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Jeddah Scan Radiology Center
King's Road Tower - King's Road
Djeddah 180
Saudi Arabia

Reference: REG-2017-0010

June 1, 2017

Field Safety Notice

Urgent Medical Device Removal - Immediate Action Required

ROTH MOBELI grab handles used with EOS System

To our valued EOS Customers,

EOS imaging is initiating this Medical Device Removal of the ROTH MOBELI grab handles used with EOS System. To date, EOS imaging has received one complaint relating to the detachment of a grab handle located outside the gantry of the EOS System and leading to the patient fall. The ROTH MOBELI grab handles shall never be used outside the EOS gantry to help the patient for standing up.

This removal affects only the two models of grab handles manufactured by ROTH GmbH (see below figures) and distributed by EOS imaging:

- MOBELI Stabi Vario grab handle (ROTH catalogue number 14002 96 S - EOS imaging catalogue number 9000111773)



- MOBELI Dual grip grab handle (ROTH catalogue number 14002 25 S – EOS imaging catalogue number 9000111774)



EOS imaging SA

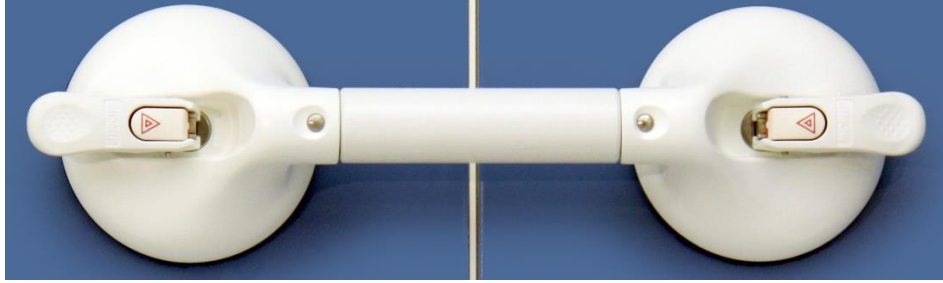
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EOS imaging, Inc.

185, Alewife Brook Parkway #205
Cambridge, MA 02138 USA
+1 (678) 564 5400

Corporate Information

Capital social : 202.887,64 €
N° TVA : FRO9 349 694 893



Our records indicate your facility received one or more of the products affected by this notice. Please note that only the products listed above are affected. No other EOS imaging product is involved in this voluntary action. If you identify any of above listed products within your facility, please segregate the affected product immediately and follow the enclosed Removal Instructions.

We are notifying affected worldwide regulatory authorities of this removal as required.

Please read carefully through the enclosed Removal Instructions.

Thank you for your immediate attention to this matter. EOS imaging is committed to providing products of the highest quality and we regret any inconvenience this revision may cause. We appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We encourage you to contact us if you need assistance or further information.

Sincerely,

Bernard Ismael
Regulatory Affairs and Quality Director

Attachments:

Removal Instructions
Verification Tracking Form



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Removal Instructions

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ROTH MOBELI grab handles used with EOS System

The Verification Tracking Form enclosed with this Field Safety Notice must be completed and returned **even if you no longer have any of the units listed in the Field Safety Notice.**

1. **Please immediately discontinue use of all the ROTH MOBELI grab handles with EOS System and remove** all the affected **units from your inventory** (whether in Radiology, Central Supply, Shipping & Receiving and any other relevant location). Segregate the units in a secure place, pending return to EOS imaging.
2. **Please complete the attached Verification Tracking Form** even if you do not have any product to return.
3. **When completed, return the Verification Tracking Form** on or before **June 16, 2017.**

Email to: regulatory@eos-imaging.com

Fax to: +33 (0)1 55 25 60 61

4. **Prepare a package.** An EOS representative will contact you shortly to arrange return.
5. Please pass this notice to any health professional of your organization that need to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide EOS imaging with details of any affected devices that have been transferred to other organizations (if appropriate).



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