

MHRA ADVERSE INCIDENT REPORT FORM

Please tick (✓) the appropriate boxes

Origin of report Reporting authority..... Address..... Reporter..... Occupation..... Telephone number..... Local reference number..... E-mail..... This report confirms a telephone report <input type="checkbox"/> a fax report <input type="checkbox"/> neither <input type="checkbox"/>	
User weight - Kg (Stones) - tick one only (to the nearest whole number) <input type="checkbox"/> 1 - 25 (1 - 4) <input type="checkbox"/> 26 - 50 (5 - 8) <input type="checkbox"/> 51 - 75 (9 - 12) <input type="checkbox"/> 76 - 100 (13 - 16) <input type="checkbox"/> 101 - 125 (17 - 20) <input type="checkbox"/> 126+ (21+) <input type="checkbox"/> Unknown	
Usage <input type="checkbox"/> Domestic/similar <input type="checkbox"/> Outdoor <input type="checkbox"/> Rough terrain <input type="checkbox"/> Sport <input type="checkbox"/> Frequent steps/kerbs <input type="checkbox"/> New/not used	
Severity of use <input type="checkbox"/> Hard <input type="checkbox"/> Fairly hard <input type="checkbox"/> Moderate <input type="checkbox"/> Light	
Type of device (tick one only) <input type="checkbox"/> Manual wheelchair <input type="checkbox"/> Powered wheelchair <input type="checkbox"/> Powered scooter <input type="checkbox"/> Tricycle, bicycle <input type="checkbox"/> Buggy <input type="checkbox"/> Ancillary equipment <input type="checkbox"/> Supportive seating system <input type="checkbox"/> Spare parts <input type="checkbox"/> Cushion <input type="checkbox"/> Transportation related equipment	
Component <input type="checkbox"/> Brakes <input type="checkbox"/> Castors <input type="checkbox"/> Electrical <input type="checkbox"/> Frame <input type="checkbox"/> Protective finish <input type="checkbox"/> Cushions <input type="checkbox"/> Supportive seating <input type="checkbox"/> Wheels <input type="checkbox"/> Accessories <input type="checkbox"/> Upholstery <input type="checkbox"/> Footrest <input type="checkbox"/> None/not applicable <input type="checkbox"/> Other (please specify):.....	
Type of failure <input type="checkbox"/> Electrical <input type="checkbox"/> Weld/braze <input type="checkbox"/> Adhesive <input type="checkbox"/> Lubrication <input type="checkbox"/> Fracture <input type="checkbox"/> Packaging <input type="checkbox"/> Not to specification <input type="checkbox"/> Transport damage <input type="checkbox"/> Not applicable <input type="checkbox"/> Other (please specify):.....	

Please send completed form to: Medicines & Healthcare products Regulatory Agency Adverse Incident Centre, 2nd Floor, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ, Fax 0207 084 3109 E-mail aic@mhra.gsi.gov.uk

WHEELED MOBILITY AND ASSOCIATED EQUIPMENT

Details of equipment Model / Item..... Manufacturer / Reconditioner..... Batch No..... Serial No..... Supplier/UK Rep..... Date of mfr..... Date supplied to user..... Is there a CE-mark? YES <input type="checkbox"/> NO <input type="checkbox"/> If YES has the manufacturer/supplier been contacted? YES <input type="checkbox"/> NO <input type="checkbox"/> Present location of equipment.....	
Details of incident Was there an injury? YES <input type="checkbox"/> NO <input type="checkbox"/> Was there a death? YES <input type="checkbox"/> NO <input type="checkbox"/> Is litigation likely? YES <input type="checkbox"/> DON'T KNOW <input type="checkbox"/> Date of incident.....	
Description of incident Contact name for further details..... Telephone number..... Action taken by staff / manufacturer / supplier..... Manufacturer's ref no (if known):..... Reporters signature..... Date.....	

Further details can be given on additional sheets if necessary FORMWHC(August 2007)

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Origin of report:

Reporting Body.....
 Address.....
 Reporter.....
 Position.....
 Telephone number.....
 Consultant-in-charge (if known).....

This report confirms a telephone report o a fax report o neither o

Type of device: (tick one only)

- Active implantable devices
- Administration & giving sets
- Anaesthetic machines & monitors
- Anaesthetic & breathing masks
- Autoclaves
- Bath aids
- Beds & mattresses
- Blood pressure measurement
- Breast implants
- Cardiovascular implants & devices
- Commodes
- Contact lenses & care products
- CT systems
- Dental materials & appliances
- Dialysis equipment
- Diathermy equipment & accessories
- Dressings
- Endoscopes & accessories
- Endotracheal tubes & airways
- Enteral feeding systems
- External defibrillators & pacemakers
- Feeding tubes
- Gloves
- Guidewires
- Hearing aids
- Hypodermic syringes & needles
- Implant materials
- Infant incubators
- Infusion pumps, syringe drivers
- Insulin syringes
- Intravenous catheters & cannulae
- Joint prostheses
- Lasers & accessories
- Magnetic resonance equipment & accessories
- Mobile x-ray systems
- Monitors & electrodes
- Non-active implants
- Ophthalmic equipment
- Patient hoists
- Patient monitoring equipment
- Physiotherapy equipment
- Radiotherapy equipment
- Radionuclide equipment
- Resuscitators
- Staples & staple guns
- Stretchers
- Surgical instruments
- Surgical power tools
- Sutures
- Thermometers
- Ultrasound equipment
- Urinary catheters
- Ventilators
- Walking sticks / frames
- Wound drains
- X-ray equipment, systems & accessories
- Other (please specify)

Further details can be given on additional sheets if necessary

MEDICAL DEVICES

Details of device:	
Product	Catalogue No
Model	Serial No
Manufacturer	
Telephone no:	
Supplier	Expiry date
Batch No	Quantity defective
Date of mfg	
Location of device now	
Is there a CE-mark? YES o NO o IF YES, was the manufacturer or supplier contacted? YES o NO	
Was there a fatality? YES o NO o Was an injury caused? YES o NO o	
Injury details:	
Nature of defect / details of incident:	
Contact name for further details	
Telephone number	
Action taken by staff / manufacturer / supplier:	
PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST	
If you still have the incident device please retain it and await further instructions from MHRA.	
Signed	Date

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