

Medical Device Alert

Immediate action

Ref: MDA/2009/039 Issued: 16 June 2009 at 14:30

Device

Prelude Short Sheath Introducer manufactured by Merit Medical.

All batches of specific models affected.



Problem

The sidearm tubing may detach from the sheath during use, which may result in excessive blood loss and potential blood-borne pathogen exposure to those in the surrounding area.

Action

- Check stock for affected devices, stop using and quarantine any devices
- Contact the manufacturer/supplier to arrange for their return.

Action by

All staff involved with the use of these devices, predominantly in renal units.

Contact

Manufacturer

Marion Robson
Merit Medical EMEA

Tel: +31 (0) 43 358 8222

Fax: +31 (0) 43 358 8221

E-mail: mrobson@merit.com

CAS deadlines

Action underway: 23 June 2009

Action complete: 07 July 2009

[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON049199)

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON049199>

Device

Prelude Short Sheath Introducer

All batches of the following models are affected

Model number and name

PSS-5F-4-018MT Sheath Introducer/Vessel Dilator with Marker Tip, 5F, 4cm length, 0.018" wire
PSS-5F-4-038MT Sheath Introducer/Vessel Dilator with Marker Tip, 5F, 4cm length, 0.038" wire
PSS-5F-4MT Sheath Introducer/Vessel Dilator with Marker Tip, 5F, 4cm length
PSS-6F-4-018MT Sheath Introducer/Vessel Dilator with Marker Tip, 6F, 4cm length, 0.018" wire
PSS-6F-4-038MT Sheath Introducer/Vessel Dilator with Marker Tip, 6F, 4cm length, 0.038" wire
PSS-6F-4MT Sheath Introducer/Vessel Dilator with Marker Tip, 6F, 4cm length
PSS-7F-4-018MT Sheath Introducer/Vessel Dilator with Marker Tip, 7F, 4cm length, 0.018" wire
PSS-7F-4-038MT Sheath Introducer/Vessel Dilator with Marker Tip, 7F, 4cm length, 0.038" wire
PSS-7F-4MT Sheath Introducer/Vessel Dilator with Marker Tip, 7F, 4cm length
PSS-8F-4-018MT Sheath Introducer/Vessel Dilator with Marker Tip, 8F, 4cm length, 0.018" wire
PSS-8F-4-038MT Sheath Introducer/Vessel Dilator with Marker Tip, 8F, 4cm length, 0.038" wire
PSS-8F-4MT Sheath Introducer/Vessel Dilator with Marker Tip, 8F, 4cm length

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC Trusts in Northern Ireland (Chief Executives)
- NHS Boards in Scotland (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Anaesthetists
- Cardiologists
- Haemodialysis nurses
- Haemodialysis units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Renal medicine departments
- Renal medicine, directors of
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Care Quality Commission (CQC) (England only) to:

Headquarters for onward distribution as appropriate to:

- Hospitals in the independent sector

Change of address or removal from address list for Care Quality Commission:

National Contact Centre
Care Quality Commission
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 03000 61 61 61

E-mail: enquiries@cqc.org.uk

Contacts

Manufacturer

Marion Robson
Merit Medical EMEA
Amerikalaan 42
6199 AE Maastricht - Airport

Tel: +31 (0) 43 358 8222

Fax: +31 (0) 43 358 8221

E-mail: mrobson@merit.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/039** or **2009/004/024/051/002**.

Technical aspects

Nicola Grainger or Geoff Ali
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3265 / 3102

Fax: 020 7084 3209

E-mail: nicola.grainger@mhra.gsi.gov.uk
geoff.ali@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast

BT16 1US

Tel: 02890 523 704

Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <https://sabs.dhsspsni.gov.uk>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh

EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

E-mail: iric.nss@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/>

Wales

Enquiries in Wales should be addressed to:

Dr Jane Ludlow

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff

CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk