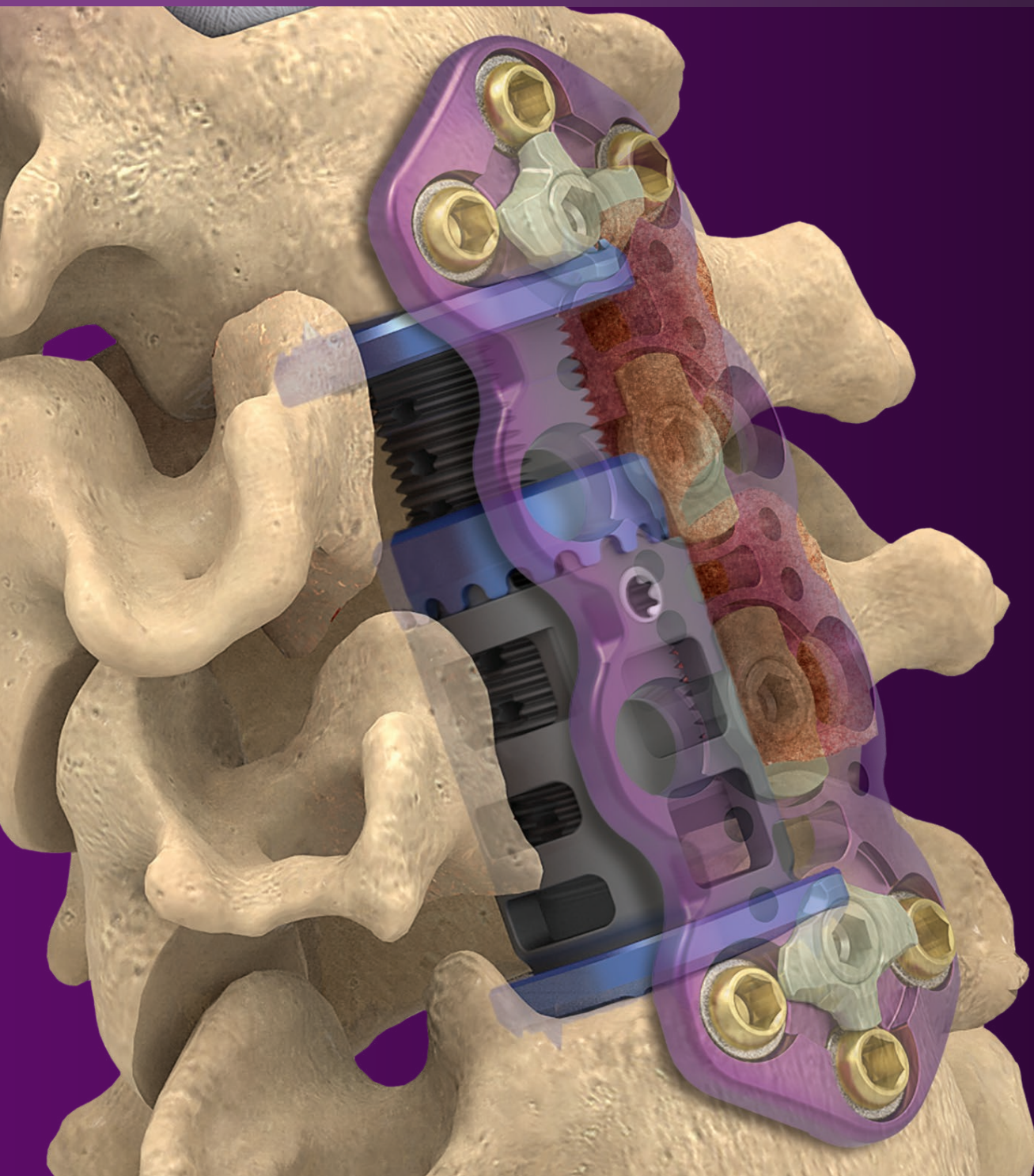
NuVasive®
Speed of Innovation®

X-CORE® MINI

Technique Guide



MICHELSON TECHNOLOGY AT WORK

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PREFACE

Fellow Colleagues,

Our charge when creating an expandable cage was three-fold. First, it had to be modular so that the implant matched the individual patient's anatomy in terms of core diameter, endplate size, and expansion heights, rather than being limited to a single option. Second, it had to be easy to expand and lock to maximize surgeon ease. Third, it had to be versatile, providing the surgeon with the same ease of insertion and expansion regardless of whether an anterior, anterolateral, or posterior approach was chosen. We feel X-CORE® Mini VBR accomplishes all three challenges.

We believe what makes this expandable cage both unique and the top of its class is the modular approach to endplate sizing. To maximize endplate coverage, surgeons have the option of traditional round endcaps or rectangular endcaps, in different sizes, convex or non-convex. For a posterior, costotransversectomy approach, the rectangular endcaps are angled to allow the same endplate coverage while maintaining the orientation of the core (with its expansion and locking mechanisms) in line with the surgical approach. No longer does the surgeon need to sacrifice endplate coverage.

In keeping with the NuVasive® philosophy of maximizing exposure access and minimizing patient risk, all instruments and implants were designed with individual patient anatomy and surgeon convenience in mind.

All the best,



Greg M. Mundis, M.D.
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San Diego Center for Spinal Disorders
San Diego, California USA



Joseph R. O'Brien, M.D.
Orthopaedic Spine Surgeon
Associate Director of Spine Surgery &
Assistant Professor at the George
Washington University School of Medicine
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Neill M. Wright, M.D.
Neurological Surgeon
H. Lourie Professor of Neurological Surgery
Washington University School of Medicine
St. Louis, Missouri USA

X-CORE® MINI VBR SYSTEM OVERVIEW

CERVICAL CORPECTOMY SOLUTION

X-CORE Mini VBR is a fully modular cervical corpectomy system with multiple core diameters, endcap shapes and footprints that allows the surgeon to customize the device to each patient's specific anatomical requirements. The low-profile instrumentation allows for predictable and controlled expansion *in situ,* proper height restoration, and sagittal correction following a corpectomy procedure. The system is designed to provide neural decompression and allow for fusion through its generous central aperture.

