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# IMPORTANT DEVICE CORRECTION

## Össur Notification Regarding Products Containing Natural Rubber Latex – Miami J

Dear Customer,

Össur is committed to providing safe and effective products to all of our customers around the world. We are sending this message because we have become aware that the products associated with this alert contained components with undeclared natural rubber latex. Latex is a known allergen which can lead to allergic reactions in persons sensitive to latex. No injuries have been reported to date.

The following products contain undeclared natural rubber latex.

### Device Correction REQUIRED:

Miami J Collar assist strap located in the patient pack (lot numbers before MX150727)

**ACTION REQUIRED:** Össur Miami J® Cervical Collars with lot numbers before MX150727 please remove and discard the assist strap, which contains natural rubber latex, located in the patient pack

### ADDITIONAL ACTION REQUIRED:

Recipients of this notice with should take the following actions:

1. 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.
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 product alert. We recommend that you include a copy of this alert notification letter.
4. If any of your customers are currently wearing a product, check for any skin irritations or other reactions consistent with natural rubber latex allergies.
5. After reviewing this document, please visit [safetyalerts.ossur.com](https://safetyalerts.ossur.com) to complete the Össur Response Survey. We will use those responses to verify that your organization has received this notification.

The specific product components with latex are identified in the images at the end of this alert.  
If you have any questions, please contact Össur Customer Service at 0845 009 8098.

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.

This product notification is being made with the knowledge of the relevant Health Authorities.

Hulda Hallgrímsdóttir  
 VP Quality & Regulatory



Miami J® Cervical  
 Collars Assist Strap

#### Item References

Article No.	Description
MJ-200B	MIAMI J BARIATRIC COLLAR
MJ-200L	MIAMI J COLLAR STOUT
MJ-200LFRT	MIAMI J COLLAR STOUT FRT ONLY
MJ-200S	MIAMI J COLLAR SUPER SHORT
MJ-200SFRT	MIAMI J COLLAR SS FRONT ONLY
MJ-250	MIAMI J COLLAR XS
MJ-250FRT	MIAMI J COLLAR XS FRONT ONLY
MJ-2530	MIAMI J COLLAR XS FRT SML BK
MJ-300	MIAMI J COLLAR SHORT
MJ-300FRT	MIAMI J COLLAR SHORT FRT ONLY
MJ-400	MIAMI J COLLAR REGULAR
MJ-400FRT	MIAMI J COLLAR REG FRONT ONLY
MJ-500	MIAMI J COLLAR TALL
MJ-500FRT	MIAMI J COLLAR TALL FRT ONLY
MJ-P2	MIAMI J COLLAR P2
MJ-P3	MIAMI J COLLAR P3
MJR-200L	MJ COLLAR STOUT W/ REPLMNT PAD
MJR-200S	MJ COLLAR SS W/ REPLMNT PAD
MJR-250	MJ COLLAR XS W/ REPLMNT PAD
MJR-2530	MJ COLLAR XS/SML W/ REPLMT PAD
MJR-300	MJ COLLAR SHORT W/ REPLMNT PAD
MJR-400	MJ COLLAR REG W/ REPLMNT PAD
MJR-500	MJ COLLAR TALL W/ REPLMNT PAD
MJR-P2	MJ COLLAR P2 W/ REPLMNT PAD
MJR-P3	MJ COLLAR P3 W/ REPLMNT PAD