

Various Dental Implant Surgical Kits and Trays / Biomet 3i Field Correction Notice (11/13)

Reason/Information:

Biomet 3i issued an Urgent Medical Device Field Correction Notice on the following materiel. Biomet 3i states that it has revised the steam gravity sterilization instructions for the products based on testing validations. Biomet 3i states that the trays did not meet the required sterility assurance level (SAL) in all locations using the previously validated steam gravity sterilization methods.

Disposition/Instructions:

Identify any affected materiel in your inventory. If you have the affected materiel, verify that you have received the 17 October 2013, Urgent Medical Device Field Correction Notice letter (See Image on Message under Additional Documentation/Attachment) from Biomet 3i. Biomet 3i states that the 2 recommended sterilization methods for the trays are steam gravity or pre-vacuum (minimum 4 min [4 pulses] at a temperature of 270 to 275°F [132 to 135°C]). After sterilization, devices should be thoroughly dried to mitigate the risk of stainless corrosion (30 min is typical). For steam gravity sterilization, follow the revised instructions (See Image on Message under Additional Documentation/Attachment). General questions, call 800-342-5454 or 919-620-2000.

Item Information:

NSN (FSC-NIIN): 6520-015180222
Part Number: CATD0
Nomenclature: CONTRA-ANGLE TORQUE DRIVER KITS
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:

N/A

NOTES:

NSN (FSC-NIIN): 6520-NS10
Part Number: SGTIKIT
Nomenclature: TAPERED NAVIGATOR CERTAIN SURGICAL KIT
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:

N/A

NOTES:

NSN (FSC-NIIN): 6520-NS2
Part Number: NCATD0
Nomenclature: CONTRA-ANGLE TORQUE DRIVER KITS
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS3
Part Number: NPSDK0
Nomenclature: CONTRA-ANGLE TORQUE DRIVER KITS FOR CERTAIN AND
EXTERNAL CONNECTION
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS4
Part Number: NCATD0C
Nomenclature: CONTRA-ANGLE TORQUE DRIVER KITS FOR CERTAIN INTERNAL
CONNECTION
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS5
Part Number: SGKIT
Nomenclature: NAVIGATOR SURGICAL KITS
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS6
Part Number: SGTRAY
Nomenclature: NAVIGATOR SURGICAL KIT
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS7

Part Number: PSDKO
Nomenclature: PROSTHETIC INSTRUMENTATION SYSTEMS
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS8
Part Number: PSDT1
Nomenclature: PROSTHETIC SYSTEM DRIVER TRAYS
UI: RA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

NSN (FSC-NIIN): 6520-NS9
Part Number: SGTTRAY
Nomenclature: TAPERED NAVIGATOR SURGICAL TRAY
UI: EA
Manufacturer: BIOMET 3I

LOT / SN:
N/A

NOTES:

POC Contact Information:

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Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

DOD

DODD 5105.22 and DODD 6025.13

Additional Documentation / Attachments

[MMQC-13-2104 1.pdf](#)

This message contains attachment(s) available on website link listed above.

*** END OF MESSAGE ***