



**URGENT: Medical Device Recall Notification
with an Important Updates for Surgeons**

AFFECTED DEVICE: ALTERA® Spacer

30 November 2020

Dear Valued Customer,

Globus Medical initiated a class 2 recall of certain lots of ALTERA® Spacers. This recall was conducted because affected implant lots have internal components that may have been manufactured using a different material than specified.

This recall is being updated with important information for surgeons and patients.

Affected Lots/Units:

A total of 131 lots (1,360 units) of ALTERA® Spacers are subject to this recall. Only devices manufactured after February 12, 2020 from specific lots are affected, and some parts in a specific lot may not be affected. The part numbers, descriptions, lot numbers and UDI numbers subject to recall are listed in the Appendix (Table 1).

Reason for Voluntary Recall:

Specific lots of ALTERA® implants have internal components that may have been manufactured using stainless steel rather than the specified cobalt chromium molybdenum alloy.

Potential Risks to Health:

Additional 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 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.)

There 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.



(Update) Required Action For Surgeons:

Surgeons must inform patients 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 for patients. 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>

A separate notification letter has been sent to surgeons informing them of these required actions.

Required Action For Customers:

Customers are instructed to immediately examine their inventory and determine if they have any of the affected implants. Alternatively, they may return all ALTERA inventory and Globus will sort out the affected implants and replace inventory with conforming implants.

Report any adverse effects believed to be associated with the product to Globus Medical immediately by filling out the attached Response Card.

Follow-up Actions by Globus Medical:

The US Food and Drug Administration has been notified of this action. The issue was identified to be a material handling error isolated to this product line and Globus has taken actions to prevent recurrence.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program.

For Questions and Support:

Globus Medical Contact	Contact Information	Areas of Support
Globus Medical Complaint Handling Unit	Fax: 610-300-1342 Email: recall@globusmedical.com	Recall Related Questions

Please complete and return the enclosed Response Form via fax or email if not already completed.



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Globus Medical is committed to serving your product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Daniel S Paul
Senior Vice President, Corporate Quality & IT
Globus Medical, Inc.

Sample surgeon email confirmation 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]



Appendix

Table 1. Items Under Recall

Part #	Description	Lot #	UDI #
1124.1111S	ALTERA Spacer, 10x31, 8-12mm, 8° (sterile)	GBX132UC	(01)00889095720723(17)250511(10)GBX132UC
1124.1011	ALTERA Spacer, 10x26, 8-12mm, 8°	BAX112RE	(01)00889095258356(10)BAX112RE
		BAX125YE	(01)00889095258356(10)BAX125YE
		BAX134BE	(01)00889095258356(10)BAX134BE
		BAX095YE	(01)00889095258356(10)BAX095YE
		BAX177TE	(01)00889095258356(10)BAX177TE
		BAX177RE	(01)00889095258356(10)BAX177RE
		BAX185AE	(01)00889095258356(10)BAX185AE
		BAX096AE	(01)00889095258356(10)BAX096AE
		BAX167ME	(01)00889095258356(10)BAX167ME
		BAX195UE	(01)00889095258356(10)BAX195UE
		BAX209SE	(01)00889095258356(10)BAX209SE
		BAX209TE	(01)00889095258356(10)BAX209TE
		BAX244HE	(01)00889095258356(10)BAX244HE
		BAX250DE	(01)00889095258356(10)BAX250DE
		BAX299JE	(01)00889095258356(10)BAX299JE
1124.1012	ALTERA Spacer, 10x26, 9-13mm, 8°	BAX398VE	(01)00889095258356(10)BAX398VE
		BAX431TE	(01)00889095258356(10)BAX431TE
		BAX096BE	(01)00889095258363(10)BAX096BE
		BAX112TE	(01)00889095258363(10)BAX112TE
		BAX112SE	(01)00889095258363(10)BAX112SE
		BAX177UE	(01)00889095258363(10)BAX177UE
		BAX195VE	(01)00889095258363(10)BAX195VE
		BAX229TE	(01)00889095258363(10)BAX229TE
		BAX279WE	(01)00889095258363(10)BAX279WE
1124.1013	ALTERA Spacer, 10x26, 10-14mm, 8°	BAX288HE	(01)00889095258363(10)BAX288HE
		BAX299GE	(01)00889095258363(10)BAX299GE
		BAX367FE	(01)00889095258363(10)BAX367FE
		BAX104GE	(01)00889095069495(10)BAX104GE
		BAX156GE	(01)00889095069495(10)BAX156GE
BAX156HE	(01)00889095069495(10)BAX156HE		
BAX195WE	(01)00889095069495(10)BAX195WE		
BAX361LE	(01)00889095069495(10)BAX361LE		



Part #	Description	Lot #	UDI #
1124.1015	ALTERA Spacer, 10x26, 12-16mm, 8°	BAX156KE	(01)00889095069518(10)BAX156KE
		BAX156LE	(01)00889095069518(10)BAX156LE
		BAX308CE	(01)00889095069518(10)BAX308CE
		BAX308DE	(01)00889095069518(10)BAX308DE
1124.1032	ALTERA Spacer, 10x26, 9-13mm, 15°	BAX095XE	(01)00889095069549(10)BAX095XE
		BAX175CE	(01)00889095069549(10)BAX175CE
		BAX185BE	(01)00889095069549(10)BAX185BE
		BAX299LE	(01)00889095069549(10)BAX299LE
1124.1033	ALTERA Spacer, 10x26, 10-14mm, 15°	BAX112VE	(01)00889095069556(10)BAX112VE
		BAX126AE	(01)00889095069556(10)BAX126AE
		BAX126WE	(01)00889095069556(10)BAX126WE
		BAX207AE	(01)00889095069556(10)BAX207AE
		BAX244KE	(01)00889095069556(10)BAX244KE
		BAX264UE	(01)00889095069556(10)BAX264UE
		BAX256DE	(01)00889095069556(10)BAX256DE
		BAX348DE	(01)00889095069556(10)BAX348DE
		BAX351NE	(01)00889095069556(10)BAX351NE
1124.1035	ALTERA Spacer, 10x26, 12-16mm, 15°	BAX112UE	(01)00889095069570(10)BAX112UE
		BAX212UE	(01)00889095069570(10)BAX212UE
		BAX219JE	(01)00889095069570(10)BAX219JE
		BAX348AE	(01)00889095069570(10)BAX348AE
		BAX367GE	(01)00889095069570(10)BAX367GE
		BAX431UE	(01)00889095069570(10)BAX431UE
1124.1111	ALTERA Spacer, 10x31, 8-12mm, 8°	BAX156ME	(01)00889095069679(10)BAX156ME
		BAX156NE	(01)00889095069679(10)BAX156NE
		BAX167PE	(01)00889095069679(10)BAX167PE
		BAX229VE	(01)00889095069679(10)BAX229VE
		BAX290TE	(01)00889095069679(10)BAX290TE
		BAX290UE	(01)00889095069679(10)BAX290UE
		BAX294WE	(01)00889095069679(10)BAX294WE
		BAX376DE	(01)00889095069679(10)BAX376DE
		BAX376CE	(01)00889095069679(10)BAX376CE
1124.1112	ALTERA Spacer, 10x31, 9-13mm, 8°	BAX137PE	(01)00889095069686(10)BAX137PE
		BAX167SE	(01)00889095069686(10)BAX167SE
		BAX178FE	(01)00889095069686(10)BAX178FE
		BAX208LE	(01)00889095069686(10)BAX208LE
		BAX250CE	(01)00889095069686(10)BAX250CE



