

SN (NI) 2002/34

DATE: 27 November 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**TRACHEOSTOMY TUBE HOLDERS: KAPITEX
TRACHI-HOLD: RECALL NOTICE**

MANUFACTURER/SUPPLIER

Kapitex Healthcare Ltd

PROBLEM

Kapitex Healthcare Ltd has issued a recall notice concerning faulty stitching where the thin Velcro strips are attached to the tracheostomy tube holder (see Appendix). The following lot numbers are affected:

Trachi-Hold Large	Lot Nos. 020305 & 020416
Trachi-Hold Small	Lot Nos. 020221 & 020503
Trachi-Hold Mono	Lot No. 020307

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff
- Accident & Emergency Departments
- Trust Pharmacy Managers
- General Medical Practitioners
- Practice Nurses
- Community Pharmacists
- Social Care Staff
- Community Care Staff
- Intensive Care
- Nurse Specialists – respiratory care
- Day Care Centres
- Residential and Nursing homes
- Hospices
- Private Clinics

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

1. Ensure that all relevant users are aware of the manufacturer's recall notice (see **Appendix**).
2. Check the lot numbers of the holders, which are printed at the bottom of the instructions for use card, against the lot numbers stated in the recall notice and remove the affected devices from service immediately.
3. Contact Kapitex Healthcare Ltd if you have not already received information about this recall. Kapitex Healthcare Ltd will provide you with replacements free of charge.

**SAFETY
NOTICE**

BACKGROUND

Kapitex Healthcare Ltd were informed of an incident in which the stitching on the Velcro straps of the tracheostomy tube holder failed. This could have lead to displacement of the tracheostomy tube.

Kapitex Healthcare Ltd examined the faulty device and found that the design was the root cause of the problem. The Velcro material is cut at a 45° angle and the weave of the thread therefore runs at 45° and has few interlocking threads. The stitching used to attach the Velcro strap to the tracheostomy tube holder was pushing the threads apart, causing the joint to weaken. Therefore as a precautionary measure, a recall of specific lot numbers was implemented.

To address this problem, Kapitex Healthcare Ltd have modified the Velcro strap. The material is now cut at 90° to ensure security of attachment.

Kapitex Healthcare Ltd has received further reports after the publication of the Recall Notice, including one incident in which the tracheostomy tube became displaced. As the users were not aware of the Recall Notice, NIAIC in conjunction with the Medical Devices Agency is alerting all users to this problem.

ENQUIRIES

Enquires to the manufacturer should be addressed to:

Customer Services
Kapitex Healthcare Ltd
Kapitex House
1 Sandbeck Way
Wetherby
West Yorkshire
LS22 7GH

Tel: 01937 580 211
Fax: 01937 580 796

Enquires to the NIAIC should quote the reference number SN(NI) 2002/34 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



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Kapitex Healthcare Ltd.



KAPITEX[®]

The Specialists in Laryngectomy
and Tracheostomy Care and
Airway Management

RECALL NOTICE

TRACHI-HOLD Large	TR ACC 0012	LOT NOs.	020305 & 020416
TRACHI-HOLD Small	TR ACC 0014	LOT NOs.	020221 & 020503
TRACHI-HOLD Mono	TR ACC 0016	LOT NO.	020307

Dear Customer

As part of our ongoing customer awareness programme, we are writing to advise you that a small number of Trachi-Hold Tracheostomy Tube Holders have been found to have faulty stitching at the point where the thin Velcro strips are stitched to the main body of the neckband.

As a precautionary measure, we are recalling all Trachi-Hold Tracheostomy Tube Holders with the above LOT numbers. The LOT number can be found at the bottom of the instructions for use card, to the right of the CE mark.

Should you find you have any suspect product please contact Customer Services at Kapitex Healthcare Ltd and they will be happy to replace it free of charge. (This may take a little time, as all stocks are being 100% inspected and repackaged).

The problem has been identified and procedures have been put in place to prevent re-occurrence.

Should you have any questions regarding replacement, or require a visit from our Product Specialist, please contact Kapitex Healthcare Ltd who will be happy to help.

We apologise for the inconvenience this has caused and appreciate your co-operation.

Address & Registered Office
Kapitex Healthcare Ltd
Kapitex House, 1 Sandbeck Way, Wetherby,
West Yorkshire LS22 7GH, England
Telephone: +44 (0) 1937 580211
Fax: +44 (0) 1937 580796
Website: <http://www.kapitex.com>

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S M Pearson
M R Eaton
L Triggs Hodge
I D Worthington

Company registration no
2527484
VAT registration no
GB 557 0960 23



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CERTIFICATE No. 257