



Technique Guide







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PREFACE

Fellow Colleagues:

The X-CORE[®] Expandable VBR marks a significant advancement in the quest for greater anterior column support and stability in corpectomy procedures. After rigorous testing and design iterations, we have developed an expandable cage that provides spine surgeons the ability to give tumor/trauma patients outcomes previously not possible.

During early evaluation, we found patients experienced significantly less subsidence than those treated with more traditional, cylinder-shaped cages. Using X-CORE, we are able to intraoperatively build the implant to patient-specific anatomy. In the process, we can attach customized endcaps that span the ring apophysis, providing maximum coverage of the endplates' most dense bone. The result is lasting foraminal height restoration, neural decompression, and sagittal balance.

X-CORE functions seamlessly with the NuVasive® tumor/trauma portfolio of products, making the implant part of a unique procedural solution for corpectomy applications. The platform includes:

- NVM5[®] nerve monitoring system
- · MaXcess[®] corpectomy optimized retractor
- XLIF[®] Corpectomy instruments
- X-CORE Expandable VBR
- Traverse® Anterior Plate system
- SpheRx[®] II Anterior system

As we aim to treat tumor/trauma patients more effectively, we need instruments and implants that allow minimal tissue disruption without compromising the primary objectives of the surgery (neural decompression, height restoration, and balance). The NuVasive X-CORE Expandable VBR, optimized for the XLIF approach and MaXcess retractor, enables a minimally disruptive approach with outstanding structural support and stability. We are confident that you will appreciate the impressive results the X-CORE device has brought our patients.

Best regards,

William D. Smith, M.D. Western Regional Center for Brain & Spine Surgery Chief of Neurosurgery at University Medical Center Las Vegas, NV USA



X-CORE° OVERVIEW

XLIF[®] – OPTIMIZED

- X-CORE[®] is the spine market's first expandable VBR designed to leverage the XLIF approach. From the inserter design to the implant's shapes and contours, every feature was developed to function seamlessly with the NuVasive[®] XLIF Corpectomy portfolio of products.
- XLIF optimized endcaps span the dense bone of the ring apophysis, providing lasting height restoration through outstanding structural support and stability.



POWERFUL DISTRACTION

• A single-step inserter delivers and distracts the implants, enabling accurate placement and anterior column height restoration.

UNIQUE IMPLANT OFFERING





- A deep and unmatched breadth of footprint and angle options designed to allow for superior fit and maximum structural support.
- The X-CORE implant is constructed intraoperatively, allowing the surgeon to custom design their implant to meet each patient's unique anatomical requirements.
- Assembly is quick, simple, and modular.

X-CORE° OVERVIEW

XLIF® CORPECTOMY. THE COMPLETE SOLUTION.

Surgeon-Driven Nerve Monitoring

 The NVM5[®] systems provide the surgeon accurate, real-time, and easy-tointerpret nerve avoidance technologies. Thoracolumbar applicable modalities include dynamic EMG, MEPs, and Free Run EMG.

MaXcess[®] Access System

• Maximum access with minimal disruption is the objective. The MaXcess retractor, enhanced with corpectomy-specialized additions, provides the solution.

XLIF Corpectomy Instruments

 The NuVasive[®] XLIF Corpectomy instruments are designed to enable reproducible corpectomies through a lateral approach.

Expandable Vertebral Body Replacement

 The X-CORE device is delivered through a minimally disruptive approach and provides first-class ease of use, distraction strength, and structural support.

Spinal Fixation

 Traverse[®] and SpheRx[®] II Anterior are designed to integrate with the MaXcess retractor and X-CORE VBR, providing a single-approach solution for placement of an implant and supplemental fixation.

Biologics

 Osteocel[®] Pro is the NuVasive cellular allograft bone matrix, providing all three essential mechanisms for bone formation – osteogenesis, osteoinduction, and osteoconduction.





X-CORE° OVERVIEW



EQUIPMENT REQUIREMENTS

- X-CORE Implant Tray (18mm)
- X-CORE Implant Tray (22mm)
- X-CORE Instruments

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

STEP 1: PERFORM CORPECTOMY

After achieving access to the target anatomy, perform the corpectomy. When taking a lateral approach to the spine, the XLIF[®] Corpectomy Surgical Technique (*Fig. 1*) may be a reference.