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Part #	Description	Lot #	UDI #
		BAX348CE	(01)00889095069686(10)BAX348CE
		BAX431NE	(01)00889095069686(10)BAX431NE
1124.1113	ALTERA Spacer, 10x31, 10-14mm, 8°	BAX178LE	(01)00889095069693(10)BAX178LE
		BAX178KE	(01)00889095069693(10)BAX178KE
		BAX189PE	(01)00889095069693(10)BAX189PE
		BAX348EE	(01)00889095069693(10)BAX348EE
1124.1115	ALTERA Spacer, 10x31, 12-16mm, 8°	BAX159RE	(01)00889095069716(10)BAX159RE
		BAX178JE	(01)00889095069716(10)BAX178JE
		BAX208RE	(01)00889095069716(10)BAX208RE
		BAX229UE	(01)00889095069716(10)BAX229UE
		BAX250BE	(01)00889095069716(10)BAX250BE
		BAX308BE	(01)00889095069716(10)BAX308BE
		BAX347YE	(01)00889095069716(10)BAX347YE
		BAX351KE	(01)00889095069716(10)BAX351KE
1124.1132	ALTERA Spacer, 10x31, 9-13mm, 15°	BAX138HE	(01)00889095069747(10)BAX138HE
		BAX177XE	(01)00889095069747(10)BAX177XE
		BAX185CE	(01)00889095069747(10)BAX185CE
		BAX195EE	(01)00889095069747(10)BAX195EE
		BAX208NE	(01)00889095069747(10)BAX208NE
		BAX299PE	(01)00889095069747(10)BAX299PE
		BAX315CE	(01)00889095069747(10)BAX315CE
		BAX348BE	(01)00889095069747(10)BAX348BE
1124.1133	ALTERA Spacer, 10x31, 10-14mm, 15°	BAX108TE	(01)00889095069754(10)BAX108TE
		BAX178ME	(01)00889095069754(10)BAX178ME
		BAX208TE	(01)00889095069754(10)BAX208TE
		BAX299NE	(01)00889095069754(10)BAX299NE
		BAX413CE	(01)00889095069754(10)BAX413CE
		BAX413GE	(01)00889095069754(10)BAX413GE
1124.1135	ALTERA Spacer, 10x31, 12-16mm, 15°	BAX178PE	(01)00889095069778(10)BAX178PE
		BAX236NE	(01)00889095069778(10)BAX236NE
		BAX398UE	(01)00889095069778(10)BAX398UE
		BAX431SE	(01)00889095069778(10)BAX431SE
1124.1211	ALTERA Spacer, 10x36, 8-12mm, 8°	BAX103VE	(01)00889095069877(10)BAX103VE
		BAX109ME	(01)00889095069877(10)BAX109ME
		BAX203PE	(01)00889095069877(10)BAX203PE
		BAX315BE	(01)00889095069877(10)BAX315BE
		BAX359ME	(01)00889095069877(10)BAX359ME



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Part #	Description	Lot #	UDI #
		BAX412WE	(01)00889095069877(10)BAX412WE
1124.1212	ALTERA Spacer, 10x36, 9-13mm, 8°	BAX103XE	(01)00889095069884(10)BAX103XE
		BAX109NE	(01)00889095069884(10)BAX109NE
		BAX250HE	(01)00889095069884(10)BAX250HE
		BAX250FE	(01)00889095069884(10)BAX250FE
		BAX256CE	(01)00889095069884(10)BAX256CE
		BAX257UE	(01)00889095069884(10)BAX257UE
1124.1213	ALTERA Spacer, 10x36, 10-14mm, 8°	BAX128PE	(01)00889095069891(10)BAX128PE
		BAX207CE	(01)00889095069891(10)BAX207CE
		BAX128NE	(01)00889095069891(10)BAX128NE
		BAX250EE	(01)00889095069891(10)BAX250EE
		BAX256BE	(01)00889095069891(10)BAX256BE
1124.1215	ALTERA Spacer, 10x36, 12-16mm, 8°	BAX112XE	(01)00889095069914(10)BAX112XE
		BAX250LE	(01)00889095069914(10)BAX250LE
1124.1232	ALTERA Spacer, 10x36, 9-13mm, 15°	BAX103UE	(01)00889095069945(10)BAX103UE
		BAX138JE	(01)00889095069945(10)BAX138JE
		BAX167VE	(01)00889095069945(10)BAX167VE
		BAX167UE	(01)00889095069945(10)BAX167UE
		BAX227JE	(01)00889095069945(10)BAX227JE
		BAX413ME	(01)00889095069945(10)BAX413ME
1124.1233	ALTERA Spacer, 10x36, 10-14mm, 15°	BAX196AE	(01)00889095069952(10)BAX196AE
		BAX196CE	(01)00889095069952(10)BAX196CE
1124.1235	ALTERA Spacer, 10x36, 12-16mm, 15°	BAX103WE	(01)00889095069976(10)BAX103WE
		BAX227VE	(01)00889095069976(10)BAX227VE