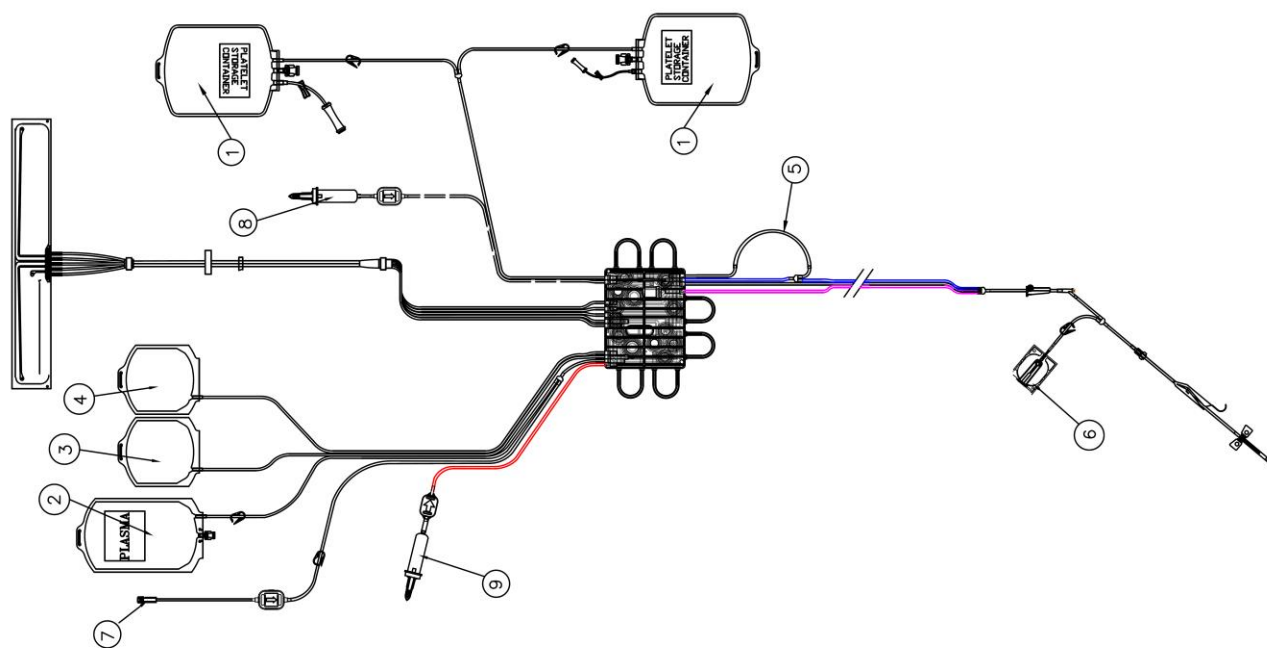


Fresenius Kabi Product Information Sheet

CODE: R6R8884

Product Description:

AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers; PAS Connector



I. Registration Regulations:

1. Registration Number:

EC Certificate	CE Mark
G1 17 04 47402 052	CE-0123

2. FDA Clearance: NOT FDA CLEARED

Class	N/A
Product Code	N/A

3. Solutions Pharmacopeia: N/A

4. Product Family: APHERESIS DISPOSABLES

5. Bar Code Type:

Shipping Carton Label	GS1-128
Primary Label	GS1-128

Storage Container Labels	ISBT-128	
6. Languages: <div style="border: 1px solid black; padding: 5px; margin-top: 10px; width: fit-content;"> ENGLISH/ GERMAN/CZECH </div>		

II. Components:

1. Containers

	Quantity	Solution Type	Volume	Material
No. (1)	1	-	1000 mL	EVA
No. (2)	1	-	800 mL	PL 1813-1 (PVC)
No. (3)	1	-	600 mL	PL 1813-1 (PVC)
No. (4)	1	-	600 mL	PL 1813-1 (PVC)
No. (6)	1	-	50 mL	PL 1813-1 (PVC)

2. Tubes

	Inner Diameter		Outer Diameter		Wall Thickness	
MAJORITY OF TUBING	3.00 mm	.118 in.	4.52 mm	.178 in.	.76 mm	.03 in.
EXCEPT No. (5)	4.24 mm	.167 in.	5.77 mm	.227 in.	1.02 mm	.040 in.

A NOTE ON SEALERS & STERILE CONNECTING DEVICES: CUSTOMERS ARE RESPONSIBLE FOR VALIDATING THAT THE SEALER AND/OR STERILE CONNECTING DEVICE OF THEIR CHOICE IS COMPATIBLE WITH THE TUBE DIMENSIONS IN THE DISPOSABLE KIT.

3. Connectors

	Connection	Type	Color Coding
No. (7)	PAS	FEMALE LUER	CLEAR and WHITE
No. (8)	SALINE	SPIKE	WHITE
No. (9)	ACD	SPIKE	RED

4. Needle(s)

	Type	Needle Length		Tubing Dimensions								Protect or	Manufacturer
No. (10)	17 GA WITH BACKEYE	37.75 mm	1.25 in.	AV Fistula		Inner Diameter		Outer Diameter		Wall Thickness		Master Guard	Medisystems Corporation
				203.20 mm	APPR OX. 8 in.	3.30 mm	.13 in.	5.20 mm	.205 in.	.95 mm	.04 in.		

III. Conditions:

<i>Kit</i>
1. <i>Sterilization</i> : IRRADIATION (MAXIMUM 50 Kgy) – E-BEAM
2. <i>Latex</i> : NOT MADE WITH NATURAL RUBBER LATEX
3. <i>DEHP</i> : CONTAINS DEHP

IV. Packaging & Manufacturing Information:

1. Kit Packaging: <div style="border: 1px solid black; padding: 5px;"> EACH KIT IS PLACED IN A HIPS THERMOFORMED TRAY AND EACH TRAY IS SHRINK WRAPPED USING A POLYOLEFIN FILM. KITS ARE THEN PACKED INTO CORRUGATED CARTON BOXES. </div>	
2. <i>Quantity per Carton</i> : 8	
3. <i>Quantity per Pallet</i> : 160	
4. <i>Expiration Date</i> :	
<div style="border: 1px solid black; padding: 5px;"> 24 MONTHS. FROM THE START OF MANUFACTURE (YYYY-MM-DD) </div>	
5. <i>Storage Conditions</i> : STORE AT ROOM TEMPERATURE	
6. <i>Manufacturing Facility</i> :	
<div style="border: 1px solid black; padding: 5px;"> FENWAL INTERNATIONAL, INC. CARRETERA SANCHEZ KM 18.5 PARQUE INDUSTRIAL ITABO ZONA FRANCA IND. DE S.C. HAINA, DOMINICAN REPUBLIC </div>	
7. <i>Batch Number Configuration</i> : FAXXYZZwwx	
FA	FENWAL HAINA
XX	YEAR
Y	MONTH (ALPHA.)
ZZ	DAY
wwx	ww(SEQ. #) x(check digit)

V. Labeling:

<i>Label Numbers</i>	
<i>Primary Label</i>	472611972
<i>IFU Product Insert</i>	472311971
<i>Shipping Carton Label</i>	470611970
<i>Platelet Storage Container</i>	471708887
<i>Plasma Storage Container</i>	471708473

A NOTE ON LABEL PART NUMBERS:

THESE PART NUMBERS ARE FROM THE CURRENT BILL OF MATERIAL. REGIONAL DIFFERENCES MAY EXIST WITH PARTICULAR LABELS DUE TO ADDITIONAL LABELING OR REGIONAL REGULATORY CLEARANCES.

VI. Compliance:

1. ISO Standard(s): 888 - ERC - 038474

VII. Document Revisions:

Revision A: 07/16/2018

Revision B: 08/15/2018

Revision C: 09/04/2018 – Change to document name

Over time, this information may be subject to change based upon modification in product manufacturing, blood banking, or clinical practice.