<DATE TBD>

To: Dentists and Health Care Professionals

Subject: **URGENT MEDICAL DEVICE REMOVAL**

Affected Product: OSSEOTITE® Certain® Implant 4 X 11.5mm (IOSS411)

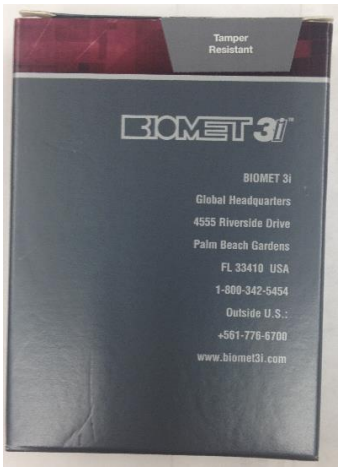
Item Number	Lot Number	UDI Number
IOSS411	2016031461	(01)00844868007098(17)210401(10)2016031461

Biomet 3i is conducting a medical device recall for OSSEOTITE Certain Implant 4 X 11.5mm (IOSS411). Our records indicate you may have received one or more of the affected product.

Through investigation, Biomet 3i determined that item IOSS411, lot 2016031461 was incorrectly packaged: A blue and white T3® Implant box was used instead of the correct red and gray OSSEOTITE box. The product label correctly identifies the product within the box as item IOSS411, lot 2016031461.

The structure, size and material of both boxes are the same. Only the graphics printed on the box are different. This affects the outer packaging only (box), and has NO effect on the inner packaging which holds the implant, or the implant itself.

Photograph examples of the correct box (red and gray) and incorrect box (blue and white) are shown below:



Correct

Incorrect (Actual box used)

Product Label – Is Correct

ZIMMER BIOMET

Risks

Risks		
Immediate / Long-range	Most Probable	Worst Case
Immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	None	Potential delay of treatment resulting in inconvenience; No injury to any person.
Long-range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	None	None

The affected units were distributed between the dates of June 3, 2016 and July 11, 2016.

Dentists and Health Care Professional's Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow up schedule.
3. Please review the instructions provided in Attachment 1 - Certificate of Acknowledgement and retain a copy with your recall records in the event of a compliance audit of your documentation.
4. If after reviewing the notice you have further questions or concerns please call the customer call center at 1-800-443-8166.

Other Information

This voluntary notification will be reported to the appropriate national competent authorities. As the manufacturer, BIOMET 3i is required to report any serious injury to the appropriate competent authorities if a product has contributed to or may have contributed to produce the Incident. Please inform BIOMET 3i of any Incident relating to this product. You may also notify your national competent authority if you experience any adverse reactions when using these products.

The undersigned confirms that this notice has been delivered to the appropriate competent authorities.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this recall.

Sincerely,

_____

Regulatory Affairs EMEA

ATTACHMENT 1
Certificate of Acknowledgement

Instructions:

1. ☐ **I have no product to return.** Fill in the customer details section, and e-mail a **signed copy** of this form to Vigilance.EU@zimmerbiomet.com or fax to **+34 93 193 42 79**, to acknowledge receipt of this letter.
2. ☐ **I do have product to return.** Complete the full form below and email a copy to Vigilance.EU@zimmerbiomet.com or fax to **+34 93 193 42 79.** Customer Service will send you an e-mail or fax with the **RMA number** within a few days and will organize the product return on our expense.
3. Please also ensure that the shipping container lists the **RMA number** for quick processing.

Product return information:

Item #	Lot #	Quantity Returning
IOSS411	2016031461	

Replacement product will be sent within a few days with an invoice. A credit note will be issued once we receive the returned product.

Customer Details:

Customer Name (doctor/clinic/lab):

Customer Number (if available):

Contact Name:

Telephone Number:

Billing Address:

Name:

Address (Street, Number):

Postal Code:

City:

Shipping Address (only needed in case it differs from the Billing address)

Name:

Address (Street, Number):

Postal Code:

City:

Please indicate below the pick-up address, if it differs from the Shipping Address:

Name:

Address (Street, Number):

Postal Code:

City:

Within a few days, Customer Service will send you an RMA number. Please indicate your e-mail address or fax number below:

E-mail address:

Fax number:

Please indicate your preferred date for product pick-up, within the next 7 days:……..

The product will be picked-up by our courier agency. Please include the RMA document within the product return package.

Signature: