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B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

34209 Melsungen
Germany

Your reference:
Our reference: FSCA 2019-04-26 SK/LS

Contact:

Fon: 62130933
Fax: 62130930
Email: bbraun.sg@bbraun.com
Internet: http://www.bbraun.com

[redacted]

To Whom It May Concern

cc Chairman Medical Board and relevant Head of Departments

Date: October 24, 2019

Urgent FIELD SAFETY NOTICE – Introcan® Safety Recall

To whom it may concern,

We would like to inform you that the following product has to be recalled from the market in the course of a Field Safety Corrective Action:

Article No.	Name	Batch
4251601-03	INTROCAN SAFETY PUR 24G, 0.7X19MM-AP	19A30G8315

Introcan® Safety is a peripheral IV catheter. It is a single-use device to generate intravascular and tissue access to sample blood, monitor blood pressure, or administer fluids and blood intravascularly.

Reason for the Recall

In the course of our post-market surveillance activities we received one complaint that revealed contamination of one Introcan® Safety Catheter with blood. The contamination was clearly visible: approximately 0.1 ml of dried blood in the form droplets at the small end of the primary package over an area of several square millimeters on the inner side of the primary package. It is common clinical practice to not use visually contaminated devices, as described in the instructions for use.
Extensive Root Cause Analysis found that the blood was brought into the product during post production period. As contamination during manufacturing can be excluded and as only one complaint was reported, the observation can be limited to the described batch.
The products were sterilized according our specification. However, while no serious injuries to patients, users, or third parties have been reported to date, there may be a remaining theoretical possibility of patient infection under usage of contaminated products.

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Actions to be taken by the customer:
Our records have shown that your institution has received the affected Introcan® Safety product as specified above.

[redacted]

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 products in your organization and other concerned persons are informed about this Field Safety Corrective Action. If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected goods.
- Do not use affected devices anymore.
- Confirm receipt of this information.

If more information is needed, please contact

Loo Bee Keong
General Manager, Sales
[redacted]

Saw Seek Fen
Senior Regulatory Affairs Executive
[redacted]

Kindly accept our apologies for any inconveniences.

Yours sincerely,

[redacted]

Loo Bee Keong
General Manager, Sales

[redacted]

Saw Seek Fen
Senior Regulatory Affairs Executive