NEXXT MATRIXX®

TLIF / TLIF Oblique Interbodies

TABLE OF CONTENTS

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

NEXXT MATRIXX® SYSTEM

Nexxt Matrixx® straight and curved Interbodies may be used in posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), or transforaminal posterior lumbar interbody fusion (tPLIF) procedures utilizing supplemental internal fixation such as the Nexxt Spine Inertia® Pedicle Screw System, Inertia® MIS Pedicle Screw System, or Facet Fixx® Screw System.

Figure 1

PATIENT POSITIONING

Following adequate general anesthesia, the patient is placed in the prone position on a radiolucent spine table (Fig. 1). Particular attention is applied to the positioning of the head and extremities to lessen the risk of ocular and nerve compression.

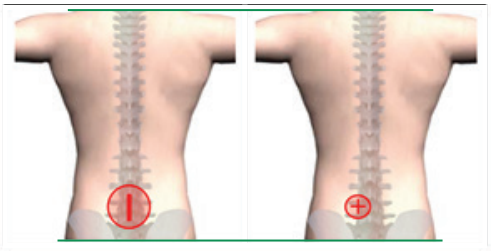


Figure 2

EXPOSURE OF OPERATIVE LEVEL(S)

Identify the affected level(s) using fluoroscopic imaging and palpation of the targeted anatomy (Fig. 2). Access the operative site using preferred instruments. Tissues should be retracted enough to allow for exposure and visualization of the targeted disc space. Insert a marker into the disc(s) to confirm the correct operative level(s) using a lateral radiograph (Fig. 3).

NOTE: Nexxt Matrixx® TLIF/TLIF Oblique Interbodies are indicated for use at up to two contiguous levels in the lumbar spine, from L2-S1.

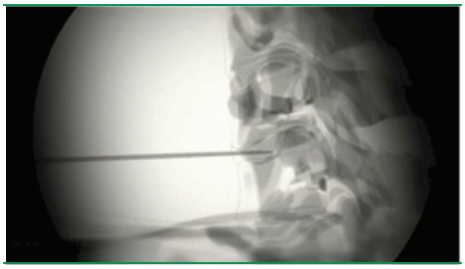


Figure 3

DISCECTOMY

Perform a complete discectomy using preferred surgical instruments. Pituitaries, cup curettes, rongeurs and interspace shavers may be used to remove the disc material (Fig. 4). If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished. The main goal of this step is to provide entry to the disc space for distraction with minimal or no nerve root retraction.

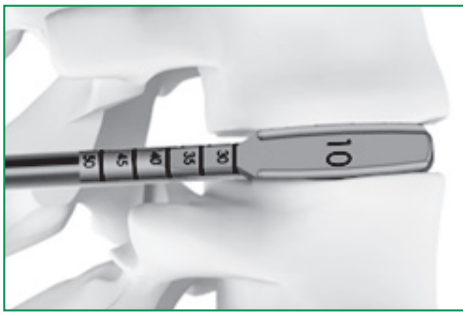


Figure 4

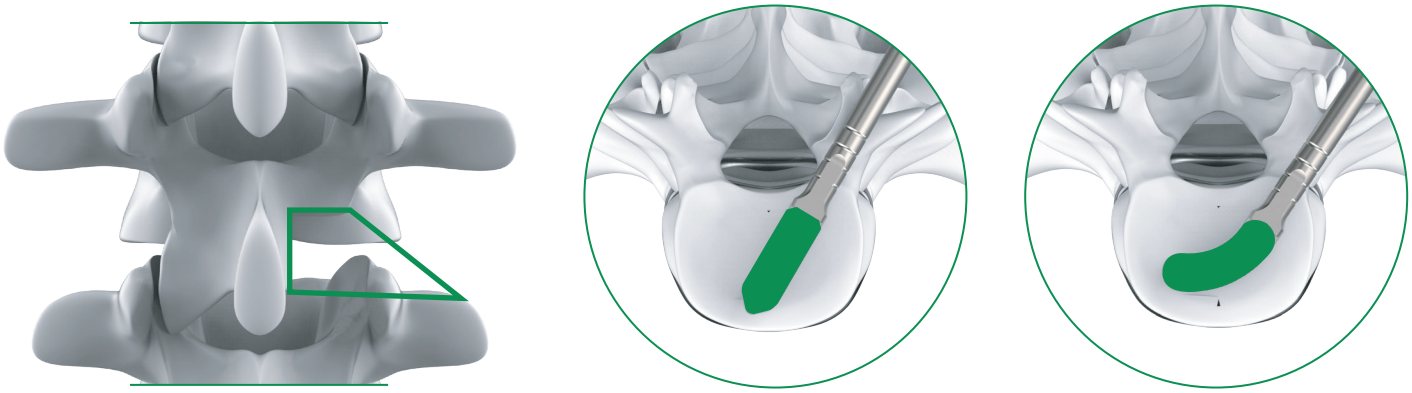
DISTRACTION

Effective distraction aids in removal of the superior articular process, decompression of the neuroforamen, preparation of the disc space and insertion of the Implant. This may be accomplished through several techniques: pedicle screw distraction, distraction between boney elements, and/or distraction with Paddle Distractors (Fig. 5).

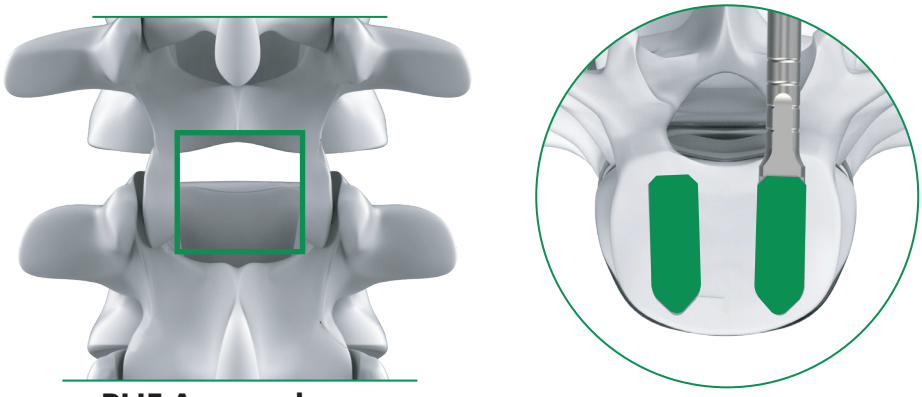
Figure 5

DECOMPRESSION

Utilizing osteotomes and rongeurs, a small section of the lamina and facet(s) should be removed to create an appropriately sized bony window for access to the targeted disc space (Fig. 6). Preserve decorticated bone to pack in or around Implant prior to implantation.



TLIF or TLIF Oblique Approach **TLIF Oblique** **TLIF**



PLIF Approach

Figure 6

ENDPLATE PREPARATION

Access to the disc space is achieved through an annulotomy made lateral to the posterior longitudinal ligament.

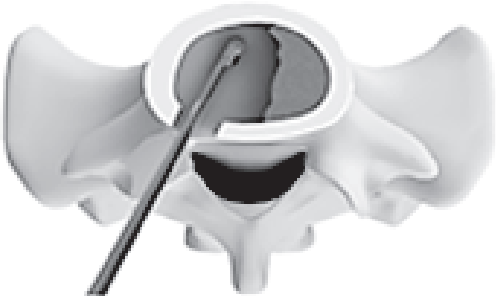
Using a scalpel, vertical cuts should be made parallel to the dura and laterally in the foramen between the superior and inferior endplate. Additional cuts extend horizontally along the endplates, connecting the vertical cuts.

