

July 30, 2019

Dear Allergan Plastic Surgery Customer,

In follow-up to Allergan's voluntary recall of unused BIOCELL® products, we created the **BIOCELL® Replacement Warranty** for all patients currently implanted with BIOCELL® textured implants.

**For patients in the U.S. who, as a result of the recall announcement on July 24, 2019, choose to replace their BIOCELL® textured devices with smooth devices in consultation with their plastic surgeon, Allergan will provide Allergan smooth device replacements for free.** The program will run for 24 months, until July 24, 2021, and will apply to revision surgeries on or after the date of the recall announcement, July 24, 2019.

The decision to get a breast implant revision is a personal decision between patients and their plastic surgeons, and must be decided based on the appropriate discussion of benefits and risks. **As part of this program, Allergan will not provide surgical fee assistance to revision patients.** This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL. Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® warranty, which includes reimbursement for up to \$1,000 in diagnostic fees and up to \$7,500 in surgical fees related to diagnosing and treating BIA-ALCL.

Some frequently asked questions about this policy are attached. You may initiate a replacement request under the BIOCELL® Replacement Warranty by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261.

Sincerely,

A handwritten signature in blue ink that reads "Carrie Strom".

Carrie Strom

Senior Vice President, U.S. Medical Aesthetics

Allergan plc



## **BIOCELL® Replacement Warranty: Surgeon Frequently Asked Questions**

### **What is the BIOCELL® Replacement Warranty?**

For patients in the U.S. who choose to replace their BIOCELL® textured devices with smooth devices, as a result of the recall announcement on July 24, 2019, Allergan will provide smooth device replacements for free.

### **When does the program take effect and for how long?**

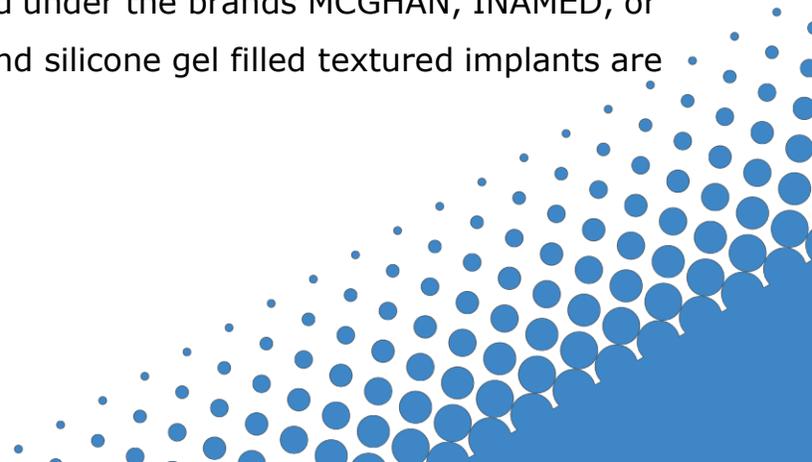
This program started on July 24, 2019 and will last until July 24, 2021.

### **What patients are covered?**

Patients must be U.S. based, and they must have a BIOCELL® textured implant. This program is intended to assist patients who, as a result of the BIOCELL® recall, are concerned about their textured implants. Patients should have carefully considered the benefits and risks of a revision surgery through a discussion with their plastic surgeon.

### **What devices are covered?**

The BIOCELL® Replacement Warranty covers all BIOCELL® textured implants that may have been originally manufactured under the brands MCGHAN, INAMED, or ALLERGAN NATRELLE®. Both saline and silicone gel filled textured implants are covered.



