Primed® Halberstadt Medizintechnik GmbH
Ihr Partner in Medizin und Kunststofftechnik
Domplatz 34 • 38820 Halberstadt

Urgent Safety Notice
Recall
concerning

Perforated Capillary Drains

05.09.2025

Sender:
Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt

Target group:
Users, distributors, hospital logistics, medical device safety officers

Identification of the affected medical devices:

Artikelnummer	Bezeichnung
21456	Capillary – drain, perforated, Ø = 6 mm, L = 300 mm with x-ray line
21457	Capillary – drain, perforated, Ø = 8 mm, L = 300 mm with x-ray line
21458	Capillary – drain, perforated, Ø = 10 mm, L = 300 mm with x-ray line
21459	Capillary – drain, perforated, Ø = 12 mm, L = 300 mm with x-ray line

Potentially affected batches: all batches with manufacturing date from **09 – 2020**

Description of the problem including the identified cause:
We have been informed that during the use of a capillary drain, it was discovered that punch residue (“slugs”) was present in the drain. The cause of the defect is likely due to a defect in the manufacturing process.

If a “slug” were to become detached, it could cause inflammation and/or infection in the patient's body. This, in turn, would require additional treatment.

There is no risk for patients who have already been treated with the aforementioned products and who do not exhibit any inflammatory reactions or other reactions related to the treatment of the capillary drain.

Capillary drains currently in use should be carefully removed immediately to rule out any potential risk.

Patients currently being treated with one of the aforementioned capillary drains should be monitored after drain removal to determine whether inflammatory reactions or infection in the wound area occur that could be attributed to the use of the drain.

To date, we have not received any reports of serious incidents in this regard.

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What actions should the recipient take?
Please perform the following actions:
1. Identify the products in your facility/company
2. Completely remove the product inventory from any use
3. Separate the products and make them available for collection
4. Confirmation to Primed Halberstadt Medizintechnik GmbH that the goods are ready for collection

We ask you to include the safety notice regarding the potentially affected capillary drains in your documentation. We also ask you to forward the safety notice to other hospitals and departments that have received the affected capillary drains.

Please complete the enclosed acknowledgement form in full and return it. Keep yourself informed of this notification and the associated measures.

Sincerely,

Contact:
Steffen Schaefer
(verantwortliche Person nach Artikel 15 MDR 2017/745 /
responsible person according to Article 15 MDR 2017/745)

Tel.: +49 3941- 668 6
vigilanz@primed-halberstadt.de | www.primed-halberstadt.de

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Subject: Safety Notice Receipt Confirmation

Dear Sir or Madam,

Thank you in advance for your cooperation. Please complete this document and return it to your local Primed Halberstadt Medizintechnik GmbH representative or via one of the following methods:

Fax: +49 (0) 3941 - 245 65
E-Mail: vigilanz@primed-halberstadt.de

Mail:
Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany

Confirmation of receipt:
I confirm receipt of the safety information issued by Primed Halberstadt Medizintechnik GmbH.
I understand the information and have passed it on to all responsible employees, departments, and facilities affected by this action.

After implementing the above-mentioned measures, we have reached the following conclusion:

Please check/complete the relevant box.

- ☐ We have the full quantity in stock. No copies have been transferred to third parties.
- ☐ We have the following number of affected products in stock: _____ pcs
- ☐ The specified product has already been distributed to third parties in quantities of _____ pcs. We will notify the customer base that received the above-mentioned product(s) of the recall.
- ☐ We do not have any of the affected products in stock and will notify our customers who have received the above-mentioned product(s) of the recall.

Name/Name, Vorname/Surname

Unternehmen/Company

Abteilung (Department)/Funktion (Position)

Unterschrift/Signature

Datum/Date