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Informed Consent
Risks and Complications Associated with Surgery

There are risks and complications associated with any type of procedure, surgery or treatment. The frequency, degree, and magnitude of complications are related to the magnitude of the surgery, location in the body where the surgery is being performed and, patient specific factors/characteristics. In general, the larger or greater the magnitude of the surgery, the greater are the risks and complications; the larger the tumor to be removed, the greater the risk and magnitude of complications associated with the surgery. Medicine and surgery are not exact sciences. They are based on statistics. While most patients may achieve similar good results, there are patients whose results may differ and may be poorer than the majority of patients because of multiple, uncontrollable patient specific factors as well as other unknown factors. Each patient is unique and different. In fact, there have been instances where I have done the same operation on the same day on 2 healthy patients of the same sex, similar age and body habitus. One patient completely rehabilitated and achieved a perfect result by 6 weeks after the surgery. The other patient took 9 months to almost completely rehabilitate and regain full range of motion. This patient took 9 months to achieve a good result (not perfect, but what I consider good). The reason for the differences in recuperation, rehabilitation and the ultimate result between these two patients remains unknown and probably has something to do with other patient specific factors.

The possible risks and complications associated with your surgery, include but are not limited, to those listed below. Additional surgery is sometimes necessary to treat a complication. The following is a list of possible complications. The risk of these complications varies with the type and magnitude of the surgical procedure, your overall health as well as other factors.

Infection of Bone or Soft Tissues: An infection can occur after any surgery. If surgery is performed on a bone, there is a risk of developing a bone infection, also called osteomyelitis. The risk of an infection is higher in patients who are undergoing big surgeries/surgeries of large magnitude, such as those in which a large tumor is being removed. The risk of an infection is also higher if patients have been operated on in the same area previously or have received radiation to the area. A previous infection in the area predisposes to another infection. Other factors that increase the risk of infection include but are not limited to diabetes, chronic medical conditions, rheumatoid arthritis, malnutrition, old age, obesity, chronic corticosteroid (i.e. prednisone) therapy, treatment with chemotherapy, smoking, peripheral vascular disease, psoriasis, skin diseases. Patients who have a problem with their skin healing after surgery are at a higher risk for an infection. Prophylactic antibiotics are administered at the time of surgery to decrease the risk of developing an infection. If you develop a fever above 101 degrees F or redness and swelling around the incision or foul smelly drainage from the incision after discharge from the hospital you must report this to Dr Wittig's office. Infections may require treatment with antibiotics as well as additional surgery to eradicate the infection. If a metal prosthesis or implant was placed at the time of surgery, it may require removal. It is extremely rare; however, an infection may ultimately result in the need for an amputation.

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Wound and Skin Complications/Failure of the Skin to Heal/Skin Necrosis/Skin Death: Wound healing problems are also a possibility after any surgical procedure. The same factors listed above as increasing the risk of an infection in a patient also increase the risk of a wound healing problem. Wound healing problems and skin death or necrosis occur more commonly when larger tumors are removed. With some procedures that are of extreme magnitude, a wound complication can be assumed to occur almost all of the time. Skin healing complications are also more common when tumors are removed from around the knee, shin bone or ankle. Wound necrosis also predisposes a patient to developing an infection. There are several ways that a wound problem may need to be treated depending on the extent. Treatment may vary from a simple debridement and changing dressings several times a day to placing a special dressing called a VAC dressing (vacuum assisted closure) to an actual surgical procedure. Multiple procedures may be required to get the wound to heal. Skin grafting and/or muscle flaps are also occasionally necessary depending on the type of surgery and extent of wound necrosis.

Bleeding: It is essential that patients stop any blood thinners several days before an operation. Patients consult their medical doctors about stopping and restarting their blood thinners. Likewise, aspirin, motrin, ibuprofen, naprosyn and other NSAIDS interfere with platelet function and should be stopped a week before surgery. Any other types of platelet inhibitors, like Plavix, should also be stopped prior to surgery. Vitamin E and Fish Oils also increase the risk of bleeding and should be stopped one week prior to surgery. Please consult your medical doctor to see if you are on any other medications that may increase your risk of bleeding. The risk of bleeding from a procedure is increased if you have had chemotherapy or if the area has been treated with radiation. It is also higher with specific tumors such as kidney cancers and thyroid cancers. There is a higher risk of bleeding associated with removal of pelvic tumors and when operating in areas that have previously undergone surgery. You may require blood transfusions depending upon how much you bleed at the time of surgery. Bleeding into the wound can also occur postoperatively. When this occurs, the collection of blood in the wound is called a hematoma. A hematoma can lead to wound healing problems, pain, swelling, nerve problems and infection.

Nerve Dysfunction or Paralysis: Anytime surgery is performed on an extremity (arm or leg) tissues are placed on traction that could result in nerve dysfunction or paralysis. This can result in sensory changes/loss of sensation or chronic pain in the extremity as well as muscle weakness or paralysis of muscles supplied by the nerve. If dysfunction or neuropraxia of the sciatic or peroneal nerve occurs, it can result in a foot drop (inability to lift the foot off the ground). When operating on an arm, dysfunction of the radial nerve can result in the wrist weakness, wrist drop or paralysis. In most cases, the nerve dysfunction is temporary and the nerve usually recuperates within 6 months of the surgery. Rarely, the dysfunction is permanent. Sometimes a tumor, or scar tissue from the tumor, may involve the nerve and the nerve may need to be removed with the tumor. Sometimes this can not be anticipated by preoperative radiology studies but can only be determined during the actual surgery. In this case the nerve dysfunction is permanent. When an incision is made, the local sensory nerves are cut, which results in numbness around the incision that is usually temporary but may take up to 2 years to improve. Diabetes, previous surgery in the area, radiation to the area, scar tissue, chemotherapy, larger surgeries all predispose to nerve dysfunction after surgery.

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Blood Vessel Injury and Dysfunction: There is always a risk that a blood vessel may be injured during surgery when the tissues are placed on traction. Extreme care is taken to protect the blood vessels and nerves during the procedure. Even though extreme care is taken, there is always a risk that a blood vessel may be transected during the surgery. This is especially true if the blood vessel is surrounded by scar tissue or stuck to a tumor. Arteries can also go into spasm and develop clots especially during or after surgeries of large magnitude that require manipulation of the artery. This can result in ischemia to the extremity and require intervention by a vascular surgeon or interventional radiologist. Sometimes, a tumor may completely wrap around the blood vessel and may require removal of the blood vessel with the tumor. This often can only be determined during the surgery or intraoperatively. If a major blood vessel is transected or injured during the surgery, it may be essential to call a vascular surgeon to the operating room to repair the problem. If the blood vessels are removed with the tumor, it may be essential for a vascular surgeon to reconstruct or repair the blood vessels or to undergo an amputation. There is always a rare risk of needing an amputation if a blood vessel is injured.

Blood Clots/Thromboses/Pulmonary Embolus: Anytime surgery is performed or a patient requires a general anesthetic, there is a risk of developing a blood clot in the veins. This is called a thrombosis. The thrombosis may develop in the extremity being operated on or in one of the other extremities. The most common site is the veins in the legs. When a blood clot travels to the lungs, it is called a pulmonary embolus. A pulmonary embolus can be life threatening. Persistent swelling in an extremity that does not improve with elevation or during sleep at night especially if associated with pain in the calf, may be a sign of a blood clot and should be reported to Dr Wittig's office. Shortness of breath, difficulty breathing, an unexplainable fever or rapid heart beat may be a sign of a pulmonary embolus. If you have difficulty breathing you should call 911 and inform Dr Wittig. Anticoagulants may be given after surgery to decrease the risk of developing a blood clot. Anticoagulants are not administered to everyone. There are bleeding complications associated with giving anticoagulants. Large surgical procedures are already at a high risk of bleeding into the wound postoperatively. It may not be appropriate to administer an anticoagulant to a patient who has undergone a major, limb sparing surgical procedure. Bleeding into the wound could result in the patient losing the extremity or requiring an amputation. Obesity, previous surgical procedures, cancer as well as other coagulation abnormalities increase the risk of a blood clot.

