

PATIENT / DOCTOR CHECKLIST

For the Patient Considering Breast Implants

ACCEPTANCE OF RISK AND INFORMED DECISION ACKNOWLEDGEMENT

This document may not be altered in any way and represents this patient's legal rights for informed consent

NOTE: In order to attain a successful 'Acknowledgment of Informed Consent', this important record is to be signed by both the patient and the surgeon and retained in the patient's file

The review and completion of this form is a critical step in helping you decide whether to have breast implants. You should carefully consider the benefits and risks associated with breast implants before you make your decision. After reviewing **this document** and the Manufacturer's Patient Information Booklet provided by your Surgeon, please read and discuss the items in **this checklist** with your Surgeon. **You should not initial or sign the document and should not undergo the procedure if you do not understand each of the sections listed below.**

MANUFACTURER REQUIREMENTS

Safety studies contingent for Health Canada's approval have not yet been completed.

WARNING: Breast implants carry Health Canada's highest risk rating (class IV) with known serious and sometimes fatal complications.

WARNING: Man made cancers resulting from implants occur at 1 - 450 user ratio. Known cancers are, Breast Implant Associated – Anaplastic Large Cell Lymphoma (T Cell), and (B – Cell) Cancers.

WARNING: All implants fail over time.

WARNING: Compliance with Canada's regulatory requirements (Health Canada's 'license' to sell the product) does not mean the product is safe or effective or that it is made as claimed by the manufacturer.

WARNING: The long-term effects are irreversibly injurious and disfiguring.

WARNING: Costs associated with the use of the products and the treatment of complications it engenders, will be elevated and disallowed by public health care services insurers (Provincial 'Medicare').

WARNING: Key chest structures adjacent to prosthesis, upper chest anatomy (lungs, heart) are compromised by failed implants.

WARNING: Gel migration, once occurred cannot be retrieved from lymph nodes and major organs.

WARNING: Mechanical changes due to deterioration and degradation of synthetic prosthetic material can cause systematic distress including Scleroderma-like and Lupus-like diseases which may be initiated or exacerbated by implant related phenomena.

MY ACKNOWLEDGEMENT :

I have received a copy of the **Patient Information Booklet provided by the Manufacturer** and have had time to read & understand that document and have been given the opportunity to ask my Surgeon questions about the information contained in the Booklet.

I understand Breast Implants may not be my only option and that there are alternatives to Breast Implants including mastopexy (breast lift) and/or fat transplant.

I understand that all surgical procedures may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain. I understand that Breast Implants are rated Class IV medical devices by Health Canada (highest risk rating) and the devices have known failures and complications, many of which are serious and have sometimes been fatal.

I understand that all Breast Implants have a silicone shell. When exposed to the body, silicone can be endocrine disruptive, cytotoxic, neurotoxic and inflammatory to healthy cells.

I understand that having breast implants can increase my risk of having symptoms related to Breast Implant Illness (BII). BII is an illness caused by the body's immune response to breast implants and their ingredients.

I understand informed consent is only possible with complete disclosure of ingredients by the manufacturer of my implants. A listing of these ingredients for each Canadian Manufacturer is shown in Appendix One.

I understand there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

Patient Initials _____

CONTRAINDICATIONS FOR GETTING BREAST IMPLANTS

- Women with active infection anywhere in their bodies
- Autoimmune disease, Weakened immune system
- Existing cancer or precancer of their breast who have not received adequate

treatment for those conditions

- Recent Chemotherapy, Radiation
- Certain Genetic Predispositions (MTHFR Mutation, HLA-B27)
- Women who are pregnant or nursing
- Chemotherapy following breast implant placement
- Radiation therapy to the breast following breast implant placement
- Patients with clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. These patients should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

Patient Initials _____

BREAST IMPLANT LIFE EXPECTANCY

I understand that breast implants are time-limited devices and that I will need additional surgeries to remove or replace the implants, and to address possible complications. Surgeries may be at my own expense and not covered by health insurance.

