

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

ICELOCK® RATCHET – LOCK RELEASE

Reference – FA230301

April 2023

ATTENTION

Dear Össur product user.

Össur is committed to providing safe, high-quality medical devices to its customers. As such, Össur is implementing a Field Safety Notice (FSN) for the affected devices due to a lock release issue. The attachment pin and lock can wear down faster than expected in certain circumstances. Faster wear can result in the potential for the pin to disengage from the lock, leading to loss of suspension, potentially leading to an injury.

AFFECTED DEVICES

Commercial Name	Product number
Icelock® 125 Ratchet	L-125000
Icelock® 600XM Ratchet	L-621200
Icelock® 621 Ratchet	L-621000
Icelock® 621 Ratchet Adaption Kit	L-621100
Ratchet Lock Body	L-692020

Lot number(s) HF210205, HF210519, HF211008, HF220303, MX210518, MX210816, MX210823, MX211022, MX220316.

DESCRIPTION AND PICTURES OF THE AFFECTED DEVICES

The device is a mechanical lock used to connect and release a locking liner into a prosthetic socket. It is part of an external prosthetic system that replaces a missing lower limb.

Icelock® 125 Ratchet	Icelock® 600XM Ratchet	Icelock® 621 Ratchet	Icelock® 621 Ratchet Adaption Kit	Ratchet Lock Body
				

DEVICE ISSUE

The attachment pin and lock can wear down faster than expected in the affected lot numbers due to a material compatibility issue. Worn or incompatible attachment pins can increase wear down of locks, even when used with a new lock.

Increased risk of wear is seen for patients that may have difficulty in engaging the lock with the attachment pin central to the lock and/or have volumetric fit issues between the residual limb and the socket.

Faster wear can result in the potential for the pin to disengage from the lock, leading to loss of suspension, potentially leading to an injury.

REQUIRED ACTIONS TO BE TAKEN

REQUIRED ACTIONS

1. PATIENT REVIEW
 - a. For affected lots in use, replace both lock body and attachment pin as soon as possible for users that have the following risk factors:
 - Trouble with socket fit due to volume changes in the residual limb.
 - Had lock replacement without having new attachment pin installed at the same time.
 - Have non-Össur attachment pin in use.
 - Complaint about loose fit of the socket or locking issues.
 - b. For other users, replace the affected lots of lock body and attachment pin during the next planned consultation, such as liner replacement. If a user suggests there is an issue with the locking mechanism, the lock and attachment pin should be inspected for wear, **regardless of lot number**. Replace the lock and attachment pin if there are signs of wear; instructions for inspection of wear are attached.
2. INFORM applicable personnel handling the products about the added warnings in the Instructions for Use.
3. PRODUCT RETURN and REPLACEMENT
Check your stock for unused affected locks. All locks and attachment pins with affected Lot numbers should be returned to Össur. Contact customer service for an RA number and inform them of how many replacement devices are required.
4. PLEASE PASS THIS NOTICE to those who need to be aware within your organization. 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 notice.
5. ACKNOWLEDGEMENT
Complete the form and return it as soon as possible.

INSTRUCTIONS FOR USE

Please be aware of the following warnings that have been added to the Instructions for Use:

Warning: Inspect the lock and pin for wear at least once per year, or if there is a change or loss in functionality. In case of wear, replace both lock and pin. Excessive wear may cause loss of suspension and an increased risk of falling.

Warning: Ensure that the pin is fully engaged. Extended use of the product without full engagement may affect safety and performance of the device.

Warning: Only use Össur components and replacement parts in combination with this device. Use of other components may affect safety and performance of the device.

ATTACHMENT

Instructions for inspection of wear on Icelock Ratchet devices.

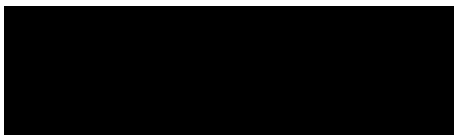
ADDITIONAL COMMENT

Please report all device-related incidents to the manufacturer and the national Competent Authority, as this provides important feedback.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Please maintain awareness of this notice and required actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this causes you and your patients. If you have questions or concerns about this notification, please contact customer service.



Vice President, Quality & Regulatory