

NEXXT MATRIX[®]
Vertebral Body Replacement

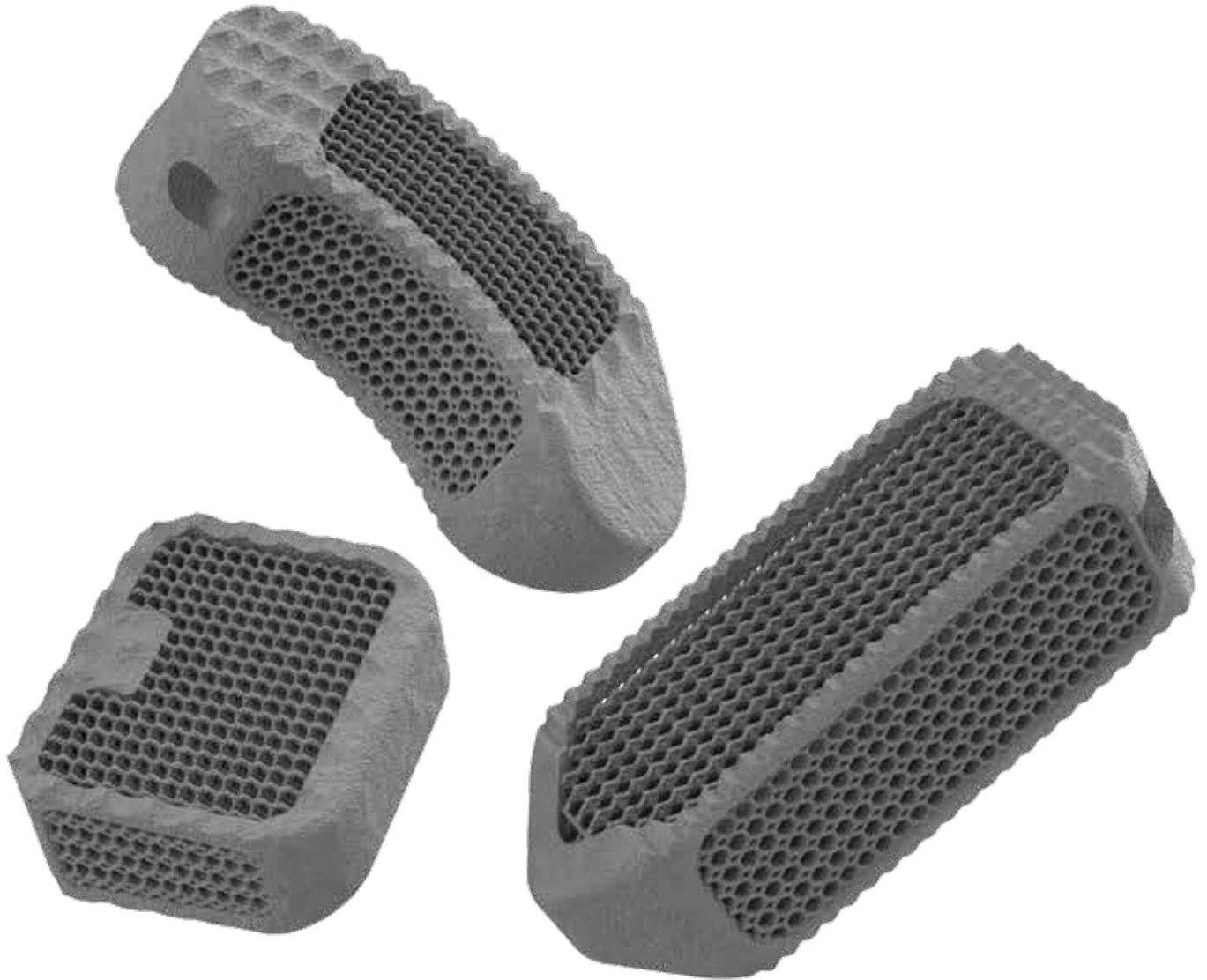


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Caution: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

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 1

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).

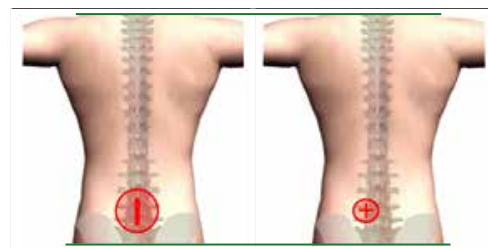


Figure 2

CORPECTOMY

Using preferred rongeurs, pituitaries, curettes and Kerrisons, perform a partial corpectomy at the indicated level. **The affected partial vertebral body and disc material is excised and both the superior and inferior surfaces are prepared.**

NOTE: Adequate preparation of the superior and inferior surfaces is critical in facilitating vascular supply to promote fusion.



Figure 3

SPACER SIZE SELECTION

A distraction device may be used at the **partial** corpectomy site to facilitate restoration of anterior column height. With a commercially available caliper (Fig. 4), measure the height of the defect in situ from the anterior aspect of the inferior **surface** to the anterior aspect of the superior **surface**. Account for the size of any distraction device used.

IMPLANT PREPARATION AND INSERTION

Open the sterile packaging of the straight or curved Nexxt Matrixx® VBR (height and footprint) that was determined with the measuring caliper.

VBR's have plateaus on the superior (cephalad) and inferior (caudal) surfaces (Fig. 5) and are measured (height) from the tallest point on the implant.

Angulation (Lordosis) of Nexxt Matrixx® VBRs are offered in 0° and 6°

Attach the VBR to the Inserter by aligning the male/female thread components and turning the knob on the threaded shaft component clockwise. Confirm the VBR is securely attached but DO NOT overtighten (Fig. 6).

NOTE:

Green emphasizes shape differentiation between straight and curved.

Gently insert the VBR into the affected 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. 7).

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



Figure 4



Figure 5

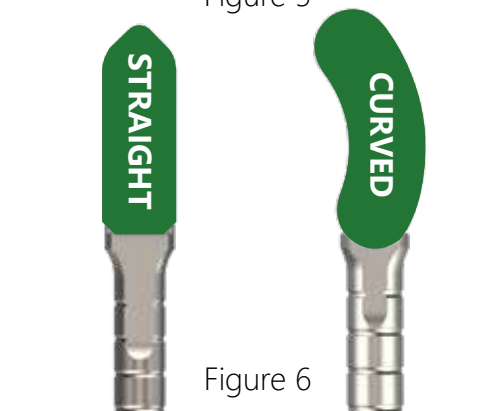


Figure 6

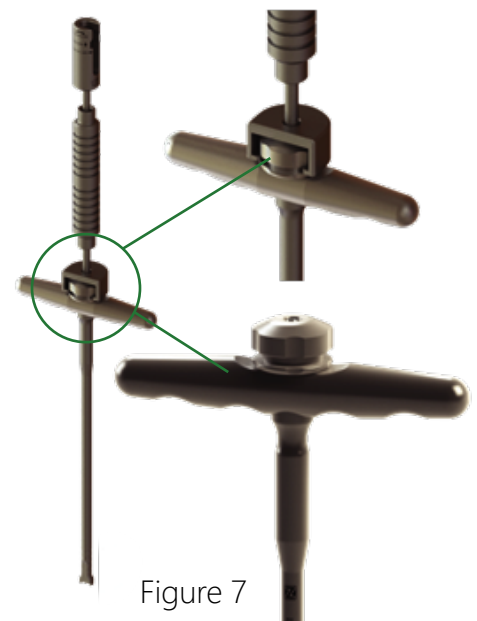


Figure 7

Turn the knob on the threaded Inserter shaft in a counterclockwise direction to release the implant from the Inserter (Fig. 8).

If the spacer requires further adjustment, a Tamp may be used to carefully manipulate the spacer 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[®] Facet Screw System.

NOTES:

- All spacer heights are measured from the tallest point on the implant.
- All Nexxt Matrixx[®] Straight and Curved VBR's have superior/inferior teeth to help resist implant migration and expulsion while providing a high degree of initial stability.



Figure 8

IMPLANT REMOVAL

Attach either the Inserter or Universal Removal Instrument in a clockwise rotation to the Implant (Fig. 9). 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.

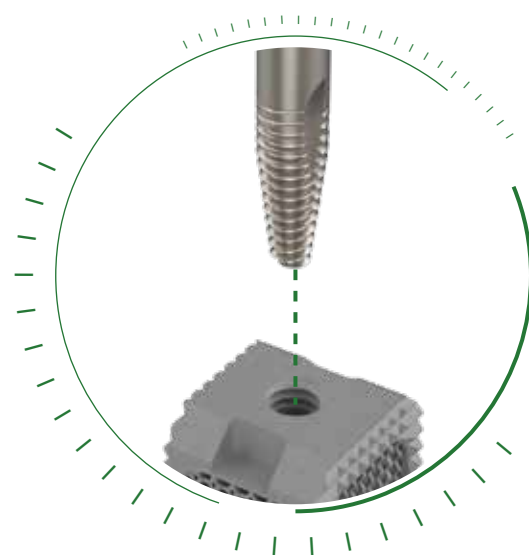


Figure 9

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 vertebral body replacement device, the Nexxt Matrixx[®] System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal 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 MATRIX[®] IMPLANT PRODUCT NUMBERS

NEXXT MATRIX[®] CURVED VBR

Standard P/N	Description
57M-31L-07-SP	TLIF Lordosed Solid 31D x 10W x 7H
57M-31L-08-SP	TLIF Lordosed Solid 31D x 10W x 8H
57M-31L-09-SP	TLIF Lordosed Solid 31D x 10W x 9H
57M-31L-10-SP	TLIF Lordosed Solid 31D x 10W x 10H
57M-31L-11-SP	TLIF Lordosed Solid 31D x 10W x 11H
57M-31L-12-SP	TLIF Lordosed Solid 31D x 10W x 12H
57M-31L-13-SP	TLIF Lordosed Solid 31D x 10W x 13H
57M-31L-14 to 17-SP*	TLIF Lordosed Solid 31D x 10W x 14 to 17H
57M-34L-XX-SP*	TLIF Solid Lordosed 34D x 10W x 7-17H
57M-31P-07-SP*	TLIF Parallel Solid 31D x 10W x 7H
57M-31P-08-SP*	TLIF Parallel Solid 31D x 10W x 8H
57M-31P-09-SP*	TLIF Parallel Solid 31D x 10W x 9H
57M-31P-10-SP*	TLIF Parallel Solid 31D x 10W x 10H
57M-31P-11-SP*	TLIF Parallel Solid 31D x 10W x 11H
57M-31P-12-SP*	TLIF Parallel Solid 31D x 10W x 12H
57M-31P-13-SP*	TLIF Parallel Solid 31D x 10W x 13H
57M-31P-14 to 17-SP*	TLIF Parallel Solid 31D x 10W x 14 to 17H
57M-34P-XX-SP*	TLIF Solid Parallel 34D x 10W x 7-17H

*Optional

NEXXT MATRIX[®] STRAIGHT VBR

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

NEXXT MATRIX[®] SQUARE VBR

Standard P/N	Description
51M-1214-05-SP*	Solid 12D x 14W x 5H
51M-1214-06-SP*	Solid 12D x 14W x 6H
51M-1214-07-SP*	Solid 12D x 14W x 7H
51M-1214-08-SP*	Solid 12D x 14W x 8H
51M-1214-09-SP*	Solid 12D x 14W x 9H
51M-1214-10-SP*	Solid 12D x 14W x 10H
51M-1212-XX-SP*	Solid 12D x 12W x 5-18H
51M-1212P-XX-SP*	Parallel Solid 12D x 12W x 5-18H
51M-1214-XX-SP*	Solid 12D x 14W x 11-18H
51M-1214P-XX-SP*	Parallel Solid 12D x 14W x 5-18H
51M-1416-XX-SP*	Solid 14D x 16W x 5-18H
51M-1416P-XX-SP*	Parallel Solid 14D x 16W x 5-18H
51M-1618-XX-SP*	Solid, 16D x 18W x 5-18H

*Optional

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 Honour®, 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



*Optional

I15-09-01 Honour®, TLIF Tamp



I21-09-01 Honour®, Implant Tamp, 90 degree



I21-09-02 Honour®, Implant Tamp, Straight



I35-50-01L Honour®, Universal Remover, Long



I40-09-05 Honour®, Bone Funnel: 7mm



I40-09-06 Honour®, Bone Plunger: 7mm



I54-20-02 Release Wheel



I35-10M-XX Cervical, Trial, 6° (0°*), 12x14xXXmm
(12x12xXX*, 14x16xXX*, 16x18xXX*)



I35-20M-XX Cervical, Trial, 6°, 12x14xXXmm
(12x12xXX*, 14x16xXX*, 16x18xXX*)



I50-01-01 Inserter



I35-40-01 Tamp



I35-50-01S Universal Remover, Short



I35-31-01 Cervical, Inserter Sleeve*





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