The annulus and any accessible disc material are removed with interspace shavers, rongeurs, curettes, etc. (Fig. 7). The discectomy is complete once superficial layers of the entire cartilaginous endplates are removed and bleeding bone is exposed.

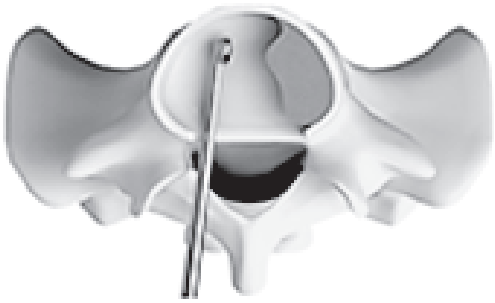
Appropriate endplate preparation will optimize surface contact with the selected Nexxt Matrixx® Interbody.

NOTE: Prior to placement of the Implant, autograft or allograft may be placed in the anterior and lateral aspects of the intervertebral disc space. The Bone Funnel and Bone Plunger may aid in the delivery of the graft.

WARNING: Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.



TLIF or TLIF Oblique Approach



PLIF - Straight Approach

Figure 7

IMPLANT SIZE SELECTION

Selection of the Trial depends on the height, width, and depth of the intervertebral space. Based on the pre-operative imaging and surgical technique, connect an appropriately sized Trial to the Quick Release T-Handle and insert it into the annulotomy window (Fig. 8).

Each Trial is labeled to differentiate height and should be used incrementally to determine the appropriate dimensions of the required Nexxt Matrixx® Implant (Fig. 9).

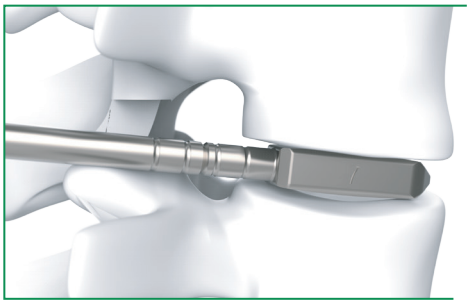
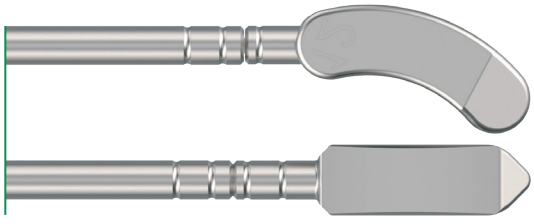


Figure 8



TLIF

TLIF
Oblique

Figure 9

IMPLANT SIZE SELECTION (CONTINUED)

Insert desired Trial into the intervertebral disc space using gentle impaction of a mallet or Slap Hammer. The Slap Hammer includes laser etched steps (Attach, Drop, and Rotate) for attachment of the Trial (Fig 10). Fluoroscopy can assist in confirming the fit and geometry of the Trial. If the Trial appears too loose or too tight, try the next larger or smaller size until the most secure fit is achieved.

The Slap Hammer can be used to facilitate the removal of the Trial from the intervertebral disc space. To use, apply an upward force to the Slap Hammer. Repeat until Trial is removed from the intervertebral disc space.

