PAUL HARTMANN AG
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Germany

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Going further for health

Urgent Field Safety Notice

Field Safety Corrective Action:
Affixing warning notice – identification and discarding affected component

Trade name:
CombiSets® containing sterile hypodermic needle – MEDOJECT of CHIRANA T. Injecta

Article number and LOT: According to attachment 1

October 8th, 2020

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

Recipient: „affiliate / authorized distributor“

Affected product:
CombiSets® containing sterile hypodermic needle – MEDOJECT of CHIRANA T. Injecta (see **attachment 1**)

Description of the problem and Product Advisory Notice:

We've been informed by our supplier CHIRANA T. Injecta about an Urgent Field Safety Notice (voluntary product recall) concerning sterile hypodermic needle – MEDOJECT (see **attachment 2**).

According to the Field Safety Notice from CHIRANA T. Injecta the affected LOTs are recalled because of following reason:
"Appearance of black spots after puncture or wiping needles by white paper towel. The observation that the needle surface gives black color when touched by white tissue may potentially rise some concerns about safety of medical device by users and patients.
Based on all gathered information there is no fact that the sterile needles MEDOJECT create any risk to patient and user. Test of In vitro toxicity proved that the surface of the needle is non- toxic and there are no particles of surface black deposit formed in terms of embolism. These needles fully comply to standards EN ISO 7864:2016, EN ISO 9626:2016 and ISO 15510:2014 and are in fact safe for use."

Sterile hypodermic needle – MEDOJECT are contained as component in our HARTMANN CombiSets®.

To assure patient care, we are performing for all available CombiSets® at our customers as well as on stock following corrective action: A respective warning notice (see **attachment 6**) that the concerned component(s) sterile hypodermic needle(s) – MEDOJECT must be identified, removed and discarded immediately before usage of the CombiSets® will be affixed by the PAUL HARTMANN AG. All other components are not affected and could be used.

Neither complaints nor (serious) incidents were registered concerning HARTMANN CombiSets® regarding the described issue.

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Corrective Action:

Please immediately examine your inventory (see **attachment 1**) and do not use the affected CombiSets® of the list any longer until affixing of the warning notice.

Your usual HARTMANN sales representative or customer service contact will get in contact with you to ensure a correct and complete affixing of the warning notice by the PAUL HARTMANN AG.

After affixing the warning notice on the CombiSets® these could be again used. During preparation procedure for surgery, we request from you to identify the affected component(s), remove and discard them immediately. All other components are not affected and could be used as usual.

We kindly ask you to confirm the receipt of this notification and return **attachment 3** (Response form 1 Affiliate Reception & Transmission) **until Friday, 16.10.2020**.

For confirmation of closure please complete and return **attachment 4** (Response form 2 Affiliate Closure) **until Friday, 30.10.2020**.

Response form 1:
Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this urgent field safety notification **until Friday, 16.10.2020**

Response form 2: Affiliate Closure after examination of your inventory and reception of the feedback from your customers (see **attachment 5**) please confirm status of all available goods **until Friday, 30.10.2020**

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

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

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 (see **attachment 5**). Customers are requested to confirm receipt of the Urgent 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.

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

Heidenheim, October, 8th 2020

PAUL HARTMANN AG

[redacted]

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Attachments:

1. List of affected products
2. Urgent Field Safety Notice CHIRANA T. Injecta
3. Response form 1 Affiliate Reception & Transmission 08.10.2020
4. Response form 2 Affiliate Closure 08.10.2020
5. Customer letter affiliate including response form Customer Reception & Transmission 08.10.2020
6. Warning notice