Form

Urgent Medical Device Field Action

Document ID: 2020-013 v01
Date: 2021-02-11

Subject: Corrrective Action Magnus 1180 Operating Table Column

Products affected:

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Item number	Serial number	Manufacturing date
118001A0	1 - 3402	2006-10-16 – 2020-12-03
118001A1	1 - 384	2010-02-18 – 2016-05-31
118001B0	1 - 1028	2007-05-10 – 2020-07-14
118001B1	1 - 1264	2010-08-18 – 2020-11-24
118001B2	1 - 401	2012-07-09 – 2020-12-01
118001B3	3 - 74	2012-07-26 – 2020-11-19
118001B4	1 – 81	2015-12-21 – 2020-11-16
118001C0	2 - 1159	2006-07-15 – 2020-11-27
118001D0	2 - 762	2008-12-08 – 2020-11-27

Description of the issue

Under certain conditions, we have found that a problem may cause the operating table not to function as intended. The tables may develop a hydraulic leakage at the inclination function. This leakage leads to an unintended Trendelenburg or anti-Trendelenburg movement of the table top depending on patient positioning. This malfunction only exhibits when tilt movement is used. We are aware of instances where this problem led to patients having to be transferred to another OR table which prolonged the procedure.

Potential hazards

The malfunction may result in an unintended Trendelenburg or anti-Trendelenburg movement of the table top. Be aware that the patient may slip off the table top. In this case the patient should be transfered to another bed or operating table, which will result in a prologation of the intervention. If this occurs, the operating table shall taken out of service until a retrofit can be performed.

Precautions

The operating tables can be used in accordance to the instructions for use, with extra attention to the following:

- Visual and functional check is required to be performed before operation.
- Stop using faulty or defective operating tables and inform the Getinge - MAQUET representative.
- Try to prevent tilt movement when the patient is in extrem cranial positioning or at least accompany and safeguard the tilt movement to be directly on the spot in case of a malfunction of (anti-) Trendelenburg.

Corrective action

A solution to correct this issue has been developed. Getinge - MAQUET will initiate an immediate field action of all affected MAGNUS 1180 operating table column.

Products manufactured between November 2016 and December 2020 have the highest probability of a hydraulic leacage and will be retrofitted first.
Products manufactured between January 2014 and October 2016 will be retrofitted afterwards. The probability of a hydraulic leacage is lower with these products, but cannot be ruled out.
Products manufactured before January 2014 should be retrofitted at the end. For products that have been in operation since January 2014 or before the probability of a hydraulic leacage is very low.

You will be contacted by your Getinge - MAQUET sales or service representative to plan for the update of your device(s).

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your MAGNUS 1180 operating table column has been updated to ensure effectiveness of the corrective action.

Distribution

This Getinge - MAQUET Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action. In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge - MAQUET cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. Where required, the competent authorities concerned have been informed about this communication and issue.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please let us know.

Sincerely,

MAQUET GmbH

Digitally signed by Holger Ullrich
Reason: Approval
Date: 2021.02.11 17:31:44 +01'00'

Name

Director Quality Regulatory Compliance

Digitally signed by Mario Mühe
Reason: created
Date: 2021.02.11 17:22:54 +01'00'

Name

Safety Officer for Medical Devices / Person Responsible for Regulatory Compliance - PMS

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