SmartPlex Spinal System

ORTHOPAEDIC™
Innovation

A MEDSMART SOLUTIONS FAMILY MEMBER

MEDSMART™

Solutions

Based in the United Kingdom, Medsmart Solutions is a dynamic 100% British owned company which is dedicated to the manufacture and supply of an extensive range of innovative clinical technology products and consumables for use in orthopaedic and trauma surgery.

Our expertise in this field is supported by over 25 years experience working closely with surgeons and healthcare professionals throughout the world. We fully understand their needs and take pride in being able to supply products and services that more than meet their specifications and the expectations of their patients.

Orthopaedic Innovation Limited is part of the Medsmart Solutions family of companies, manufacturing a range of specialist instruments and consumables for use in orthopaedic surgical procedures.

The SmartPlex Posterior Spinal System featured in this brochure is just one of many complimentary products from our extensive range of orthopaedic and trauma products.

Trust Orthopaedic Innovation Limited to deliver...

Introduction

Orthopaedic Innovation Limited has combined biomechanical principles with high-tech production to create the SmartPlex Posterior Spinal System, a new stablisation system for thoracic, lumbar and lumbar-sacral instrumentation using pedicle screws, pedicle hooks, laminar hooks for posterolateral spondylodeses, fractures, spondylolisthesis, stenosis of the spinal canal of the lower backbone, wear of vertebral discs, herniated vertebral discs, correction of failed fusion or pseudoarthosis and in cases of unstable backbone conditions.

The SmartPlex Posterior Spinal System is made of titanium Ti6A14V in conformation with ASTM F.136-ISO 5832/3 international standards, which has been specifically designed for use in implant surgery. This alloy is characterised by demonstrating excellent biocompatibility, together with a high resistance to corrosion, superiormechanical strength and compatibility with current CTI and MRI scanning technology.

This system has many features and benefits including:

- **A low-profile system.**
- **Minimises soft tissue interaction.**
- **Excellent anchoring stability of the implants guarantees lasting safety.**
- **Simple and functional instrumentation.**
- **Reduced instrument set containing only essential tools.**
- **Post-operative treatment without corset.**
- **All implant components are compatible to CTI-MRI.**

Surgical Technique

Patient Positioning

The patient is positioned on the operating table in the prone position.

The surgical approach is carried out through a standard mid-line incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinious process should extend a additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.

Please note: This document is intended as a guide for the surgeon only. There are multiple techniques for the insertion of the Orthopaedic Innovation Smartplex Posterior Spinal System and, as with any surgical procedure, a surgeon should be thoroughly trained and beware that this procedure is appropriate for the patient before proceeding.

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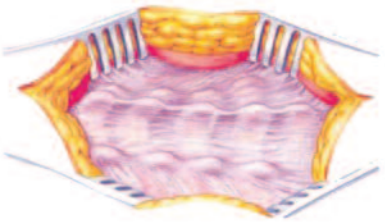
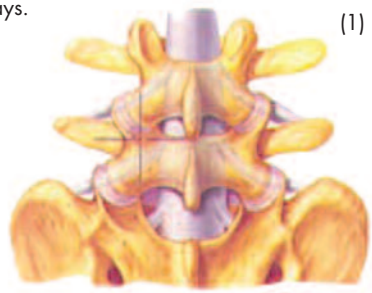
Subperiosteal Dissection



Incise the mid-line of the lumbar spine under general anaesthesia. Perform subperioseal dissection of the musculature from the spinous processes. On both sides, dissection is carried out to the level of the transverse processes in the region of the intended fusion. Meticulously remove the musculature and the periosteum in the region of the segment to be fused.

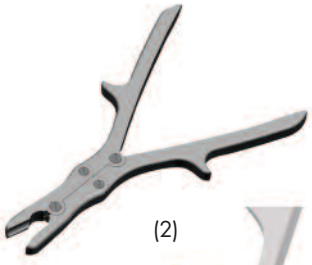
Pedicle Entry Level

The pedicle entry point (1) is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars interarticularis and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and notes on the pre-operative MRI, CT images on the intra-operative x-rays.



