



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

Your reference:
Our reference: RECALL 2019-02-19 STK/AS

Contact:

TO WHOM IT MAY CONCERN

Fon: **Phone number**
Fax: **Fax number**
Email: **E-Mail address**
Internet: <http://www.bbraun.de>

Date: February 19, 2019

Urgent FIELD SAFETY NOTICE – Intrapur Neonat (0.2µm)

To whom it may concern,

we, the B. Braun Melsungen AG have decided to recall the following product in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4099451	INTRAPUR NEONAT I.V.FILTER 0.2MICRON	18N14F0000

Reason for the Recall

In the course of internal quality test we discovered that in some instances the femal Luer Connector of INTRAPUR NEONAT I.V.FILTER 0.2MICRON (Art. No. 4099451) was not tight due to an injection molding issue. The effect is limited to one batch (18N14F0000). No other batches or products are affected. No harm or any other adverse patient outcome, which could be associated to the above described observation, has been reported to the B. Braun Melsungen AG.

Actions to be taken by the customer:

Our records have shown that your institution has received the affected batch of INTRAPUR NEONAT I.V.FILTER 0.2MICRON as specified in the table above.

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 Corrective Action. If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Confirm receipt of this information.

If more information is needed, please contact

Local contact 1
Name

Local contact 2

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Heinz-Walter Große
(Chairman)
Dr. Annette Beller
Anna Maria Braun, LL.M.

Dr. Meinrad Lugin
Caroll H. Neubauer, LL.M.
Dr. Joachim Schulz
Markus Strotmann

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB II 000
WEEE-Reg.-No. DE 42690900

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Carl-Braun-Straße 1
34212 Melsungen
Germany



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Title
Email
telephone

Kindly accept our apologies for any inconveniences.

Yours sincerely,