Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/044 Issued: 12 December 2019 at 12:00

BritePro Solo and BriteBlade Pro single-use fibre optic laryngoscope blades and handles – risk of choking

Summary

Manufactured by Flexicare Medical – loose bearings and retaining ring may enter patient's airway causing choking hazard if the laryngoscope blade is disengaged from the handle above the patient.

Action

- Check all stock for affected devices listed in the manufacturer's Field Safety Notice (FSN).
- Quarantine all affected stock immediately.
- Complete the response form on the FSN and return to the manufacturer.
- If you do not have any of the affected devices, please indicate this on the response form.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Note: the last MDA we issued (MDA/2019/043) was not sent to all organisations - more information here.

Action by
All healthcare professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 19 December 2019
Actions complete: 06 January 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Part number	Product description	Lot numbers	NHS Supply Chain code
040-333	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 3	180802595 180900401 180901083 181100289 181100290 181100301 181200353 181201031	FSM1632
040-342	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Miller Blade Size 2	190100335	FSM3313
040-713	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3	180900316 181102912 180900404	FSM1363

Background

Due to the use of components that are out of specification, there is the potential for the bearings and retaining ring that secure the blade in place to disconnect from the blade block.

Manufacturer contacts

Flexicare Medical
Email: Quality@Flexicare.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff

- Anaesthetists
- Equipment stores
- Equipment libraries and stores
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Operating department practitioners
- Resuscitation officers and trainers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/044** or **2019/010/010/701/010**.

Technical aspects

Ben Satchell or Emma Rooke, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).