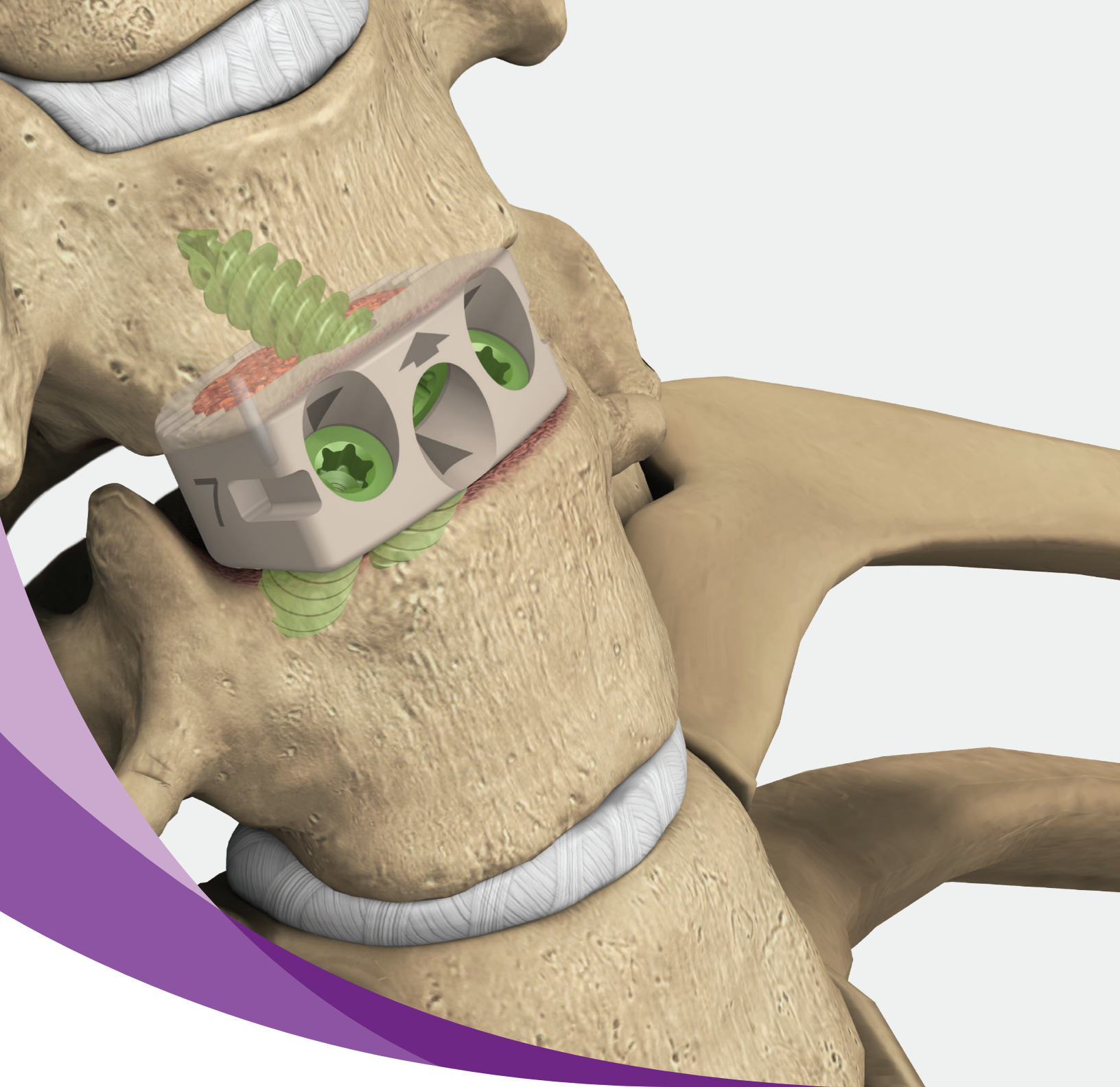




Coroent Small Interlock

Technique guide



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. 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.

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Preface

Fellow colleagues,

The anterior cervical discectomy and fusion (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 pre-op indications and as well post-op complications. Intervertebral fixation systems are designed to provide maximum stability with less material and less OR 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:

- the required surgical exposure is limited to the intervertebral disc;
- elimination of the implant-retropharyngeal soft-tissue interface, and thereby minimizing the risk of post-op implant-induced dysphagia and delayed esophageal injury due to erosion;
- ideal for use at segments adjacent to previously instrumented levels, as implant (i.e., anterior cervical plate) removal is not required;
- fully integrated interbody PEEK spacer and fixation device minimizes number of implants and simplifies implantation procedure;
- screws are inserted at a 40° angle through the bony vertebral endplates, helping to increase resistance to pull-out forces; and
- large central aperture of the implant provides ample space for fusion to occur.

Although intervertebral 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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Coroent Small Interlock features

Design rationale

Our main objective was to provide value to surgeons with the introduction of a standalone intervertebral fixation system that accomplishes the goals listed below.

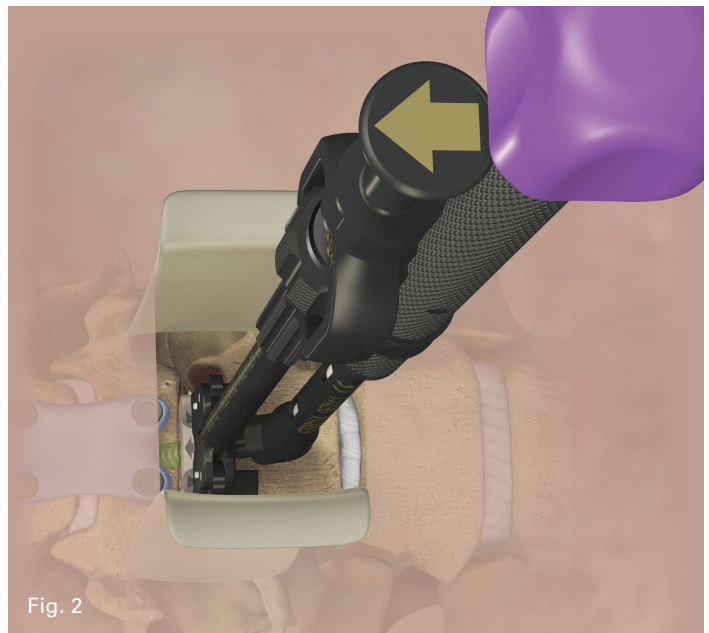
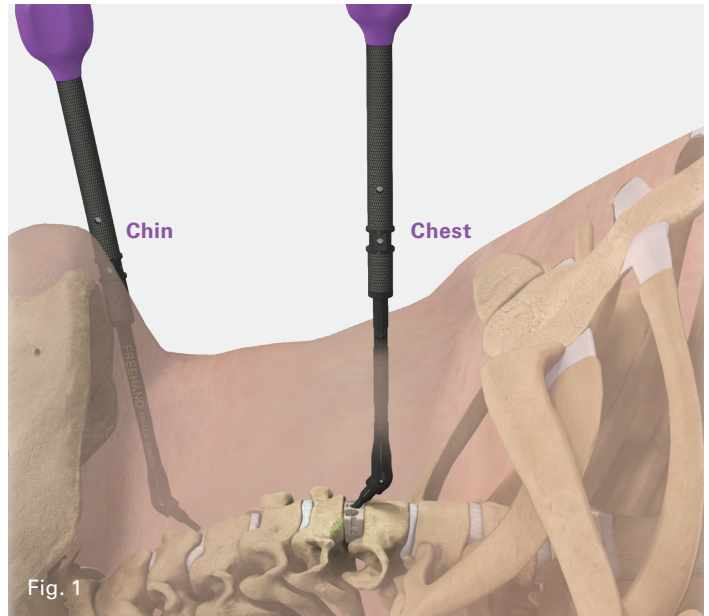
- Unique design allows implantation in difficult anatomic locations (*Fig. 1*):
 - chin at C3–C4,
 - chest at C6–C7, and
 - adjacent level plate.
- Requires fewer steps than using an anterior plate
- Helps stabilize the operative segment to promote a robust fusion

Surgeon value

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

The system has low-profile instrumentation with both straight and angled configurations. The robust three-screw implant design provides strong fixation while allowing the surgeon to place a single screw between screws from an existing adjacent level plate. The implant may be inserted using the freehand or drill, tap, screw (DTS) guided techniques (*Fig. 2*).

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



Two technique options

Freehand

Offers the surgeon assistance in screw placement while the implant is anchored securely in place (*Fig. 3*).



Fig. 3

DTS guided

Offers the surgeon assistance in screw trajectory and alignment (*Fig. 4*).

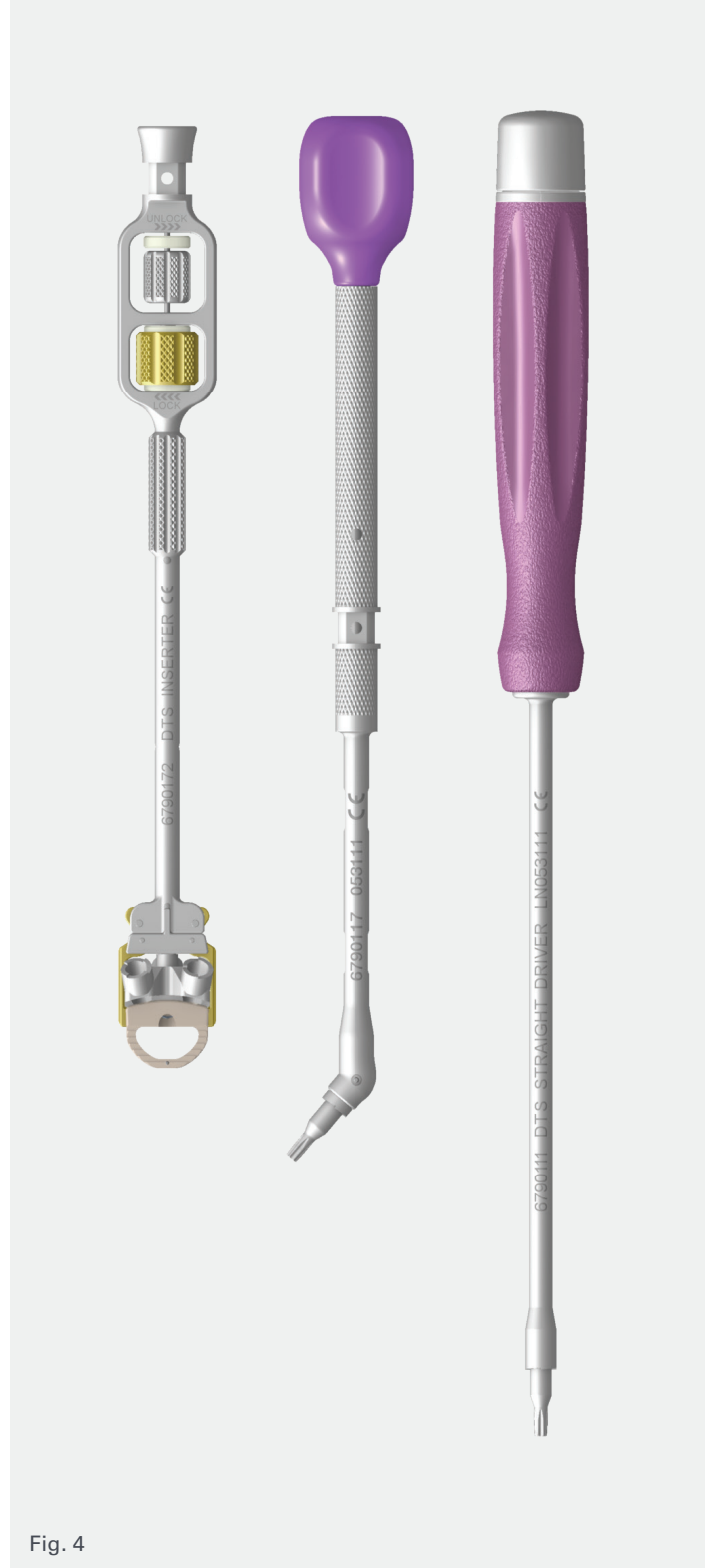


Fig. 4

Locking mechanism

Peek (360°) circumferential locking ledge

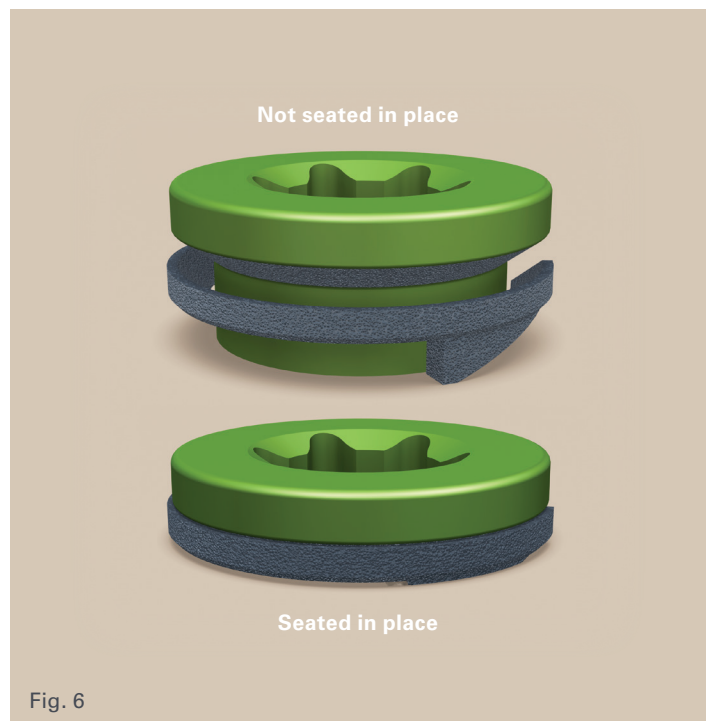
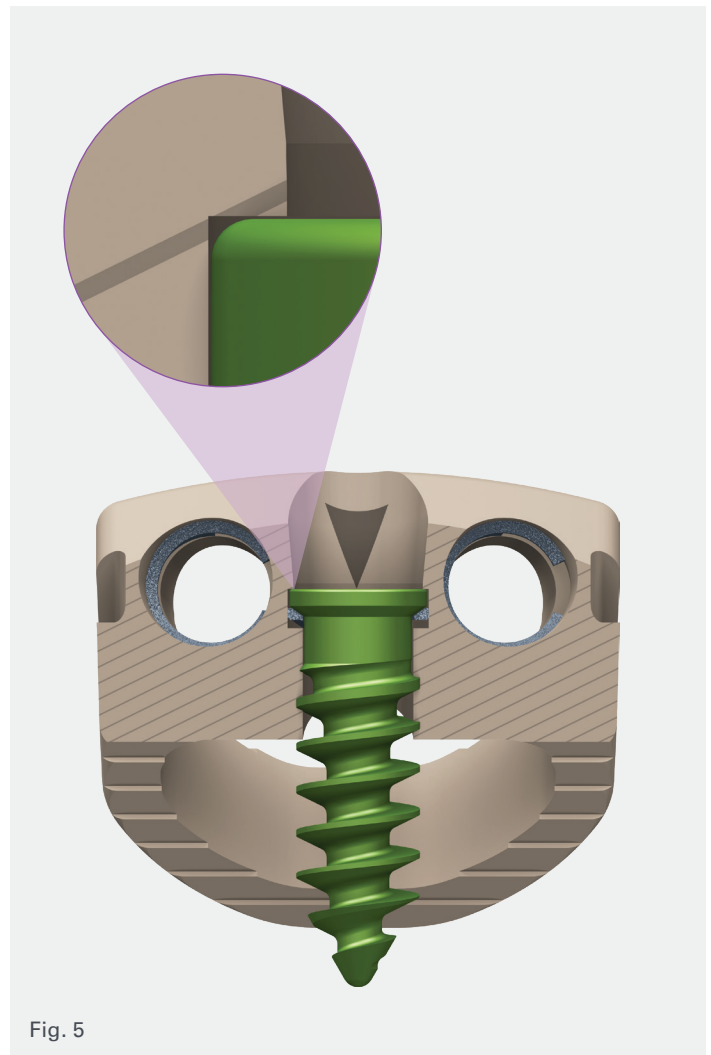
The screw head is locked underneath the ledge once it passes beyond the ledge and into the pocket (*Fig. 5*).

Visual confirmation

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

Tactile stop

- The tactile feedback washer provides tactile feedback that the screw is seated in place (i.e., locked under the PEEK ledge and past the triangle) (*Fig. 6*).
- 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.



Three screw construct *(Fig. 7)*

Robust screws for purchase and fixation

- 4 mm primary
- 4.5 mm rescue

Accommodates 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 placing the center screw caudal or cranial, respectively, to avoid the interfering anatomy.

Simplicity

Only three instruments are required *(Fig. 8)*.

