MySpine

PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS

Surgical Technique

Joint | **Spine** | Sports Med

S2-ALAR/ALAR-ILIAC

Medacta International

INDEX

1. INTRODUCTION

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 spinal fixation surgery.

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

1.1 INDICATIONS

MySpine S2-Alar/Alar-Iliac is intended for use with the Medacta M.U.S.T. pedicle screw system and its cleared indications for use.

MySpine S2-Alar/Alar-Iliac guides (referred to from this point on as, MySpine guides) are custom-made devices intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intra-operatively in the preparation of the screw trajectory in S1, S2 and in the Ilium.

The guides are created using a surgical planning software which pre-operatively plans the positions of the components based upon radiological images of the patients' anatomical landmarks and the surgical equipment selected.

My Spine guides are intended for single use only.

1.2 CONTRAINDICATIONS

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

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

The MySpine 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 Report (see page 6), is meant to assess the main surgical parameters regarding the screw implantation in order to manufacture dedicated single patient matched MySpine guides.

The surgeon chooses the guide configuration and is entitled to set the surgical parameters as follows:

1. Screw size:
   - Diameter
   - Length
2. Actual evaluation of screw gap:
   - screw tip distance from the anterior cortex
   - screw shaft distance from the sciatic notch
3. Angulation of the screws in relation to the:
   - Sagittal Plane
   - Transverse Plane
4. Position of the screw on the coronal plane:
   - Horizontal shift
   - Vertical shift

A 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 guides to precisely fit the patient's vertebral anatomy.

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.

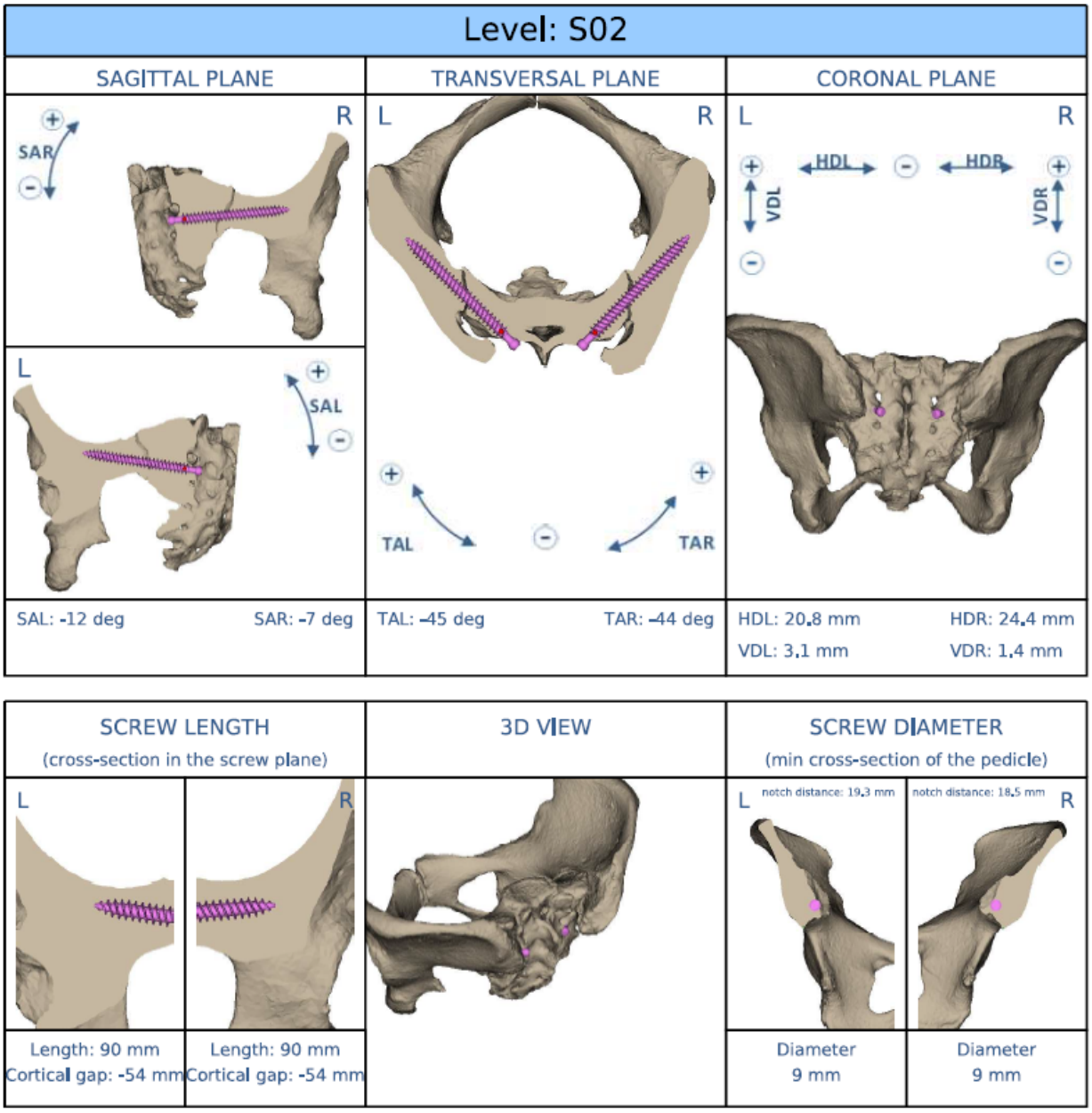
CAUTION

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 guides will be manufactured and delivered.

CAUTION

The 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.

1.

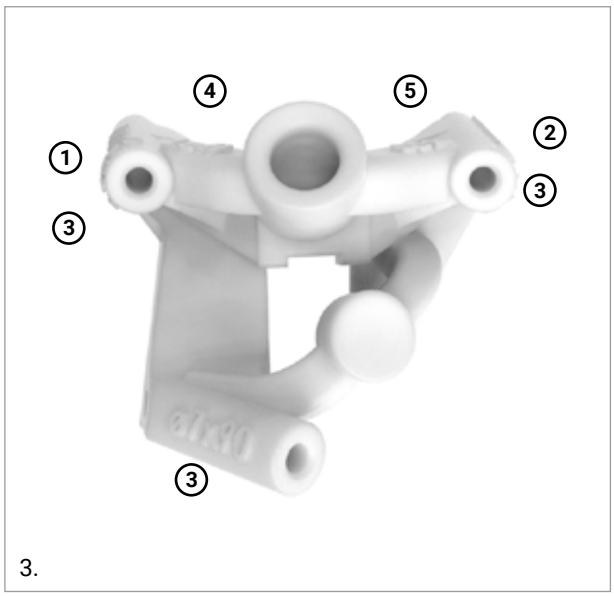

Level: S02
SAGITTAL PLANE
TRANSVERSAL PLANE
CORONAL PLANE
SAR
SAL
TAL
TAR
HDL
HDR
VDL
VDR
SAL: -12 deg
SAR: -7 deg
TAL: -45 deg
TAR: -44 deg
HDL: 20.8 mm
HDR: 24.4 mm
VDL: 3.1 mm
VDR: 1.4 mm
SCREW LENGTH
(cross-section in the screw plane)
3D VIEW
SCREW DIAMETER
(min cross-section of the pedicle)
notch distance: 19.3 mm
notch distance: 18.5 mm
Length: 90 mm
Cortical gap: -54 mm
Length: 90 mm
Cortical gap: -54 mm
Diameter
9 mm
Diameter
9 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.

1.4 MYSPINE DEVICE PRODUCT SPECIFICATION

The MySpine guides displays the following information:

1. Reference number
2. Lot number
3. Implants size (left and right)
4. Vertebral level
5. Side



3.

CAUTION

Before starting the surgery, please check the lot number reported on the planning report is specific to the patient and matches the lot number marked on each guide.

CAUTION

If the MySpine Guides do not clearly indicate the lot number, they MUST NOT be used for the surgery. In such a case please contact Medacta staff immediately.

CAUTION

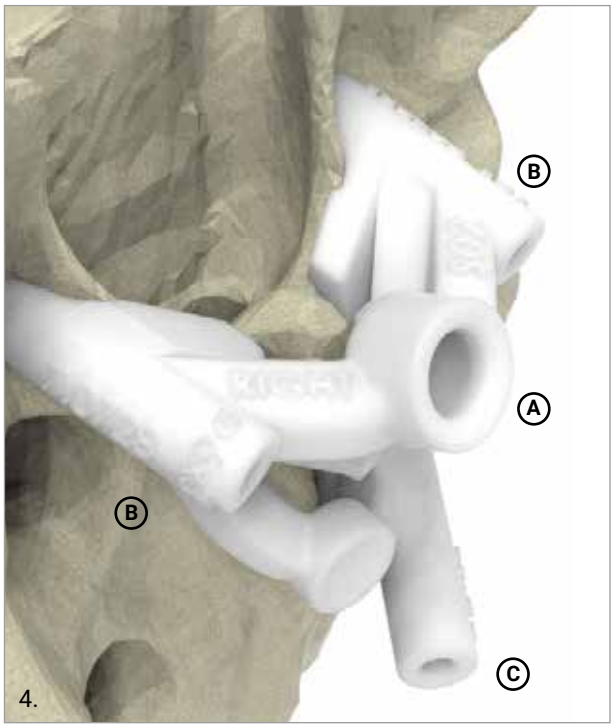
Do not use MySpine Guides on a patient for whom the pre-operative planning has not been carried out. Also, the MySpine device used on a different patient will lead to unpredictable outcomes.

