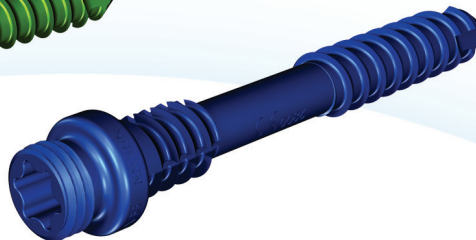
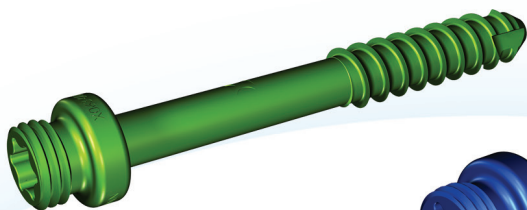
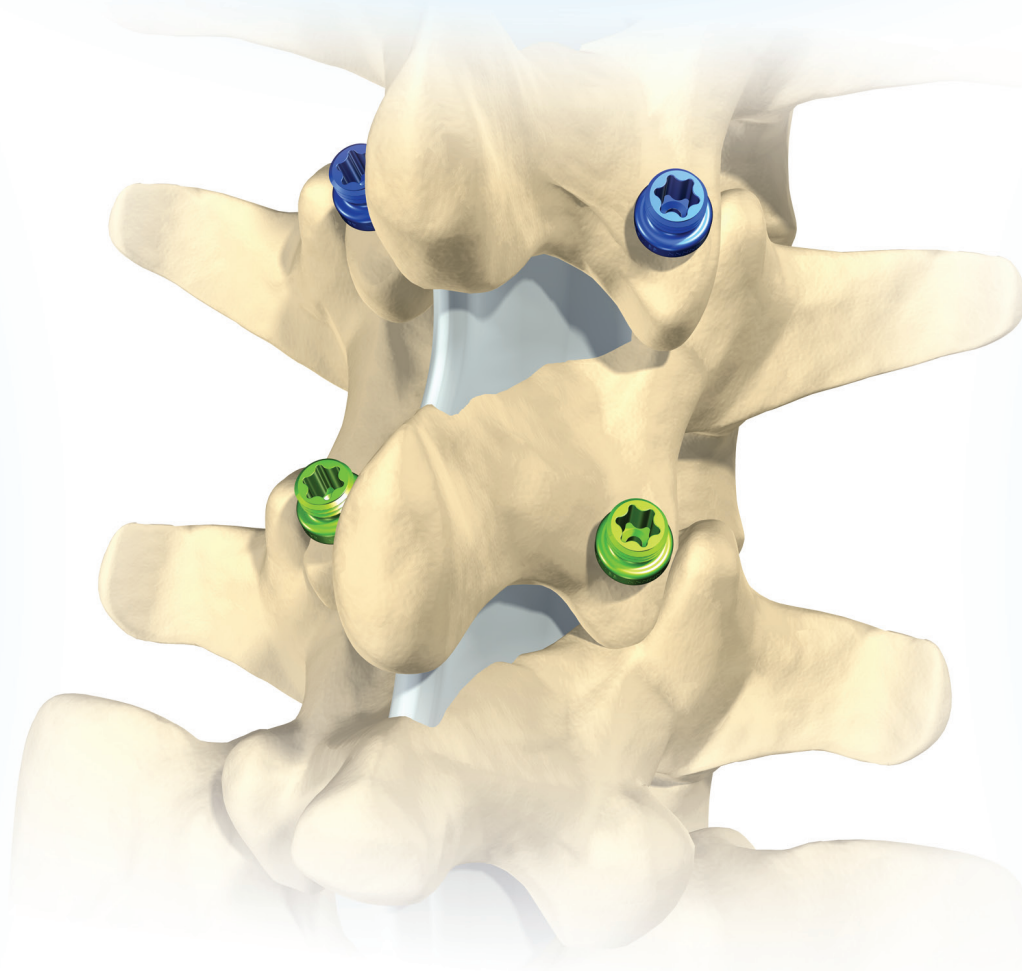




