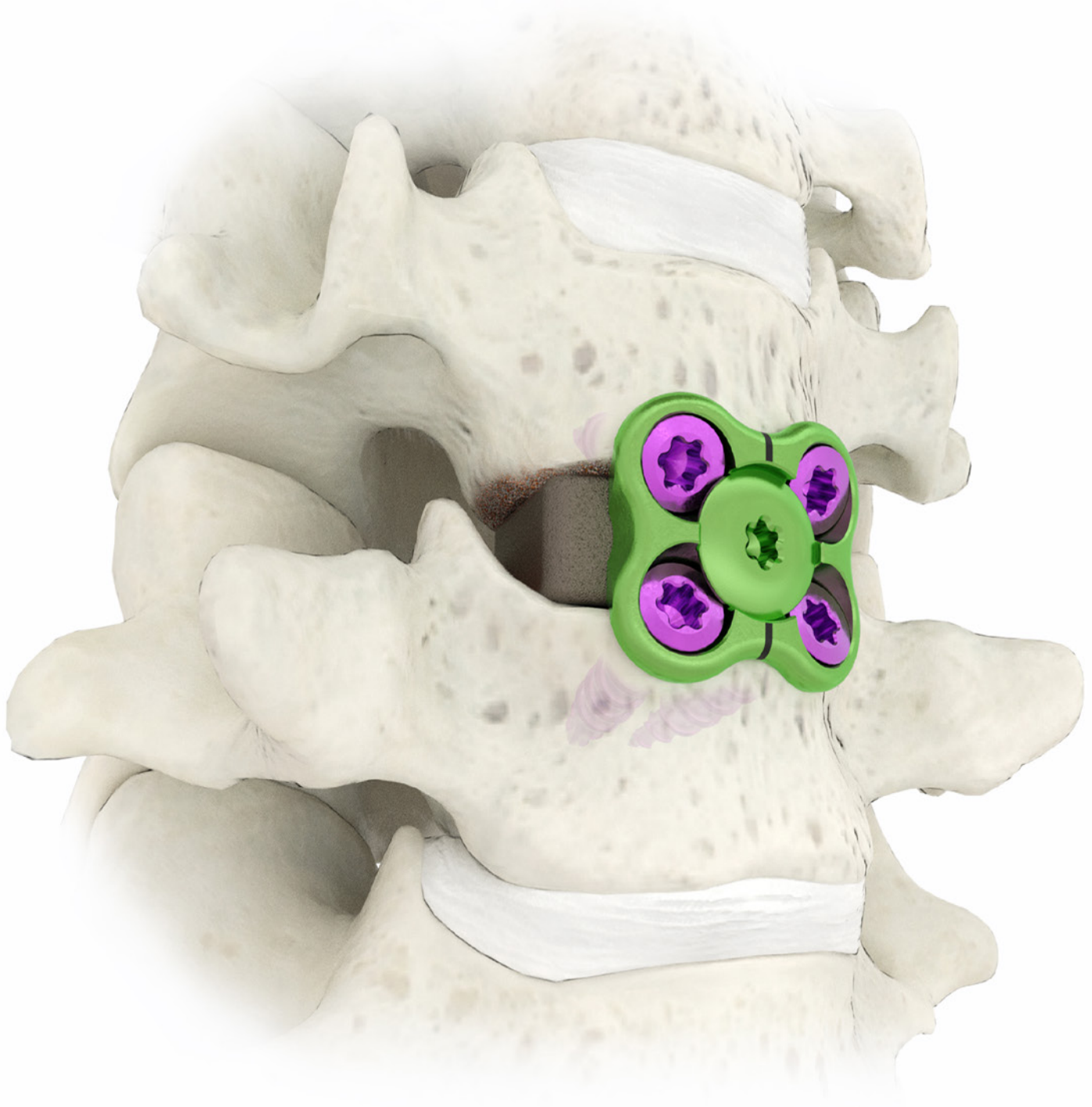




SHORELINE® ACS

ANTERIOR CERVICAL FIXATION SYSTEM
SURGICAL TECHNIQUE

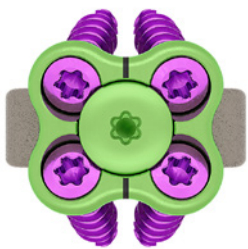
CONTENTS

SHORELINE® ACS

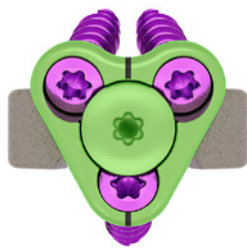
DESIGN RATIONALE	4	TruProfile® Implantation.....	24
SYSTEM FEATURES.....	5	Step 5: TruProfile Assembly	25–26
SURGICAL TECHNIQUE	6–34	Step 6: TruProfile Insertion.....	27–28
Step 1: Access.....	6	Step 7: TruProfile Screw Preparation.....	29
Step 2: Discectomy & Endplate Preparation.....	7	Step 8: TruProfile Screw Placement	30
Step 3: Implant Sizing.....	8–9	Step 9: TruProfile Final Locking	31
Step 4: Implant Selection.....	10	Step 10: TruProfile Verify Final Implant Position	32
No-profile Implantation	11	Step 11: TruProfile Closure	32
Step 5a: No-profile Insertion	12–13	TruProfile Implant Removal	33
Step 6a: No-profile Screw Preparation.....	14–15	ORDERING INFORMATION.....	34–43
Step 7a: No-profile Screw Placement.....	16–17	Tray Configuration	36–37
Step 5b: No-profile Insertion Using Optional DTS Guide	18	Instrumentation	38–41
Step 6b: No-profile Screw Preparation Using Optional DTS Guide	19	Interbody Totes.....	42–43
Step 7b: No-profile Screw Placement Using Optional DTS Guide	20	INSTRUCTIONS FOR USE	44–47
Step 8: No-profile Final Locking	21	Indications for Use.....	46
Step 9: No-profile Verify Final Implant Position	22	Contraindications.....	46
Step 10: No-profile Closure	22	Sterilization For NanoMetalene® Implants	47
No-profile Implant Removal	23	Cleaning & Sterilization	47

DESIGN RATIONALE

The Shoreline® ACS is a premier product providing TruProfile® and No-profile cervical spinal fixation and realignment with ultimate system flexibility, complete construct modularity, and streamlined instrumentation.



TruProfile construct
with 4-hole plate
designed for
maximum fixation



TruProfile construct
with 3-hole plate
designed for
adjacent level surgery



TruProfile construct
with 2-hole plate
designed for
maximum efficiency



No-profile 2-hole construct
2-hole construct
designed for
adjacent level surgery

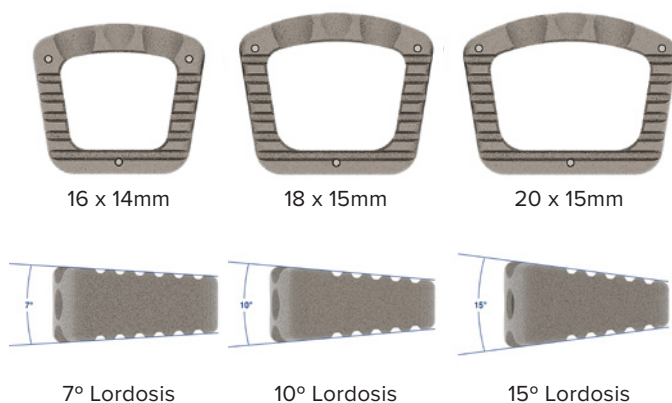
TruProfile Features

- 2-, 3-, 4-hole plate options
- NanoMetalene® surface technology
- Maximized graft aperture
- Minimized adjacent level plate overhang
- Three footprint and lordosis options

No-profile Features

- Threaded locking cover
- NanoMetalene surface technology
- Maximized graft aperture
- Two footprint options
- 7° of lordosis

TruProfile Footprint Options



No-profile Footprint Options



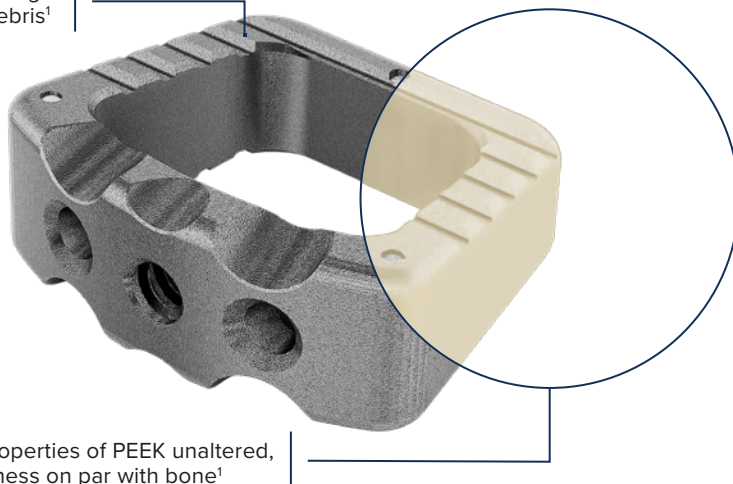
SHORELINE[®] ACS

ANTERIOR CERVICAL FIXATION SYSTEM

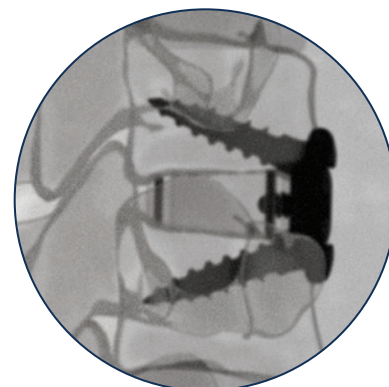
NANOMETALENE[®] TECHNOLOGY

Submicron titanium layer molecularly bonded to entire PEEK implant

Titanium surfacing
resists wear debris¹

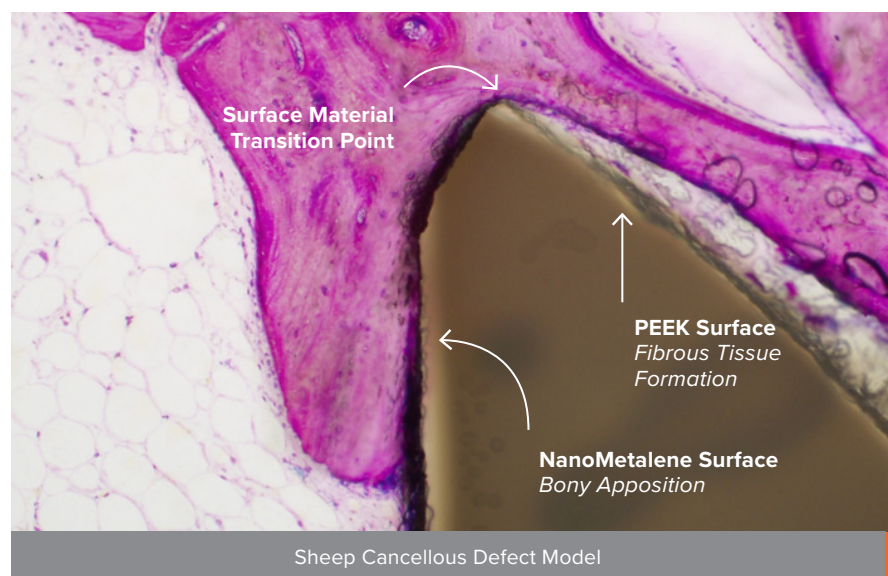


Mechanical properties of PEEK unaltered,
providing stiffness on par with bone¹



Radiolucent for post-op
fusion assessment²

Preclinical results show greater bone ongrowth on NanoMetalene[®] vs. PEEK^{3,†}

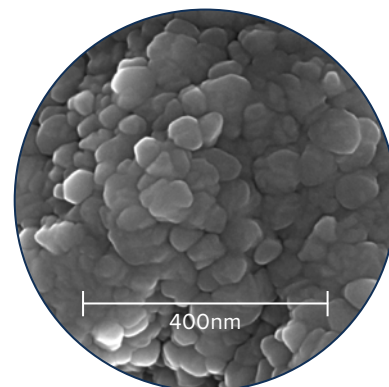


Surface Material
Transition Point

PEEK Surface
Fibrous Tissue
Formation

NanoMetalene Surface
Bony Apposition

Sheep Cancellous Defect Model



Rough submicron topography
encourages integration^{3,4}

[†]Preclinical testing, such as animal studies, may not be indicative of human results.

¹Results from mechanical testing. Data on file. TR-0010-11-01

²Results from imaging study. Data on file. TR-0010-11-01

³Walsh, et al. The in vivo response to a novel Ti coating compared with polyether ether ketone: evaluation of the periphery and inner surfaces of an implant. *Spine Journal* 2018 Jul; 18(7): 1231-1240

⁴NanoMetalene SEM images on file. TR-0094-19-01

STEP 1. ACCESS

Approach the desired level of the anterior cervical spine using the standard ACDF technique (FIG. 01).



FIG. 01

STEP 2. DISECTOMY & ENDPLATE PREPARATION

Remove the disc material and cartilaginous endplates as required to prepare the implantation site and create space for the implant (FIG. 02).

TIP

If the disc space is collapsed, the Disc Wedge may be used as a starter trial to help open the space. If using the TruProfile® implantation, the Plate Template tool should be used to help guide placement of the Caspar pin. This will ensure enough room for the plate when the construct is implanted (FIG. 03).



FIG. 02

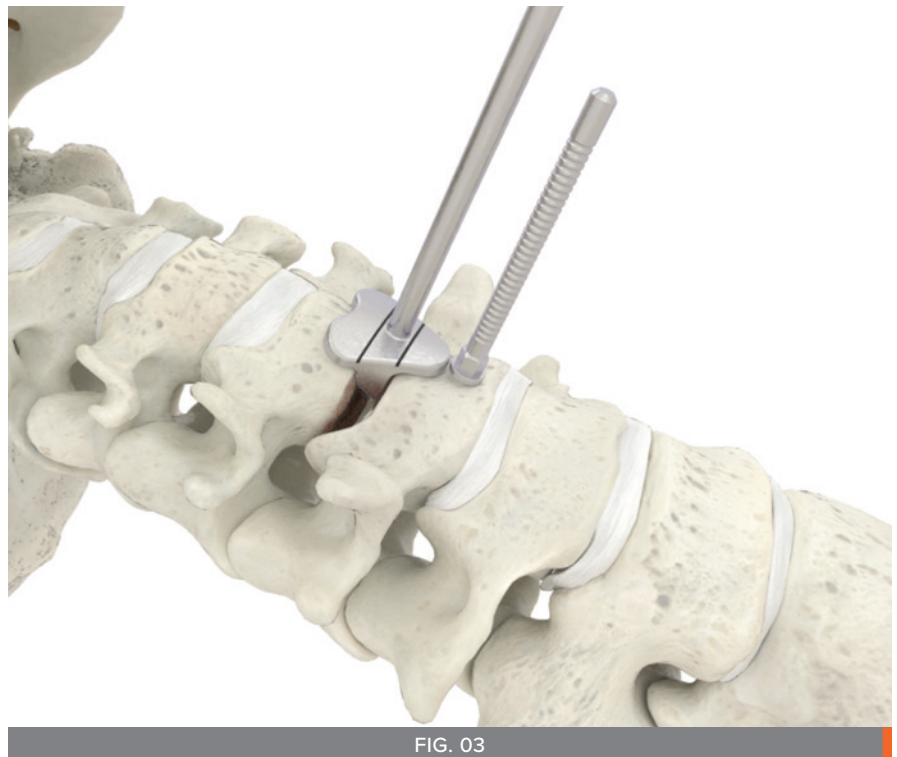


FIG. 03

STEP 3. IMPLANT SIZING

Select the appropriate trials for the desired implant footprint. Insert the trial into the disc space to determine the appropriate implant height (FIG. 04).

TIP

Trials are “line-to-line” with the interbodies.

The trials have built-in stops to set the final implant depth at 1.25mm sub-flush to the anterior surface of the vertebral body.



FIG. 04

STEP 3. IMPLANT SIZING CONTINUED

The trials are color-coded by footprint and height for easy reference. See chart to right:

If using a TruProfile® construct, the trial height and proximal color band should be used to identify the proper plate height and locking cover. The plate and locking cover should match the color band on the trial (FIG. 05).

Footprint

Size	Trial Color
16 x 14mm, NP, TP	Gold
18 x 15mm, NP, TP	Black
20 x 15mm, TP	Chrome

Height

Size	Color Band
5mm	Light Blue
6mm	Purple
7mm	Green
8mm	Dark Blue
9mm	Bronze
10mm	Magenta
11mm	Aqua
12mm	Medium Blue

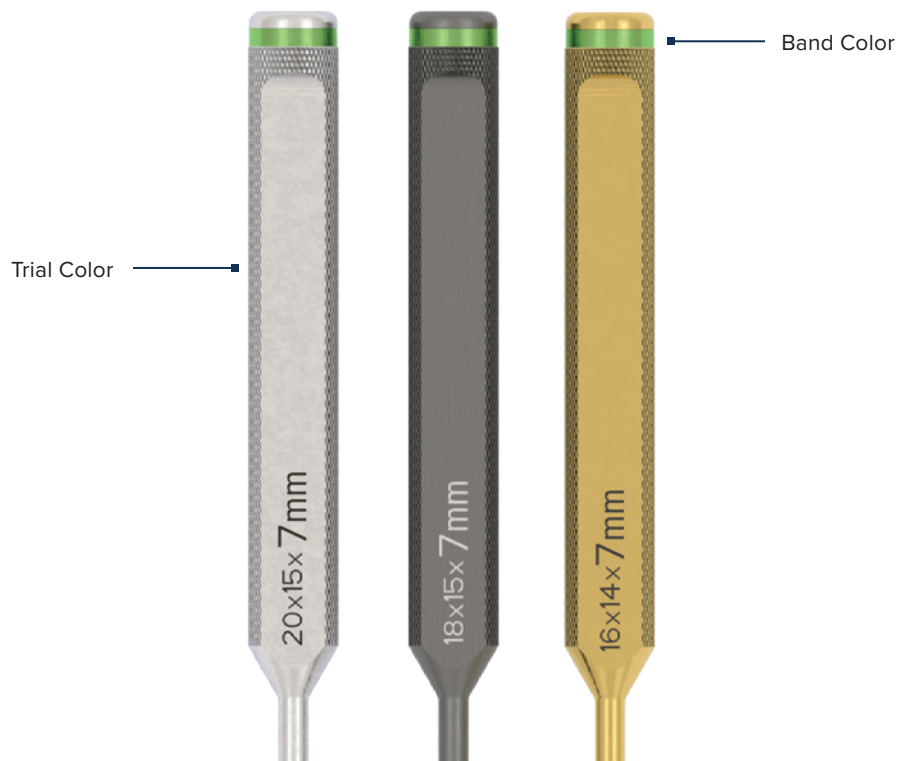


FIG. 05

STEP 4. IMPLANT SELECTION

Select the desired Shoreline® ACS Implant depending on surgeon preference and desired construct to best fit the patient anatomy.

