CHIESI FARMACEUTICI S.p.A.
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FSN Ref: MD-FSN-CHIESI-2022-001 FSCA Ref: MD-FSCA-CHIESI-2022-001

Urgent Field Safety Notice

LISAcath® catheter for oral endotracheal use

Legal Manufacturer: Chiesi Farmaceutici S.p.A.

Type of action: PRODUCT RECALL

Details on affected devices

Batch/Lot number	Manufacturing date
1. 0000103055	1. 26 Oct 2021
2. 0000103056	2. 01 Nov 2021
3. 0000103058	3. 15 Nov 2021
4. 0000117726	4. 18 Nov 2021
5. 0000122457	5. 26 Nov 2021
6. 0000103057	6. 30 Nov 2021
7. 0000123601	7. 03 Dec 2021
8. 0000126032	8. 19 Jan 2022
9. 0000130074	9. 25 Jan 2022
10. 0000131514	10. 31 Jan 2022
11. 0000135361	11. 21 Feb 2022
12. 0000136637	12. 28 Feb 2022
13. 0000139464	13. 12 Mar 2022

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 surfactant for the treatment of neonatal Respiratory Distress Syndrome (nrDS).

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Description of the problem

The legal manufacturer Chiesi Farmaceutici Spa is initiating a voluntary recall of 13 batches of LISAcath® device from the market with immediate effect.

The recall is correlated to a product quality issue. During an internal inspection a number of finished products were found to contain unacceptable defects such as braid wire partially exposed, surface delamination and flashes, including additional surface defects as burn marks, outer filament partially exposed, embedded foreign matter, catheter mark not complaint on the body of the catheter.

Despite only a limited number of faulty catheters have been identified so far, Chiesi Farmaceutici Spa decided to recall all the identified batches as a precautionary measure to avoid any potential risk to the fragile patient population of neonates for which LISAcath® is intended to be used.

This issue was discovered by an in place procedure in Chiesi Farmaceutici Spa and there were no complaints reported for this issue from customers nor reports of injuries associated with this issue.

Hazard giving rise to the FSCA

The greatest hazard to the patient/end user could be particle release that can stay in lungs. This could potentially cause temporary or permanent serious deterioration of a patient's state of health. An additional potential hazard is the upper airway tissue injury in case there are portion of the wire exposed or surface delamination/flashes.

Type of Action to mitigate the risk

Advice on action to be taken by the user

1. Immediately identify and quarantine any remaining stock of the affected product codes and batch/lot numbers

2. If you do not have stock of the affected batch numbers, stated above, mark the according checkbox on the enclosed Field Safety Notice Customer Reply Form, complete the form and send it to the reference email.

3. If you have stock from the affected batch numbers, stated above, mark the according checkbox on the enclosed Field Safety Notice Customer Reply Form, provide the additional information requested and send the completed form to the reference email.

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4. On receipt of the completed Field Safety Notice Customer Reply Form, a Chiesi Farmaceutici Spa. representative will contact you to arrange return of the affected stock

5. Please complete these actions immediately upon receiving the FSN

Chiesi recommends stopping immediately use in your Hospital of LISAcath® of the list of batches in the front page.

Action Being taken by the Manufacturer

Chiesi Farmaceutici Spa will take care of recalling the catheters belonging to potentially impacted batches of LISAcath®.

Transmission of this Field Safety Notice

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

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative as this provides important feedback.

Best regards,

Barbara Del Carlo

Barbara Del Carlo

Head of GPV Operations,
Deputy EU-UK QPPV
Global Pharmacovigilance