Terufusion® Blood Administration Set - TB*PU300SYE

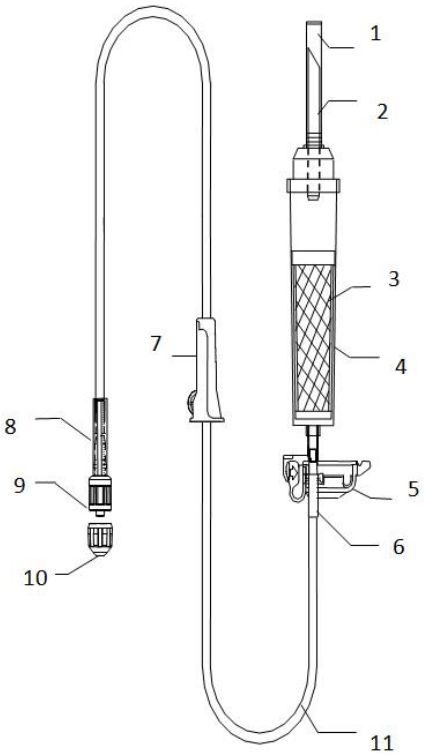
Product Information Card

for use with Terumo Terufusion® infusion pumps TE-LM800, TE-LM700

Description:

The product is intended for single use in infusing blood or blood product by using Terumo Terufusion® infusion pumps TE-LM800, TE-LM700, TE-171 and TE-172.
It is also ready to use for gravity infusion.

Components:



Description	Raw Materials
1. Protective cap	Polypropylene
2. Spike	ABS
3. Blood filter	Polystyrene / polyamide
4. Drip chamber	Polyvinylchloride
5. Anti-Free Flow clamp	Polyoxymethylene
6. Supporting tube	Polybutadiene + master batch orange
7. Flow regulator housing Flow regulator wheel	ABS + master batch orange ABS + master batch white
8. Piercing tube for pump	Polyvinylchloride
9. Connector	Polypropylene
10. Connector cap	Polypropylene
11. Pump tubing	Polyvinylchloride (TOTM)
Lubricant	Silicone oil

Additional Product Details	
Spike	1-way spike
Vented	No
Drip chamber	20 drops/ml
Blood filter	200µm
Roller clamp	Orange with white wheel
Connector	Without filter
Pump tubing length	2200 mm
Priming volume (empty drip chamber)	17.4 ml
Total length	2385 mm

DEHP CE 0123 LATEX No natural rubber latex components

Packaging:

Single unit:	plastic	
Unit box:	20 pieces	
	Gross weight =	*1.50 kg*
	Dimensions =	*280 x 230 x 135 mm*
Shipping carton:	200 pieces	
	Gross weight =	*16.90 kg*
	Dimensions =	*710 x 485 x 309 mm*

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ISO Classification:	EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 15223-1:2012, EN 1041:2008, EN ISO 11135-1:2007, EN556-1:2001/cor.1:2006, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-11:2009, USP, EN 20954-1:1993/AC:1996, ISO 594-1:1986, EN ISO 10993-7:2008/AC:2009, EN ISO 1135-4:2012, EN ISO 8536-8:2004, EN ISO 14155:2011,EN 868-5:2009, ISO 594-2:1998, EN 980:2088
Sterilization:	With ethylene oxide to a Sterility Assurance Level of at least 10^{-6} Validation and control of sterilisation process in accordance with EN ISO 11135-1 standard
Storage:	Shelf life of 30 months ** The batch number and expiry date are printed on the blister pack* ** Do not store at extreme temperature*
Precautions for Use:	Check integrity of the unit package before use Do not use if protective caps are loose or displaced For single use only Dispose of safely after single use to avoid risk of infection For use with Terufusion® pumps TE-LM800, TE-LM700, TE-171 and TE-172
Status of Regulation:	Class IIa following MDD 93/42/EEC
Notified body:	TÜV SÜD Product Service GmbH
Manufacturer:	Terumo Medical Products (Hangzhou) Co. Ltd.
EC representative:	TERUMO EUROPE N.V. Interleuvenlaan 40 B - 3001 Leuven Belgium

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HO 156GB-0813TE-II(01.14)E

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