The MySpine guides are composed as follows:

A) One central spinous contact, 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 on S1;

C) One caudal cylindrical guide with distal pin, aimed to perfectly match the vertebral anatomical sites on S2



4.

The cylindrical guides support the insertion of the instruments for the screws implantation.

1.5 THE MYSPINE DEVICE PROFILE

The MySpine guide profile is specifically designed for treatment of the sacral spinal segments with the aim to provide maximum stability and optimal screw entry point.

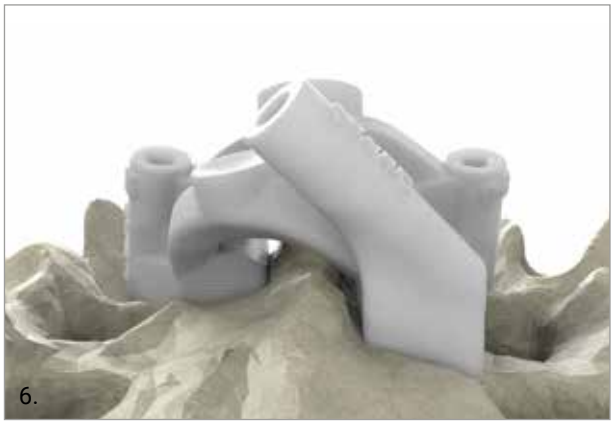
The MySpine guides are designed to optimize the contacts to the vertebrae at the spinous process and the lamina.

5.

NOTE: The MySpine guides profile is custom and specifically designed by Medacta International on the submission of a specific geometry confirmed by the surgeon with the MySpine Surgical Planning.

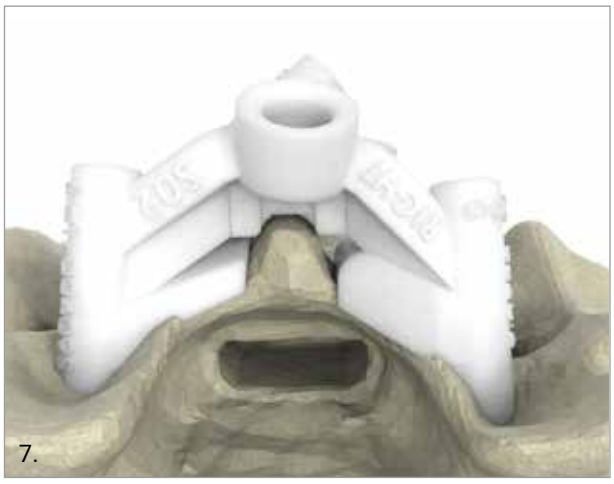
1.6 THE MYSPINE DEVICE CONFIGURATION

The MySpine guide is designed in left and right configuration to support the insertion of the instruments for the screws implantation in S2 in two consequent steps.



6.

The myspine guide can be designed with or without a handle interface according to the surgeon's preference.



7.

2. SURGICAL APPROACH

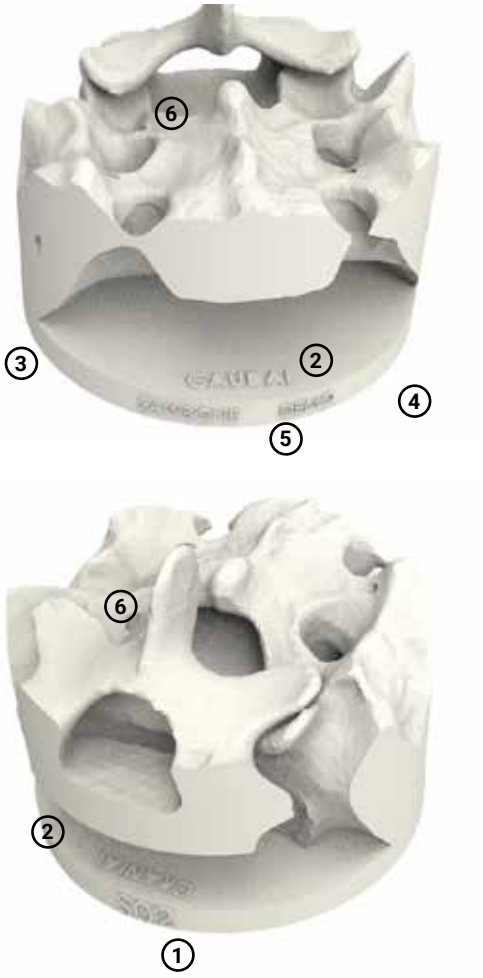
The MySpine guides are meant to guide the implant of the M.U.S.T. pedicle screw via a posterior approach. Other choices of the surgical approach are at the discretion of the surgeon.