In addition, NuVasive® offers an innovative anterior cervical reconstruction system differentiated from all other systems currently on the market. Multi-level cervical reconstruction corpectomy procedures can have up to a 71% incidence of failure and often require additional posterior fixation.[1] With the Archon® Reconstruction system, additional posterior fixation not required for one and two level procedures, as determined by the surgeon. The Archon Reconstruction plate is indicated for use only in patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.

X-CORE MINI VBR

Modular Endcap Options

- Available in multiple shapes and footprints, customizable to patient's anatomy.

Robust Expanding Core

- Double lead threads for quicker expansion



Simple Insertion/ Expansion

- Robust spinning sleeve
- Low-profile Inserter

Large Central Aperture

- Central core aperture allows for large fusion column
- Large anterior graft window allows for additional packing *in situ*
- Available in 12 and 14mm cores

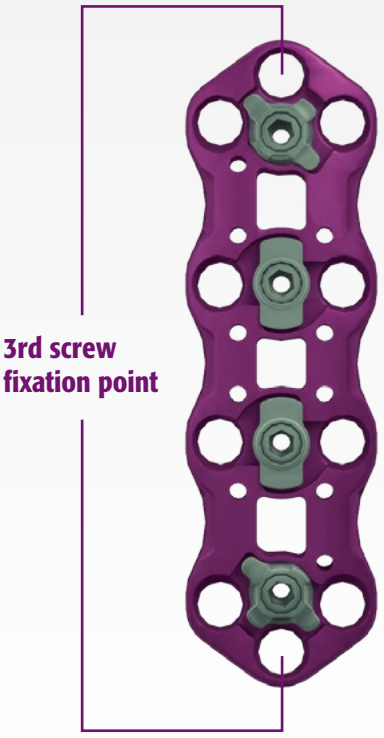
[1]*Sasso RC, Ruggiero RA Jr, Reilly TM, et al. Early reconstruction failures after multilevel cervical corpectomy. Spine 2003;28(2):140-142.*

ARCHON® RECONSTRUCTION ACP SYSTEM

Additional Fixation

Designed to:

- Provide a 3rd screw fixation point at cranial/caudal ends of construct
- Resist screw pullout
- Increase rigidity of overall construct



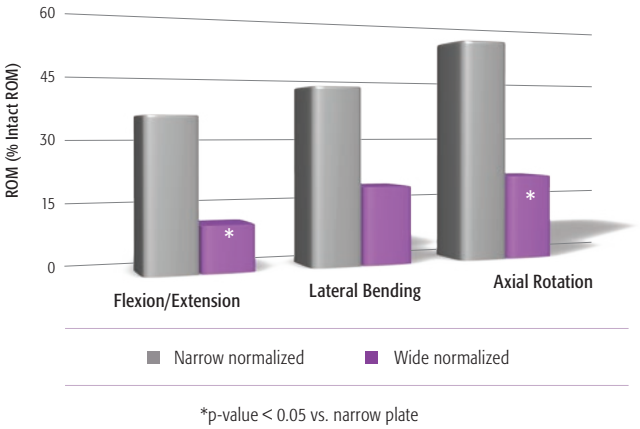
Optimized Plate Width and Geometry

Designed to:

- Provide for large bone wedge to reduce pullout (13mm between fixation points)
- Increase rigidity of overall construct
- Remain no wider than currently marketed plates (20mm)

BIOMECHANICAL TESTING RESULTS

In a two-level corpectomy construct following 1,000 cycles of flexion/extension, the Archon Reconstruction plate, paired with the X-CORE® Mini VBR system, had increased rigidity when compared to a narrow plate, with a reduction in motion of 70% in flexion/extension (p-value < 0.05), 59% in lateral bending, and 68% in axial rotation (p-value < 0.05).[1]



[1]*Sawin PD, Schwartz D, Baldwin NG, et al. Biomechanical investigation of anterior-only reconstruction of the cervical spine. ISASS 14th Annual Conference. April 30 - May 2, 2014. Miami, FL, USA.*

X-CORE® MINI VBR ENDCAP OVERVIEW

X-CORE MINI VBR ENDCAP OVERVIEW

The size, shape and strength of the vertebral bodies and endplates are dependent on many factors such as age, gender, race, pathology and personal health. X-CORE Mini VBR was designed to provide surgeons with the ability to intraoperatively adapt to and provide solutions for these variations in patient anatomy. Multiple cores and endplates are included as part of the X-CORE Mini VBR system.

12mm Core Aperture



14mm Core Aperture





ENDCAP SHAPE OPTIONS

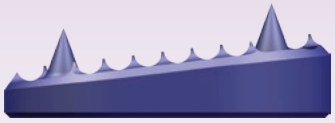
Parallel



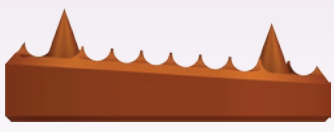
Contoured



Lordotic 7°



Kyphotic 4°



Angled 30°



ENDCAP FOOTPRINT OPTIONS

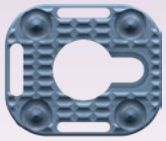
Oval 15x12mm



Oval 17x14mm



Oval 19x16mm



Round 14mm



Round 16mm



EQUIPMENT REQUIREMENTS

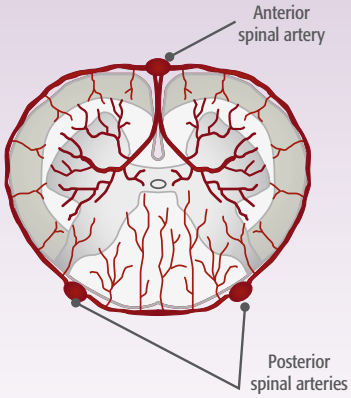
- X-CORE Mini VBR Instruments
- X-CORE Mini VBR Implants

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.

