

Safety Notice – Voluntary Product Recall

Product	Item number	Lot number
Support Ring, height 10 mm	15-8502/66	1249055
		1249056
		1230047

Problem description:

The affected support rings could not be placed over the stem with a diameter up to 18 mm. The reason is that the set screw was screwed too far into the inner diameter of the ring. Due to a press-thread it is not possible to screw the screw out of the ring.



The figure shows the inner diameter of the support ring with a protruding set screw with blunt tip (red arrow).

Figure 1: Support ring affected by the FSCA

Clinical consequences

Use of an affected support ring by removing the set screw can lead to the following effects:

- Deviation of the planned surgery procedure,
- Deviations of the planned and common bone cement technique. A bone cement compression with the support ring is not possible anymore and
- Metal debris, which might result from micromovements of the not fixed support ring.

Corrective action

Recall and replacement of the affected support rings.

Immediate actions:

- Should you have any of the affected support rings (lots 1249055, 1249056 and 1230047) in your inventory, please send the support rings back to Waldemar Link GmbH & Co. KG.
- Products affected by this recall are the item numbers (REF) listed in the reply fax together with the batch numbers (LOT) quoted.
- Replacement of the affected support rings will not incur any costs to you. Should you have a question on acquiring replacements for forthcoming surgeries, please contact your local sales representative or customer service for Link products. We would be grateful if you could return the fax reply to us in any event until the 15th April 2013, as documentation of the recall, even if you have none of the listed products in stock or if these products do not exhibit the defect in question.
- Please ensure that all users of the above products within your organization and other relevant persons have been notified of this **safety information**. If you have transferred the products to third parties, please pass on a copy of this information or notify the contact person indicated below.
- The responsible Authorities have been notified of this Field Safety Corrective Action.

Affected countries:

Belarus, China, Colombia, Germany, Great Britain, Italy, Poland, Russia, Sweden, Switzerland

Contact persons at Waldemar Link GmbH & Co. KG:

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