MAKING AN INFORMED DECISION

Serene™
BREAST IMPLANT

WARNING:

- Breast Implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured surface breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

The sale and distribution of this device is restricted to users and/or facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bimini Health Tech.

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Glossary

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size and position between the two breasts.
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Baffle shell	Perforated shell inside the outer lumen of the implant that restricts saline movement.
Bilateral	Pertaining to both the left and right breast.
Biopsy	Removal and examination of sample tissue for diagnosis.
Body dysmorphic disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Breast augmentation	Enlargement of the breast by surgical implantation of a breast implant. The first time a breast implant is placed to increase breast size, it is called Primary Augmentation. All subsequent times the implant is replaced, it is called Revision Augmentation.
Breast implant associated anaplastic large cell lymphoma (BIA-ALCL)	BIA-ALCL is a cancer of the immune system. This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
Breast reconstruction	A surgery to reconstruct a breast after tissue was removed because of cancer or injury.
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.
Capsular contracture	Tightening of the tissue surrounding a breast implant which results in a firmer breast. Capsular contracture may result in the need for additional surgery because of pain or unacceptable appearance. Capsular contracture is a risk for implant rupture.

	Capsular contracture is classified by Baker Grades: Grade I - Normally soft and natural appearance Grade II - A little firm, but breast looks normal Grade III - More firm than normal, and looks abnormal Grade IV - Hard, obvious distortion, tenderness with pain
Capsulectomy	Surgical removal of the scar capsule surrounding a breast implant.
Capsulotomy, closed	Compression on the outside of the breast to break the capsule and relieve contracture.
Capsulotomy, open	Surgically cutting or removing part of the capsule through an incision.
Carcinoma	Invasive malignant tumor.
Congenital anomaly	Abnormality existing at birth.
Connective tissue diseases (CTD)	A disease or group of diseases affecting connective tissue. The cause of these diseases is unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.
Core Study	The primary clinical study of Primary Breast Augmentation and Revision Augmentation patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness date are collected yearly through 10 years.
Deflation/Rupture	Refers to loss of saline from a saline-filled breast implant due to a tear or cut in the implant shell or possibly a valve leak, resulting in a partial or complete collapse of the implant.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision takes longer to heal or fails to heal normally.
Extrusion	A breast implant being pressed out of the body through the surgical wound or skin.
Fibrous tissues	Connective tissues composed mostly of fibers.
Hematoma	A swelling or mass of blood (usually clotted) confined to a space and caused by a break in a blood vessel.
Hypertrophic scarring	Enlarged scar that remains after a wound heals.
Inflammation	The response of the body to infection or injury characterized by redness, swelling, warmth, and/or pain.
Inframammary	Below the breast.

Inframammary fold	The crease at the base of the breast and the chest wall.
Inframammary incision	A surgical incision at the inframammary fold.
Inner lumen	A space inside the inner shell of the implant that holds saline.
Inner shell	The innermost shell of the implant.
Inpatient surgery	Surgery performed in a hospital requiring an overnight stay.
Lactation	The production and secretion of milk by the breast glands.
Lymphadenopathy	Enlarged lymph node(s).
Malposition	The implant is not in the usual or proper position.
Mammary	Pertaining to the breast.
Mammography	Use of radiography (X-rays) of the breast to detect breast cancer. Recommended as a screening technique for early detection of breast cancer.
Mastitis	Inflammation of the breast.
Mastopexy	Plastic surgery to raise and reshape sagging (ptotic) breasts into a more elevated position.
Necrosis	Death of tissue may be caused by insufficient blood supply, trauma, radiation, chemical agents or infectious disease.
Outer lumen	A space between the inner shell and outer shell of the implant that holds saline. The baffle shell(s) is within in this space.
Outer shell	The outermost shell of the implant.
Outpatient surgery	Surgery performed in a hospital or surgery center not requiring an overnight stay.
Palpability	The ability to feel the implant with the hand.
Pectoralis	The major muscle of the chest.
Periareolar Incision	A surgical incision at the edge of the areola, the pigmented area surrounding the nipple.
Plastic surgery	Surgery intended to improve, restore, repair, or reconstruct portions of the body following trauma, injury or illness.
Postoperative	After surgery.

Ptosis	Sagging of the breast usually due to normal aging, pregnancy or weight loss.
Saline	A solution of sodium chloride (salt) and water.
Seroma	Localized collection of serum, the watery portion of blood.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of the breast implant behind the skin and mammary gland, but on top of the chest (pectoralis) muscle. Also called prepectoral placement.
Submuscular placement	Placement of the breast implant under the chest (pectoralis) muscle. Also called retropectoral or subpectoral placement.
Subsequent Operation	Any surgical procedure following the initial procedure for placement of a breast implant.
Surgical incision	Cut made in tissue for surgical purposes.
Toxic shock syndrome	A rare, but life-threatening infection that may occur after surgery. Symptoms include sudden, high fever, vomiting, diarrhea, decreased blood pressure, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if toxic shock syndrome is suspected.
Transaxillary incision	Incision across the long axis of the armpit (axilla).
UDI number	Unique Device Identifier (UDI) is a unique code to identify a specific device, model, serial number, and manufacturer.
Umbilical	Relating to the navel.
Unilateral	Affecting only left or right breast.

1.0 Considering Breast Implant Surgery

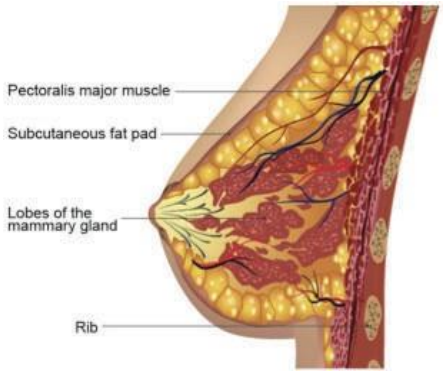
The purpose of this booklet is to assist you in making an informed decision about having breast augmentation surgery to increase the size of your breasts or revision augmentation surgery to correct or improve a previous breast augmentation. This educational booklet is not intended to replace consultation with your surgeon. This educational booklet has been prepared to help you talk with your surgeon, as well as provide you with general information on breast augmentation surgery and give you specific details about Puregraft Serene Breast Implants.

Please read this entire brochure carefully, and if you have any questions or there are things you do not understand, please discuss them with your surgeon before making any decisions. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. Your results will depend on many individual factors, such as your overall health, chest and breast shape, tissue thickness, and implant size. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect about the length of surgery, recovery, risks and potential complications.

You should complete and receive a copy of the Patient Decision Checklist in Appendix B, and wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. To help ensure that the material is read, reviewed, discussed and understood, you and your physician should initial and/or sign the Checklist where indicated. In the case of a revision-augmentation; however, your surgeon may find it medically advisable to perform surgery sooner.

1.1 What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle of the chest wall. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age combine to stretch the skin, which may cause the breast to droop or sag. Your surgeon may suggest an additional procedure at the time of breast augmentation, such as mastopexy, to lift and reshape the breasts.



1.2 What is the PUREGRAFT SERENE BREAST IMPLANT?

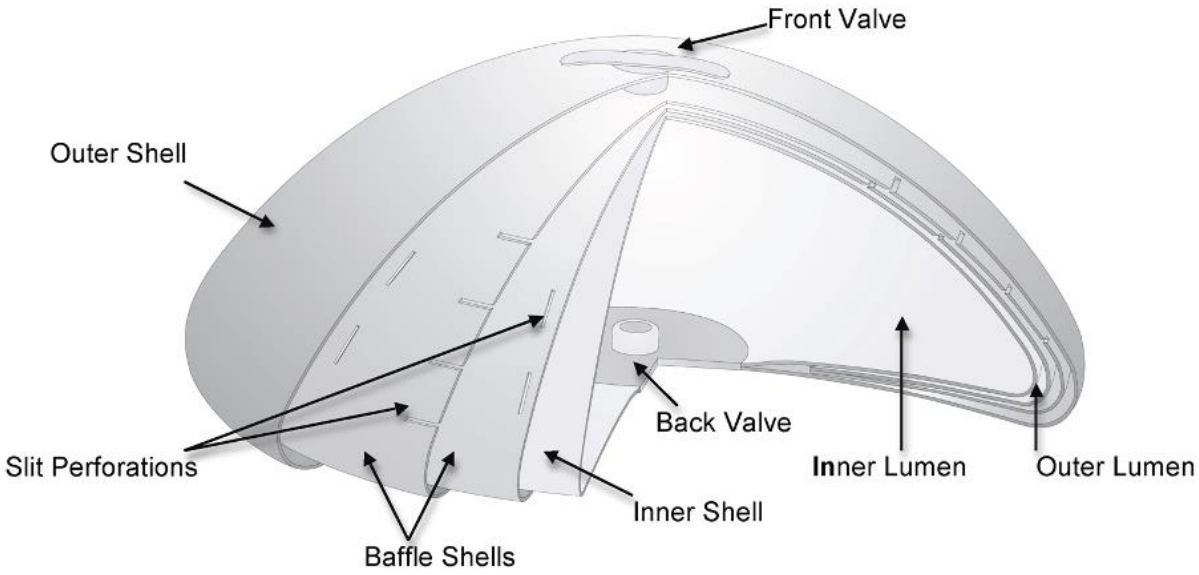
Puregraft Serene Breast Implant on a curved surface simulating the curve of the chest wall.

