

Medical device adverse incident report form

Cochlear implants

Reporter details

Name _____

Occupation/position _____

Organisation _____

Address _____

Tel _____ Email _____

Local reference number _____

Consultant-in-charge (if known) _____

Type of injury

Death Serious Revision Distress Minor None

Patient information

Patient identification code _____

Gender Male Female

Date of birth _____

Date of implantation _____

Implantation side Left Right

Date of follow-up prior to incident _____

Details of cochlear implant system

Implant model _____ Catalogue No. _____ Serial No. _____

Speech processor _____ Catalogue No. _____ Serial No. _____

Manufacturer _____

Date of manufacture _____ Expiry date _____

Incident details

Date of incident _____

Date problem confirmed (if different) _____

Component involved Implant Speech processor Accessory

Device explanted? Yes No Date of explanation _____

Location of device now _____



Nature of defect/details of incident

Device failure details

- Loss of output from device
- Loss of telemetry
- Change in electrode function
- Other

Patient factors (if any)

- Patient suffered from infection
- Patient suffered impact to head or device area

Further details about the incident or factors that may have contributed to the problem

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Action taken by staff/manufacturer/supplier

Has the patient been re-implanted? Yes No

Re-implanted device

Model Catalogue No. Serial No.

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