

Image
URGENT MEDICAL DEVICE RECALL



BIOMET 3i
4555 Riverside Drive.
Palm Beach Gardens, FL 33410
1.800.342.5454
www.biomet3i.com

November 18, 2015

To: Dentists and Health Care Professionals

Affected Product:

Item	Description
ART 1036	Radiographic Transparency for Certain® and External Connection Tapered Implants

Radiographic Transparency For Certain® And External Connection Tapered Implants

This transparency should only be used as a reference guide in conjunction with the use of a 5.0mm Radiographic Ball. Twist drill length, including the tip, exceeds the implant dimensions represented and must also be taken into account during treatment planning.

Drill Tip Depth Mark
(5.12mm)

3.25mm Implant Body		5.0mm Implant Body	
<p>ACTUAL SIZE ⊕</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>3.25mm Implants</p>	<p>25% LARGER ⊕ THAN ACTUAL SIZE</p> <p>5.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>3.25mm Implants</p>	<p>ACTUAL SIZE ⊕</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>5.0mm Implants</p>	<p>25% LARGER ⊕ THAN ACTUAL SIZE</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>5.0mm Implants</p>
4.0mm Implant Body		6.0mm Implant Body	
<p>ACTUAL SIZE ⊕</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>4.0mm Implants</p>	<p>25% LARGER ⊕ THAN ACTUAL SIZE</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>4.0mm Implants</p>	<p>ACTUAL SIZE ⊕</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>6.0mm Implants</p>	<p>25% LARGER ⊕ THAN ACTUAL SIZE</p> <p>6.0MM RADIOGRAPHIC BALL</p> <p>8.5mm 10.0mm 11.5mm 13.0mm 15.0mm</p> <p>6.0mm Implants</p>

BIOMET 3i

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ART1036
REV C 09/15

The image above is not actual size, it is for illustration only.

BIOMET 3i is conducting a voluntary recall of the above product. Our records indicate that your office has previously received a shipment of the affected product between August 27th, 2014 and August 10th, 2015.

Through investigation, BIOMET 3i determined that a single purchase order of ART 1036 was received undersized. Both the overall size of the transparency as well as the images represented in ART 1036 are

URGENT: DEVICE RECALL NOTICE**Radiographic Transparency for Certain and External Connection Tapered Implants
ART 1036**

undersized. The images are undersized by approximately 8.4%. Use of this transparency may lead the user to believe that more anatomical space is available for implant placement than the patient's anatomy actually provides.

Risks (Placing Oversized Implant Diameter)

- If the clinician uses an affected ART 1036 unit and places a larger implant than is appropriate for the site, there may be insufficient space between the implant and adjacent teeth (or between adjacent implants). Due to lack of blood flow, the implant may fail to integrate. Alternatively, the implant could initially integrate but eventually fail due to less bone support.
- If the clinician uses an affected ART 1036 unit and places a larger implant than is appropriate for the site, there may be insufficient space between the implant and the adjacent tooth and the patient could suffer damage to the adjacent tooth root. Due to tooth damage, the patient may require endodontic treatment. Alternatively, the adjacent tooth could fail and the patient may require additional implant placement.

Risks (Oversized Implant Length/Drill Depth)

NOTE: The BIOMET 3i Surgical Manual recommends a 2 mm margin of safety, from the apical end of the implant to the adjacent vital structures. As the amount of error is within the recommended margin of safety, no injury is expected. However, it is possible that the clinician may inadvertently place an implant into the "margin of safety".

- If the clinician uses an affected ART 1036 unit and places a longer implant than is appropriate for the site, there may be insufficient space allowing the implant to be placed within the vertical 2mm margin of safety. If the implant is placed sufficiently close to a vital structure, it may cause temporary or permanent damage. Harms may include impingement of the mandibular inferior alveolar nerve and/or maxillary sinus; pain; temporary nerve paresthesia or anesthesia; perforation of the mandibular inferior alveolar canal causing permanent trauma to the inferior alveolar nerve.

Responsibilities:

1. Please review this notice and check your inventory for the affected item by comparing any on-hand ART 1036 Transparencies to a standard 8.5" x 11" sheet of paper. The non-conforming ART 1036 is approximately 7.8" x 10.2".
2. Immediately quarantine and remove all affected items from service.
3. Complete the attached Business Reply Form and either
 - a. fax it to **561-514-6316** or
 - b. email it to postmarket@biomet.com or
 - c. return it along with the affected product using the included shipping label
4. Return affected product to BIOMET 3i.

Please maintain a copy of this notice and a signed copy of Attachment 1 for your records to assist in any future regulatory agencies audits of this field action.

Other Information

This voluntary notification will be reported to the U.S. Food and Drug Administration.

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Biomet 3i informed of any adverse events associated with this device or any other BIOMET3i product. Adverse events may be reported to BIOMET 3i at domesticcomplaints@biomet.com or 3ipbg-intcomplaint@biomet.com.

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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 regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

BIOMET 3i prioritizes quality and patient safety, and we are committed to helping improve lives by developing and delivering high quality, safe and effective products. We apologize for any inconvenience this may have caused and appreciate your continued business.

For assistance or other questions that you may have relative to this notice, please contact BIOMET 3i at **1-800-342-5454** or 1-561-776-6700. Team members are available to assist you 8:00am to 6:00pm (Eastern), Monday through Friday.



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ART 1036

ATTACHMENT 1 BUSINESS REPLY FORM / PACKING SLIP

Instructions:

1. If you have product to return, please call **BIOMET 3i** at **1-800-342-5454** to obtain a RMA number and to return products.
2. Complete the form below and email a copy to postmarket@biomet.com or fax to **561-514-6316**;
3. Ensure that a copy of this form is included with your product return shipment.
4. Please also ensure that the shipping container lists the RMA number for quick processing.

Please Return Affected Product to:

BIOMET 3i
 Attention: Recall Coordinator
 4555 Riverside Drive.
 Palm Beach Gardens, FL 33410
 1-800-342-5454

Please complete this Business Reply Form within five (5) business days. Please complete the information below:

Item	Quantity On-Hand	Quantity Nonconforming	Quantity Returning
ART 1036			

Alpine Dental Health
 Dr. Todd Rosenzweig
 910 16th Street Mall Suite 711
 Denver, CO 80202
 9704845297

Name _____

Address _____ Phone Number: _____

Signature _____ Date _____

Please complete and fax or email to: Fax – 561-514-6316 Email – postmarket@BIOMET.com