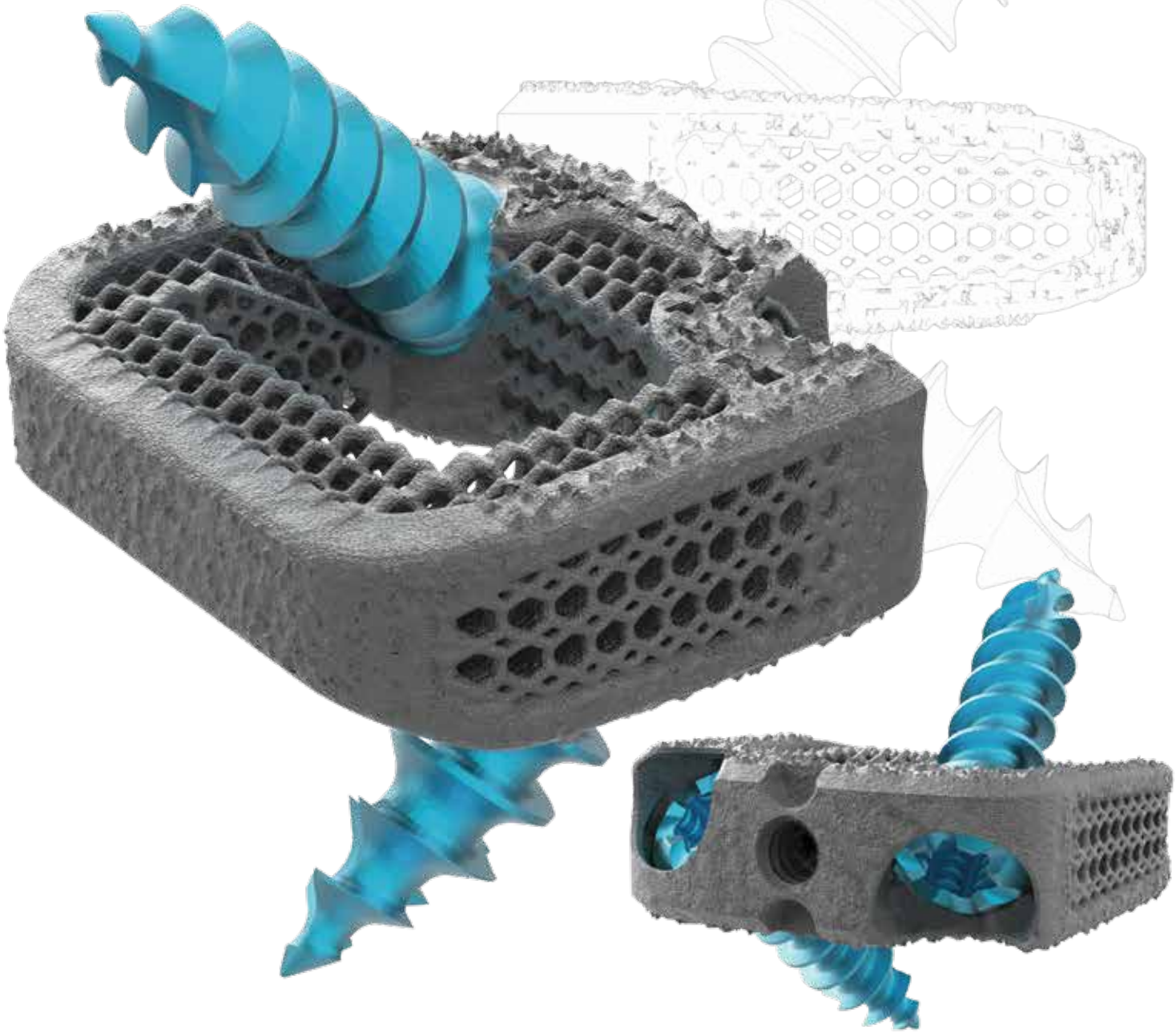
NEXXT MATRIXX®

Stand Alone Cervical System



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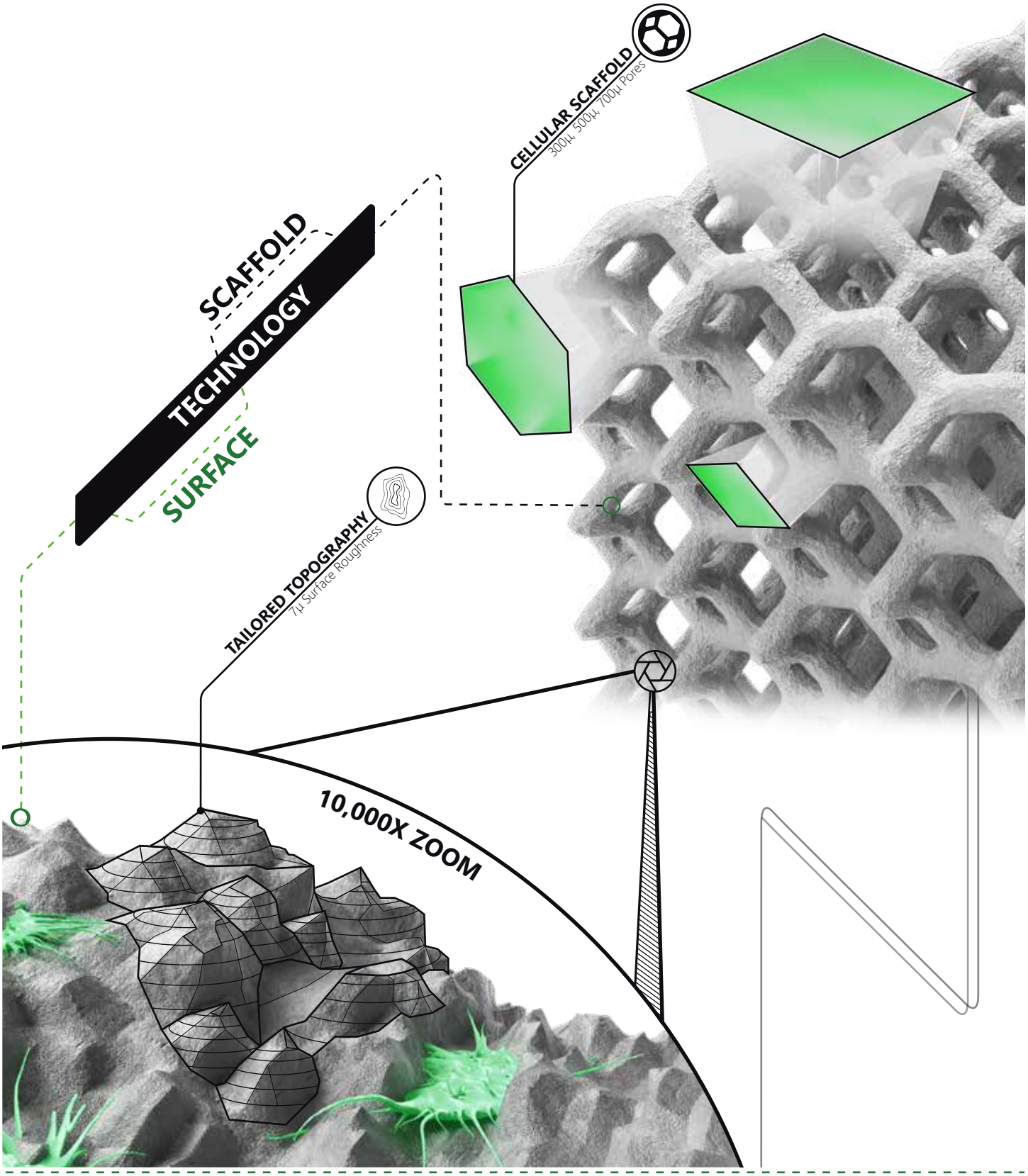
Indications for Use

The NEXXT MATRIXX® Stand Alone Cervical System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical System is intended to be used with the bone screw fixation provided and requires no additional fixation.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

NEXXT MATRIXX Technology®

3D Printed Porous Titanium



System Features

NEXXT MATRIXX® | Stand Alone Cervical System

The Stand Alone Cervical System possesses combined functionality and benefits of a cervical interbody and an anterior cervical plate. The implant is contained within the region of the excised disc space and is designed to not protrude past the mid-line edge of the vertebral bodies, reducing the amount of soft tissue damage or irritation. Stand Alone Cervical implants are comprised of various heights and footprints to accommodate individual patient anatomy.

Implant Features: Interbody

3D printed porous titanium alloy (Ti-6Al-4V ELI per ASTM F3001) material, integrated with Nexxt Matrixx® technology.

Roughened surface provides initial stabilization.

Integrated features to allow for one-step locking.

Implant Features: Screws

Titanium alloy (Ti-6Al-4V ELI per ASTM F136) screws provide fixation to the adjacent superior and inferior vertebral bodies.

Screws preassembled with locking collets allow for one-step construct locking.

Screws are designed as self-tapping

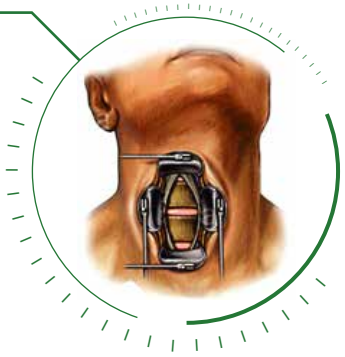
Cephalad/Caudal Angulation: 40°

Medial/Lateral Angulation: 12.5°

Surgical Approach ❶

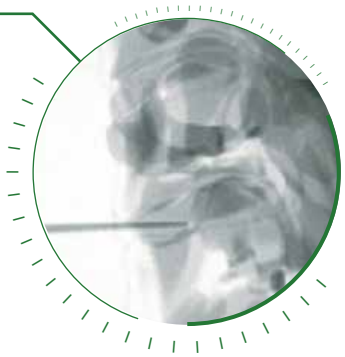
Patient Positioning

Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.



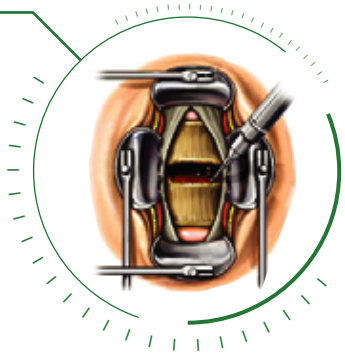
Exposure of Operative Level

Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc and confirm the correct operative level using a lateral radiograph.



Discectomy

Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression. The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.



Endplate Preparation ❷

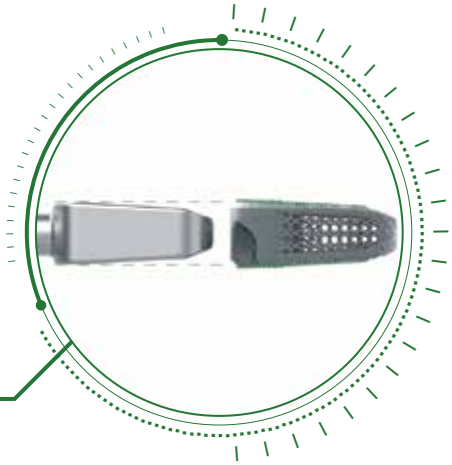
A 12 x 14 x 5mm universal Rasp is included as a standard in the surgical set to remove the superficial layer on the endplates. This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected interbody. Additional Rasp sizes are available upon request.

NOTE: Adequate preparation of endplates is critical in facilitating vascular supply to promote fusion.

WARNING: Excessive removal of bone during endplate preparation may weaken the bone, leading to subsidence and/or segmental instability.

Interbody Selection ❸

Selection of Interbody height and footprint is dependent on the Trial spacer. A mallet may be used to aid in insertion of the Trials. Trials are color coded to differentiate height and should be used incrementally to determine the appropriate dimensions of the interbody to be implanted.

