Medical device adverse incident report form

Hip or knee implants

Reporter details

Name .....

Organisation .....

Address .....

.....

Tel ..... E-mail .....

Consultant-in-charge (if known) .....

Local reference number .....

This report confirms ☐ a telephone report ☐ a fax report ☐ neither

Type of injury

☐ Fatality ☐ Serious ☐ Revision ☐ Distress ☐ Minor ☐ None

Patient information

Patient identification code: .....

Date of birth: .....

Date of primary implantation: .....

Gender: Male ☐ Female ☐

Implant type: Hip ☐ Knee ☐

Implant side: Left ☐ Right ☐

Indication for primary implantation

☐ Avascular necrosis
☐ Congenital dysplasia
☐ Fracture of the bone
☐ Metabolic or bone disease
☐ Osteoarthritis
☐ Rheumatoid arthritis
☐ Unknown
☐ Other (please specify)

.....

Failed component:

☐ Hip – femoral stem, femoral head, acetabular cup, cup liner
☐ Knee – femoral component, tibial insert, tibial tray, patella

Reason for revision

	Femoral (Hip or knee)	Acetabular (Hip)	Tibial (Knee)
Loosening			
Wear			
Infection			
Implant fracture			
Malposition/misalignment			
Fracture of the bone			

Other (please specify)			

Please **retain retrieved implants** and discuss what to do with them with the MHRA's Adverse Incident Centre.
Do not send medical devices to the MHRA unless you have been specifically requested to do so.

Revision details

Date of revision: .....

Hospital for revision operation: .....

Hospital for primary operation: .....

Is the retrieved implant from a ☐ revision or ☐ re-revision

Retrieved prosthesis information

Components (Hip/knee)	Manufacturer	Model name	Model/ catalogue No	Batch/lot No
Femoral stem/ Femoral component				
Femoral head/ tibial insert				
Acetabular cup/ tibial tray				
Cup liner/ patella				

Cement type: ☐ Boneloc ☐ CMW ☐ Simplex ☐ Palacos ☐ Other ☐ None ☐ Not known

If 'other' please specify: .....

Are radiographs available from the initial implantation? ☐ Yes ☐ No

Current location of explanted device: .....

Comments - enter further relevant information in the space below or on a separate sheet.

Date of completion of this report: .....

Return the form to us via e-mail: 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