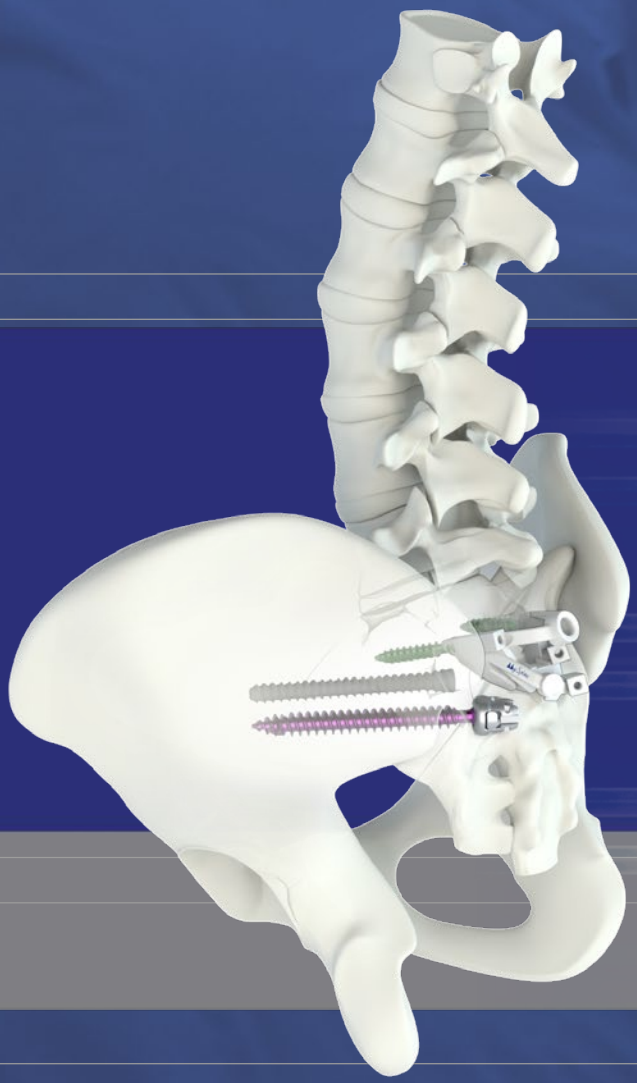
MySpine®
PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

UNIQUE ANATOMIES, PATIENT-MATCHED SOLUTIONS



Surgical Technique

Joint | **Spine** | Sports Med

S2-ALAR/ALAR-ILIAC, ANCHOR AND UNILATERAL

Medacta International

CAUTION

Federal law (USA) restricts this device to sale distribution and use by, or on the order of, a physician.

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1. INTRODUCTION

The MySpine guides are intended to be used as anatomical perforating guide, specific to a single patient's anatomy to assist intraoperatively in the positioning of posterior screws in spinal fixation surgery. The MySpine platform allows the surgeon to complete a 3D preoperative planning on the patient's spinal CT scans.

1.1 INDICATIONS

MySpine S2-Alar/Alar-Iliac and MySpine Anchor guides are intended to be used with any 510(k) cleared, legally marketed, pedicle screw system (for its approved indications for use) and its respective compatible components for noncervical open, posterior spinal fixation procedures intended for fusion. The SI trajectory of the MySpine Anchor guide is only intended to be used with M.U.S.T. SI Headless Screw System and its cleared indications for use.

MySpine S2-Alar/Alar-Iliac and MySpine Anchor guides (hereinafter referred to as "MySpine guides") are intended to be used as anatomical perforating guides, specific to a patient's anatomy, to assist intraoperatively in the preparation of the screw trajectory in S1, S2 and in the Ilium. The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment.

The MySpine guides are intended for single use only. Please see MySpine guides labelling for compatibility requirements between the MySpine guides and the 510(k) cleared posterior fixation screw system intended to be used.

1.2 COMPATIBILITY REQUIREMENTS/ INFORMATION

Please see the following compatibility requirements between the MySpine guides and the 510(k) cleared posterior fixation screw system intended to be used:

- Refer to the labeling of the posterior fixation screw system to be used for information such as contraindications, warnings, precautions, and instructions for use.
- The surgical planning software provides indications about the M.U.S.T. Pedicle Screw System. If different posterior fixation screw system is used, it is the surgeon's responsibility to verify the corresponding implant size (diameter and length) and its compatibility.
- The selected diameter of the MySpine drill-based guide represents the nominal value of the corresponding drill bit to be used during the surgery; it is the surgeon's responsibility to verify the corresponding drill diameter and its compatibility.

1.3 CONTRAINDICATIONS

Contraindications in using the MySpine instrumentation are the same as contraindications for spinal fusion with pedicle and/or sacro-iliac screw. 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.

1.4 PREOPERATIVE PLANNING

The preoperative 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 patient-matched MySpine guides.

1.

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 modeling.

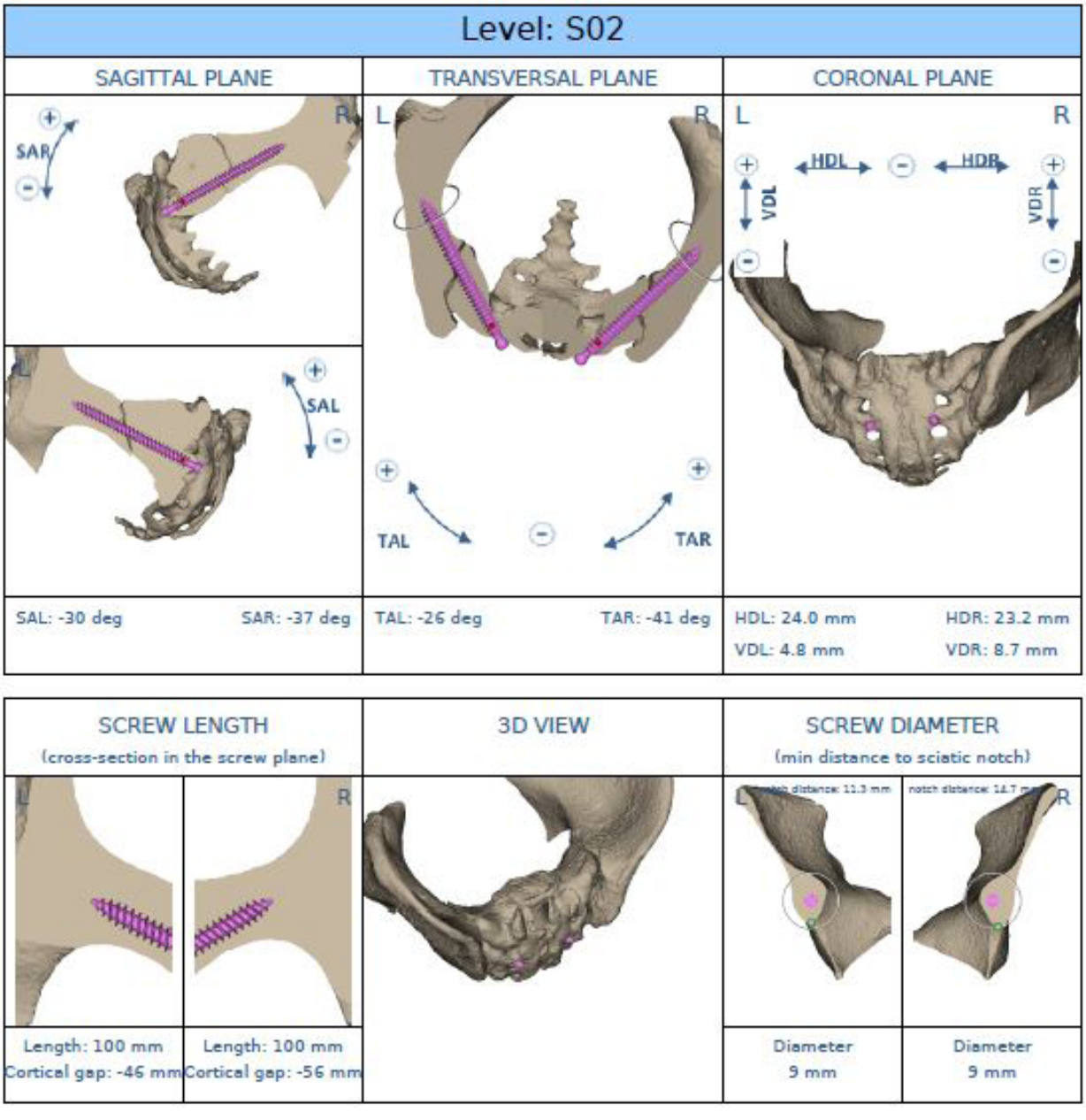
NOTE: Before using MySpine procedures, every Surgeon/ Radiological Centre must contact Medacta International.

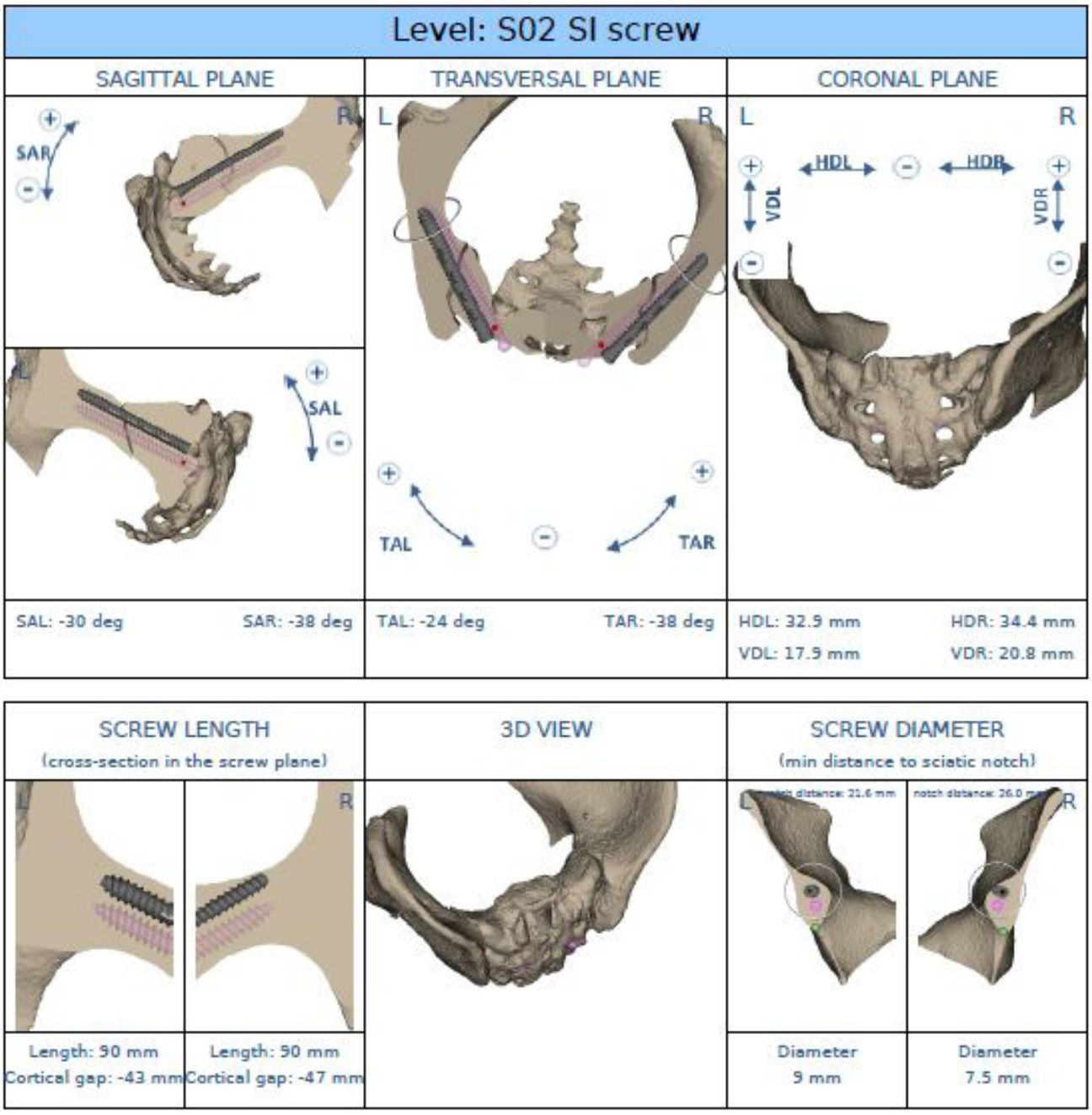
CAUTION

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/her 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 devices, it is the healthcare institution's responsibility to clean and sterilize them before use, following the appropriate instructions.





WARNING

The surgical planning software provides indications about the M.U.S.T. pedicle and M.U.S.T. SI screw system placement. If different pedicle system is used, it is the surgeon's responsibility to verify the corresponding implant size (diameter and length) and its compatibility.

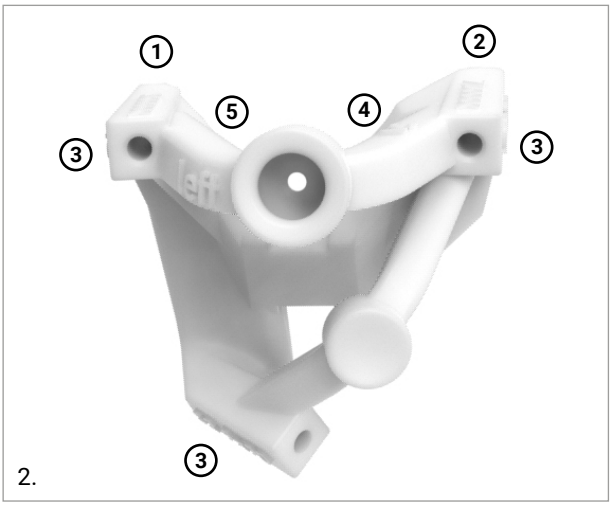
WARNING

The surgeon should confirm that the CT imaging accurately represents the patient's anatomy at the time of surgery, and should not use the MySpine guides if significant changes to the patient's anatomy have occurred since the acquisition of the CT images. The expiration date is set at 6 months post CT scan for skeletally mature patients and 3 months post CT scan for skeletally immature patients.

1.5 MYSPINE S2-ALAR/ALAR-ILIAC AND S2-ALAR/ALAR-ILIAC UNILATERAL DEVICES PRODUCT SPECIFICATION

The MySpine S2AI and S2AI Unilateral guides display the following information:

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



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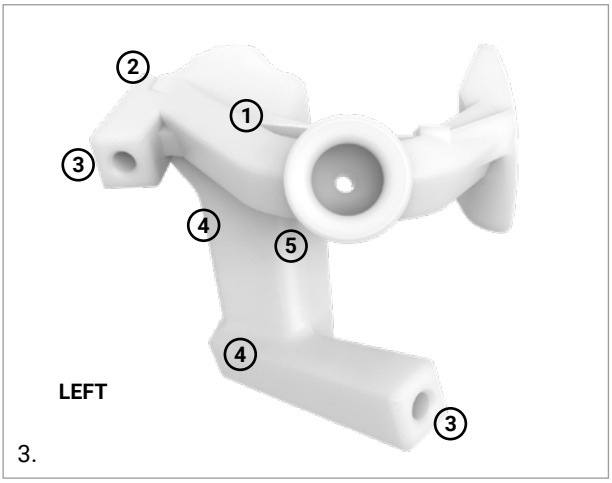

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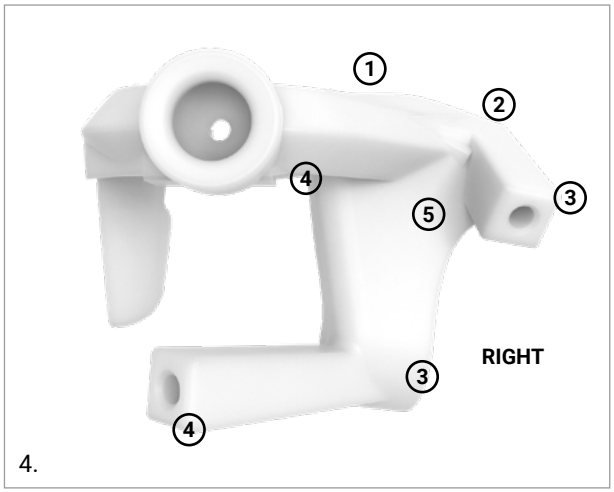


4.

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 S2AI guides are composed as follows:

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

B) Two lateral tapered rectangular guides (left and right) with distal pins, aimed to perfectly match the vertebral anatomical sites on S1.

C) One caudal tapered rectangular guides with distal pin, aimed to perfectly match the vertebral anatomical sites on S2.

5.

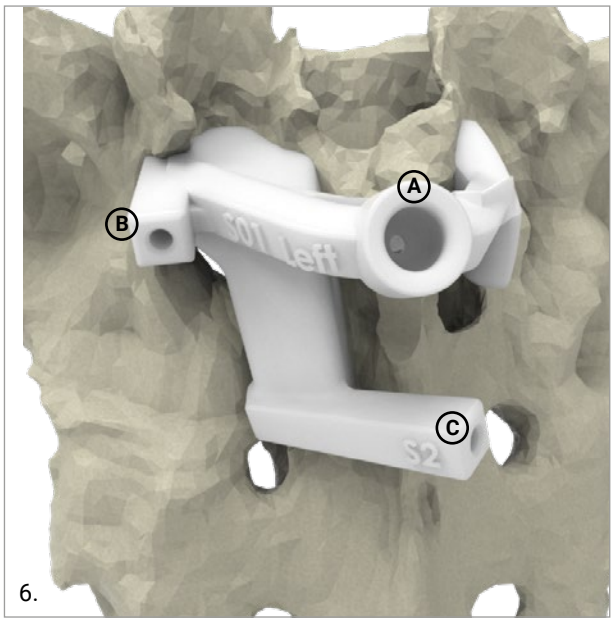
The rectangular guides support the insertion of the instruments for the screw implantation.

The MySpine Unilateral guides (both left and right) are composed as follows:

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

B) One lateral tapered rectangular guide with distal pin, aimed to perfectly match the vertebral anatomical site on S1.

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



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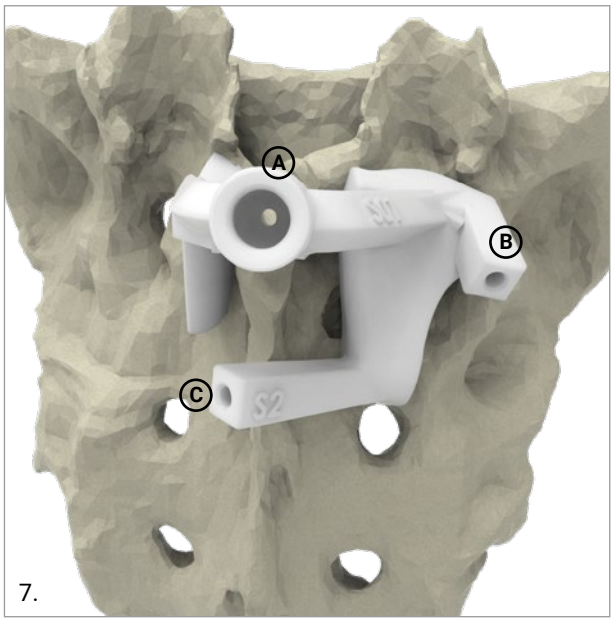


7.

The rectangular guides support the insertion of the instruments for the screw implantation.

1.6 CONFIGURATION OF THE MYSPINE S2-ALAR/ ALAR-ILIAC AND S2-ALAR/ALAR-ILIAC UNILATERAL DEVICES

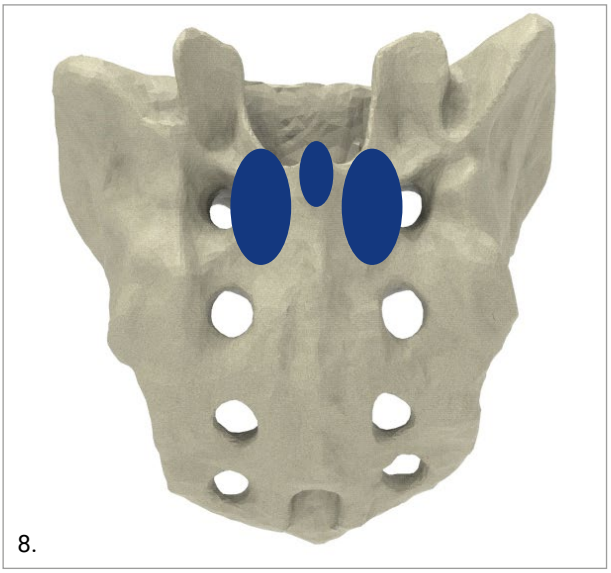
The MySpine guide profile, also in the Unilateral configuration, is specifically designed for treatment of the sacral spinal segments with the aim to provide maximum stability and optimal screw entry point.

MySpine S2-Alar/Alar-Iliac and S2-Alar/Alar-Iliac Unilateral guides are intended to perform the pilot holes to implant S1 and S2AI screws.

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

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

NOTE: The MySpine Unilateral guides have a small contact area also on the controlateral side.



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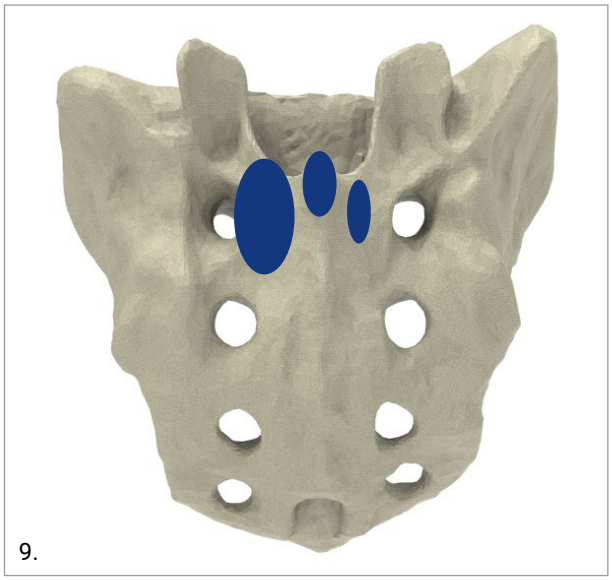

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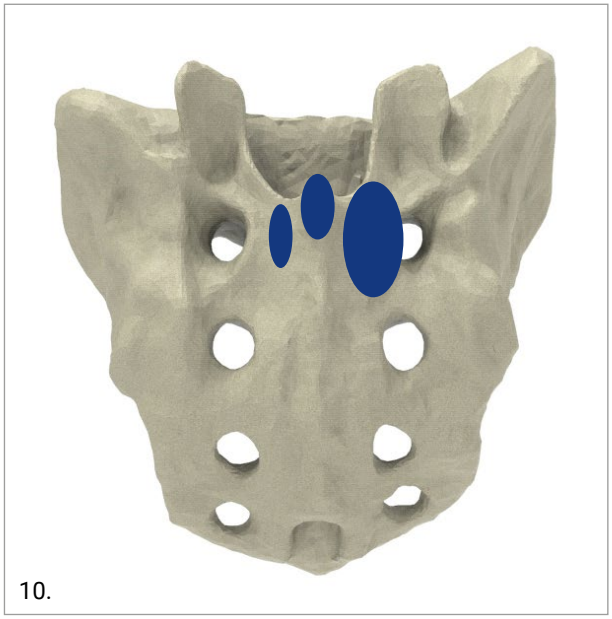

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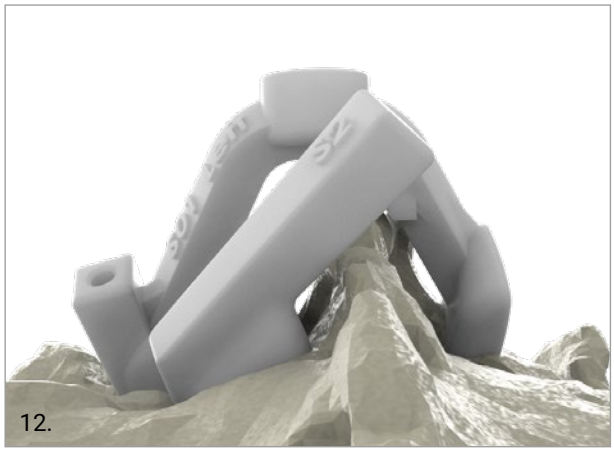
1.7 CONFIGURATION OF THE MYSPINE S2-ALAR/ ALAR-ILIAC AND S2-ALAR/ALAR-ILIAC UNILATERAL DEVICES

The MySpine S2AI and S2AI Unilateral guides are designed in left and right configuration to support the insertion of the instruments for the screw implantation in S1 and S2 in two consequent steps.

11.



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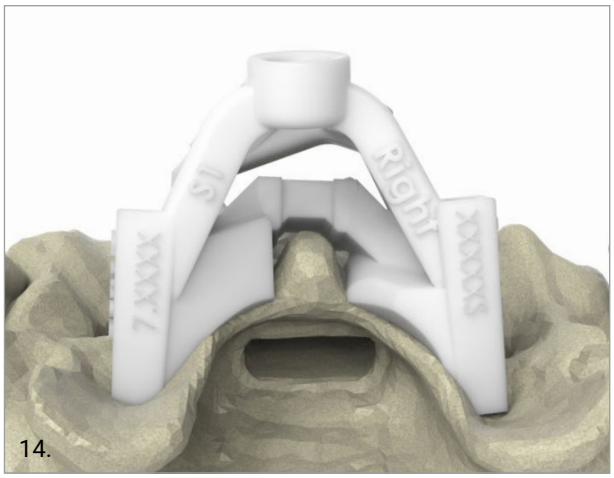
13.

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



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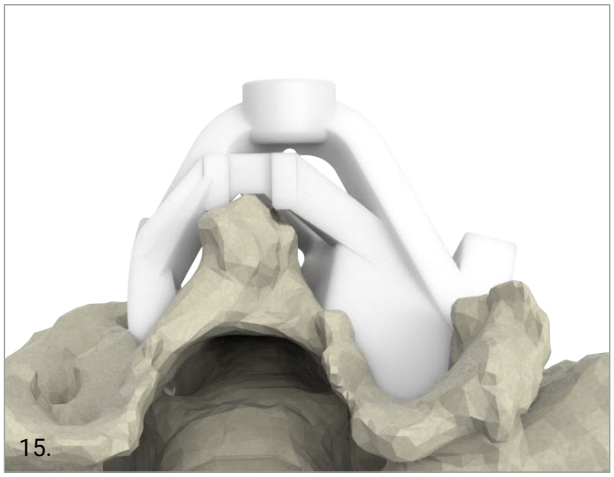
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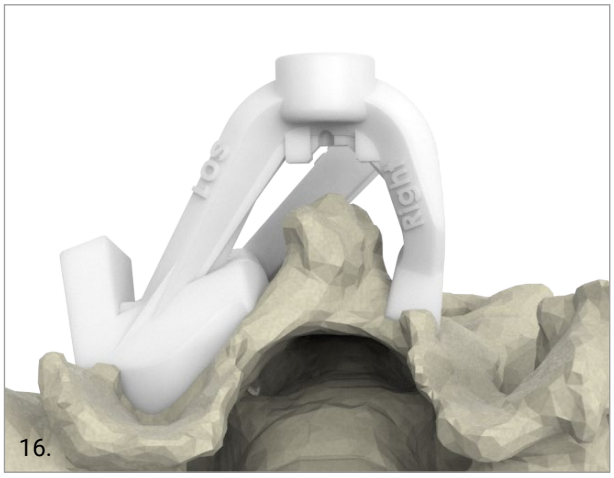

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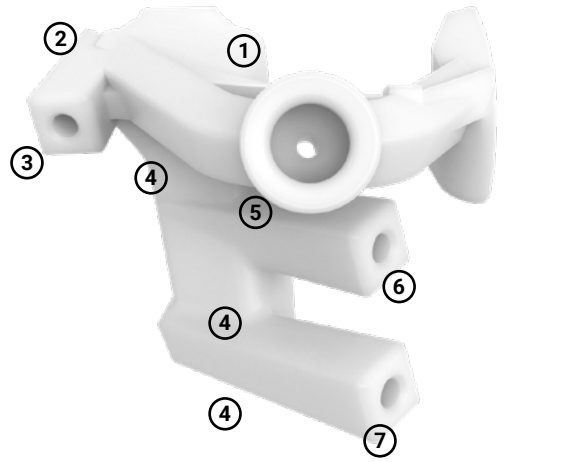
1.8 MYSPINE ANCHOR AND ANCHOR UNILATERAL DEVICES PRODUCT SPECIFICATION

The MySpine guides display the following information:

1. Reference number
2. Lot number
3. S1 implants size (left and right)
4. Vertebral level
5. Side
6. SI implant size (left or right)
7. S2 implant size (left or right)

17.



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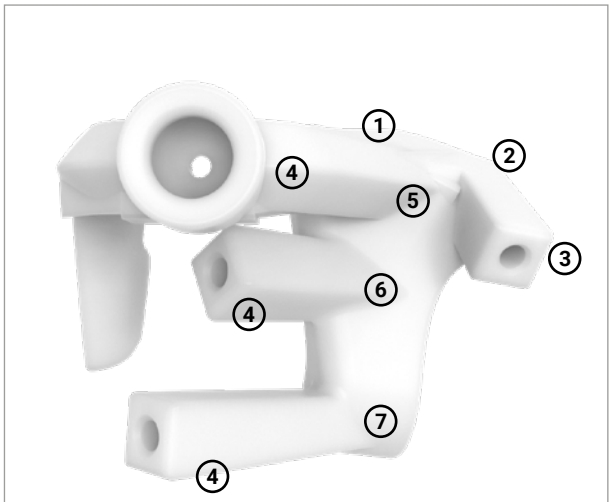


19.

CAUTION

Before starting the surgery, please check that the lot number indicated 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 immediately 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.

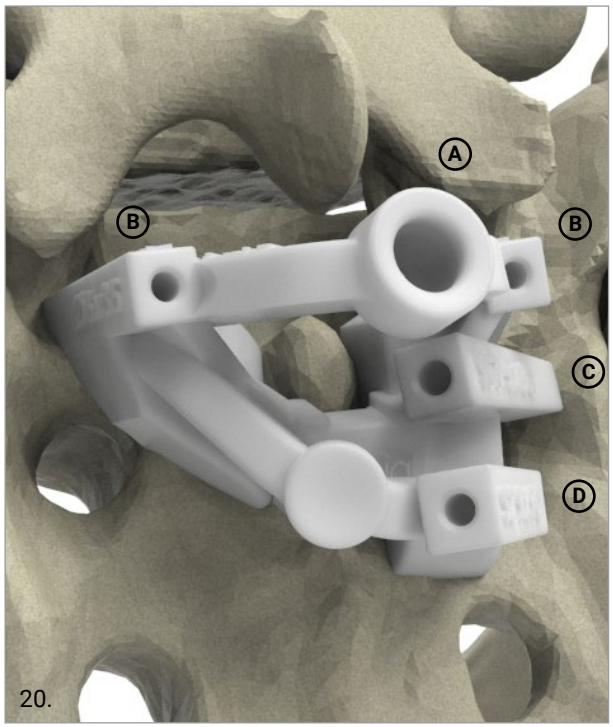
The MySpine guides are composed as follows:

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

B) Two lateral tapered rectangular guides (left and right) with distal pins, aimed to perfectly match the vertebral anatomical sites on S1.

C) One caudal tapered rectangular guide with distal pin, aimed to perform a pilot for the SI screw.

D) One caudal tapered rectangular guide with distal pin, aimed to perform a pilot for the S2 screw.



20.

The rectangular guides support the insertion of the instruments for the screw implantation.

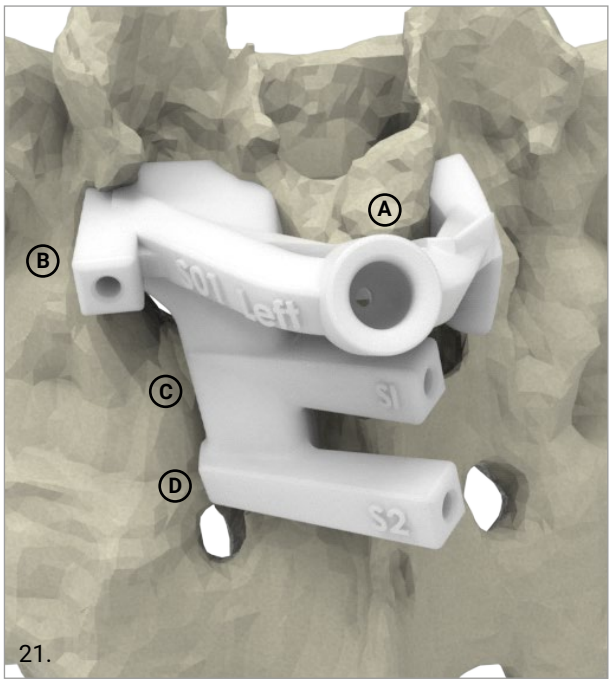
The MySpine Unilateral guides (both left and right) are composed as follows:

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

B) One lateral tapered rectangular guide with distal pin, aimed to perfectly match the vertebral anatomical site on S1.

