

## URGENT DEVICE RECALL NOTICE



BIOMET 3i

4555 Riverside Drive.  
Palm Beach Gardens, FL 33410  
1.800.342.5454  
www.BIOMET3i.com

September xx, 2015

To: Dentists and Health Care Professionals

**Affected Product:** Provide® Protection Caps  
Provide Impression Copings  
All lots are affected

	Catalog Number
Provide Protection Caps	PPC484, PPC485, PPC654, PPC655
Provide Protection Cap Kits	PAK4140, PAK4155, PAK4240, PAK4255, PAK4340, PAK4355, PAK4440, PAK4455, PAK5140, PAK5155, PAK5240, PAK5255, PAK5340, PAK5355, PAK5440, PAK5455, PAK6140, PAK6155, PAK6240, PAK6255, PAK6340, PAK6355, PAK6440, PAK6455
Provide Impression Copings	PIC484, PIC484H, PIC485, PIC485H, PIC654, PIC654H, PIC655, PIC655H
Provide Impression Coping Kits	PRK484, PRK485, PRK654, PRK655

Dear Valued Customer:

BIOMET 3i is conducting a voluntary recall of the above products. Our records indicate that your office previously received a shipment of the affected product.

Through investigation, BIOMET 3i determined that the Provide Protection Caps (PPC\*\*\*) and the Provide Impression Copings (PIC\*\*\*) elicit a cytotoxic response (Grade 4). The Affected Products are intended for single, short-term use. The Affected Products were also distributed within Certain® Provide Abutment Placement Kits (PAK\*\*\*\*) as well as within Certain Provide Abutment Restorative Kits (PRK\*\*\*), so please search all of your kits. All lots are affected by this recall.

Normal clinical monitoring is recommended and clinicians are encouraged to keep the issue in mind if patients describe or present the potential harm(s) described below.

### Risks:

- Both the Provide Protection Caps and the Provide Impression Copings are single-use, temporary devices. If the clinician uses either of these products, the patient may experience soft tissue irritation and discomfort.

### Responsibilities:

- Please review this notice and check your inventory for the affected units.
- Immediately quarantine and remove all affected products from service.



## URGENT: DEVICE RECALL NOTICE

Provide®Protection Caps  
Provide Impression Copings

3. If you have product to return, please **call BIOMET 3i Complaints Department at 1-800-443-8166 or 1-561-776-6700** to obtain a RMA number and to setup a FedEx pick-up to return the products.
4. Complete the attached Business Reply Form and fax it to +1-561-514-6316 or email to [postmarket@BIOMET.com](mailto:postmarket@BIOMET.com).
5. Return affected product to BIOMET 3i along with the RMA number. Your account will be credited upon return of product.

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.

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 any other questions that you may have, please contact BIOMET 3i Complaints Department at 1-800-443-8166 or 1-561-776-6700. The Complaints Department is available 8:00am to 6:00pm (Eastern), Monday through Friday.



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### ATTACHMENT 1

### BUSINESS REPLY FORM / PACKING SLIP

#### Instructions:

1. If you have product to return, please **call BIOMET 3i Complaints Department at 1-800-443-8166 or 1-561-776-6700** to obtain a RMA number and to set up a FedEx pick-up to return products.
2. Complete the form below and email a copy to [postmarket@BIOMET.com](mailto:postmarket@BIOMET.com) or fax to +1-561-514-6316;
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: Complaints & Returns  
4555 Riverside Dr.  
Palm Beach Gardens, FL 33410

**Please complete this Business Reply Form within five (5) business days. It is very important that we receive the information from you so we can expedite the return and credit process. Please check your status below:**

	Catalog Number	Part # Returning	Lot # Returning	Quantity Returning
<b>Provide Protection Caps</b>	PPC484, PPC485, PPC654, PPC655			
<b>Provide Protection Cap Kits</b>	PAK4140, PAK4155, PAK4240, PAK4255, PAK4340, PAK4355, PAK4440, PAK4455, PAK5140, PAK5155, PAK5240, PAK5255, PAK5340, PAK5355, PAK5440, PAK5455, PAK6140, PAK6155, PAK6240, PAK6255, PAK6340, PAK6355, PAK6440, PAK6455			
<b>Provide Impression Copings</b>	PIC484, PIC484H, PIC485, PIC485H, PIC654, PIC654H, PIC655, PIC655H			
<b>Provide Impression Coping Kits</b>	PRK484, PRK485, PRK654, PRK655			

Name \_\_\_\_\_

Address \_\_\_\_\_ Phone Number: \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Please complete and fax or email to: **Fax – +1-561-514-6316 / Email – [postmarket@BIOMET.com](mailto:postmarket@BIOMET.com)**