

Medical device adverse incident report form

Breast implants – surgeons

Reporter details

Name: _____

Position/occupation: _____

Organisation: _____

Address: _____

Tel: _____ Email: _____

Consultant-in-charge (if known): _____

This report confirms: a telephone report a fax report neither

Local reference number _____

Type of injury

Fatality Serious Revision Distress Minor None

Patient information

First two letters of surname then first two letters of first name (four letters): _____

Date of birth: _____ Date of original operation: _____

Hospital for original operation: _____

Placement of implant(s): submuscular subglandular

Incision site(s): _____

Indication for implantation

Cosmetic augmentation Replacement
 Post mastectomy Developmental asymmetry
 Other (please specify) _____

Retrieved implants

Breast implant	Manufacturer	Model name*	Serial No.	Batch/lot No.
Left				
Right				

* If unknown give type of filler material (e.g. silicone) and volume



Reason(s) for revision/removal

Left Right

- Rupture/leak
- Capsular contracture
- Breast swelling
- Shape change
- Inflammation
- Infection
- Possible systemic adverse reactions
- Other (please specify) _____

Revision details

Date of revision: _____

Hospital for revision operation: _____

Current location of retrieved implant(s): _____

Has the patient consented to analysis of the implant by the manufacturer? Yes No
(The surgeon is responsible for obtaining and recording consent)

Comments

e.g. any observations of the implant(s) at removal, comments on the explant procedure or complications noted in immediate post-implant period.

Date of completion of this report: _____

Further details can be given on additional sheets if necessary

Do not send medical devices to the MHRA unless you have been specifically requested to do so.

Return the form to us via email: aic@mhra.gsi.gov.uk
 or by fax: 020 3118 9814 or post: Adverse Incident Centre, MHRA, Floor 4, 151 Buckingham
 Palace Road, London SW1W 9SZ
 Enquiries: Tel: 020 3080 7080