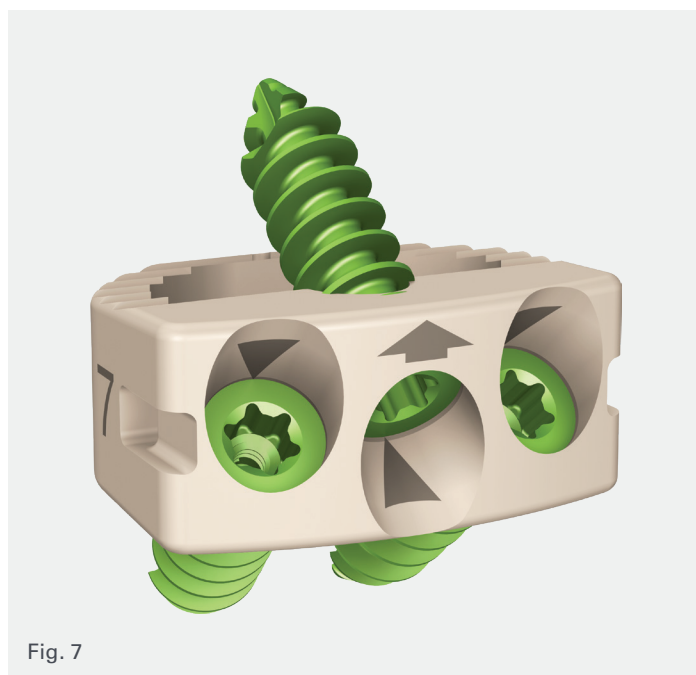


Fig. 7

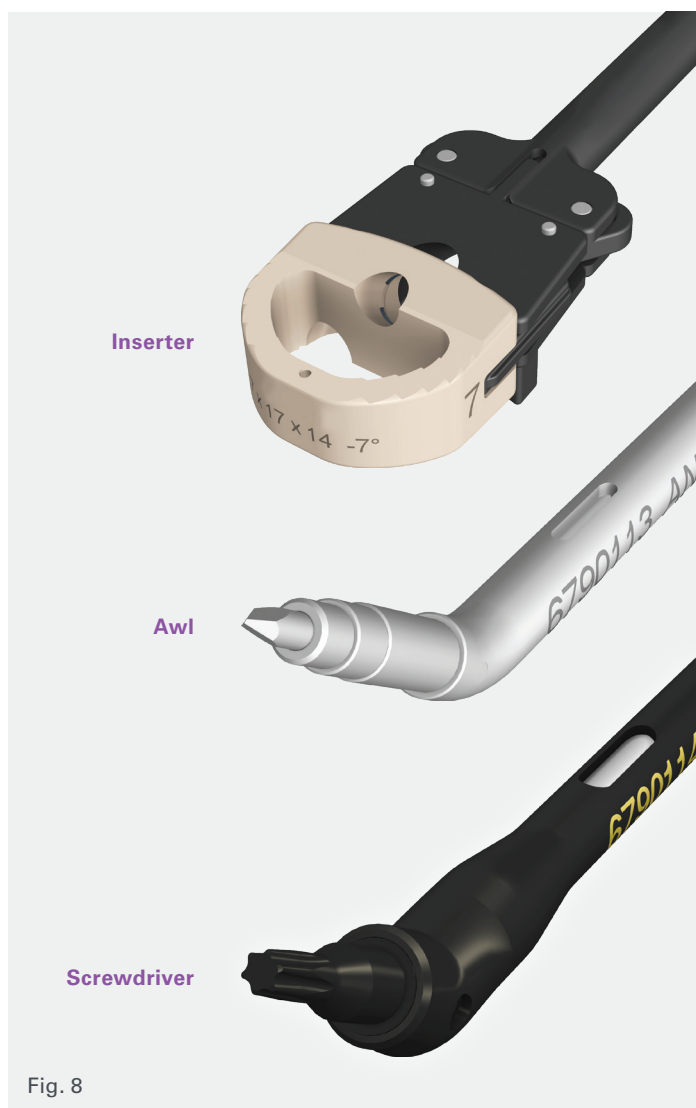


Fig. 8

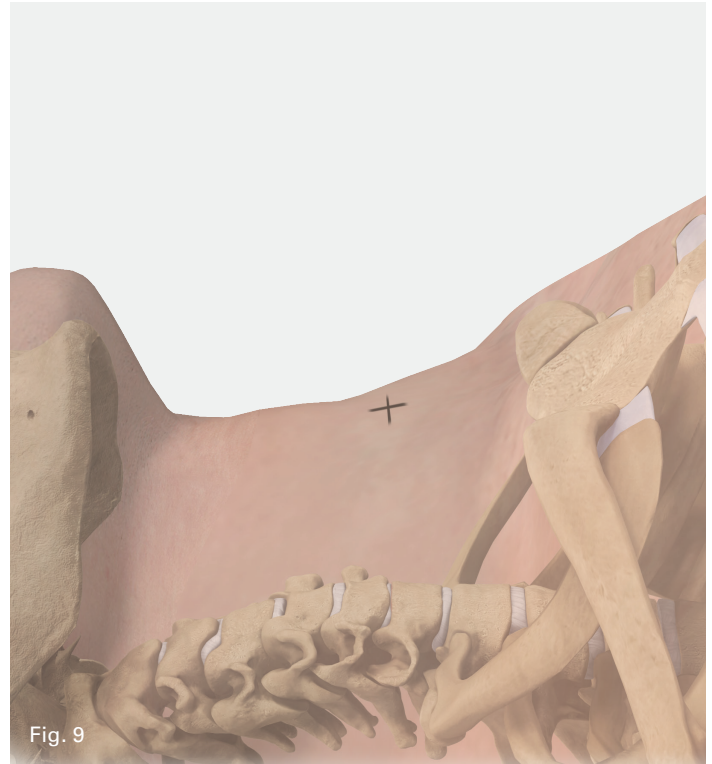
Coroent Small Interlock technique guide

Pre-op positioning and imaging

The patient is in the supine position with the head in slight extension with chin in up position (*Fig. 9*).

Fluoroscopy

A/P and lateral imaging is used to locate the operative level and assess the bony anatomy (*Figs. 10, 11*).



Step 1

Access and 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. 12). The anterior surface of the vertebral body may require some preparation as direct anterior access to the disc and adjacent vertebral bodies is necessary.

Tip: Careful attention to osteophyte removal assists in optimal implant placement in the majority of patients. If using Caspar pins, be aware that midline placement may interfere with the center screw placement; consider more lateral placement of the Caspar pins.

Step 2

Discectomy and decompression

Perform a complete discectomy and decompression to thoroughly remove the disc material (Fig. 13).

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

NVM5

The NVM5 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 NVM5 in the cervical spine.

