[Addressee name, address]

Date

Urgent Voluntary Field Safety Notice

Reference: R536

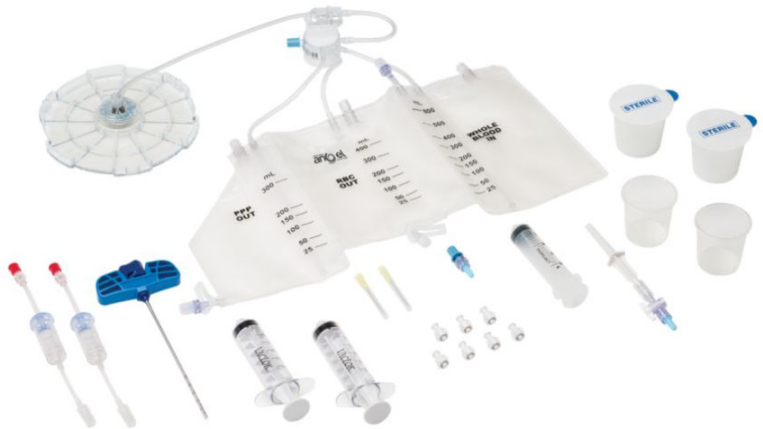
Purpose

This Field Safety Notice (FSN) is to inform you about a recall of the Angel cPRP Processing Set ABS-10064.

The Angel Concentrated Platelet-Rich Plasma (cPRP) Set is intended for use with the Angel® Concentrated Platelet-Rich Plasma (cPRP) System to separate and collect an autologous plasma fraction rich in platelets and red blood cells from the patient's whole blood or a small mixture of blood and bone marrow perioperative to a surgical procedure.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
Angel cPRP Processing Set	ABS-10064	2023050119	(01)00888857084018(17)260430(10)2023050119



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Bank of America
IBAN DE45 5001 0900 0020 9490 11
SWIFT/BIC BOFADEFX

Description of the issue

The disk top housing component may be occluded, preventing the blood from reaching the centrifuge chamber and being separated.

The Angel Centrifuge will not be able to spin the blood and separate the PRP. Due to the occlusion, the blood will not reach the bag in the centrifuge and will not be spun and separated. The blood will advance through the tubing but will not reach the occluded part due to the presence of air in the tubing. Depending on the amount of air in the line, the blood may either not reach the sensor, likely triggering an alarm, or move past the sensor, allowing the centrifuge to continue and complete the cycle that is expected to take less than 15 minutes. The blood can be withdrawn from the consumable "BLOOD IN" bag using the same or any syringe with a luer lock and transferred to another, likely available, Angel consumable without blood loss or further need to withdraw blood. Therefore, as worst credible harm is a procedural delay greater than 15 minutes was determined.

To date, Arthrex is not aware of adverse events associated with this issue. The complaint data shows that no adverse events have occurred.

Advise on action to be taken by the addressee of this notice

1. Immediately discontinue use, sale, and distribution of the affected product.

2. Immediately identify and quarantine all the indicated product/batch numbers you have in your control.

3. **For German Customers:** Please contact Arthrex Customer Returns Department at +49 (89) 90 90 05 89 00 or via e-mail under CustomerReturns@arthrex.de for a Return Merchandise Authorization No. (RMA) and product return instructions.
   Our Customer Returns Specialists can provide assistance regarding alternative solutions and are available to answer questions regarding credit for affected devices in your possession.

   For Customers outside Germany: Please contact your local responsible Arthrex Representative.

4. Please complete the “Arthrex customer’s response form” and fax it back to +49 (89) 90 90 05 52 01 or email to vigilance@arthrex.de.

Transmission of this Field Safety Notice

Please forward this Field Safety Notice (FSN) to all those who need to be aware of it within your organization or to any organization where the potentially affected devices have been transferred.

The relevant National Competent Authorities have been advised of this voluntary recall.

Contact information

Product-specific questions:
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Feldfunktion geändert

Customer Returns Service:
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Supervisor Customer Returns Service Center
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E-mail: CustomerReturns@arthrex.de

Product Surveillance:
Sarah Merkle
Manager Vigilance & Product Surveillance
Phone: +49 (89) 90 90 05 52 40
E-mail: vigilance@arthrex.de

If you have any questions, please call Arthrex GmbH at +49 89 90 90 05 52 40 and ask for Sarah Merkle. You can also send questions by email to vigilance@arthrex.de.

Sincerely,

i.V. Sarah Merkle
Manager Vigilance & Product Surveillance

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