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B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

34209 Melsungen

Our Reference FSCA-2022-05-13

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URGENT Field Safety Corrective Action – Discofix® C Manifolds

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the below batches of Discofix® C Manifolds in the course of a Field Safety Corrective action from the market:

Article Number	Article Name	Batch
16611C	DISCOFIX C HAHNBANK-3 BUNT 180CM/DISC	22B10D9046
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22B11D9042
16615C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22B11D9044
16605C	DISCOFIX C MANIFOLD 3 BLUE	22B16D9043
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22B17D9042
16610C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22B17D9043
16608C	DISCOFIX C MANIFOLD 5 (MULTI)	22B19D9048
16617C	DISCOFIX-C MANIFOLD5 MULTICOLOR BULK RAD	22B23D1040
16620C	DISCOFIX C MANIFOLD-3 MULTICOLOR PROSET	22C03D1041
16615C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22C03D9046
16610C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22C06D9047
16605C	DISCOFIX C MANIFOLD 3 BLUE	22C12D9042
16616C	DISCOFIX-C MANIFOLD-5 BLUE BULK RAD	22C16D1041
16610C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22C18D9044
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22C19D9041
16615C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22C22D9047
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22C23D9040
16605C	DISCOFIX C MANIFOLD 3 BLUE	22C23D9041
78803	DISC C MANIFOLD PN 3 BLUE	22C24D1040

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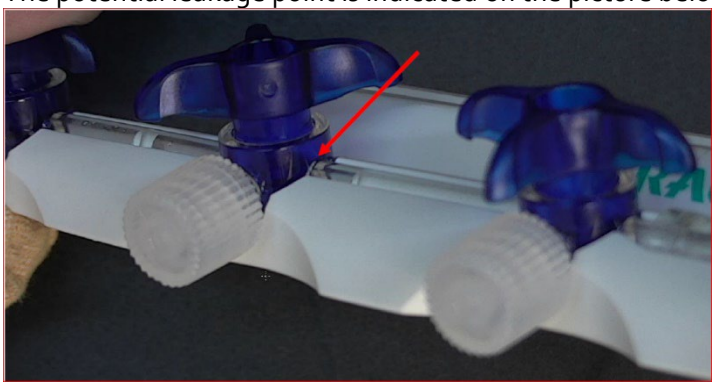
Article Number	Article Name	Batch
16615C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22C31D9050
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22D07D9049
16610C	DISCOFIX C MANIFOLD 3 BLUE, 150CM TUBE	22D12D9040
16600C	DISCOFIX C MANIFOLD 3 BYR-COLORED	22D15D9043
16611C	DISCOFIX C-3 MANIF.COLORED 180CM+STOPC.	22D22D9048

Reason for the Recall
In course of our internal quality controls we identified, that due a timely restricted deviation in the production process, leakages at the manifold might be observed for a small proportion of devices.

The potential leakage point is indicated on the picture below:



While no serious injuries to patients, users, or third parties have been reported to date, the deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.

In view of the identified risks, we decided to proactively recall all affected devices from the market.

Based on additional internal controls the effect can limited to the above mentioned batches. No other batches or products are affected.

Actions to be taken
Our records have shown that your institution has received affected Discofix® C Manifolds.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customer.
- Identify, quarantine and return affected articles.
- Do not use affected devices anymore.
- A follow-up of patients already treated with the devices is not required.

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- It is recommended to exchange devices from the above mentioned batches, which are currently in use.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

If more information is needed or you require devices for replacement, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,