PUREGRAFT Serene™ BREAST IMPLANT

The following material is specifically compiled to help facilitate discussions that hospital product board review committees may conduct prior to approving the Puregraft Serene Breast Implant for purchase.

BIMINI HEALTHTECH

ABOUT PUREGRAFT SERENE BREAST IMPLANT

The **Puregraft Serene Breast Implant** (formerly Ideal Implant) is a smooth, round, structured, saline-filled breast implant that is supplied sterile in a dual-tray packaging system with two disposable fill tubes and reflux valves. It was developed to provide women and surgeons with an alternative to other saline-filled implants that lack an internal structure or silicone gel-filled implants.

GENERAL INFORMATION

MANUFACTURER:
Bimini Health Tech
8400 Belleview Drive, Suite 125
Plano, TX 75024
Telephone: 858-348-8050
Fax: 858-217-5134

FEDERAL TAX ID: 46-3228559

FDA PMA NUMBER: P120011

PRICING: Please refer to current price list.

Proprietary Name:
Puregraft Serene Breast Implant

Device Class: 3
Regulation Number: 21 CFR 878.3530
Medical Specialty: General & Plastic Surgery
Registered Establishment Name: Bimini Health Tech

FDA Status: PMA Approved P120011

FDA Investigational Device Exception (IDE): None

MATERIAL / ENVIRONMENT:
Does this product contain latex? No
Is product sterile? Yes
Is product disposable? No
Is product implantable? Yes

MATERIAL SAFETY DATA SHEET (MSDS): None

PRODUCT DESCRIPTION

INDICATION FOR USE:
The Serene Breast Implant is indicated for women at least 18 years old for the following:

- Primary breast augmentation to increase breast size
- Revision augmentation to correct or improve the result of a primary breast augmentation surgery

CONTRAINDICATIONS:
Breast implant surgery should not be performed in:

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions
- Women with active infection anywhere in their body
- Women who are currently pregnant or nursing

NAME OF PRODUCT:
Puregraft Serene Breast Implant

OFFERED IN FOURTEEN SIZES:

210cc	440cc
240cc	475cc
270cc	515cc
300cc	555cc
335cc	595cc
370cc	635cc
405cc	675cc

FOR QUESTIONS RELATED TO ADMINISTRATION, ORDERS OR ACCOUNTING, PLEASE CONTACT:

Bimini Health Tech
8400 Belleview Drive
Suite 125
Plano, TX 75024

Telephone:
858-348-8050

Fax:
858-217-5134

Email:
info@biminihealthtech.com

Website:
www.biminihealthtech.com

BIMINI
HEALTHTECH

FOR QUESTIONS RELATED TO ADMINISTRATION, ORDERS OR ACCOUNTING, PLEASE CONTACT:

Bimini Health Tech
8400 Belleview Drive
Suite 125
Plano, TX 75024

Telephone:
858-348-8050

Fax:
858-217-5134

Email:
info@biminihealthtech.com

Website:
www.biminihealthtech.com

How Is Product Shipped: Via FedEx Delivery
How Much Lead Time is Needed: Next Day if ordered before 4:00pm, CST.

Method of Purchase: Direct purchase

Does this product require special storage considerations? No

Is this a dated product? Yes, product contains expiration date on package label.

What specific departments / clinical areas will use the product / procedure?
Plastic surgery and General surgery operating room (OR)

What department(s) will use and/or be affected by this product?
Plastic Surgery, General surgery OR, Purchasing

UTILIZATION

Is there a requirement for staff training? Bimini Health Tech recommends hospital staff review we recommend staff review the IFU or package insert.

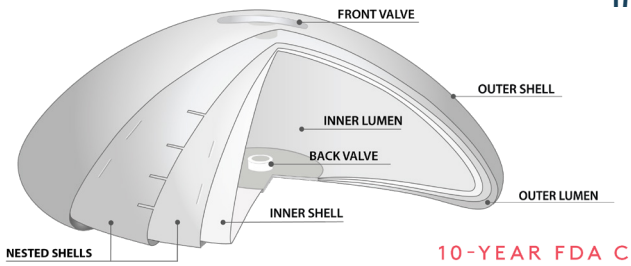
Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space? No.

Does the product/procedure require a company representative to be present to operate equipment or to provide assistance to the physicians? Per institution's plastic surgery protocol.

Will other equipment need to be leased,purchased, consigned or rented? No.

Will this equipment interface with any other equipment / supplies currently utilized at this facility? Yes, saline, tissue expanders, sutures.

