



INFORMED CONSENT

Please read the following carefully and sign that you fully understand the risks. If you have any questions or do not understand the following information, please ask your physician during your consultation.

ANESTHESIA: General anesthesia comes with related risks, all of which are discussed during your appointment. Some may range from common risks such as damaged teeth, hoarse voice, allergic reactions to drugs, damage to the nerves, or asthma attacks. Other more serious related risks include stroke, heart attack, kidney or lung damage, paralysis, or even death.

OBESITY (BMI>40): In any operative case, increased body mass increases complication rates across the board, specifically infection, hematomas, delayed healing, venous thromboembolism, and even death. If a patient's BMI is greater than 40 (calculated in consultation), we may require additional medical clearance before we can determine if surgery is an option. Be aware, the weight limit for our outpatient surgery center is a BMI of 40 +/- 5%. Weight gain increasing BMI > 5% of 40 may jeopardize your scheduled procedure. A patient may be referred to their primary care physician for a weight loss consultation, and we may ask a patient to consider weight reduction surgery.

NICOTINE USE: Patients are advised that any result that they wish to achieve from surgery would be significantly improved by not smoking or using nicotine from 6 weeks prior to the procedure and for 6 weeks afterward. Each patient should acknowledge that continued nicotine use significantly increases the likelihood of a local wound complication, to include but may not be limited to: infection, hematoma, compromise of any implant, and suboptimal quality of the scar once definitive healing is obtained. This is aside from any pulmonary sequelae or other more serious risks of general anesthesia. Complication rates are increased approximately 12-24 times with nicotine use. If you suffer complications that require additional care, you will be subject to charges for that care, as it is not covered in your quote. You may be offered a surgery today based on tobacco/nicotine cessation and the use of our "Tobacco/Nicotine Protocol." Among other specifics, this policy allows for cancellation of any surgery with **NO REFUND** if you **test positive** during the urine cotinine test on the **morning of surgery**.

BREAST SURGERY PATIENTS: Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a very rare type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This very rare disease is currently being investigated as to its relationship with breast implants. The family of ALCL is an extremely rare cancer of the immune system, which can occur anywhere in the body. Based on adverse event reports, the United States Food and Drug Administration (FDA) estimates the total number of US cases of BIA-ALCL to be up to 250. A predominance of BIA-ALCL patients have been noted to have a history of textured surface devices. An exact single-number estimate of the risk for both textured and non-textured implants is not possible with the currently available data. The lifetime risk of BIA-ALCL has been estimated to be between 1:1,000 and 1:30,000 in women with textured breast implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves a swelling of the breast, on average 3 to 14 years after the operation to insert the breast implant. Most cases were cured by removal of the implant and capsule surrounding the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment. Patients with breast implants should be followed by a surgeon over time and seek professional care for implant-related symptoms such as pain, lumps, swelling, or asymmetry. Patients should monitor their breast implants with routine breast self-exams and follow standard medical recommendations for imaging (e.g., mammography, ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional costs and expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include, but may not be limited to, obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement. **Continued on next page!**

Breast implant-associated illness (BIAI) is a term used to refer to a wide range of symptoms that can develop after undergoing reconstruction or cosmetic augmentation with breast implants. It is also sometimes referred to as autoimmune/inflammatory syndrome induced by adjuvants (ASIA). BIAI can occur with any type of breast implant, including silicone gel-filled, saline-filled, smooth surface, textured surface, round, or teardrop-shaped. BIAI impacts each individual in a unique way. Symptoms can include joint and muscle pain, chronic fatigue, memory and concentration problems, breathing problems, sleep disturbance, rashes and skin problems, dry mouth and dry eyes, anxiety, depression, headaches, hair loss, and gastrointestinal problems. The symptoms can appear any time after implant surgery. A lot of the symptoms of BIAI are associated with autoimmune and connective tissue disorders. In many cases, surgery to remove the breast implants improves or completely resolves the BIAI symptoms.

Additional COVID-19 Consent

In the current environment with COVID-19 infections, the risks of any planned procedure are incalculable. Although we have practiced social distancing and proper screening of all patients in the building and that staff has subscribed to the same social distancing and screening requirements (i.e., symptom and exposure reporting, temperature checks, and the wearing of masks), it is probable that the risk of a COVID-19 infection, asymptomatic or symptomatic with a pulmonary complication from the procedure, is higher than current community transmission rates (as of this time, there is no screening test that we can offer asymptomatic patients). Indeed, hospitalization may be required, of which we have little or no control. Our understanding of your informed consent is that you wish to proceed with the consultation at this time, given the discussion above. Updates regarding our COVID-19 policies will be made as available.

Patient signature: _____ Date: _____