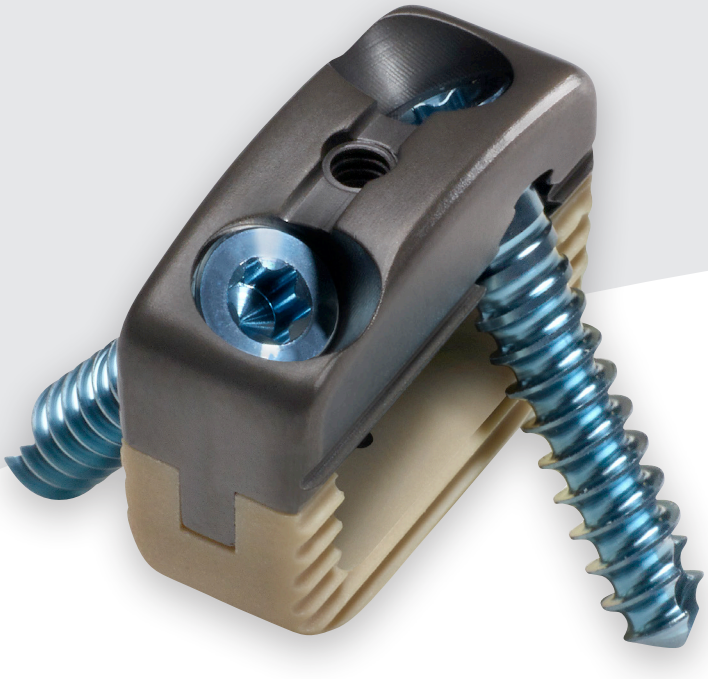
Complete Cervical IBD*

Surgical Technique



SeaSpine™

*Intervertebral Body Fusion Device

Table of Contents

Complete Cervical IBD

System Features

Stand-Alone Stability

- Off-set superior and inferior screws maximize screw purchase
- Fixed screw to plate interface provides a rigid construct
- Smooth, no-profile plate
- Bulleted geometry enables simple insertion
- Unique anti-migration tooth pattern

Simple Surgical Protocol

- Variety of instruments to accommodate surgeon needs.
- Multiple footprint options to treat a wide range of patient anatomies.

Surgical Exposure

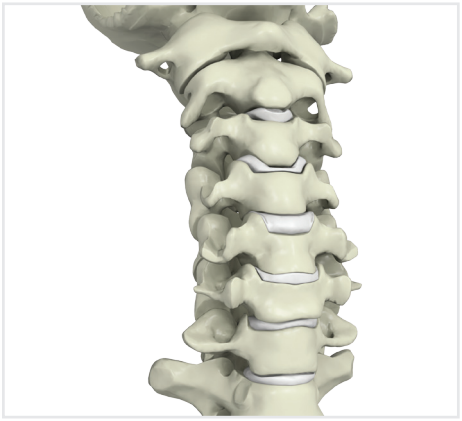
Perform the anterior approach to the appropriate cervical level using the standard surgical technique. Ensure direct anterior access to the disc.

Surgical Technique

STEP 1 Site Preparation

Identify and access the appropriate level of the anterior cervical vertebral column (C2 – C7) and perform a complete discectomy and decompression using standard surgical techniques.

After thorough removal of vertebral osteophytes and disc material, completely remove cartilaginous end plates with standard Curettes to encourage bony healing. Be cautious to leave the lateral annulus and bony endplates intact. Excessive endplate preparation may result in implant subsidence.

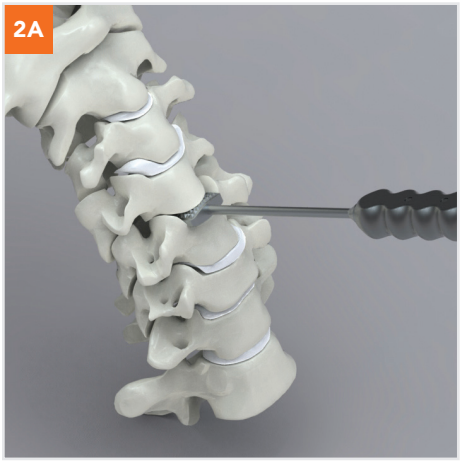


STEP 2 Implant Size Selection (Trialing/Rasping)

2A Complete IBD implants are available in two footprints: 14 x 16mm and 15 x 18mm (depth x width). All footprints are available in heights of 6 to 12mm (1mm increments) and feature 6° of lordosis.

Rasps (27-40-00XX) are provided to roughen vertebral endplates and can be used as an alternative to smooth Trials for sizing. Rasps are available in a single footprint (14mm x 16mm) in all heights.

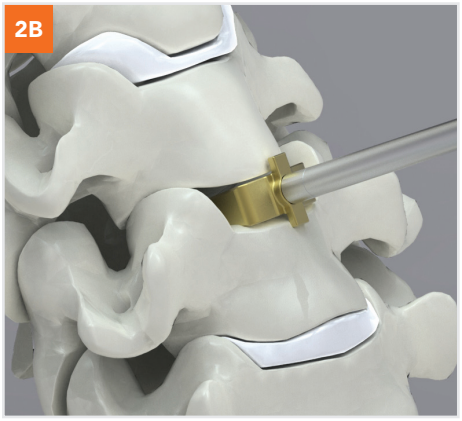
▶ Note: The Rasps are 0.5mm undersized in height. See image 2A.



2B Trials (27-40-1XXX) are provided to determine the appropriate footprint size and height of the implant. A 5mm Starter Trial (27-40-1005) is also provided for collapsed disc spaces.

The Starter Trial is available in 14 x 16mm footprint only.

▶ Note: Trials are 0.5mm undersized in height. All height measurements are in reference to anterior height of implants. See image 2B.

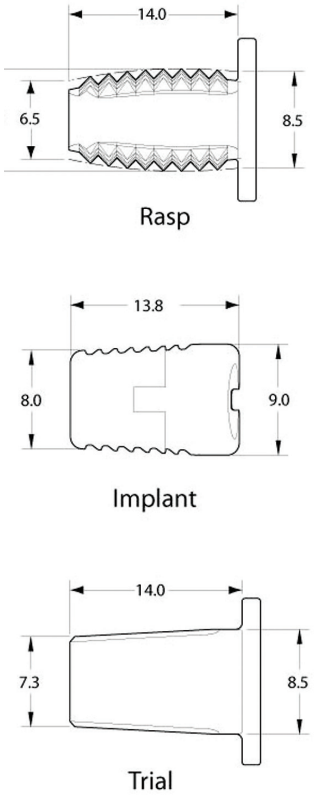


STEP 2 Implant Size Selection (Trialing/Rasping) continued

2C Determine footprint (depth x width) prior to height. See figure 2C. Once footprint is determined, sequentially increase height of Trial until it fits firmly in disc space. Use lateral fluoroscopic and radiographic assessment to confirm proper fit.

Note: A Slap Hammer (27-40-0900) is available in the set if Trial or Rasp gets bound in the disc space.

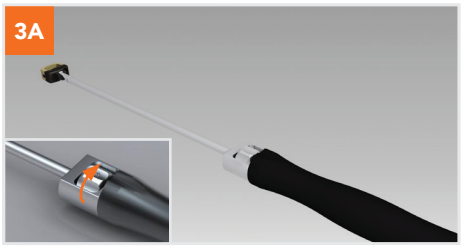
2C



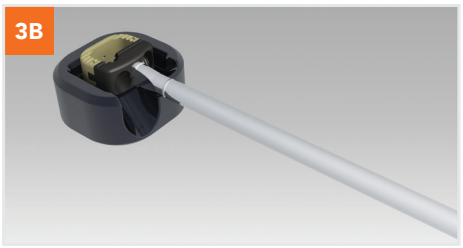
Dimension reference example for a 9mm, 14x16mm implant

STEP 3 Implantation

3A Attach desired Complete Implant to Implant Inserter (27-40-0000). Ensure black line on Inserter shaft is aligned in the groove on implant. Thread thumbwheel clockwise until implant is fully engaged; take care not to over-tighten.