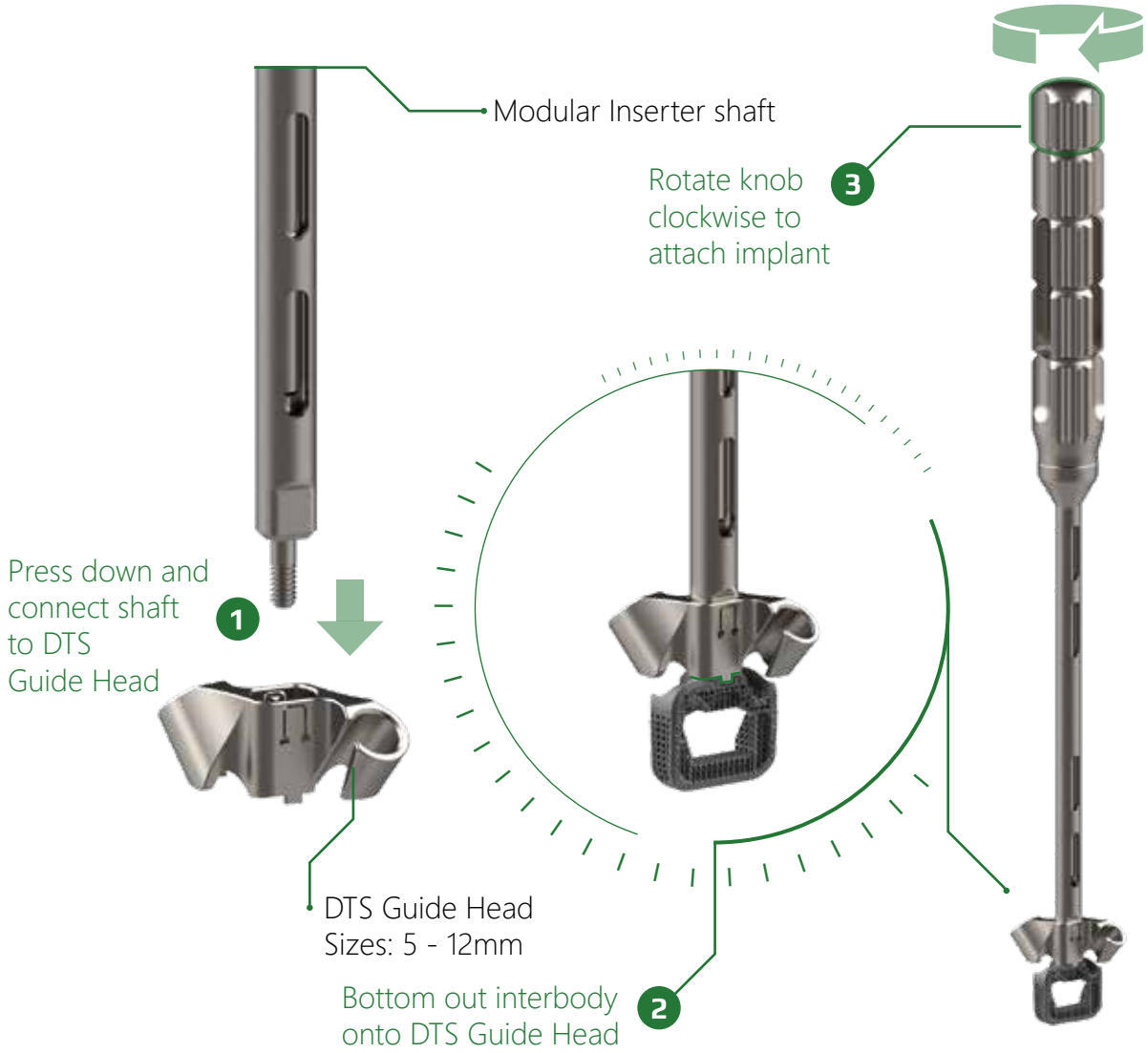


NOTE: The Trials are color coded according to the height of the implant. Trials are line to line with the corresponding implant.

NOTE: All labeled heights are measured from the area representing the highest point on the anterior wall of the implant.

Interbody Insertion 4

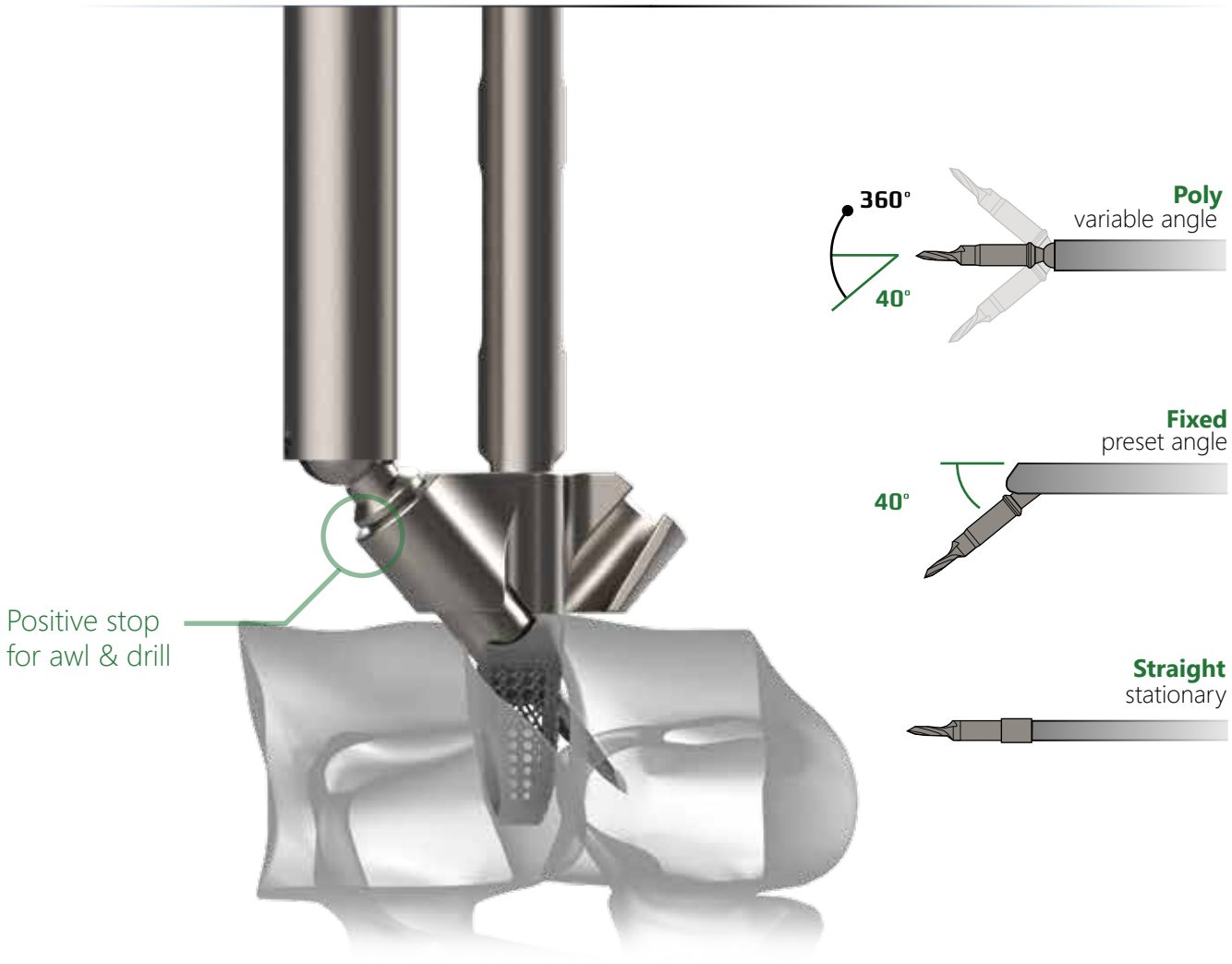
Open the sterile packaged Interbody, where the Interbody size has been determined by trialing. Connect the Modular Inserter Shaft to the appropriate DTS Guide Head via the integrated press-and-retain feature and align the DTS Guide Head prongs with the corresponding Interbody footprint. (Each DTS Guide Head has a 1:1 precise implant match for every footprint available.) Rotate the knob on the Modular Inserter Shaft clockwise until thread bottoms out in the Interbody. Pack the center cavity of the implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Introduce the implant into the disc space, mallet when necessary. Interbodies have been designed to have symmetric superior/inferior surfaces relative to the vertebral endplates. Verify placement of the interbody in the AP and lateral direction before continuing the procedure.



Hole Preparation 5

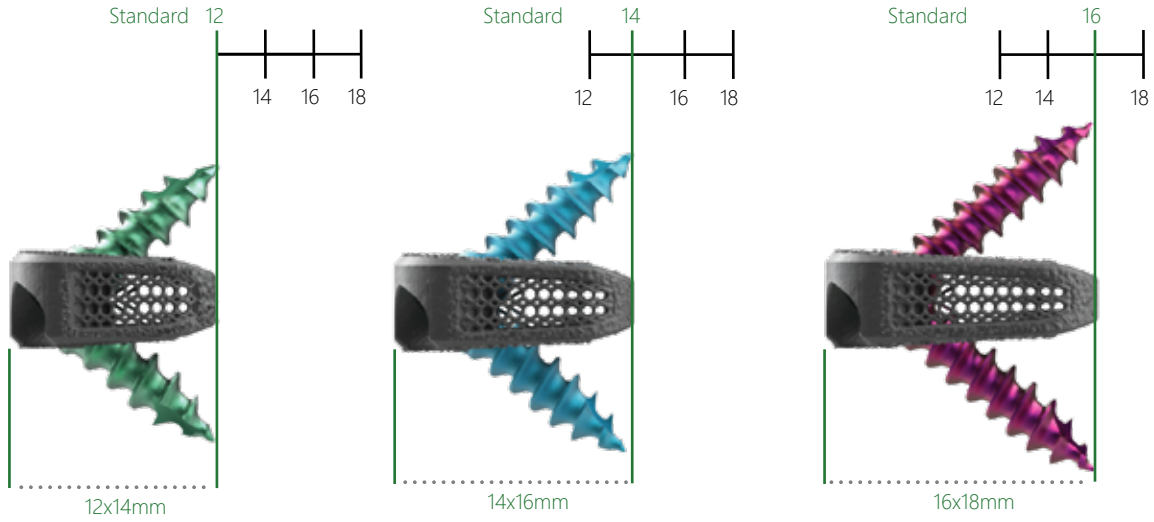
Use either the Awl or Drill (straight, fixed angle or poly angle) to penetrate the cortex of the endplate through the DTS Guide Head and Interbody pocket. Instruments will encounter a physical stop on the face of the DTS Guide Head to ensure the instrument tips do not protrude beyond the intended depth.

