Field Safety Notice (FSN)

31 July 2019

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

Voluntary Worldwide Recall of BIOCELL® Textured Breast Implants and BIOCELL® Textured Tissue Expanders

Allergan has announced a voluntary worldwide recall of BIOCELL® textured breast implants and BIOCELL® textured tissue expanders. Allergan is taking this global action as a precaution after being notified of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the U.S. Food and Drug Administration (FDA).

ADVISORY TO HEALTHCARE PROFESSIONALS

Effective immediately, Allergan recommends that healthcare providers cease implanting BIOCELL® textured breast implants and BIOCELL® textured tissue expanders and requests that all unused product be returned to Allergan.

It's important to note that the FDA and other global health authorities do not recommend the removal or replacement of textured breast implants or textured tissue expanders in asymptomatic patients.

The FDA issued a press release and posted materials on its website announcing the voluntary recall. In these materials, the FDA included a section entitled "Recommendations for Health Care Providers", as well as a section for patients entitled "Patients: Important Recommendations If You Have Allergan BIOCELL Breast Implants". You should review the FDA's communications which can be found at https://www.fda.gov/medical-devices/safety-communications/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan

This global recall does not affect Allergan's NATRELLE® smooth or MICROCELL® breast implants and tissue expanders. NATRELLE® smooth breast implants and smooth tissue expanders will continue to be available to physicians and for patients.

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The recalled products include the BIOCELL® textured breast implants and BIOCELL® textured tissue expanders from the following product families.

Natrelle Saline breast implant styles 168, 363, 468
Natrelle and McGhan 410 breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
Natrelle and McGhan 410 *Soft Touch* breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
Natrelle 510 Dual-Gel styles LX, MX, FX
Natrelle INSPIRA breast implants, styles TRL, TRLP, TRM, TRF, TRX, TSL, TSLP, TSM, TSF, TSX, TCL, TCLP, TCM, TCF, TCX
Natrelle and McGhan Round Gel Implants, styles 110, 110 Soft Touch, 115, 120, 120 Soft Touch
Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM
Natrelle Ritz Princess breast implant styles RML, RMM, RFL, RFM
Natrelle 150 Full Height and Short Height double lumen implants
Natrelle 133 tissue expanders with and without suture tabs: styles 133FV, 133MV, 133LV, 133FX, 133MX, 133SX, 133SV, T-133FV, T-133MV, T-133LV, T-133FX, T-133MX, T-133SX, T-133SV, 133FV-T, 133MV-T, 133LV-T,133FX-T, 133MX-T, 133SX-T, 133SV-T
Natrelle 133 Plus tissue expander styles 133P-FV, 133P-MV, 133P-LV, 133P-FX, 133P-MX, 133P-SX, 133P-SV, T-133P-FV, T-133P-MV, T-133P-LV, T-133P-FX, T-133P-MX, T-133P-SX, T-133P-SV, 133P-FV-T, 133P-MV-T, 133P-LV-T, 133P-FX-T, 133P-MX-T, 133P-SX-T, 133P-SV-T

Details of the affected models can be found in **Attachment 1**.

ACTIONS REQUIRED

Upon receipt of this FSN, please take the following actions:

1. Customers/Physicians should identify if they have the BIOCELL® textured breast implants and BIOCELL® tissue expanders and immediately quarantine any product listed in **Attachment 1**.

2. Carry out a physical count of the affected product in your possession and record this data on the Business Reply Form (BRF) **(Attachment 2)**.

3. As acknowledgment of the receipt of this FSN, please return the BRF to the Zuellig Pharma fax number or email address on the BRF form within 48 hours, even if you do not have the affected products.

4. If you have any inventory of the affected products indicated in your returned BRF, a customer service representative will be in contact with you to help process the return. Keep a copy of the BRF to be sent with the returned product.

5. Should you have any questions or concerns regarding the above instructions, please call customer service at +6565481795.

6. A credit will only be issued for product returned that is listed in **Attachment 1**.

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As you know, patient safety is of primary importance to Allergan. All breast implant patients should discuss benefits and risk of breast implants along with any specific concerns with their plastic surgeon.

Allergan will continue to partner with global health authorities on patient registry initiatives including Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Etiology and Epidemiology (PROFILE) and National Breast Implant Registry (NBIR) as we believe these registries will promote better understanding of patients' experiences with breast implants.

QUERIES RELATED TO THE RECALL

Healthcare providers in Singapore with questions regarding this announcement should contact Allergan using the contact details below:

Country	Country Medical Information Contact Email	Country Medical Information Contact Phone number
Singapore	medinfo.singapore@allergan.com	+65 3158 0552

We appreciate your cooperation in this product recall and regret any inconvenience that this may have caused. At Allergan, our priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products. Thank you for your assistance in this matter.

Yours Sincerely,

[redacted]

Lainey Lei
Country Manager, SMP
Allergan

Appendix:
Attachment 1 List of affected models
Attachment 2 Business Reply Form (BRF)

Allergan Singapore Pte Ltd
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URGENT DEVICE RECALL

BIOCELL® Textured Breast Implants
BIOCELL® Textured Tissue Expanders

BUSINESS REPLY FORM

Affected Product:	BIOCELL® Textured Breast Implants BIOCELL® Textured Tissue Expanders
Models	Refer to Attachment 1 for List of affected models

☐ We **have** stock of the recalled product listed in Attachment 1 and we will coordinate return of the stock with Allergan representative *(Please complete the table below)*

☐ We **do not have** any stock of the recalled product listed below and will not be making a return.

Device Name	Device Identifier	Quantity to be Returned

Your timely response to this recall notification is requested. Please complete and return this form within 48 hours **even if you do not have the recalled product in your possession** to:

Fax: +65 6548 1733

Email: SGZPSAllergan@zuelligpharma.com

ACKNOWLEDGEMENT

By returning the completed and signed form, the Healthcare Professional hereby acknowledges having received, read, and understood the content of the Field Safety Notice (FSN) and has taken the appropriate actions.

Customer Name & Address: _____

Name & Title of Person completing this form: _____

Contact Number: _____

Email Address: _____

Signature & date: _____