foreign bodies into nearby tissues, spaces, and cavities.
 - (B) Root amputation (surgical removal of portion of one root of a multi-rooted tooth).
 - (i) Shrinkage of the gums and crown margin exposure.
 - (ii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iii) Displacement of teeth or foreign bodies into nearby tissues, spaces, and cavities.

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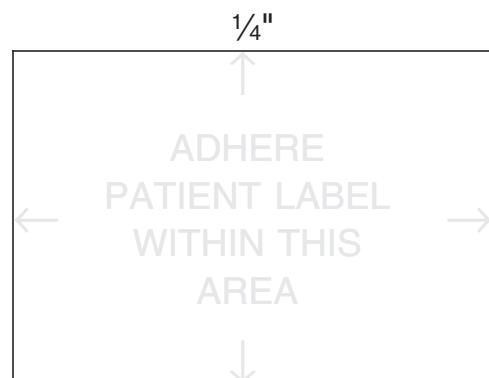
<p>(C) Root canal therapy (from an occlusal access in order to clean and fill the canal system).</p> <ul style="list-style-type: none"> (i) Instrument separation (tiny files which break within the tooth canal system). (ii) Fenestration (penetration of walls of tooth into adjacent tissue). (iii) Failure to find and/or adequately fill all canals. (iv) Expression of irrigants or filling material past the apex of the tooth (chemicals used to clean or materials used to fill a root may go out the end of the root and cause pain or swelling). (v) Damage to adjacent tissues from irrigants or clamps. (vi) Fracture or loss of tooth. 	<p>PT INITIALS</p> <p>(K) Sub epithelial connective tissue graft procedures.</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (iii) Rejection of graft. <p>(L) Distal or proximal wedge procedure (taking off gum tissue from the very back of the last tooth or between teeth). Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.</p> <p>(M) Soft tissue allograft and connective tissue double pedicle graft from below (creates or augments gum tissue).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.
<p><input type="checkbox"/> (3) Periodontal surgery (surgery of the gums).</p> <p>(A) Gingivectomy and gingivoplasty (involves the removal of soft tissue).</p> <ul style="list-style-type: none"> (i) Tooth sensitivity to hot, cold, sweet, or acid foods. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(B) Anatomical crown exposure (removal of enlarged gingival tissue and supporting bone to provide an anatomically correct gingival relationship).</p> <ul style="list-style-type: none"> (i) Tooth sensitivity to hot, cold, sweet, or acid foods. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(C) Gingival flap procedure, including root planing (soft tissue flap is laid back or removed to allow debridement (cleaning) of the root surface and the removal of granulation tissue (unhealthy soft tissue)).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(D) Apically positioned flap (used to preserve keratinized gingival (attached gum tissue) in conjunction with osseous resection (removal) and second stage implant procedure).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(E) Clinical crown lengthening (removal of gum tissue and/or bone from around tooth).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(F) Osseous surgery-including flap entry and closure (modification of the bony support of the teeth).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Tooth sensitivity to hot, cold, sweet, or acid foods. (iii) Loss of tooth. (iv) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. <p>(G) Guided tissue regeneration-resorbable barrier.</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Accidental aspiration (into the lungs) of foreign matter. (iii) Rejection of donor materials. <p>(H) Guided tissue regeneration-nonresorbable barrier (includes membrane removal).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (iii) Accidental aspiration (into the lungs) of foreign matter. (iv) Rejection of donor materials. <p>(I) Pedicle soft tissue graft procedure.</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (iii) Rejection of donor materials. <p>(J) Free soft tissue graft protection-including donor site surgery.</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth. (iii) Rejection of graft. 	<p>PT INITIALS</p> <p><input type="checkbox"/> (4) Implant procedures.</p> <p>(A) Bone grafting (replacing missing bone).</p> <ul style="list-style-type: none"> (i) Permanent or temporary numbness or altered sensation. (ii) Rejection of bone particles or graft from donor or recipient sites. (iii) Damage to adjacent teeth or bone. <p>(B) Surgical placement of implant body.</p> <ul style="list-style-type: none"> (i) Blood vessel or nerve injury. (ii) Damage to adjacent teeth or bone fracture. (iii) Sinus communication (opening from tooth socket into the sinus cavity). (iv) Failure of implant requiring corrective surgery. (v) Cyst formation, bone loss, or gum disease around the implant. <p>PT INITIALS</p>

