Augmentable Pedicle Screws for Osteoporotic Bone

Perforated Click’X

Surgical Technique
Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
# Table of Contents

## Introduction
- Perforated Click’X 2
- AO Spine Principles 4
- Indications and Contraindications 5

## Surgical Technique
- Preoperative Planning 6
- Surgical Technique 7
- Notes and Warnings 13

## Product Information
- Implants and Instruments 14
Perforated Click’X. Augmentable Pedicle Screws for Osteoporotic Bone.

Improved Anchoring and Shear Stability in Osteoporotic Bone

- Screw anchoring and vertebral body support thanks to cement cloud
- Six radial screw openings for 360° cement distribution
- Controlled cement injection, performed simultaneously or alternated at different levels
- Augmentation after final screw positioning
**Syringe**

- Syringe provides tactile feedback during injection

**Adapter**

- Adapter with Luer lock fits any commercial syringe
- Press-fit connection for leak-proof cement injection

**Perforated dual-core pedicle screw**

- Cylindrical large core with low and broad thread flanks designed for higher strength in dense cortical bone shell of pedicle
- Cylindrical small core with high and thin thread flanks for cancellous bone in vertebral body
- Six radial openings for 360° cement distribution and improved screw anchoring
- Large cannulation diameter for low cement injection resistance
- Kirschner Wire cannulation for guided screw insertion over 1.6 mm Kirschner Wire
- Reduced cement outflow from screw tip
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.\textsuperscript{1,2}

**Stability**  
Stabilization to achieve a specific therapeutic outcome

**Alignment**  
Balancing the spine in three dimensions

**Biology**  
Etiology, pathogenesis, neural protection, and tissue healing

**Function**  
Preservations and restoration of function to prevent disability

Indications and Contraindications

**Intended use**
The Perforated Click’X system is a transpedicular screw/rod system intended for the posterior stabilization of the thoracolumbar and lumbar spine. The Perforated Click’X screws are cannulated. However, they may be inserted like standard solid Click’X screws or like Cannulated Click’X screws by means of Kirschner Wire guidance. The lateral perforations allow direct cement augmentation of the screw in the osteoporotic bone.

**General indications**
The implants can be used for the following indications in the area of the lower thoracic and lumbar spine
- Degenerative instabilities
- Instabilities following decompression
- Type A1 fractures and related types of the B and C group
- Type A2 and A3 fractures as well as similar fractures of the C group, if combined with an anterior intervention
- Tumors without anterior defect
- Osteoporosis when used concurrently with bone cement indicated for internal spinal fixation supplementation

**Contraindications**
- Deformities
- In fractures and tumors with severe anterior vertebral body disruption, an additional anterior support is required
- Osteoporosis when used without cement augmentation
- Severe osteoporosis

**Note:** Refer to the manufacturer's directions accompanying the bone cement for specific information on its use, indications, contraindications, precautions, warnings and side effects.
Preoperative Planning

Preoperative planning includes evaluation and assessment of the patient with regard to the specifications of the bone cement used for augmenting perforated Click’X screws.

Proper imaging equipment must be used to determine correct implant dimensions in relation to the anatomy.

The decision whether or not to augment Perforated Click’X screws can be taken intraoperatively, based on tactile feedback upon pedicle preparation and screw insertion. If screws are augmented, bilateral screw augmentation is recommended.

**Note:** Do not reinforce more than six vertebrae with bone cement in one session. The injected cement pushes bone marrow into the blood circulation and can cause fat embolization. The amount of cement that is injected in one session should therefore be limited to about 25 ml or even less if a patient shows severely compromised cardiopulmonary function.

**Note:** Handling knowledge of bone cement is required. Image intensifier control is highly recommended while injecting bone cement.
This surgical technique contains complementary instructions on handling Perforated Click’X screws. For the standard surgical Click’X procedure consult the Click’X System surgical technique.

Notes on working with Kirschner Wires

- If Perforated Click’X screws are inserted over Kirschner Wires also consult the technique guide on handling Cannulated Click’X screws.
- Under image intensifier control ensure that each Kirschner Wire is in the appropriate position for screw insertion. Especially the tip of the Kirschner Wire should be radiologically monitored to confirm that it does not penetrate the anterior wall of the vertebral body and thus risking damage of the vessels in front of it.
- Kirschner Wires are for single use.

