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B. Braun Melsungen AG
Division Aesculap
Vascular Systems

Sieversufer 8

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Date: November 03, 2023

[Hospital]
[Address]

Your customer no.: [123456789]

Our reference no.: FSCA-VS-2023-04

Urgent Field Safety Notice

Product recall

Product name	REF no.	LOT no.
SeQuent® Neo 2.0 x 10 mm	5021713D	22F29844
SeQuent® Neo 2.5 x 20 mm	5021735D	22F30844

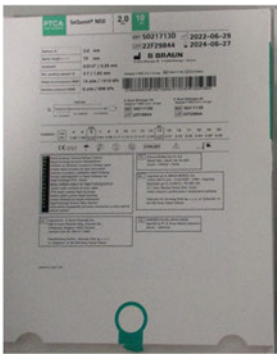
Dear customer,

the medical device **SeQuent® Neo** (Rapid Exchange Coronary Balloon Catheter) 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 from the batch SeQuent® Neo 2.0 x 10 mm (REF 5021713D, LOT 22F29844:

A product measuring 2.5 x 20 mm was in a product box marked 2.0 x 10 mm. The sterile packaging and the product itself on its adapter are marked with the correct size:

Product box: Sterile packaging (peel bag):



The incorrect labeling has so far been confirmed for one 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 2.0 x 10 mm on the sterile packaging of a 2.5 x 20 mm product. Therefore, both batches are considered affected.

Risk to patients

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

In the unlikely event of accidental product use, the likelihood of possible serious harm to the patient from the balloon size discrepancy is considered minimal:

- In the event of device use, due to the significant difference in balloon length (50% or 200% of expected device length), there is a high probability that this will be detected by the user during mandatory angiographic imaging prior to balloon dilatation.
- In the very unlikely event of accidental balloon dilatation, there is a potential clinical risk when using a larger and longer (2.5 x 20 mm) balloon. In this case, inflation of a 2.5 mm balloon in a 2.0 mm vessel would result in a moderate overdistension of the vessel of approximately 0.5 mm or 25%, which is within the error range of visual angiographic determination of vessel diameter. The potential risk of such overextension would be high-grade dissection or acute vascular occlusion (both known procedural risks). The treatment of choice in such a case would be implantation of a stent, which is the standard treatment for coronary lesions after balloon angioplasty in >90% of cases.
    - The difference in length would have no acute clinical impact and could potentially require implantation of a longer stent at the end of the procedure.
    - Accidental use of a smaller and shorter balloon does not pose a significant clinical risk.

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- Overall, the consequence and risk would be a slight prolongation of the procedure and possibly the implantation of a longer stent.

In the known case, the discrepancy in the size information led to the product not being used and to being exchanged for a new product. The product exchange takes a few minutes and can therefore be seen as a slight extension of the procedure.

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.

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Dr. Christian Sperling
PRRC-Vigilance
CoE Vascular Systems Berlin

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[redacted]
Head of Quality Management
CoE Vascular Systems Berlin

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Annex 1

Confirmation of the batch recall from November 3rd, 2023 for SeQuent Neo 2.0 x 10 mm / 2.5 x 20 mm

Ref. no. FSCA-VS-2023-04

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
SeQuent® Neo 2.0 x 10 mm	5021713D	22F29844	
SeQuent® Neo 2.5 x 20 mm	5021735D	22F30844	

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

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Date	Signature