The **Puregraft Serene Breast Implant** is a round, smooth-surface, saline-filled implant with an internal structure. It was developed to provide women and surgeons with an alternative to saline-filled implants without an internal structure or silicone gel-filled implants. The **Puregraft Serene Breast Implant** was previously marketed under the Ideal Implant tradename.

FDA-approved saline-filled implants without an internal structure have a single lumen within a single shell made from cross-linked silicone elastomer. The **Puregraft Serene Breast Implant** has two lumens within two nested shells that are attached at the patch on the back of the implant. The inner lumen within the inner shell is filled through a valve in the patch. The outer lumen within the outer shell and surrounding the inner shell is filled through a valve on the front. Unattached and floating within the outer lumen is a baffle structure designed to restrict movement of the saline in the outer lumen. The amount of material required for the baffle structure is proportionate to the size of the implant and the fill volume in the outer lumen (Table 1). This internal structure is comprised of one to three nested baffle shells that are perforated with slits so the saline is free to move through the slits, as well as around and between the shells. The inner and outer lumens are filled with saline before or after the implant has been placed in a submuscular or prepectoral pocket. The materials, chemicals and heavy metals in the **Puregraft Serene Breast Implant** are listed in Appendix A.

A cut-away drawing of a **Puregraft Serene Breast Implant** (335 cc to 555 cc size) shows the inner shell, the outer shell, the baffle structure floating in the outer lumen comprised of two baffle shells perforated with slits, the valve in the patch to fill the inner lumen and the valve on the front to fill the outer lumen. See Section 4.4 for more information about the **Puregraft Serene Breast Implant.**

The device design was modified after the initiation of the clinical study. Early in the trial, the valve attachment diameter was increased from 6.3mm to 8mm. This was done to improve the bond strength, possibly reducing the risk of spontaneous deflation. The valve attachment can be seen in the figure below- it is depicted as a darker gray round shape, called out as “Back Valve”. The valve attachment is also used in the front valve, but is not shown in the figure below. Additional modifications to the device consisted of changing the shape of the baffle perforations (openings) from slits to holes late in the trial. The slit perforations are depicted in the image below. Neither the 6.3mm diameter valve attachment breast implant, nor the baffle hole perforations breast implant are available commercially.



Cut-away drawing of Puregraft Serene Breast Implant (335 cc to 555 cc size) to show internal structure

Table 1 - Number of Shells Relative to Implant Size				
Implant Size	Inner Shell	Baffle Shells	Outer Shell	Total Shells
210 cc	1	1	1	3
240 cc	1	1	1	3
270 cc	1	1	1	3
300 cc	1	1	1	3
335 cc	1	2	1	4
370 cc	1	2	1	4
405 cc	1	2	1	4
440 cc	1	2	1	4
475 cc	1	2	1	4
515 cc	1	2	1	4
555 cc	1	2	1	4
595 cc	1	3	1	5
635 cc	1	3	1	5
675 cc	1	3	1	5

1.3 Are You Eligible for Puregraft Serene Breast Implants?

These implants are indicated for women at least 18 years old for the following:

- Primary Breast Augmentation - This procedure is done to increase the size and proportion of a woman's breasts.
- Revision Augmentation - This procedure is done to correct or modify existing saline-filled or silicone gel-filled augmentation implants.

1.4 Who is Not Eligible for Puregraft Serene Breast Implant Breast Implants?

These implants are contraindicated for:

- Women with existing malignant or pre-malignant cancer of the breast without adequate treatment
- Women with an active infection anywhere in her body
- Women who are currently pregnant or nursing

1.5 What are the Precautions?

Before you have surgery, you should have a detailed conversation with all of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history. Your medical history will impact the complications and outcomes you encounter.

CAUTION: Tell your doctor if any of the following conditions apply to you, as the safety and effectiveness of the **Puregraft Serene Breast Implant** has not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma.
- A compromised immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Conditions or medications that interfere with wound healing or blood clotting.
- Inadequate tissue cover or reduced blood supply to breast tissue.
- Absent or substantially altered breast as a result of treatment for cancer or other pathologic conditions.

- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

1.6 What are the Warnings?

- There is a boxed warning for all breast implants (see Cover page 1).
- There is no guarantee that your results will match those of other women. Results will depend on many factors, such as your general health, chest shape, breast shape and position, skin quality, healing capability that may be slowed by smoking or various medications, tendency to bleed, previous breast surgery, surgeon's skill, type of procedure, and size of implant.
- Be aware that many of the changes to your breast following implantation cannot be undone. If you later choose to have your implants removed and not replaced, you may experience unacceptable skin dimpling, puckering, wrinkling or other changes in appearance that may be permanent.
- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You likely will need additional unplanned surgery on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal or replacement, or other breast procedures. Surgery to replace implants, revision augmentation, carries higher risks of complications than the initial implant procedure. Therefore, consider the complication rates for revision augmentation, since you may experience these risks in the future.
- Breast implants may affect your ability to produce milk for breast-feeding. Also, breast implants will not prevent your breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- Insurance does not cover breast augmentation and may not cover subsequent breast operations and additional surgeon visits following augmentation. For patients who have undergone breast implantation, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complication may not be covered as well. You should check with your insurance company regarding these coverage issues.
- The **Puregraft Serene Breast Implant** has not been studied for use in breast reconstruction and therefore is not indicated for primary breast reconstruction, revision breast reconstruction or if there will be radiation of the breast.

1.7 What are the Other Important Factors for You to Consider?

Pre-implantation Mammography

You may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.

Interference with Mammography

With breast implants, routine screening mammography for breast cancer will be more difficult. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will

receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

Distinguishing the Implant from Breast Tissue During Breast Self-Examination

You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps or an abnormal finding on the mammogram should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.

Capsulotomy

You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule is not recommended as this may result in breakage of the implant.

2.0 Breast Implant Benefits and Risks

Any type of surgical procedure involves risks such as infection, swelling, redness, bleeding, pain, effects of anesthesia and even death. While some risks are more serious than others, all risks need to be balanced against the benefits of the procedure.

2.1 What are the Benefits?

Breast augmentation can increase the size and improve the proportion of the breasts. Revision augmentation replaces existing breast implants and can correct or improve the result of the initial procedure. Breast augmentation has the potential to offer psychological benefits as well as the physical benefits. Section 3.6 provides more information on benefits seen in the Puregraft Serene Breast Implant study.

2.2 What are the Potential Risks?

Potential risks specific to breast implants are described below. The likelihood of an event occurring in primary augmentation patients and revision augmentation patients is shown below in Table 2. Sections 3.2-3.5 provide more information on risks seen in the Puregraft Serene Breast Implant study.

