



ANNOUNCEMENT OF FIELD ACTION

SCOPE: This action covers all lots of Whole Blood Collection Sets Identified by the Product Codes listed herein.

Chief Medical Director
Site Director
[Street Address]
[City, State, Zip Code]

Dear Chief Medical Director and Site Director:

The purpose of this letter is to inform you that there is the potential for a leak to occur, at a very low frequency, in the flexible Y connector of the donor line in some Whole Blood Collection Sets shipped to you. Haemonetics has determined that all product lots for the product codes identified in the attached Protocol require examination. *Note: Because of the recent acquisition from Pall Corporation, all of these lots are labeled as being manufactured by Medsep Corporation, A Subsidiary of Pall Corporation.*

We are requesting that during the pre-phlebotomy and post-phlebotomy examination of the collection sets listed in the attached Protocol you especially examine the Y connectors. As noted in the Protocol, if a defect is detected before collection, the set must be discarded. If a defect is detected during collection, the collection must be halted and any collected blood must be discarded, and if a defect is detected after collection, the blood must be discarded.

We regret any inconvenience the examination process may cause, but trust that these added steps will continue to assure you of our commitment to provide you with products that meet your needs.

Should you have any questions regarding the above, please contact Mr. Djoeffree Hermanto, Sr. Manager Quality Assurance, at 626-915-8248 or dhermanto@Haemonetics.com.

Sincerely,

Warren Nighan, RN
Vice President of Worldwide QA/RA

Protocol for Examining Flexible Y Connector in Whole Blood Collection Sets

Pre-Phlebotomy Examination

Prior to phlebotomy please examine the flexible Y connector in the donor line to look for the presence of a mold defect, a pin hole, or a split Y. The following shows a normal Y connector:

Normal (Good) Flexible Y Connector:

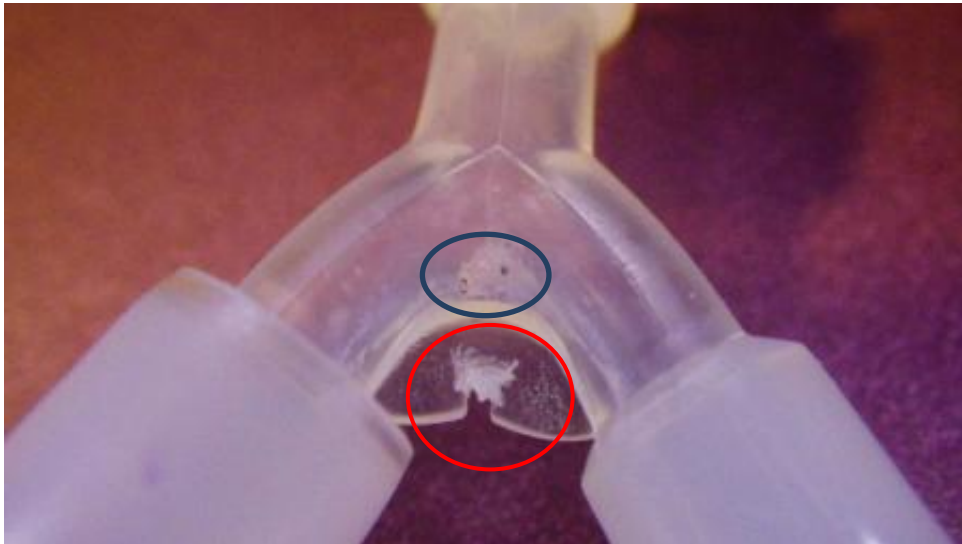


The following photos show Y connectors with defects or potential defects:

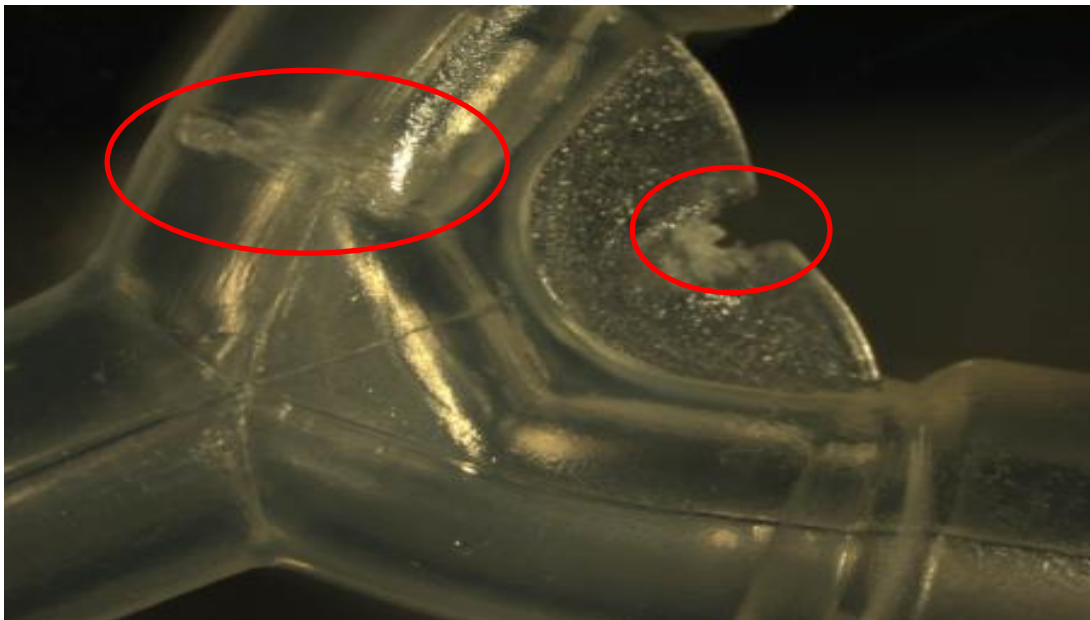
This photo shows a mold defect and a split Y (tear) defect in the Y connector:



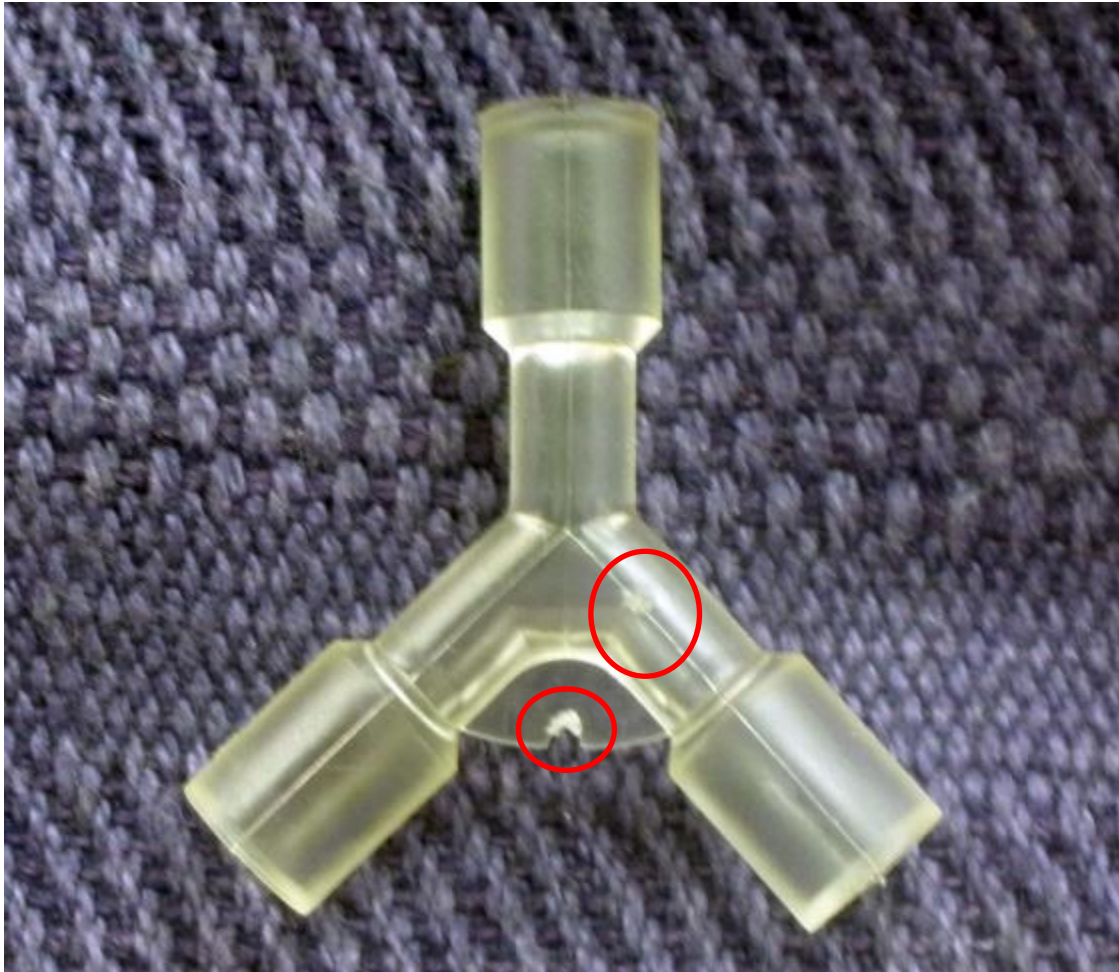
This photo shows a pin hole (blue circle) and molding defect (red circle)
Note: Pin holes may occur as pictured or in other locations on the Y set:



