

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.



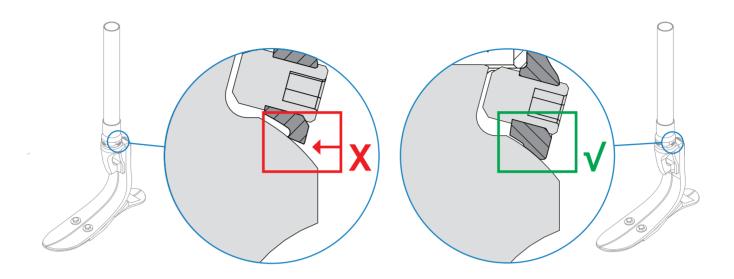


Figure 1. Incompatible non Össur female mating adapter vs. Compatible Össur female mating adapter.

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



AFFECTED DEVICES PART NUMBERS

Male pyramid for Flex-Foot Assure and Balance J when used with Cat 5 feet	Male Pyramid for Vari- Flex and Talux	Vari-Flex with Male pyramid	Vari-Flex with Male pyramid, Unity	Re-Flex Rotate Standard	Re-Flex Rotate Standard - Unity	Re-Flex Ro- tate High profile	Re-Flex Shock, High profile	Re-Flex Shock Standard Unity	Talux	Vari-Flex XC	Vari-Flex XC, Unity	Flex-Foot Assure	Flex-Foot Assure, Unity	Balance Foot J	Balance Foot J, Unity
SFX00165	FFC2210002	VFPE630	VFPU630	RSPE630	RSPE630	RHPE630	SHPE630	SSPU630	TLP0630L/R	XCPE630	XCPU630	FAPE430L/R	FAPU430L/R	JBPE430L/R	JBPU430L/R
	FFC2210001 (when used with cat 6, size 30)	VFPE727	VFPU727	RSPE727	RSPU727	RHPE727	SHPE727	SSPU727	TLP727L/R	XCPE727	XCPU727	FAPE525L/R	FAPU525L/R	JBPE525L/R	JBPU525L/R
		VFPE728	VFPU728	RSPE728	RSPU728	RHPE728	SHPE728	SSPU728	TLP0728L/R	XCPE728	XCPU728	FAPE526L/R	FAPU526L/R	JBPE526L/R	JBPU526L/R
		VFPE729	VFPU729	RSPE729	RSPU729	RHPE729	SHPE729	SSPU729	TLP0729L/R	XCPE729	XCPU729	FAPE527L/R	FAPU527L/R	JBPE527L/R	JBPU527L/R
		VFPE730	VFPU730	RSPE730	RSPU730	RHPE730	SHPE730	SSPU730	TLP0730L/R	XCPE730	XCPU730	FAPE528L/R	FAPU528L/R	JBPE528L/R	JBPU528L/R
		VFPE824	VFPU824	RSPE825	RSPU825	RHPE825	SHPE825	SSPU825	TLP0827L/R	XCPE825	XCPU825	FAPE529L/R	FAPU529L/R	JBPE529L/R	JBPU529L/R
		VFPE825	VFPU825	RSPE826	RSPU826	RHPE826	SHPE826	SSPU826	TLP0828L/R	XCPE826	XCPU826	FAPE530L/R	FAPU530L/R	JBPE530L/R	JBPU530L/R
		VFPE826	VFPU826	RSPE827	RSPU827	RHPE827	SHPE827	SSPU827	TLP0829L/R	XCPE827	XCPU827				
		VFPE827	VFPU827	RSPE828	RSPU828	RHPE828	SHPE828	SSPU828	TLP0830L/R	XCPE828	XCPU828				
		VFPE828	VFPU828	RSPE829	RSPU829	RHPE829	SHPE829	SSPU829		XCPE829	XCPU829				
		VFPE829	VFPU829	RSPE830	RSPU830	RHPE830	SHPE830	SSPU830		XCPE830	XCPU830				
		VFPE830	VFPU830				SHPE925	SSPU925		XCPE925	XCPU925				
		VFPE923	VFPU923				SHPE926	SSPU926		XCPE926	XCPU926				
		VFPE924	VFPU924				SHPE927	SSPU927		XCPE927	XCPU927				
		VFPE925	VFPU925				SHPE928	SSPU928		XCPE928	XCPU928				
		VFPE926	VFPU926				SHPE929	SSPU929		XCPE929	XCPU929				
		VFPE927	VFPU927				SHPE930	SSPU930		XCPE930	XCPU930				
		VFPE928	VFPU928												
		VFPE929	VFPU929												
		VFPE930	VFPU930												