

Urgent Field Safety Notice
Combitrans® / Combidyn® Monitoring Sets
Changes to the instructions for use

Dear Sir/Madam,

You use one or more of the medical devices listed in Appendix 1 in your hospital.

Combitrans® / Combidyn® Monitoring Sets are invasive, disposable monitoring systems for measuring physiological blood pressure and blood sampling. They are supplied sterile and for single patient use.

As users already know, prolonged contact with organic solvents (spray disinfectants) can promote the formation of stress cracks in plastic tubing connectors and multidirectional stopcocks.

A corresponding warning (see Appendix 2) has already been introduced in the IFU of the Discifix multidirectional stopcocks integrated in the affected sets. However, it is not yet distributed with the sets as we were only recently informed about it by the manufacturer. We would therefore like to inform you that in the future the affected Combitrans® / Combidyn® monitoring sets will include also a separate warning notice for the Discifix multidirectional stopcocks.

Risk for the patient

In extremely rare cases, stress cracks can lead to fluid leakage and the risk of an associated change in pressure signal transmission. Furthermore, air entry with the risk of an air embolism cannot be ruled out.

The risks mentioned in connection with leaky connections are generally known and are already listed in the current instructions for use:

"Risks: Potential complications include infection, embolism caused by air bubbles or blood clots, over-infusion or leakage. A leaking connection will allow air to enter the system and produce incorrect low pressure readings. (...) Furthermore, air bubbles may have a negative effect on the pressure reading. Air bubbles should carefully be removed from the flush reservoir and tubing to prevent any air bubbles from entering the transducer."

Measure by B. Braun Melsungen AG

In order to further reduce the actual occurrence of these risks, the instructions for use will contain a corresponding additional note in the future:

"Multidirectional stopcocks and tubing connections may tend to crack formation when influenced with alcohol-based disinfectants. These cracks can result in leaks or air ingress. We recommend inspecting the entire infusion line for these hazards."

Due to a requirement from the manufacturer of the Discifix multidirectional stopcock, the products listed in Appendix 1 will contain an additional separate warning (see Appendix 2).

Recommended measures until the new instructions for use are available

- 1) If components of the Combitrans® / Combidyn® monitoring system are being disinfected in your hospital, please pay attention to the formation of stress cracks in tubing connections and multidirectional stopcocks during further use.
- 2) If you notice stress cracks and/or fluid leakage, please change the entire monitoring system.
- 3) If you require further information on correct product use or training, please contact your responsible B. Braun sales representative. They will contact you and provide you with the information you require.
- 4) Please ensure that all users of the above-mentioned products and other persons to be informed are informed of this urgent safety information. If you have given the products to third parties, please forward a copy of this information to them.
- 5) If you are a distributor, please forward this urgent safety information to your customers.
- 6) Please note the warning notice for the Discifix® multidirectional stopcock (Appendix 2).
- 7) Please confirm receipt of the Field Safety Notice 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 **Thursday 30th November 2023**, or sooner if possible.*

The Health Products Regulatory Authority (HPRA) has been informed about the distribution of this Field Safety Notice.

If you have any questions, please contact:

Patrick Hartnett, Aesculap Business Lead – Tel: 087 4186850; Email: patrick.hartnett@bbraun.com

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

Yours sincerely,

Susan O'Connor
Head of Hospital
B. Braun Medical Ltd.

Roberta Egan
Regulatory Affairs Manager
B. Braun Medical Ltd.

Appendix 1

| REF No. | Product Name |
|----------------|--|
| 5209127 | SPECIAL ARTERIAL MONITORING KIT |
| 5209135 | SPECIAL CVP MONITORING KIT |
| 5311630 | DOUBLE CMS EC Set (ART/CVP/ADD-ON) |
| 5311631 | SINGLE CMS EC SET |
| 5311632 | ADD-ON CMS-EC SET |
| 5311633 | TRIPLE CMS-EC SET (ART/CVP/LAP/ADD-ON) |

Appendix 2**Discofix Warning Notice**

See separately attached document "15328312_Discofix_A3_IFU_0520"