Breast Implants

Key Reportable Adverse Events

Reporting adverse events helps the MHRA to identify and address device-related safety problems. We need your help in bringing the following to the attention of the MHRA or the relevant manufacturer/distributor.

Problem	Do I report to the MHRA?
Suspected implant rupture	Reportable where there is clinical evidence of a rupture e.g. MRI, ultrasound or where implant replacement is necessary and if failure occurred within expected life of the device (or within 10 years of insertion if this has not been specified)
Valve failure	Reportable if failure occurred within expected life of the device (or within 10 years of insertion if this has not been specified)
Capsular contracture	Reportable if it occurs after the first year
Breast swelling	Reportable if it occurs after the immediate postoperative phase
Inflammation	Reportable if it occurs after the immediate postoperative phase
Possible systemic adverse reactions	Reportable irrespective of demonstrated association
Malpositioning	Not reportable unless it is considered to be a consequence of the design of the implant
Infection	Not reportable
Others	Reportable if considered an unanticipated device-related event

What to do when you are reporting one of the above events

- Quarantine the implant if removed
- Report events to the MHRA as soon as possible after they occur (see below)
- Obtain and record the explanted woman's consent to return the implant to the manufacturer for analysis
- Contact the manufacturer/UK distributor and follow their guidance regarding decontamination and return of the implant

How to report adverse incidents

Please report adverse incidents online via our website: www.mhra.gov.uk
Or download a form and email or fax it back to us:
Email: aic@mhra.gsi.gov.uk Fax: 020 3118 9814 Hotline: 020 3080 7080

This poster is intended as guidance for healthcare professionals and does not replace or alter the guidance to manufacturers published by the MHRA in September 2006 (Guidance on the medical devices vigilance system for CE marked breast implants).

Medicines and Healthcare products Regulatory Agency

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