(1)

A small rongeur (2) or a burry may be used to decorticate the pedicle entry point.

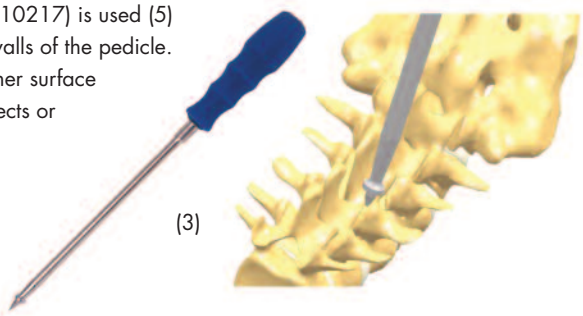


(2)

The Trocar Awl - Straight (Product Code OI10216) is used to make an entry hole (3) through the cortex at the pedicle entry point.

The Pedicular Probe (Product Code OI10218) is inserted through the entry hole (4) and gently pressed into the pedicle canal. The probe is passed through the pedicle canal until the anterior cortex of the vertebra body is reached. Caution should be taken not to violate the anterior wall of the vertebral body or cortical wall.

After the use of the probe, the Pedicular Guide Wire, a ball type control probe (Product Code OI10217) is used (5) to confirm continuity of the cortical walls of the pedicle. It can also be used to palpate the inner surface of the pedicle canal to check for defects or perforations of the cortical wall.



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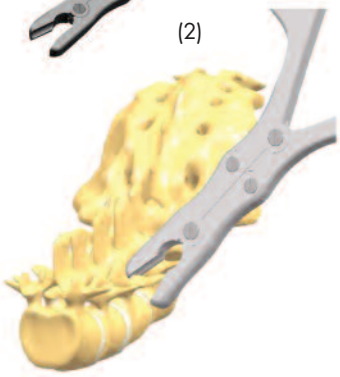

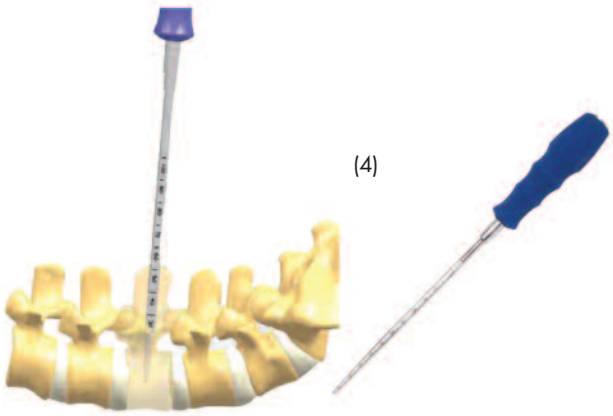

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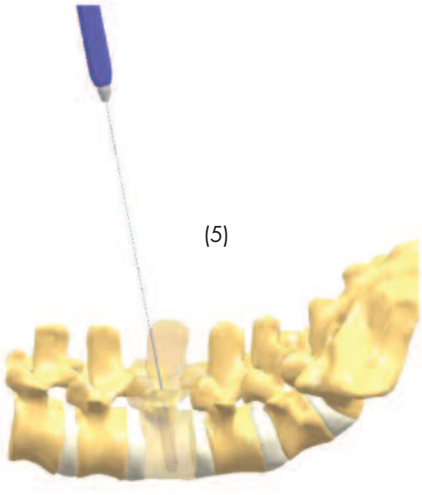
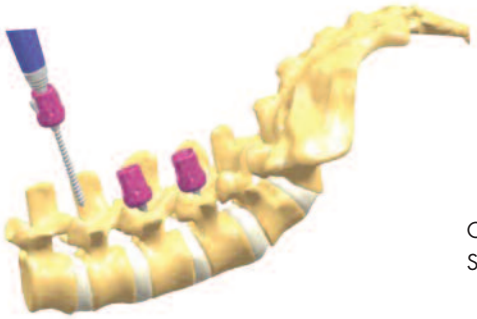


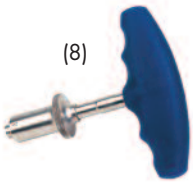
(5)

Screw Selection and Insertion

The pedicle screws are available in several diameters and lengths. The appropriate screw length is determined by using the depth gauge on the ball type control probe or the Pedicular Probe.

The pedicle screws are inserted using the Combined Screwdriver (6) for Polyaxial Screw (Product Code OI10212) and the Open Pedicular Screwdriver for Monoaxial Screw (Product Code OI10209) (7) with Modular T Torque Handle (Product Code OI10215) (8). The screwdriver head is inserted in to the fusion screw housing. The pedicle screw is inserted into the vertebral body to the desired depth.





(8)

Open Pedicular Screw Driver

(6)

(7)

Polyaxial Screw Driver

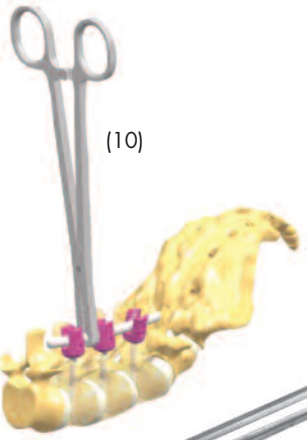
Rod Selection

The rods are provided pre-cut in lengths ranging from 60 mm to 480 mm. The rod should extend approximately 5 mm beyond the outer edges of the proximal screw bodies of the most superior and most inferior pedicle screws.

Rod Bending

After the appropriate legnth of rod has been selected, lordosis may be bent into the rod via the French Rod Bender (Product Code OI10221) (9). The polyaxial adjustability of the system eliminates the need for precision bending of the rod. A simple Lordodic bend is sufficient and the amount of lordosis is based on the patients' anatomy and the amount of reduction to be achieved.

After insertion of the fusion screws and rod bending, the rod is placed with a Small Threaded Rod Clamp (Product Code OI10205) (10) in the fusion scew housing.



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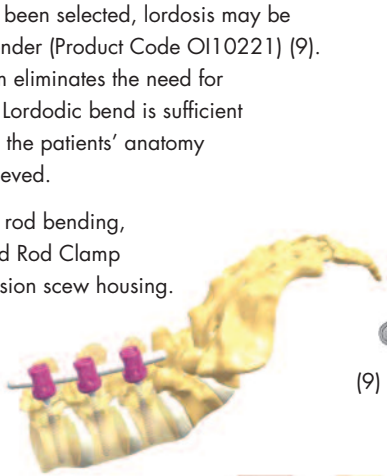
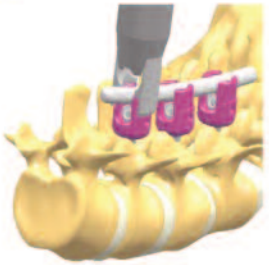


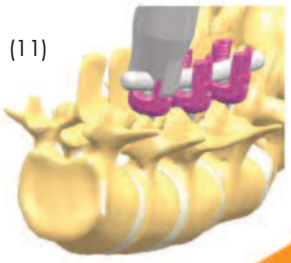
(9)

Rod Linkage and Set Screw Application

The Rod Persuader (Product Code OI10228) (11) is used when additional force is needed to bring the rod to the implant.

After the Rod Persuader is connected to the head of the implant, turn the head of the Rod Persuader to link it to the implant. From this position the rod can be pushed into the screw. The rod is now fully seated, allowing for insertion of the Set Screw.





(11)

(14)

(13)

(12)

Silicone Ring

When all the screws have been inserted and the rods have been placed in the head of the screw, the construction is then secured using set screws and following the procedure below for each screw.

