Mallinckrodt Pharmaceuticals

Urgent Field Safety Notice

CELLEX Photopheresis Procedural Kit
Product Code: CLXECP
Kit Lot #: K257
FSCA-Identifier: FA-R-0024
Type of action: Return of impacted medical device

Date: 18-Aug-2022

Attention: Chief Executive Officer and/or Head of the Medical Center

Details on affected devices:
CELLEX Photopheresis Procedural Kit
Product Code: CLXECP
Kit Lot #: K257
Expiration Date:01-Dec-2023

Description of the problem and potential hazard:
There have been several reports of a leak being observed at the connection between the saline spike chamber and the associated tubing for CELLEX Photopheresis Procedural Kit ("Kit") Lot # K257. No adverse events/incidents have been reported through 18-Aug-2022. The following health consequences could occur should a Kit exhibiting a leak be identified prior to, during, or after an Extracorporeal Photopheresis ("ECP") treatment:

- A delayed or aborted ECP treatment
- The necessity for a blood transfusion
- Contamination with subsequent risk of infection and sepsis (especially in populations at greatest risk)

Advise on action to be taken by the user:
Any remaining inventory of the impacted Kit, CLXECP Lot # K257, must be returned to Mallinckrodt Pharmaceuticals using the provided return label.

Transmission of this Field Safety Notice:
This Field Safety Notice ("FSN") is to be provided to all relevant hospital staff members, including, nursing staff and physicians operating the CELLEX Photopheresis System.

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. The Health Products Regulatory Authority ("HPRA"), located in Ireland, is the lead Competent Authority for this Field Safety Corrective Action.

Please continue to report all device-related incidents as per the normal process via your local Clinical Specialist or ecphelp@therakos.com.

Mallinckrodt Recall Contact Reference Person:
Mark Wendelken
Senior Manager, Product Monitoring
productrecalls@mnk.com

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

Mark Wendelken

Digitally signed by Mark Wendelken
DN: o=Mallinckrodt Inc, c=US, cn=Mark Wendelken, email=mark.wendelken@mnk.com
Reason: I am approving this document
Date: 2022.08.18 12:53:00 -04'00'

ACKNOWLEDGEMENT OF RECEIPT

PRODUCT	THERAKOS CELLEX Procedural Kit
PRODUCT CODE	CLXECP
Lot #	K257

I acknowledge receipt of this Field Safety Notice FA-R-0024.

DATE	
FACILITY	
NAME	
POSITION / TITLE	
EMAIL	
UNUSED QUANITY OF LOT K257 AVAILABLE FOR RETURN	

The impacted, unused kits have been set aside, will not be used, and will be returned using the provided return mailing label.

Please return acknowledgement by replying to productrecalls@mnk.com