

CUSTOMER

Address

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

Valence, March 16th 2021

FIELD SAFETY NOTICE (FSN) / BATCHES RECALL

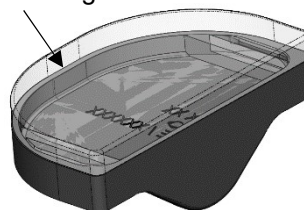
Reference AMPLITUDE: ISSUE-0676

Concerned device: Unicompartmental knee prosthesis - UNISCORE[®] tibial tray for fixed bearing insert

Reference	Designation	Batch
1-0202501 to 1-0202507	UNISCORE [®] tibial tray for fixed bearing insert – Cemented – Size 1 to 7	All batches with an expiry date before or egal to March 2024*
1-0205701 to 1-0205707 1-0205801 to 1-0205807	UNISCORE [®] tibial tray for fixed bearing insert – HA coated – Cementless (RM / LL and LM/ RL) - Sizes 1 to 7	All batches with an expiry date before or egal to April 2023**



Lateral flange



* the batches 295104 and 295402 are also involved. The list of involved batches in your facility, according to our traceability, data is in Annex 1.

** the batches, 249704, 270458, 273480, 273898, 273900, 273901, 275904, 278275, 278278, 278279, 278284, 278286, 278287, 278288, 286827 are also involved. The list of involved batches in your facility, according to our traceability, data is in Annex 1.



Reason for recall

The UNISCORE® tibial tray is a component of a unicompartamental knee prosthesis. It has a lateral flange designed to maintain the insert after clipping. We have identified that the thickness of this flange was not inspected on the tibial trays manufactured before 2018 and 2019 (depending on version). Therefore the dimensions of the flange may be slightly lower than the specifications. As a precautionary measure, Amplitude initiates a recall of the batches which may be involved.

Circumstances and risks for the user and/or the patient

There is a risk of breakage of the lateral flange of the UNISCORE® tibial tray. Currently, the occurrence rate is 0.07%.

The breakage of the flange (visible on the X-rays) could lead to pain (dissociation of the broken part) or an instability of the PE insert requiring a revision surgery.

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) (a precise list is in the back form in Annex 1 of this notice)

We ask you to circulate this notice to the related individuals in order 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.

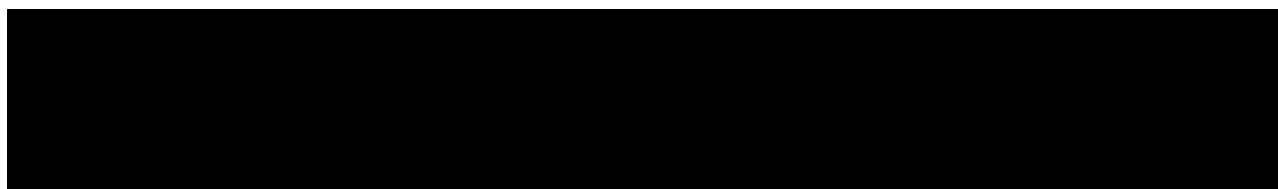
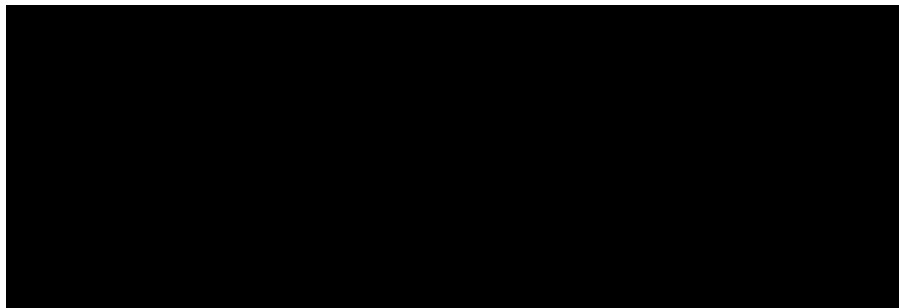
Your local representative will contact you to organize the exchange of the devices and is available to provide any requested additional information.

Other information

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

The national competent authority is advised about this recall procedure.

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





ANNEXE 1- Customer Reply Form

FIELD SAFETY NOTICE (FSN) - RECALL

Reference AMPLITUDE: ISSUE-0676

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

- ☐ I confirm receipt of the FSN and that I read and understood its content. The information and required actions have been brought to the attention of all relevant person
- ☐ I confirm that all inventory locations 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 (xx) or by email (xx).

Reference	Designation	Batch	Quantity
<i>In the FSN sent to the involved Healthcare Facilities, the involved devices in each Healthcare facility will be listed in this table, based on traceability data of the SBU/Distributor.</i>			

Name of Healthcare facility / SBU / Distributor:
Country:

Your name:

Function:

Date:

Signature: