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Date: July 8, 2021

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Urgent Safety Information

Regarding the correct use of

Combitrans® Monitoring kits with Hämofix® reservoir for closed blood sampling

Article numbers 5200181, 5200182, 5200183, 5200184, 5201428, 5201432, 5201819, 5204781,
5208388, 5210349, 5213505, 5213516, 5213527, 5218347, 5218655, 5219655, 5319553,
5770063, 5770064, 5770543, 5770544, 5770546

To whom it may concern;

You use the medical devices listed above and in Appendix 1 in your hospital.

Based on representative market observations and the Covid19 pandemic situation of the last few months, we would like to bring to the attention of our customers that the instructions for use provided with the aforementioned products must be carefully respected. In particular, the following handling information must be taken into account:

- Always ensure that the filled **tubing system is free of air bubbles**.
- **Slowly unlock the green reservoir cap** to start blood sampling procedure: For blood sampling the green reservoir cap has to first be slowly turned counter-clockwise by approx. 15 ° and thereby unlocked.
- **Avoid active aspiration:** The reservoir aspirates automatically after unlocking. Active aspiration with the reservoir (pulling on the green cap) can lead to outgassing of blood or the

ingress of air. In this case, the blood should not be returned to the patient, but must be discarded.

If these instructions are not followed correctly an accumulation of an increased amount of air in the tubing system and in the reservoir can't be excluded.

No abnormalities were observed during the precautionary testing of our products. All products on the market meet the specifications and can still be used in accordance with the instructions for use.

Possible risk for patients

Air bubbles in the tubing system may negatively affect the blood pressure signal transmission of the monitoring kit.

If large amounts of air enter a patient's arterial bloodstream unnoticed, this could lead to distal circulatory disorders in the affected limb. The increased amount of air provoked by incorrect handling of the product would most likely trigger reversible and very circumscribed circulatory disorders only.

This safety information is provided as a precautionary measure to minimize the risk of incorrect pressure measurements and clinically relevant complications due to incorrect use.

Required measures

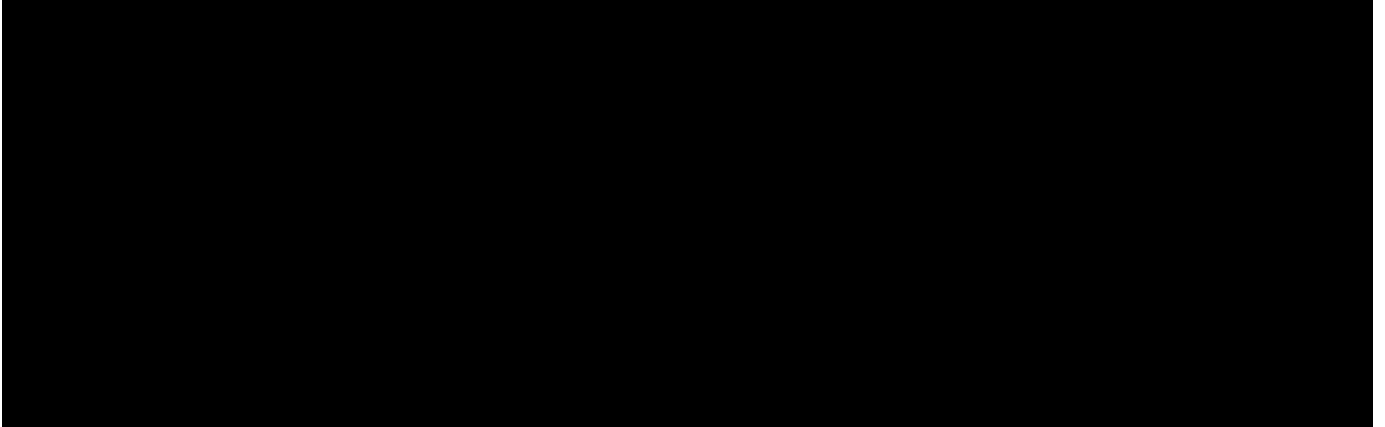
- 1) Please carefully follow the instructions for use, specifically the handling information for the HämoFix reservoir for closed blood sampling (REF no. 8914823, 02/99).
- 2) If you require further information on correct product handling or training, please contact your B. Braun sales representative. They will provide you with the information you require.
- 3) Please ensure that all users of the above-mentioned products and other persons to be informed will be informed of 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 the receipt of this Field Safety Notice on the enclosed form (Appendix 2) until July 15, 2021.

B. Braun Melsungen AG has informed the National Competent Authority about the distribution of this urgent safety information.

We thank you for your support!

If you have any questions please contact Dr. Christian Sperling, Safety Officer CoE Vascular Systems, Phone: +49 30 568207-120, E-Mail: vigilance-vs@bbraun.com, or your responsible marketing contact at B. Braun Vascular Systems.

B. Braun Melsungen AG



Vascular Systems

Appendix 1

Product name	Article no.
HAEMOFIX-MONITORING-SET 2-FACH, BEH	5200181
HAEMOFIX-MONITORING-SET ARTERIELL, BEH	5200182
HAEMOFIX-MONITORING-SET ART/VEN BEH	5200183
HAEMOFIX EXADYN SET LANGE LEITUNGEN	5200184
CMS HÄMOFIX BEH 2-FACH PLUS	5201428
ADD-ON-SET HÄMOFIX BLAU	5201432
HAEMOFIX EXADYN SET (1 ENTNAHMEPORTS)	5201819
HAEMOFIX SET TICINO	5204781
HAEMOFIX-COMBITRANS-SET 2-FACH	5208388
COMBITRANS HAEMOFIX EXADYN MIT BEH	5210349
HAEMOFIX-COMBITRANS MONITORING-SET ARTER	5213505
HAEMOFIX-EXADYN MONITORING-SET ART. + VE	5213516
HAEMOFIX-COMBITRANS MONITORING-SET 2-FAC	5213527
COMBITRANS SET PS MAGDEBURG	5218347
HAEMOFIX-EXADYN-SET ST. GALLEN	5218655
COMBITRANS-HÄMOFIX-SET MEPPEN	5219655
COMBITRANS EC HÄMOFIX SET HKZ ROTENBURG	5319553
COMBITRANS ART / VEN HF BEH	5770063
COMBITRANS ART HF BEH	5770064
COMBITRANS 2 GBE HZL	5770543
COMBITRANS 1 GBE ROT HZL	5770544
COMBITRANS 2 PLUS GBE HZL	5770546

Appendix 2

Confirmation of the receipt of the Field Safety Notice for Combi- trans® Monitoring kits with Hämofix reservoir for closed blood sam- pling from 08.07.2021

REF no. CC 400500713

Please return the completed form to the email address below until 22.07.2021.

✉ vigilance-vs@bbraun.com

☐ We confirm the receipt and the consideration of the information provided in the Field Safety Notice.

Name:

Position:

Hospital:

Street:

Postal code, City

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Date

.....
Signature