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FCA Ref. No: Trumpf8

Urgent Field Safety Information

concerning

Subject: Leg Holder HEAVY T pads

Dear Customer:

Within the framework of our product monitoring, we consider it our responsibility to inform you of the risks for patients which could arise when using:

Leg Holder HEAVY T (Material Number 1506318)

Description of the problem:

Trumpf Medical has received one complaint describing the temporary paresthesia of the patient leg (leg “falling asleep”) following the use of the Leg Holder HEAVY T. The reported incident occurred during surgery when the position of the pad shifted, causing the patient’s leg to rest on the plastic support plate located under the pad.

The investigation of this issue has determined the root cause is due to the improper manufacture of the Leg Holder HEAVY T pad. When this issue is present, the pad is able to shift and allow the leg of the patient to rest on the plastic support plate, which could lead to the temporary paresthesia.

Actions to be taken

1. Remove the current pad from operation.
2. Trumpf Medical will send out new pads to all customers to replace the old pads.
3. Upon receipt of the replacement pad, sign the Acknowledgement of Receipt form that will accompany the replacement product and send to Trumpf Medical for completion of this action.

www.Trumpfmedical.com

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: Simone Faath, Taylor Smith

Enhancing outcomes for
patients and their caregivers!

Hill-Rom

Passing along this information:

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

Confirmation of receipt:

Please confirm that you have received this Urgent Safety Information by sending back the completed form listed in Attachment 1. The on-time return will stop you from receiving further letters on this issue. We highly recommend executing these measures to guarantee patient safety and we ask for your understanding.

Best Regards,



Trumpf Medical

Attachment

Attachment 1: Confirmation of Receipt