



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

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**SULZER CARBOMEDICS HEART VALVE
TESTERS: RISK OF FRACTURE DURING
OPEN HEART SURGERY**

MANUFACTURER/SUPPLIER

Sulzer Carbomedics

PROBLEM

Fracture of plastic distal head of heart valve testers during heart valve surgery.

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
- Device Managers
- Medical Directors
- Clinical Directors
- Directors of Nursing
- Supplies Staff
- Sterile Services Departments
- Operating Theatre Staff
- Coronary Care
- Resuscitation Officers
- Directors of Cardiothoracic Surgery
- Cardiothoracic Surgeons and staff
- Operating Theatre Managers
- Theatre Supplies Officers
- Private Clinics

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.

IMMEDIATE ACTION

1. Identify and immediately remove from use all current stocks of Sulzer Carbomedics heart valve testers (sometimes referred to as leaflet testers). Do not reuse them. Return these testers to Sulzer Carbomedics. New valve testers will be delivered by company representatives.
2. Put all of the replacement heart valve testers into circulation and continue to clean and resterilize them in accordance with the manufacturer's instructions for use. Continue to use them until further advised by the manufacturer.
3. Sterile Services Departments should check all valve testers for fractures and visible signs of ageing after cleaning and before sterilization, paying particular attention to the areas adjacent to the metal/plastic interface. Isolate and retain any damaged valve testers.

**H A Z A R D
NOTICE**



HEALTH ESTATES
ESTATE POLICY

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HAZARD

NOTICE

4. Theatre staff should check valve testers for fractures and visible signs of ageing immediately before use. Do not use damaged valve testers.
5. Notify NIAIC and the manufacturer of any heart valve testers found to have suffered cracks or of any adverse incidents involving the Sulzer Carbomedics heart valve testers. Isolate and retain any instruments which exhibit signs of fracture and/or ageing for examination.

BACKGROUND

Sulzer Carbomedics heart valve testers are reusable devices, used by surgeons to check the function of bileaflet prosthetic heart valves after they have been sewn into the heart. The handle and head of the heart valve testers are made from plastic, and will eventually crack due to the effects of multiple reprocessing. The manufacturer provides a warning in the heart valve tester instructions for use that these instruments should not be used if they show signs of crazing or evidence of ageing that may affect their function.

NIAIC has been notified by the Medical Devices Agency (MDA) of a fatal incident involving breakage of a Sulzer Carbomedics heart valve tester during a heart valve replacement procedure. The plastic head of the instrument broke away from the metal shaft during use, and the fragment could not be located. The Department has also been notified by the same hospital that cracks have been found in the heads of some other reused Sulzer Carbomedics heart valve testers, at the point where the plastic head joins the metal shaft.

Sulzer Carbomedics is currently assessing a more durable plastic for use in its heart valve testers and will provide further advice within the next three months (i.e. before the end of July 2002).

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Enquires to the manufacturer should be addressed to:

Ms M MacFayden

Sulzer Carbomedics UK Ltd

Newmains Avenue

Inchinnan

Renfrewshire PA4 9RR

Scotland

Tel: 0141 812 5555

Fax: 0141 812 7650



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Enquires to the NIAIC should quote the reference number HN(NI) 2002/03 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*