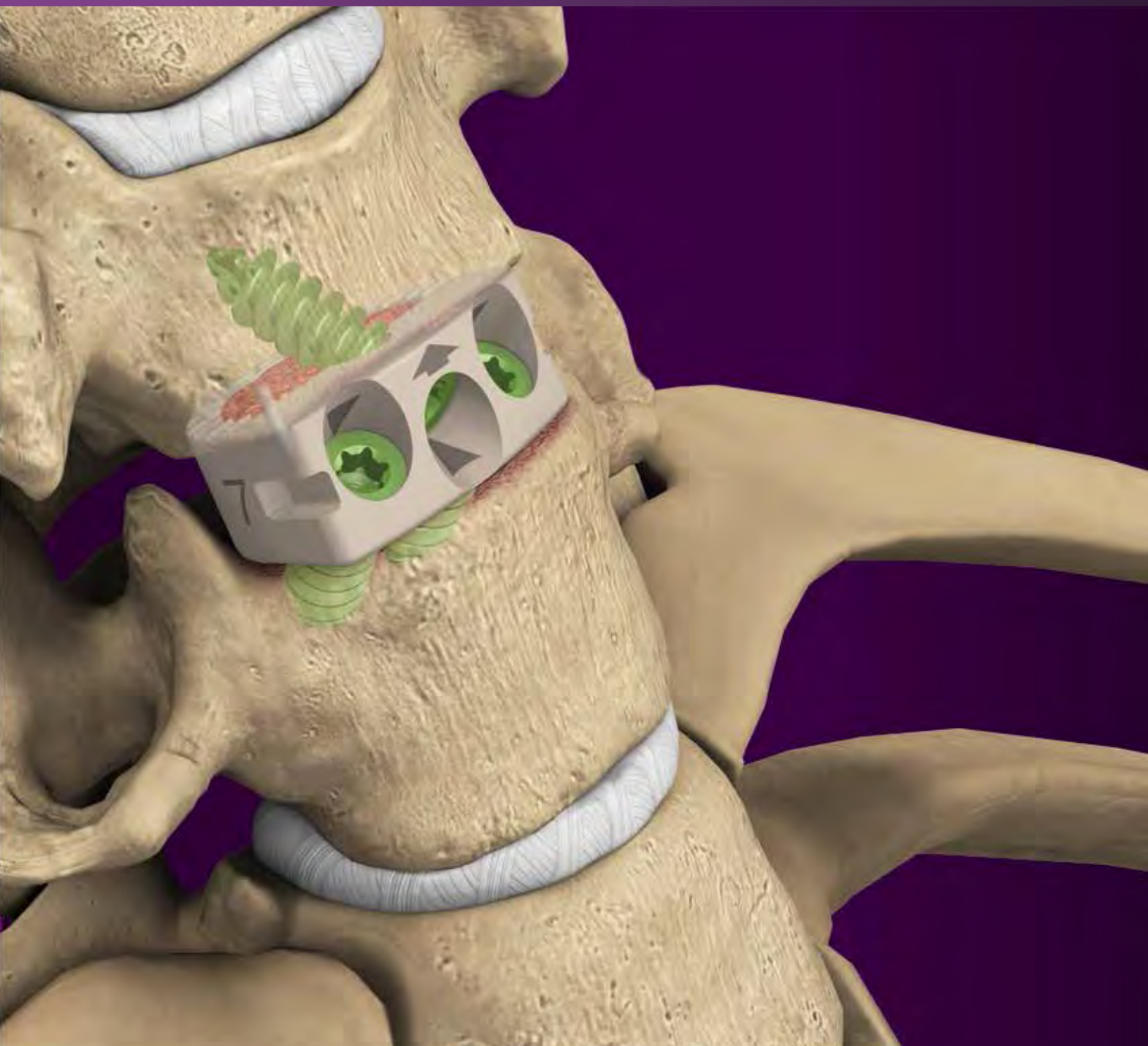
NuVasive®
Speed of Innovation®

CoRoent® SMALL INTERLOCK™

Technique Guide



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PREFACE

Fellow colleagues,

The ACDF Procedure has evolved greatly over the past three decades. Spine surgeons have seen bulky anterior plating systems slowly give way to lower profile plating systems and more recently now to no-profile, completely intervertebral fixation systems. The evolution is taking place to address patient pre-op indications and as well patient post-op complications. Intervertebral fixation systems provide maximum stability with less material and less O.R. time.

The CoRoent® Small Interlock™ system was designed as a TRUE "no-profile" device that is implanted entirely within the confines of the intervertebral disc space. As such, it confers the following advantages over ACP implants:

- Minimization of the longitudinal extent of exposure required for implantation to the dimensions of the intervertebral disc
- Elimination of the implant-retropharyngeal soft-tissue interface, and thereby 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 implant (i.e., ACP) removal is not required.
- Monolithic/fully integrated interbody PEEK spacer and fixation device minimizes number of implants and simplifies fusion process
- Screws are inserted at a 40˚ angle through the bony vertebral endplates, increasing resistance to pull-out forces
- Large central aperture of the implant provides ample space for fusion to occur

Although Inter-vertebral fixation devices will never obsolete the use of anterior plates, they are a compelling and viable advancement to the ACDF procedure from which both surgeon and patient can benefit.

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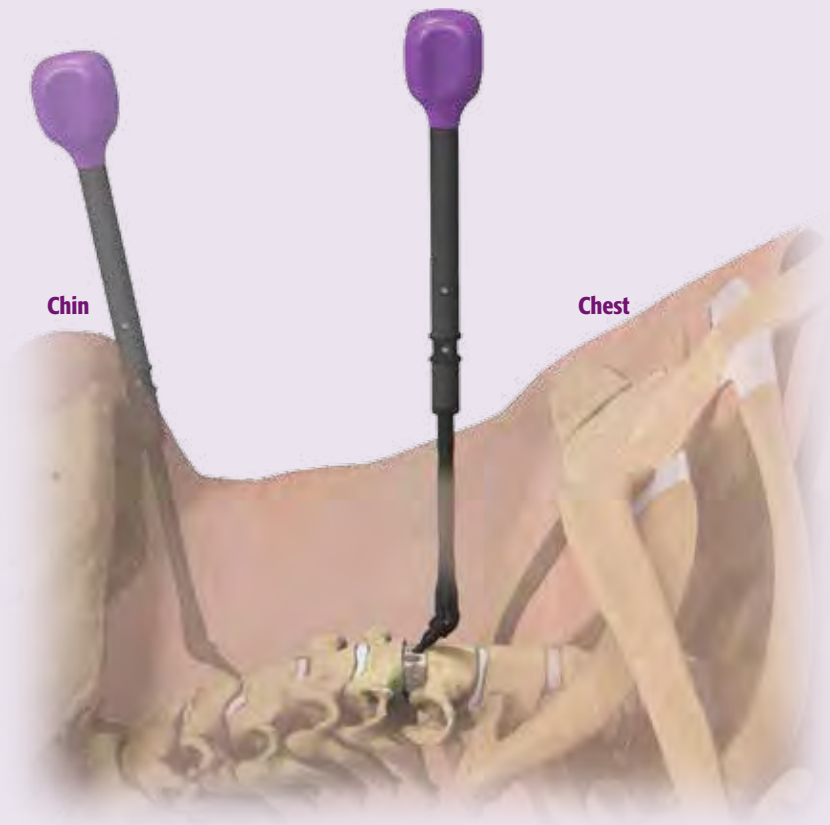
DESIGN RATIONALE

Our main objective was to provide surgeon value with the introduction of a standalone intervertebral fixation system that accomplishes the following goals:

1. Provides value in difficult anatomical situations:
    - Chin at C3-C4
    - Chest at C6-C7
    - Adjacent level plate

2. Requires fewer steps than using an anterior plate

3. Stabilizes the operative segment to promote a robust fusion



SURGEON VALUE

The CoRoent® Small Interlock™ system was designed to reduce the number of steps in the ACDF procedure, maximize intraoperative visibility and versatility, while helping to minimize the length of intraoperative exposures.