3. BEFORE STARTING THE PROCEDURE

3.1 CHECK THE POSITIONING

The MySpine guide is made to specifically match the vertebral anatomy of the patient, thus allowing maximum stability on the vertebra as well as the correct placement of the screws.

A plastic 3D model anatomically reproducing the patient's vertebra is provided to simulate the correct positioning of the MySpine guide in the surgical theatre.



8.

The vertebral 3D model provides the following information:

1. Vertebral level
2. Caudal / Cranial side
3. Patient ID
4. Reference
5. Lot number
6. Entry points

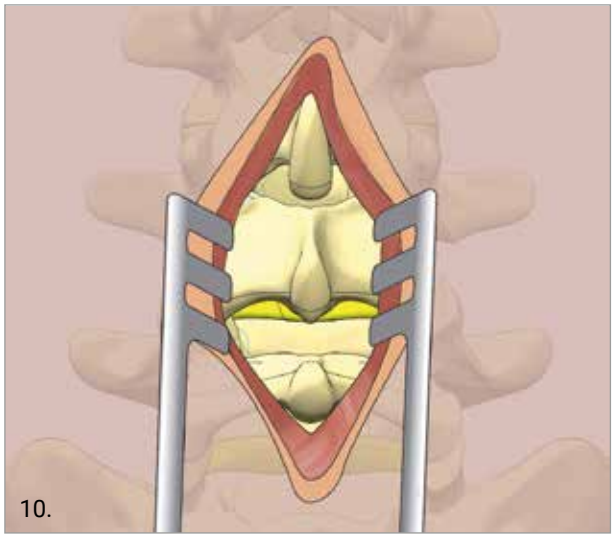
Check the correct fit between the vertebra's plastic model and the MySpine guides to verify the contact surface and the screw entry points; to facilitate the identification of the entry point, a hole is replicated on the vertebral model ⑥.

9.

NOTE: 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 guide positioning to the contact surfaces and the entry points.

3.2 SPINE EXPOSURE AND PREPARATION

Perform a skin incision and dissect laterally from the midline by locating the screw entry points of the corresponding levels.


10.

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 surface.


11.

NOTE: In order to avoid impingement between the guide and the adjacent screws, always start with the most cranial vertebra and proceed caudally.

As the correct placement corresponds to the maximum stability of the guide and allows optimal screw insertion, verify that the contact between the MySpine guides and the anatomical sites on the vertebra are respected.

Once the MySpine guides are optimally placed, the screw entry points are consequently set as per the pre-operative planning and the spine tract is ready for surgery.

CAUTION
Always match the dedicated MySpine guide with the corresponding patient's vertebra.

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

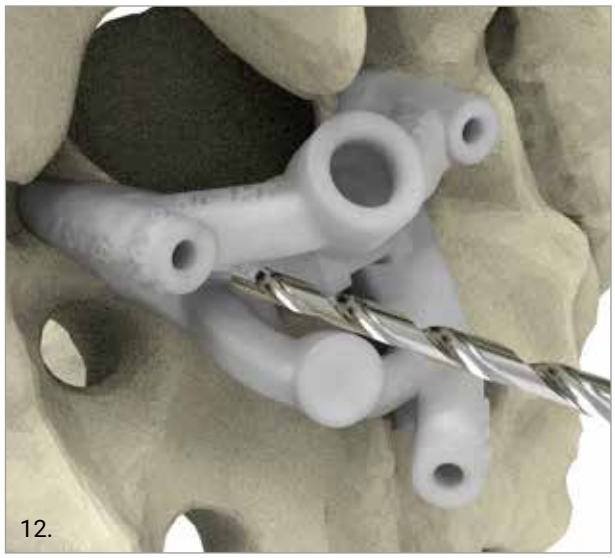
3.3 PEDICLE PREPARATION

With the MySpine guide securely attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the positon.

It is a surgeon's discretion to start the surgery either with the left or the right guide configuration.

Drill a pilot hole through the guide tubes in both left and right S1 pedicles using the proper drill diameter.

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


12.

CAUTION
For safety, use the instrument with S1 mechanical stop according to the planned screw length. In case of screws shorter than 30mm the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

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.

