

URGENT: Field Safety Notice LP Rotate

Recall 022015

Device Exchange

March 04 2015

Dear Sir/Madam,

This is to inform you of a product recall involving:

- **LP Rotate**, sizes 25-27 cat.1-6. Product numbers LRP062, LRF062, LRPU62, LRFU62. All from manufacturing lot number HF141022.



See enclosed picture of lot marking on the shock for ease in identifying defected products.

This recall has been initiated due to a defect discovered during assembly, where the threads of the outer tube of the shock module of LP Rotate are too short, resulting in insecure assembly. Use of the product may cause the patient to fall with continued use, as the shock module can become loose from the foot blade.

We began shipping this product on December 15th 2014.

Immediately examine your inventory and quarantine products subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

In case your customers are wearing a faulty product, we recommend scheduling a visit to have the product replaced with a new LP Rotate that is currently available. We will also organize a pick-up of the defected product when convenient.

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent your patient's injury.

This letter will be followed up with a phone call from customer service. If you have any question before that please call [REDACTED] (+44 8450 065 [REDACTED]).

This recall is being made with the knowledge of the MHRA.

[REDACTED]
Quality Assurance Director

Picture of where lot number is marked on product:

