
Attention: Urgent Field Safety Notice

Date: 4th April 2018

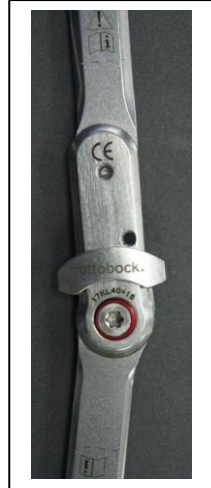
Affected article

17KL40=16 Orthotic knee joints

Delivered between 03/01/2018 – 22/01/2018

Actions required:

Inspect and if required replace



Addressee:

- User
- Customer

Description of the problem:

During the assembling of the knee joints, the knee heads were filed undersize, plus the radius of the lower joint head was oversized. This led to excessive movement of the option lock ring plus reduction of the locking surface this created excessive forces on the option ring. When under load it led to loss of function causing the knee locks to fail.

Cause of the problem:

In combination, the excessive movement of the option lock ring plus the reduction of the locking surface area resulted in a concentrated loading of the option locking ring. This excessive force resulted in the option locking ring yielding leading to both the knee locks failing to lock, causing the users to fall.

Risk assessment:

Due to risk of falling it is recommend that the affected joints, as highlighted below are replaced. For further information please contact the issuer as highlighted within this document

Corrective actions:

Affected joints should be returned back to Ottobock and replaced by the end of April 2018

Transmission of this Field Safety Notice:

This notice needs to be disseminated to all those who need to be aware within your organisation or users which have been identified as being affected.

Please transfer this notice to other persons / organisations on which this action has an impact.

Advise on action to be taken by the customer:

Please return all products in stock with the LOT numbers listed above by end of April 2018, contact details are shown below. Articles that have been issued to users should be recalled and fitted with replacement joints.

Sender and Contact Information:

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Attention:

Customers who received one or more of the products listed below.

Details on affected products:

Products which have to be returned can be identified by the LOT number on the packaging

OR by the LOT number on the joint sidebars.

The following LOT numbers are affected:

You can identify the LOT number according to the pictures as below:

Article number	Packaging	Sidebar
17KL40=16	0011201750	11201750



Please note: all affected articles have now been returned and replacements fitted to any affected end users. Therefore no further action is required to this FSN. This notice is for information only!

Yours sincerely,

Russell Pizze

Technical Services Manager

Ottobock Healthcare PLC