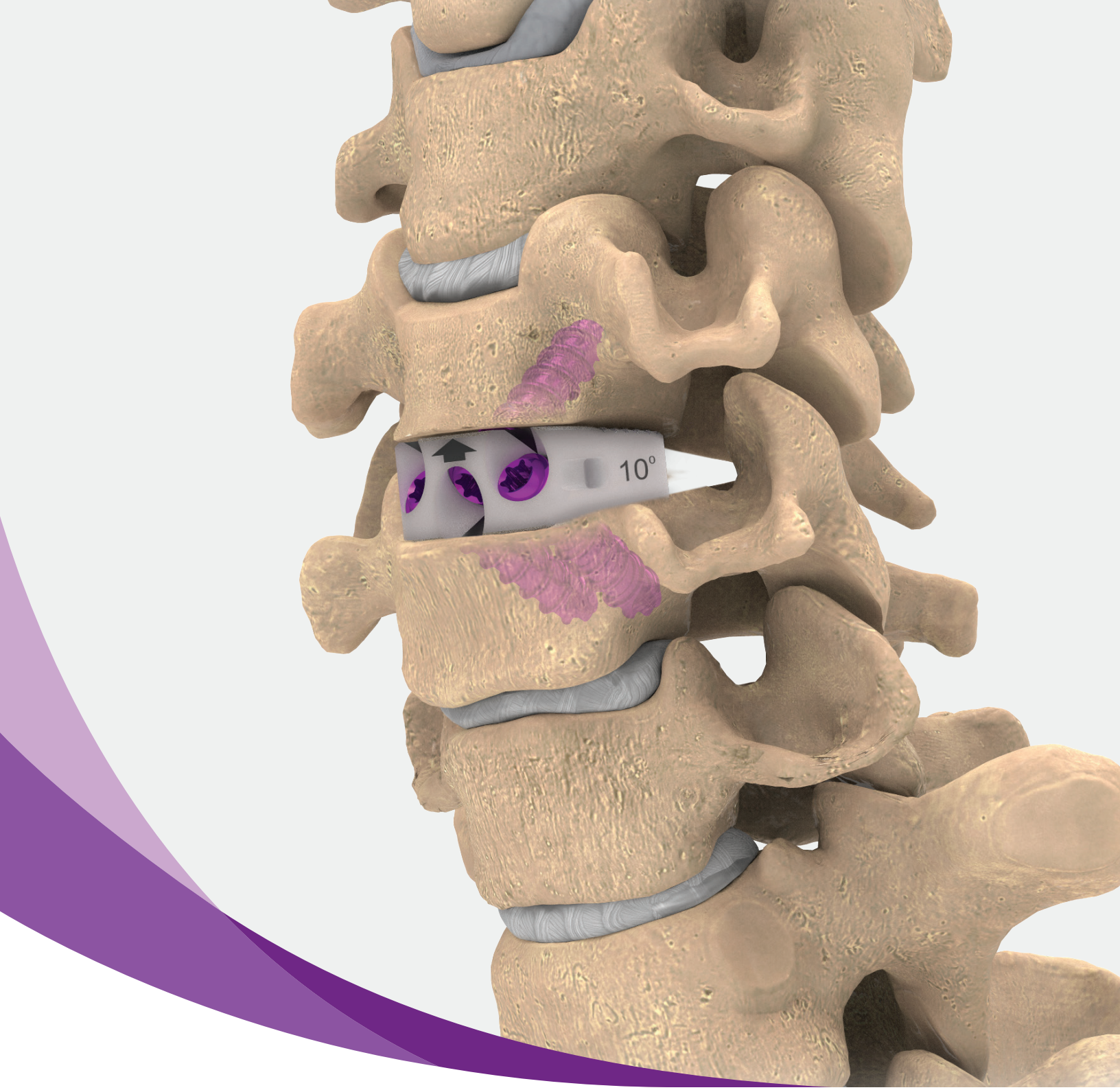

Coroent Small Interlock 2

Technique guide

NuVasive

This document is intended exclusively for physicians.

This document contains general information on the products and/or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of Coroent Small Interlock 2. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

Contents

Preface

Fellow Colleagues:

The ACDF procedure has advanced significantly over the past three decades. Spine surgeons have seen bulky anterior plating systems slowly give way to lower profile plating systems and, even more recently, to no-profile, completely integrated intervertebral fixation systems. The evolution is taking place to address pre-op indications as well as post-op complications. Intervertebral fixation systems are designed to provide maximum stability with fewer implants and less O.R. time. The Coroent Small Interlock Hyperlordotic and Coroent Small Interlock 2 systems were both designed as true no-profile devices that are implanted entirely within the confines of the intervertebral disc space. As such, they confer the following advantages:

- The required surgical exposure may be limited to the intervertebral disc space
- Elimination of the implant-retropharyngeal soft-tissue interface, thereby potentially minimizing the risk of postoperative implant-induced dysphasia and delayed esophageal injury due to erosion
- Ideal for use at segments adjacent to previously instrumented levels, as in situ implant (i.e., anterior cervical plate) removal is not required
- Fully integrated PEEK interbody spacer and screw fixation device minimizes the number of implants components and simplifies the implantation procedure
- The large central aperture of the implant provides space to promote fusion
- Multiple hyperlordotic angles in multiple footprints designed to address both the preservation and restoration of sagittal alignment in the cervical spine
- Titanium plasma-sprayed PEEK interbody that is designed to provide the bony on-growth benefits of titanium, while maintaining the stiffness and radiolucency of traditional PEEK*
- Fixation screw angulation provides compression across the fusion interface, theoretically increasing segmental stability and minimizing the potential for screw toggle and implant loosening

Integrated intervertebral fixation devices are a compelling advancement to the ACDF procedure, from which both surgeon and patient can benefit.

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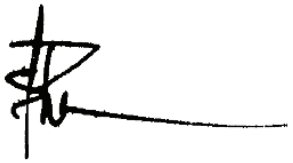

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USA

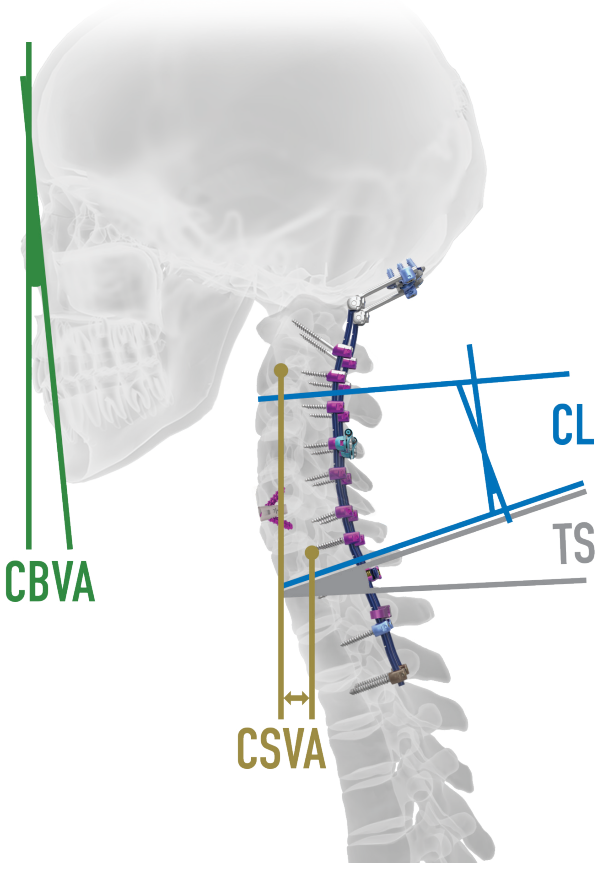
Integrated Global Alignment

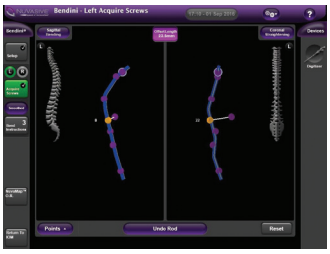
Integrated Global Alignment (iGA) is a platform comprised of procedurally based technologies, designed to enhance clinical and economic outcomes by increasing the predictability of achieving global alignment in all spinal procedures. Integration across the surgical workflow allows the surgeon to confidently and reproducibly:

- Calculate alignment parameters with preoperative planning tools.
- Correct the anterior and posterior column with comprehensive procedural solutions from NuVasive with the industry's only real-time intraoperative assessment.
- Confirm the restoration and preservation of global alignment postoperatively.

Why alignment matters

Spinal regions are not independent of one another. Cervical lordosis depends heavily on thoracolumbar alignment and vice versa. Early progress in clinical data has demonstrated a strong correlation between cervical alignment and successful patient outcomes (HRQOL). Specific cervical parameters and their relationship (including cervical lordosis (CL), cervical sagittal vertical axis (CSVA), T1 slope (TS), and the chin-brow vertical angle (CBVA)) are significant indicators of successful outcomes in the body's natural attempt to maintain the head over the pelvis and sustain a horizontal gaze.[1-3] NuVasive is committed to a global approach for assessing, preserving, and restoring spinal alignment in an effort to promote surgical efficiencies, lasting patient outcomes, and improved quality of life. **Cervical Alignment Matters.**





Value of Cervical Anterior Column Realignment (ACR)

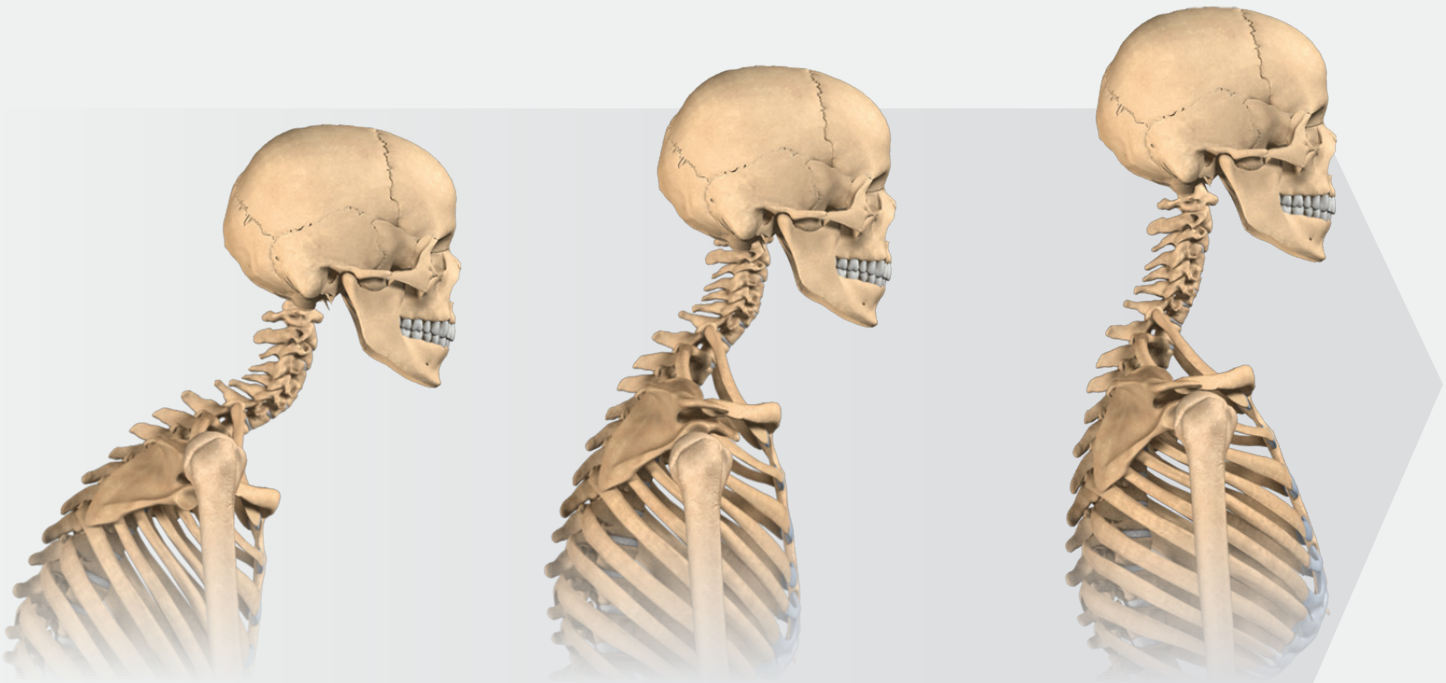
The NuVasive XLIF ACR and ALIF ACR procedures have pioneered solutions designed to achieve sagittal correction of the anterior column. Based on similar principles of spinal alignment and balance, the Cervical ACR procedure is designed to provide a full system to address sagittal plane deformity in the cervical spine.The NuVasive XLIF ACR and ALIF ACR procedures have pioneered solutions designed to achieve sagittal correction of the anterior column. Based on similar principles of spinal alignment and balance, the Cervical ACR procedure is designed to provide a full system to address sagittal plane deformity in the cervical spine.

With a rich clinical history, ACDF is a popular and clinically accepted procedure for treating certain pathologies of the cervical spine. Like other cervical fusion procedures, the surgical goals of an ACDF include:

- Restoring and maintaining natural disc space and posterior foraminal height
- Decompressing the neural elements
- Introducing or restoring proper sagittal and coronal alignment of the spinal column

Restoring sagittal alignment

Utilizing the same anterior approach as a traditional ACDF, Cervical ACR, facilitated through the multiple lordosis options offered in the Coroent Small Interlock 2 Interbody system, is designed to allow surgeons to better restore sagittal alignment.



Return to table of contents

Coroent Small Interlock 2 technique guide

Pre-op positioning and imaging

The patient is in the supine position with the head in slight extension, with chin in an "up" position *(Fig. 1)*.

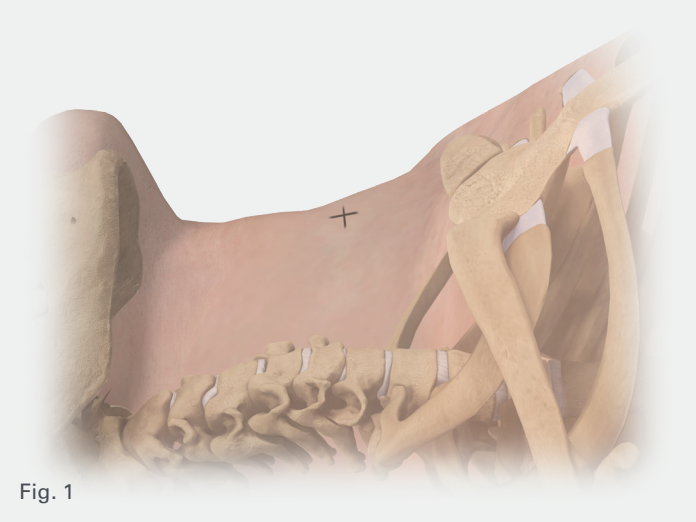


Fig. 1

Fluoroscopy

A/P and lateral imaging is used to locate the operative level and assess the bony anatomy *(Figs. 2, 3)*.

Tip: *"For imaging consideration, you can use a CT scan to assess uncinate morphology to rule out facet ankylosis. An MRI can also be used to r ule out an ectatic vertebral artery."*

- David Vincent, M.D.

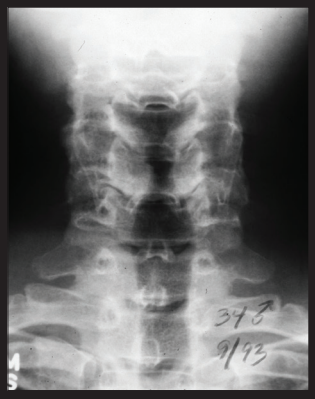


Fig 2. A/P fluoro

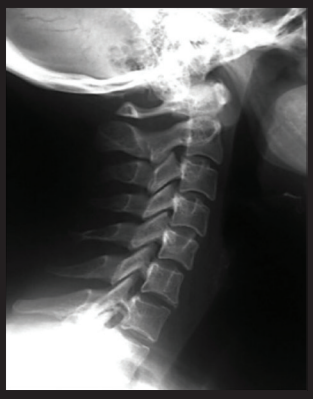


Fig. 3 Lateral fluoro

Coroent Small Interlock 2 trays ordering guide

- Coroent Small Interlock 2 Instrument and implant trays
- Optional: Maxcess-C Retractor System
- Supplemental fixation tray

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

Step 1

Discectomy

Place the patient's neck in a supine position, chin extended, on the operating table. Carry out the anterior approach to the appropriate level(s) in the usual manner. The technique must allow for direct anterior access to the disc and the adjacent vertebral bodies.

A retractor can be utilized to help maintain visualization during the procedure *(Fig. 4)*. Additionally, a standard vertebral distractor can be used in the adjacent vertebra to distract open the disc space.

Tip: *Careful attention to osteophyte removal enables optimal implant placement. If using Caspar pins, be aware that midline placement may interfere with the medial screw placement; consider more lateral placement of the Caspar pins.*

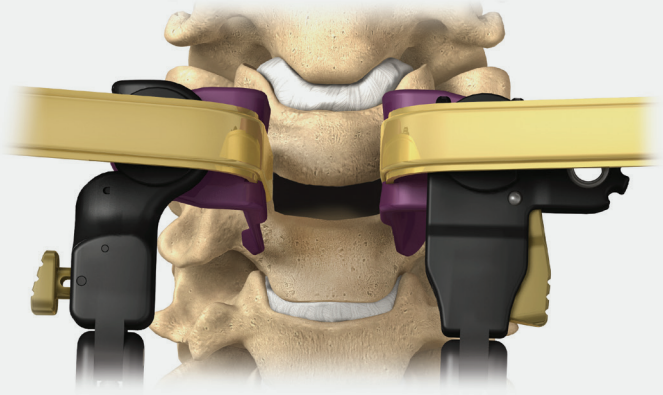


Fig. 4

Step 2

Decompression

Perform a complete discectomy and decompression. After thorough removal of the disc material, remove the cartilaginous endplates with standard curettes or drill.

Tip: *Perform a full posterior-lateral decompression to allow for the 17x14 mm footprint.*

NuvaMap/NuvaLine

After using NuvaMap or NuvaLine software to preoperatively measure cervical parameters, input values into NuvaMap O.R. to intraoperatively assess cervical lordosis and CSVA in real-time on imported fluoro images throughout key points of the procedure *(Fig. 5)*.

Fig. 5

NVM5 can provide comprehensive diagnostic technology during the procedure.

- Recurrent laryngeal nerve monitoring (EMG endotracheal tube)
- Nerve root monitoring (EMG)
- Anterior and posterior spinal cord monitoring (MEP, SSEP)
- Monitoring for potential positional deficits (SSEP)

Step 3

Trial configuration

Select the desired trial from the multiple options available *(Figs. 6, 7).*

Note: *Non-contoured interbody trial with depth stop allows for controlled placement of the interbody in the disc space by limiting the interbody placement to be flush with the anterior of the disc space.*

10° trial

Fig. 6

15° trial

Fig. 7

Step 4

Interbody sizing

Determine interbody height by sequentially increasing the height of the trial until it fits firmly in the disc space, while maintaining full endplate contact *(Figs. 8, 9)*. When sizing for the interbody, verify that endplates are making good contact with the trial to ensure an ideal graft-loading environment. Confirm the correct height by radiographic imaging.

Note: *The trials can be used as wedges to open the collapsed disc space when necessary.*

Caution: Over-distraction of the disc space can lead to facet over-distraction and spinous process contact. Confirm lateral fluoroscopy shows healthy sagittal alignment.

Note: *The anterior and posterior heights are indicated on the right of the interbody with the anterior height being toward the anterior portion of the interbody (Fig. 10). The degrees of lordosis are shown on the left side. This information is also included on the Trial.*

Fig. 8

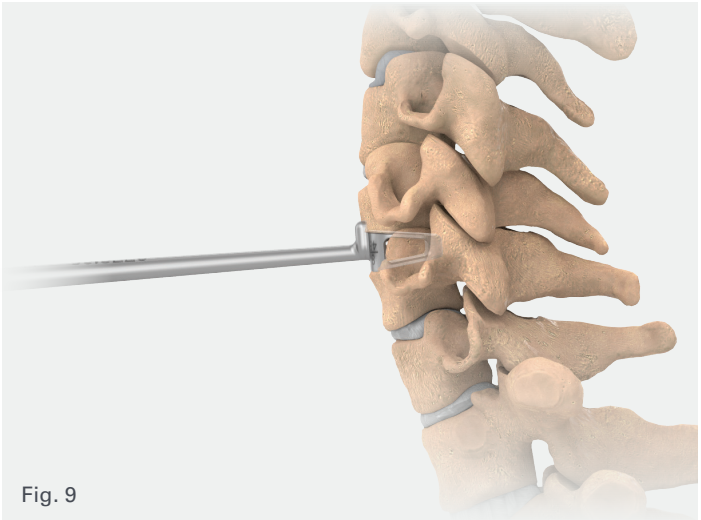


Fig. 9

Fig. 10

Step 5

Implant loading

Load implant onto Inserter.

For proper orientation of the implant on the Inserter, line up the lasermark arrow on the proximal end of the Inserter with the arrow on the face of the implant. Both arrows should be facing the same direction *(Fig. 11)*.

With the alignment arrows pointing in the same direction, place the Inserter on the face of the appropriate size implant *(Fig. 12, Step 1)* and rotate the tightening knob clockwise until tight *(Fig. 12, Step 2)*.

Tip:

- *Always double-check tight engagement of the implant on the Inserter by pinching the engagement arms onto the implant and making sure there is a tight fit*
- *The arrow on the Inserter also indicates which direction the medial screw is headed (i.e., arrow pointing cranial indicates the medial screw's trajectory will also be cranial)*

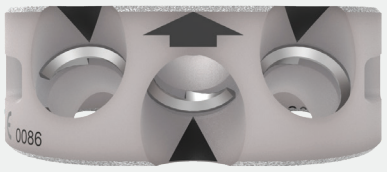


Fig. 11

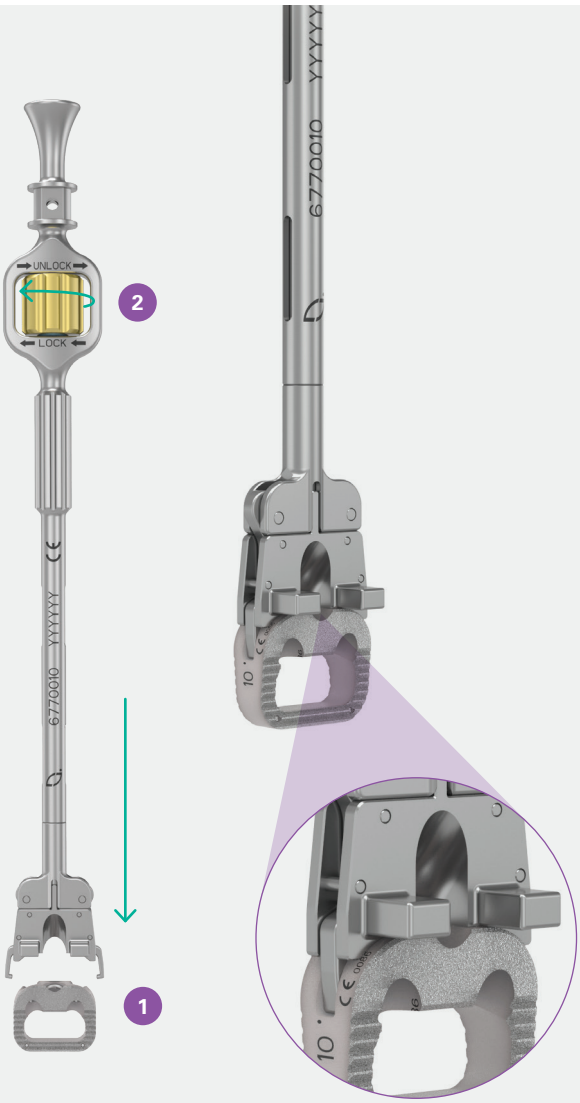


Fig. 12

Step 6

Interbody replacement

Insert the desired Coroent Small Interlock 2 Interbody into the disc space *(Fig. 13)*. Confirm position with fluoroscopy as needed (Fig. 14). The Inserter should not be detached until the first medial screw is placed. Detach the inserter from the interbody by rotating the thumbwheel counterclockwise *(Fig. 15)*.

Note: *If additional manipulation is required after removing the inserter, the tamp and mallet can be used to gently tap the interbody into place (Fig. 16).*

Note: *Posterior marker is 1.5 mm from the posterior of the interbody.*

Tip: *Removal of the anterior osteophytes may allow for a better trajectory to place the screws. A burr can be used to create a channel where the screw will be placed to prevent having to work against the osteophyte (Fig. 17).*

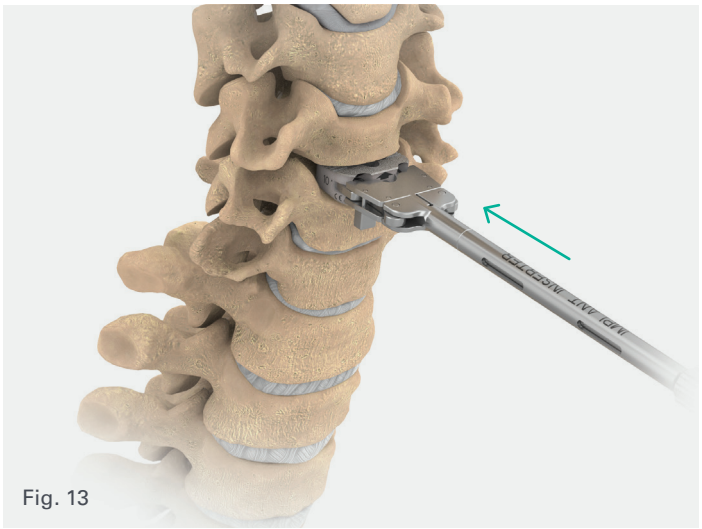


Fig. 13

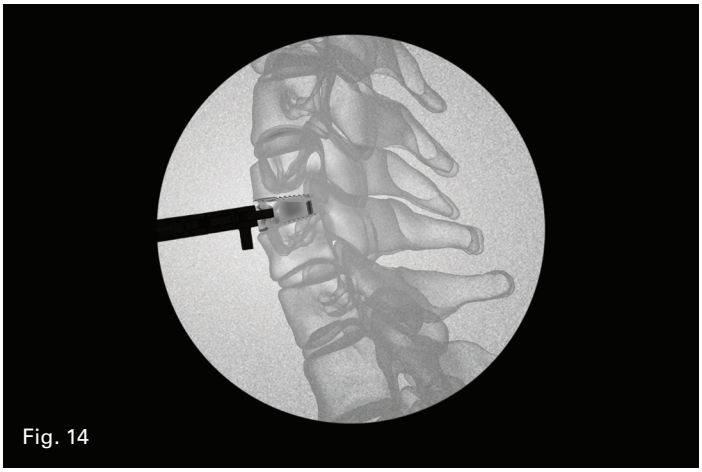


Fig. 14

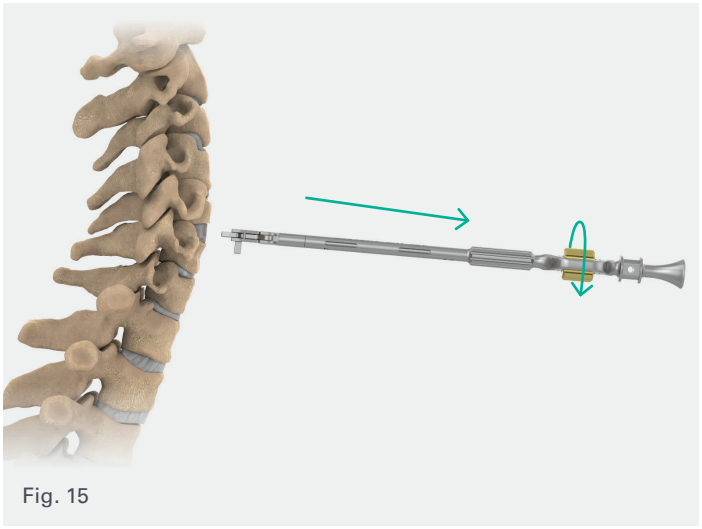


Fig. 15

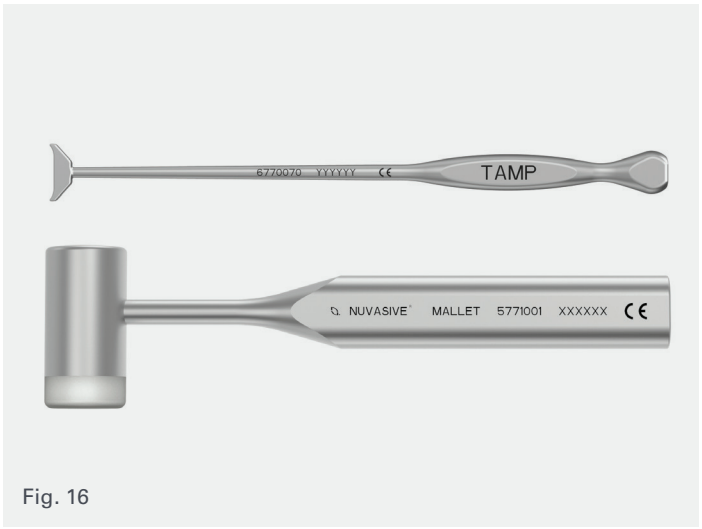


Fig. 16

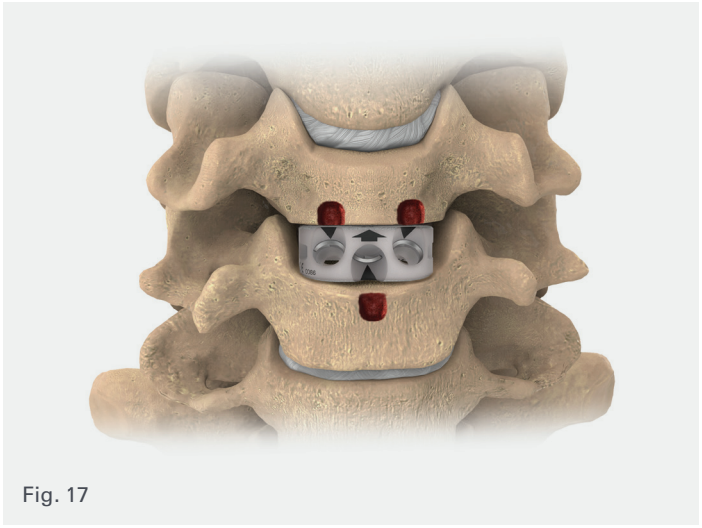


Fig. 17

Step 7

Screw preparation (awl or drill)

Once the implant is seated at the proper depth, the awl or drill may be used to initiate the screw pathway and trajectory. for the straight awl, make sure the arrow of the awl is pointed in the direction of the endplate you are preparing *(Fig. 18)*. This will help to verify that the sharp beveled tip punctures the endplate properly.

Awl

If desired, attach the wrench handle to the angled awl during the technique for better control and force distribution *(Fig. 19)*.

To retract the awl, either pull on the proximal end of the awl or twist the proximal end to gradually retract the awl. For the angled awl, rotate the thumbwheel clockwise to retract the awl.

Drill

Select the desired drilling depth by pulling the distal part of the adjustable drill guide forward and away from the handle and turning the instrument to the desired depth, noted by the small metal slide which sits in the numbered slot *(Fig. 20)*.

Note: *Drilling beyond 14 mm will advance the drill past the posterior aspect of the implant.*

Caution: The 12–16 mm Drill MUST be used with the adjustable drill guide.

Fig. 18

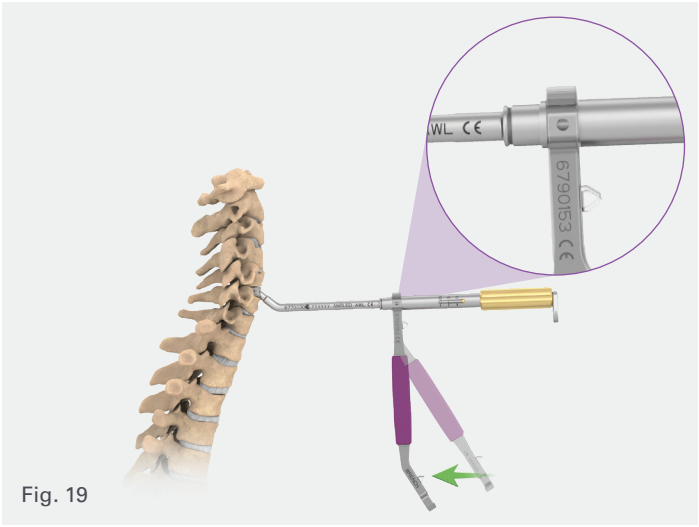


Fig. 19

Fig. 20

Step 8

Screw selection and insertion

The length of the screws is measured from the anterior portion of the implant to the total distance reached posteriorly. This takes into account the 40˚ angle *(Fig. 21)*.

A straight or angled driver can be used first to drive in the medial screw, and then the lateral screws *(Figs. 22, 23)*.

Note: *The angled instruments were designed to work perpendicular to the spine so the correct screw angle and trajectory are automatically achieved when the Awl and Screwdrivers are seated properly within the screw hole.*

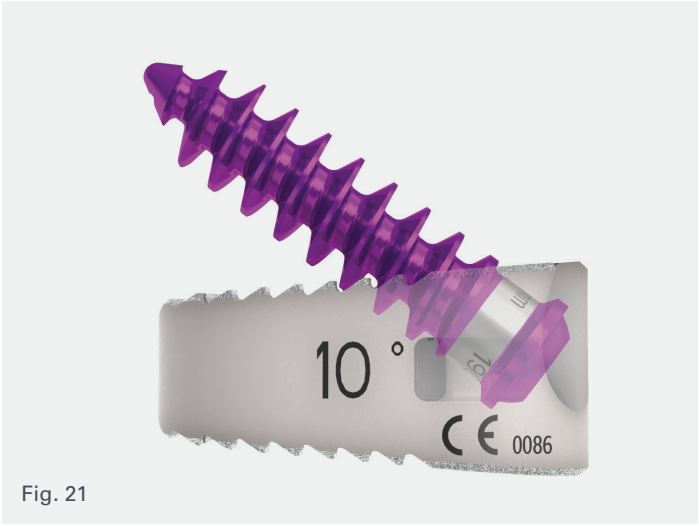


Fig. 21

4 mm self-tapping screws

12 mm 13 mm 14 mm 15 mm 16 mm


Fig. 22

4.5 mm self-tapping rescue screws

12 mm 13 mm 14 mm 15 mm 16 mm


Fig. 23

Step 9

Locking verification

Tactile confirmation:
The primary locking indicator is the tactile feedback washer in the interbody. This is designed to confirm when the screw is fully past the locking mechanism and the tip of the triangle indicator. The tactile feedback washer is not an integral part of the locking mechanism.

Visual confirmation:
The secondary locking indicator is the visualization of the locking triangle. After the screw has been placed into the hole with tactile confirmation and the driver has been removed, you can verify the screw is locked when you have FULL visualization of the triangle. You will see the tip of the triangle exposed when the screw is locked beneath the ledge *(Fig. 24).*

Tip: *Before driving the screws forward into the interbody, turn each screw about a half turn to a full turn counterclockwise to countersink the screw before driving it into place. This is a way to confirm you have seated and aligned the screw before threading the screw into the bone. When making the counterclockwise turn, you will feel the screw seat and then you know you can continue to drive the screw clockwise into the bone. When using this technique, in combination with using the arrows on the implants as a locking indicator, you can confirm that the screws are locked in place*

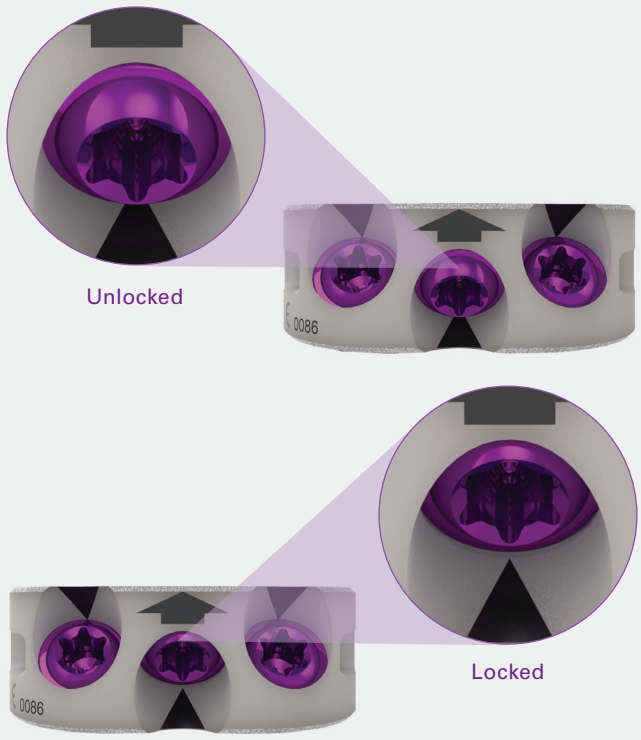


Fig. 24

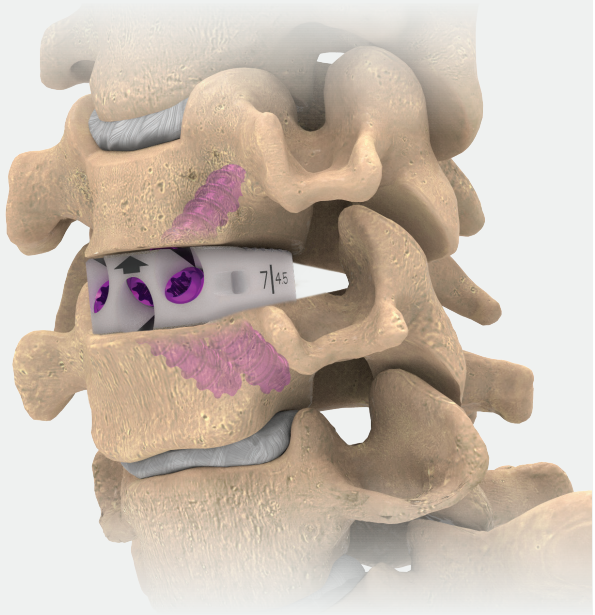


Fig. 25

Step 10

Post-op verification

Confirm placement of the implant with A/P and lateral fluoro shots *(Figs. 26, 27)*.

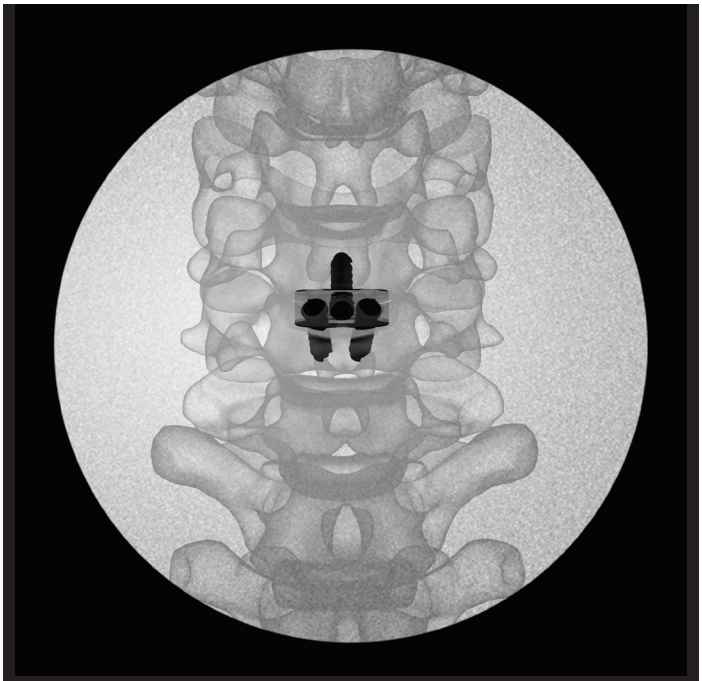


Fig. 26 A/P flouro

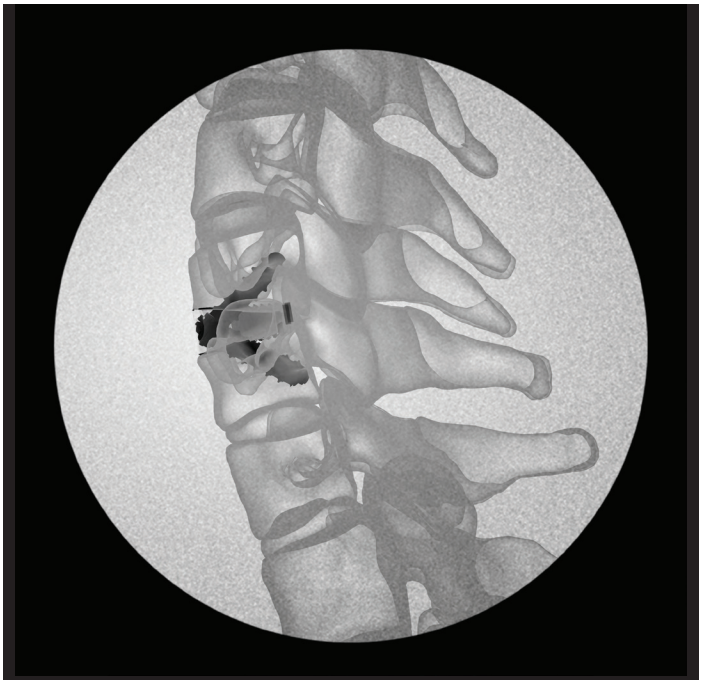


Fig. 27 Lateral flouro

Implant removal

Should an implant need to be removed, follow the steps below.

Follow these steps:
At the proximal end of the screw extractor, tighten the inner shaft of the instrument into the female engagement of the selected screw *(Fig. 28, Step 1)*. Do not overtighten.

Rotate the collet sleeve of the screw extractor clockwise down to the anterior surface of the interbody, which acts as a counter-torque *(Fig. 28, Step 2)*.

With the collet sleeve held static against the interbody, rotate the purple handle of the screw extractor counterclockwise to remove the screw from the construct *(Fig. 28, Step 3)*.

Repeat Steps 1 through 3 for all three screws, if necessary *(Fig. 28, Steps 1-3)*.

Attach Inserter to implant to remove implant from disc space.

Tip:

- *Maintain the same 40˚ trajectory while engaging the extractor*
- *Place downward pressure on the extractor while turning the silver engagement knob*

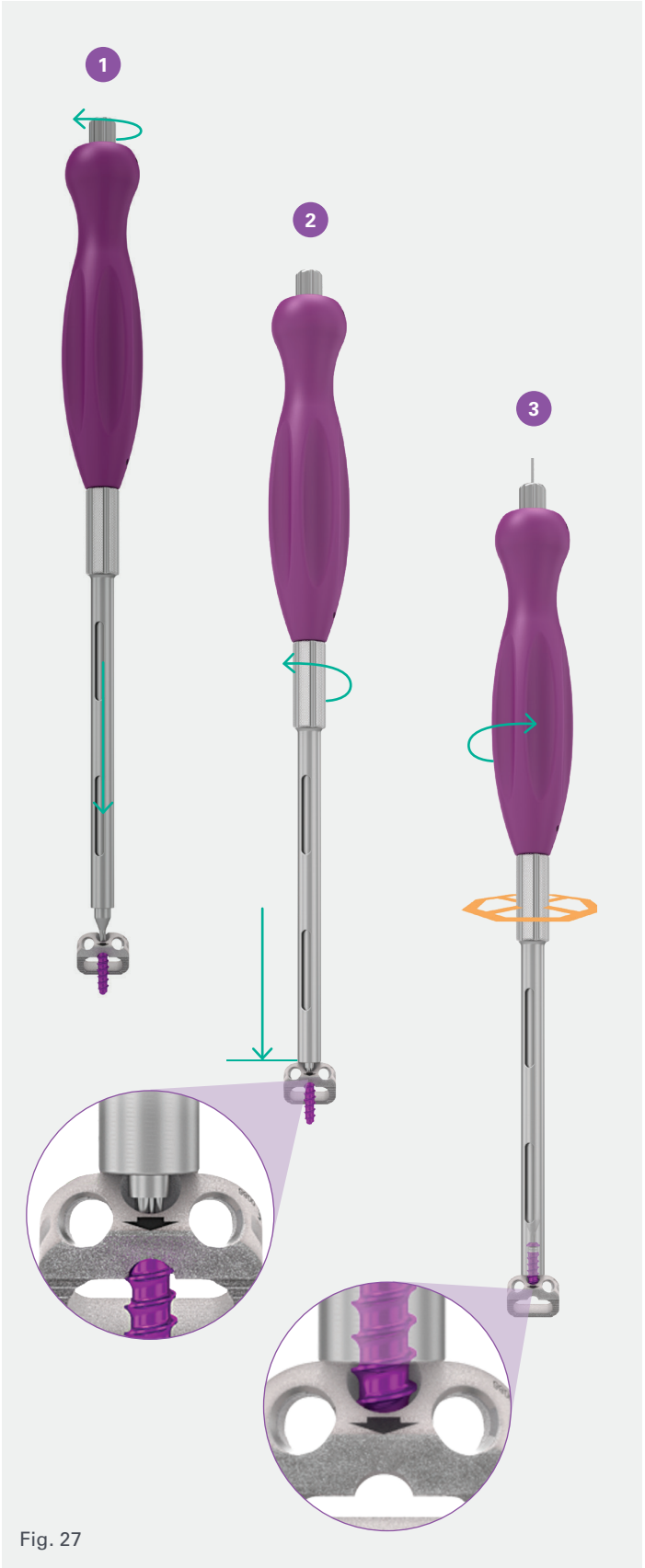
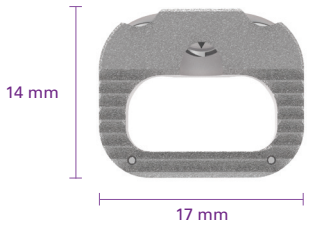


Fig. 27

Coroent small interlock 2 interbodies



Footprint	17x14 mm	
Lordosis	**10°**	**15°**
Anterior height (mm)	**Posterior (mm)**	**Posterior (mm)**
6	3.5	n/a
7	4.5	3.5
8	5.5	4.5
9	6.5	5.5
10	7.5	6.5
11	8.5	7.5
12	9.5	8.5

Footprint	17x14 mm	
Lordosis	**10°**	**15°**
Anterior height (mm)	**Graft volume (cm3)**	**Graft volume (cm3)**
6	0.33	n/a
7	0.40	0.35
8	0.48	0.42
9	0.55	0.49
10	0.62	0.57
11	0.69	0.64
12	0.77	0.71

Coroent small interlock 2 instruments

Trial

Rasp

Inserter

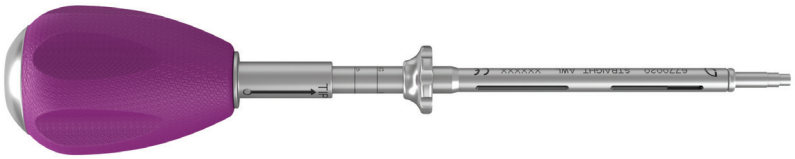
Tamp

Straight driver

Angled driver

Coroent small interlock 2 instruments (cont.)

Straight awl



Angled awl

Universal handle

Coroent small interlock handle, counter-torque

Adjustable drill guide (12–16 mm)

12–16 mm drill shaft

Screw extractor

Coroent small interlock 2 implants

4 mm self-tapping screw	4.5 mm rescue screw	Coroent Small Interlock 2 implants
		 Axial View  Lateral View

Catalog

Coroent Small Interlock 2 implants

Description	Catalog no.
Implant, 6x17x14 mm, 10°	6770610CP2
Implant, 7x17x14 mm, 10°	6770710CP2
Implant, 8x17x14 mm, 10°	6770810CP2
Implant, 9x17x14 mm, 10°	6770910CP2
Implant, 10x17x14 mm, 10°	6771010CP2
Implant, 7x17x14 mm, 15°	6770715CP2
Implant, 8x17x14 mm, 15°	6770815CP2
Implant, 9x17x14 mm, 15°	6770915CP2
Implant, 10x17x14 mm, 15°	6771015CP2
Implant, 11x17x14 mm, 15°	6771115CP2
Self-tapping bone screw, 12x4 mm	1903012
Self-tapping bone screw, 13x4 mm	1903013
Self-tapping bone screw, 14x4 mm	1903014
Self-tapping bone screw, 15x4 mm	1903015
Self-tapping bone screw, 16x4 mm	1903016
Self-tapping rescue screw, 12x4.5 mm	1903022
Self-tapping rescue screw, 13x4.5 mm	1903023
Self-tapping rescue screw, 14x4.5 mm	1903024
Self-tapping rescue screw, 15x4.5 mm	1903025
Self-tapping rescue screw, 16x4.5 mm	1903026

Coroent Small Interlock 2 instruments

Description	Catalog no.
Trial, 6x17x14 mm, 10°	6772006
Trial, 7x17x14 mm, 10°	6772007
Trial, 8x17x14 mm, 10°	6772008
Trial, 9x17x14 mm, 10°	6772009
Trial, 10x17x14 mm, 10°	6772010
Trial, 7x17x14 mm, 15°	6772107
Trial, 8x17x14 mm, 15°	6772108
Trial, 9x17x14 mm, 15°	6772109
Trial, 10x17x14 mm, 15°	6772110
Trial, 11x17x14 mm, 15°	6772111
Cervical mallet	1006278
Adjustable drill guide	6770090
Drill bit	6770080
Implant inserter	6770010
Straight awl	6770020
Angled awl	6770030
Straight driver	6770040
Angled driver	6770050
Screw extractor	7730072
Universal handle	8789700
Tamp	6770070
Rasp	6770060
Counter-torque	6790153

Instructions for use

DESCRIPTION

The NuVasive Coroent Small Interlock 2 System is an anterior cervical interbody device consisting of a PEEK (Polyether-ether-ketone) implant cage with or without commercially pure titanium coating, tantalum radiographic markers, titanium alloy washers, and three (3) titanium alloy bone fixation screws. The devices are manufactured from PEEK-Optima LT-1 (Polyether-ether-ketone) conforming to ASTM F2026, commercially pure titanium (CP Ti) conforming to ASTM F1560, titanium alloy (Ti6A1-4V ELI) conforming to ASTM F136/ISO 5832-3, and Tantalum (Ta) conforming to ASTM F560/ISO 13782. The implants are available in a variety of sizes to accommodate anatomical conditions.

INDICATIONS FOR USE

The NuVasive Coroent Small Interlock 2 System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radioculopathy, myleopathy, and/or pain at multiple contiguous levelsfrom C2–T1. The Coroent Small Interlock 2 System (lordotic angles of 7° to 15°) is a standalone system. The Coroent Small Interlock 2 System (lordotic angles of 20° to 30°) must be used with supplemental fixation cleared by the FDA. The System is intended to be used with autogenous or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reusable or multiple uses.

CONTRAINDICATIONS FOR STANDALONE APPLICATION

Contraindications for Standalone application include but are not limited to:

1. Spondylolisthesis greater than Grade 1.
2. Severe segmental instability

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated. This system should not be used with components of any other system or manufacturer. Unless otherwise specified, do not combine dissimilar materials, such as titanium and stainless steel.

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

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic and internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Based on fatigue testing results, when using the Coroent Small Interlock 2 System, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The Coroent Small Interlock 2 System (lordotic angles of 7° to 15°) is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. If fewer than the maximum number of screws accommodated by the device are used, then the system is intended to be used with additional supplemental fixation (cleared by the FDA) for use in the cervical spine.

Care should be taken to insure that all components are ideally fixated prior to closure.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Single Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

Magnetic Resonance (MR) Safety: The Coroent Small Interlock 2 System has not been evaluated for safety and compatibility in the MR environment. The Coroent Small Interlock 2 System has not been tested for heating or migration in the MR environment.

Compatibility: Do not use Coroent Small Interlock 2 System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

Careful attention to osteophyte removal enables optimal implant placement.

If using Caspar pins, be aware that midline placement may interfere with the center screw placement, consider more lateral placement of the Caspar pins.

Be careful not to over-distract the disc space, this will ensure good implant-endplate contact.

The 12–16mm Drill MUST be used with the Adjustable Drill Guide.

Always double check that the screws are locked after removing the DTS guide. If not locked, proceed driving the screw until past the triangle.

Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.

Confirm lateral fluoroscopy shows healthy sagittal alignment.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.

2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

3. Care should be used in the handling and storage of the Coroent Small Interlock 2 System implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
   For Sterile Implants: Assure highly aseptic surgical conditions, and use aseptic technique when removing the Coroent Small Interlock 2 System implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the Coroent Small Interlock 2 System implants if there is any evidence of damage.

4. All non-sterile parts should be cleaned and sterilized before use.

5. Devices should be inspected for damage prior to implantation.

6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POSTOPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

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References

1. Ames CP, Smith JS, Eastlack R, et al. Reliability assessment of a novel cervical spine deformity classification system. *J Neurosurg Spine* 2015;23(6):673-83.

2. Tang JA, Scheer JK, Smith JS, et al. The impact of standing regional cervical sagittal alignment on outcomes in posterior cervical fusion surgery. *Neurosurg* 2012;71(3):662-9.

3. Protopsaltis T, Fehlings M, Liu S, et al. Impact of regional and focal cervical alignment on myelopathy severity: report of 151 patients. *Global Spine J* 2015;05-A030.

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