PROCEDURAL VALUE OF NEUROMONITORING WITH NVM5®

- Real-time feedback communicated directly to the surgeon if nerve roots are impinged.
- Intraoperative monitoring of spinal cord integrity.

VASCULAR CONCERNS



- MEPs and SSEPs can facilitate intraoperative notification if the anterior spinal artery or posterior spinal arteries are obstructed.

NERVE ROOT MONITORING

FREE RUN EMG



CORD MONITORING

MOTOR EVOKED POTENTIALS (MEP)



SOMATOSENSORY EVOKED POTENTIALS (SSEP)



X-CORE® MINI VBR TECHNIQUE GUIDE

Note

Refer to the thoracic corpectomy steps within this technique guide when performing a cervical corpectomy procedure as they are identical in nature to the thoracic corpectomy procedure demonstrated here.

STEP 1:
CORPECTOMY

After achieving access to the target anatomy, perform an anterior corpectomy at the appropriate spinal level(s) following a standard technique *(Fig. 1)*.

Avoid breaching the subchondral bone during preparation of the vertebral endplates to reduce the potential for implant subsidence and vertebral body fracture.

Alternatively, for a posterior thoracic approach, perform a costotransversectomy to reach the anterior spinal column and resect the vertebral bodies of choice *(Fig. 2)*.

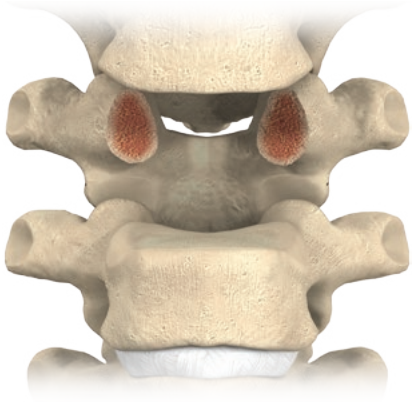
Note

All following steps (sizing, assembly, insertion and assembly) are illustrated using an anterior approach, but are identical for the posterior thoracic approach.

MOTOR EVOKED POTENTIALS (MEP)



Confirm spinal cord integrity using MEPs after completing the corpectomy.

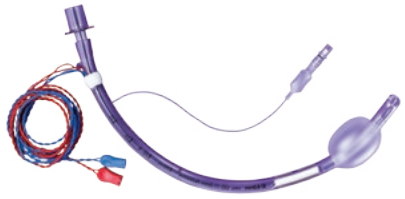


(Fig. 1)



(Fig. 2)

RECURRENT LARYNGEAL NERVE



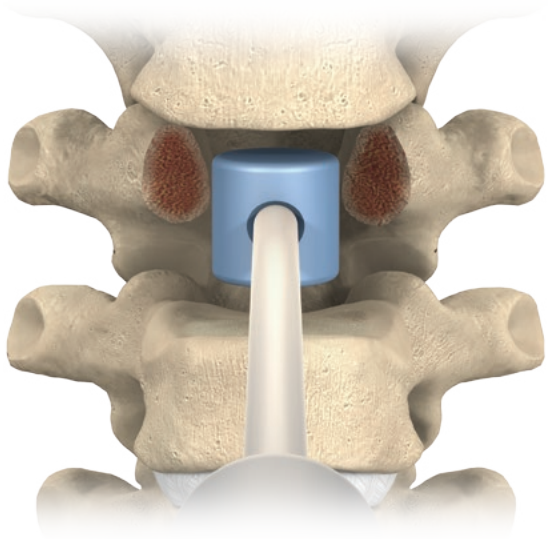
- *The NVM5® EMG ET Tube monitors for Free Run EMG responses from the recurrent laryngeal nerve (RLN).*
- *Visualization of real-time responses from the RLN allows the surgeon to respond to RLN irritation intraoperatively.*

STEP 2:
CORE SIZING

First, place the Core Sizer into the prepared space to determine which core diameter best fits the patient anatomy. Cores are available in 12mm and 14mm diameters *(Fig. 3)*.

Second, place the Caliper into the prepared space to determine the optimal core height. Based on the construct type (parallel, lordotic or hybrid), read the grid on the Caliper to define the proper height *(Fig. 4)*.

Third, confirm that the selected height of the device will be consistent with the spinal segment height estimated during preoperative planning to reduce the risk of potential spinal cord and nerve root injuries that may be caused by over-distraction.



(Fig. 3)



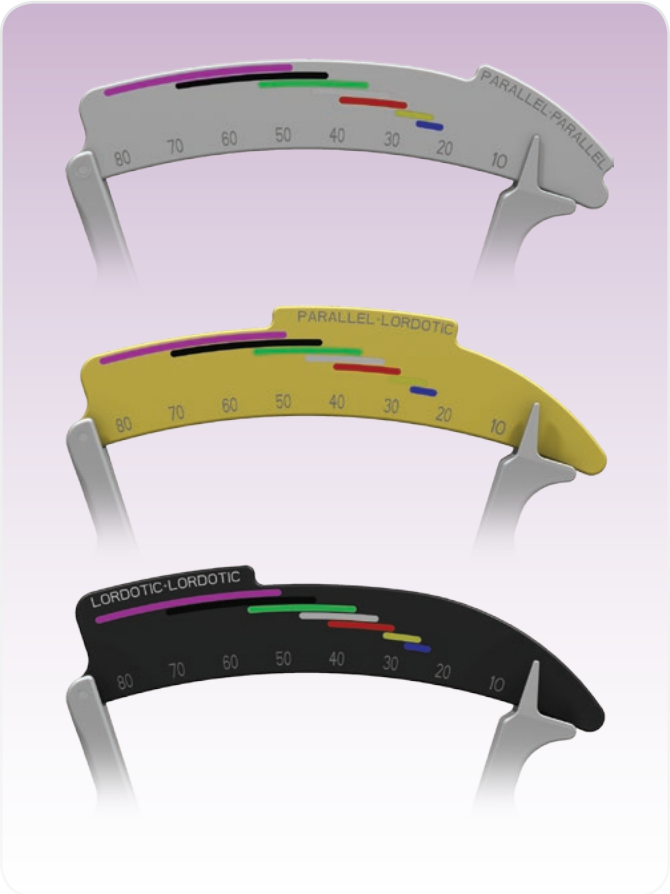
(Fig. 4)

HOW TO READ THE CALIPER MEASUREMENTS

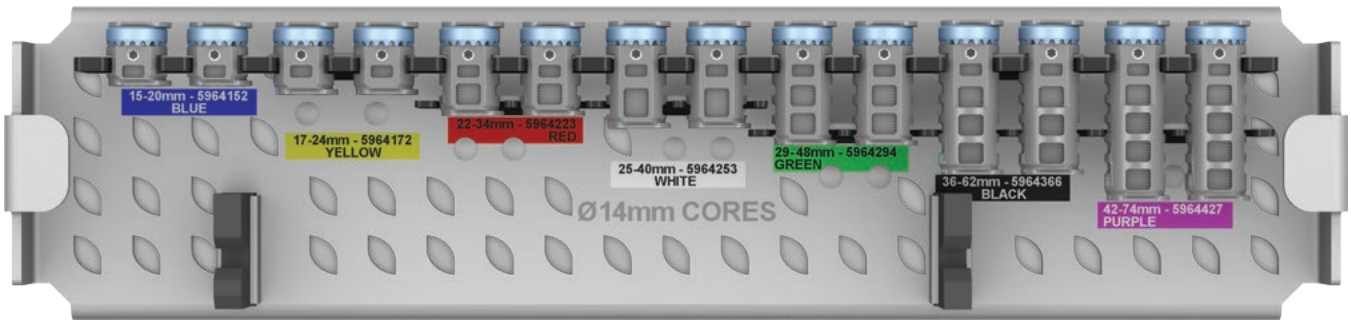
The colored bars on the Caliper will direct the selection of the proper core (e.g., red for 22-34mm cores) *(Fig. 5)*. Based on the determined core diameter and height, now select the appropriate core *(Fig. 6)*.

> ***Tip***
>
> *The Caliper already accounts for the height of the endcaps and spikes that will be added to the core to make up the final construct height. No additional calculation is necessary.*

> ***Tip***
>
> *Parallel endcaps add 1.5mm to the height of the core; contoured, lordotic and kyphotic endcaps add 2.5mm. The endcap spikes add 2mm.*



(Fig. 5)

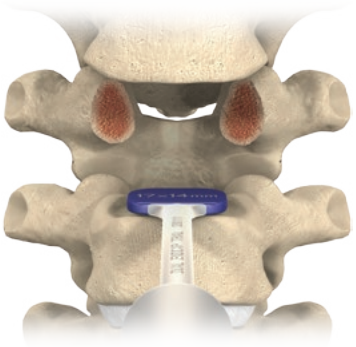


(Fig. 6)

STEP 3:
ENDPLATE SIZING

Place the Endplate Sizer into the prepared space to determine which endcap footprint fits best *(Fig. 7)*. This must be repeated for both the superior and inferior endplates. Endcaps are available in oval footprints (15x12mm, 17x14mm, and 19x16mm), round footprints (14mm and 16mm diameters), and several shapes (parallel, contoured, lordotic, and kyphotic). Angled endcaps are also available for a posterior thoracic approach via a costotransversectomy.

During the templating and endcap sizing, select the endcap options that provide maximum endplate coverage to reduce the potential for implant subsidence.



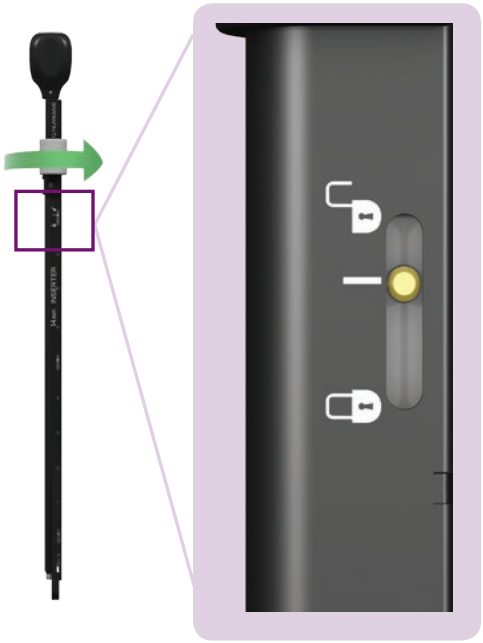
(Fig. 7)

STEP 4:
CONSTRUCT ASSEMBLY

First, load the core onto the Inserter. Prior to engaging the core, turn the knurled knob on the Inserter all the way counterclockwise to ensure it is fully unlocked. Grasp the core with the Inserter so that the expansion barrel driver mates with the colored spinning wheel. Turn the silver knurled knob clockwise to fully lock the core onto the Inserter *(Fig. 8)*.

> ***Tip***
> *Tighten the Inserter to the core using a two finger grip. Overtightening is unnecessary. Once indicator pin passes the vertical line, the inserter is locked as soon as resistance is felt.*

> ***Tip***
> *The colored spinning wheel indicates the top of the core. There is a lasermark on the top of the core that says "T", and a mark on the bottom that says "B".*

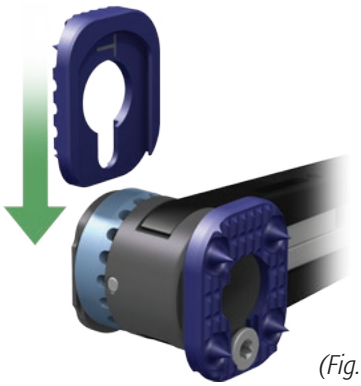


(Fig. 8)

X-CORE® MINI VBR TECHNIQUE GUIDE

STEP 4:
CONSTRUCT ASSEMBLY CONT.