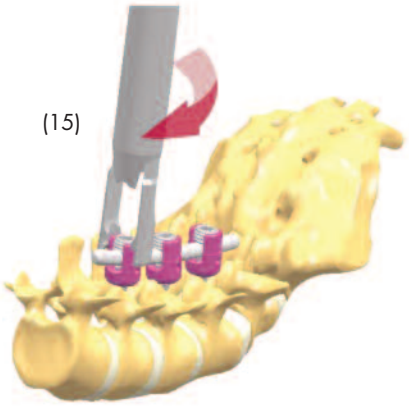
Load the Set Screw (12) onto the Set Screw Driver (13). The Set Screw is firmly pressed onto one end of the Set Screw Driver. Introduce the Set Screw Driver with T Handle (14) through the Rod Persuader. Set Screws should be applied in sequential order and provisionally tightened. Final tightening can be applied if no additional alignments (distraction, compression) are needed.

To remove the Rod Persuader, first take back the Set Screw Driver, turn the head of the instrument counter clockwise (15) and rotate the complete instrument in any direction.

In the event the rod is forced down while tightening the Set Screw, be sure that the Set Screw is fully engaged into the screw head. This will help resist the high reactive forces generated by the final tightening steps.

Attention: Extra caution is advised when:

1. The rod is not horizontally placed into the screw head.
2. The rod is high in the screw head.
3. An acute convex or concave bend is contoured into the rod.

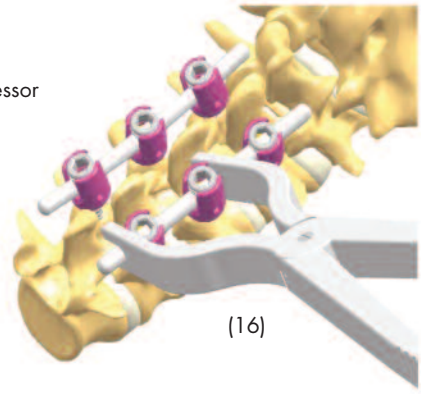


(15)

Additional Surgical Options

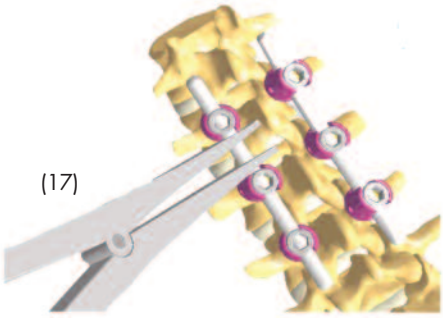
After the construction has been properly assembled, segmental compression and distraction is accomplished as needed to adjust frontal deformities or maintain plane deformities.

Compression is accomplished using the Compressor (Product Code OI10232) (16). The Compressor fits on to the rod on the outside of the provisionally tightened and final tightened Fusion Screw. As the Compressor handle is closed, the loose Fusion Screw is drawn towards the other provisionally tightened Fusion Screw, accomplishing compression of the required segment. When the desired amount of compression has been achieved, the set screw of the provisionally tightened Fusion Screw is tightened using the T Handle - Large, whilst the position is fixed by the Compressor.



(16)

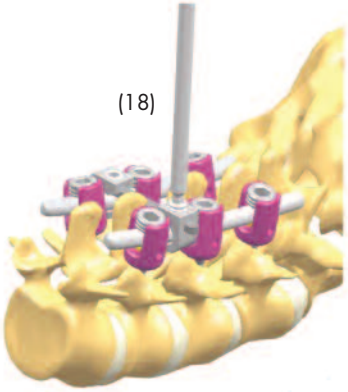
Distraction is accomplished using the Distractor (Product Code OI10233) (17). The Distractor fits onto the rod on the inside of the provisionally tightened Fusion Screw and the finally tightened Fusion Screw. As the Distractor is in the right position, the provisonally tightened Fusion Screw is pushed away from the finally tightened Fusion Screw, accomplishing distraction of the required segment. When the desitred amount of distraction has been achieved, the set screw of the provsionally tightened Fusion Screw is tightened using the Set Screw Driver - Small (Product Code OI10211) while the position is being fixed with the Distractor.