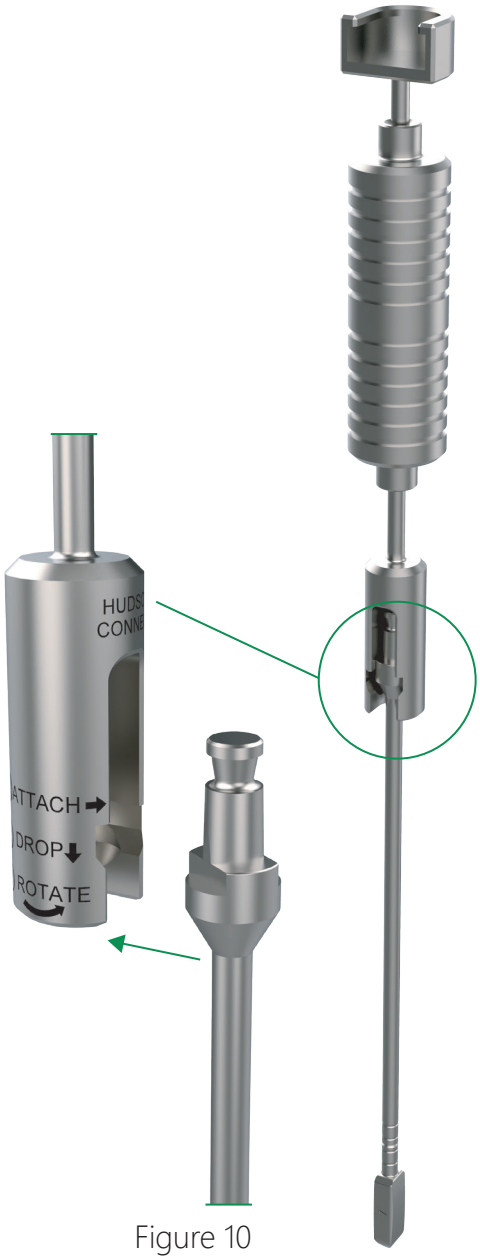


Figure 10

NOTES:

-Adequate preparation of the endplates is critical in facilitating vascular supply to promote fusion.
-Trial sizes (d x w x h) are a line to line match to the corresponding Implant. There is no need to under-size or over-size the Implant.
-Standard Angulation (Lordosis) of Curved TLIF Trials and corresponding TLIF Implants is 6°. 0° parallel are offered as optional.
-Standard Angulation of TLIF Oblqiue Trials and corresponding TLIF Oblique Implants is 0°. 6° lordodic are offered as optional.
-All Implant heights are measured from the tallest point on the Implant (Fig. 11).
-All TLIF and TLIF Oblique Implants have superior/inferior teeth to help resist implant migration and expulsion while providing a high degree of initial stability.

IMPLANT PREPARATION AND INSERTION

Open the sterile packaging of the TLIF/TLIF Oblique Implant size (height and footprint) that was determined with the Trial (Fig. 11).

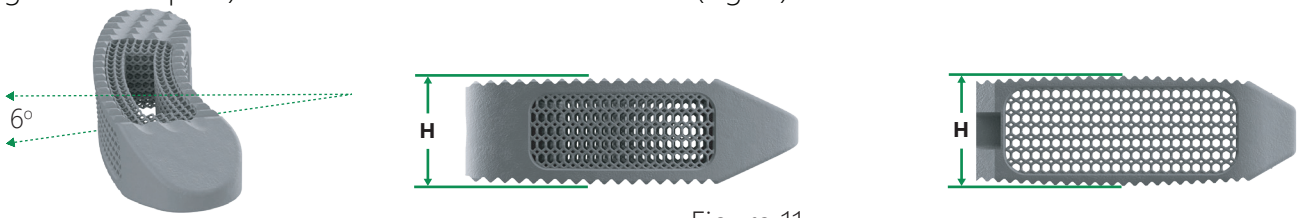
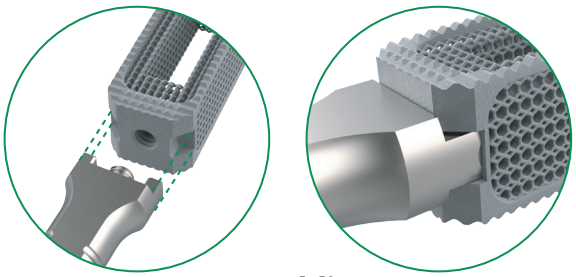


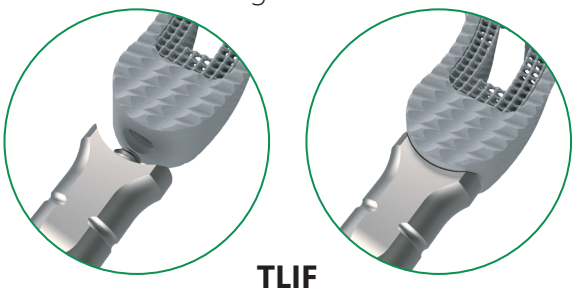
Figure 11

IMPLANT PREPARATION AND INSERTION (CONTINUED)

For TLIF Oblique, mate the Alignment Keys to the implant (Fig. 12) and commence insertion by turning the knob on the threaded shaft component clockwise. For TLIF, place the end of the Implant into the circular cup and thread into the Implant by turning the knob on the threaded shaft component clockwise (Figure 13). Confirm the implant is securely attached but DO NOT overtighten.



TLIF Oblique
Figure 12



TLIF
Figure 13

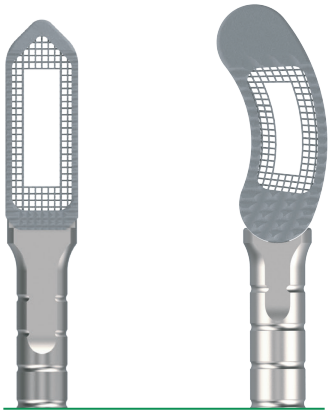
GRAFT MATERIAL PLACEMENT

Prior to insertion, pack the center cavity of the implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. In addition, autograft or allograft may be placed in the anterior and lateral aspects of the intervertebral disc space. The Bone Funnel and Bone Plunger may aid in the delivery.

NOTE: Diameter of Bone Funnel Tip is 7mm.

Insert the Implant into the intervertebral disc space. If necessary, controlled and light hammering with a Slap Hammer or mallet can be used to help advance the implant to the desired position (Fig. 14).

The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper positioning.



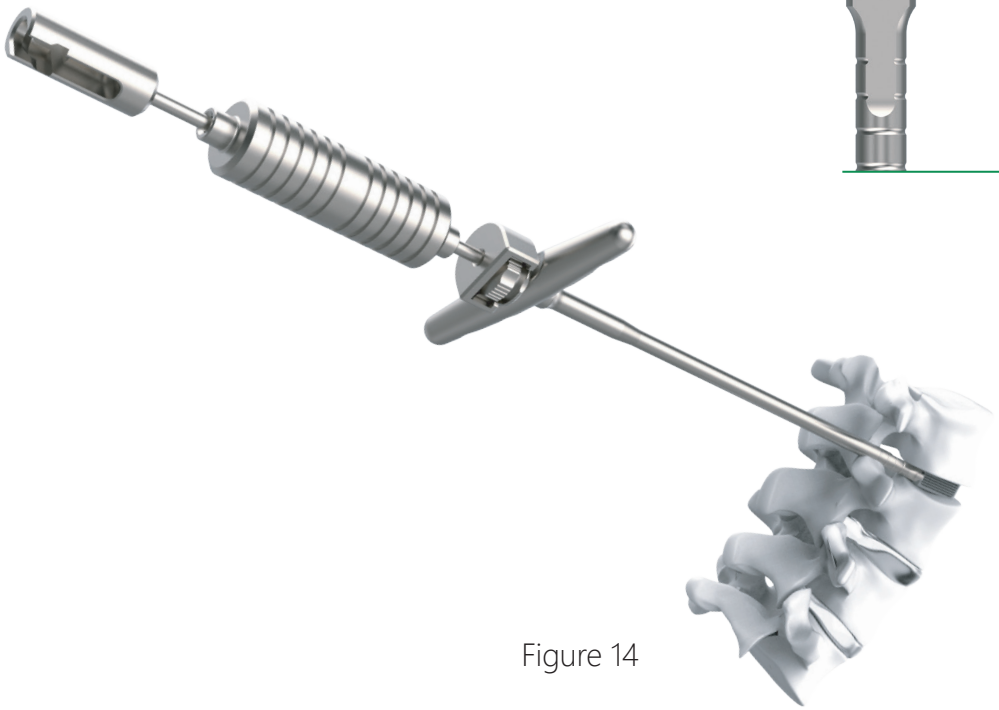


Figure 14

IMPLANT PREPARATION AND INSERTION (CONT.)

Turn the knob on the threaded inserter shaft in a counterclockwise direction to release the implant from the Inserter (Fig. 15).

If the Implant requires further adjustment, a Tamp may be used to carefully manipulate into desired position.

Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the Nexxt Spine Inertia® Pedicle Screw System, Inertia® MIS System, or Facet Fixx® Screw System.

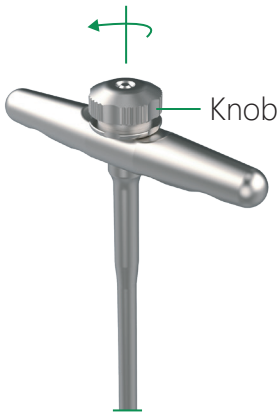


Figure 15

OPTIONAL: Insert and Rotate Technique

The Insert and Rotate Technique provides potential for less neural retraction compared to straight interbody impaction[1]. The Implants are aligned in-situ by rotation and allow an atraumatic restoration of disc height and natural lordosis.

A bilateral posterior approach (PLIF) or unilateral posterior approach (tPLIF) may be utilized. If performing a bilateral surgery, leave enough space beneath the annulotomy to allow for placement of the contralateral implant.

Attach the Implant to the Inserter by aligning the male/female thread components and turning the knob on the threaded shaft component clockwise. Confirm the implant is securely attached but DO NOT overtighten (Fig. 13).

Insert a TLIF Oblique Implant horizontally (on its side) into the intervertebral disc space utilizing the tapered nose to distract the disc space (Fig. 16). If necessary, controlled and light hammering with a Slap Hammer or mallet can be used to help advance the implant to the desired position. Once the Implant is in position, rotate the Inserter 90° to distract the disc space for final Implant positioning (Fig. 17).

The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper Implant positioning.

Turn the knob on the threaded inserter shaft in a counterclockwise direction to release the implant from the Inserter.

If the Implant requires further adjustment, a Tamp may be used to carefully manipulate into desired position.

Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the Nexxt Spine Inertia® Pedicle Screw System, Inertia® MIS System, or Facet Fixx® Screw System.

1 Cages inserted horizontally

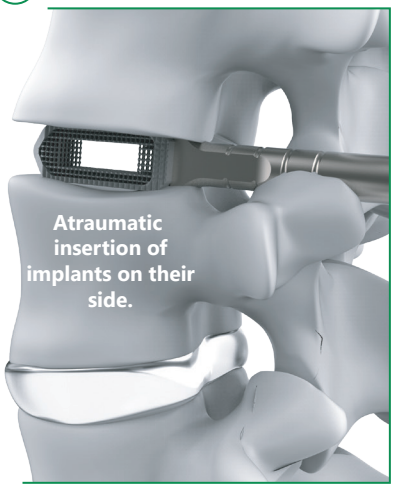


Figure 16

2 Cages rotated 90° in-situ

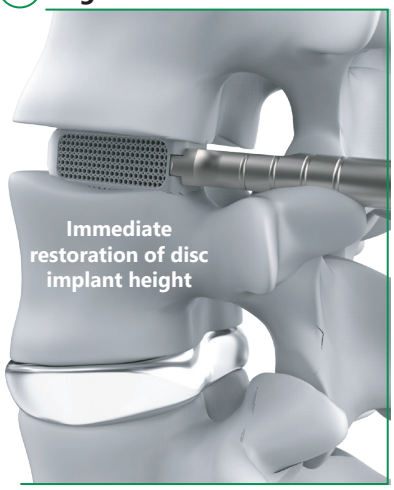


Figure 17

1. Mirkovic SR, Schwartz DG, and Glazier KD. 1995. Anatomic Considerations in Posterolateral Percutaneous Procedures. Spine 20 (18): 1965-1971.

