

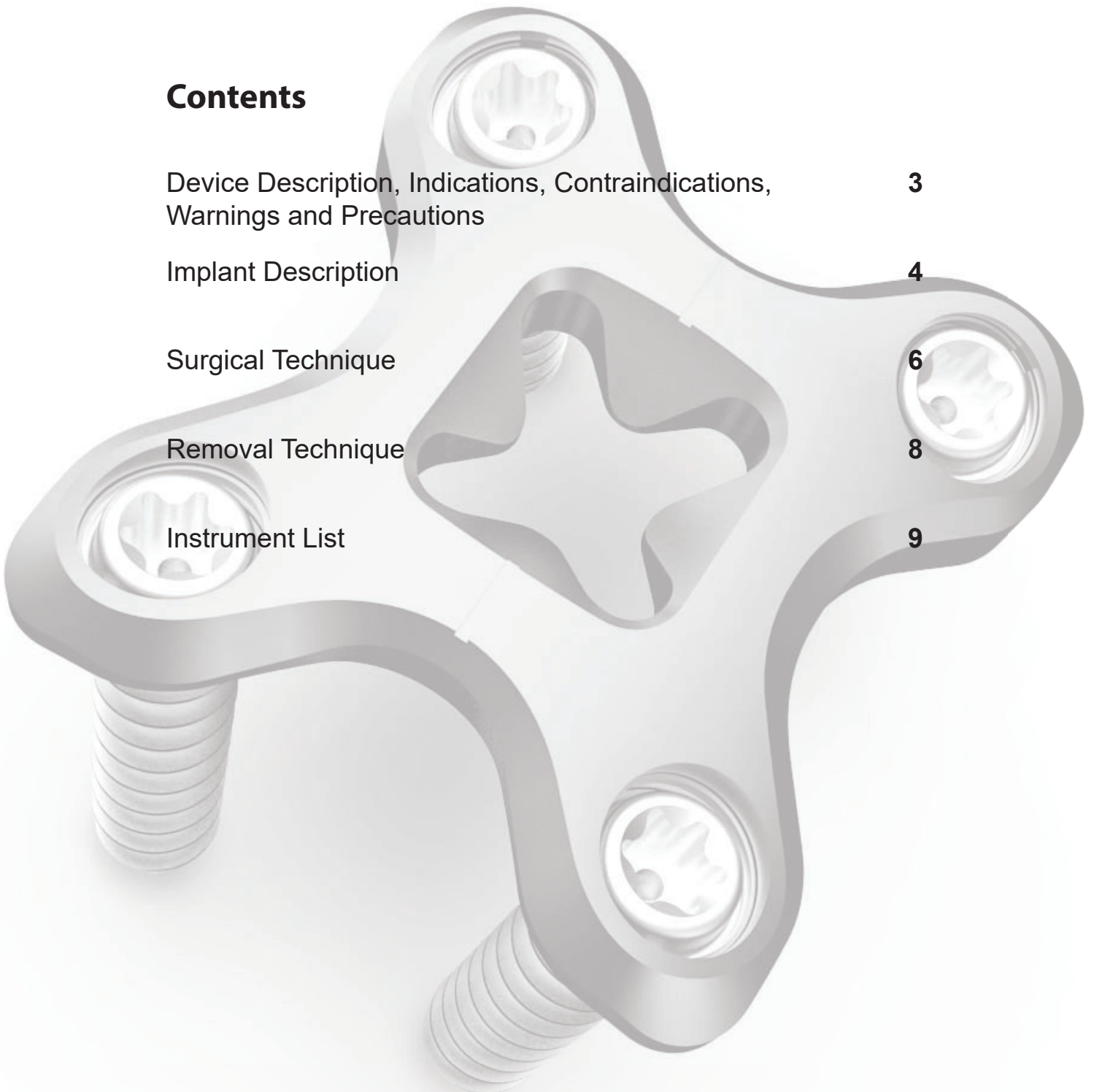


XM ALIF Plate

SURGICAL TECHNIQUE AND BROCHURE
REV A

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Device Descriptions

XM plate is supplied individually sterile packed and is intended for single patient use only. Additionally, the subject device is available in a range of sizes to allow correct selection to match the patient's anatomy.

Material: The XM anterior lumbar plate system is manufactured from Ti6Al4V per ISO 5832-3 and ASTM-F136.

The XM Anterior Lumbar Plate System is a temporary supplemental fixation device consisting of a variety of shapes and sizes of plate and screw. The subject system is used as an implant for the correction and stabilisation of the lumbosacral spine. The subject plate is low profile and anatomically designed to provide optimal fit from anterior, lateral or anterolateral approach. The XM screws come with a circlip that prevents the screws from backing-out after implantation.

Indications

The Signature Orthopaedics XM Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The subject system is indicated in the treatment of lumbar or lumbosacral (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis, trauma (i.e. fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Contraindications

The Signature Orthopaedics XM anterior lumbar plate is contraindicated for use under the following conditions:

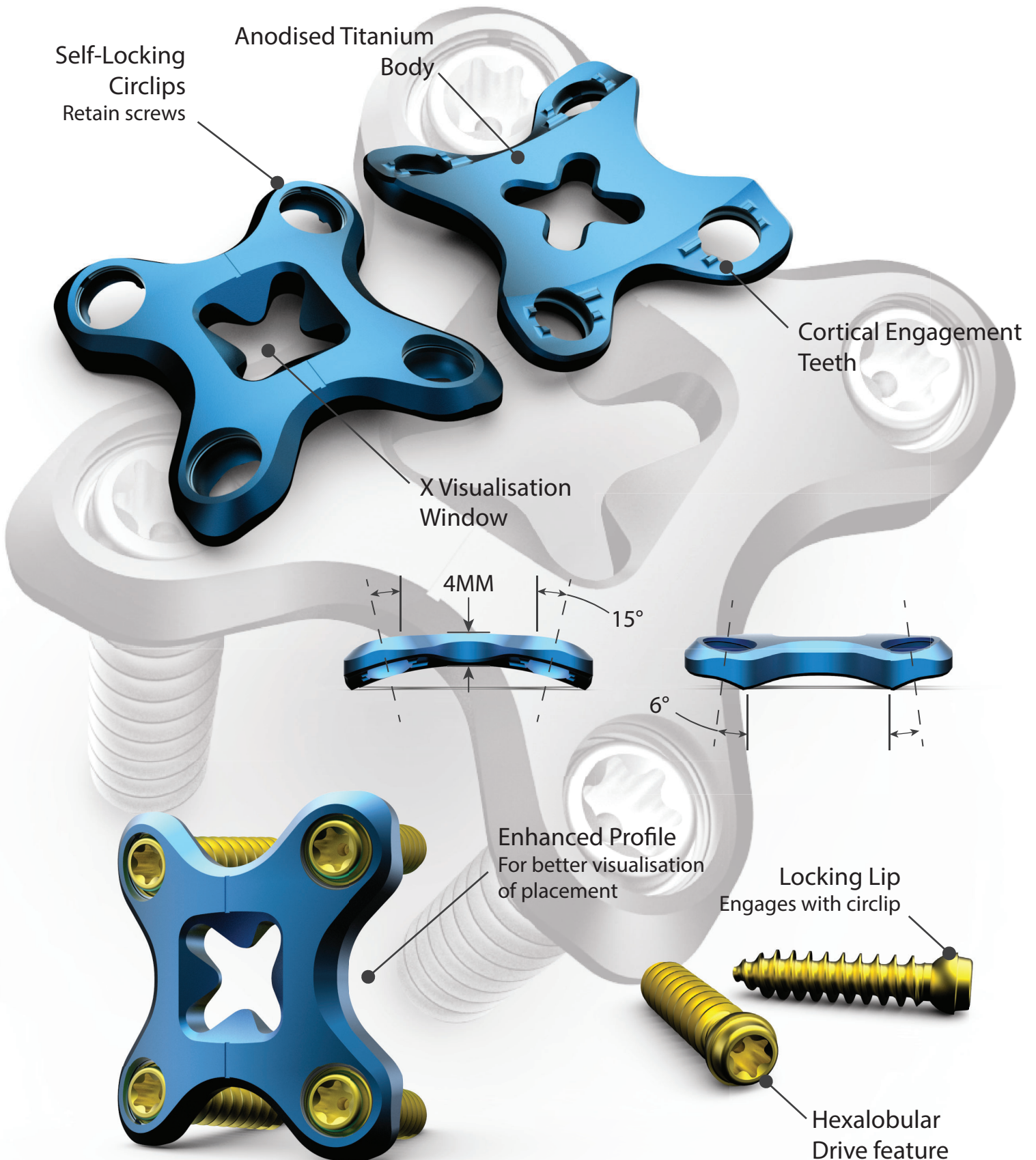
- Extensive calcification of the great vessels
- Retroperitoneal fibrosis
- High-grade spondylolisthesis
- Tumor or trauma necessitating multiple vertebral segment stabilization
- Active systematic infection or infection localised to the site of the proposed implantation
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, osteopenia, obesity, or foreign body sensitivity
- Patients whose activity, mental capacity, mental illness, or lifestyle may interfere with their ability to follow postoperative restrictions

Warnings and Precautions

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

See Instruction For Use (IFU) for warnings, precautions, adverse effects and other essential product information. The IFU can be accessed online at:
<http://www.signatureortho.com.au/eifu/>

Plate Features



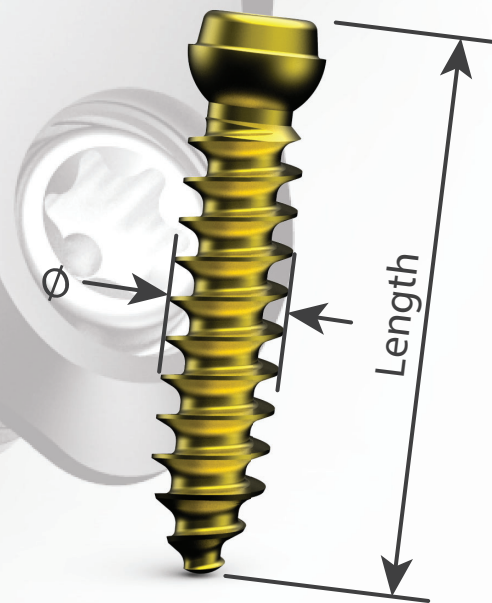
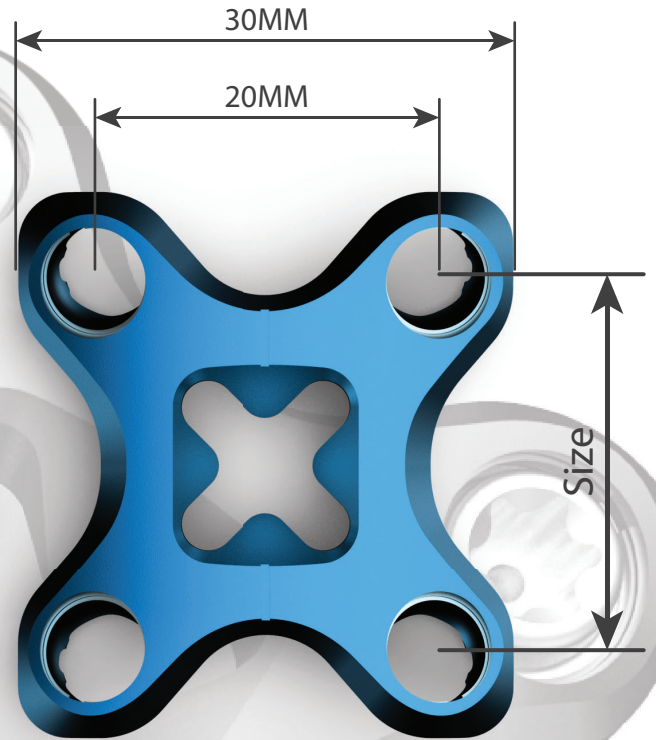
Sizing

