



Dear EE Customer

Allergan is reaching out to you to notify you of an issue regarding the availability of our textured breast implants in the EE.

Effective immediately, Allergan is suspending sales of textured breast implants and tissue expanders and withdrawing any remaining supply in European markets. The withdrawal decision follows a compulsory recall request from Agence Nationale de Sécurité du Médicament (ANSM), the French regulatory authority. The suspension of sales stems from the expiration of the company's CE Mark for these products.

Although Allergan disagrees with ANSM's request, the Company is fully cooperating with the authority. Allergan stands behind the benefit/risk profile of our breast implant products. The ANSM request, and this action, is not based on any new scientific evidence. Furthermore, ANSM has not identified any immediate risk to the health of women with textured breast implants.

The CE Mark for Allergan's smooth implants has been renewed by GMED. Smooth implants are not affected and continue to be available.

Patient safety and product quality are Allergan's highest priorities. We are committed to strict adherence to all regulatory requirements, to the most rigorous scientific evidence and to the highest industry standards for our products. Allergan takes this situation very seriously and is committed to providing all stakeholders with timely and informative updates on this issue as more information becomes available.

Importantly the safety profile of textured breast implants is well-known and surgical removal is not being recommended on this information alone given the known risks removal can have for patients.

**As a precautionary measure, we request that you immediately hold Allergan brand textured implants you have on hand in your facility, and we will contact you soon to organize the return of these products.**

Textured implants affected by this communication:

- Textured NATRELLE INSPIRA Breast Implants: TRL / TSL / TRLP / TSLP / TRM / TSM / TRF / TSF / TRX / TSX
- NATRELLE 410 Breast Implants: LL / ML / FL / LM / MM / LF / MF / FF / LX / MX / FX
- BRST Breast Implants: RLP / CLP / RMP / CMP / RHP / CHP / CXP
- Tissue expanders 133Plus: SV / LV / MV / FV / SX / MX / FX

If you have any questions please use the contact details below.

HC21 Customer Service can be reached on 0845 6055521 [info@hc21.eu](mailto:info@hc21.eu)

HC21 customer service will be contacting you to agree the product withdrawal and product reconciliation process.

Regards,

On behalf of Allergan Ltd,

Nicholas Hill

Allergan Regulatory Affairs, European Region