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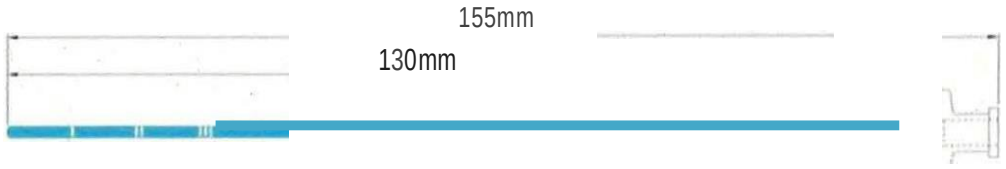
FSN Ref: MD-FSN-CHIESI-2020-001 **FSCA** Ref: MD-FSCA-CHIESI- 2020-001

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 g total, nominal length of 155.0 mm, a nominal working length of 130.0 mm presenting a 1.7 mm Outer Diame ter (correspon ing toa 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 LISAcat h® isreported 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 neon'atal 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 batch(;!S in involved Countries.

Two different German Hospitals filed tw_o 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 belang to 2 different batches. Chiesi started an immediate internal investigation involving the producer of the device (Creganna Medica!).

First firidings: the two batches involved seem to include sampies whose tip dimension is out of the acceptance limit desc;ribed in the technica! 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 decid d 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 1mmediate recall and replacement with a safe batch avoiding leaving hospitals in shortage of LISAcath®.

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

Chiesi will take care of recalling the catheters belonging to potentially iinpacted batches of LISAcath® and will substitute them with no additional casts for the Hospita1.

The Competent (Regulatory) Authority of *yow* country has been informed about this communication to custo mers.

Best regards,
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Table 1	
NR	Batch
1	D517166
2	D517138
3	DS17121
4	D517199
5	DS17208
6	DS17216
7	DS17237
8	DS17249
9	DS17262
10	D517270
11	DS17321
12	DS17328
13	. DS17366
14	DS17402
15	D517367
16	DS17306
17	DS17436
18	OS17437
19	DS17477
20	DS17478
21	D$17548

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22	0517549
23	0517550
24	0517551
25	0517607
26	0517608
27	0517632
28	0517672
29	0517673
30	0517674
31	ds17725
32	OS17726
33	OS17759
34	0$17781
35	0517782
36	0$17800
37	0517799
38	0518512
39	0$18513
40	ds18573
41	0518574
42	D518593
43	D518614

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44	D518663
45	D518689
46	D518722
47	D518765
48	DS18795