

Allergan withdraws BIOCELL Textured Breast Implants and Tissue Expanders from the worldwide market



We would like to inform our members that Allergan today voluntarily withdrew BIOCELL Textured Breast Implants and Tissue Expanders from the worldwide market.

Effective immediately, healthcare providers should no longer implant new BIOCELL® textured breast implants and tissue expanders and unused products should be returned to Allergan. Allergan will provide additional information to customers about how to return unused products.

Thus, the breast implant manufacturer followed a request of the US FDA, which was based on new available data.

It is emphasized again that there is still no recommendation to remove or replace textured breast implants from patients without symptoms.

This global recall does not affect Allergan's NATRELLE® smooth or MICROCELL® breast implants and tissue expanders.

LEARN MORE

The recalled products include:

- 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, 120, 120 Soft Touch
- Natrelle Komuro breast implants styles KML, KMM, KLL, and
- Natrelle Ritz Princess breast implant styles RML, RMM, RFL.
- Natrelle 150 Full Height and Short Height double lumen implants
- Natrelle 133 tissue expanders with and without suture tabs: styles 133FV, 133MV, 133LV, 133MX, 133SX, 133SV, T-133FV, T-133MV, T-133LV, T-133MX, T-133SX, T-133SV, 133FV-T, 133MV-T, 133LV-T, 133MX-T, 133SX-T, 133SV-T • Natrelle 133 Plus tissue expander styles 133P-FV, 133P-MV,
- 133P-LV, 133P-MX, 133P-SX, 133P-SV, T-133P-FV, T-133P-MV, T-133P-LV, T-133P-MX, T-133P-SX, T-133P-SV, 133P-FV-T, 133P-MV-T, 133P-LV-T, 133P-MX-T, 133P-SX-T, 133P-SV-T

Allergan has set up the **FOLLOWING HOTLINES:**

U.S. healthcare providers with questions regarding this announcement can contact Medical Information at 1-800-678-1605 option #2 or IR-Medcom@allergan.com.

For all other countries, please use the contact details at the following link on Allergan's website: Allergan Global Medical Information Contacts.

Deutschland

ET-Medinfo@Allergan.com, Tel: +49 69 92038 1050

Österreich

medinfo.austria@allergan.com, Tel: +43 1 99 4606355

Schweiz

medinfo.switzerland@allergan.com, Tel: 0800 007 124

Sources:

https://www.allergan.com/news/news/thomson-reuters/allergan-voluntarily-recalls-biocelltextured-brea.aspx

https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-riskcertain-textured-breast-implants-requests-allergan

