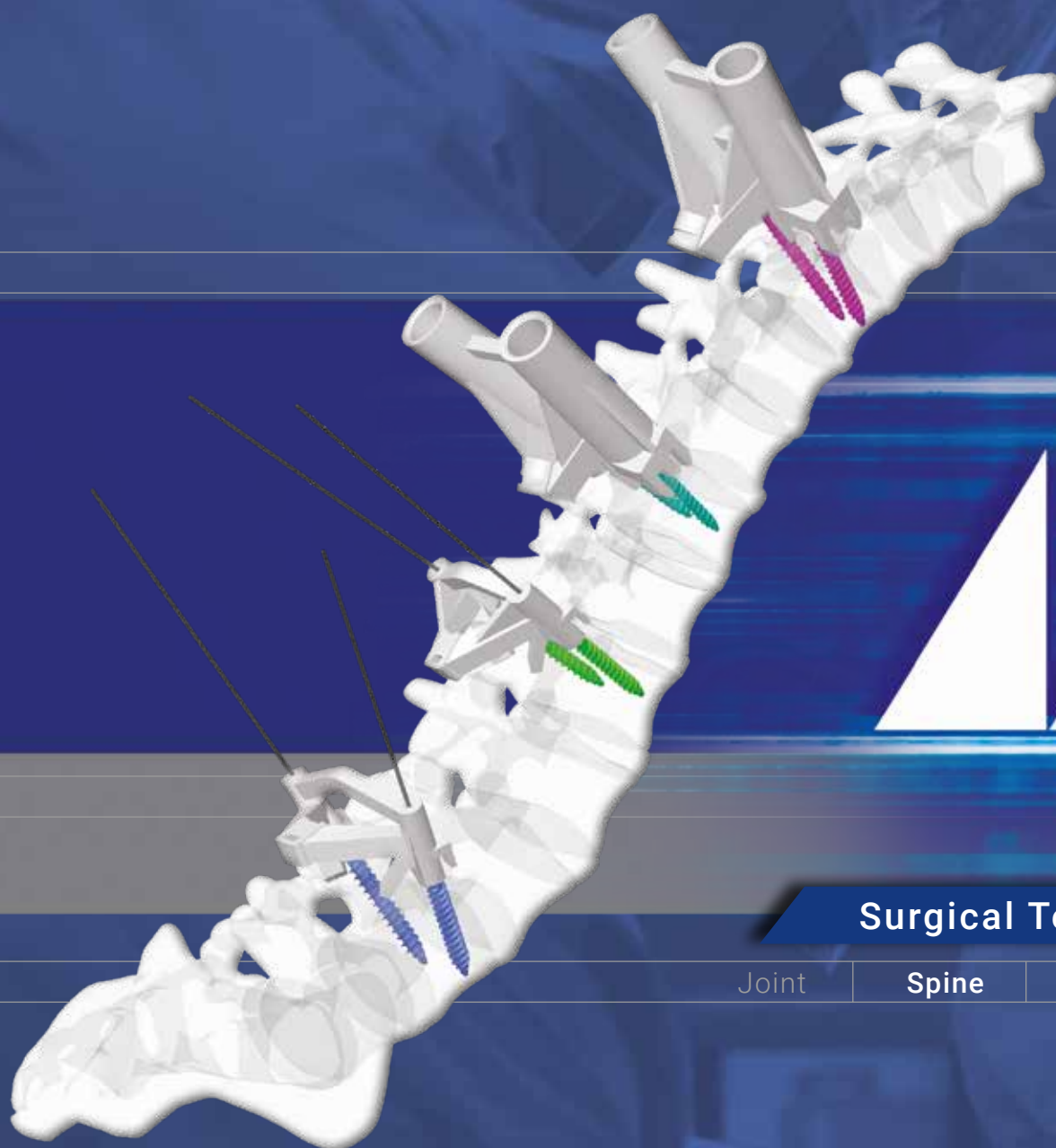


UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS



Surgical Technique

Joint

Spine

Sports Med

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1. INTRODUCTION

MySpine is a patient matched, pedicle targeted technology involving the production of patient specific, guides for placement of the M.U.S.T. pedicle screws, based on the patient's anatomy.

The MySpine platform allows the surgeon to complete pre-operative planning in 3D based on the patient's spinal CT scans.

Different screw placement guide configurations are available:

1. Standard: for pedicle screw guidance with conventional screw trajectory
2. Low Profile: for K-wire guidance with conventional screw trajectory
3. Drill Pilot: Low Profile for pedicle path preparation with conventional screw trajectory
4. MC: Drill Pilot and K-wire guidance with cortical bone path

1.1 INDICATIONS

MySpine is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5. A dedicated guide has been developed for the pedicle screw implantation on the Sacrum.

MySpine Screw Placement Guides are custom-made devices intended to be used as anatomical perforating guides specific to a single patient's anatomy to assist intra-operatively in the positioning of pedicle screws in the vertebral body. My Spine guides are intended for single use only.

As the MySpine guides are specifically designed for a single patient, i.e. custom-made for corresponding vertebral anatomies, they provide a sensitive patient-matched technology.

MySpine Screw placement guides are exclusively intended for use with the Medacta M.U.S.T. pedicle screw system and related instruments when the clinical evaluation complies with the need of spinal fixation.

1.2 CONTRAINDICATIONS

Contraindications for using MySpine instrumentation are the same as in situations where a spinal fusion with pedicle screws is contraindicated.

Please refer to the M.U.S.T. surgical technique for a comprehensive list of the contraindications.

The MySpine Screw placement guides are made of Polyamide-PA12; it is strictly the surgeon's responsibility to verify that the patient is not allergic to this material.

1.3 PREOPERATIVE PLANNING

The pre-operative planning, namely MySpine Surgical Planning (see page 6), is meant to assess the main surgical parameters regarding the screw implantation in order to manufacture dedicated single patient matched Screw Placement Guides. The pre-operative planning is managed exclusively between the surgeon and Medacta International. The surgeon chooses the guide configuration and is entitled to modify the surgical parameters as follows:

- Pedicle screw size:
 - Diameter
 - Length
- Actual evaluation of screw tip distance
 - from the anterior cortex
 - to the endplate
- Angulation of the screws in relation to the pedicle centre referred to:
 - Sagittal Plane
 - Transverse Plane
- Horizontal and Vertical shift of the screw on the coronal plane

Specific protocol (99.MYS.1P_CT) regarding CT imaging is used to create a 3D model of the vertebrae according to the specific patient's anatomy.

The subsequent vertebral model represents the template used to generate the corresponding MySpine Screw Placement Guides to fit precisely the patient's vertebral anatomy.

NOTE: Scans taken using different protocols may lead to improper imaging and may compromise the 3D modelling.

During the pre-operative planning phase the surgeon may receive, through the planning report, some cautions due to the particular anatomical condition and trajectory in order to take precautions during insertions or to potentially modify the planning and prevent guide instability and potential suboptimal screw positioning (fig. 1).

CAUTION

A small portion of the population is characterized by congenital spinal anomalies, in which the last lumbar vertebra fuses, at varying degrees, with the first sacral segment. This can be referred to as "sacralized vertebrae" and can be accompanied by transitional vertebrae also at T12/L1.

The correct level identification is a critical point of a MySpine surgery. In fact, the counting performed by the surgeon during the operation must be consistent with the planning.

A sacralized vertebra could lead to a debatable counting of the last lumbar vertebra; according to the literature, it could be called L5, L6 or L4.

Independently from the surgeon's nomenclature, Medacta ensures the production of proper anatomical corresponding guides. There is no contraindication in producing "L6" (or "T13") devices. The actual MySpine guide will be designed starting from the usual template of the last lumbar (or the last thoracic) vertebra.

There are 6 kinds of cautions:

1. Drill Bit Skiving Warning:

Due to the patient's vertebral anatomy and the preplanned trajectory, there is the possibility that the drill bit may skive during the entry point preparation step. It is recommended to use the spherical-tip burr to prepare the entry point prior to using the drill bit. It is also advised to not apply a downward force onto the drill bit during the drilling process to minimize the likelihood of skiving.

2. Partial Spinous Process Osteotomy:

Due to the patient's vertebral anatomy and the preplanned trajectory, there will be impingement between the MySpine guide and the spinous process. The surgeon will have to perform a partial spinous process osteotomy so that the patient's anatomy matches that of the white MySpine vertebral block in order to ensure proper docking of the MySpine guide on the patient's vertebrae.

3. Partial Facetectomy:

Due to the patient's vertebral anatomy and the preplanned trajectory, there will be impingement between the MySpine guide and the facet joints. The surgeon will have to perform a partial facetectomy so that the patient's anatomy matches that of the white MySpine vertebral block in order to ensure proper docking of the MySpine guide on the patient's vertebrae.

4. Specific Depth Gauge Required:

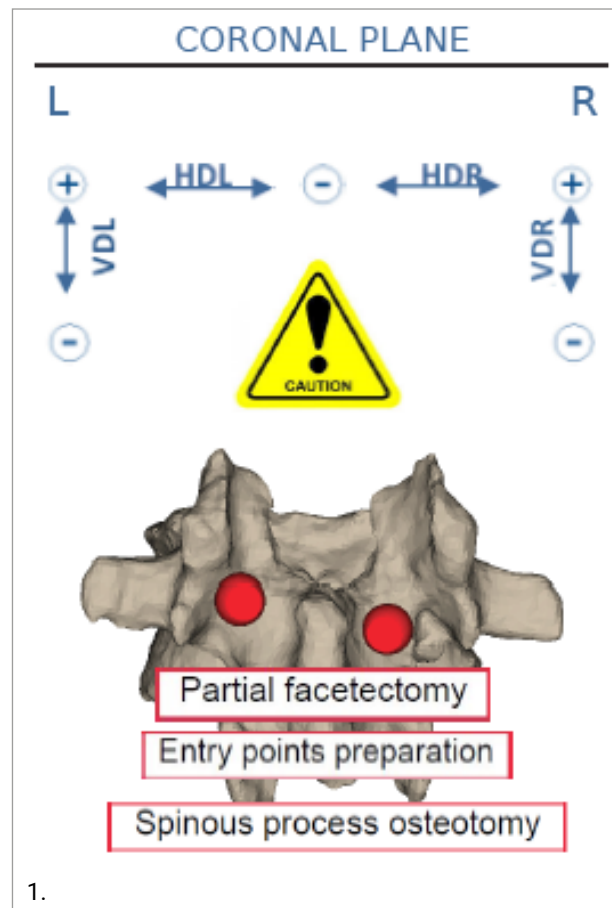
Due to the patient's vertebral anatomy and the preplanned trajectory, the drill-tubes of the MySpine guide have been modified from their standard length. The surgeon will have to use a specific depth gauge to ensure that they are drilling line-to-line with the pre-planned screw length.

5. Fractured vertebra:

The surgeon, in order to ensure a proper docking of the MySpine guide, must be aware that the vertebra is fractured, which could potentially lead to a guide instability.

6. Transitional vertebra:

Due to the abnormal anatomy, the surgeon must pay special attention to the level identification, which must be consistent with the planning counting.



CAUTION

As previously mentioned, the surgeon will receive a MySpine Surgical Planning Report (ref. M 08.78) showing the surgical parameters. It is the surgeon's responsibility to validate the preliminary planning or set different parameters according to his own assessment. Both validation and changes to the planning must be communicated to Medacta International. When the planning has been confirmed by the surgeon, the MySpine Screw Placement Guides will be manufactured and delivered.

CAUTION

MySpine device can be supplied sterile or non-sterile (see pictures below). In case of non-sterile supply, it is the health care institution's responsibility to clean and sterilise them before use, following the instructions

MySpine Surgical Planning Report

CASE CODE
BATCH NUMBER
SURGEON
SURGERY DATE
CONFIGURATION

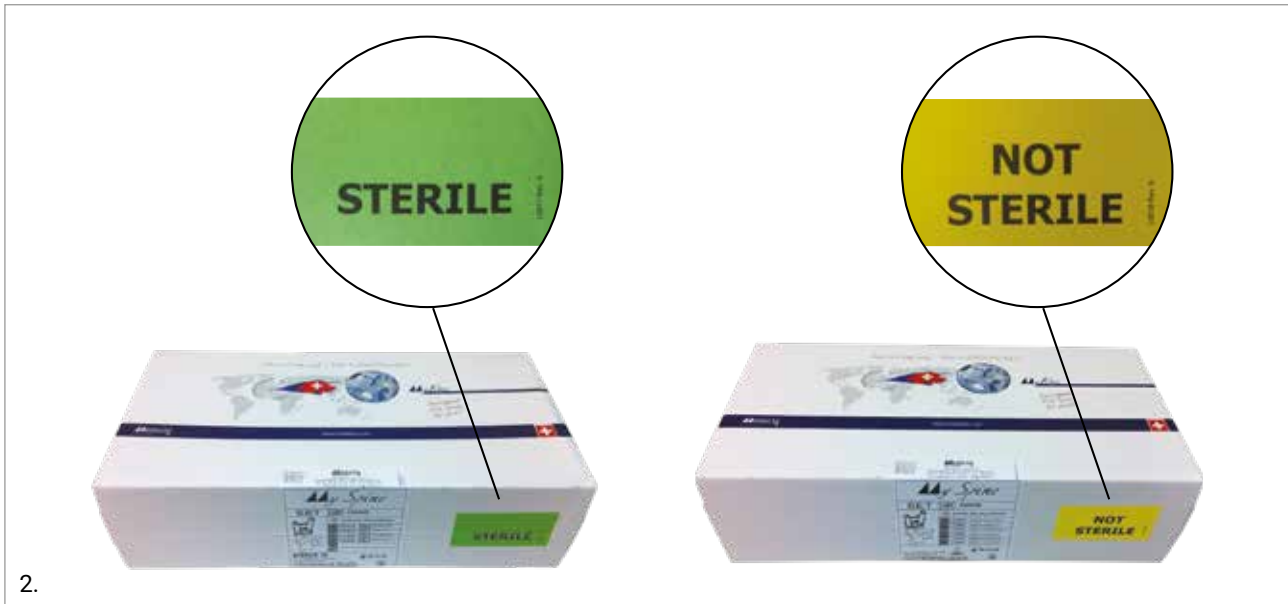


Level: T02

SAGITTAL PLANE		TRANSVERSAL PLANE		CORONAL PLANE	
 SAR	R	 TAL TAR	L	 HDL HDR VDL VDR	R
 SAL	L				
SAL: 1 deg	SAR: 2 deg	TAL: 15 deg	TAR: 8 deg	HDL: -1.25 mm VDL: 0.25 mm	HDR: -1 mm VDR: -0.75 mm

SCREW LENGTH (cross-section in the screw plane)		3D VIEW	SCREW DIAMETER (min cross-section of the pedicle)	
L	R		L	R
Length: 30 mm Cortical gap: 2 mm	Length: 25 mm Cortical gap: 3 mm		Diameter: 4.5 mm	Diameter: 4.5 mm

SAR/SAL: Sagittal plane angle right/left, angulation of the screw shaft in relation to pedicle center line, center of rotation is located at the minimal cross section of the pedicle (Red dot)
 TAR/TAL: Transversal plane angle right/left, angulation of the screw shaft in relation to the pedicle center line, center of rotation is located at the minimal cross section of the pedicle (Red dot)
 HDL/HDR: Horizontal distance left/right
 VDL/VDR: Vertical distance left/right

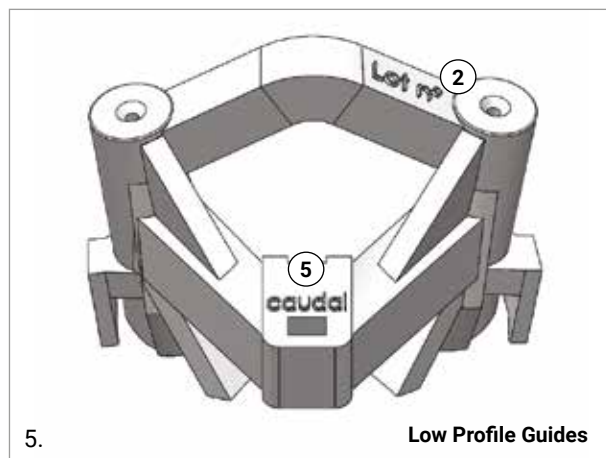
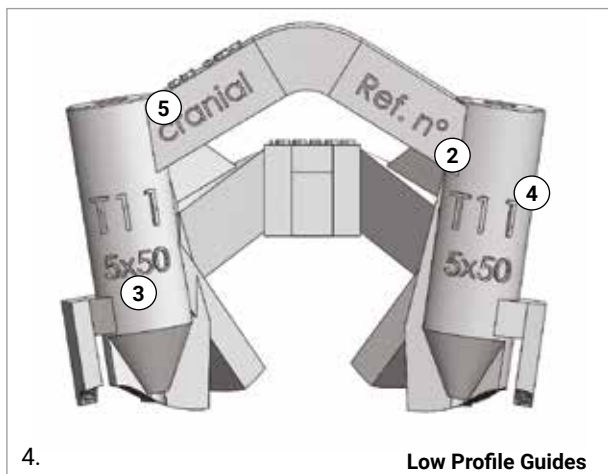
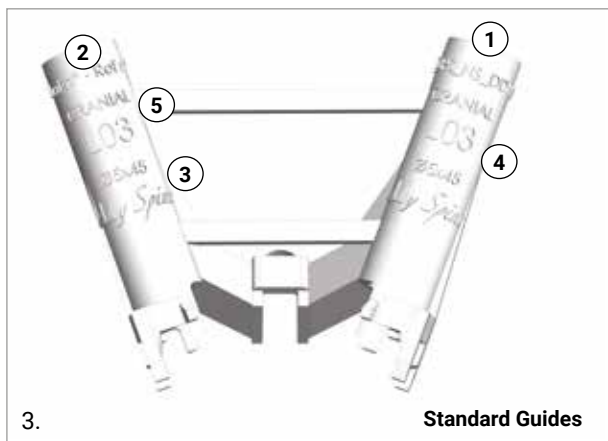


2. THE MYSPINE DEVICE

2.1 PRODUCT SPECIFICATION

The MySpine Screw Placement Guides display the following information:

7. The patient ID (in case of usage of the MySpine Low Profile Guides, MySpine MC, MySpine S1 and MySpine Drill Pilot Guides the Patient ID is displayed only on the 3D model of the vertebra)
8. The reference and lot number
9. Implant size (left and right)
10. Vertebral level
11. Cranial / Caudal side



Before starting the surgery, check the accuracy of the patient-specific ID data.

An example of patient-specific ID data is as follows:
N_SUR_TTT_NS_DDMMYYYY

- N. First letter of patient's name
- SUR. First three letters of patient's surname
- TTT. Type of surgery name
- NS. First letter of surgeon's name and surname
- DD. Day of birth of the patient
- MM. Month of birth of the patient
- YYYY. Year of birth of the patient

Example:

The case code for a MySpine surgery with pedicle screws, of a patient whose name is Alice Smith, born on 23 February 1943, performed by Dr. John White would be A_SMI_OPS_JW_23021943.

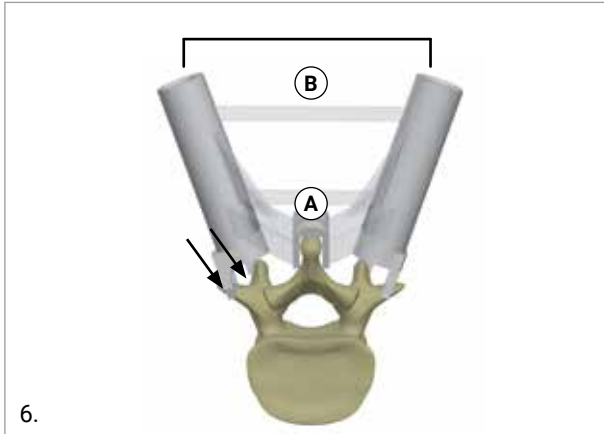
CAUTION

If the placement guides do not clearly indicate the patient identification string, they **MUST NOT** be used for the surgery. In such a case please contact Medacta immediately.

CAUTION

Do not use MySpine Screw placement guides on a patient for whom the pre-operative planning has not been carried out. Also, MySpine devices used on a different patient will lead to unpredictable outcomes.

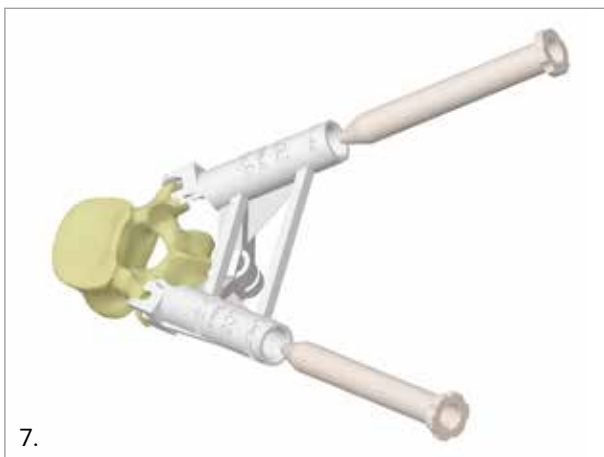
The MySpine Screw Placement Guides are composed as follows:



A) One central spinous process snap, aimed to couple the guide with the vertebral spinous process.

