B. Braun Melsungen AG
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Date: March 31, 2025

Aesculap AG

Am Aesculap Platz

78532 Tuttlingen

Urgent Field Safety Notice
VASCUGRAFT FLOW 6MM X 50CM SW HEP
VASCUGRAFT FLOW 5MM X 70CM TW HX HEP

For Attention of*:Users, Importers and Distributors of the affected products.

Contact details of local representative (name, e-mail, telephone, address etc.)*
B. Braun Melsungen AG Vascular Systems Siefersufer 8 12359 Berlin Germany **Safety Officer MD** Dr. Christian Sperling Phone: +49 30 568207120 Mail: vigilance-vs@bbraun.com **Quality Management** Harri Reiter Phone: +49 151 58493587 Mail: harri.reiter@bbraun.com

Dear Customer,

B. Braun Melsungen AG as the legal manufacturer of the affected products has voluntarily decided to recall the affected products under point 1.2 as a precaution due to the risk scenario mentioned below.

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FSCA-VS-2025-01

1. Information on Affected Devices*	
1.1	**Device Type(s)***
	Covalently heparin-bonded vascular ePTFE prosthesis
1.2	**Commercial name(s)**
	VASCUGRAFT FLOW 6MM X 50CM SW HEP VASCUGRAFT FLOW 5MM X 70CM TW HX HEP
1.3	**Unique Device Identifier(s) (UDI-DI)**
	Not available
1.4	**Primary clinical purpose of device(s)***
	The prosthesis is indicated for peripheral arterial reconstructions, extra-anatomical procedures and dialysis shunt placement.
1.5	**Device Model/Catalogue/part number(s)***
	V1103721 - VASCUGRAFT FLOW 6MM X 50CM SW HEP V1103880 - VASCUGRAFT FLOW 5MM X 70CM TW HX HEP
1.6	**Software version**
	N/A
1.7	**Affected serial or lot number range**
	REF V1103721 – LOT 1296546 REF V1103721 – LOT 1296550 REF V1103880 – LOT 1302119
1.8	**Associated devices**
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.1	**Description of the product problem***
	7 expired products were distributed to customers. At the time of distribution to customers, the labeled expiry date was exceeded by 19 – 56 days.
2.2	**Hazard giving rise to the FSCA***
	Expired products must not be used because the sterility, safety and performance of the device can't be assured.

2.3	**Probability of problem arising**
	An expired product will be most likely detected during incoming goods inspection at the hospital and during regular checks of the hospital's inventory. If the expired products are not detected before the start of the preparation for vascular reconstruction, the implantation of an expired vascular graft is very unlikely because the correct expiration date is stated on the product's label and should therefore be easily detected by the implanting user and surgical team before implantation. The arising of problems in case of the unlikely implantation of an expired graft is furthermore considered unlikely because of the very short exceedance of the expiry date of a few weeks.
2.4	**Predicted risk to patient/users**
	If the expiry of the product is detected during preparation for vascular reconstruction, a delay in treatment of few minutes may arise because of the required new device. In case of the very unlikely implantation of an expired graft, the occurrence of a graft infection due to implantation of an unsterile graft can't be excluded.
2.5	**Further information to help characterise the problem**
	The complete inventory of Vascugraft FLOW and Vascugraft Neo was checked and no other affected products were identified. Internal measures have been implemented to prevent the distribution of expired products in the future.
2.6	**Background on Issue**
	Based on market feedback, B. Braun Vascular Systems detected, that due to a system error, expired products were mistakenly delivered to the customer by a distributor.
2.7	**Other information relevant to FSCA**
	N/A

	3. Type of Action to mitigate the risk*
3.1	**Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations

	☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.2	**By when should the action be completed?**	B. Braun Melsungen AG plans to complete this FSCA within 3 months.
3.3	**Particular considerations for:** Implantable device **Is follow-up of patients or review of patients' previous results recommended?** Yes, only in case of implantation of an expired graft: In the unlikely case that a vascular graft was implanted after its expiration date, a graft infection would represent the worst however unlikely complication. So called perigraft fluid layers could be indicative for a graft infection which could be detected not only immediately after the implantation, but they may also continue to present 3, 6 and 9 months after implantation. Evidence suggests that if no perigraft seam is present around the vascular graft, the likelihood of a graft infection is low. For this reason, in case an expired vascular graft was implanted, a non-invasive ultrasound i.e., B-mode along the vascular graft would be recommended at close time intervals post-surgery. This preventive measure may pick up an early graft infection before clinical symptoms occur at a much later follow-up interval.	
3.4	**Is customer Reply Required? * (If yes, form attached specifying deadline for return)**	Yes See point 4.9.
3.5	**Action Being Taken by the Manufacturer** The affected products are recalled.	
3.6	**By when should the action be completed?**	After receipt of the FSN the requested actions should be implemented in the hospital.
3.7	**Is the FSN required to be communicated to the patient /lay user?**	No
3.8	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Choose an item.	

4. General Information*		
4.1	**FSN Type***	New
4.2	**For updated FSN, reference number and date of previous FSN**	Provide reference and date of previous FSN if relevant
4.3	**For Updated FSN, key new information as follows:**	
	Summarise any key difference in devices affected and/or action to be taken.	
4.4	**Further advice or information already expected in follow-up FSN? ***	No
4.5	**If follow-up FSN expected, what is the further advice expected to relate to:**	
	Eg patient management, device modifications etc	
4.6	**Anticipated timescale for follow-up FSN**	For provision of updated advice.
4.7	**Manufacturer information (For contact details of local representative refer to page 1 of this FSN)**	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.8	**The Competent (Regulatory) Authority of your country has been informed about this communication to customers. ***	
4.9	**List of attachments/appendices:**	Annex 1 – Customer feedback form
4.10	Name/Signature	**Dr. Christian Sperling** **Safety Officer / PRRC Vigilance**
		Harri Reiter **Team Lead Post Market Surveillance & Risk Management**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

	Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

FSCA-VS-2025-01

Annex 1 – Customer feedback form

Confirmation of the batch recall from March 31, 2025 for Vascugraft FLOW

Ref. no. FSCA-VS-2025-01

Please return this completed form by email back to the following email address immediately, even if you no longer have any of the listed products:

✉ vigilance-vs@bbraun.com

Name: ..... Position: .....

Hospital: .....

Address: ..... Country: .....

☐ We confirm the receipt of this information and the initiation of the required action.

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Date Signature