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# IMPORTANT DEVICE CORRECTION

## Össur Notification Regarding Products Containing Natural Rubber Latex

Dear Customer,

Össur is committed to providing safe and effective products to all of our customers around the world. Subsequent to previous identification of latex in some products, we conducted a thorough review of the entire supply chain to ensure safety in relation to this topic and discovered further latex content in some products. 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:

Thermobrace  
Assist 8 Extra  
Duo Standard Belt  
Dual Maternity Belt  
Double Shoulder Brace  
Wrist/thumb brace elastic  
Velastic Plus  
Wrist/thumb brace neoprene  
Wrist/thumb wrap abducted  
Elastic Thumb Spica  
Simpla Wrist Brace  
Thermowrap knee sleeves/wraps  
Temp hernia Support (Custom only)  
Fabric Hip Spica  
Thomas Splint Traction Kit (Adult & Paediatric Adhesive)

**ACTION REQUIRED:** Include the latex caution notice in any existing inventory of affected products.

The latex caution notices can be retrieved at the conclusion of the response survey or by going directly to [advisorynotice.ossur.com](https://www.ossur.com). Should you require Össur to provide pre-printed notices for your existing inventory, please contact Össur customer service.

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**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 organisation 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 [advisorynotice.ossur.com](https://advisorynotice.ossur.com) to complete the Össur Response Survey. We will use those responses to verify that your organisation has received this notification.

All new product shipments containing latex will now include the proper natural rubber latex caution notice.

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

Article No.	Description
0442	FABRIC HIP SPICA M/L
0443	FABRIC HIP SPICA L/L
0446	FABRIC HIP SPICA S/R
0447	FABRIC HIP SPICA M/R
0448	FABRIC HIP SPICA L/R
0692	DOUBLE SHOULDER BRACE XS
0693	DOUBLE SHOULDER BRACE S
0695	DOUBLE SHOULDER BRACE M
0697	DOUBLE SHOULDER BRACE L
0698	DOUBLE SHOULDER BRACE XL
0292+/HE	T/WRAP & H/E STRAPS XS
0293+/HE	T/WRAP & H/E STRAPS S
0295+/HE	T/WRAP & H/E STRAPS M
0297+/HE	T/WRAP & H/E STRAPS L
0298+/HE	T/WRAP & H/E STRAPS XL
130/WB/SGL	T/BRACE 7IN W/B (SINGLE) XS/L
130/WB+	T/BRACE 7IN W/B XS/L (5PC)
131/WB/SGL	T/BRACE 7IN W/B (SINGLE) S/L
131/WB+	T/BRACE 7IN W/B S/L (5PC)
132/WB/SGL	T/BRACE 7IN W/B (SINGLE) M/L
132/WB+	T/BRACE 7IN W/B M/L (5PC)
133/WB/SGL	T/BRACE 7IN W/B (SINGLE) L/L
133/WB+	T/BRACE 7IN W/B L/L (5PC)
134/WB/SGL	T/BRACE 7IN W/B (SINGLE) XL/L
134/WB+	T/BRACE 7IN W/B XL/L (5PC)
135/WB/SGL	T/BRACE 7IN W/B (SINGLE) XS/R
135/WB+	T/BRACE 7IN W/B XS/R (5PC)
136/WB/SGL	T/BRACE 7IN W/B (SINGLE) S/R
136/WB+	T/BRACE 7IN W/B S/R (5PC)
137/WB/SGL	T/BRACE 7IN W/B (SINGLE) M/R
137/WB+	T/BRACE 7IN W/B M/R (5PC)
138/WB/SGL	T/BRACE 7IN W/B (SINGLE) L/R
138/WB+	T/BRACE 7IN W/B L/R (5PC)
139/WB/SGL	T/BRACE 7IN W/B (SINGLE) XL/R
139/WB+	T/BRACE 7IN W/B XL/R (5PC)
150/ET	ELASTIC W/T BRACE XS/L
151/ET	ELASTIC W/T BRACE S/L
152/ET	ELASTIC W/T BRACE M/L
153/ET	ELASTIC W/T BRACE L/L
154/ET	ELASTIC W/T BRACE XL/L
155/ET	ELASTIC W/T BRACE XS/R
156/ET	ELASTIC W/T BRACE S/R
157/ET	ELASTIC W/T BRACE M/R
158/ET	ELASTIC W/T BRACE L/R
159/ET	ELASTIC W/T BRACE XL/R
160/NT	NEOPRENE W/T BRACE XS/L
161/NT	NEOPRENE W/T BRACE S/L
162/NT	NEOPRENE W/T BRACE M/L
163/NT	NEOPRENE W/T BRACE L/L
164/NT	NEOPRENE W/T BRACE XL/L
165/NT	NEOPRENE W/T BRACE XS/R
166/NT	NEOPRENE W/T BRACE S/R
167/NT	NEOPRENE W/T BRACE M/R
168/NT	NEOPRENE W/T BRACE L/R
169/NT	NEOPRENE W/T BRACE XL/R

