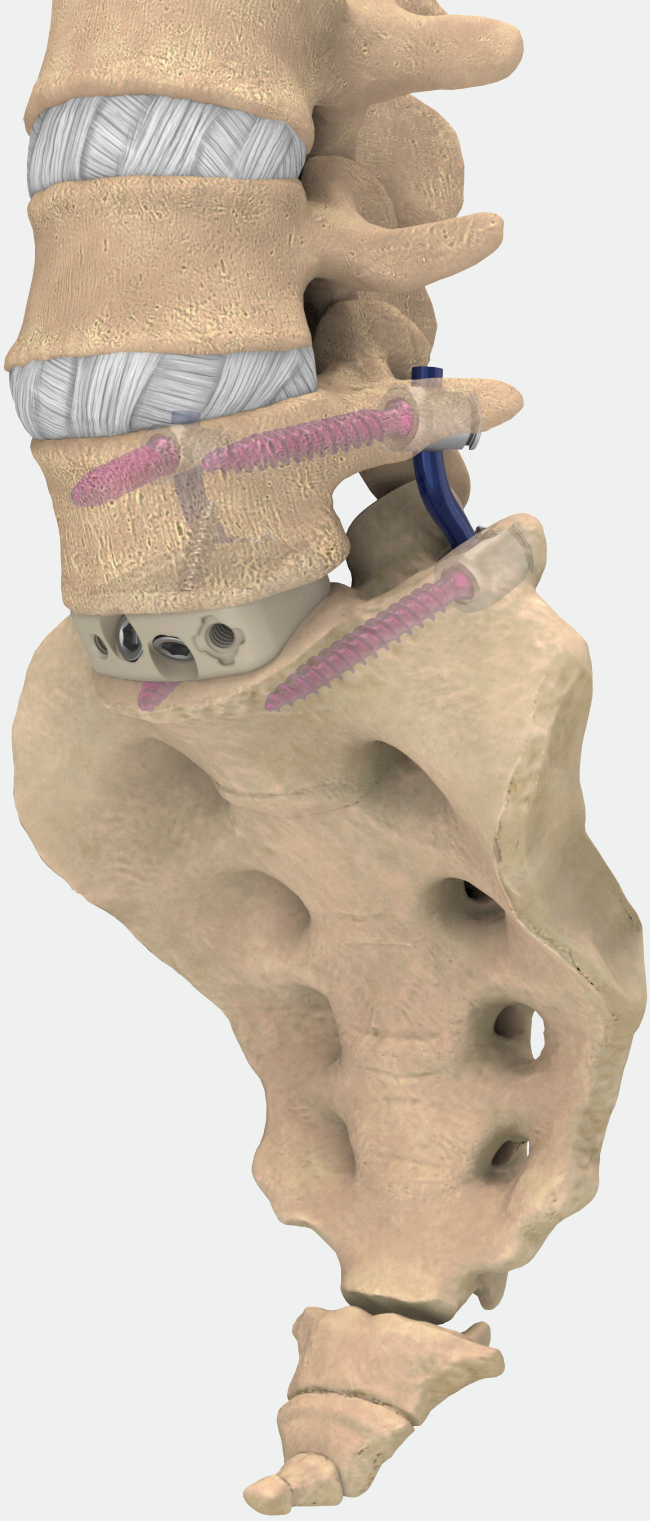


Brigade Lateral

Surgical Technique Guide

NuVasive

Contents

Introduction

The Brigade Lateral Interbody

A lumbar interbody device that is intended for use in a variety of pathologies, including restoration of sagittal alignment in the anterior column and degenerative disc disease. Implants are available in a variety of sizes and degrees of lordosis to accommodate anatomical conditions.

The Brigade Lateral interbody *(Fig. 1)* is designed to be used with either supine or lateral approaches for anterior lumbar interbody fusion (ALIF).

The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. A complete list of indications and contraindications can be found in the system IFU.

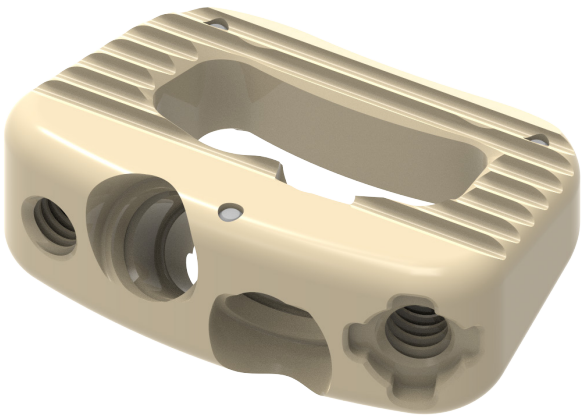
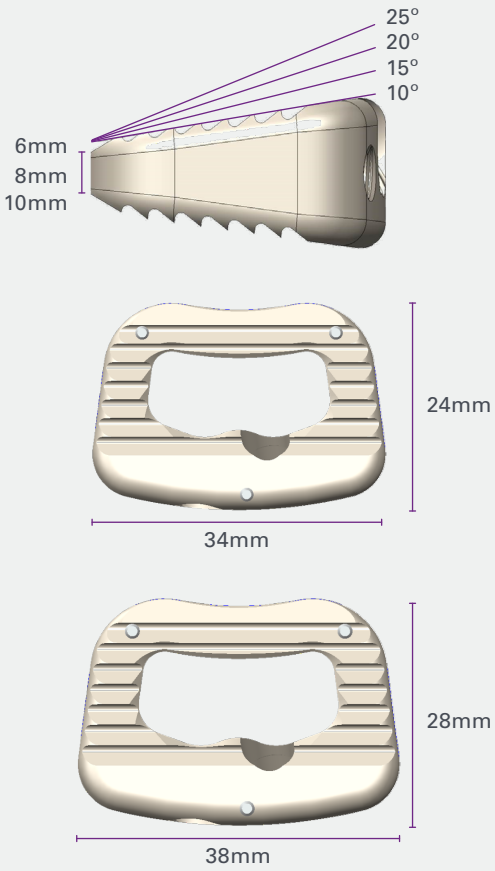
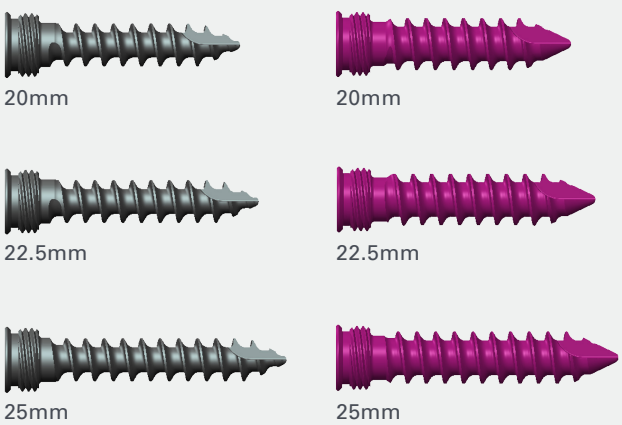


Fig. 1

Brigade Lateral Interbody Size



Screw Options



Brigade Lateral Operative Technique

Equipment Requirments

- Brigade Lateral Implant Tray (BRIGADELATIMP)
- Brigade Lateral Instrument Tray (BRIGADELATINS)
- ALIF Disc Prep Tray 1 (ALIFDISCPREP1)
- ALIF Disc Prep Tray 2 (ALIFDISCPREP2)
- Access Instrumentation
  Note: *Order one system, depending on approach.*

  Supine:

  - MASALIFACCESS
  - LATALIFARM (QTY x2)

  Lateral:

  - LATALIFACCESS
  - LATALIFARM (QTY x1)
  - M4AARM (QTY x1)

Patient Positioning

Place the patient on a radiolucent operating table in a supine *(Fig. 2)* or lateral position *(Fig. 3)*, depending on surgical approach. Secure, prepare, and drape the patient appropriately. Fluoroscopy should have adequate access to the surgical field for both lateral and anteroposterior (A/P) views. The disc space can be localized using lateral and A/P fluoroscopy.