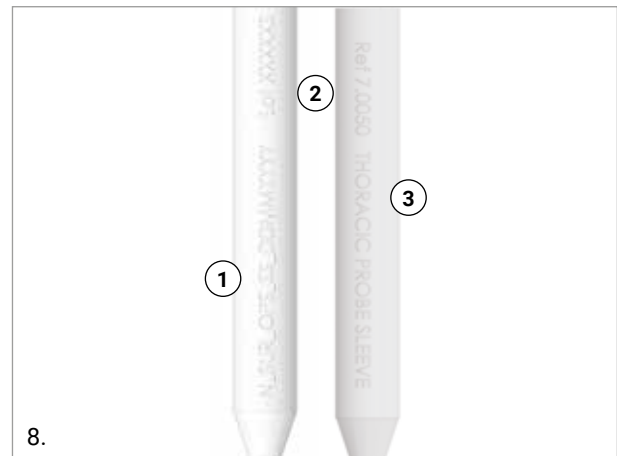
B) Two lateral cylindrical guides (left and right) with distal pins, aimed to perfectly match the vertebral anatomical sites.

The cylindrical guides represent hollow supports that host dedicated sleeves, i.e. the tools that aim to optimally support insertion of the instruments for the pedicle screws placement (Standard Guides only).



Each sleeve reports the following information:

1. The patient ID {N_SUR_TTT_NS_DDMMYYYY}
2. The reference and lot numbers
3. The corresponding Instrument to be matched



The MySpine Screw Placement Low Profile Guides and the MySpine MC K-wire based guides are specifically designed to be used with K-wires. It is therefore mandatory to use cannulated instruments and implants.

NOTICE: Depending on the instrument used during the surgery, the sleeves can be made of different materials:

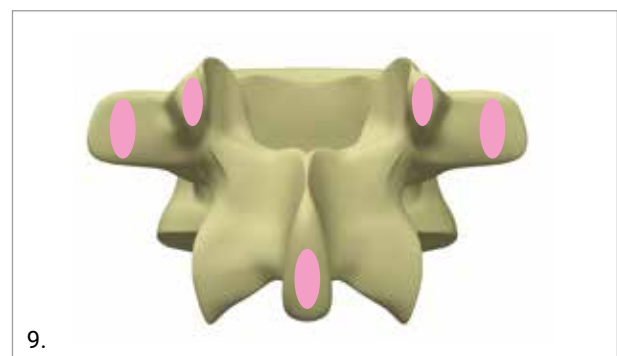
- Plastic (for Awls, Probes and Screwdrivers)
- Stainless Steel (for Taps and Drills)

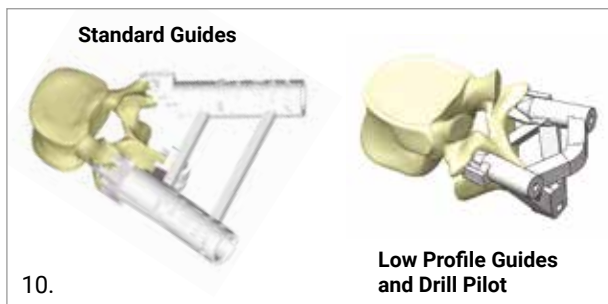
2.2 THE MYSPINE DEVICE PROFILE

To address the maximum stability and optimal screw entry points, the MySpine placement guides profiles are specifically designed for treatment of the spinal segments.

In lumbar spine treatment, the MySpine guides are designed to optimise vertebrae contact at the spinous process and both transverse and upper articular processes. However, depending on the patient's anatomically matched model, the guide can also be designed to maximise contacts at just one of the following areas:

- Spinous process and transverse processes or
- Spinous process and upper articular processes





In the treatment of the thoracic spine segments the MySpine guides are developed to maximise vertebrae contact at the spinous process and both lamina and transverse processes.

However, depending on the patient's anatomically matched model, the guide can also be designed to maximise the contacts at just one couple of the following areas:

- Spinous process and transverse processes or
- Spinous process and laminae

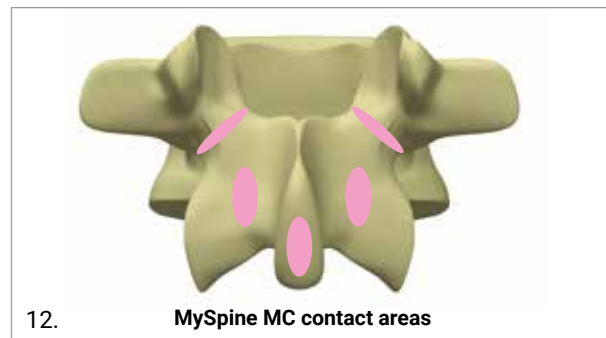


CAUTION

The bone surface of the vertebra at the MySpine Placement Guide contact areas should be suitably exposed to ensure an optimal fit.

NOTE: The MySpine guide profiles are custom-made and specifically designed by Medacta International following the submission of an individual geometry and confirmed by the surgeon via the MySpine Surgical Planning on-line portal.

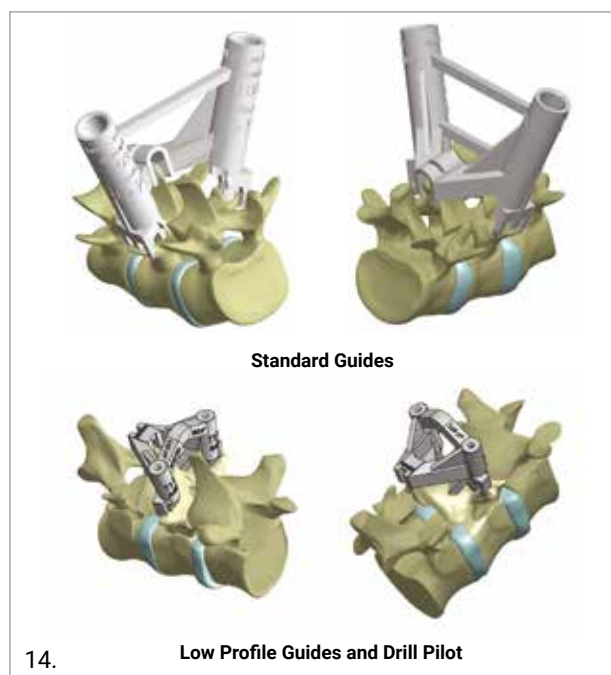
The MySpine MC and S1 guides are designed to optimise vertebrae contact at the spinous process and both lamina and pars interarticularis. However, depending on the patient's anatomically matched model, the guide can also be designed to maximize the contact at just one couple of those areas.



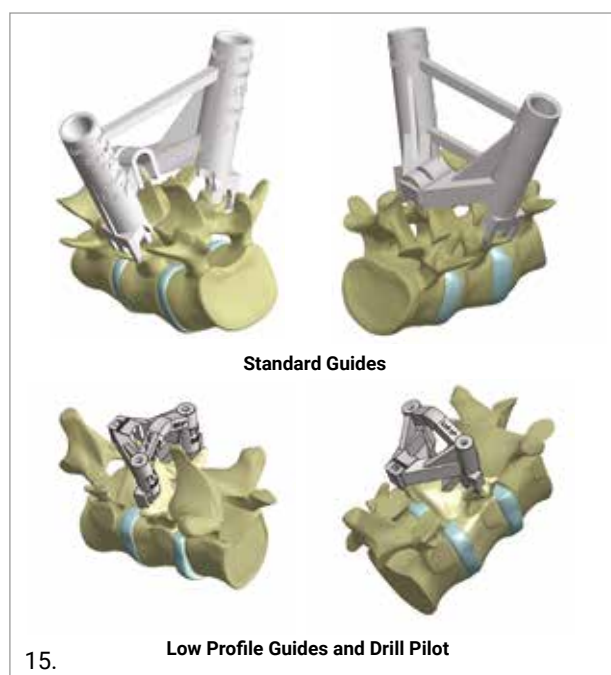
2.3 THE MYSPINE DEVICE CONFIGURATION

MySpine guides can be designed in three different configurations to provide optimal flexibility depending on the surgical approach used by the surgeon. These configurations equate to different levels of invasiveness, depending on the ligament manipulation and can be ranked as follows:

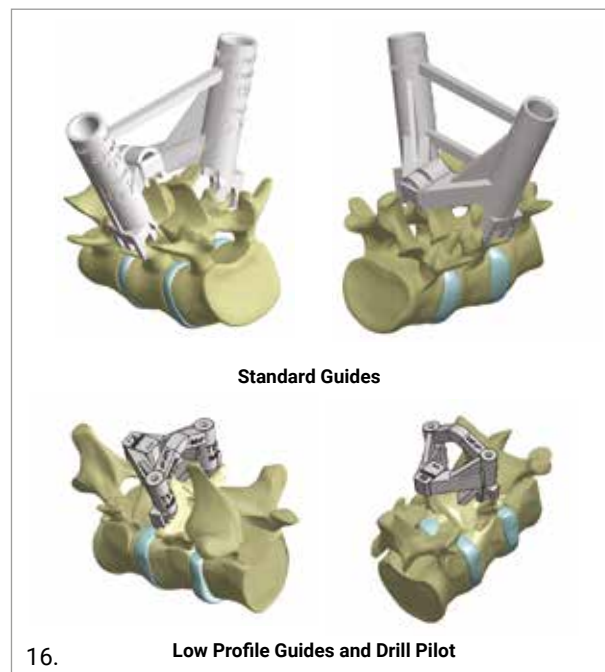
1) Open. The guide presents a fully open snap profile at the spinous process side, thus allowing the surgeon to preserve both the cranial and caudal supraspinous ligament.



2) Semi-Open. With a partially open snap profile, the surgeon can decide to cut the supraspinous ligament either at the cranial or caudal level preserving the complementary portion.



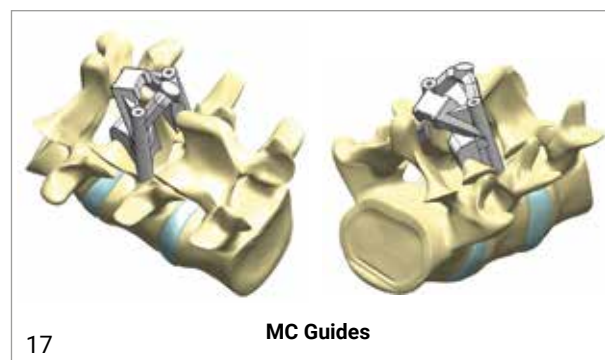
3) Closed. The guide has a fully closed snap to be used in open spine surgeries when the supraspinous ligament can be cut at the cranial and caudal levels.



NOTE: The configuration of the MySpine guides must be chosen during the pre-operative planning phase.

IMPORTANT

Because of the reduced incision size and the surgical approach, the MySpine MC and S1 guides are available in the open and semi-open configurations only.



3. SURGICAL APPROACH

The MySpine placement guides are intended to guide the implant of the M.U.S.T. Pedicle Screw System using a posterior approach. Other surgical approaches are at the discretion of the surgeon.

4. BEFORE STARTING THE PROCEDURE

4.1 CHECK THE POSITIONING

The MySpine guide is created to match the vertebral anatomy of the patient to help ensure maximum stability on the vertebra and correct screw placement. A plastic 3D anatomical model reproducing the patient's vertebra is provided to simulate the correct positioning of the MySpine guides in the OR.



The vertebral 3D model provides the following information:

1. Vertebral level
2. Caudal / Cranial side
3. Patient ID {N_SUR_TTT_NS_DDMMYYYY}
4. Reference and Lot numbers

Check the fitting between the vertebra's plastic model and the MySpine guides to verify the contact surface and pedicle screw entry points; to help identify the entry points, the pedicle screw heads are provided on the vertebral model (shown as red spots on the diagrams above and below).

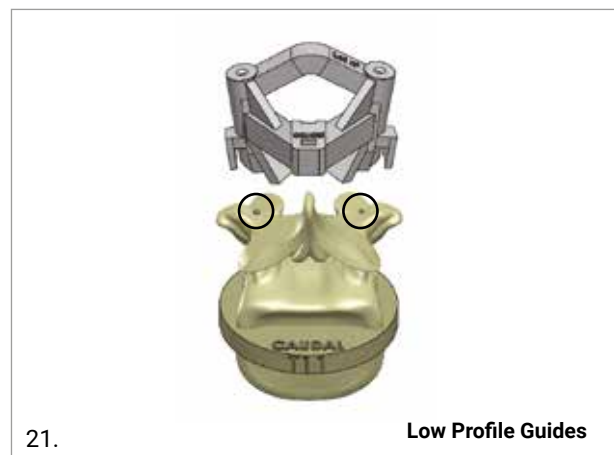


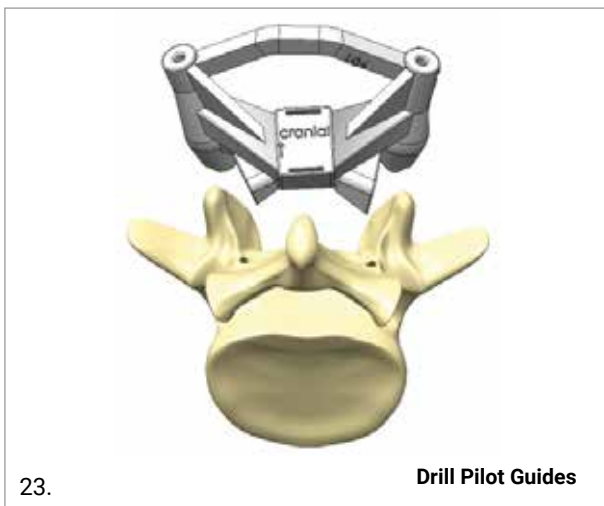
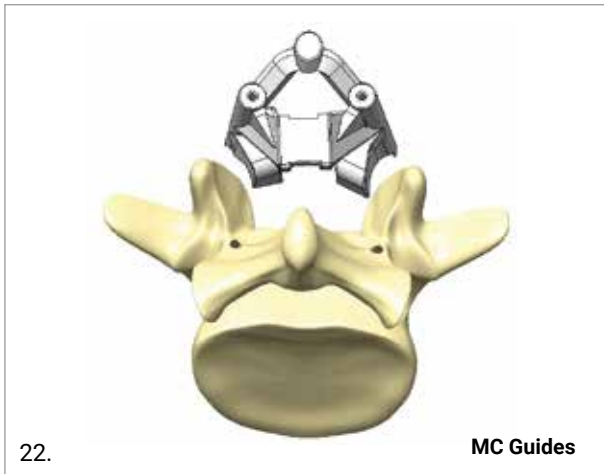
IMPORTANT

Always check the coupling between the vertebra's plastic model and the MySpine guides in order to become familiar with the overall system and simulate the position of the guides on the contact surfaces and entry points.

NOTE: When using the standard guides, prepare all of the MySpine instruments (i.e. awls, probes) by matching them with their corresponding sleeves in order to have them ready for use.

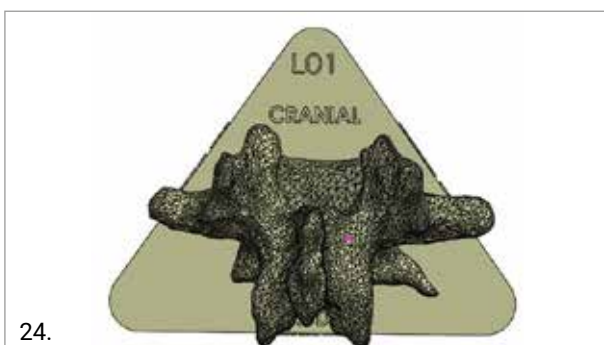
NOTE: When using the MySpine Low Profile Guide, the entry points in the 3D model reconstruction appear smaller than those in the model for the standard guides.





4.2 CAUTIONS

During the pre-operative planning phase the surgeon may receive, through the planning report, some cautions (refer to paragraph 1.3). For those vertebrae with cautions, the corresponding vertebral 3d models are designed with a triangular base, rather than circular, to remind the surgeon about the caution (fig. 24). On the back side of the vertebral 3d model there is a brief description of the caution, corresponding to the validated pre-operative planning (fig. 25).



4.3 INSTRUMENT PREPARATION

Prepare in advance all the instruments required to place the M.U.S.T. pedicle screws; in particular prepare the probes, awls and polyaxial pedicle screwdrivers by covering them with the corresponding dedicated sleeve that fits the MySpine guide.



CAUTION

Always cover the instruments with their corresponding sleeves ensuring the reference codes match. The screwdriver sleeve must be attached with the "handle" and "screw" tags correctly orientated.

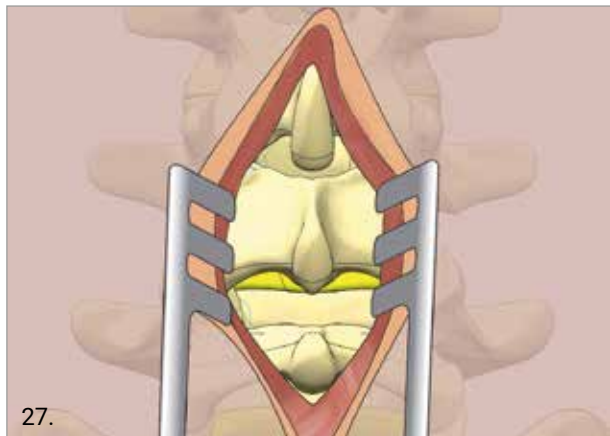
4.4 INSTRUMENT PREPARATION - LOW PROFILE GUIDES

Prepare in advance all the instruments required to place the M.U.S.T. pedicle screws; in particular prepare the K-wires, a Power Tool with the appropriate K-wire attachment, the polyaxial pedicle screwdrivers, cannulated awls and the cannulated taps.

For the MySpine MC and S1, skip to chapter 8.

5. SPINE EXPOSURE AND PREPARATION

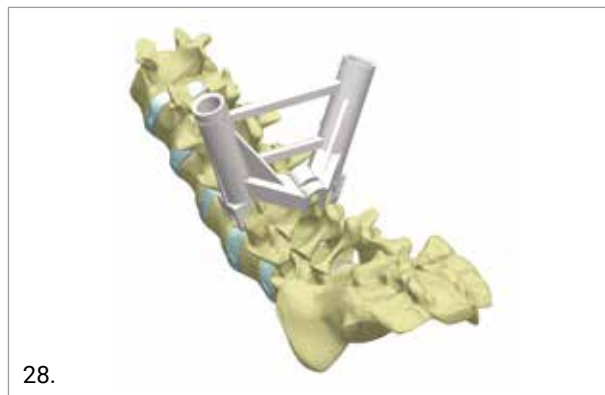
Perform a skin incision and dissect laterally from the midline by locating the transverse processes and the laminae of the corresponding levels.



Clean the vertebra(e) and treat the ligament according to the operative approach.

Place the MySpine guides on the corresponding vertebra and check the contact surfaces. As the correct placement corresponds to maximum guide stability and optimal screw insertion, verify that the contact points between the MySpine guides and the anatomical sites on the vertebra are exact.

Once the MySpine guides are correctly placed and the pedicle screw entry points set, as per the pre-operative planning, the spine levels to be treated are now ready for surgery.



CAUTION

Always match the dedicated MySpine guide(s) with the corresponding patient's vertebra(e).

CAUTION

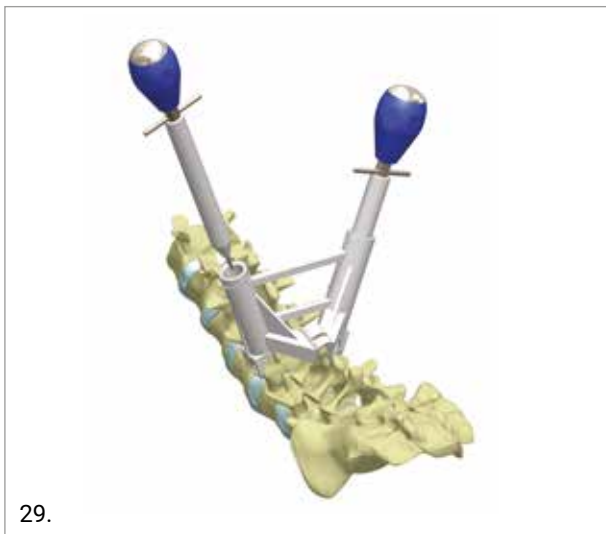
Inaccurate positioning may lead to the screws not being in line with the planning.