Joint Stiffness Next to the Area Undergoing Surgery: Anytime an incision is made on an extremity, changes occur in the nervous system that affects the way muscles are innervated. It is a protective mechanism. This combined with swelling from surgery, muscle retraction, presurgical pain, muscle atrophy and preexisting joint stiffness lead to joint stiffness in the operated extremity after surgery. Rehabilitation will be needed after surgery to decrease the stiffness and improve the motion of the joints. It will take longer than usual if you had preexisting pain, muscle weakness, joint stiffness or muscle atrophy especially if you have had it for a prolonged period before surgery.

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Previous surgery, radiation, malnutrition, and obesity also increase the risk of stiffness after surgery. It usually takes at least 6-8 weeks after surgery for the nervous system to begin functioning normally again so that a patient can start to regain motion and then make gains in strength.

Muscle Weakness and Stiffness: Surgery on an extremity results in muscle atrophy and weakness. Larger surgeries result in more weakness and atrophy. Surgery makes preexisting weakness and atrophy worse. Rehabilitation is necessary after most surgical procedures. While most people recuperate their strength within 3-6 months, patients who undergo particular types of surgeries may require up to a year to fully rehabilitate. Depending on the surgery, especially if a significant amount of muscle is removed at the time of surgery or if a large part of the bone and joint are replaced, there may be a very prolonged period of rehabilitation and patients may never regain full motion or strength in the extremity. Much depends on patient participation in rehabilitation however there are instances because of the location and size of the tumor that the patient may never fully recuperate to normal. Malnutrition, radiation, chemotherapy, cancer, chronic medical illnesses, previous surgeries in the area and diabetes, as well as other surgery related complications increase the risk of permanent muscle weakness and atrophy.

Chronic Pain/Nerve Pain/Reflex Sympathetic Dystrophy: Pain always occurs after a surgical procedure. In most cases, the pain dissipates over the course of time and usually resolves completely or almost completely. Sometimes, however, the pain persists for various reasons like scar tissue formation, muscle and joint stiffness and muscle atrophy, other pre-existing conditions like arthritis, nerve irritation and previous radiation therapy. If major nerves need to be moved and placed on traction during surgery, the nerve can become irritated and painful. Most nerve pain will dissipate over the course of a few months. Rarely, the nerve pain becomes a chronic problem. Reflex sympathetic dystrophy (RSD) also known as causalgia is a rare pain syndrome that can occur after any type of surgery. It results in chronic pain, swelling, muscle atrophy, joint stiffness and skin changes. RSD, nerve pain and chronic pain may require special medications or procedures for treatment on a chronic basis. Rehabilitation is helpful in preventing and alleviating chronic pain and pain syndromes.

Bruising and Swelling: Bruising and swelling occur after any operation. They usually disappear within 6-12 weeks after most typical surgeries. Swelling may become chronic with certain procedures such as those in which a large tumor is removed; after having lymph nodes removed; as a result of previous radiation or radiation after surgery; in an extremity that has been operated on previously. Chronic swelling can result in lymphedema that can be debilitating. If lymphedema develops, special therapy will be needed to help control, minimize or eradicate the lymphedema.

Amputation Related Pain/Phantom Limb Pain: When an extremity is amputated, the nerves are cut. After an amputation almost everybody feels as though the amputated part is still there. This is called phantom limb sensation. If this sensation is painful, it is called phantom limb pain. Approximately 15-20% of patients develop some degree of phantom limb pain after an amputation. The phantom limb pain may or may not last their entire life.

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Special medications or procedures may be necessary if phantom limb pain develops. Phantom limb pain is more common in patients who have had pain in the extremity prior to the amputation and in patients previously treated with radiation or chemotherapy.

Leg or Limb Length Discrepancy: Whenever a metal prosthesis (artificial bone or joint) is placed in the body there is always a chance that there will be a limb length discrepancy. In some instances, particularly when a large prosthesis is placed after removing a tumor, the extremity may be shortened purposely to prevent undue traction on nerves and blood vessels that can result in dysfunction or injury. Alternatively, sometimes an extremity may be lengthened to accommodate for growth of the other extremity; to enable the prosthesis to function properly; to prevent prosthesis from dislocating. Fixation of some fractures may result in shortening or lengthening of the extremity. A shoe lift may be required after surgery. Tumors that occur next to children's growth plates can result in the growth plate closing (stops functioning). This can result in angular deformity or shortening of the extremity. Additionally, surgery on a child who is still growing can result in more rapid growth of the growth plates. This can result in overgrowth to the extremity lengthening, leg length discrepancy or angular deformity may require surgical correction.