Table 2 - Risks of Breast Augmentation through 10 Years with Puregraft Serene Breast Implant

Event (Includes all levels of severity)	Likelihood of Event Occurring in Primary Augmentation Patients (N=399)	Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)	Possible Resulting Effects of the Event
Key Risks			
Additional Surgeries* (Reoperations)	39 out of 100 patients (39%)	50 out of 100 patients (50%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Table 2 - Risks of Breast Augmentation through 10 Years with Puregraft Serene Breast Implant			
Event (Includes all levels of severity)	**Likelihood of Event Occurring in Primary Augmentation Patients (N=399)**	**Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)**	**Possible Resulting Effects of the Event**
Implant Removal with or without Replacement*	32 out of 100 patients (32%)	43 out of 100 patients (43%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture (Baker Grade III/IV)	7 out of 100 patients (7%)	12 out of 100 patients (12%)	• Pain or Discomfort • Breast hardness/firmness • Reoperation • Implant Removal
Deflation (Rupture)*	4 out of 100 patients (4%)	5 out of 100 patients (5%)	• Implant removal • Reoperation
Other Risks Occurring in 1% or more of Patients			
Implant Malposition	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Implant visibility • Asymmetry • Reoperation • Implant removal
Breast Pain	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Resulting effects are contingent on underlying cause(s)
Ptosis	4 out of 100 patients (4%)	6 out of 100 patients (6%)	• Undesirable cosmetic result • Wrinkling/rippling • Reoperation • Implant removal
Infection	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Dissatisfaction with Cosmetic Results	11 out of 100 patients (11%)	16 out of 100 patients (16%)	• Resulting effects are contingent on underlying cause(s) • Reoperation • Implant removal • Undesirable cosmetic result • Asymmetry
Seroma/Fluid Accumulation	Less than 1 out of 100 patients (0.3%)	4 out of 100 patients (4%)	• Swelling • Pain or discomfort • Infection • Incision / drainage (reoperation) • Implant removal

Table 2 - Risks of Breast Augmentation through 10 Years with Puregraft Serene Breast Implant

Event (Includes all levels of severity)	Likelihood of Event Occurring in Primary Augmentation Patients (N=399)	Likelihood of Event Occurring in Revision-Augmentation Patients (N=103)	Possible Resulting Effects of the Event
Delayed Wound Healing	2 out of 100 patients (2%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Hematoma	2 out of 100 patients (2%)	0 out of 100 patients (0%)	• Swelling • Pain or Discomfort • Infection • Incision / drainage (reoperation) • Implant removal
Dissatisfaction with Implant Size Selected	9 out of 100 patients (9%)	14 out of 100 patients (14%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hypertrophic/Other Abnormal Scarring	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Scar revision procedure (reoperation)
Wrinkling/Rippling (excludes mild severity)	9 out of 100 patients (9%)	21 out of 100 patients (21%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Extrusion	Less than 1 out of 100 patients (0.3%)	2 out of 100 patients (2%)	• Pain or Discomfort • Scarring • Reoperation • Implant removal
Lesion - Benign	7 out of 100 patients (7%)	8 out of 100 patients (8%)	• Reoperation • Pain or Discomfort
Mastopexy Unsatisfactory	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Reoperation • Pain or Discomfort • Undesirable cosmetic result
Inadequate Milk Supply	3 out of 100 patients (3%)	1 out of 100 patients (1%)	• Breast feed difficulties • Pain or Discomfort

*Rates for Reoperation, Implant removal and Spontaneous deflation are based upon analyses of subjects with bilateral final design of the implants: N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort. The other 36 primary augmentation subjects and 10 revision augmentation subjects received an early design of the implant which is not being manufactured, and therefore were excluded from the complication rates for these 3 events.
**There was one death reported in the Primary Augmentation Cohort; a patient died of cervical cancer. There were two patient deaths reported in the Revision Augmentation Cohort: one case of cardiopulmonary arrest and one case of pancreatic cancer.
***There were no unanticipated adverse device effects in either the Primary Augmentation Cohort or the Replacement Augmentation Cohort.
Both 6.3mm and 8mm valve attachment diameters are included in the safety and effectiveness analyses although the 6.3mm design option is not commercially available.

Deflation (Rupture)

Breast implants deflate when the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or slowly over a period of days and is noticed by loss of size or shape of your breast. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses

such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate. Deflated implants require additional surgery to remove and to possibly replace the implant.

In the **Puregraft Serene Breast Implant** study, excluding implants with pilot manufacturing site defects (6.3 mm valves), for women receiving augmentation implants for the first time, the risk of deflation was 3.7% through 10 years. For women receiving revision augmentation implants, the risk of deflation was 4.7% through 10 years. This means that 4 out of 100 primary augmentation patients and 5 out of every 100 revision augmentation patients may experience spontaneous deflation within 10 years after receiving implants.

Capsular Contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant making it feel firm. This is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. It is also more common in revision augmentation than in primary augmentation. Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant. There is a scale for describing the severity of the contracture. It is called the Baker Grading Scale. The Grades are:

- Grade I - contracture is observed, but the breast feels and looks normal and soft
- Grade II - the breast is a little firm, but looks normal
- Grade III - the breast is firm and looks abnormal
- Grade IV - the breast is hard, painful, and looks abnormal

Additional surgery is often needed in cases where pain and /or firmness is severe, such as Grades III and IV. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries. In the **Puregraft Serene Breast Implant** study, for women receiving augmentation implants for the first time, the risk of severe capsular contracture was 6.6% through 10 years. For women receiving revision augmentation implants, the risk of severe capsular contracture was 11.5% through 10 years. This means that 7 out of 100 primary augmentation patients and 12 out of 100 revision augmentation patients may experience Baker Class III or IV capsule contracture within 10 years after receiving implants.

Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain or pain that does not go away.

Additional Surgeries (Reoperations)

You should know that there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. A common reason for subsequent surgery is a desire by the patient to change the size or style of her implants. Also, problems such as deflation, capsule contracture, infection, shifting, and calcium deposits can require removal of the implants. See Section 3.4 for more information on implant removal. The costs of additional surgeries may not be covered by insurance. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

In the **Puregraft Serene Breast Implant** study, for women receiving augmentation implants for the first time, the risk of additional breast surgery was 39.4% through 10 years. For women receiving revision augmentation implants, the risk of additional breast surgery was 50.3% through 10 years. This means that 39 out of 100 primary augmentation patients and 50 out of 100 revision augmentation patients may have additional breast surgery within 10 years after receiving implants. Section 3.3 provides more information on reoperations reported in the clinical study.

Dissatisfaction with cosmetic results

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic (irregular, raised scar) scarring may occur. Careful surgical planning and technique can minimize but not always prevent such results. Pre-existing asymmetry may not be entirely correctable by implant surgery. You should understand the possible cosmetic results and discuss them carefully with your doctor before surgery. Revision surgery may be necessary to improve an unsatisfactory result but carries additional considerations and risks.

Infection

Infection can occur with any surgery. Most infections resulting from surgery appear in a few days to weeks after the operation. However, infection is possible at any time after surgery. Signs that you have an infection include: redness or rash, tenderness or pain, swelling, and fever. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A surgeon should be seen immediately for diagnosis and treatment of this condition.

Hematoma or Seroma

Hematoma is a collection of blood within the space around the implant, and a seroma is a collection of the watery portion of the blood within the space around the implant. Postoperative hematoma and seroma may contribute to infection and/or capsule contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will potentially require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.

Changes in Nipple and Breast Sensation

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast feeding below.)

Breast Feeding

Breast implant surgery can interfere with your ability to successfully breast feed. It is possible that you will produce less milk or not be able to produce milk at all. The periareolar incision site may significantly reduce the ability to successfully breast feed. Section 3.5 provides additional information on lactation problems.

Calcium Deposits in the Tissue Around the Implant

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish the calcium deposits from cancer.

Delayed Wound Healing

In some cases, the incision site takes longer to heal than normally. Delayed healing may increase the risk of infection, implant extrusion, and necrosis. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal in the period of time your surgeon described.

Extrusion

Unstable or compromised tissue covering the breast implant and/or delayed wound healing may result in extrusion, which is when the breast implant comes through the skin. Additional surgery is needed to fix implant extrusion, which can result in more scarring or loss of breast tissue. An extruding implant may need to be removed and cannot be replaced until the wound has healed.

Necrosis

Necrosis is the formation of dead or dying breast tissue or skin around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink. When this happens, you may be able to see and/or feel the implant through the skin. This can occur while implants are still in place or following implant removal without replacement. Additional surgery may be needed to correct either of these conditions, which may mean more scarring, and removal of your breast implants, with or without replacement.

2.3 What are the Other Reported Conditions?

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, connective tissue diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

Connective Tissue Disease (CTD)

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, fibromyalgia, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants.

CTD Signs and Symptoms

Some women, even without breast implants, may have some of the signs or symptoms of connective tissue diseases, without having the actual disease. Breast implants have been linked with some of these signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. If you have these CTD signs and symptoms, it does not mean you have a CTD, but you should consider seeing a rheumatologist for evaluation.

Cancer

Women with breast implants do not seem to have a greater risk of developing breast cancer (Brinton, et al 2006; Deapen, et al 2007).

Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL):
One exception is the rare development of Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) in women with breast implants. Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.

If you have breast implants, you have a very small, but increased risk of developing breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer – it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases it can spread throughout the body. In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to FDA to date, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was less than one year after implant placement and the latest was 40 years after the implant surgery per the FDA report published June 30, 2023. About half the cases occurred within the first 8 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if after you have recovered from your breast implant operation, you later notice changes in the way your breast looks or feels — including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation, which may involve obtaining fluid and tissue samples from around your breast implant. If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.

