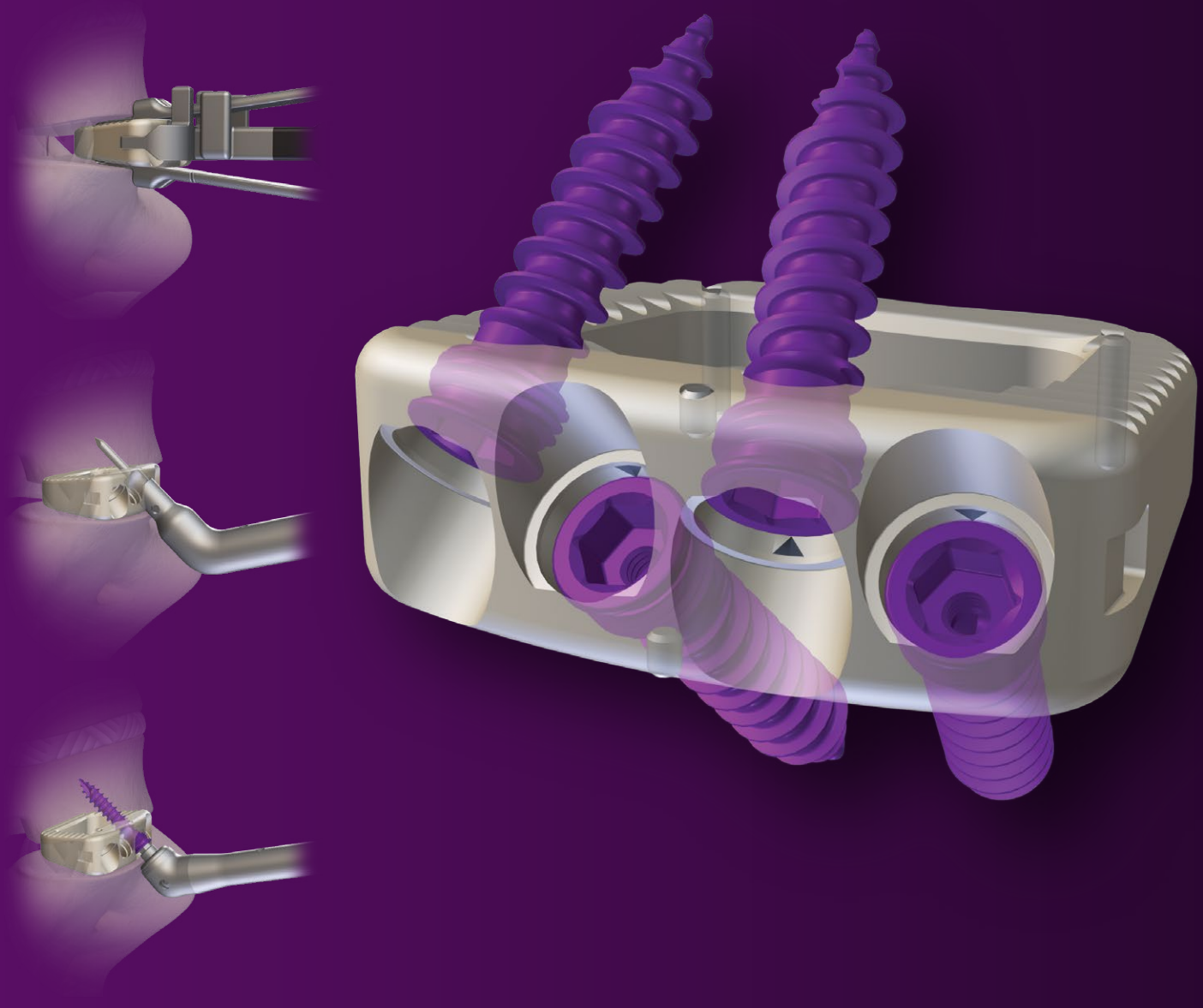
NuVasive®
Speed of Innovation®

BRIGADE®
STANDALONE ALIF

Surgical Technique



CONTENTS

PREFACE

Fellow Colleagues:

It is our pleasure to introduce you to the Brigade® Standalone ALIF system, a comprehensive interbody device with integrated screws, designed for anterior lumbar fusion and support through a single approach.

Leveraging thoughtful design principles crucial to successful anterior lumbar fusion, we have designed each instrument and implant to help enhance safety, stability, and efficiency. In our experience, Brigade has shortened procedure times, even while driving greater confidence in access safety and subsequent fusion.

The innovative design of the Brigade system provides a number of clinical benefits, including:

- The ability to place four screws for maximum rigidity in even the most difficult access situations
- A vascular conscious implant with no profile extending beyond the anterior border of the vertebral body
- An easy-to-confirm, single-step, screw-to-implant locking mechanism that easily creates a rigid and stable construct
- Low-profile, self-centering instruments with sheathed moving parts
- Unique and outstanding array of angled instruments
- An innovative awl/depth gauge allowing for proper determination of screw length in 2.5mm increments

Our design and clinical evaluation experience has confirmed the ability of the Brigade system to provide an effective solution to single-approach ALIFs. We are confident that you will see the same results in your practice and will be pleased with the benefits that the Brigade system will provide to your patients.

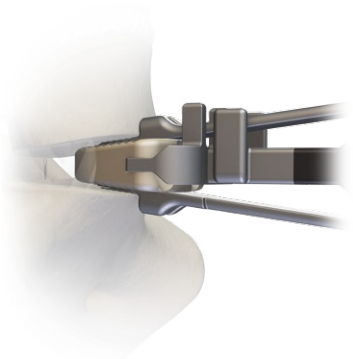
Cordially,

Frank M. Phillips, M.D.
Midwest Orthopaedics at Rush
Chicago, IL
USA

Martin B. Kornblum, M.D.
Mendelson Kornblum Orthopedic & Spine Surgeons
Warren, MI
USA

COMPLETE ALIF SOLUTION

ACCESS



ENVOY™

ALIF EnVoy™ – Implant Delivery System

- Simultaneous distraction and delivery
- Smooth, singular motion for efficient disc space distraction and implant delivery
- Slim, sleek design for optimal visualization

BIOLOGICS

OSTEOCEL®
Osteoconductive • Osteoinductive • Osteogenic TECHNOLOGY

Osteocel® – Allograft Cellular Bone Matrix*

Osteocel is cancellous bone that is rich in viable cells, combined with demineralized bone matrix from the same donor, and cryogenically preserved to ensure cell viability is maintained. The cells retained are a native population of bone-forming cells that are adherent to the surface of the cancellous bone and consist of mesenchymal stem cells (MSCs) and other cells further along the osteogenic lineage.

- Complete – osteogenic, osteoinductive, osteoconductive
- Physiologic – mimics biologic profile of autograft
- Consistent – each lot tested for cell count, viability, and activity
- Experienced – 150,000+ patients treated since 2005

**Only cleared for use with Brigade as a partial VBR.*

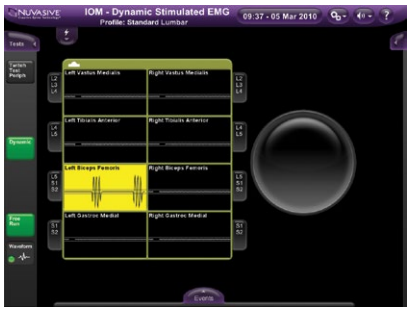
FORMAGRAFT®
Collagen Bone Graft Matrix

FormaGraft® – Collagen Bone Graft Matrix*

- Controlled degradation rate
- Absorbent collagen network
- Convenient shapes and sizes

**Only cleared for use with posterolateral fusion when applying posterior fixation.*

NVM5®



NVM5

NVM5 – Free Run EMG

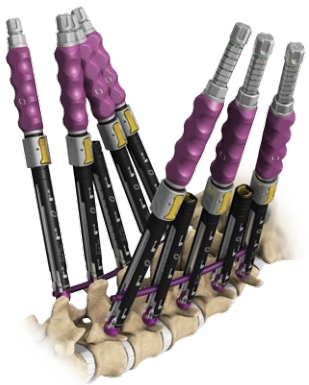
- Continuous monitoring throughout the ALIF procedure to provide immediate notice of potential neurological disturbances
- Audible and visual response with indication of spinal level

FIXATION*

AFFIX II

Affix® II – Spinous Process Plate

- Integrated Canted Coil Locking Mechanism – eliminates secondary locking step
- Improved Fixation – contains 36 fixation teeth to maximize pull-out strength and fixation for fusion



PRECEPT

Precept® - Practical, Elegant MAS® Fixation

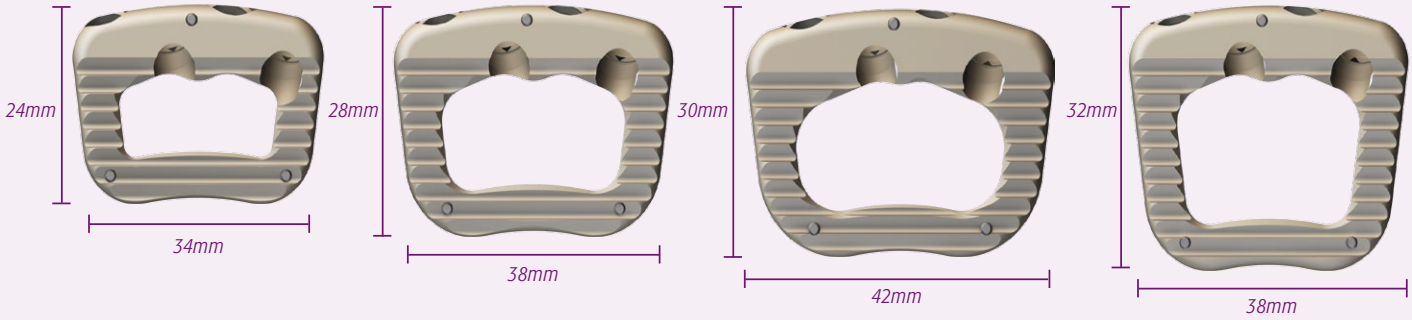
- Market Differentiating Implant Design
- Advanced Guide Technology
- Refined Rod Passage
- Elegant Reduction Options
- Powerful Compression/Distraction
- Multifunctional Instruments to Reduce Steps

**Recommended if fewer than maximum number of screws accommodated by the Brigade implant are used.*

BRIGADE® OVERVIEW

STABILITY. HEIGHT RESTORATION. FUSION.

Multiple Implant Footprints and Lordosis Options



- Four footprints for optimal posterior height restoration while maintaining sub-flush anterior placement
- Two lordotic options for anatomically appropriate restoration
- 4.5mm and 5.5mm self-tapping, self-drilling screws
- Large unimpeded central apertures

IMPLANT DIMENSIONS						
ANTERIOR HEIGHT	*10mm*	*12mm*	*14mm*	*16mm*	*18mm*	*20mm*
LORDOSIS	*8°*	*8°, 12°*	*8°, 12°*	*8°, 12°*	*8°, 12°*	*8°, 12°*

Multi-Function Screw Design

- Self-tapping/Self-drilling screws for increased procedural efficiency
- Maximum screw purchase and tactile feel

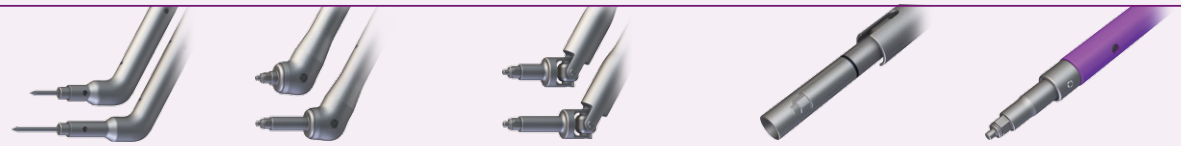
SCREW DIMENSIONS	
DIAMETER	**LENGTH**
4.5mm	20mm
4.5mm	22.5mm
4.5mm	25mm
4.5mm	27.5mm
4.5mm	30mm
4.5mm	35mm

SCREW DIMENSIONS	
DIAMETER	**LENGTH**
5.5mm	20mm
5.5mm	22.5mm
5.5mm	25mm
5.5mm	27.5mm
5.5mm	30mm
5.5mm	35mm

SAFETY. SIMPLICITY.

Innovative Instrumentation

ANGLED INSTRUMENTS | **STRAIGHT INSTRUMENTS**



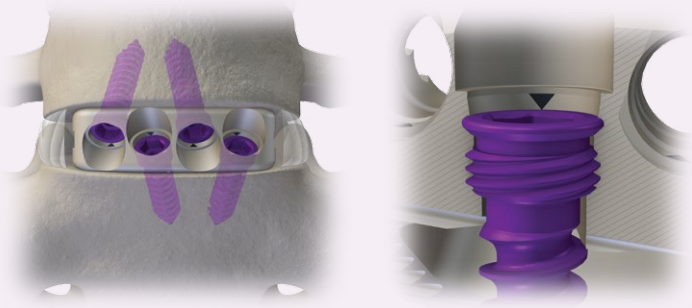
- Self-guiding, self-centering instruments
- Innovative sheathed instruments for maximum protection of surrounding anatomy
- Multiple driver options to accommodate varying anatomies
- Depth stops on awls and drill to help prevent over-advancement and help determine proper screw length
- Screw access holes are medialized to increase ability to place four screws in most anatomical situations

Ball End Driver

Adjustable Depth Stop

Threaded Taper Block

Single-Step Locking Mechanism



- Single-step Threaded Taper Block is designed to prevent screw backout and increase construct stability
- Visual indicator allows proper seating of screw

BRIGADE® SURGICAL TECHNIQUE

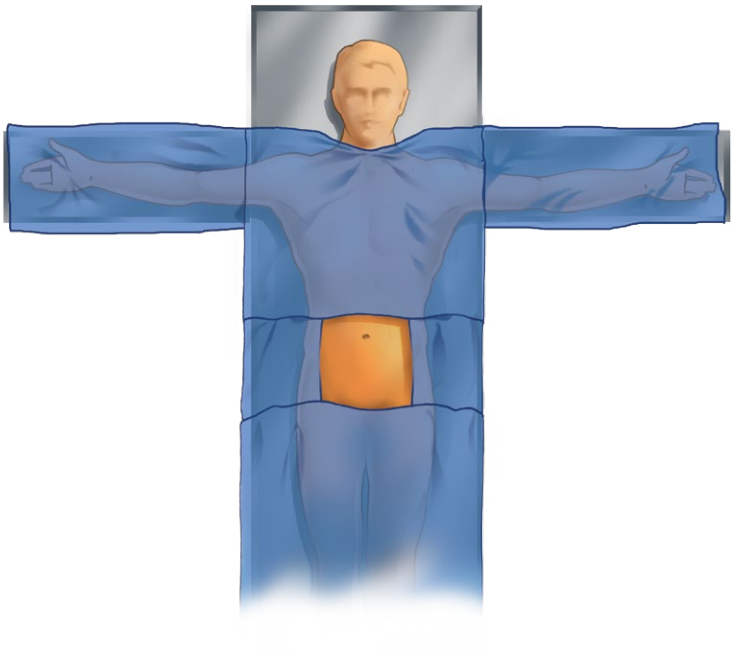
EQUIPMENT REQUIREMENTS

- Brigade Implants Tray (BRIGADEIMP)
- Brigade Instruments Tray One (BRIGADEIN1)
- Brigade Instruments Tray Two (BRIGADEIN2)
- Anterior/Lateral General Instruments Tray One (ALGIN1)
- Anterior/Lateral General Instruments Tray Two (ALGIN2)
- ALIF Instruments Tray (ALIF2)

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 surgical technique guide.

PATIENT POSITIONING AND O.R. SETUP

Place the patient on a radiolucent operating table in the supine position. Prepare and drape in the conventional manner *(Fig. 1)*. The fluoroscope should have adequate access to the surgical field for both the lateral and anteroposterior views.



(Fig. 1)

NVM5® – FREE RUN MODE

During distraction, trialing, and graft placement, NVM5 may be set to Free Run mode to detect mechanical irritation of the lumbar roots and spinal nerves.

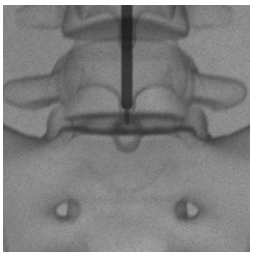
STEP 1:
ACCESS

Perform standard anterior approach to the spine per surgeon preference.

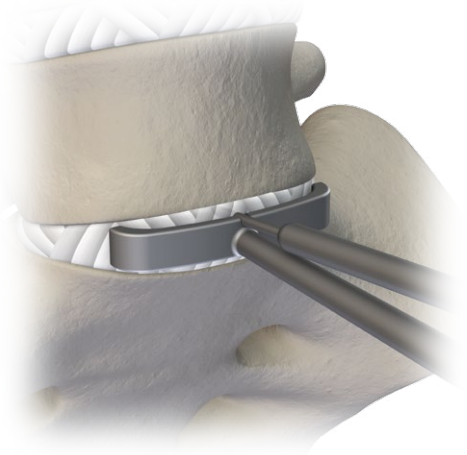
STEP 2:
MIDLINE VERIFICATION

Place the Annulotomy Template on the disc space. Insert Centering Pin into midline *(Fig. 2)*. Use A/P fluoro to verify midline and lateral fluoro to check depth *(Fig. 3)*. The length of the Centering Pin is 20mm.

A/P



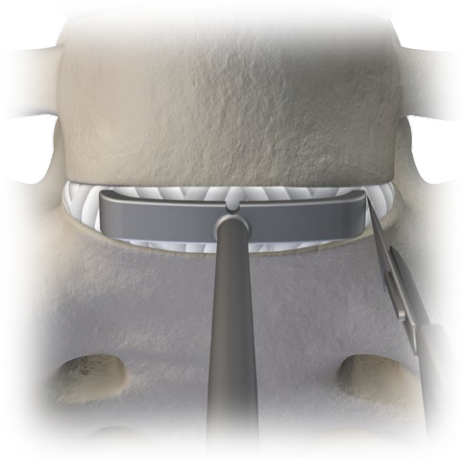
(Fig. 3)



(Fig. 2)

STEP 3:
DISC REMOVAL

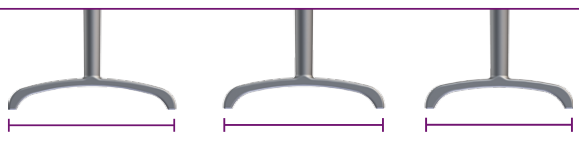
Use an annulotomy knife to cut into the annulus along the lateral edges of the Annulotomy Template *(Fig. 4)*. The Annulotomy Template matches the width of the implant. If using the implant as a partial vertebral body replacement, make necessary resections to the vertebral body.



(Fig. 4)

> ***Tip***
>
> *"I do not extend the annulotomy beyond the dimensions of the template as the proper cut maintains the centering of the disc. Moreover, the remaining preserved annulus provides a measure of stability when tensioned by distraction."*
>
> *– Martin B. Kornblum, M.D.*

ANNULOTOMY TEMPLATE MATCHES IMPLANT WIDTHS



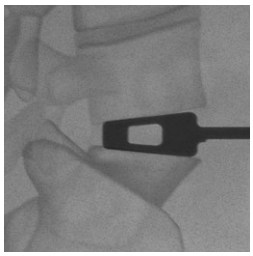
BRIGADE® SURGICAL TECHNIQUE

STEP 4:
TRIAL

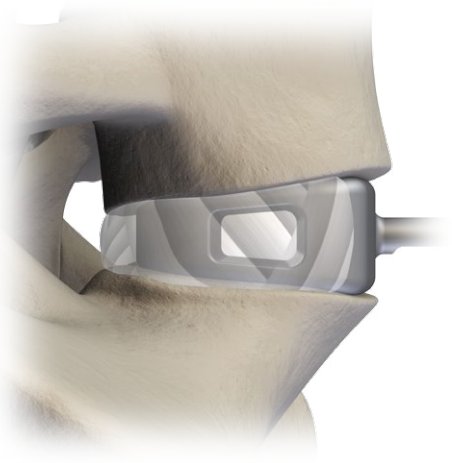
Attach the desired Trial to the Trial Inserter by simultaneously pushing down on the Trial Inserter collar and placing it over the Trial connection tip *(Figs. 5, 5a)*. Gently impact the Trial into the disc space *(Fig. 6)*. Final Trial positioning should be verified using fluoroscopy *(Fig. 7)*.

> ***Note***
> *It is important to place the Trial sub-flush, approximately 2mm from the anterior lip of the vertebral body, in order to mimic proper implant placement.*

LATERAL



(Fig. 7)



(Fig. 6)

(Fig. 5)

(Fig. 5a)

STEP 5:
IMPLANT PLACEMENT

When satisfied with placement and fit of the Trial, the corresponding implant should be selected, attached to the proper size Implant Inserter, and filled with autograft from partial vertebrectomy if using implant as a partial VBR *(Figs. 8, 8a)*.

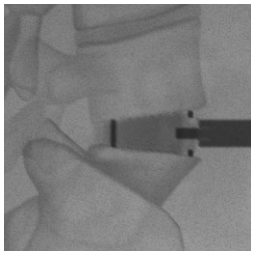
Gently impact the implant into the disc space *(Fig. 9)*. Without removing the Inserter, use lateral fluoroscopy to confirm the implant is placed in proper location *(Fig. 10)*. Use A/P fluoro to verify the implant is centered *(Fig. 11)*. All Brigade implants have radiodense anterior and posterior markers to assist with radiographic visualization.

Tip

"It is important to place the implant just sub-flush with the anterior border of the vertebral body. This enhances stability by seating the cage on the anterior apophyseal ring. The anterior placement also allows for full seating of the self-centering instruments and results in longest possible screw lengths."

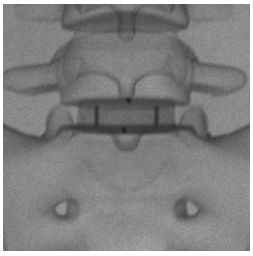
– Martin B. Kornblum, M.D.

LATERAL

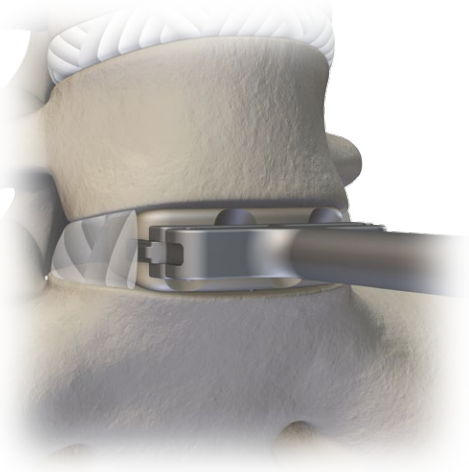


(Fig. 10)

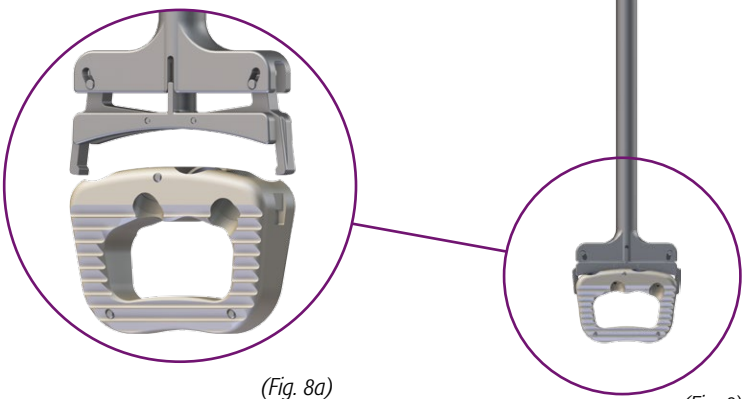
A/P



(Fig. 11)



(Fig. 9)



(Fig. 8a)

(Fig. 8)

INSERTER OPTIONS

Implant Inserter

Anterolateral Inserter

EnVoy™ Adapter

Medial Grip Implant Inserter

BRIGADE® SURGICAL TECHNIQUE

STEP 6:
PILOT HOLE PREPARATION

According to surgeon preference and anatomical requirements, a selection of fully sleeved, self-centering instruments can be used to prepare the vertebral body for Screw insertion.

Attach T-handle to the proximal end of an Awl. Insert the Awl into the desired Screw hole *(Figs. 12, 13, 13a)*. It is recommended to start with the most easily accessible Screw hole, typically using the Straight Awl. Deploy the Awl by gently impacting the strike plate on the handle. Fully retract the Awl tip before disengaging the Awl from the implant. Before making the next pilot hole, deliver the desired length Screw.

