

Urgent Field Safety Notice

Date:
May 16, 2018

Ref: FSN 2018-05-15 LS/STK

Vasofix Safety (product range)

Field Safety Corrective Action (FSCA):
Advice regarding the use of the device

Product Description	Product Code
VASOFIX SFTY PUR 14G, 2 IN, 2.2X50MM	4269225S-01
VASOFIX SFTY PUR 16G, 2 IN, 1.7X50MM	4269179S-01
VASOFIX SFTY PUR 18G, 1.25 IN, 1.3X33MM	4269330S-01
VASOFIX SFTY PUR 18G, 1.75 IN, 1.3X45MM	4269136S-01
VASOFIX SFTY PUR 20G, 1 IN, 1.1X25MM	4269217S-01
VASOFIX SFTY PUR 20G, 1.25 IN, 1.1X33MM	4269110S-01
VASOFIX SFTY PUR 22G, 1 IN, 0.9X25MM	4269098S-01
VASOFIX SFTY PUR 24G, 0.75 IN, 0.7X19MM	4269071S-01
VASOFIX SAFETY FEP 22G, 1 IN, 0.9X25MM	4268091S-01

To whom it may concern,

B. Braun Medical Ltd has become aware that Vasofix Safety ported cannulas are being used with power injectors in many hospital Radiology Departments. This may, in some cases, result in fluid leakage at the injection port due to the silicon valve being unable to withstand exposure to the high pressures of a power injector.

We take this opportunity to highlight that the Vasofix Safety product group is suitable for use with pressure up to 3 bar. Use of these products with greater pressures is considered off-label use. The Instructions for Use for Vasofix Safety will be updated accordingly.

Please contact B. Braun to discuss suitable alternative products.

Actions to be taken:

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

- Inform all responsible personnel within your facility.
- Complete and sign the enclosed 'Field Safety Notice Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice.

Please maintain awareness of this notice for an appropriate period to ensure awareness of this information.

The Health Products Regulatory Authority (HPRA) has been informed of this Field Safety Corrective Action (FSCA).

If more information is needed, please contact:

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

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,



Robert Egan
Business Unit Manager



Roberta Egan
Regulatory Affairs Manager

May 16, 2018

Field Safety Notice CONFIRMATION FORM**- Vasofix Safety product range**

Please complete this form and fax it back to Fax No. 01-7091889

We hereby confirm that we are aware of the Field Safety Notice from 16th May 2018 concerning the Vasofix Safety product range.

Organisation:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	