

April 2025

Subject: Notification of label change for COBE™ 2991 Cell Processor disposable sets, catalog numbers 90819, 90901, 90904, and 90912

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 changes to the labeling of the disposable sets for COBE 2991. These changes affect the kit label, case label, and Instructions for Use (IFU) for catalog numbers 90819, 90901, 90904, and 90912. The changes are described below:

1. We have updated the labeling to remove the CE mark.
2. For the case label and kit labels, the Korean License Number was corrected and the template part number (TPN) was updated.

Examples of the change are included in Attachment 1. The updated labels will begin with lot number 05J15001, which has a manufacture date of 2025-05-02 and an expiry date of 2027-05-01.

We appreciate your continued support and look forward to serving you. If you have any questions or require device support, please visit TerumoBCT.com/Contact-us for complete contact information.

Sincerely,



Allison Hoffman
Sr. Manager, Global Product Marketing
Global Therapy Innovations

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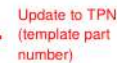
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Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

CT-2991-00046

Removed
gap



Corrected
Korean License
Number



TERUMOBCT.COM

COBE® 2001 BLOOD CELL PROCESSING SET
 COBE® 2001 BLUTKÖRPERCHEN-VERARBEITUNGS-SET
 EQUIPO DE PROCESAMIENTO PARA EL PROCESADOR DE CELULAS
 SANGUINAS COBE® 2001
 ENSEMBLE DE TRAITEMENT POUR PROCESSEUR DE CELLULES
 SANGUINES COBE® 2001
 SET COBE® 2001 PER LA MANIPOLAZIONE DELLE CELLULE EMATICHE
 ZESTAW DO PRZETWARZANIA KOMÓREK KRWI COBE 2001

1

一次使用血細胞分離器
 '賽德美' 科羅2001細胞處理元集器組
 COBE® 2001 BLOOD CELL PROCESSING SETS
 血球洗淨處理器セット 1セット

STERILE AND NON-PROGENIC BLOOD PATHWAY. DO NOT USE THE SET IF THE END CAPS ARE NOT IN PLACE. READ INSTRUCTIONS FOR USE BEFORE APPLICATION. STERILIZED BY GAMMA RADIATION. INTENDED FOR SINGLE USE ONLY. DO NOT RE-STERILIZE. CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. CONTAINS OR PRESENCE OF PHTHALATES (Bis-2-ethylhexyl phthalate (DEHP)). KEEP AWAY FROM SUNLIGHT. KEEP DRY.

無菌且無致熱原の血液通路。エンドキャップが正しく取り付けられていない場合はセットを使用しないでください。使用前に使用説明書をお読みください。滅菌はガンマ放射線による単回使用を目的としたものです。再滅菌はできません。注意：米国連邦法律（米国）は、この装置を医師の指示または医師の処方箋なしに販売することを禁止しています。DEHP（Bis-2-ethylhexyl phthalate）を含む可能性があります。日光から遠ざけ、乾燥を保ちます。

無菌且無致熱原の血液通路。エンドキャップが正しく取り付けられていない場合はセットを使用しないでください。使用前に使用説明書をお読みください。滅菌はガンマ放射線による単回使用を目的としたものです。再滅菌はできません。注意：米国連邦法律（米国）は、この装置を医師の指示または医師の処方箋なしに販売することを禁止しています。DEHP（Bis-2-ethylhexyl phthalate）を含む可能性があります。日光から遠ざけ、乾燥を保ちます。

Terumo BCT, Inc.
 16611 W. Collins Ave.
 Lakeview, CO 80215
 MADE IN USA

Japan Product Code: 502058308192
 TPN - 0000000113

EXPIRY DATE 2025-07-01
 失效日期
 保存期限
 有効期限

MANUFACTURE DATE 2023-07-02
 生产日期

CATALOG NO. REF 90819
 产品编号
 目录编号
 カタログ番号

LOT NO. 07G12345
 批号
 批號
 제품번호
 ロット番号

STERILE R

DEHP

35 °C / 95 °F

0 °C / 32 °F

CE 2797

0601

(01)09602058308192;171250761(10)07G12345

Figure 3: Current kit label for catalog number 90819

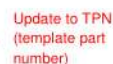


Figure 4: New kit label for catalog number 90819

Removed
CE mark

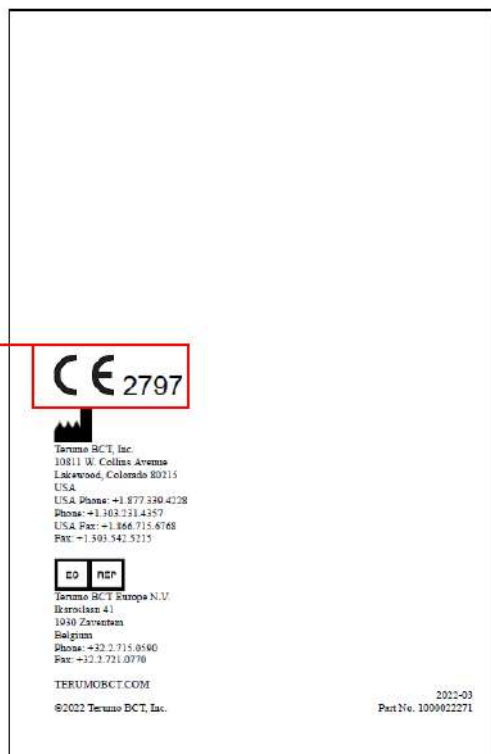


Figure 5: Current IFU for catalog number 90819, last page

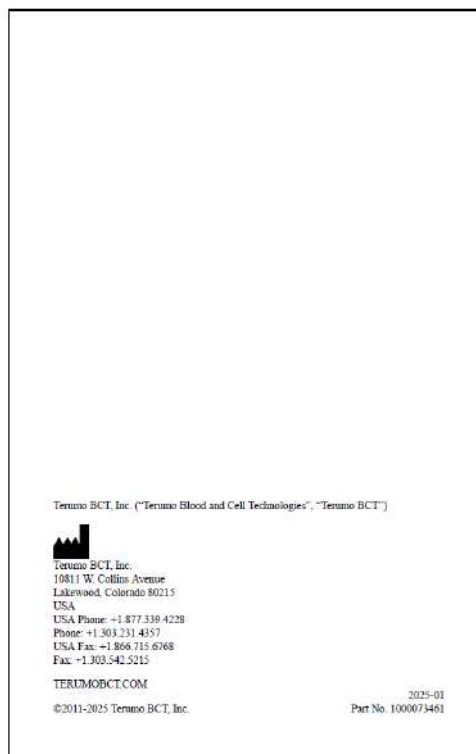


Figure 6: New IFU for catalog number 90819, last page