

Sonoma™ Anterior Cervical Plate System

Surgical Technique





Table of Contents

Sonoma™ Anterior Cervical Plate System..... 1

Surgical Technique.....2

 Step 1: Plate Selection and Placement2-4

 Step 2: Drill Guide Options.....5

 Step 3: Screw Hole Preparation5

 Step 4: Selecting the Screws.....6

 Step 5: Set Screw Placement.....7

 Step 6: Securing the Plate8

 Step 7: Removal..... 9-10

Ordering Information..... 11-13

Indications and Contraindications..... 13-Back Cover

Sonoma™ Anterior Cervical Plate System

The Sonoma™ Anterior Cervical Plate System combines all the elements of modern, cervical plate design into a versatile, easy-to-use system offering the surgeon multiple construct options to meet the needs of the patient. The pre-contoured plates are low profile, have a narrow footprint for a better anatomic fit, and have a window at each level to provide visualization of the end plates and disc space.

Sonoma takes advantage of a super-elastic, split ring locking mechanism that offers one-step, passive locking with excellent resistance to screw back-out. Our patented Five Point removal design provides simple, reliable screw removal.



Surgical Technique

STEP 1

Plate Selection and Placement

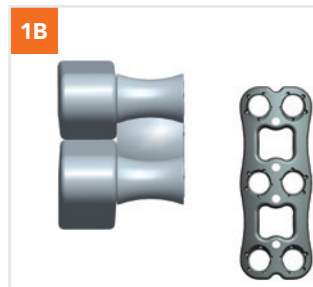
- 1A** Sonoma™ offers over 30 lengths of **Cervical Plates** covering one level to four level procedures. After selecting the appropriate length **Plate**, place the **Plate** onto the anterior cervical spine and verify length and fit. The **Sonoma Plates** are pre-lordosed to help achieve a more anatomic fit. If additional contouring of the Plate is required, the **Plate Bender** may be used to increase the lordotic curvature.



Plate Bending Techniques

Option 1 – Plate Bender

- 1B** Insert plate sideways into **Plate Bender** as shown. Align plate graft window directly over main bending wheel and gently bend plate as desired.



- 1C**  **Precautions:**
- Take care not to bend plate with screw holes over bending wheel. Locking mechanism may be impaired if bent.

- 1D**
- Excessive bending may damage the plate.

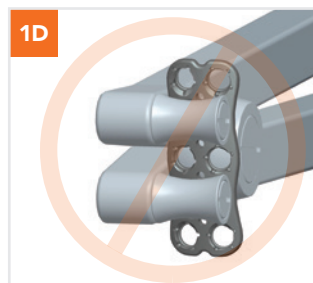
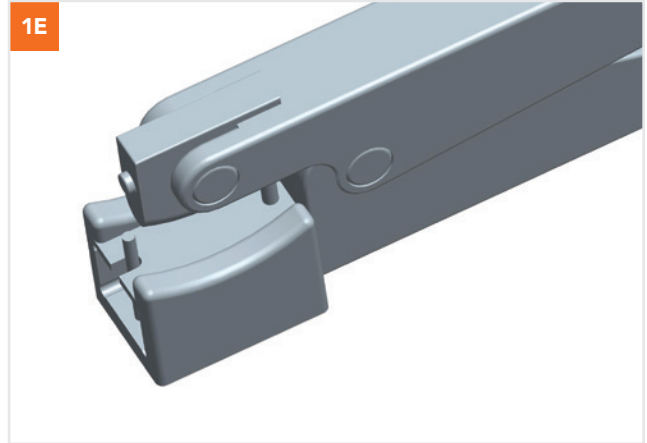


Plate Bending Techniques

Option 2 – Plate Bending Pliers

1E Insert plate sideways into **Plate Bending Pliers**. Bend over graft window by gently clamping down on **Pliers**.

1F Take care not to bend over screw holes as the locking mechanism may be impaired if bent.



STEP 1

Plate Selection and Placement continued

Small and **Large Temporary Fixation Pins** are available to temporarily secure the **Plate** to the vertebral bodies. The **Fixation Pins** have a fine thread and can be threaded into the bone using the **Cervical Screw Driver** or impacted into the bone using a small mallet.

1G

The Sonoma™ Plate has small, midline holes adjacent to the screw holes. The **Small Temporary Fixation Pin** can be placed through these holes and because of the small head, will not interfere with the **Guides** during screw hole preparation.

1H

► **Note:** The **Cervical Screw Driver** is used to insert both the **Fixation Pins** and the **Bone Screws**.

1I

The **Large Temporary Fixation Pin** may be used to temporarily secure the **Plate** by inserting it through the screw holes.

1J

If so desired, the surgeon may use the **Fixation Pin** hole as a pilot hole for the **Screws**.

1G



1H



1I



1J



STEP 2

Drill Guide Options

The surgeon may choose between using a **Limited Angle Screw** or a **Variable Screw**.

- 2A** When using a **Limited Angle Screw**, the **Limited Angle Guide** must be used to prepare the pilot hole to ensure that the **Limited Angle Screw** will properly seat in the **Plate**. The **Limited Angle Guide** is designed to keep the screw angulation within the acceptable limits of the plate.



- 2B** When using a **Variable Screw**, the surgeon can choose the screw trajectory to maximize purchase. The **Variable Guide** is designed to keep the screw angulation within the acceptable limits of the plate.

► **Note:** To prevent over angulation of the **Screw**, keep the **Variable Guide** tip fully in the **Plate** when drilling the pilot hole. Excessive angulation of the **Variable Screw** may prevent secure locking of the **Screw** to the **Plate**.



STEP 3

Screw Hole Preparation

Drills are available in 12mm, 14mm, and 16mm lengths. Attach the appropriate **Drill** onto the **Quick Connect Handle**, insert through the selected guide shaft, and advance the **Drill** until the stop hits the top of the **Guide**.

The Sonoma™ Screws are designed with a moderately sharp tip and cutting flutes to advance through the bone without the need to tap.



STEP 4

Selecting the Screws

4A



4.0mm
Variable Screws
(Blue)



4.0mm
Limited Angle Screws
(Magenta)



4.5mm
Variable Screws
(Gold)



4.5mm
Limited Angle Screws
(Dark Gray)



4.0mm Optional
Self-Drilling Screws
(Light Green)

4A

The Sonoma™ System features screw options in lengths from 10mm to 18mm.

4B

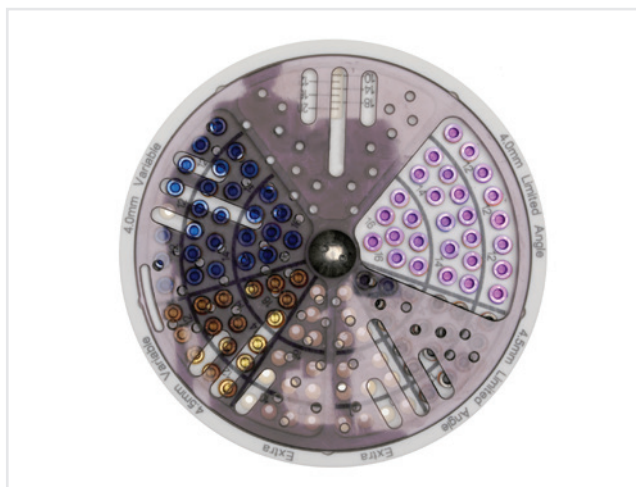
All **Screws** are sorted by type and length in the **Screw Caddy**. The **Screw Caddy** has a rotating lid which can be turned to the appropriate screw type. The screw length can be measured by inserting the **Screw** into the hole on the side of the **Caddy** and reading the length from the gage on top.

► **Note:** Always return the lid to the closed position when done with the case to prevent **Screws** from falling out during handling.

4B



Verifying Length of a 4.0 x 16mm Limited Angle Screw



Screw Caddy Open to 4.0mm Limited Angle Screws



Screw Caddy with Lid in Closed Position

STEP 5**Set Screw Placement**

The Sonoma™ ACP System can be configured in several **Plate/Screw** combinations to obtain patient-specific construct rigidities.

Some typical Plate and Screw constructs are listed below:

4 Limited Angle Screws

- Provides the most rigid construct with minimal load sharing

4 Variable Screws

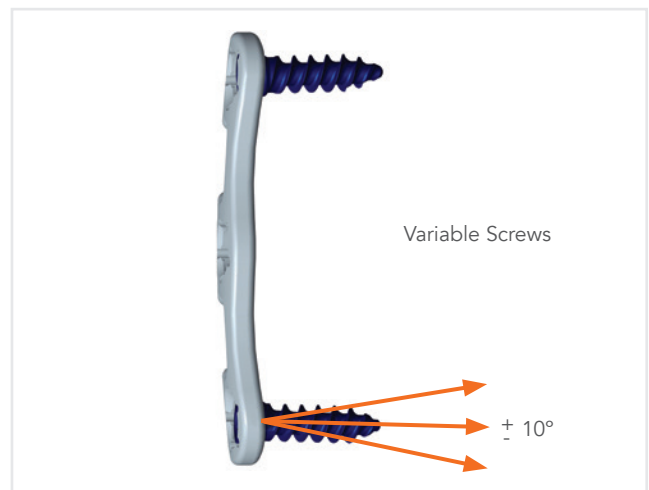
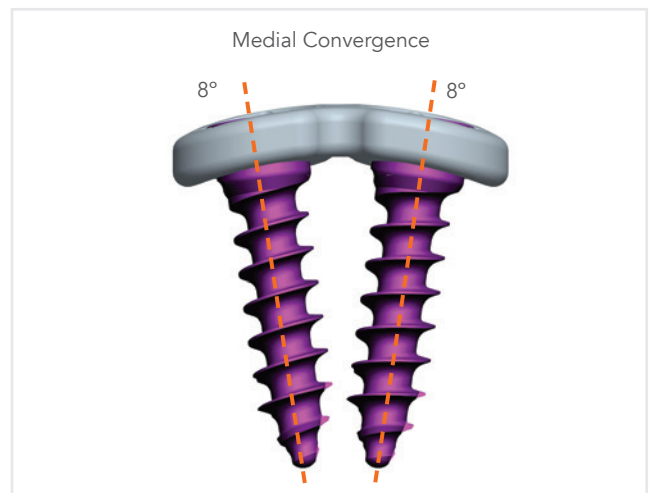
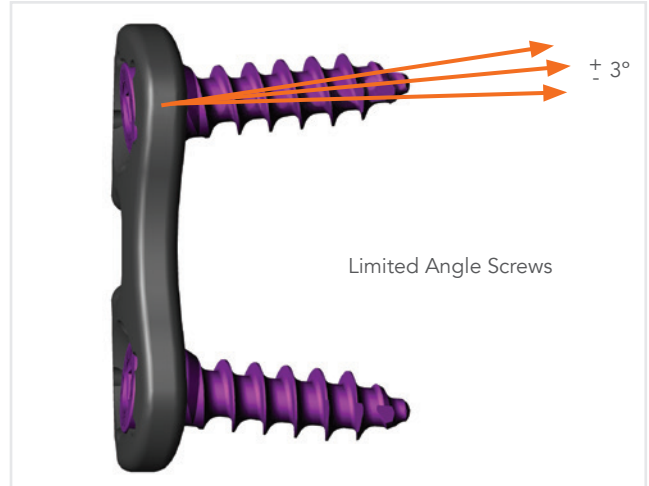
- Provides surgeon with the most flexibility in screw placement.
- Allows for “rotational” subsidence and load sharing at both ends of the Plate.

2 Limited Angle, 2 Variable Screws

- Provides a semi-rigid construct

The Nominal Screw angles for the Sonoma™ Plate are:

- 8° Cephalad for the superior screw holes
- 8° Caudal for the inferior screw holes
- Neutral for any middle holes (2 or more levels)
- 8° of medial convergence for all screw holes
- The Limited Angle Screw offers an additional 3° of angulation from the nominal angles.
- The Variable Screw offers an additional 10° of angulation from the nominal angles.

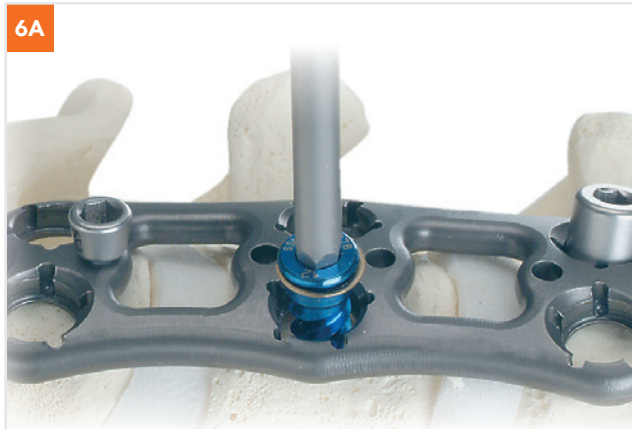


STEP 6

Securing the Plate

6A After selecting the appropriate **Screws**, the **Cervical Screw Driver** is used to insert the **Screw** into the **Plate**. The **Cervical Screw Driver** has a tapered tip that, when pressed firmly into the **Screw** hex, will hold the **Screw**.

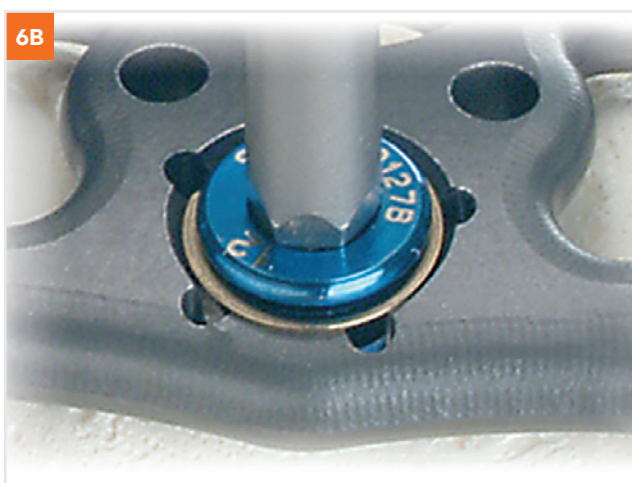
► **TIP:** When inserting the **Screws**, leave the first one or two **Screws** slightly proud until satisfied with the final **Plate** position. This will eliminate the need for the **Removal Tool** if the **Plate** or **Screw** needs to be re-positioned.



6B Locking the Screw

The Sonoma™ System uses a super-elastic Nitinol locking ring to secure the **Bone Screw** in the **Plate**. The locking ring compresses as it enters the **Plate** and then expands once it is properly seated.

When the ring snaps past the top edge of the **Plate**, it makes a “click”. This click indicates the ring is in the locked position and can often be heard and felt by the surgeon. Please note that the strength of the click varies and may not always be noticeable.



Locking ring is clearly visible prior to fully seating screw.

6C Visual Inspection

Verify that all **Screws** are locked by visually inspecting that the ring is captured by the top lip of the **Plate**. The ring is colored in a contrasting gold to make it more visible.



Locking ring captured by top lip of plate when fully seated.

STEP 7

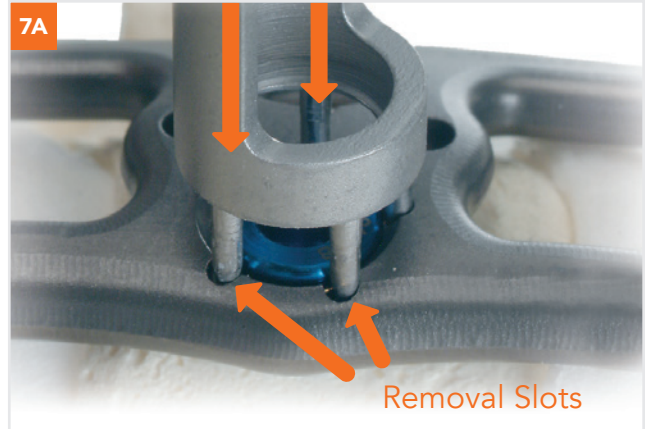
Removal

The Sonoma™ System has a patented **Five Point** removal design for simple, reliable **Screw** removal. The **Five Points** on the **Removal Tool** are designed to compress the locking ring and allow the **Screw** to be backed out.

Option 1 – Screw Removal

It is important to first back-out the **Screw** a half turn with the Screwdriver (to move the locking ring to the top of the **Plate**).

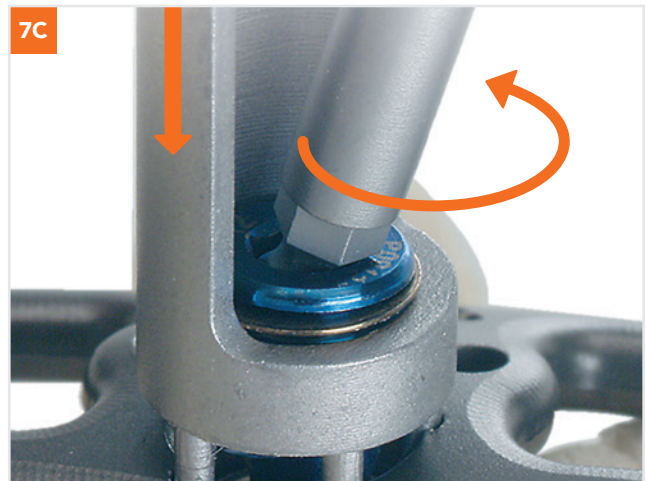
- 7A** Insert the **Five Point Removal Tool** into the appropriate hole and firmly press all the way into the **Plate**. (You may hear a “click” as the tool passes over the locking ring). While applying firm pressure with the **Removal Tool**, back-out the **Screw** with the **Screwdriver**.
- 7B**



- 7C** ▶ **Tip:** On occasion, it may help to toggle the **Removal Tool** as you are backing out the **Screw**.

The **Ball Tip Screwdriver** can be used to remove a Screw when the angulation of the Screw prevents access of the standard **Cervical Screwdriver**. This may occur when a **Variable Screw** has been placed at its maximum angle.

- ▶ **Note:** SeaSpine does not recommend that the **Ball Tip Screwdriver** be used for routine Screw insertion because it may lead to the premature wear and stripping of the **Driver** tip.



STEP 7

Removal continued

Option 2 – Extractor

- 7D** The Sonoma™ Screws feature an internal reverse thread in the hex of the screw.

Insert the threaded top of the **Extractor** into the hex of the screw.

- 7E** Turn the **Red Capped Axial Handle** counter-clockwise to thread the top of the driver into the hex of the screw.

► **Note:** It is important to ensure that all of the threads are fully engaged.

- 7F** While Holding the **Red Capped Axial Handle** - Turn the **Silver T-Handle** clockwise until the bottom of the sleeve meets up with the top of the plate.

- 7G** Turn the **Red Capped Axial Handle** counter-clockwise to remove the screw. To remove the screw from the extractor, an extractor block has been added to the Sonoma sets.