This photo shows molding defects
Note: Mold defects may occur as pictured or in other locations on the Y set:



This photo shows molding defects:



This photo shows a molding defect:

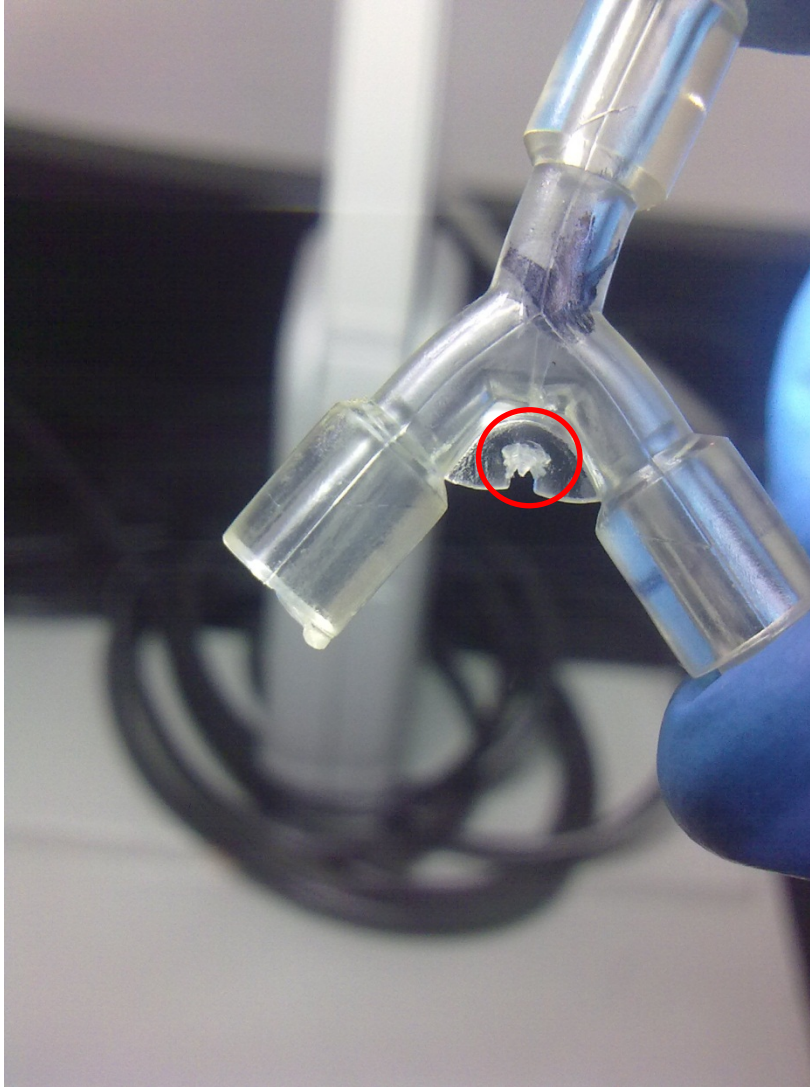


Photo showing drop of blood from pin hole in the flexible Y connector



If a defect is detected before collection, the set should be discarded. If a defect is detected during collection the collection should be aborted and any collected blood must be discarded. If a defect is detected after collection the blood must be discarded.

Please complete the attached form to document the defect. Any defects should be reported to us immediately via fax at (626)-859-8139 or by email at QABlood@Haemonetics.com using the attached form.



Post-Phlebotomy Examination

After phlebotomy and transfer of blood to the Sample Diversion Pouch, please close the blue clamp and then re-examine the flexible Y connector to verify that there has been no blood leak, prior to opening the Breakaway Closure (BAC) to initiate collection of the unit. The user should then wipe the Y connector with gauze to help determine if a leak has occurred (see the photo above). If no leak is observed, open the BAC and collect the unit.

Post-Collection Examination

After collection of the units, please re-examine the Y connector as described above to verify no blood leak has occurred.