IMPLANT RUPTURE & CONTRACTURE COMPARISONS, IMPLANT DESIGN AND SIZING



10-YEAR FDA CLINICAL TRIAL PERFORMANCE

Deflation/Rupture

Augmentation:	Primary	Revision
IDEAL IMPLANT	3.7%	4.7%
Allergan Gel	9.3%	5.4%
Mentor Gel	24.2%	23.7%
Sientra Gel	8.7%	6.8%

Kaplan-Meier Risk Rates of First Occurrence; MRI Cohort

Capsular Contracture

Augmentation:	Primary	Revision
IDEAL IMPLANT	6.6%	11.5%
Allergan Gel	18.9%	28.7%
Mentor Gel	12.1%	24.4%
Sientra Gel	12.9%	13.7%

Kaplan-Meier Risk Rates of First Occurrence; Baker III/IV

SERENE BREAST IMPLANT SIZING CHART

PURESHAPE Serene BREAST IMPLANT

Moderate Profile *at Minimum Fill*
Full Profile *at Maximum Fill*

	EMPTY + INNER + OUTER = TOTAL VOLUME					
IMPLANT SIZE	EMPTY IMPLANT VOLUME	INNER LUMEN SALINE	OUTER LUMEN SALINE	TOTAL IMPLANT VOLUME	BASE DIAMETER	PROJECTION
210cc	30cc	120cc	60 - 85cc	210 - 235cc	10.1 - 10.0cm	3.5 - 4.3cm
240cc	33	142	65 - 95	240 - 270	10.5 - 10.4	3.6 - 4.5
270cc	35	165	70 - 105	270 - 305	11.0 - 10.8	3.8 - 4.7
300cc	37	188	75 - 115	300 - 340	11.4 - 11.2	3.9 - 4.9
335cc	52	188	95 - 135	335 - 375	11.9 - 11.7	4.0 - 5.1
370cc	56	214	100 - 145	370 - 415	12.2 - 12.0	4.1 - 5.2
405cc	60	235	110 - 160	405 - 455	12.5 - 12.4	4.2 - 5.4
440cc	64	261	115 - 170	440 - 495	12.9 - 12.8	4.3 - 5.6
475cc	68	287	120 - 180	475 - 535	13.3 - 13.1	4.4 - 5.7
515cc	72	318	125 - 190	515 - 580	13.6 - 13.4	4.5 - 5.8
555cc	76	344	135 - 205	555 - 625	13.9 - 13.8	4.6 - 6.0
595cc	94	346	155 - 230	595 - 670	14.3 - 14.2	4.7 - 6.1
635cc	102	373	160 - 235	635 - 710	14.6 - 14.5	4.8 - 6.2
675cc	110	405	160 - 240	675 - 755	14.9 - 14.8	4.9 - 6.3

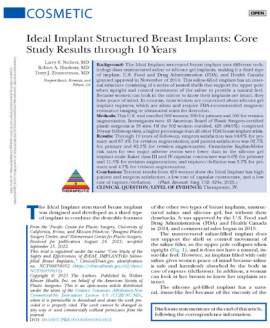
CLINICAL DATA (Released by former Ideal Implant)

CLINICAL HIGHLIGHTS:

IDEAL IMPLANT Structured Breast Implants: Core Study Results Through 10 Years

Conclusion: Ten-year results from 426 women show that the structured breast implant has a high patient and surgeon satisfaction, a low rate of capsular contracture, and a low rate of rupture/deflation.

Key Takeaway: Through 10 years of follow up, surgeon satisfaction was 94.8% for primary and 87.4% for revision augmentation; and patient satisfaction was 93% for primary and 82.3% for revision augmentation. Cumulative Kaplan-Meier risk rates for two major adverse events were than than in the silicone gel implant trials: Baker class III & IV capsular contracture was 6.6% for primary and 11.5% for revision augmentation; rupture/deflation was 3.7% for primary and 4.7% for revision augmentation.


COSMETIC

Ideal Implant Structured Breast Implants: Core Study Results through 10 Years

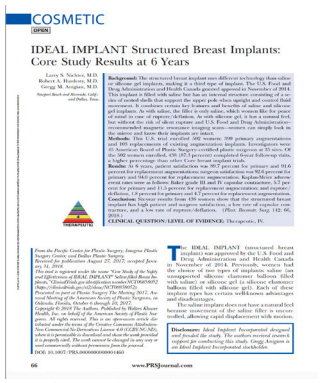
Larry S. Nichter, M.D.; Robert A. Hardesty, M.D.; Terry J. Zimmerman, M.D. IDEAL IMPLANT Structured Breast Implants: Core Study Results at 6 Years *Plast. Reconstr. Surg.Journal*; 152:3, 2022.

