

Biomet 3i OSSEOTITE Certain Implant 4 X 11.5mm (IOSS411) RECALL (9/16)

Reason/Information:

Biomet 3i issued an Urgent Medical Device Removal on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: Through investigation, Biomet 3i determined that the implants were incorrectly packaged: A blue and white T3 Implant box was used instead of the correct red and gray OSSEOTITE box. The materiel label correctly identifies the product within the box and the inner packing is unaffected.

Disposition/Instructions:

Actions to be taken:

----Identify any affected materiel in customer's inventory.

1. Review this notification (See Image on Message under Additional Documentation/Attachment) for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond existing follow up schedule.
3. Review the instructions provided in Attachment 1 - Certificate of Acknowledgement (See Image on Message under Additional Documentation/Attachment) and retain a copy with customers recall records in the event of a compliance audit of documentation.

If customers have any questions or concerns regarding this notification contact Biomet 3i at 800-443-8166 or 561-776-6700.

Note: The affected units were distributed between the dates of 3 June 2016 and 11 July 2016.

Item Information:

NSN (FSCNIIN): 6520 - NS1

PartNo: IOSS411

Nomenclature: OSSEOTITE(R) CERTAIN(R) IMPLANT 4 X 11.5MM

UI: EA

Manufacturer: BIOMET 3I

Distributor:

LOT / SN:

2016031461

NOTE 1:

UDI No. (01)00844868007098(17)210401(10)2016031461

Additional information and documentation can be found by clicking [here](#).