



PURE CONFIDENCE
Warranty Program

PURE DRAFT
Serene[™]
BREAST IMPLANT

Please see back cover for Important Safety Information, including Boxed Warning

Important **TERMS** and **CONDITIONS** to know



Products covered:

The Serene™ PURE CONFIDENCE warranty applies to all FDA-approved Serene Structured Saline Breast Implants, provided the products have been used:

- As intended by appropriately qualified and licensed surgeons and in accordance with current and accepted plastic surgery techniques
- In accordance with the current Serene™ Structured Saline Breast Implant Directions for Use, found at www.serenebreastimplants.com/IFU

Events covered:

- Non-conforming or unexpected qualifying deflation of implant

Events not covered:

- Any event other than deflation or breach of the limited warranty described herein
- Removal of intact implants due to rippling or wrinkling
- Removal of intact implants for size or shape alteration

To submit a claim:

To make a claim under our Limited Warranty, the patient or surgeon must contact us at complaints@biminihealthtech.com



BIMINI
HEALTHTECH

www.serenebreastimplants.com

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The sale and distribution of this device is restricted to users and/or user 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.

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 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 these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.