



## URGENT MEDICAL DEVICE FIELD CORRECTION NOTICE

October 17, 2013

*Insert Clinician  
Name and  
Address  
here*

Dear Dr. Sir/Madam:

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 and all Surgical Manuals.

This instruction change affects only the below kits/trays. Two methods of sterilization for the below kits are recommended per P-IFSCSS and our Surgical Manuals:

1. Steam Gravity Sterilization Method or Pre-Vacuum Sterilization Method (Minimum four (4) minutes (four pulses) at a temperature of 270 - 275°F (132-135°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 following items:**

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
PSDKO	Prosthetic Instrumentation System

Tray Part Number	Tray Description
SGTRAY	Navigator® Surgical Kit
SGTTRAY	Tapered Navigator® Surgical Tray
PSDTI	Prosthetic System Driver Tray

BIOMET 3i recently conducted revised sterilization validation testing on all commercial surgical kits / trays. These validations further challenged the original sterilization validations and were conducted with more difficult requirements. During these validations, the below surgical trays 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).



Due to recent sterilization re-validation testing, BIOMET 3i is now recommending that the following sterilization instructions be followed for the surgical kits listed below:

Kit Type	Product Code / Tray Code	Previous Recommendation for Steam Gravity Time	Current Recommendation for Steam Gravity Time
NSK Contra-Angle Torque Driver Kits	NPSDK0 / PSDT1 / PSKDO	(20) minutes at a temperature of 270 – 275°F (132-135°C)*	(40) minute cycle time at a temperature of 270 – 275°F (132-135°C)*
	NCATD0 / PSDT1 / CATD0	(20) minutes at a temperature of 270 – 275°F (132-135°C)*	(40) minute cycle time at a temperature of 270 – 275°F (132-135°C)*
	NCATD0C / PSDT1	(20) minutes at a temperature of 270 – 275°F (132-135°C)*	(40) minute cycle time at a temperature of 270 – 275°F (132-135°C)*
Parallel-Wall Implant Navigator® Kit	SGKIT / SGTRAY	(20) minutes at a temperature of 270 – 275°F (132-135°C)*	(40) minute cycle time at a temperature of 270 – 275°F (132-135°C)*
Tapered Implant Navigator Kit	SGTIKIT / SGTTRAY	(20) minutes at a temperature of 270 – 275°F (132-135°C)*	(40) minute cycle time at a temperature of 270 – 275°F (132-135°C)*

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

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<sup>-6</sup>. There is no change to the pre-vacuum sterilization method.

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

Please confirm receipt of this notification by returning a copy signed per e-mail or fax.

Fax to: + 44 (0) 800-840-6814  
E-mail: carmen.esrich@biomet.com

Thank you for your attention to this notice. If you have any questions or concerns, please contact Biomet 3i customer service at + 44 (0) 800-652-1233.

Sincerely,

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

**Acknowledgement of receipt:**

Doctor's Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_