B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail:
productcomplaints.ie@bbraun.com
http://www.bbraun.com

TO WHOM IT MAY CONCERN

Date:
March 08, 2022

Ref: FSCA-2022-03-03 STK/AS

Urgent FIELD SAFETY CORRECTIVE ACTION

Vasofix® Safety 24G

Dear Sir/Madam,

B. Braun Melsungen AG has decided to proactively recall the below batches of Vasofix® Safety 24G in the context of a Field Safety Corrective Action (FSCA) from the market:

Article Number	Article Name	Batch
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	See Appendix

Reason for the Recall
In the course of our post market surveillance activities we identified that the injection port of the above mentioned article might be leaky.

The defect might result in potentially critical clinical consequences for the patient such as blood loss, underdosage or delay of therapy. The user or third parties are at risk due to contact with incompatible substances or foreign blood. Based on the identified risks and the consideration that the concerned products are mainly used for infants or in general for patients with difficult veins, we decided to proactively recall all affected devices from the market.
No additional follow-up activities are required for patients already treated with the devices.

The effect is limited to the batches listed in the appendix.
The defect is due to a production deviation starting from September 2019 onwards. The corrective action has been implemented in June 2020. All batches manufactured from July 2020 onwards are not affected.
No other products besides the above mentioned are affected.

Actions to be taken
We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organisation and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected articles.
- Do not use affected devices anymore.

- Confirm receipt of this information by completing and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

*Please return the completed form by **Friday 11th March 2022**, or sooner if possible.*
A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority (HPRA) has been informed of this action.

If more information is needed, please contact:

Rob Egan
Business Unit Manager
Medical Technologies Division
B. Braun Medical Ltd
Tel: 086- 2606917
Email: rob.egan@bbraun.com

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,

egarobie Digitally signed by egarobie Date: 2022.03.08 09:21:26 Z

Rob Egan
Business Unit Manager
Medical Technologies Division

eganroie Digitally signed by eganroie Date: 2022.03.08 09:17:57 Z

Roberta Egan
Regulatory Affairs Manager

Appendix – Affected Batches

Article Number	Article Name	Batch
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K03G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K27G8346
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19N17G8383
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20B18G8332
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20B19G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20C08G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D02G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D04G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D06G8331
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D07G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D14G8345
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D17G8345
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D18G8346
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D29G8330