XLIF CORPECTOMY SURGICAL TECHNIQUE





EXPANDABLE VBR

STEP 2: CORE SELECTION

Use the Distractor to select the proper size core for implantation. After gently distracting the vertebral bodies, take a length (*Fig. 2*) reading from the proximal feature of the Distractor (*Fig. 2a*). This measurement will aid in accurate core selection.

Note

If natural endcap concavity exists, it can be effective to choose a core one size smaller than the Distractor reading indicates. This may allow for smoother implant delivery through the ipsilateral anatomy.



Note

It is also recommended to take a reading from either the ipsilateral or contralateral side of the endplate (whichever is shorter) in order to obtain the shortest height required to accommodate the X-CORE[®] implants.



CORE HEIGHT		
SIZE	RANGE WITHOUT ENDCAPS	RANGE WITH O [°] ENDCAPS (Two O [°] endcaps add 5mm)*
1	20-22mm	25-27mm
2	21-25mm	26-30mm
3	24-31mm	29-36mm
4	28-40mm	33-45mm
5	35-52mm	40-57mm
6	41-65mm	46-70mm
7	47-75mm	52-80mm
*NOTE: Different angle endcaps add varying height amounts.		

Note

In order to select appropriate core height, be sure to account for additional height added by the selected angle endcap. For example, 0° endcaps provide a total height of 5mm. Note that different angle endcaps add varying height amounts. See page 4 for reference.

STEP 3: ENDCAP SELECTION

Determine the proper size endcaps for implantation by resting the Endcap Trials adjacent to the vertebral endplates (*Fig. 3*). Confirm proper fit using A/P fluoroscopy.

Note

Trial for both the superior and inferior endcap, as the footprint requirement may be different for each.

In order to accommodate for varied vertebral body anatomy, two different length (when using $XLIF^{\circ}$ shape) or diameter (when using round) endcaps may be selected when building the X-CORE construct.





STEP 4: IMPLANT CONSTRUCTION

Place the selected core, endcaps, and two Endcap Lock Screws into the X-CORE[®] Loading Block (*Fig. 4*). Begin implant assembly by first engaging the inserter to the core while the core is still in the Loading Block (*Fig. 5*). While holding the inserter, apply downward pressure on the core's gold set screw and squeeze the trigger handle (*Fig. 6*). Continue squeezing the trigger handle until the Speed-Lock is rotated to the locked position, indicated when the Speed-Lock Nut is touching the trigger handle. Confirm proper inserter-to-core connection by expanding and compressing the implant.

CAUTION

In order to ensure proper inserter/implant engagement, the core's gold set screw must be facing up when inside the Loading Block. When you are connecting the inserter to the core, the gold side of the inserter's distal tip must face up toward the gold spinning sleeve of the implant.



CAUTION

To ensure proper anatomical alignment, the rounded corners of the XLIF[®] shape endcaps must face anterior during implant construction and placement.

Note

Gold spinning sleeve of core is loaded facing cephalad, matching up with gold indents on Loading Block.



Note

Gold face of inserter should face cephalad, matching up with gold spinning sleeve of core.

(Fig. 5)

(Fig. 6)

B. D.

STEP 4:

IMPLANT CONSTRUCTION (CONT.)

Lock the superior endcap to the core by driving an Endcap Lock Screw over the endcap and into the core until hand-tight (*Fig.* 7). Repeat the process to connect the inferior endcap.

Note

After completion of implant assembly, the core may be filled with graft material. The X-CORE Cylinder Tamp can aid in packing the core.



EXPANDABLE VBR



STEP 5: IMPLANT DELIVERY

With the implant fully compressed, guide the X-CORE[®] VBR through the MaXcess[®] retractor into the desired position (*Fig. 8*).

Note

Before you distract the implant, lateral fluoroscopy can be used to confirm proper anterior/posterior placement. The handle can also be removed for increased visibility.

Note

If the implant fits tightly between the ipsilateral endplates, the XLIF[®] Slides can be used to protect the endplates while you deliver the implant to the desired position.



(Fig. 8)

STEP 5: IMPLANT DELIVERY (CONT.)

Expand the implant by turning the inserter handle clockwise until the desired amount of distraction is achieved (*Fig. 9*). To remove the inserter, fully loosen the Speed-Lock, release grip of the trigger handle, and gently pull up until the inserter disengages the implant (*Fig. 10*).

Note

When the implant is expanded to its maximum height, further attempts to distract the implant will result in a clicking sensation without achieving additional height. If the height achieved is not adequate, compress the implant and select a taller core.