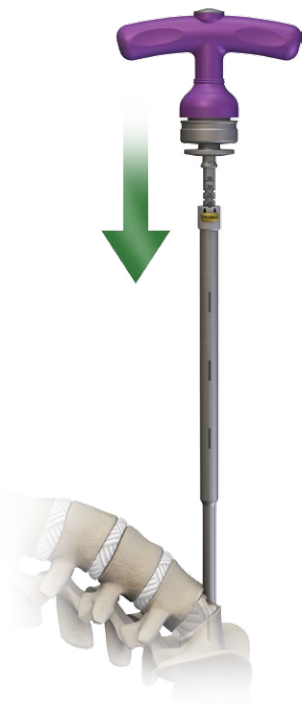
Tip

"Do NOT advance the Awls until they are fully seated within the cage. To avoid accidental deployment and excessive advancement of the instruments, I use the adjustable depth stops during pilot hole preparation."

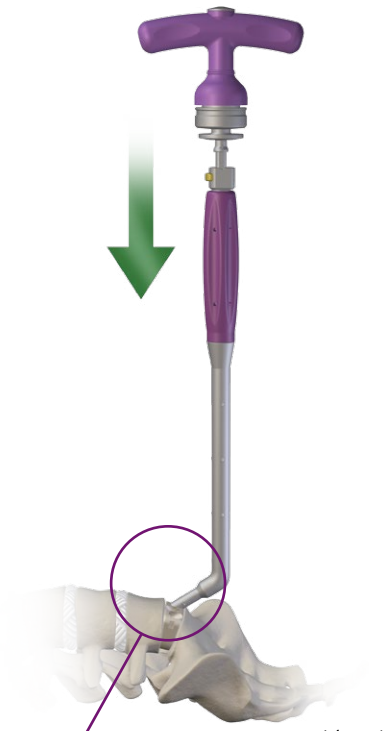
– Frank M. Phillips, M.D.

Note

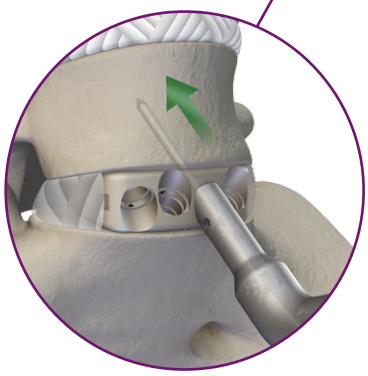
In order to ensure proper Screw trajectory, use lateral fluoroscopy after seating and after engaging the Drill or Awl for visual confirmation of the pilot path 45° to midline of the implant (Figs. 14, 15).



(Fig. 12)

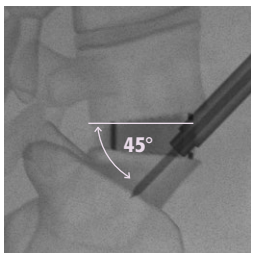


(Fig. 13)



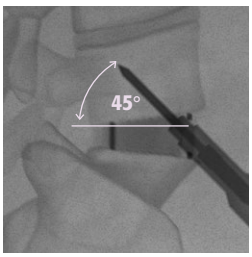
(Fig. 13a)

LATERAL



(Fig. 14)

LATERAL



(Fig. 15)

PILOT HOLE OPTIONS

Straight Awl

Angled Awls 15mm, 25mm

Straight Drill

STEP 7:
SCREW PLACEMENT

Depending on surgeon preference and anatomical requirements, a variety of straight and angled Drivers are available for Screw placement. Select the desired length 4.5mm Screw. Screw length is determined by using the pilot hole depth for reference. 5.5mm Rescue Screws are available, if needed.

Guided Straight Driver

Place a handle on the Guided Straight Driver. Place the distal end of the Driver directly over the desired Screw while in the Screw caddy. Press the Driver down until the sheath on the distal end is fully retracted *(Fig. 16a)*. Turn the thumbwheel on the Guided Straight Driver clockwise until solid resistance is felt in order to thread it into the Screw head *(Fig. 16)*.

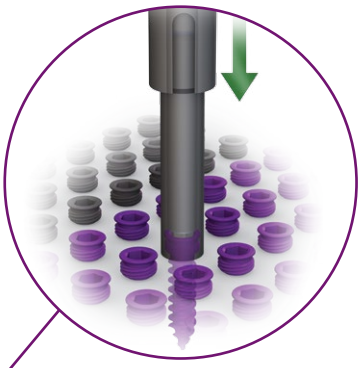
> ***Note***
> *When loading Screws, if the thumbwheel is not tightening, turn the Driver handle in order to ensure the Screw socket is fully engaged.*

Insert the distal end of the Driver into the prepared Screw hole and ensure the Driver sheath is fully seated in the implant. Turn the attached handle clockwise to drive the Screw *(Fig. 18)*.

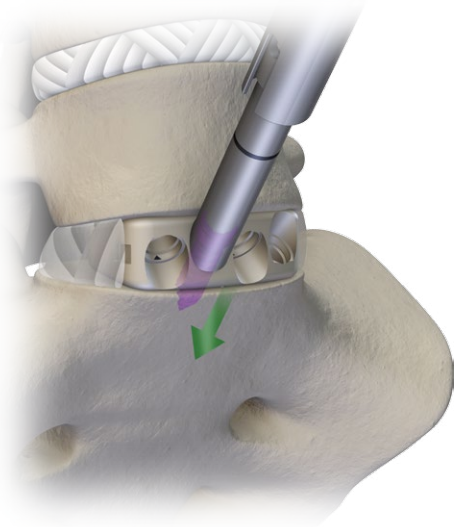
> ***Note***
> *The black indicator mark on retractable sheath will give visual confirmation of Screw advancement (Fig. 17).*

(Fig. 16)

> ***Tip***
> *"I prefer to use the Guided Straight Driver for S1 and L4 screws because of the safety provided by the retractable sheath and angled drivers for L5."*
> *– Frank M. Phillips, M.D.*

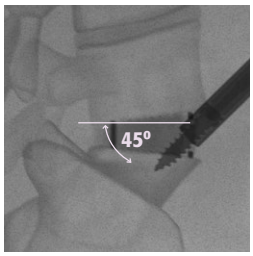


(Fig. 16a)



(Fig. 17)

LATERAL



(Fig. 18)

STRAIGHT DRIVER OPTIONS

Guided Straight Driver

Solid Driver – Non-Retaining

Solid Driver – Self-Retaining

BRIGADE® SURGICAL TECHNIQUE

STEP 7:
SCREW PLACEMENT (CONT.)

Angled Driver

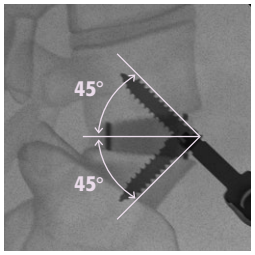
Place the handle on the Angled Driver – Retaining. Place the desired Screw on the Driver *(Fig. 19)*.

Insert the Screw into the desired pilot hole and advance the Screw by turning the handle clockwise *(Figs. 20, 20a)*.

The Counter-Torque Handle mates with fixed-angle Drivers to enable increased axial force on the Screw when maximum torque is being applied. This is intended to mimic Straight Driver axial force for greater control in high torque situations.

> ***Note***
>
> *During Screw placement, use lateral fluoroscopy to ensure proper Screw trajectory of 45° cranial or caudal (Fig. 21).*

LATERAL



(Fig. 21)

(Fig. 19)

(Fig. 20)

(Fig. 20a)

ANGLED DRIVER OPTIONS:

RETAINING ***NON-RETAINING*** ***FINAL TIGHTENING***

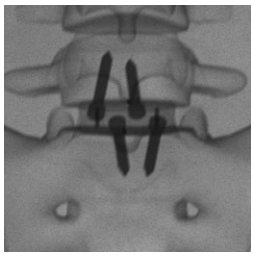
Angled Driver – Retaining	*Angled Driver – Short*	*U-Joint Driver – Retaining*	*U-Joint Driver – Short*	*U-Joint Driver – Non-Retaining*	*Angled Driver – Non-Retaining*	*Solid Driver – Ball End*	*Allen Wrench*

STEP 8:
THREADED TAPER BLOCK LOCKING MECHANISM

Proper Screw seating is confirmed through the use of visual indicators. The proximal head of the Screw will pass visual indicator triangles to ensure proper seating depth. Full view of the triangle indicator confirms proper seating depth *(Figs. 22, 23)*.

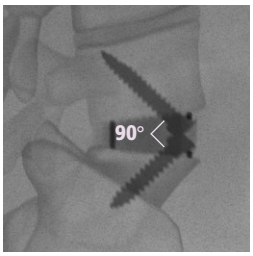
Check final placement. The implant should rest in the disc space with the spinous process midway between the posterior markers under A/P fluoroscopy (*Fig. 24).* Under lateral fluoroscopy, the Screws and posterior markers of the implant should be superimposed with the screws creating a 90° angle *(Fig. 25)*.

A/P



(Fig. 24)

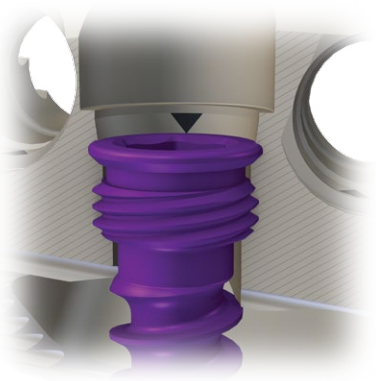
LATERAL



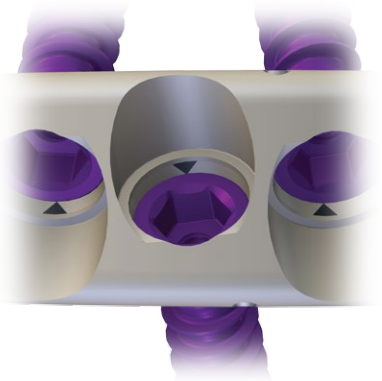
(Fig. 25)

IMPLANT REMOVAL

For implant removal or revision, non-retaining Drivers or Screw retrieval tools can be used for Screw extraction, and implant retrieval tools can be used to remove implant.

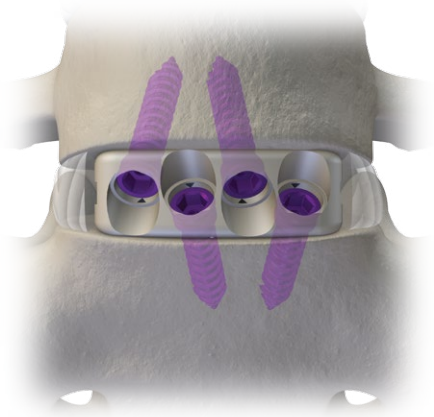


(Fig. 22)

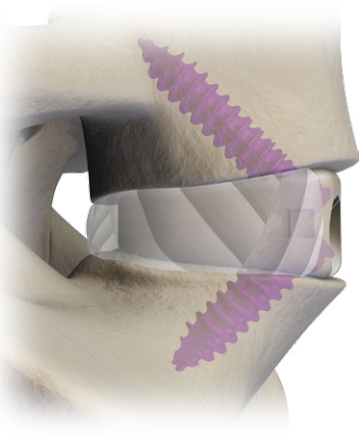


(Fig. 23)