NOTE: Awl and Drill diameters are ∅2.0mm



Screw Insertion 6

Screws are color-coded by length and diameter. Lengths have been designed to match spacer depth. Stand Alone Cervical implant assemblies will come sterile packaged with one Interbody and two corresponding Screws; the Screws are designated to the chosen Interbody footprint. Press the Screw Inserter (straight, fixed angle or poly angle) tip into the female drive feature of the Screw in order to retain the Screw onto the Screw Inserter. Guide the attached Screw and Screw Inserter into the barrel of the DTS Guide Head, then thread the Screw into the pilot hole created in Step 5. Verify Screw placement and angulation prior to final tightening. Repeat the above steps for implanting the second Screw.



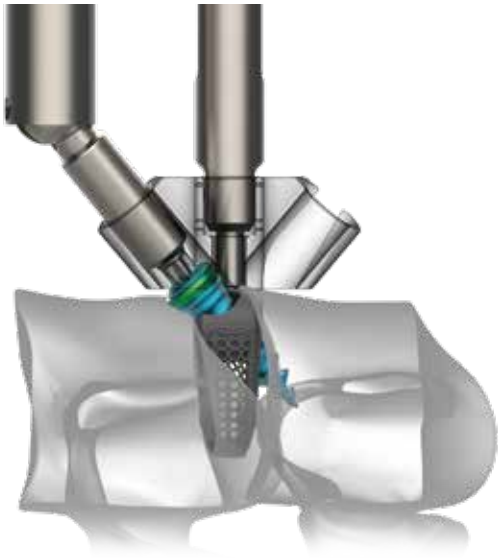
Note: Screw lengths are measured from the back of the footprint to the front.

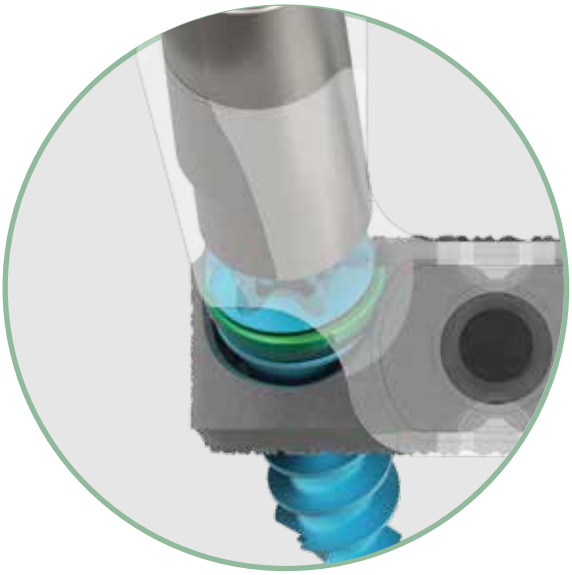
The standard screw lengths (12mm for the 12 x 14mm footprint, 14mm for the 14 x 16mm footprint, and 16mm for the 16 x 18mm footprint) are recommended as each terminate with the posterior edge of their respective implant.

Construct Locking 7

The integrated locking collet will produce a slight click when properly inserted into the interbody, as seen below. The slight click indicates the Screw is in a "locked" position, but has not yet lagged the Implant to the adjacent vertebral body. Continue tightening ¼ turn in order to lag the Implant to the vertebral body. Do not overtighten the Screw beyond the recommended amount, for the Screw could strip out the bone.

