

Urgent: Medical Device Recall Notification and Response Form

December 7, 2006

[REDACTED] (International Template)

Dear Affiliate:

It has come to BIOMET 3i's attention that an item labeled as 6mm healing abutment, incorrectly contains an 8mm healing abutment. The part is Certain EP Healing Abutment [IWTH56, lot # 586192]. Because we adhere to the highest quality standards and believe that patient care is paramount, we are voluntarily recalling this device. We can offer you an immediate replacement or credit, whichever you prefer.

Our records indicate that you have been shipped the quantities listed below. Please reconcile your inventory for the following product and lot number to determine whether the product has already been used in patients, sent to clinicians, but not used, or is still in your inventory. If you still have these products, or your records indicate they have been shipped to clinicians, but not used, please indicate the total number of units in the "Quantity To Be Returned" column below. Also list any product already used in the "Quantity Used" column.

Please fax this completed sheet to BIOMET 3i at [REDACTED] and indicate whether you prefer replacement or credit. Then return the product and a copy of this faxed response to the following address:

[REDACTED]
BIOMET 3i
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Incident No. CC36891

Cat. No.	Lot No.	3i Order #	Order Date	Quantity Shipped	Quantity Used	Quantity To Be Returned
IWTH56	586192	XXXXXXXX	xx/xx/xxxx	XX		

Replacement (Check One) Credit

We apologize for the inconvenience and thank you for your assistance with this product return. If you have any questions or concerns, please contact Regulatory Services at Ext. [REDACTED]

Sincerely,

[REDACTED]
[REDACTED]
[REDACTED]
Director, Regulatory Affairs & Quality Assurance