

9th March 2022**Ref : FSCA FSCA-2022-03-03 STK/AS****Urgent FIELD SAFETY CORRECTIVE ACTION****Vasofix[®] Safety / Vasofix[®] Certo / VasoVet[®] 24G**

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the below batches of Vasofix[®] Safety, Vasofix[®] Certo and VasoVet G24 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
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	
4269071	VASOFIX CERTO G24X19MM YELLOW	
4269075	VASOVET PUR G24X19 MM	

Reason for the Recall

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

The defect might result in potentially critical clinical consequences for the patient such as a 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 above-mentioned batches.

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 organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customer.
- Identify, quarantine and return affected articles.
- Do not use affected devices anymore.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

If more information is needed, please contact

For Technical Issues

Rachel Kent

Marketing Manager – IV Therapy

rachel.kent@bbraun.com

Tel 07772 115 887

For Stock/Returns Issues

Catherine Clulow

Team Leader Product Complaints

productcomplaints.bbmun@bbraun.com

Tel : 0114 2259155

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above-mentioned contact person. The Competent Authority MHRA has received a copy of this safety information.

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

PP  (Theresa Cavill)

Karen Jackson

Head of Regulatory Affairs, QM and Environmental



Catherine Clulow

Team Leader Product Complaints

Please complete this form and return to
Catherine Clulow
Fax: 0114 2259141
E-mail: productcomplaints.bbmuk@bbraun.com

FEEDBACK FORM

Article Number	Article Name	Batch
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	See Appendix
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	
4269071	VASOFIX CERTO G24X19MM YELLOW	
4269075	VASOVET PUR G24X19 MM	

☐ *We have received the Field Safety Notice and confirm that we have no remaining products in stock.*

☐ *We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:*

<i>Product Code</i>	<i>Quantity to be returned</i>	<i>Lot/Batch Number</i>

☐ *We have not shipped any products affected by this Field Safety Notice to third parties.*

☐ *We have notified our customers who are affected by this recall notice and we will contact our customers to arrange collection of any affected products for onward return to B Braun Medical Limited.*

NAME:

TELEPHONE NUMBER.....

POSITION:

COMPANY NAME.....

Appendix – Affected Products

Article Number	Article Name	Batch
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	19K04G8332
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	19M30G8330
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	19N10G8382
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20A13G8347
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20A27G8345
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20B17G8345
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20B20G8381
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20D05G8330
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20D08G8345
4269071S-20	VASOFIX SFTY PUR 24G,0.75IN,0.7X19MM-CIS	20F02G8330
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20C21G8346
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	19L12G8345
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	19L20G8345
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	19L29G8330
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	19N09G8381
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20A07G8345
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20C03G8382
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20E08G8331
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20F01G8345
4269071S-03	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-AP	20F24G8348
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	19K20G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K21G8345
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K22G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K25G8345
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	19K28G8345
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	19K30G8330
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	20A07G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20A10G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20A23G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20B15G8345
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	20C05G8345
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	20C22G8331
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20C26G8331
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D01G8345
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	20D05G8330
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	20D11G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D11G8382
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D13G8382
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	20D14G8381
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D15G8381
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
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20D29G8382
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20E01G8348
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20E03G8330
4269071S-01	VASOFIX SFTY PUR 24G,0.75 IN,0.7X19MM-EU	20E09G8345
4269075	VASOVET PUR G24X19 MM	19K06G8330
4269075	VASOVET PUR G24X19 MM	19K06G8331
4269075	VASOVET PUR G24X19 MM	19K14G8345
4269075	VASOVET PUR G24X19 MM	19L22G8345
4269075	VASOVET PUR G24X19 MM	19M18G8382
4269075	VASOVET PUR G24X19 MM	19N11G8330
4269075	VASOVET PUR G24X19 MM	19N12G8381
4269075	VASOVET PUR G24X19 MM	19N18G8331
4269075	VASOVET PUR G24X19 MM	20A17G8330
4269075	VASOVET PUR G24X19 MM	20A18G8330
4269075	VASOVET PUR G24X19 MM	20B21G8381
4269075	VASOVET PUR G24X19 MM	20B26G8330
4269075	VASOVET PUR G24X19 MM	20B26G8331
4269075	VASOVET PUR G24X19 MM	20D21G8331
4269075	VASOVET PUR G24X19 MM	20D25G8330
4269075	VASOVET PUR G24X19 MM	20E05G8382
4269075	VASOVET PUR G24X19 MM	20F16G8381
4269075	VASOVET PUR G24X19 MM	20F04G8346
4269075	VASOVET PUR G24X19 MM	20F04G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19K06G8332

4269071	VASOFIX CERTO G24X19MM YELLOW	19K17G8331
4269071	VASOFIX CERTO G24X19MM YELLOW	19K26G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	19L11G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	19L22G8332
4269071	VASOFIX CERTO G24X19MM YELLOW	19K07G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19K09G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	19L25G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	19L25G8331
4269071	VASOFIX CERTO G24X19MM YELLOW	19K19G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19L28G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	19L30G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19M14G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	19M15G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	19M18G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19M18G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	19M18G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	19M20G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19M20G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	19M21G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	19M22G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	19M24G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	19N12G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	19N13G8331
4269071	VASOFIX CERTO G24X19MM YELLOW	19N14G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	19N15G8384
4269071	VASOFIX CERTO G24X19MM YELLOW	20A03G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20A04G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	20A04G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20A15G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20A16G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20A16G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	20A17G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20A19G8334
4269071	VASOFIX CERTO G24X19MM YELLOW	20A21G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20B01G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20B01G8332
4269071	VASOFIX CERTO G24X19MM YELLOW	20B02G8383
4269071	VASOFIX CERTO G24X19MM YELLOW	20B04G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20B08G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20B09G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20B11G8346

4269071	VASOFIX CERTO G24X19MM YELLOW	20B12G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20B12G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	20B21G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20B23G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	20C09G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20C09G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	20C19G8332
4269071	VASOFIX CERTO G24X19MM YELLOW	20C24G8331
4269071	VASOFIX CERTO G24X19MM YELLOW	20D19G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	20D20G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20D22G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20A06G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20D23G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20D24G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20D26G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	20E01G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	20E06G8346
4269071	VASOFIX CERTO G24X19MM YELLOW	20E07G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	20E08G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20E12G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	20E12G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20E12G8382
4269071	VASOFIX CERTO G24X19MM YELLOW	20E14G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20F04G8348
4269071	VASOFIX CERTO G24X19MM YELLOW	20F06G8330
4269071	VASOFIX CERTO G24X19MM YELLOW	20F09G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20F12G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20F14G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20F05G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20F09G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20F10G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20F11G8345
4269071	VASOFIX CERTO G24X19MM YELLOW	20F13G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20F15G8347
4269071	VASOFIX CERTO G24X19MM YELLOW	20F17G8381
4269071	VASOFIX CERTO G24X19MM YELLOW	20F19G8345