

URGENT

Össur Papoose® Infant Spine Immobilizers Recall

Dear Customer,

Össur is committed to providing safe and effective products to all of our customers around the world. Though we are not aware of any injuries and have not received a single complaint we are sending this message because we have identified 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 product contains undeclared natural rubber latex:

Papoose® Infant Spine Immobilizers

Part numbers affected:

PA-100 Papoose

PAR-100 Papoose w/replace pads

PO-100 Papoose w/o P0 FRT

POR-100 Papoose w/o P0 FRT w/pad

This recall has been initiated due to the use of natural rubber latex in the leg (Perineal) strap associated with this Össur product line.

ACTION REQUIRED: Please examine your inventory, quarantine products subject to the recall and contact customer service for a return authorization to return the product to Össur.

Please note: Papoose Infant Spine Immobilizers only requires recall for lot numbers before MX150727.

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 product recall.
4. If any of your customers are currently wearing a product, we recommend replacing that unit with one shipped after the transition lot number MX150727. Please check for any skin irritations or other reactions consistent with natural rubber latex allergies.

All new product shipments commencing with lot number (MX150727) do not contain natural rubber latex.

If you have any questions, please contact Össur Customer Service at 08450098098.

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

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

Hulda Hallgrímsdóttir

VP Quality & Regulatory

Picture of component containing Natural Rubber

Latex



Leg (Perineal) Strap