20. PLASTIC SURGERY AND SURGERY OF THE INTEGUMENTARY SYSTEM.

<p><input type="checkbox"/> (1) Augmentation mammoplasty (breast enlargement with implant).</p> <ul style="list-style-type: none"> (A) Bleeding around implant. (B) Sensory changes or loss of nipple sensitivity. (C) Failure, deflation, or leaking of implant requiring replacement. (D) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape). (E) Problems with or the inability to breastfeed. (F) Capsular contracture (hardening of breast). 	<p>PT INITIALS</p>
<p><input type="checkbox"/> (2) Bilateral breast reduction.</p> <ul style="list-style-type: none"> (A) Skin flap or fat necrosis (injury or death of skin and fat). (B) Loss of nipple or areola. (C) Sensory changes or loss of nipple sensitivity. (D) Problems with or the inability to breastfeed. (E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape or not desired size). 	<p>PT INITIALS</p>
<p><input type="checkbox"/> (3) Rhinoplasty or nasal reconstruction with or without septoplasty (repairing the middle wall of the nose).</p> <ul style="list-style-type: none"> (A) Development of new problems, such as perforation of the nasal septum (hole in wall between the right and left halves of the nose) or breathing difficulty. (B) Spinal fluid leak. (C) Worsening or unsatisfactory appearance. 	<p>PT INITIALS</p>
<p><input type="checkbox"/> (4) Reconstruction and/or plastic surgery operations of the face and neck.</p> <ul style="list-style-type: none"> (A) Impairment of regional organs, such as eye or lip function. (B) Recurrence of the original condition. (C) Worsening or unsatisfactory appearance. 	<p>PT INITIALS</p>



<input type="checkbox"/> (5) Liposuction (removal of fat by suction). (A) Shock. (B) Pulmonary fat embolism (fat escaping with possible damage to vital organs). (C) Damage to skin with possible skin loss. (D) Loose skin. (E) Worsening or unsatisfactory appearance. PT INITIALS	
<input type="checkbox"/> (6) Breast reconstruction with other flaps and/or implants. (A) Bleeding around implant. (B) Sensory changes or loss of nipple sensitivity. (C) Failure, deflation, or leaking of implant requiring replacement. (D) Damage to internal organs. (E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape). PT INITIALS	
<input type="checkbox"/> (7) Nipple Areolar Reconstruction. (A) Loss of graft. (B) Unsatisfactory appearance. PT INITIALS	
<input type="checkbox"/> (8) Panniculectomy (removal of skin and fat). (A) Persistent swelling in the legs. (B) Nerve damage. (C) Worsening or unsatisfactory appearance. PT INITIALS	
<input type="checkbox"/> (9) Tendonitis, tendon release, and trigger releases. (A) Recurrence of symptoms. (B) Damage to blood vessels, nerves, tendons, or muscles. (C) Worsening function. PT INITIALS	
<input type="checkbox"/> (10) Breast reconstruction with flaps. (A) Damage to blood vessels, nerves, or muscles. (B) Loss of flap possibly requiring additional surgery. (C) Damage to internal organs. (D) Increased risk of abdominal wall complications with pregnancy. (E) Abdominal hernias with abdominal flaps. (F) Chronic abdominal pain with abdominal flaps. (G) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape). PT INITIALS	
<input type="checkbox"/> (11) Flap or graft surgery. (A) Damage to blood vessels, nerves, or muscles. (B) Deep vein thrombosis (blood clot in legs or arms). (C) Loss of flap possibly requiring additional surgery. (D) Worsening or unsatisfactory appearance. PT INITIALS	
<input type="checkbox"/> (12) Tendons, nerves, or blood vessel repair. (A) Damage to nerves. (B) Deep vein thrombosis (blood clot in legs or arms). (C) Rupture of repair. (D) Worsening of function. PT INITIALS	



Informed Consent/Authorization to Donate Tissue for Medical Research

Sometimes tissue, blood, body fluids or cells are removed from your body during surgery. For simplicity we are calling all these things "tissue". Any removed tissue is used for your care, diagnosis and treatment first. After all tests are done, tissue may be left over. You may choose to donate it for medical research. No more tissue will be removed than would normally be removed for your care.



HM2227

Before you decide to donate your tissue, read this information and talk to your doctor or nurse and make sure all your questions are answered.

- You do not have to donate.
- Your choice to donate or not will not affect your healthcare in any way.
- If you change your mind after donating, we will discard any unused tissue.

What is the purpose of donating this tissue?

- Human tissue research can help find new or better ways to diagnose, treat, cure and prevent disease.
- Human tissue research may develop new commercial medical products.

What will happen if you donate this tissue?