Plate

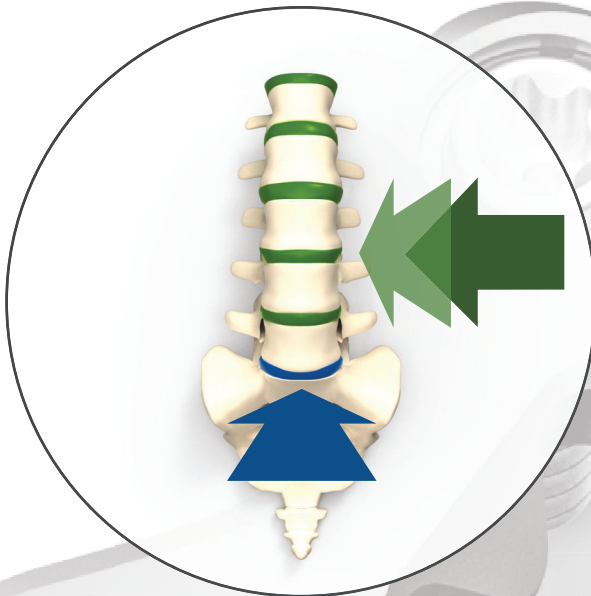
131-29-0008	17MM
131-29-0009	19MM
131-29-0010	21MM
131-29-0011	23MM
131-29-0012	25MM
131-29-0013	27MM

Screw

131-29-0014	Ø5.5x20
131-29-0015	Ø5.5x24
131-29-0016	Ø5.5x28
131-29-0017	Ø5.5x32
131-29-0018	Ø6.0x20
131-29-0019	Ø6.0x24
131-29-0020	Ø6.0x28
131-29-0021	Ø6.0x32



Surgical Technique

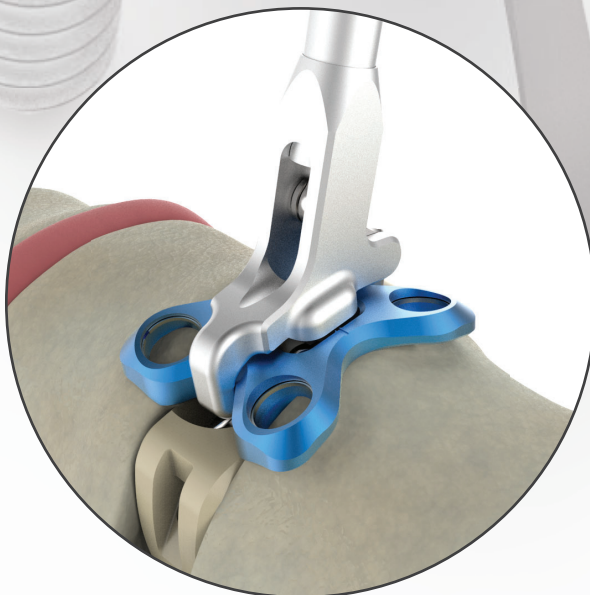


Approach

Approach is based on targeted level:
- For L1-L4 (above bifurcation) use Anterolateral or Lateral approach
- For L5-S1 use Anterior approach

Preparation

Debride any anterior osteophytes adjacent to the interspace. Ensure the previously inserted cage is properly recessed within the disc space.

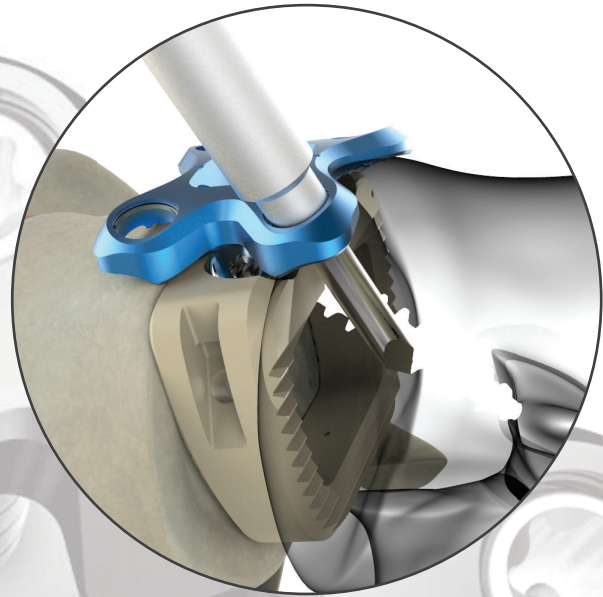


Placement

Use the **XM Plate Holder (PS2-09-0006)** to pick up the plate and place it into position.

