



Field Safety Notice

Incorrect Assembly on OrthoPat reservoirs

Jul 23th, 2018

Attention: Risk Management Director and Material Management - Please forward this communication to all potential users of the product.

Dear Customer:

Haemonetics Corporation is voluntarily initiating a Field Safety Corrective Action (FSCA) and is issuing this Field Safety Notice (FSN) on OrthoPat reservoirs that have an assembly error.

Reason for the FSN:

Haemonetics has received a customer report that some reservoirs are missing the cannula inside the reservoirs. The absence of this cannula prevents the blood to be taken from the reservoirs.

Risk to Health:

The inability to empty the reservoir means that the collected blood cannot be processed. This would then cause a delay in delivering processed autologous blood back to the patient.

Action to be taken by Distributor:

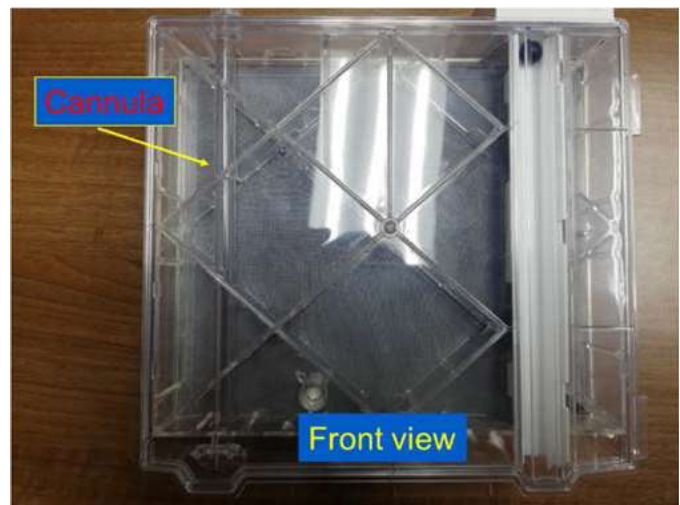
As this is a visible defect, we ask our customers to check their stock of the product lots listed in the "Product and Distribution Information" section and isolate all units that do not have the cannula. Please see the pictures on the next page for easy identification. This inspection can easily be done through the primary packaging. Please document your inspection results in the attached acknowledgement sheet. We will obviously replace any defective units.

If you do not wish to perform this inspection of your stock, we can take the remaining units of these lots back and replace them with non-affected units.

We ask that ALL CUSTOMERS complete the attached customer acknowledgement form in its entirety whether or not you still have affected product at your site. Once complete, return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this FSCA.

Please contact your local customer service representative should you need to coordinate the return.

Correct Assembly (with cannula)



Incorrect Assembly (missing cannula)



Product and Distribution Information:

The products lots impacted by this FSN are the following:

Product ID	Description	Lot #
1150H-00	ORTHOPAT INTEGRATED SET	1017049
1150H-00	ORTHOPAT INTEGRATED SET	1017050
1150H-00	ORTHOPAT INTEGRATED SET	1017072
OPT-R-1000	OPAT QUICK CONNECT RESERVOIR	1117066

Thank you for your business and continued support. We apologize for any disruption this situation may cause you. This action is being performed by Haemonetics with the full knowledge of the regulatory authorities.

If you have any questions about this action please do not hesitate to contact me or send a message to [REDACTED]

Sincerely,

[REDACTED]
John Siew Gan
Senior Manager, Quality Assurance & Regulatory Affairs

cc.: Chairman Medical Board and Relevant Head of Departments

Urgent Field Safety Notice
ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics within 14 days

- ☐ We do not have any of the following products on hand any longer
- ☐ I acknowledge receipt of this Field Safety Notice, understand the instructions provided and have inspected the remaining units in our stock with the following results:
- _____
- _____
- ☐ We have the following quantity of the affected lots in inventory and request replacement
- _____
- _____

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

City: _____ Country: _____

SIGNATURE

DATE

PLEASE RETURN BY SCAN AND E-MAIL TO