The Shoreline ACS system offers two styles of ACDF construct:

No-profile

Utilizing the No-profile integrated interbody spacer, two screws and a locking cover, this construct provides 2-screw fixation with no additional profile added to the anterior spine. No plate assembly is required (FIG. 06).

TruProfile®

Offering 2-screw, 3-screw or 4-screw fixation when utilizing the TruProfile plate, Shoreline interbody and locking cover (FIG. 07).

Shoreline interbodies come sterile packaged. Review the box and ensure the tamper seal is intact. Also, review the label for correct footprint and height prior to opening.

CAUTION

Due to sterile contents, once package seal has been broken, it cannot be returned to the manufacturer.

Once the box is opened, refer to the IFU for handling and transfer of implant to sterile field.



FIG. 06



FIG. 07

NO-PROFILE IMPLANTATION

STEP 5A. NO-PROFILE INSERTION

Load the Shoreline® No-profile interbody onto the stopped inserter and turn the knurled knob on the proximal end clockwise until the implant is fully engaged. Do not over-tighten (FIG. 08).

TIP

The No-profile implants have no required directionality and can be inserted in either the cranial or caudal orientation depending on surgeon preference and patient needs.

TIP

Graft Packing: Place the appropriate Shoreline implant into the packing block and insert bone graft into the central cavity. The graft tamp may be used to pack the graft material.

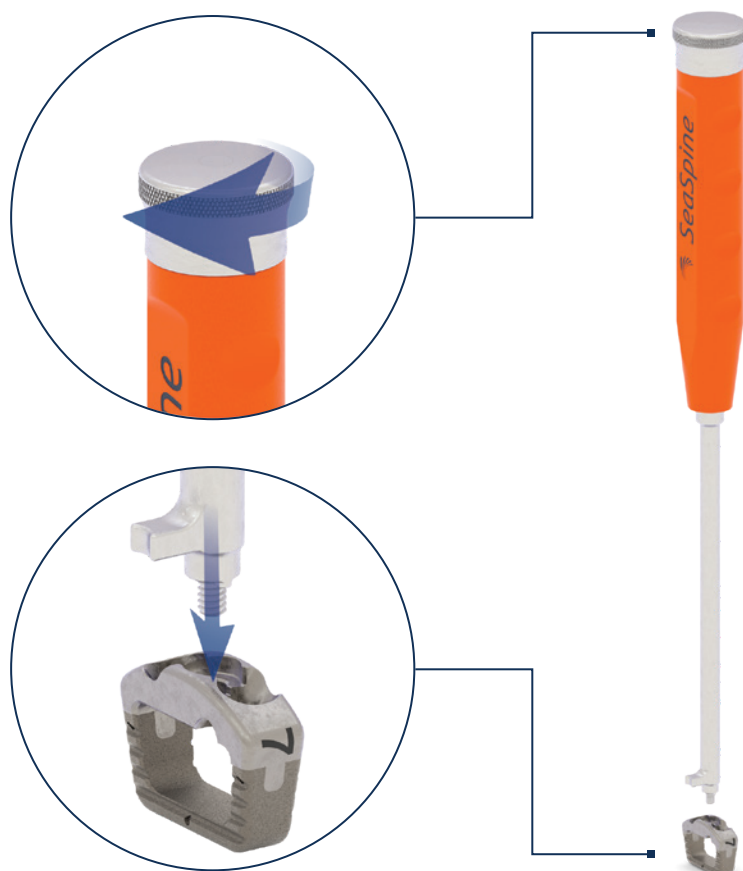


FIG. 08

STEP 5A. NO-PROFILE INSERTION CONTINUED

Gently impact the No-profile implant into the disc space using a cervical mallet (FIG. 09). Once the implant is properly positioned 1mm sub-flush to the spine, remove the inserter leaving the implant in place.

Remove the inserter by turning the knurled inserter knob counterclockwise to disengage from the implant. Once disengaged, simply pull up on the inserter (FIG. 10).

Remove the Caspar pins.



FIG. 09



FIG. 10

STEP 6A. NO-PROFILE SCREW PREPARATION

Once the No-profile implant has been delivered into the disc space, select the desired awl or drill to create the pilot holes (FIG. 11).

The Shoreline® system offers both straight and angled instruments for screw preparation.

No-profile screw prep options:

- Angled Guide, Fixed
- Angled Guide, Variable
- Straight Awl, 10mm
- Straight Drills, 12mm and 14mm
- Angled Awl
- DTS Guide
- Angled DTS Awl
- Straight DTS Drill

Cranial/Caudal angulation:

- 35° Fixed
- $\pm 8^\circ$ Variable
- 43° Maximum

Medial/Lateral angulation (per screw):

- 10° Fixed
- $\pm 8^\circ$ Variable
- 18° Maximum



FIG. 11

STEP 6A. NO-PROFILE SCREW PREPARATION CONTINUED

The angled awl can be used in areas where the anatomy prohibits the use of straight instrumentation (FIG. 12).

TIP

Use the down force handle if more downward force is desired when using the angled awl.

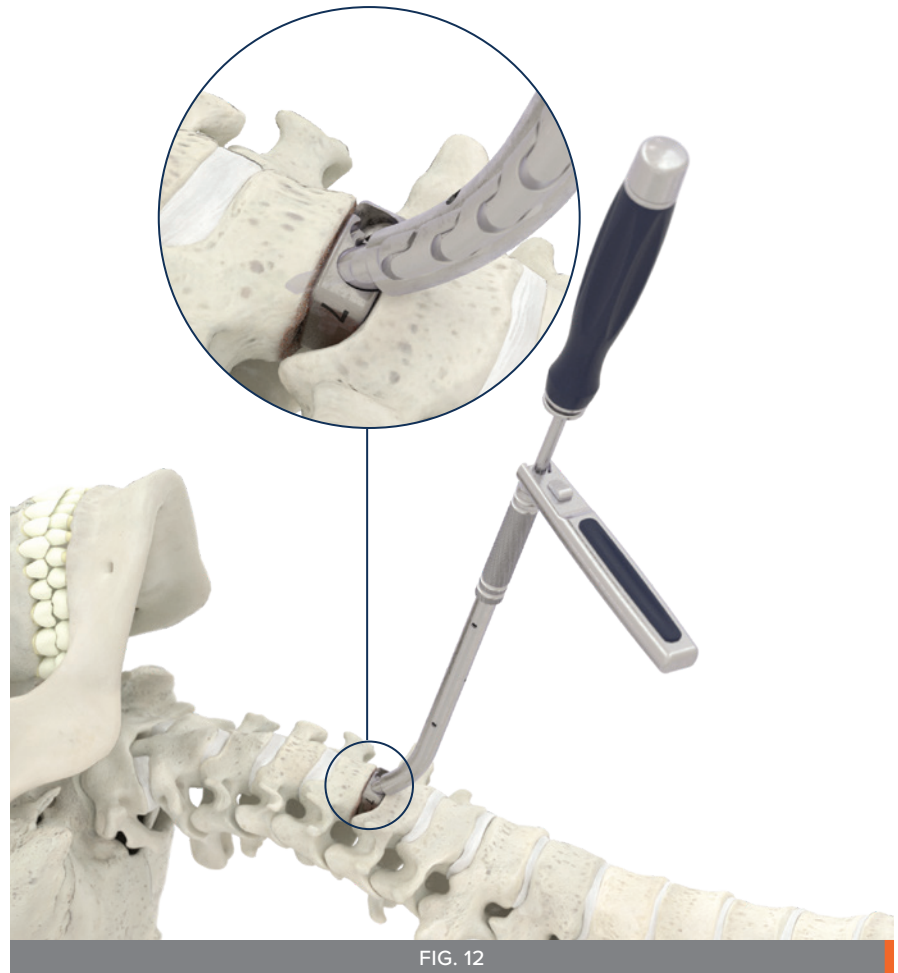


FIG. 12

STEP 7A. NO-PROFILE SCREW PLACEMENT

Once screw holes have been prepared, select the desired screws to be used for final construct fixation (FIG. 13).

