LimaCorporate
Orthopaedic motion

URGENT FIELD SAFETY NOTICE
Possible sterility issue with various items

Product name:	H-MAX S stem; DELTA Liner, MINIMA S stem, DELTA Multihole TT Cup, Protruded DELTA Liner
FSCA number:	08/2019
Action type:	Voluntary Field Safety Notice on medical device
Date:	20th December 2019
To the kind attention of:	Health Directors; Orthopaedic Head Physicians; Orthopaedic Surgeons; Vigilance Directors; Chief Executive Officers (only for Private Facilities)
Codes:	**Please refer to Product codes listed in Table 1**
Device type:	Hip stems and acetabular cups
Lot number:	**Please refer to Batch/Sterilization numbers listed in Table 1**
Notes:	/

During the routine microbiological analysis of the Clean Room wash taken on the 26th of November 2019, a noncompliant total count value was found in comparison to the acceptability value internally required.
Further sterility tests showed that there is the concrete possibility that items with code and lot numbers listed in Table 1 below are affected by a sterility issue.
To avoid any potential harm to the patient in implanting the involved items, LimaCorporate is conducting an immediate recall action of the products listed in Table 1.
To date, no medical complaints involving the items listed in Table 1 were reported to LimaCorporate, therefore we kindly ask you to take the following action.

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ACTION TO BE TAKEN

1. Check your stock to locate and quarantine the affected devices received. Affected items are required to be sent back to LimaCorporate together with a hard copy of the attached Response Form;
2. Fill out, sign and send the attached Response Form to the email address pms@limacorporate.com, as a confirmation that you have read and acknowledged the content of this FSN;

If needed, please address any inquiry on this FSN to the email address medicalcomplaints@limacorporate.com.

Product code and description	Batch #	Sterilization lot#	N. of pieces
4503.21.090 - *MINIMA S STANDARD STEM #9*	1919715	1900433	2
4250.20.080 - *H-MAX S STANDARD FEM. STEM #8*	1919710	1900433	1
5885.42.155 - *DELTA LINER ØINT32MM # SMALLBIOLOX ® DELTA*	1981169	1900433	1
5886.51.058 – *DELTA PROTR. LINER ØINT32MM*	1920233	1900430	1
5548.14.440 - *DELTA MULTIHOLE TT CUPØ44MM - LINER #SMALL*	1911463	1900433	1

Table 1 – Items involved in a possible sterility issue

Note that, on 5th of December 2019, an immediate recall action on the Custom made device code 9617.14.A08 - included among the product codes washed on 26th of November 2019 – occurred in a precautionary way already performed to avoid any potential harm to the patient in the surgery planned on the 6th of December 2019. Sterility issue for the Custom made device with Code 9617.14.A08 is not yet confirmed (investigation ongoing).
The involved Custom Made device is now quarantined in LimaCorporate.

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Dissemination of this FSN

This notice needs to be passed on all those who need to be aware within your organization, or to any organization where the devices involved have been received

This Field Safety Notice will be also sent to the Competent Authorities of the Countries involved in this Field Safety Corrective Action.

Roberto Gabetta
Regulatory Manager
LimaCorporate SpA

Limacorporate spa

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