

## ICELOCK® RATCHET RECALL– LOCK RELEASE

Reference – FA230301

May 2023

Össur is committed to providing safe, high-quality medical devices to its customers. As such, Össur is implementing an Urgent Medical Device Recall 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.

## CUSTOMER ACTIONS

Urgent Medical Device Recall letter was sent to customers with the following recommendations:

### 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.

We recommend that you reach out to your patients as soon as possible to inform them about the potential risk of the pin disengaging from the lock, leading to loss of suspension.

### 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. PLEASE MAINTAIN AWARENESS of this notice and required actions for an appropriate period to ensure effectiveness of the corrective action.

Customers were requested to complete and return an enclosed response form.

#### 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.

Updated Instructions for Use are available on our website [Ossur.com](http://Ossur.com)

- [Icelock 621 Ratchet and Icelock 621 Ratchet Adaption Kit](#)
- [Icelock 600XM](#)
- [Icelock 125 Ratchet](#)

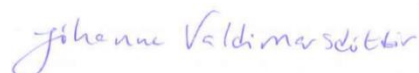
#### INSPECTION OF WEAR

For inspection of the lock please follow the instructions provided below.

#### ADDITIONAL COMMENT

Please report all device-related incidents to the manufacturer and the Competent (Regulatory) Authority of your country.

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



Jóhanna Valdimarsdóttir  
Vice President, Quality & Regulatory

# Inspection for wear - Icelock® Ratchet series

## Inspection for wear:

1. Remove the Lock from the socket (remove Release Mechanism and Funnel)
2. Use compressed air to blow out lint and other particles
3. Inspect the Lock under lighting, paying special attention to: Inside the Lock, Guide Plate and Locking Plate
4. Inspect Attachment Pin, focus on 5 proximal ratchet rows (run fingernail over surface, should feel smooth)

**NOTE:** Insert the Release Mechanism in bottom of lock to more easily visualize internal parts of lock

## Acceptable wear:

Small indents and shiny surface on material (not roughened)

## Unacceptable wear

- Material removed in area of contact with the pin
- Large indents, scratches or gouges
- Roughened surfaces

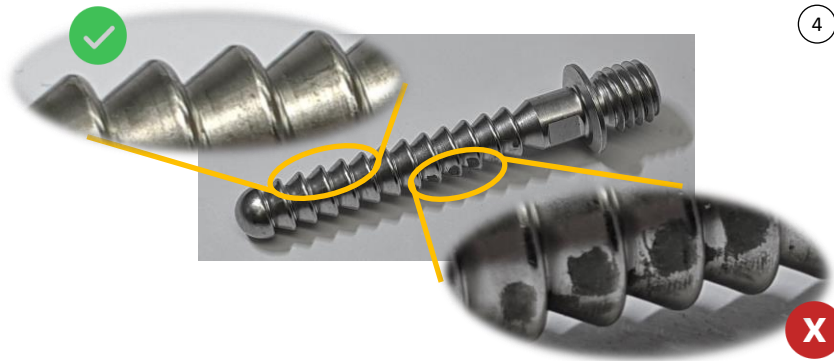
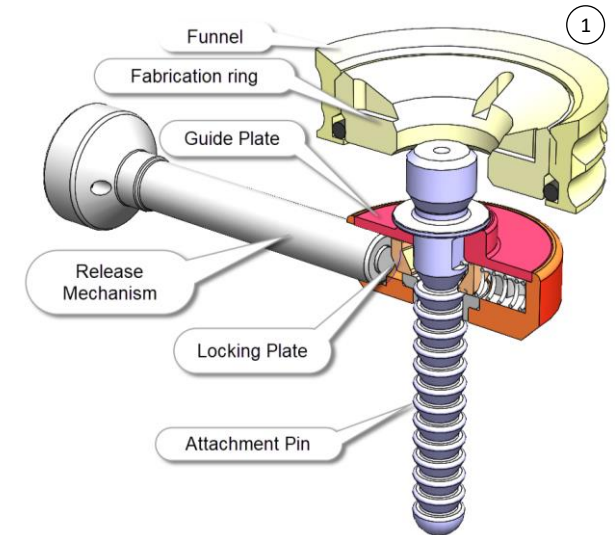
**NOTE:** Only part of the pin may show wear, indicating also wear on the locking mechanism.

Irrespective of one part showing wear, Lock and Attachment pin must be replaced.

Wear on **Guide Plate** is usually concentrated but can be oriented differently from the guide plate. Wear would be identified as material removal with deep scratches visible (see red area on image 2).

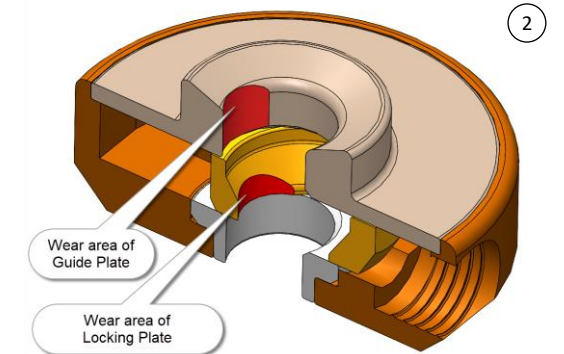
Wear on **Locking Plate** is mostly concentrated in one location and wear can be seen by material being removed and scratches are visible (see red area on image 2).

Shiny surface, being different from other similar surfaces is usually acceptable as this is normal to see with steel parts rubbing against each other. Indents, scratches and gouges of darker color may be sign of early wear through steel outer protective layer which can escalate into higher degree of wear.



## Assistive tools:

- Directional light or other good lighting
- Compressed Air for cleaning
- Magnifying glass for inspection or mobile phone with camera to zoom in on areas



# General Considerations

**About Wear:** Wear is normal to some degree in Icelock Ratchet but can be a sign of issues related to donning of the prosthesis and/or general compromised socket fit. A high degree of wear can become hazardous and indications of such must be looked out for during regular patient consultation.

**Assistive Tools:** Inserting the release mechanism in the bottom of the lock may help to visualize wear. Good directional lighting is important for visualization by using light reflection from surfaces at different angles. Guide Plate and Locking Plate holes are supposed to be round. Mobile phone can be an effective way to take photo of area of interest and zoom in on.

- Indications for premature wear:**
- Clicking noise coming from the socket
  - User indicating looseness of socket
  - Indications of socket not fitting well, user unable to fully don the socket
  - If user may have older liner used as a spare (may have worn pin)
  - User suggesting issues with donning the socket

**Troubleshooting and causes of Lock wear**

**One sided wear on guide plate**

- Review patient donning method to secure good central position of Attachment Pin.
- Make sure the Lock is positioned in the socket to allow the patient to achieve central engagement with the Attachment Pin

**Attachment pin shows high wear proximally**

- Patient may not be well supported in distal part of socket, causing pistoning along with side to side movement.
- Patient may not be using volume socks appropriately
- Attachment Pin may be from other manufacturer than Össur.

**Attachment Pin shows wear at 2<sup>nd</sup> to 5<sup>th</sup> rows from proximal end of Attachment Pin**

- Patient may be having volume changes which causes Attachment Pin not being pre-tensioned in the lock at all times.
- Patient may not be donning fully the socket adequately which may be as a result of socket fit issues.

**Locking Plate is worn but limited wear observed on Attachment Pin**

- Patient may have alternative liner with worn pin
- Previous Attachment Pin in liner may have been worn, starting wear on the lock