Spinal Facet Screw System



 X·spine™
X·treme Innovations

Distribuidor exclusivo em Portugal:

 yourspine





Single-Thread Screw

Available in 25 - 45mm lengths
(5mm Increments)



Dual-Thread Screw

Available in 30 - 45mm lengths
(5mm Increments)

- 4.5mm diameter screws
- All screws cannulated
- 12mm percutaneous incision
- No washer required
- Simple instrumentation
- Various lengths for different spinal anatomies
- Lower profile than traditional pedicle screws
- Only 2 small incisions required for bi-lateral fixation
- Graft packer included for easy graft insertion

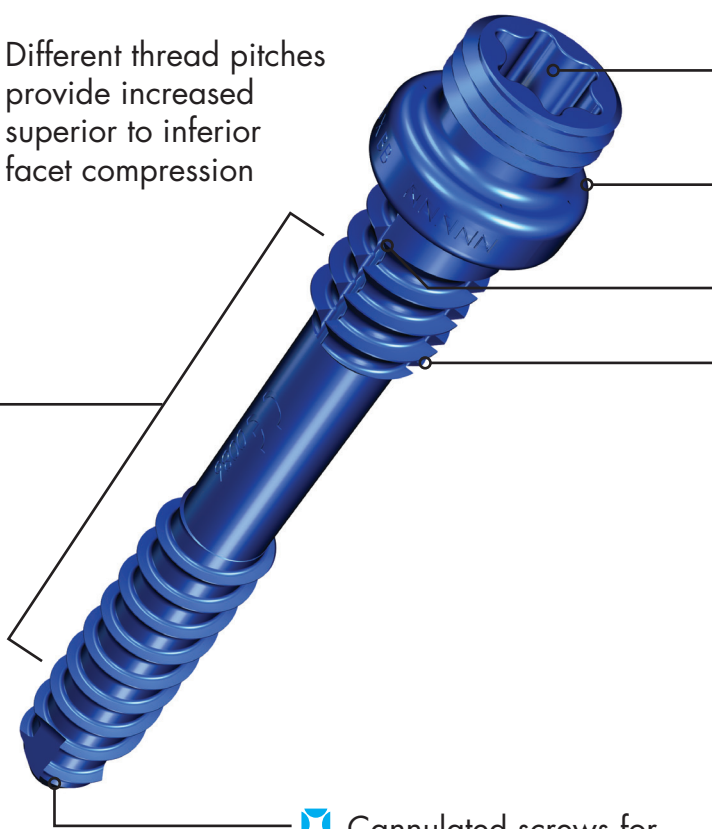
❑ Different thread pitches provide increased superior to inferior facet compression

❑ Screw heads used for screwdriver engagement

❑ Washer not required thus reduces profile

❑ Anti-migration indent

❑ Top threads provide additional locking without need of a washer



❑ Cannulated screws for percutaneous approach

* Optional 10mm washer is also available



Instrumentation is available for both percutaneous and open approaches with the FIXCET Spinal Facet Screw System.



