

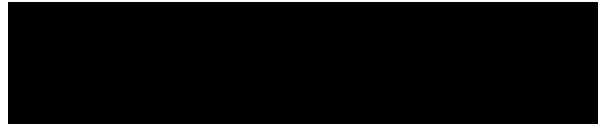
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**FCA Ref. No: Trumpf11**

## **Urgent Field Safety Notice**

### **Field Safety Corrective Action**

concerning

### **Double joint struts, OR Adapter, OR-Extension Manufactured prior to September 2004**

**Date:** March 3, 2016

**Attention:** Department of Medical Engineering, User

**Affected Products:**

<b>Name</b>	<b>Material-No.</b>	<b>Serial-No.</b>
Strut pair system	4544463	all
Double joint strut pair	4544466	up to 100165494
OR-EXTENSION SATURN FAMILIE	4545525	all
OR-EXTENSION SATURN System	4545526	all
OR Extension JUPITER	4545527	up to 100509155
OR-EXTENSION JUPITER V. 1	4545533	all
OR-EXTENSION JUPITER V. 2	4545534	all
OR-EXTENSION MARS V. 2	4545536	all
OR Adapter SATURN System	1242174	up to 100227640
OR Adapter JUPITER/TITAN	1259051	up to 100175030
Adapter for SATURN GE/GS	4544450	up to 100294053
Adapter for SATURN System	4544462	all
OR Adapter JUPITER	4544111	all
OR Adapter JUPITER	4544175	all
OR Adapter SATURN Select	4544342	up to 100169539
OR Adapter MARS	4544380	up to 100169300

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Amtsgericht München HRB 139265  
Managing Board: Simone Faath, Taylor Smith

Enhancing outcomes for  
patients and their caregivers!



**Description of the problem:**

Trumpf Medical surgical table accessories have been designed for a lifetime of 10 years. During this period we recommend to follow the maintenance recommendation mentioned in our user manual. Our internal testing results show that at the end of the product lifetime the double joint strut to the OR-adapter can become worn and less secure resulting in potential for the unintentional release of locking mechanisms. Trumpf Medical has received 3 complaints in the past 3 years related to product manufactured prior to September 2004 releasing without intention, which can result in a detached strut. No injury has been reported and this is unlikely to occur, but we find it our responsibility to inform you of this risk.

**Advice on Actions to be taken:**

Trumpf Medical is advising customers with products manufactured prior to September 2004 to stop the use of the equipment, which have exceeded their life expectancy. Trumpf Medical has new and updated solutions for Trauma and Orthopedics. Please contact your Trumpf Medical representative to quote a replacement option.

**Passing along this information:**

Please make sure that, in your organization, all users of the devices listed above as well as any other personnel who must be informed, have been made aware of this safety information. If you have provided devices to third parties, please forward them a copy of this information, or inform the contact person listed above.

**Confirmation of receipt:**

We have tracked the delivery of this letter as confirmation of receipt. We highly recommend executing these measures to guarantee patient safety and we ask for your understanding.

The appropriate National Competent Authorities have been informed of this notification.

Please contact your Trumpf Medical representative or Trumpf Medical Technical Customer Support with questions concerning this notification.

Best Regards,

