Rev 1: September 2018
FSN Ref: FSN-18-001 FSCA Ref: FSCA-18-001

Date: 19-DEC-2018

Urgent Field Safety Notice
Allergan Textured Breast Implants and Tissue Expanders

For Attention of*:All Healthcare Professionals holding stock of Allergan textured breast implants and tissue expanders

Contact details of local representative (name, e-mail, telephone, address etc.) *
Arvind Patel, Arvind.Patel@Allergan.com, +44 (0)7983 166546, Allergan, Marlow International, Parkway, Marlow, Bucks, SL7 1YL, UK.

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Based on expiration of CE Mark, ANSM (France) requested Allergan perform a market withdrawal of all affected product in healthcare institutions

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Allergan textured breast implants are sterile, silicone gel-filled implantable devices designed to reconstruct or augment the breast. The implant may vary in shape, profile, volume, surface and shell thickness. Allergan textured tissue expanders are inflatable sterile devices implanted temporarily over a period of time to enlarge the tissue.
1.	2. Commercial name(s)
	See Appendix 1
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Allergan Breast Implants are used in augmentation and reconstruction mammaplasty. Allergan Tissue Expanders are intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage.
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix 1
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	All products as detailed in the Appendix
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	Allergan textured breast implants and tissue expander CE mark certification expired on 16 December 2018. Allergan's Notified Body GMED, advised on 14 December 2018 that additional information was requested, and that the renewal was not completed at this time. The renewal review process is continuing, and Allergan continues to work with GMED to a satisfactory conclusion. ANSM (France) requested Allergan perform a market withdrawal of all affected product in healthcare institutions.
2.	2. Hazard giving rise to the FSCA*
	None. As noted by ANSM, no immediate risk for the health of women having the affected implants has been identified. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
2.	3. Probability of problem arising
	No problem has been identified. This is considered a precautionary activity conducted at request of ANSM. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
	4. Predicted risk to patient/users

2.	Allergan is confident in the risk/benefit profile of our family of implant products. The safety profile of Allergan's breast implants is supported by extensive pre-clinical and clinical data. There is more than a decade of successful U.S. and European clinical use as well as a large number of peer-reviewed and published studies. At this stage no immediate risk for the health of women having the affected implants has been identified and this is noted by ANSM. The ANSM request, and this action, is not based on any new scientific evidence regarding these products.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Allergan's breast implant portfolio is regulated in Europe by the French Notified Body, GMED. On a periodic basis, like all medical device manufacturers, Allergan is required to submit for renewal of its CE mark to manufacture and supply its devices, including its families of breast implants and tissue expanders. Allergan submitted its renewal for these products in August 2018. Allergan's current certificates for its family of breast implant products were set to expire on December 16, 2018.Allergan was informed late Friday, December 14, 2018 by GMED that the routine review and renewal of our CE Mark for textured breast implants and tissue expanders has not been completed. As a result, the CE Mark for these products expired on December 16, 2018. Subsequently, Allergan was informed by ANSM, the French regulatory authority, that they are requiring the withdraw of any remaining supply in France. While Allergan is fully cooperating with the request, the Company 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 regarding these products.
2.	7. Other information relevant to FSCA
	Allergan were requested by ANSM to perform a market withdrawal of all textured breast implants and tissue expanders. The action has been extended across the European region due to consistency of Competent Authority decisions.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately.

3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Based on the available scientific information, international health agencies are not recommending prophylactic removal or changes to current practice. As per standard of care, routine check-up will healthcare provider is recommended.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Withdrawal of Allergan textured breast implants and tissue expanders. No action with regards to already implanted devices.	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Allergan**
	b. Address	**Marlow International, Parkway, Marlow, Bucks, SL7 1YL, United Kingdom**
	c. Website address	**www,allergan.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Appendix 1: Product ranges affected**
4.	10. Name/Signature	**Roisin Shanley. Associate Vice President, Quality Operations – Third Party, Commercial Quality**
		DocuSigned by: Roisin Shanley A06DC6AF43E94A9...

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.