

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Ossur H / F Icelock Ratchet for Attachment Pin and Lock Wearing Down Quickly

Recall Date	Product Description	Recalling Firm	Recall Reason
6/21/2023	Icelock Ratchet REF: L-125000; Icelock 600XM Ratchet, REF: L- 621200; Icelock 621 Ratchet, REF: L-621000; Icelock 621 Ratchet Adaption Kit, REF: L- 621100; Ratchet Lock Body, REF: L-692020	Ossur H / F Reykjavik, Iceland	A mechanical lock used to connect and release a locking liner into a prosthetic socket have an attachment pin and lock that can wear down faster than expected, leading to the potential for the pin to disengage from the lock, leading to loss of suspension of the external prosthetic system that replaces a missing lower limb, which can lead to falling and injury.

Recall Class	Product Identification	Distribution	Affected Dates
II	Icelock Ratchet	422 Units	May 2023 and
	REF/UDI-DI: L-	in California	Prior
	125000/05690967566142; L-		
	621200/05690967596590; L-		
	621000/05690967118334; L-		
	621100/05690967155322; L-		
	692020/05690967128548. Lots:		
	HF210205, HF210519,		
	HF211008, HF220303,		
	MX210518, MX210816,		
	MX210823, MX211022,		
	MX220316.		

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

