CURE 2.0 ACP

ANTERIOR CERVICAL PLATE SYSTEM

CONTENT

CONCEPT AND DESIGN

The CURE™ 2.0 Anterior Cervical Plate System is a next generation titanium plate and screw system designed by a group of tenured and practicing spine surgeons.
The design philosophy with the surgical team was to leverage their experience, keep things simple and yet be innovative. The plate has a balanced design which maximizes the surgeon's ability to see the graft both medially and laterally while placing either variable or fixed angle screws. The system features low-profile plates and integrated locking mechanism to prevent screw back out. The CURE™ 2.0 plate is pre-lordosed to facilitate insertion and match the natural contour of the spine.

AT A GLANCE

Tactile and Visual Locking Mechanism
Pre-Lordosed
Low Profile
Large Graft Visualization Windows

INDICATIONS

CURE™ 2.0 ACP System is intended for use during anterior cervical discectomy with fusion, between C2 and C7, and up to 4 consecutive levels in skeletally mature patients. It is indicated for the surgical treatment of:

- Radiculopathy and/or myelopathy, secondary to cervical degenerative disc disease and/or spondylosis, and for patients that are resistant to conservative management;
- Traumatology;

CONTRAINDICATIONS

Include but not limited to

- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the plate system.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy.
- Bone tumor in the region of implant.
- Suspected or documented metal allergy or intolerance.

Please refer to the CURE™ 2.0 ACP Instructions for Use for complete system description, indications, contraindications, precautions and warnings.

IMPLANTS

PLATES

1-LEVEL PLATE	
ITEM SIZE	**STERILE PART #**
16 MM	S1-10-00001-16
17 MM	S1-10-00001-17
18 MM	S1-10-00001-18
19 MM	S1-10-00001-19
20 MM	S1-10-00001-20
21 MM	S1-10-00001-21
22 MM	S1-10-00001-22
24 MM	S1-10-00001-24
26 MM	S1-10-00001-26
• 28 MM	S1-10-00001-28

2-LEVEL PLATE	
ITEM SIZE	**STERILE PART #**
• 30 MM	S1-10-00002-30
32 MM	S1-10-00002-32
34 MM	S1-10-00002-34
36 MM	S1-10-00002-36
38 MM	S1-10-00002-38
40 MM	S1-10-00002-40
42 MM	S1-10-00002-42
44 MM	S1-10-00002-44
46 MM	S1-10-00002-46
• 48 MM	S1-10-00002-48
• 50 MM	S1-10-00002-50

3-LEVEL PLATE	
ITEM SIZE	**STERILE PART #**
47 MM	S1-10-00003-47
50 MM	S1-10-00003-50
53 MM	S1-10-00003-53
56 MM	S1-10-00003-56
59 MM	S1-10-00003-59
62 MM	S1-10-00003-62
• 65 MM	S1-10-00003-65
• 68 MM	S1-10-00003-68
• 70 MM	S1-10-00003-70

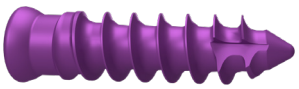
4-LEVEL PLATE	
ITEM SIZE	**STERILE PART #**
• 64 MM	S1-10-00004-64
68 MM	S1-10-00004-68
72 MM	S1-10-00004-72
76 MM	S1-10-00004-76

4-LEVEL PLATE	
ITEM SIZE	**STERILE PART #**
80 MM	S1-10-00004-80
84 MM	S1-10-00004-84
• 88 MM	S1-10-00004-88
• 92 MM	S1-10-00004-92

• Optional

IMPLANTS

SCREWS



SELF-TAPPING SCREWS - VARIABLE Ø 4.1	
ITEM SIZE	**STERILE PART #**
12 MM	S2-7-42141-12
14 MM	S2-7-42141-14
16 MM	S2-7-42141-16
• 18 MM	S2-7-42141-18
• 20 MM	S2-7-42141-20

SELF-TAPPING SCREWS - VARIABLE Ø 4.5	
ITEM SIZE	**STERILE PART #**
12 MM	S1-7-42145-12
14 MM	S1-7-42145-14
16 MM	S1-7-42145-16
• 18 MM	S1-7-42145-18
• 20 MM	S1-7-42145-20

SELF-DRILLING SCREWS - VARIABLE Ø 4.1	
ITEM SIZE	**STERILE PART #**
12 MM	S2-7-42241-12
14 MM	S2-7-42241-14
16 MM	S2-7-42241-16
• 18 MM	S2-7-42241-18

