February 2022

Labeling Update to Spectra Optia® Apheresis System Disposable Sets

Dear Valued Customer,

Terumo Blood and Cell Technologies is dedicated to providing you with the highest quality support and remains committed to communicating information regarding our products. This letter is to notify you of an update to the labeling for Spectra Optia disposable sets.

To comply with the European Union Medical Device Regulation (EU MDR), Terumo Blood and Cell Technologies is updating the set labels and case labels for the Collection Set (catalog no. 10120, 12120, 12123 and 10116), Exchange Set (catalog no. 10220, 12220, 12223 and 10226), IDL Set (catalog no. 10310, 12320 and 12323), Platelet, Plasma Set (catalog no. 12400), BMP Accessory Set (catalog no. 11303), Single-Needle Connector (catalog no. 11220) and Accessory Waste Bag (catalog no. 70040). Product availability varies by country. The new set label and case label are scheduled to be implemented in production in February 2022. You will begin to receive the sets with the revised labeling depending upon regional/country regulatory approval.

Set label and case label contain the following updates:

- Added new symbol for “Medical Device.”
- Added the EC REP information.
- Replaced the “DEHP” symbol with the “Contains hazardous substances” symbol. This change applies only to the set label. This update is already included on the case label.
- Removed the “Terumo BCT” logo.
- Corrected the UDI barcode to the single-line industry standard. This change applies only to the set label. This update is already included on the case label.
- For disposable sets made in Costa Rica, removed “MADE IN THE USA” and added “USA” as a part of the legal manufacturer address.
- For disposable sets made in Costa Rica, added “MADE IN COSTA RICA” and added the Costa Rica facility information.

These updates have been made because our labeling requirements have changed. Our manufacturing processes and materials have not changed.

In addition, all set packages now contain an insert (part no. 1000003614) that defines the new symbols on the case labels and set labels that are not defined in the Instructions for Use (IFU).

Please refer to Attachment A for an example of the current and new labels.
We appreciate your continued support and look forward to serving you. If you have any questions, please visit terumobct.com/contact-us for complete contact information.

Sincerely,

Keith M. Kazmer
Product Manager, Therapeutic Systems

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.0590
Fax: +32.2.721.0770

Terumo BCT Asia Pte. Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

ATTACHMENT A: Example Disposable Set Label Change

Current Label

Spectra Optia® IDL Set
Sada Spectra Optia® IDL
Spectra Optia® IDL-sæt
Spectra Optia® IDL-Set
Σετ λιποπρωτεϊνών IDL Spectra Optia®
Equipo de IDL Spectra Optia®
Spectra Optia® IDL -setti
Kit IDL Spectra Optia®
Spectra Optia® IDL-szerelék
Set per IDL Spectra Optia®
Spectra Optia® IDL-set

再使用禁止

Spectra Optia® IDL-sett
Zestaw IDL Spectra Optia®
Conjunto IDL Spectra Optia
Комплект для IDL к системе Spectra Optia
Spectra Optia IDL-set
Spectra Optia IDL Seti
"泰爾茂"思倍壯亞普緹亞管路組
Spectra Optia® 수혈용세혈세트
管理医療機器
遠心型血液成分分離装置用血液回路
スペクトラ　オプティア用血液回路
ＩＤＬセット　１セット

Sterile and non-pyrogenic fluid pathway. Do not use the set if the end caps are not in place. Read instructions for use before application. Sterilized with ethylene oxide. Intended for single use only. Do not resterilize.
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

無菌且無致熱源的液體通道。如果端蓋沒有蓋好，請勿使用套件。使用之前請閱讀使用說明。
使用環氧乙烷滅菌。僅供單次使用。請勿重新滅菌。 注意: 美國聯邦法律規定，
本裝置僅限由醫師銷售或憑醫囑銷售。本產品含有塑化劑DEHP。衛部醫器輸字第028980號
藥商名稱：台灣泰爾茂醫療產品股份有限公司 藥商地址：台北市松山區敦化北路170號7樓

제품명: 수혈용채혈세트. 수입원: ㈜케이에스메디칼. 서울 강남구 논현로38길 16 재경빌딩 2층 (T:02-2088-8814).
수입업허가번호: 제 1600호. 품목허가번호: 수인 09-804호. 제조 원: Terumo BCT, Inc.(미국).
사용목적, 사용방법 및 사용상의 주의사항: 사용설명서 참조. 실온보관. 포장단위: 낱개포장. 사용기간: 멸균일로부터 2년. 멸균방법: EO가스멸균. 본 제품은 "일회용 멸균의료기기" 임. DEHP를 첨가한 PVC가 사용됨. 재사용 금지.