- The tissue will be stored in a 'tissue bank' or repository for future use.
- Researchers may use donated tissue by submitting a research plan to either:
 - The Biorepository Resource Allocation Committee (BioRAC) for de-identified tissue (with no information given to the researchers that may personally identify the tissue), or
 - A committee called the Institutional Review Board (IRB). Requests are made to the IRB if the researchers plan to use patients' health information in addition to the tissue. In this case, the research plan will describe how the researchers will keep released information private.
- The BioRAC or IRB must approve the research plan before any tissue is released.
- The researchers will be primarily at Houston Methodist but the tissue or information from research on it may be shared with researchers from other universities and private companies.
- At Houston Methodist, your tissue will only be used for research and will not be sold.

Will this tissue be used for genetic research?

This tissue could be used for genetic research or the study of genes. A gene is made from a long chain of molecules in cells called DNA. The molecules are arranged in pairs. The order of the pairs is called "DNA sequencing". Every person has a unique combination of molecule pairs so it is called a genetic code. Researchers are trying to find out if certain codes are linked to diseases.

- Researchers may release the genetic code information to public databases on the Worldwide Web.
- Only genetic code information will be released. Your name or personal information that could identify you will not be released.
- Researchers and others can search these databases for codes that may be linked to certain diseases.
- There is a very small chance that the genetic code could be traced to you. This is only possible if another specimen or information that was already linked to you could be compared to all the information in the database.



What are the possible benefits to you or to others?

There will be no direct medical or personal benefit to you as a result of donating the tissue. The research may benefit other people in the future.

What are the risks?

- There are no medical risks to you.
- Genetic studies may have results that are unique and individual to you and there is a small possibility that it could still be linked to you in the future even though personal information is removed from the sample. A new law prevents employers and health insurers from using genetic information to make hiring or insurance decisions.
- Your tissue could be used in research you would find personally objectionable. It is impossible to predict what kinds of research could be performed in the future. Some research may be controversial or sensitive and you will not be able to select in which research your tissue might be used. When you agree to donate tissue, you agree to allow Houston Methodist, its researchers and collaborators to use the tissue in any research that the hospital IRB committee approves.

Are there any financial considerations?

- There will be no cost to you if you decide to donate tissue.
- You will not be paid for your tissue.
- If a commercial product is developed from a research project that used your sample, the commercial product will be owned by the sponsor and you will not receive any money or rights to the product.

How will your privacy and the confidentiality be protected?

Houston Methodist Tissue Bank personnel will take careful steps to prevent private information that could identify you from being released.

- Personal information will be taken off any record associated with your tissue before it is studied.
- A code number will be assigned to the tissue.
- Researchers may publish or present their research results in scientific journals or at scientific meetings but will not include any information that will let others know who you are.

How long will you participate and will you be contacted?

If you agree to donate your tissue, it will be saved after the testing for your care is completed. You will not need to do anything and no further participation is required. However, there might be situations when additional information is needed. If you agree to be contacted, the tissue bank may give your contact information to committee-approved researchers.



AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

By signing below, you consent to the use of your excess tissue/blood/body fluid/cell samples and authorize the use and disclosure of your personal health information for research as described in the previous pages.

I have voluntarily agreed to donate my tissue, blood, bodily fluids or cells ("tissue") to Houston Methodist to be used for medical research. I understand that Houston Methodist will not condition treatment, payment, or enrollment or eligibility for benefits (as applicable) on whether I agree to this authorization. As part of this donation, I understand and agree that Houston Methodist may use my personal health information in conducting medical research on my tissue. It may also release my personal health information to other researchers or institutions, or to government agencies, as part of Houston Methodist's research. Finally, I understand that Houston Methodist may release my personal information to other researchers or institutions who may wish to conduct their own research on my tissue.

This authorization is valid until all research activities directly or indirectly related to the tissue bank program of Houston Methodist are terminated, or until I revoke it. I understand that I may revoke this authorization at any time and any identifiable tissue that has not been released from the tissue bank will be destroyed. I understand that the revocation will not apply to information that already has been released or actions that have already been taken in response to this authorization. I understand that if I revoke this authorization, I must do so by contacting Dr. Blythe Gorman, or her designee in Houston Methodist Department of Pathology at 713-441-6409 or write to the Pathology Department MS 205, 6565 Fannin, Houston, TX 77030. I have a right to request a copy of any of my health information that is released under this authorization.

I understand that other researchers or institutions to which Houston Methodist may release my health information may not be covered by Federal or Texas privacy laws. As such, my information may not be protected under these laws once it is disclosed and, therefore, may be subject to re-disclosure or use by such individuals or institutions.

I will be given a copy of this form to keep.

INITIAL HERE if you agree to be contacted by researchers if additional information is needed.

Signature of Subject or
Legally Authorized Representative

Date

Time

