

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
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hartmann.info



Field Safety Notice **Set d'accouchement**

Field Safety Correction Action: Voluntary Product Recall

Trade name: Set d'accouchement

Article number / LOT: Article Nr. 4787763, LOT 200233253

Manufacturer FSN Ref.: 20230726-Setd'accouchement

26 July 2023

Sender: PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
Germany

Recipient: „Distributors; Hospitals; Health Care Professionals“

Affected product: 4787763 Set d'accouchement, LOT 200233253

With this letter we would like to inform you about a Field Safety Corrective Action (FSCA) of PAUL HARTMANN AG. This is a recall of the article Set d'accouchement.

Description of the problem:

The aforementioned procedure pack **Set d'accouchement** is a sterile disposable component set which is used for delivery procedure.

Pinholes were found in the packaging of the set d'accouchement. Our preliminary investigation results suggest that the pinholes result from the manufacturing process.

When using the product, there is a risk of contamination due to a sterile barrier system rupture caused by the pinholes and the insertion of germs into the surgical area and the patient's tissue. A possibly occurring inflammatory reaction cannot be completely excluded.

The products affected by this issue were immediately quarantined in our warehouse.

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

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For the PAUL HARTMANN AG safety of patients, users and third parties have the highest priority. Therefore, we voluntarily recall the product **4787763 Set d'accouchement**.

PAUL HARTMANN AG has performed a root cause investigation and taken immediate corrective action. There are no other lots involved in that. Other lots were already inspected for the condition after manufacture.

Instruction for Affiliates:

Please examine your inventory, block available stocks and do not use the affected products of the list any longer.

We kindly ask you to confirm the receipt of this notification and return "FSN_A1_Affiliate Reception&Transmission" **until Tuesday, 24.08.2023**.

For confirmation of closure please complete and return "FSN_A2_Affiliate Closure" **until Tuesday, 24.08.2023**.

A1: Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this field safety notification.

A2: Affiliate Closure after examination of your inventory and reception of the feedback from your customers please confirm status of all available goods.

Please kindly complete and return the attached response forms to your contact.

Your internal contact for further information is [REDACTED], E-Mail: [REDACTED]

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred to. Therefore, please take adequate measures. A template for a customer letter is enclosed ("FSN_A3_Customer letter including Customer Closure"). Customers are requested to confirm receipt of the Field Safety Notice to the local HARTMANN affiliate.

Due to regulatory reasons, we do require your written confirmation of implementation and closing of the Field Safety Corrective Action above.

ILN 040 9500 00000 0

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Instructions for Users:

- All users of the affected products must have read and considered all instructions and information in this FSN.
- Identify the affected product.
- Check your stocks.
- Block the stocks.
- Notify us of the quantities on hand.

We will gladly exchange these for you free of charge.

Please confirm receipt of this information, the stocks you have and the forwarding of this information to all relevant departments in your company that need to know about this by sending us the attached reply.

We apologize for any inconvenience caused and thank you for your cooperation.

This Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA).

Heidenheim, 26 July 2023

PAUL HARTMANN AG



Attachments:

1. FSN_A1_Affiliate Reception&Transmission
2. FSN_A2_Affiliate Closure
3. FSN_A3_Customer letter including Customer Response Form

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Affiliate Closure:

„**affiliate / authorized distributor address**“

Affiliate Closure

→ **latest until August 24th 2023**

Please kindly **upload your documentation** as signed PDF in your respective country folder *in the Vigilance SharePoint* – please use the following link:

customer FR

Only in case of any technical problem as backup solution please send to:

PAUL HARTMANN AG

[REDACTED]

Email: [REDACTED]

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Field Safety Notice – PAUL HARTMANN AG

Set d'accouchement

We hereby confirm that the actions, as described in the Field Safety Notice, has been closed.

Please indicate:

According to the feedback of our customers:

- after thorough examination no stocks of the affected articles
- affiliate stocks** existing as follows:

Please enter only articles from Attachment 4 Article List!

| REF (article number) | commercial name | LOT | stock quantity |
|-----------------------------|---|------------|-----------------------|
| „number“ | „product name“ (customer individual) | „number“ | „number of packs“ |
| | | | |
| | | | |
| | | | |

- according to the feedback of our **customers stocks** existing as follows:

Please enter only articles from Attachment 4 Article List!

| REF (article number) | commercial name | LOT | stock quantity |
|-----------------------------|---|------------|-----------------------|
| „number“ | „product name“ (customer individual) | „number“ | „number of packs“ |
| | | | |
| | | | |
| | | | |

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We hereby confirm that the whole stocks of affected articles according to article list have been identified, removed and discarded immediately before usage of the Set d'accouchement.

Date:

Stamp:

Signature:

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
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Customer Response Form:

„Affiliate / authorized distributor address“

Customer Response Form

→ please **until 24.08.2023** per Email

PAUL HARTMANN AG

E-Mail: [REDACTED]

Field Safety Notice of PAUL HARTMANN AG

Set d'accouchement , Artikel Nr. 4787763, LOT 200233253

We hereby acknowledge receipt of the Field Safety Notice dated 26.07.2023, concerning the above-mentioned articles (Set d'accouchement , article no. 4787763, LOT 200233253) and the forwarding of the Field Safety Notice to all persons and organizations concerned.

Please tick:

- After careful examination we could not find any stock in the warehouse
- Stock has been available and blocked as follows. We ask for replacement:

| REF (article number) | Trade name | Charge | Stock quantity (number of sets) |
|----------------------|---------------------------|-----------|---------------------------------|
| 4787763 | Set d'accouchement | 200233253 | |

We hereby confirm that the complete stock of these items has been blocked and will no longer be used. PAUL HARTMANN AG will replace the above-mentioned stocks.

Date:

Stamp:

Signature customer:

GLN 404 9500 00000 0

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