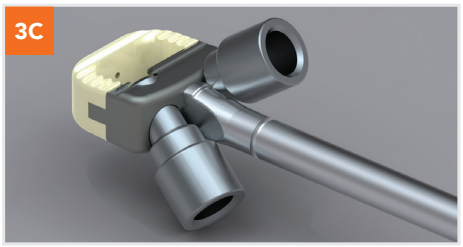


3B Place selected implant into Graft Packing Block (27-40-0600). The provided Bone Tamp (27-40-0700) may be used to firmly pack bone graft material into implant cavity.



3C ### Optional – Implantation Technique with Drill Guide Tubes

Utilize the Drill Guide Inserter/Remover (27-40-0803) to thread Drill Guide Tubes (27-40-0820) into implant screw holes one at a time by turning clockwise until secure.



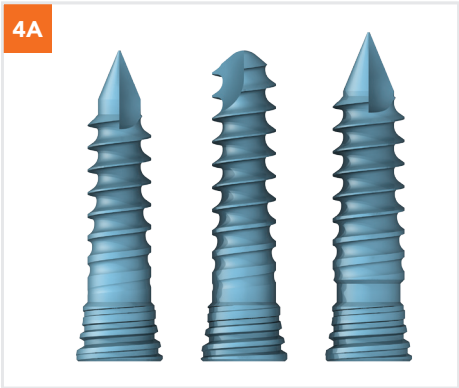
Attach Implant Inserter to implant. Ensure black line on Inserter shaft is aligned in the groove on implant. Thread thumbwheel clockwise until implant is fully engaged; take care not to over-tighten.

Place selected implant into Graft Packing Block. The provided Bone Tamp may be used to firmly pack bone graft material into implant cavity.

Insert implant into disc space. After implant has been properly positioned, turn Inserter knob counter-clockwise until implant is completely disengaged. The Bone Tamp may be used to further adjust implant position if necessary. Release the distraction on the disc space. If implant size is suitable, remove distraction pins.

STEP 4 Bone Screw Options and Nominal Screw Angles

4A Complete IBD Bone Screws are available in Self-Tapping and Self-Drilling options. The Self-Tapping screws have a rounded tip and aggressive cutting flutes to advance through the bone without the need to tap. The Self-Drilling screws have a sharper tip and cutting flute, eliminating the need to drill however the Awl should be used with a drill guide to ensure proper screw trajectory.

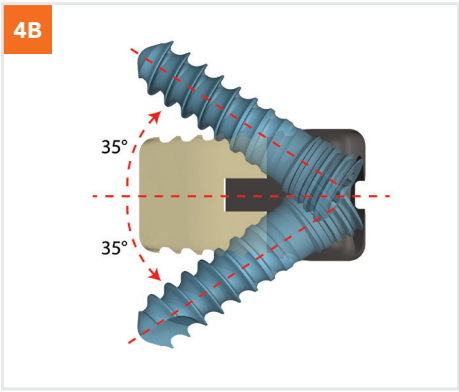


4B The screws are offered in 3.5 and 4.0mm diameters. The 3.5mm screw lengths are 12-18mm (2mm increments).

4C The 4.0mm rescue screw lengths are 13-19mm (2mm increments).

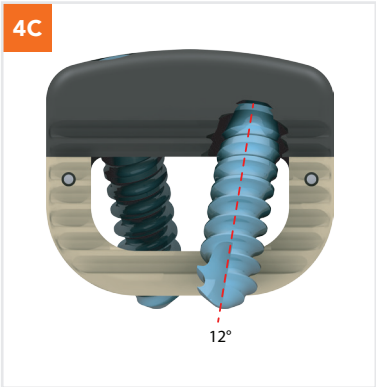
The fixed screw angles for the Complete implant are:

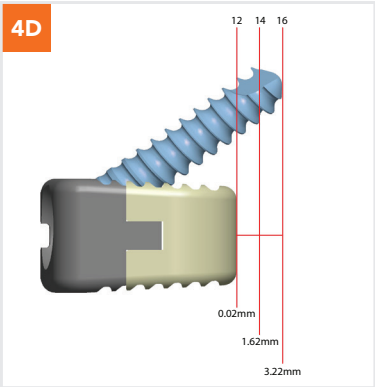
- 35° Cephalad divergence (superior screw hole)
- 35° Caudal divergence (inferior screw hole)
- 12° Medial/Lateral (each screw hole)