1. Prepare pedicles and insert screws

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>01.606.203</td>
<td>Click’X Basic Instrument Set in Vario Case</td>
</tr>
<tr>
<td>03.620.220</td>
<td>Screwdriver Shaft Stardrive, T25, cannulated, with Hexagonal Coupling, Ø 6.0 mm</td>
</tr>
</tbody>
</table>

**Optional instrument**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>01.624.103</td>
<td>Cannulated Instruments for Pedicle Preparation, in Vario Case</td>
</tr>
</tbody>
</table>

Open and prepare the pedicles and insert the screws as defined in the Click’X System surgical technique. Use the cannulated screwdriver shaft. Do not attach the 3-D heads yet.
Assess the cortical shell for perforations.

Note: In case of any perforation, special caution is required when bone cement is applied. Cement leakage and its related risks may compromise the physical condition of the patient.

Select appropriate screw lengths. Choose screws with the maximum possible diameter and length to achieve improved stability.

The Perforated Click’X screw must enter in approximately 80% of the vertebral body.

Notes on screw length

• If screws are too short, the bone cement risks being injected too close to the pedicle.
• If screws are too long, or placed bicortically, the anterior cortical wall may be penetrated and cement leakage may occur.

Precaution: It is imperative that the screw perforations are located in the vertebral body, close to the anterior cortical wall. For this reason 35 mm screws should only be placed in the sacrum.
2. Assess proper screw placement

Use a Ø 2.0 mm Kirschner Wire to clean the cannula for proper cement injection.

3. Prepare bone cement

Prepare the bone cement according to the manufacturer’s direction. Use syringes with Luer-Lock for injecting the bone cement.
4. Inject bone cement

Place the C-Arm in a lateral position to monitor the extrusion of the cement into the vertebral body.

Additional image intensifier control in the AP projection is recommended.

**Note:** Do not augment more than four screws at once.

**Note:** Ensure that there is a firm connection between the adapter and the screw recess.
1. Inject approximately 0.5 ml cement per screw until cement extrudes from the perforations.

**Note:** Ensure that no cement leakage occurs outside the intended area. Immediately stop the injection in the event of leakage.

2. Following the same order of screws, add another 0.5–1 ml of cement to each screw. The cement extrusion needs to be monitored under continuous image intensifier control. A growing cloud pattern should form. If a spider web-like pattern forms, wait approx. 30 to 45 seconds or proceed with another screw and return to the present screw later.

3. If more cement is needed or the injection pressure is too high, switch to the 1 ml syringes and inject more cement. Start again with the first screw. Augmentation is complete when each screw has been augmented with a total volume of approximately 2 to 3 ml.

**Note:** Do not remove or replace syringes immediately after injection. This avoids contaminating the screw drive and the patient’s soft tissues with cement drips. The longer the syringe remains connected to the screw, the lower the risk of contamination.

**Warning:** Any cement remaining in the screw drive must be removed while it is still soft (or has not hardened) e.g. with the screwdriver shaft. This will ensure that future revision surgeries remain possible.

**Warning:** The cement flow follows the path of least resistance. Therefore it is mandatory, during the whole injection procedure, to maintain real-time image intensifier control in the lateral projection. If the filling pattern does not behave as expected or if the cement is not clearly visible, the injection must be stopped.

Wait until the cement has cured before removing adapters and continuing with the instrumentation.
5. Attach Click’X 3-D heads and assemble construct

Prior to attaching the 3-D heads ensure that the pedicle screw heads are clean and not contaminated with any bone cement. Remove any cement from the soft tissues.

Attach the 3-D heads and continue with the following steps according to the Click’X System surgical technique.
Notes and Warnings

Cement leakage
The inherent risk of this technique is cement leakage. Risks can be decreased and complications rate reduced by observing the above mentioned technique. The second challenge that needs to be emphasized is fat embolism – since the injected cement will push bone marrow into the blood circulation the amount of cement that is injected in one session should be limited to about 25 ml and less if a patient shows severely compromised cardiovascular function. Furthermore, systemic reactions during cement injection can occur as a consequence of cement monomer release.

If significant leakage occurs, stop the procedure. Return your patient to the ward and perform a clinical assessment in order to clarify the neurological situation. If the neurological state is not compromised, there is no need for further surgical measures. If neurological function is severely compromised, an emergency CT scan should be performed in order to assess the amount and location of the extravasation. If applicable, open surgical decompression and cement removal may be performed as an emergency procedure.

