

URGENT DEVICE CORRECTION

Össur Notification Regarding Products Containing Natural Rubber Latex

February 26, 2016

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 products contain undeclared natural rubber latex (see Attachment A for a list of product numbers).

DEVICE CORRECTION REQUIRED: PRODUCT GROUP 1

Knee Shield / Patella Cup
Knee Undersleeve Gray
NecLoc® Extrication Collar (Lot numbers before MX151001)
Rebound® Cartilage
Rebound® Cartilage Custom
Rebound® Air Walker
Rebound® Diabetic Walker
Back Support Suspenders Clip on Black
Back Support Suspenders Sew On Black
Extreme® Custom
Unloader® Custom XT
Unloader® Custom Lite
Unloader® Custom

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

Please note: Necloc Collar only requires device correction for lot numbers before MX151001.

The latex caution notice can be retrieved at the conclusion of the response survey or by going directly to safetyalerts.ossur.com. Should you require Össur to provide pre-printed notices for your existing inventory, please contact Össur customer service.

DEVICE CORRECTION REQUIRED: PRODUCT GROUP 2

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: PRODUCT GROUP 1 & 2

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 affected devices have been transferred.
2. Maintain awareness on this notification for an appropriate period.
3. If you have further distributed these products, 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. To verify you have received this notification, please visit safetyalerts.ossur.com to complete the Response Survey.

The specific product components with latex are identified in the images at the end of this alert.

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

If you have any questions, please contact Össur Customer Service at (800) 233-6263.

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 Food and Drug Administration.

Hulda Hallgrímsdóttir
VP Quality & Regulatory

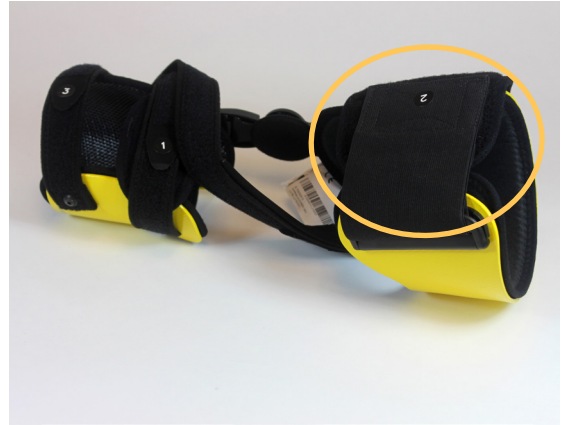
Pictures of components containing Natural Rubber Latex



Miami J® Cervical Collars Assist Strap



Necloc® Extrication Collars Attached Assist Strap



Unloader® Custom. Unloader® XT
Unloader® Extreme



Rebound® Diabetic Walker



Rebound® Air Walker



Rebound® Cartilage Wraparound



Rebound® Cartilage Wraparound

Pictures of components containing Natural Rubber Latex



Knee Undersleeve



Knee Shield



Suspenders Clip On



Suspenders Sew On

ÖSSUR SAFETY ALERTS ATTACHMENT A

Item no.	Description
10912	SUSPENDERS CLIP ON BLACK
10913	SUSPENDERS SEW ON BLACK
B-102500010	UNLOADER XT RIGHT
B-102500020	UNLOADER XT R
B-102600010	UNLOADER XT LEFT
B-102600020	UNLOADER XT L
B-107500020	UNLOADER LITE R
B-107600020	UNLOADER LITE L
B-108500010	EXTREME RIGHT
B-108500020	EXTREME R
B-108600010	EXTREME LEFT
B-108600020	EXTREME L
B-112500010	HALF KAFO EXTREME RIGHT US VER
B-112600010	HALF KAFO EXTREME LEFT US VER
B-122500020	UNLOADER CUSTOM RIGHT
B-122600020	UNLOADER CUSTOM LEFT
B-123500020	EXTREME CUSTOM RIGHT
B-123600020	EXTREME CUSTOM LEFT
B-154500001	REBOUND CRT CUSTOM RIGHT
B-154600001	REBOUND CRT CUSTOM LEFT
B-154700001	REBOUND CRT FX CUSTOM RIGHT
B-154800001	REBOUND CRT FX CUSTOM LEFT
B-242500002	REBOUND DIABETIC WALKER SM
B-242500003	REBOUND DIABETIC WALKER MD
B-242500004	REBOUND DIABETIC WALKER LG
B-242500005	REBOUND DIABETIC WALKER XL
B-242900001	REBOUND AIR WALKER XS
B-242900001E	REBOUND AIR WALKER XS - EU STAND
B-242900001SE	REBOUND AIR WALKER XS - EU SLIM
B-242900002	REBOUND AIR WALKER SM
B-242900002E	REBOUND AIR WALKER SM - EU STAND
B-242900002SE	REBOUND AIR WALKER SM - EU SLIM
B-242900003	REBOUND AIR WALKER MD
B-242900003E	REBOUND AIR WALKER MD - EU STAND
B-242900003SE	REBOUND AIR WALKER MD - EU SLIM
B-242900004	REBOUND AIR WALKER LG
B-242900004E	REBOUND AIR WALKER LG - EU STAND
B-242900004SE	REBOUND AIR WALKER LG - EU SLIM
B-242900005	REBOUND AIR WALKER XL
B-242900005E	REBOUND AIR WALKER XL - EU STAND
B-242900005SE	REBOUND AIR WALKER XL - EU SLIM
B-242900061	REBOUND AIR WALKER LOW TOP XS
B-242900061E	REBOUND AIR WALKER LOW TOP XS
B-242900061SE	REBOUND LOW TOP XS - EU SLIM
B-242900062	REBOUND AIR WALKER LOW TOP SM
B-242900062E	REBOUND AIR WALKER LOW TOP SM
B-242900062SE	REBOUND LOW TOP SM - EU SLIM
B-242900063	REBOUND AIR WALKER LOW TOP MD
B-242900063E	REBOUND AIR WALKER LOW TOP MD
B-242900063SE	REBOUND LOW TOP MD - EU SLIM
B-242900064	REBOUND AIR WALKER LOW TOP LG
B-242900064E	REBOUND AIR WALKER LOW TOP LG
B-242900064SE	REBOUND LOW TOP LG - EU SLIM
B-242900065	REBOUND AIR WALKER LOW TOP XL
B-242900065E	REBOUND AIR WALKER LOW TOP XL
B-242900065SE	REBOUND LOW TOP XL - EU SLIM