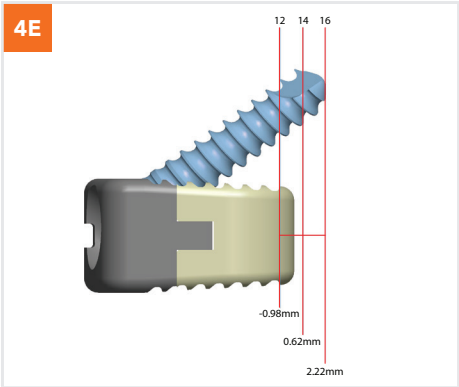
4D The distance between the screws and back of Interbody are shown below.

4E





14 x 16 mm

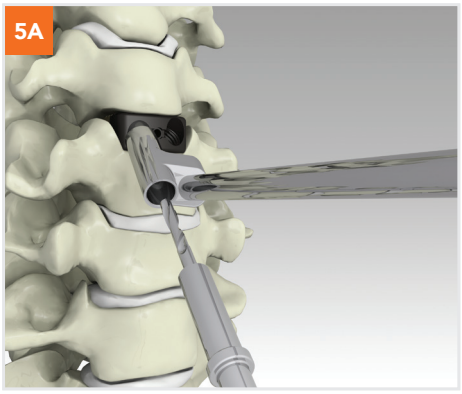


15 x 18 mm

STEP 5 Screw Hole Preparation/Screw Placement

Straight Drills are available in 12, 14, and 16mm lengths. Flexible and Fixed Angled Drills are available in 12mm. Select appropriate Drill and attach it to Quick Connect Handle. Alternatively, Awls are available in 4 different styles (Straight, Spring-loaded, Flexible*, and Fixed Angle*) for preparing holes to 12mm penetration depth.

- Note: Awls and Taps are available in 12mm length only.
- Tip: Taps are available in 3 different styles (Straight, Flexible* and Fixed Angle*). Depth of penetration is 12mm.



5A
5B
5C

Option A – Cephalad/Caudad Drill Guides

The straight Drills, Awls, and Taps are used with the Cephalad and Caudad Drill Guides. Insert tip of Cephalad Guide (27-40-0810) into superior screw hole (patient's right side) and insert drill as shown. Drills have depth stops to limit penetration to stated depth.

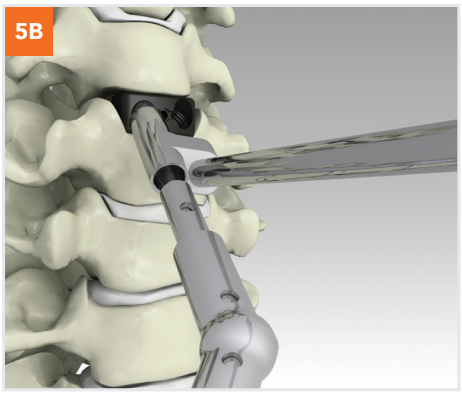
- Note: Awls and Taps are available in 12mm length only.

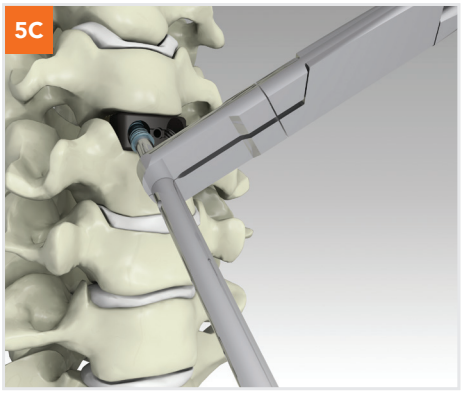
If using flexible or fixed angle instruments the Angled Instrument Guide (27-40-0812) should be used.

