**B. Braun Medical Ltd.**
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Date:
April 29, 2024

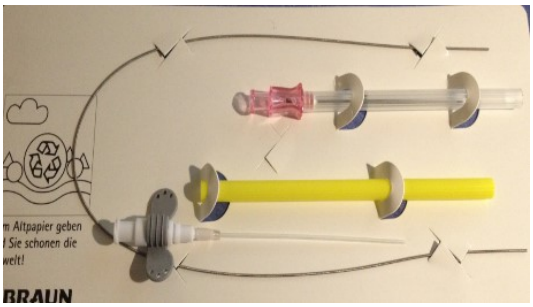
Ref: FSCA-VS-2024-01

## Urgent Field Safety Notice

## Product recall

Our reference no.: FSCA-VS-2024-01

| Product name | REF no. | LOT no. |
|---|---|---|
| **ARTERIOFIX 20G X 80MM** | **5206324** | 23B2184401<br>23B2784402<br>23D07844<br>23G18844 |

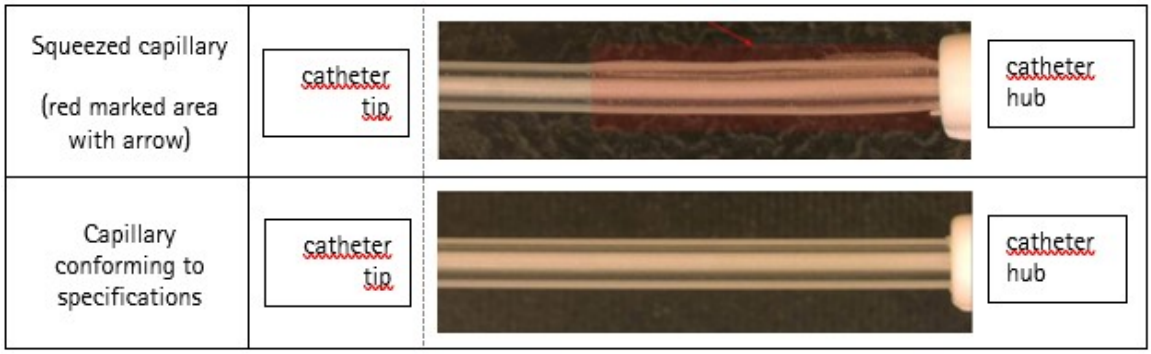



Dear Sir/Madam,

The medical device Arteriofix® arterial catheter has been supplied to your facility from the Lot numbers mentioned above.

Based on two customer reports, B. Braun Melsungen AG Vascular Systems has become aware of leaks in products from the mentioned Lots. In both cases, this resulted in minor blood loss in the affected patients, which was discovered promptly and could be remedied quickly and without further consequences by replacing the product.

Our investigations showed that during production, the capillary was occasionally squeezed at the transition to the adapter. When the catheter is in place, this area is outside the patient. During use, leaks can therefore occur in the area of these squeezes. The squeezes were confirmed for two supplier batches that were used to manufacture the Arteriofix lots mentioned in the subject line.




Other affected lots were excluded as part of the root cause analysis by testing stock items.

To prevent this error from recurring, the manufacturing processes of all component manufacturers involved are currently being checked for possible corrective measures. Furthermore, all Arteriofix catheters have been subjected to an additional leak test since February 2024. This error pattern can therefore be ruled out for all products manufactured since then. This can also be confirmed by the fact that no further customer complaints have been observed.

**Risk for the patient**

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

As observed in both customer complaints, a leak in the affected product area can lead to a minor loss of blood. Arteriofix arterial catheters are used as arterial access for invasive blood pressure measurement systems, for example. In this case, patients are continuously monitored, so that a minor loss of blood is noticed promptly and can be remedied by replacing the product. Therefore, no significant blood loss possibly affecting the patient's health is to be expected.

However, it cannot be completely ruled out that the leak could impair the transmitted pressure signal in the connected blood pressure measurement systems. Incorrect pressure values can lead to an incorrect diagnosis and, accordingly, incorrectly derived treatment for the patient. The potential risk for patients in such cases would therefore be assessed as serious.

In addition, air can enter the tube system if there are leaks during the necessary flushing of the blood pressure measurement system. Air bubbles in the line system must generally be removed by the trained user and must not get into the patient. If this is not implemented, the potential risk for patients in the event of air bubble application (e.g. air embolism) is considered to be serious.

We currently assume that the majority of the affected products have already been used without complications.

**Measure by B. Braun Melsungen AG**

We have decided to recall any remaining stocks of the affected lots that customers may still have.

**Actions to be taken by the user**

1) Please check your inventory for the product/lots named in the subject line and please ensure that none of the named product/lots are in use.

2) Please quarantine and return any affected product/lots.

3) Please ensure that all users of the above mentioned product/lots 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 by completing and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

*Please return the completed form by **Friday 3rd May 2024**, or sooner if possible.*
A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority has been informed of this action.

If more information is needed please contact:

Patrick Hartnett
Aesculap Business Lead
B. Braun Medical Ltd
Email: patrick.hartnett@bbraun.com

We apologise for any inconvenience this may cause you and thank you very much in advance for your understanding and support.

Yours sincerely,

hartpaie
Digitally signed by hartpaie
Date: 2024.04.29 16:24:48 +01'00'

**Patrick Hartnett**
**Aesculap Business Lead**

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**Roberta Egan**
**Regulatory Affairs Manager**