Low profile instrumentation and a 3-screw implant design facilitates adjacent level surgery above or below the previous surgery, allowing the surgeon to place the single screw between the existing screws of the plate.

Our goals were accomplished with the development of a system that offers low-profile straight and angled instrumentation for differing anatomy, a robust 3-screw implant design for strong yet anatomically forgiving fixation, and 2-insertion options via the Freehand or DTS guided techniques.

Ultimately we wanted to provide a system that has the simplicity, strength and versatility to provide value in every surgery.

2 TECHNIQUE OPTIONS

FREEHAND

Offers the surgeon assistence in screw placement while the implant is anchored securely in place.

DTS GUIDED

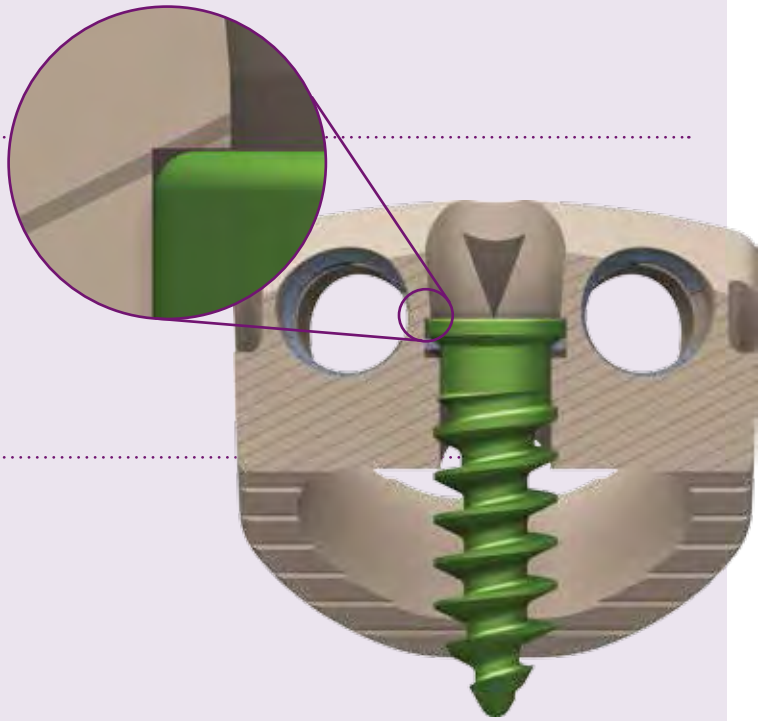
Offers the surgeon assistance in screw trajectory and alignment.

Simply LOAD IT. LOCK IT. LEAVE IT.

LOCKING MECHANISM

PEEK (360°) CIRCUMFERENTIAL LOCKING LEDGE

- The screw head is locked underneath the ledge once it passes beyond the ledge and into the pocket



VISUAL CONFIRMATION

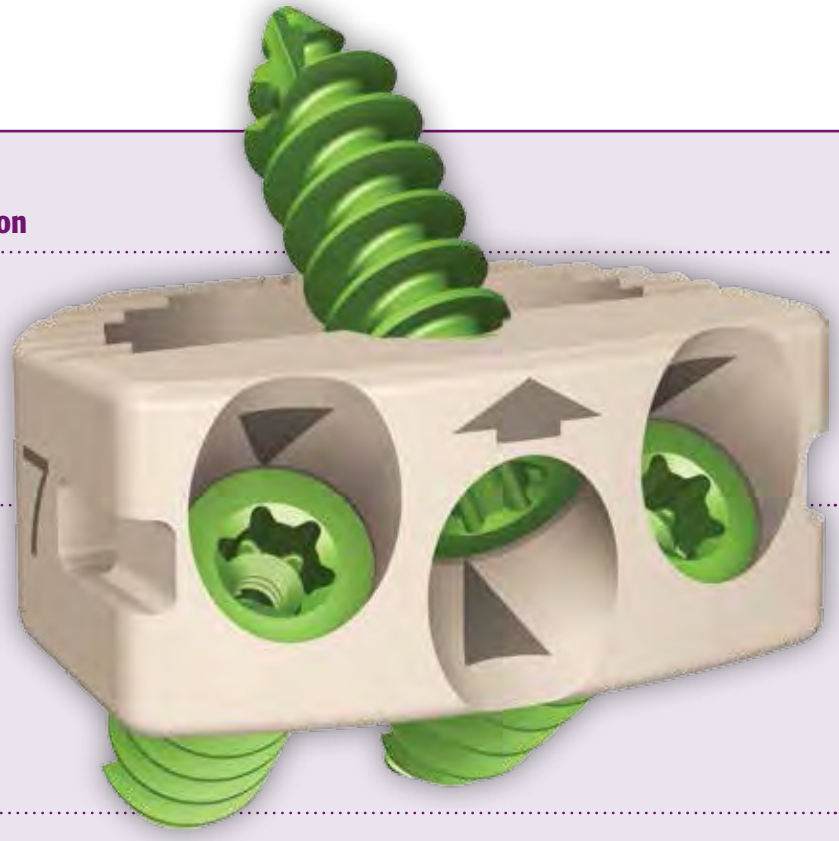
- Triangle laser marks within the screw hole provide visual confirmation that the screw is locked

TACTILE STOP

Tactile Feedback Washer

- Provides tactile feedback that the screw is seated in place (i.e., locked under the PEEK ledge and past the triangle)
- The bottom of the screw head interacts with the Tactile Feedback Washer under compression to create a sandpaper-on-sandpaper feel, which increases drag and the torque required to turn the screw

3 SCREW CONSTRUCT



Robust screws for purchase and fixation

- 4.0mm primary
- 4.5mm rescue

Accomodates adjacent levels

- The center screw fits between existing screws of the adjacent level plate

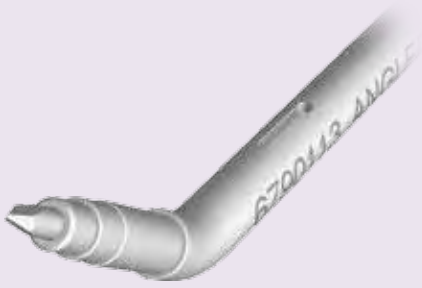
Provides surgeon placement options in tough anatomy

- Only fight the chin or chest once by respectively placing the center screw caudal or cranial to avoid the interfering anatomy

