

medi GmbH & Co. KG Medicusstraße 1 · D-95448 Bayreuth

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4. August 2014

Field Safety Notice

Voluntary recall medi Clutch Lock and medi Modular Clutch Lock

Dear XXXXX.

during our internal product tests of our medi Clutch Lock (Art. No. M.660.601, M.660.602) and our medi Modular Clutch Lock (Art. No. M.660.603) we recognized safety related variations.

The safety and the satisfaction of our customers and patients are most important to us. Therefore we decided to change the "locking device" of our above mentioned products.

In addition to this letter, you will receive an exchange locking device free of charge. The change of the locking device can be done easily in your or your customers facility by a certified CPO.

We ask you also to check your stock and change all the locks that are affected by our voluntary call back action.

Please be informed that a not changed locking device can cause a malfunction of the prosthesis and can result into injury of your clients.

Please change the locking device of the following lot numbers. You can find the lot numbers on the locking device, the red arrow shows the exact position of the lot number.

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medi Clutch Lock	medi Modular Clutch Lock
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- 1093	- 0293
- 2651	
- 2082	
- 2482	

We ask you to confirm the change of the "locking device" on the attached reply letter as well as forwarding the changed "locking device".

We are very sorry for the inconvenience and thank you for your cooperation.

Best regards,

medi GmbH & Co. KG

Mathias Leitloff Head of Product Management Medical Stefan Dormann Head of Service Center National

Attachments

1x reply letter

1x Instructions for exchange of locking device