Medical Device Alert

Action

Ref: MDA/2009/028 Issued: 21 April 2009 at 11:30

Device

Goldmann applanation tonometer prism.

Manufactured by Haag-Streit Ag.

Problem

Damage to the tonometer prism due to the use of inappropriate disinfectants may result in corneal irritation.

Action by

Ophthalmologists
Opticians
Optometrists
Ophthalmic nurses

CAS deadlines

Action underway: 06 May 2009

Action complete: 04 June 2009

Action

- Establish if you have this device.
- Check tonometer prisms for cracks or scratches using the 'Tonometer Prisms Field Test' instruction sheet supplied by the manufacturer.
- Do not use tonometer prisms if they fail this test.
- Return damaged tonometer prisms to the manufacturer as instructed.
- Only use disinfectants recommended by the manufacturer from the list available on their website.

Contact

Manufacturer
Gino Ostacchini
Haag Streit UK Ltd

Tel: 01279 414 969

E-mail: gostacchini@clement-clarke.com

Link to full Medical Device Alert

Device

The Goldmann applanation tonometer prism is a device used with the Haag Streit Goldmann tonometer and the Perkins hand held tonometer to determine intraocular pressure.

Problem

The manufacturer has received three reports of damage to tonometer prisms caused by disinfectants not recommended for use with this device.

Once damaged, the tonometer prism may take up some of the disinfectant solution during the cleaning process. This solution may then come into contact with the patient's eye during the measuring procedure resulting in an increased risk of irritation to, or erosion of, the cornea.

As a result of these reports, Haag-Streit issued a Field Safety Notice (FSN) in October 2008 to all customers, (published on the MHRA website). Included in the FSN is a field test for clinicians to check the tonometer prism for cracks and scratches. Any tonometer prism that shows cracks or scratches should not be used but should instead be returned to the manufacturer.

A list of recommended disinfectants can be found on the manufacturer's website (www.haag-streit.com).

The MHRA has published this Medical Device Alert to support the manufacturer's actions due to a poor response to the FSN.

Distribution

This MDA has been distributed to:

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

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:

- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Community opticians
- Dispensing opticians
- Optometrists

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

Headquarters for onward distribution as appropriate to:

- Eye treatment centres
- Private ophthalmic practitioners
- Private opticians

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 6161

E-mail: enquiries@cqc.org.uk

Contacts

Manufacturer
Gino Ostacchini
Haag Streit UK Ltd
Edinburgh Way
Harlow
Essex CM20 2TT

Tel: 01279 414 969
Fax: 01279 635 232

E-mail: gostacchini@clement-clarke.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/028 or 2008/009/001/061/002**

Technical aspects
Michelle Kelly or Ian Smith
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3145/3306
Fax: 020 7084 3106

E-mail: michelle.kelly@mhra.gsi.gov.uk
ian.smith@mhra.gsi.gov.uk

Clinical aspects
Dr Christopher Brittain
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3126
Fax: 020 7084 3111

E-mail: christopher.brittain@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@shs.csa.scot.nhs.uk

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