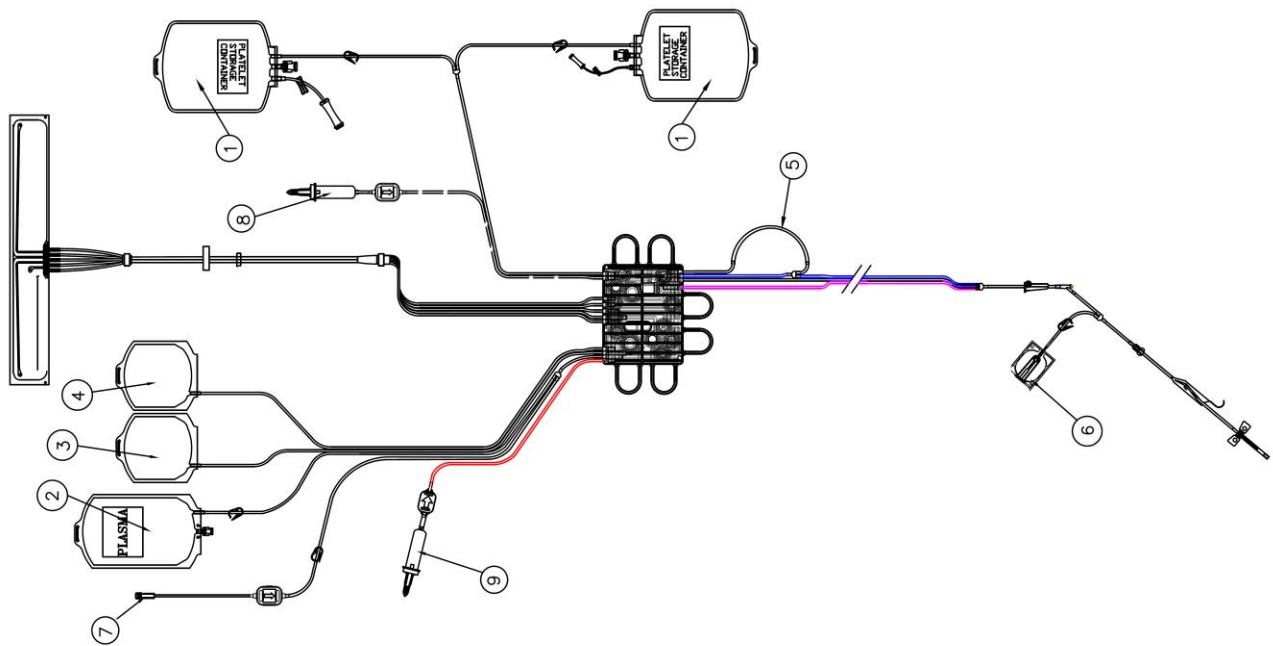


Fresenius Kabi Product Information Sheet

CODE: **R6R8884**

Product Description:

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



I. Registration Regulations:

1. Registration Number:

<i>EC Certificate</i>	<i>CE Mark</i>
G1 17 04 47402 052	CE-0123

2. FDA Clearance: NOT FDA CLEARED

<i>Class</i>	N/A
<i>Product Code</i>	N/A

3. Solutions Pharmacopeia: N/A

4. Product Family: APHERESIS DISPOSABLES

5. Bar Code Type:

<i>Shipping Carton Label</i>	GS1-128
<i>Primary Label</i>	GS1-128

<i>Storage Container Labels</i>	ISBT-128
6. Languages:	
ENGLISH/ GERMAN/CZECH	

II. Components:

1. Containers

	<i>Quantity</i>	<i>Solution Type</i>	<i>Volume</i>	<i>Material</i>
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

	<i>Inner Diameter</i>		<i>Outer Diameter</i>		<i>Wall Thickness</i>	
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

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

4. Needle(s)

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

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:

<i>1. Kit Packaging:</i>	
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.	
<i>2. Quantity per Carton:</i> 8	
<i>3. Quantity per Pallet:</i> 160	
<i>4. Expiration Date:</i>	
24 MONTHS. FROM THE START OF MANUFACTURE (YYYY-MM-DD)	
<i>5. Storage Conditions:</i> STORE AT ROOM TEMPERATURE	
<i>6. Manufacturing Facility:</i>	
FENWAL INTERNATIONAL, INC. CARRETERA SANCHEZ KM 18.5 PARQUE INDUSTRIAL ITABO ZONA FRANCA IND. DE S.C. HAINA, DOMINICAN REPUBLIC	
<i>7. 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.