TIP

Use the Straight Screwdriver when possible for best control.

Shoreline® ACS screw options:

- 3.5 or 4.0mm
- Self-drilling or self-tapping
- Fixed or variable
- Lengths 10–18mm

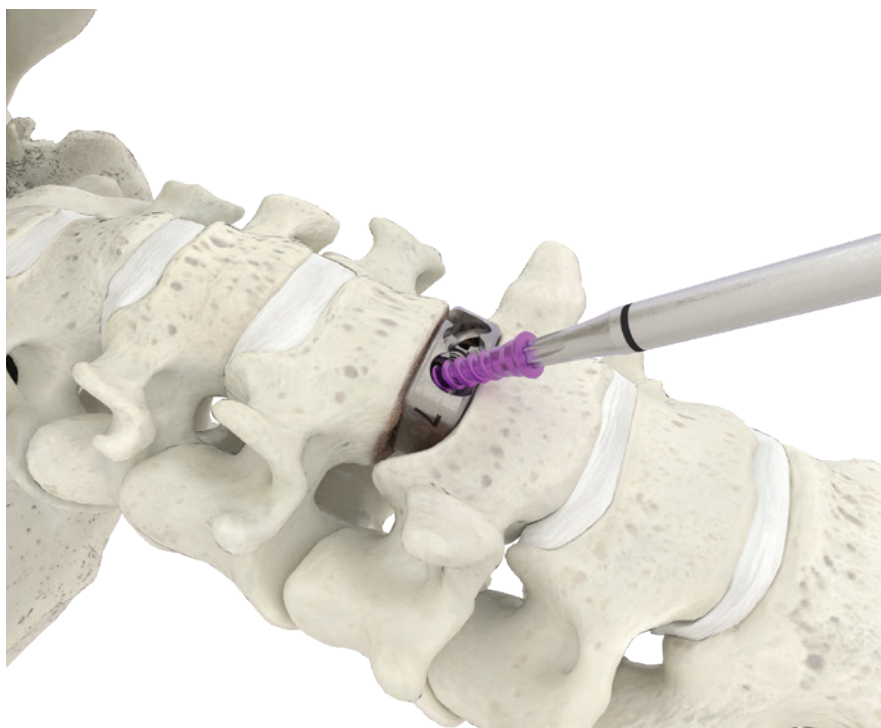
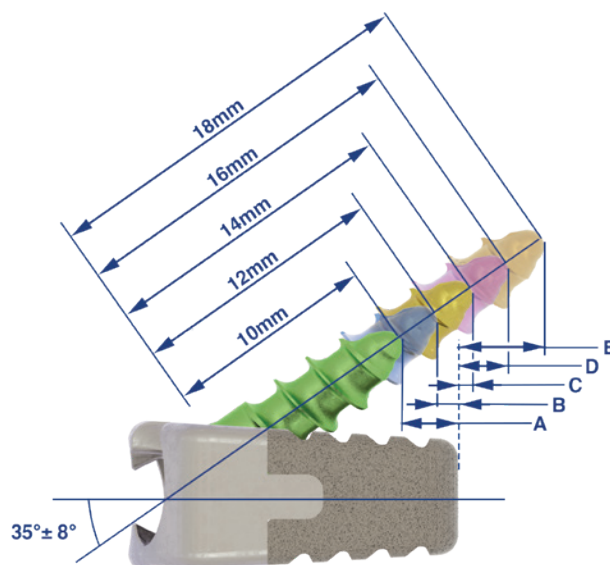


FIG. 13

No-Profile Implant

Screw Length	10mm	12mm	14mm	16mm	18mm
16 x 14mm	-1.7	-0.1	1.6	3.2	4.8
18 x 15mm	-2.7 (A)	-1.1 (B)	.5 (C)	2.2 (D)	3.8 (E)

Depths are calculated at 35° C/C and 10° M/L (Depth relative to posterior wall)



STEP 7A. NO-PROFILE SCREW PLACEMENT CONTINUED

The screws are color-coded by length. See chart to right:

After the desired screws have been identified, load the screws on the drivers by stabbing and grabbing them out of the caddy. Next, drive the screws into place using an alternating pattern until both screws are fully seated within the implant (FIG. 14).

NOTE

Straight and angled screwdrivers are available.

TIP

Use the down force handle if more downward force is desired when using the angled screwdriver.

Screw Chart

Length	Screw Color
10mm	Green
12mm	Medium Blue
14mm	Gold
16mm	Magenta
18mm	Bronze
20mm*	Purple

*Size not included in standard set



FIG. 14

STEP 5B. NO-PROFILE INSERTION USING OPTIONAL DTS GUIDE

Once interbody height is selected from trials, select the corresponding DTS guide from the SHORDTS tray (e.g., if 7mm height was selected use the corresponding 7mm DTS guide). Press-fit the DTS guide onto the DTS inserter until it snaps into place (FIG. 15).

Then thread onto corresponding No-profile implant ensuring the holes of the DTS guide are correctly aligned with the No-profile interbody (FIG. 16).

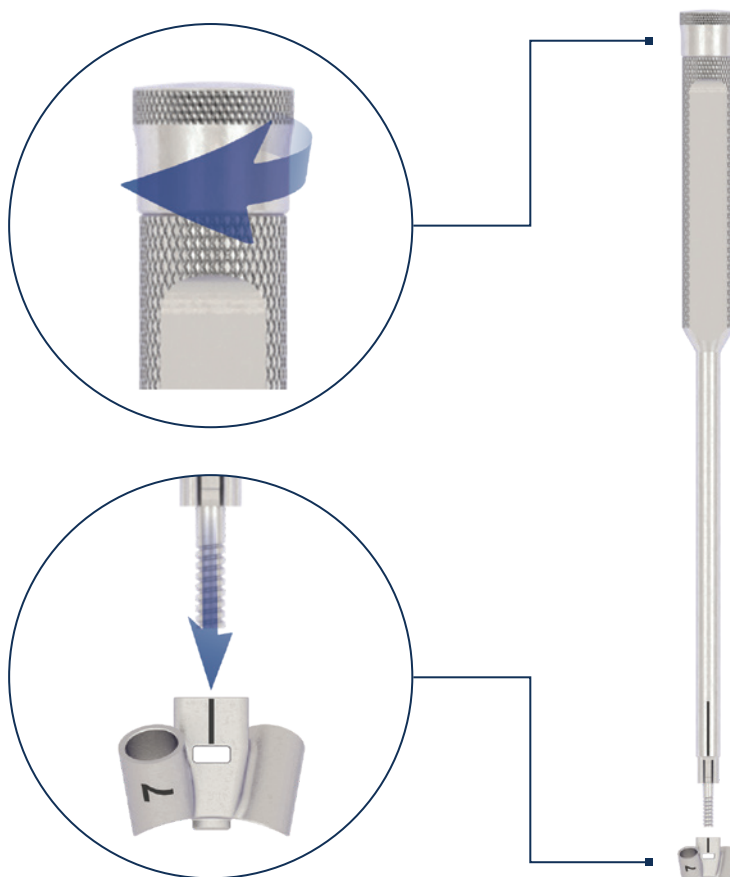


FIG. 15



FIG. 16

STEP 6B. NO-PROFILE SCREW PREPARATION USING OPTIONAL DTS GUIDE

Gently impact the No-profile implant into the disc space using a cervical mallet until the DTS guide is flush to the spine. Select the desired straight DTS drill or DTS awl, or angled DTS awl to create the pilot holes (FIG. 17).



FIG. 17

STEP 7B. NO-PROFILE SCREW PLACEMENT USING OPTIONAL DTS GUIDE

Once screw holes have been prepared, select the desired screws to be used for final construct fixation. The straight or angled screwdriver can be used to place the screws (FIG. 18).

When both screws are fully inserted, rotate distal knob on DTS inserter counterclockwise to disengage.



FIG. 18

STEP 8. NO-PROFILE FINAL LOCKING

With the screws snugged in their final position, sub-flush to the anterior surface of the implant, select and deliver the appropriate height locking cover and final tighten clockwise until the final torque breaks away (FIG. 19). Once the handle provides an audible click, the construct will be complete and final tightened at 5 in-lbs.

TIP

There are two No-profile locking covers that cover all implant heights. See chart.

No-profile Locking Cover

Height	Color
6–7mm	Blue
8–12mm	Gray

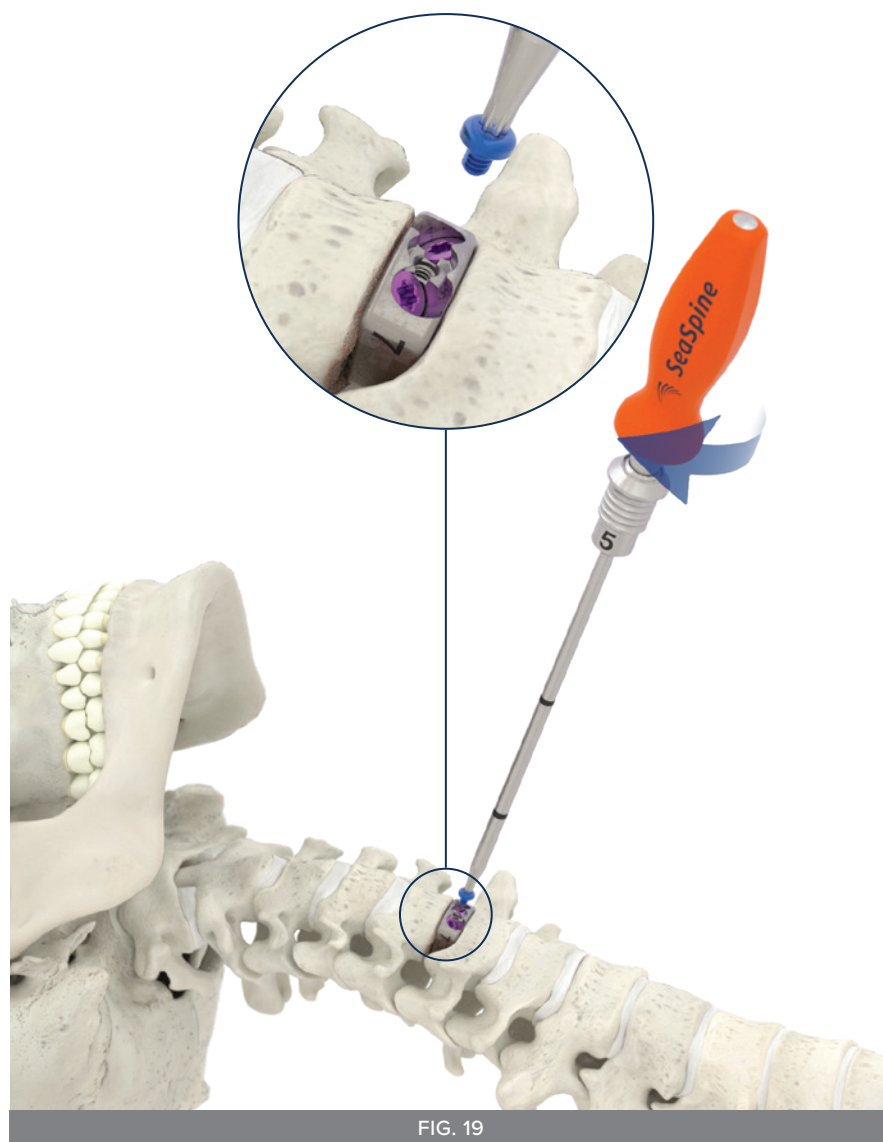


FIG. 19

STEP 9. NO-PROFILE VERIFY IMPLANT POSITION

Using fluoroscopy, verify final anterior/posterior and lateral positioning is satisfactory (FIG. 20).

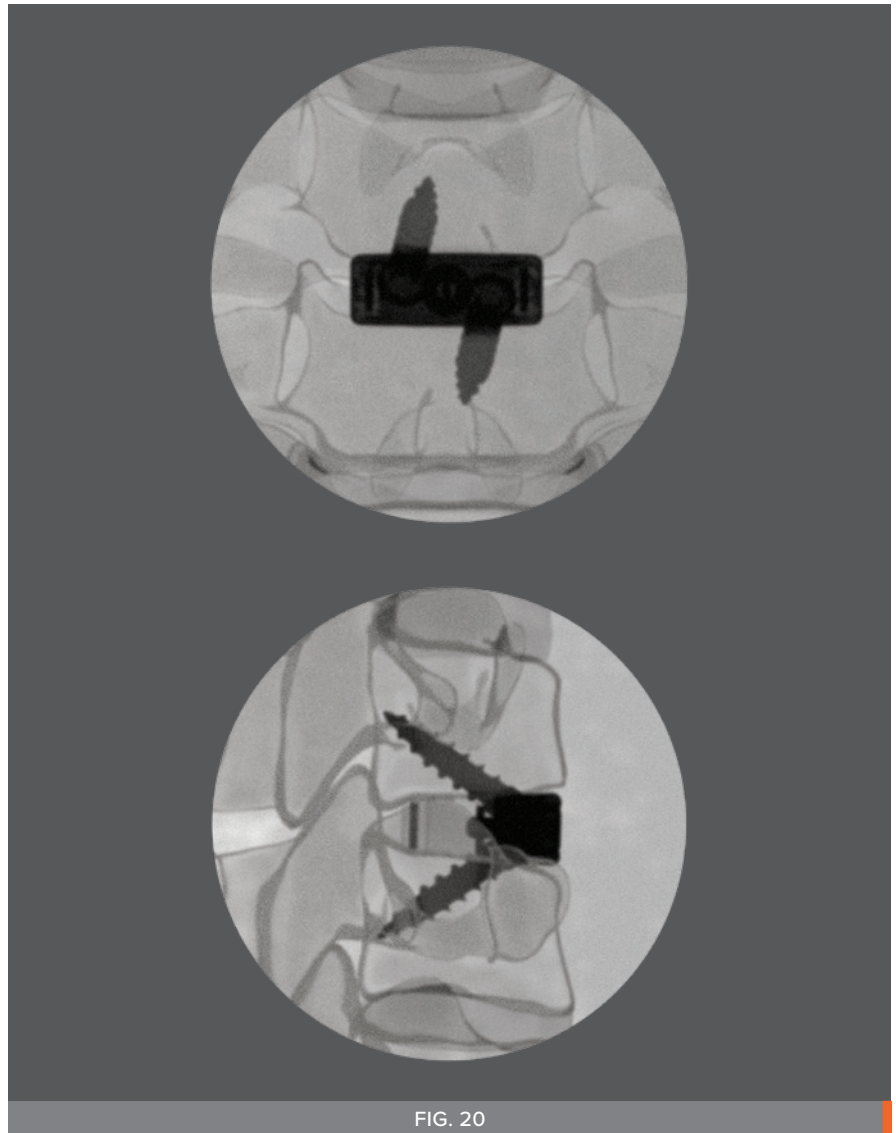


FIG. 20

STEP 10. NO-PROFILE CLOSURE

Close the surgical site using the standard closure technique required for the procedure.

REMOVAL. NO-PROFILE IMPLANT REMOVAL

If removal of the No-profile implant is necessary, remove the locking cover and screws using the appropriate drivers. Next, thread the inserter onto the implant by tightening the proximal knob until snug. Do not over-tighten (FIG. 21).

Once the implant is fully re-engaged with the inserter, gently rock the assembly medial/laterally and pull up to remove from the disc space.



FIG. 21

TRUPROFILE® IMPLANTATION

STEP 5. TRUPROFILE® ASSEMBLY

Assemble the desired TruProfile® plate with the Shoreline® interbody of choice. Press the plate alignment pins into the holes on the interbody. Ensure that the plate sits flush on the interbody (FIG. 22).

TIP

The Plate Assembly Tool can be used to press the plate onto the interbody (FIG. 23).

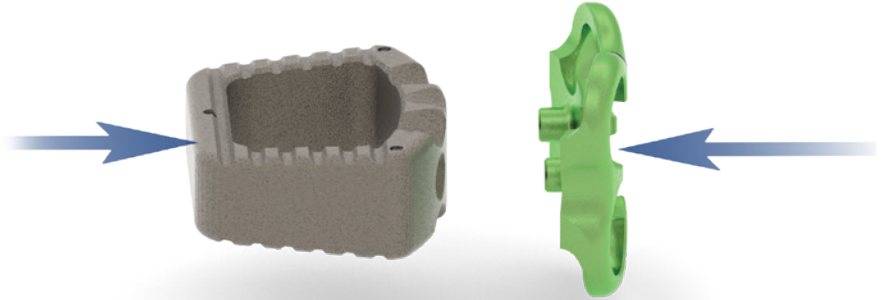


FIG. 22

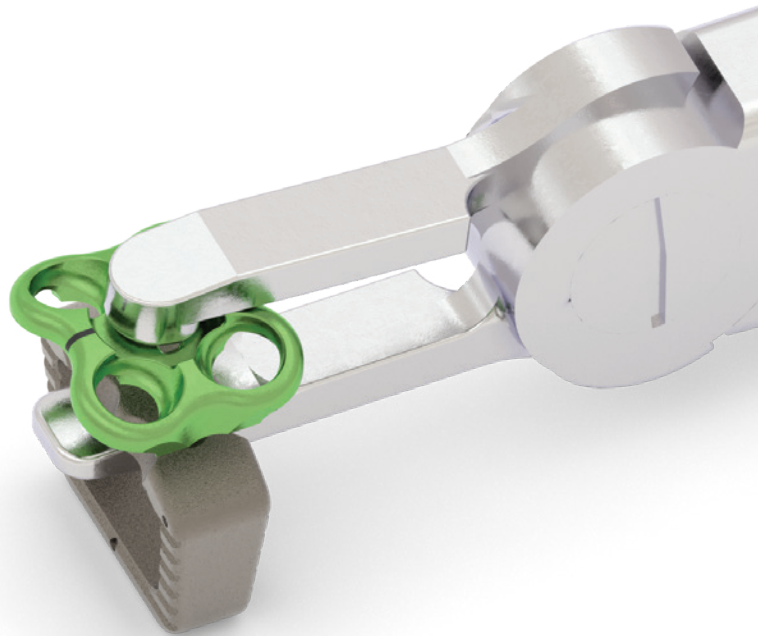


FIG. 23

STEP 5. TRUPROFILE® ASSEMBLY CONTINUED

Once the TruProfile® construct is assembled, load it onto the inserter by aligning the laser marked lines on the front of the plate with the laser marked lines on the distal end of the inserter (FIG. 24). Ensure the connection is “line-to-line.” Next, turn the knurled knob on the proximal end of the Inserter clockwise until the implant is fully engaged. Do not over-tighten.

TIP

The TruProfile implants have no required directionality and can be inserted in either the cranial or caudal orientation.

TIP

If the TruProfile plate can be removed by inserting the plate into the cutout surface on the loading block. Place downward pressure on the plate while rocking the interbody away from the plate.

TIP

Graft Packing: Place the TruProfile implant into the Packing Block and insert bone graft into the central cavity. The Graft Tamp may be used to pack the graft material (FIG. 25).



FIG. 24

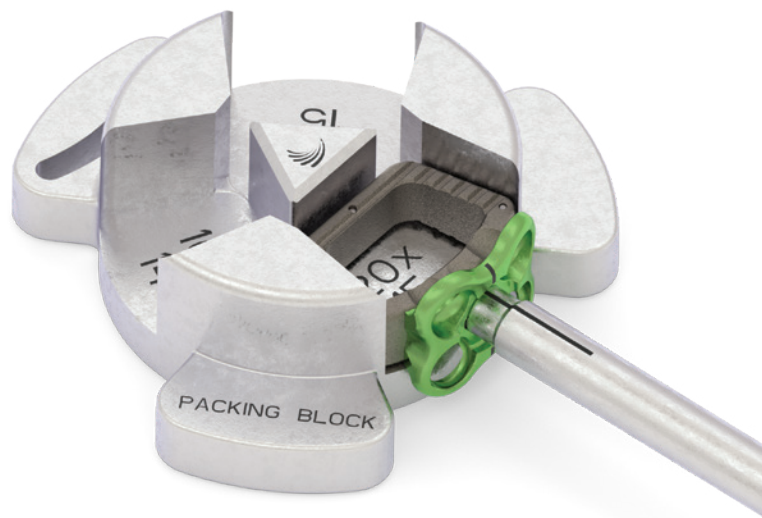


FIG. 25

STEP 6. TRUPROFILE® INSERTION

Ensure proper anterior surface preparation has been performed to remove any large osteophytes.

Gently impact the TruProfile® construct into the disc space using a cervical mallet (FIG. 26).

Once the implant is properly positioned with the plate against the spine, remove the inserter leaving the implant in place.



FIG. 26

STEP 6. TRUPROFILE® INSERTION CONTINUED

Remove the inserter by turning the knurled inserter knob counterclockwise to disengage from the implant. Once disengaged, simply pull up on the inserter.

Remove the Caspar pins (FIG. 27).

TIP

If the plate does not sit flush, check for remaining osteophytes and vertebral body misalignment. In some cases lagging the screws can be done to align the vertebral bodies.

Fluoroscopic imaging may be used to confirm final implant positioning.



FIG. 27

STEP 7. TRUPROFILE® SCREW PREPARATION

Once the TruProfile® Implant has been delivered into the disc space, select the desired awl or drill to create the pilot holes (FIG. 28–29).

TruProfile® Screw Prep Options:

- Straight Guide, Fixed
- Straight Guide, Variable
- Straight Drills, 12 and 14mm
- Straight Taps, 12 and 14mm
- Speed Awl, Fixed, 10mm

Cranial/Caudal Angulation:

- 20° Fixed
- $\pm 8^\circ$ Variable
- 28° maximum

Medial/Lateral Angulation (per screw):

- 10° Fixed
- $\pm 8^\circ$ Variable
- 18° maximum

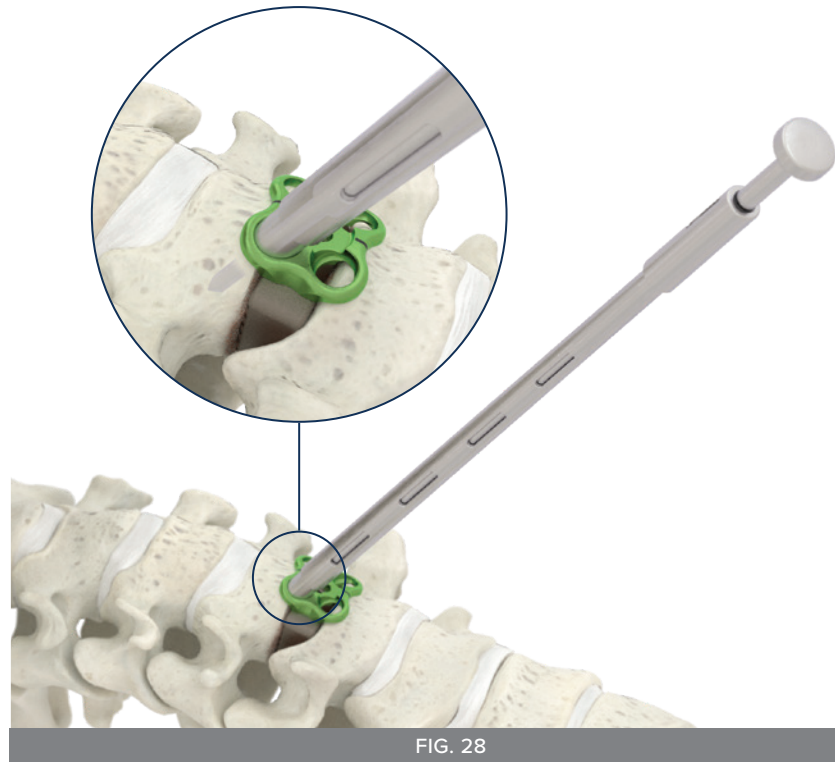


FIG. 28



FIG. 29

STEP 8. TRUPROFILE® SCREW PLACEMENT

Once screw holes have been prepared, select the desired screws to be used for final construct fixation (FIG. 30).

Shoreline® ACS Screw Options:

- 3.5mm or 4.0mm
- Self-drilling or self-tapping
- Fixed or variable
- Lengths: 10–18mm

The screws are color coded by length. See chart below.

Screw Chart

Length	Screw Color
10mm	Green
12mm	Medium Blue
14mm	Gold
16mm	Magenta
18mm	Bronze
20mm*	Purple

*Size not included in standard set

After the desired screws have been identified, load the screws on the drivers by stabbing and grabbing them out of the caddy. Next, drive the screws into place using an alternating pattern until the screws are fully seated within the implant.

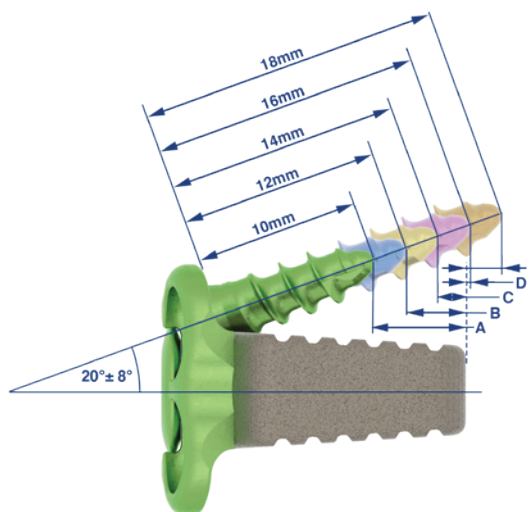


FIG. 30

No-Profile Implant

Screw Length	10mm	12mm	14mm	16mm	18mm
16 x 14mm	-4.3	-2.5	-0.6	1.3	3.2
18 x 15mm	-5.3	-3.5	-1.6	0.3	2.2
20 x 15mm	-5.3 (A)	-3.5 (B)	-1.6 (C)	0.3 (D)	2.2 (E)

Depths are calculated at 20° C/C and 10° M/L (Depth relative to posterior wall)



STEP 9. TRUPROFILE® FINAL LOCKING

With the screws snugged in their final position, sub-flush to the center surface of the plate, select and deliver the appropriate height locking cover and final tighten clockwise until the final torque breaks away (FIG. 31). Once the handle provides an audible click, the construct will be complete and final tightened at 5 in-lbs.

TIP

The TruProfile® Locking Covers are color coded to match the plates by height. See chart below.

Screw Chart

Length	Screw Color
5mm	Light Blue
6mm	Vector Purple
7mm	Green
8mm	Dark Blue
9mm	Bronze
10mm	Magenta
11mm	Aqua
12mm	Medium Blue

TIP

If the locking cover will not torque off, remove cover and utilize a backup locking cover of the same color. The backup cover is denoted by the large black line across the diameter (FIG. 32).



FIG. 31

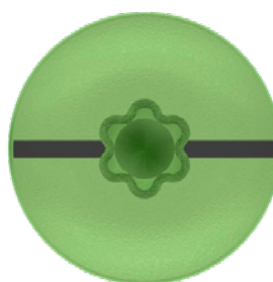


FIG. 32

STEP 10. TRUPROFILE® VERIFY FINAL IMPLANT

Using fluoroscopy, verify final anterior/posterior and lateral positioning is satisfactory (FIG. 33).

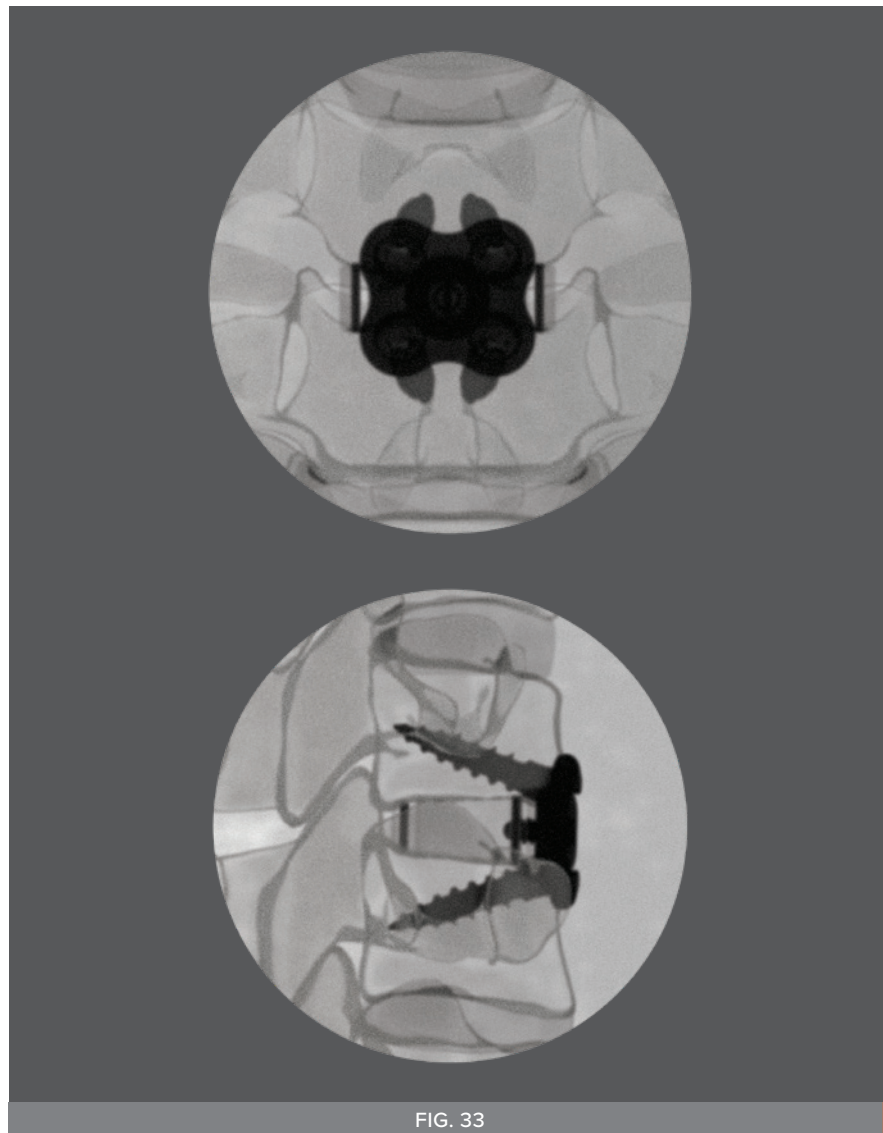


FIG. 33

STEP 11. TRUPROFILE® CLOSURE

Close the surgical site using the standard closure technique required for the procedure.

REMOVAL TRUPROFILE® IMPLANT REMOVAL

If removal of the TruProfile® implant is desired, remove the locking cover and screws using the appropriate drivers. Engage the inserter by aligning the laser-marked lines on the front of the plate with the laser-marked lines on the distal end of the inserter. Ensure the connection is “line-to-line”. Next, turn the knurled knob on the proximal end of the inserter clockwise until the implant is fully engaged. Do not over-tighten (FIG. 34).

Once the implant is fully re-engaged with the inserter, gently rock the assembly medial/laterally and pull up to remove from the disc space.



FIG. 34

ORDERING INFORMATION

TRAY CONFIGURATION SHORINSTFX

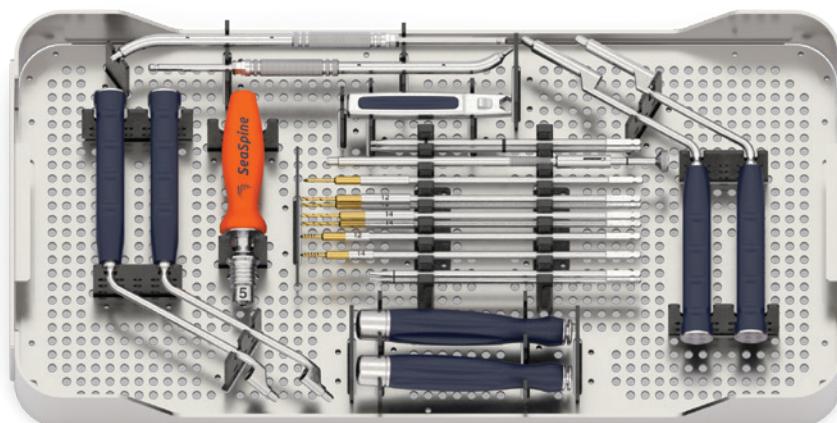
TOP TRAY

Plates, Screws & Locking Covers



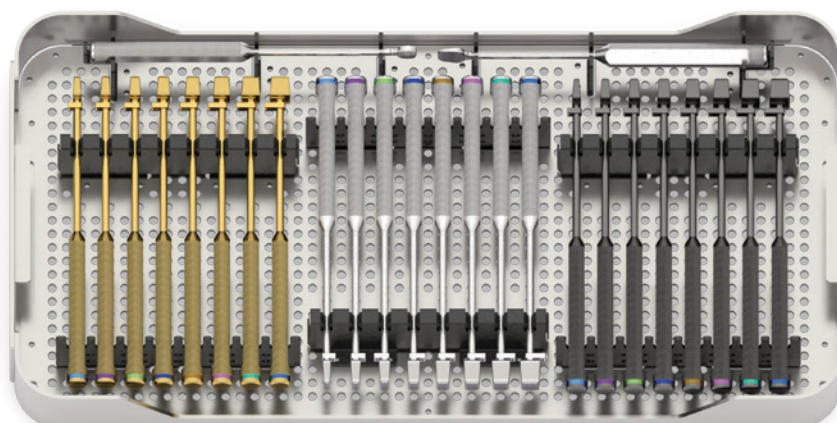
MIDDLE TRAY

Instrumentation



BOTTOM TRAY

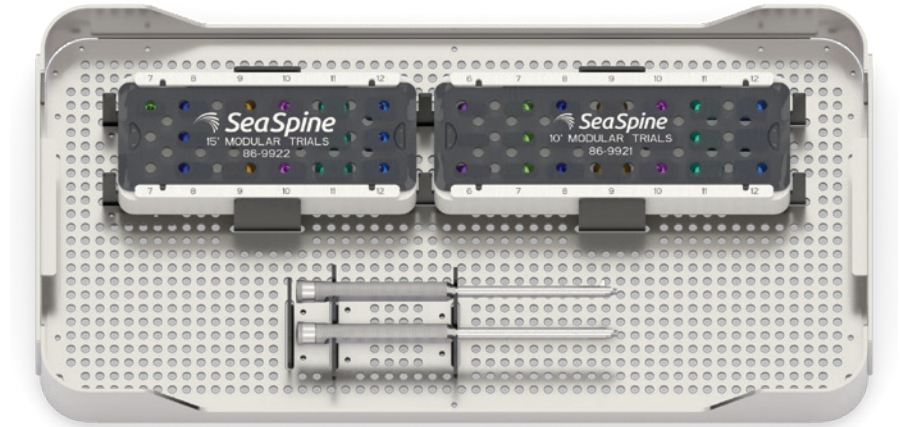
Trials



TRAY CONFIGURATION SHORHLINST & SHORDTS

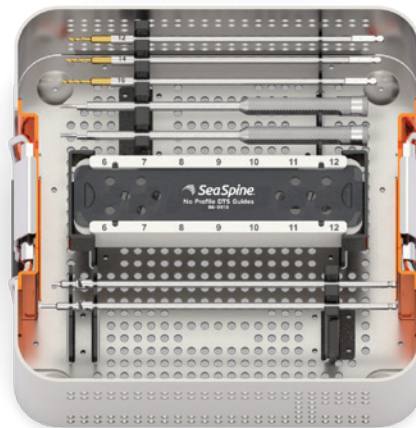
Hyperlordotic Instrument Tray (Optional)

Instrumentation & Modular Trials



DTS No-profile Tray (Optional)

