

Guidance on the vigilance system for CE-marked medical devices

DSVG 04 **Breast Implants**

March 2019

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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)	Incidents that may be agreed to include in periodic summary reports (PSR)*		Report at the time of a significant increase in the frequency or severity of incidents
<p>CLINICAL/SYMPTOMATIC</p> <p>Breast cancer</p> <p>Suspected and confirmed cases of BIA-ALCL</p> <p>Double capsule</p> <p>Siliconoma</p> <p>Recurrent seroma/fluid collections</p> <p>Unexpected breast swelling (seroma / fluid collections with no clinical history for trauma or infections)</p> <p>Unexpected breast inflammatory reaction (Breast inflammatory reaction and/or lymphadenopathy with no clinical history for trauma or infections)</p> <p>Unexpected breast infection (Breast Infections with no clinical history for previous systemic infections)</p> <p>Systemic adverse reaction, Hypersensitivity, allergic reaction</p> <p>Autoimmune disease or Syndrome Induced by Adjuvants (ASIA)</p> <p>DEVICE</p> <p>Silicone migration</p> <p>Valve failure (during or after implantation)</p>	<p>CLINICAL/SYMPTOMATIC</p>	<p>Periodicity</p>	<p>CLINICAL/SYMPTOMATIC</p> <p>Extrusion of the implant</p> <p>Wrinkling of the breast</p> <p>Loss of nipple sensitivity</p> <p>Breast swelling/ infection/ inflammatory reaction and/or Lymphadenopathy with positive clinical history for previous systemic infections or trauma</p> <p>Calcium deposits</p> <p>DEVICE</p> <p>Rotation /folding/ displacement of the implant</p>
	<p>Capsular contracture causing breast deformity and/or pain and/or hard breast</p>	<p>3 months</p>	
	<p>DEVICE</p>		
	<p>Implant ruptures (independently by the implantation time)</p>	<p>3 months</p>	
	<p>Post FSCA/FSN incidents**</p>	<p>X month to be agreed with the CA</p>	

* 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