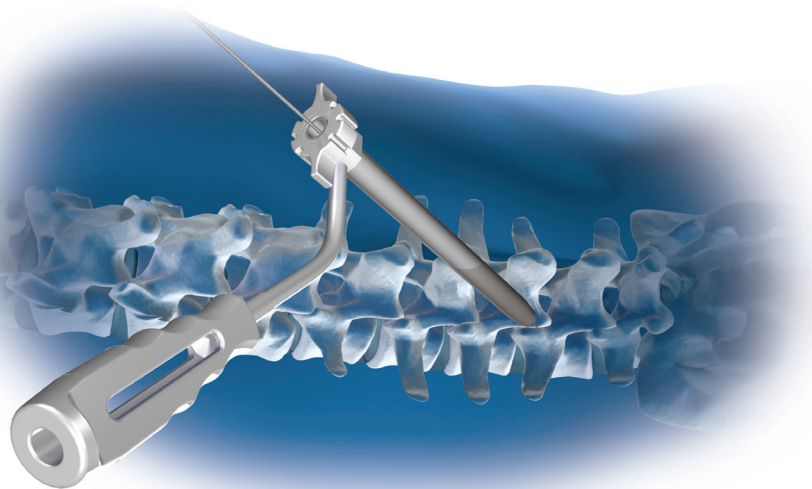
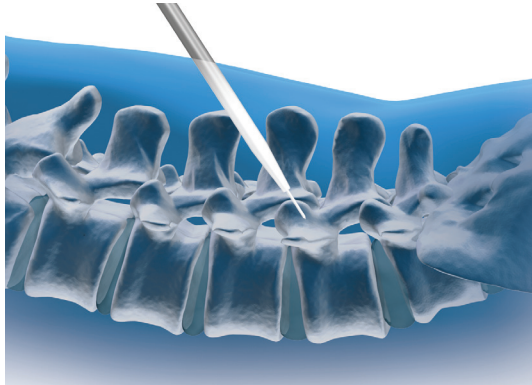
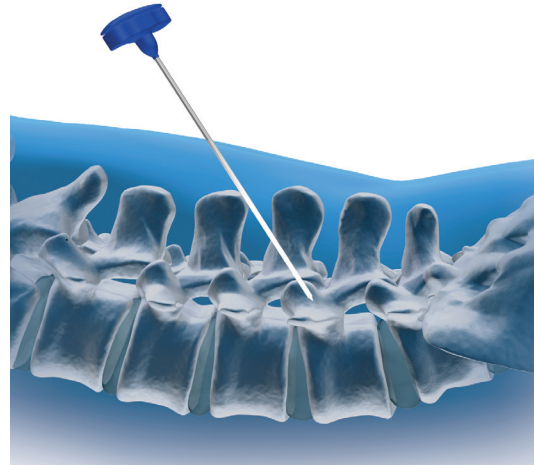
Spinal Facet Screw System

❑ Step 1 – Patient Positioning

The patient is positioned on the operating table in the prone position. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral region.

❑ Step 2 – Exposure

The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The laminae, pedicles, superior and inferior facets of the levels to be fused should be visualized directly and/or by intraoperative fluoroscopy.



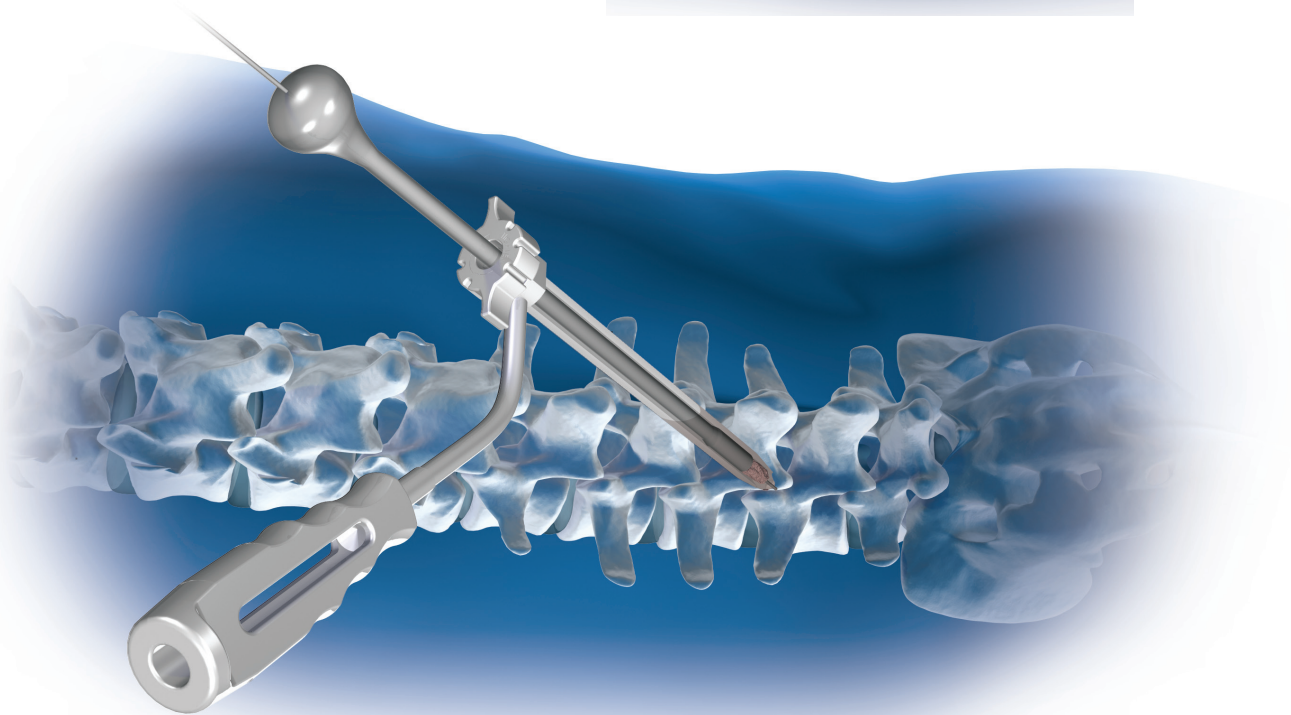
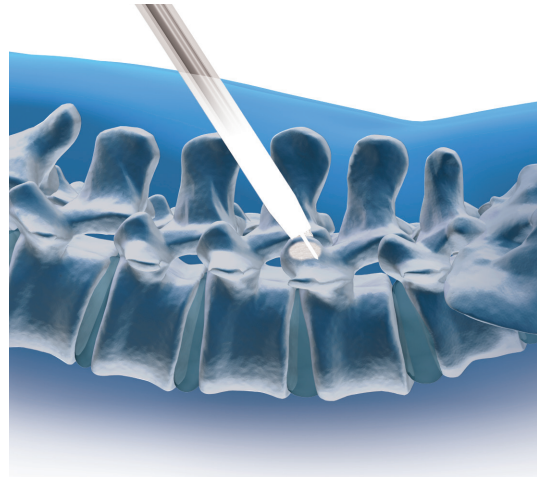
This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

Information contained in this document was gathered and compiled by experts in the field and X-spine employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. X-spine does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and X-spine is not liable for any losses whatsoever of any kind or any nature that may be caused by the use of said information.

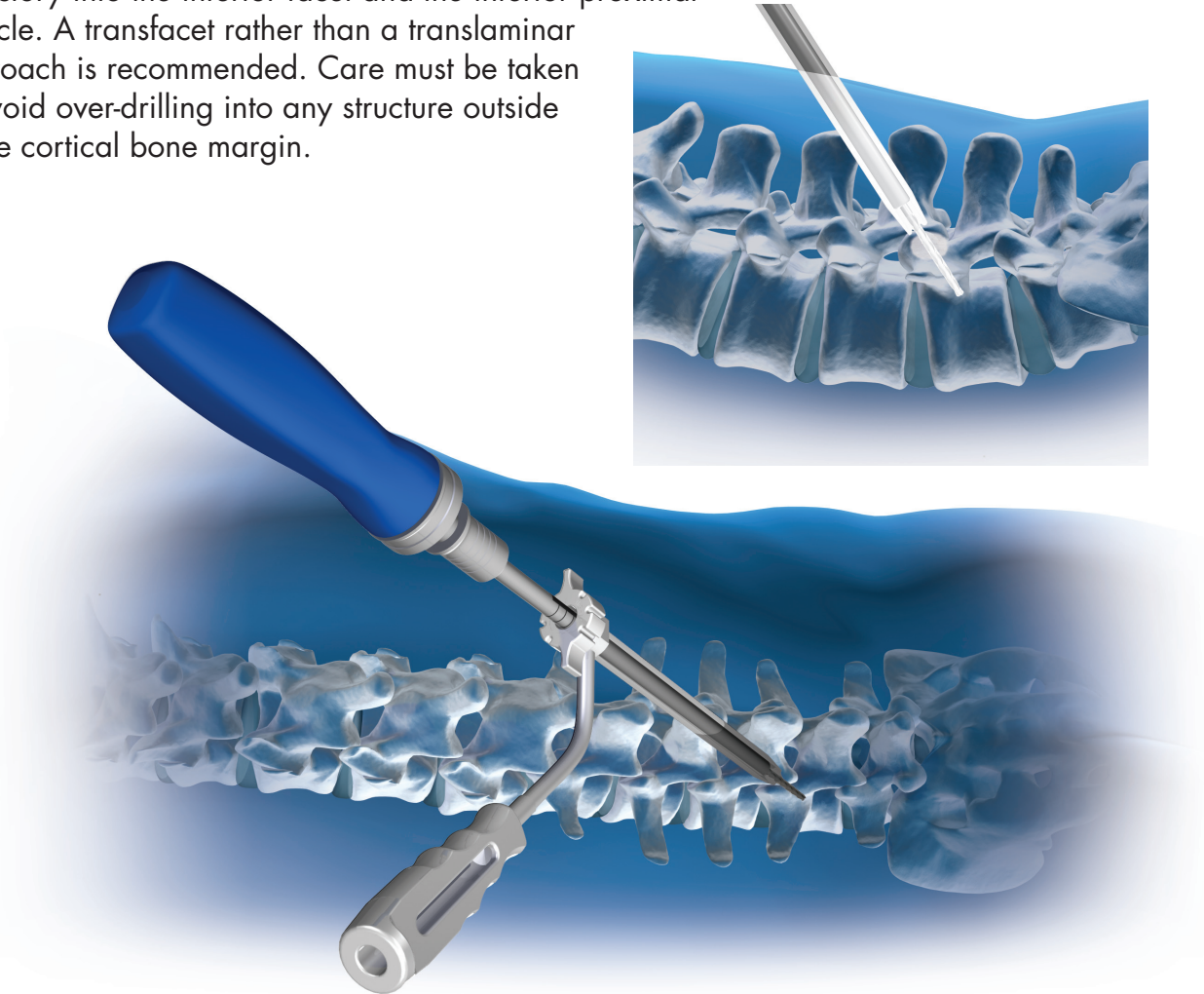
Step 3 – Placement of Bone Graft

Appropriate arthrodesis and interbody fusion with a load-bearing construct should be performed prior to screw placement. Care should be taken to avoid any removal or anatomic compromise of the facet joints. Anterior column support and meticulous fusion techniques are required for a successful procedure.



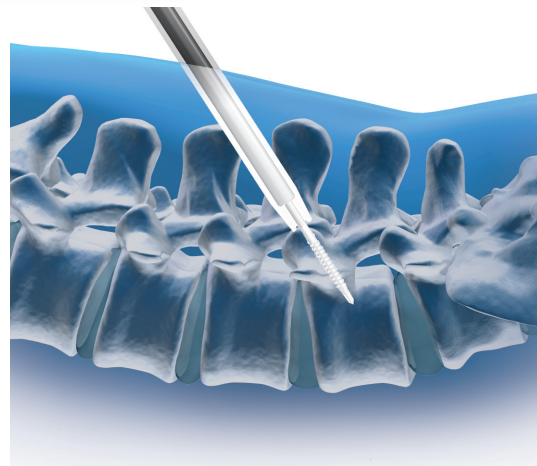
Step 4 – Drilling

Under fluoroscopic guidance, a K-wire, drill and Drill Outer Dilator are placed over the superior facet with a trajectory into the inferior facet and the inferior proximal pedicle. A transfacet rather than a translaminar approach is recommended. Care must be taken to avoid over-drilling into any structure outside of the cortical bone margin.