Simplicity

- Requires only 3 instruments

Inserter

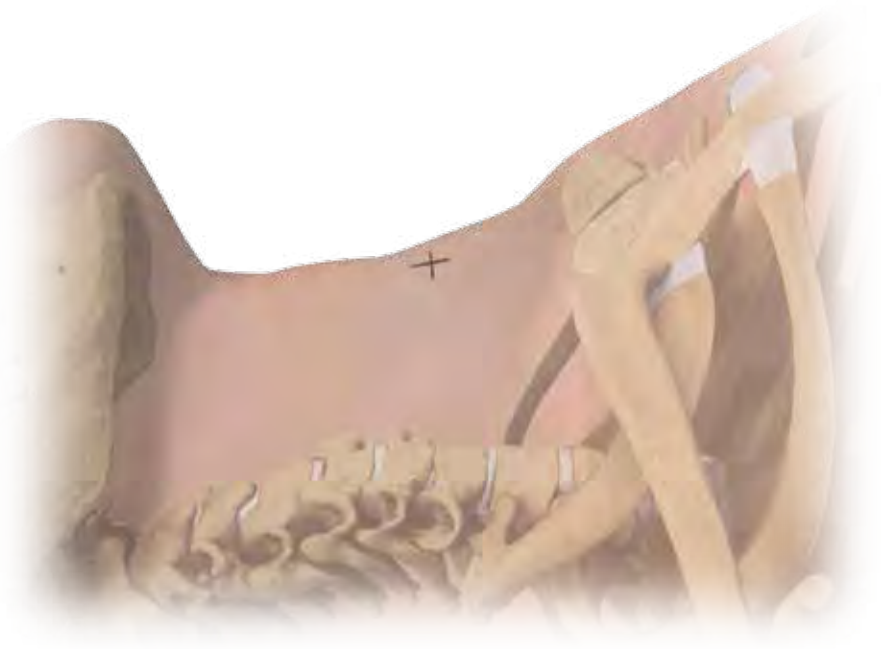


Awl

Screwdriver

COROENT® SMALL INTERLOCK™ – SURGICAL TECHNIQUE

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 surgical technique guide.

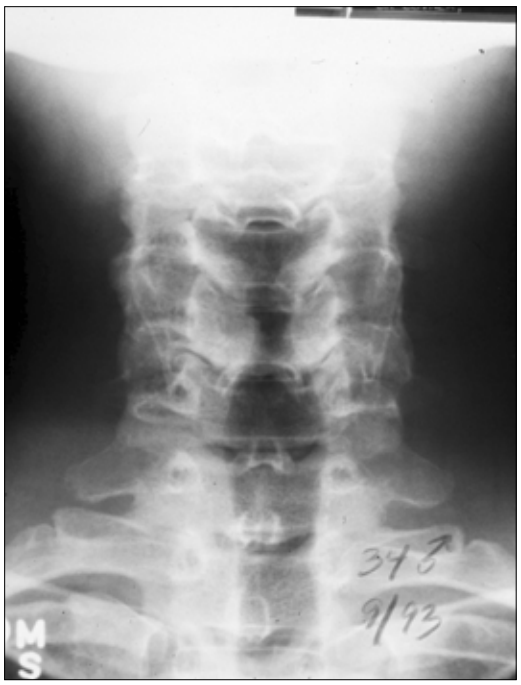


Pre-op positioning and imaging

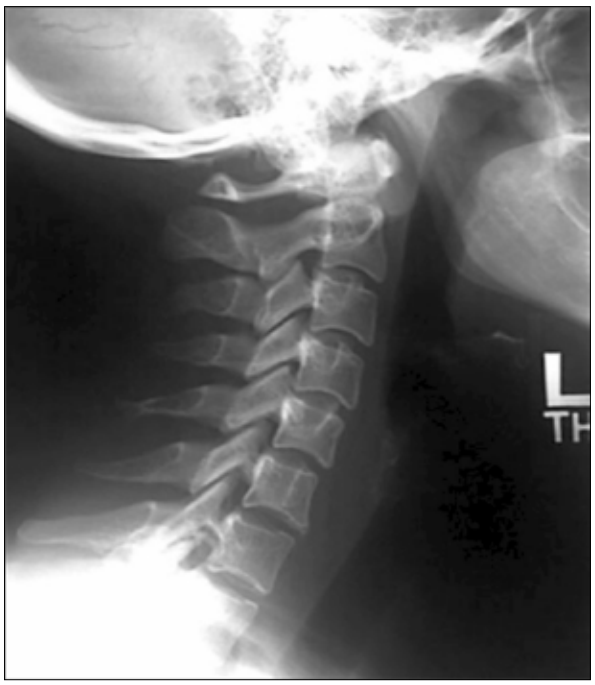
The patient is in the supine position with the head in slight extension with chin in up position.

Fluoroscopy

A/P and lateral imaging is used to locate the operative level and assess the bony anatomy.



A/P Fluoro



Lateral Fluoro

Step 1: ACCESS/APPROACH

Carry out your anterior approach to the appropriate levels of the cervical spine in the usual manner. Direct anterior access to the disc and adjacent vertebral bodies is necessary *(FIG. 1)*.

Tips and Tricks:

- *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*

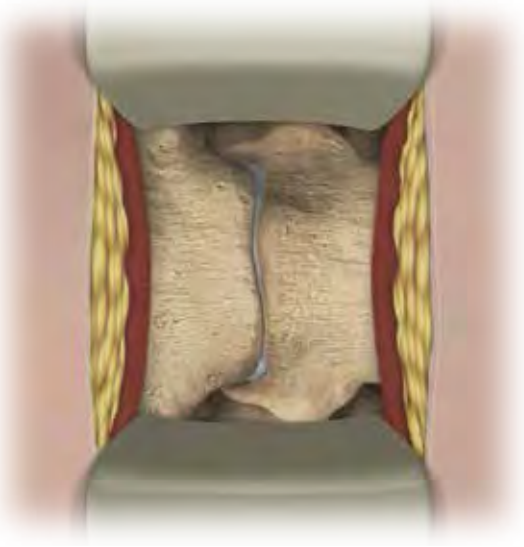


FIG. 1 (Pre-Op Level)

Step 2: DISCECTOMY/DECOMPRESSION

Perform a complete discectomy and decompression to thoroughly remove the disc material *(FIG. 2)*.

Tips and Tricks:

- *Ensure a full posterior-lateral decompression to allow for the 17x14mm footprint*

The NVJJB®/M5® system is useful when used in Free Run mode to monitor for any spontaneous neurological activity during discectomy, decompression, interbody placement, and screw placement. Refer to the NVM5® Reference Guide for further information on the utility of NVJJB/M5 in the cervical spine.

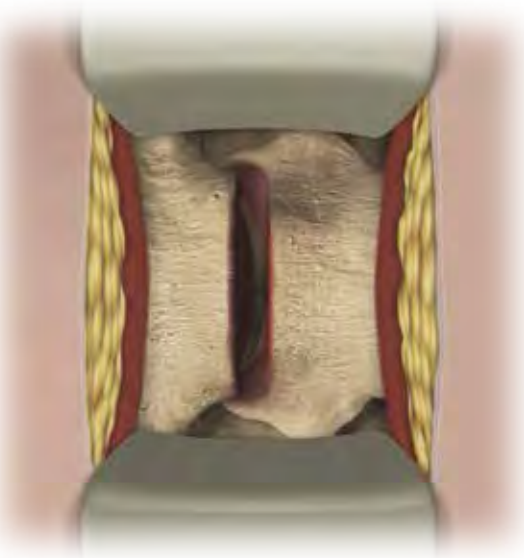


FIG. 2 (Discectomy)

Step 3: TRIAL AND RASP

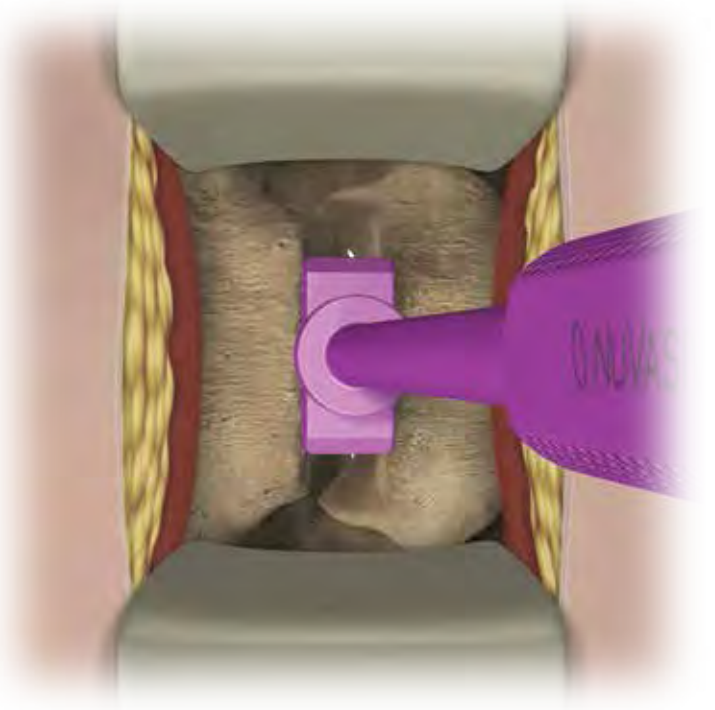
Select the appropriate implant height by using the implant matching trials. Start with a smaller height and work your way up to the appropriate height.

Rasps can then be used to decorticate the endplates.

(Trials and Rasps are available in 5-12mm heights via 1mm increments).

Tips and Tricks:

- *The depth stop on the Trials will stop it at 1mm subflush to the anterior aspect of the verteral body, mimicking the final implant position*



NOTE:
The Trials and Rasps are the exact size as the implants.

Trial **Rasp** **Implant**

Step 4a: IMPLANT LOADING

Freehand Technique

Steps: Load implant onto Freehand Inserter (black).

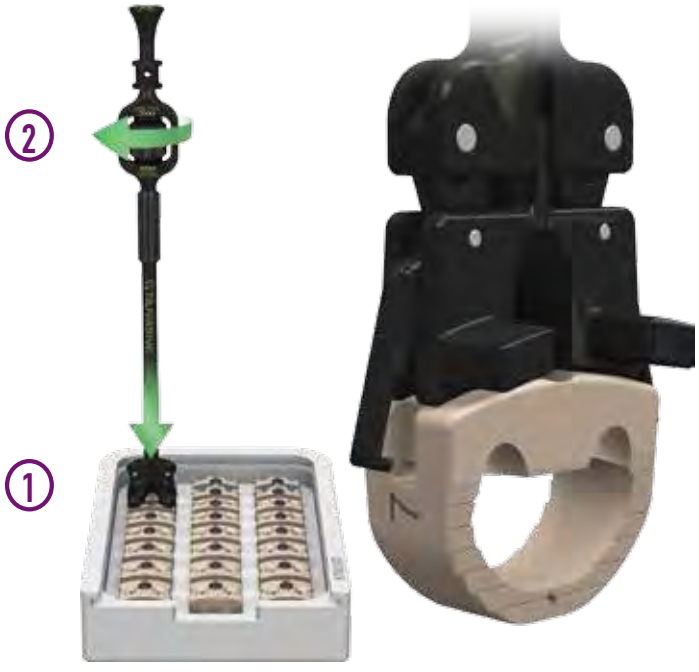
1. For proper orientation of the implant on the inserter, line up the laser marked arrow on the proximal end of the Freehand Inserter with the arrow on the face of the implant. Both arrows should be facing the same direction (*FIG. 1*)

2. With the alignment arrows headed in the same direction, place the Inserter on the face of the appropriately sized implant (*STEP 1)* and rotate the tightening knob clockwise until tight (*STEP 2)*

FIG. 1

Tips and Tricks:

- *For easiest engagement, load implant straight out of the caddy*
- *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 center screw is headed (i.e., arrow pointing cranial means the center screw is headed cranially)*



Step 4b: IMPLANT LOADING

DTS Guide Technique

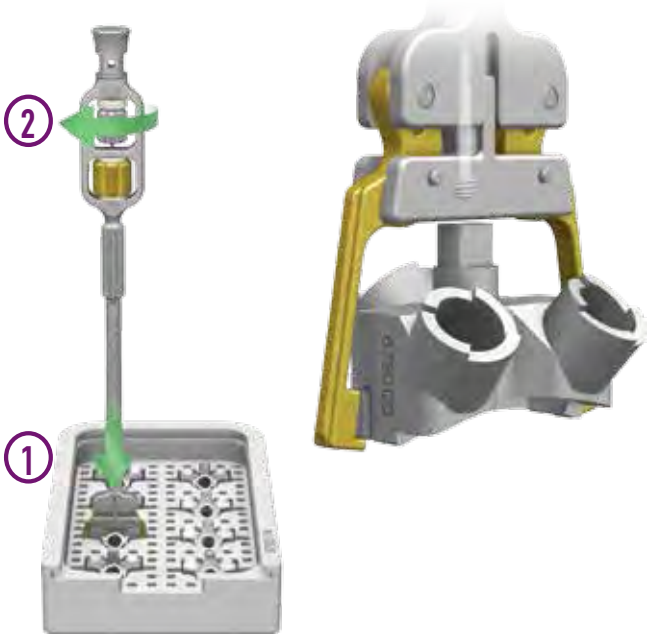
Steps: Load DTS Guide and implant onto DTS Inserter (silver).

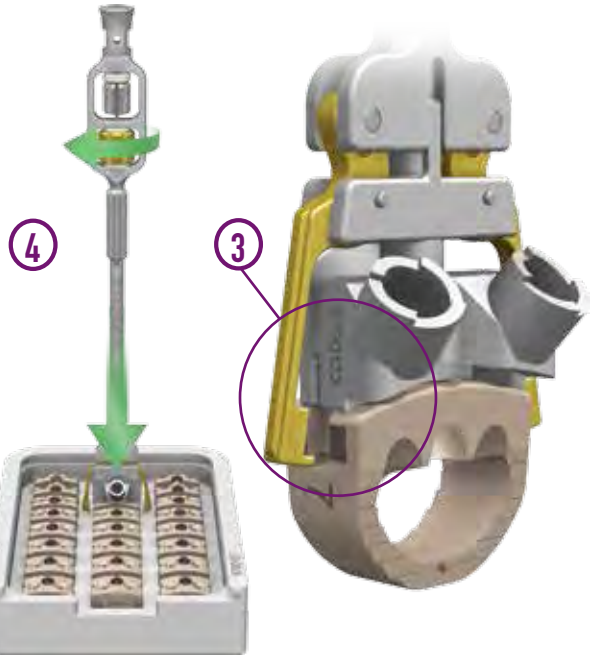
1. Place the DTS Inserter over the appropriate size DTS Guide in the caddy, orientation doesn't matter (*STEP 1*)

2. With one finger, tighten the silver knob to positively engage the DTS Guide to the inserter (*STEP 2*) **Caution – *DO NOT OVERTIGHTEN!***

3. For proper orientation of the implant on the Inserter/DTS Guide assembly, line up the laser marks (part numbers) on the side of the DTS Guide with the laser marks (stripes) on the side of the implant (*STEP 3*)

4. To load the implant, set the Inserter/DTS Guide assembly on the face of the appropriately sized implant and rotate the gold knob clockwise until tight (*STEP 4*)





Tips and Tricks:

- *Always final check implant engagement by squeezing the gold arms into the implant and slightly turn the gold knob once more to ensure a tight fit*
- *To release the implant, the surgeon only needs to turn the gold knob counterclockwise*

Step 5: SPACER INSERTION

Once the proper implant has been selected, and loaded onto the Freehand Inserter or DTS Guide, fill the implant aperture with autograft of choice.

