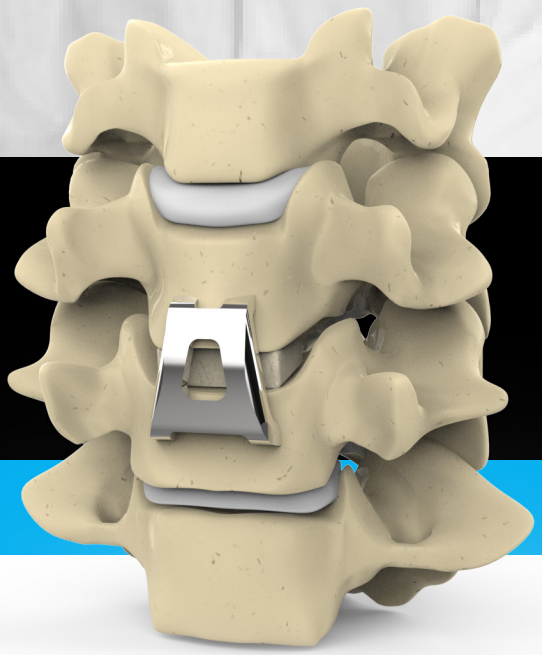


CONTINUUM™ ACDF

NITINOL FIXATION SYSTEM

Surgical Technique

pressio spine™

Focused Innovation for Spinal Fixation

THIS IS AN INTERACTIVE DOCUMENT

Contents

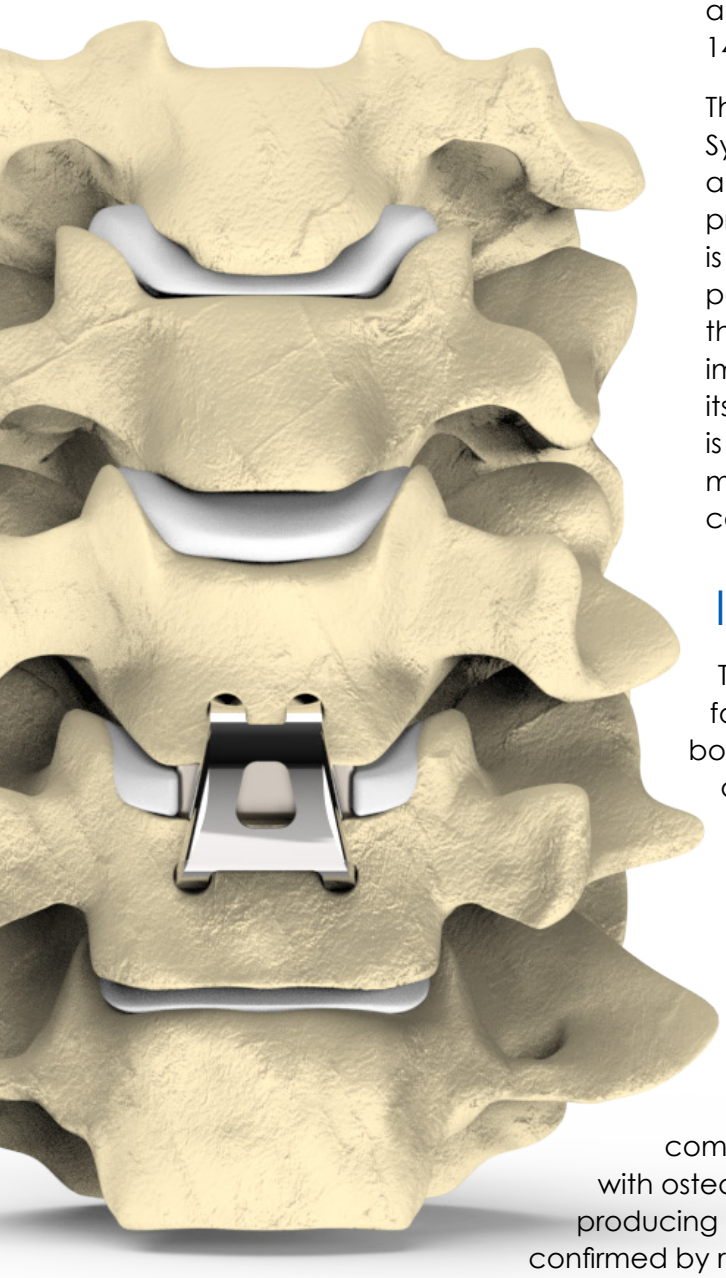
Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

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

Introduction

The CONTINUUM™ ACDF Nitinol Fixation System consists of plate-like staple implants offered in various sizes to match patient anatomies. To accommodate different patient anatomies, implant sizes are offered in bridge length from 14mm to 20mm, with leg lengths of 12mm.

The implants of the CONTINUUM ACDF Nitinol Fixation System are made from biocompatible shape memory alloy Nitinol (NiTi) and are designed to exhibit superelastic properties at room and body temperatures. The implant is retained in an active open position with its legs held parallel by the insertion device. Upon release from the insertion device, the active compression from the implant is transferred to the bones at the fusion site. In its implanted position, the CONTINUUM ACDF Implant is intended to provide continuous compression and maintain stability across the fusion site at the desired cervical level (C3-C7).



Indications

The CONTINUUM ACDF Nitinol Fixation System is intended for anterior instrumentation for cervical intervertebral body fusion. This system is indicated for patients as part of an anterior cervical fusion procedure for the indications listed below. The intended levels for treatment range from C3 to C7.

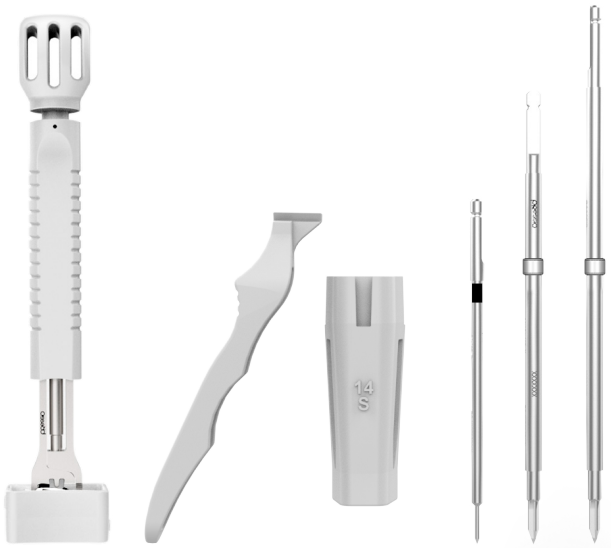
Indications are limited to patients with degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), at one level, with radiculopathy and/or myelopathy with herniated disc producing symptomatic nerve root and or spinal compression confirmed by radiographic studies and/or with osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and or spinal compression confirmed by radiographic studies.

The CONTINUUM ACDF Nitinol Fixation System is limited to one level fusion. A single CONTINUUM Implant must be implanted per functional segment unit fused. It MUST be used with a cervical interbody fusion device filled with autograft.

WARNING: This device is not approved for attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

System Overview

The CONTINUUM ACDF Nitinol Fixation System is single-use and pre-sterilized. Package contents include an outer box and a sealed, transparent outer tray. The clamshell tray contained within the outer tray is intended to be transferred to the sterile field.

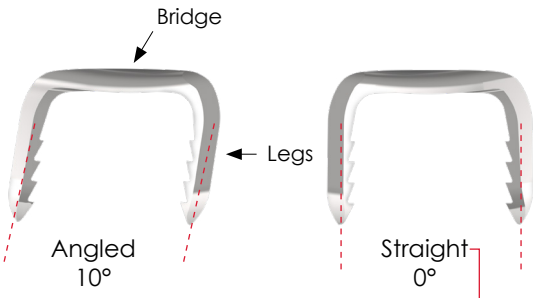


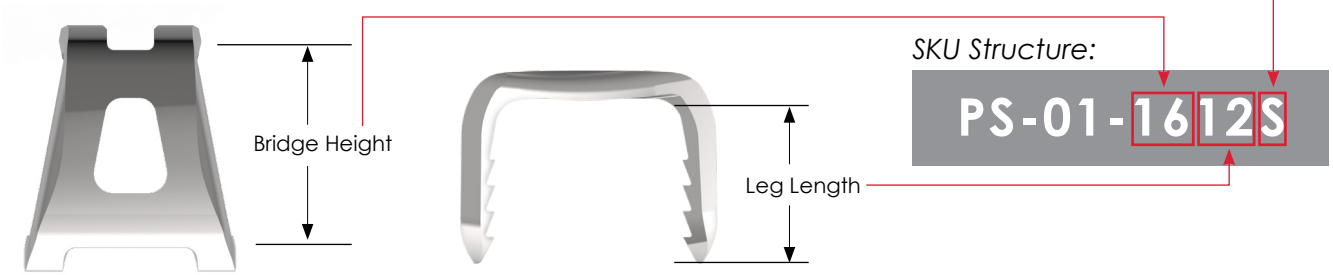
Components contained in the clamshell trays include the implant insertion assembly, drill guide, drill guide handle, temporary fixation pin, short drill pin, and long drill pin.

The implant insertion assembly consists of the wide bender with spacer, narrow bender, sleeve, fixation pin with bulb handle, CONTINUUM Implant, and the retention block.

Implant Sizing and Kit SKUs

The CONTINUUM ACDF Nitinol Fixation System consists of 4 straight implant kits and 4 angled implant kits. Straight implants have parallel legs in the open position, while angled implants have legs that are angled 10-degrees from parallel. Implants are available in 14mm, 16mm, 18mm, and 20mm bridge heights. All implants have 12mm leg lengths.





CONTINUUM ACDF Implant selection is based on the anterior height of the interbody of choice.

Straight

SKU	Part Description	Bridge Height*	Leg Length*	Shape
PS-01-1412S	ACDF IMPLANT KIT, 14X12MM STRAIGHT	14	12	Straight
PS-01-1612S	ACDF IMPLANT KIT, 16X12MM STRAIGHT	16		Straight
PS-01-1812S	ACDF IMPLANT KIT, 18X12MM STRAIGHT	18		Straight
PS-01-2012S	ACDF IMPLANT KIT, 20X12MM STRAIGHT	20		Straight

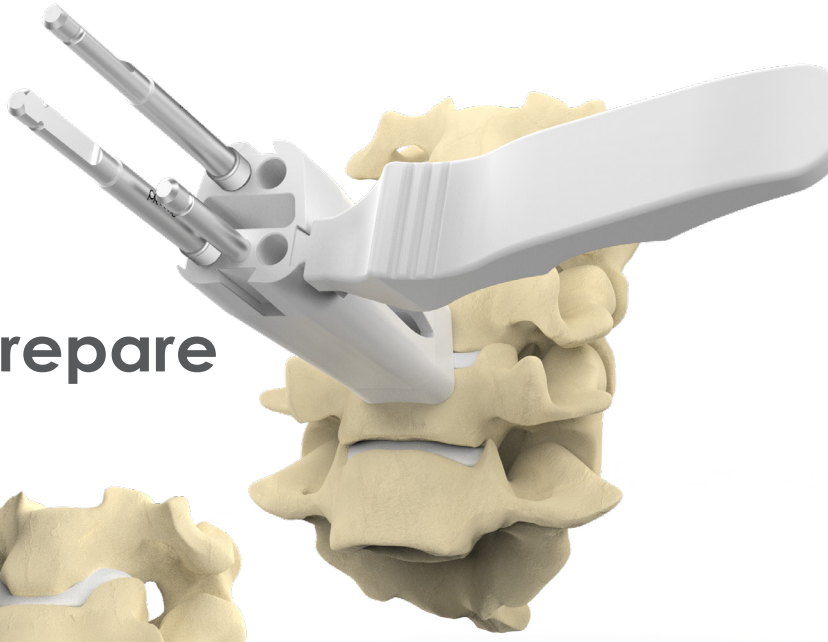
Angled

SKU	Part Description	Bridge Height*	Leg Length*	Shape
PS-01-1412A	ACDF IMPLANT KIT, 14X12MM ANGLED	14	12	Angled
PS-01-1612A	ACDF IMPLANT KIT, 16X12MM ANGLED	16		Angled
PS-01-1812A	ACDF IMPLANT KIT, 18X12MM ANGLED	18		Angled
PS-01-2012A	ACDF IMPLANT KIT, 20X12MM ANGLED	20		Angled

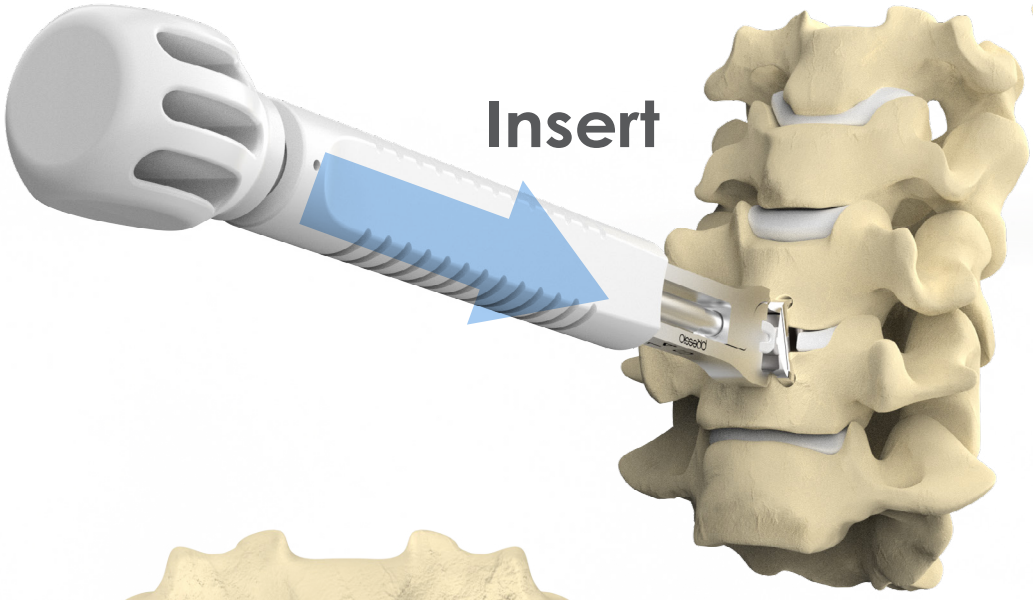
**Sizes for Bridge Height and Leg Length are in mm.*

Technique Summary

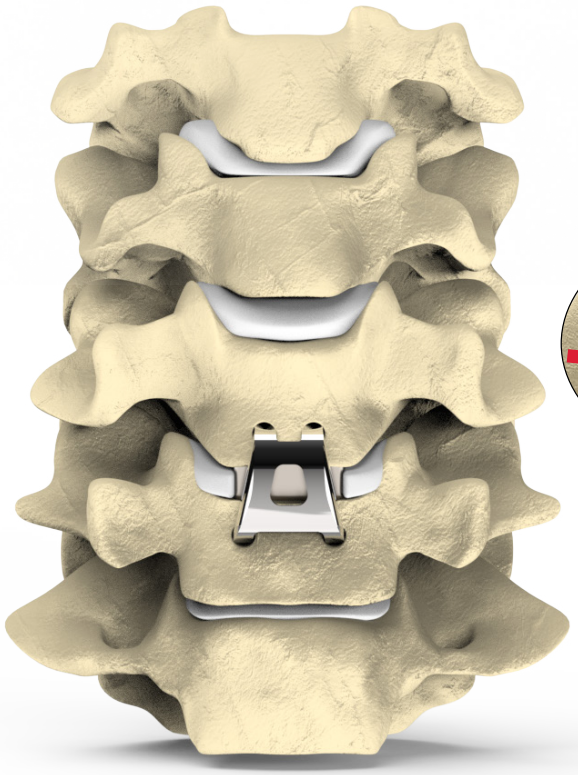
Simple and intuitive technique that results in continuous compression and stability across the fusion site at the desired cervical level (C3-C7).



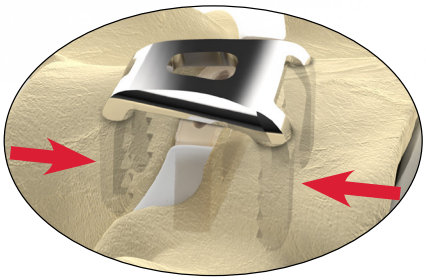
Prepare

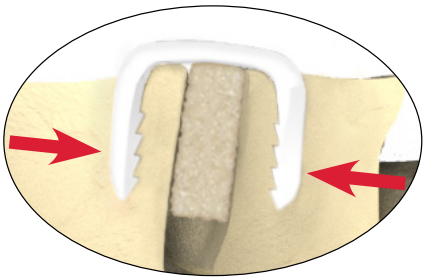


Insert

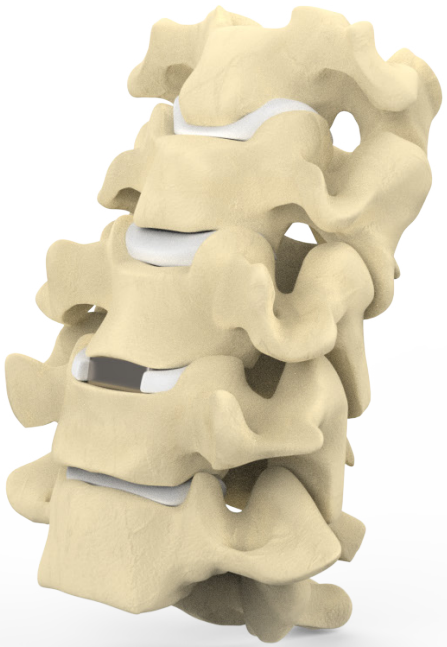


Continuous Compression





CONTINUUM ACDF Nitinol Fixation System Surgical Technique

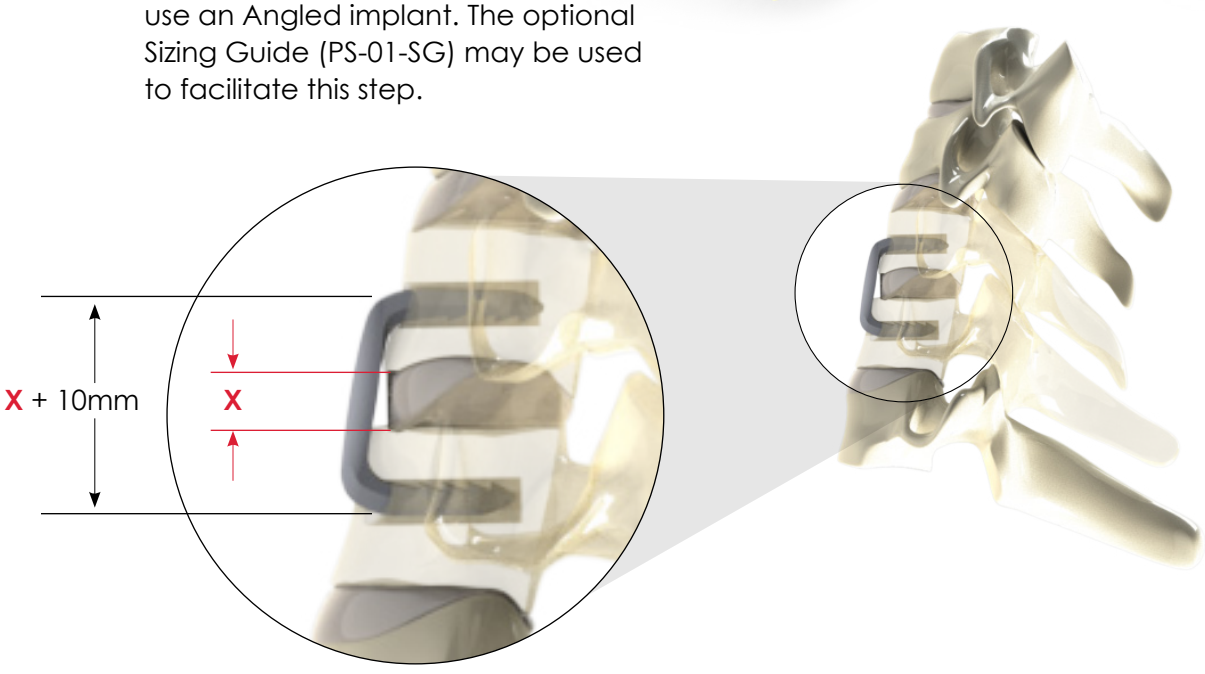


1 STEP 1: Prepare for Use

Using standard surgical technique, perform disc excision and spinal decompression and remove anterior osteophytes to allow for proper seating of the Pressio Spine CONTINUUM ACDF Implant. Place the interbody of choice using its pertinent surgical technique, while ensuring that the interbody does not extend beyond the anterior edges of the vertebral bodies.

A. To select the proper CONTINUUM ACDF Implant, add 8-10mm to the size of the interbody used such that each implant leg lies 3-4mm away from each endplate.

Next, determine the orientation of the endplates in relation to the anterior surface of the vertebral bodies. If perpendicular or a mild angle in present, use a Straight implant. If a high angle is present, use an Angled implant. The optional Sizing Guide (PS-01-SG) may be used to facilitate this step.



B. Open the kit containing the appropriate size and angle of the CONTINUUM ACDF Implant. Connect the Drill Guide Handle onto one of the dovetail slots on the Drill Guide oriented per surgeon preference. The Drill Guide may be used without the handle, if preferred (Figure 1).

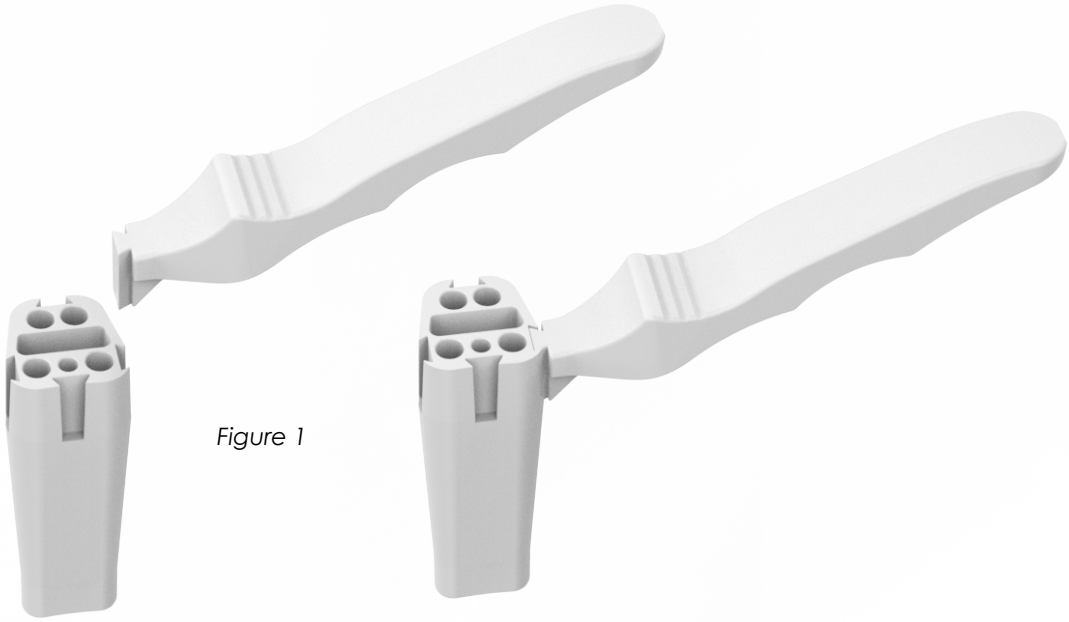
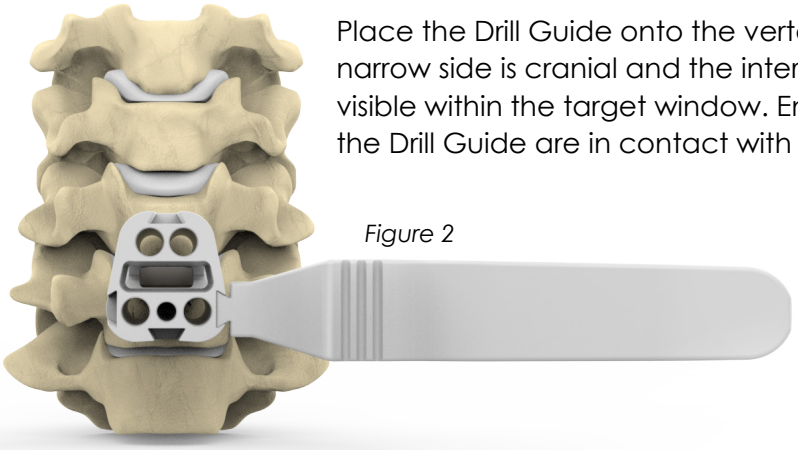


Figure 1

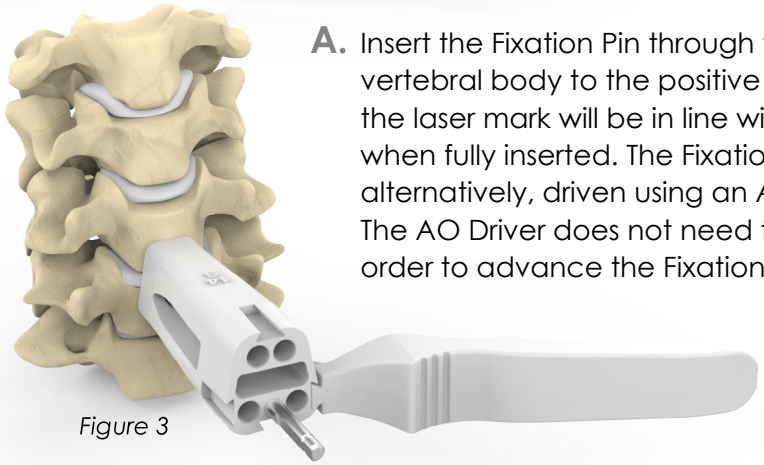
2 STEP 2: Drill Pilot Holes

Using standard surgical technique, perform disc excision and spinal decompression and remove anterior osteophytes to allow for proper seating of the Pressio Spine CONTINUUM ACDF Implant.



Place the Drill Guide onto the vertebral bodies so that the narrow side is cranial and the interbody is centered and fully visible within the target window. Ensure that all four corners of the Drill Guide are in contact with bone (Figure 2).

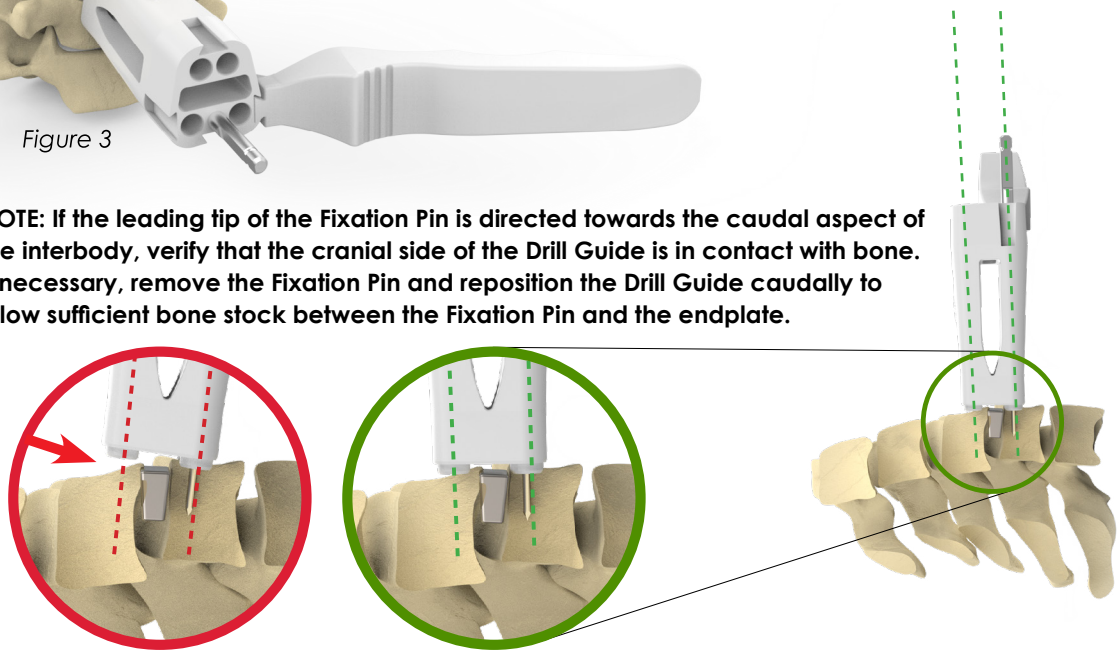
Figure 2



A. Insert the Fixation Pin through the center hole and into the vertebral body to the positive stop (Figure 3). The top of the laser mark will be in line with the top of the Drill Guide when fully inserted. The Fixation Pin may be tamped, or alternatively, driven using an AO Quick-Disconnect Driver. The AO Driver does not need to be positively connected in order to advance the Fixation Pin.

Figure 3

NOTE: If the leading tip of the Fixation Pin is directed towards the caudal aspect of the interbody, verify that the cranial side of the Drill Guide is in contact with bone. If necessary, remove the Fixation Pin and reposition the Drill Guide caudally to allow sufficient bone stock between the Fixation Pin and the endplate.



INCORRECT CORRECT

B. Using an AO Quick-Disconnect Driver, insert the Short Drill Bit into the vertebral body to the positive stop. The AO Driver does not need to be positively connected in order to advance the Short Drill Bit.

Connect the Long Drill Bit to the AO driver and create the three remaining holes by sequentially drilling to the positive stops (Figure 4).

Remove the Drill Bits, Fixation Pin and Drill Guide (Figure 5).

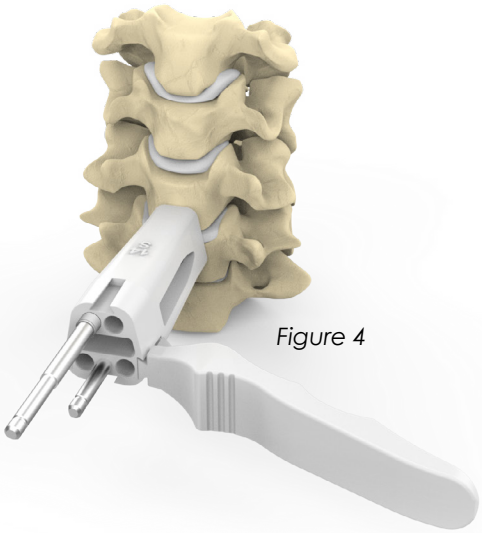


Figure 4

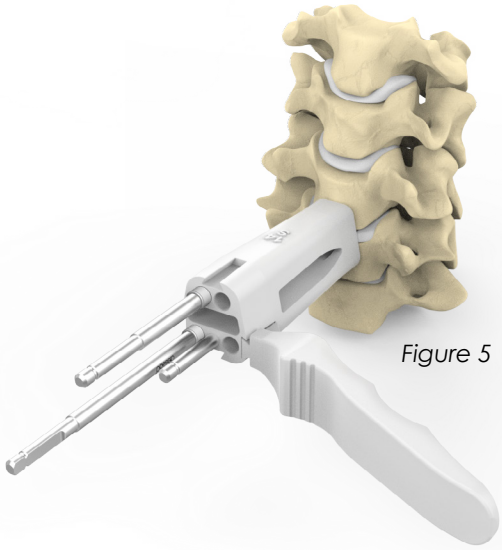
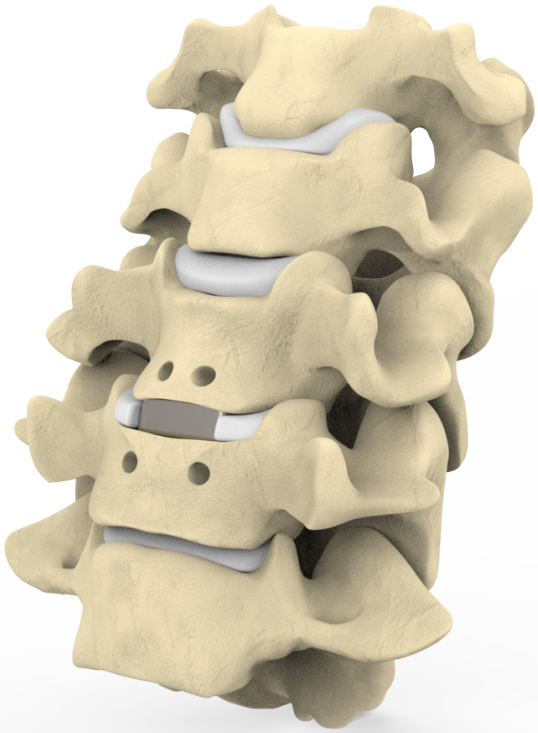


Figure 5



3 STEP 3: Place Implant

A. Remove the Inserter Assembly containing the CONTINUUM ACDF Implant from the packaging and rotate the Locking Pin's knob clockwise, approximately one half (1/2) turn, until the Retention Block can be easily removed (Figure 6).

NOTE: DO NOT rotate the knob in the wrong direction or the implant will come off the inserter and can't be reassembled.

Align the Inserter Assembly so that the narrow side of the implant is cranial, and the implant legs are in line with the drill holes (Figure 7). Insert the implant completely, tamping lightly, if necessary, until fully seated (Figure 8).

NOTE: When using straight implants, the Inserter will be perpendicular to the anterior bony surfaces. When using angled implants, the Inserter will be angled caudally.

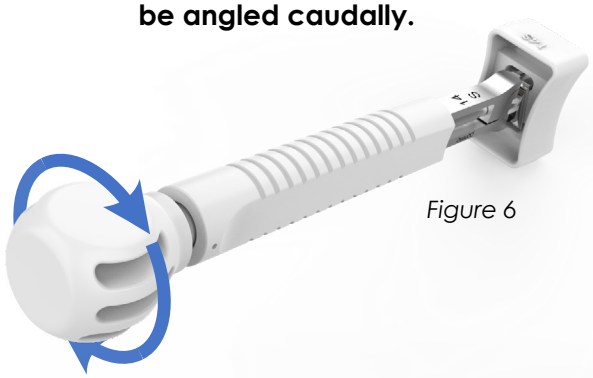


Figure 6

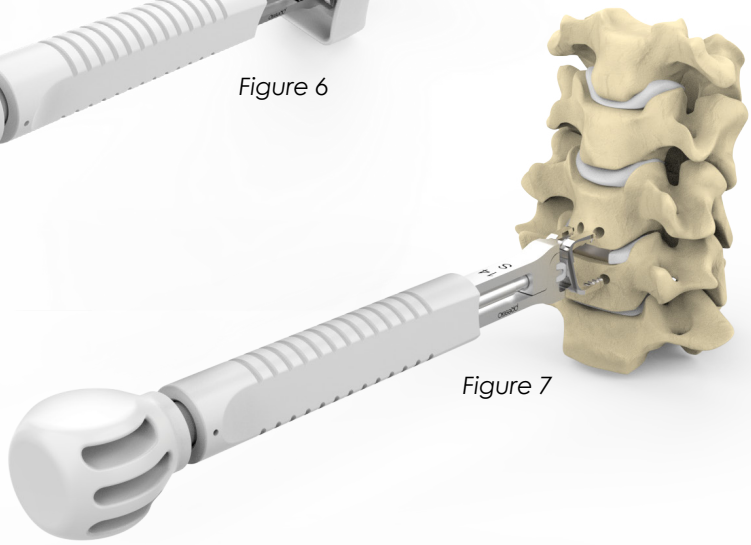


Figure 7

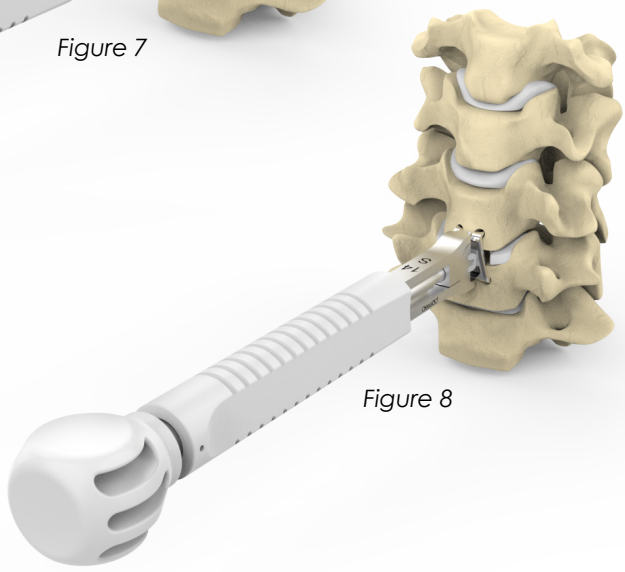


Figure 8

B. While firmly holding the Sleeve on the Inserter Assembly, turn the Locking Pin counterclockwise until it can be easily removed (Figure 9). Do not pull the Locking Pin until the threads have completely disengaged from the Benders. Remove the Sleeve and rotate the metal benders away from each other to detach them from the implant (Figures 10 and 11). Confirm implant positioning using fluoroscopy. If tamping is necessary, advance the tamp feature towards the threaded end of the Locking Pin and rotate until the metal tip of the Locking Pin is completely recessed. The Locking Pin may now be used as a tamp.

Close the surgical site using desired technique.

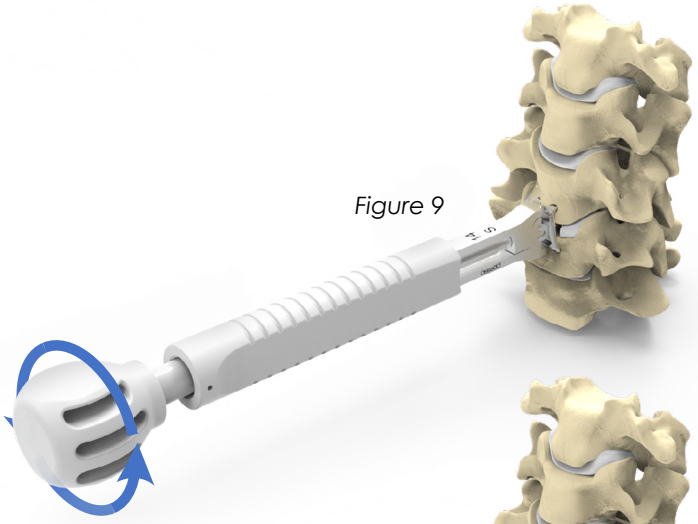


Figure 9

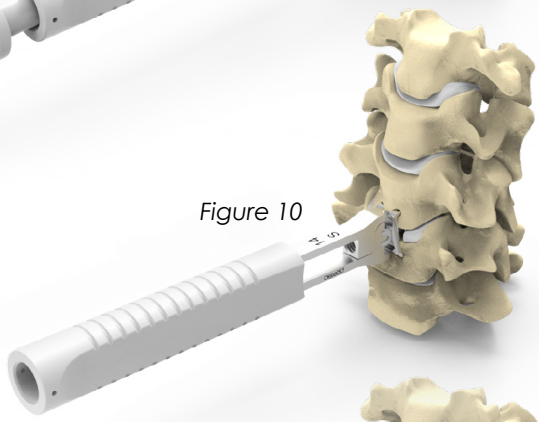
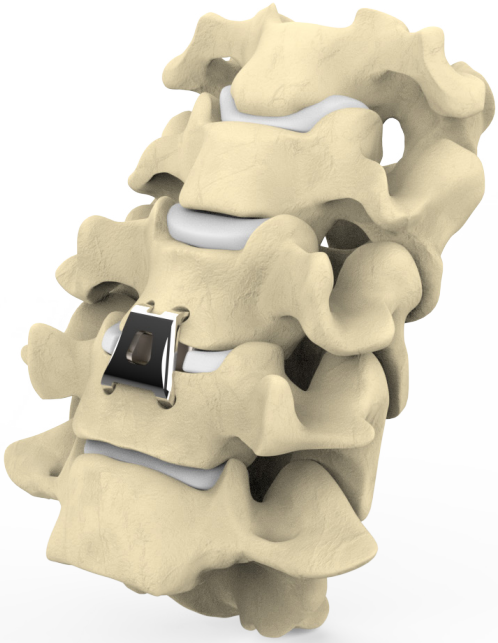
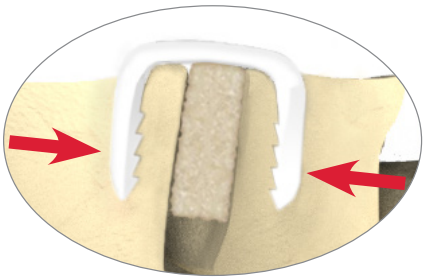


Figure 10





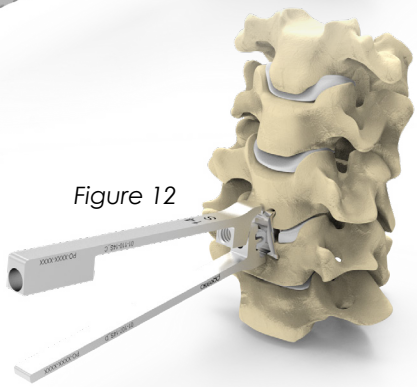


Figure 12

Removal Instructions

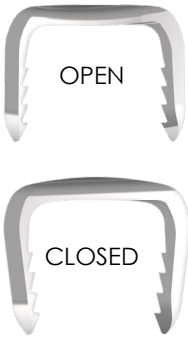
Expose the site and the bridge of the implant and if necessary, use a small osteotome, freer or similar instrument to engage the underside of the caudal aspect of the implant bridge and leverage the implant to facilitate the insertion of the Benders under the implant.

Remove the Spacer from the Wide Bender, using a clamp if necessary, and slide the Wide Bender under the caudal aspect of the implant bridge. Next, slide the Narrow Bender under the cranial aspect of the implant bridge. The arms of both Benders should be angled away from each other to facilitate engagement. After verifying engagement, approximate the Benders until they contact each other.

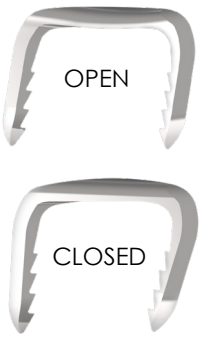
Slide the Sleeve over both Benders and insert the Locking Pin through the Sleeve until the threads at the tip engage the Bender thread holes. While firmly holding the Sleeve, rotate the Locking Pin clockwise until the implant loosens from the bone and remove the implant.

Ordering Information

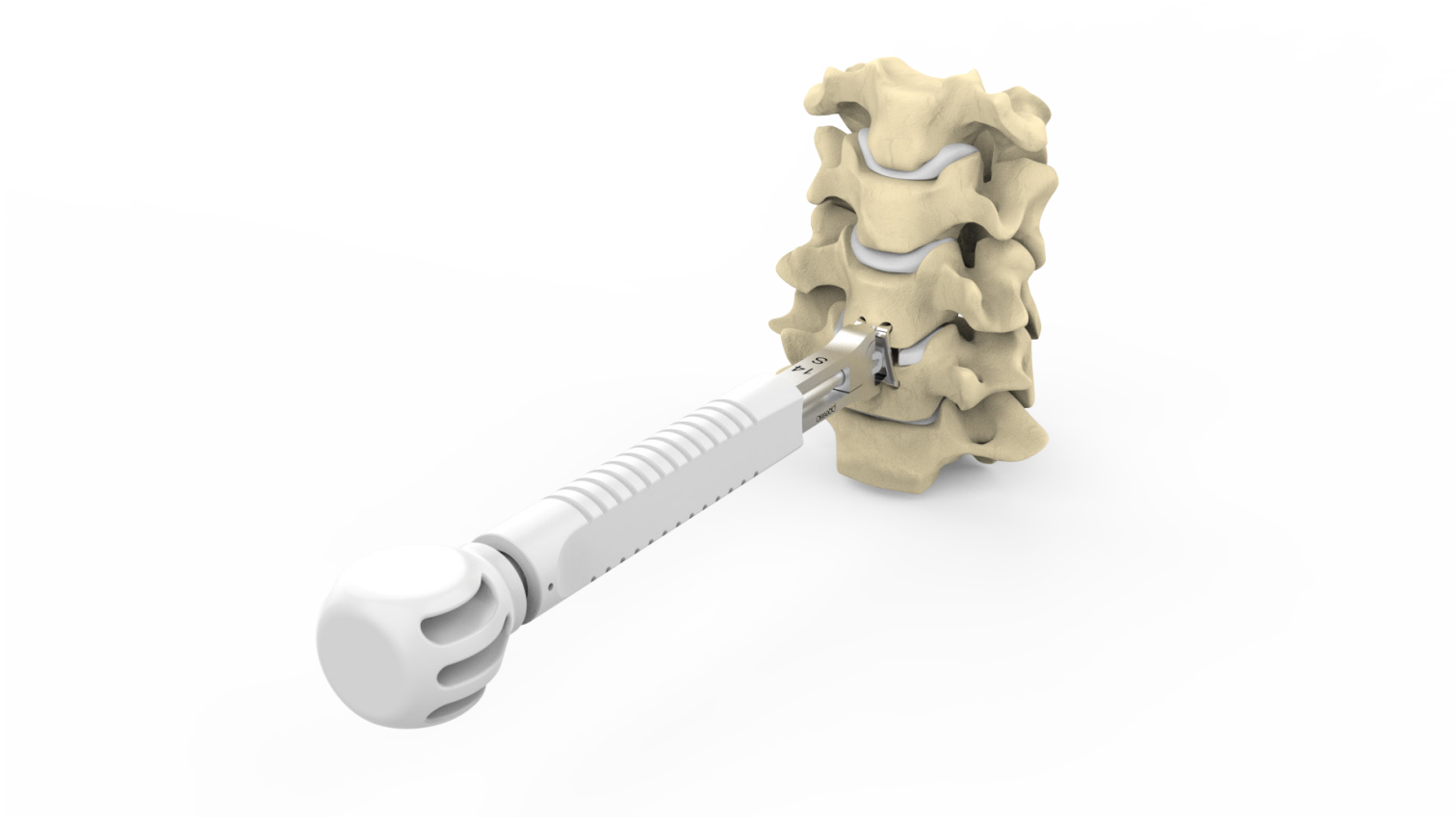
Straight

	SKU	Part Description	Bridge Height*	Leg Length*	Shape
	PS-01-1412S	ACDF IMPLANT KIT, 14X12MM STRAIGHT	14	12	Straight
	PS-01-1612S	ACDF IMPLANT KIT, 16X12MM STRAIGHT	16		Straight
	PS-01-1812S	ACDF IMPLANT KIT, 18X12MM STRAIGHT	18		Straight
	PS-01-2012S	ACDF IMPLANT KIT, 20X12MM STRAIGHT	20		Straight

Angled

	SKU	Part Description	Bridge Height*	Leg Length*	Shape
	PS-01-1412A	ACDF IMPLANT KIT, 14X12MM ANGLED	14	12	Angled
	PS-01-1612A	ACDF IMPLANT KIT, 16X12MM ANGLED	16		Angled
	PS-01-1812A	ACDF IMPLANT KIT, 18X12MM ANGLED	18		Angled
	PS-01-2012A	ACDF IMPLANT KIT, 20X12MM ANGLED	20		Angled

**Sizes for Bridge Height and Leg Length are in mm.*



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