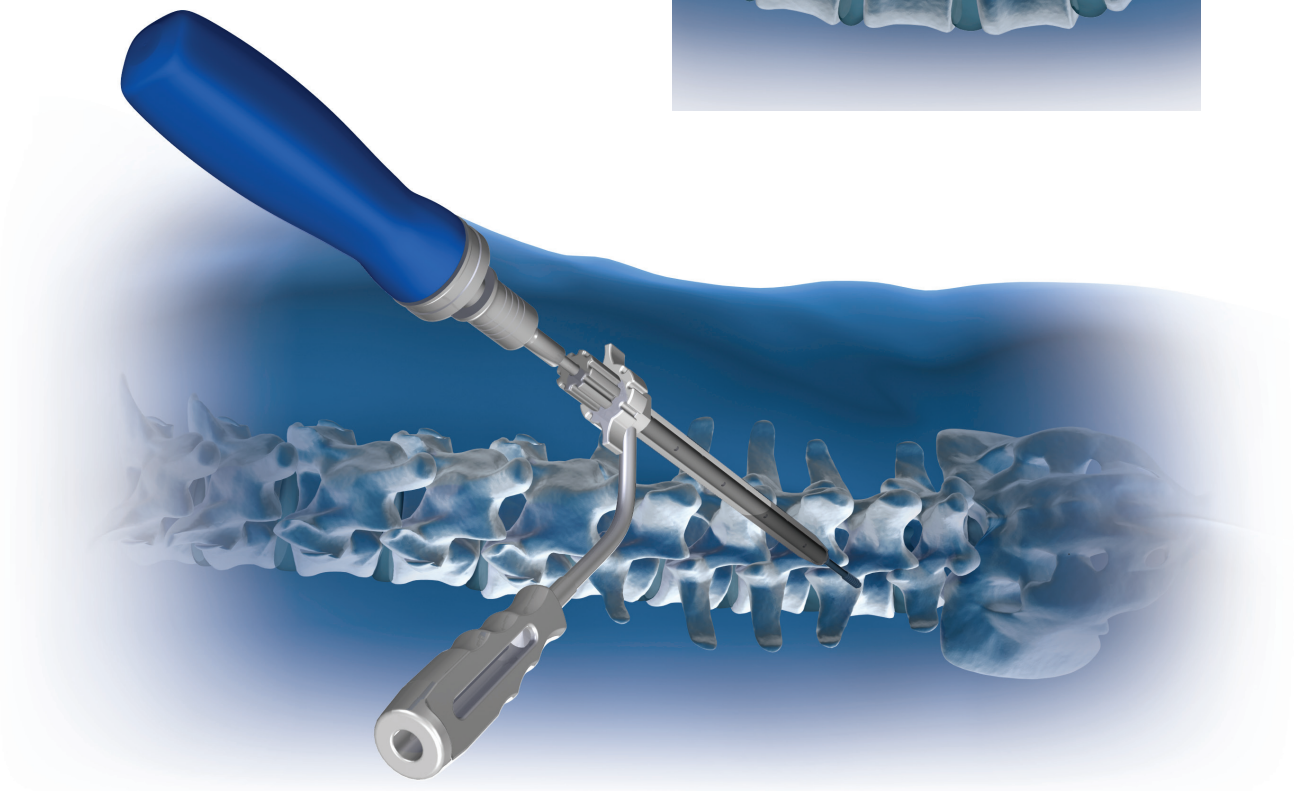
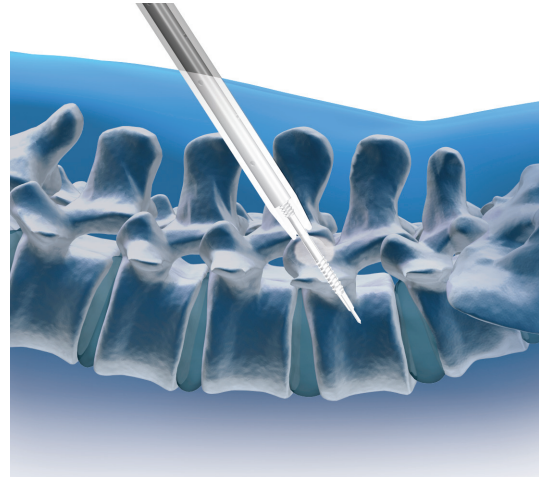
Step 5 – Tapping

After confirmation of appropriate depth, a 4.5mm tap is used to create threading and an appropriately sized screw is introduced over the K-wire into the superior facet.



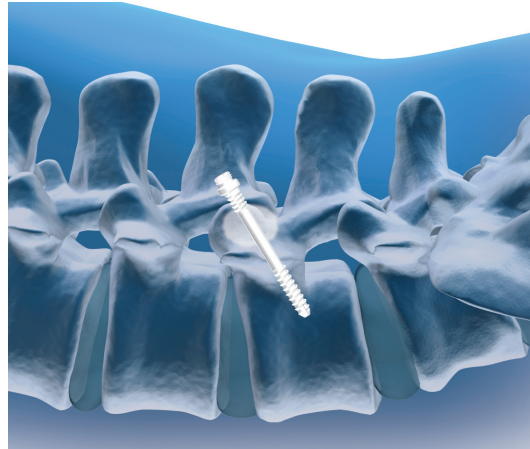
Step 6 – Screw Placement

The screw should be rotated gradually under biplanar fluoroscopic guidance to confirm distal entry into the inferior facet. The screw should be rotated until the screw head contacts the superior facet. Over-tightening of the screw can result in facet fracture. Bilateral screws are required for adequate fixation strength.