If you have breast implants, you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms and you have not been diagnosed with BIA- ALCL.

If you are diagnosed with BIA-ALCL, you can help the FDA understand the disease and the effectiveness of treatment.

You or your doctor should report all confirmed cases of BIA-ALCL to the FDA https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home. In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.

In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry https://www.thepsf.org/research/registries/profile.

Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information:
https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants.

For additional information on FDA's analysis and review of BIA-ALCL, please visit: https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma.

Reports of Squamous Cell Carcinoma (SCC) and Various Lymphomas:

- There have been reported cases of cancers, including squamous cell carcinoma (SCC) and various lymphomas, in the scar tissue (capsule) that forms around the breast implant[50]. These cancers are not the same as BIA-ALCL. The occurrence of SCC and various lymphomas in the capsule around the breast implant may be rare and the cause, incidence, and risk factors remain unknown.

Effects on Children

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. There is no evidence that shows breast implants have any harmful effects on the children of implanted women (Signorello, et al 2001; Kjoller, et al 2002).

Suicide

Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety. The strongest predictor for suicide is having been hospitalized for any psychiatric condition.

3.0 Puregraft Serene Breast Implant's 10-Year Clinical Study

This section describes complications and outcomes associated with the **Puregraft Serene Breast Implants**, as reported in the Core clinical study and Post Approval Core Study. Bimini Health Tech's study indicates that the chance of additional surgery through 10 years is 39 in 100 for Primary Augmentation patients and 50 in 100 for Revision Augmentation patients. The information below provides more details about the complications and benefits you may experience.

3.1 Description of Study

Clinical testing was conducted on the breast implants to determine the 10-year rates of adverse events, patient's satisfaction with how their breasts appear, and patient and surgeon satisfaction with the outcome of the surgery. This Core study enrolled 399 Primary Augmentation patients and 103 Revision Augmentation patients. Of these enrolled patients, 342 of the Primary Augmentation patients (93%) and 84 of the Revision Augmentation patients (97%) returned for their 10-year visit. The outcomes of patients lost to follow-up are not known. The Core study is a 10-year study to assess safety and effectiveness; results in this booklet represent data through 10 years.

As described in Section 1.2, the clinical study included breast implants with both 6.3mm and 8mm valve attachment types, as well as the two different baffle perforation shapes. However, neither the 6.3mm diameter valve attachment breast implant nor the baffle hole perforations breast implant are available commercially. Table 3 shows the operative details per implant for women in the Primary Augmentation and the Revision Augmentation Cohorts.

Table 3 - Surgical Operative Data, per Implant

Measure	Primary Augmentation (N=798)	Revision Augmentation (N=206)
Diameter valve attachment		
8mm	91.6% (731/798)	90.3% (186/206)
6.3mm[1]	8.4% (67/798)	9.7% (20/206)
Baffle perforations		
Slits	98.0% (782/798)	97.1% (200/206)
Holes[1]	2.0% (16/798)	2.9% (6/206)
Incision site		
Inframammary[2]	70.8% (565/798)	61.2% (126/206)
Periareolar	22.2% (177/798)	37.9% (78/206)
Axillary	7.0% (56/798)	1.0% (2/206)
Location		
Subglandular	8.0% (64/798)	19.4% (40/206)
Submuscular	92.0% (734/798)	80.6% (166/206)
Concurrent breast procedure	19.7% (157/798)	74.8% (154/206)
Capsule procedure	0% (0/157)	81.2% (125/154)
Mastopexy	91.7% (144/157)	26.0% (40/154)
Other[3]	8.3% (13/157)	18.8% (29/154)

Numbers are Mean ± SD (N), Median [Min, Max] for continuous measures and Percent (Count/N) for discrete measures.
1 Design option not commercially available
2 Two subjects each had two devices implanted via abdominoplasty and are reported as inframammary due to the approach used.
3 Other measures for primary augmentation were IMF (inframammary fold) repair, Correction of inverted nipples, Periareolar breast lift, Nipple reconstruction, Removal simple nipple benign growth (superficial), Bx -mass benign, Excise breast mass, Scar revision, Internal nipple lift, and Lipoma excised left chest wall. Other measures for revision augmentation were Breast reduction, Capsulectomy, Capsuloplasty, Capsulorrhaphy, Change to submuscular, Elevated Nipple - Areolar Complex, IMF repair, Lateral capsule repair, Mastopexy, Partial capsulotomy, Plicate lateral sulcus, Reduction, Removal ruptured silicone gel implant, and Scar revision breasts.

This study was conducted by Ideal Implant, Inc. with implants labeled with the Ideal Implant tradename. These names have been replaced with Bimini Health Tech and Puregraft Serene Breast Implant, respectively, to avoid confusion while reading this document.

3.2 Study Population: Patient Demographic Profiles

Table 4 shows the subject demographics and medical history for the women in the Primary Augmentation Cohort and the Revision Augmentation Cohort. Approximately 83% of patients were Caucasian. The median age of the primary augmentation patients was 34.0 years (range 18-68); the median age of the revision augmentation patients was 47.0 years (range 21-67).

Table 4 – Subject Demographics and Medical History, per Subject		
Measure	**Primary Augmentation (N=399 subjects)**	**Revision Augmentation (N=103 subjects)**
Median Age Years [Minimum, Maximum] [1]	34.0 [18.0, 68.0]	47.0 [21.0, 67.0]
Race[2]		
American Indian Alaska Native	1.3% (5/399)	0% (0/103)
Asian	3.0% (12/399)	1.9% (2/103)
Black / African American	5.0% (20/399)	1.9% (2/103)
Native Hawaiian / Pacific Islander	0.8% (3/399)	0% (0/103)
Caucasian	82.7% (330/399)	83.5% (86/103)
Other	9.5% (38/399)	14.6% (15/103)
Ethnicity		
Hispanic or Latino	11.8% (47/399)	14.6% (15/103)
Non-Hispanic or Latino	88.2% (352/399)	85.4% (88/103)
Median BMI [Minimum, Maximum] (kg/m^2)	21.6 [14.4, 53.2]	21.5 [18.1, 48.7]
Any Pregnancy History	73.9% (295/399)	89.3% (92/103)
Number of pregnancies *	2.6±1.4 2.0 [1.0, 8.0]	2.6±1.4 2.0 [1.0, 7.0]
Number of live births *	2.1±1.2 2.0 [0.0, 7.0]	2.0±1.0 2.0 [0.0, 5.0]

*Numbers are in the following formats: Mean ± standard deviation (SD) and Median [Min, Max] for continuous measures.
[1] Age calculated at date of implant.
[2] More than one race category may be selected for each subject.

3.3 What were the Complication Rates from the 10-Year Study?

The 2-year, 5-year and 10-year complication rates are shown in Table 5 below. The rates reflect the number of Primary Augmentation and Revision Augmentation patients out of 100 who experienced the listed complication at least once within 10 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 10 years of implantation for the Primary Augmentation patients were Subsequent Breast Operations (39.4% or 39 patients out of 100) and Implant Removal with or without Replacement (32.1% or 32 patients out of 100). The two most common complications experienced within the first 10 years of implantation for the Revision Augmentation patients were Subsequent Breast Operations (50.3% or 50 patients out of 100) and Implant Removal with or without Replacement (42.6% or 43 patients out of 100).

Table 5 – Risk of Complications within 2 Years, 5 Years and 10 Years, per Subject						
Event (Includes all levels of severity)	**Primary Augmentation (N= 399 subjects)**			**Revision Augmentation (N=103 subjects)**		
	2 yr	**5 yr**	**10 yr**	**2 yr**	**5 yr**	**10 yr**
All subsequent breast operations*	12.8%	22.7%	39.4%	21.5%	39.3%	50.3%
Implant removal with or without replacement*	5.9%	14.9%	32.1%	12.9%	30.6%	42.6%
Connective Tissue Disease diagnosis	0.5%	0.8%	1.1%	0.0%	2.1%	2.1%
Reproductive problem	0.8%	1.3%	3.4%	0.0%	3.3%	3.3%

Other Adverse Event**	12.4%	21.3%	36.9%	14.0%	29.1%	42.6%
Capsular contracture Grade III/IV	3.8%	5.7%	6.6%	8.2%	11.5%	11.5%
Wrinkling/scalloping (excludes mild severity)	3.8%	7.3%	9.0%	12.0%	16.2%	21.1%
Spontaneous deflation*	0.3%	1.5%	3.7%	1.1%	4.7%	4.7%
Seroma	0.3%	0.3%	0.3%	2.9%	2.9%	4.1%
Dissatisfaction with cosmetic result	4.1%	7.8%	11.4%	8.9%	10.0%	15.6%
Hematoma/bleeding	1.8%	1.8%	1.8%	0.0%	0.0%	0.0%
Wound Healing delay/tissue necrosis/dehiscence	1.3%	1.3%	1.5%	1.0%	1.0%	1.0%
Wound Infection	1.3%	1.3%	1.3%	1.0%	1.0%	1.0%
Implant exposure/extrusion	0.0%	0.0%	0.3%	2.0%	2.0%	2.0%
Skin scar unsatisfactory	1.5%	1.5%	1.5%	3.9%	3.9%	3.9%
Mastopexy unsatisfactory	1.5%	1.5%	2.1%	1.1%	2.2%	2.2%
Implant position unsatisfactory (malposition)	2.6%	2.8%	3.4%	1.0%	3.2%	3.2%
Persistent breast pain	0.5%	1.0%	1.0%	1.1%	1.1%	1.1%
Inadequate milk supply	0.3%	1.6%	3.3%	1.1%	1.1%	1.1%
Dissatisfaction with implant size selected	3.0%	7.0%	9.3%	3.9%	10.2%	13.6%
Breast ptosis - after implant procedure	0.5%	2.1%	4.4%	4.1%	5.1%	6.2%
Breast lesion - benign	1.5%	4.3%	6.6%	4.1%	5.2%	7.6%
Breast lesion - malignant	0.5%	0.8%	1.6%	0.0%	1.1%	1.1%

* Risk rates for Subsequent breast operation, Implant removal and Spontaneous deflation are based upon analyses of subjects with initial bilateral 8mm final design of valve attachment component implants, N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort. For the rest of the rates, they are based on a combination of 6.3mm valve and 8mm valve attachment components. The 11 subjects with hole baffle shell perforations are included in this analysis.
**Other adverse events: For the Primary Augmentation Cohort: breast tissue atrophy, interference with mammography, nipple/breast sensitivity change, mastitis, lactation pain, lymphadenopathy, melanoma arm, seasonal allergy, squamous cancer skin, nasal polyps, seizure disorder, bowel obstruction, hemorrhoids, irritable bowel syndrome, hypothyroidism, hyperthyroidism, emotional issue, neck rash, abdominal muscle bleed, rotator cuff problem, cholecystitis, foot fracture, contact dermatitis, back pain, tubular breast, liver cyst, herpes zoster infection, syncopal episode, myasthenia gravis, staph infection nose, leukemia, cervical cancer, anxiety, cystitis, diabetes, depression, acid reflux, head trauma, migraine, urinary retention, drug overdose, borderline personality disorder, anal fissure, arm cyst, abdominal incision pain, cold, herniated disc, enlarged thymus, kidney infection, rectal prolapse, abdominal wound infection, basal cell carcinoma nose, arm pain, sinus infection, nausea, ovarian cancer, eczema arms and renal stone. For the Revision Augmentation Cohort: sciatic neuritis, sebaceous cysts of scalp, sinus obstruction, renal stone, seroma to abdomen, abdominal wound infection, anemia, ganglion cyst thigh, femoral hernia, hand numbness, multiple sclerosis, stasis ulcer ankle, pancreatic cancer, superficial burn, intra-arterial septal communication, cholecystitis, sleep apnea, depression, rash abdomen, EKG abnormality, back pain, diverticulitis, lipoma hip, hyperthyroidism, whooping cough and knee trauma.

3.4 What were the Reasons for Subsequent Breast Operations?

The reasons for subsequent breast operations through 2 years, 5 years and 10 years are shown below in Table 6.

There were 179 subsequent breast operations performed in 134 Primary Augmentation patients through 10 years. The most common reason for subsequent breast operation through 10 years was dissatisfaction with implant size selected (13.4% of the 179 subsequent breast operations). There were 77 subsequent breast operations performed in 45 Revision Augmentation patients through 10 years. The most common reason for subsequent breast operation through 10 years was dissatisfaction with implant size selected (13.0% of the 77 subsequent breast operations).

Table 6 - Primary Reasons for Subsequent Breast Operation through 2, 5 and 10 Years, per Operation

Reason	Primary Augmentation [percent (count/total number of operations)]			Revision Augmentation [percent (count/total number of operations)]		
	2 Year	5 Year	10 Year	2 Year	5 Year	10 Year
Capsular contracture (II)	5.4% (3/56)	5.8% (6/104)	5.6% (10/179)	3.0% (1/33)	3.4% (2/59)	2.6% (2/77)
Capsular contracture (III-IV)	8.9% (5/56)	8.7% (9/104)	6.1% (11/179)	3.0% (1/33)	6.8% (4/59)	7.8% (6/77)
Wrinkling/scalloping	5.4% (3/56)	4.8% (5/104)	5.6% (10/179)	12.1% (4/33)	8.5% (5/59)	10.4% (8/77)
Spontaneous deflation	1.8% (1/56)	2.9% (3/104)	6.7% (12/179)	3.0% (1/33)	1.7% (1/59)	1.3% (1/77)
Other related to presence of implant*	1.8% (1/56)	10.6% (11/104)	24.6% (44/179)	0.0%	5.1% (3/59)	10.4% (8/77)
Hematoma/bleeding	5.4% (3/56)	2.9% (3/104)	1.7% (3/179)	0.0%	0.0%	0.0%
Healing delay/necrosis/dehiscence	3.6% (2/56)	1.9% (2/104)	1.1% (2/179)	0.0%	0.0%	0.0%
Infection (peri-prosthetic)	0.0%	0.0%	0.0%	6.1% (2/33)	3.4% (2/59)	2.6% (2/77)
Implant exposure/extrusion	0.0%	0.0%	0.6% (1/179)	24.2% (8/33)	13.6% (8/59)	10.4% (8/77)
Skin scar unsatisfactory	3.6% (2/56)	1.9% (2/104)	1.1% (2/179)	0.0%	0.0%	0.0%
Mastopexy unsatisfactory	5.4% (3/56)	3.8% (4/104)	2.8% (5/179)	0.0%	1.7% (1/59)	1.3% (1/77)
Implant position unsatisfactory	8.9% (5/56)	4.8% (5/104)	2.8% (5/179)	0.0%	1.7% (1/59)	1.3% (1/77)
Other related to procedure	1.8% (1/56)	1.0% (1/104)	0.6% (1/179)	3.0% (1/33)	3.4% (2/59)	2.6% (2/77)
Dissatisfaction with implant size selected	12.5% (7/56)	15.4% (16/104)	13.4% (24/179)	12.1% (4/33)	11.9% (7/59)	13.0% (10/77)
Breast ptosis prior to implant placement	5.4% (3/56)	2.9% (3/104)	2.2% (4/179)	0.0%	1.7% (1/59)	1.3% (1/77)
Breast ptosis after implant placement due to pregnancy, change in weight, and/or change in breast size	1.8% (1/56)	2.9% (3/104)	2.2% (4/179)	0.0%	1.7% (1/59)	3.9% (3/77)
Breast lesion – benign or malignant	3.6% (2/56)	5.8% (6/104)	5.0% (9/179)	0.0%	1.7% (1/59)	1.3% (1/77)
Breast reconstruction post trauma/cancer	0.0%	1.0% (1/104)	0.6% (1/179)	3.0% (1/33)	3.4% (2/59)	2.6% (2/77)
Inadequate saline volume	14.3% (8/56)	10.6% (11/104)	6.1% (11/179)	18.2% (6/33)	10.2% (6/59)	7.8% (6/77)
Absence of implant	0.0%	0.0%	0.0%	3.0% (1/33)	1.7% (1/59)	1.3% (1/77)
Dissatisfaction with cosmetic result	1.8% (1/56)	1.9% (2/104)	1.1% (2/179)	9.1% (3/33)	5.1% (3/59)	5.2% (4/77)
Other**	8.9% (5/56)	10.6% (11/104)	10.1% (18/179)	0.0%	11.9% (7/59)	11.7% (9/77)

Numbers are Percent (Count/N)
One primary reason is summarized per operation.
This table only includes reoperations of bilateral 8mm valve attachment diameters as the 6.3mm design option is not commercially available.
* Reasons under this category for primary augmentation are cosmetic (asymmetry, irregularities with knuckling, desire for larger size, wide sternum or deformity, matching replacement implant, asymmetrical deflation). Reasons under this category for revision augmentation are cosmetic (asymmetry), and dissatisfaction with feel of implant.
** Reasons under this category for primary augmentation are cosmetic (asymmetry, cosmetic dissatisfaction, dissatisfaction with overall breast size, tubular breast anatomy), preference (implants no longer desired, silicone implants desired, elective exchange in conjunction with exchange of defective side, replaced to match other implant, dissatisfaction with feel of implants), crunchy implant feel, fat grafting, thin breast tissue, and not specified. Reasons under this category for revision augmentation are cosmetic (asymmetry), preference (implants no longer desired, felt strange), crunchy implant feel, resection cyst

IMF (inframammary fold), abrasion open area, and replacement with new implant of this same brand.

3.5 What were the Reasons for Implant Removal?

Table 7 below shows the reasons for implant removal through 2 years, 5 years and 10 years. Through 10 years, there were 157 implants removed from Primary Augmentation patients. The most common reason for implant removal through 10 years was asymmetry (31.8% of the implants removed; asymmetry was reported in the categories labeled "Other related to presence of implant" and "Other") followed by dissatisfaction with implant size selected (22.9% of the implants removed). Through 10 years, there were 68 implants removed from Revision Augmentation patients. The most common reason for implant removal through 10 years was dissatisfaction with implant size selected (20.6% of the implants removed).

Table 7 - Primary Reasons for Implant Removal through 2, 5 and 10 Years, per Implant

Reason Category	Primary Augmentation [Percent (count/total number of implants removed)]			Revision Augmentation [Percent (count/total number of implants removed)]		
	2 Year	5 Year	10 Year	2 Year	5 Year	10 Year
Capsular contracture (II)	3.4% (1/29)	2.7% (2/74)	3.2% (5/157)	4.5% (1/22)	6.7% (3/45)	4.4% (3/68)
Capsular contracture (III-IV)	10.3% (3/29)	8.1% (6/74)	3.8% (6/157)	4.5% (1/22)	13.3% (6/45)	11.8% (8/68)
Wrinkling/scalloping	3.4% (1/29)	5.4% (4/74)	7.0% (11/157)	9.1% (2/22)	4.4% (2/45)	11.8% (8/68)
Spontaneous deflation	3.4% (1/29)	4.1% (3/74)	7.6% (12/157)	4.5% (1/22)	2.2% (1/45)	1.5% (1/68)
Other related to presence of implant*	0.0%	13.5% (10/74)	33.8% (53/157)	0.0%	8.9% (4/45)	13.2% (9/68)
Healing delay/necrosis/dehiscence	3.4% (1/29)	1.4% (1/74)	0.6% (1/157)	0.0%	0.0%	0.0%
Infection (peri-prosthetic)	0.0%	0.0%	0.0%	4.5% (1/22)	2.2% (1/45)	1.5% (1/68)
Implant exposure/extrusion	0.0%	0.0%	0.6% (1/157)	18.2% (4/22)	8.9% (4/45)	5.9% (4/68)
Implant position unsatisfactory (malposition)	0.0%	0.0%	0.6% (1/157)	0.0%	0.0%	0.0%
Dissatisfaction with implant size	44.8% (13/29)	36.5% (27/74)	22.9% (36/157)	27.3% (6/22)	22.2% (10/45)	20.6% (14/68)
Breast ptosis prior to implant	0.0%	0.0%	1.3% (2/157)	0.0%	0.0%	0.0%
Breast ptosis after implant due to pregnancy, change in weight, and/or change in breast size	0.0%	0.0%	0.0%	0.0%	0.0%	2.9% (2/68)
Breast lesion – benign or malignant	3.4% (1/29)	1.4% (1/74)	1.3% (2/157)	0.0%	0.0%	0.0%

Breast reconstruction post trauma/cancer	0.0%	1.4% (1/74)	0.6% (1/157)	0.0%	0.0%	0.0%
Dissatisfaction with cosmetic result	6.9% (2/29)	5.4% (4/74)	2.5% (4/157)	27.3% (6/22)	13.3% (6/45)	8.8% (6/68)
Other**	20.7% (6/29)	20.3% (15/74)	14.0% (22/157)	0.0%	17.8% (8/45)	17.6% (12/68)

This table only includes bilateral 8mm valve attachment diameters as the 6.3mm design option is not commercially available.
* Reasons under this category for primary augmentation are cosmetic (asymmetry within breast, asymmetry between breasts, irregularities with knuckling, desire for larger size), and pain in one breast and lump. Reasons under this category for revision augmentation are cosmetic (asymmetry within breast, asymmetry between breasts), and dissatisfaction with feel of implant.
** Reasons under this category for primary augmentation are cosmetic (asymmetry within breast, asymmetry between breasts, cosmetic dissatisfaction), preference (implants no longer desired, requests removal, silicone implants desired, elective exchange in conjunction with exchange of defective side), preventive mastectomy, dissatisfaction with feel of implants. Reasons under this category for revision augmentation are cosmetic (asymmetry between breasts), preference (implants no longer desired), dissatisfaction with feel of implants, and replacement with new implant of this same brand

3.6 What were the Other Reported Conditions?

Breast disease and signs and symptoms of connective tissue disease (CTD) were reported in some patients through 10 years after implantation. Although there were 502 patients enrolled in the Core Study, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be reported. Without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between these breast implants and breast disease and CTD events.

In the Primary Augmentation Cohort, there were 28 reports of abnormal mammogram findings: 2 breast cancer, 9 benign breast lesions or masses, 2 calcification, 7 cysts, 1 fibroadenoma, 1 engorged breasts, 3 ruptured implant, 1 dense breasts, 1 scarring and 1 additional evaluation necessary. In the Revision Augmentation Cohort, there were 8 reports of abnormal mammogram findings: 1 cyst, 3 calcifications, 2 masses and 2 additional evaluation necessary.

Through 10 years, there were no reports of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in any patient.

Patients underwent a screening for connective tissue disorders at each follow-up visit.

Approximately 4 of out 100 Primary Augmentation patients and 1 out of 100 Revision Augmentation patients were referred to a board certified Rheumatologist at the 10 year visit. An initial diagnosis of CTD was made in approximately 1 out of 100 Primary Augmentation patients and 2 out of 100 Revision Augmentation patients through 10 years.

Approximately 3 out of 100 Primary Augmentation patients and 1 out of 100 Revision Augmentation patients had inadequate milk production.

Approximately 3 out of 100 patients in the Primary Augmentation Cohort and 3 out of 100 patients in the Revision Augmentation Cohort experienced a reproductive problem. The risk of inadequate milk supply through 10 years was 3.3% for patients in the Primary Augmentation Cohort and 1.1% for patients in the Revision Augmentation Cohort. In the Primary Augmentation Cohort, 12 patients had a reproductive problem of which 9 were miscarriages, 1 was patient diagnosed with endometriosis and underwent laparoscopic lysis of adhesions and removal of some endometriosis, 1 was a non-viable birth, and the other unknown. In the Revision Augmentation Cohort, 3 patients experienced a reproductive problem of which 2 were miscarriages, the other was unknown.

There were no reports of suicide in either cohort through 10 years.

There was one death reported in the Primary Augmentation Cohort; a patient died of cervical cancer. There were two patient deaths reported in the Revision Augmentation Cohort: one case of cardiopulmonary arrest and one case of pancreatic cancer.

3.7 What were the Benefits?

The benefits of **Puregraft Serene Breast Implants** were assessed by a variety of outcomes, including change in chest circumference, patient and surgeon satisfaction with the outcome of the surgery, and patient satisfaction with the appearance of their breasts. These outcomes were assessed for patients with both Primary Augmentation and Revision Augmentation before implantation and at 10 years after surgery, except for change in chest circumference, which was assessed at 1 year after surgery for Primary Augmentation patients only.

A total of 375 (94%) of the original 399 Primary Augmentation patients had a breast measurement at 1- year after surgery. Of these patients, the mean increase in chest circumference was 2.5 inches.

At 10 years after surgery, patients completed the Breast Evaluation Questionnaire (BEQ), which measures how satisfied patients were with the appearance of their breasts before and after surgery while fully dressed and not fully dressed, and satisfaction with certain aspects of their breasts, such as size, shape and firmness. Primary Augmentation and Revision Augmentation patients reported improvements in how satisfied they were with the appearance of their breasts, both fully and not fully dressed, and their physical attributes, such as size and shape.

