



August 9, 2019

Name

Title

Address

Address

City, State, ZIP

RE: IMPORTANT PRODUCT SAFETY ALERT for BIOCELL TEXTURED BREAST IMPLANTS and TISSUE EXPANDERS

Dear [Insert Patient Name here],

Why are we writing to you? Our records indicate that you may currently have, or have had, BIOCELL® textured breast implants and/or tissue expanders. These products may have been sold under the brands McGhan, Inamed, Allergan or NATRELLE®.

Why is this important? On July 24, 2019, Allergan announced a voluntary worldwide withdrawal of unused stock of BIOCELL textured breast implants and tissue expanders from doctors' offices and hospitals, and a suspension of any future sales which is part of the voluntary recall of BIOCELL textured breast implants and tissue expanders. NATRELLE smooth breast implants are not subject to this withdrawal.

How to identify your implant type? You may have received an information card from your surgeon or the surgical facility at the time that your implant was inserted. If you do not have this, ask your surgeon or contact the facility where your surgery was performed for a record of your surgery (operative notes). Implant types impacted by this alert are listed below:

WITHDRAWN AFFECTED PRODUCT NAMES AND STYLES These products may have been sold under the McGhan, Inamed or NATRELLE brands.	
NATRELLE Saline Breast Implants	Styles 168, 163, 363, 468
NATRELLE 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants	Styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
McGhan BioDIMENSIONAL® Silicone-Filled BIOCELL® Textured Breast Implants	Style 153
NATRELLE INSPIRA Silicone-Filled Breast Implants	Styles TRL, TRLP, TRM, TRF, TRX, TSL, TSLP, TSM, TSF, TSX, TCL, TCLP, TCM, TCF, TCX
NATRELLE Silicone-Filled Breast Implants	Styles 110, 115, and 120
Natrelle 133 Tissue expanders with and without suture tabs Style 133 BIOSPAN Tissue Expander McGhan Magna-Site Tissue Expander	Styles 133FV, 133MV, 133LV, 133FX, 133MX, 133SX, 133SV, 133FV-T, 133MV-T, 133LV-T, 133FX-T, 133MX-T, 133SX-T, 133SV-T
NATRELLE 133 Plus Tissue Expanders	Styles 133P-FV, 133P-MV, 133P-LV, 133P-FX, 133P-MX, 133P-SX, 133P-SV, 133P-FV-T, 133P-MV-T, 133P-LV-T, 133P-FX-T, 133P-MX-T, 133P-SX-T, 133P-SV-T

Why did we do this? We took this action following notification by the U.S. Food and Drug Administration (FDA) of their recently updated global safety information. This information showed a higher occurrence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in patients who have, or have had, Allergan BIOCELL textured breast implants.

How does this affect you? This withdrawal of unused stock and discontinuation of sales does **NOT** mean your textured implants need to be removed unless you are experiencing specific symptoms. You do, however, need to be aware of the symptoms to watch out for in this uncommon, but serious, condition.

THE US FOOD AND DRUG ADMINISTRATION (FDA) NOTES THAT WOMEN WHO HAVE THESE IMPLANTS BUT NO SYMPTOMS DO NOT NEED TO HAVE THEIR IMPLANTS OR EXPANDERS REMOVED.

What is BIA-ALCL? BIA-ALCL is not breast cancer—it is a type of non-Hodgkin’s lymphoma (cancer of the immune system). At this time, the likelihood of developing BIA-ALCL is thought to be low, occurring in less than 0.03% of patients with BIOCELL textured breast implants. However, BIA-ALCL is a serious condition and can lead to death, especially if not diagnosed early or treated promptly.

What are the symptoms of BIA-ALCL? Symptoms include breast enlargement or hardening, persistent pain, lump in the breast or armpit, or a large fluid collection surrounding an implant. These symptoms typically develop 8 to 10 years after implant placement.

IF YOU HAVE ANY OF THESE SYMPTOMS, NOTICE ANYTHING OF CONCERN ABOUT YOUR BREASTS, OR SUSPECT ANYTHING MAY BE WRONG WITH YOUR IMPLANTS OR EXPANDERS, PLEASE SPEAK WITH YOUR PLASTIC SURGEON IMMEDIATELY.

How is BIA-ALCL treated? In most patients, BIA-ALCL is treated successfully with surgery to remove the implant and the scar tissue surrounding it. Some patients may require additional treatment with chemotherapy and/or radiation therapy.

Where can I get more information? For more information please contact Allergan Medical Information at **1-800-678-1605, option #2 or email IR-Medcom@allergan.com**. For additional information, including what assistance may be available to you through the NATRELLE ConfidencePlus® and BIOCELL® Replacement Warranties from Allergan, please visit www.Allergan.com.

Paper copies, including translations, of resources can be provided upon request by calling Allergan Medical Information at 1-800-678-1605, option #2 or email IR-Medcom@allergan.com.

Copias físicas de los recursos, incluyendo las traducciones, pueden ser proporcionadas bajo solicitud al Departamento de Información Médica (Teléfono: 1-800-678-1605 opción #2; E-mail: IR-Medcom@allergan.com).

Des copies papiers des différentes ressources sont disponibles dans différentes langues et peuvent être obtenues en communiquant avec les informations médicales au 1-800-678-1605 option #2 ou par courriel au IR-Medcom@allergan.com.

相關資源的書面副本（包括翻譯）可以聯繫醫學信息部獲取（電話：1-800-678-1605選項#2；電子郵件：IR-Medcom@allergan.com）。

Sincerely,



Charles Hugh-Jones MD, FRCP

Global Chief Medical Officer

Allergan plc

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