Blood Transfusion Related Complications

Failure of Hardware: Anytime hardware (plate, screws, wires, pins, intramedullary rods) is placed to fix a fracture of a bone or hold a bone together, the hardware may break inside the patient. If the bone does not heal, the hardware will ultimately break. This may or may not require additional surgery. If an external fixation device is placed, there is a risk that the pins can loosen or become infected. The external fixation device can also fail. Hardware can also get infected and require surgical removal.

Failure of a Bone or Fracture to Heal/Nonunion of the Fracture/Malunion: This can occur especially in Cancer Patients, patients treated with radiation and chemotherapy, diabetics, patients with neuropathy, smokers, malnourished patients, elderly, and patients with chronic medical conditions. It may require additional surgery or other treatments to get the bone to heal.

Bone Graft Related Complications: When your own bone is utilized as a bone graft there can be pain at the bone graft harvest site; infection can occur and the bone may fail to heal. When donated bone is utilized there is an extremely rare risk of HIV and Hepatitis transmission. The donated bone has a risk of not healing that is greater than the risk of not healing with your own bone in most cases (except in the case of treating fibrous dysplasia)

Anesthesia Related Complications: Nausea and vomiting are the most common complications. These can help be controlled with medication after surgery. There are additional potential complications that will be discussed with the anesthesiologist.

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Medication Related Complications and Allergic Reactions

Cardiac, Pulmonary, Kidney, Urinary Tract, Prostate, Gastrointestinal Tract Complications and Dysfunction

Admission to an Intensive Care Unit

Fracture of the Bone (Intraoperative or Postoperative): Anytime surgery is performed on a bone or a bone or joint is manipulated, there is a risk of the bone fracturing. In most situations this is a very small risk but if it occurs, additional procedures may be necessary intraoperatively including placing metal fixation devices. Additional surgeries may be required in the future, especially if the fracture does not heal.

METAL ENDOPROSTHETIC COMPLICATIONS/TOTAL JOINT RELATED COMPLICATIONS/ COMPLICATIONS ASSOCIATED WITH PLACEMENT OF AN ARTIFICIAL METAL BONE AND JOINT:

Loosening of the Prosthesis: Overtime the prosthesis may mechanically loosen. The interface between the prosthesis and bone may become loose. This may cause pain and the prosthesis can break. Surgery may be required to redo (revise) the prosthesis and place a new prosthesis. The revision surgery is more difficult and the revision prosthesis may not function as well as the original.

Bone Loss: There can be bone loss around a prosthesis that can lead to loosening and failure. Bone loss may need to be addressed at the time of surgery with a bone graft, cement or a larger/longer prosthesis, if surgery needs to be done again. Rarely bone loss can be so severe that an amputation is needed for treatment.

Infection of the Prosthesis: Anytime a foreign body is placed in the human body, there is a risk it can become infected at any point in time. Antibiotics will need to be taken around the time of any dental procedures including teeth cleaning. Antibiotics will also be needed around the time of any other surgeries. The prosthesis may need to be removed if an infection develops. Multiple surgeries may be necessary to eradicate the infection and place a new prosthesis. Rarely an infection will be impossible to eradicate and the patient will need an amputation.

Breakage of the Prosthesis or its Parts: A prosthesis is an inanimate object. It does not have the ability to heal like a normal bone or joint. It is usually made of metal and plastic pieces. Any of these pieces can break over the course of time. Breakage will result in malfunction of the prosthesis and will probably require additional surgery to replace broken parts or change the entire prosthesis.

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Dislocation of the Prosthesis: This occurs most commonly with prostheses around the hip and shoulder. Certain guidelines will need to be followed postoperatively to minimize the risk of a dislocation. Dislocations are more common with revision surgeries especially revision hip replacements. The patella can dislocate after a knee, proximal tibia or distal femur replacement.

Stiffness of the Joint; Muscle Atrophy; Weakness; Nerve Dysfunction: Joint stiffness may require a manipulation of the joint or surgery to remove scar tissue that is blocking the joint from moving correctly. These complications are more common with revision surgeries, infections, patients who form a lot of scar tissue, previous treatment with radiation or postoperative treatment with radiation.

Limb or Leg Length Discrepancy

Revision of the Prosthesis/Removal of the Prosthesis: Whenever a prosthesis is revised, meaning the old one is removed and a new one placed, the new prosthesis may not function as well as the old prosthesis functioned.

Cryosurgery Complications: Skin burns, skin necrosis, blistering, change in skin pigment, bone necrosis, failure of a fracture to heal, fracture of the bone, arthritis in the adjacent joint, failure of hardware, tumor recurrence, infection, nerve dysfunction, blood vessel dysfunction.

Tumor Recurrence: (the tumor can come back) may require additional surgery or ultimately require an amputation for treatment. Tumor recurrence can lead to other problems in the extremity including a fracture or failure of metal hardware. Depending upon the type of tumor, it could even lead to death.

Radiation or Chemotherapy Related Complications

Please be advised that any prosthesis related complication may require removal of the prosthesis, multiple surgeries, replacement of a new prosthesis and even possibly an amputation. A tumor or infection can come back or recur after being treated. This may require multiple surgeries or even an amputation for treatment. There are instances when a tumor comes back and can not be removed even with an amputation. Please also be advised that preoperative radiological studies (MRI, CT Scans, X-rays, Bone Scans, Arteriograms, Venograms, etc) do not always correlate with what is encountered intraoperatively. Depending upon what is seen intraoperatively, the surgical plan may need to be altered. Additional unforeseen procedures may be needed at that time or in the future. The surgery may need to be modified. It may be discovered that the tumor can not be removed or that an amputation is needed to remove the tumor instead of a limb preserving surgery. Once a tumor is removed and thoroughly analyzed it may be found that the actual diagnosis from the final specimen does not correlate with the interpretation from the biopsy. Remember,

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the biopsy is sampling only a small piece of the entire tumor. When the entire tumor is analyzed it may be found that the tumor is more aggressive than initially thought and the overall diagnosis and anticipated prognosis may be different than originally determined. This scenario occurs in less than 5% of cases but is still possible. If the final diagnosis after examining the entire specimen is different than the biopsy result, additional surgery and even possibly an amputation may be needed for adequate treatment.

It may also be discovered after the final tumor is analyzed that microscopic residual tumor was left behind and additional surgery may be needed even possibly an amputation depending on the diagnosis.

It is important to understand that many of these risks and complications occur infrequently however if any do occur, the patient may require additional surgical procedures and the complication(s) may compromise the final outcome, result, or prognosis. Some of the complications occur rarely however some occur very frequently with procedures of large magnitude (like wound healing problems with large procedures) All risks are higher and complications occur more frequently and may be greater or more serious in the elderly patients; smokers; patients who have received chemotherapy; patients who have received radiation therapy; patients with poor nutrition; diabetics; immunocompromised patients; patients with chronic obstructive pulmonary disease; patients with other chronic medical problems or who are taking chronic medications; patients taking steroid medications like prednisone. Some complications may require an amputation for treatment and can rarely result in death. Death and amputation are extremely rare outcomes/risks/complications and are unlikely to occur. It is important however that the patient be informed of any possible complication no matter how rare the risk.

Please sign that you understand the above list of risks and complications and that all your questions have been answered regarding the surgery that you have been scheduled with Dr. James C. Wittig. By signing, you willingly agree to undergo surgery. You also agree to release Dr. James C. Wittig from any and all liabilities and legal claims that may occur as a result of, in conjunction with or in relation to the surgical procedure and/or any complications that develop as a result of, in conjunction with and/or in relation to the surgical procedure. You also understand that during the time of surgery additional procedures may be required that were not anticipated prior to surgery. You grant Dr. James C. Wittig full permission to perform any and all procedures that he deems necessary at the time of surgery.

Patient Signature Date