



**KAPITEX**<sup>®</sup>

The Specialists in Laryngectomy,  
Tracheostomy, Dysphagia and  
Airway Management

**URGENT FIELD SAFETY NOTICE**

Product Commercial Name: TRACHIDRESS

Field Safety Corrective Action (FSCA) reference number/identifier: FSCA 001( Rev1)

Date of Notice: 26/03/2010

**For the Attention of:** All users

**Details of the affected device(s):**

Device type: Tracheostoma Dressing

Model name: TRACHIDRESS TR DRE 0001

Serial No.: N/A

Order No.: N/A

Lot/Batch No.: WO 25700 – WO 25702

**Type of action:**

- Tick as applicable
- Return the device
- Quarantine the device
- Modification
- Exchange/Upgrade
- Destroy
- Instructions for Use
- Labelling
- Other

**Action to be taken by the patient or user:**

Inspect dressing prior to use, to ensure the outer layers do not freely peel away.

The shiny skin contact layer should be well bonded and not able to be peeled without tearing the dressing apart.

The front layer has a light bond and can be peeled away with a small amount of force. THIS IS WITHIN SPECIFICATION AND NORMAL. (DO NOT RETURN)

Any dressings which the shiny side easily peels apart should be returned to Kapitex for replacement.

**This only applies to LOT: WO 25700 – WO 25702.  
Supplied between 28-07-09 to 11-01-10**

**Description of the problem and reason for FSCA:**

The dressing material had localised poor lamination primarily on the shiny side. (Patient contact side)

The dressing may de-laminate in use, over time.

**Transmission of this Field Safety Notice:**

Please forward this notice to all those who should be aware of it within your organisation or to any other organisation where the potentially affected devices have been transferred. If necessary, please pass this notice to other organisations on which this action has an impact. For a suitable period, please maintain awareness of this notice and resulting action to ensure effectiveness of the corrective action.

**Contact reference:** Name: Helen Jones      Tel: 01937 580211      Fax: 01937 580796  
Customer Services Team Leader

Address (if different to letterhead): As per letterhead.

The undersigned confirms that this Field Safety Notice has been notified to the Regulatory Agency.

Ian Worthington  
Technical Director

Signature:

Date:

15/04/2010