(17)

In the event that additional torsional stability is required, a cross connector may be utilised. After tightening of the Fusion Screws, a transverse link can be assembled if desired.

The tansverse link assembly consists of one SmartPlex Cross Link Shaft and two SmartPlex Cross Link Hooks. There are six shaft lengths, 40, 50, 60, 70, 80 and 90 mm. Once the desired location of the cross link has been determined, the appropriate Cross Link Shaft length is selected. The shaft is assembled with one Cross Link Hook and the hook shaft assembly is placed over the rod with the Set Screw Driver - Small. The second cross link hook is then assembled on the cross link shaft and placed into position on the opposite rod Set Screw Driver - Small (Product Code OI10211) (18).



(18)

The Compressor may be used to adjust and position the cross link on the rods. The Set Screw Driver - Small is used to tighten each transverse hook set screw onto the rods.

Instruments and Trays

SmartPlex Hook Clamp

Product Code

OI10224

SmartPlex Cross Link Shaft Clamp

Product Code

OI10225

Small Threaded Rod Clamp

Product Code

OI10205

SmartPlex Rod Rotation Forceps

Product Code

OI10204

SmartPlex C Ring

Product Code

OI10226

SmartPlex Hook Pusher

Product Code

OI10229

SmartPlex Hook Pusher Attachment

Product Code

OI10230

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Pedicular Starter

Product Code

OI10206

Laminar Starter

Product Code

OI10207

SmartPlex Transversal Starter

Product Code

OI10227

SmartPlex Distractor

Product Code

OI10233

SmartPlex Compressor

Product Code

OI10232

Rod Pusher

Product Code

OI10208

Open Pedicular Screwdriver

Product Code

OI10209

Hexagonal Wrench for Rod

Product Code

OI10210

Combined Screwdriver for Polyaxial Screw

Product Code

OI10212

Screwdriver for Polyaxial Screw

Product Code

OI10233

SmartPlex Set Screw Driver - Small

Product Code

OI10211

SmartPlex Set Screw Driver - Large

Product Code

OI10234

SmartPlex Set Screw Driver with T Handle - Large

Product Code

OI10214

ORTHOPAEDIC™ Innovation

Modular T Torque Handle Polyaxial

Product Code

OI10215

SmartPlex Rod Persuader

Product Code

OI10228

SmartPlex Trocar Awl - Straight

Product Code

OI10212

SmartPlex Trocar Awl - Sacral

Product Code

OI10216

Hammer - 500 g

Product Code

OI10203

Pedicular Guide Wire

Product Code

OI10217

Pedicular Probe

Product Code
OI10218

Control Probe - Type 1

Product Code
OI10219

Control Probe - Type 2

Product Code
OI10220

French Rod Bender

Product Code
OI10216

Rod Bender with Slot - Right

Product Code
OI10222

Rod Bender with Slot - Left

Product Code
OI10223

Trays and Box

Type	Product Code
Tray 1	OI10235 (1)
Tray 2	OI10235 (2)
Tray 3	OI10235 (3)
Box	OI10236

SmartPlex Posterior Spinal Instrument Set - Complete

Product Code
OI10237

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PSP and ASP Rod

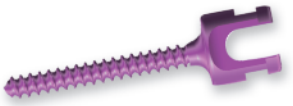
Length (mm)	Product Code (Titanium)	Length (mm)	Product Code (Titanium)
60	OI10176	200	OI10187
80	OI10177	230	OI10188
90	OI10178	250	OI10189
100	OI10179	260	OI10190
120	OI10180	280	OI10191
130	OI10181	300	OI10192
140	OI10182	320	OI10193
150	OI10183	340	OI10194
160	OI10184	400	OI10195
170	OI10185	450	OI10196
180	OI10186	480	OI10197