Extravasation
In order to reduce the risk of extravasation, it is strongly recommended to follow the described surgical technique, i.e.:
• Use a Kirschner Wire for pedicle screw placement
• Use a high-quality C-arm in lateral position
• Use highly viscous and highly radiopaque bone cement

Additional image intensifier control in the AP projection is recommended.

Leakage outside the vertebra
What action is required if leakage occurs? If you recognize leaking outside the vertebra, stop the injection immediately. Wait for 45 seconds. Then slowly continue with the injection. Due to the faster curing in the vertebral body, the cement occludes the small vessels and the filling can be accomplished. It is possible to recognize amounts of cement as small as 0.2 ml. If filling cannot be performed as described, stop the procedure.

Leakage into the spinal canal
What action is required if leakage into the spinal canal occurs? Stop the injection. If the leak is very small, you may proceed as described in step 4.

Fracture
The risk of a fracture at adjacent levels appears to be increased after cement reinforcement. Patients and their doctors should therefore be made aware that if new pain occurs, a new fracture may have occurred. Radiological control should be performed and, if necessary, further reinforcement should be considered – in such cases also including the adjacent vertebrae.

All patients with osteoporotic fractures should be evaluated and treated by an osteologist or their family doctor and, if applicable, receive systemic treatment with vitamin D and bisphosphonates.

Pregnancy
Refer to the manufacturer’s directions accompanying the bone cement indicated for internal spinal fixation supplementation for indications, contraindications, precautions, warnings and side effects (e.g. infertility, teratogenic effects).
Implants and Instruments

Perforated Click’X pedicle screws

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>04.606.223S–227S</td>
<td>Click’X Pedicle Screw Ø 5.2 mm, perforated, with dual core, TAN, length 35–55 mm, sterile</td>
</tr>
<tr>
<td>04.606.233S–237S</td>
<td>Click’X Pedicle Screw Ø 6.2 mm, perforated, with dual core, TAN, length 35–55 mm, sterile</td>
</tr>
<tr>
<td>04.606.243S–247S</td>
<td>Click’X Pedicle Screw Ø 7.0 mm, perforated, with dual core, TAN, length 35–55 mm, sterile</td>
</tr>
</tbody>
</table>

All screw lengths available in **5 mm increments**.

**Precaution:** It is imperative that the screw perforations are located in the vertebral body, close to the anterior cortical wall. For this reason 35 mm screws should only be placed in the sacrum.

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<tbody>
<tr>
<td>03.620.220</td>
<td>Screwdriver Shaft Stardrive, T25, cannulated, with Hexagonal Coupling, Ø 6.0 mm</td>
</tr>
<tr>
<td>492.200</td>
<td>Kirschner Wire Ø 2.0 mm with trocar tip, length 150 mm, Titanium Alloy (TAV)</td>
</tr>
</tbody>
</table>
Augmentation material

07.702.211.02S  Adapter for Stardrive, T25, with Luer-Lock, 2 pieces, sterile

07.702.212.02S  Screw Cementation Kit, sterile

07.702.016S  Vertecem V+ Cement Kit, sterile
1 x Vertecem V+ Mixer prefilled with cement powder
1 x Monomer glass ampoule

03.702.215S  Vertecem V+ Syringe Kit
Content:
8 x blue 1 cc syringes
5 x white 2 cc syringes
1 x one-way stop-cock
Implants and Instruments

Click’X Vario Cases

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>01.606.203</td>
<td>Click’X Basic Instrument Set in Vario Case (make sure ratchet 388.652 or 388.654 is included)</td>
</tr>
<tr>
<td>01.606.404</td>
<td>Click’X Implants in Vario Case</td>
</tr>
</tbody>
</table>

Cannulated Pedicle Preparation Set

<table>
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<tbody>
<tr>
<td>01.624.103</td>
<td>Cannulated Instruments for Pedicle Preparation in Vario Case</td>
</tr>
</tbody>
</table>
Click’X implants*

04.606.000*  Click’X Locking Cap Stardrive, T25, Titanium Alloy (TAN)

498.571*  Click’X 3D-Head for Pedicle Screw, posterior open, Titanium Alloy (TAN)

04.620.135*–180*  Rod Ø 6.0 mm, soft, curved, lengths 35–80 mm, Pure Titanium

498.139*–143*  Click’X Rod Ø 6.0 mm, curved, normalized, lengths 45–85 mm, Pure Titanium

498.150*–154*  Rod Ø 6.0 mm, soft, lengths 50–150 mm, Pure Titanium

* Available non-sterile and sterile packed. Add suffix “S” to article number to order sterile product.