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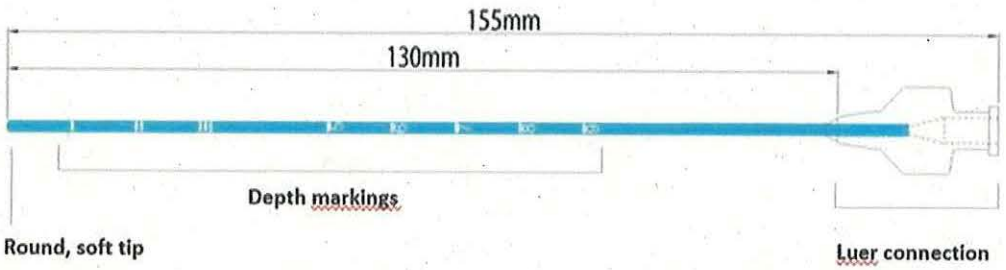
FSN Ref: MD-FSN-CHIESI-2020-001 FSCA Ref: MD-FSCA-CHIESI-2020-001

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 drawings 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 intratracheally Poractant Alfa (Curosurf®) for the treatment of neonatal Respiratory Distress Syndrome (nrDS). LISAcath® catheter has been specifically

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designed to allow Curosurf intratracheal administration, without intubation with a standard endotracheal tube, while maintaining the infant on non-invasive ventilation (NIV) typically nasal CPAP, to permit spontaneous breathing.

Chiesi Group informs you about the voluntary recall of some batches of LISAcath® from Hospitals that has received these batches in involved Countries.

Two different German Hospitals filed two similar complaints to Chiesi of LISAcath® relevant to the soft Tip (the distal edge of the catheter) unsealed or partially sealed from the shaft. The defect was detected before administering surfactant to neonates. No harm to infants therefore occurred. The samples belong to 2 different batches. Chiesi started an immediate internal investigation involving the producer of the device (Creganna Medical).

First findings: the two batches involved seem to include samples whose tip dimension is out of the acceptance limit described in the technical drawings.

The defect could impact 48 batches in validity. In March 2019, Creganna has implemented a 100% tactile test to select acceptable pad printed items, rubbing the unit between the thumb and forefinger applying this control for all batches. This test confirmed that the tip was correctly bonded to the shaft. All the Batches that have undergone this inspection are to be considered out of the scope of the recall.

Due to the severity of the potential impact on a patient using a lifesaving drug, Chiesi has decided to recall all the 48 batches in the braket of the investigation as a precautionary measure. The product in stock in our warehouse ensures that we can afford an immediate recall and replacement with a safe batch avoiding leaving hospitals in shortage of LISAcath®.

Chiesi recommends stopping immediately use in your Hospital of LISAcath® of the list of batches in Table 1.

Chiesi will take care of recalling the catheters belonging to potentially impacted batches of LISAcath® and will substitute them with no additional costs for the Hospital.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Best regards,

Gian Nicola Castiglione, MD

Global Vigilance Manager

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Table 1	
NR	Batch
1	DS17166
2	DS17138
3	DS17121
4	DS17199
5	DS17208
6	DS17216
7	DS17237
8	DS17249
9	DS17262
10	DS17270
11	DS17321
12	DS17328
13	DS17366
14	DS17402
15	DS17367
16	DS17306
17	DS17436
18	DS17437
19	DS17477
20	DS17478
21	DS17548

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22	DS17549
23	DS17550
24	DS17551
25	DS17607
26	DS17608
27	DS17632
28	DS17672
29	DS17673
30	DS17674
31	ds17725
32	DS17726
33	DS17759
34	DS17781
35	DS17782
36	DS17800
37	DS17799
38	DS18512
39	DS18513
40	ds18573
41	DS18574
42	DS18593
43	DS18614

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44	DS18663
45	DS18689
46	DS18722
47	DS18765
48	DS18795