Medical Device Alert

Action update

Ref: MDA/2010/006 Issued: 18 January 2010 at 11:30

Device

Devices used for endometrial ablation.

All makes and models.

Problem

The MHRA continues to receive reports of uterine wall injury, wall perforation, or the creation of a false passage following use of endometrial ablation devices. In some cases resection of damaged tissue has been required.

The majority of complications occur due to either poor patient selection or endometrial ablation procedures being performed in difficult situations.

Patients with either a retroverted uterus or a fixed uterus (e.g. due to significant endometriosis or adhesions), or those that have had previous uterine surgery are at a higher risk.

Action

Clinicians should confirm that there is no evidence of uterine perforation or false passage.

Clinicians are recommended to:

- employ hysteroscopy prior to the insertion of the ablation device to establish the condition of the uterus
- employ ultrasound to ensure correct uterine placement of the ablation device. If the device uses a balloon, this should remain inflated during the ultrasound scan.

This Medical Device Alert replaces SN9812 (issued March 1998) and SN1999(18) (issued April 1999).

Action by

Gynaecologists, theatre nurses, theatre managers, day surgery units, theatres, medical directors, nursing executive officers.

CAS deadlines

Action underway: 18 February 2010
Action complete: 18 March 2010

Contact

Relevant manufacturer for technical advice.

Device

Endometrial ablation devices that use thermal means (cryogenic, hot fluid, laser, microwave, radiofrequency energy).

Action

The manufacturer's instructions for use should be strictly adhered to and users should have full training for the specific equipment.

Clinicians are advised to consider carefully the use of thermal endometrial ablation in the following circumstances:

- previous uterine surgery
- a small (thin walled) uterus
- a history of recurrent pelvic infections (e.g. where fibrosis and bowel adhesions are more likely to be present)
- clinical history of patient indicates a contra-indication of the ablation device manufacturer's instructions for use.

Additionally, concurrent use of diathermy (electrosurgery) during such procedures should not be undertaken due to the risk of the ablation device acting as a source of alternative site burns.

This notice should be brought to the attention of, and actioned by, all staff that need to know, including those listed in the distribution list.

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:

- Day surgery units
- Gynaecologists
- Medical directors
- Nursing executive directors
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

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

The MHRA considers this information to be important to:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/006** or **SZT/001/001/449**.

Technical aspects
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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

Email: 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 http://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

Email: nss.iric@nhs.net

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

This alert supersedes (in Scotland):

Safety Action Notice SAN(SC)98/12, Thermal devices used for endometrial ablation: risk of tissue damage, 30 March 1998.

Safety Action Notice SAN(SC)99/19, Devices used for endometrial ablation: risk of heat damage to tissue, 04 June 1999.

Wales

Enquiries in Wales should be addressed to:

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Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk