

FIELD SAFETY NOTICE

INCOMPATIBLE NON - ÖSSUR FEMALE ADAPTERS ON PROSTHETIC FEET

DATE

15.07.2015

AFFECTED DEVICES

Össur prosthetic feet with attached aluminum male adapter, see the product numbers in the table on page 3.

Talux®, Vari-Flex®, Vari-Flex® XC, Re-Flex Shock™, Re-Flex Rotate™

Cat 7 sizes 28 – 30

Cat 8 sizes 25 – 30

Cat 9 all sizes

Flex-Foot® Assure™, Balance™ Foot J

Cat 4 size 30

Cat 5 all sizes

ATTENTION

Össur customers who have purchased products with item numbers listed in the table on page 3.

Recent findings suggest that non-Össur female mating adapters connected to Össur ankle male pyramids have caused early failure of the male pyramid connector. This is due to incompatible geometry of the female mating adapters used and/or improper set up of the prosthesis.

The risk is evident in case of improper settings for higher categories and sizes.

Össur titanium/stainless componentry is recommended for these connections

ACTION

NEW PATIENTS

Ensure that the female mating adapter is an Össur adapter and the set-up is done according to the instructions for use. For secure fastening use the loctite recommended and apply rated torque twice.

CURRENT PATIENTS

Ensure that the female mating adapter in use is a compatible Össur adapter and the set-up has been done according to the instructions for use. If that is not the case both the male foot adapter and the female mating adapter should be replaced since metal fatigue may have begun already without any visual damage. For secure fastening use the loctite recommended and apply rated torque twice.

At this stage, only Össur female mating adapters have been tested for use with an Össur male foot adapter.

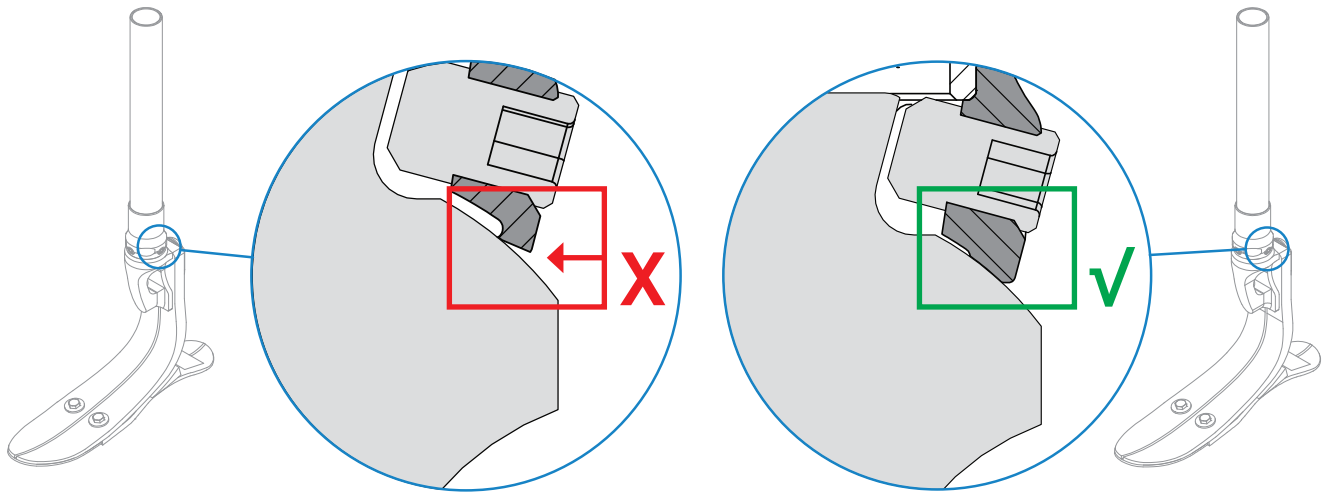


Figure 1. Incompatible non Össur female mating adapter vs. Compatible Össur female mating adapter.

BACKGROUND

Össur products and components are designed and tested according to the applicable official standards or an in-house defined testing process when no official standard applies. Compatibility and compliance with these standards are achieved only when Össur products are mated with other recommended Össur components.

This notice needs to be communicated to all those who need to be aware within your organisation and to any organisation where affected devices may have been provided or serviced.

Please maintain awareness of this notice and recommended actions.

Please contact customer service in this phone number for further information and assistance:

Tel: 0161 475 6320 / 08450 065 065

Jóhanna Valdimarsdóttir
Quality Assurance Director

