SPECIAL eBULLETIN

FOR PROFESSIONAL AND FACILITY **NOVEMBER 15, 2019**

FDA RECALLS BREAST IMPLANTS

Allergan BIOCELL Textured Breast Implants and Tissue Expanders Affected Due to Lymphoma Risk

The Food and Drug Administration (FDA) requested that Allergan recall its BIOCELL textured breast implants and tissue expanders based on newly submitted Medical Device Reports (MDRs) reporting worldwide cases of implant-associated anaplastic large cell lymphoma (BIA-ALCL) aassociated with these devices.

Allergan is removing these products from the global market. The FDA will continue to evaluate any new information and may, as a result, take action regarding other breast implants, if warranted.

You should immediately stop implanting these Allergan BIOCELL breast implants; and work with your facility to return existing inventory.

Review and Follow the FDA Safety Communication

The FDA has released a Safety Communication on Allergan BIOCELL textured breast implants and tissue expanders. This communication has more detailed information about patient and provider recommendations.

We encourage you to read this communication, share with your patients and staff, and follow the recommendations in this communication.

HIGHMARK