Urgent Field Safety Notice

Instructions to Affiliate

Field Safety Corrective Action: Voluntary Product Recall

Trade name: **Vivano® Med Abdominal Kit**
REF / LOT: according to attachment 1

March 8th, 2017

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

Recipient: „affiliate / authorized distributor“

Affected product:

Affected Vivano® Med Abdominal Kits see attachment 1

Description of the problem and Product Advisory Notice:

The listed respective named Vivano® Med Abdominal Kits are wound dressing sets for the negative pressure wound care in conjunction with a Vivano® Tec negative pressure therapy system. These include in addition to the hydrophobic PU foam dressing a PE organ protection layer. The organ protection layer is a round, micro-perforated polyethylene film (ø 65 cm) with 6 welded application pockets, which are designed to facilitate the introduction of this organ protection layer between the abdominal wall and the internal organs (see attachment 2).

In our internal routine controls a deviation in the manufacturing process for the above mentioned organ protection layer has been identified. This could lead to a lower stability of the weld seams, which connects the application pockets to the PE organ protection layer. An increased mechanical load could lead to a potential risk that one of the applicator pockets could be detached.

We have not received any reports of events related to this issue in connection with HARTMANN Vivano® Med Abdominal Kits at this time.

For the PAUL HARTMANN AG safety of patients, users and third parties has the highest priority. Due to the low potential risk that could not be completely excluded, we voluntarily recall the products and batches listed in attachment 1.

Product recall:

Please examine your inventory 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 attachment 3 (Response form 1 Affiliate Reception & Transmission 08.03.2017) **until Wednesday, 15.03.2017**.

For confirmation of closure please complete and return attachment 4 (Response form 2 Affiliate Closure) **until Friday, 31.03.2017**.

Response form 1:
Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this urgent field safety notification **until 15.03.2017**

Response form 2: Affiliate Closure after examination of your inventory and reception of the feedback from your customers please confirm status of all available goods **until 31.03.2017**

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

Your contact for further information is [redacted], telephone: (+49) 7321 – 36 1410.

Transmission of this Urgent Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred to. Therefore please take adequate measures. A template for a customer letter is enclosed. Customers are requested to confirm receipt of the Urgent Field Safety Notice to the local HARTMANN affiliates / authorised distributor.

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

This Urgent Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA). In countries outside the EEA the respective affiliate is responsible to fulfil the relevant notification duties.

Heidenheim, March, 8th 2017
PAUL HARTMANN AG

[redacted]

Attachments:

1. List of affected HARTMANN products
2. Picture PE organ protection layer
3. Response form 1 Affiliate Reception & Transmission 08.03.2017
4. Response form 2 Affiliate Closure 08.03.2017
5. Customer letter affiliate
6. Response form Customer Reception & Transmission 08.03.2017