C) One caudal tapered rectangular guide with distal pin, aimed to perform a pilot for the SI screw.

D) One caudal tapered rectangular guide with distal pin, aimed to perform a pilot for the S2 screw.



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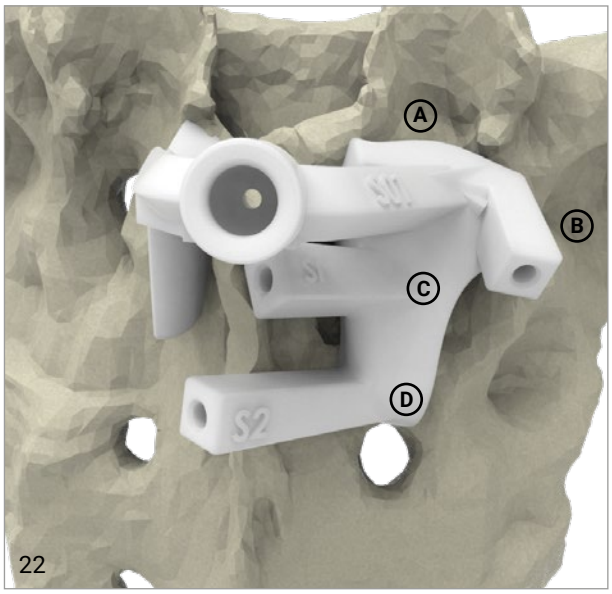


22

The rectangular guides support the insertion of the instruments for the screw implantation.

WARNING

The selected drill guide diameter represents the nominal value of the corresponding drill bit to be used during the surgery. It is the surgeon's responsibility to verify the corresponding drill diameter and its compatibility.

1.9 PROFILE OF THE MYSPINE ANCHOR AND ANCHOR UNILATERAL DEVICES

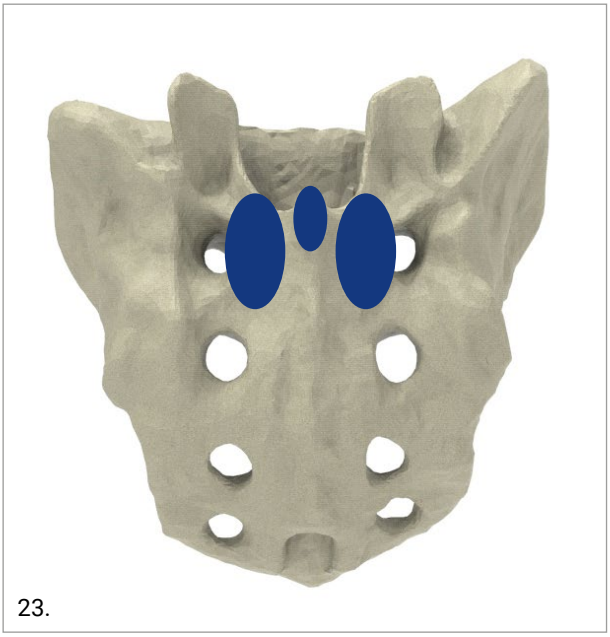
The MySpine guide profile, also in the Unilateral configuration, is specifically designed for treatment of the sacral spinal segments, with the aim of providing maximum stability and optimal screw entry point.

The MySpine Anchor and Anchor Unilateral guides are intent to perform the pilot holes to implant S1, S2AI and SI screws.

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

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

NOTE: The MySpine Unilateral guides have small contact area also on the controlateral side.



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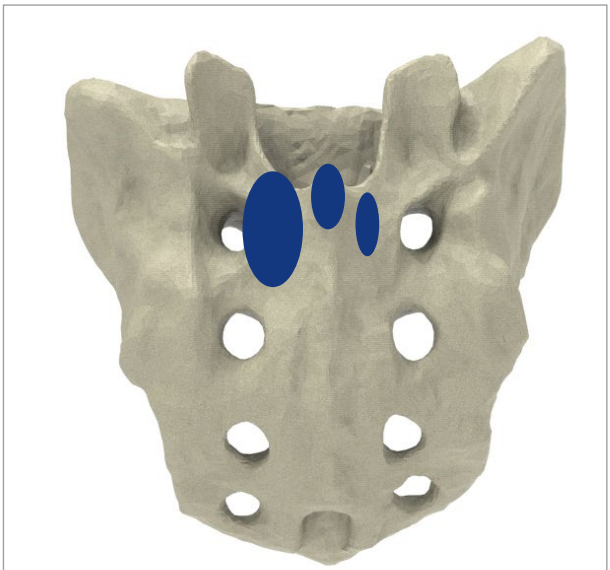

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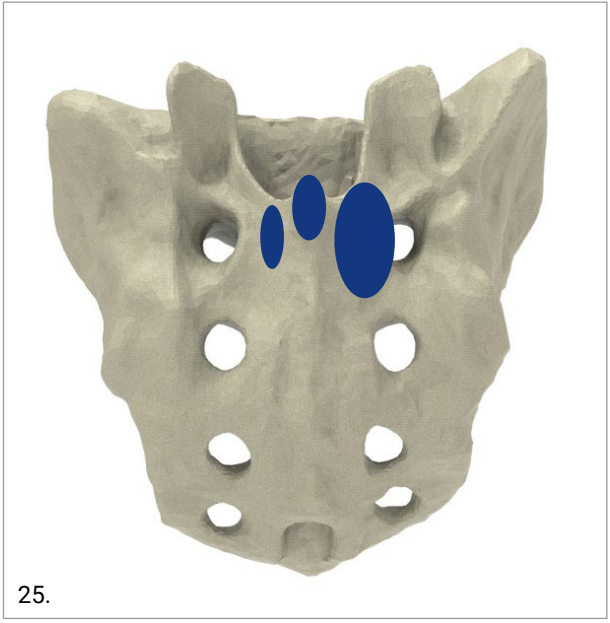

25.

1.10 PROFILE OF THE MYSPINE ANCHOR AND ANCHOR UNILATERAL

The MySpine guide is designed in left and right configuration to support the insertion of the instruments for the screws implantation in S2 and the sacro-iliac joint.

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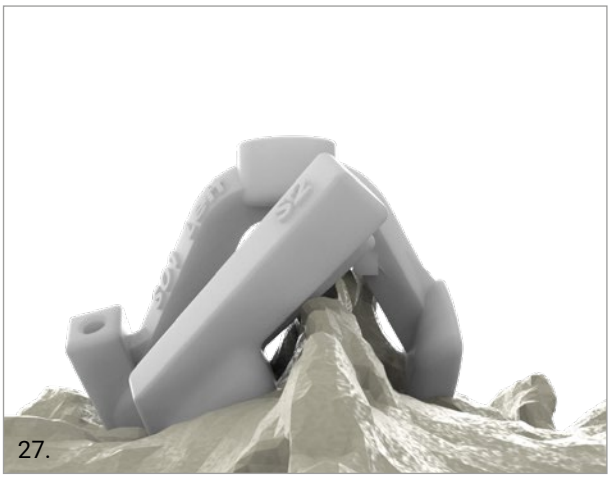
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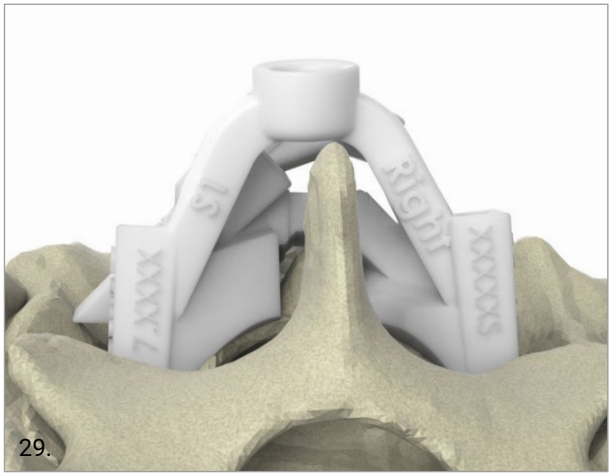
28.

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



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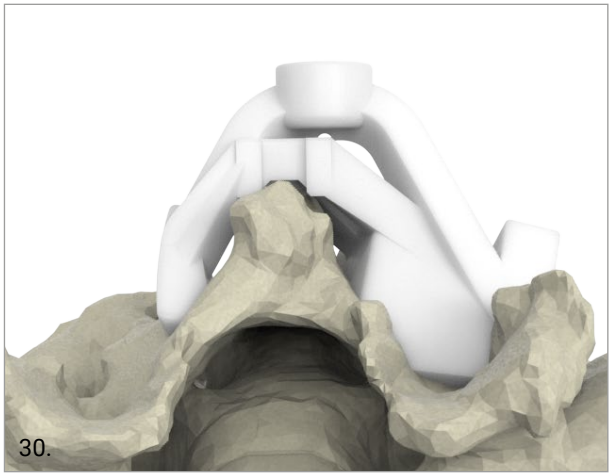
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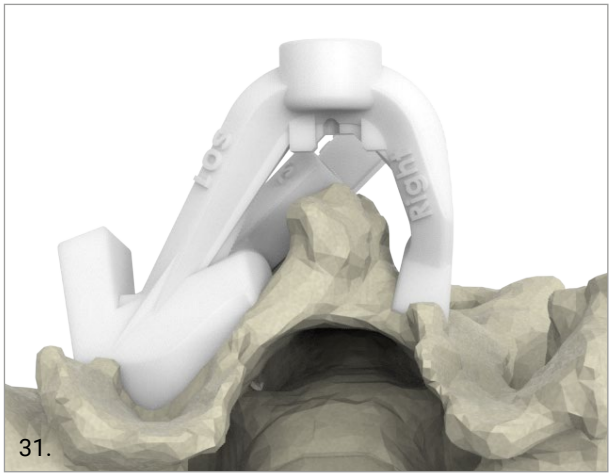


31.

2. SURGICAL APPROACH

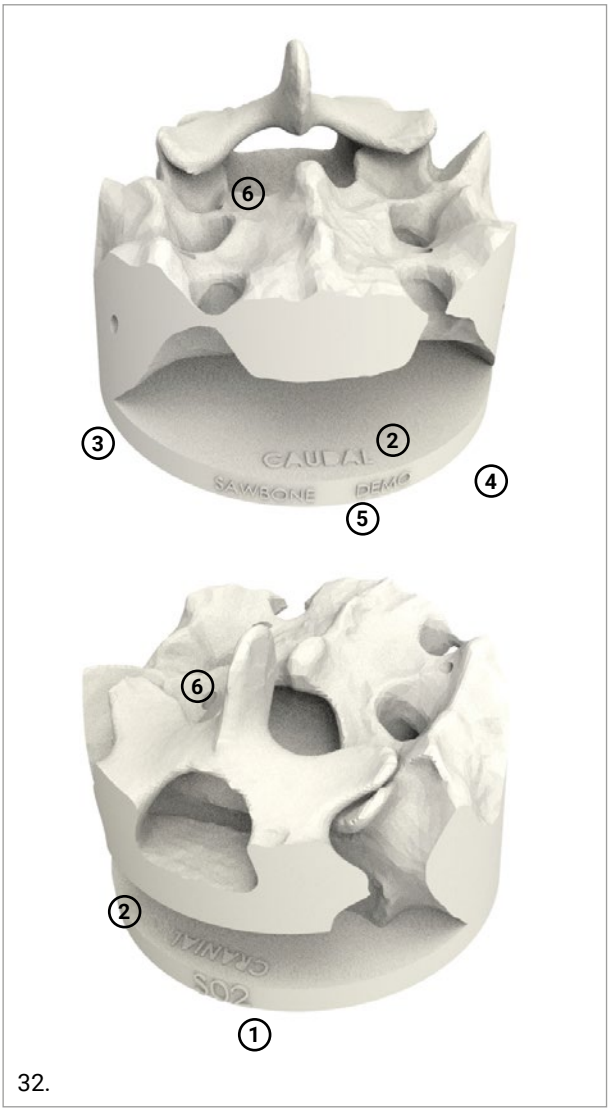
The MySpine guides are meant to guide the implantation of pedicle and sacro-iliac screws via a posterior approach. The selection of a different surgical approach is at the discretion of the surgeon.

3. BEFORE STARTING THE PROCEDURE - S2AI AND S2AI UNILATERAL

3.1 CHECK OF THE POSITIONING

The MySpine S2AI and S2AI Unilateral guides are designed to specifically match the vertebral anatomy of the patient, thus allowing for 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.

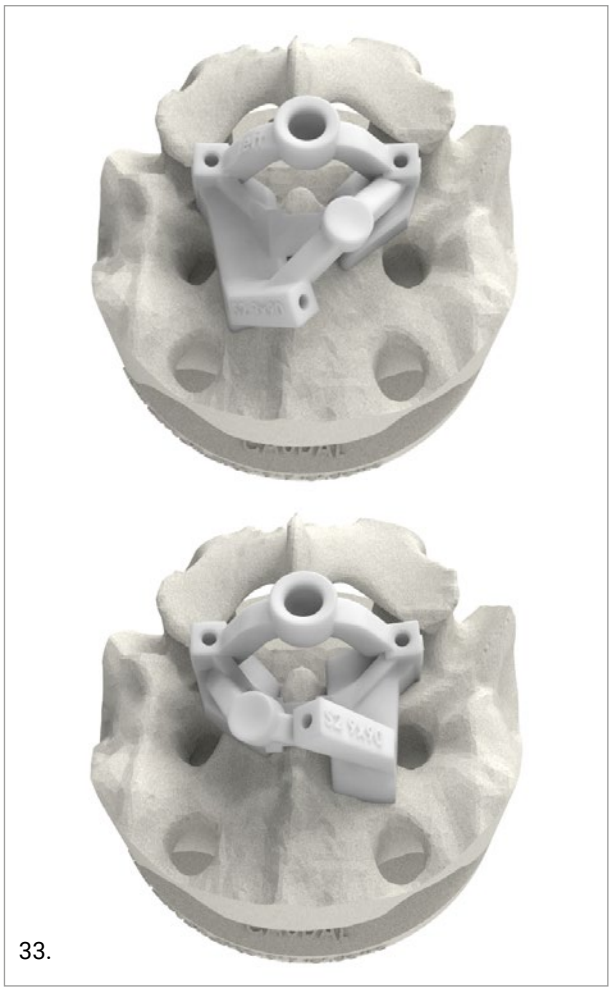


32.

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).



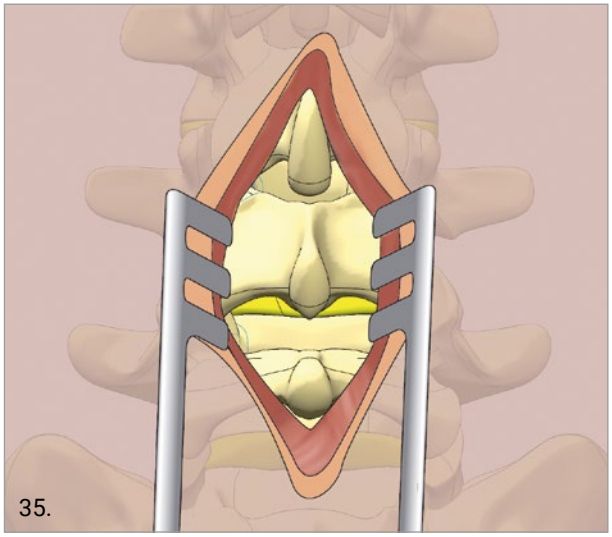
33.

34.

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

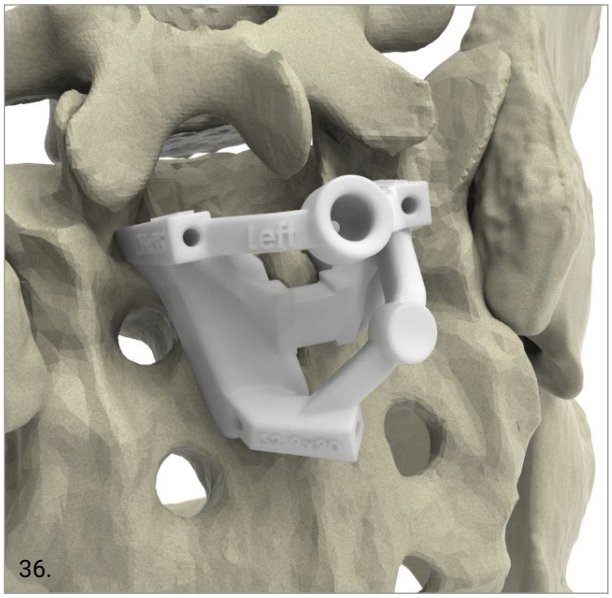
Perform a skin incision and dissect laterally from the midline by locating the screw entry points of the corresponding levels.



35.

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

Place the MySpine S2AI and S2AI Unilateral guides on the corresponding vertebra and check the contact surface.



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38.

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 for optimal screw insertion, verify that the contact between the MySpine guides and the anatomical sites on the vertebra are respected.

Once the MySpine guides, also in Unilateral configurations, are optimally placed, the screw entry points are consequently set as per the preoperative 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.

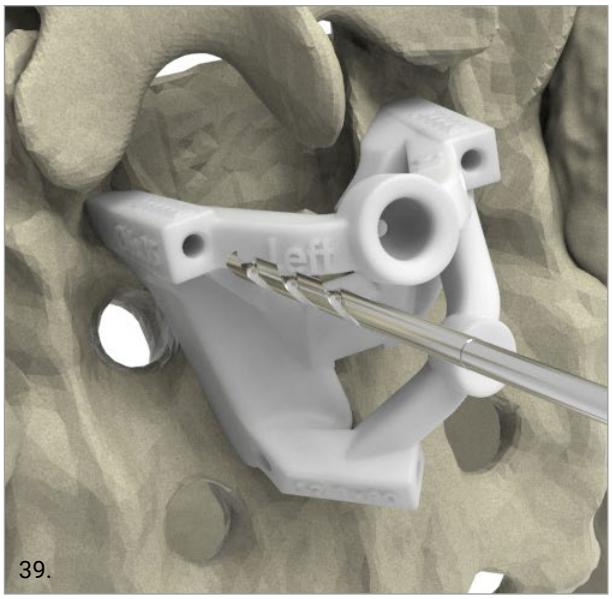
3.3 PEDICLE PREPARATION FOR S2AI

With the MySpine S2AI guide attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position.

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

Drill a pilot hole through the S2AI 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.


39.

CAUTION
For safety, use the instrument with the S1 mechanical stop according to the planned screw length. If the screws are shorter than the minimum depth reachable with the stopper sleeves, the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

CAUTION
Apply pressure to the guide to prevent it from slipping.

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

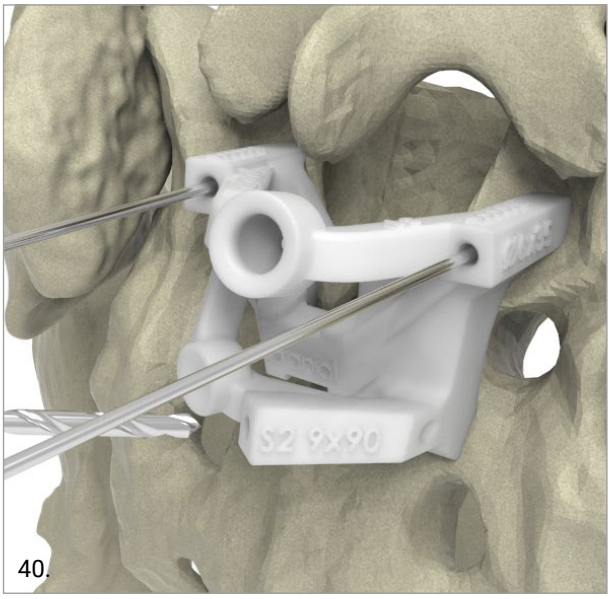
NOTE: It is mandatory to use fluoroscopy to ensure that the drill tip is inserted into the correct entry point through the guide.

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 the 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.



40.

Slide away the guide leaving the K-wire in the 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 S2AI guide configuration (left/right) and insert the 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 (inline and undersized taps are included in the Medacta instruments set). Medacta recommends to tap the pilot hole before screw insertion.

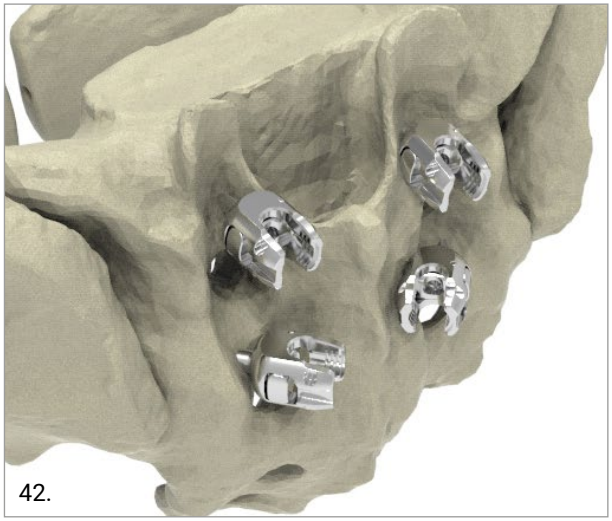
POLYAXIAL SCREW PREPARATION

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


41.

POLYAXIAL SCREW PLACEMENTS

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


42.

WARNING

Before inserting screws larger than 7mm in 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.

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

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the pedicle screw system Surgical Technique.

Following satisfactory fixation of the 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 guides must be used on the patient for whom the preoperative planning was planned for.

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

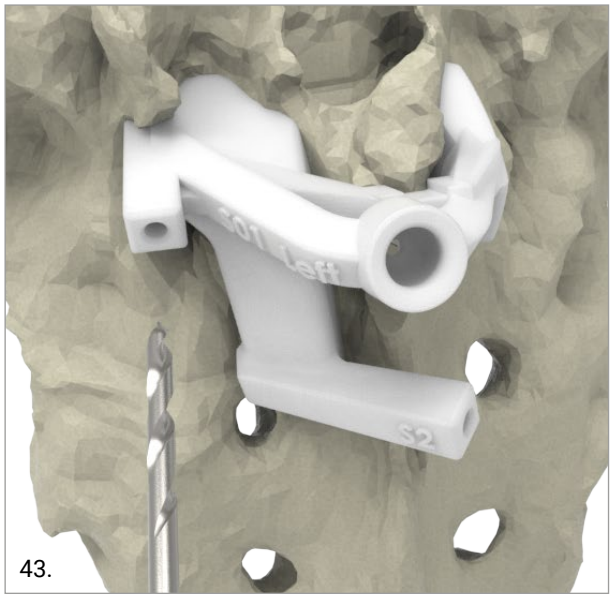
3.4 PEDICLE PREPARATION FOR S2AI UNILATERAL

With the MySpine Unilateral guide attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position.

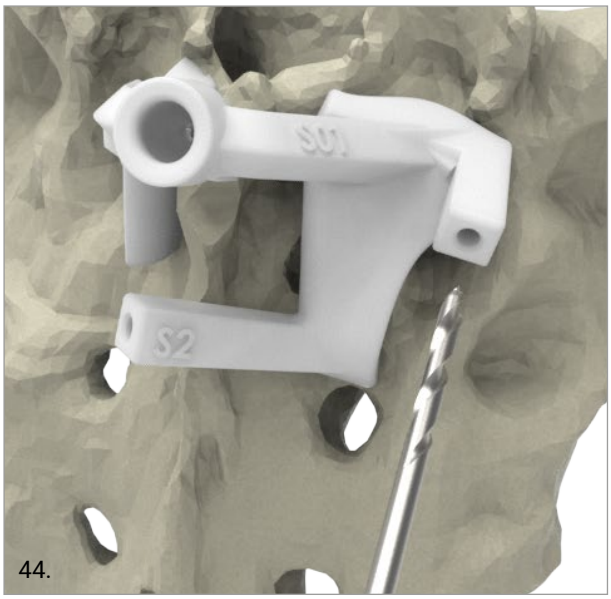
It is at the surgeon's discretion to start the surgery either with the left or the right guide configuration.

Drill a pilot hole through the S2AI Unilateral guide tube in the S1 pedicle (left/right) using the proper drill diameter.

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



43.



44.

CAUTION
For safety, use the instrument with the S1 mechanical stop according to the planned screw length. If the screws are shorter than the minimum depth reachable with the stopper sleeves, the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

CAUTION
Apply pressure to the guide to prevent it from slipping.

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

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

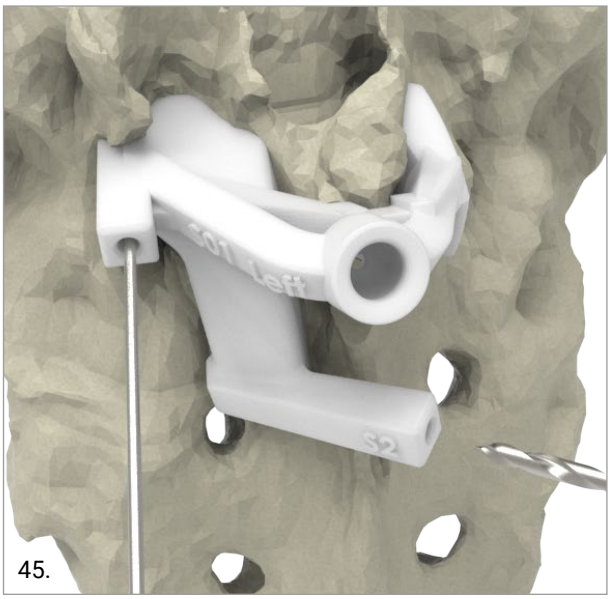
NOTE: Fluoroscope control is recommended during the perforation.

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

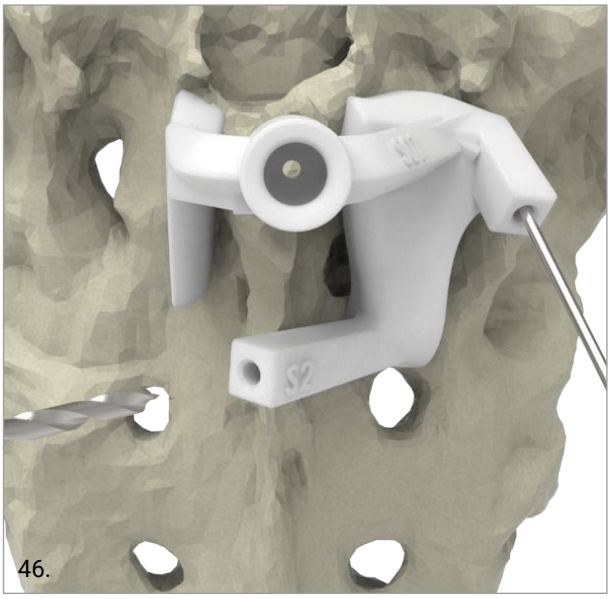
Drill a pilot hole through the caudal left/right guide tube in S2 pedicle using the proper drill diameter.

Repeat the drilling of the pilot holes in the contralateral S1 and S2 pedicles using the other guide configuration (left/right).

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



45.



46.

Before screw insertion, tap the pilot holes using the cannulated tap with the corresponding diameter (inline and undersized taps are included in the Medacta instruments set). Medacta recommends to tap the pilot hole before screw insertion. The screw placement must be the final step.

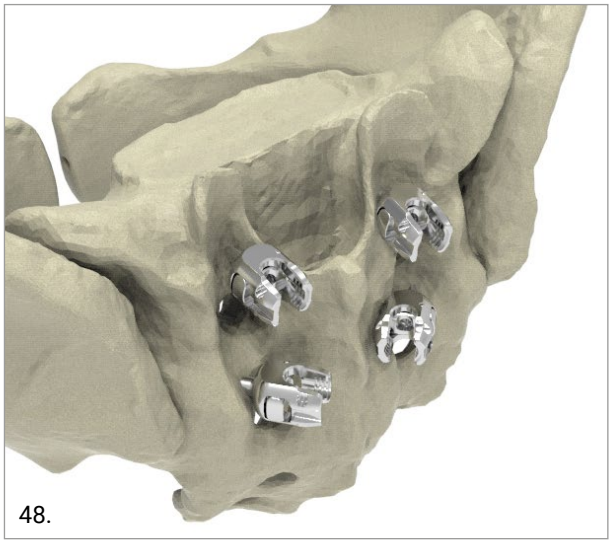
POLYAXIAL SCREW PREPARATION

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


47.

POLYAXIAL SCREW PLACEMENTS

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


48.

WARNING

Before inserting screws larger than 7mm in diameter, it is mandatory to tap the pedicles. In the 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.

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

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the pedicle screw system Surgical Technique.

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

NOTE: Remove the K-wires when used.

IMPORTANT
The MySpine Unilateral guides must be used on the patient for whom the preoperative planning was planned for.

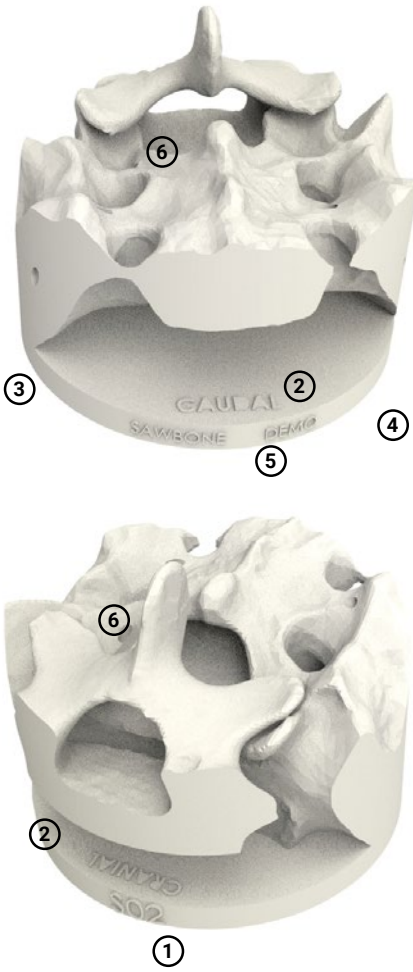
NOTE: Wash the surgical field with normal saline or water after MySpine Unilateral guide usage.

4. BEFORE STARTING THE PROCEDURE - ANCHOR AND ANCHOR UNILATERAL

4.1 CHECK OF THE POSITIONING

The MySpine Anchor and Anchor Unilateral guides are made to specifically match the vertebral anatomy of the patient, thus allowing for 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.

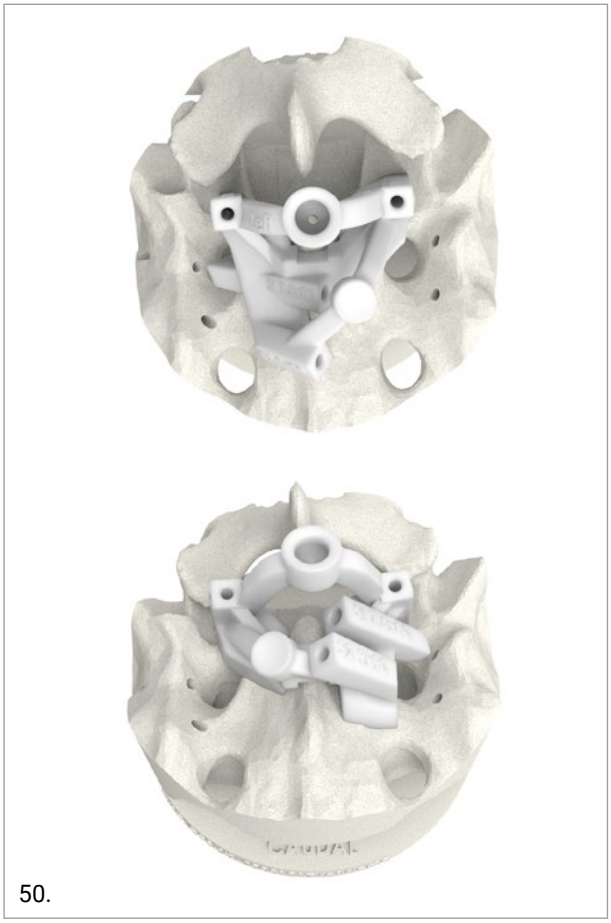


49.

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).

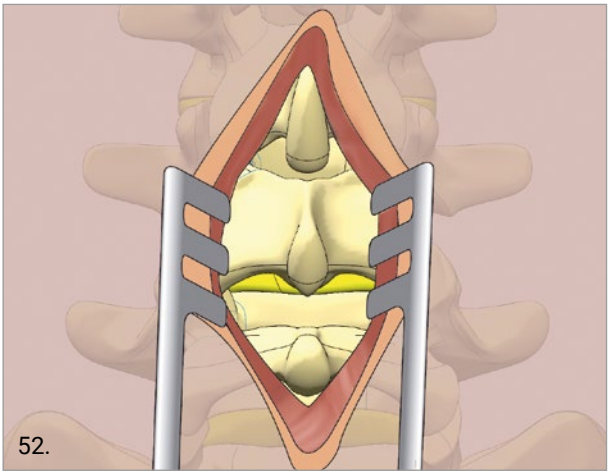

50.

51.

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.

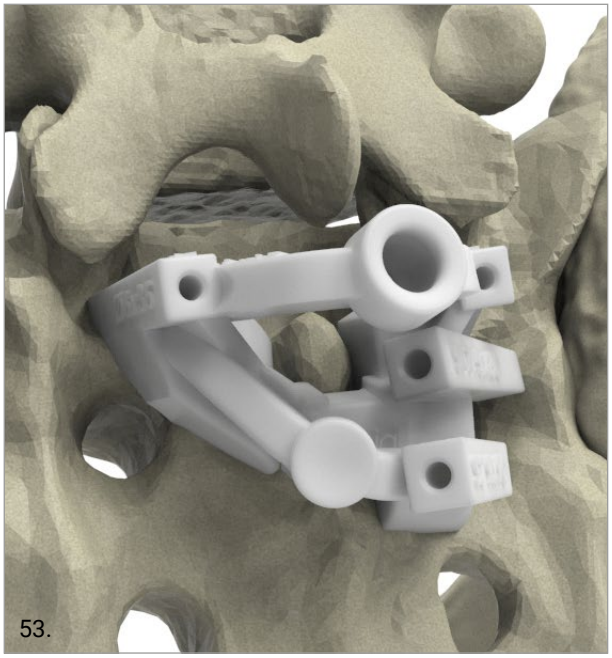
4.2 SPINE EXPOSURE AND PREPARATION

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



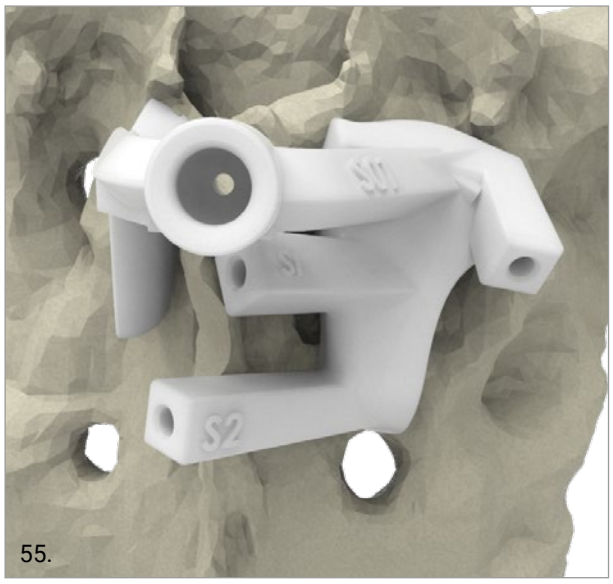
52.

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.

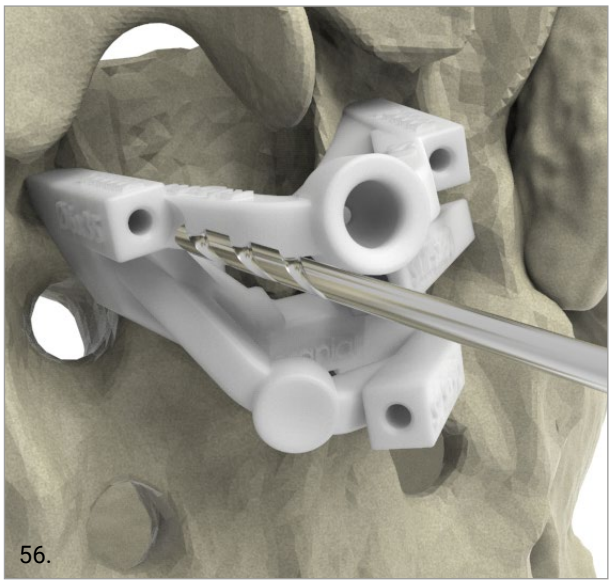


53.

54.



55.


56.

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 for optimal screw insertion, verify that the contact between the MySpine guides and the anatomical sites on the vertebra are respected.

Once the MySpine guides, also in Unilateral configurations, are optimally placed, the screw entry points are consequently set as per the preoperative 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.

4.3 PEDICLE PREPARATION FOR ANCHOR

With the MySpine guide attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. It is at the 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 the left and right S1 pedicles using the proper drill diameter.

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

CAUTION
For safety, use the instrument with the S1 mechanical stop according to the planned screw length. If the screws are shorter than the minimum depth reachable with the stopper sleeves, the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

CAUTION
Apply pressure to the guide to prevent it from slipping.

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

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.

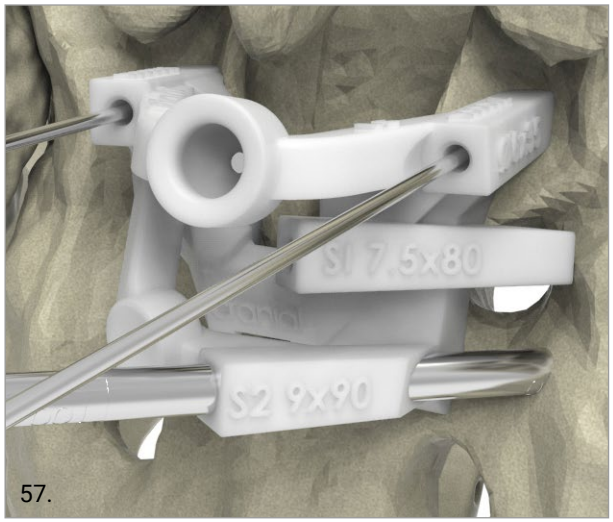
Drill a pilot hole through the S2AI guide tube using the proper drill diameter. Next, drill a pilot hole through the SI guide tube using the proper drill diameter. The position of the S2AI and SI screws can be inverted according to the Surgeon's preferences.

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

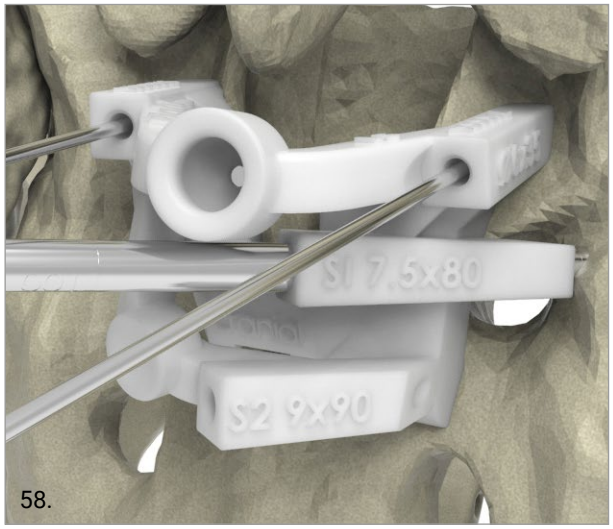
Following satisfactory pilot hole drilling, insert the blunt K-wires through the S2AI and SI holes for a better guide stability during the next surgical steps.

NOTE: Do not remove the K-wires during the preparation of the S2AI and SI pilot holes.

WARNING
Bleeding may occur after the pilot hole drilling phase. Pay attention to the possible interference between the guide and soft tissues while sliding away the guide leaving the wires in place.



57.



58.

Before S2AI screw insertion, tap the pilot hole using the cannulated tap, choosing its diameter according to the planned screws.

Insert the S2AI screw into the prepared pilot hole.

Before SI screw insertion, tap the pilot holes using the cannulated tap, choosing its diameter according to the planned screws. For the SI tapping, both M.U.S.T. and M.U.S.T. SI taps are compatible. It is recommended to tap firstly with 6mm diameter tap and then to use the in-line or undersized 0.5mm tap to enlarge the SI pilot hole. It is mandatory to tap the pilot hole before screw insertion.

Insert the SI screw into the prepared pilot hole.

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

NOTE: Do not drill again the S1 pilot holes while the second guide configuration (left/right) is in place.

WARNING
During the planning and guide design phases, the interference between the guide and the implanted screws is checked. While docking the contralateral guide, make sure that there is no interference with the implanted screws.

Insert S2AI and SI screws into the prepared pilot holes. Tap and insert the S1 screws.

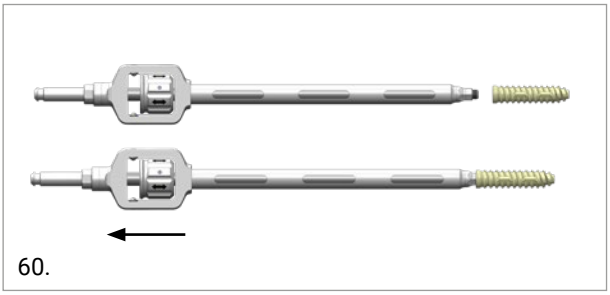
POLYAXIAL SCREW PREPARATION
Prepare the Polyaxial Pedicle Screwdriver and attach the screw to it.


59.

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

NOTE: It is recommended to insert the S2AI before the sacro-iliac screw in order to firstly complete the engagement with the construct.

SACRO-ILIAC SCREW PREPARATION
Prepare the Sacro-Iliac Screwdriver and attach the sacroiliac screw to it.


60.

SACRO-ILIAC SCREW PLACEMENTS
Insert the sacro-iliac screw into the prepared pilot hole using the Sacro-Iliac Screwdriver. Either solid or cannulated screws can be used.


61.

NOTE: Fluoroscope control is recommended during insertion of the pedicle screws and sacro-iliac screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the pedicle screw or sacro-iliac system Surgical Technique.

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

NOTE: Remove the K-wires when used.

WARNING
Before inserting screws larger than 7mm in diameter, it is mandatory to tap the pedicles. In the 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. In the case of osteoporotic bone, the tapping and insertion of SI and S2AI screws must be performed carefully and under fluoroscopic control.

IMPORTANT
The MySpine guides must be used on the patient for whom the preoperative planning was planned for.

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

4.4 PEDICLE PREPARATION FOR ANCHOR UNILATERAL

With the MySpine Anchor Unilateral guide attached to the corresponding vertebra, firmly press the guide onto the lamina to secure the position. It is at the surgeon's discretion to start the surgery either with the left or the right guide configuration. Drill a pilot hole through the Anchor Unilateral guide tube in S1 pedicle (left/right) using the proper drill diameter.

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


62.

63.

CAUTION
For safety, use the instrument with the S1 mechanical stop according to the planned screw length. If the screws are shorter than the minimum depth reachable with the stopper sleeves, the surgeon must evaluate the perforation with fluoroscopy control to reach the proper depth.

CAUTION
Apply pressure to the guide to prevent it from slipping.

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

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 for possible violation.

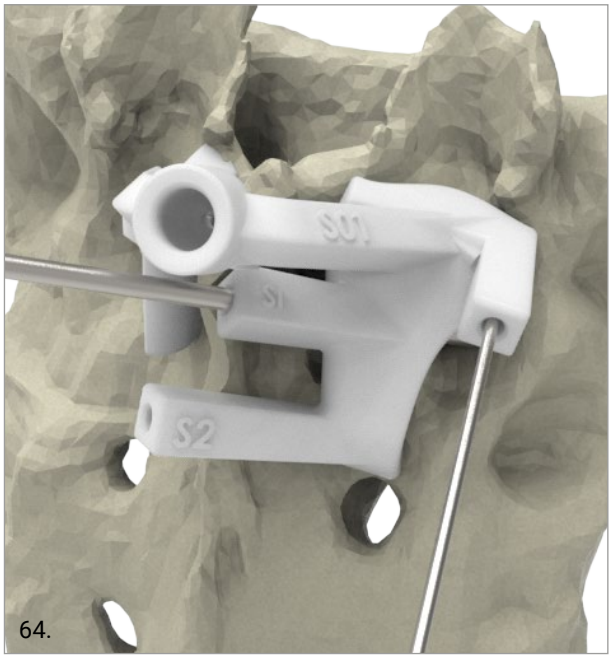
Drill a pilot hole through the S2AI guide tube using the proper drill diameter. Next drill a pilot hole through the SI guide tube using the proper drill diameter. The position of the S2AI and SI screws can be inverted according to the Surgeon's preferences.

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

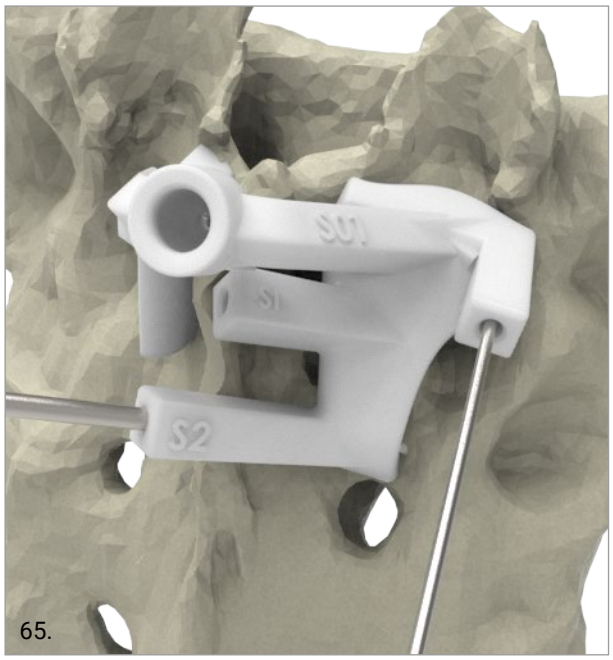
Following satisfactory pilot hole drilling, insert the blunt K-wires through the S2AI and SI holes for a better guide stability during the next surgical steps.

NOTE: Do not remove the K-wires during the preparation of the S2AI and SI pilot holes.

WARNING
Bleeding may occur after the pilot hole drilling phase. Pay attention to the possible interference between the guide and soft tissues while sliding away the guide leaving the wires in place.



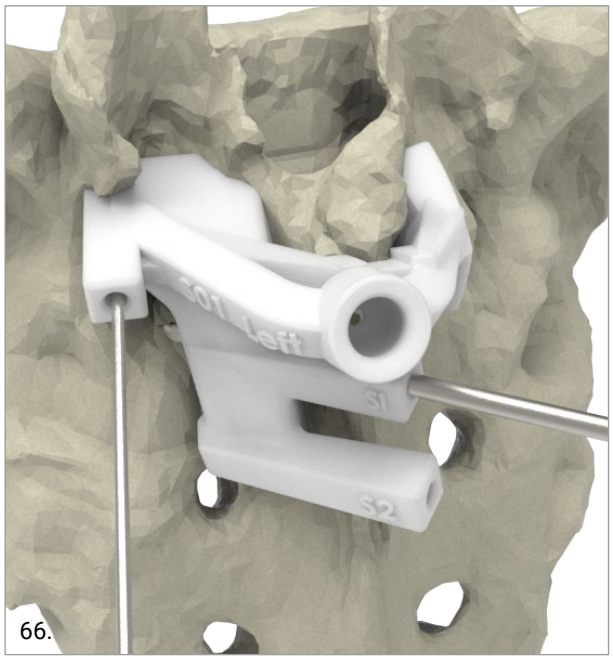
64.



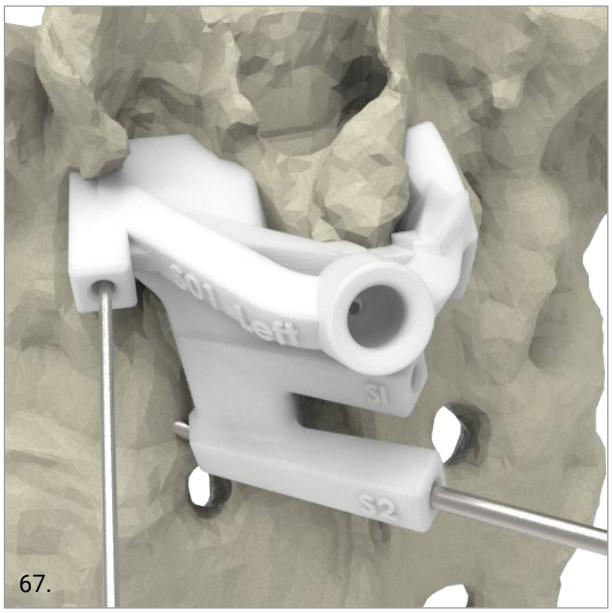
65.

Before S2AI screw insertion, tap the pilot hole using the cannulated tap, choosing its diameter according to the planned screws.

Insert the S2AI screw into the prepared pilot hole.



66.



67.

Before SI screw insertion, tap the pilot holes using the cannulated tap, choosing its diameter according to the planned screws. For the SI tapping, both M.U.S.T. and M.U.S.T. SI taps are compatible. It is recommended to tap firstly with 6mm diameter tap and then to use the in-line or undersized 0.5mm tap to enlarge the SI pilot hole. It is mandatory to tap the pilot hole before screw insertion.

Insert the SI screw into the prepared pilot hole.

Repeat the drilling of the pilot holes to the contralateral S1, S2 and SI guide tubes using the other guide configuration (left/right). After removal of the guide, the K-wire can be inserted as a guide for the following tapping and screw insertion process.

WARNING

During the planning and guide design phases, the interference between the guide and the implanted screws is checked. While docking the contralateral guide, make sure that there is no interference with the implanted screws.

Insert S2AI and SI screws into the prepared pilot holes. Tap and insert S1 screws.

POLYAXIAL SCREW PREPARATION
Prepare the Polyaxial Pedicle Screwdriver and attach the pedicle screw to it.

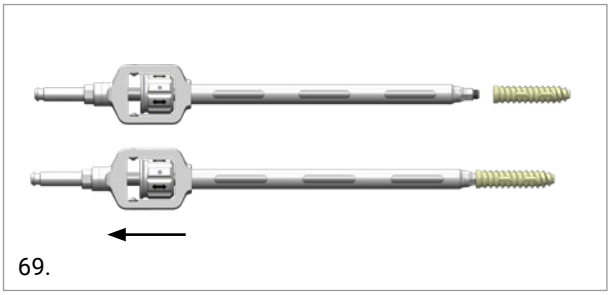
68.

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

NOTE: It is recommended to insert the S2AI before the sacro-iliac screw in order to first complete the engagement with the construct.

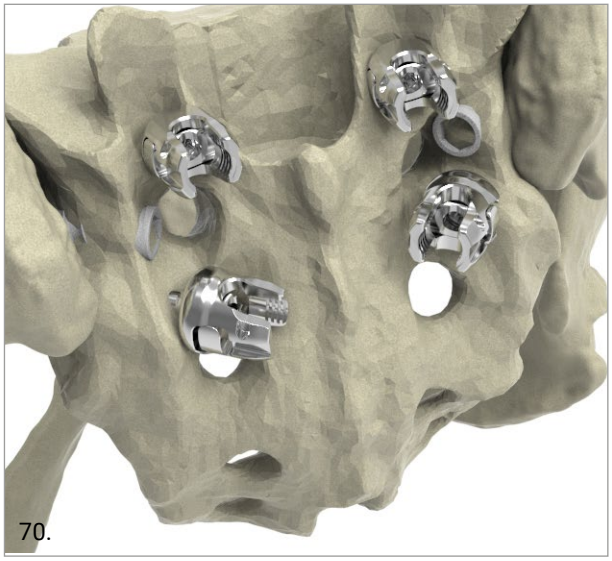
SACRO-ILIAC SCREW PREPARATION

Prepare the Sacro-Iliac Screwdriver and attach the sacro-iliac screw to it.



69.

SACRO-ILIAC SCREW PLACEMENTS
Insert the sacro-iliac screw into the prepared pilot hole using the Sacro-Iliac Screwdriver. Either solid or cannulated screws can be used.



70.

NOTE: Fluoroscope control is recommended during insertion of the pedicle screws and sacro-iliac screws.

NOTE: For the correct manipulation of the screwdriver and screw fixation, follow the same procedure as described in the pedicle screw or sacro-iliac system Surgical Technique.

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

NOTE: Remove the K-wires when after use.

WARNING
Before inserting screws larger than 7mm in diameter, it is mandatory to tap the pedicles. In the 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. In the case of osteoporotic bone, the tapping and insertion of SI and S2AI screws must be performed carefully and under fluoroscopic control.

IMPORTANT
The MySpine Unilateral guides must be used on the patient for whom the preoperative planning was planned for.

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

5. 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

6. 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

7. ROD BENDING IN SITU

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

8. SET SCREW TIGHTENING

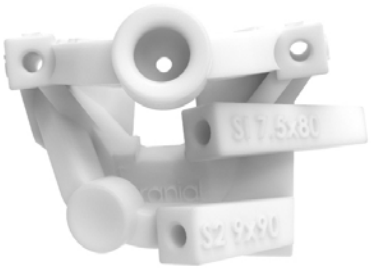
Please follow the same procedure previously described in the dedicated surgical technique of the Medacta M.U.S.T. posterior screw system

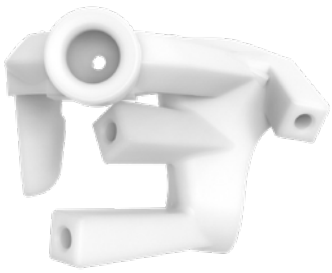
9. MYSPINE ARTICLE REFERENCES

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
MySpine vertebra S2-SI		7.0730S	7.0730

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

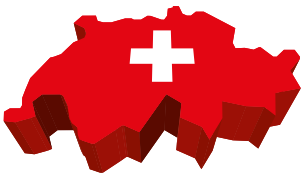
DESCRIPTION	PICTURE	STERILE REF.	UNSTERILE REF.
MySpine S02 left guide		7.0727S	7.0727
MySpine S02 right guide		7.0728S	7.0728
MySpine S2-SI left guide		7.0731S	7.0731
MySpine S2-SI right guide		7.0732S	7.0732

DESCRIPTION	PICTURE	STERILE REF.	UNSTERILE REF.
MySpine Unilateral left guide S02		7.1028S	7.1028
MySpine Unilateral right guide S02		7.1058S	7.1058
MySpine Unilateral left guide S2-SI		7.1029S	7.1029
MySpine Unilateral right guide S2-SI		7.1059S	7.1059

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave, respecting the US regulations and directives where applicable, and following the instructions for use of the autoclave's manufacturer. For detailed instructions, please refer to the document "Recommendations for cleaning, decontamination and sterilization of Medacta International orthopaedic devices" available at www.medacta.com.



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Strada Regina, 34 - 6874 Castel San Pietro - Switzerland
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info@medacta.ch

Find your local dealer at: medacta.com/locations

MySpine® S2-Alar/Alar-Iliac,
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