Next, slide the endcaps onto the core. The lasermarked arrow on the anterior portion of the endcap indicates the direction it should slide onto the core. Use hands or loading blocks to hold the endcaps while sliding them onto the core. Ensure top ("T") and bottom ("B") endcaps are placed appropriately *(Fig. 9)*. Place and final tighten endcap set screws using the Final Tightening Handle to lock endcaps to the core *(Fig. 10)*.

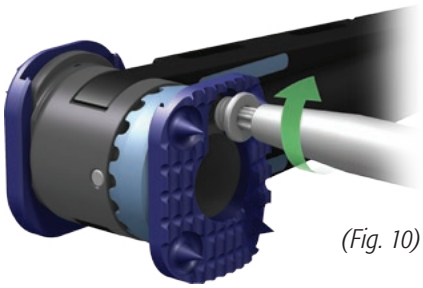


(Fig. 9)

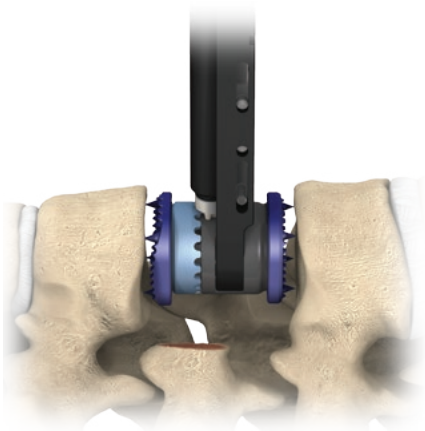
STEP 5:
INSERT THE CONSTRUCT

Insert the assembled construct into the prepared space *(Fig. 11)*.

> ***Tip***
> *Core can be placed right side up or upside down.*



(Fig. 10)



(Fig. 11)

STEP 6:
EXPAND THE CONSTRUCT

Expand the construct by turning the black knob on the Inserter until the desired height is reached. A positive stop will be felt when the core is fully expanded *(Fig. 12)*.

When expanding the X-CORE Mini Cervical VBR, use radiographic confirmation and intraoperative neuromonitoring to reduce the risk of potential spinal cord and nerve root injuries that may be caused by over-distraction. Confirm that the height of the restored spinal segment on intraoperative radiographs is consistent with preoperative planning.

WARNING:
Careful preoperative planning, intraoperative sizing, radiographic confirmation of proper spinal segment height restoration, and intraoperative neuromonitoring are critical in avoiding spinal cord and nerve root injuries that may be caused by over-distraction. Do not over-distract the spinal segment.

Tip

One (1) full rotation of the black knob = 0.5mm of expansion. Ten (10) rotations = 5mm of expansion.

Tip

If expanding the core, expand close to final height prior to graft packing. This simplifies the final packing in situ and allows for maximum graft material can be loaded into the core.

Tip

Take a final x-ray with the Inserter still attached to the core so adjustments can be made. This is easier to accomplish than reattaching the Inserter.



(Fig. 12)

FREE RUN EMG



Real-time notification of nerve root impingement while inserting and expanding the construct.

X-CORE® MINI VBR TECHNIQUE GUIDE

STEP: 7
RELEASE THE INSERTER

Once the desired expansion is reached, turn the silver knurled knob counterclockwise to release it from the core. Then pull the Inserter straight off *(Fig. 13)*.

STEP 8:
FINAL TIGHTENING

To confirm the construct is locked, engage the Core Set Screw with the Screw Driver with breakaway Final Tightening Handle. Turn the Core Set Screw clockwise until the Final Tightening Handle torques off (10 in/lbs). Once the Final Tightening Handle clicks, the Core Set Screw is locked *(Fig. 14)*.

> ***Tip***
> *One click of the breakaway Final Tightening Handle confirms the lock screw is final tightened.*

MOTOR EVOKED POTENTIALS (MEP)



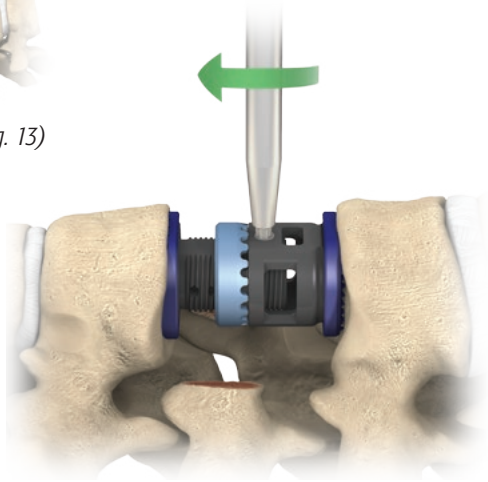
Confirm spinal cord integrity intraoperatively using MEPs after completing the construct.

SUPPLEMENTAL FIXATION

Place supplemental fixation at the necessary levels to reduce the risk of implant subsidence and vertebral body fracture as well as the potential for implant migration. See the supplemental fixation system package insert and surgical technique for instructions.

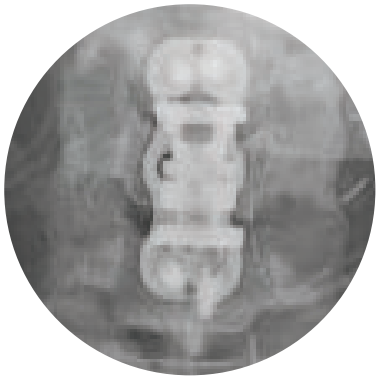


(Fig. 13)

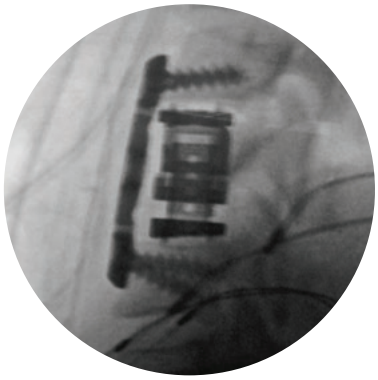


(Fig. 14)

FINAL CONSTRUCT X-RAYS



Final Construct: A/P View



Final Construct: Lateral View

CONSTRUCT REMOVAL

STEP 1. LOOSEN THE CORE SET SCREW

Reengage the set screw using the Set Screw Driver and turn the set screw ½ turn counterclockwise *(Fig. 15)*.

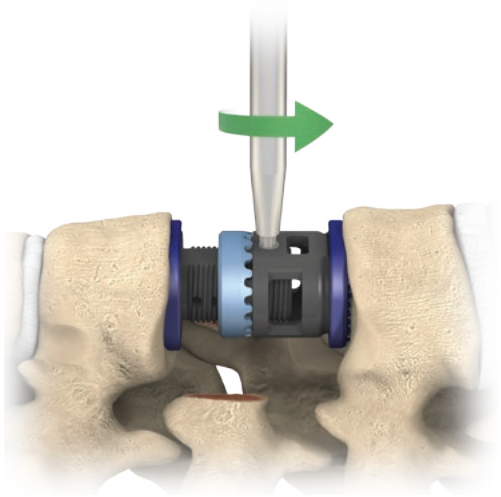
> ***Tip***
>
> *Only a ½ turn is required to release the set screw. If backed out too far, the set screw can block the Inserter from properly reengaging the core.*

STEP 2. RETRACT THE CORE

Prior to engaging the core, turn the knurled knob on the Inserter all the way counterclockwise to ensure it is fully unlocked. Grasp the core with the Inserter so that the expansion barrel driver mates with the colored spinning wheel. Turn the silver knurled knob clockwise to fully lock the core onto the Inserter. Retract the core by rotating the black handle counterclockwise until fully collapsed *(Fig. 16)*.

STEP 3. REMOVE THE CORE

Carefully remove the core and unload on the back table.



(Fig. 15)

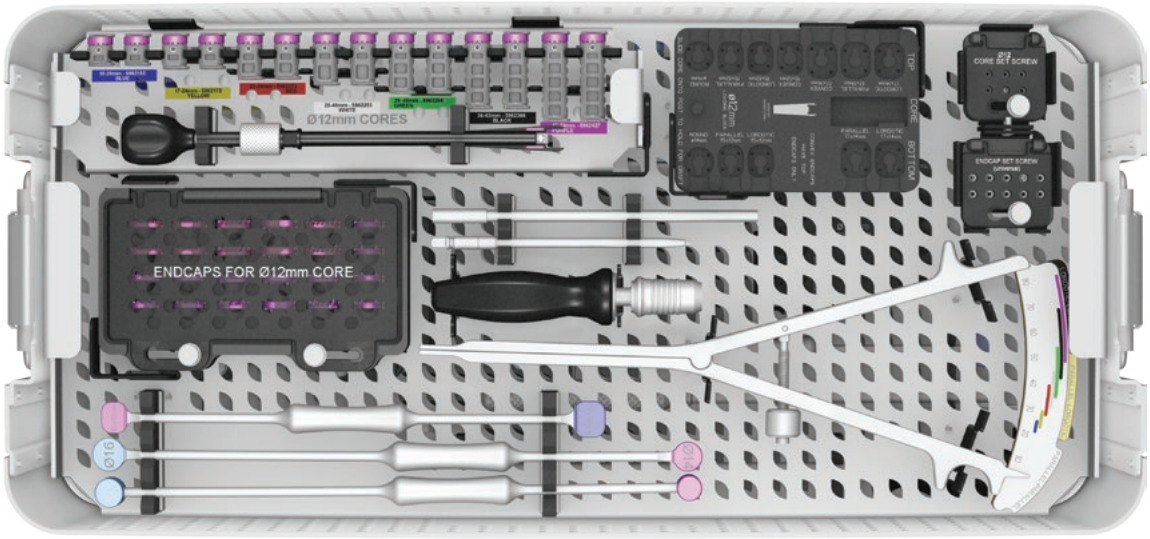


(Fig. 16)

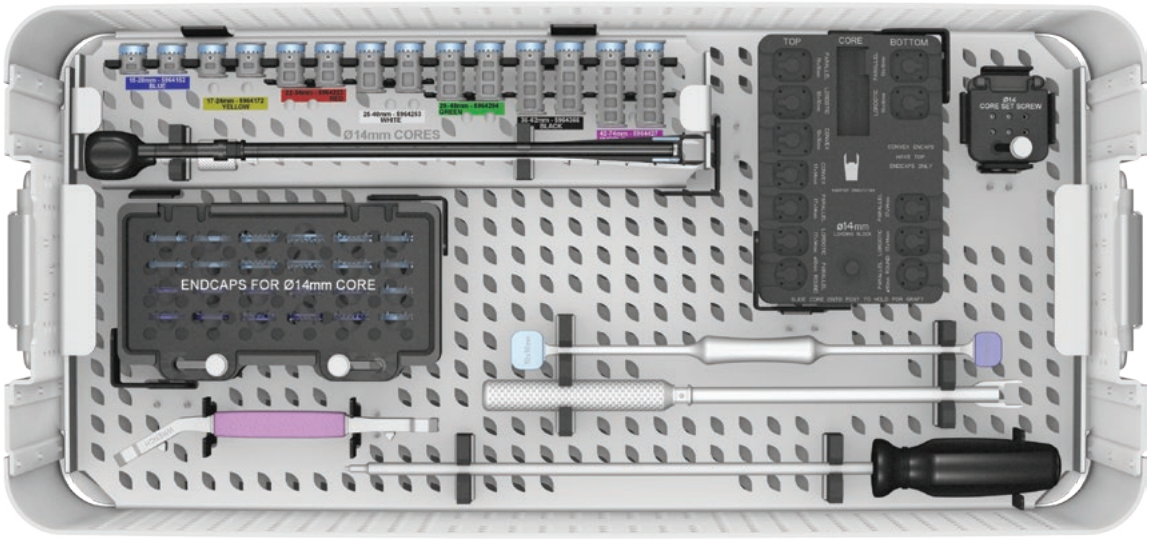
X-CORE® MINI VBR SYSTEM

X-CORE MINI INSTRUMENTS

TOP TRAY

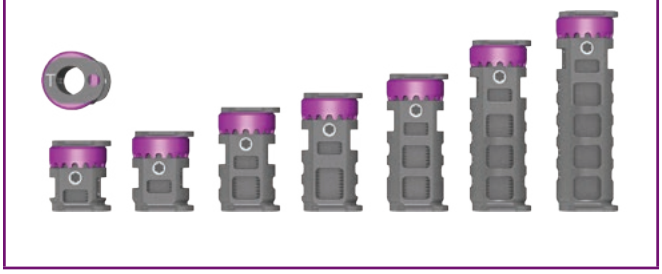


BOTTOM TRAY

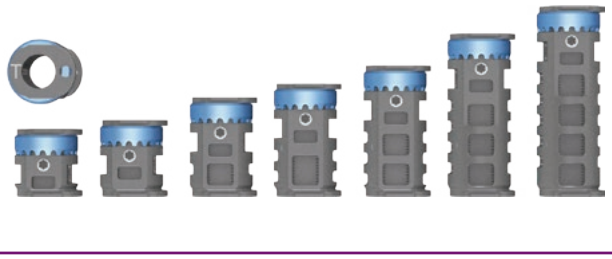


X-CORE MINI INSTRUMENTS

Ø12mm CORES



Ø14mm CORES



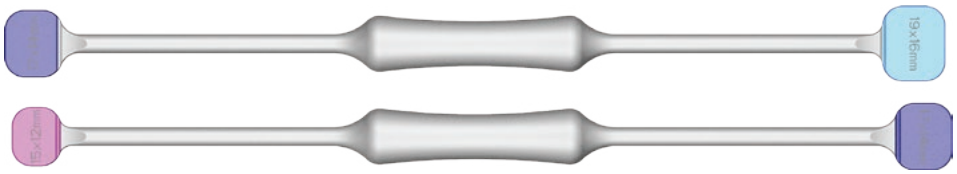
SHAPES		FOOTPRINTS						
		Oval Straight			Oval Angled 30°		Round	
								
	Core Ø	15x12mm	17x14mm	19x16mm	17x14mm	19x16mm	14mm	16mm
Parallel 	(Ø 12)	5962520	5962740				5960200	
	(Ø 14)		5964740	5964960	5963740 (T) 5963745 (B)	5963960 (T) 5963965 (B)		5960400
Contoured 	(Ø 12)	5962521 (T)	5962741 (T)					
	(Ø 14)		5962741 (T)	5964961 (T)				
Lordotic 	(Ø 12)	5962527 (T) 5962526 (B)	5962747 (T) 5962746 (B)					
	(Ø 14)		5964747 (T) 5964746 (B)	5964967 (T) 5964966 (B)				
Kyphotic 	(Ø 14)				5963747 (T) 5963746 (B)	5963967 (T) 5963966 (B)		

ENDCAPS

X-CORE® MINI VBR SYSTEM

X-CORE MINI INSTRUMENTS

ENDCAP SIZERS (5960007, 5960010)



CORE SIZERS (5960001, 5960006)



INSERTERS (Ø12mm 5961200, Ø14mm 5961400)



FINAL TIGHTENING SHAFT (5962007)



FINAL TIGHTENING HANDLE (5950008)

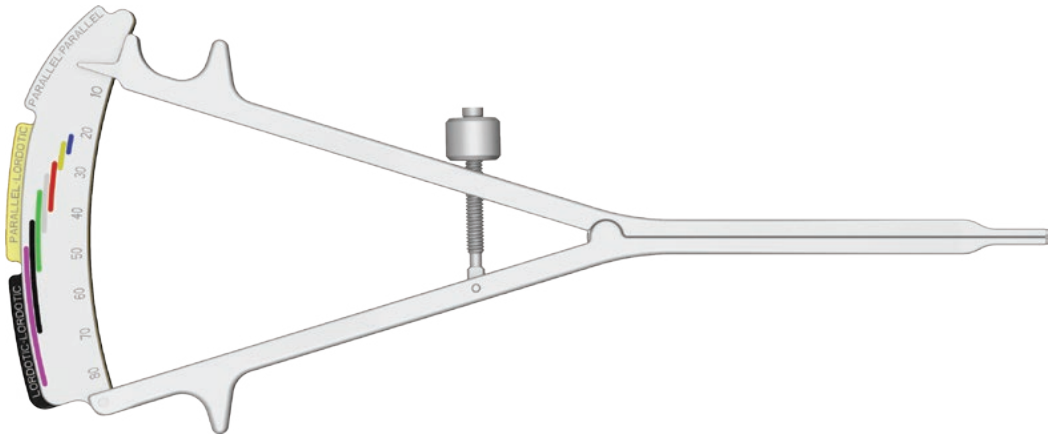


Ø14mm COUNTER TORQUE (5960015)



X-CORE MINI INSTRUMENTS

CALIPER (5960004)



FINAL TIGHTENING DRIVER (7110002)



INSERTER COUNTER TORQUE (6790153)



GRAFT LOADING TOOL (5960009)



