B. Braun Melsungen AG
Division Aesculap
Vascular Systems

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B. Braun Organization / Distributor

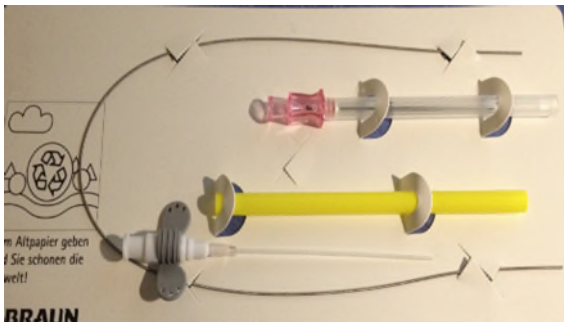
Date: April 24, 2024

Letter to B. Braun Organizations / Distributors

regarding an Urgent Field Safety Notice - Product recall

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

Product name	REF no.	LOT no.
ARTERIOFIX KIT GÖRLITZ	**5019475**	23G10844
RADIALIS ARTERIOFIX KIT GENER.HOSP.HAGEN	**5200015**	23G18844, 23G22844
ARTERIOFIX 20G X 80MM	**5206324**	23B2184401, 23B27844, 23B2784401, 23B2784402, 23C02844, 23C0484401, 23C04844, 23C0784402, 23C07844, 23C0784401, 23C08844, 23C0884401, 23C0884402, 23C1784401, 23C17844, 23C18844, 23C2084401, 23C1784402, 23C22844, 23C2284404, 23C2284402, 23C2284403, 23C24844, 23C2484401, 23C2484402, 23C2784401, 23C25844, 23C2584402, 23C2584401, 23D04844, 23D07844, 23G27844, 23G28844, 23G31844, 23G0584401, 23G1284402, 23G12844, 23G1284401, 23G13844, 23G14844, 23G1384401, 23G18844, 23G1784401, 23G17844, 23G1984401, 23G1984402, 23H0584401, 23H04844, 23H05844, 23H09844, 23H11844, 23H14844, 23H2284401, 23H22844



Dear B. Braun Organization / Distributor,

We would like to inform you about an urgent Product Recall for Arteriofix arterial catheters issued by B. Braun Melsungen AG - Vascular Systems because of leakage at the capillary.

One or more of the affected batches listed on page 1 of this letter have been distributed to you. A detailed overview of the affected batches distributed to your organization is provided with this email.

We therefore kindly ask you to perform the following actions:

1) Please identify all customers in your country who received affected products.
2) Please finalize the attached Field Safety Notice (Annex 1, provided additionally as MS Word file in English language) with your local contact information and signature.
3) Please inform the identified customers with the Field Safety Notice.
4) Please make sure that the receipt of the Field Safety Notice is confirmed by each customer. An exemplary form is attached as Annex 2.
5) Please report this Field Safety Corrective Action to your local authority, if required. You will find a reporting template (used in European Union) attached to this email. Please add the name of your authority in section 1 and your local contact details in section 5.
6) Please confirm receipt of this Field safety notice **until Mai 1, 2024**.
7) Please send an update about the progress of customer information until **June 30, 2024.**

Please send confirmations / updates to the following email addresses:

vigilance-vs@bbraun.com

fsca_vs@bbraun.com

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.

Dr. Christian Sperling
PRRC-Vigilance
CoE Vascular Systems Berlin

Dr. Susanne Vogelbein
Head of Quality Management
CoE Vascular Systems Berlin

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Annex 1

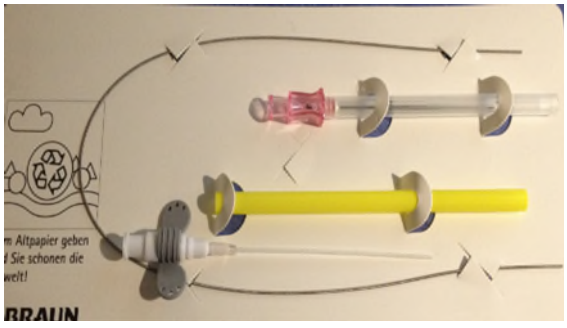
[Add: *Customer address*]