Step 7 – Screw Placement Confirmation

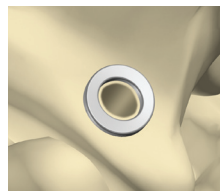
Anteroposterior and lateral radiography should be performed to confirm screw position. Additionally, neurophysiologic testing of the screw is recommended to confirm that there is no nerve root conductance.



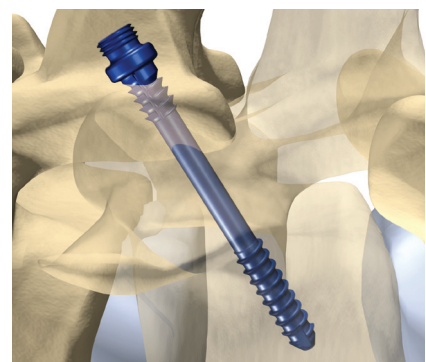
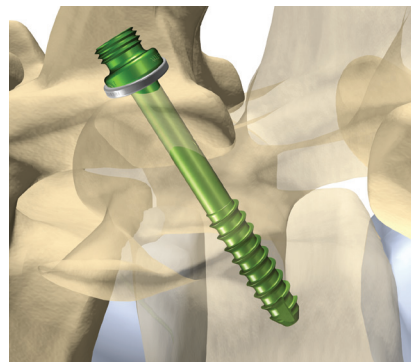
Step 8 – Optional Open Technique

A. Drilling - Use X063-0038 and X063-0031

B. Optional Washer



C. Screw Placement
with or without washer





Spinal Facet Screw System

Instruments

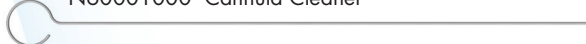
N60000473 Ratcheting Screwdriver Handle



X063-0025 Screwdriver Assy



N60001000 Cannula Cleaner



X063-0028 Cannulated Drill Bit



X063-0029 Tap



X063-0035 Inner Dilator



X063-0036 Outer Dilator 7.25



X063-0040 Graft Packer



X063-0055 Mallet



X063-0045 Guide Handle



WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

X-spine™ the X-spine logo and FIXCET™ are trademarks of X-spine Systems, Inc.

Products Patented and Patents Pending

All products are not currently available in all markets.

© 2012 X-spine Systems, Inc., All rights reserved.

F-1000.13 Rev. A 5/12 FIXCET BROCHURE CI I2M
EC 60-1171

CE0086

Open Approach Instruments

X063-0038 Outer Dilator 4.75



X063-0031 Drill Bit



X063-0000 Bone Awl



Optional Instrumentation

X063-0066 Rasp



Implants and Disposable Instruments

Item#	Description
X063-0005	4.5mm x 30mm Dual Thread Screw
X063-0006	4.5mm x 35mm Dual Thread Screw
X063-0007	4.5mm x 40mm Dual Thread Screw
X063-0008	4.5mm x 45mm Dual Thread Screw
X063-0015	4.5mm x 25mm Single Thread Screw
X063-0016	4.5mm x 30mm Single Thread Screw
X063-0017	4.5mm x 35mm Single Thread Screw
X063-0018	4.5mm x 40mm Single Thread Screw
X063-0019	4.5mm x 45mm Single Thread Screw
X063-0063	K-Wire, .054 Trocar End, 500mm
X063-0073	K-Wire, .054 Blunt End, 500mm
X063-0022	10mm Washer



X-spine Systems, Inc.

452 Alexandersville Rd., Miamisburg, OH 45342

Phone: 800-903-0640 • Direct: 937-847-8400 • Fax: 937-847-8410

www.x-spine.com

