Summary of Labeling Changes for All Breast Implants

To help ensure that patients are aware of the benefits and risks of breast implants, FDA approved new labeling for all breast implants, a new requirement intended to enhance pre-operative discussions between patients and surgeons, and new restrictions on the sale of all breast implants effective November 26, 2021.

Labeling Changes

Instructions for Use (IFU) and Patient Information Booklet

The new versions are available at idealimplant.com/labeling. Important updates and changes include:

- **Screening for Silent Rupture of Silicone Gel Implants:** Recommended with an MRI or ultrasound scan at 5-6 years after implantation and then every 2-3 years thereafter.
- **Boxed Warning:** Notes that (1) breast implants are not lifetime devices, (2) there is an association of breast implants with development of BIA-ALCL, and (3) patients with breast implants have reported a variety of systemic symptoms.
- **Restriction of Sales:** Breast implants may only be sold to users and/or user facilities who comply with the new requirements specified in the new labeling.

Patient Information Booklet

Also includes:

- **Patient Decision Checklist:** Manufacturer-specific information about benefits and risks of breast implants and breast implant surgery that is to be reviewed with the patient.
- **Materials Description:** Lists of the specific (1) materials used to manufacture the breast implant, (2) chemicals released from the breast implant, and (3) heavy metals found in the breast implant.

Patient Implant Card and Implant Record Label

Contains information about the boxed warning, manufacturer contact, device tracking, and the specific implant received by the patient.

Requirements to Comply with New Labeling

You will be required to follow these steps pre-operatively:

- Provide the Patient Information Booklet for the implant that will be implanted. Review the included.
- Patient Decision Checklist with the patient to assure understanding of the benefits, risks, and other information.
- Provide the patient an opportunity to initial and sign confirming they were made aware of the risks.
- Sign as the implanting surgeon confirming you discussed the benefits and risks with the patient.
- Provide a copy of the signed checklist to the patient and file a copy in their medical record to document your compliance with the requirements.

Restriction of Sales

Manufacturers may only sell breast implants to surgeons and facilities who comply with the new labeling requirements.