BAUERFEIND

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Urgent Safety Information

Recall

relating to

VenoTrain business compression stockings because of an insufficiently stretchy band

April 17, 2023

Sender:
Ines Exner
Person Responsible for Regulatory Compliance (Person Responsible – MDR)
Bauerfeind AG
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Recipient:
Medical retailers and pharmacies that have ordered the VenoTrain business medical compression stockings from Bauerfeind AG during the specified period.

Identification of affected medical products:
VenoTrain business medical compression stockings, AD, Ccl2, closed toe, short foot, Size M normal long, navy, batch number 0015587117. A list of the affected customers is enclosed.

Description of the issue including the identified cause:
Issue: The stockings are hard to put on because the band is not sufficiently stretchy. If they are worn anyway, it may lead to significant feelings of pressure and pain. We therefore have to recall these products.

Reason: When making the faulty stockings, an additional yarn parallel to the weft thread was mistakenly incorporated in the band. The fault was immediately corrected after its detection, and the bands are now being thoroughly checked using additional measures.

Risks for patients: If the compression stockings with the excessively tight band are worn for too long and not taken off, it may lead to significant feelings of pressure and pain. In the worst-case scenario, there may be a risk of tissue destruction (skin necrosis) and other damage caused by pressure.

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What action does the recipient need to take?
All affected medical retailers and pharmacies will receive "Urgent Safety Information" from Bauerfeind AG and are asked to return the affected products. At the same time, the relevant sales staff will get in touch with the customers in question. Returns are handled in accordance with Bauerfeind AG's Returns Policy which allows a credit note or replacement. Additionally, medical retailers can order new goods straight away.

Schedule:

- From April 17 to April 24, 2023, all affected medical retailers and pharmacies will be notified: in writing via "Urgent Safety Information" as well as by the relevant sales staff.
- All products should be returned by May 15, 2023.
- On Wednesday May 31, 2023, the BfArM (Federal Institute for Drugs and Medical Devices) will receive the closing report.

Contact:
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[redacted]

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Enclosures:
List of affected customers