Attach the Torque Limiter Handle (27-40-0500) to Split-Tip Screwdriver. Advance screw by turning Torque Limiter Handle clockwise until one click is heard, and remove Driver. Repeat using Caudad Drill Guide (27-40-0811) for inferior screw (patient's left side).

- Note: The Torque Limiter Handle is set at 10 inch pounds of resistance
- Tip: To prevent over angulation of screw, keep guide tip securely seated in plate when drilling pilot hole. Excessive angulation of screw will prevent screw from locking into implant. If screw is not seated flush, use Self Retaining Screw Inserter (27-40-0135) to tighten until screw is flush with plate. Repeat for alternate screw.

An optional Flexible Driver (27-40-0330)is available if you have a difficult angle and need to avoid tissue interference. A Flexible Instrument Guide (27-40-0340) may be used to guide screws during placement.





* Indicates optional instruments not standard in set.

STEP 5 Screw Hole Preparation/Screw Placement continued

5D Option B – Drill Guide Tubes (not standard in set)

5E

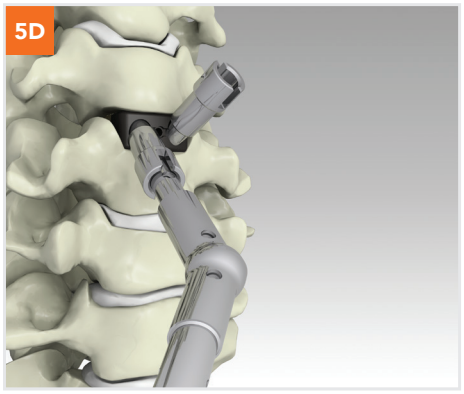
Attach Quick Connect Handle to Flexible/Fixed Awl or Drill. Advance through the Drill Guide Tube until it stops. To remove, reattach Drill Guide Inserter/Remover to tube and back out counter-clockwise.

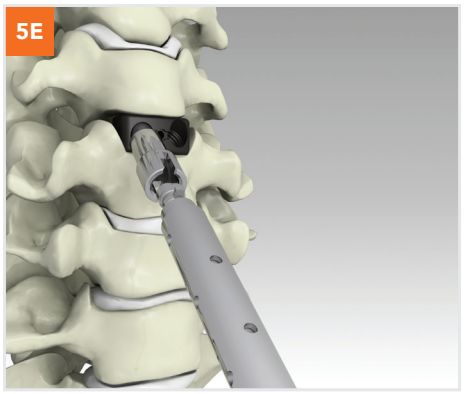
Attach the Torque Limiter Handle (27-40-0500) to the Driver. Advance screw and turn Torque Limiter Handle clockwise until one click is heard and remove Driver. Repeat preparation and screw placement for alternate screw.

Tip: If screw is not seated flush, use Self-Retaining Screw Inserter (27-40-0135) to tighten until screw is flush with plate. Repeat for alternate screw. After first hole is drilled, insert first screw. Next, prepare the second hole and insert second screw. This will prevent implant from drifting while you drill second hole.

Screw Driver Options:

There are several screw driver options available for Complete IBD Set: Straight Split-Tip Screw Driver, *Flexible Split-Tip Driver, Fixed Angle Split-Tip Driver and a Straight Driver, non Split-Tip. All can be used with screws.



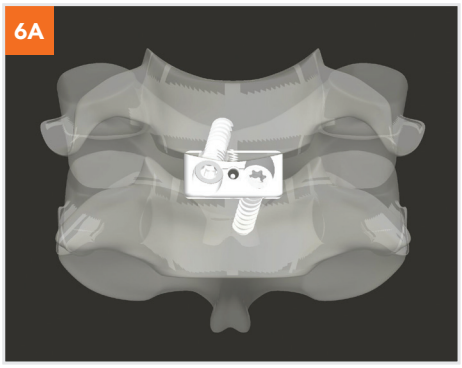


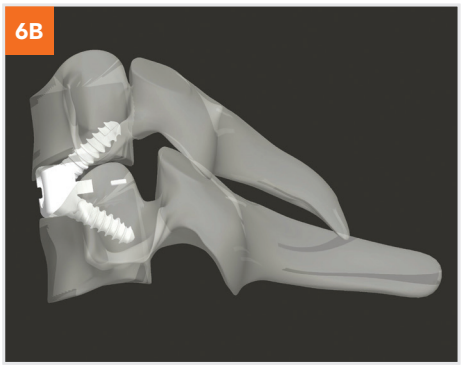
* Indicates optional instruments not standard in set.

