Mallinckrodt Pharmaceuticals

Urgent Field Safety Notice

INOmax DSIR Delivery System
FSCA-Identifier: FA-R-0023
Type of action: Advice given by the manufacturer regarding the use of the device

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Date: 22-Jun-2022

Attention: Chief Executive Officer, Medical Device Liaison Officer (MDLO), Head of the Respiratory Department, and Head of the Medical Center

The INOmax DSIR Delivery System is distributed and marketed by Linde GmbH and its affiliates in Europe.

Details on affected devices:
INOmax DSIR Delivery System v. 2.x SSR #US-MF-000010457

Description of the problem and potential hazard:
The INOmax DSIR Delivery System, manufactured by Mallinckrodt Pharmaceuticals, is not compatible with the upgraded version of the Leoni Plus ventilator, manufactured by Lowenstein Medical. The Leoni Plus ventilator was recently upgraded in 2021 by Lowenstein Medical, with new hardware and software, and the upgraded version cannot be appropriately connected with the INOmax DSIR as instructed in the INOmax DSIR Operators Manual (OM). The INOmax DSIR OM requires the use of a one-way valve with the Leoni Plus ventilator during High Frequency Oscillatory Ventilation mode and warns that use of the device without a one-way valve *may result in high Nitric Oxide (NO) delivery*.

Advise on action to be taken by the user:
Upon receipt of this Field Safety Notice (FSN), INOmax DSIR operators are advised not to use an upgraded Leoni Plus ventilator with the INOmax DSIR.

The INOmax DSIR Validated Ventilator List, supplied as Technical Bulletin TB-20005, will be revised to remove the Leoni Plus ventilator and distributed as soon as it is available.

Transmission of this Field Safety Notice:
This Field Safety Notice is to be provided to all relevant hospital staff members including nursing staff and physicians using INOmax in intensive care units according to hospital procedures.

A response form is required for this FSN. Please complete the attached form and return as instructed.

The relevant Competent Authorities have been notified of this FSN. BfArM is the lead Competent Authority for this Field Safety Corrective Action.

Please report all device-related incidents to the distributor or local representative.

Linde Contact Information:	**Mallinckrodt Contact reference person:**
Contact your local BOC/Linde Sales Representative: Matt Hamblett, Product Manager, INO Therapy matthew.hamblett@boc.com	Megan Vernak Sr. Director, Product Monitoring and Quality Systems productrecalls@mnk.com

The undersigned confirms that this notice has been notified to the appropriate Competent Authority.

Megan Vernak

Digitally signed by Megan Vernak
DN: postalCode=63042, o=Mallinckrodt Inc, street=675 McDonnell Boulevard, st=Missouri, l=Hazelwood, c=US, cn=Megan Vernak, email=megan.vernak@mnk.com
Reason: I am approving this document
Date: 2022.06.30 10:22:27 -05'00'

[signed by the Department Head responsible for Field Actions – Name and title, followed by a physical signature]

ACKNOWLEDGEMENT OF RECEIPT

PRODUCT	INOmax DSIR Delivery System

By returning below, I acknowledge receipt of FA-R-0023 and have made all users of the INOmax DSIR Delivery System aware of the change.

DATE	
FACILITY	
NAME	
POSITION/TITLE	
EMAIL	

Please return acknowledgement by replying to email address sending the FSN.