Medical Device Alert

Ref: MDA/2012/029 Issued: 24 May 2012 at 14:00

Device

Neonatal endotracheal tube SCP clamp/holder.
Product codes:
CM – SCP020 – ENDO
CM – SCP025 – ENDO
CM – SCP030 – ENDO
CM – SCP035 – ENDO
CM – SCP040 – ENDO

Lot numbers up to and including 1002853

Manufactured by Capatex Medical

Problem

Risk of airway loss due to slippage or airway obstruction, as a result of over-tightening of the clamp/holder.

Capatex is recalling affected products and has advised users of the issue in Field Safety Notices (see appendix). This Medical Device Alert is being issued to reinforce the manufacturer's actions.

Action by

All staff who may use or handle this device, particularly supplies and paediatric departments.

Action

- Identify affected devices and quarantine them.
- Contact Capatex to arrange for devices to be exchanged or to confirm that you have none in stock.
- Follow the advice in the FSN dated February 2012 (see appendix). In particular, follow advice on Capatex clamp/holder size and corresponding size of endotracheal tube to be used.

CAS deadlines

Action underway: 31 May 2012

Action complete: 12 June 2012

Contact

Manufacturer
Capatex Medical
Tel: 0115 9786 111
Fax: 0115 9786 222
Email: info@capatex.com

Device

For use with neonatal patients. It may also be used with paediatric patients, but this is not specified in the Field Safety Notices. This is a device to assist in securing an endotracheal tube (ETT) in position.

Problem

A change was made to the composition of the plastic material used, to make the clamps/holder DEHP-free. This affected the physical properties of the clamps, resulting in an increased risk of slippage. To counteract this, Capatex added an extra notch on the clamp. However, this introduced the possibility of over-tightening and occlusion of the internal diameter of the endotracheal tube.

All clamps from lot number 1002854 onwards have been manufactured using a new material.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

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

- A&E departments
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- ENT medical staff
- Equipment stores
- Health and safety managers
- Intensive care medical staff (paediatric)
- Intensive care nursing staff (paediatric)
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Nutrition nurses
- Paediatric surgery, directors of
- Paediatric wards
- Resuscitation officers and trainer
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Primary care trusts

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

- Community children's nurses
- Community hospitals
- Community nurses
- District nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer
Capatex Medical, a division of Capatex Ltd
127 North Gate
New Basford
Nottingham
NG7 7FZ UK

Tel: 0115 9786 111
Fax: 0115 9786 222
Email: info@capatex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/029** or **MHRA Ref. 2011/009/006/401/009**

Technical aspects
Louise Mulroy or Elke Kerwick
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7344 / 6826
Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
elke.kerwick@mhra.gsi.gov.uk

Clinical aspects
Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6648
Fax: 020 8754 3965

Email: 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
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

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/

Wales

Enquiries in Wales should be addressed to:

Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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

Appendix

Attention: Nurse in Charge

Neonatal Intensive Care Unit

February 2012

URGENT Product information notice

Neonatal Endotracheal Tube Clamps SCP clamps

In our notice October 2011 we reported that some customers experienced issues in the use of the clamps due to the change in the materials used in the manufacture of the SCP clamp and the Portex Endotracheal tubes (ET), due to legislative requirements.

Issues reported were possible slippage between the clamp and the ET tube. An interim modification was made to the clamp. This interim change meant that it was possible to over tighten and partially occlude the ET tube. Our SCP clamp have now been further modified and tested with a new material.

As a precaution we offer to exchange Capatex medical product prior to batch 1002854.

Further to our notice sent out in October 2011, we wish to inform all users that all current production and stock are now made from the new design and new material.
Please, however, note if you are using old or new stock it is imperative that the correct diameter clamp is selected and checks must be made to ensure that the ET tube is not slipping or being compressed. As per our instructions for use and the note on the product packaging, if a Vygon tube is used select a size larger clamp.

Product Code	Description		NSV Code	Use Portex	Use Vygon
CM-SCP20-ENDO	Neonatal Endotracheal Tube Holder	2.0mm	FTH073	2.0 tube	
CM-SCP25-ENDO	Neonatal Endotracheal Tube Holder	2.5mm	FTH074	2.5 tube	2.0 tube
CM-SCP30-ENDO	Neonatal Endotracheal Tube Holder	3.0mm	FTH075	3.0 tube	2.5 tube
CM-SCP35-ENDO	Neonatal Endotracheal Tube Holder	3.5mm	FTH076	3.5 tube	3.0 tube
CM-SCP40-ENDO	Neonatal Endotracheal Tube Holder	4.0mm	FTH077	4.0 tube	3.5 tube

If you require any further information please contact our customer services team on 0115 978 6111

Yours sincerely

Gabriel Straus

Managing Director

Please Fax this sheet back to Capatex to acknowledge receipt and understanding to the following number. 01159 786222

Hospital		Name		Position	

Capatex Medical
www.capatexmedical.com
info@capatex.com

Attention: Nurse in Charge

Neonatal Intensive Care Unit

October 2011

URGENT Product information notice

Neonatal Endotracheal Tube Clamps

SCP clamps

The SCP clamp is now manufactured from a DEHP free material as required by recent changes in regulation. The change in material may result in a potential slippage between the SCP clamp and the Portex ET tube who's material has also changed . The clamp has been modified and it has been reported that the modification has resulted in a possible compression of the ET tube when the clamp is over tightened, which could cause obstruction when a suction catheter is passed through.

Recommendation

We are working with a new material to resolve the issue and make the clamp more tactile against the ET tube. In the interim, our recommendation is to test the clamp on the penultimate notch to check that the tube does not move in situ

Product Code	Description		NSVCode
CM-SCP20-ENDO	Neonatal Endotracheal Tube Holder	2.0mm	FTH073
CM-SCP25-ENDO	Neonatal Endotracheal Tube Holder	2.5mm	FTH074
CM-SCP30-ENDO	Neonatal Endotracheal Tube Holder	3.0mm	FTH075
CM-SCP35-ENDO	Neonatal Endotracheal Tube Holder	3.5mm	FTH076
CM-SCP40-ENDO	Neonatal Endotracheal Tube Holder	4.0mm	FTH077

All of the above are supplied in boxes of 20

If you require any further information please contact our customer services team on 0115 978 6111

Yours Sincerely

Gabriel Strauss
Managing Director

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