Mallinckrodt Pharmaceuticals

Urgent Field Safety Notice

THERAKOS™ CELLEX™ Photopheresis System
FSCA-identifier: 2018-08-03 CELLEX Labeling V34584
Type of action: Advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users, or others

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Date: 09-AUG-2018

Attention: Photopheresis Department

Details on affected devices:
The CELLEX™ Photopheresis System Operator's Manual is affected by this Field Safety Notice.

The Operator's Manual numbers for the CELLEX™ instrument are as identified below:

Language	Software Version	Material Number
English - US	3.0	1460415
English - US	5.1	1470096
Italian	4.1	1460440
Italian	5.1	1470103
German	4.1	1460438
German	5.1	1470100
French	4.1	1460437
French	5.1	1470106
Turkish	4.1	1460547
Turkish	5.1	1470154
Swedish	4.1	1460540
Swedish	5.1	1470136
Portuguese	4.1	1460454
Portuguese	5.1	1470163
Norwegian	4.1	1460539
Norwegian	5.1	1470145
Greek	4.1	1460529
Greek	5.1	1470181
Finnish	4.1	1460537
Finnish	5.1	1470172
Dutch	4.1	1460517
Dutch	5.1	1470190
Danish	4.1	1460526
Danish	5.1	1470127
English – UK	4.1	1460436
English – UK	5.1	1470097
Spanish	4.1	1460439
Spanish	5.1	1470109
Hungarian	5.1	1470407
Croatian	5.1	1470437
Canadian – English	3.0	1460451
Canadian – French	3.0	1460452

Description of the problem:
Mallinckrodt has received reports of thromboembolic events associated with the use of the THERAKOS™ CELLEX™ Photopheresis System in the treatment of Graft versus Host Disease (GvHD). Patients with GvHD have an increased risk of thromboembolic events. The Caution Statement will be updated in the device Operator's Manual section, titled "Anticoagulation."

Advise on action to be taken by the user:

A Technical Bulletin will be issued as follows:

The following CAUTION statement will be added to "*Anticoagulation"* section of the device Operator's Manual:

"Special attention to adequate anticoagulation is advised when treating patients with Graft versus Host Disease (GvHD), a condition associated with an increased risk of thromboembolic events.

Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported with the use of the THERAKOS™ CELLEX™ Photopheresis System in the treatment of GvHD, an indication not approved in some countries, including the United States and Canada."

Once received, please add this Technical Bulletin to your Operator's Manual. The Technical Bulletin will be released as follows:

- English Language: issued by 01-OCT-2018
- Translations/Non-English Language: issued by 01-DEC-2018

The Technical Bulletin will be posted to mytherakos.com once approved and released.

No product will need to be returned.

Transmission of this Field Safety Notice:
This Field Safety Notice should be communicated to all personnel within your organisation who in any way are engaged in the administration of the THERAKOS™ CELLEX™ Photopheresis System.

Contact reference person:

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Megan Vernak
Director, Product Monitoring – Specialty Brands