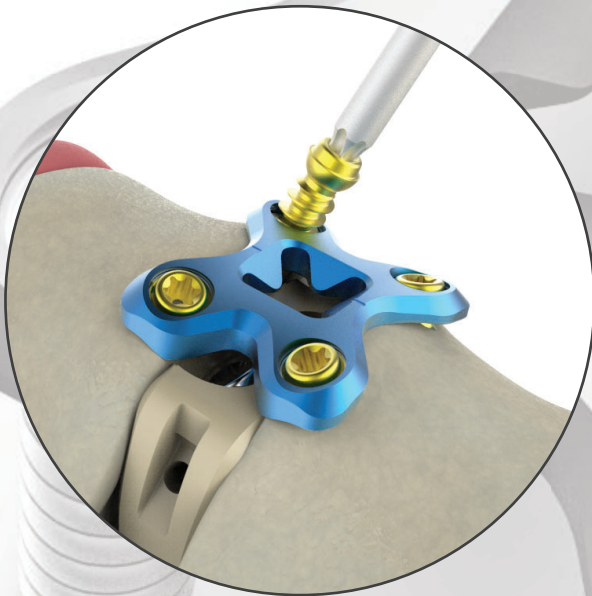
Hole Preparation

Use the **XM Awl (PS2-09-0009)** to perforate the cortex in preparation for screw insertion.

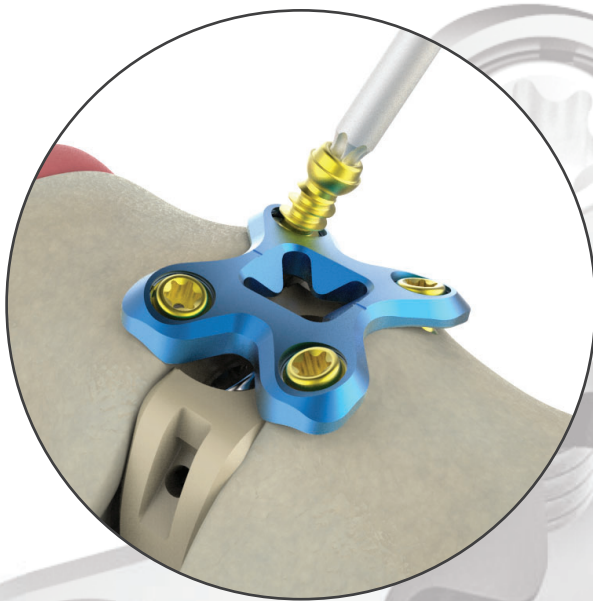


Screw Insertion

Select the appropriate screw length that will terminate between 5-10mm from the posterior cortex when fully inserted. Use the **XM Screwdriver (PS2-09-0000)** to insert screws into the prepared holes. Do not tighten completely until all screws have been inserted.



Removal Technique

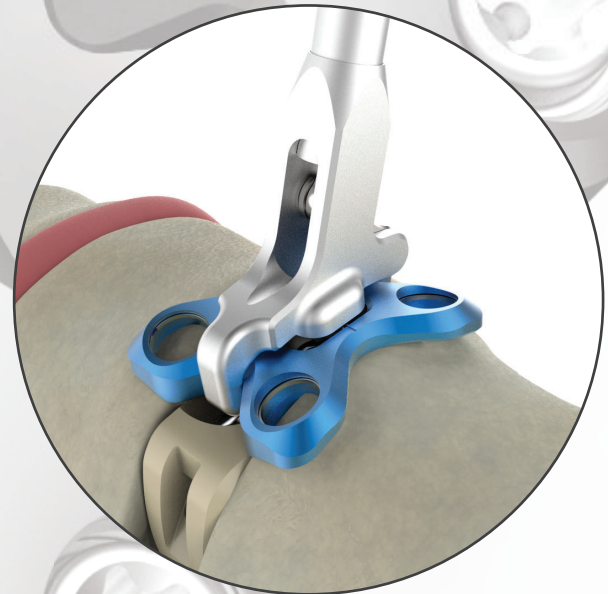


Remove Screws

Unscrew and extract screws using the XM Screwdriver whilst grasping the plate with the XM Plate Holder.

Remove Device

Use the plate holder to remove the device.



Instrument List

- 
- 132-25-0001** XM Screwdriver
 - 132-25-0003** XM Plate Holder
 - 132-25-0006** XM Awl
 - 132-25-0100** XM ALIF Plate Instrument Tray



The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.