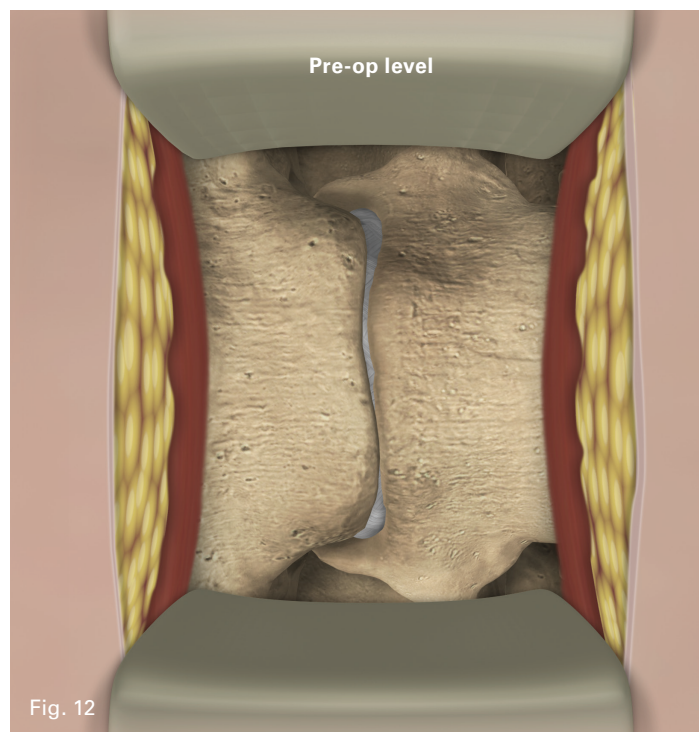


Fig. 12

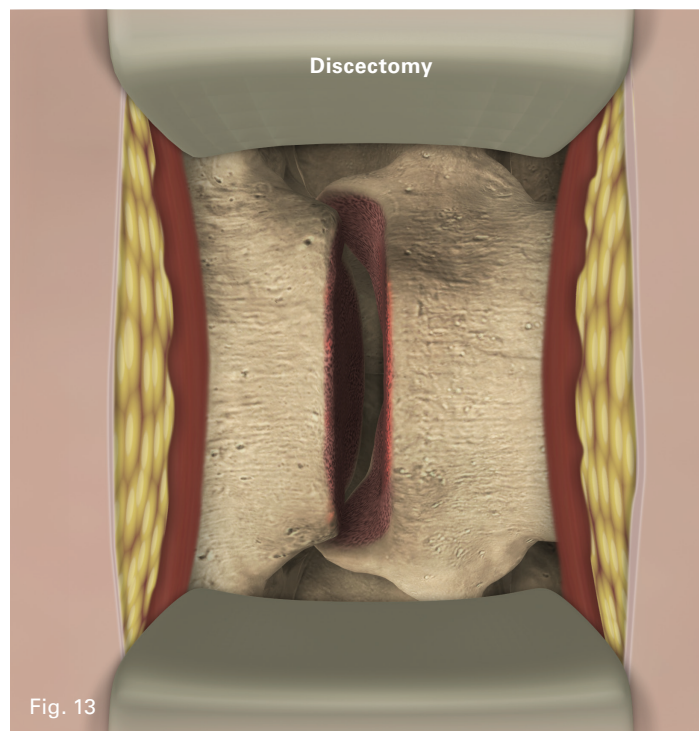


Fig. 13

Step 3

Trial and rasp

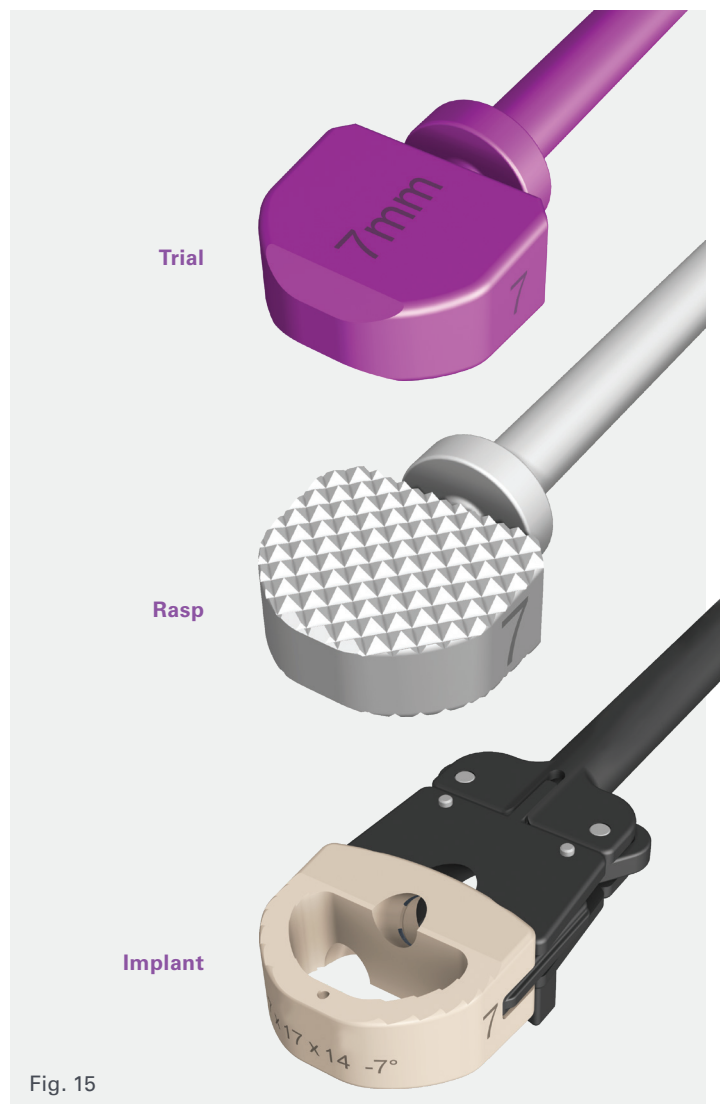
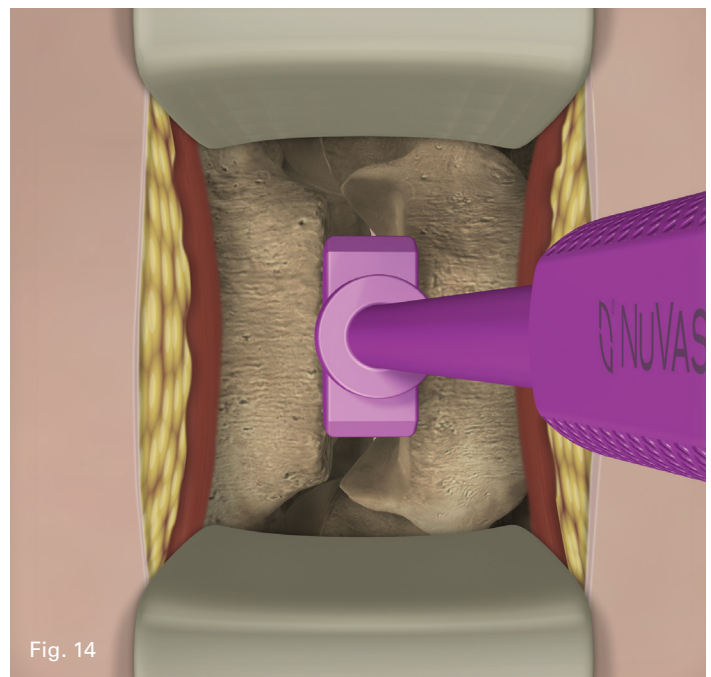
Select the appropriate implant height and width by using the implant matching trials (Fig. 14). Start with a smaller size and work your way up to the appropriate footprint.

Rasps can then be used to decorticate the endplates.

Trials and rasps are available in 5–12 mm heights via 1 mm increments.

Tip: The depth stop on the trials will stop it at 1 mm subflush to the anterior aspect of the vertebral body, mimicking the final implant position.

Note: The trials and rasps are the exact size as the implants (Fig. 15).



Step 4a

Implant loading

Freehand technique

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. 16).
2. With the alignment arrows headed in the same direction, place the inserter on the face of the appropriately sized implant (Fig. 17a) and rotate the tightening knob clockwise until tight (Fig. 17b).

Tip: For easiest engagement, load the 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 confirming there is a tight fit.

Tip: 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).

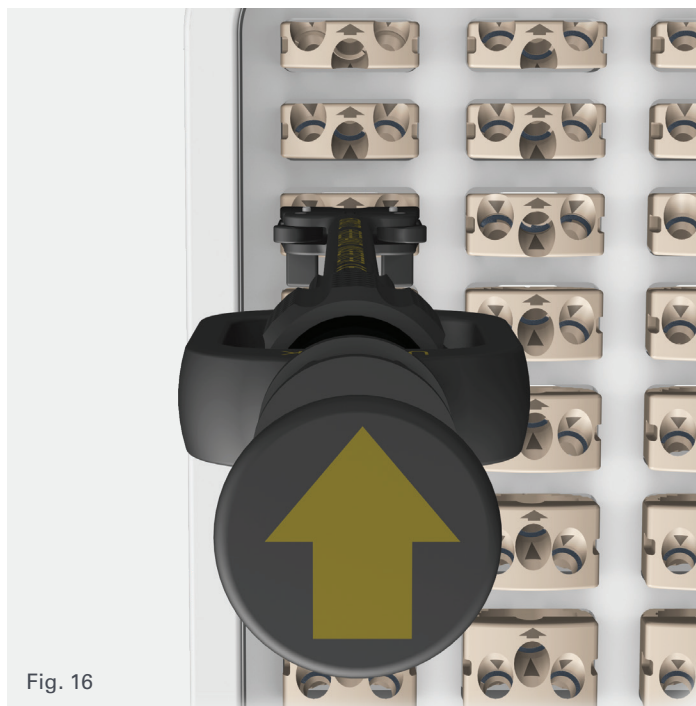


Fig. 16

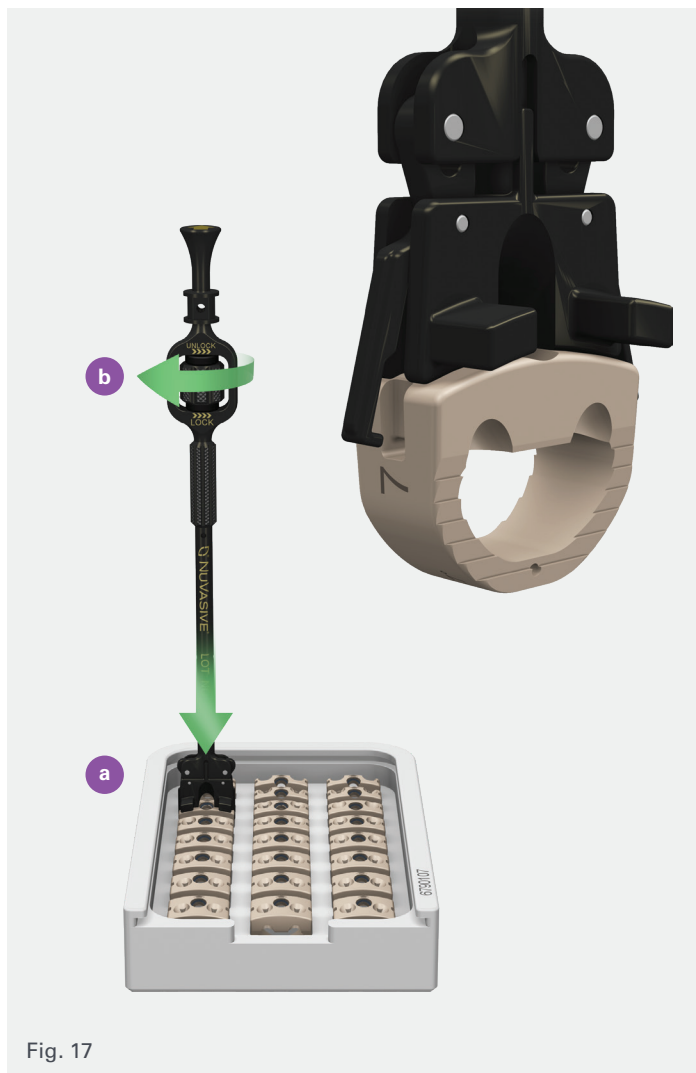


Fig. 17

Step 4b

Implant loading

DTS guide technique

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 (Fig. 18a).
2. With one finger, tighten the silver knob to positively engage the DTS guide to the inserter (Fig. 18b).

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 (Fig. 19a).
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 (Fig. 19b).

Tip: Always final check implant engagement by squeezing the gold arms into the implant and slightly turn the gold knob once more to confirm a tight fit.

Tip: To release the implant, the surgeon only needs to turn the gold knob counterclockwise.

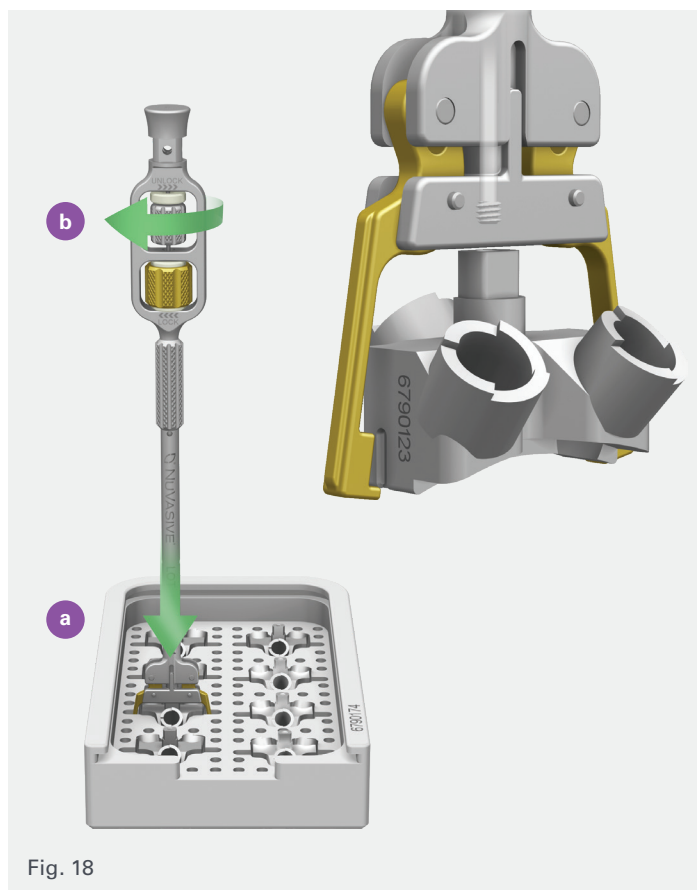


Fig. 18

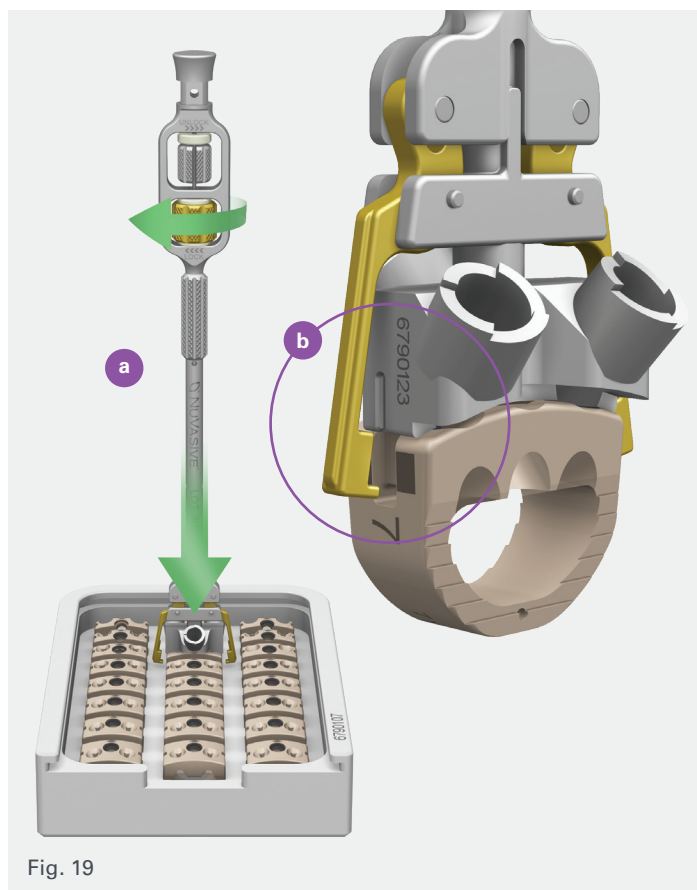


Fig. 19

Step 5

Spacer insertion

Once the appropriate implant is selected, engage either the DTS or the freehand inserter followed by the implant. Pack autograft and/or allograft (comprised of cancellous, cortical and/or corticocancellous allograft) into the implant aperture.

Place the inserter/implant assembly into the prepared disc space.

Confirm the inserter is positioned parallel to the disc space during impaction to assist the implant in reaching the optimal sagittal position.

The ideal implant depth is 1 mm sub-flush. Position the implant until the depth stops reach the anterior edge of the vertebral bodies. Without removing the inserter, use lateral fluoroscopy to confirm the implant is in the proper location. Use A/P fluoro to confirm the implant is centered.

Tip: 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.

Tip: Be careful not to over-distract the disc space, this will assist in good implant-endplate contact.

Note: The implant is 17 mm wide x 14 mm deep, once countersunk 1 mm, the total construct will be 15 mm deep (Fig. 21).

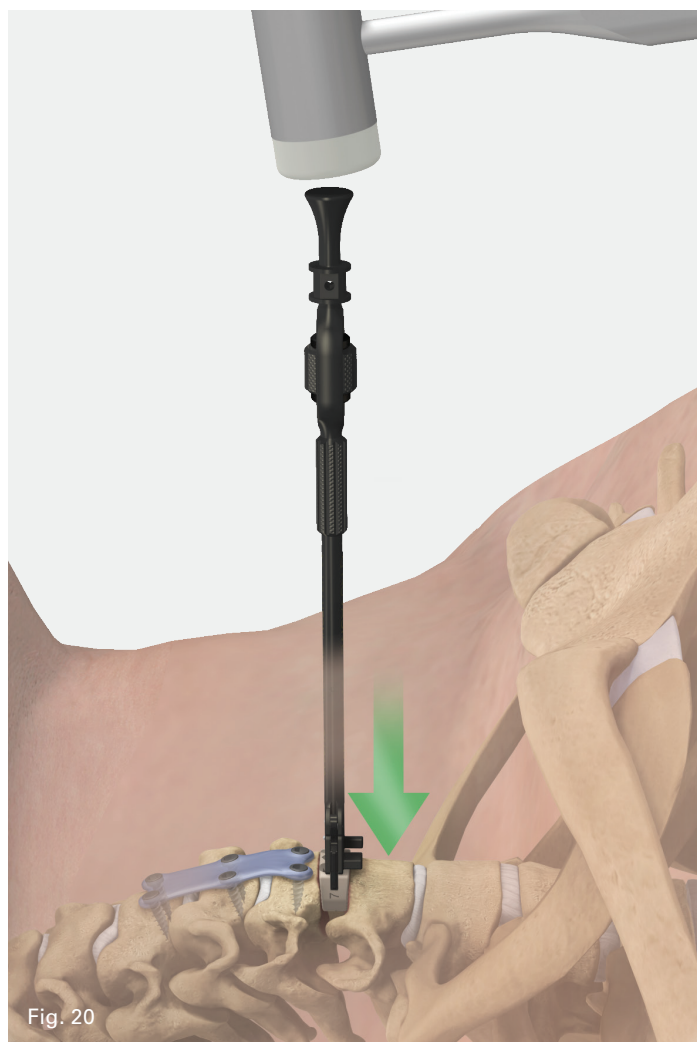


Fig. 20

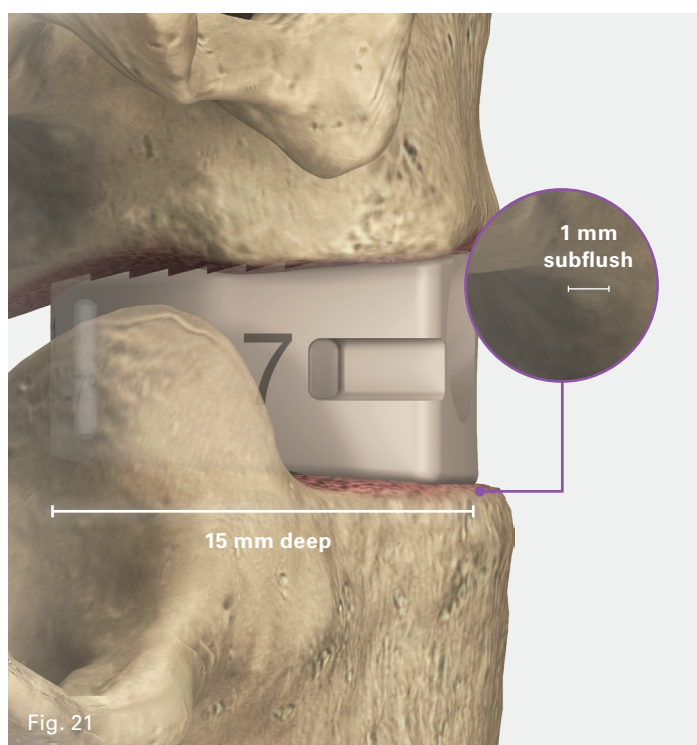


Fig. 21

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. Both angled and straight drills and awls are offered.

Awl

If desired, attach the wrench handle to the angled awl during the freehand technique for better control and force distribution (Fig. 22).

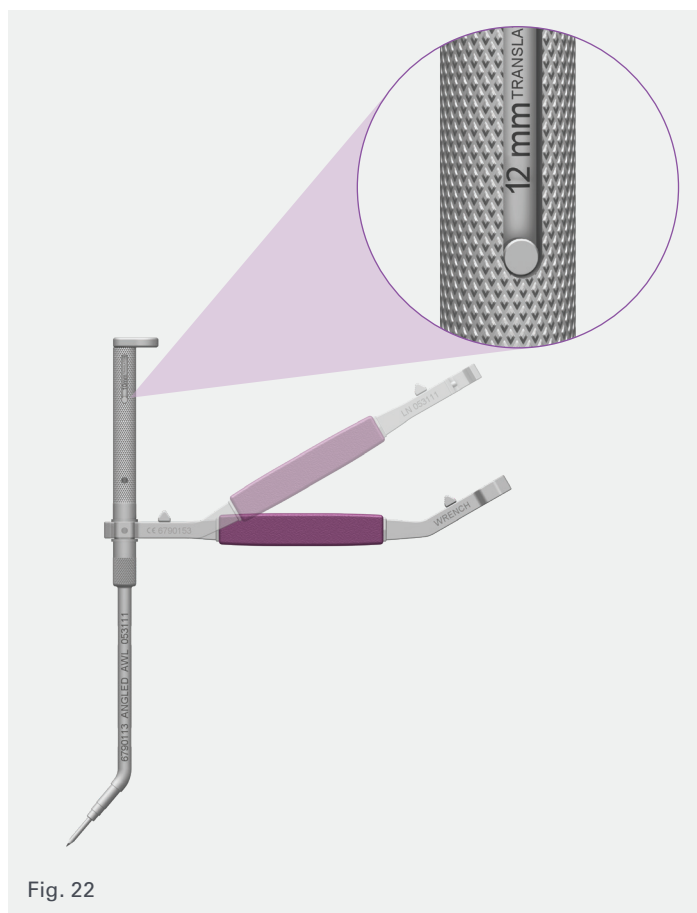
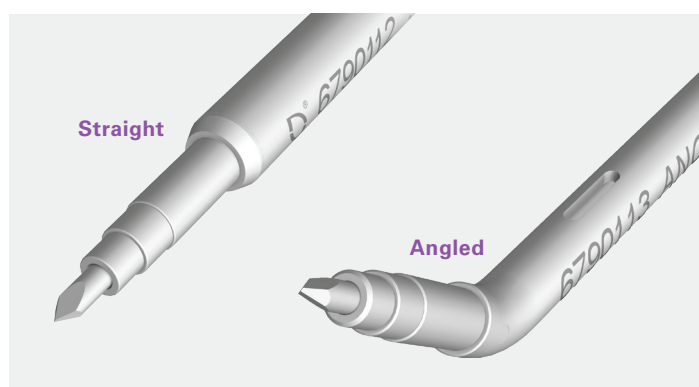
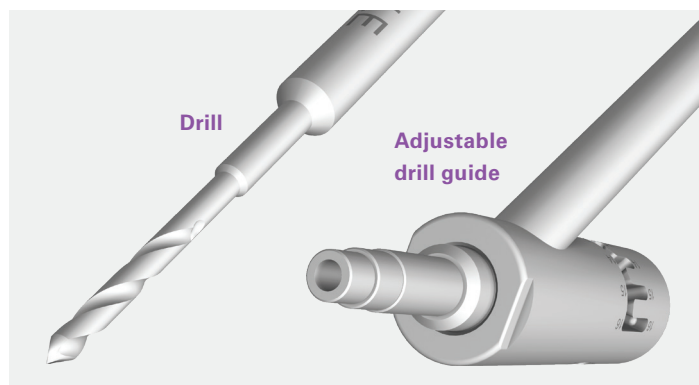


Fig. 22

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. 23).



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.

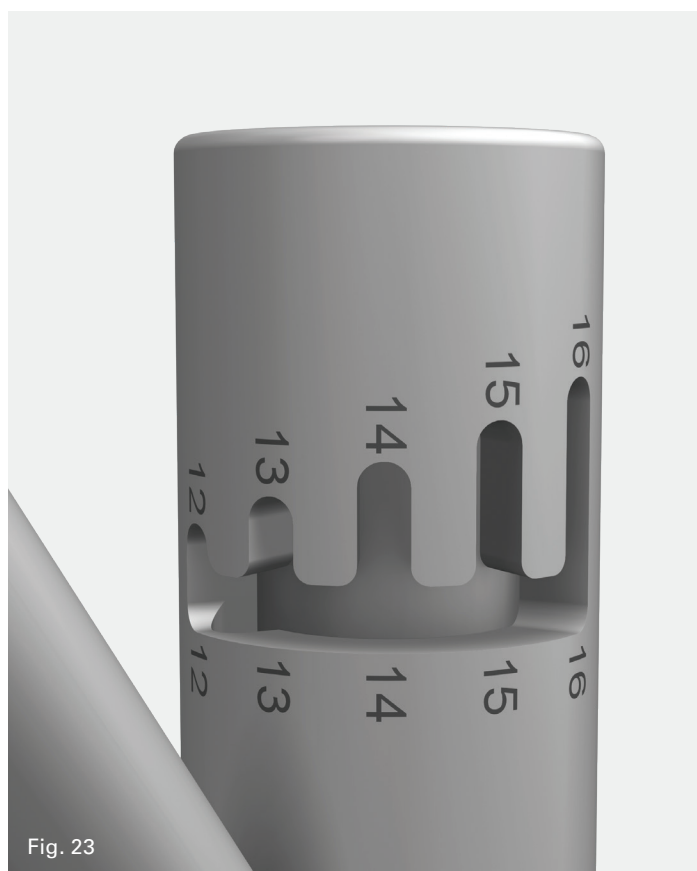


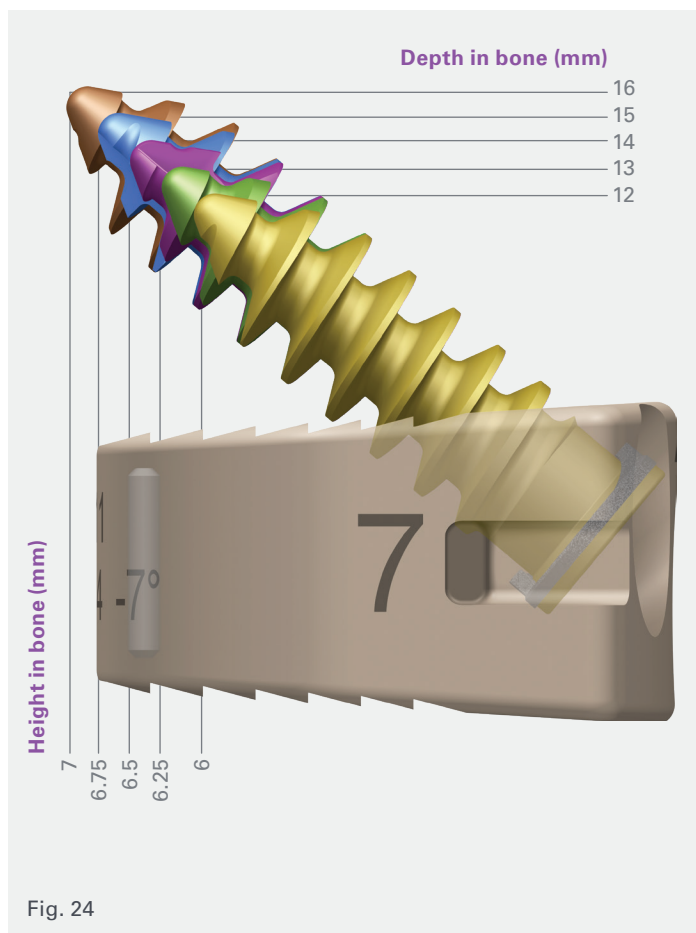
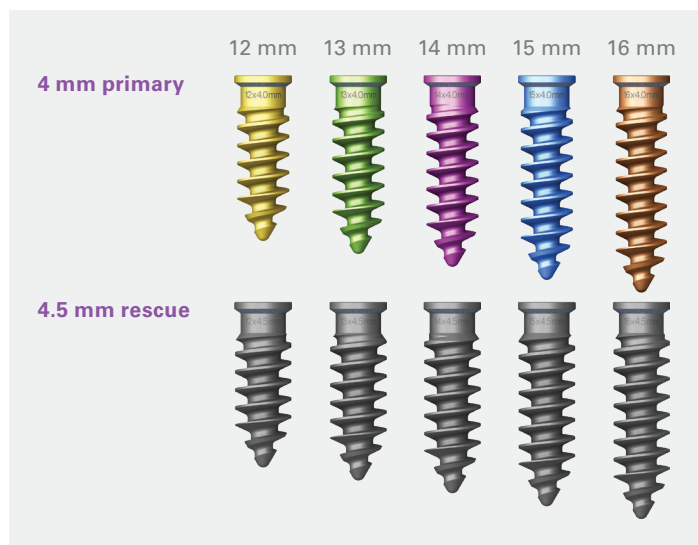
Fig. 23

Step 7

Screw selection

The length of the screws is measured from the anterior portion of the implant to the total distance reached posteriorly, accounting for the 40° angle (Fig. 24).

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



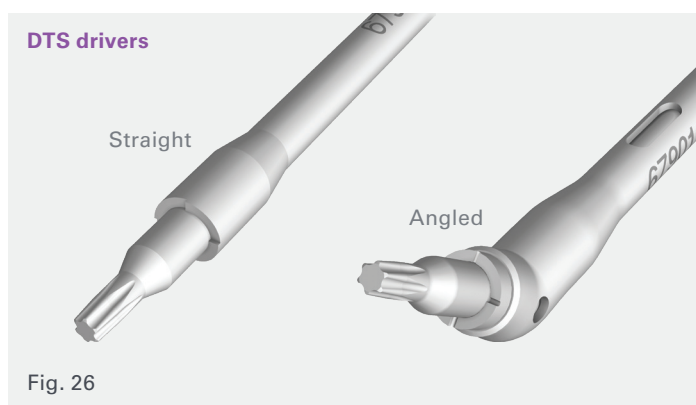
Step 8

Screw insertion

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

Note: The angled freehand instruments were designed to work perpendicular to the spine so the appropriate screw angle and trajectory are automatically achieved when the awl and screwdrivers are seated properly within the screw hole.

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.



Step 9

Locking verification

Visual confirmation

The locking mechanism is a circumferential PEEK ledge built into the implant that stretches as the screw head passes through and shrinks back to size to keep it locked in place.

The tactile stopping mechanism is created by a washer located in the screw hole that interacts with the screw head as it reaches its final position to create a friction-feel stopping point. As the screw is placed in the hole, full visualization of the locking triangle indicates the screws are locked down (Fig. 27).

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.

Step 10

Post-op verification

Confirm position with fluoroscopy as needed (Figs. 28, 29).

Step 11

Multilevel placement

For use at two contiguous levels, repeat steps 2–7.

