

URGENT FIELD SAFETY NOTICE

MIAMI J SELECT – INSTRUCTIONS FOR USE

FSCA – 022021

ADDITIONAL USER INSTRUCTIONS & SAFETY WARNINGS

October 2021

AFFECTED DEVICES

Miami J Select

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

ISSUE

Össur is committed to providing safe, high-quality medical devices to its customers. Whilst Össur has not received any reports of injury related to the Miami J Select, it has been identified that the Instructions for Use require additional information to facilitate the selection and use of the device. As such, Össur is implementing a Field Safety Corrective Action in relation to the Instructions for Use for the Miami J Select device.

To ensure compliance the Instructions for Use (Rev. 3 2018) have been updated to include the additional information required (Rev. 6 2021).

PICTURE OF THE AFFECTED DEVICE



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

ACTION - ORGANISATIONS

ACTION REQUIRED:

1. Please ensure the updated Instructions for Use are distributed to the necessary persons within the organisation and that they are adhered to when selecting and using the Miami J Select device. A copy of the updated instructions accompanies this notice.
2. Please pass this notice to those who need to be aware within your organisation or to any organisation where the listed devices have been transferred.
3. Please retain this letter in a prominent position for one month.
4. If you have further distributed this product, please identify your customers, and notify them at once of this Field Safety Notice. We recommend that you include a copy of this notice.
5. Complete and return the attached Customer Acknowledgement Form to the address provided, even if your facility is no longer in possession of a Miami J Select device as we require this information to reconcile this process.

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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Vice President, Quality & Regulatory

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