

URGENT FIELD SAFETY NOTICE

VARI-FLEX® JUNIOR – INSTRUCTIONS FOR USE

FSCA - FA220301

2022-05-23

AFFECTED DEVICES

Vari-Flex® Junior

Item Number: VJB0xyz

PICTURE OF THE AFFECTED DEVICE



DEVICE ISSUE

At Össur patient safety is the number one priority and special care is taken in case of our youngest users, children, and adolescents. Össur has received customer complaints related to broken Vari-Flex Junior feet with failures occurring in situations where sudden high impact twisting or bending is applied to the foot. Such circumstances can happen in sports activities, including for example football / soccer.

Whilst Össur has not received any reports of injuries related to the Vari-Flex Junior, it has been identified that the Instructions for Use for the device require an update to clarify the Intended Use of the device and to add related warnings. As such, Össur is implementing a Field Safety Notice to notify customers that have already purchased Vari-Flex Junior feet.

To ensure compliance and user safety the Instructions for Use, IFU 1121_001 for Vari-Flex Junior, have been updated from version 6 to version 7 to include the additional information required. The specific updates are outlined below, added text is highlighted in **yellow**.

IFU 1121_001 REV.7

INTENDED USE

Indications For Use and Target Patient Population

- Lower limb loss, amputation, or deficiency
- No known contraindications

The device is intended for children and adolescent users.

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Warning: The device may break or delaminate if sudden high impact side bending and/or twisting occurs.

Warning: If there is a change or loss on device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional. The device is for single patient use.

DEVICE SELECTION

Verify that selected variant of the device is suitable for the weight limit according to the following table.

Warning: Do not exceed weight limit. Risk of device failure.

Incorrect category selection may also result in poor device function.

CATEGORY SELECTION CHART

Weight kg	15-24	25-34	35-45	46-55
Weight lbs	33-53	54-75	76-99	100-121
Size 16	1	N/A	N/A	N/A
Size 17	1	N/A	N/A	N/A
Size 18	1	2	N/A	N/A
Size 19	1	2	3	N/A
Size 20	N/A	2	3	4
Size 21	N/A	2	3	4
Size 22	N/A	2	3	4
Size 23	N/A	2	3	4
Size 24	N/A	N/A	3	4

For high impact sport activities please consider other options, refer to catalog.

Information for the device has been updated in both the Össur catalog and the Össur website. In addition, impact level has been removed as it is not applicable for this user group; selection should be based on size and weight. It has been stated within the selection chart chapter that other options should be considered for sport activities.

The recommended actions in relation to this case are outlined below:

ACTION - ORGANISATIONS

ACTION REQUIRED:

1. Please monitor and review the activities of those patients that have already been fitted with the Vari-Flex Junior. If the Vari-Flex Junior is not suitable, another type of device or an additional foot should be considered, depending on the patient's needs.
2. Please ensure the updated Instructions for Use and this notice are distributed to the necessary persons within the organization. A copy of the updated instructions accompanies this notice.
3. Please pass this notice to those who need to be aware within your organization or to any organization where Vari-Flex Junior devices have been transferred.
4. Please retain this letter in a prominent position for one month.
5. If you have further distributed this product, please identify your customers, and notify them at once of this Field Safety Notice. We recommend that you include a copy of this notice.
6. Reply to the email/mail that you received confirming receipt of this notice and the updated instructions for use, as we require this information to reconcile this process.

This notice is to be communicated to all those within your organization, and to any other organization where affected devices may have been provided or serviced.

Please maintain awareness of this notice and recommended actions.

Please contact customer service for further information and assistance. A list of the contact numbers is provided at the end of this notice.

Hulda Hallgrímsdóttir

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