



URGENT

ÖSSUR LIL'ANGEL HALO VEST RECALL

March 1, 2016

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 may show a partial or complete fracture of the plastic stabilizer strap on the vest. The stabilizing straps are important to maintaining cervical immobilization. No injuries have been reported to date.

The following product may be at risk of failure:

Lil'Angel Halo Vest Affected Part Numbers:

545100K	Vest with Kodel liner
545100L	Vest with Lambswool liner
545100S	Vest with Sorbatex liner
545150K	Vest with Kodel liner
545150L	Vest with Lambswool liner
545150S	Vest with Sorbatex liner

This recall has been initiated due to the potential partial or complete fracture of the plastic stabilizer strap on the vest associated with this Össur product.

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.

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 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 a detailed inspection of the product vest structure to ensure there is no visible cracks on the vest.



Össur will re-instate sales of this product by April 8, 2016.
Please contact Össur Customer Service for a return authorization at:

Country	Office	Phone Number
AUSTRIA	Germany	+49 (0) 2234 6039 102
BELGIUM	Eindhoven	+31 (0) 499 462 840
CYPRUS	Greece	+30 210 90 24 115
DENMARK	Nordic	+ 46 1818 2200
FRANCE	Eindhoven	+31 (0) 499 462 840
GERMANY	Germany	+49 (0) 2234 6039 102
ITALY	Eindhoven	+31 (0) 499 462 840
LEBANON	Eindhoven	+31 (0) 499 462 840
SAUDI ARABIA	Eindhoven	+31 (0) 499 462 840
SLOVENIA	Eindhoven	+31 (0) 499 462 840
SOUTH AFRICA	South Africa	+27 (0)21 9818979
SPAIN	Iberia	00 800 3539 3668
TURKEY	Eindhoven	+31 (0) 499 462 840
UNITED KINGDOM	UK	+44 (0)8450 065 065
UNITED STATES	Foothill Ranch	1-800-233-6263
CHINA	Shanghai	86 021-6127-1707
JAPAN	Tokyo	86 21 6127 1707
AUSTRALIA/NEW ZEALAND	Melbourne	61 3 8761 6408
INDIA	New Delhi	800 3000 6220
KOREA	Seoul	02 868 5482
SINGAPORE	Singapore	65-6397-7190
MALAYSIA	Shanghai	86 21 6127 1747
TAIWAN	Shanghai	86 21 6127 1747
HONG KONG	Shanghai	86 21 6127 1747
PHILIPPINES	Shanghai	86 21 6127 1747
THAILAND	Shanghai	86 21 6127 1747
MEXICO	Foothill Ranch	1-800-233-6263
SRI LANKA	New Delhi	800 3000 6220
DOMINICAN REPUBLIC	Foothill Ranch	1-800-233-6263

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 Food and Drug Administration.

Hulda Hallgrímsdóttir
VP Quality & Regulatory



Picture of breakage point for Lil'Angel Halo Stabilizing Strap:

