

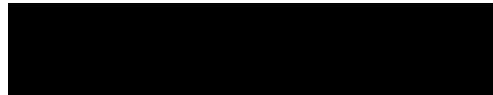
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Date September 2016

FSCA Ref. No.: TM1254

Urgent Field Safety Notice

Device Inspection

concerning

Operating Table Tops for Modular Exchangeable Table Top Systems

Please forward this information to all affected users and the medical technical department!

Dear customer,

with this letter we would like to inform you of a potential issue with our operating table tops which could result in a risk for patients. The potential failure is limited to the listed serial numbers, **other OR table tops are not affected by this corrective action.**

Material Numbers	Device Names	Serial Numbers
1909793	OR table top U26 H V	102394262 - 102974610
1909794	OR table top U26 H V U	102884276
1909796	OR table top U24 H V	102505944 - 102958989
1909797	OR table top U24 H V U	102757564 - 102958935
1909798	OR table top U24 H V W	102831498 - 102831519
1909799	OR table top U14 H V	102393683 - 102847352

Description of the problem including the determined cause:

Trumpf Medical has been informed of one event in which an OR table top failed to operate properly during a procedure. There was no harm associated with the event.

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TRUMPF Medizin Systeme GmbH + Co. KG, Sitz Saalfeld, Amtsgericht Jena HRA 502248
Unlimited Liability Partner: TRUMPF Medizin Systeme Beteiligungs-GmbH, Puchheim,
Amtsgericht München HRB 139265
Managing Board: Dr. Dirk H. Ehlers, Simone Faath

Enhancing outcomes for
patients and their caregivers:



If the failure will reoccur during a surgery the adjusted patient position cannot be changed or the OR table top cannot be removed from the OR table column. Emergency transfer is still possible as described in the user manual. Please note that the OR table column functions are not affected by the failure mode.

The root cause of the malfunction was identified to be a manufacturing error. We are not able to exclude the possibility that one of the above listed devices are also affected by the failure.

Actions to be taken by the customer:

To rule out the scenario described and in order to avoid any risk to patients, Trumpf Medical or an authorized service engineer will inspect the affected operating table tops and correct them if necessary.

You may continue to use the device until we are able to inspect the units. Only the longitudinal movement must not be activated to avoid the malfunction.

Trumpf Medical service or a Trumpf Medical authorized service engineer will be contacting you to arrange an appointment to carry out an inspection of your devices. Please help us to arrange setting up the visits by completing appendix 1 and returning it within one week.

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 **Urgent Field Safety Notice**. If you have provided devices to third parties, please forward them a copy of this notice, or inform the Trumpf Medical contact person you are aware of or contact the person listed above.

Please keep this notice at least until the action has been completed.

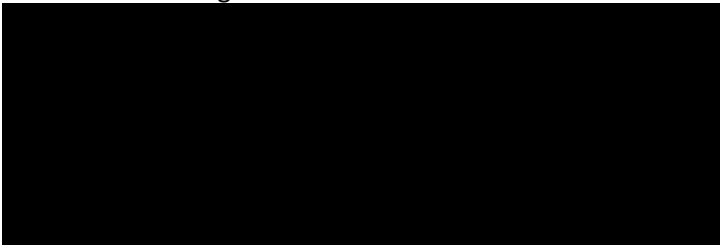
The appropriate Regulatory Agency has been received a copy of the Urgent Field Safety Notice.

Confirmation of receipt

Please confirm that you have received this Urgent Field Safety Notice by sending back the completed form listed in Appendix 1 within one week after the receipt of this letter. The on-time return will stop you from receiving further letters on this issue.

Trumpf Medical apologies for any inconvenience this action brings to and thank you for your assistance in the timely implementation of this Field Action.

With best regards



Enclosures:

Appendix 1 Confirmation of receipt

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Enhancing outcomes for
patients and their caregivers:



Appendix 1

Confirmation of receipt



Urgent Field Safety Notice Operating Table Tops for Modular Exchangeable Table Top Systems

Please return this confirmation within 1 week after receiving the safety information to:

Fax +49 (0) 3671 586 41487 or

E-mail med-service@trumpfmedical.com **(Subject: "TM1254")**

Please enter your address here:

- Affected devices are in use at this facility
- None of the affected devices are still in use at this facility
- Affected devices are no longer in use at this facility and was donated/resold (in this case, please provide any contact information available)

If any of the affected devices are in use, please state all serial numbers on page 2.

With your signature, you acknowledge that you have received the urgent safety information and understand the outlined risks.

Name in block capitals / position: _____

Tel.: _____ E-mail: _____

Date: _____ Signature: _____

Appendix 1

Confirmation of receipt



The following serial numbers are in use:
