

## URGENT MEDICAL DEVICE RECALL

### MIAMI J SELECT – PSA HOOK ADHESION

Össur Reference – FA240601

August 2024

#### AFFECTED DEVICES

Device Description	Catalog Number	GTIN	Lot	Sold in the period
Miami J Select Collar	MJS-101	05690967817008	MX220516 to MX230104	2022-05-19 to 2023-06-05
Miami J Select Collar Set	MJSR-101	05690967817145		

Dear Össur customer,

Össur is conducting a Medical Device Recall of the above Miami J Select devices.

The potentially affected device has been supplied to your organization.

#### DEVICE ISSUE

It has been identified that the pressure sensitive adhesive (PSA) hooks attached to the sides of the anterior collar panel can occasionally exhibit poor adhesion, which may lead to them gradually peeling off with repeated doffing, possibly leading to reduced immobilization of the cervical spine. These hooks attach to straps on the posterior panel of the collar.

No immobilization issues or injuries associated with this fault have been reported to date.

To ensure compliance we are initiating a device recall of all Miami J Select collars with lot numbers ranging from MX220516 to MX230104, sold in the period of 2022-05-19 to 2023-06-05. The affected lots are outlined in Appendix A at the end of this notice.

PICTURE OF THE AFFECTED DEVICE & LOT LOCATION

Lot numbers will be found on the product packaging label and in some cases on the product label.



The required actions in relation to this case are outlined below:

## ACTION - ORGANIZATIONS

**ACTION REQUIRED:** Please examine your inventory, quarantine devices subject to the recall, and return the Customer Acknowledgement Form to the email address listed on the form. A return authorization will then be provided to return the device to Össur.

Recipients of this notice should take the following actions:

- Please pass this notice to those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Maintain awareness on this notice for an appropriate period.
- If you have further distributed this device, please identify your customers, and notify them at once of this recall. We recommend that you include a copy of this recall letter.
- Össur recommends healthcare professionals perform a detailed inspection of the device to verify lot number, and to ensure structural stability for any patients' currently wearing impacted device.
- If any of your customers are currently wearing a device, the packaging label and product label should be inspected for the lot number:
  - If the lot number is outside of the affected range, no actions need to be taken.
  - If the lot number is inside the affected range or if the packaging label or lot number on the product label is not available, healthcare professionals are advised to contact customer service for replacement device.
- Complete and return the attached Customer Acknowledgement Form to the email address provided.

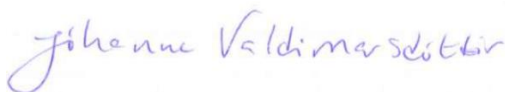
## ADDITIONAL COMMENT

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.

Please contact customer service for further information and assistance:

Össur sincerely regrets any inconvenience caused to your organization.



Jóhanna Valdimarsdóttir  
Vice President, Quality & Regulatory

Appendix A – Impacted Lot Numbers

Impacted Lot Numbers		
MX220516	MX220715	MX220905
MX220517	MX220716	MX220906
MX220519	MX220718	MX220907
MX220523	MX220719	MX220908
MX220524	MX220720	MX220909
MX220525	MX220721	MX220914
MX220526	MX220725	MX220915
MX220527	MX220726	MX220919
MX220530	MX220727	MX220920
MX220616	MX220728	MX220921
MX220617	MX220730	MX220922
MX220618	MX220801	MX220923
MX220620	MX220802	MX221003
MX220621	MX220803	MX221004
MX220622	MX220804	MX221005
MX220623	MX220805	MX221006
MX220624	MX220808	MX221007
MX220625	MX220809	MX221010
MX2206258	MX220810	MX221011
MX220627	MX220811	MX221012
MX220628	MX220812	MX221013
MX220629	MX220815	MX221017
MX220630	MX220816	MX221018
MX220701	MX220817	MX221019
MX220704	MX220818	MX221020
MX220705	MX220819	MX221021
MX220706	MX220822	MX221031
MX220707	MX220823	MX221101
MX220709	MX220824	MX221103
MX220711	MX220827	MX221107
MX220712	MX220831	MX221109
MX220713	MX220901	MX221110
MX220714	MX220902	MX230104