April 23, 2018

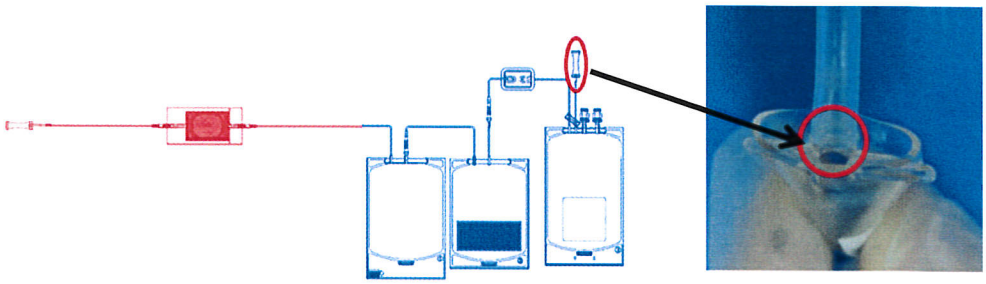
IMPORTANT USER ADVISORY INFORMATION

INTERCEPT Processing Set for Platelets

Dear Cerus Valued Customer:

Description of the issue:

Cerus Corporation has recently become aware of an issue that affects the INTERCEPT Processing Sets for Platelets. Cerus has received some reports of an incomplete seal that has been identified at the base of the sampling pouch where the tubing is joined to the sampling pouch on the final storage container (see graphic below).



While we expect the rate of occurrence of this issue to be very low, we are taking a precautionary measure to ask customers to follow the Instructions for Use (IFU) to inspect all processing sets prior to use. We are requesting you pay particular attention to the connection of the tubing to the sampling pouch on the platelet storage container. In the event that you are using INTERCEPT Platelet Processing Sets with Dual Storage Containers, the sampling pouch on each storage container should be inspected.

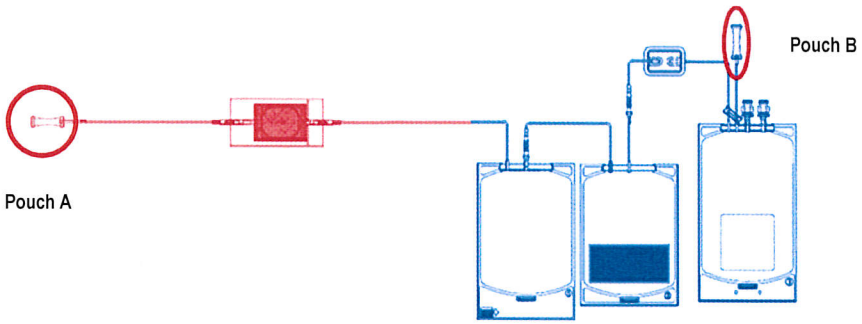
The following graphics and instructions are provided to assist you in locating any possible issue with the seal between the tubing and the sampling pouch. In addition, there is a second pouch on the lead end of the set which has not been associated with leaks but should also be examined before use. This inspection should be performed prior to connecting the INTERCEPT Processing Set to the collected platelets.

Inspection instructions:

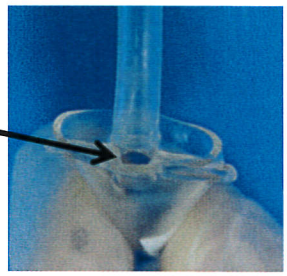
Remove the INTERCEPT Processing Set from the package. Unwrap only the illumination container from the organizer according to the IFU. Examine pouches A and B (refer to graphic below). Inspect the junction of the tubing and each pouch for intact seal. Check the interior and exterior areas where the tubing joins the pouch. Examples of incomplete seals are shown in the following graphics.

P.O. Box 1769, 3800 BT Amersfoort, The Netherlands | T +31 33 4960 600 | E customer_services@cerus.com | www.interceptbloodsystem.com
Stationsstraat 79-D, 3811 MH Amersfoort, The Netherlands | F +31 33 4960 606 | Chamber of Commerce 32113897 | www.cerus.com

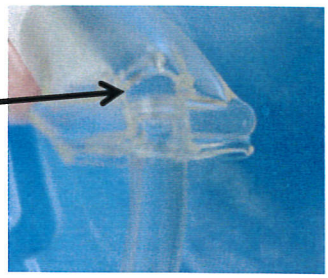
Graphics and Instructions:



Example of incomplete interior seal.



Example of incomplete exterior seal.



Any INTERCEPT processing sets which are found with evidence of incomplete seal or fluid path closures are loose or not intact should not be used. Please continue to report any defective product to Cerus through our customer service office. Contact info: +31 33 496 0600 or customer_services@cerus.com.

