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Urgent Field Safety Notice

LISAcath® catheter for oral endotracheal use

Legal Manufacturer: Chiesi Farmaceutici S.p.A.

1. Device Type
LISAcath® is class I sterile medical device (CE 0546) which is a thin catheter with a total, nominal length of 155.0 mm, a nominal working length of 130.0 mm presenting a 1.7 mm outer diameter (corresponding to a 5 French OD). The shaft presents a mono luer connection at the proximal end and a rounded, soft tip at the distal edge. The outer surface includes printed markings that provide a visual guide to the depth of the device insertion during clinical use. A representative drawing of LISAcath® is reported below: 
2. Commercial name
LISAcath® catheter for oral endotracheal use
3. Primary clinical purpose of device
LISAcath® is a sterile, single-use, oral catheter that is intended to provide neonatologists with a less invasive method to administer surfactant intratracheally for the treatment of neonatal Respiratory Distress Syndrome (nRDS). LISAcath® catheter has been specifically designed to allow intratracheal surfactant administration, without intubation with a standard endotracheal tube, while maintaining

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the infant on non-invasive ventilation (NIV) typically nasal continuous positive airway pressure (CPAP), to permit spontaneous breathing.

Chiesi Ltd. would like to inform you about a precautionary voluntary company led recall of 2 batches of LISAcath® that have been supplied to hospitals in the Republic of Ireland .

Two German hospitals filed two similar complaints to Chiesi regarding LISAcath®. The complaints related to the soft tip (the distal edge of the catheter) being unsealed or only partially sealed to the shaft. The defect was detected before administering surfactant to neonates and no harm to infants occurred. The complaints involved LISAcath® from two different batches. Chiesi started an immediate internal investigation with the manufacturer of the LISAcath® (Creganna Medical).

Initial findings: the two batches involved have a soft tip diameter that is outside of the acceptable limit (1.7 mm outer diameter). It was identified that the defect could have an impact on 2 batches supplied to the Irish market.

In March 2019, the manufacturer, Creganna Medical implemented a 100% tactile test for all batches of LISAcath®. This test confirms that the soft tip is correctly bonded to the shaft. All batches that have undergone this test since March 2019 are considered out of the scope of the recall.

Due to the severity of the potential impact of an unsealed/partially sealed soft tip on a patient, Chiesi Ltd. has decided to immediately recall all 2 batches supplied to the Irish market that could potentially be affected as a precautionary measure. Chiesi Ltd. will substitute all recalled LISAcath® with no additional costs for the hospital.

Actions to be taken

Chiesi recommends immediately stopping use of LISAcath® from the list of batches detailed in the below table.

DS17608	DS17726

Please identify and quarantine all remaining stocks of LISAcath® from listed batches in your warehouse/stores.

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Please complete the attached 'Customer Recall Form' and return the completed form to us by Date and we will be in contact to arrange uplift and replacement.

This notice needs to be passed on to all those who need to be aware within your organisation and to any organisation where the concerned batches of LISAcath® have been transferred.

If you have any questions regarding this voluntary product recall, please contact us at the email: QA.UK@chiesi.com

Please accept our apologies for any inconveniences caused and thank you for your cooperation.

Best regards,

Mr David Barnes
Technical Director (QP)