

TERUMOBCT

82300

Trima Accel® LRS® Platelet, Plasma Set

General Specifications

Catalog Number	82300
First Commercialization Date	2016
Manufacturing Location	 Terumo BCT Inc., Lakewood, Colorado
Referenced Standards	ISO 594 Series:1998 EN 1041:2008 EN ISO 1135-4:2010 EN ISO 3826-1:2003; 3826-2:2008; 3826-3:2006 EN ISO 8536-4:2010 EN ISO 10993 Series EN ISO 11135-1:2007 EN ISO 11607:2006 EN ISO 13485:2003 EN ISO 14644-1:1999; 14644-2:2000 EN ISO 14971:2007(E) EN ISO 15223-1:2012 EN 15986:2011 IEC 62366:2007
Notified Body Within the European Union	BSI
GMDN Code	44903, Blood Collection Tubing Set

Packaging Specifications

Quantity of Tubing Sets Per Case	
External Case Dimension	381 mm × 356 mm × 349 mm (15.00 in × 14.02 in × 13.74 in) (L × W × H)
Case Weight	Containing disposables: 5.89 kg (13.0 lb)
Tubing Set Primary Packaging Dimension	358 mm × 335 mm (14.1 in × 13.2 in) (L × W)
Recycling	 • Disposable Tray Lid: 0.009 kg (0.02 lb) • Disposable Tray: 0.09 kg (0.20 lb) • Box: Cardboard, 0.83 kg (1.83 lb) • Box divider: Cardboard, 0.1 kg (0.22 lb) • IFU: Paper (variable)

Lot Number and Expiry Date Location	Refer to the Terumo BCT Support Center (TERUMOBCT.COM) for certificates of compliance.	
		Users can find the lot number adjacent to this symbol in the following locations on the packaging: box label, disposable package label, collection bag label.
		Users can find the expiration date adjacent to this symbol in the following locations on the packaging: box label, disposable package label, collection bag label.

Technical Specifications

Extracorporeal Volume	Platelet-capable tubing sets: Approximately 196 mL	
Sterilization		Indicates a sterile fluid pathway using ethylene oxide (EtO).
		Indicates that the product is non-pyrogenic.
		Indicates that the product should not be reused.
		Indicates that the product should not be re-sterilized.
Expiry Date	2 years from the date of manufacture. Refer to product labeling for Expiry Date.	
Tubing Set Storage Conditions		Indicates that the product must be kept away from sunlight.
		Indicates that the product must be kept dry.
Access Needle Size	Gauge: 17 Cannula length: 24.3 mm (0.96 in)	
Tare Weight of the Product Bag	See the document titled <i>Example SOP: Tare Bag Preparation & Weighing Blood Products</i> in the Terumo BCT Knowledge Center (portal.TERUMOBCT.COM) about how to identify the tare weight of the product bag.	
Tubing Set Composition	- Primary tubing material: PVC plasticized with DEHP - Platelet storage bags: PVC plasticized with butyryl trihexyl citrate (BTHC) - Plasma storage bag: PVC plasticized with DEHP - Cassette: polyethylene terephthalate (PET-G) - Sampling needle: stainless steel - Access needle: stainless steel 	
	This product is not made with natural rubber latex.	

Storage Bag Specifications

Table 1: Storage Bag Specifications for Platelets in Plasma

Storage Parameters	Storage Ranges	Conditions
Platelet storage bag volume	100 mL to 400 mL	
Platelet concentration	0.7 to $2.1 \times 10^6/\mu\text{L}$	
Maximum total platelets per bag	$\leq 5.1 \times 10^{11}$ platelets	Yield = volume $\times$ concentration
Platelet storage temperature	22 °C $\pm$ 2 °C	

Table 2: Plasma Storage Bag Specifications

Storage Parameters	Storage Ranges	Conditions
Maximum plasma storage bag volume	Up to 600 mL + 6% Up to 1,000 mL + 6%	If product is frozen If product is not frozen

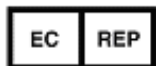
Tubing Specifications (non-sterile, nominal* dimensions)

Item	Wall Thickness	Outer Diameter	Inner Diameter
Tubing to Platelet and Plasma Bags	0.56 mm (0.022 in)	4.06 mm (0.160 in)	2.94 mm (0.116 in)
Access Needle Tubing	1.00 mm (0.040 in)	5.00 mm (0.197 in)	3.00 mm (0.118 in)

***Note:** The tubing dimensions listed on this document are nominal values and are intended for use in determining compatibility with various types of laboratory equipment. The nominal values are specified target dimensions; however, because they are based on non-sterile tubing measurements, and due to variations in the manufacturing process, the actual dimensions may be slightly different.



Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215
USA
USA Phone: +1.877.339.4228
Phone: +1.303.231.4357
USA Fax: +1.866.715.6768
Fax: +1.303.542.5215



Terumo BCT Europe N.V.
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

TERUMOBCT.COM

©2016 Terumo BCT, Inc.

2016-01
Part No. 777020-378