When implanted at two contiguous levels, the Coroent Small Interlock system implants must be implanted in the same orientation to prevent impingement or potential bone fracture. It is important to select the appropriate length Coroent Small Interlock system screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

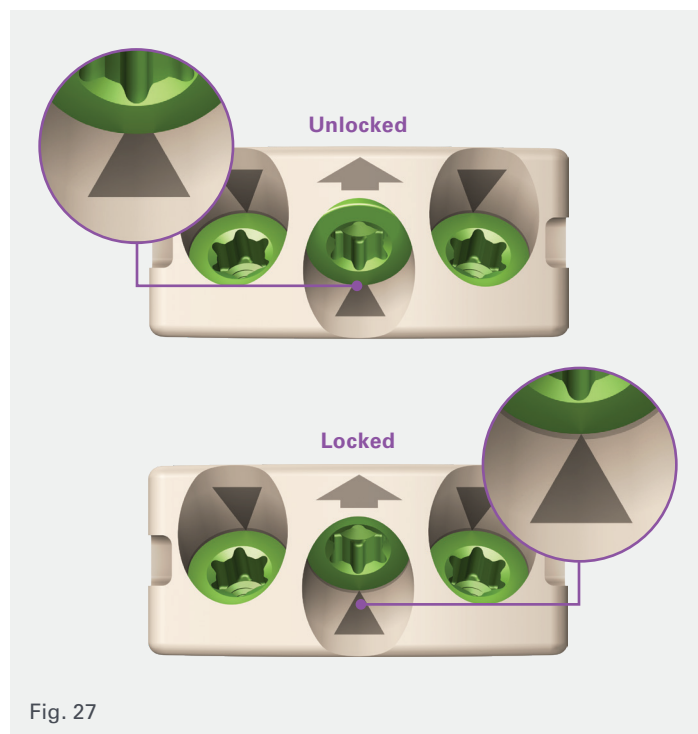


Fig. 27



Fig. 28

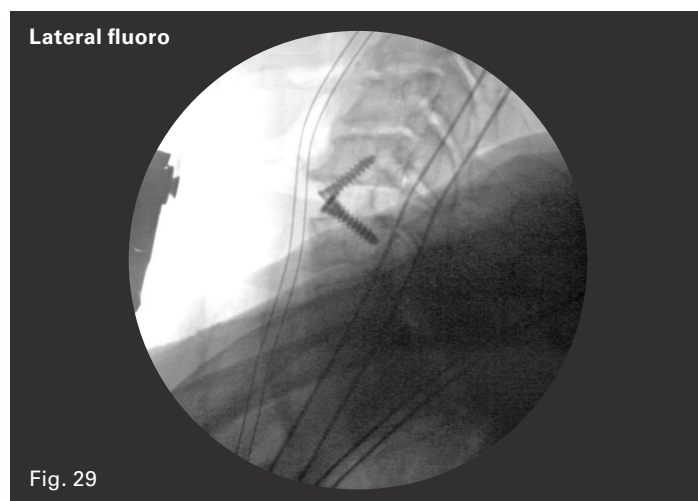


Fig. 29

Implant removal

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

1. Simply thread the inner shaft of the removal tool into the selected screw to positively engage the screw (Fig. 30a).

Caution: Do not overtighten.

2. Next, spin the counter torque shaft down onto the face of the implant to hold it in place (Fig. 30a).
3. Next, while holding the counter torque steady, rotate the main handle counter-clockwise to remove the screw (Fig. 30b).
4. Repeat steps one through three for all three screws if necessary (Fig. 30a–c).
5. The freehand inserter can be used for removal of the implant if necessary.

Tip: Maintain the same 40° trajectory while engaging the extractor.

Tip: Place downward pressure on the extractor while turning the silver engagement knob.

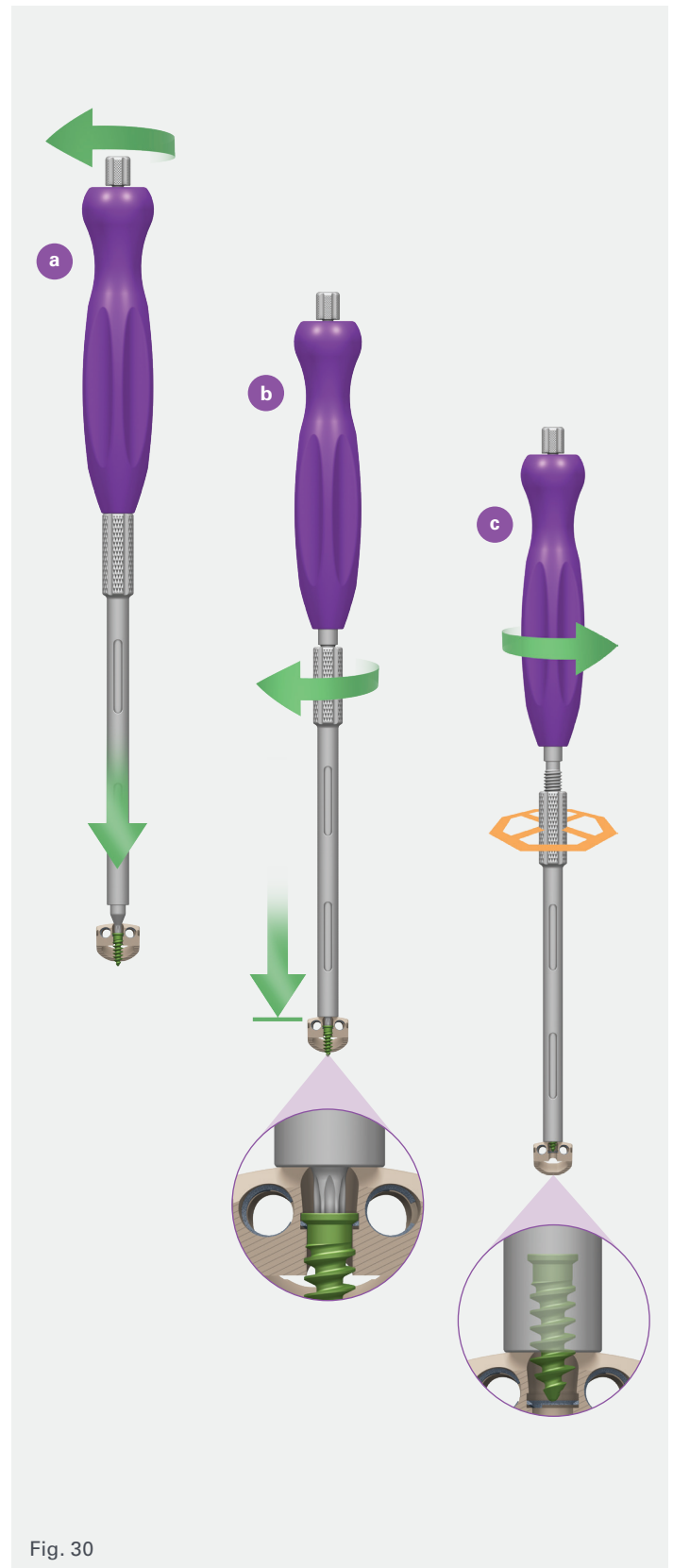
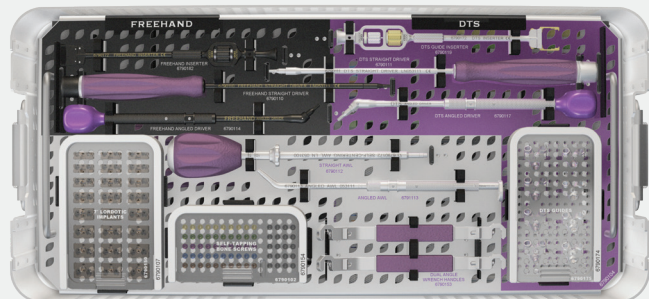