I understand that removing or replacing implants is recommended after 10 years, but implants may fail sooner, and I may experience complications at any time after the implants are placed.

I understand that undergoing multiple surgeries can increase my chances of nerve damage, breast deformity and scarring that can be irreversible.

I understand that the rate of complications increases with each surgery. Chest wall damage is possible especially for reconstruction patients.

Patient Initials _____

FOLLOW UP CARE

I understand that I cannot have Breast Implants placed and forget about them. I will require annual follow-up visits with my plastic surgeon. Routine High Definition Ultrasound or MRI is recommended after three years and every two years following. MRI's should be done without 'dye contrast' (Gadolinium) and recommended MRI obligations will possibly be at my own expense.

Patient Initials _____

PRECAUTIONS

Breast Implants are rated Class IV medical devices by Health Canada (highest risk rating) and the devices have known failures and complications, many of which are serious and have sometimes been fatal.

Mammography: If you have breast implants, routine mammograms will require additional, specialized views and can cause **rupture**.

Breast implant examination techniques for rupture can yield False positives / negatives

Smoking: Delays Wound Healing / Can cause blood clots and cardiopulmonary post operative complications.

Effects on offspring: Health Canada has received reports of damaging effects on children born to mothers with breast implants, and breastfed infants.

Reconstruction re Post-Mastectomy Surgery: Increased incidence of complications and re-operation.

Revision and Replacement Surgeries: Increased incidence of local complications such as pain, infection, capsular contracture, requiring additional surgery or explantation

Financial burden: Multiple surgeries, increased medical insurance costs, and lost wages.

Patient Initials _____

RISKS OF SURGERY

I understand that all surgical procedures may involve the risk of complications such as the effects of anesthesia, infection, pain, swelling, bleeding / haematoma (which may require surgical intervention and/or blood transfusion); blood clots; infection; scarring (Keloid); allergic reaction to the anesthetic.

Patient Initials _____

SPECIFIC POPULATIONS

Safety and effectiveness have not been established in patients with:

- Autoimmune diseases (e.g., lupus and scleroderma)
- A compromised immune system (e.g., currently receiving

immunosuppressive therapy).

- Patients with conditions or medications which interfere with wound healing ability (e.g., poorly controlled diabetes, or corticosteroid therapy) or blood clotting (such as concurrent coumadin therapy).
- Reduced blood supply to breast or overlying tissue
- Patients undergoing radiation therapy and chemotherapy

Patient Initials _____

BREAST IMPLANT ILLNESS SYMPTOMS (BII)

I understand some women with breast implants have experienced signs and symptoms that could be related to the immune system but that do not fit into any specific definable disease. BII cannot be ruled out even if blood test results are within normal range.

There are two basic types of breast implants: saline and silicone gel. Both have an outer silicone shell. Both are associated with risks and potential for BII.

I understand CTD (Connective Tissue Disease) symptoms have been reported. CTD's are caused when the patient's immune system mistakenly attacks parts of its own body tissues or cell types, including the connective tissues of the body, like fibrous tissues (tendons), cartilage and bones.

Lupus - inflammation and tissue damage in different body parts and organs

Rheumatoid Arthritis - inflamed and deteriorating joints

Polymyositis - inflamed, weakened muscles

Dermatomyositis - inflamed, weakened muscles or skin

Sclerosis & Scleroderma - damaged skin or organs because of excess collagen, the main protein in connective tissue

Fibromyalgia – ongoing fatigue, widespread pain in muscles and joints, difficulty sleeping and morning stiffness

Chronic Fatigue Syndrome – ongoing mental and physical exhaustion, often with muscle and/or joint pain

Patient Initials _____

I understand that Auto-Immune system problems such as those mentioned below have been reported:

Graves Disease - an immune system disorder that results in the overproduction of

thyroid hormones (hyperthyroidism)

Hashimoto Thyroiditis - a condition in which the immune system attacks your thyroid. The thyroid gland is part of your endocrine system, which produces hormones that coordinate many of your body's functions. Inflammation from Hashimoto's disease often leads to an underactive thyroid gland (hypothyroidism).