Article No.	Description
184/AW	ABDUCTED W/T WRAP S/L
185/AW	ABDUCTED W/T WRAP M/L
186/AW	ABDUCTED W/T WRAP L/L
187/AW	ABDUCTED W/T WRAP S/R
188/AW	ABDUCTED W/T WRAP M/R
189/AW	ABDUCTED W/T WRAP L/R
191/TS	ELASTIC THUMB SPICA S/L
192/TS	ELASTIC THUMB SPICA M/L
193/TS	ELASTIC THUMB SPICA L/L
194/TS	ELASTIC THUMB SPICA XL/L
196/TS	ELASTIC THUMB SPICA S/R
197/TS	ELASTIC THUMB SPICA M/R
198/TS	ELASTIC THUMB SPICA L/R
199/TS	ELASTIC THUMB SPICA XL/R
210/WB/SGL	SIMPLA 7IN W/B (SINGLE) XS/L
210/WB+	SIMPLA 7IN WRST BRACE XS/L (6)
211/WB/SGL	SIMPLA 7IN W/B (SINGLE) S/L
211/WB+	SIMPLA 7IN WRIST BRACE S/L (6)
212/WB/SGL	SIMPLA 7IN W/B (SINGLE) M/L
212/WB+	SIMPLA 7IN WRIST BRACE M/L (6)
213/WB/SGL	SIMPLA 7IN W/B (SINGLE) L/L
213/WB+	SIMPLA 7IN WRIST BRACE L/L (6)
214/WB/SGL	SIMPLA 7IN W/B (SINGLE) XL/L
214/WB+	SIMPLA 7IN WRST BRACE XL/L (6)
215/WB/SGL	SIMPLA 7IN W/B (SINGLE) XS/R
215/WB+	SIMPLA 7IN WRST BRACE XS/R (6)
216/WB/SGL	SIMPLA 7IN W/B (SINGLE) S/R
216/WB+	SIMPLA 7IN WRIST BRACE S/R (6)
217/WB/SGL	SIMPLA 7IN W/B (SINGLE) M/R
217/WB+	SIMPLA 7IN WRIST BRACE M/R (6)
218/WB/SGL	SIMPLA 7IN W/B (SINGLE) L/R
218/WB+	SIMPLA 7IN WRIST BRACE L/R (6)
219/WB/SGL	SIMPLA 7IN W/B (SINGLE) XL/R
219/WB+	SIMPLA 7IN WRST BRACE XL/R (6)
221/VLP	VELASTIC PLUS XS
222/VLP	VELASTIC PLUS S
223/VLP	VELASTIC PLUS M
224/VLP	VELASTIC PLUS L
225/VLP	VELASTIC PLUS XL
256/LS	ASSIST 8IN EXTRA SPT S
257/LS	ASSIST 8IN EXTRA SPT M
258/LS	ASSIST 8IN EXTRA SPT L
259/LS	ASSIST 8IN EXTRA SPT XL
331/MS	DUAL MATERNITY BELT 90 96
332/MS	DUAL MATERNITY BELT 96 102
333/MS	DUAL MATERNITY BELT 102 108
334/MS	DUAL MATERNITY BELT 108 116
335/MS	DUAL MATERNITY BELT 116 126
336/MS	DUAL MATERNITY BELT 126 136
337/MS	DUAL MATERNITY BELT 136 146
338/MS	DUAL MATERNITY BELT 146 156
TSTK1	THOMAS SPL TRAC KIT ADH-PAED
TSTK2	THOMAS SPL TRAC KIT ADH-ADULT
CTM-00001	Custom Spinal



Fabric Hip Spica



Double Shoulder  
Brace



Thermowrap™  
Knee Brace



Thermobrace™  
Wrist Brace



Wrist/Thumb Brace  
Elastic & Neoprene



Elastic Thumb Spica



Abducted  
Wrist/Thumb Wrap



Simpla™ Wrist  
Brace



Velastic™ Plus



Assist 8 Extra™



Dual Maternity Belt



Thomas Splint  
Adhesive Traction Kit



Temporary Hernia  
Support (Custom Only)