

Medical Device Alert

Action

Ref: MDA(NI)2009-008 Issued: 05 February 2009 at 17:00

Device

Ligating clips distributed by Teleflex Medical.
Weck brand including Hem-o-lok, Horizon, Hemoclip Traditional and Hemoclip Plus.

Problem

Holes have been detected in the tray of certain sterile packaged units, which may compromise the sterility of the product.

Action by

All staff using and distributing these devices.

SABS deadlines

Action underway: 12 February 2009
Action complete: 05 March 2009

Action

- Identify if you have received affected product from the product codes listed on page 2.
- If you have received affected product contact Teleflex Medical to determine if you have received any affected lot numbers.
- Ensure that affected devices are quarantined immediately and returned to Teleflex Medical.

Contact

Supplier

Karen O'Leary
Complaints Officer
Teleflex Medical

Tel: +353 (0) 90 646 0804
E-mail: <mailto:koleary@teleflexmedical.com>

Device

The affected product codes are as follows:

HORIZON	HEM-O-LOK	HEMOCLIP AUTO	HEMOCLIP traditional	HEMOCLIP Plus
001200	544210	527100	523100	533700
001201	544220	527200	523135	533702
002200	544230	527203	523160	533735
003200	544240		523170	533737
004200	544250		523300	533800
005200			523335	533802
			523360	533835
			523370	533837
			523400	533860
			523435	533862
			523460	533870
			523470	533872
			523600	534735
			523635	534737
			523660	534835
			523670	534837
			523700	
			523735	
			523760	
			523770	
			523800	
			523835	
			523860	
			523870	

Problem

A failure during manufacture of the tray for the packaging of these devices produced holes in some trays. This could render the clips stored in this packaging as non-sterile.

Only product manufactured between January 2006 and July 2008 is affected by this problem.

Teleflex Medical has issued two Field Safety Notices (FSN) to customers concerning this problem. These have been published on the MHRA website.

The first FSN (September 2008) advised of the recall of this product and gave each customer a tailored list of the product codes and lot numbers of affected devices that they had purchased.

The second FSN (January 2009) notified customers of an extension to the recall and listed additional lot numbers, omitted from the original list, for specific product code 544240.

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

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:

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

- | | |
|--|--|
| • Anti-coagulation clinics | • Haematologists |
| • Cardiology departments | • Haemodialysis nurses |
| • Cardiology nurses | • Haemodialysis units |
| • Cardiology, directors of | • Infection control departments |
| • Cardiothoracic departments | • Infection control nurses |
| • Cardiothoracic surgery directors | • Infection prevention and control directors |
| • Colposcopy departments | • Maternity units |
| • Coronary care departments | • Medical directors |
| • Coronary care nurses | • Medical oncology, directors of |
| • Day surgery units | • Neurosurgeons |
| • EBME departments | • Orthopaedic surgeons |
| • Endocrinology units | • Outpatient theatre nurses |
| • Endocrinology, directors of | • Paediatric intensive care units |
| • ENT departments | • Paediatric medicine, directors of |
| • ENT services, directors of | • Paediatric nurse specialists |
| • Equipment stores | • Paediatric oncologists |
| • Fracture clinics | • Paediatric surgery, directors of |
| • Gastroenterology departments | • Purchasing managers |
| • Gastroenterology, directors of | • Risk managers |
| • Gastro-intestinal surgeons | • Supplies managers |
| • General surgery | • Theatre managers |
| • General surgical units, directors of | • Theatre nurses |
| • Gynaecology departments | • Theatres |
| • Gynaecology nurses | • Urological surgery, directors of |
| | • Urology departments |

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

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

- Staff with responsibility for purchasing

Contacts

Supplier

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NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NAIC quoting reference number **MDA(NI)2009-008** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868

Fax: 02890 523900

E-mail: NIAIC@dhsspsni.gov.uk

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

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

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

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