FINAL CONSTRUCT A/P VIEW



FINAL CONSTRUCT LATERAL VIEW



BRIGADE® SYSTEM

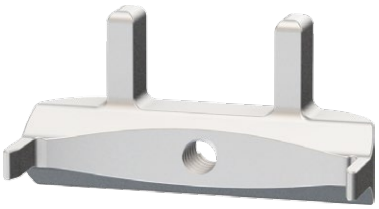
BRIGADE INSTRUMENTS TRAY ONE

IMPLANT INSERTER – SMALL

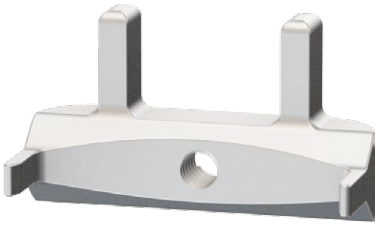
IMPLANT INSERTER – LARGE

STRAIGHT TAMP

ENVOY™ ADAPTER – SMALL



ENVOY ADAPTER – LARGE



QUICK CONNECT STRAIGHT HANDLE

BRIGADE® SYSTEM

QUICK CONNECT T-HANDLE

QUICK CONNECT GEARSHIFT HANDLE

ANTEROLATERAL IMPLANT INSERTER – SMALL

ANTEROLATERAL IMPLANT INSERTER – LARGE

ANTEROLATERAL TAMP

MEDIAL GRIP IMPLANT INSERTER

BRIGADE® SYSTEM

IMPLANT RETRIEVAL GRASPER

IMPLANT RETRIEVAL LATERAL GRASPER

TRIAL REMOVAL TOOL

TRIAL INSERTER

ANNULOTOMY TEMPLATE – 34mm

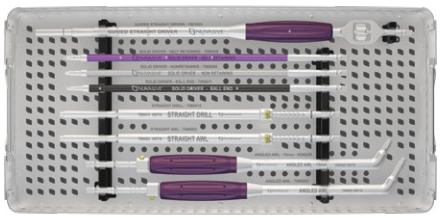
ANNULOTOMY TEMPLATE – 38mm

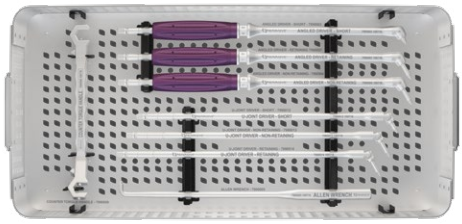
ANNULOTOMY TEMPLATE – 42mm

CENTERING PIN

BRIGADE® SYSTEM

BRIGADE INSTRUMENTS TRAY TWO





STRAIGHT AWL

ANGLED AWL

ANGLED AWL – 15mm

STRAIGHT DRILL

SOLID DRIVER – SELF-RETAINING

BRIGADE® SYSTEM

SOLID DRIVER – NON-RETAINING

SOLID DRIVER – BALL END

GUIDED STRAIGHT DRIVER

U-JOINT DRIVER – SHORT

U-JOINT DRIVER – NON-RETAINING

U-JOINT DRIVER – RETAINING

BRIGADE® SYSTEM

COUNTER-TORQUE HANDLE

ANGLED DRIVER – SHORT

ANGLED DRIVER – NON-RETAINING

ANGLED DRIVER – RETAINING

ALLEN WRENCH

BRIGADE® SYSTEM

BRIGADE IMPLANTS

BRIGADE IMPLANTS TRAY

BRIGADE SCREW – 4.5mm

BRIGADE SCREW – 5.5mm

BRIGADE IMPLANT

BRIGADE® INSTRUMENTS

DESCRIPTION	CATALOG #
Trial – 10 x 34 x 24mm, 8°	7921034
Trial – 12 x 34 x 24mm, 8°	7921234
Trial – 14 x 34 x 24mm, 8°	7921434
Trial – 16 x 34 x 24mm, 8°	7921634
Trial – 18 x 34 x 24mm, 8°	7921834
Trial – 20 x 34 x 24mm, 8°	7922034
Trial – 10 x 34 x 24mm, 12°	7931034
Trial – 12 x 34 x 24mm, 12°	7931234
Trial – 14 x 34 x 24mm, 12°	7931434
Trial – 16 x 34 x 24mm, 12°	7931634
Trial – 18 x 34 x 24mm, 12°	7931834
Trial – 20 x 34 x 24mm, 12°	7932034
Trial – 10 x 38 x 28mm, 8°	7921038
Trial – 12 x 38 x 28mm, 8°	7921238
Trial – 14 x 38 x 28mm, 8°	7921438
Trial – 16 x 38 x 28mm, 8°	7921638
Trial – 18 x 38 x 28mm, 8°	7921838
Trial – 20 x 38 x 28mm, 8°	7922038
Trial – 12 x 38 x 28mm, 12°	7931238
Trial – 14 x 38 x 28mm, 12°	7931438
Trial – 16 x 38 x 28mm, 12°	7931638
Trial – 18 x 38 x 28mm, 12°	7931838
Trial – 20 x 38 x 28mm, 12°	7932038
Trial – 10 x 38 x 32mm, 8°	7941038
Trial – 12 x 38 x 32mm, 8°	7941238
Trial – 14 x 38 x 32mm, 8°	7941438
Trial – 16 x 38 x 32mm, 8°	7941638
Trial – 18 x 38 x 32mm, 8°	7941838
Trial – 20 x 38 x 32mm, 8°	7942038
Trial – 12 x 38 x 32mm, 12°	7951238
Trial – 14 x 38 x 32mm, 12°	7951438
Trial – 16 x 38 x 32mm, 12°	7951638
Trial – 18 x 38 x 32mm, 12°	7951838
Trial – 20 x 38 x 32mm, 12°	7952038
Trial – 10 x 42 x 30mm, 8°	7921042
Trial – 12 x 42 x 30mm, 8°	7921242
Trial – 14 x 42 x 30mm, 8°	7921442
Trial – 16 x 42 x 30mm, 8°	7921642
Trial – 18 x 42 x 30mm, 8°	7921842
Trial – 20 x 42 x 30mm, 8°	7922042
Trial – 12 x 42 x 30mm, 12°	7931242
Trial – 14 x 42 x 30mm, 12°	7931442
Trial – 16 x 42 x 30mm, 12°	7931642
Trial – 18 x 42 x 30mm, 12°	7931842
Trial – 20 x 42 x 30mm, 12°	7932042

BRIGADE INSTRUMENTS

DESCRIPTION	CATALOG #
Quick Connect Straight Handle	6180016
Quick Connect T-handle	6180018
Quick Connect Gearshift Handle	6180019
Solid Driver – Self-Retaining	7990008
Solid Driver – Non-Retaining	7990009
Solid Driver – Ball End	7990011
U-Joint Driver – Short	7990012
U-Joint Driver – Non-Retaining	7990013
U-Joint Driver – Retaining	7990014
Counter-Torque Handle	7990006
Guided Straight Driver	7980001
Angled Driver – Short	7990001
Angled Driver – Non-Retaining	7990004
Angled Driver – Retaining	7990007
Straight Awl	7980003
Angled Awl	7990003
Angled Awl – 15mm	6590229
Straight Drill	7980015
Implant Inserter – Small	7981001
Implant Inserter – Large	7981002
Anterolateral Implant Inserter – Small	7981003
Anterolateral Implant Inserter – Large	6590277
Trial Inserter	7981004
Medial Grip Implant Inserter	7981005
EnVoy™ Adapter – Small	7981011
EnVoy Adapter – Large	7981019
Allen Wrench	7990005
Implant Retrieval Grasper	7981012
Implant Retrieval Hooked Grasper	7981009
Implant Retrieval Lateral Grasper	7981010
Annulotomy Template – 34mm	7981013
Annulotomy Template – 38mm	7981014
Annulotomy Template – 42mm	7981015
Centering Pin	7981018
Straight Tamp	7981020
Anterolateral Tamp	7981021
Trial Removal Tool	6590228

