<DATE TBD>

To: Dentists and Health Care Professionals

Subject: **URGENT MEDICAL DEVICE REMOVAL**

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

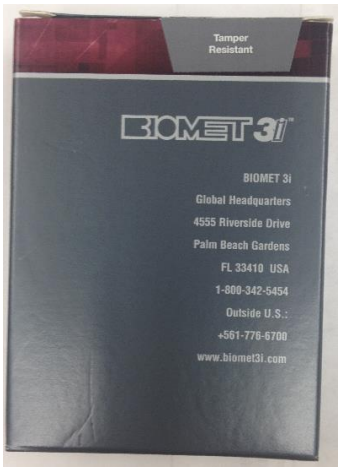
Item Number	Lot Number	UDI Number
IOSS411	2016031461	(01)00844868007098(17)210401(10)2016031461

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. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to postmarket@zimmerbiomet.com, if you have no affected product.
    b. Or, if you have product to return, include a copy of the Certificate of Acknowledgement and return the affected product to the location shown below.

Please Return Affected Product to:

Biomet 3i
Attention: Post Market Returns
4555 Riverside Drive
Palm Beach Gardens, FL 33410
United States of America
1-800-443-8166

    c. Upon receipt of the returned affected product, replacement product will be ordered by Biomet 3i customer service and immediately shipped.
    d. Retain a copy of the Certificate of Acknowledgement 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 between 8:00 am and 6:00pm EST, Monday through Friday.

Other Information
This voluntary medical device recall was reported to the U.S. Food and Drug Administration, and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Biomet 3i informed of any adverse events associated with this product or any other Biomet 3i product by emailing DomesticComplaints@zimmerbiomet.com

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,

_____
Chris McKee
Quality and Compliance Assoc. Director

ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:** ___/____/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to BIOMET 3i before this action can be considered closed for your account. It is important that you complete this form and email a copy to: postmarket@zimmerbiomet.com.