STEP 6 Placement Verification

6A Verify that screws are fully seated and implant is in desired position using a lateral and AP radiograph.

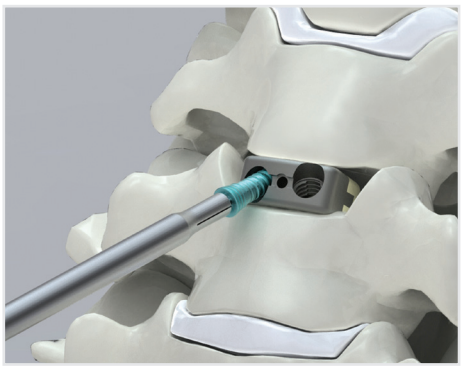
6B Each Complete Implant has 1 Tantalum and 2 Titanium radiographic markers which aid in visualization on x-ray (one flush with the posterior edge and two 1mm away from each of the lateral edges).





STEP 7 Removal/Revision

The Compete IBD system is designed for seamless removal when required. First remove each screw utilizing Spin Top Handle (27-40-0400) and Straight Driver, non Split Tip (27-40-0135). Next, reattach the Implant Inserter (27-40-0000) to the implant by turning thumbwheel on handle clockwise until implant is fully engaged. Grip Inserter handle and carefully remove implant. A Slap Hammer is available if further assistance is required.



* Indicates optional instruments not standard in set.

Ordering Information

Catalog Number	Description
Implants	
27-10-1606	Implant 16x14x6mm 6 deg
27-10-1607	Implant 16x14x7mm 6 deg
27-10-1608	Implant 16x14x8mm 6 deg
27-10-1609	Implant 16x14x9mm 6 deg
27-10-1610	Implant 16x14x10mm 6 deg
27-10-1611	Implant 16x14x11mm 6 deg
27-10-1806	Implant 18x15x6mm 6 deg
27-10-1807	Implant 18x15x7mm 6 deg
27-10-1808	Implant 18x15x8mm 6 deg
27-10-1809	Implant 18x15x9mm 6 deg
27-10-1810	Implant 18x15x10mm 6 deg
27-10-1811	Implant 18x15x11mm 6 deg
Instruments	
27-40-0000	Inserter - Implant
27-40-2112	Awl - Straight-12mm
27-40-0810	Cephalad Screw Drill Guide
27-40-0811	Caudad Screw Drill Guide
27-40-2212	12mm Drill
27-40-2214	14mm Drill
27-40-2216	16mm Drill
27-40-0130	Split Tip Driver - Straight
27-40-0230	Split Tip Driver - Fixed Angle
27-40-0135	Straight Driver- non Split Tip
27-40-0400	Handle - Non-Ratcheting Spin Top
27-40-0500	Handle - Torque Limiter (10lb)
27-40-0600	Packing Block
27-40-0700	Bone Tamp
27-40-0900	Slap Hammer
27-40-5212	Awl - Spring Loaded - 12mm
27-40-1005	Trial - 16x14x5mm
27-40-1206	Trial - 16x14x6mm
27-40-1207	Trial - 16x14x7mm
27-40-1208	Trial - 16x14x8mm
27-40-1209	Trial - 16x14x9mm
27-40-1210	Trial - 16x14x10mm
27-40-1211	Trial - 16x14x11mm
27-40-1306	Trial - 18x15x6mm
27-40-1307	Trial - 18x15x7mm
27-40-1308	Trial - 18x15x8mm
27-40-1309	Trial - 18x15x9mm
27-40-1310	Trial - 18x15x10mm
27-40-1311	Trial - 18x15x11mm
27-40-0006	Rasp - 16x14x6mm
27-40-0007	Rasp - 16x14x7mm
27-40-0008	Rasp - 16x14x8mm
27-40-0009	Rasp - 16x14x9mm
27-40-0010	Rasp - 16x14x10mm
27-40-0011	Rasp - 16x14x11mm

