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Going further for health

Urgent Field Safety Notice

Field Safety Corrective Action:
Caution / Advisory from BD for application of affected components

Trade name:
CombiSet® for ophthalmology containing affected syringes and needles from BD

Article number and LOT: According to attachment 1

January 22nd, 2021

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

Recipient: „affiliate / authorized distributor“

Affected product:
CombiSet® for ophthalmology containing affected BD syringes and needles (see **attachment 1**)

Description of the problem and Product Advisory Notice:

We have been informed by our supplier BD (Becton, Dickinson and Company) about an Urgent Field Safety Notice – MPS-18-1209 concerning syringes and needles (see **attachment 2**).

According to information from BD this Field Safety Notice is providing a caution for listed syringes and needles (see table 1 FSN MPS-18-1209) and a recommendation to apply this caution when using the products:

“Intraocular use is not validated by BD:
BD has become aware that when syringes and needles are used for intraocular injections, the potential exists for “floaters” in patients’ eyes which are believed to be due to silicone. (Note: Syringes and needles manufactured by BD have silicone applied to the inside of the barrels to provide lubrication for the plunger stopper, allowing it to move easily). The potential hazard is deposition of silicone oil (SO) droplets in the vitreous. The potential harm could be symptomatic “floaters” in the patient’s field of vision which, normally, are tolerable and resolve over a few months. However, if sufficiently bothersome, floaters may lead to a vitrectomy for their removal.
BD became aware of other potential risks associated with intraocular injections, such as endophthalmitis (inflammation of the interior of the eye), which may be associated with failure modes not previously identified by BD.
To reduce this risk of silicone floaters and inflammation or irritation that may occur, HCPs should only use the syringes and needles provided with ocular medications that are specifically designed and labelled for intravitreal injection.”

BD syringes and two of the needles (see table 1 of FSN MPS-18-1209 from BD) are contained as components in our HARTMANN CombiSet® for ophthalmology.

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Please take note and confirm receipt of this Urgent Field Safety Notice. Upon written confirmation the CombiSet® for ophthalmology can still be applied. During usage of affected syringes and needles the caution from BD should be considered. All other components are not affected and can be used as usual.

Up to this point of time neither complaints nor (serious) incidents were registered concerning HARTMANN CombiSet® regarding the described issue.

Advice on actions:

Please immediately examine your inventory (see **attachment 1**) to ensure that before usage of listed CombiSet® the caution from BD was noticed.

We kindly ask you to confirm the receipt of this Urgent Field Safety Notice and return **attachment 3** (Response form 1 Affiliate Reception & Transmission) **until Friday, 29.01.2021**.

For confirmation of closure please complete and return **attachment 4** (Response form 2 Affiliate Closure) **until Friday, 19.02.2021**.

Response form 1:
Affiliate Reception & Transmission to confirm having informed all respective people and organizations of this urgent field safety notification **until Friday, 29.01.2021.**

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, 19.02.2021.**

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 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 Urgent 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, January, 22nd 2021

PAUL HARTMANN AG

[redacted]

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Attachments:

1. List of affected products
2. Urgent Field Safety Notice BD
3. Response form 1 Affiliate Reception & Transmission 22.01.2021
4. Response form 2 Affiliate Closure 22.01.2021
5. Customer letter affiliate including response form Customer Reception & Transmission 22.01.2021