If a blood leak is observed before or after collecting the unit, complete the attached form to document the defect.

Please report any defects to us immediately via fax at (626)-859-8139 or by email at QABlood@Haemonetics.com using the attached form.

An acknowledgement letter confirming receipt of the flexible Y connector defect complaint and containing the assigned POR complaint number will be provided to you by Haemonetics Quality Assurance department

Please complete and return the enclosed Acknowledgement of Receipt Form immediately as indicated in the form.

If you have any additional questions or concerns, please do not hesitate to contact Haemonetics QA Department at 1-800-537-2802.



Flexible Y Connector Defect Form

Fax to 626-859-8139/QABlood@Haemonetics.com

Person Reporting Difficulty: _____

Customer Name: _____

Address: _____

Phone Number: _____

Reorder Code of Product: _____

Set Lot Number of Product: _____

Nature of Difficulty (indicate with "X"): _____ Defect in Flexible Y; _____ Leak in Flexible Y

Process Step when difficulty occurred (indicate with "X"):

_____ Found prior to use of the set

_____ After phlebotomy but before opening breakaway closure

_____ During or after collection of the unit

_____ Other (explain) _____

Date of Occurrence: _____

Number of Implicated Products: _____

Best Time And Telephone Number To Be Reached For Additional Information (if needed) for investigation: _____

Additional Comments:

Form Completed By: _____ Date: _____



Scope: This action covers all lots of Whole Blood Collection Sets identified by the Product Codes listed below:

List of Product Codes:

SKU	Description
120-92	BLOOD BAG CP2D/AS3 DBL 500 SP
121-93	BLOOD BAG CP2D/AS3 TR500MLSP
121-94	BLOOD BAG CP2D/AS3 QD500MLSP
123-93	RC-PL TRIP CP2D/AS3 SDP
123-94	RC-PL QUAD CP2D/AS3 SDP
125-93	PL TRIP CP2D/AS3 500ML SDP
125-94	PL QUAD CP2D/AS3 500ML SDP
126-92	WBV DBL CP2D/AS3 500ML SDP
126-93	WBV TRIP CP2D/AS3 500ML SDP
129-92	RC2D DBL CP2D/AS-3 500ML SDP
129-93	RC2D TRIP CP2D/AS3 500ML SDP
129-94	RC2D QUAD CP2D/AS3 500 ML SDP
130-92	BLOOD BAG CPDA-1 DBL 500 SP
136-92	WBV DBL CPDA-1 500ML SDP
136-93	WBV TRIP CPDA-1 500ML SDP
136-94	WBV QUAD CPDA-1 500ML SDP
626-92	VWB CP2D/AS3 DBL 500ML SDP
626-93	VWB CP2D/AS3 TRIP 500ML SDP
629-93	RC2D TRIP CP2D/AS3 500ML SDP
720-92	BLOOD BAG CP2D/AS3 DBL 450 SP

SKU	Description
721-93	BLOOD BG CP2D/AS3 TRP 450ML SP
722-92	RC DBL CP2D/AS3 450ML SDP
723-93	RC-PL TRIP CP2D/AS3 SDP
726-63	VWB,CP2D/AS-3 TRIPLE 450ML SDP
726-63Q	VWB,CP2D/AS-3 TRIPLE 450ML SDP
726-92	WBV DBL CP2D/AS3 450ML SDP
726-92RE02699	WBV DBL CP2D/AS3 450ML SDP
726-93	WBV TRIP CP2D/AS3 450ML SDP
730-92	BLOOD BAG CPDA-1 DBL 450ML
736-92	WB V DBL CPDA-1 450 ML SDP
736-94	CDPA-1, 450 ML CAPACITY, QUAD
ATSBC1EB	FILTSYSHELEUKO ATS BC PL BL LB
ATSBC1EPSL	FILT SYS HELEUKOATSBCPLW/NDL L
ATSBC1ESB	FILT SYS HELEUKOATSBCPLW/NDL B
ATSBC1ESN	FILT SYS HELEUKOATSBCPLW/NDL N
ATSBC1EU	FILTER SYSTEMLEUKOATSBCPLUK LB
ATSBCIESB	FILT SYS HELEUKOATSBCPLW/NDL B
BPF4BWL	FILT BLOODPROCSET BPF4 LEUKO L
NFB434CCL	T&B QUAD CPD/SAG-M 450 ML
NFB434CCLRE2691	T&B QUAD CPD/SAG-M 450 ML
RC2VAYE	F PURECELLRC2F/BLOODW/YSETEULB
RCB434CCL	T&T QUAD WB CPD/SAG-M 450ML
RCB434CCL	T&T QUAD WB CPD/SAG-M 450ML