[Add: *B. Braun Country Organization or Distributor*]

Urgent Field Safety Notice

Product recall

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

Product name	REF no.	LOT no.
ARTERIOFIX KIT GÖRLITZ	**5019475**	23G10844
RADIALIS ARTERIOFIX KIT GENER.HOSP.HAGEN	**5200015**	23G18844, 23G22844
ARTERIOFIX 20G X 80MM	**5206324**	23B2184401, 23B27844, 23B2784401, 23B2784402, 23C02844, 23C0484401, 23C04844, 23C0784402, 23C07844, 23C0784401, 23C08844, 23C0884401, 23C0884402, 23C1784401, 23C17844, 23C18844, 23C2084401, 23C1784402, 23C22844, 23C2284404, 23C2284402, 23C2284403, 23C24844, 23C2484401, 23C2484402, 23C2784401, 23C25844, 23C2584402, 23C2584401, 23D04844, 23D07844, 23G27844, 23G28844, 23G31844, 23G0584401, 23G1284402, 23G12844, 23G1284401, 23G13844, 23G14844, 23G1384401, 23G18844, 23G1784401, 23G17844, 23G1984401, 23G1984402, 23H0584401, 23H04844, 23H05844, 23H09844, 23H11844, 23H14844, 23H2284401, 23H22844
		

Dear customer,

the medical device Arteriofix® arterial catheter is used in your hospital from at least one of the batches or LOT numbers mentioned above.

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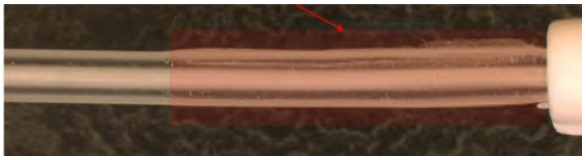
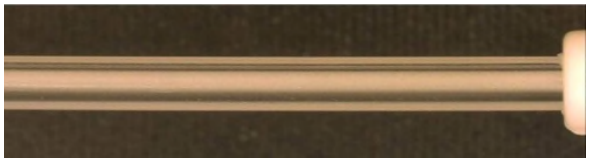
Based on two customer reports, B. Braun Melsungen AG Vascular Systems has become aware of leaks in products from the batches mentioned above. In both cases, this resulted in minor blood loss in the affected patients, which was discovered promptly and could be remedied quickly and without further consequences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

Squeezed capillary (red marked area with arrow)	catheter tip  catheter hub
Capillary conforming to specifications	catheter tip  catheter hub

Other affected batches 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 batches.

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 batches that customers may still have.

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 or credit note will be arranged by our customer service immediately after the return.

3) Alternatively, you can destroy affected products in your hospital and confirm this on the enclosed attachment. A replacement delivery or credit note will be arranged by our customer service immediately after the receipt of the confirmation.

4) 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.

5) Please confirm receipt of this safety information and the number of affected products in your inventory on the enclosed attachment.

[Add: *Local B. Braun Organization / Distributor*] has informed the [Add: *local authority*] 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 [Add: *telephone number*] or contact us at [Add: *email address*]. Thank you very much in advance for your understanding and support.

Signed by
[Local B. Braun Organization / Distributor]

Annex 2

Confirmation of the batch recall from April 24, 2024 for Arteriofix
Ref. no. FSCA-VS-2024-01

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:

✉ **[Add: *local email address*]**

Name: ..... Position: .....

Hospital: .....

Address: ..... Country: .....

☐ We confirm receipt of this information:

☐ We do not have any affected products in stock.

☐ We still have stock of the affected products, which should be picked up from us, see overview below.

☐ There is still stock of the affected products, which we have destroyed within our clinic, see overview below.

Product name	REF no.	LOT no.	Number
ARTERIOFIX KIT GÖRLITZ	5019475		
RADIALIS ARTERIOFIX KIT GENER.HOSP.HAGEN	5200015		
ARTERIOFIX 20G X 80MM	5206324		

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

....
Date Signature