Item no.	Description
B-250110000	KNEE SHIELD CUSTOM
B-250150201	OSSUR KNEE UNDERSLEEVE GRY XS
B-250150202	OSSUR KNEE UNDERSLEEVE GRY S
B-250150203	OSSUR KNEE UNDERSLEEVE GRY M
B-250150204	OSSUR KNEE UNDERSLEEVE GRY L
B-250150205	OSSUR KNEE UNDERSLEEVE GRY XL
B-250150206	OSSUR KNEE UNDERSLEEVE GRY XXL
B-254500001	REBOUND CRT RIGHT CUSTOM
B-254510002	REBOUND CRT RIGHT MEDIAL SM
B-254510003	REBOUND CRT RIGHT MEDIAL MD
B-254510004	REBOUND CRT RIGHT MEDIAL LG
B-254510005	REBOUND CRT RIGHT MEDIAL XL
B-254520002	REBOUND CRT RIGHT LATERAL SM
B-254520003	REBOUND CRT RIGHT LATERAL MD
B-254520004	REBOUND CRT RIGHT LATERAL LG
B-254520005	REBOUND CRT RIGHT LATERAL XL
B-254600001	REBOUND CRT LEFT CUSTOM
B-254610002	REBOUND CRT LEFT MEDIAL SM
B-254610003	REBOUND CRT LEFT MEDIAL MD
B-254610004	REBOUND CRT LEFT MEDIAL LG
B-254610005	REBOUND CRT LEFT MEDIAL XL
B-254620002	REBOUND CRT LEFT LATERAL SM
B-254620003	REBOUND CRT LEFT LATERAL MD
B-254620004	REBOUND CRT LEFT LATERAL LG
B-254620005	REBOUND CRT LEFT LATERAL XL
B-254700001	REBOUND CRT FX RIGHT CUSTOM
B-254710002	REBOUND CRT FX RIGHT MEDIAL SM
B-254710003	REBOUND CRT FX RIGHT MEDIAL MD
B-254710004	REBOUND CRT FX RIGHT MEDIAL LG
B-254710005	REBOUND CRT FX RIGHT MEDIAL XL
B-254720002	REBOUND CRT FX RIGHT LAT SM
B-254720003	REBOUND CRT FX RIGHT LAT MD
B-254720004	REBOUND CRT FX RIGHT LAT LG
B-254720005	REBOUND CRT FX RIGHT LAT XL
B-254800001	REBOUND CRT FX LEFT CUSTOM
B-254810002	REBOUND CRT FX LEFT MEDIAL SM
B-254810003	REBOUND CRT FX LEFT MEDIAL MD
B-254810004	REBOUND CRT FX LEFT MEDIAL LG
B-254810005	REBOUND CRT FX LEFT MEDIAL XL
B-254820002	REBOUND CRT FX LEFT LATERAL SM
B-254820003	REBOUND CRT FX LEFT LATERAL MD
B-254820004	REBOUND CRT FX LEFT LATERAL LG
B-254820005	REBOUND CRT FX LEFT LATERAL XL
B-254900070	RC CRT SLEEVELESS RM/LL
B-254900072	RC CRT WRAPAROUND SM RM/LL
B-254900073	RC CRT WRAPAROUND MED RM/LL
B-254900074	RC CRT WRAPAROUND LG RM/LL
B-254900075	RC CRT WRAPAROUND XL RM/LL
B-254900080	RC CRT SLEEVELESS LM/RL
B-254900082	RC CRT WRAPAROUND SM LM/RL
B-254900083	RC CRT WRAPAROUND MED LM/RL
B-254900084	RC CRT WRAPAROUND LG LM/RL
B-254900085	RC CRT WRAPAROUND XL LM/RL
B-700290002	RC CRT CPS KIT SM
B-700290003	RC CRT CPS KIT MED
B-700290004	RC CRT CPS KIT LG
B-700290005	RC CRT CPS KIT XL

ÖSSUR SAFETY ALERTS ATTACHMENT A

Item no.	Description
B-701000502	KIT STRAP CUSTOM UNLOADER XT
B-701000507	KIT STRAP CUSTOM UNLOADER LITE
B-701000508	KIT STRAP CUSTOM EXTREME
B-701290002	RC CRT STRAP KIT SM
B-701290003	RC CRT STRAP KIT MED
B-701290004	RC CRT STRAP KIT LG
B-701290005	RC CRT STRAP KIT XL
B-705000505	KIT STRAP/Liner CUSTOM UNL XT
B-705000506	KIT STRAP/Liner CUSTOM EXT
B-705000508	KIT STRAP/Liner CUSTOM LITE
B-709000500	KIT REPAIR EXTREME REFURB
B-709000502	KIT REPAIR XT REFURB
B-709000514	KIT REPAIR LITE REFURB
B-711130014	KIT PAT Cup V2 CTI XL-OBSOLETE
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
NL-200EL	NECLOC COLLAR STOUT
NL-250E	NECLOC COLLAR XS
NL-300E	NECLOC COLLAR SMALL
NL-400E	NECLOC COLLAR MEDIUM
NL-500E	NECLOC COLLAR LARGE
NL-P1	NECLOC COLLAR P1
NL-P2	NECLOC COLLAR P2
NL-P3	NECLOC COLLAR P3