CURE LP

LUMBAR PLATE

CONTENT

AT A GLANCE

Tactile and Visual Locking Mechanism
Pre-Lordosed
Low Profile
Large Graft Viewing Window

INDICATIONS

The Cure™ Lumbar Plate (LP) System is used from L1 to S1, strictly anterior below the bifurcation (L5-S1), and anterior or anterolateral above the bifurcation (L1-L5) for:

- Degenerative intervertebral disc diseases,
- Spinal fractures (L1-S1),
- Spinal tumours (L1-S1),
- Pseudoarthrosis,
- Spondylolisthesis,
- Revisions after failed decompression surgery that have sufficient, biomechanically stable, ventral support.

CONTRAINDICATIONS

- Infection, local to the operative site.
- Morbid obesity and patients who are unwilling to restrict activities or follow medical advice.
- Pregnancy.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Severely damaged bone structures that could prevent stable implantation of the plate.
- Suspected or documented metal allergy.
- Any case not described in the indications.

Please refer to the Cure® LP Instructions for Use for complete device description, indications, contraindications, precautions and warnings.

IMPLANTS

PLATES

ANTERIOR LUMBAR PLATE		
ITEM SIZE	**STERILE PART #**	**NON-STERILE PART #**
33 MM	S1-9-00001-33	9-00001-33
35 MM	S1-9-00001-35	9-00001-35
37 MM	S1-9-00001-37	9-00001-37
39 MM	S1-9-00001-39	9-00001-39
• 41 MM	S1-9-00001-41	9-00001-41
• 43 MM	S1-9-00001-43	9-00001-43
• 45 MM	S1-9-00001-45	9-00001-45

SACRAL PLATE		
ITEM SIZE	**STERILE PART #**	**NON-STERILE PART #**
33 MM	S1-9-00051-33	9-00051-33
35 MM	S1-9-00051-35	9-00051-35
37 MM	S1-9-00051-37	9-00051-37
39 MM	S1-9-00051-39	9-00051-39
• 41 MM	S1-9-00051-41	9-00051-41
• 43 MM	S1-9-00051-43	9-00051-43
• 45 MM	S1-9-00051-45	9-00051-45

LATERAL LUMBAR PLATE		
ITEM SIZE	**STERILE PART #**	**NON-STERILE PART #**
27 MM	S1-9-00011-27	9-00011-27
29 MM	S1-9-00011-29	9-00011-29
31 MM	S1-9-00011-31	9-00011-31
33 MM	S1-9-00011-33	9-00011-33
35 MM	S1-9-00011-35	9-00011-35
37 MM	S1-9-00011-37	9-00011-37

SACRAL PLUS PLATE		
ITEM SIZE	**STERILE PART #**	**NON-STERILE PART #**
• 33 MM	S1-9-00061-33	9-00061-33
• 35 MM	S1-9-00061-35	9-00061-35
• 37 MM	S1-9-00061-37	9-00061-37
• 39 MM	S1-9-00061-39	9-00061-39
• 41 MM	S1-9-00061-41	9-00061-41

• Optional

IMPLANTS

VARIABLE SELF-TAPPING SCREWS

Ø 5.5MM LUMBAR VARIABLE SELF-TAPPING SCREWS

ITEM SIZE	STERILE PART #	NON-STERILE PART #
25 MM	S2-9-42355-25	9-42355-25
30 MM	S2-9-42355-30	9-42355-30
35 MM	S2-9-42355-35	9-42355-35
• 40 MM	S2-9-42355-40	9-42355-40
• 45 MM	S2-9-42355-45	9-42355-45
• 50 MM	S2-9-42355-50	9-42355-50
• 55 MM	S2-9-42355-55	9-42355-55
• 60 MM	S2-9-42355-60	9-42355-60

Ø 6.0 LUMBAR VARIABLE SELF-TAPPING SCREWS

ITEM SIZE	STERILE PART #	NON-STERILE PART #
25 MM	S2-9-42360-25	9-42360-25
30 MM	S2-9-42360-30	9-42360-30
35 MM	S2-9-42360-35	9-42360-35
• 40 MM	S2-9-42360-40	9-42360-40
• 45 MM	S2-9-42360-45	9-42360-45
• 50 MM	S2-9-42360-50	9-42360-50
• 55 MM	S2-9-42360-55	9-42360-55
• 60 MM	S2-9-42360-60	9-42360-60

FIXED SELF-TAPPING SCREWS

Ø 5.5MM LUMBAR FIXED SELF-TAPPING SCREWS

ITEM SIZE	STERILE PART #	NON-STERILE PART #
• 25 MM	S1-9-41355-25	9-41355-25
• 30 MM	S1-9-41355-30	9-41355-30
• 35 MM	S1-9-41355-35	9-41355-35

Ø 6.0 LUMBAR FIXED SELF-TAPPING SCREWS

ITEM SIZE	STERILE PART #	NON-STERILE PART #
• 25 MM	S1-9-41360-25	9-41360-25
• 30 MM	S1-9-41360-30	9-41360-30
• 35 MM	S1-9-41360-35	9-41360-35

• Optional

TECHNICAL FEATURES

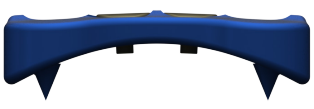
PLATES

Plate thickness: 3.35 mm
Composed of Ti Alloy (Ti-6AL-4V ELI)
Color anodize- dark blue
Large graft visibility window

ANTERIOR PLATES:
Width: 24 mm
Waist: 16 mm

SACRAL PLATES:
Width: 24 mm
Waist: 16 mm

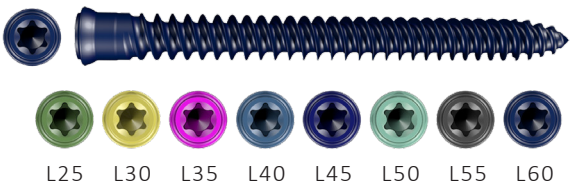
SACRAL PLUS PLATE:
Width: 24 mm
Waist: 16 mm



LATERAL PLATES:
Width: 17 mm
Waist: 10 mm

TECHNICAL FEATURES

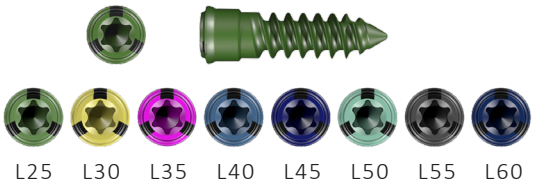
VARIABLE & FIXED ANGLE SCREWS



VARIABLE SCREWS

Cephalad/Caudal:
Anterolateral Plate: 12° +/- 4°
Sacral Plate: 8° +/- 4°
Sacral Plus Cephalad: 8° +/- 4°
Sacral Plus Caudal: 4° +/- 4°
Lateral: 10° +/- 4°

Medial/Lateral:
Anterolateral Plate: 4° +/- 4°
Sacral Plate: 4° +/- 4°
Sacral Plus: 4° +/- 4°
Lateral: 0° +/- 4°



FIXED SCREWS

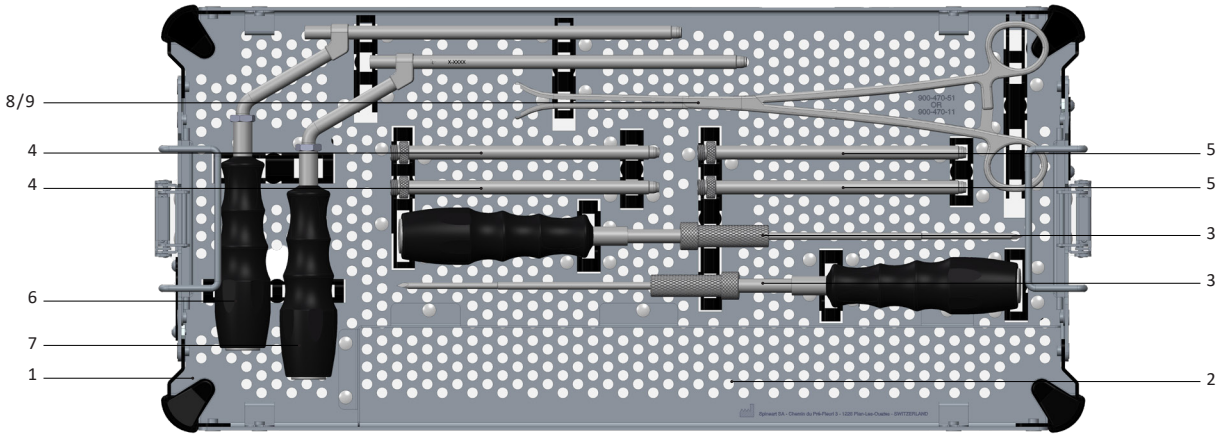
Cephalad/Caudal:
Anterolateral Plate: 12°
Sacral Plate: 8°
Sacral Plus Cephalad: 8°
Sacral Plus Caudal: 4°
Lateral: 10°

Medial/Lateral:
Anterolateral Plate: 4º
Sacral Plate: 4°
Sacral Plus: 4°
Lateral: 0°

HIGH PERFORMANCE SCREWS

Anodized colors for easier length identification
Ti Alloy (Ti-6AL-4V ELI)
T20 hexalobe drive
Standard screw diameter: 5.5mm
Revision screw diameter: 6.0mm
Self-tapping
Dual Lead

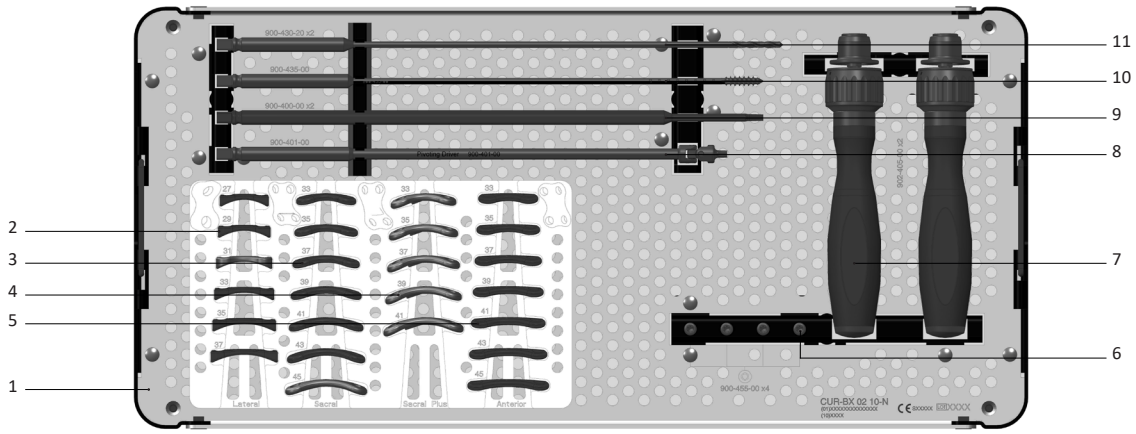
INSTRUMENTS



N°	INSTRUMENT	REFERENCE
1	CURE LP BOX - BASE	CUR-BX 02 00-N
2	UNIVERSAL LID	LID-BX 11 10-N
3	SHEATHED AWL	900-460-00
4	AWL SHEATH - VARIABLE	900-462-00
5	AWL SHEATH - FIXED	900-461-00
6	FIXED DRILL GUIDE	900-410-00
7	VARIABLE DRILL GUIDE	900-420-00
8	ANTERIOR PLATE HOLDER	900-470-51
9	LATERAL PLATE HOLDER	900-470-11

* Optional

INSTRUMENTS



N°	INSTRUMENT	REFERENCE
1	CURE LP BOX - INSERT	CUR-BX 02 10-N

LATERAL LP TEMPLATES

2	LATERAL PLATE TEMPLATE L27	T-9-41141-27
	LATERAL PLATE TEMPLATE L29	T-9-41141-29
	LATERAL PLATE TEMPLATE L31	T-9-41141-31
	LATERAL PLATE TEMPLATE L33	T-9-41141-33
	LATERAL PLATE TEMPLATE L35	T-9-41141-35
	LATERAL PLATE TEMPLATE L37	T-9-41141-37

SACRAL PLATE TEMPLATES

3	SACRAL PLATE TEMPLATE L33	T-9-41051-33
	SACRAL PLATE TEMPLATE L35	T-9-41051-35
	SACRAL PLATE TEMPLATE L37	T-9-41051-37
	SACRAL PLATE TEMPLATE L39	T-9-41051-39
	SACRAL PLATE TEMPLATE L41*	T-9-41051-41*
	SACRAL PLATE TEMPLATE L43*	T-9-41051-43*
	SACRAL PLATE TEMPLATE L45*	T-9-41051-45*

SACRAL PLUS PLATE TEMPLATES

4	SACRAL PLUS PLATE TEMPLATE L33*	T-9-41061-33*
	SACRAL PLUS PLATE TEMPLATE L35*	T-9-41061-35*
	SACRAL PLUS PLATE TEMPLATE L37*	T-9-41061-37*
	SACRAL PLUS PLATE TEMPLATE L39*	T-9-41061-39*
	SACRAL PLUS PLATE TEMPLATE L41*	T-9-41061-41*

ANTERIOR LP TEMPLATES

5	ANTERIOR LUMBAR PLATE TEMPLATE L33	T-9-41041-33
	ANTERIOR LUMBAR PLATE TEMPLATE L35	T-9-41041-35
	ANTERIOR LUMBAR PLATE TEMPLATE L37	T-9-41041-37
	ANTERIOR LUMBAR PLATE TEMPLATE L39	T-9-41041-39
	ANTERIOR LUMBAR PLATE TEMPLATE L41*	T-9-41041-41*
	ANTERIOR LUMBAR PLATE TEMPLATE L43*	T-9-41041-43*
	ANTERIOR LUMBAR PLATE TEMPLATE L45*	T-9-41041-45*
6	LUMBAR THREADED FIXATION TACK	900-455-00
7	HANDLE 1/4" RATCHET	902-405-00
8	PIVOTING DRIVER	900-401-00
9	DRIVER	900-400-00
10	TAP	900-435-00
11	LUMBAR DRILL, L20	900-430-20

* Optional

INSTRUMENTS

ANTERIOR PLATE HOLDER	900-470-51

LATERAL PLATE HOLDER	900-470-11

TAP	900-435-00

DRIVER	900-400-00

PIVOTING DRIVER	900-401-00

LUMBAR DRILL, L20	900-430-20

HANDLE ¼" RATCHET	902-405-00

INSTRUMENTS

FIXED DRILL GUIDE	900-410-00

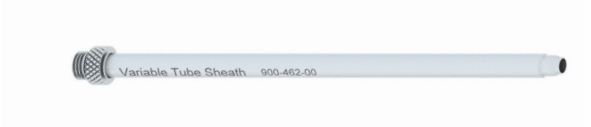
LATERAL PLATE TEMPLATE LXX	T-9-41141-XX
SACRAL PLATE TEMPLATE LXX	T-9-41051-XX
ANTERIOR LUMBAR PLATE TEMPLATE LXX	T-9-41041-XX
SACRAL PLUS PLATE TEMPLATE LXX	T-9-41061-XX

VARIABLE DRILL GUIDE	900-420-00

THREADED FIXATION TACK	900-455-00

SHEATHED AWL	900-460-00

AWL SHEATH - VARIABLE	900-462-00



AWL SHEATH - FIXED	900-461-00

SURGICAL TECHNIQUE

_STEP 1

PREPARATION

Proper patient positioning should be obtained using a frame or spine table. The patient should be in the supine position. Either a retroperitoneal or transperitoneal approach is utilized depending on the level of the spine and the surgeon's preference. An experienced vascular or general surgeon can help provide the proper exposure for the spine surgeon. Once the diseased level is exposed, a k-wire or similar tool can be safely inserted into the disc space and x-ray or fluoroscopic images should be used to help determine the proper level and midline.

The site should be exposed, and a bone graft or an intervertebral disc can be placed. Complete the preparation of the vertebral site by removing osteophytes so that the LP Plate can lie on the surface properly.

_STEP 2

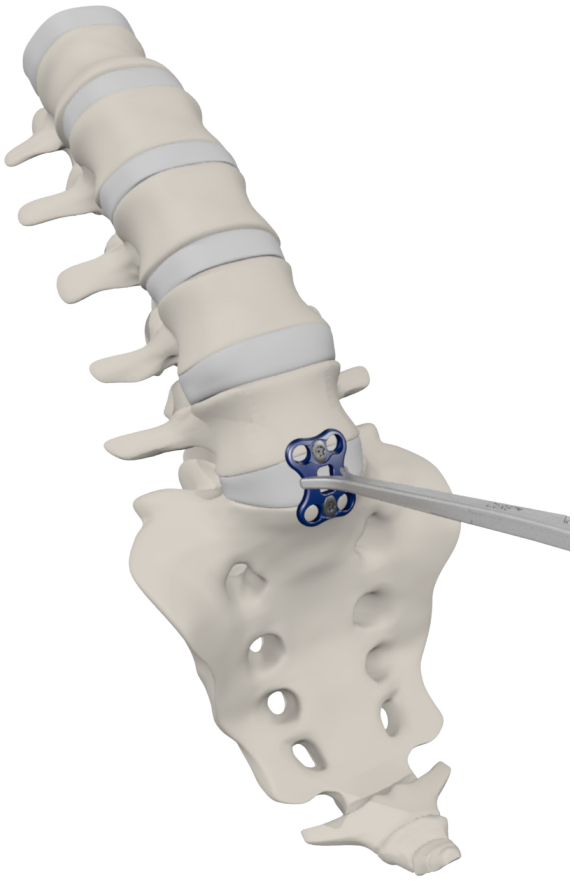


PLATE SIZE SELECTION

To ensure ideal anatomical fit, the surgeon can use one of the **Plate Templates** provided in the set or the actual implant.

The **Anterior Plate Holder or the Lateral Plate Holder** can be used to position the **Template** or CURE LP implant on the vertebral bodies.

The **Plate Templates** help to identify correct size and position of the final plate.

⚠ **WARNING:** Do not implant the **Plate Template**.

⚠ **WARNING:** Do not bend the plates since the plate holes could deform and prevent screws to lock properly in the plate holes.

Both sacral and anterolateral plates are available depending on the level being fused and the anatomy of the patient.

INSTRUMENT	REFERENCE
LATERAL PLATE TEMPLATE LXX	T-9-41141-XX
SACRAL PLATE TEMPLATE LXX	T-9-41051-XX
ANTERIOR LUMBAR PLATE TEMPLATE LXX	T-9-41041-XX
SACRAL PLUS PLATE TEMPLATE LXX	T-9-41061-XX
ANTERIOR PLATE HOLDER	900-470-51
LATERAL PLATE HOLDER	900-470-11

_STEP 3

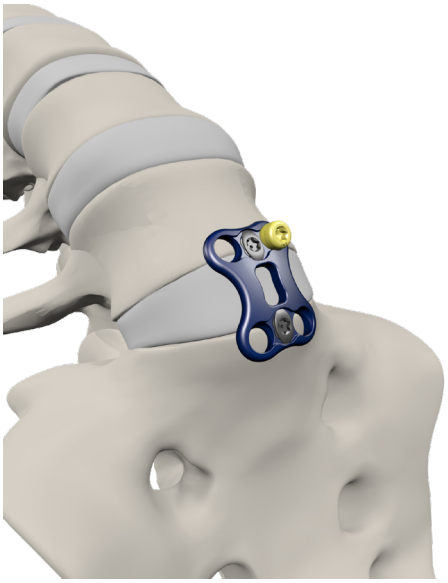


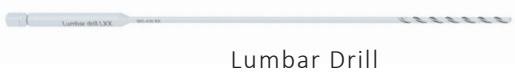
PLATE POSITIONING

After the proper plate is selected, it can be placed on the spine and temporarily held in place with a **Threaded Fixation Tack**. The tacks are loaded onto the **Driver** and threaded through one of the open screw holes in the plate and into the vertebral body. The **Anterior Plate Holder or the Lateral Plate Holder** can also be used to hold and position the plate.

NOTE: It is recommended to use two **Threaded Fixation Tacks** sequentially at opposite plate corners, in order to avoid any shift or rotation of the plate during pilot hole drilling.

INSTRUMENT	REFERENCE
THREADED FIXATION TACK	900-455-00
ANTERIOR PLATE HOLDER	900-470-51
DRIVER	900-400-00
LATERAL PLATE HOLDER	900-470-11

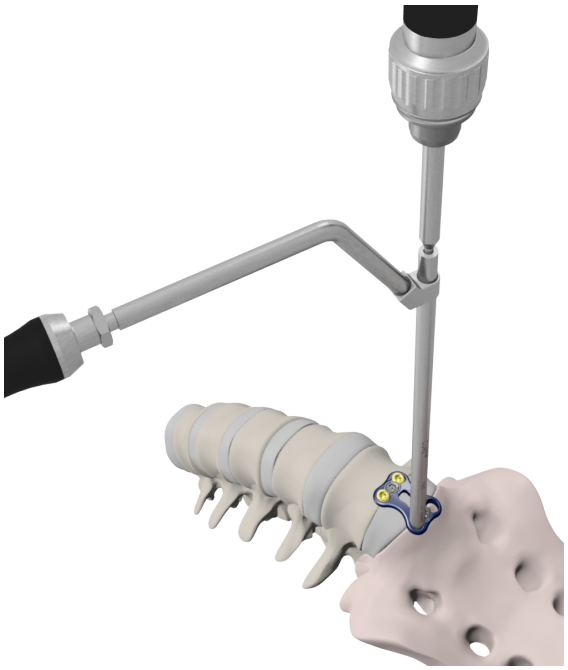
_STEP 4A



Lumbar Drill

Fixed Drill Guide

Variable Drill Guide



PREPARATION OF THE SCREW HOLES: SELF-TAPPING SCREW

With the plate in the proper position, select the **Variable or Fixed Drill Guide** and place it into the desired bone screw hole of the plate.

Insure that the **Drill Guide** is well placed into the hole of the plate so that the correct variable or fixed angle screw trajectory is obtained.

Connect the **Lumbar Drill** to the **Handle 1/4" Ratchet**.

Slide the **Lumbar Drill** through the **Variable or Fixed Drill Guide** and turn clockwise to produce a hole at an appropriate depth for the screw length.

⚠ **WARNING:** Always use the **Lumbar Drill** with the **Drill Guide**. If not the **Lumbar Drill** depth into the bone could be too long.

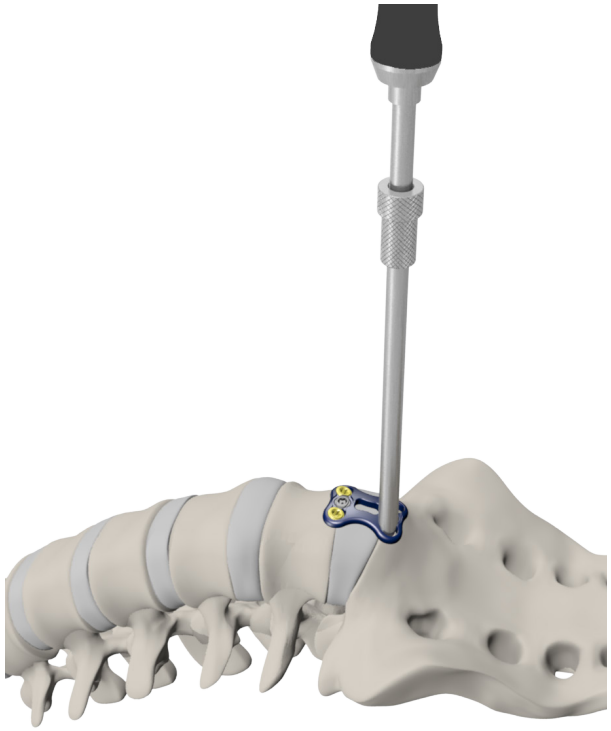
NOTE: ONLY Variable screws can be used with 27mm / 28mm Lateral plates.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
FIXED DRILL GUIDE	900-410-00
VARIABLE DRILL GUIDE	900-420-00
LUMBAR DRILL, 20	900-430-20
HANDLE 1/4" RATCHET	902-405-00

_STEP 4B

Sheathed Awl and guide



OPTION: PREPARATION OF THE SCREW HOLES

Connect the **Sheathed Awl** to the **Variable or Fixed Awl Sheath**.

Then, use the threads on top of the **Variable or Fixed Awl Sheath** to lock it onto the spring loaded **Awl**. And then place the tip of the **Variable or Fixed Awl Sheath.**

Downward pressure is applied to release the awl from the protective sheath of the **Variable or Fixed Awl Sheath** in order to break through the cortex.

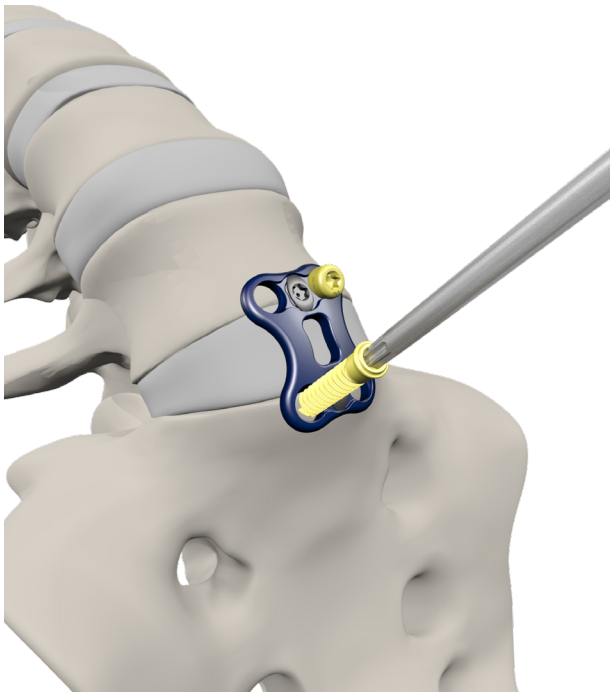
NOTE: The standard depth of the awl is 20mm.

⚠ **WARNING:** Always use the **Sheathed Awl** with the **Awl Sheath (variable or fixed)**. If not the **Sheathed Awl** depth into the bone could be too long.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SHEATHED AWL	900-460-00
AWL SHEATH - VARIABLE	900-462-00
AWL SHEATH - FIXED	900-461-00

_STEP 5



PLACEMENT OF SCREWS

After each pilot hole has been prepared for the bone screws, the **Driver** should be attached to the **Handle 1/4" Ratchet** and the appropriate bone screw loaded onto the proximal end of the **Driver**. The tapered **Driver** provides a friction fit with the hexalobe of the screw head.

NOTE: Make sure the screw is well loaded onto the **Driver**.

The bone screws can be identified by their color, tip configuration and laser markings.

The screw can be inserted through the hole on the plate by placing the **Handle 1/4" Ratchet** in the forward or neutral position taking care not to over-tighten.

⚠ **WARNING:** in case of sclerotic bone, a **Tap** should be used to prepare the screw holes.

If a **Threaded Fixation Tack** (see STEP 3) is used to temporarily secure the plate while inserting screws, it should be removed and replaced with a standard bone screw. The underside of the screw head should sit flush into the plate.

Repeat the process for all necessary screws.

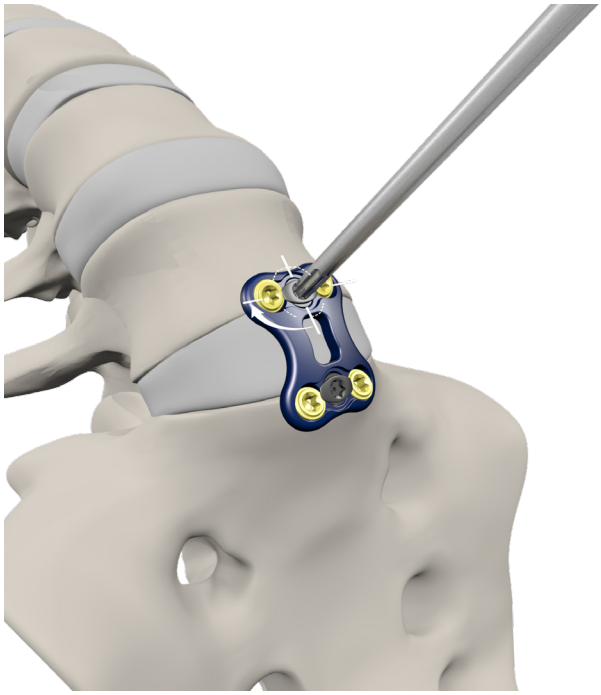
If desired, final tightening of screws can be achieved by going in opposite corners to keep plate from rising up and off the vertebral body.

Additionally, with the plate secured by the **Anterior Plate Holder,** screws can be inserted after each hole is drilled or after each pass of the **Sheathed Awl**.

NOTE: A **Pivoting Driver** is available if the trajectory or angle of the **Driver** is impeded by patient anatomy or a retractor frame.

INSTRUMENT	REFERENCE
DRIVER	900-400-00
HANDLE 1/4" RATCHET	902-405-00
PIVOTING DRIVER	900-401-00
TAP	900-435-00

_STEP 6



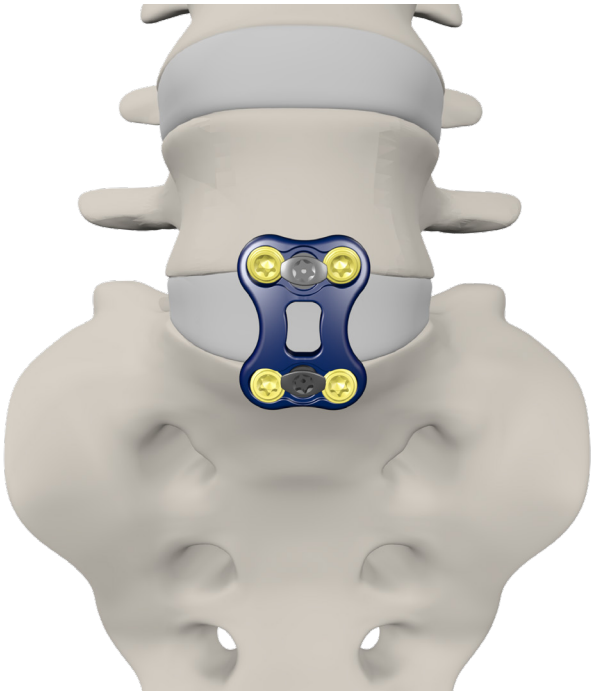
SECUREMENT OF THE SCREWS

Once all screws have been properly placed, use the **Driver** to rotate the central locking mechanism 90° clockwise into the locked position.

CAUTION: The central locking mechanism should not be rotated past 90°. Trying to rotate the locking mechanism past 90° will result in permanent damage and the plate should be immediately discarded.

INSTRUMENT	REFERENCE
DRIVER	900-400-00

_FINAL CONSTRUCT



_IMPLANT REMOVAL

If the need to remove the screws from the plate arises, use the **Driver** to rotate the central locking mechanism 90° counterclockwise.

Position the **Driver** into the hexalobe drive feature in the identified screw and rotate counterclockwise until the screw is completely removed from the plate.

INSTRUMENT	REFERENCE
DRIVER	900-400-00
HANDLE 1/4" RATCHET	902-405-00

NOTE

NOTE

SPINEART

MANUFACTURED BY:
SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

DISTRIBUTED BY:
SPINEART USA INC
23332 MILL CREEK DR. SUITE 150
LAGUNA HILLS, CA 92653
USA

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