URGENT FIELD SAFETY NOTICE

REBOUND® FOOT-UP PRODUCT RECALL – ELASTIC STRAP SUPPORTING FOOT CAN SLIP THROUGH ANKLE BUCKLE

July 2017

AFFECTED DEVICES

Rebound® Foot-Up

RFU50001	Rebound® Foot-Up Ankle S/M
RFU500011	Rebound® Foot-Up Bundle S/M
RFU50002	Rebound® Foot-Up Ankle L/XL
RFU500021	Rebound® Foot-Up Bundle L/XL

ATTENTION

Össur is committed to providing safe, high-quality medical devices to its customers. As such Össur is implementing a voluntary FSCA (Field Safety Corrective Action) in relation to the Rebound® Foot-Up device. It has been reported the elastic support strap on the product can slip through the buckle leading to abrupt loss of support from the device. Due to the risk involved with the outlined potential loss of support, Össur has decided to implement a voluntary recall of the affected devices.

The recommended actions outlined in relation to this case are outlined as follows:

ACTION - ORGANISATIONS

ACTION REQUIRED: Please examine your inventory, quarantine products subject to the recall, with LOT numbers 651 or 706 on the inside of the cuff, and contact customer service for a return authorisation to return the product to Össur, a list of the contact numbers is provided at the end of this notice. The previous version of the product with no such failures reported can be provided in exchange for the recalled item.

ADDITIONAL ACTION REQUIRED: Recipients of this notice should take the following actions:

1. Please pass this notice to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

2. Maintain awareness on this notice for an appropriate period.

3. If you have further distributed this product, please identify your customers and notify them at once of this product alert. We recommend that you include a copy of this product recall.

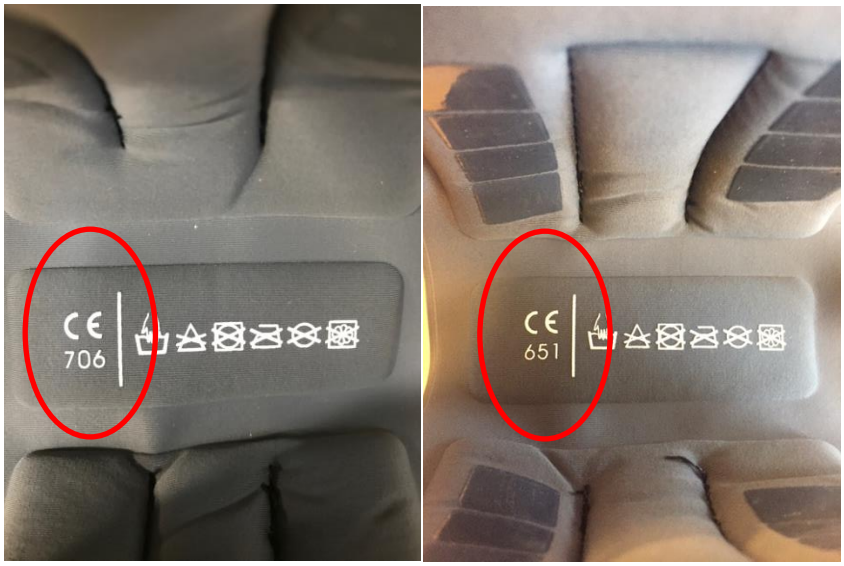
4. If any of your customers are currently wearing a product, we recommend the device is replaced with the previous version of the product.

ACTION – END USERS

ACTION REQUIRED: Please examine your brace for LOT numbers 651 or 706 on the inside of the cuff, and contact customer service for a return authorisation to return the product to Össur, a list of the contact numbers is provided at the end of this notice. The previous version of the product with no such failures reported can be provided in exchange for the recalled item.

PICTURES OF THE AFFECTED DEVICE

Affected product



LOT number location

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

Please maintain awareness of this notice and recommended actions.

Please contact customer service on this phone number for further information and assistance:
Tel: +44 (0)8450 065 065

Hulda Hallgrímsdóttir

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Vice President, Quality & Regulatory

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