Patients and surgeons reported their satisfaction with the overall cosmetic outcome of surgery on a five-point scale: definitely satisfied, somewhat satisfied, neither satisfied or dissatisfied, somewhat dissatisfied and definitely dissatisfied. At 10 years, 330 of the original 399 Primary Augmentation patients were included in an analysis of satisfaction and 79 of the original 103 Revision Augmentation patients were included in an analysis of satisfaction. Surgeons were definitely or somewhat satisfied with the outcomes in 94.8% (313/330) of the cases in the Primary Augmentation Cohort and 87.3% (69/79) in the Revision Augmentation Cohort. For patients in the Primary Augmentation Cohort, 92.7% (306/330) were definitely or somewhat satisfied with the outcomes. For patients in the Revision Augmentation Cohort, 82.3% (65/79) were definitely or somewhat satisfied with the outcomes.

The SF-36v2® Health Survey was utilized to measure overall quality of life. The SF-36 measures eight scales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). After 10 years, comparison to baseline scores showed small decreases in certain quality of life scales that were assessed to be not clinically relevant.

4.0 Surgical Considerations for Breast Augmentation

4.1 What Are the Alternatives to Breast Augmentation with Puregraft Serene Breast Implant?

For primary augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery
- Wear a padded bra or external prostheses
- Have mastopexy surgery (breast lift) without an implant
- Have surgery with silicone gel-filled implants
- Have fat injections

For revision augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery
- Wear a padded bra or external prostheses
- Removal of implants without replacement
- Have surgery with silicone gel-filled implants
- Have fat injections

You are advised to wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary augmentation surgery. In the case of a revision augmentation; however, your surgeon may find it medically advisable to perform surgery sooner.

4.2 What Questions Should You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help you to remind you of topics to discuss with your surgeon. You may have additional questions as well.

1. What are the risks and complications associated with having breast implants?
2. How many additional operations on my implanted breast(s) can I expect over my lifetime?
3. How will my breasts look if I decide to have the implants removed without replacement?
4. What shape, size, surface texturing, incision site, and placement site is recommended for me?
5. How will my ability to breast feed be affected?
6. How can I expect my implanted breasts to look over time?
7. How can I expect my implanted breasts to look after pregnancy? After breastfeeding?
8. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
9. What alternate procedures or products are available if I choose not to have breast implants?
10. Do you have before and after photos I can look at for each option?
11. Do you think my expectations are reasonable?

Early in the consultation process, be sure to speak directly to your surgeon about your expectations and desired results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery.

4.3 Choosing a Surgeon

When choosing a surgeon who is experienced with breast implantation, you should ask the following questions.

1. How many breast augmentation implantation procedures does he/she perform per year?
2. How many years has he/she performed breast implantation procedures?
3. Is he/she board certified, and if so, with which board?
4. In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or online.
5. What is the most common complication he/she encounters with breast implantation?
6. What is his/her reoperation rate with breast implantation and what is the most common type of reoperation he/she performs?

4.4 What are the Choices and Options Associated with the Surgery?

Puregraft Serene Breast Implants

The **Puregraft Serene Breast Implant** is available in 14 sizes (Table 8). Each size can be adjusted within a specified volume range at the time of surgery, by varying the amount saline used to fill the implant. This size adjustability can be useful when the breasts are not symmetrical in size. The Puregraft Serene Breast Implant is round and has a smooth surface.

Table 8 –Implant Sizes

Size	Volume Range
210 cc	210 - 235 cc
240 cc	240 - 270 cc
270 cc	270 - 305 cc
300 cc	300 - 340 cc
335 cc	335 - 375 cc
370 cc	370 - 415 cc
405 cc	405 - 455 cc
440 cc	440 - 495 cc
475 cc	475 - 535 cc
515 cc	515 - 580 cc
555 cc	555 - 625 cc
595 cc	595 - 670 cc
635 cc	635 - 710 cc
675 cc	675 - 755 cc

Puregraft Serene Breast Implant *on a curved surface simulating the curve of the chest wall*

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

Implant Size

Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

Palpability

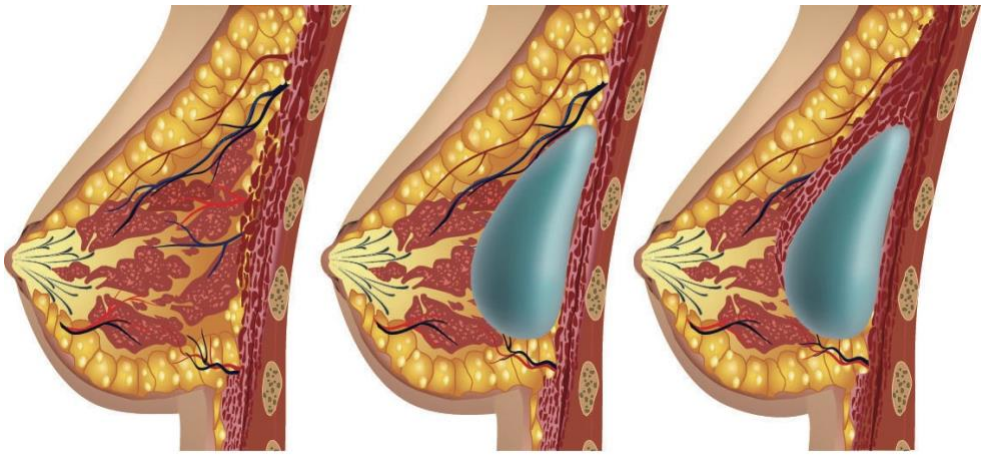
The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant.

Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast gland (subglandular) depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. You should discuss with your surgeon the pros and cons of the implant placement selected for you.

The submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have a subsequent breast procedure than the subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography.

The subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for a subsequent breast operation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.



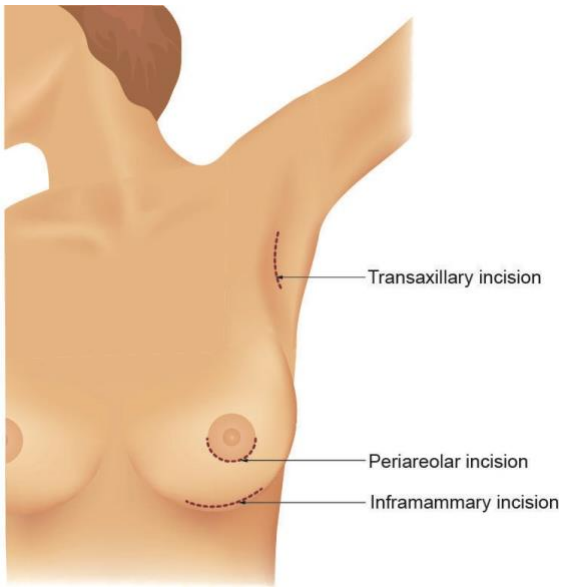
Incision Site

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

There are three common incision sites: within the breast fold (inframammary), around the nipple (periareolar), or under the arm (transaxillary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant. A fourth incision site around the belly button (peri-umbilical) was not studied and should not be used. This approach may cause damage to the implant.

Periareolar

This incision is the most concealed but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.



Inframammary

This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.

Transaxillary

This incision is less concealed than periareolar and associated with less difficulty than the periareolar

incision site when breast feeding.

Other Procedures at the Time of the Breast Augmentation

Your surgeon may recommend having other cosmetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If you have previously lost a lot of weight, been pregnant, or breast-fed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. To remove the excess skin from your breast tissue, your doctor may recommend doing a breast lift (mastopexy) to one or both breasts.

During mastopexy, excess skin is usually removed from around the nipple area and lower part of the breast. Stitches are used to close the incision. This procedure lifts the breast tissue, raises the nipple location, and tightens the skin over the breast tissue. There is more scarring and possibly a longer recovery time than if just have implants placed. Mastopexy and breast augmentation may be done at the same time, or as separate procedures. Your doctor can discuss the risks and benefits of this procedure with you.

Surgical Setting and Anesthesia

Breast augmentation surgery is usually preformed on an outpatient basis, either in a hospital operating room, surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia is also an option. The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

4.5 Post-operative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. Post-operative care may involve the use of a special post-operative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood pressure for at least a couple of weeks. Your surgeon may also recommend breast massage exercises. Note: If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

Following breast augmentation, you should continue breast self-examination to monitor your breasts and breast implants. If you have pain, lumps, hardening, swelling, or changes in shape, report these to your surgeon. To protect your implants, you should make sure that any health care provider treating you knows that you have breast implants. If they do not know, they could damage them by accident during a procedure, such as a breast biopsy.

5.0 Additional Information

5.1 If You Experience a Problem, Should You Report It?

If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to FDA and/or to Bimini Health Tech. You are encouraged to report any adverse events through your health professional. Women may also report any serious problem directly through the FDA's MedWatch voluntary reporting system.