6. PEDICLE PREPARATION - STANDARD GUIDES

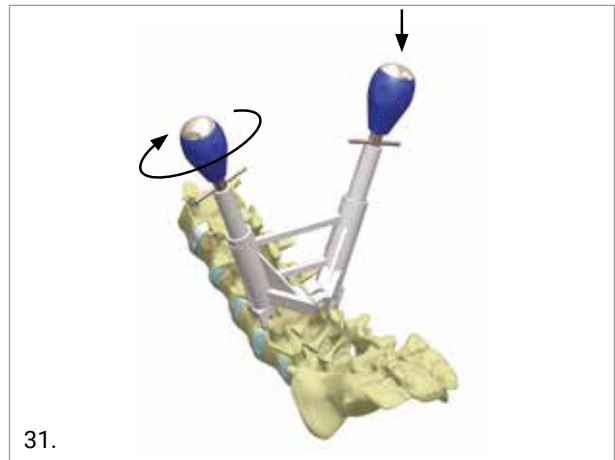
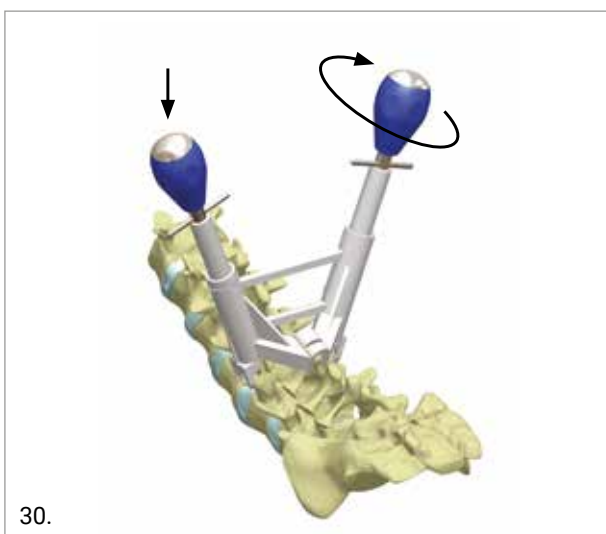
With the MySpine guide securely attached to the corresponding vertebra and held firmly by hand, insert both pedicle awls, previously mounted, into their corresponding sleeves.

CAUTION

Hold the guide, to avoid it slipping and insert the awls one by one in subsequent steps.

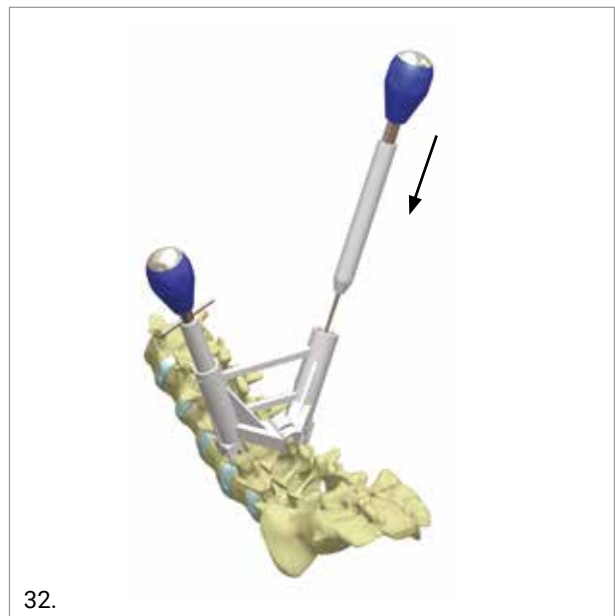


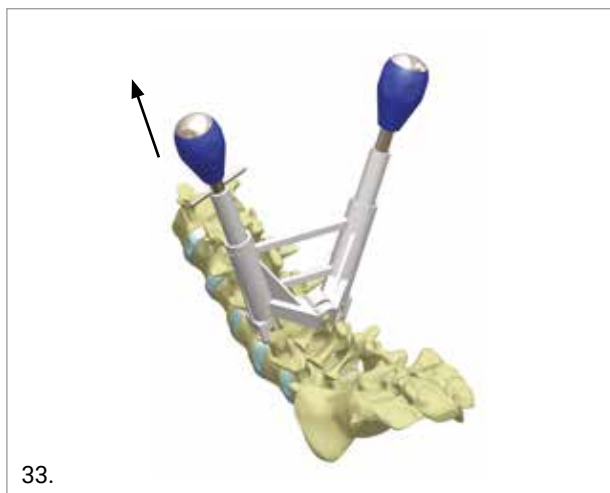
Whilst holding one pedicle awl (eg. left), perforate the outer cortex of the opposite side (ie. right) with the corresponding pedicle awl (fig. 30). Repeat in order to perforate the other side of the cortex (ie. left, fig. 31).



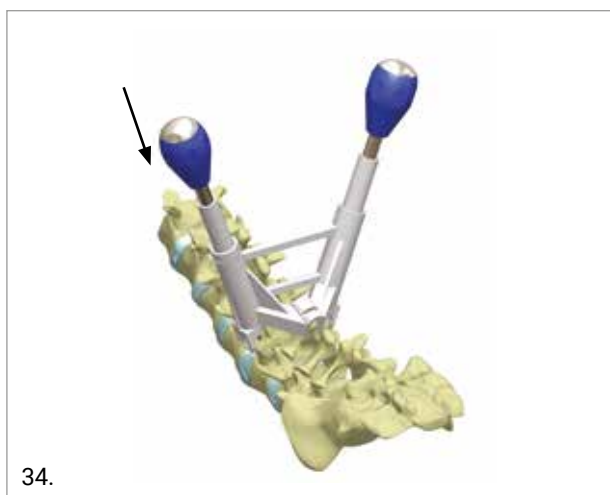
NOTE: Fluoroscope control is recommended during the awls perforation.

Hold the MySpine guide, remove the awl/sleeve system from one side (eg. right) and insert the corresponding pedicle probe, previously inserted in the sleeve (fig. 32). Repeat the same action on the other side (eg. left, fig. 33). Both pedicle probes are now inserted in the MySpine guide (fig. 34).



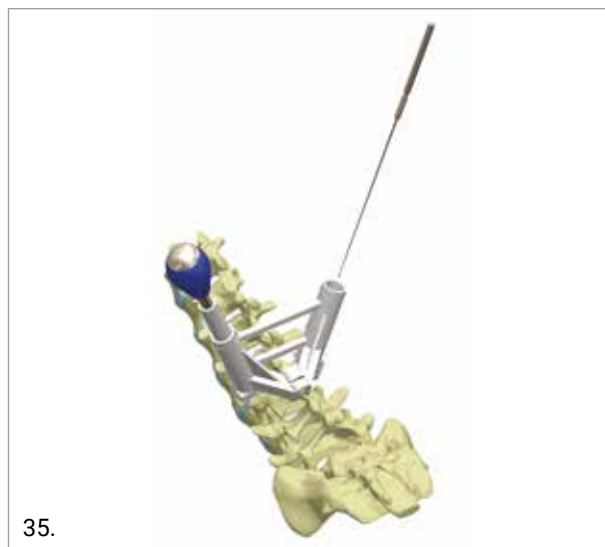


33.



34.

In two separate steps, manipulate the pedicle probes to open the pedicular canals of both sides. The 10mm incremental markings on the probe shaft provide an initial visual indication of the pedicle canal depth. Use the Ball Tip Feeler to check the walls on both sides for possible violation.



35.

OPTION

The M.U.S.T. bone screws are self-tapping. However, taps of different diameters are available and may be used at the surgeon's discretion. To tap the pedicle, taps must be inserted into the corresponding metallic sleeves using the Tap with the Quick Connector Ratcheting T-Handle.

NOTE: The use of Taps is highly recommended for sclerotic bone and for screws with a diameter larger than 7mm. Metallic sleeves are also required.

CAUTION

Hold the guide firmly during the implantation steps to comply with the planned screw positioning.

CAUTION

To provide maximum stability, all steps of the pedicle preparation and perforation procedures must be performed with both instruments inserted in the MySpine guide.

7. POLYAXIAL SCREW INSERTION

7.1 POLYAXIAL SCREW PREPARATION - STANDARD GUIDES

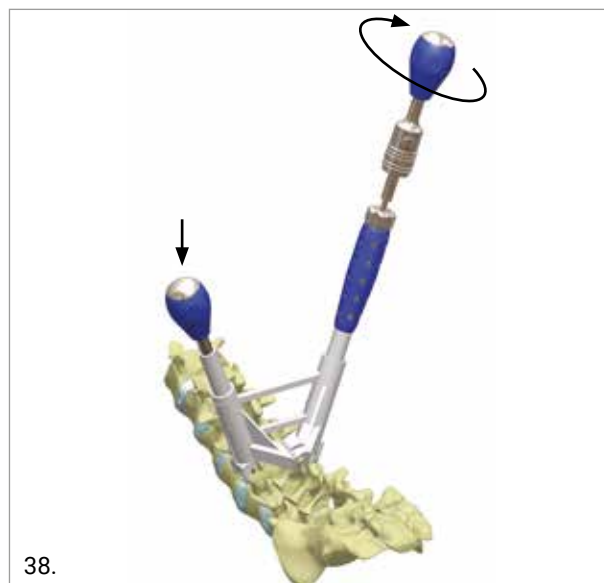
After the pedicle canal has been prepared, the surgeon can plan to insert the M.U.S.T. polyaxial screw.



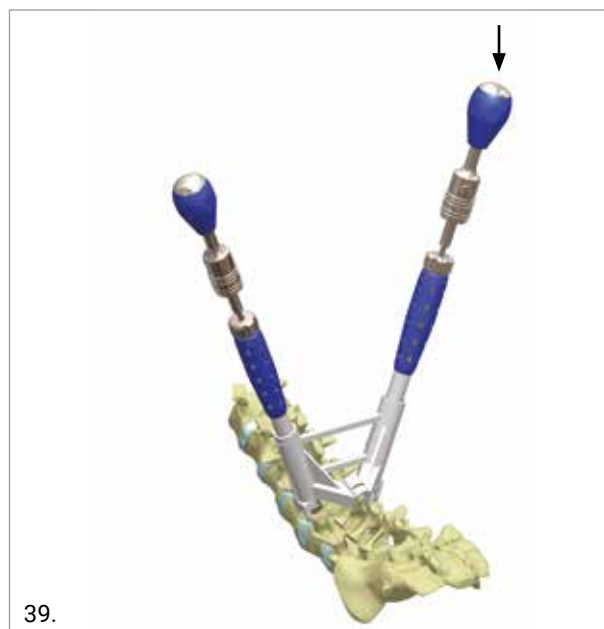
Prepare the Polyaxial Pedicle Screwdriver previously covered with the appropriate sleeve and attach the M.U.S.T. screw to it. To perform the screw preparation steps, follow the procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

7.2 POLYAXIAL SCREW PLACEMENTS - STANDARD GUIDES

Once the Polyaxial Pedicle Screwdriver has been prepared with the M.U.S.T. screw attached, proceed with the screw fixation procedure. Retract the probe on one side (eg. right) and insert the Polyaxial Pedicle Screwdriver, keep the opposite side (ie. left) stable with the probe still inserted. Now insert the screw into the prepared pedicle canal (ie. right, fig. 37) using the Polyaxial Pedicle Screwdriver whilst firmly holding the probe on the other side (ie. left), to provide the required stability to the overall system (fig. 38).



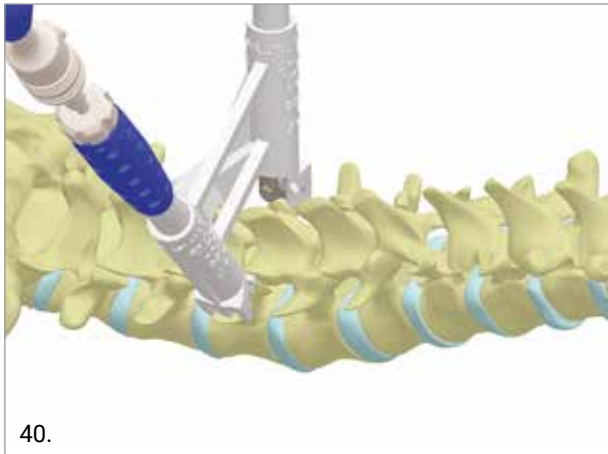
Then, retract the pedicle probe at the remaining side (ie left) and couple the Polyaxial Pedicle Screwdriver in the same way as previously indicated. Now insert the screws into the prepared pedicle canals using the Polyaxial Pedicle Screwdriver on this side (i.e left) while keeping the Polyaxial Pedicle Screwdriver on the other side (i.e. right), to provide the required stability to the overall system.



NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

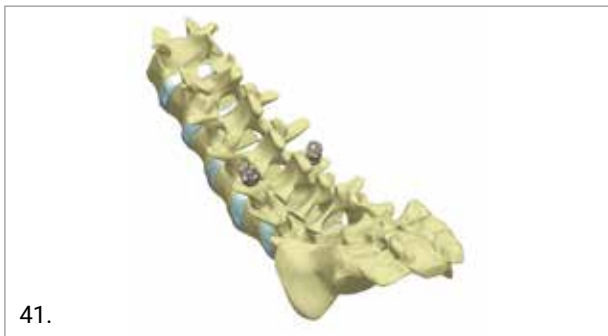
NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

NOTE: The distal side of the MySpine guide is fenestrated, allowing the surgeon to check every step during the polyaxial pedicle screw insertion whilst maintaining full control.



40.

Following satisfactory fixation of the pedicle screws, the screwdrivers can be easily removed. The result of this insertion should mirror the planning.



41.

IMPORTANT

The MySpine Screw Placement Guides must be used on the patient for whom the pre-operative planning has been carried out.

NOTE: Wash with normal saline or water the surgical field after MySpine guide usage.

CAUTION

Hold the guide firmly during the manipulation steps to comply with the planned screw positioning.

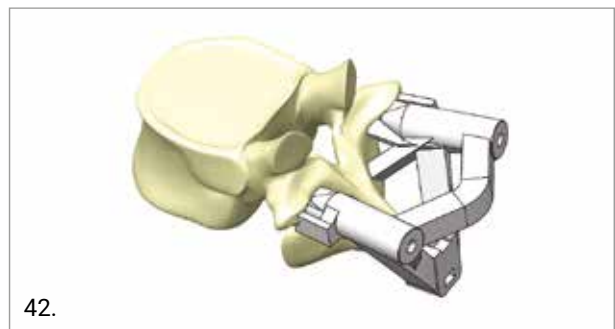
CAUTION

To provide maximum stability, all steps of the pedicle preparation and perforation procedures must be performed with both instruments inserted in the guide.

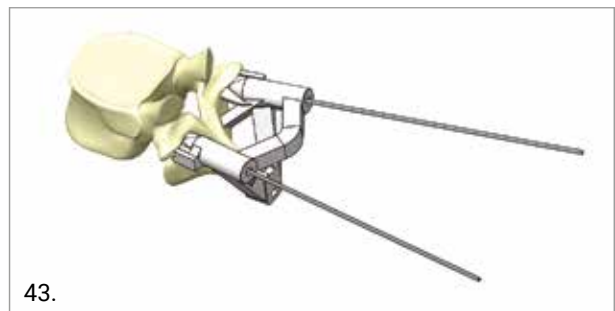
7.3 POLYAXIAL SCREW PREPARATION AND PLACEMENT - LOW PROFILE GUIDE

After checking the contact and entry points on the 3D model of the vertebra, the surgeon can start inserting the M.U.S.T. cannulated polyaxial screw. Prepare the Polyaxial Pedicle Screwdriver, previously coupled and attach the M.U.S.T. screw to it. To perform the screw preparation steps, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

With the MySpine guide securely attached to the corresponding vertebra and held firmly by hand, start to insert the K-wire through the pedicles using a Power Tool and a K-wire attachment (fig. 42-43).

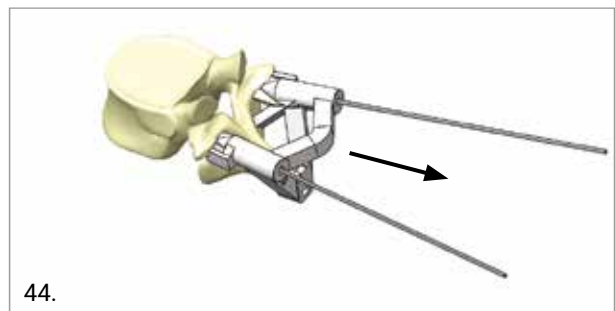


42.



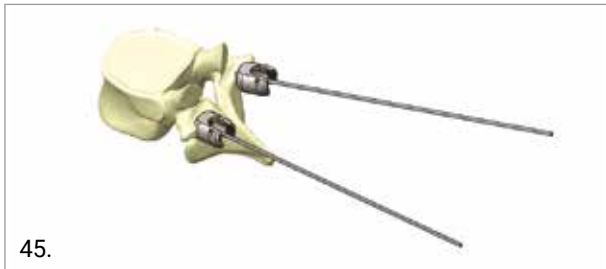
43.

When both K-wires are correctly positioned in the pedicles, slide the screw placement guide upwards (fig. 44) and leave the previously inserted K-wires in place. If required, the pedicles can be prepared using a cannulated awl and cannulated taps of 5,6 or 7mm in diameter. The cannulated pedicle screws can now be placed (already attached to the Polyaxial Pedicle Screwdrivers).



44.

When the cannulated pedicle screws reach their correct position, remove the K-wires from both pedicles (fig. 45-46).



45.



46.

Following satisfactory fixation of the pedicle screws, the screwdrivers can be easily removed. The result of this insertion should mirror the planning.

IMPORTANT

The MySpine Screw Placement Guides must be used on the patient for whom the pre-operative planning has been carried out.

CAUTION

Hold the guide firmly during the manipulation steps to comply with the planned screw positioning.

NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

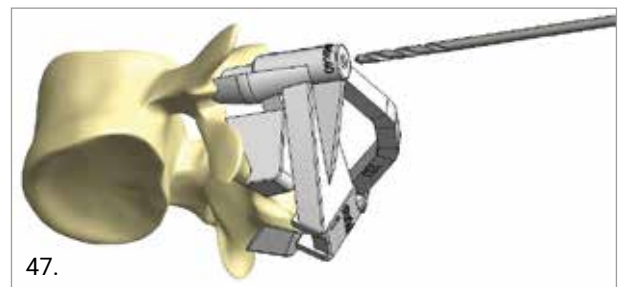
NOTE FOR LOW PROFILE GUIDE: To remove the K-wire using a screwdriver, it is recommended to use the 'spherical ratcheting' rather than the 'straight' to ensure that the K-wire still protrudes from the screwdriver itself.

Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

7.4 POLYAXIAL SCREW PREPARATION AND PLACEMENT - DRILL PILOT GUIDE

With the MySpine Drill Pilot Guide securely attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. Drill a pilot hole through the guide tubes in both pedicles, using the drill diameter selected in the the preoperative planning and the standard 30mm mechanical stop. In case of screws shorter than 30mm the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

NOTE: Before drilling use the high speed round burr to flatten the entry point.



47.

Use the Ball Tip Feeler to check the walls on both sides for possible violation.

NOTE: Fluoroscope control is recommended during the perforation.

NOTE: It is mandatory to use fluoroscopy to ensure that the drill tip is inserted into the correct entry point through the guide.

CAUTION

Apply pressure to the guide to avoid it slipping.

CAUTION

When drilling the initial hole at the surface of the cortical bone, take care to stop the drill tip from slipping towards the cranial direction. Start the drilling slowly at first and make sure you are drilling in the right direction.

CAUTION

For safety, depth lines are marked on the instrument.



48.

After guide removal, K-wire can be inserted as a guide for the following tapping and screwing process.

If required, the pedicles can be prepared using the corresponding tap. The pedicle screws can now be placed (already attached to the Polyaxial Pedicle Screwdrivers).

Following satisfactory fixation of the pedicle screws, the screwdrivers can be easily removed. The result of this insertion should mirror the planning.

IMPORTANT

The MySpine Screw Placement Guides must be used on the patient for whom the pre-operative planning was planned for.

CAUTION

Hold the guide firmly during the manipulation steps to comply with the planned screw positioning.

NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

NOTE: Wash with normal saline or water the surgical field after MySpine guide usage.

8. MYSPINE MC AND S1 TECHNIQUE

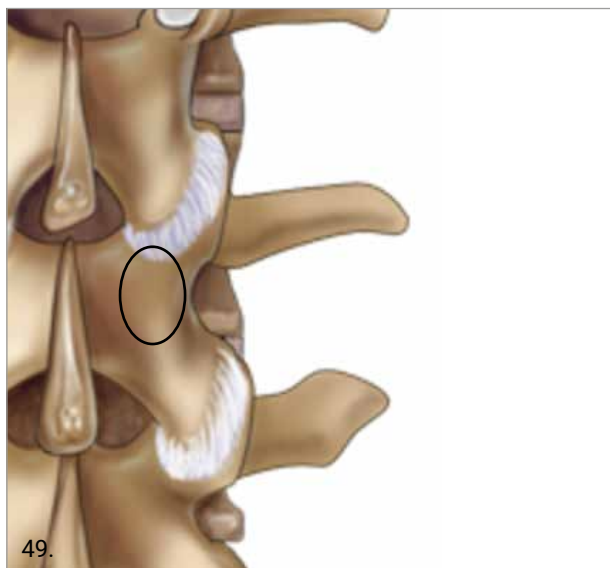
The MySpine MC is an addition to the MySpine system, the Medacta patient matched technology that provides support to surgeons to accurately position pedicle screws.

In particular, the MySpine MC guides are designed to support the surgeon with the option of a midline approach, in combination with the cortical bone screw trajectory, in order to achieve more cortical bone purchase when compared to a traditional pedicle screw trajectory.

