Urgent Field Safety Notice
Recall

regarding

Bort X-Walker – Possible breakage of the closure rivets

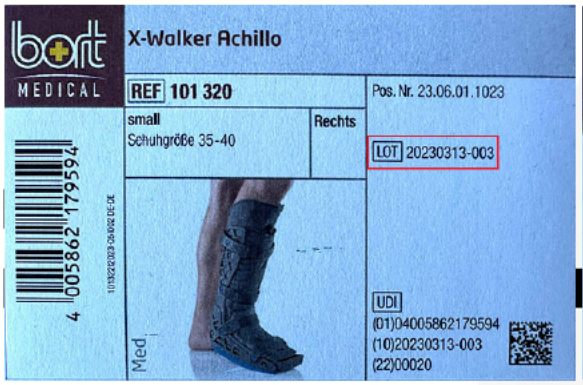
October 2023

Sender and contact Information::
Bort GmbH
Am Schweizerbach 1
71384 Weinstadt
Germany

[redacted]
PRRC (Person Responsible for Regulatory Compliance)
[redacted]

Attention:
Healthcare providers, customers and patients who were supplied with the Bort X-Walkers.

Details on and identification of affected products:
Affected products can be identified using the LOT number.
The LOT number can be found on the packaging label and the LOT number is printed on the back of the textile sew-in label. LOT numbers are marked with a leading “LOT”.



Packaging label

textile sew-in label

Bort X-Walkers of the following versions are affected by the recall:

- 101300 Bort X-Walker long, sizes Small, Medium and Large
  Affected LOT: 20230313-001, 20230313-002, 20230313-003
- 101320 Bort X-Walker Achillo right and left, sizes small, medium and large
  Affected LOT: 20230313-001, 20230313-002, 20230313-003
- 101350 Bort X-Walker short, sizes Small, Medium and Large
  Affected LOT: 20230313-001, 20230313-002, 20230313-003

101350 Bort X-Walker short

Description of the problem:
Due to a material and design issue, the blue connecting bolts which attach the fasteners and D-rings to the gray walker shell may break.
This leads to a functional failure of the walker, which means it no longer provides its medical purpose.
The connecting bolt can break abruptly.

The cause can be traced back to a material and design issue on the part of the supplier of the connecting bolt.

[redacted]vas found on LOT 20230313-001, 20230313-002, 20230313-003 of item 101300.
[redacted]

Advise on action to be taken by the user:
Please complete the attached confirmation form and return it to Bort GmbH by mail, email or fax by November 3rd, 2023.
Please return all existing stocks of the affected LOT to Bort GmbH immediately, latest by November 17th, 2023.

It is urgently necessary to refrain from further use of the affected Bort X-Walkers

The return is processed according to the return policy of Bort GmbH. You are welcome to send the return “freight collect” or against a credit note for your shipping expenses.

If users (patients) have already been treated by service providers, the service providers must urgently and immediately contact the patients being treated, inform them about the facts and ensure that the Bort X-Walkers are replaced with an alternative product.

Timetable for implementation of this measure:

- [redacted] By Oct. 25, 2023, all affected healthcare providers will be notified in writing via " Urgent Field Safety Notice" and via the responsible field representative
- [redacted] By 17.11.2023, the affected products are to be returned.
- On 30.11.2023, the final notification will be sent to BfArM.

Transmission of this Field Safety Notice:
Please ensure in your organization that all users of the above mentioned products and others Persons to be informed are made aware of this “**Urgent Field Safety Information**”.
If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
If you have provided the products to a third party, please forward a copy of this information or inform the contact person specified below.
Please keep this information at least until the action has been completed.
The “Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)” has received a copy of this “Urgent Safety Information” letter.

Contact reference person:
[redacted], Bort GmbH
PRRC (Person Responsible for Regulatory Compliance)
[redacted]

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Acknowledgement Form for Customers

On behalf of this organization, I acknowledge receipt of the "URGENT FIELD SAFETY NOTICE" letter pertaining to above product.

From:

Organization: [redacted]	
Customer number: [redacted]	
Name:	
Date:	
Signature and stamp:	

Please return the completed form by mail, fax or email to:

Recipient:	Bort GmbH
Address:	Am Schweizerbach 1 71384 Weinstadt Germany
Email:	medical@bort.com
[redacted]ct:	Urgent Field Safety Notice – Bort X-Walker
Fax: [redacted]	+49 7151-99200-50
Phone:	+49 7151-99200-0