BIOMET 3i™

NEW INFORMATION REQUIRED BY FDA

# URGENT MEDICAL DEVICE FIELD CORRECTION NOTICE

October 7, 2014

Insert Clinician
Name and
Address
Here

Dear Dr. Sir/Madam:

The FDA has requested that BIOMET ***3i*** issue a follow-up notification to all consignees providing a copy of the new sterilization instructions of the kits mentioned below and a confirmation of receipt of this Field Correction Notice. Please note; this is not a new Field Correction Notice but a follow-up to the initial notification made on October, 2013.

BIOMET ***3i*** requires a response that you have received this new information—even if you have responded previously.

The purpose of this letter is to notify you of a labeling change affecting all BIOMET ***3i*** sterilization instructions including, but not limited to P-IFSCSS Revision A and Surgical Manual Revision G.

This instruction change affects only the kits/trays. Two methods of sterilization for the kits (reference Table 1.0) are recommended per P-IFSCSS and our Surgical Manual:

1. Steam Gravity Sterilization Method or Pre-Vacuum Sterilization Method *(*Minimum four (4) minutes (four pulses) at a temperature of 270 - 275$^{0}$F (132-135$^{0}$C))*

* *Post sterilization, devices should be thoroughly dried to mitigate the risk of stainless corrosion (30 minutes is typical).*

**Only the Steam Gravity Sterilization Method is affected by this notification and only for the items depicted in Table 1.0 and Table 2.0 of this notification.**

***Table 1.0 – Affected Kits***

| Kit Part Number | Kit Description |
|---|---|
| SGKIT | Navigator® Surgical Kit |
| SGTIKIT | Tapered Navigator Certain® Surgical Kit |
| NCATD0 | Contra-Angle Torque Driver Kit |
| NCATD0C | Contra-Angle Torque Driver Kit For Certain Internal Connection |
| NPSDK0 | Contra-Angle Torque Driver Kit For Certain and External Connection |
| CATD0 | Contra-Angle Torque Driver Kit |
| PSDK0 | Prosthetic Instrumentation System |

***Table 2.0 – Affected Trays***

| Tray Part Number | Tray Description |
|---|---|
| SGTRAY | Navigator® Surgical Kit |
| SGTTRAY | Tapered Navigator Surgical Tray |
| PSDT1 | Prosthetic System Driver Tray |

BIOMET 3i European Headquarters
WTC Almeda Park, Ed. 1, planta 1
Pl. de la Pau s/n
08940 – Cornellá de Llobregat
(Barcelona) Spain
Tel: +34 93 470 55 00
Fax: +34 93 371 78 49

In 2013, BIOMET *3i* conducted additional sterilization validation testing on all commercial surgical kits / trays. These validations further challenged the original sterilization validations and were conducted with more stringent requirements. During the execution of these validations, the surgical trays (reference Tables 3.0) did not meet the Sterility Assurance Level (SAL) of $10^{-6}$ in all locations using the previously validated steam gravity sterilization method at twenty (20) minutes (testing was conducted at a half cycle time of ten (10) minutes). These devices, however, were shown to achieve an SAL of $10^{-6}$ in all challenged locations using a forty (40) minute exposure (testing was conducted at a half cycle time of twenty (20) minutes).

Included with this notification is a copy of the current revision of the sterilization instructions, P- IFSCSS.

Please **destroy any copies of P-IFSCSS Rev A and Surgical Manual Rev G.** Confirm receipt of this notification and destruction of these documents or that the referenced trays are no longer in use by your office by completing and returning the attached response fax sheet below at your earliest convenience.

Only the steam gravity method of sterilization is affected by this notice. The 40 minute cycle has been validated and provides an SAL of $10^{-6}$. There is no change to the pre-vacuum sterilization method.

Due to individual clinical handling procedures, cleaning methods, bio-burden levels, and other conditions, clinicians should use professional judgment to ensure proper sterilization of all devices and instruments. The use of non-sterilized devices or instruments may cause or contribute to clinical sequelae.

Thank you for your attention to this notice. If you have any questions or concerns, please contact Biomet 3i customer service at + 353 1800 552752.

Sincerely,

Elsa Folch
Regulatory Affairs & Quality Assurance Manager EMEA
Biomet 3*i*

BIOMET 3i European Headquarters
WTC Almeda Park, Ed. 1, planta 1
Pl. de la Pau s/n
08940 – Cornellà de Llobregat
(Barcelona) Spain
Tel: +34 93 470 55 00
Fax: +34 93 371 78 49

BIOMET 3i

# NEW INFORMATION REQUIRED by FDA
# MEDICAL DEVICE FIELD CORRECTION NOTICE
# RETURN RESPONSE

## Acknowledgement Receipt Form

Response is Required

Customer Name: Acct Number: #XXXXXX

**PRODUCT:**
Sterilization instructions for:

| Kit Type | Product Code / Tray Code |
|---|---|
| NSK Contra-Angle Torque Driver Kits | NPSDK0 / PSKD0 / PSDT1 |
| | NCATD0 / CATD0 / PSDT1 |
| | NCATD0C / PSDT1 |
| Parallel-Wall Implant Navigator® Kit | SGKIT / SGTRAY |
| Tapered Implant Navigator Kit | SGTIKIT / SGTTRAY |

By signing below, I certify that old revisions of P-IFSCSS Rev A and Surgical Manual Rev. G have been destroyed or that the office no longer uses the referenced items and that I have read and understand the Correction instructions provided in this letter.

Signature of Receipt:

Print Name/ Title: _____

Signature: _____ Date: _____

Please **EMAIL** completed response form to 3iEUComplaints@biomet.com

or

Send by **FAX** to at + 353 1800 656608. ATTN: Elsa Folch

or

**MAIL** to:
BIOMET 3i European Headquarters ATTN: Elsa Folch
WTC Almeda Park, Ed. 1, planta 1
Pl. de la Pau s/n
08940 – Cornellá de Llobregat, Barcelona, Spain

Thank you for your attention to this notice. If you have any questions or concerns, please contact Biomet 3i customer service at + 353 1800 552752.

BIOMET 3i European Headquarters
WTC Almeda Park, Ed. 1, planta 1
Pl. de la Pau s/n
08940 – Cornellá de Llobregat
(Barcelona) Spain
Tel: +34 93 470 55 00
Fax: +34 93 371 78 49

KTS