

INTRAUMA s. r. l.  
Via Rovigo 4  
10098 RIVOLI  
ITALIE

May 12, 2014

### **Field Safety Notice N°20140507**

Dear Sir,

C2F IMPLANTS is performing a voluntary recall of the batch **010608036000** of standard femoral stem CLEVELAND® size 12 (References: **IMP41112**)

Ours records indicate that your facility may have received one or more of these products.

We are observed three cone of the stem of this batch with micro scratch. Not all devices are concerned but, as a precaution, C2F IMPLANTS recall all devices, no incident was declared.

**Please immediately discontinue use of any CLEVELAND® femoral stem of batch 010608036000 and isolate them for return to C2F IMPLANTS.**

Your C2F IMPLANTS sales representative will contact you in the near future to facilitate removal of the above listed devices. Your company will be issued full credit or a free of charge replacement for all removed product.

C2F IMPLANTS is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you. If you have any questions or concerns, please contact your C2F IMPLANTS Sales Representative.

Thank you for continued support,

Yours sincerely,



Elise GROSJEAN  
*Quality and regulatory affairs director – C2F Implants*

Mail : [elise.grosjean@c2f-implants.com](mailto:elise.grosjean@c2f-implants.com)  
Zi Rue Lavoisier – BP10  
52800 NOGENT

Tél : 03-25-02-72-89  
Fax : 03-25-31-29-99



Patrick MINOT  
*Managing Director – C2F Implants*

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**FORM OF CUSTOMER ANSWER – FSCA20140507**

**Customer:** INTRAUMA s. r. l. (000060)

**Medical device concerned:** Standard CLEVELAND femoral stem size 12

**References concerned:** IMP41112

**Batches concerned:** 010608036000

**Quantities send:** 1

**To be completed**

*Please send us this form even if you have not any device to return.*

- I received C2F IMPLANTS Notice
- I sent this notice to every person concerned

**Check the good suggestion:**

- I checked my stock and I have medical device(s) concerned by the recall. **The quantity is** \_\_\_\_\_.
- I checked my stock and I have **not** medical device(s) concerned by the recall.

Contact name :		Customer mark :	
Job :			
Signature :			
Phone :		Date :	
E-mail :			

*Complete and return this form by fax (number +33(0)3 25 31 29 99), e-mail or mail to Mrs. Elise GROSJEAN.*