NOTES:
-Tactile feedback during Implant rotation reduces potential for overstretching/oversizing. Primary distraction takes place in the intervertebral space. The distraction produced by the width of the Implant results in effective tensioning of the anterior and posterior longitudinal ligaments without damaging them. This rotation step also ensures that the neural structures remain protected throughout the implantation process.
-The Insert & Rotate Technique reduces the need for expandable Implant and their associated graft containment issues.

IMPLANT REMOVAL
Attach either the Inserter or Universal Removal Instrument in a clockwise rotation to the Implant (Fig. 18). Be careful to avoid pushing the implant anteriorly. A Slap Hammer or slotted mallet may be used in conjunction with the Inserter for removal of the Implant if desired. To use, apply an upward force to the Slap Hammer. Repeat until Implant is removed from the intervertebral disc space.

If distraction was utilized during implantation, be sure to re-apply distraction to allow easier removal of the implant. Vertebral bone overgrowth or osteophytes may be removed to facilitate retrieval of the Implant.

NOTES:
-An osteotome can be used at the interface between the Implant and endplates to disengage the construct.
-Use of distraction is suggested to allow easier access to the Implant/endplate interface.

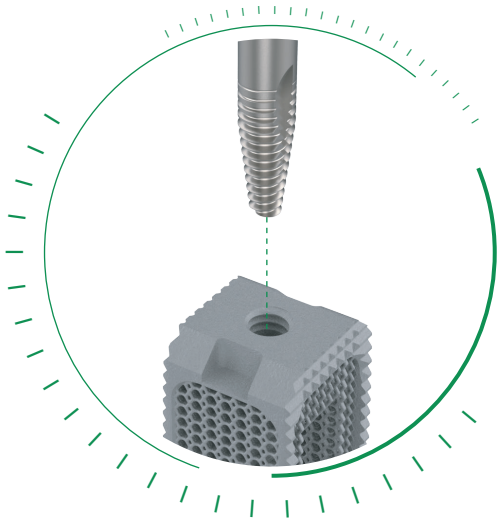


Figure 18

DEVICE DESCRIPTION

Nexxt Matrixx® is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants 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 pores 300-700µm. The inferior/superior aspects of the Nexxt Matrixx® open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/superior aspects of the Nexxt Matrixx® solid devices are closed and do not permit the packing of bone graft within the implant. The solid devices are only to be used for partial vertebral body replacement. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient. The Nexxt Matrixx® implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS

When used as a lumbar intervertebral fusion device, Nexxt Matrixx® open devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, Nexxt Matrixx® lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

CONTRAINDICATIONS

Nexxt Matrixx® 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. Nexxt Matrixx® 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. Nexxt Matrixx® solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. Nexxt Matrixx® is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. 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.
7. 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.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. Components of this system should not be used with components of any other system or manufacturer.
10. 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.

NEXXT MATRIXX® INSTRUMENT PRODUCT NUMBERS

I54-XXL-XX TLIF Oblique Trial Lordotic*

I54-XXP-XX TLIF Oblique Trial Parallel

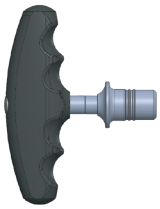
I56-XXL-XX TLIF Trial Lordotic

I56-XXP-XX TLIF Trial Parallel*

I15-01-01, TLIF, Implant Inserter

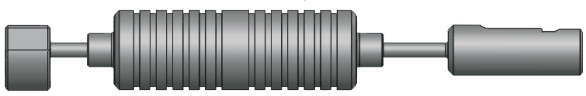
I54-01-01 TLIF Oblique Inserter

I10-01-43 T-Handle, Silicone, Hudson Connect



I10-01-34 T-Handle, Silicone, Hudson Connect*

I54-20-01 Nexxt Matrixx® Slap Hammer



I15-09-01, TLIF Tamp

I21-09-01, Implant Tamp, 90 degree

I21-09-02, Implant Tamp, Straight

I35-50-01L, Universal Remover, Long

I40-09-05, Bone Funnel: 7mm

I40-09-06, Bone Plunger: 7mm

I54-20-02 Release Wheel

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70-042, Rev. B

NEXXT MATRIXX® IMPLANT PRODUCT NUMBERS

NEXXT MATRIXX® TLIF

Standard P/N	Description
56M-31L-07-SP	TLIF Lordosed 31D x 10W x 7H
56M-31L-08-SP	TLIF Lordosed 31D x 10W x 8H
56M-31L-09-SP	TLIF Lordosed 31D x 10W x 9H
56M-31L-10-SP	TLIF Lordosed 31D x 10W x 10H
56M-31L-11-SP	TLIF Lordosed 31D x 10W x 11H
56M-31L-12-SP	TLIF Lordosed 31D x 10W x 12H
56M-31L-13-SP	TLIF Lordosed 31D x 10W x 13H
56M-31L-14 to 17-SP*	TLIF Lordosed 31D x 10W x 14 to 17H
56M-34L-XX-SP*	TLIF Lordosed 34D x 10W x 7-17H
56M-31P-XX-SP*	TLIF Parallel 31D x 10W x 7-17H
56M-34P-XX-SP*	TLIF Parallel 34D x 10W x 7-17H

*Optional

NEXXT MATRIXX® TLIF OBLIQUE

Standard P/N	Description
54M-22-07-SP	TLIF Oblique 22D x 9W x 7H
54M-22-08-SP	TLIF Oblique 22D x 9W x 8H
54M-22-09-SP	TLIF Oblique 22D x 9W x 9H
54M-22-10-SP	TLIF Oblique 22D x 9W x 10H
54M-22-11-SP	TLIF Oblique 22D x 9W x 11H
54M-22-12-SP	TLIF Oblique 22D x 9W x 12H
54M-22-13-SP	TLIF Oblique 22D x 9W x 13H
54M-22-XX-SP*	TLIF Oblique 22D x 9W x 14-17H
54M-26-07-SP	TLIF Oblique 26D x 9W x 7H
54M-26-08-SP	TLIF Oblique 26D x 9W x 8H
54M-26-09-SP	TLIF Oblique 26D x 9W x 9H
54M-26-10-SP	TLIF Oblique 26D x 9W x 10H
54M-26-11-SP	TLIF Oblique 26D x 9W x 11H
54M-26-12-SP	TLIF Oblique 26D x 9W x 12H
54M-26-13-SP	TLIF Oblique 26D x 9W x 13H
54M-26-XX-SP*	TLIF Oblique 26D x 9W x 14-17H
54M-30-XX-SP*	TLIF Oblique 30D x 10W x 7-17H
54M-34-XX-SP*	TLIF Oblique 34D x 10W x 7-17H
54M-22L-XX-SP*	Lordotic TLIFO, 22D x 9W x 7-17H, 6°
54M-26L-XX-SP*	Lordotic TLIFO, 26D x 9W x 7-17H, 6°
54M-30L-XX-SP*	Lordotic TLIFO, 30D x 10W x 7-17H, 6°
55M-22L-XX-SP*	Lordotic TLIFO Solid, 22D x 9W x 7-17H, 6°
55M-26L-XX-SP*	Lordotic TLIFO Solid, 26D x 9W x 7-17H, 6°
55M-30L-XX-SP*	Lordotic TLIFO Solid, 30D x 10W x 7-17H, 6°