



URGENT:
Medical Device Removal - BellaTek® Zirconia Abutments

August __, 2013

*Insert Clinician /Laboratory
Name and
Address
here*

Dear Dr. Sir/Madam:

As a medical device manufacturer, BIOMET *3i* takes patient safety and product quality very seriously. BIOMET *3i* has received a number of reports relating to BellaTek Zirconia Abutment fractures. As a precautionary measure, BIOMET *3i* has initiated a voluntary recall of BellaTek Patient Specific Zirconia Abutments.

To address this issue, BIOMET *3i* also has decided to initiate a design change to mitigate the fracture risk, and consequently, we will cease distribution of BellaTek Zirconia Abutments until the corrective actions are completed.

Our records indicate that you have received one or more of the following products since April 2011:

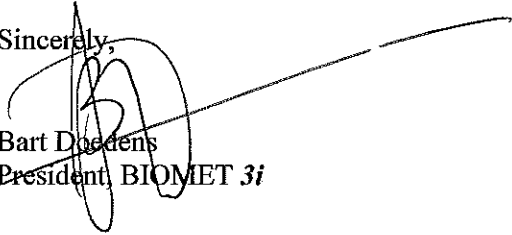
--Insert TABLE-- *** Zirconia Abutments**

If you have any BellaTek Zirconia Abutment cases in process in your laboratory or practice, please return the abutments to BIOMET *3i* in exchange for BellaTek Titanium Abutments. Alternatively, you may return the BellaTek Zirconia Abutment for full credit.

We also ask that you confirm receipt of this notification by completing the attached Recall Return Response Form.

No other BIOMET *3i* products are affected by this recall. Based on our investigation of this issue, BIOMET *3i* does not believe that it is necessary for your clinicians to contact their patients with BellaTek Zirconia Abutments, however we understand that it is up to each health care provider to assess his/her patients at regular oral hygiene appointments. Please advise your clinicians of this Medical Device Removal Notice and our recommendations by forwarding a copy of this Notice to them, or if you prefer, BIOMET *3i* can contact clinicians directly if you provide us with the contact information in the attached acknowledgment letter.

Thank you for your support -- we are committed to re-releasing the BellaTek® Zirconia Abutment product line as soon as we have implemented the design change noted above that we feel confident will mitigate the risk of fracture. If you have any further questions, please contact Customer Service at CS # for assistance.

Sincerely,

Bart Doedens
President, BIOMET 3i