Multiple Sclerosis - the immune system attacks the protective sheath (myelin) that covers nerve fibers and causes communication problems between your brain and the rest of your body. Eventually, the disease can cause permanent damage or deterioration of the nerves.

Raynaud's Syndrome - causes some areas of the body (eg fingers and toes) to feel numb and cold in response to cold temperatures or stress. Smaller arteries that supply blood to the skin narrow, limiting blood circulation to affected areas (vasospasm).

Rheumatoid Arthritis - an autoimmune disease, in which immune cells attack and inflame the membrane around joints. It also can affect the heart, lungs, and eyes.

Sjogren's Syndrome - a disorder of your immune system identified by its two most common symptoms - dry eyes and a dry mouth. The condition often accompanies other immune system disorders, such as rheumatoid arthritis and lupus.

Ulcerative Colitis - a severe inflammatory bowel disease (IBD) that causes long-lasting inflammation and ulcers (sores) in your digestive tract

Lymphadenopathy Syndrome - a condition occurring in immunocompromised individuals, characterized by unexplained lymphadenopathy for 3 or more months that involves extralingual sites, which on biopsy reveal nonspecific lymphoid hyperplasia.

Patient Initials _____

I understand Neurological Symptoms such as those listed below have been reported:

- Tingling / numbness
- memory problems / memory loss
- Headaches / migraines
- Burning sensation
- Vision problems / blurred vision
- Brain fog / cognitive dysfunction
- Seizures / body jerking / tremor / involuntary movement
- Balance / walking problems / dizziness / vertigo

Patient Initials _____

OTHER SYMPTOMS REPORTED TO HEALTH CANADA by women with breast implants include:

<ul style="list-style-type: none"> ● Chronic inflammation ● Breast pain ● Burning / itching in breast ● Cold breasts ● Joint pain ● Flu-like symptoms ● Depression ● Respiratory issues / Difficulty breathing / COPD / Lung Damage / Pulmonary fibrosis ● Throat clearing/ Cough, Choking feeling, Reflux, Metallic tastes ● Liver dysfunction (fatty liver, enlarged liver) ● Esophageal motility disorder ● Laryngospasm ● Difficulty swallowing ● Choking feeling ● Tinnitus (ear ringing) ● Digestive / Abdominal issues / Bloating / Pain / Food intolerances ● Gastrointestinal issues such as acid reflux, GERD, Gastritis ● Adrenal Gland Disorders ● Fatigue ● Premature aging ● Low libido ● Muscle weakness / Muscle pain ● Suicide ● Anxiety / Panic attacks ● Gallbladder problems ● Pancreatitis ● Loss of nipple sensation 	<ul style="list-style-type: none"> ● Lumps / masses / lesions / cysts / lipomas ● Silicone granulomas ● Dry eyes / dry mouth / tooth decay / inflamed gums ● Red eyes ● Cold hands and feet ● Allergic Hypersensitivity ● Overactive Immune response ● Insomnia / Poor sleep ● Heart Palpitations ● Frequent infections (sinus infections, urinary tract infections, yeast infections) ● Bladder spasms ● Frequent urination ● Miscarriage ● Swollen glands or lymph nodes ● Lymphedema ● Feeling like you're dying ● Parathyroid problems ● Skin rash ● Reddened swollen skin ● Swollen hands and feet ● Weight changes ● Heaviness in chest ● Slow healing ● Bruising easily ● Neck & Shoulder pain ● Hair loss ● Kidney dysfunction (impaired kidney function) <p>THIS IS NOT AN EXHAUSTIVE LIST</p>
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Patient Initials _____

I understand that if I experience any of the health conditions mentioned, I may or may not recover from said condition(s) even after proper removal of the prostheses. If my breast implants need to be removed, the surgery may not be covered by insurance.

Patient Initials_____

POTENTIAL COMPLICATIONS

Toxic shock - A sudden, potentially fatal condition; a rapidly developing toxemia caused by the bacterium *Staphylococcus aureus*

Necrosis - A type of gangrene / Skin death

Biofilms - A thin, slimy film of bacteria that adheres to an implant surface

Hematoma - A blood-filled swelling

Seroma - A seroma is a pocket of clear serous fluid that sometimes develops in the body after surgery

Pneumothorax - The presence of air or gas in the cavity between the lungs and the chest wall, causing collapse of the lung

Extrusion of implants - Is when a breast implant comes through the skin and becomes exposed

Capsular contracture - The most common reason for reoperations. Scar capsule builds around implants over time causing them to become hard and painful.

Breast tissue atrophy - loss of natural tissue in the breast breast tissue

Chest wall damage - Implants sit over vital organs including heart and lungs. Gel bleed and gel migration can cause damage of these organs. Bones and muscles in the **chest wall**, including the ribs, sternum (breastbone) can be affected by the length of implant dwell time and surgeries.

Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness.

Breastfeeding / Lactation - Changes in nipple and breast sensation may occur from implant surgery.

Following breast implant surgery some mothers find their breasts are painful and sensitive even to normal touch making breastfeeding difficult. Others may have a loss of feeling or numbness in the nipple affecting the neurohormonal reflex needed for milk production. Loss of sensation causes difficulty knowing if baby is latched on properly.

Periareolar surgical incision may further increase the chance of breastfeeding difficulties. Gel bleed / gel migration, and silent rupture can expose baby to gel toxins.

Undiagnosed implant related abscess / infection or ALCL could harm baby.

Other Complications:

Infection	Delayed wound healing	Unsatisfactory results
Mass/cyst	Asymmetry	Breast Pain
Chest Wall Deformity	Capsule Calcification	Wrinkling/rippling
Generalized Pain	Scarring	Implant Rotation
Nipple & Breast Sensation Changes	Risk of Re-operation	Death due to Metastatic Cancers

Patient Initials _____

SURGICAL MESH - Use of mesh together with breast implants has not been studied. Check with your surgeon to ensure that you will be implanted only with the product shown to you at consult.

TYPES OF SILICONE DEVICE FAILURE:

GEL BLEED - Breast implants experience gel bleed

Gel bleed refers to microscopic diffusion of silicone gel through the breast implant shell. The implant shell, made of silicone, is a semipermeable membrane that allows gel bleed. Fluorosilicone barriers do not prevent all gel bleed.

GEL MIGRATION - I understand that migrated silicone gel in my body can travel to my lungs, liver, lymph nodes and other vital organs where it cannot be removed. Silicone can migrate into nearby tissues and distant places including lymph nodes; chest wall; lungs; upper abdominal wall; armpit; thyroid; liver; ovaries; brain; cornea; down the arms and into the groin and leg.

MIGRATED SILICONE - I understand that Gel can cause granulomas (small hardened lumps of silicone) throughout the body. The long-term consequences of migrated silicone may result in future serious health complications perhaps not covered by my insurance.

GEL RUPTURE - I understand there is a chance that my breast implants can rupture. Symptoms of rupture can include breast pain; burning; underarm pain; enlarged lymph nodes; swelling; masses; rashes; itching and changes in breast shape and firmness.

SILENT RUPTURE - I understand that a silent rupture may not show classic symptoms of a ruptured implant. Therefore, a delay in prompt intervention of the implant failure could occur. This type of rupture may not be detectable by my doctor or by MRI.

GEL FRACTURE - Gel fracture can occur with vigorous manipulation of gummy-bear / cohesive-gel implants causing the filler to separate from the inside of the shell resulting in misshapen breasts and loss of implant integrity.

DELAMINATION

Delamination is when the surface of a breast implant peels off layer by layer in situ. Breast implant macro-texturing plays an important role in delamination which contributes to double capsule formation associated with late seromas and biofilms.