To remove the screw from the extractor, insert the tip of the screw into one of the holes in the extractor block. Turn the **Red Capped Axial Handle** clockwise to remove the screw from the extractor. To remove the screw from the extractor block, the Sonoma screwdriver may be used. The extractor block may be re-used (after several uses it should be exchanged for a new block).

► **Note:** The Sonoma Extractor should be used as an alternative to the **Sonoma Removal Tool** if a surgeon needs to adjust the screw plate position. The **Extractor** will damage the **Ring** of the screw making it unable to be reused whereas the **Removal Tool** should not cause any damage.



For complete product information, please see the Instructions for Use accompanying each product.

Ordering Information

Sonoma™ One Level Plates

Catalog Number	Description
20-0114	Anterior Cervical Plate, 14mm
20-0116	Anterior Cervical Plate, 16mm
20-0118	Anterior Cervical Plate, 18mm
20-0120	Anterior Cervical Plate, 20mm
20-0122	Anterior Cervical Plate, 22mm
20-0124	Anterior Cervical Plate, 24mm
20-0126	Anterior Cervical Plate, 26mm

Sonoma Three Level Plates

Catalog Number	Description
20-0345	Anterior Cervical Plate, 45mm
20-0348	Anterior Cervical Plate, 48mm
20-0351	Anterior Cervical Plate, 51mm
20-0354	Anterior Cervical Plate, 54mm
20-0357	Anterior Cervical Plate, 57mm
20-0360	Anterior Cervical Plate, 60mm
20-0363	Anterior Cervical Plate, 63mm
20-0366	Anterior Cervical Plate, 66mm
20-0369	Anterior Cervical Plate, 69mm

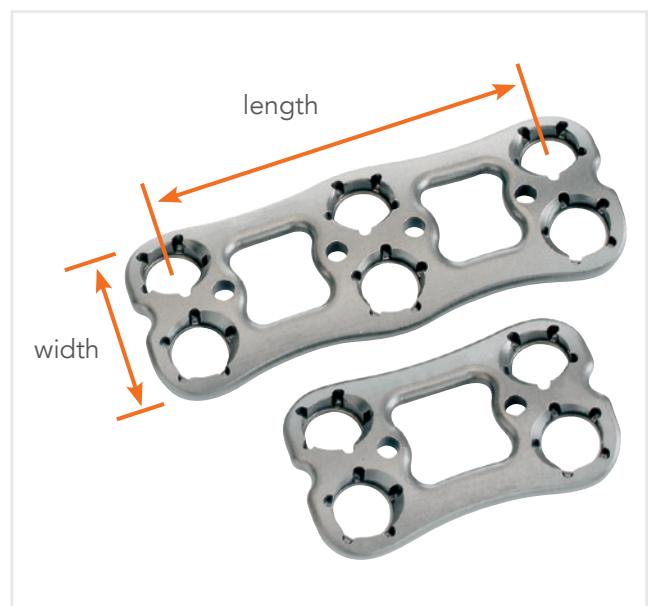
Sonoma Two Level Plates

Catalog Number	Description
20-0228	Anterior Cervical Plate, 28mm
20-0231	Anterior Cervical Plate, 31mm
20-0234	Anterior Cervical Plate, 34mm
20-0237	Anterior Cervical Plate, 37mm
20-0240	Anterior Cervical Plate, 40mm
20-0243	Anterior Cervical Plate, 43mm
20-0246	Anterior Cervical Plate, 46mm

Sonoma Four Level Plates

Catalog Number	Description
20-0460	Anterior Cervical Plate, 60mm
20-0464	Anterior Cervical Plate, 64mm
20-0468	Anterior Cervical Plate, 68mm
20-0472	Anterior Cervical Plate, 72mm
20-0476	Anterior Cervical Plate, 76mm
20-0480	Anterior Cervical Plate, 80mm
20-0484	Anterior Cervical Plate, 84mm

► **Note:** Plates are measured from the middle of the superior screw hole to the middle of the most inferior screw hole.



