

Radiographic Transparency and External Connection Tapered Implants / BIOMET 3i/ RECALL (12/15)

Reason/Information:

BIOMET 3i issued an Urgent Medical Device Recall on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: 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 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.

Disposition/Instructions:

Actions/Responsibilities required by the customer:

-- Review this notice (See Image on Message under Additional Documentation/Attachment) and check 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".

--Immediately quarantine and remove all affected items from service.

--Complete the Business Reply Form (See Image on Message under Additional Documentation/Attachment) and either fax it to 561-514-6316 or email it to postmarket@biomet.com or return it along with the affected materiel using the included shipping label.

--Return affected materiel to BIOMET 3i.

BIOMET 3i request customers to maintain a copy of this notice and signed copy of Attachment A (See Image on Message under Additional Documentation/Attachment) for customers records to assist in any future regulatory agencies audits of this field action.

For assistance or other questions regarding this notice contact BIOMET 3i at 800-342-5454 or 561-776-6700, 8 a.m. to 6 p.m. (Eastern Time), Monday through Friday.

Item Information:

NSN (FSC-NIIN): 6525-NS1
Part Number: ART 1036
Nomenclature: RADIOGRAPHIC TRANSPARENCY FOR CERTAIN AND EXTERNAL
CONNECTION TAPERED IMPLANTS
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:

ALL

Service/Additional Instructions:

CONSIGNEES: Camp Pendleton Commanding Officer, Naval Hospital Receiving Officer, Dental Bldg. H-135 Camp Pendleton, CA 92055; (Tele: 619 -725 -1419; Shipping Date: 06/22/15; Order #3646391; QTY: 7); Naval Medical Center of San Diego, NMCS, DDS, Supply Dept. Branch Dental Clinic, NAB 3538 Bougainville Road/Bldg. 506 San Diego CA 92155; (Tele: 619-532-8600; Shipping Date: 04/22/15; Order #3622291; Qty: 3)

Additional Information can be found by clicking [here](#).