TYPES OF SALINE DEVICE FAILURE:

Rupture, Deflation, Rippling, Osmosis, Valve Failure, Mold, Bio-contamination

Patient Initials _____

CANCERS LINKED TO BREAST IMPLANTS

BREAST IMPLANT ASSOCIATED - ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

I understand individuals with breast implants have a risk of developing Breast Implant Associated - Anaplastic Large Cell Lymphoma. BIA-ALCL is not breast cancer. It is a manmade cancer, a type of non-Hodgkin's lymphoma (cancer of the immune system).

Textured surface breast implants, especially highly textured, are most linked to BIA-ALCL., however Health Canada reports that both silicone and saline are associated with BIA-ALCL.

Lymphomas associated with implants are predominantly of T-cell type-with anaplastic large cell lymphoma (ALCL) being most reported. B-cell lymphoma associated with breast implants have been reported.

- Brain Cancer

- Breast Cancer
- Lung / Respiratory Cancer
- Liver Cancer
- Ovarian Cancer
- Cervical / Vulvar Cancer
- Lymphohematopoietic cancer

SUICIDE

An increased risk of suicide has been reported.

LONG TERM RISKS

- Migrated silicone that cannot be removed
- Permanent destructive changes from surgery
- Permanent destructive changes from implants being in place
- BII symptoms may not fully resolve, especially when there is residual silicone

CONFIRMATION OF DISCUSSION OF RISKS

In signing this Informed Consent Document, I am indicating that I have read and understood ALL the information presented in this document.

Patient signature _____ **Date** _____

Patient print name _____

Surgeon signature _____ **Date** _____

Surgeon print name _____

Witness signature _____ **Date** _____

Witness print name _____

ELEMENTS AND HEAVY METALS

Aluminum	Mercury
Antimony	Molybdenum
Arsenic	Nickel
Barium	Phosphorus
Beryllium	Platinum
Cadmium	Potassium
Calcium	Selenium
Chromium	Silver
Cobalt	Sodium
Copper	Thallium
Iron	Tin
Lead	Titanium
Magnesium	Vanadium
Manganese	Zinc

Mentor MemoryGel™ Silicone Gel Filled Breast Implants

DEVICE MATERIALS

Component	Raw Material
Shell, inner/outer layers	Dimethyl Silicone Elastomer Dispersion
Shell, barrier layer	Diphenyl Silicone Elastomer Dispersion
Shell textured layer	MED 4750 Silicone Elastomer
Patch assembly	MED 4750 Silicone Elastomer
Gel	Silicone Gel: Base and Crosslinker; platinum cure

ELEMENTS AND HEAVY METALS

Antimony	Mercury
Arsenic	Molybdenum
Barium	Nickel
Beryllium	Platinum
Cadmium	Selenium
Chromium	Silver
Cobalt	Tin
Copper	Titanium
Lead	Vanadium
Magnesium	Zinc
Mercury	

SIENTRA SILICONE GEL BREAST IMPLANTS

COMPONENT	RAW MATERIAL
Shell, inner/outer layers	High strength silicone elastomer
Shell, barrier layer	Fluorosilicone elastomer
Spherical cap	Liquid silicone rubber
Patch sheeting	High strength silicone elastomer Fluorosilicone elastomer High consistency rubber
Silicone gel filler	High strength silicone gel
Titanium dioxide pigmented silicone ink	Liquid silicone rubber
Position indicator	High consistency rubber Titanium dioxide

ELEMENTS AND HEAVY METALS

Antimony	Manganese
Arsenic	Mercury
Barium	Molybdenum
Beryllium	Nickel
Bromine	Phosphorus
Cadmium	Platinum
Calcium	Potassium
Cesium	Selenium
Chromium	Silver
Cobalt	Sodium
Copper	Thallium
Germanium	Tin
Iron	Vanadium
Lead	Zinc
Magnesium	Zirconium

References:

- https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056b.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120011B.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030053b.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004b.pdf

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