B|BRAUN

**B. Braun Avitum AG**

Am Buschberg 1
34212 Melsungen

Contact:

Fon:
Fax:
Email:
Internet:

Date: July xx, 2022

# Urgent Field Safety Notice

## Diacan® Flex 14G 2,2x25mm
## Safety Shield could fail

## R-2023-001

**Absender:**
B. Braun Organisation

**To:**
Users, operators, distributors and patients who were supplied with the following products.

**Affected Medical Device:**

| Article Description | Article Code | Batch |
|---|---|---|
| Diacan® Flex 14G 2,2x25mm | 7021425-01 | 22K19G8371 |

The above-mentioned single-use flexible peripheral vascular access safety catheter is equipped with an incorporated safety shield which is designed to automatically cover the needle tip to provide additional safety against needle stick injury.
Generally any needle has to be immediately discarded into a sharps container after cannulation (see picture).

**Chairman of the Supervisory Board (Deputy):**
Benjamin Kuhnsch

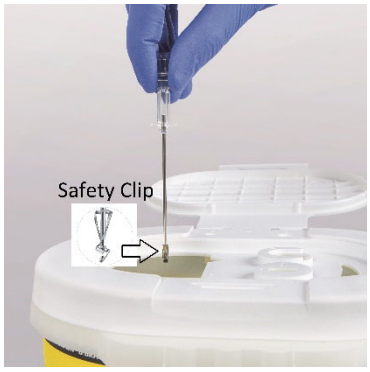
**Executive Board:**
Anna Maria Braun, LL.M.
(Chief Executive Officer)
Michael Becker
Dr. Holger Seeberg

**Corporate Office: Melsungen**
Register Court: Local Court
Fritzlar
HRB 11 263
VAT reg.no. DE210567578
WEEE-reg.-no. DE 95624383

**Address:**
B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

B|BRAUN






**Description of the Problem, Root Cause and Corrective Measures:**

In the course of internal quality control, we became aware that the safety shield of one batch could fail in very rase cases. Therefore it cannot be excluded that the safety mechanism does not correctly cover the needle tip when removing the steel needle after canulation.

No failed safety shield became known from the market.

The potential failure is due to a deviation in the production process. The cause of the deviation was identified and the affected batch could be identified unequivocally.

**Due to this field safety notice, we kindly ask you to take the following measures:**

1) Check whether you have the above-mentioned product in stock, and quarantine it.
2) Confirm the receipt of this Field Safety Notice on the enclosed confirmation form.
3) Additionally record on the enclosed confirmation form the received amount of potentially affected products as well as the amount used and the amount to be returned.
4) Return the completely filled out and signed confirmation form in a timely manner to the fax number or e-mail address given on the form.

At the next delivery the quarantined products will be exchanged according to your information given on the return fax. For returned products you will of course receive a credit note.

**Distribution of Information:**
Please make sure 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 have forwarded the products to a third party, please forward a copy of the Field Safety Notice to them or inform the contact person mentioned below.

Please retain this Field Safety Notice until you have completed all the above measures.

The National Competent Authority has been notified of this Field Safety Corrective Action.

. . .

B|BRAUN



If you have any questions regarding this Field Safety Notice, please contact:

*National contact*

We apologize for the inconvenience caused by this Field Safety Corrective Action and thank you for your understanding and co-operation.

Best regards,

Please fill in your signature, job title, etc. here

B|BRAUN



## Confirmation of Receipt of the Field Safety Notice R-2023-001

**You received the Diacan® Flex catheter listed in the table below.**

**Please fill out this form including the table completely.**

**Please return the form immediately to the following fax number or e-mail address.**

Please enter the fax number and/or e-mail address of the national contact person

The result of the inventory check due to this Urgent Field Safety Notice is as follows:

| Article Description | Article Code | Batch | Amount Received | Amount Used | Amount to be Returned |
|---|---|---|---|---|---|
| Diacan® Flex 14G 2,2x25mm | 7021425-01 | 22K19G8371 | | | |

Herewith, we confirm that we received and noticed the Field Safety Notice from 2023-07-xx concerning the above mentioned medical devices. The Field Safety Notice was distributed and communicated within our organization.

Name: _____

Address: _____

Phone number _____

Date and Signature: _____

**Stamp**: