Urgent Safety Information

2024-07-16

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Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

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Urgent Safety Information

Products affected	Foot abduction splints • ALFA-Flex • BETA-Flex
Potential damage	Risk of injury or death from swallowing small parts that become detached
Information relevant for	• Service providers (e.g., orthopaedic technicians) • Carers / parents of children being treated using the products

This document contains important information, in addition to the instructions for use that are included with the product, with which the relevant products can continue to be used safely and correctly.

Please give this information to the parents of the children being treated by you using the named products. It is important that these persons understand the meaning of this notice.

Please retain this letter for your records.

Dear Customer,

Semeda has become aware, based on market feedback, that there are potential safety risks that can occur when using foot abduction splints.
The problem is associated with the fact that components of the product can be torn out of the product if product application / maintenance is carried out incorrectly or if extraordinary load is placed on the product.

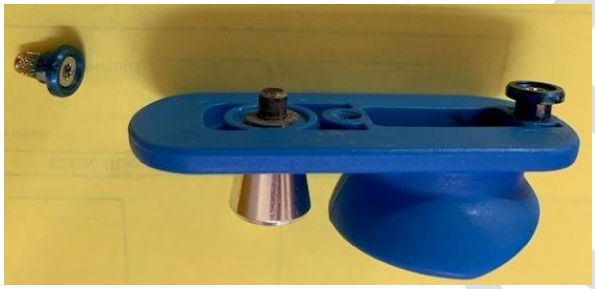
1. What is the problem and under what circumstances can it occur.

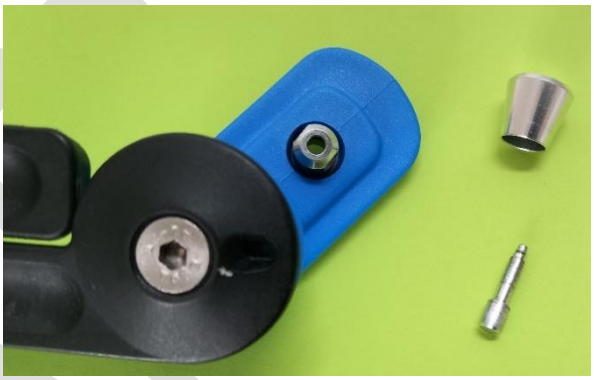
It was found in the market surveillance carried out by Semeda that screws and other fastening elements can be torn out of the foot abduction splints in rare cases and can then be present in the form of loose small parts within the reach of small children.

In the cases of which Semeda has become aware, screws or other fastening elements became loose under the following conditions:

- when screw connections were carried out incorrectly, contrary to the handling, maintenance and adjustment instructions of the manufacturer
- application of great forces and loads to the screw connection points on the foot abduction splints, e.g., through excessive boisterous activity by the child or because an adult stepped on the splint as it lay on the ground, as well as other loads not related to the application.

Example images of loose small parts:





2. Risk associated with the problem

Loose small parts within the reach of small children can be swallowed by the children. In the worst case, the swallowing of small parts can lead to injury or to death from choking.
Semeda has not received any reports of this kind of damage to persons since the products were introduced on the market and up to July 2024.

3. Measures to be taken by the customer / user in order to avoid putting patients, users or third persons at risk.

- You can continue to use undamaged products in line with their intended use.
- Parents or carers of the children being treated with the products named above should check the products regularly (daily) for missing parts and damage.
    - If product components are missing, it must be ensured that they are not within the reach of children.
- Screw connections on the product must not be manipulated by the user or by the orthopaedic technician without instruction from the manufacturer (Semeda). Among other things, screws must not be tightened autonomously as this can damage the screw attachment in the splint.
- Supplement the instructions for use that were supplied with the product to include a copy of this urgent safety information if the enclosure provided by Semeda with the relevant safety notice was not included with the product. This relates to products that were distributed before 25 June 2024.

4. **Administrative requirements for the persons providing the care service (orthopaedic technician)**

- Submit a copy of this urgent safety information to the parents / carers of children who have been treated using the above-named products in the last three years.

  This relates to the products that did not yet include the insert provided by Semeda with the relevant safety note (i.e., products that you received prior to 25 June 2024).
- Please file your correspondence with the affected parents / carers (letter or e-mail) with the care records of the patients concerned for official control purposes.
- Please complete the attached replay form and return it promptly to Semeda, at the latest 30 days after receipt. By completing this form, you confirm
  - receipt of the urgent safety information.
  - that you have understood the problem and the required measures
  - that you have informed the parents / carers of the affected patients.

Contact person

If you require further information or support in connection with this problem, please contact your Semeda contact person:

Lara Ueckerseifer
phone: 05824/9855514

The Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices) has received a copy of this "Urgent Safety Information".

Kind regard

Harald Kujus
General management Semeda GmbH

Geschäftsführer: Harald Friedrich Kujus
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Es gelten unsere allgemeinen Geschäftsbedingungen

SPECTARIS
Mitglied im deutschen Industrieverband für optische, medizinische und mechatronische Technologien e.V.