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Date July 2016

FSCA Ref. No.: TM1251

Urgent Field Safety Notice

Device Modification

concerning

OR table column TruSystem7500/5500; OR table column ARTIS and OR table TruSystem 7000

Dear customer,

with this letter we would like to inform you of a potential issue with our operating tables. The problem can only occur at operating tables manufactured between 14-Feb-2013 and 20-Nov-2013. The potential failure is limited to one production batch of the main lift spindles. Other not listed OR-tables are not affected by this corrective action.

Potentially affected are the following 84 OR tables:

Material Number	Product Name	Serial Number
1717023	Mobile column TruSystem 7500	101281354; 101856082; 101858789; 101858794; 101861232; 101871990; 101871991; 101871994; 101871995; 101871998; 101872002; 101872003; 101875823; 101884649; 101884662; 101890660; 101890661; 101890683; 101895634; 101912771; 101912832; 101912833; 101912837; 101912838; 101916174; 101924149
1717020	Stationary column TruSystem 7500	101863421; 101863427; 101863433; 101875827; 101879148; 101879149; 101882031; 101884650; 101884651; 101884653; 101884654; 101890658; 101890659; 101895636; 101904999; 101907202; 101907203

1730732	Floor mounting column TS 7500 U	101900011; 101900018
1607822	Mobile column TruSystem 5500	101863428; 101875818; 101882033; 101882034; 101882037; 101882038; 101901949; 101901951; 101904490; 101904492; 101907204; 101907205; 101909370; 101909371; 101909372; 101909464; 102052657
1501878	Floor mounting column ARTIS	101904491; 101904998
1604788	Operating table TruSystem 7000 U	101863316; 101872464; 101879109; 101880571; 101880672; 101880673; 101928935; 101932527; 101937343; 101941055; 101941064; 101941995; 101942798; 101948309; 101954296; 102051758; 102051764
1604786	Operating table TruSystem 7000 U (MB)	101926753; 101928934; 101941978; 101941994;

Description of the problem including the determined cause:

Within the framework of our post market surveillance, we have been made aware of three complaints in which a malfunction of the main lift was described, while the operating table should be moved upwards.

The investigation of these incidents revealed abnormalities regarding the Trumpf Medical required consistent quality of the spindle fixing. Thereby, the strength of the fixing over the entire lifetime of the product cannot be guaranteed. Please note, that it may be caused by premature failure in an unintended position change.

Actions to be taken by the customer:

To rule out the scenario described and in order to avoid any possible risk to patients, you should not continue to use the above-mentioned operating table columns as long as to Trumpf Medical or an authorized service engineer has exchanged the spindles of the affected operating tables.

Trumpf Medical service or Trumpf Medical authorized service technicians will be contacting you to arrange an appointment to carry out the retrofitting free of charge.

This is a voluntary by Trumpf Medical initiated preventive action. Thus far, no event has been reported in which a person has been injured.

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.

We require executing these measures to guarantee patient and user safety and we ask for your understanding. 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

[redacted]

Enclosures:

Appendix 1 Confirmation of receipt