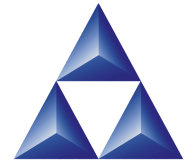


# SN (NI) 2001/19

DATE: 3 May 2001

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



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ESTATE POLICY

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**

**Inadvertent Advancement of Guide Wires used with  
Trauma/Orthopaedic Guided Cannulated Screw  
Systems**

**MANUFACTURER/SUPPLIER**

Manufacturers of guide wires for trauma/orthopaedic applications including: B Braun (Aesculap); Biomet Merck; DePuy International (a Johnson and Johnson company); Smith and Nephew; STRATEC Medical; Stryker Howmedica Osteonics and Zimmer.

**PROBLEM**

Risk of advancement of guide wires into the surrounding tissues during:

- insertion of guide wires;
- reaming/tapping over guide wires with cannulated instruments;
- insertion of screws.

The Department is aware of one fatal incident where a cannulated drill became jammed over a screw guide wire which then advanced into the pelvis damaging the iliac vein.

**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
- Orthopaedic Surgeons
- Risk Managers
- Health & Safety Officers/Advisors
- Orthopedic Managers
- Operating Theatre Managers
- Directors of Surgery
- Directors of Radiology
- Superintendent Radiographers

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**

Clinicians should:

- check the position of cannulated screw guide wires frequently using an image intensifier (fluoroscopy) to prevent unintended guide wire advancement and penetration into the surrounding tissues;
- not re-use guide wires or instruments labelled for "single-use only" or those displaying the single use symbol as detailed on Appendix 1;
- clean cannulated instruments intra-operatively to prevent accumulation of bone debris in the cannulation.

**SAFETY**

**NOTICE**

## BACKGROUND

The Department is aware of one fatal incident where, during fixation of a fractured neck of femur with a guided cannulated screw system, a cannulated drill bit became jammed over a re-used guide wire. In consequence the guide wire was inadvertently advanced and penetrated the acetabulum, damaging the iliac vein. The patient died as a result of subsequent complications.

The guide wires used in this case were not labelled as being for “single-use only”. It is possible that the use of a bent or scratched guide wire, combined with accumulation of bone debris in the drill bit cannulation during reaming, may have caused the drill bit to jam over the guide wire.

The Medical Devices Agency (MDA) has reviewed manufacturers’ instructions for use of cannulated screw systems as a result of this incident and has reached the following conclusions:

- **Use of Image Intensifiers**

Recommendations on the extent to which image intensifiers should be used to monitor guide wire position vary between manufacturers. MDA considers it particularly important to continuously screen with an image intensifier during guide wire insertion and whenever cannulated instruments are advanced over a guide wire. Frequent screening should also be carried out during screw insertion.

In all cases the benefit of fluoroscopy should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations, 2000: SR 2000 No.194.

MDA will review instructions for use with manufacturers of cannulated screw systems who do not specifically recommend continuous screening during guide wire insertion and when cannulated instruments are advanced over guide wires. MDA will encourage these manufacturers to amend their instructions accordingly.

- **Re-use of Guide Wires**

MDA has received reports of inadvertent guide wire advancement associated with both new and re-used guide wires. Nevertheless, re-use increases the risk of employing a damaged guide wire.

It is MDA’s view that guide wires should be discarded at the end of a procedure and not re-used, even if they appear to be undamaged. The majority of manufacturers label their cannulated screw guide wires as being for “single-use only”. Guide wires designated by the manufacturer as being for “single-use only” must not be re-used.

MDA will review the labelling of cannulated screw guide wires with manufacturers who do not currently designate these products as being for “single-use only” and will encourage these manufacturers to re-label their guide wires for “single-use only”.

- **Intra-Operative Cleaning of Instrument Cannulations**

Intra-operative cleaning of the cannulation in instruments (drill bits and taps) ensures that bone debris does not accumulate and reduces the risk that instruments will bind about the guide wire.

Some manufacturers recommend intra-operative cleaning of cannulated instruments and provide cleaning stylets designed for this purpose. Users should



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clean cannulated instruments at appropriate intervals accordingly to the manufacturer's recommendations.

MDA will review instructions for use with manufacturers of cannulated screw systems where no instructions for intra-operative cleaning are provided and will encourage these manufacturers to amend their instructions accordingly.



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## ENQUIRIES

Enquires to NIAIC should quote the reference number SN(NI) 2001/18 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy  
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](mailto: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) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Health 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*