BAUERFEINO AG • TRIEBESER STR. 16 • 07937 ZEULE NROOA- TRIEBES

Urgent Safety Information

Recall

concerning

MOS-Genu knee orthosis

because of a quality problem with the frame of the orthosis

November 15, 2021

Sender:

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Person Responsible for Regulatory Compliance (Person Responsible - MDR)
Bauerfeind AG
Triebeser StraBe 16
07937 Zeulenroda-Triebes, Germany
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Recipient:

Medical retailers supplied with the MOS-Genu knee orthosis by Bauerfeind AG during the specified time.

Identification of affected medical products:

MOS-Genu knee orthosis: material numbers from batches that were delivered from October 21, 2021 onwards. A list with the material numbers from the affected batches is enclosed.

Description of the issue including the identified cause:

The aluminum frame of the MOS-Genu knee orthosis (short and long versions) does not have the required material rigidity. That means it does not provide the stability needed to combat the indication. It may distort when the product is being worn and therefore represents a quality problem that poses a safety risk for users.

The cause was a fault with the supplier's material which has already been remedied.

ANSCHRIFT
Bauerf eind AG
Tri ebeser Slrafle 16
07937 Zeul enroda-Triebes

KONTAKT
T +49 (0) 36628 66-10 00
F +49 (0) 36628 66-1999
E info@baue rf eind.com

LIEFERANSCHRIFT
Weiflendorf er Slrafle S
07937 Zeul enroda-Triebes

Bauerfeind AG
AG Jena HRB 206561

VORSITZENOER DES VORSTANOES
…

MITGLIED DES VORSTANDES
…

VORSITZENOER DES AUFSICHTSRATES
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BAUERFEIND.COM

What action does the recipient need to take?

All affected medical retailers 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:

by November 22, 2021, all affected medical retailers will be notified: in writing via "Urgent Safety Information" as well as by the relevant sales staff.
All products should be returned by November 30, 2021.
On December 15, 2021, the BfArM (Federal Institute for Drugs and Medical Devices) will receive the closing report.

If users have been provided with orthoses by medical retailers in accordance with the patient's needs and indication, the medical retailers must urgently notify the affected users and ask them to return to the medical retail store so their product can be replaced. The medical retailers have until November 30, 2021 to let us know whether they were able to replace all orthoses for their patients.

Contact:

Ines Exner, Person Responsible - MOR
Tel.: +4936628-66-1350 / Email: Ines.Exner@bauerfeind.com

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Chief Technical Officer

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Person Responsible - MOR