Fig. 30

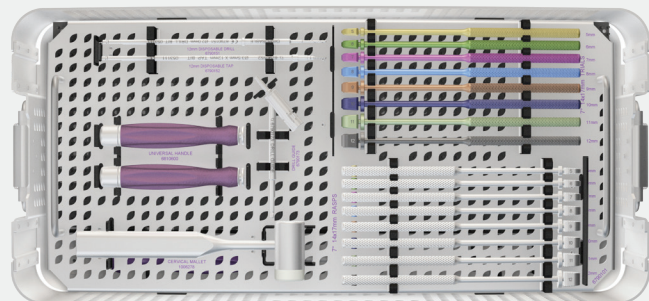
Coroent Small Interlock system

Instrument tray

Top tray



Middle tray

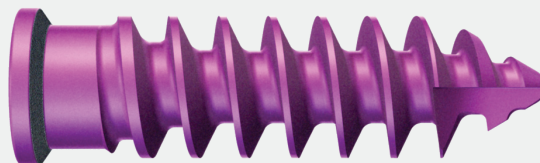


Bottom tray

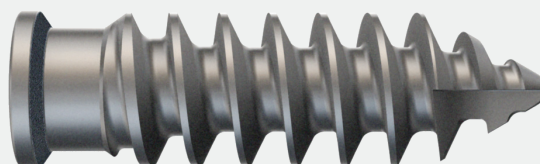


Implants

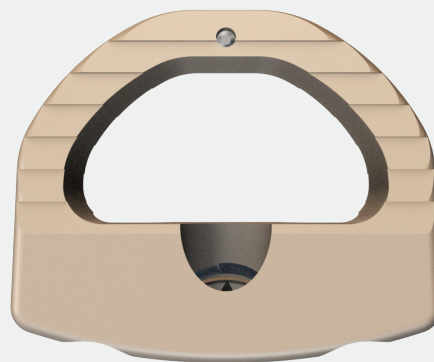
4 mm screw



4.5 mm rescue screw



Implant—axial view



Implant—lateral view



Trials

5 mm



6 mm



7 mm



8 mm



9 mm



10 mm



11 mm



12 mm



Rasps

5 mm



6 mm



7 mm



8 mm



9 mm



10 mm



11 mm



12 mm



Instruments

Freehand inserter



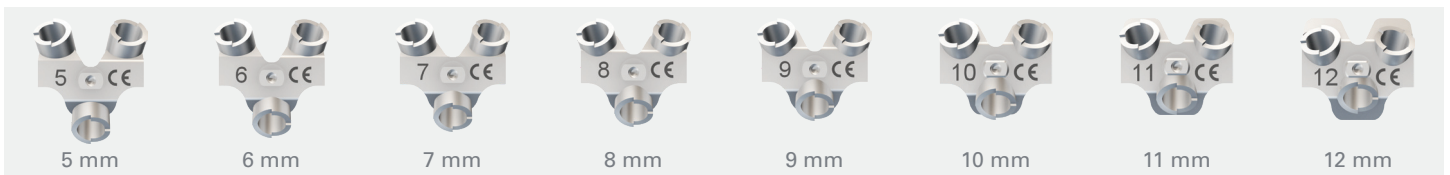
Straight freehand driver



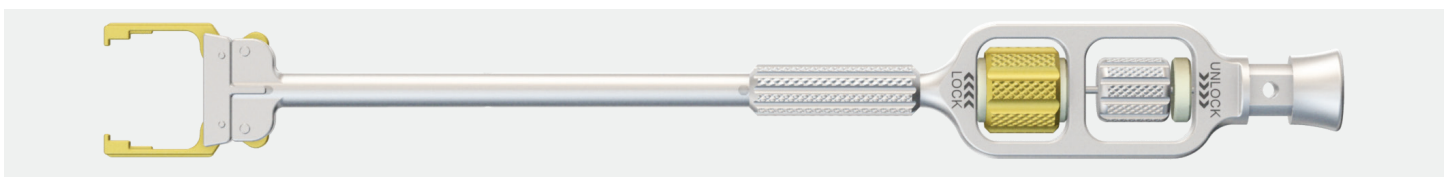
Angled freehand driver



DTS guide



DTS inserter



Straight DTS driver

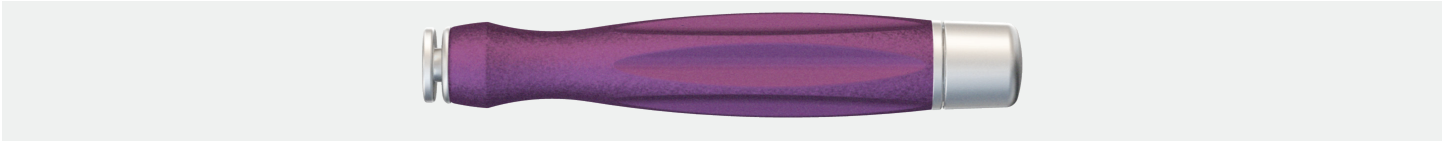


Angled DTS driver



Instruments (cont.)

Universal handle



12–16 mm drill shaft



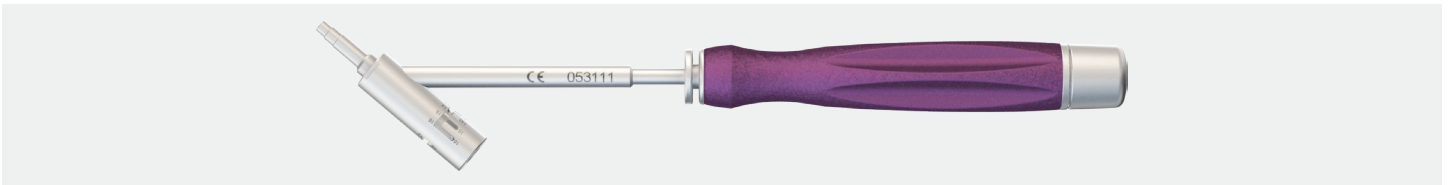
12 mm tap



Wrench handle, dual angle



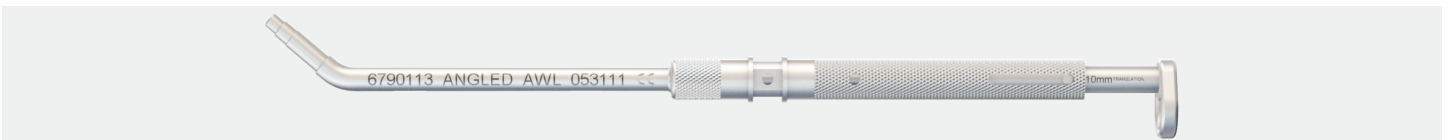
Adjustable drill guide (12–16 mm)



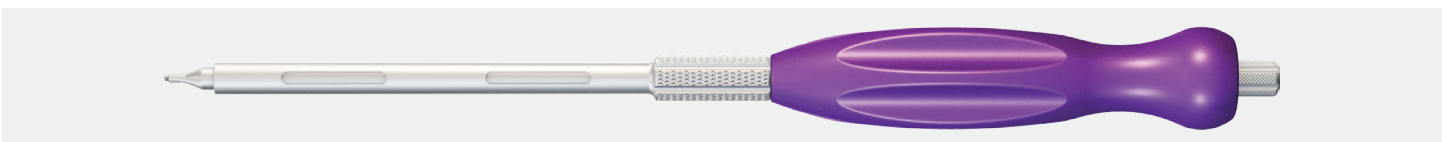
Straight awl



40° angled awl



Screw extractor



Catalog

Implants	
Description	Catalog no.
Implant: 5x17x14 mm, 7°	6790225
Implant: 6x17x14 mm, 7°	6790226
Implant: 7x17x14 mm, 7°	6790227
Implant: 8x17x14 mm, 7°	6790228
Implant: 9x17x14 mm, 7°	6790229
Implant: 10x17x14 mm, 7°	6790230
Implant: 11x17x14 mm, 7°	6790231
Implant: 12x17x14 mm, 7°	6790232
Screw: 4x12 mm	6791712
Screw: 4x13 mm	6791713
Screw: 4x14 mm	6791714
Screw: 4x15 mm	6791715
Screw: 4x16 mm	6791716
Screw: 4x12 mm, rescue	6791812
Screw: 4x13 mm, rescue	6791813
Screw: 4x14 mm, rescue	6791814
Screw: 4x15 mm, rescue	6791815
Screw: 4x16 mm, rescue	6791816

Instruments	
Description	Catalog no.
Trial: 5x17x14 mm, 7°, gold	6790161
Trial: 6x17x14 mm, 7°, green	6790162
Trial: 7x17x14 mm, 7°, magenta	6790163
Trial: 8x17x14 mm, 7°, blue	6790164
Trial: 9x17x14 mm, 7°, bronze	6790165
Trial: 10x17x14 mm, 7°, purple	6790166
Trial: 11x17x14 mm, 7°, seafoam	6790167
Trial: 12x17x14 mm, 7°, grey	6790168
Rasp: 5x17x14 mm, 7°	6790141
Rasp: 6x17x14 mm, 7°	6790142
Rasp: 7x17x14 mm, 7°	6790143
Rasp: 8x17x14 mm, 7°	6790144
Rasp: 9x17x14 mm, 7°	6790145
Rasp: 10x17x14 mm, 7°	6790146
Rasp: 11x17x14 mm, 7°	6790147
Rasp: 12x17x14 mm, 7°	6790148
DTS guide: 5 mm	6790121
DTS guide: 6 mm	6790122
DTS guide: 7 mm	6790123
DTS guide: 8 mm	6790124
DTS guide: 9 mm	6790125
DTS guide: 10 mm	6790126
DTS guide: 11 mm	6790127
DTS guide: 12 mm	6790128

Instruments (cont.)	
Description	Catalog no.
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: 12–16 mm	6790173
Universal screw extractor	7730072
Drill: 12–16 mm, disposable	6790151
Tap: 12 mm, disposable	6790152
Universal handle, AO	6790150
Wrench handle, dual angle	6790153
Coroent Small Interlock IFU	9401314

Instructions for use

DESCRIPTION

The NuVasive CoRoent Small Interlock System and the NuVasive CoRoent Small Interlock II System is a standalone anterior cervical interbody device consisting of a PEEK (Polyether-ether-ketone) implant cage with titanium alloy or 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 (Ti-6Al-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 System and the NuVasive CoRoent Small Interlock II System are an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one level from C2-T1. The NuVasive CoRoent Small Interlock System and the NuVasive CoRoent Small Interlock II System (lordotic angles of 7° to 15°) are a standalone system. The NuVasive CoRoent Small Interlock System and the NuVasive CoRoent Small Interlock II System (lordotic angles of 20° to 30°) must be used with supplemental fixation. The Systems are 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.

INDICATIONS FOR USE U.S.

The NuVasive CoRoent Small Interlock System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The System is intended to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in the intervertebral body fusion 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. Reuse 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 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 and CoRoent Small Interlock II 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 II 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 for use in the cervical spine.

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

Confirm lateral fluoroscopy shows healthy sagittal alignment.

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/Do Not Re-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.

MRI Safety Information: Refer to CoRoent Small Interlock System eIFUs for MR safety information.

Compatibility: Do not use CoRoent Small Interlock System and CoRoent Small Interlock II 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).

PRE-OPERATIVE 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 implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. 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.

Please refer to the CoRoent Small Interlock System IFU found at www.nuvasive.com/eifu for additional important labeling information.

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For important product safety information, visit [nuvasive.com/eIFU](https://www.nuvasive.com/eIFU)

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