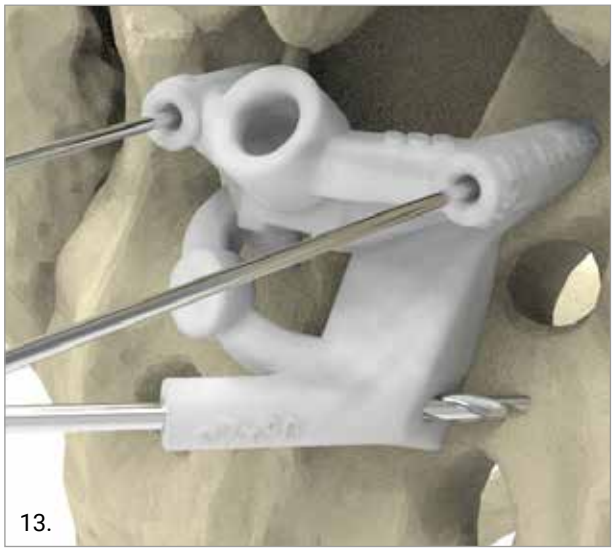
NOTE: It is mandatory to use fluoroscopy to ensure that the drill tip is inserted into the correct entry point through the guide.

NOTE: Fluoroscope control is recommended during the perforation.

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

Following satisfactory pilot hole drilling, insert blunt K-wires through the guide holes for a better guide stability during the next surgical step.

Drill a pilot hole through the caudal guide tube in S2 pedicle using the proper drill diameter.



13.

Slide away the guide leaving the K-wire in S1 pedicles. Use the K-wires to place the second, opposite side, guide configuration for a more accurate positioning.

Repeat the drilling of the pilot holes to the contralateral S2 pedicle using the other guide configuration (left/right) and insert blunt k-wires in the guide holes.

NOTE: while the second guide configuration is in place do not drill again the S1 pilot holes.

Before screw insertion, tap the pilot holes using the cannulated tap with the corresponding diameter (taps are 0.5mm undersized). Medacta recommend to tap the pilot hole before screw insertion.

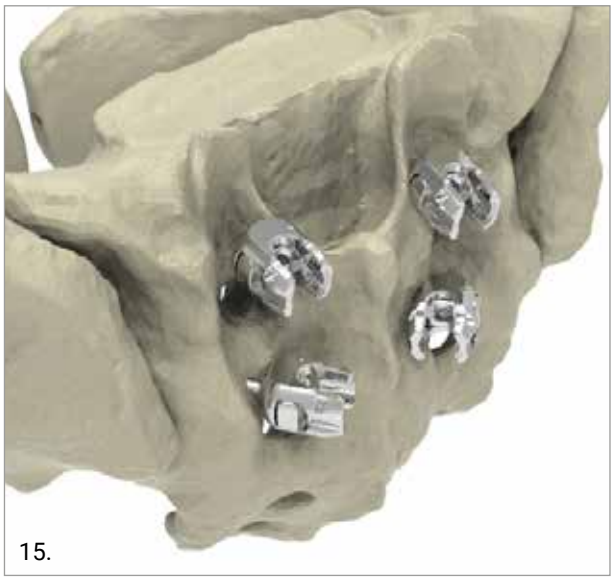
POLYAXIAL SCREW PREPARATION

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

14.

POLYAXIAL SCREW PLACEMENTS

Insert the screw into the prepared pedicle canal using the Polyaxial Pedicle Screwdriver. Either solid or cannulated screws can be used.



15.

WARNING

Before inserting pedicle screws larger than 7mm in diameter, 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: 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.

NOTE: remove K-wires when used.

IMPORTANT

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

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

4. ROD CONTOURING AND INSERTION

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta® M.U.S.T. posterior screw system

5. COMPRESSION OR DISTRACTION

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta® M.U.S.T. posterior screw system

6. ROD IN SITU BENDING

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta® M.U.S.T. posterior screw system

7. SET SCREW TIGHTENING

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta® M.U.S.T. posterior screw system

8. MYSPINE ARTICLES REFERENCE

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

DESCRIPTION	PICTURE	STERILE REF.	UNSTERILE REF.
MySpine vertebra S02		7.0707S	7.0707

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

DESCRIPTION	PICTURE	STERILE REF.	UNSTERILE REF.
MySpine S02 left guide		7.0727S	7.0727
MySpine S02 right guide		7.0728S	7.0728

NOTES

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave in accordance with the regulations 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 sterilisation of Medacta International orthopaedic devices” available at www.medacta.com.

REDEFINING BETTER
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