Urgent Medical Device Field Action

APR-04-2024 | FA 2023-016 | Rev 02

Subject: FA 2023-016 – 100380A0 leg holder - 4 screws potentially missing

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	Getinge Order Reference	Serial number	Manufacturing date
100380A0	103065378	581, 582, 583, 584, 585	05.09.2023
100380A0	103066202	601, 602, 603, 604, 605	08.09.2023
100380A0	103066203	606, 607, 608, 609, 610	12.09.2023
100380A0	103067329	626, 627, 628, 629, 630	15.09.2023
100380A0	103067334	651, 652, 653, 654, 655	05.10.2023
100380A0	103083208	661, 662 ,663, 664, 665	13.10.2023
100380A0	103083209	686, 687, 688, 689, 690	20.10.2023
100380A0	103111968	696, 697, 698, 699, 700	30.10.2023
100380A0	103111979	716, 717, 718, 719, 720	13.11.2023
100380A0	103127381	723, 724, 725	15.11.2023
100380A0	103139834	744	01.12.2023
100380A0	103167375	756, 757, 758, 759, 760, 766, 767, 768, 769, 770	11.12.2023
100380A0	103200395	781, 782, 783, 784, 785, 786, 787, 788, 789, 790	18.12.2023
100380A0	103200397	811, 812, 813, 814	21.12.2023
100380A0	103200500	806, 807, 808, 809, 810, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830	22.12.2023
100380A0	103200501	831, 832, 833, 834, 835	11.01.2024
100380A0	103200505	836, 837, 838, 839, 840	12.01.2024
100380A0	103200506	846, 847, 848, 849, 850	19.01.2024
100380A0	103200507	866, 867, 868, 869, 870	25.01.2024
100380A0	103200508	861, 862, 863, 864, 865	29.01.2024
100380A0	103200509	883, 884, 885	02.02.2024
100380A0	103200510	901	13.02.2024
100380A0	103200511	906, 909	16.02.2024
100380A0	103240394	711, 713, 714, 715	22.03.2024

Record the total number of affected products currently located at your facility here please □ ___.

Form: SOP-0921-A7 rev2

Description of the issue

We have identified that an issue might prevent the devices listed above from performing as intended. Therefore, the device could break apart during surgery. We are currently not aware of any incidents where this issue has occurred in the field.

Potential hazards

This issue may stop the intended functioning of the device resulting in the leg of the patient falling down, so that in the worst case, the nerves in the patient leg may be overstretched.

Precautions

The user cannot easily detect the malfunction. Hence the device cannot be used in accordance with the instructions for use.
For safety reasons, the products should not be used until they have been checked by a Getinge service technician and corrected if necessary.

Corrective action

A solution that will correct this issue is available.
Getinge will initiate an immediate field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

Please complete and return the attached acknowledgement form and maintain awareness on this notice and related actions until your leg holder has been updated to ensure effectiveness of the corrective action.

Return it to DL-DE30-QRCFieldActionHandling@getinge.com, please.

Distribution

This Getinge Field 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 cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

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

Attachments:

- FA 2023-016 Reply Form (for customer)
- FA 2023-016 Confirmation of Distribution

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

Sincerely,

QcRM, Maquet GmbH
DL-DE30-QRCFieldActionHandling@getinge.com

Thomas Kanzler	Diana Gutekunst / Bastian Wiemer (Deputy)
LCC, Quality Compliance Engineer	PRRC; LQM / LQM (Deputy)

Reply Form

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Confirmation:

Please check the boxes below as appropriate. Make sure to tick the first box. Should you not understand the communication please reach us for guidance. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

- ☐ We have read the Field Safety Notice and we understand the communication and the required actions.
- ☐ The devices are in our use and located at the address this communication was sent to.
- ☐ The devices are in our use but in a location different from where this communication was sent to, namely: *
- ☐ We have sold / moved our devices to another facility. *

* New device location (if applicable)

Serial numbers at this new location: _____

_____

New Facility Name	Contact name / title	e-Mail address
New Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)

For device distributors only:

- ☐ We have checked our stock and quarantined inventory. We have reviewed the list of devices to identify any affected customers.
- ☐ We will share the list of devices, updated with customer details with Getinge in order to be able to report this information to the applicable authorities that request this information.

  - or -
- ☐ We will share the list of devices with Getinge after finalizing the field action, and identify the state of each device in the list.

Please return your completed form to:

Getinge market organisation	Contact name / title	e-Mail address
Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)