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

<table>
<thead>
<tr>
<th>Breast implant</th>
<th>Manufacturer</th>
<th>Model name*</th>
<th>Serial No.</th>
<th>Batch/lot No.</th>
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* If unknown give type of filler material (e.g. silicone) and volume
Reason(s) for revision/removal

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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