SmartPlex Set Screw

Product Code
OI10140

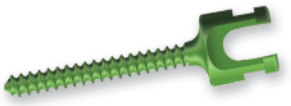
Ø 4.5 mm SmartPlex Monoaxial Screws

Length (mm)	Product Code (Titanium)
30	OI10176
35	OI10177
40	OI10178

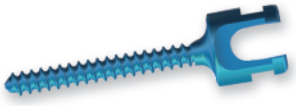


Ø 5.5 mm SmartPlex Monoaxial Screws

Length (mm)	Product Code (Titanium)
30	OI10131
35	OI10132
40	OI10133
45	OI10134
50	OI10135



Ø 6.5 mm SmartPlex Monoaxial Screws



Length (mm)	Product Code (Titanium)
35	OI10136
40	OI10137
45	OI10138
50	OI10139

Ø 4.5 mm SmartPlex Polyaxial Screws

Length (mm)	Product Code (Titanium)
30	OI10141
35	OI10142
40	OI10143

Ø 5.5 mm SmartPlex Polyaxial Screws

Length (mm)	Product Code (Titanium)
30	OI10144
35	OI10145
40	OI10146
45	OI10147
50	OI10148

Ø 6.5 mm SmartPlex Polyaxial Screws

Length (mm)	Product Code (Titanium)
35	OI10149
40	OI10150
45	OI10151
50	OI10152

SmartPlex Transversal Hook 5 x 7

Product Code
OI10163

ORTHOPAEDIC™ Innovation

SmartPlex Transversal Hook - Long

Product Code

OI10164

SmartPlex Pedicular Hook 8 x 7

Product Code

OI10153

SmartPlex Pedicular Hook 8 x 9

Product Code

OI10154

SmartPlex Laminar Hook 5 x 5

Product Code

OI10155

SmartPlex Laminar Hook 5 x 7

Product Code

OI10154

SmartPlex Laminar Hook 5 x 9

Product Code

OI10154

SmartPlex Laminar Hook - Long 5 x 9

Product Code

OI10157

SmartPlex Angled Laminar Hook - Right 5 x 7

Product Code
OI10159

SmartPlex Angled Laminar Hook - Left 5 x 7

Product Code
OI10161

SmartPlex Angled Laminar Hook - Right 5 x 9

Product Code
OI10160

SmartPlex Angled Laminar Hook - Left 5 x 9

Product Code
OI10162

SmartPlex Sacral Screw

Length (mm)	Product Code (Titanium)
35	OI10166
40	OI10167
45	OI10168

SmartPlex Cross Link Shaft

Length (mm)	Product Code (Titanium)	Length (mm)	Product Code (Titanium)
40	OI10166	70	OI10168
50	OI10167	80	OI10168
60	OI10168	90	OI10168

SmartPlex Sacral Block

Product Code
OI10165

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SmartPlex Cross Link Hook

Product Code
OI10175

SmartPlex Rod Connector - Single

Product Code
OI10198

SmartPlex Rod Connector - Double

Product Code
OI10199

Trays and Box

Type	Product Code
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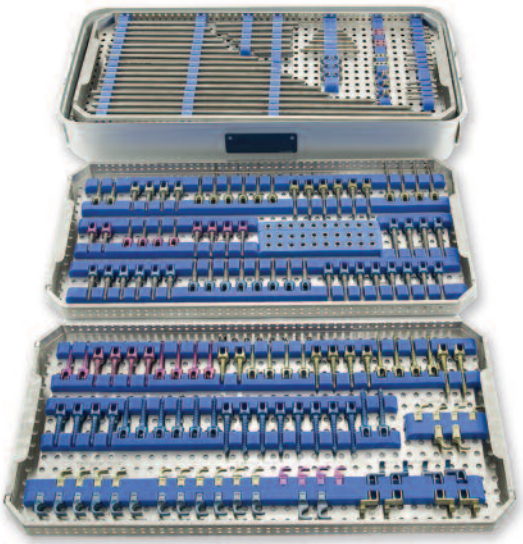
Tray 2	OI10200 (2)
Tray 3	OI10200 (3)
Box	OI10201



SmartPlex Spinal Implant Set - Complete

Product Code
OI10202

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