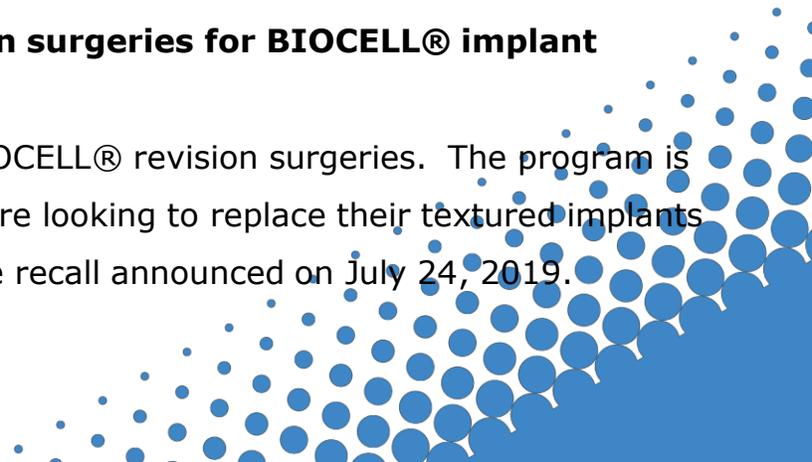


## **Which replacement devices may patients select as part of this replacement program?**

Silicone gel-filled texture implant patients are eligible for gel-filled smooth implant replacements, and saline-filled texture implant patients are eligible for saline-filled smooth replacements. Allergan will provide replacement implants within a similar product type, gel or saline, but the exact material fill or product dimensions do not need to match exactly. For example, a Style 410 (e.g. SKU FM-410-310) textured anatomical implant may be replaced with any similar size NATRELLE INSPIRA® smooth implant containing either Responsive (e.g. SKU SRM-310), SoftTouch (e.g. SSM-310), or Cohesive gel (e.g. SCM-310). Or, a Style 168 textured saline (e.g. SKU 168-300) implant may be replaced with any similar size NATRELLE® Style 68 smooth saline-filled implant (e.g. SKU 68-300). In these examples, all implants have a similar base width, projection, and volume. In some cases, an exact matchup of the device dimensions may not be possible, in which case a similar device will be allowed. The program is not intended to assist patients with reoperations for size changes or correcting non-implant related changes to the breast over time. However, Allergan understands that some exceptions to this rule will be required based on patient needs, and Allergan will evaluate these requests as necessary. The BIOCELL® Replacement Warranty is intended to assist patients concerned about their BIOCELL® textured implants as a result of the recall.

## **Does this apply to all of my revision surgeries for BIOCELL® implant patients?**

This program is not intended for all BIOCELL® revision surgeries. The program is intended for BIOCELL® patients who are looking to replace their textured implants with smooth implants as a result of the recall announced on July 24, 2019.





### **How do I initiate a claim?**

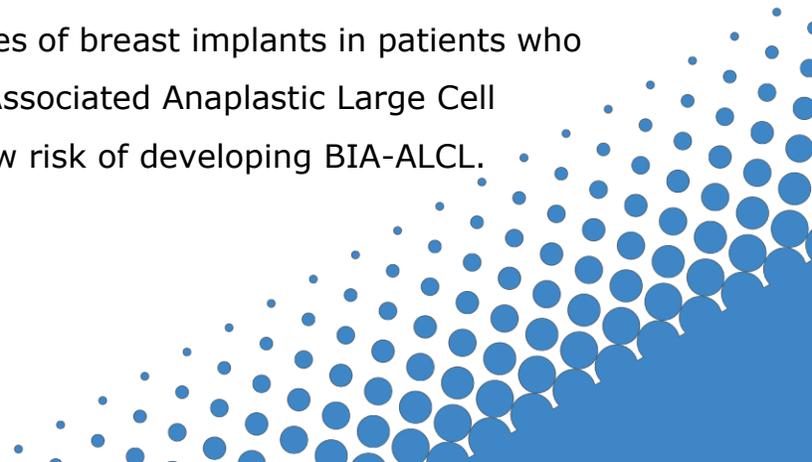
You may initiate a replacement request by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261. Allergan Product Surveillance will request information about the devices being replaced and devices being requested. Allergan Product Surveillance will also provide a BIOCELL® Replacement Warranty program informed consent document for the patient to acknowledge that she has reviewed her options with you, her plastic surgeon, and has accepted the program conditions. Upon receipt of the signed consent document, replacement devices will be shipped to the specified address, or credited to the account if new products are used from your consignment.

### **Do explanted BIOCELL® devices need to be returned to Allergan as part of the BIOCELL® Replacement Warranty?**

Yes. This process will be the same as other device replacement programs at Allergan. When you open a BIOCELL® Replacement Warranty request with Allergan, we will send a return kit to you and we request that you please send the explanted devices back to Allergan in the return kit.

### **Are surgery fees covered?**

As part of this program, Allergan will not be providing surgical fee assistance to revision patients. This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL.





Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® Warranty, which includes reimbursement for up to \$1,000 in diagnostic fees and up to \$7,500 in surgical fees related to diagnosing and treating BIA-ALCL. More information about the NATRELLE® ConfidencePlus® Warranty can be found at [www.natrelle.com/warranty](http://www.natrelle.com/warranty).

**Will patients be notified of the BIOCELL® Replacement Warranty?**

Allergan is proactively reaching out to patients who may have BIOCELL® textured implants to notify them of the BIOCELL® recall. In those communications, Allergan is not proactively discussing this warranty coverage. Allergan believes that discussions about treatment options, including revision surgeries, are most appropriately handled between the patients and their surgeons. However, information about the BIOCELL® Replacement Warranty will be publicly available at [www.allergan.com](http://www.allergan.com). This website includes a copy of the letter Allergan is sending to patients in the Allergan device tracking database who may have BIOCELL® textured implants. To see which of your patients will be receiving this letter, you may request a list by emailing Allergan Product Support at [DL-AUS-DeviceTracking@Allergan.com](mailto:DL-AUS-DeviceTracking@Allergan.com).

**Where can I find more information about the BIOCELL® recall and the BIOCELL® Replacement Warranty?**

More information about the BIOCELL® recall and the BIOCELL® Replacement Warranty are available on our website at [www.allergan.com](http://www.allergan.com).

