

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

Your reference:

Our reference:

Contact:

Fon:

Fax:

Email:

Internet:

<http://www.bbraun.de>

Date:

August 12, 2020

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE

GASTRIC TUBE – DEHP content

To whom it may concern,

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

| Article Number | Article Name | Batch |
|----------------|----------------------------|--------------------------------------|
| 4396049 | GASTRIC TUBE L CH4.5, 38CM | ALL that are still within shelf life |
| 4396057 | GASTRIC TUBE L CH4.5, 50CM | |
| 4396154 | GASTRIC TUBE L CH6, 50CM | |
| 4396251 | GASTRIC TUBE L CH9, 50CM | |
| 4396308 | GASTRIC TUBE L CH9, 100CM | |
| 4396359 | GASTRIC TUBE L CH12, 50CM | |
| 4396405 | GASTRIC TUBE L CH12, 100CM | |

Gastric tubes are feeding tubes to be used for nasogastric feeding application (Enteral Nutrition Therapy) and are meant to convey enteral nutrition or medications to the stomach or duodenum.

Enteral feeding applications with feeding tubes concern mainly undernourished, critically and/or chronically ill patients.

Reason for the Field Safety Notice

It has been identified that the use of the above mentioned medical devices in certain patient groups might exceed the tolerable daily intake for DEHP according to European Union Risk Assessment Report¹ on bis (2-ethylhexyl) phthalate (DEHP).

DEHP is labelled according to regulation (EC) No 1272/2008 as toxic to reproduction category 1B (H360FD: May damage fertility. May damage the unborn child)

Given the current state of scientific knowledge, the risk especially for premature male babies cannot be completely excluded. Those considerations are based on studies in rodent animal models.

¹ European Union Risk Assessment Report - bis (2-ethylhexyl) phthalate (DEHP). 2008. Available via: <https://publications.jrc.ec.europa.eu/repository/bitstream/JRC45705/dehpreport042.pdf>

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

Executive Board:
Anna Maria Braun, LL.M.
(Chief Executive Officer)
Dr. Annette Beller
Dr. Meinrad Lugin

Caroll H. Neubauer, LL.M.
Dr. Joachim Schulz
Markus Strotmann
Priv.-Doz. Dr. Stefan Ruppert
(Deputy Member)

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

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

B|BRAUN

Page 2 to the letter of August 12, 2020 to whom it may concern

As of now we have not received any relevant market feedback. A review of the recent epidemiological studies investigating DEHP exposure associated with effects on sexual development in humans were either inconclusive or inconsistent.²

The above-mentioned products are only specified for short-term use. Therefore, clinically relevant effects caused by the exposure to the devices are considered as unlikely based on the currently available information.

In order to mitigate any residual risk for vulnerable patient groups, the above mentioned products are by way of precaution proactively recalled from the market.

Actions to be taken

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, quarantine and return affected goods.
- Do not use affected devices anymore.
- Contact the below mentioned persons for possible alternatives.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

² Scientific Committee on Emerging and Newly-Identified Health Risks SCENIHR – Opinion on The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update)

B|BRAUN

Page 3 to the letter of August 12, 2020 to whom it may concern

If more information is needed, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,