Field Safety Notice (FSN)
Allergan

FSCA_EAME_01_15
Missing Printed Material from Instructions for Use Booklet (Consent Form, Fill Volume Record Card, ID Card)

Date:
Attention:

Dear Customer,

You are receiving this communication as our records indicate that you have received Allergan product that is the subject of this Field Safety Notice (FSN). Information describing the issue and any actions to be taken are provided below.

Details of Affected Devices:

Product Type: Tissue expanders

Product Name: Natrelle™ 133 Plus Tissue Expanders

Product Description: The Natrelle™ 133 Plus Tissue Expanders are intended for use in tissue expansion during breast reconstruction. The Natrelle™ 133 Plus Tissue Expanders achieve tissue expansion via inflation with sequential injections of sterile saline solution through an integrated injection site.

Description of the problem:
The instructions for use booklet supplied with the Natrelle™ 133 Plus Tissue Expanders should include the following items at the back of the booklet:

1) **Consent Form (Patient and Surgeon Copies)** - Facilitates patient awareness and acceptance of risk associated with tissue expander surgery.
2) **Fill Volume Record Card** - Enables a record of fill volumes and intervals to be completed.
3) **ID Card** for the patient – Used to provide the patient with written information about the specific implanted device(s).

However, the Consent Form (4 pages), Fill Volume Record Card (2 pages) and ID Card (2 pages) are missing from the back of the instructions for use booklet supplied with the Natrelle 133 Plus Tissue Expanders. In total, there are 8 pages missing.

Affected Product Catalogue Numbers:
A list of the affected product catalogue numbers together with the serial and lot numbers is enclosed in appendix 1 of this Field Safety Notice.

Risk Assessment:
The likelihood of the missing information in the product instructions for use booklet leading to patient harm has been assessed by Allergan to be negligible. There is no known failure of the device to perform in accordance with its intended purpose, when used in accordance

with the manufacturer's instructions for use. These use instructions are in the booklet supplied with the product.

The following assessment was made for each missing item in the instructions for use booklet:

1) **Consent Form** – While this is a useful guide, it does not take the place of a proper informed consent dialogue about the risks and benefits of treatment that should take as part of a thorough consultation discussion.

2) **Fill Volume Record Card** – This card may be useful for providing a secondary written record of fill volumes. However, as per standard of care, the fill session and volumes should be recorded in the patient's written or electronic medical record for continuity of care.

3) **ID Card** - The ID Card is one method of reminding the patient about the product (manufacturer, style etc) that has been implanted. There are, of course, other methods to inform the patient such as telling them. Although the patient may not recall the manufacturer or style etc of an implanted device, this information should be recorded in the patient's medical records.

Action to be taken by customer:
To resolve this matter, Allergan has enclosed the following missing items:

1) Consent Form (Patient and Surgeon Copies) – 4 pages
2) Fill Volume Record Card – 2 pages
3) ID card sheet – 2 pages

If the device has already been implanted, Allergan recommends that that the patient is provided with a completed ID card sheet.

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.

Allergan will inform all relevant regulatory agencies of this FSN.

We apologise for any inconvenience this incident may have caused you. If you have any questions regarding this FSN, please contact Allergan Customer Service using the details provided below.

Contact reference person:
Name / organisation, address, contact details (to be added by each country).

Signature