B|BRAUN

B. Braun Melsungen AG
Division Aesculap
Vascular Systems

Sieversufer 8

Contact: Dr. Christian Sperling

Fon: +49 30 568207-120

Email: vigilance-vs@bbraun.com
Internet: http://www.bbraun.com

Date: November 03, 2023

[Hospital]
[Adress]

Your customer no.: [123456789]

Our reference no.: FSCA-VS-2023-02

Urgent Field Safety Notice

Product recall

Product name	REF no.	LOT no.
Coroflex® ISAR Neo 2.5x19 mm	5028933	23F03809
Coroflex® ISAR Neo 2.75x24 mm	5028941	23F03809

Dear customer,

the medical device Coroflex® ISAR Neo (Drug-eluting coronary stent system) is used from one or both of the batches mentioned above in your hospital.

Based on customer feedback, B. Braun Melsungen AG Vascular Systems has become aware of incorrect labeling of at least one of the products in the batch Coroflex® ISAR Neo 2.5x19 mm (REF 5028933, LOT 23F03809):

A product with the stent size 2.75 x 24 mm was distributed in a product box marked with the size 2.5 x 19 mm. The sterile packaging and the product itself on its adapter are marked with the correct size:

Product box:

Sterile packaging:

The incorrect labeling has so far only been confirmed for a single product. However, it cannot be excluded that other incorrectly labeled products were placed on the market.

Furthermore, it cannot be excluded that there is a label with the size 2.5 x 19 mm on the sterile packaging of a 2.75 x 24 mm product. Therefore, both batches are considered affected.

Risk for the patient

There are no safety concerns for patients who have already been successfully treated with products from these batches.

In the event of product use, due to the difference in stent length, there is a high probability that this will be discovered by the user before implantation:

According to the instructions for use, the stent should be perfectly embedded in the vascular wall and cover the entire length of the lesion. Once the stent is inserted into the vasculature, a 5 mm shorter stent would be expected than is actually contained in the primary packaging. If this difference was detected angiographically, the catheter would be removed and a different stent chosen.

In the unlikely event of accidental implantation of a 2.75 x 24 mm stent into a 2.5 x 19 mm lesion, this would not result in a complication or unexpected results for the following reasons:

- The 0.25 mm discrepancy in balloon/stent diameter would only marginally overdilate the intended lesion by 10%, with no significant clinical impact.
- The 5 mm longer stent length would completely cover the length of the lesion and also cover 2-3 mm of the arterial wall proximal/distal to the intended lesion, which is not expected to have significant clinical impact.

B|BRAUN

Measure by B. Braun Melsungen AG

We have decided to recall both affected batches.

Actions to be taken by the user

1) Please check your inventory for the products named in the subject line and please ensure that none of the named products are in use.
2) Our sales representative will contact you within the next few days to receive the affected products. A replacement delivery will be arranged by our customer service immediately after the return.
3) For your part, please ensure that all users of the above-mentioned products and other persons who need to be informed are informed about this urgent safety information. If you have given the products to third parties, please forward a copy of this information to them.
4) Please confirm receipt of this safety information and the number of affected products in your inventory on the enclosed attachment.

B. Braun Melsungen AG - Vascular Systems has informed the Federal Institute for Drugs and Medical Devices (BfArM) about the distribution of this urgent safety information.

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to call us on +49 30 568207-120 or contact us at vigilance-vs@bbraun.com. Thank you very much in advance for your understanding and support.

B. Braun Melsungen AG
i.A. i.V.

…… ……

[redacted] [redacted]

B|BRAUN

CoE Vascular Systems Berlin

CoE Vascular Systems Berlin

B|BRAUN

Annex 1

Confirmation of the batch recall from November 3rd, 2023 for Coroflex ISAR Neo 2.5x19 mm / 2.75 x 24 mm
Ref. no. FSCA-VS-2023-02

Please return this completed form by email back to the following email address immediately, even if you no longer have any of the listed products:

✉ fsca-vs@bbraun.com

Name: .....

Position: .....

Hospital: .....

Address: .....

Country: .....

☐ We confirm receipt of this information and do not have any affected products in stock.

☐ We confirm receipt of this information. There is still stock of the affected products, which should be picked up from us:

Product name	REF no.	LOT no.	Number
Coroflex® ISAR Neo 2.5x19 mm	5028933	23F03809	
Coroflex® ISAR Neo 2.75x24 mm	5028941	23F03809	

If you return products affected by the recall to us yourself, please enclose this form with the return and use the following address:

B. Braun Melsungen AG; Vascular Systems; Sieversufer 8; 12359 Berlin Germany

. . .

B|BRAUN

.....	.....
Date	Signature