EXPANDABLE VBR

(Fig. 9)

STEP 6: FINAL POSITIONING

Confirm final placement with A/P and lateral fluoroscopy (*Figs. 11, 12*). From an anterior/posterior and medial/lateral perspective, the implant should be centered. When using the XLIF[®] shape endcaps, the endcaps should extend across the ring apophysis (*Figs. 13, 14*). Once final X-CORE[®] VBR position is confirmed, use the Set Screw Driver to lock the gold set screw. This ensures the implant maintains its achieved distraction. Once locked, the torque handle will break away.

Note

Small position adjustments can be performed using the X-CORE implant tamps. More significant repositioning may require reattaching the inserter.













(Fig. 14)

Note

Placing the core tamp onto the implant core while removing the inserter can assist in inserter removal.

STEP 7: PLACE SUPPLEMENTAL FIXATION

After delivering the X-CORE device, place supplemental fixation (*Figs. 15-18*). NuVasive[®] offers several fixation options, including Traverse[®] and SpheRx[®] II Anterior, which are both designed for lateral placement using the MaXcess[®] retractor.



(Fig. 15)



(Fig. 16)

FINAL CONSTRUCT



(Fig. 17)

EXPANDABLE VBR



REMOVAL INSTRUCTIONS

If X-CORE VBR removal is necessary, attach the inserter to the implant, compress the core by turning the handle counterclockwise, and extract the device.



X-CORE° SYSTEM

INSTRUMENTS OVERVIEW

Distractor

Provides distraction and measurement for accurate core selection.



Trials and Trial Inserter

Allow proper sizing of endcaps.



Loading Block

Loading station for simple implant construction. (Available for 18mm and 22mm)



Lock Screw Driver

Drives lock screws into core, securing the endcap to core connection. (Available for 18mm and 22mm)



X-CORE° SYSTEM

INSTRUMENTS OVERVIEW (Cont.)

Inserter and Handle

Inserts and distracts the implant.



Set Screw Driver

Advances the set screw to locked position.

Cylinder Tamp

Two-sided (18 and 22mm) tamp packs graft material before implantation.

EXPANDABL



X-CORE° SYSTEM

INSTRUMENTS OVERVIEW (Cont.)

Graft Spatula

Provides graft material manipulation in the exposure.

Graft Impactor

Enables graft impaction in the exposure.

Core Tamps

Custom fit the 18 and 22mm cores for final implant positioning.



Endcap Tamp

Safely engages the endcap for manipulation of final placement.

CATALOG

X-CORE° INSTRUMENTS

DESCRIPTION	CATALOG #
18 x 30mm Trial	6538130
18 x 40mm Trial	6538140
18 x 50mm Trial	6538150
22 x 40mm Trial	6538240
22 x 50mm Trial	6538250
22 x 60mm Trial	6538260
22mm Round Trial	6538322
26mm Round Trial	6538326
30mm Round Trial	6538330
Trial Inserter	6539060
Torque Handle	6539005
Teardrop Handle	6539006
Set Screw Driver	6539007
VBR Distractor	6539008
Cylinder Tamp	6539009
Graft Impactor	6539010
Graft Spatula	6539011
Endcap Tamp	6539013
Core Tamp 18	6539014
Core Tamp 22	6539015
XLIF® VBR Instruments Tray Lid	6539020
XLIF VBR Instruments Tray Base	6539021
XLIF VBR Instruments Tray Insert	6539022

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CATALOG

X-CORE° IMPLANT TRAY (18mm)

DESCRIPTION	CATALOG #
18mm Diameter Core, 20-22mm	6591011
18mm Diameter Core, 21-25mm	6591012
18mm Diameter Core, 24-31mm	6591013
18mm Diameter Core, 28-40mm	6591014
18mm Diameter Core, 35-52mm	6591015
18mm Diameter Core, 41-65mm	6591016
18mm Diameter Core, 47-75mm	6591017
18 x 30mm Endcap, 0°	6533131
18 x 40mm Endcap, 0°	6533141
18 x 50mm Endcap, 0°	6533151
18 x 30mm Endcap, 4°	6533231
18 x 40mm Endcap, 4º	6533241
18 x 50mm Endcap, 4°	6533251
18 x 30mm Endcap, 8°	6533331
18 x 40mm Endcap, 8°	6533341
18 x 50mm Endcap, 8°	6533351
18 x 30mm Endcap, -4°	6533431
18 x 40mm Endcap, -4°	6533441
18 x 50mm Endcap, -4°	6533451
22mm Round Endcap, 0° – 18mm Core	6537124
26mm Round Endcap, 0° – 18mm Core	6537125
22mm Round Endcap, 8º – 18mm Core	6537134
26mm Round Endcap, 8º – 18mm Core	6537135
Inserter – 18mm Core	6539118
Small Lock Screw	6539001
Small Lock Screw Driver	6539056
Teardrop Handle	6539006
18mm Lock Screw Caddy	6539040
18mm Implant Caddy	6539041
XLIF [®] VBR Loading Block – 18mm Core	6539036
XLIF VBR 18mm Implants Tray Lid	6539026
XLIF VBR 18mm Implants Tray Base	6539027
XLIF VBR 18mm Implants Tray Insert	6539028

X-CORE IMPLANT TRAY (22mm)

DESCRIPTION	CATALOG #
22mm Diameter Core, 20-22mm	6591021
22mm Diameter Core, 21-25mm	6591022
22mm Diameter Core, 24-31mm	6591023
22mm Diameter Core, 28-40mm	6591024
22mm Diameter Core, 35-52mm	6591025
22mm Diameter Core, 41-65mm	6591026
22mm Diameter Core, 47-75mm	6591027
22 x 40mm Endcap, 0°	6535241
22 x 50mm Endcap, 0°	6535251
22 x 60mm Endcap, 0°	6535261
22 x 40mm Endcap, 4°	6535341
22 x 50mm Endcap, 4°	6535351
22 x 60mm Endcap, 4°	6535361
22 x 40mm Endcap, 8°	6535441
22 x 50mm Endcap, 8°	6535451
22 x 60mm Endcap, 8º	6535461
22 x 40mm Endcap, 12°	6535541
22 x 50mm Endcap, 12°	6535551
22 x 60mm Endcap, 12°	6535561
26mm Round Endcap, 0° – 22mm Core	6537225
30mm Round Endcap, 0° – 22mm Core	6537226
26mm Round Endcap, 8º – 22mm Core	6537235
30mm Round Endcap, 8° – 22mm Core	6537236
Inserter – 22mm Core	6539122
Large Lock Screw	6539002
Large Lock Screw Driver	6539057
Teardrop Handle	6539006
22mm Lock Screw Caddy	6539046
22mm Implant Caddy	6539047
XLIF VBR Loading Block – 22mm Core	6539037
XLIF VBR 22mm Implants Tray Lid	6539030
XLIF VBR 22mm Implants Tray Base	6539031
XLIF VBR 22mm Implants Tray Insert	6539032

INSTRUCTIONS FOR USE

DESCRIPTION

The NuVasive XLIF Expandable VBR System is manufactured from Ti-6A1-4V ELI conforming to ASTM F136 and ISO 5832-3. The implants are available in a variety of sizes to accommodate anatomical conditions.

INDICATIONS FOR USE

The NuVasive XLIF Expandable VBR System is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive XLIF Expandable VBR System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

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. Reusable or multiple uses.
- 9. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS AND CAUTIONS

- The subject device is intended for use only as indicated.
- 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. These devices are
 not designed to withstand the unsupported stress of full weight or load bearing alone.
- These devices can break when subjected to the increased load associated with delayed union
 or non-union. 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.
- Care should be taken to insure that all components are ideally fixated prior to closure.
- Single 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. Resterilization may result in damage or decreased
 performance.
- In order to ensure proper inserter/implant engagement, the core's gold set screw must be facing up
 when inside the Loading Block. When you are connecting the inserter to the core, the gold side of
 the inserter's distal tip must face up toward the gold spinning sleeve of the implant.
- To ensure proper anatomical alignment, the rounded corners of the XLIF shape endcaps must face anterior during implant construction and placement.

PREOPERATIVE 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 implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
- Unless stated otherwise, the device is not to be combined with the components of another system.
 All parts should be cleaned and sterilized before use.



NOTES

NOTES



X-CORE EXPANDABLE VBR





To order, please contact your NuVasive[®] Sales Consultant or Customer Service Representative today at: **NuVasive, Inc.** 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134 **NuVasive UK Ltd.** Suite B, Ground Floor, Caspian House, The Waterfront, Elstree, Herts WD6 3BS UK phone: +44 (0) 208-238-7850 fax: +44 (0) 207-998-7818

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