We want to emphasize that we are taking these steps as a precautionary measure to assure the safety of our patients and express our commitment to quality. We sincerely apologize for any inconvenience this request may cause and have taken actions in our manufacturing facility to address this issue. We understand how disruptive any product problem can be to your operation and want to make sure your expectations are met regarding the quality of our product and that our service and support of your requirements are addressed. Please feel free to contact me, your Sales Representative, or Cerus Customer Services (+31 33 496 0600 or customer_services@cerus.com) if further information is needed or you have specific questions regarding this action or our products.

Respectfully,

Carol M. Moore
Senior Vice President, Quality Assurance and Regulatory Affairs
Cerus Corporation
cmoore@cerus.com
Phone: 925-288-6361

CERUS

FIELD SAFETY NOTICE

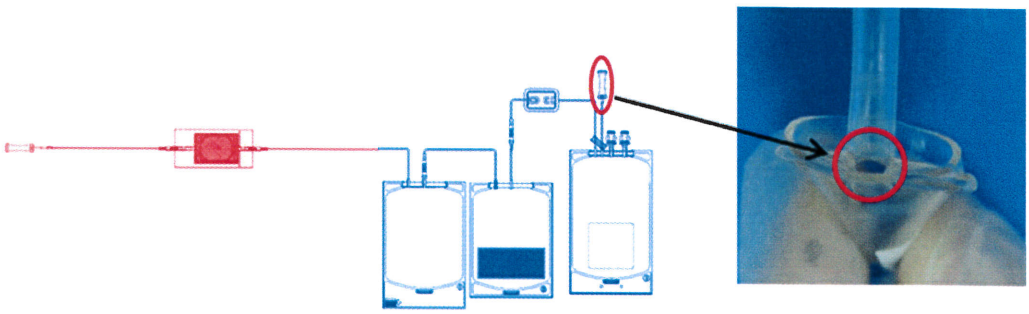
Affected Product: INTERCEPT Processing Set for Large Volume Platelet Units (INTERCEPT Platelet Processing Sets): Lot CE17J26L71, Code: INT2203B

Date: April 20, 2018

Type of Action: Return of unused INTERCEPT Processing Sets Lot CE17J26L71

Details of affected device and description of the problem:

Cerus Corporation has recently become aware of an issue that affects the INTERCEPT Processing Set for Large Volume Platelet Units, Lot CE17J26L71 Code INT2203B. Leaks have been reported on Lot CE17J26L71 due to an incomplete seal that has been identified at the base of the sampling pouch where the tubing is joined to the pouch. (This area has been circled in the graphic below.)



This incomplete seal can result in a small leak when using the sampling pouch to obtain a sample of INTERCEPT treated platelets. The incomplete seal has the potential to compromise the sterility of the platelet storage container and/or the platelets that have been INTERCEPT treated.

It is important to note that Cerus has not received any reports of patient or operator safety issues that have occurred when using this lot of processing sets.

Advice on action to be taken by the user:

- Any remaining INTERCEPT Platelet Processing Sets from Lot CE17J26L71 should not be used.
- Please check your inventory to see if you have remaining affected INTERCEPT processing set Lot CE17J26L71 in your inventory.
- Send all unused processing sets Lot CE17J26L71 from your inventory back to Cerus. Your Sales Representative or Cerus Customer Services can assist you in returning any remaining inventory. Contact information for Customer Services: +31 33 496 0600 or customer_services@cerus.com.

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The Belgium Competent Authority has been advised of this Field Safety Notice.

While Cerus expects this incomplete sealing of the sampling pouch to be a very low frequency event, as an additional precaution, Cerus will be advising all customers with INTERCEPT Processing Sets for platelets to inspect their sets prior to use. The incomplete seal can be readily detected by a simple visual inspection. Cerus is preparing a field communication to all customers who have received INTERCEPT Platelet Processing Sets that will outline additional inspection steps; INTERCEPT Platelet Processing Sets that are found with this incomplete seal should not be used. Please continue to report any product issues to Cerus through Customer Services.

Cerus wants to emphasize that we are taking these steps as a precautionary measure to assure the safety of our patients and express our commitment to quality. We sincerely apologize for this product defect and have taken corrective actions in our manufacturing facility to address this issue. We understand how disruptive any product problem can be to your operation and want to make sure your expectations are met regarding the quality of our product and that our service and support of your requirements are addressed. Please feel free to contact me, your Sales Representative, or Cerus Customer Services (+31 33 496 0600 or customer_services@cerus.com) if further information is needed or if you have specific questions regarding this action or our products.

Respectfully,

Carol M Moore
Senior Vice President, Quality Assurance and Regulatory Affairs
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