

Registered letter with acknowledgment of receipt

FIELD SAFETY NOTICE

Subject: FSCA / Information about implantation of some batches of Oceane+ Hip Stems, Meije Duo Cementless Hip Stems, Linea cemented and cementless Hip Stems, HLS Noetos Knee Stems, HLS Kneetec Knee Stems

Devices concerned: **See Appendix 1**

Our /Ref.: **FA COF 2021 004 – FSN Rev02**

Person in charge of the follow-up: **Elodie Papot**

Date: 19th March 2021

Dear Customer,

Following Field Safety Notice raised beginning of March 2021, voluntary recalling of some batches of Oceane+ Hip Stems, Meije Duo Cementless Hip Stems, Linea cemented and cementless Hip Stems, HLS Noetos Knee Stems, HLS Kneetec Knee Stems, Corin has completed the evaluation of the potential risks of the devices implanted into patients from the same batches involved in the recall. Please refer to the Appendix 1 attached for the batches concerned.

Potential risk for the patient:

The safety assessment from the toxicologist has shown that the patient safety risk is low from implantation of the impacted devices given to the amount of adhesive potentially can be present on the implants. The maximum admissible quantity calculated by our toxicological risk assessment is 5,51 mg that could cause potential safety risk to the patient, whereas the maximum amount (worst case scenario) of adhesive physically measured on a taper was 0,1 mg. Considering that the femoral head is attached to the part where the adhesive may adhere, in the worst case, only a small amount of adhesive (less than 0,1 mg) comes into direct contact with the human body. This amount is significantly less than the toxicological maximum admissible value of 5,51 mg.

In addition, mechanical tests have been made with implants contaminated with adhesive. All tests have passed their acceptance criteria. This mitigates the risk of dislocation or ceramic head fracture as a result of the adhesive on the device.

Due to the risk assessment performed, we believe that the risk to patients is low and it is not necessary to inform patients who have received any of the implants concerned. We recommend that surgeons do not need to deviate from their normal follow-up protocol.

To date, we have not received reports of any health damage caused by this issue.

Summary of the recall initiated beginning of March:

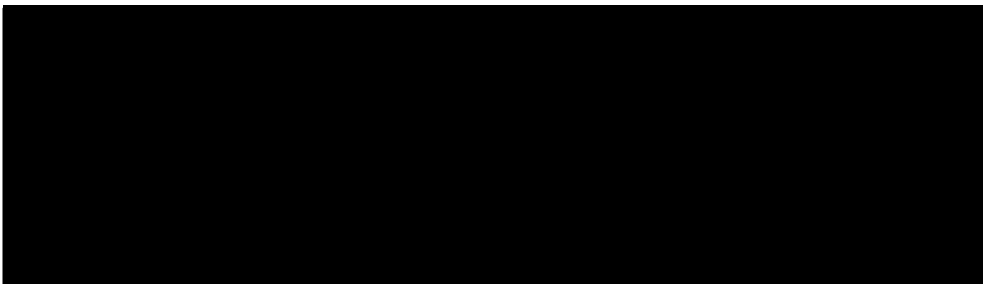
Following reports from the field, Corin has identified that in a number of cases, there is the possibility of a small amount of adhesive being transferred from one of the packaging components (foam) onto the devices. All non-implanted devices are retrieved from the market following the previous FSN named "FA COF 2021 004 – FSN Rev01" sent to the concerned establishments.

Actions to be taken by the Customer:

Complete the acknowledgement of receipt and forward it to the vigilance department of Corin to confirm receipt of this Field Safety Notice to the following address:
Corin France SAS, 157, Rue Lavoisier, 38330 Montbonnot, Saint Martin, France or by e-mail to vigilance.france@coringroup.com

For all questions on this notice, please contact at +33 (0)4 56 60 90 46 or by e-mail to vigilance.france@coringroup.com from Monday to Friday, 9:00AM to 6:00PM, French Time.

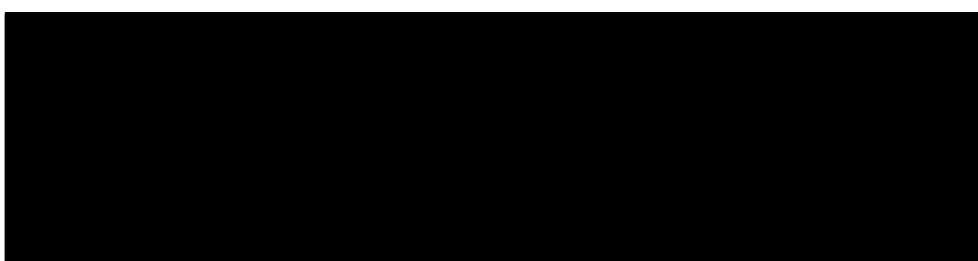
Yours faithfully,



FA COF 2021 004 - Appendix 1: Customer Response Form

Regulatory Action:	Field Safety Notice
Description:	FSCA / Information about implantation of some batches of Oceane+ Hip Stems / Meije Duo Cementless Hip Stems, Linea cemented and cementless Hip Stems, HLS Noetos Knee Stems, HLS Kneetec Knee Stems.
Part Numbers:	See below
Lot Numbers:	See below
Our/Ref. / Date	FA COF 2021 004 Rev02 /19 March-21

Product Code	Designation	Lot code	Quantity
Surgeon name			



Please sign and return this form to acknowledge receipt to the Vigilance department of Corin France to confirm the receipt of this notice.

Distributor / Hospital Name and Address:	
Contact Name:	
Contact Title:	
Contact Signature:	
Contact Phone No:	
Date:	

We would appreciate it if you return this form completed, within 7 days, by:

-fax : +33(0)4.76.41.00.68, or

-e-mail: vigilance.france@coringroup.com

-adress : Corin France – 157 Rue Lavoisier 38330 Montbonnot Cedex – France