Gently impact the Inserter/implant assembly into the prepared disc space. Ensure the Inserter is positioned parallel to the disc space during impaction. Advance until the 1mm depth stops reach the anterior surface of the vertebral bodies (*FIG. 1*). This is the optimal implant depth.

Without removing the Inserter, use lateral fluoroscopy to confirm the implant is in the proper location. Use A/P fluoro to verify the implant is centered.

Tips and Tricks:

- *If the individual's anatomy presents a challenge to the screw angles, aim the center screw away from the challenging anatomy to limit the screwdriver encounter to one time*
- *Example: At C6-C7, shoot the center screw away from the chest and up into C6 so the screw driver is only fighting the chest one time*
- *Be careful not to over-distract the disc space, this will ensure good implant-endplate contact*

NOTE: The implant is 17mm wide x 14mm deep, once countersunk 1mm, the total construct will be 15mm deep (FIG. 2)

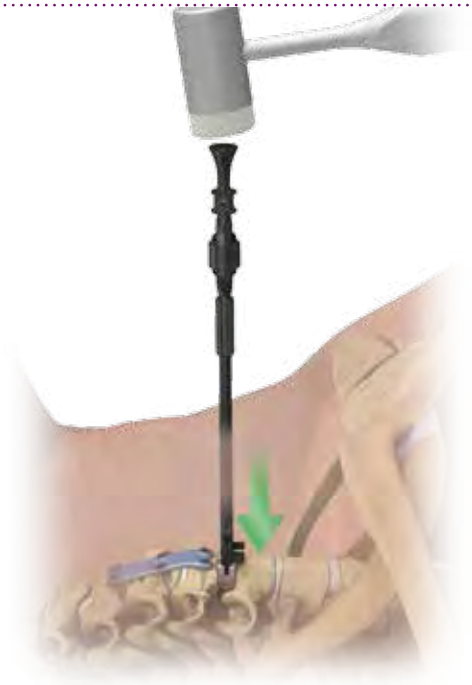


FIG. 1

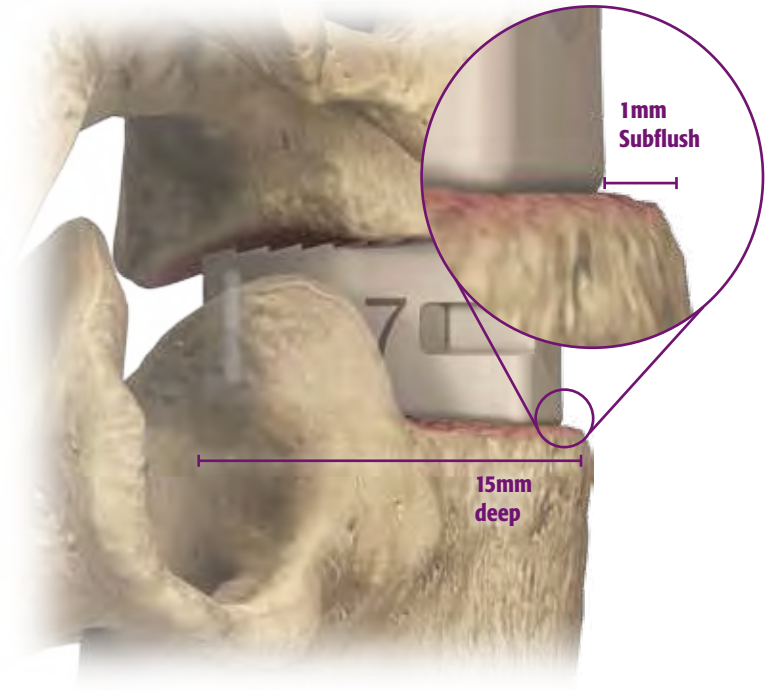


FIG. 2

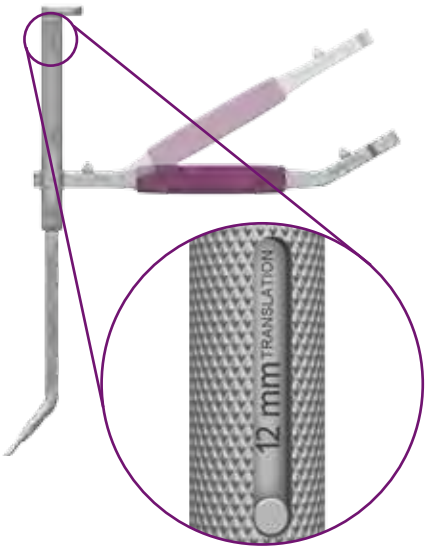
Step 6: AWL OR DRILL (TAP OPTIONAL)

Once the implant is seated at the optimal depth, the Awl or Drill may be used to initiate the screw pathway and trajectory.

Awl

Straight

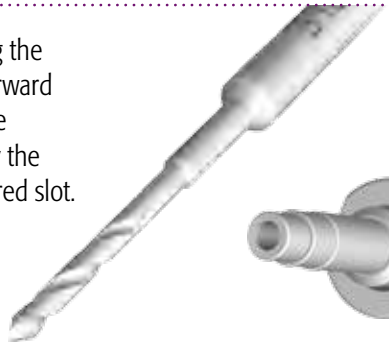
Angled



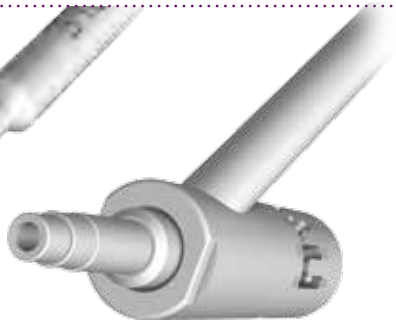
If desired, attach the Wrench Handle to the Angled Awl during the Freehand Technique for better control and force distribution.

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.



Drill



Adjustable Drill Guide

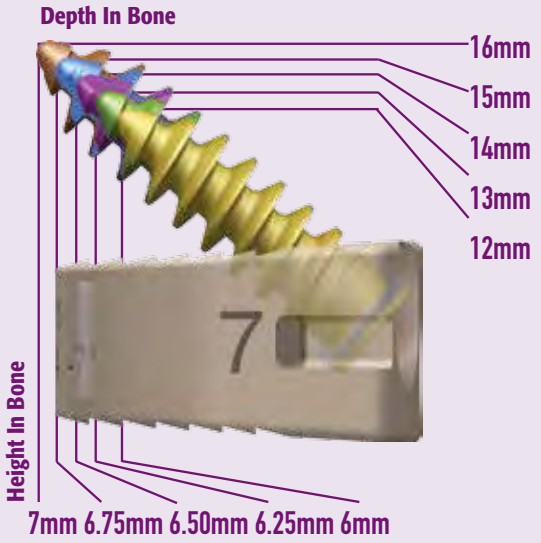
FIG. 1

NOTE: Drilling beyond 14mm will advance the drill past the posterior aspect of the implant

NOTE: The 12-16mm Drill MUST be used with the Adjustable Drill Guide

Step 7: SCREW SELECTION

The length of the screws are measured from the anterior portion of the implant to the total distance reached posteriorly. This takes into account the 40˚ angle (*FIG. 1*).



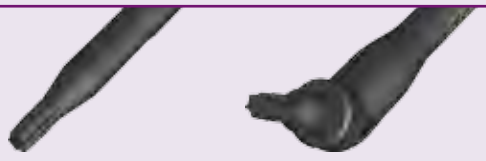
NOTE:
The 14mm screw will extend to the posterior aspect of the implant when the implant is neutral to the spine.

FIG. 1

SCREW INSERTION

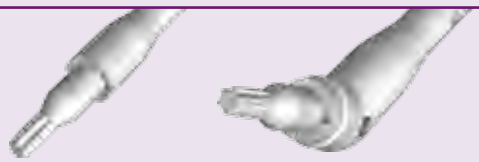
Four screw delivery options are available based on surgeon preference and anatomical demands.

FREEHAND



NOTE:
The Angled Freehand 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.

DTS DRIVERS



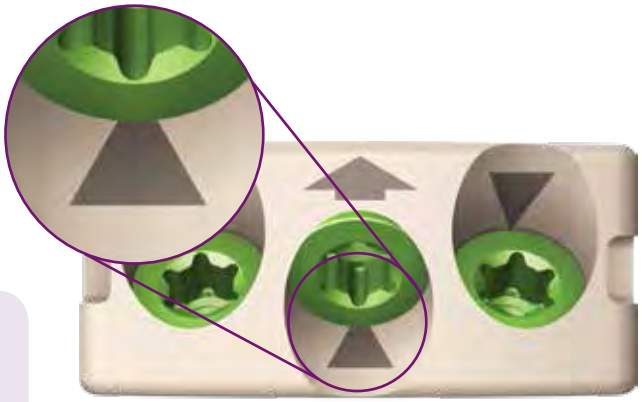
NOTE:
The DTS Driver has a positive stop on the DTS Guide (Metal on Material) that indicates when the screw is past the locking ledge.

LOCKING VERIFICATION

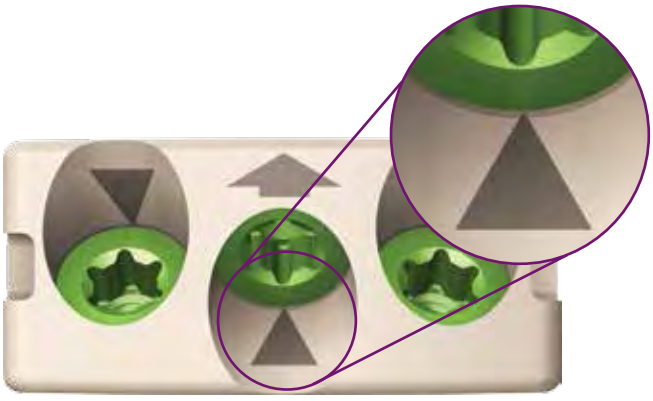
VISUAL CONFIRMATION:

The primary locking indicator is visualization of the locking triangle. As you are placing the screw into the hole, you know you are locked when you have FULL visualization of the triangle. You will see the very tip of the triangle exposed when the screw is locked beneath the ledge.

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



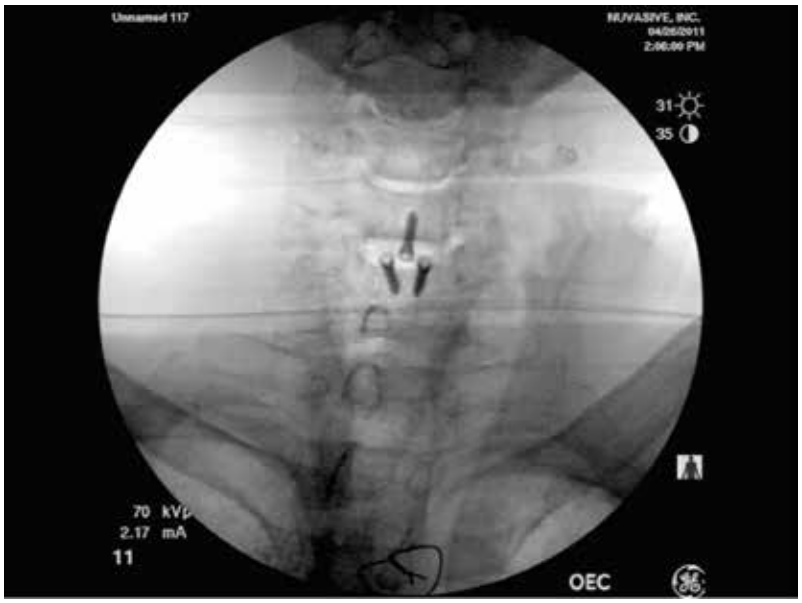
Unlocked



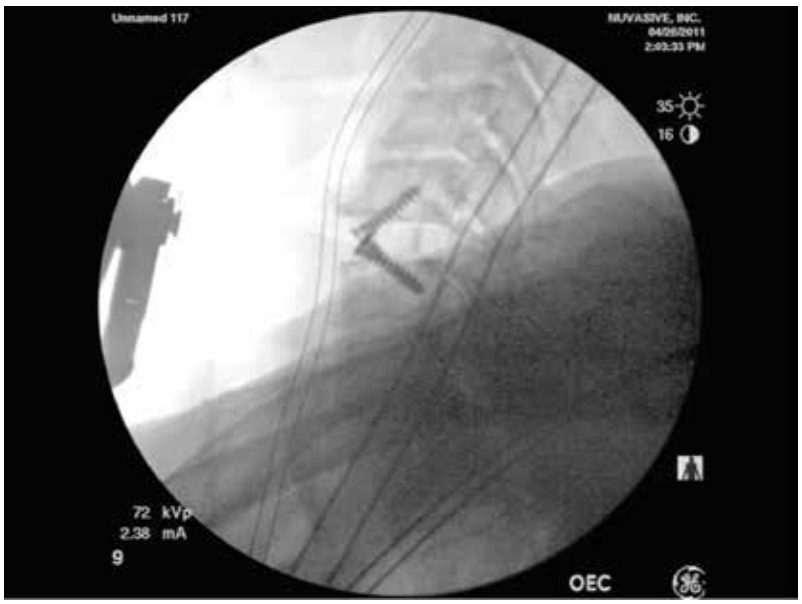
Locked

POST-OP VERIFICATION

A/P Fluoro



Lateral Fluoro



SCREW REMOVAL

Should a screw need to be removed, follow the steps below.

Follow these steps:

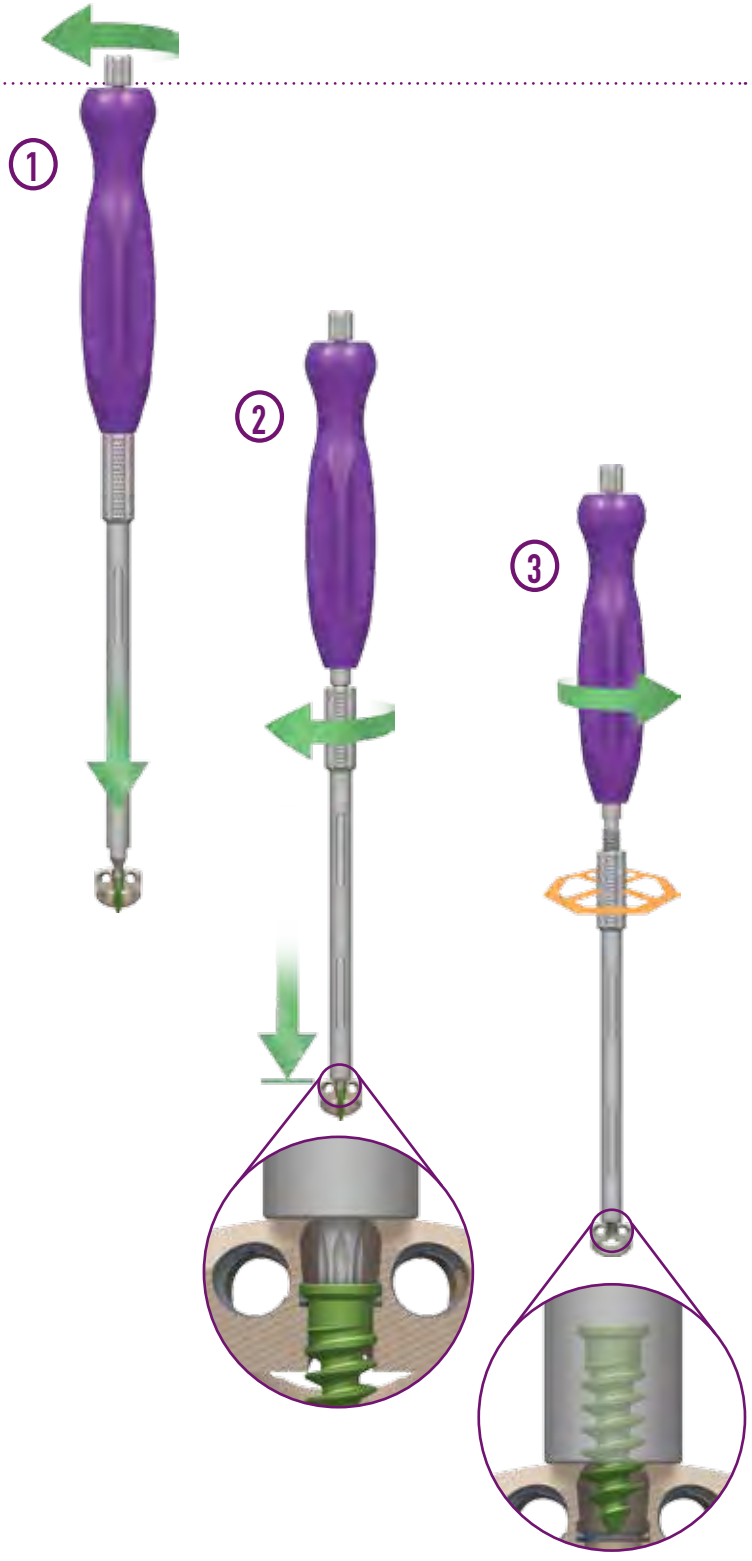
1. At the proximal end of the screw extractor, tighten the inner shaft of the instrument into the female engagement of the selected screw *DO NOT OVERTIGHTEN!*

2. Rotate the collet sleeve of the screw extractor clockwise down to the anterior surface of the interbody, which acts as a counter torque

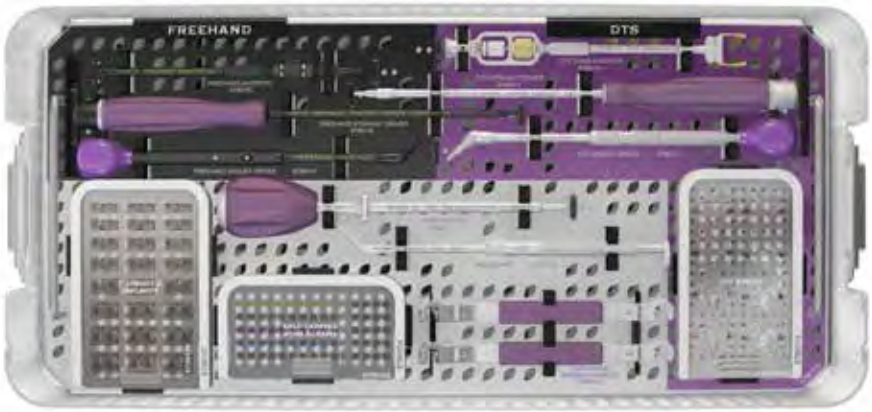
3. With the collet sleeve held static against the interbody, rotate the purple handle of the screw extractor counterclockwise to remove the screw from the construct

Tips and Tricks:

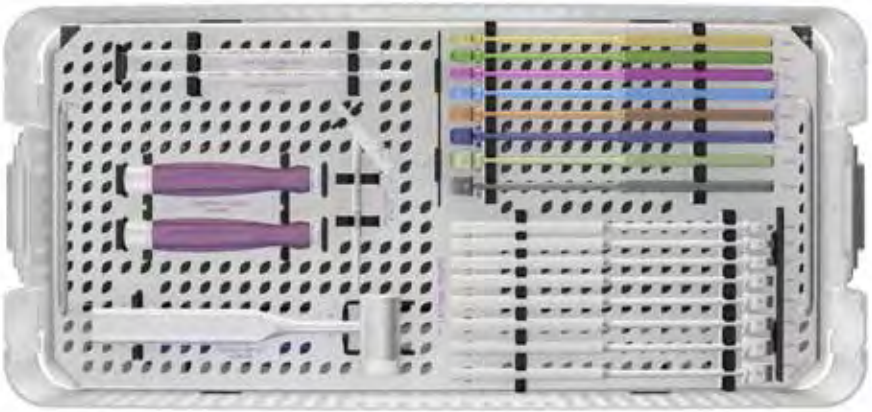
- *Maintain the same 40˚ trajectory while engaging the extractor*
- *Place downward pressure on the extractor while turning the silver engagement knob*



INSTRUMENT TRAY



Top Tray



Middle Tray

Bottom Tray

IMPLANTS

4.0mm Screw

4.5mm Rescue Screw

CoRoent Small Interlock Implant (Axial View)

CoRoent Small Interlock Implant (Lateral View)

INSTRUMENTS

5mm Trial

6mm Trial

7mm Trial

8mm Trial

9mm Trial

10mm Trial

11mm Trial

12mm Trial

INSTRUMENTS

5mm Rasp

6mm Rasp

7mm Rasp

8mm Rasp

9mm Rasp

10mm Rasp

11mm Rasp

12mm Rasp

COROENT® SMALL INTERLOCK™ SYSTEM

INSTRUMENTS

Freehand Inserter

Straight Freehand Driver

Angled Freehand Driver

DTS Guides:

5mm **6mm** **7mm** **8mm** **9mm** **10mm** **11mm** **12mm**

DTS Inserter

Straight DTS Driver

Angled DTS Driver

INSTRUMENTS

Universal Handle

12-16mm Drill Shaft

12mm Tap

Wrench Handle, Dual Angle

Adjustable Drill Guide (12-16mm)

Straight Awl

40° Angled Awl

Screw Extractor

CATALOG

DESCRIPTION	CATALOG #
IMPLANTS	
Implant - 5x17x14mm, 7°	6790225
Implant - 6x17x14mm, 7°	6790226
Implant - 7x17x14mm, 7°	6790227
Implant - 8x17x14mm, 7°	6790228
Implant - 9x17x14mm, 7°	6790229
Implant - 10x17x14mm, 7°	6790230
Implant - 11x17x14mm, 7°	6790231
Implant - 12x17x14mm, 7°	6790232
Screw - 4.0x12mm	6791712
Screw - 4.0x13mm	6791713
Screw - 4.0x14mm	6791714
Screw - 4.0x15mm	6791715
Screw - 4.0x16mm	6791716
Screw - 4.5x12mm, Rescue	6791812
Screw - 4.5x13mm, Rescue	6791813
Screw - 4.5x14mm, Rescue	6791814
Screw - 4.5x15mm, Rescue	6791815
Screw - 4.5x16mm, Rescue	6791816

DESCRIPTION	CATALOG #
INSTRUMENTS	
Trial - 5x17x14mm, 7° Gold	6790161
Trial - 6x17x14mm, 7° Green	6790162
Trial - 7x17x14mm, 7° Magenta	6790163
Trial - 8x17x14mm, 7° Blue	6790164
Trial - 9x17x14mm, 7° Bronze	6790165
Trial - 10x17x14mm, 7° Purple	6790166
Trial - 11x17x14mm, 7° Seafoam	6790167
Trial - 12x17x14mm, 7° Grey	6790168
Rasp - 5x17x14mm, 7°	6790141

DESCRIPTION	CATALOG #
INSTRUMENTS	
Rasp - 6x17x14mm, 7˚	6790142
Rasp - 7x17x14mm, 7˚	6790143
Rasp - 8x17x14mm, 7˚	6790144
Rasp - 9x17x14mm, 7˚	6790145
Rasp - 10x17x14mm, 7˚	6790146
Rasp - 11x17x14mm, 7˚	6790147
Rasp - 12x17x14mm, 7˚	6790148
DTS Guide - 5mm	6790121
DTS Guide - 6mm	6790122
DTS Guide - 7mm	6790123
DTS Guide - 8mm	6790124
DTS Guide - 9mm	6790125
DTS Guide - 10mm	6790126
DTS Guide - 11mm	6790127
DTS Guide - 12mm	6790128
Cervical Mallet	1006278
Freehand Inserter	6790172
Freehand Straight Driver	6790110
Freehand Angled Driver, 40˚	6790114
DTS Inserter	6790119
DTS Straight Driver	6790111
DTS Angled Driver	6790117
Straight Awl, Self-Centering	6790112
Angled Awl, Self-Centering	6790113
Adjustable Drill Guide - 12-16mm	6790173
Implant Rescue Tool	6790130
Drill- 12-16mm, Disposable	6790151
Tap- 12mm, Disposable	6790152
Universal Handle, AO	6790150
Wrench Handle, Dual Angle	6790153

INSTRUCTIONS FOR USE

DESCRIPTION

The NuVasive CoRoent Small Interlock System is a standalone anterior cervical interbody device consisting of a PEEK (polyetheretherkeytone) implant cage with titanium alloy radiographic markers and washers, and three (3) titanium alloy bone fixation screws. The is manufactured from PEEK-OPTIMA® LT-1 (Polyether-ether-ketone) conforming to ASTM standard F2026 and Ti-6Al-4V ELI conforming to ASTM standard F136/1472 or Tantalum (Ta) conforming to ASTM standard F560 or ISO 13782. The implants are available in a variety of sizes to accommodate anatomical conditions. The CoRoent Small Interlock System is a standalone system intended to be used with the bone screws provided, and when used as such requires no additional supplementary fixation systems.

INDICATIONS FOR USE

The CoRoent Small Interlock System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the CoRoent Small Interlock System. The CoRoent Small Interlock System is intended for use with autograft.

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.
9. Any case not described in the indications.

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 known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNING, 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.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

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 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 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.

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

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.

Single Use Only: 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.

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.

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

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

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 implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
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.

POST-OPERATIVE 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.

CLEANING AND DECONTAMINATION

All instruments must first be cleaned using the following validated methods before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer for full processing. Cleaning instructions for the instruments are as follows:

1. Prior to soaking the instruments in an enzymatic cleaning solution, rinse the instruments under running tap water and wipe off any residual soil or debris with a disposable towel. Ensure to flush out any lumens, cracks or crevices while rinsing under running tap water.
2. Prepare an enzymatic cleaning solution, such as Enzol®, per manufacturer's recommendations (1oz/gal minimum) using tap water. Place the instruments in the solution in the open position (as appropriate) and allow to soak for a minimum of 5 minutes. While soaking, actuate the instruments through a full range of motion (as appropriate for the specific instrument) to allow complete penetration of the cleaning solution.
3. After the 5 minute soak time, remove the instruments and wipe off any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of an enzymatic cleaning solution, and using a soft bristled brush, brush all accessible surfaces of the instrument. As appropriate for the specific instrument, actuate the instruments while brushing to ensure hard to reach areas are reached. Use a syringe and lumen brush to clean hard to reach areas.
4. Remove the instruments from the detergent and rinse by agitating and actuating in ambient RO/DI water for a minimum of 30 seconds. Flush all hard to reach areas with a sterile syringe.
5. Prepare a detergent solution, such as Renu-Klenz,® per manufacturer's recommendations (1oz/gal) using warm tap water in a sonication unit. Allow the instruments to sonicate for 10 minutes.
6. Remove the instruments from the detergent and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds. Actuate through a full range of motion while rinsing and flush hard to reach areas with a sterile syringe.
7. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Below is the validated and recommended cycle:

Phase	Recirculation Time	Water Temperature	Detergent Type & Concentration (if applicable)
Pre-wash	1 minute	Cold Tap Water	N/A
Enzyme Wash	1 minute	Hot Tap Water	Enzol, ¼ oz/gallon
Wash	2 minutes	65.5°C (set point)	Renu-Klenz, ¼ oz/gallon
Rinse	1 minute	RO/DI Water	N/A
Drying	7 minutes	115°C	N/A

8. Dry the instruments using a clean soft towel.

Visually inspect the instruments following performance of the cleaning instructions prescribed above. Ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps above. Otherwise, contact your NuVasive representative – contaminated instruments should not be used, and should be returned to NuVasive.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

Contact your NuVasive representative for any additional information related to cleaning and sterilization of NuVasive surgical instruments.

STERILIZATION

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components of the CoRoent Small Interlock System are sterilizable by steam autoclave using standard hospital practices. Devices are to be packaged in a woven sterilization wrap prior to placement in an autoclave. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

Method: Steam	Method: Steam
Cycle: Gravity	Cycle: Pre-Vacuum
Temperature: 270°F (132°C)	Temperature: 270°F (132°C)
Exposure Time: 30 minutes	Exposure Time: 6 minutes
Minimum Dry Time: 30 minutes	Minimum Dry Time: 30 minutes

Always sterilize the devices in the disassembled, open, unlocked position, and avoid sudden cooling of the components. Ensure that all functions are unimpaired before use.

NOTES

To order, please contact your NuVasive® Sales Consultant or Customer Service Representative today at:
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