

## URGENT FIELD SAFETY NOTICE MEDICAL DEVICE RECALL

### MIAMI J SELECT – POTENTIAL DEFORMATION OF CHIN SUPPORT

May 2021

#### AFFECTED DEVICES

##### Miami J Select

Item No.	Description
MJS-101	Miami J Select Collar
MJSR-101	Miami J Select Collar Set

Affected Lot Numbers: MX180425 through MX200306.

Note: Lot numbers will be found on the product packaging label.

#### DEVICE ISSUE

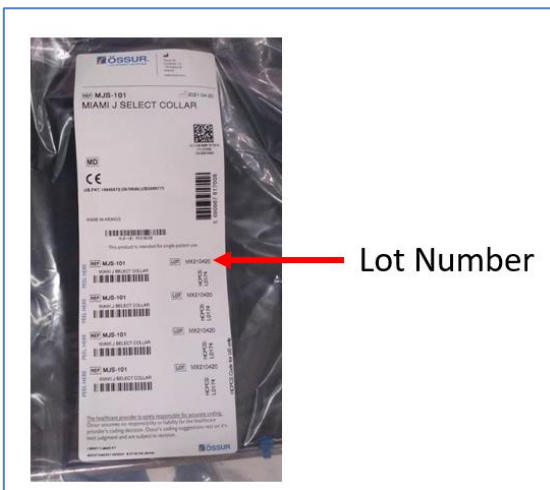
Össur is implementing an Urgent Medical Device Recall in relation to the Miami J Select device. It has been identified that Miami J Select devices with the affected lot numbers may deform under certain conditions, possibly leading to reduced immobilization of the cervical spine. The likelihood of deformation is higher when in use at higher height configurations. Further, the risk of deformation increases with the number of days the device is worn. No injuries associated with this fault have been reported to date.

To ensure compliance we are initiating a product recall of all Miami J Select collars with lot numbers from MX180425 through MX200306.

#### PICTURE OF THE AFFECTED DEVICE



#### PICTURE OF THE PACKAGING LABEL



The recommended actions outlined in relation to this case are outlined as follows:

## ACTION - ORGANISATIONS

**ACTION REQUIRED:** Please examine your inventory, quarantine products 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 product to Össur.

**ADDITIONAL ACTION REQUIRED:** Recipients of this notice should take the following actions:

1. Please pass this notice to those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
2. Maintain awareness on this notice for an appropriate period.
3. If you have further distributed this product, please identify your customers, and notify them at once of this recall. We recommend that you include a copy of this recall letter.
4. Ossur recommends healthcare professionals perform a detailed inspection of the device to verify lot number, and to ensure proper fit and structural stability for any patients' current wearing impacted product.
5. If any of your customers are currently wearing a product, the packaging label should be inspected for the lot number (Note: The number inside the collar is not the lot number; that is the device serial 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, healthcare professionals are advised to assess whether a removal and replacement of impacted product currently in use is warranted on a case-by-case basis.
  - If the packaging label/lot number is not available, healthcare professionals are advised to assess whether a removal and replacement of the impacted product currently in use is warranted on a case-by-case basis.
6. Complete and return the attached Customer Acknowledgement Form to the email address provided.

This notice is to be communicated to all those within your organisation, and to any other organisation where affected devices may have been provided or serviced.

Please maintain awareness of this notice and recommended actions.

Please contact customer service for further information and assistance. A list of the contact numbers is provided at the end of this notice.



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