CLINICAL HIGHLIGHTS:

IDEAL IMPLANT Structured Breast Implants: Core Study Results at 6 Years

Conclusion: Six-year results from 438 women show that the structured breast implant has a high patient and surgeon satisfaction, a low rate of capsular contracture, and a low rate of rupture/deflation.

Key Takeaway: Investigators and patients were satisfied with the outcome of the procedure at 6 years. Investigators and patients were definitely or somewhat satisfied in 92.6% of the outcomes, and 94.0% in revision outcomes. Patient satisfaction of 89.7% of their primary outcomes and 91.6% in revision outcomes.


COSMETIC

IDEAL IMPLANT Structured Breast Implants: Core Study Results at 6 Years

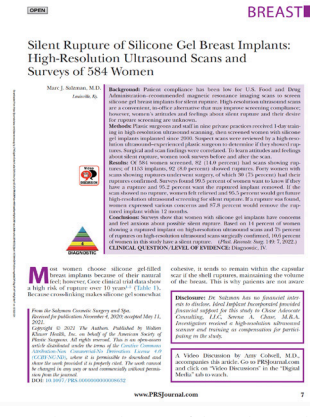
Larry S. Nichter, M.D.; Robert A. Hardesty, M.D.; Gregg M. Anigan, M.D. IDEAL IMPLANT Structured Breast Implants: Core Study Results at 6 Years *Plast. Reconstr. Surg.Journal*; 142:66, 2018.

CLINICAL HIGHLIGHTS:

Silent Rupture of Silicone Gel Breast Implants: High-Resolution Ultrasound Scans and Surveys of 584 Women

Conclusion: Surveys show that women with silicone gel implants have concerns and feel anxious about possible silent rupture. Based on 14 percent of women showing a ruptured implant on high-resolution ultrasound scans and 75 percent of ruptures on high-resolution ultrasound scans surgically confirmed, 10.6 percent of women in this study have a silent rupture.

Key Takeaway: Silicone gel rupture is only associated with silicone-filled breast implants and requires an MRI, Ultrasound, or Surgical Procedures to detect. Surveys of women who have received silicone gel implants found that 99.5% want to know if they have a rupture, and if so, 95.2% want the ruptured implant surgically removed, resulting in a secondary procedure.


BREAST

Silent Rupture of Silicone Gel Breast Implants: High-Resolution Ultrasound Scans and Surveys of 584 Women

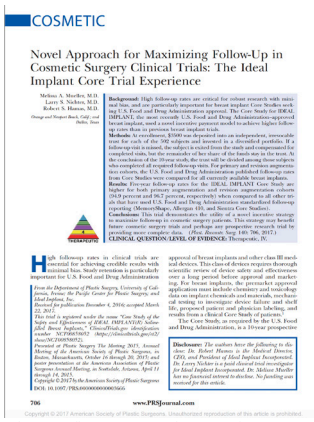
Marc J. Salzman, M.D. Silent Rupture of Silicone Gel Breast Implants: High-Resolution Ultrasound Scans and Surveys of 584 Women *Plast. Reconstr. Surg.Journal*; 149:7, 2022

CLINICAL HIGHLIGHTS:

Novel Approach for Maximizing Follow-Up in Cosmetic Surgery Clinical Trials: The Ideal Implant Core Trial Experience

Conclusion: This trial demonstrates the utility of a novel incentive strategy to maximize the follow-up in cosmetic surgery patients. This strategy may benefit future cosmetic surgery trials and perhaps any prospective research trial by providing more complete data.

Key Takeaway: Significant investment by one manufacturer for long-term patient follow-up yielded favorable results. Five-Year patient follow up for the Ideal Implant Core Study are higher for both primary augmentation and revision augmentation cohorts (94.9% and 96.7%, respectively) when compared to all other trials that have used U.S. Food and Drug Administration standardized follow-up reporting (MemoryShape, Allergan 410, and Sientra Core studies).


COSMETIC

Novel Approach for Maximizing Follow-Up in Cosmetic Surgery Clinical Trials: The Ideal Implant Core Trial Experience

Melissa A. Mueller, M.D., Larry S. Nichter, M.D.; Robert S. Hamas, M.D. Novel Approach for Maximizing Follow-Up in Cosmetic Surgery Clinical Trials: The Ideal Implant Core Trial Experience *Plast. Reconstr. Surg. Journal*; 140:706, 2017.

BIMINI HEALTHTECH

FOR QUESTIONS RELATED TO ADMINISTRATION, ORDERS OR ACCOUNTING, PLEASE CONTACT:

Bimini Health Tech
8400 Belleview Drive
Suite 125
Plano, TX 75024

Telephone:
858-348-8050

Fax:
858-217-5134

Email:
info@biminihealthtech.com

Website:
www.biminihealthtech.com

500-076-01 REV B