4.0mm Variable Screws

Catalog Number	Description
23-4012	Variable Bone Screw, 4.0 x 12mm
23-4014	Variable Bone Screw, 4.0 x 14mm
23-4016	Variable Bone Screw, 4.0 x 16mm



4.5mm Variable Screws

Catalog Number	Description
21-4512	Variable Bone Screw, 4.5 x 12mm
21-4514	Variable Bone Screw, 4.5 x 14mm
21-4516	Variable Bone Screw, 4.5 x 16mm



4.0mm Limited Angle Screws

Catalog Number	Description
20-4012	Limited Angle Bone Screw, 4.0 x 12mm
20-4014	Limited Angle Bone Screw, 4.0 x 14mm
20-4016	Limited Angle Bone Screw, 4.0 x 16mm



4.5mm Limited Angle Screws

Catalog Number	Description
22-4512	Limited Angle Bone Screw, 4.5 x 12mm
22-4514	Limited Angle Bone Screw, 4.5 x 14mm
22-4516	Limited Angle Bone Screw, 4.0 x 16mm



4.0mm Self-Drilling Variable Screws (optional)

Catalog Number	Description
21-8012	Self-Drilling Variable Bone Screw, Single Lead, 4.0mm x 12mm
21-8014	Self-Drilling Variable Bone Screw, Single Lead, 4.0mm x 14mm
21-8016	Self-Drilling Variable Bone Screw, Single Lead, 4.0mm x 16mm



Instruments

Catalog Number	Description
92-0110	Cervical Awl
92-0111	Removal Tool
92-0115	Cervical Plate Bender
92-0117	Small Temporary Fixation Pin
92-0118	Large Temporary Fixation Pin
92-0120	Cervical Screw Driver
92-0121	Ball Tip Screw Driver
92-0130	Quick Connect Handle
92-0143	Variable Drill Guide
92-0148	Limited Angle Guide
92-0122	Extractor
92-0126	Extractor Block

Optional Instruments

Catalog Number	Description
92-0155	Small Smooth Temporary Fixation Pin
92-0112	Plate Bending Pliers
92-0141	All-In-One Guide
92-0144	Double Barrel Variable Guide
92-0147	Double Barrel All-In-One Guide
92-0109	Awl with Sleeve
92-0113	Tap, Single Lead
92-0114	Tap, Double Lead
92-0119	Plate Holder, Inner
92-0125	Plate Holder, Outer

Drills

Catalog Number	Description
92-0182	2mm Drill
92-0184	14mm Drill
92-0186	16mm Drill

Indications for Use

This system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with:

- degenerative disc disease (DDD) as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,

- trauma (including fracture),
- primary and metastatic malignant tumors
- deformity (defined as kyphosis, lordosis or scoliosis),
- pseudoarthrosis,
- failed previous fusion, and/or
- spinal cord stenosis and cervical myelopathy.

Contraindications

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

Absolute contraindications:

- Infection in or around the operative site
- Allergy or sensitivity to implant materials
- Any case not described in the indication

Relative contraindications:

- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- Prior fusion at the level(s) to be treated
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any case not requiring bone graft and fusion or where fracture healing is not required
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support
- Bone immaturity
- The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the postoperative instructions
- Any case where implant utilization would interfere with anatomical structures or expected physiological performance
- Use of incompatible materials from other systems

Warnings and Precautions

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to severe spondylolisthesis, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.

The implantation of this system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system

Ensure all implants, components or instruments are sterilized prior surgery. The use of non-sterile devices may lead to inflammation, infection or disease.

Implants should never be reused under any circumstances. A used implant should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. The risks include, but are not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. The ACP System should not be used with components from any other system or manufacturer. As with all orthopedic implants, the ACP System should never be reused under any circumstances.

SeaSpine Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.



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



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