PRE-OPERATIVE PLANNING

The pre-operative planning is versatile software, meant to assess the screw implantation surgical parameters also in case of cortical bone trajectory.

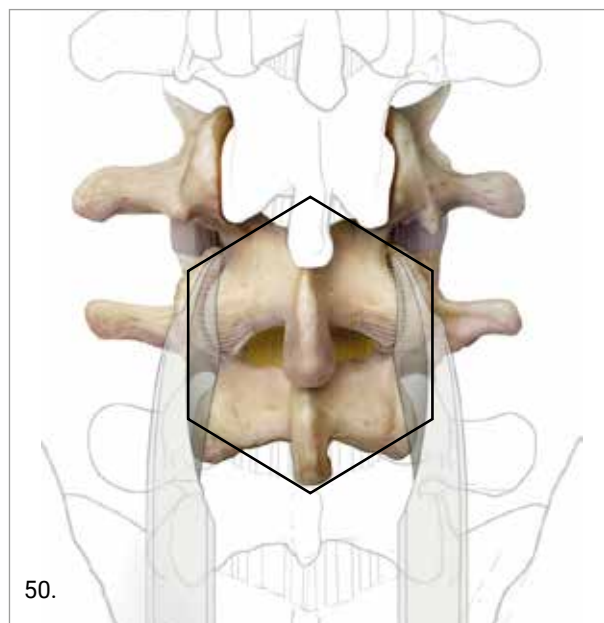
It is, in fact, possible to set the screw entry point and trajectory according to the cortical bone path. In particular, for the proper cortical bone entry point, move the entry point 3-5mm medial to the superior lateral edge of the pars and, for the proper cortical bone trajectory, the screw direction must be medial-to-lateral and caudal-to-cranial.



For the most cranial vertebra it is important to avoid any impingement with and/or any violation of the adjacent facet capsule, eventually move the entry point slightly inferior.

SPINE EXPOSURE AND PREPARATION

Perform a posterior midline incision and dissect laterally from the midline by locating the articular processes and the laminae of the corresponding levels. The use of the M.U.S.T. Mini-Open retractor is suggested to maintain the exposure.



Clean the vertebra(e) and treat the ligament according to a standard posterior midline approach. Additionally, removal of periosteum and exposure of bony surface of the caudal part of the lamina is required as this is where the hook structure of the guide will be set.

Exposure of the most cranial facets is not necessary. In order to preserve the facet capsule, but the cortical bone entry points have to be clearly exposed.

Extend the approach, in order to identify the facets and pars, in a medial-lateral direction; in a cranio-caudal direction, ensure to expose the most cranial facets and the most caudal lamina.

Proceed carefully with meticulous bone surface exposure in order to best secure the MySpine guide to the contact surface. At the same time, preserve the contact point to avoid instability of the guide.

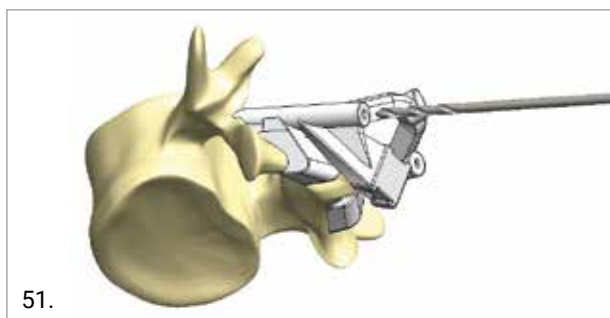
Once the guide is stable, insert the screws with a small incision or exposure.

8.1 MYSPINE MC AND S1 DRILL BASED OPTION

PEDICLE PREPARATION

With the MySpine MC or S1 guide securely attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. Drill a pilot hole through the guide tubes in both pedicles, using the drill diameter selected in the the preoperative planning and the standard 30mm mechanical stop. In case of screws shorter than 30mm the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

NOTE: Before drilling use the high speed round burr to flatten the entry point.



Use the Ball Tip Feeler to check the walls on both sides for possible violation.

NOTE: Fluoroscope control is recommended during the perforation.

NOTE: It is mandatory to use fluoroscopy to ensure that the drill tip is inserted into the correct entry point through the guide.

CAUTION

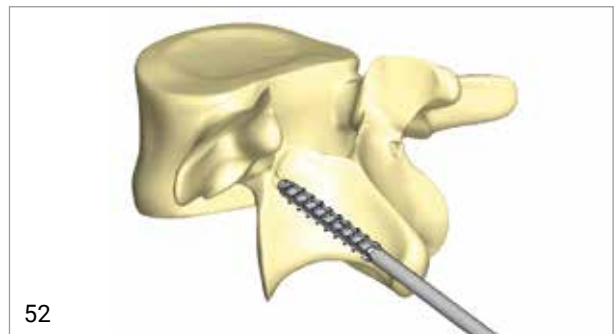
Apply pressure to the guide to avoid it slipping.

CAUTION

When drilling the initial hole at the surface of the cortical bone, take care to stop the drill tip from slipping towards the cranial direction. Start the drilling slowly at first and make sure you are drilling in the right direction.

CAUTION

For safety, always use the mechanical stop mounted on the drill bit. After guide removal, K-wire can be inserted as a guide for the following tapping and screwing process.



CAUTION

Whilst drilling, take care to avoid unintentional guidewire advancement or rotation. Use caution not to bend or kink the guidewire whilst advancing the drill.

POLYAXIAL SCREW PREPARATION

Prepare the Polyaxial Pedicle Screwdriver and attach the M.U.S.T. screw to it. To perform the screw preparation steps, follow the procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.



POLYAXIAL SCREW PLACEMENTS

Now insert the screw into the prepared pedicle canal using the Polyaxial Pedicle Screwdriver.

NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique. Following satisfactory fixation of the pedicle screws, the screwdrivers can be easily removed. The result of this insertion should mirror the planning.



8.2 MYSPINE MC AND S1 K-WIRE BASED OPTION

With the MySpine MC or S1 guide securely attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. Insert the K-wire through the guide tubes in both pedicles.

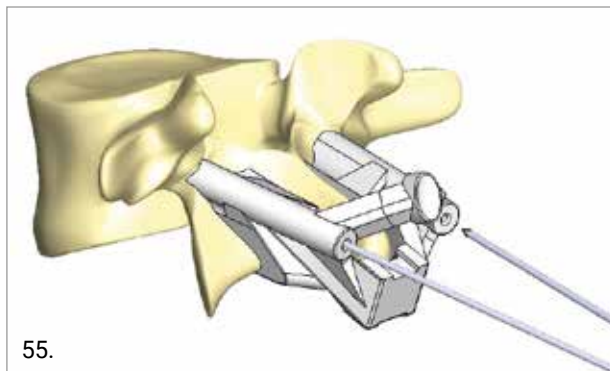
NOTE: It is mandatory to use fluoroscopy to ensure that the K wire tip is inserted into the correct entry point through the guide.

CAUTION

For safety, depth lines are marked on the instrument.

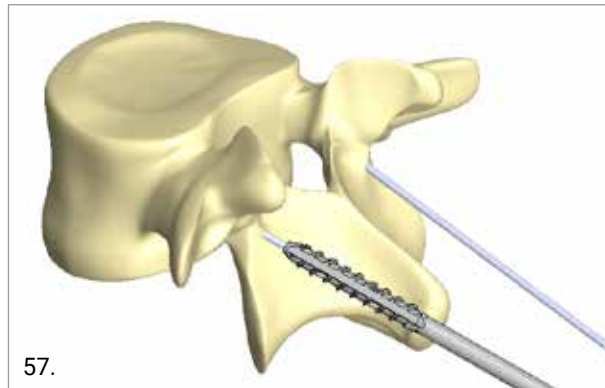
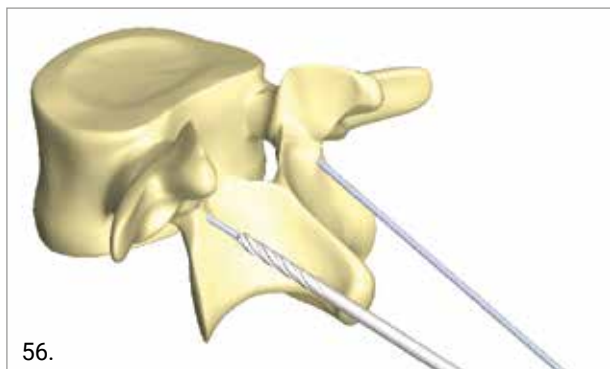
CAUTION

Apply pressure to the guide to avoid it slipping.



When both K-wires are correctly positioned in the pedicles, slide the screw placement guide upwards and leave the previously inserted K-wires in place.

The pedicles can be prepared using the cannulated awl or the cannulated drill and, for further canal preparation, cannulated taps can be used.



NOTE: Fluoroscope control is recommended during these preparation steps.

CAUTION

Whilst tapping, take care to avoid unintentional K-wires advancement or rotation. Use caution not to bend or kink the K-wires whilst advancing the tap.

CAUTION

For safety, always use the mechanical stop mounted on the drill bit.

POLYAXIAL SCREW PREPARATION

Prepare the Polyaxial Pedicle Screwdriver and attach the M.U.S.T. cannulated screw to it. To perform the screw preparation steps, follow the procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

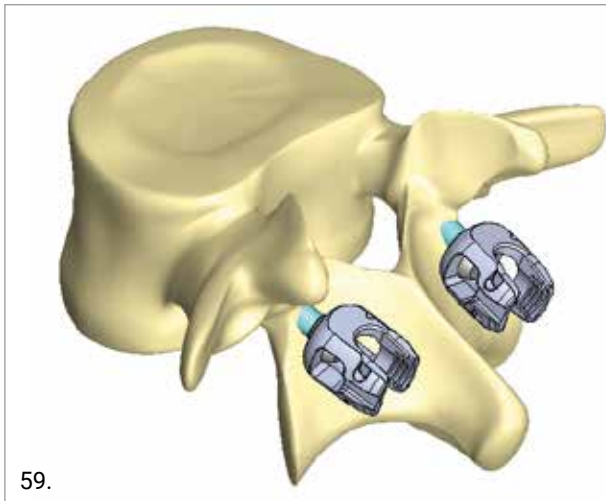


POLYAXIAL CANNULATED SCREW PLACEMENTS

Now insert the cannulated screw over the positioned K-wires using the Polyaxial Pedicle Screwdriver.

NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique. Following satisfactory fixation of the pedicle screws, the screwdrivers and the K-wires can be easily removed. The result of this insertion should mirror the planning.



IMPORTANT

The MySpine Screw Placement Guides must be used on the patient for whom the pre-operative planning was planned for.

