Guidance on the vigilance system for CE-marked medical devices

DSVG 04

Breast Implants

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1. **Introduction**

This document provides guidance for manufacturers of Breast Implants. It outlines specific scenarios that should be considered when determining if an incident is reportable, however it is not a comprehensive list. This document should be read in conjunction with DSVG 00 Introduction to Device Specific Vigilance Guidance.

The aim of this guidance is to complement the requirements of the Medical Devices Directives [1] and the MEDDEV [2] and should be read in conjunction with the aforementioned documents. Device specific guidance does not replace or extend these requirements.

2. **What Incidents Should Be Reported:**

The following table details examples of incidents associated with Breast Implants, indicating what should be reported as problems associated with the device that may have caused or contributed to the incident, these are complementary to the general reporting requirements already outlined in the MDD and Vigilance MEDDEV and do not replace them. The examples are for illustrative purposes only and do not constitute an exhaustive list:

Individual incident reports (in line with MEDDEV timescales)
CLINICAL/SYMPTOMATIC
Breast cancer
Suspected and confirmed cases of BIA-ALCL
Double capsule
Siliconoma
Recurrent seroma/fluid collections
Unexpected breast swelling (seroma / fluid collections with no clinical history for trauma or infections)
Unexpected breast inflammatory reaction (Breast inflammatory reaction and/or lymphadenopathy with no clinical history for trauma or infections)
Unexpected breast infection (Breast Infections with no clinical history for previous systemic infections)
Systemic adverse reaction, Hypersensitivity, allergic reaction
Autoimmune disease or Syndrome Induced by Adjuvants (ASIA)
DEVICE
Silicone migration
Valve failure (during or after implantation)

Incidents that may be agreed to include in periodic summary reports (PSR)*	
CLINICAL/SYMPTOMATIC	**Periodicity**
Capsular contracture causing breast deformity and/or pain and/or hard breast	3 months
DEVICE	
Implant ruptures (independently by the implantation time)	3 months
Post FSCA/FSN incidents**	X month to be agreed with the CA

Report at the time of a significant increase in the frequency or severity of incidents
CLINICAL/SYMPTOMATIC
Extrusion of the implant
Wrinkling of the breast
Loss of nipple sensitivity
Breast swelling/ infection/ inflammatory reaction and/or Lymphadenopathy with positive clinical history for previous systemic infections or trauma
Calcium deposits
DEVICE
Rotation /folding/ displacement of the implant

* If you can't use PSR, then report these events individually

** Post FSCA adverse incidents provided they have been previously agreed with CA

3. Clinical Reference Guidelines

Manufacturers of Breast Implants may refer to relevant local clinical guidelines when identifying incident examples and complications.

4. Medical Device Directives References

1. Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993

last amended by Directive 2007/47/EC.

2. The European Commission Guidelines on a Medical Devices Vigilance System,

MEDDEV 2.12-1 rev 8, January 2013