Catalog Number	Description
Screws	
27-13-3512	Screw - Self-Tapping 3.5x12mm
27-13-3514	Screw - Self-Tapping 3.5x14mm
27-13-3516	Screw - Self-Tapping 3.5x16mm
27-13-3518	Screw - Self-Tapping 3.5x18mm
27-14-3512	Screw - Self-Drilling 3.5x12mm
27-14-3514	Screw - Self-Drilling 3.5x14mm
27-14-3516	Screw - Self-Drilling 3.5x16mm
27-14-3518	Screw - Self-Drilling 3.5x18mm
27-13-4013	Screw Self-Tapping - 4.0x13mm
27-13-4015	Screw Self-Tapping - 4.0x15mm
27-13-4017	Screw Self-Tapping - 4.0x17mm
27-13-4019	Screw Self-Tapping - 4.0x19mm
Implants/Screws/Instruments (optional)	
27-40-2312	Tap - Straight-12mm
27-40-0803	Drill Guide Inserter/Remover
27-40-0820	Drill Guide - Tubes
27-40-0812	Drill Guide - Hand Held - Angled Instruments
27-40-4112	Awl - Fixed Angle
27-40-4212	Drill - Fixed Angle
27-40-4312	Tap - Fixed Angle
27-40-3112	Awl - Flexible
27-40-3212	Drill - Flexible
27-40-3312	Tap - Flexible
27-40-0330	Driver - Flexible
27-40-0340	Flexible Instrument Guide
27-40-1212	Trial - 16x14x12mm
27-40-1312	Trial - 18x15x12mm
27-40-0012	Rasp - 16x14x12mm
27-10-1612	Implant - 16x14x12mm - 6 deg
27-10-1812	Implant - 18x15x12mm - 6 deg
27-14-4013	Screw Self-Drilling - 4.0x13mm
27-14-4015	Screw Self-Drilling - 4.0x15mm
27-14-4017	Screw Self-Drilling - 4.0x17mm
27-14-4019	Screw Self-Drilling - 4.0x19mm

Indications for Use

The Complete Cervical IBD is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Complete Cervical IBD implants are to be used with autogenous bone graft and implanted via an anterior approach. The cervical device is to be used in patients who have had six (6) weeks of non-operative treatment. The cervical device is to be used with two titanium alloy screws which accompany the implant.

SeaSpine Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

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

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome:

- Acute or chronic infectious diseases of any etiology and localization
- Morbid obesity
- Signs of local inflammation
- Fever or leukocytosis
- Metal/polymer sensitivity/allergies to the implant materials
- Medical or surgical conditions, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the autogenous bone graft)
- Any case not needing an autogenous bone graft and fusion or where fracture healing is not required
- Any case requiring the mixing of metals from different components
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support, bone immaturity
- Any case not described in the indication
- A patient unwilling to cooperate with the postoperative instructions
- The patient's activity level, mental condition, or occupation
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level(s) to be treated

These contraindications can be relative or absolute and must be taken into account by the physician. The above list is not exhaustive.

Warnings and Precautions

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the cervical spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is unknown. Only experienced spinal surgeons should perform the implantation of spinal systems 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 or death. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system. The device has not been evaluated for safety and comparability in the MR environment. The device has not been tested for heating or migration in the MR environment.

Notes

For more information or to place an order, please contact:
Phone 866.942.8698 USA | Fax 760.525.0337
Info@SeaSpine.com | **SeaSpine.com**

Outside USA
Phone #: + 1 866-942-8698
Fax #: + 1 877-558-6227
EMEA Customer Service:
EMEACustomerService@seaspine.com
LAPAC Customer Service:
CustSvcSpine@seaspine.com
SeaSpine.com

Manufacturer:
SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081 USA
Phone 866.942.8698 USA | **Fax** 760.525.0337

Warning: Applicable laws restrict these products to sale by or on the order of a physician.