この回路はエチレンオキサイド滅菌 / 非発熱性です。キャップが外れている場合は回路を使用しないで下さい。
使用前には必ず添付文書をご参照下さい。
製造販売業者：テルモＢＣＴ株式会社　東京都新宿区西新宿三丁目２０番２号
製造業者：Terumo BCT, Inc.（米国）　医療機器認証番号: 22200BZX00554000

EXPIRY DATE 2023-12-01
保存期限
사용기한
有效期限

MANUFACTURE DATE 2021-12-02

CATALOG NO. REF 10310
型號
제품번호
カタログ番号

LOT NO. 2112011234
製造批號
제품로트
ロット番号

STERILE EO

Rx Only

0 °C 32 °F　35 °C 95 °F

CE 2797

Japan Product Code: 5020583103108

製造廠名稱
TERUMOBCT
10811 W. Collins Ave.
Lakewood, CO 80215
MADE IN USA
製造廠地址

0001
(01)05020583103108
(17)231201(10)2112011234

TPN - 0000007590

New Label

Spectra Optia® IDL Set
Sada Spectra Optia® IDL
Spectra Optia® IDL-sæt
Spectra Optia® IDL-Set
Σετ λιποπρωτεϊνών IDL Spectra Optia®
Equipo de IDL Spectra Optia®
Spectra Optia® IDL -setti
Kit IDL Spectra Optia®
Spectra Optia® IDL-szerelék
Set per IDL Spectra Optia®
Spectra Optia® IDL-set

Spectra Optia® IDL-sett
Zestaw IDL Spectra Optia®
Conjunto IDL Spectra Optia
Комплект для IDL к системе Spectra Optia
Spectra Optia IDL-set
Spectra Optia IDL Seti
"泰爾茂"思倍壯亞普緹亞管路組
Spectra Optia® 수혈용채혈세트
管理医療機器
遠心型血液成分分離装置用血液回路
スペクトラ　オプティア用血液回路
ＩＤＬセット　１セット

再使用禁止

Sterile and non-pyrogenic fluid pathway. Do not use the set if the end caps are not in place. Read instructions for use before application. Sterilized with ethylene oxide. Intended for single use only. Do not resterilize.
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

無菌且無致熱源的液體通道。如果端蓋沒有蓋好，請勿使用套件。使用之前請閱讀使用說明。
使用環氧乙烷滅菌。僅供單次使用。請勿重新滅菌。 注意: 美國聯邦法律規定，
本裝置僅限由醫師銷售或憑醫囑銷售。本產品含有塑化劑DEHP。衛部醫器輸字第028980號
藥商名稱：台灣泰爾茂醫療產品股份有限公司 藥商地址：台北市松山區敦化北路170號7樓

제품명:수혈용채혈세트. 수입원:㈜케이에스메디칼. 서울 강남구 도곡동 412-4 재경빌딩 2층 (T:02-2088-8814).
수입업허가번호:제1600호. 품목허가번호:제 수허 09-804호. 제조원:Terumo BCT, Inc.(미국).
사용목적,사용방법 및 사용상의 주의사항:사용설명서참조. 실온보관. 포장단위:낱개포장.사용기간:멸균일로부터 2년.
멸균방법: EO가스멸균. 본 제품은 "일회용 멸균의료기기"임. DEHP를 첨가한 PVC가 사용됨

この回路はエチレンオキサイド滅菌 / 非発熱性です。キャップが外れている場合は回路を使用しないで下さい。
使用前には必ず添付文書をご参照下さい。
製造販売業者：テルモＢＣＴ株式会社　東京都新宿区西新宿三丁目２０番２号
製造業者：Terumo BCT, Inc.（米国）　医療機器認証番号: 22200BZX00554000

製造廠名稱
製造廠地址

TERUMO BCT, INC.
10811 W. Collins Ave.
Lakewood, CO 80215, USA

EC REP
TERUMO BCT EUROPE N.V.
Ikaroslaan 41
1930 Zaventem
Belgium

TFB MANUFACTURING SRL
Calle 58, Zona Franca La Lima
Planta de Terumo BCT - Calle Duan y Avenida Turrialba
La Lima, Guadalupe, 30106
Cartago, Costa Rica
MADE IN COSTA RICA

TPN - 0000023152
Japan Product Code: 5020583103108

EXPIRY DATE 2024-01-01
保存期限
사용기한
有效期限

MANUFACTURE DATE 2022-01-02

CATALOG NO. REF 10310
型號
제품번호
カタログ番号

LOT NO. 2201011234
製造批號
제품로트
ロット番号

STERILE EO

Rx Only MD

0 °C 32 °F　35 °C 95 °F

CE 2797

0001
UDI
(01)05020583103108(17)240101(10)2201011234