CAUTION

Hold the guide firmly during the manipulation steps to comply with the planned screw positioning.

NOTE: Fluoroscope control is recommended during insertion of the Pedicle Screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

NOTE FOR WIRE BASED GUIDE: To remove the K-wire using a screwdriver, it is recommended to use the 'spherical ratcheting' rather than the 'straight' to ensure that the K-wire still protrudes from the screwdriver itself.

Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

NOTE: Wash with normal saline or water the surgical field after MySpine guide usage.

9. ROD CONTOURING AND INSERTION

Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

10. COMPRESSION OR DISTRACTION

Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

11. ROD IN SITU BENDING



Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

12. SET SCREW TIGHTENING



Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

13. MYSPINE ARTICLES REFERENCE

The following table lists the available MySpine vertebrae divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine vertebra T01		7.0001S	7.0001
MySpine vertebra T02		7.0002S	7.0002
MySpine vertebra T03		7.0003S	7.0003
MySpine vertebra T04		7.0004S	7.0004
MySpine vertebra T05		7.0005S	7.0005
MySpine vertebra T06		7.0006S	7.0006
MySpine vertebra T07		7.0007S	7.0007
MySpine vertebra T08		7.0008S	7.0008
MySpine vertebra T09		7.0009S	7.0009
MySpine vertebra T10		7.0010S	7.0010
MySpine vertebra T11		7.0011S	7.0011
MySpine vertebra T12		7.0012S	7.0012
MySpine vertebra T13		7.0013S	7.0013
MySpine vertebra L01		7.0021S	7.0021
MySpine vertebra L02		7.0022S	7.0022
MySpine vertebra L03		7.0023S	7.0023
MySpine vertebra L04		7.0024S	7.0024
MySpine vertebra L05		7.0025S	7.0025
MySpine vertebra L06		7.0026S	7.0026



The following table lists the available MySpine Pedicle Screw Placement Standard Guides divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine Standard guide T01		7.0101S	7.0101
MySpine Standard guide T02		7.0102S	7.0102
MySpine Standard guide T03		7.0103S	7.0103
MySpine Standard guide T04		7.0104S	7.0104
MySpine Standard guide T05		7.0105S	7.0105
MySpine Standard guide T06		7.0106S	7.0106
MySpine Standard guide T07		7.0107S	7.0107
MySpine Standard guide T08		7.0108S	7.0108
MySpine Standard guide T09		7.0109S	7.0109
MySpine Standard guide T10		7.0110S	7.0110
MySpine Standard guide T11		7.0111S	7.0111
MySpine Standard guide T12		7.0112S	7.0112
MySpine Standard guide T13		7.0113S	7.0113
MySpine Standard guide L01		7.0121S	7.0121
MySpine Standard guide L02		7.0122S	7.0122
MySpine Standard guide L03		7.0123S	7.0123
MySpine Standard guide L04		7.0124S	7.0124
MySpine Standard guide L05		7.0125S	7.0125
MySpine Standard guide L06		7.0126S	7.0126

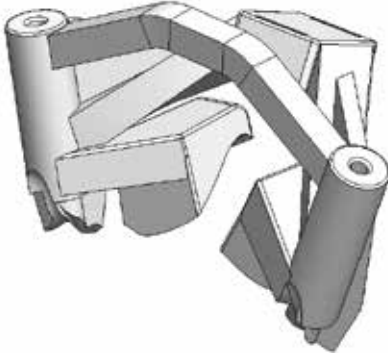
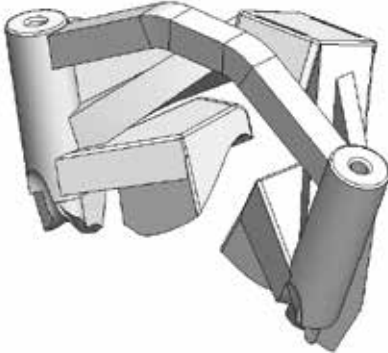
The following table lists the available MySpine vertebrae divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine LP vertebra T01		7.0401S	7.0401
MySpine LP vertebra T02		7.0402S	7.0402
MySpine LP vertebra T03		7.0403S	7.0403
MySpine LP vertebra T04		7.0404S	7.0404
MySpine LP vertebra T05		7.0405S	7.0405
MySpine LP vertebra T06		7.0406S	7.0406
MySpine LP vertebra T07		7.0407S	7.0407
MySpine LP vertebra T08		7.0408S	7.0408
MySpine LP vertebra T09		7.0409S	7.0409
MySpine LP vertebra T10		7.0410S	7.0410
MySpine LP vertebra T11		7.0411S	7.0411
MySpine LP vertebra T12		7.0412S	7.0412
MySpine LP vertebra T13		7.0413S	7.0413
MySpine LP vertebra L01		7.0421S	7.0421
MySpine LP vertebra L02		7.0422S	7.0422
MySpine LP vertebra L03		7.0423S	7.0423
MySpine LP vertebra L04		7.0424S	7.0424
MySpine LP vertebra L05		7.0425S	7.0425
MySpine LP vertebra L06		7.0426S	7.0426

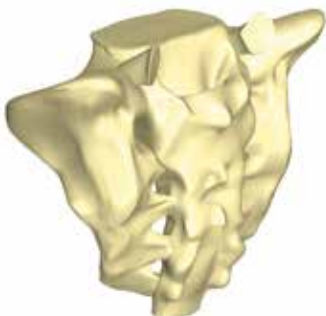
The following table lists the available MySpine Pedicle Screw Placement Low Profile Guides divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine LP guide T01		7.0501S	7.0501
MySpine LP guide T02		7.0502S	7.0502
MySpine LP guide T03		7.0503S	7.0503
MySpine LP guide T04		7.0504S	7.0504
MySpine LP guide T05		7.0505S	7.0505
MySpine LP guide T06		7.0506S	7.0506
MySpine LP guide T07		7.0507S	7.0507
MySpine LP guide T08		7.0508S	7.0508
MySpine LP guide T09		7.0509S	7.0509
MySpine LP guide T10		7.0510S	7.0510
MySpine LP guide T11		7.0511S	7.0511
MySpine LP guide T12		7.0512S	7.0512
MySpine LP guide T13		7.0513S	7.0513
MySpine LP guide L01		7.0521S	7.0521
MySpine LP guide L02		7.0522S	7.0522
MySpine LP guide L03		7.0523S	7.0523
MySpine LP guide L04		7.0524S	7.0524
MySpine LP guide L05		7.0525S	7.0525
MySpine LP guide L06		7.0526S	7.0526

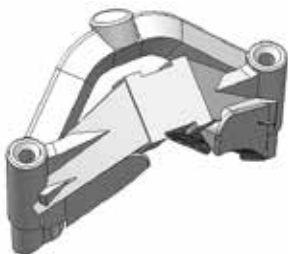
The following table lists the available MySpine Drill Pilot Guides divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine Drill pilot guide T01		7.0531S	7.0531
MySpine Drill pilot guide T02		7.0532S	7.0532
MySpine Drill pilot guide T03		7.0533S	7.0533
MySpine Drill pilot guide T04		7.0534S	7.0534
MySpine Drill pilot guide T05		7.0535S	7.0535
MySpine Drill pilot guide T06		7.0536S	7.0536
MySpine Drill pilot guide T07		7.0537S	7.0537
MySpine Drill pilot guide T08		7.0538S	7.0538
MySpine Drill pilot guide T09		7.0539S	7.0539
MySpine Drill pilot guide T10		7.0540S	7.0540
MySpine Drill pilot guide T11		7.0541S	7.0541
MySpine Drill pilot guide T12		7.0542S	7.0542
MySpine Drill pilot guide T13		7.0543S	7.0543
MySpine Drill pilot guide L01		7.0551S	7.0551
MySpine Drill pilot guide L02		7.0552S	7.0552
MySpine Drill pilot guide L03		7.0553S	7.0553
MySpine Drill pilot guide L04		7.0554S	7.0554
MySpine Drill pilot guide L05		7.0555S	7.0555
MySpine Drill pilot guide L06		7.0559S	7.0559


The following table lists the available MySpine Sacrum vertebral model divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine S01 drill based guide		7.0706S	7.0706

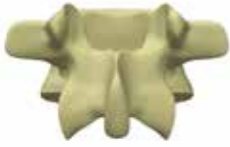
The following table lists the available MySpine Sacrum Guides divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine S01 drill based guide		7.0726S	7.0726
MySpine S01 wire based guide		7.0716S	7.0716


The following table lists the available MySpine MC Guides divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine MC wire based guide L01		7.0711S	7.0711
MySpine MC wire based guide L02		7.0712S	7.0712
MySpine MC wire based guide L03		7.0713S	7.0713
MySpine MC wire based guide L04		7.0714S	7.0714
MySpine MC wire based guide L05		7.0715S	7.0715
MySpine MC wire based guide L06		7.0719S	7.0719
MySpine MC drill based guide L01		7.0721S	7.0721
MySpine MC drill based guide L02		7.0722S	7.0722
MySpine MC drill based guide L03		7.0723S	7.0723
MySpine MC drill based guide L04		7.0724S	7.0724
MySpine MC drill based guide L05		7.0725S	7.0725
MySpine MC drill based guide L06		7.0729S	7.0729

The following table lists the available MySpine MC Vertebrae divided into sterile and non-sterile versions.

DESCRIPTION	PICTURE	STERILE REFERENCE	NON-STERILE Reference
MySpine MC vertebra L01		7.0701S	7.0701
MySpine MC vertebra L02		7.0702S	7.0702
MySpine MC vertebra L03		7.0703S	7.0703
MySpine MC vertebra L04		7.0704S	7.0704
MySpine MC vertebra L05		7.0705S	7.0705
MySpine MC vertebra L06		7.0709S	7.0709

The following table lists the available MySpine full spine models representing the patient's pre-operative anatomy.

DESCRIPTION	PICTURE	NON-STERILE Reference
Full Spine Model Short		7.0030
Full Spine Model Medium		7.0031
Full Spine Model Long		7.0032
Full Spine Model - Scaled 1:2 - Short		7.0033
Full Spine Model - Scaled 1:2 - Medium		7.0034
Full Spine Model - Scaled 1:2 - Long		7.0035
Full Spine Model - Scaled 1:3 - Short		7.0036
Full Spine Model - Scaled 1:3 - Medium		7.0037
Full Spine Model - Scaled 1:3 - Long		7.0038

NOTE

Part numbers subject to change.

NOTE FOR STERILISATION

In case the instrumentation is not sterile upon delivery, it must be cleaned before use and sterilized in an autoclave respecting the regulation of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer.

For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta International reusable orthopedic devices" available at www.medacta.com.



**REDEFINING BETTER
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MySpine®
Surgical Technique

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