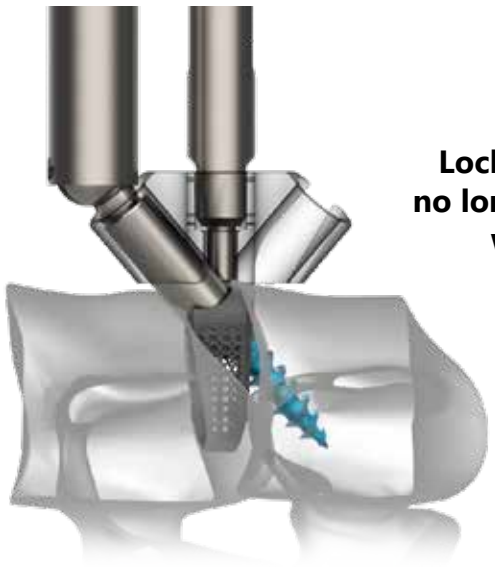
Inserting Screw



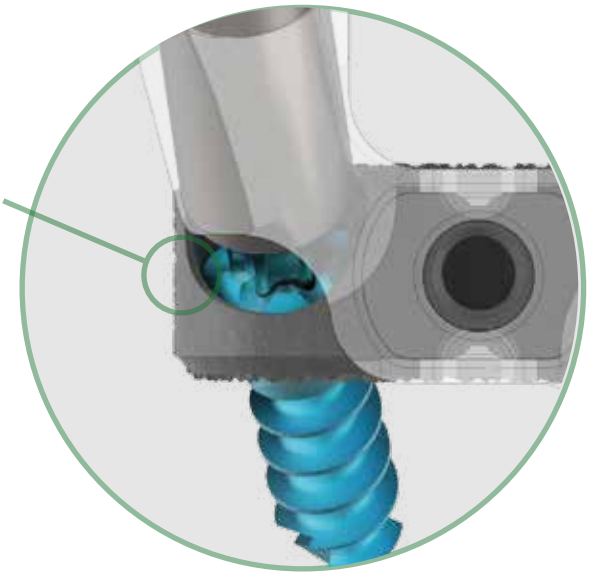


Top View

Fully Inserted



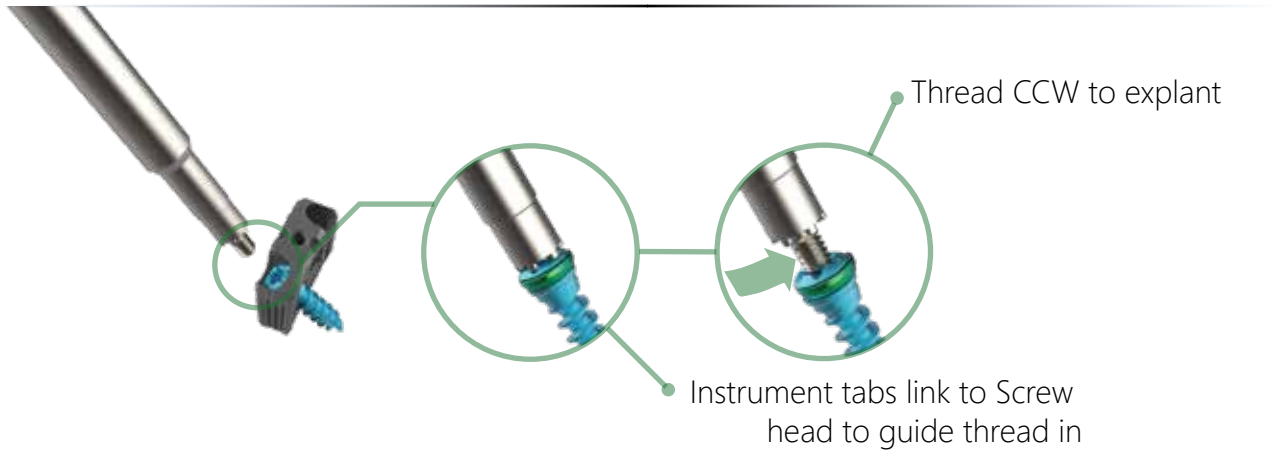
Locking collet will no longer be visible when properly inserted



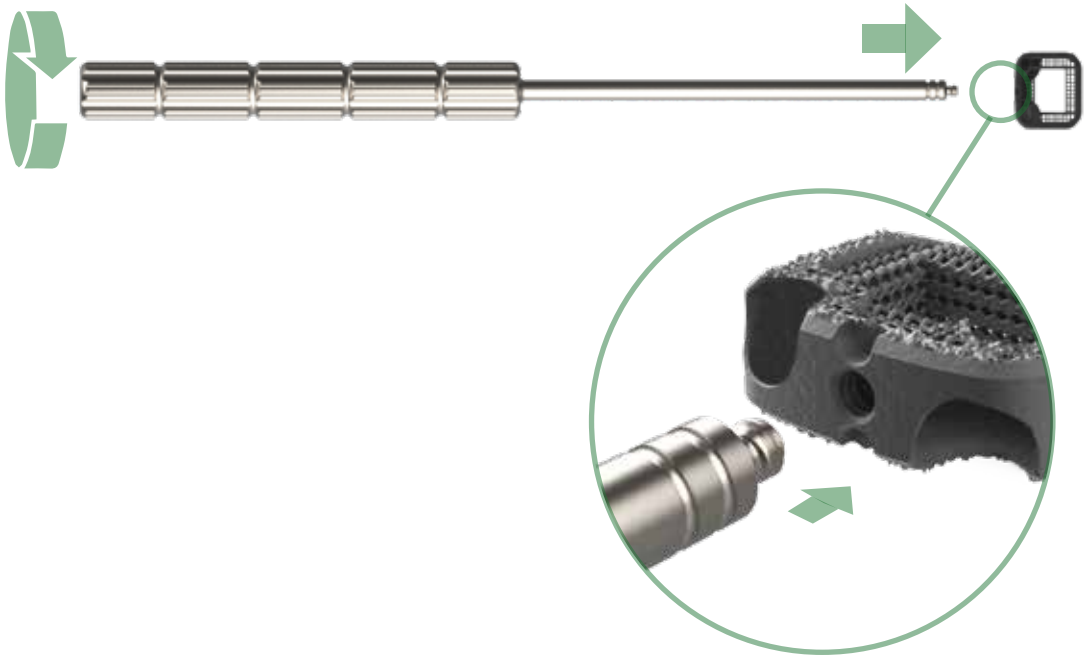
Top View

Implant Removal 8

1) Screw Removal: A Screw Removal Tool is included in the event Screw removal is required. (Fixed and Poly Angle Screw Removal Tools are available.) Insert the Screw Removal Tool into the Screw Removal Tool Shaft and mate the Sleeve castle to the Screw head. Rotate the Screw Removal Tool counterclockwise into the Screw to engage the integrated threads within the Screw hexalobe. After the threads of the instrument are fully engaged, continue to rotate counterclockwise to back out the screw. Rescue Screws are provided and should be used to replace the explanted Screw.



2) Interbody Removal: Drive the thread of the Fixed Interbody Inserter into the implant and rotate clockwise until bottomed out. Toggle medial/lateral while pulling up to remove implant.



SA Cervical Implants 9

12D x 14W Interbodies + 2 Screws

Part Number	Description
52-1214-05-ASM	12 x 14 x 5mm
52-1214-06-ASM	12 x 14 x 6mm
52-1214-07-ASM	12 x 14 x 7mm
52-1214-08-ASM	12 x 14 x 8mm
52-1214-09-ASM	12 x 14 x 9mm
52-1214-10-ASM	12 x 14 x 10mm
52-1214-11-ASM	12 x 14 x 11mm
52-1214-12-ASM	12 x 14 x 12mm

14D x 16W Interbodies + 2 Screws

Part Number	Description
52-1416-05-ASM	14 x 16 x 5mm
52-1416-06-ASM	14 x 16 x 6mm
52-1416-07-ASM	14 x 16 x 7mm
52-1416-08-ASM	14 x 16 x 8mm
52-1416-09-ASM	14 x 16 x 9mm
52-1416-10-ASM	14 x 16 x 10mm
52-1416-11-ASM	14 x 16 x 11mm
52-1416-12-ASM	14 x 16 x 12mm

16D x 18W Interbodies + 2 Screws

Part Number	Description
52-1618-05-ASM	16 x 18 x 5mm
52-1618-06-ASM	16 x 18 x 6mm
52-1618-07-ASM	16 x 18 x 7mm
52-1618-08-ASM	16 x 18 x 8mm
52-1618-09-ASM	16 x 18 x 9mm
52-1618-10-ASM	16 x 18 x 10mm
52-1618-11-ASM	16 x 18 x 11mm
52-1618-12-ASM	16 x 18 x 12mm

Rescue Screws

Ø3.5mm Screws

Part Number	Description
52-35-12-SP	Ø3.5 x 12mm
52-35-14-SP	Ø3.5 x 14mm
52-35-16-SP	Ø3.5 x 16mm
52-35-18-SP	Ø3.5 x 18mm

Ø4.0mm Screws

Part Number	Description
52-40-12-SP	Ø4.0 x 12mm
52-40-14-SP	Ø4.0 x 14mm
52-40-16-SP	Ø4.0 x 16mm
52-40-18-SP	Ø4.0 x 18mm

Indications for Use

Device Description
NEXXT MATRIXX® is a collection of additively manufactured implants. The Stand Alone Cervical System implants include additively manufactured spacers and traditionally machined fixation screws. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have 300-700µm pores. The inferior/superior aspects of the spacer incorporate a vertical cavity which can be packed with bone graft material. Each fixation screw is preassembled to a locking collet which secures the spacer and screw components. NEXXT MATRIXX® Stand Alone Cervical System spacers and fixation screws are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001 and F136, respectively.

Indications
The NEXXT MATRIXX® Stand Alone Cervical System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical System is intended to be used with the bone screw fixation provided and requires no additional fixation.

Contraindications
The Stand Alone Cervical System contraindications include, but are not limited to:
1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Any condition not described in the Indications for Use.
4. Prior fusion at the level(s) to be treated.

Warnings and Precautions
1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. The NEXXT MATRIXX® Stand Alone Cervical System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
5. The NEXXT MATRIXX® Stand Alone Cervical System is used to augment the development of a spinal fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

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