B|BRAUN

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

34209 Melsungen

Our reference: FSCA-2024-09-27

Contact: Dr. Stephan Krause

Fon: +49 5661 71-1339
Email: stephan.krause@bbraun.com
Internet: http://www.bbraun.com

Date: Sep 27, 2024

URGENT Field Safety Corrective Action
Nutrifix Bag – Infusomat Space Line ENFit

Dear Valued Customer,

The B. Braun Melsungen AG has decided to proactively provide additional information on the use of the below defined article/batch combinations of Nutrifix Bag and Infusomat Space Line ENFit in the context of a Field Safety Notice.

Article Number	Article Name	Batch Number
9240677	NUTRIFIX 1000 ML-HF	See Appendix 1
9240678	NUTRIFIX 1000 ML SAFETY	See Appendix 1
9240679	NUTRIFIX ENFIT SET 1000ML - TRANSITION	See Appendix 1
9240680	NUTRIFIX SET 1000 ML ENFIT	See Appendix 1
8721734	ENTEROPORT PLUS SET 1000	See Appendix 1
8721736	ENTEROPORT PLUS ENFIT SET 1000ML-TRANSIT	See Appendix 1
8721737	ENTEROPORT PLUS SET 1000 ENFIT	See Appendix 1
9240685	NUTRIFIX 2500 ML-HF	See Appendix 1
9240800	ENTEROFIX 1000 ML SAFETY	See Appendix 1
8721726	ENTEROPORT PLUS SET 500	See Appendix 1
8721742	ENTEROPORT PLUS SET 2500	See Appendix 1
8250830SP	INF.SP.LINE,EN 1L NUT.BAG,ENFIT CON230CM	See Appendix 1
8250831SP	INF.SP.LINE,EN 1L NUT.BAG,ENFIT 260CM TS	See Appendix 1

8250839SP	INF.SP.LINE,1000ML NUTRIFIX,PVC,LL,230CM	See Appendix 1
8700380	INF. PLUS LINE ENTERAL W.1000ML NUTR.BAG	See Appendix 1

Reason for the FSCA
Biocompatibility tests revealed a potential release of phthalate-containing plasticizers used in the PVC bag of the affected devices during intended use scenarios.

Potential Risks to Health
Whilst the phthalate containing plasticizers and their derivatives are of an overall low concern in the exposed adult patient population, a borderline situation may be anticipated in pediatric patients. The concern for pediatric patients refers to the potential reproductive and endocrine disruptor activity.

Nature of the FSCA
This FSCA is a Field Safety Notice informing the customers that paediatric patients should not be treated with the affected products anymore. Affected devices are not withdrawn from the market.

Actions to be taken
Our records have shown that your institution has received one or more of the affected article batch combinations.

We kindly ask you to initiate the following activities 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 notification to your customers.
- Affected products should be used only in adult patients.
- Pediatric patients should not be treated with affected articles.
- It is not necessary to exchange devices from the above mentioned batches, which are currently used in pediatric patients.
- 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, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

B|BRAUN

Patient and user satisfaction is our highest priority. We are sorry for any inconvenience. Thank you in advance for your cooperation to resolve this matter quickly.