Instrumentation & DTS Guides



INSTRUMENTATION

Inserter

PN 86-0010



Inserters with Stop

PN 86-0011



Rasp, 18 x 15mm

PN 86-0401



Disc Wedge

PN 86-0101



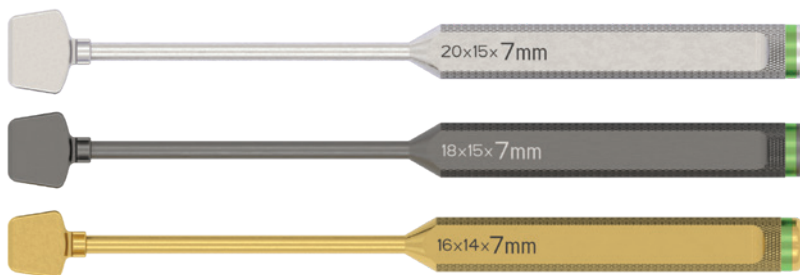
Trial with Depth Stop

PN 86-0207 16 x 14 x 7mm

PN 86-0307 18 x 15 x 7mm

PN 86-0407 20 x 15 x 7mm

*See Ordering Information for additional sizes



Modular Trial Handle

PN 86-2190



Modular Trial Handle with Depth Stop

PN 86-2191



Speed Awl, 10mm

PN 86-0051



INSTRUMENTATION

Awl, 10mm

PN 86-0050



Drill

PN 86-0712 12mm

PN 86-0714 14mm



Tap

PN 86-0812 12mm

PN 86-0814 14mm



DTS Awl, 10mm

PN 86-1021



DTS Drills

PN 86-1022 12mm

PN 86-1024 14mm



Angled DTS Awl, 10mm

PN 86-1121



Angled DTS Driver

PN 86-1130



DTS Guide Inserter

PN 86-1000



DTS Guide

PN 86-1007

*See Ordering Information for additional sizes



INSTRUMENTATION

Angled Awl, 10mm

PN 86-0052



Angled Screwdriver

PN 86-0031



Screwdriver

PN 86-0030



Locking Cover Driver

PN 86-0040



Implant Tamp

PN 86-0071



Plate Template, Flat

PN 86-0103



Universal AO Handle

PN 86-9801



Downforce Handle

PN 86-0026



Locking Cover Torque Handle 5 in-lbs

PN 86-9802



INSTRUMENTATION

Angled Drill Guide, Variable

PN 86-0022



Angled Drill Guide, Fixed

PN 86-0025



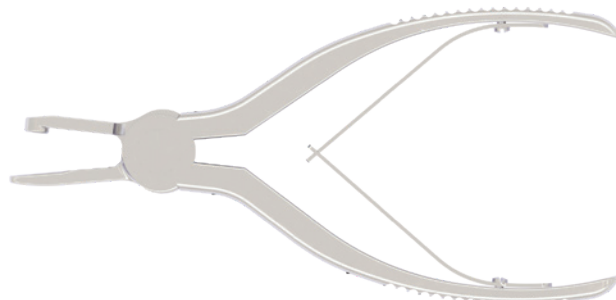
Packing Block

PN 86-0072



Plate Assembly Tool

PN 86-1128



INTERBODY TOTES: SHORELINE® NO-PROFILE INTERBODIES

SHORNPS: 16 x 14mm Implants

Part Number	Part Description
85-0206-S	Spacer, 16 x 14 x 6mm, 7°, Sterile
85-0207-S	Spacer, 16 x 14 x 7mm, 7°, Sterile
85-0208-S	Spacer, 16 x 14 x 8mm, 7°, Sterile
85-0209-S	Spacer, 16 x 14 x 9mm, 7°, Sterile
85-0210-S	Spacer, 16 x 14 x 10mm, 7°, Sterile
85-0211-S	Spacer, 16 x 14 x 11mm, 7°, Sterile
85-0212-S	Spacer, 16 x 14 x 12 mm, 7°, Sterile
U89-0018	Product Case, Small, Sterile Pack

SHORNPM: 18 x 15mm Implants

Part Number	Part Description
85-0306-S	Spacer, 18 x 15 x 6mm, 7°, Sterile
85-0307-S	Spacer, 18 x 15 x 7mm, 7°, Sterile
85-0308-S	Spacer, 18 x 15 x 8mm, 7°, Sterile
85-0309-S	Spacer, 18 x 15 x 9mm, 7°, Sterile
85-0310-S	Spacer, 18 x 15 x 10mm, 7°, Sterile
85-0311-S	Spacer, 18 x 15 x 11mm, 7°, Sterile
85-0312-S	Spacer, 18 x 15 x 12mm, 7°, Sterile
U89-0018	Product Case, Small, Sterile Pack

INTERBODY TOTES: SHORELINE® TRUPROFILE® INTERBODIES

SHORTPS: 16 x 14mm Implants

Part Number	Part Description
85-0905-S	Interbody, 16 x 14 x 5mm, 7°, Sterile
85-0906-S	Interbody, 16 x 14 x 6mm, 7°, Sterile
85-0907-S	Interbody, 16 x 14 x 7mm, 7°, Sterile
85-0908-S	Interbody, 16 x 14 x 8mm, 7°, Sterile
85-0909-S	Interbody, 16 x 14 x 9mm, 7°, Sterile
85-0910-S	Interbody, 16 x 14 x 10mm, 7°, Sterile
85-0911-S	Interbody, 16 x 14 x 11mm, 7°, Sterile
85-0912-S	Interbody, 16 x 14 x 12mm, 7°, Sterile
U89-0018	Product Case, Small, Sterile Pack

SHORTPL: 20 x 15mm Implants

Part Number	Part Description
85-1105-S	Interbody, 20 x 15 x 5mm, 7°, Sterile
85-1106-S	Interbody, 20 x 15 x 6mm, 7°, Sterile
85-1107-S	Interbody, 20 x 15 x 7mm, 7°, Sterile
85-1108-S	Interbody, 20 x 15 x 8mm, 7°, Sterile
85-1109-S	Interbody, 20 x 15 x 9mm, 7°, Sterile
85-1110-S	Interbody, 20 x 15 x 10mm, 7°, Sterile
85-1111-S	Interbody, 20 x 15 x 11mm, 7°, Sterile
85-1112-S	Interbody, 20 x 15 x 12mm, 7°, Sterile
U89-0018	Product Case, Small, Sterile Pack

SHORTPM: 18 x 15mm Implants

Part Number	Part Description
85-1005-S	Interbody, 18 x 15 x 5mm, 7°, Sterile
85-1006-S	Interbody, 18 x 15 x 6mm, 7°, Sterile
85-1007-S	Interbody, 18 x 15 x 7mm, 7°, Sterile
85-1008-S	Interbody, 18 x 15 x 8mm, 7°, Sterile
85-1009-S	Interbody, 18 x 15 x 9mm, 7°, Sterile
85-1010-S	Interbody, 18 x 15 x 10mm, 7°, Sterile
85-1011-S	Interbody, 18 x 15 x 11mm, 7°, Sterile
85-1012-S	Interbody, 18 x 15 x 12mm, 7°, Sterile
U89-0018	Product Case, Small, Sterile Pack

NOTE

10° and 15° hyperlordotic options available.
Contact Customer Service at
customerservice@seaspine.com

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

Indications For Use

The Shoreline® ACS Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2–T1) for multiple contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline ACS Interbody System, which includes the TruProfile® plates and No-profile spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2–T1) and must be used with bone screw fixation and locking covers. The Shoreline ACS interbody spacers with $\geq 20^\circ$ lordosis are intended to be used with supplemental fixation.

When the Shoreline ACS Interbody (excluding the No-profile spacer) is used with supplemental fixation, such as anterior cervical plates, the Shoreline ACS Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2–T1).

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 indications

Relative contraindications:

- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- 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

INSTRUCTIONS FOR USE

Sterilization for NanoMetalene® Implants

NanoMetalene® implants in the Shoreline® system are provided “STERILE.” Refer to the IFU for handling and transfer of implant to sterile field.

Cleaning and Sterilization for Instruments

Instruments are supplied “NON-STERILE” and must be decontaminated and sterilized before use. Refer to the IFU for details.

RxOnly



CAUTION Federal law restricts this device to sale by or on the order of a physician or practitioner.



www.seaspine.com/eIFU
QF-10-01-102-ENGL

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.

SHORELINE[®] ACS

ANTERIOR CERVICAL FIXATION SYSTEM

For more information or to place an order, please contact:
TEL 866.942.8698 | FAX 877.558.6227
customerservice@seaspine.com | seaspine.com

Outside USA

TEL +1.760.727.8399 | FAX +1.760.727.8809
INTERNATIONAL INQUIRIES intlcustomer@seaspine.com

 **SeaSpine Orthopedics Corporation**
5770 Armada Drive
Carlsbad, CA 92008 USA
TEL 760.727.8399 USA | FAX 760.727.8809



SeaSpine, Orthofix, their respective logos, NanoMetalene, Shoreline, and TruProfile are trademarks or registered trademarks of Orthofix Medical Inc. and/or its affiliate companies.
© SeaSpine Orthopedics Corporation. 12/2023. All rights reserved. D0000975N 02