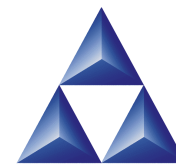


AN (NI) 2002/02

DATE: 7 May 2002

**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:

USE OF ANGIOPLASTY BALLOON CATHETERS

MANUFACTURER/SUPPLIER

Various

PROBLEM

Failure to follow the manufacturer's instructions for use could lead to serious patient injury.

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
- Nurse Directors
- Consultant Cardiologists
- Consultant Vascular Surgeons
- Superintendent Radiographers
- Catheter Laboratories
- Consultant Radiologists

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

- Any balloon-protected sheath should be removed prior to insertion of the catheter into the patient.
- Balloon catheters must undergo full preparation in accordance with manufacturers' instructions prior to commencement of the procedure and insertion into the patient. This should include:
 - purging the balloon of air with appropriate saline/contrast medium mixture according to the method described by the manufacturer;
 - increasing the pressure gradually;
 - using a commercially available balloon inflation device so that the balloon rated burst pressure is not exceeded.

ADVISE

NOTICE

BACKGROUND

NIAIC has received reports from the Medical Devices Agency (MDA) of incorrect use of angioplasty balloon catheters during peripheral arterial revascularisation procedures.

In some instances users have failed to remove the balloon protective sheath prior to insertion into a patient's vasculature. This can prevent the balloon from being inflated and may result in migration of the sheath into the vasculature with potential serious consequences for the patient.

Incidents of balloon bursting have also been reported attributed to users unknowingly exceeding the rated burst pressure during inflation.

Purging the balloon of air with the appropriate saline/contrast medium mixture allows it to be checked for correct inflation and deflation functions. It also prevents the release of air into the patient in the event of balloon failure.

ENQUIRIES

Enquires to the NIAIC should quote the reference number AN (NI) 2002/02 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



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

ADVICE

NOTICE

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, Serbhístí Sóisialta agus Sábháilteacht Phoiblí*