Valley Forge Business Center
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www.globusmedical.com

URGENT: Medical Device Recall Notification
with Important Updates for Surgeons and Patients

AFFECTED DEVICE: ALTERA® Spacer

30 November 2020

Dear Dr. [Surgeon],

On July 22, 2020, Globus Medical notified ALTERA® Spacer customers that a voluntary recall of ALTERA® Spacers was initiated. This notice is being updated with important information for patients and requires surgeon confirmation.

This recall was initiated because specific lots of ALTERA® implants have internal components that may have been manufactured using stainless steel rather than the specified cobalt chromium molybdenum alloy. Only devices made after February 12, 2020 from specific lots are affected, and some parts in a specific lot may not be affected.

No reports of adverse reactions related to the stainless steel components have been received to date.

Evaluation and analysis of affected implants shows that MR safety is not compromised with the use of the stainless steel material. Patients with affected devices may be safely scanned in an MR system using the MRI SAFETY INFORMATION provided in the current ALTERA instructions for use (insert). (Evaluation for image artifact has not been performed but is expected to be more than 35mm for affected ALTERA devices.)

Potential Risks: There is a potential for implant corrosion over time, which may result in localized pain, swelling, and tenderness, and may weaken the implant. If fusion does not occur, there is an increased potential for implant failure. Patients with nickel allergies may experience allergic reactions to the implant material and implant removal may be necessary to alleviate these effects. Patients should report any adverse symptoms to their surgeon.

Patients must be informed of this recall and potential risks. Globus Medical requires written confirmation from the surgeon by 31 January 2021 stating that all patients have been properly informed. Send email confirmation to recall@globusmedical.com and copy Dragan.Stefanovic@swissmedic.ch;Materiovigilance@swissmedic.ch (See sample email confirmation on the next page).

Special monitoring visits are required. Surgeons are expected to schedule more than routine visits with patients and report all adverse symptoms to Swissmedic at https://www.swissmedic.ch/swissmedic/en/home/medical-devices.html

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Recall notification has been sent to all hospitals and other institutions that have purchased ALTERA® implants. They are asked to complete a response card, if not already completed, return all ALTERA® implants for inspection and sorting, and report any adverse effects believed to be associated with ALTERA®. Globus sales representatives and distributors must immediately return all ALTERA® implant inventory in their possession as well as any inventory currently placed in a hospital or surgery center. Returned inventory will be sorted to remove nonconforming implants, and returned with implants that conform to specifications.

Please contact Globus directly if you have questions about the ALTERA® recall at recall@globusmedical.com or call Customer Service at 1-866-456-2871 (U.S.) or +1-866-456-2871 (International).

Globus is committed to ensuring patient safety, exceptional product reliability, and the highest level of customer satisfaction. We ask for your patience as we work to replenish inventory with conforming ALTERA® implants.

Sincerely,

Dave Demski
Chief Executive Officer
Globus Medical, Inc.

Sample confirmation email notification to Globus Medical and Swissmedic

Email to:
recall@globusmedical.com; Dragan.Stefanovic@swissmedic.ch;
Materiovigilance@swissmedic.ch

Suggested text

All patients have been properly informed about the ALTERA® Spacer recall and associated potential risks. Arrangements for additional, non-routine, follow-up visits have been made with patients.

Sincerely,
[Surgeon]