SELF-DRILLING SCREWS - VARIABLE Ø 4.5	
ITEM SIZE	**STERILE PART #**
12 MM	S1-7-42245-12
14 MM	S1-7-42245-14
16 MM	S1-7-42245-16
• 18 MM	S1-7-42245-18

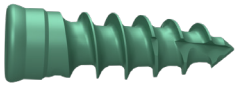
• Optional

IMPLANTS

SCREWS

SELF-TAPPING SCREWS - FIXED Ø 4.1	
ITEM SIZE	**STERILE PART #**
12 MM	S2-7-41141-12
14 MM	S2-7-41141-14
16 MM	S2-7-41141-16
• 18 MM	S2-7-41141-18

SELF-TAPPING SCREWS - FIXED Ø 4.5	
ITEM SIZE	**STERILE PART #**
12 MM	S1-7-41145-12
14 MM	S1-7-41145-14
16 MM	S1-7-41145-16
• 18 MM	S1-7-41145-18



SELF-DRILLING SCREWS – FIXED Ø 4.1	
ITEM SIZE	**STERILE PART #**
12 MM	S2-7-41241-12
14 MM	S2-7-41241-14
16 MM	S2-7-41241-16
• 18 MM	S2-7-41241-18

SELF-DRILLING SCREWS – FIXED Ø 4.5	
ITEM SIZE	**STERILE PART #**
12 MM	S1-7-41245-12
14 MM	S1-7-41245-14
16 MM	S1-7-41245-16
• 18 MM	S1-7-41245-18

• Optional

TECHNICAL FEATURES

PRE-LORDOSED PLATES

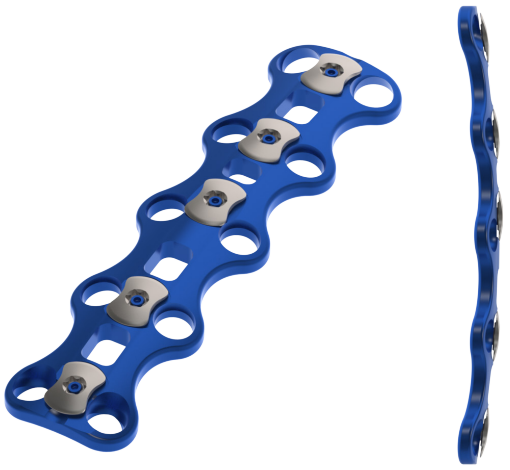


Plate thickness is 2.0mm
Large graft visualization windows
16.5mm wide and 10mm waist
Composed of Titanium Alloy (Ti-6Al-4V ELI)
*Lengths are measured end to end
**For proximal screw hole to distal screw hole measurement: subtract 8mm

FIXED SCREWS

VARIABLE SCREWS

Color anodization and laser marking to identify function and length
Composed of Ti Alloy (Ti-6Al-4V ELI)
2.8mm hexalobe drive feature
Two screw diameter options : 4.1mm & 4.5mm
*Screw length is measured from the underside of the plate

TECHNICAL FEATURES

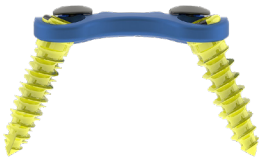
VARIABLE ANGLE SCREWS

CEPHALAD/CAUDAL ANGULATION

MEDIAL/LATERAL ANGULATION

CURE™ 2.0 ACP
Cephalad/caudal: 30°-14° range
Medial/lateral: 11°-1° range

FIXED ANGLE SCREWS



CEPHALAD/CAUDAL ANGULATION

MEDIAL/LATERAL ANGULATION

CURE™ 2.0 ACP
Cephalad/caudal: 22°
Medial/lateral: 6°

INSTRUMENTS

UNIVERSAL PLATE HOLDER	GS 82-8040

AO QUICK CONNECT HANDLE	700-405-RF

SINGLE BARREL DRILL GUIDE - FIXED	700-410-05

• DOUBLE BARREL DRILL GUIDE 2 - FIXED	1000-412-00

• DOUBLE BARREL DRILL GUIDE 2 - VARIABLE	1000-422-00

DRIVER	700-400-00

DRILL 12 MM	700-430-12
DRILL 14 MM	700-430-14
DRILL 16 MM	700-430-16
• DRILL 18 MM	700-430-18
• DRILL 12 MM STERILE	S1-700-430-12*
• DRILL 14 MM STERILE	S1-700-430-14*
• DRILL 16 MM STERILE	S1-700-430-16*
• DRILL 18 MM STERILE	S1-700-430-18*

SINGLE BARREL DRILL GUIDE 2 - VARIABLE	1000-420-00

* These references are sterile

• Optional

INSTRUMENTS

SHEATHED AWL	700-460-00

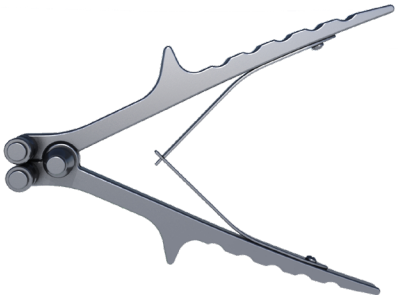
FIXED AWL SHEATH	700-461-00

TEMPLATES	T-10-0000#-XX

VARIABLE AWL SHEATH 2	1000-462-00

THREADED FIXATION TACK	700-455-00

PLATE BENDER 2	1000-475-00



SURGICAL TECHNIQUE

_STEP 1

PATIENT POSITIONING

Standard anterior exposure techniques should be utilized to expose the spinal segment(s) to be fused.

A properly-sized plate should span the distance between the caudal and cephalad vertebrae. The surgeon should obtain an anterior exposure to the spine according to preference of incision, approach angle and side (left or right) of the patient.

_STEP 2

EXPOSURE OF SPINE

A retractor is used to provide adequate exposure during dissection, disc preparation, and interbody placement.

Depending on dissection preference, the surgeon should expose the mid-line of the intervertebral disc above and below the diseased level. Fluoroscopy should be used to verify position. Distractors, whether a spreader or distraction pins can be used to help with gentle distraction of the disc space.

SURGICAL TECHNIQUE

_STEP 3

PLATE SELECTION

After the appropriate disc has been removed and an interbody device has been placed, the CURE™ 2.0 plate can be applied to the spine.

To ensure ideal anatomical fit, determine the appropriate plate size using a supplied plate **Template** from the rack.

Use the **Plate Holder** to position the template in the desired position to check if the size is appropriate.

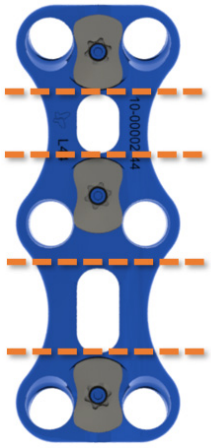
CAUTION: Do not bend the plate template. Do not implant the plate template.

INSTRUMENT	REFERENCE
TEMPLATES	T-10-0000#-XX
UNIVERSAL PLATE HOLDER	GS 82-8040

SURGICAL TECHNIQUE

_STEP 4

CONTOURING / PLATE POSITIONING



The CURE™ 2.0 plate has a pre-lordosed curve in the sagittal plane. If increased or decreased lordosis is desired, the plates can be further contoured with the **Plate Bender**.

CAUTION: Only bend the plate at the middle of the graft window(s). Repeated bending may weaken the plate.

⚠ **WARNING:** Do not bend at plate hole locations to avoid locking ring damage and compromise.

Use the **Plate Holder** to position the plate in the desired position.

Threaded Fixation Tacks can be used to temporarily hold the plate in place.

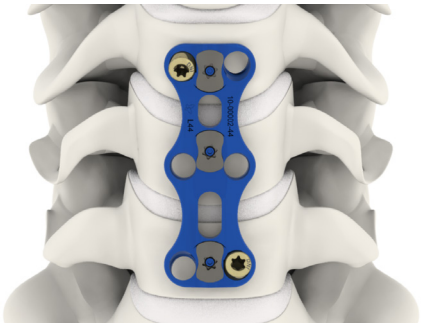
The **Tacks** are loaded onto the **Driver** and advanced through one of the open screw holes in the plate and into the vertebral body.

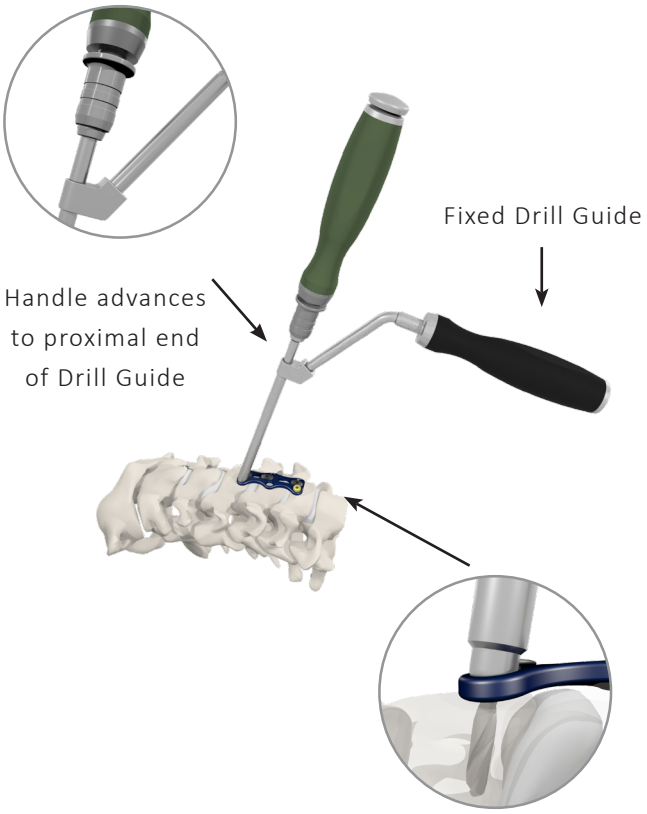
NOTE: It is recommended to use two **Threaded Fixation Tacks** sequentially at opposite plate corners, in order to avoid any shift or rotation of the plate during preparation of the screw holes.

INSTRUMENT	REFERENCE
UNIVERSAL PLATE HOLDER	GS 82-8040
THREADED FIXATION TACK	700-455-00
PLATE BENDER	1000-475-00
DRIVER	700-400-00
AO QUICK CONNECT HANDLE	700-405-RF

SURGICAL TECHNIQUE

_STEP 5A





PREPARATION OF SCREW HOLES - FIXED ANGLE, SELF-TAPPING SCREW

NOTE : It is recommended to insert screws sequentially at opposite plate corners. This helps to secure the plate in position on the vertebrae, thus ensuring proper screw placement.

With the plate in proper position, select the **Single Barrel Drill Guide - Fixed or the Double Barrel Drill Guide 2 - Fixed** and place it into the desired screw hole(s) of the plate.

Securely seat the distal end of the drill guide into the hole(s) of the plate so the correct, fixed angle screw trajectory is obtained.

Select the proper **Drill** bit length to match the chosen screw length and attach to the **AO Quick Connect Handle**. Once the **Drill** bit is attached to the handle, it may be introduced through the drill sleeve and advanced to its permitted depth stop when it meets the proximal end of the drill guide.

NOTE: Screw lengths are measured from the underside of the plate and do not include the screw head. Repeat this procedure for all additional holes in the plate.

NOTE: If **Double Barrel Drill Guide 2 - Fixed** is used, remove one **Tack** at a time prior to positioning the guide in the plate holes.

INSTRUMENT	REFERENCE
SINGLE BARREL DRILL GUIDE - FIXED	700-410-05
DRILL	700-430-XX
AO QUICK CONNECT HANDLE	700-405-RF
DOUBLE BARREL DRILL GUIDE 2 - FIXED (OPTIONAL)	1000-412-00

_STEP 5B

PREPARATION OF SCREW HOLES - FIXED ANGLE, SELF-DRILLING SCREWS

Assemble the **AO Quick Connect Handle** with the **Sheathed Awl** and the **Fixed Awl Sheath**.

With the plate in the proper position, place the assembly into the desired screw hole of the plate.

Securely seat the distal end of **Fixed Awl Sheath** into selected hole of the plate.

Push down the handle to release the awl and so the correct fixed angle screw trajectory is obtained.

If necessary, drilling can be used to ease the screw insertion (refer to previous section).

NOTE: Screw lengths are measured from the underside of the plate and do not include the screw head.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SHEATHED AWL	700-460-00
FIXED AWL SHEATH	700-461-00
AO QUICK CONNECT HANDLE	700-405-RF
DRILL	700-430-XX

_STEP 5C

PREPARATION OF SCREW HOLES - VARIABLE ANGLE, SELF-TAPPING SCREWS

With the plate in proper position, select the **Single Barrel Drill Guide 2 - Variable or the Double Barrel Drill Guide 2 - Variable** and place it into the desired screw hole(s) of the plate.

Securely seat the distal end of the **Drill Guide** into the hole(s) of the plate so the variable angle screw trajectory is obtained.

Select the proper **Drill** bit length to match the chosen screw length and attach to the **AO Quick Connect Handle**.

Once the **Drill** bit is attached to the handle, it may be introduced through the drill sleeve and advanced to its permitted depth stop when it meets the proximal end of the **Drill Guide**.

NOTE: Screw lengths are measured from the underside of the plate and do not include the screw head.

Repeat this procedure for all additional holes in the plate.

NOTE: If **Double Barrel Drill Guide 2 - Variable** is used, remove one **Tack** at a time prior to positioning the guide in the plate holes.

INSTRUMENT	REFERENCE
SINGLE BARREL DRILL GUIDE 2 - VARIABLE	1000-420-00
DOUBLE BARREL DRILL GUIDE 2 - VARIABLE (OPTIONAL)	1000-422-00
DRILL	700-430-XX
AO QUICK CONNECT HANDLE	700-405-RF

_STEP 5D

PREPARATION OF SCREW HOLES - VARIABLE ANGLE, SELF-DRILLING SCREWS

Assemble the **AO Quick Connect Handle** with the **Sheathed Awl** and the **Variable Awl Sheath 2**.

With the plate in the proper position, place the assembly into the desired screw hole of the plate.

Securely seat the distal end of **Variable Awl Sheath 2** into selected hole of the plate so the desired, variable angle screw trajectory is obtained.

Push down the handle to release the awl and so the correct variable angle screw trajectory is obtained.

If necessary, drilling can be used to ease the screw insertion (refer to previous section).

NOTE: Screw length are measured from the underside of the plate and does not include the screw head.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SHEATHED AWL	700-460-00
VARIABLE AWL SHEATH 2	1000-462-00
AO QUICK CONNECT HANDLE	700-405-RF
DRILL	700-430-XX

SURGICAL TECHNIQUE

_STEP 6

PLACEMENTS OF SCREWS

After each pilot hole has been prepared for the bone screws, the **Driver** should be attached to the **AO Quick Connect Handle** and the appropriate bone screw loaded to the torx tip of the **Driver**.

The **Driver** interface with the bone screw is a friction fit. Care should be taken to ensure the screw is loaded securely onto the **Driver**.

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

The screw can be inserted through the hole on the plate taking care not to over-tighten.

If a **Threaded Fixation Tack** 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 this procedure for all additional holes in the plate.

NOTE: According to surgeon preference, the following screw options are available : variable and fixed self drilling or self tapping. In case of hard bone, it is recommended to use the self-drilling screws.

Preoperatively and after control of stability and to get better bone anchorage, a Ø4.1mm screw can be replaced by a Ø4.5mm screw.

INSTRUMENT	REFERENCE
DRIVER	700-400-00
AO QUICK CONNECT HANDLE	700-405-RF
THREADED FIXATION TACK	700-455-00

SURGICAL TECHNIQUE

_STEP 7

UNLOCKED

ROTATE 90° CLOCKWISE

LOCKED

SECUREMENT OF SCREWS

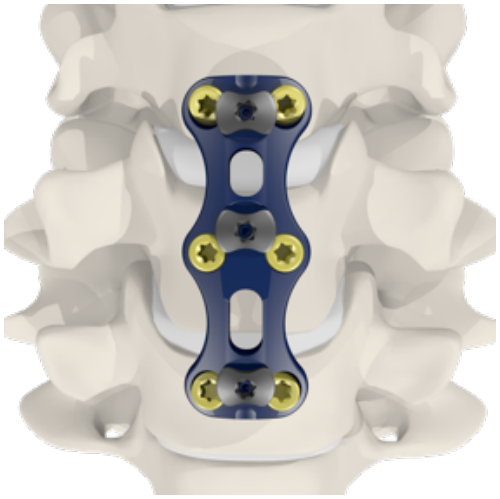
Once all screws have been properly placed, use the **Driver** to rotate all central locking mechanisms 90° clockwise into the locked position (see image opposite).

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	700-400-00

SURGICAL TECHNIQUE

_FINAL CONSTRUCT



Once the CURE™ 2.0 plate is implanted, a final x-ray confirming proper placement may be performed and a standard closing technique should be utilized.

_IMPLANT REMOVAL

If a need to remove the screws from the plate occurs, 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.

Once all the screws are removed, remove the plate with the **Plate Holder**.

INSTRUMENT	REFERENCE
DRIVER	700-400-00
UNIVERSAL PLATE HOLDER	GS 82-8040
AO QUICK CONNECT HANDLE	700-405-RF

NOTE

N O T E

NOTE

N O T E

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