CATALOG

DESCRIPTION	CATALOG#
Final Tightening Driver	5950008
Core Sizer, Ø14-Ø16 mm	5960001
Caliper	5960004
Core Sizer, Ø12-Ø14 mm	5960006
Endcap Sizer, 15x12mm-17x14mm	5960007
Graft Loading Tool	5960009
Endcap Sizer, 17x14mm-19x16mm	5960010
Endcap Set Screw	5960011
Loading Block, Ø12mm	5960012
Loading Block, Ø14mm	5960014
Counter Torque, Ø14mm	5960015
Core Set Screw, Ø12mm	5960033
Core Set Screw, Ø14mm	5960034
Endcap, Ø14mm Core, Round Ø12mm	5960200
Endcap, Ø16mm Core, Round Ø14mm	5960400
Base	5961001
Tray, Top	5961002
Tray, Middle	5961003
Tray, Bottom	5961004
Lid	5961005
Caddy, Core Set Screw, Ø12mm	5961022
Caddy, Endcap Set Screw	5961023
Caddy, Core Set Screw, Ø14mm	5961024
Lid, Caddy, Core Set Screw, Ø12mm	5961122
Lid, Caddy, Endcap Set Screw	5961123
Lid, Caddy, Core Set Screw, Ø14mm	5961124
Inserter, Ø12mm	5961200
Inserter, Ø14mm	5961400
Tray, Ø12mm Core	5962000
Caddy, Ø12mm Endcap	5962001
Final Tightening Shaft	5962007
Lid, Caddy, Ø12mm Endcap	5962101
Core, Ø12mm, 15-20mm	5962152
Core, Ø12mm, 17-24mm	5962172
Core, Ø12mm, 22-34mm	5962223
Core, Ø12mm, 25-40mm	5962253
Core, Ø12mm, 29-48mm	5962294
Core, Ø12mm, 36-62mm	5962366
Core, Ø12mm, 42-74mm	5962427

DESCRIPTION	CATALOG#
Endcap, Ø12mm Core, Parallel, 15x12mm	5962520
Endcap, Ø12mm Core, Contoured, Top, 15x12mm	5962521
Endcap, Ø12mm Core, Lordotic, Bottom, 15x12mm	5962526
Endcap, Ø12mm Core, Lordotic, Top, 15x12mm	5962527
Endcap, Ø12mm Core, Parallel, 17x14mm	5962740
Endcap, Ø12mm Core, Contoured, Top, 17x14mm	5962741
Endcap, Ø12mm Core, Lordotic, Bottom, 17x14mm	5962746
Endcap, Ø12mm Core, Lordotic, Top, 17x14mm	5962747
Loading Block, Angled Endcap	5963000
Caddy, Angled Endcap, Ø14mm	5963001
Lid, Caddy, Ø14mm Angled Endcap	5963101
Endcap, Ø14mm Core, Angled, Parallel, Top, 17x14mm	5963740
Endcap, Ø14mm Core, Angled, Parallel, Bottom, 17x14mm	5963745
Endcap, Ø14mm Core, Angled, Kyphotic, Bottom, 17x14mm	5963746
Endcap, Ø14mm Core, Angled, Kyphotic, Top, 17x14mm	5963747
Endcap, Ø14mm Core, Angled, Parallel, Top, 19x16mm	5963960
Endcap, Ø14mm Core, Angled, Parallel, Bottom, 19x16mm	5963965
Endcap, Ø14mm Core, Angled, Kyphotic, Bottom, 19x16mm	5963966
Endcap, Ø14mm Core, Angled, Kyphotic, Top, 19x16mm	5963967
Tray, Ø14mm Core	5964000
Caddy, Ø14mm Endcap	5964001
Lid, Caddy, Ø14mm Endcap	5964101
Core, Ø14mm, 15-20mm	5964152
Core, Ø14mm, 17-24mm	5964172
Core, Ø14mm, 22-34mm	5964223
Core, Ø14mm, 25-40mm	5964253
Core, Ø14mm, 29-48mm	5964294
Core, Ø14mm, 36-62mm	5964366
Core, Ø14mm, 42-74mm	5964427
Endcap, Ø14 Core, Parallel, 17x14mm	5964740

CATALOG

DESCRIPTION	CATALOG#
Endcap, Ø14 Core, Contoured, Top, 17x14mm	5964741
Endcap, Ø14 Core, Lordotic, Bottom, 17x14mm	5964746
Endcap, Ø14 Core, Lordotic, Top, 17x14mm	5964747
Endcap, Ø14 Core, Parallel, 19x16mm	5964960
Endcap, Ø14 Core, Lordotic, Bottom, 19x16mm	5964966
Endcap, Ø14 Core, Lordotic, Top, 19x16mm	5964967
Inserter Counter Torque	6790153
Final Tightening Driver	7110002
X-CORE® IFU	9400903

INSTRUCTIONS FOR USE

DESCRIPTION

The *NuVasive® X-CORE® Expandable VBR System* is manufactured from Ti6Al-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 X-Core Mini Cervical Expandable VBR System* is a vertebral body replacement device indicated for use in the cervical spine in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The *NuVasive X-Core Mini Cervical Expandable VBR System* is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The *NuVasive X-Core Mini Cervical Expandable VBR System* is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft 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.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; dysphagia; dysphonia; dural tear or CSF leak; esophageal injury; worsened neurologic status; vertebral artery injury; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Implant subsidence
- Neurological, vascular or visceral injury
- Spinal cord or nerve root injury (particularly C5) due to over-distraction
- Nerve damage due to surgical trauma
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS AND CAUTIONS

The subject device is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons 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.

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. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Based on fatigue testing results, when using the *X-CORE® Mini Cervical Expandable VBR System*, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Careful preoperative planning, intraoperative sizing, radiographic confirmation of proper spinal segment height restoration, and intraoperative neuromonitoring are critical in avoiding spinal cord and nerve root injuries that may be caused by over-distraction. Do not over-distract the spinal segment.

Careful preoperative planning and intraoperative sizing to maximize endplate coverage are important in helping avoid implant subsidence.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or nonunion. 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 (e.g., titanium and stainless steel) 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.

When used in the cervical spine at one or two levels, the NuVasive X-Core Mini Cervical Expandable VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

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.

Magnetic Resonance (MR) Safety: The *X-CORE Mini Cervical Expandable VBR System* has not been evaluated for safety and compatibility in the MR environment. The *X-CORE Mini Cervical Expandable VBR System* has not been tested for heating or migration in the MR environment.

Compatibility: Do not use *X-CORE Mini Cervical Expandable VBR System* with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.

In order to ensure proper inserter/implant engagement, the inserter's colored distal tip must face up toward the like-colored 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.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Inspect all components for damage before use.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

It is important to instruct the patient in appropriate postoperative activity restrictions to minimize the risk of potential vertebral body fracture and implant migration.



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