

For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency



HEALTH ESTATES
ESTATE POLICY

NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

TITLE:

**REMOVAL OF IMPLANTABLE
CARDIOVERTER DEFIBRILLATORS (ICDS)**

MANUFACTURER/SUPPLIER

Non-manufacturer specific

PROBLEM

- Risk of electric shock to clinicians / mortuary personnel while removing implantable cardioverter defibrillators (ICDs).
- Risk of explosion during ICD incineration.
- Need to maintain device / data integrity for ICDs subject to investigation.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Cardiology Directors
- Cardiac Pacing Technicians
- Pathology Directors
- Mortuary Technicians
- Private Clinics
- General Medical Practitioners

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

Do not remove an implantable cardioverter defibrillator (ICD) from a cadaver without first disabling all high voltage shock therapies.

Identify the implant

Before removing the ICD / implant, establish the manufacturer and / or model name:

1. By consulting hospital or GP patient records or the patient's device registration card (this may be held by a relative).
2. By consulting the National Pacemaker and ICD Database (see details below).
3. By visual examination of the markings on the implant.
 - The identity of the manufacturer can be determined from an X-ray of the device in situ where the manufacturer's radiopaque identification symbol can be observed.
 - Identification of the manufacturer and model can be determined by making a lateral incision across the implant location and dissecting to reveal the ICD casing (the ICD is usually implanted with the manufacturer / device legend outermost). Where the device is implanted with the legend on the reverse side,

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rotate the exposed ICD to reveal the manufacturer / model details. When making an incision, take care to avoid the coiled heart lead, which may be located behind or adjacent to the ICD.

Reprogramming of the ICD

4. Once the ICD manufacturer / model details have been established, contact the patient's follow-up centre (or contact the nearest cardiac centre) to obtain reprogramming support to permanently set the device to a **non-shock delivery mode**. (Note: this may require onward referral by the local cardiac centre to a specialist ICD follow-up centre).
5. Following ICD reprogramming (e.g. by a cardiac technician), ensure that this action has been clearly recorded in the accompanying patient documentation.

Disposal of the ICD

6. Ensure that the ICD is not disposed of by incineration.
7. Where known, advise the implanting hospital of patient death and the intention to remove / dispose, to enable information stored in the device to be accessed for patient records.

Where the ICD is subject to an adverse incident investigation

8. Prior to removal and reprogramming, carry out a full ICD interrogation using an appropriate programmer, and print hard copies of all device parameter settings and internal memory data areas. Where available save all parameter settings electronically (e.g. 'save to disk').
9. During ICD removal, ensure that the complete system (including heart leads) is removed intact. Do not cut the heart leads.

BACKGROUND

The Medical Devices Agency (MDA) has become aware of electric shocks being given to mortuary personnel and general medical practitioners during removal of ICDs from deceased people. ICD removal is necessary where a body is to be cremated, or where the ICD is needed for analysis / testing as part of an adverse incident investigation.

About implantable cardioverter defibrillators (ICDs)

ICDs are provided to patients who suffer life-threatening heart arrhythmias. They comprise a programmable implantable pulse / shock generator plus one or more heart leads. ICDs are normally implanted in the pectoral region but older units may have been implanted in the abdominal cavity.

ICDs sense electrical heart signals associated with ventricular tachycardia (VT) and ventricular fibrillation (VF) through a lead positioned within the heart. Upon detection of such signals corrective therapy may be delivered in the form of an electric shock to the heart muscle.

Care during ICD removal

On removing an ICD, the sensing pathway may be disturbed, particularly if the heart lead is cut. This may cause the ICD to 'think' it is sensing VT or VF and to deliver an electric shock.

The shock is normally delivered between the exposed electrode(s) on the heart lead, and the metal casing of the ICD. Any shock accidentally delivered to personnel handling the device would be very uncomfortable and **could be harmful**.

Note: ICDs contain a magnetic switch which is used during clinical programming. Placing a magnet over the implant site will not guarantee inhibition of shock therapy for all ICD models and is dependent upon how the device is programmed. If attempting to inhibit shock therapy by magnet placement, care should be taken to ensure close registration between the magnet and the ICD at all times. Separation of the magnet during



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or after removal may restore the potential for shock delivery. ICDs that are temporarily disabled and removed will therefore need to be packaged appropriately and labelled to prevent accidental shock to personnel.

ICDs and adverse incident investigations

Failure of an ICD system to deliver appropriate therapy may relate to either the ICD itself or the attached heart leads. Where an ICD is subject to an adverse incident investigation it is important to protect the integrity of the ICD / heart lead(s) and to access all electronic data held within the ICD's memories. It is therefore important that no part of the ICD system is damaged, especially the heart lead(s) which should be kept intact.

Important Note: *As for implantable pacemakers (and some neurostimulators and drug pumps), ICDs usually contain a lithium battery, which may explode if exposed to high temperatures (such as those used in the incineration of clinical waste). Ensure that ICDs are not disposed of by incineration.*

ENQUIRIES

National Pacemaker & ICD Database
Mrs Morag Cunningham
PO Box 9205
Bridge of Weir
Strathclyde
PA11 3DZ

Tel/Fax: 01505 612829

Enquires to the NIAIC should quote the reference number SN(NI) 2002/40 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



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