CATALOG

BRIGADE® IMPLANTS

DESCRIPTION	CATALOG #
Implant – 10 x 34 x 24mm, 8°	6941034
Implant – 12 x 34 x 24mm, 8°	6941234
Implant – 14 x 34 x 24mm, 8°	6941434
Implant – 16 x 34 x 24mm, 8°	6941634
Implant – 18 x 34 x 24mm, 8°	6941834
Implant – 20 x 34 x 24mm, 8°	6942034
Implant – 10 x 34 x 24mm, 12°	6951034
Implant – 12 x 34 x 24mm, 12°	6951234
Implant – 14 x 34 x 24mm, 12°	6951434
Implant – 16 x 34 x 24mm, 12°	6951634
Implant – 18 x 34 x 24mm, 12°	6951834
Implant – 20 x 34 x 24mm, 12°	6952034
Implant – 10 x 38 x 28mm, 8°	6941038
Implant – 12 x 38 x 28mm, 8°	6941238
Implant – 14 x 38 x 28mm, 8°	6941438
Implant – 16 x 38 x 28mm, 8°	6941638
Implant – 18 x 38 x 28mm, 8°	6941838
Implant – 20 x 38 x 28mm, 8°	6942038
Implant – 12 x 38 x 28mm, 12°	6951238
Implant – 14 x 38 x 28mm, 12°	6951438
Implant – 16 x 38 x 28mm, 12°	6951638
Implant – 18 x 38 x 28mm, 12°	6951838
Implant – 20 x 38 x 28mm, 12°	6952038
Implant – 10 x 38 x 32mm, 8°	6961038
Implant – 12 x 38 x 32mm, 8°	6961238
Implant – 14 x 38 x 32mm, 8°	6961438
Implant – 16 x 38 x 32mm, 8°	6961638
Implant – 18 x 38 x 32mm, 8°	6961838
Implant – 20 x 38 x 32mm, 8°	6962038
Implant – 12 x 38 x 32mm, 12°	6971238
Implant – 14 x 38 x 32mm, 12°	6971438
Implant – 16 x 38 x 32mm, 12°	6971638
Implant – 18 x 38 x 32mm, 12°	6971838
Implant – 20 x 38 x 32mm, 12°	6972038
Implant – 10 x 42 x 30mm, 8°	6941042
Implant – 12 x 42 x 30mm, 8°	6941242
Implant – 14 x 42 x 30mm, 8°	6941442
Implant – 16 x 42 x 30mm, 8°	6941642
Implant – 18 x 42 x 30mm, 8°	6941842
Implant – 20 x 42 x 30mm, 8°	6942042
Implant – 12 x 42 x 30mm, 12°	6951242
Implant – 14 x 42 x 30mm, 12°	6951442
Implant – 16 x 42 x 30mm, 12°	6951642
Implant – 18 x 42 x 30mm, 12°	6951842
Implant – 20 x 42 x 30mm, 12°	6952042

BRIGADE IMPLANTS

DESCRIPTION	CATALOG #
Screw – 4.5 x 20mm	8594520
Screw – 4.5 x 22.5mm	8594522
Screw – 4.5 x 25mm	8594525
Screw – 4.5 x 27.5mm	8594527
Screw – 4.5 x 30mm	8594530
Screw – 4.5 x 35mm	8594535
Screw – 5.5 x 20mm	8595520
Screw – 5.5 x 22.5mm	8595522
Screw – 5.5 x 25mm	8595525
Screw – 5.5 x 27.5mm	8595527
Screw – 5.5 x 30mm	8595530
Screw – 5.5 x 35mm	8595535

DESCRIPTION

The NuVasive® BRIGADE Standalone System is manufactured from PEEK-OPTIMA® (polyetheretherkeytone) and Titanium alloy conforming to recognized standards. The implants are available in a variety of sizes to accommodate anatomical conditions. The BRIGADE Standalone System is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

INDICATIONS

- When used as an intervertebral body fusion device:

  The BRIGADE Standalone System is a standalone system indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The BRIGADE Standalone System is intended for use with autograft.

- When used as a partial Vertebral Body Replacement (VBR):

  The BRIGADE Standalone System is a standalone system indicated for use in the thoracolumbar spine (T1-L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The BRIGADE Standalone System is also indicated for treating fractures of the thoracic and lumbar spine. The BRIGADE Standalone System is intended to be used with autograft or allograft.

CONTRAINDICATIONS

Contraindications include but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Patients with known sensitivity to the materials implanted.
- Patients who are unwilling to restrict activities or follow medical advice.
- Patients with inadequate bone stock or quality.
- Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
- Use with components of other systems.
- Reuse or multiple use.
- Any case not described in the indications.
- Prior fusion at the level(s) to be treated.

CONTRAINDICATIONS FOR STANDALONE APPLICATION

Contraindications for Standalone application include but are not limited to:

- Spondylolisthesis greater than Grade 1.
- Severe segmental instability.
- Prior fusion at the level(s) to be treated.

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 PRECAUTIONS

- 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. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- 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.
- 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.
- The BRIGADE Standalone System is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. If fewer than the maximum number of screws accommodated by the device are used, the system is intended to be used with additional supplemental fixation (cleared by FDA) for use in lumbar spine.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 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.
- All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

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 ONLY: 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 BRIGADE Standalone System has not been evaluated for safety and compatibility in the MR environment. The BRIGADE Standalone System has not been tested for heating or migration in the MR environment.

COMPATIBILITY: Do not use BRIGADE Standalone with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

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. Devices should be inspected for damage prior to implantatior.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

NOTES

NOTES

To order, please contact your NuVasive® Sales Consultant or Customer Service Representative today at:
EC REP **NuVasive, Inc.** 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134
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