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
CONTENTS

1 INDICATIONS 6
   1.1 MySpine Standard and Low Profile Indications 6
   1.2 MySpine MC and Drill Pilot Indications 6

2 CONTRAINDICATIONS 6

3 PRE-OPERATIVE PLANNING 6

4 THE MYSPINE DEVICE 9
   4.1 Product specification 9
   4.2 The MySpine device profile 11
   4.3 The MySpine device configuration 12

5 SURGICAL APPROACH 13

6 BEFORE STARTING THE PROCEDURE 14

7 SPINE EXPOSURE AND PREPARATION - STANDARD AND LOW PROFILE GUIDES 15

8 SURGICAL TECHNIQUE - STANDARD GUIDES 16
   8.1 Instrument preparation 16
   8.2 Pedicle preparation - standard guides 16
   8.3 Polyaxial screw preparation - standard guides 18
   8.4 Polyaxial screw placement - standard guides 18

9 SURGICAL TECHNIQUE - LOW PROFILE GUIDES 20
   9.1 Instrument preparation - Low Profile guides 20
   9.2 Polyaxial screw preparation and placement - Low Profile Guide 20
   9.3 Polyaxial screw preparation and placement - Drill Pilot guide 21
10 SURGICAL TECHNIQUE - MYSPINE MC AND S1  22
  10.1 MySpine MC drill based option  22
  10.2 MySpine MC K-wire based option  24
  10.3 MySpine S1 drill based option  25
  10.4 MySpine S1 K-wire based option  26

11 ROD CONTOURING AND INSERTION  28

12 COMPRESSION OR DISTRACTION  28

13 ROD IN SITU BENDING  28

14 SET SCREW TIGHTENING  28

15 MYSPINE ARTICLES REFERENCE  29
1 INDICATIONS

1.1 MySpine Standard and Low Profile 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.

MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of Pedicle screws in the vertebral body. MySpine is intended for use with M.U.S.T. Pedicle Screw System and its cleared indications for use. MySpine Low Profile screw placement guides are intended for the placement of K-wires to assist in the positioning of pedicle screws.

Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine Screw placement guides are intended for single use only.

1.2 MySpine MC and Drill Pilot Indications

MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use. MySpine Drill Pilot is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5. The device is intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC is intended as a lumbar and sacral posterior pedicle targeting guide for patients requiring spinal fusion between the levels of L1 to S1.

The device is provided with two options:

- Drill based
- K-wire based

MySpine MC drill based are intended for perforating a guiding hole to assist in the positioning of pedicle screws in the vertebral body. MySpine MC k-wire based are intended for the placement of K-wires to assist in the positioning of pedicle screws in the vertebral body.

Use of the guides involves a surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine MC and Drill Pilot guides are intended for single use only.

2 CONTRAINDICATIONS

Contraindications in using MySpine instrumentation are the same as in situations when a spinal fusion with pedicle screws contraindicated. Please refer to the M.U.S.T. surgical technique for a comprehensive discussion 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.

3 PRE-OPERATIVE PLANNING

The MySpine Surgical Planning (see page 8), is meant to assist in planning screw placement and allowing for production of the 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 patient's anatomy.

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

**NOTE:** There are different Screw Placement guide configurations:
1. Standard
2. Low Profile
3. Drill Pilot
4. MC

It is up to the surgeon to decide in advance which guide profile has to be used according to surgical approach and preferences as well as patient's anatomy and needs. This is described in the pre-operative planner manual.

The MySpine system pre-operative planning allows for the selection of only one guide profile for each vertebra. While the guide selection may differ, the MySpine pre-operative planning process remains the same for all guide types.

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

**NOTE:** Before using MySpine procedures, every Surgeon / Radiological Centre must contact Medacta International.

**NOTE:** The MySpine low dose CT protocol is consistent whether the surgeon decides to use different guide configuration.

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**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 of 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.

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**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

**Level: T02**

<table>
<thead>
<tr>
<th>SAGITTAL PLANE</th>
<th>TRANSVERSAL PLANE</th>
<th>CORONAL PLANE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR: 1 deg</td>
<td>L</td>
<td>HDL: -1.25 mm</td>
</tr>
<tr>
<td>SAR: 2 deg</td>
<td>R</td>
<td>HDR: -1 mm</td>
</tr>
<tr>
<td>SAL: 15 deg</td>
<td>TAL: 15 deg</td>
<td>VDL: 0.25 mm</td>
</tr>
<tr>
<td>TAL: 8 deg</td>
<td>TAR: 8 deg</td>
<td>VDR: -0.75 mm</td>
</tr>
</tbody>
</table>

**Screw Length**
- L: Length: 30 mm, Cortical gap: 2 mm
- R: Length: 25 mm, Cortical gap: 3 mm

**3D View**
- L: Diameter: 4.5 mm
- R: Diameter: 4.5 mm

**Screw Diameter**
- L: Diameter: 4.5 mm
- R: Diameter: 4.5 mm

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*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)
TAL/TAR: 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*
4.1 Product specification

The MySpine system is mainly composed of two devices’ configurations:
1. Standard Guides
2. Low Profile Guides

Both the Standard and Low Profile MySpine Screw Placement Guides display the following information:

- 1. 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)
- 2. The reference and lot number
- 3. Implant size (left and right)
- 4. Vertebral level
- 5. 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:

4. 

A) One central spinous process interface, 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 properly support insertion of the instruments for the pedicle screws placement (Standard Guides only).

NOTE: The central spinous process interface is the same for: standard, low profile and drill pilot guides. Therefore, there is no difference between these options.

5. 

Each sleeve reports the following information:

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

6. 

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

CAUTION

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)
4.2 The MySpine device profile

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

In lumbar spine treatment, the MySpine guides are designed to enhance 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 maximize 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 maximize contact at the spinous process and both lamina and transverse processes.

NOTE: The different guide options can be used in every vertebra from T1 to S1 according to patient’s anatomy and surgeon’s preferences. There is no difference in the pre-operative plan when using different guide options.

However, depending on the patient’s anatomically matched model, the guide can also be designed to the contacts to only one of the following areas:

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

NOTE: The MySpine guide profiles is custom 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.
MySpine Surgical Technique

4.3 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:

1) Open. The guide presents a fully open 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 opened 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 profile 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.

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

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

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5 **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.
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 anatomic 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_DDMWYYYY}
4. Reference and Lot numbers

Check the fit 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.
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 effective 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.
8.1 Instrument preparation

Prepare 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.

8.2 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.

While holding one pedicle awl (e.g. left), perforate the outer cortex of the opposite side (i.e. right) with the corresponding pedicle awl (fig.28). Repeat in order to perforate the other side of the cortex (i.e. left, fig.29).

**NOTE:** Use of fluoroscopy is recommended during the awl perforation.
Hold the MySpine guide, remove the awl/sleeve system from one side (e.g., right) and insert the corresponding pedicle probe, previously inserted in the sleeve (fig. 28). Repeat the same action on the other side (e.g., left, fig. 31). Both pedicle probes are now inserted in the MySpine guide (fig. 32).

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.

**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.

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**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.
8.3 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 screw preparation, follow the procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.

8.4 Polyaxial screw placement - 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 (e.g., right) and insert the Polyaxial Pedicle Screwdriver, keep the opposite side (i.e., left) stable with the probe still inserted. Now insert the screw into the prepared pedicle canal (i.e., right, fig.35) using the Polyaxial Pedicle Screwdriver whilst firmly holding the probe on the other side (i.e., left), to provide the required stability to the overall system (fig.36).
Then, retract the pedicle probe at the remaining side (i.e. 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.

**WARNING**

Before inserting pedicle screws larger than 7mm diameter, it is mandatory to tap the pedicles. In case of sclerotic bone or any other reason that can cause high resistance during screw insertion apply the same procedure for all the other diameters. Please note that the taps are 0.5mm undersized.

**NOTE:** Use of fluoroscopy 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 while maintaining full control.

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.

**CAUTION**

To provide maximum stability, all steps of the pedicle preparation and perforation procedures must be performed with both instruments inserted in the guide.
The surgeon can now start inserting the M.U.S.T. cannulated polyaxial screw. Prepare the Polyaxial Pedicle Screwdriver, 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.

**WARNING**

Before inserting pedicle screws larger than 7mm diameter, it is mandatory to tap the pedicles. In case of sclerotic bone or any other reason that can cause high resistance during screw insertion apply the same procedure for all the other diameters. Please note that the taps are 0.5mm undersized.

When the cannulated pedicle screws reach their correct position, remove the K-wires from both pedicles (fig.44).
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:** Use of fluoroscopy 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.

### 9.3 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, using the drill diameter that corresponds to the pre-operative planning, through the guide tubes in both pedicles.

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

**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.

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.
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-tolateral 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.

**PEDICLE PREPARATION**

With the MySpine MC guide securely attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. Drill a pilot hole, using the drill diameter that corresponds to the pre-operative planning, through the guide tubes in both pedicles.
49. Use the Ball Tip Feeler to check the walls on both sides for possible violation.

NOTE: Fluoroscopy 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.

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

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

CAUTION

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.
10.2 MySpine MC K-wire based option

With the MySpine MC 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-wire advancement or rotation. Use caution not to bend or kink the K-wires whilst advancing the tap.

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.

![Image](57.png)

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.

10.3 MySpine S1 drill based option

PEDICILE PREPARATION
With the MySpine S1 guide securely attached to the S1 vertebra, firmly press the guide onto the lamina to secure the position. Drill a pilot hole, using the drill diameter that corresponds to the pre-operative planning, through the guide tubes in both pedicles.

![Image](58.png)

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.

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

With the MySpine S1 guide securely attached to the S1 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.

**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.

---

**NOTE:** Fluoroscope control is recommended during these preparation steps.

**CAUTION**

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

**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.

**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.
11 ROD CONTOURING AND INSERTION

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

12 COMPRESSION OR DISTRACTION

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

13 ROD IN SITU BENDING

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

14 SET SCREW TIGHTENING

Please follow the same procedure as described in the Medacta M.U.S.T. Implant Surgical Technique.
The following table lists the available MySpine vertebrae divided into sterile and non-sterile versions.

<table>
<thead>
<tr>
<th>Description</th>
<th>Picture</th>
<th>STERILE Reference</th>
<th>NON-STERILE Reference</th>
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The following table lists the available MySpine Pedicle Screw Placement Standard Guides divided into sterile and non-sterile versions.

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

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

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

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

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

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

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</table>
The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable and following the instruction for use of the autoclave manufacturer.

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

NOTE FOR STERILIZATION

Part numbers subject to change.