

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

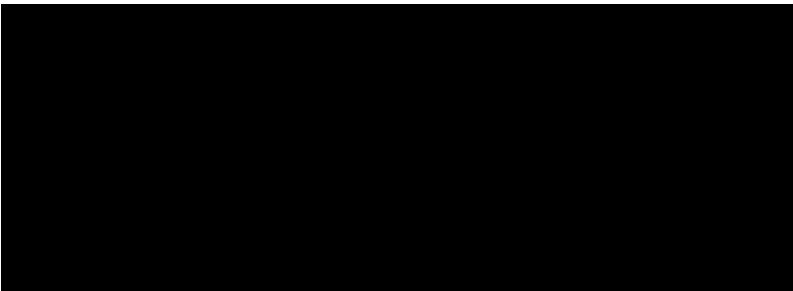
ACTION REQUIRED:

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.



Country	Office	Phone Number
AUSTRALIA	Melbourne	1300 123 268
AUSTRIA	Germany	+49 (0) 2234 6039 102
BELGIUM	Eindhoven	0800 - 70927
BRAZIL	Brazil	+55 51 3377 8355
CANADA	Richmond	1-800-663-5982
CANARY ISLANDS	Iberia	00800 3539 3668
CHILE	Foothill Ranch	+1 949-532-7300
CHINA	Shanghai	+(86 21) 6127 1700
CURACAO	Foothill Ranch	+1 949-532-7300
CYPRUS	Eindhoven	00800 161 220 67300
CZECH REPUBLIC	Czech Republic	800 142 005
DENMARK	Nordic	+ 46 1818 2200
FINLAND	Nordic	+ 46 1818 2200
GERMANY	Germany	+49 (0) 2234 6039 102
HONDURAS	Foothill Ranch	+1 949 382 3899
HONG KONG	Shanghai	+852 2331 8166
ICELAND	Nordic	+46 18 18 23 80
INDIA	New Delhi	1-800-3000-6220
IRELAND	UK	+44 (0)3450 065 065
JAPAN	Tokyo	+81 (03) 4588 8135
JERSEY	UK	+ 44 161 475 6320
KOREA	Seoul	+(82-02)-868-5482
LUXEMBOURG	Eindhoven	00800 3539 3668
MALAYSIA	Singapore	+65 6397 7190
MEXICO	Tijuana	+52 664 748 0135
NAMIBIA	South Africa	+27 (0)21 9818979
NETHERLANDS	Eindhoven	00800 3539 3668
NEW ZEALAND	Melbourne	+61 3 8761 6408
NORWAY	Nordic	+ 46 1818 2200
PANAMA	Foothill Ranch	+1 949 382 3899
PHILIPPINES	Shanghai	+(86 21) 6127 1700
POLAND	Eindhoven	00800 3539 3668
PUERTO RICO	Foothill Ranch	+1 949-532-7300
ROMANIA	Eindhoven	0800 360 134
SINGAPORE	Singapore	+65 6397 7190
SOUTH AFRICA	South Africa	+27 (0)21 9818979
SPAIN	Iberia	00800 3539 3668
SWEDEN	Nordic	+ 46 1818 2200
SWITZERLAND	Switzerland	+41 (0)800 344 000
TAIWAN	Shanghai	+86 21 6127 1747
UKRAINE	Eindhoven	00800 022 1738
UNITED KINGDOM	UK	+44 (0)3450 065 065
UNITED STATES	Foothill Ranch	1-800-233-6263