B BRAUN

B. Braun Melsungen AG
Division Aesculap
Vascular Systems

[redacted]

[Hospital]
[Adress]

Date: February 17, 2020

Your reference no.: [123456789]

Urgent Field Safety Notice

Product recall

Product name	Article no.	Batch
Coroflex® ISAR Neo 2.25 x 24 mm	5028939	19H08809

Dear customer,

in your hospital the medical device Coroflex® ISAR Neo is used and devices of batch 19H08809 with the size 2.25 x 24 mm (article number REF 5028939) were delivered to your institution.

B. Braun Melsungen AG Vascular Systems has been noticed by a customer about a labeling mistake affecting at least one product of this batch: A stent catheter with the size 3.0 x 24 mm has been found in a box labeled with the size 2.25 x 24 mm. The product was labeled with the correct size on its hub but the outer box was labeled with the wrong size. Only the mentioned batch is affected and the failure has been confirmed for only one product. However, at the moment it cannot be excluded that further products may also be affected. Until now we are not aware of any further customer complaints.

Applying the required care during preparation of a stent catheter for implantation, it can be assumed that the inconsistency in the size information between the product and the packaging will be noticed before use. However, in order to further minimize the potential risk of a vessel damage to the patient, we voluntarily decided to initiate a recall for all potentially affected products.

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

We kindly ask you to check your stocks regarding the affected products and to prepare the goods concerned for handover to our sales representative. They 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 return.

[redacted]

B BRAUN

Please make sure that all users of above mentioned products as well as other persons who have to be informed receive knowledge of this field safety notice. In case that such products have been forwarded to third parties please forward a copy of this information accordingly.

Please confirm receipt of this safety information and the number of affected products in your inventory on the attached form.

B. Braun Melsungen AG has informed the responsible competent authority Bundesinstitut für Arzneimittel und Medizinprodukte about the release of the field safety notice in written form.

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

B|BRAUN

Annex 1

Confirmation regarding the batch recall for Coroflex ISAR Neo 2.25 x 24 mm from February 17, 2020

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:

✉ vigilance-vs@bbraun.com

☐ 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	Article no.	Batch no.	Number
Coroflex ISAR Neo 2.25 x 24 mm	5028939	19H08809	

If you independently send back the products affected by the recall, please enclose this form with the return.

Name: .....

Position: .....

Hospital: .....

Adress: .....

Contry: .....

....

Date Signature