AMPLITUDE

Healthcare Facility
Address

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

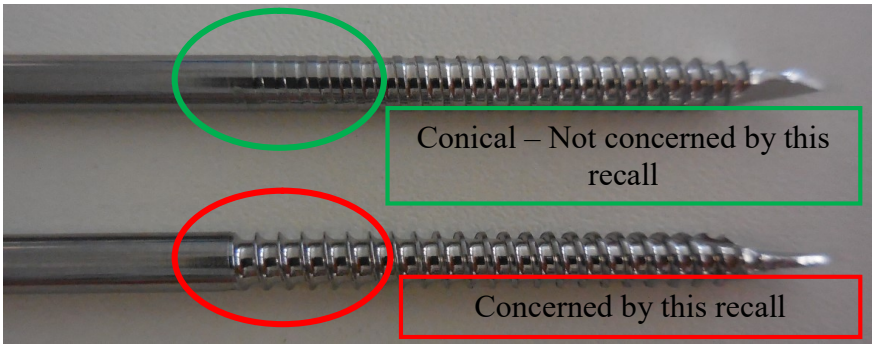
Valence, July 19th 2019

Ref. AMPLITUDE : ISSUE-0563

Object: **RECALL**
AMPLIVISION®- Fixation K-wire

Reason for recall
Following feedback from the market regarding breakages of fixation K-wires during use, new references of K-wire have been marketed. These new fixations K-wire have a conical core of threaded parts, strengthening herewith the area submitted to the maximal torsion torque.

Amplitude initiates a marketing cessation of the previous K-wire in order to prevent the use of these versions. Although these versions are not distributed anymore, there may still be some K-wires in some instrument sets on the market.



Comparative picture of previous version of K-wire (below) and new version (above)

Circumstances and risks for the user and/or the patient
In case of breakage of K-wire during use, the broken part may remain implanted into the patient's bone. Whereas no associated patient consequences were reported, it could induce a sensitization patient reaction following implantation of a non-implantable device.

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Concerned device

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

Reference REF	Designation
2-0208702	AMPLIVISION® - Fixation K-wire Ø4 length 100 mm
2-0208700	AMPLIVISION® - Fixation K-wire Ø4 length 150 mm
2-0223700	AMPLIVISION® - Fixation K-wire Ø4 length 150 mm - STERILE

It has to be noted that the new references of AMPLIVISION® conical K-wire (2-0235900, 2-0235500, 2-0252200) are not concerned by this recall.

What you must do

- Please circulate this notice to the related individuals in order to prevent the use of those devices in the hospital.
- Hold the devices concerned by this recall in quarantine.
- In any case, fill and return the attached return form to your local representative. They will contact you to set the return of the devices, if applicable.

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

Other information

The French competent authority is advised about this recall procedure.

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

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

Attached: Back form

BACK FORM

Recall – ISSUE-0563
(AMPLIVISION®- Fixation K-wire)

Our inventory has been reviewed and the results are as follow (tick one box):

☐ We have physically checked all inventory locations and we do not have products concerned by this recall.

☐ We have physically checked all inventory locations and we have some products concerned by this recall (quantities in the table below). We have put them in quarantine, awaiting for the exchange.

Reference	Designation	Quantity
2-0208702	AMPLIVISION® - Fixation K-wire Ø4 length 100 mm	
2-0208700	AMPLIVISION® - Fixation K-wire Ø4 length 150 mm	
2-0223700	AMPLIVISION® - Fixation K-wire Ø4 length 150 mm - STERILE	

Name of Healthcare facility:

Name:

Function:

Date:

Signature:

Please return this form as soon as possible by fax or email to your local representative.