

11 March 2015

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTICE – FSN2014525
Pedicle Awls: Technique Guides & Outer Labels

Please distribute this information to the appropriate personnel at your facility

Technique Guide Description	Technique Guide Number
Pangea Spine System, Technique Guide	036.000.080
USS II Polyaxial Spine System, Technique Guide	036.000.216
MATRIX Spine System – Deformity, Technique Guide	036.001.180
MATRIX Spine System – Degenerative, Technique Guide	036.001.185
Affected Labeling Description	Product Code
Pedicle Awl 4.0mm w/Canevasit Handle	388.550
Pedicle Awl 4.0mm w/Silicone Handle	388.656

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device Field Safety Notice for the Surgical Technique Guides for Pangea, USS II Polyaxial, Matrix Deformity, and Matrix Degenerative systems as well as outer labels for two Pedicle Awls (388.550 and 388.656).

Our records indicate that you may have inventory that is impacted by this Field Safety Notice.

Reason for this Field Safety Notice:

Technique Guides for these four systems describe the Pedicle Awls as 4.0mm for use with screws (4.0mm – 7.0mm). These awls should be used with 5.0mm – 7.0mm screws. This Field Safety Notice is being issued in order to communicate changes being made to Technique Guides and outer labels in order to clarify the intended use of these two awls within these systems. *There has been no change to the design or manufacture of the Pedicle Awls.*

The revised Surgical Technique Guides contain the following corrections related to this Field Safety Notice:

Pangea Spine System: Technique Guide 036.000.080, Pedicle Awl 388.656		
Page	Current	Revision
8	Pedicle Awl 4.0mm with Silicone Handle, for Pedicle Screws	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 5.0 to 7.0mm
58	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 4.0 to 7.0mm	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 5.0 to 7.0mm

USS II Polyaxial Spine System: Technique Guide 036.000.216, Pedicle Awl 388.550		
Page	Current	Revision
10	Pedicle Awl, length 230mm	Pedicle Awl 4.0mm with Canevasit Handle, length 230mm, for Pedicle Screws 5.0 to 7.0mm

MATRIX Spine System – Deformity: Technique Guide 036.001.180, Pedicle Awl 388.656		
Page	Current	Revision
10	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 4.0 to 7.0mm	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 5.0 to 7.0mm

MATRIX Spine System – Degenerative: Technique Guide 036.001.185, Pedicle Awl 388.656		
Page	Current	Revision
8	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 4.0 to 7.0mm	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 5.0 to 7.0mm
66	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 4.0 to 7.0mm	Pedicle Awl 4.0mm with Silicone Handle, length 255mm, for Pedicle Screws 5.0 to 7.0mm

**All applicable translations will also be updated and made available accordingly.*

The revised outer labels contain the following corrections related to this Field Safety Notice:

Product Label	Current	Revision
388.550	Pedicle Awl 4.0mm w/Canevasit Handle, L 230mm, f/Pedic. Screws 4.0 to 7.0mm	Pedicle Awl 4mm w/Canevasit Handle, length 230mm, for Pedicle Screws 5.0 to 7.0mm
388.656	Pedicle Awl 4.0mm w/Silicone Handle, L 255mm, f/Pedic.Screws 4.0 to 7.0mm	Pedicle Awl 4mm w/Silicone Handle, length 255mm for Pedicle Screws 5.0 to 7.0mm

Please note that there has been no change to the design or manufacturing of these Pedicle Awls. This Field Safety Notice impacts information in Technique Guides and outer labels only.

Clinical Implications:

In the event that a Ø4mm Awl is used for a Ø4mm screw, there is a risk that perforation of the cortex will be too wide and may result in screw pull-out or loosening. In the event that the cortex is perforated wider than needed for insertion of a 4mm screw, the failure would not typically be recognized. Cases may occur, however, where a surgeon's perception of torque to insert the screw does not have the desired level of fixation. In this case, the issue may be recognized.

Please be advised that Technique Guides containing the updates referenced above will be available at www.Synthes.com as is customary for Synthes GmbH systems. Your facility may temporarily receive Pedicle Awls without the above referenced labeling clarifications due to their previous release to distribution channels. As we work to implement these labeling updates in our inventory, please note that there have been no updates made to the design or manufacture of these instruments. This Field Safety Notice impacts information in Technique Guides and outer labels only.

To date, there have been zero reports of related failure modes with the 4.0mm screws in these four systems that would lead to the aforementioned harms.

Customer immediate actions:

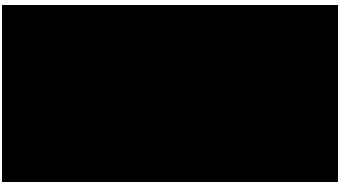
1. Read the **Field Safety Notice** carefully.
2. Complete the **Verification Section** and pass it to your DePuy-Synthes representative or fax it to **6720 0750 within 2 business days.**
3. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.
4. Review the revisions being made to surgical Technique Guides and outer labels.
5. Forward this notice to anyone in your facility that needs to be informed.
6. If any of the affected Technique Guides or outer labels have been forwarded to another facility, contact that facility to inform them of revisions.
7. Maintain awareness of this notice until all Technique Guides and outer labels have been updated.
8. Keep a copy of this notice.

Applicable Regulatory Agencies will be notified.

We apologize for any inconvenience that this Field Safety Notice may create and appreciate your attention to this matter. Should you have any inquiries, please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Yours sincerely,



Lee Ching Hwee
Professional Affairs Associate

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Verification Section

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Please note that there has been no change to the design or manufacturing of these Pedicle Awls. This Field Safety Notice impacts information in Technique Guides and outer labels only.

_____ We acknowledge the receipt of this information but do not have the Synthes Spine Pedicle Awl 4.0mm w/Canevasit Handle and/or Pedicle Awl 4.0mm w/Silicone Handle within our stock at this facility.

_____ We acknowledge the receipt of this information and have located the Synthes Spine Pedicle Awl 4.0mm w/Canevasit Handle and/or Pedicle Awl 4.0mm w/Silicone Handle within our stock at this facility.

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

 Customer Name

 Title

 Signature & Date

 Stamp (**Stamp shall bear facility name**)

Please complete this **Verification Section** and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(2) two business days** of receipt of the Field Safety Notice.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.