



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

Your reference:

Our reference:

Contact:

TO WHOM IT MAY CONCERN

[REDACTED]
[REDACTED]
[REDACTED]

Internet:

[REDACTED]
[REDACTED]
[REDACTED]

<http://www.bbraun.de>

Date:

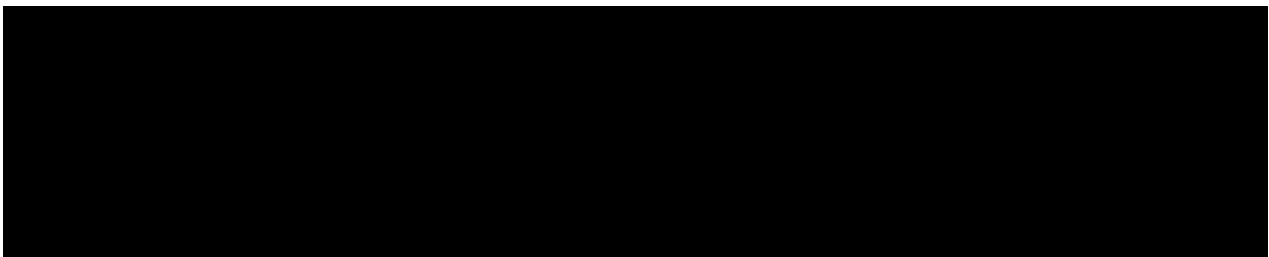
July 06, 2020

Urgent FIELD SAFETY NOTICE

ECOBAG Irrigation solution

To whom it may concern,

B. Braun Melsungen AG has decided to communicate an advisory notice in the context of an urgent FIELD SAFETY NOTICE for the following products:



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Article Number	Article Name	Batch
FREU812	AQUA B. BRAUN EBC 1000 ML EU	201727641N
FREU850	NACL 09 % B. BRAUN EBC 2000 ML EU	201217672
FREU910	NACL 09 % B. BRAUN EBC 3000 ML EU	201067672
		201077671
		201077672
		201117671
		201117672
		201627671N
		201657671N
		201737671N
		201757671N
		201847671N
FREU924	RINGER B. BRAUN EBC 3000 ml EU	201127671
FREU950	NACL 09 % B. BRAUN EBC 5000 ML EU	201127672
		201137671
		201237671
		201767671N
FREU964	RINGER B. BRAUN EBC 5000 ML EU	201917671N

Reason for the Field Safety Notice

In the course of our quality surveillance activities we observed that the wall thickness of the breakable cap of the round port (please see picture below) may be irregular at the break line and may exhibit holes with a diameter of up to 300 µm outside of the membrane. Complaints from the market or patient injuries are not known to us. The described failure is limited to the above mentioned product / batch combinations. No other products or batches are affected by this Field Safety Notice.

Depending on storage time and storage conditions potential microbial contamination of the membrane of the port cannot be excluded. We therefore advise the following actions:

Actions to be taken

Our records have shown that your hospital has received one or more of the above listed affected articles.

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 products 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 customers.
- Identify affected devices and inform the responsible personnel/user staff in the affected facilities .
- When using the irrigation solution, please always disinfect the port membranes after breaking off the breakable cap.
- For disinfection the hospital's standard protocol shall be used.
- After disinfection, the Irrigation solution can be safely used.
- 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

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Local contact 1

Name

Title

Email

telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,

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ECOBAG with breakable ports.

The red labelled port is potentially affected by irregular wall thickness and holes outside of the membrane.