An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly, or medical or surgical intervention to prevent lasting damage. This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

To report to FDA, use MedWatch form 3500 which may be obtained through FDA's website at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home. You may also call 1-888-INFO-FDA (1-888-463-6332), from 10:00am – 4:00pm Eastern Time, Monday through Friday, to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by you or your surgeon for your records. To report to Bimini Health Tech, call 858-348-8050.

There is a National Breast Implant Registry (NBIR) where information regarding your breast implant and health can be entered by your physician. In collaboration with the U.S. Food and Drug Administration (FDA), breast implant device manufacturers, patients, The Plastic Surgery Foundation (PSF) has developed the National Breast Implant Registry (NBIR) for the purpose of strengthening national surveillance for breast implant devices in the United States. The NBIR is a database that collects information on breast implant procedures and devices. Collecting this information will allow the NBIR, plastic surgeons, and breast implant manufacturers to identify trends and other helpful safety information that can be used to improve the safety of breast implants for you and future patients. You are encouraged to ensure that your surgeon is participating in this registry.

5.2 Limited Warranty

The Bimini Health Tech Breast Implant Limited Warranty provides lifetime replacement and limited financial assistance in the event of implant failure, subject to certain conditions as described in the Breast Implant Limited Warranty posted at https://www.puregraft.com/serene. For more information, contact Bimini Health Tech.

5.3 What are Other Sources of Additional Information?

You may see the most current versions of this Patient Information Booklet, the Instructions for Use (IFU), the boxed warning and the Patient Decision Checklist at https://www.puregraft.com/serene.

For more detailed information on the preclinical and clinical studies conducted by Bimini Health Tech, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product at https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120011b.pdf.

After surgery, you will be given a Patient Implant Card with Implant Record Labels attached showing the UDI, size, and serial number of your breast implant(s). Keep this card for future reference.

Food and Drug Administration
1-800-INFO-FDA or 301-827-3990
fda.gov/breastimplants

Bimini Health Tech
8400 Belleview Drive, Suite 125
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7.0 Index

Appendix A: Materials / Chemicals / Metals

The potential toxicity of the chemicals and metals listed in the following tables have been evaluated with both toxicity testing and risk assessments to assess the exposure levels in comparison to the amount determined to likely be safe. However, individual responses to chemicals may vary, and all reactions cannot be predicted.

Materials Used to Make the Puregraft Serene Breast Implant

Material	Implant Component(s)
Polydimethylsiloxane ("silicone")	Shells, patch, valves, valve straps
Tin catalyst	Shells
Platinum catalyst	Patch, valves, valve straps
Saline	Filler

Chemicals Released from the Puregraft Serene Breast Implant

Volatiles: Chemicals that are released by breast implants as a gas.

Compound	Concentration (ppm*)	Compound	Concentration (ppm*)
D_3 cyclic siloxane	<0.3	Toluene	<0.05
D_4 cyclic siloxane	<0.3	m/p-Xylenes	<0.05
D_5 cyclic siloxane	<1.0	o-Xylene	<0.05
Isopropanol	0.9		
**ppm = parts per million* *Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method detection limit indicated.*			

Extractables: Chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid).

Compound	Concentration (ppm*)	Compound	Concentration (ppm*)
D_4 cyclic siloxane	BDL** - 4.3	MD_5M - $MD_{19}M$ linear siloxane	5.0 - 193
D_5 cyclic siloxane	0.2 - 15.0	1,2-Diphenyltetramethyldisilane	59.1
D_6 cyclic siloxane	0.7 - 48.0	Ethanedioic acid, Bis(trimethylsilyl)ester	22.3
D_7 - D_{21} cyclic siloxanes	4,083 - 11,188	1,3,5-Tris(trimethylsiloxy)benzene	38.9
MD_2M linear siloxane	BDL - 1.1	Ocatadecanoic acid, butyl ester	14.5
MD_3M linear siloxane	BDL - 2.2	Hexadecanoic acid, butyl ester	42.7
MD_4M linear siloxane	BDL - 2.1	Tetrahydro-2,5-dimethylfuran	19.6
Cyclohexane	19.6	Total by weight	2.6 - 3.1%
** ppm = parts per million ** BDL = not detected, below detectable limits*			

Heavy Metals Found in the Puregraft Serene Breast Implant

Metal	Concentration (ppm*)	Metal	Concentration (ppm*)
Aluminum	BDL** - 6.3	Manganese	BDL - 0.95
Antimony	BDL - 0.38	Nickel	BDL - 2.9
Barium	BDL - 0.25	Phosphorous	3.5 - 5.8
Calcium	< 26	Platinum	< 3
Chromium	BDL - 5.0	Potassium	BDL - 20
Copper	BDL - 0.35	Sodium	BDL - 3.4
Iron	1.1 - 23	Tin	BDL - 10.5
Lead	BDL - 1.5	Zinc	< 10
Magnesium	BDL - 12		
Arsenic, Beryllium, Cadmium, Cobalt, Molybdenum, Selenium, Silver, Thallium, Titanium, and Vanadium			BDL

** ppm = parts per million ** BDL = not detected, below detectable limits*
Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method detection limit indicated.

Appendix B: Patient Decision Checklist

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. You should receive a patient booklet/brochure that includes important information about your specific breast implant, as well as a boxed warning and patient decision checklist. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;

- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, anti-thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Having other products permanently implanted in the breast

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. These rates below were reported in the 10 year Core clinical study for Puregraft Serene Breast Implant up through May 14, 2021. Each rate specified herein represents the largest percentage reported in either the primary augmentation or revision augmentation cohorts. I understand that risks of undergoing breast implant surgery may include:

- breast pain (persistent breast pain reported in up to 1.1% of patients),
- skin or nipple areola sensitivity changes or loss (reported in up to 0.3% of patients),
- asymmetry (specific rate was not reported),
- impact of aging or weight change on size and shape of breast (breast ptosis was reported in up to 6.2% of patients),
- infection requiring possible removal of implant (reported in up to 1.3% of patients),
- swelling (may occur but specific rate was not reported),
- scarring (skin scar unsatisfactory reported in up to 3.9% of patients),
- fluid collections (seroma) (reported in up to 4.1% of patients),
- hematoma (reported in up to 1.8% of patients),
- tissue death of breast skin or nipple (reported in up to 1.5% of patients),
- inability to breast feed (reported in up to 3.3% of patients),
- complications of anesthesia (reported in up to 1.0% of patients),
- bleeding (reported in up to 1.8% of patients),
- chronic pain (may occur but specific rate was not reported),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rate was not reported),
- impact on imaging (i.e. mammography interference) of breast tissue (reported in up to 0.3% of patients).

My physician has discussed these risks and has provided me with the patient information booklet/brochure (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website**. As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates range from a high of 1 per 3,817 patients to a low estimate of 1 in 30,000 patients (Clemens et al, 2017; Loch-Wilkinson et al, 2017; De Boer et al, 2018). I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of include: swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

** See “Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma,” available at https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-largecell-lymphoma.

Patient Initials: _____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule, however not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some women with breast implants have reported health problems in their children after birth or breastfeeding. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breast feed.

Patient Initials: _____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my implant. As many as 42.6 percent of women who received Puregraft Serene Breast Implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer time (the percentage reported is from the clinical study for Puregraft Serene Breast Implants. This rate specified represents the largest reported cumulative rate across all groups of augmentation patients in the study (both primary and revision)).

I understand that my breast implants may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall,

lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include the following. These rates were reported in the clinical study used to support approval of the Puregraft Serene Breast Implant up through May 14, 2021. Each rate specified herein represents the largest percentage reported in either the primary augmentation or revision augmentation cohorts:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture grade III/IV reported in up to 11.5% of patients),
- rupture or leaking of the implant (reported in up to 4.7% of patients),
- wrinkling of the implant (reported in up to 21.1% of patients),
- visibility of the implant edges (may occur but specific rate was not reported)
- shifting of the implant (may occur but specific rate was not reported),
- reoperation (reported in up to 50.3% of patients).

I understand that I will receive a patient device card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my physician need to know what kind of implant I have many years later.

I understand that all breast implants contain chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant, but small quantities have been found to diffuse (gel bleed) through the shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure.

Patient Initials: _____

Recommended Follow-up

If I have silicone gel-filled breast implants, even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long- term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma

(ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants. PROFILE also collects all cancers in the breast implant capsules in patients with breast implants.

Patient Initials: _____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or a different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

_____
Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____
Physician Signature and Date