HEALTHCARE FACILITY
Adress

To the attention of the vigilance Safety Officer
and orthopedic surgery departments

Valence, December 9th 2021

FIELD SAFETY NOTICE (FSN) / RECALL

Reference AMPLITUDE: ISSUE-0737

Concerned device: Unicompartmental knee prosthesis - UNISCORE® tibial tray for fixed bearing insert, cemented.

Reference	Designation	Batch
1-0202501 to 1-0202507	UNISCORE® tibial tray for fixed bearing insert – Cemented – Size 1 to 7	All batches

Reason for recall

The UNISCORE® cemented tibial tray is a component of a unicompartmental knee prosthesis.

During the post-market surveillance of the devices, it has been detected that due to insufficient quantity of clinical data, AMPLITUDE cannot determine the long-term safety and performance of this implant. Cases of loosening linked to the use of UNISCORE® cemented tibial tray for fixed bearing insert have been reported.

AMPLITUDE decides to cease the marketing of this tibial tray version and perform a recall of devices on the market.

Circumstances and risks for the user and/or the patient

The main risk for the patients in case of implant loosening is the revision of the prosthesis. Currently, the calculated rate is 0.44% of the involved prosthesis.

No additional follow-up is recommended for the patient. We recommend to assess any sign of similar event and the associated risks during the regular post-operative follow-up of the implanted patients.

What you must do

Our traceability data indicates that you were provided the concerned device(s)

We ask you to circulate this notice to the related individuals to prevent the use of those devices in the Healthcare facility. These devices have to be hold in in quarantine pending the return to your local representative.

Your local representative will contact you to organize the exchange of the devices and is available to provide any requested additional information.

Please fill and return the attached return form to Amplitude. (Annexe 1 of this notice)

Others information

The national competent authority is advised about this recall procedure.

We remind you that any adverse event experienced using these devices must be declared to the competent authority and your local representative.

We apologize for the inconvenience and thank you for your comprehension.

Mireille LEMERY
Vice-President Quality and Regulatory Affairs
vigilance@amplitude-ortho.com

Attached document: ANNEXE 1 - Customer reply form

ANNEXE 1 – Customer Reply Form
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- ☐ I confirm receipt of the FSN and that I read and understood its content. The information and required actions have been bought to the attention of all relevant customers / users / distributors.

- ☐ I confirm that all inventory locations (of our company / Healthcare facility and our customers) have been reviewed

Please fill the table below with the quantities (specify 0 if you have no stock) and return this form within 3 days by fax (+33 04.75.41.41.78) or by email vigilance@amplitude-ortho.com

Reference	Designation	Quantity
1-0202501	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 1	
1-0202502	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 2	
1-0202503	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 3	
1-0202504	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 4	
1-0202505	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 5	
1-0202506	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 6	
1-0202507	UNI SCORE tibial tray for fixed bearing insert – Cemented - Size 7	

Name of SBU / Distributor:

Your name:

Function:

Date:

Signature: