

Orthopaedic Implants: Reporting Adverse Events

What Should I Report?

Any implant failure

All early revisions

Failure of an implanting accessory

e.g. instrumentation, trial implants,
drills and drill bits

Incorrect implant labelling

Component incompatibility

Sterilization issues

e.g. degraded packaging, problems
with cleaning or re-assembly

Unclear instructions for use

Lack of clarity has, or may have, led to
incorrect implantation



Immediate Action after an Adverse Incident

- Quarantine device
- Report to MHRA
- Contact the manufacturer
- Return device to manufacturer after consulting MHRA

MHRA Recommendations

- Devise local protocols to facilitate adverse incident reporting
- Ensure new staff and locums are made aware of reporting procedures

Why Should I Report?

Reporting adverse events helps the
MHRA to identify and address
device-related safety problems

How Can I Report?

Online at www.mhra.gov.uk
E-mail: aic@mhra.gsi.gov.uk
Fax: 020 7084 3109
Hotline: 020 7084 3080

This poster is published by the Medicines and Health-care products Regulatory Agency (MHRA) and is intended as guidance for healthcare professionals. The MHRA is an executive agency of the Department of Health.