SKU	Description
RCB434CCLS	T&B QUAD RCS CPD/SAG-M 450 ML
RCB434CEL	RCT&B4PVCBAG63MLCPD/100MLSAG-M
RCB434CEL3	RCT&B4PVCBAG63MLCPD/100MLSAG-M
RCB434CUP	RCT&B4PVCBAGS63MLCPD/100ML SAG
RCB436CCU	RED CELL SYSTEM
RCB436CCURE2700	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CCURE2701	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CCURE2721	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CCURE2727	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CCURE2740	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CCURE2743	T&B QUAD RC CPD/SAG-M 450 ML
RCB436CEU3	RCT&B4PVCBAGS63MLCPD/100MLSAG
RCB436CU3	RCT&B4PVCBAGS63MLCPD/100ML SAG
RCB436KCE	T&B QUAD RC CPD/SAG-M 475 ML
RCB438DCGS	T&B QUAD RCS CPD/SAG-M 500 ML
RCB438DCGSR2750	T&B QUAD RC CPD/SAG-M 500 ML
RCT434CCL	T&T QUAD RC CPD/SAG-M 450ML
RCT434CEL	RCT&T4PVCBG63MLCPD/100MLSAG-M
RLB434GEB	RC T&B 4 PVC BAGS PAGGS- M
RPT434CCL	T&T QUAD RCPL CPD/SAG-M 450ML
RPT434CEL	RCT&T4PVCBAG63MLCPD/100M SAG-M
WBB424CG	WBT&B4PVCBG63MLCPD/100ML SAG-M
WBB434CB	WBT&B4PVCBG63MLCPD/100ML SAG-M
WBT244AB	WB T&T 2 PVC BAGS 63ML CPDA-1
WBT254AB	WB T&T 2 PVC BAGS 63ML CPDA-1

SKU	Description
WBT334AL	WB T&T 3 PVC BAGS 63ML CPDA-1
WBT424DEG	CPD/SAG-M 70/110ml
WBT428GG	WBT&T4PVCBGCPD/PAGGS-M63/100ML
WBT434AM	WB T&T 4 PVC BAGS 63ML CPDA-1
WBT434CC	WBT&T4PVCBAGSCPD/SAG-M63/100ML
WBT434CCL	T&T Quad WB CPD/SAG-M 450ML
WBT434CEL	WBT&T4PVCBAGSCPD/SAG-M63/100ML
WBT434CEU	10.WBT&T4PVCBGCPD/SAG-M63100ML
WBT434CN	WB T&T4PVCBAGSCPD/SAGM63/100ML
WBT434CUP	WBT&T4PVCBAGSCPD/SAG-M63/100ML
WBT434GB	WB T&T 4 BAGS / PAGGS- M
WBT434GEB	WB T&T 4 BAGS / PAGGS- M
WBT434HG	WBT&T4PVCBGCPD/PAGGS-M70/110ML
WBT436CCU	T & T QUAD WB CPD/SAG-M 450ML
WBT436CEA	WBT&T4PVCBAGSCPDSAGM63100ML
WBT436CEU	WBT&T4PVCBAGSCPDSAGM63100ML
WBT436KCE	T&T QUAD WB CPD/SAG-M 475 ML
WBT438DCG	T&T QUAD WB CPD/SAG-M 500 ML
WBT438DEG	WBT&T4PVCBAG70MLCPD/110MLSAG-M
WBT438DG	WBT&T4PVCBAG70MLCPD/110MLSAG-M



Acknowledgment of Receipt Form

In order for Haemonetics to advise the Food and Drug Administration about the receipt of this Field Action Letter, you are requested to complete and return this form promptly.

Customer Information:

Customer Name _____

Institution _____

Street Address _____

City, State, Zip Code _____

Regarding: Field Action Letter for Examination of Flexible Y Connectors

I have read and understand the instructions provided in the letter. Yes ___ No ___

Signature of Receipt: _____ Date: _____

Name/Title	
Telephone	
Email Address	

PLEASE FAX COMPLETED RESPONSE FORM TO: 626-915-8253 ATTN: Elizabeth Mason

or EMAIL TO emason@Haemonetics.com

**or MAIL TO: Ms. Elizabeth Mason
Regulatory Affairs Department
Haemonetics Manufacturing Inc.
1630 Industrial Park
Covina, CA 91722**