

Medical Device Alert

Action

Ref: MDA/2010/071 Issued: 13 September 2010 at 14:00

Device

Tracheostomy dressing.
Manufactured by Kapitex Healthcare Ltd.
Trachi-Dress TR DRE 0001.

Lots: WO 25700 – WO 25702.
Supplied in the UK from 28/07/09 to 11/01/10.



Problem	Action
<p>The dressing material may have poor lamination, primarily on the shiny side (patient contact side). It may de-laminate in use over time with the possibility of viscose fibres detaching and entering the tracheal stoma.</p> <p>This is described in the manufacturer's Field Safety Notice FSN 001 Rev 1.</p>	<ul style="list-style-type: none"> Do not use affected lots. Contact the manufacturer to arrange return and replacement of affected stock. Ensure that all relevant members of staff are aware of this alert.
Action by	
<p>All those involved in the use, supply and/or distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 13 October 2010 Action complete: 15 November 2010</p>	<p>Manufacturer Helen Jones Kapitex Healthcare Ltd Tel: 01937 580211 Fax: 01937 580796 Email: hcj@kapitex.com</p>

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- 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 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:

- A&E departments
- All wards
- Clinical governance leads
- ENT departments
- ENT medical staff
- ENT services, directors of
- General surgery
- General surgical units, directors of
- Health and safety managers
- Hospital at home units
- Infection prevention and control directors
- Intensive care medical staff
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Primary care trusts to:

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

- Community children's nurses
- Community hospitals
- Community nurses
- Directors of public health
- District nurses
- Health visitors
- Palliative care team
- Practice nurses

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

The MHRA considers this information to be important to:

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Contacts

Manufacturer

Helen Jones
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Wetherby
West Yorkshire
Tel: 01937 580211
Fax: 01937 580796
Email: hcj@kapitex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/071** or **2010/002/010/401/021**.

Technical aspects

Sally Mounter or Moji Ajeneye
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3168/3271
Fax: 020 7084 3106
Email: sally.mounter@mhra.gsi.gov.uk
mojisola.ajeneye@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3126
Fax: 020 7084 3111
Email: nicola.lennard@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.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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