Safety Notice

Voluntary Product Recall – A-642100 FIXED OFFSET ADAP.14 5MM-9/16

ÖSSUR

Life Without Limitations

October 25, 2013

Dear Valued Customer,

Össur is implementing a worldwide voluntary recall of the A-642100 Fixed Offset Adapter. We have been able to successfully identify all customers affected by this recall. You are receiving this letter because we have on record that you received A-642100 January 1st 2008 or later.

Our decision to implement this recall is based on a finding that A-642100 can develop fatigue cracks in normal use over extended period of time and ultimately separate completely. Since there is hardly any visible or audible sign indicating potential breakage, Össur strongly recommends **retrieval of all A-642100 in the field**.

A-642100

No injuries resulting from this failure mode have been reported to the company so far.

Össur takes the issue of patient safety very seriously. Therefore, we are implementing a replacement program where all A-642100's sold July 1st 2011 and later will be substituted with a replacement component, which will be credited upon return of the suspect A-642100.
It is our intent to work with you to urge your patients who are wearing A-642100 to return to your office and obtain a replacement.

A-342430

Please note that A-642100 carries 12 months Limited Warranty. We understand that components are normally used for longer periods than that, regardless of warranties. Therefore and given the serious nature of the case, Össur decided to reach out with free replacement components up to approximately 2 years after purchase.

For A-642100's sold BEFORE July 1st 2011, please retrieve and replace with A-342430 as soon as possible. Össur will not credit these items upon return.

As noted above, continued use of the prosthetic may lead to patient injuries.

Össur is committed to providing superior customer service and we will do our utmost to minimize any inconvenience this may cause your practice. To ensure patient safety we kindly ask you to take the following action:

- Please identify the users of each of the A-642100 adapters, see attached list.
- Also, please check your inventory for any A-642100's you may have on hand but have not fitted on users.

A representative from customer service will be contacting you in the next few days to coordinate replacements.

Össur has informed the U.S. Food and Drug Administration and regulatory authorities in other countries of its decision to implement this voluntary recall of A-642100, which is an external prosthetic device, classified as a Class I medical device.

Thank you for your cooperation.

Sincerely,

[redacted]
Executive Vice President of Sales & Marketing / President of Sales and Marketing Asia