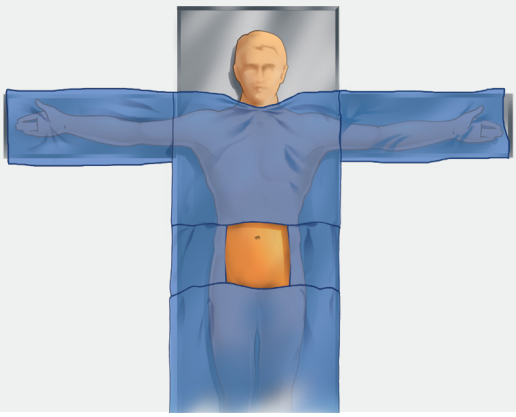


Fig. 2

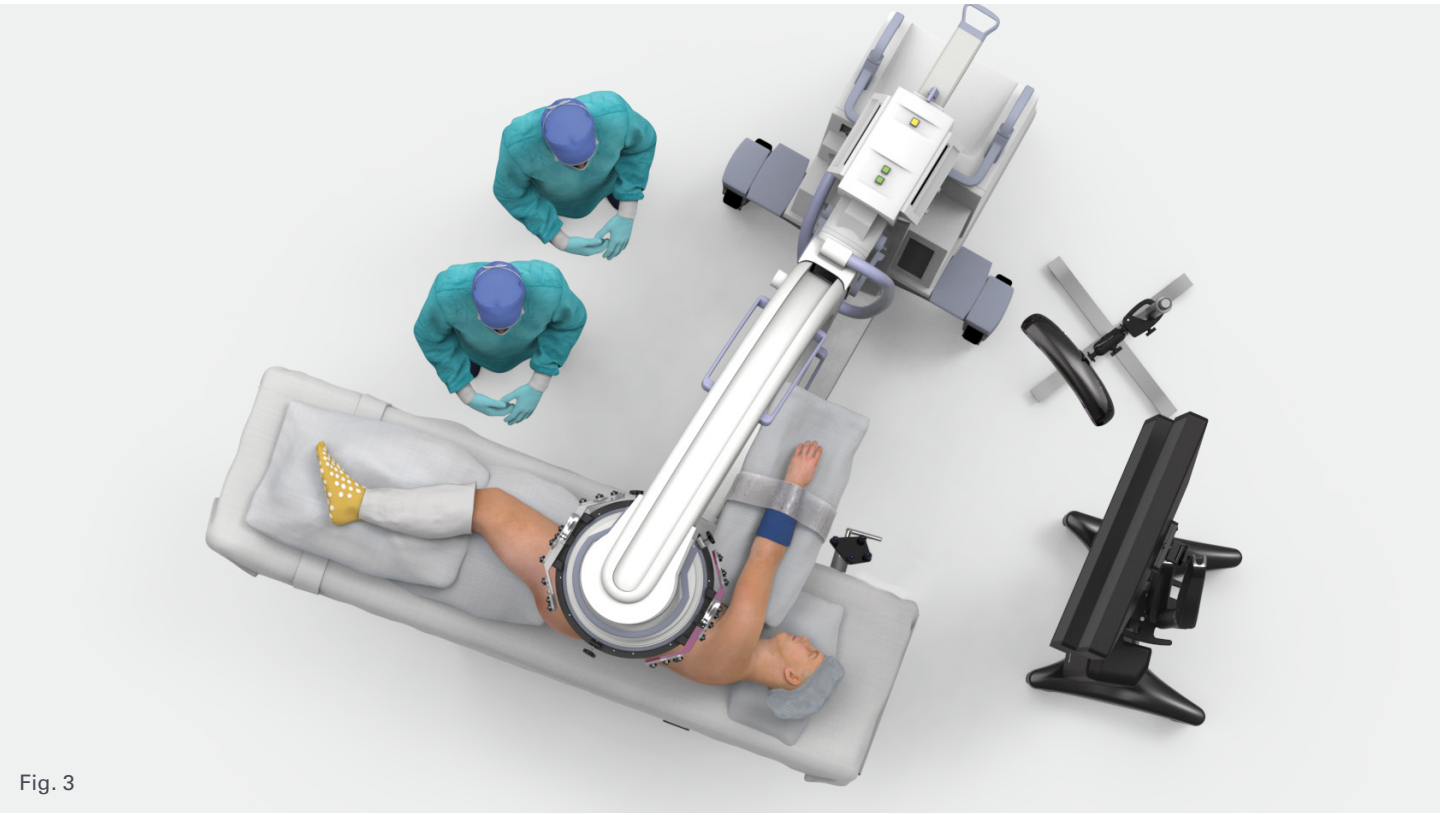


Fig. 3

Step 1

Access

Perform a lateral or supine approach to the spine per surgeon preference.

Step 2

Midline Verification

Use A/P fluoro to locate midline on the disc space in order to establish orientation *(Fig. 4)*.

Step 3

Annulotomy and Disc Removal

The annulus is incised, and a conventional discectomy is performed. Cobbs, pituitaries, curettes, disc cutters, endplate scrapers and other conventional disc preparation instruments can be used to thoroughly evacuate the disc, release the contralateral annulus, and prepare the endplates for fusion.

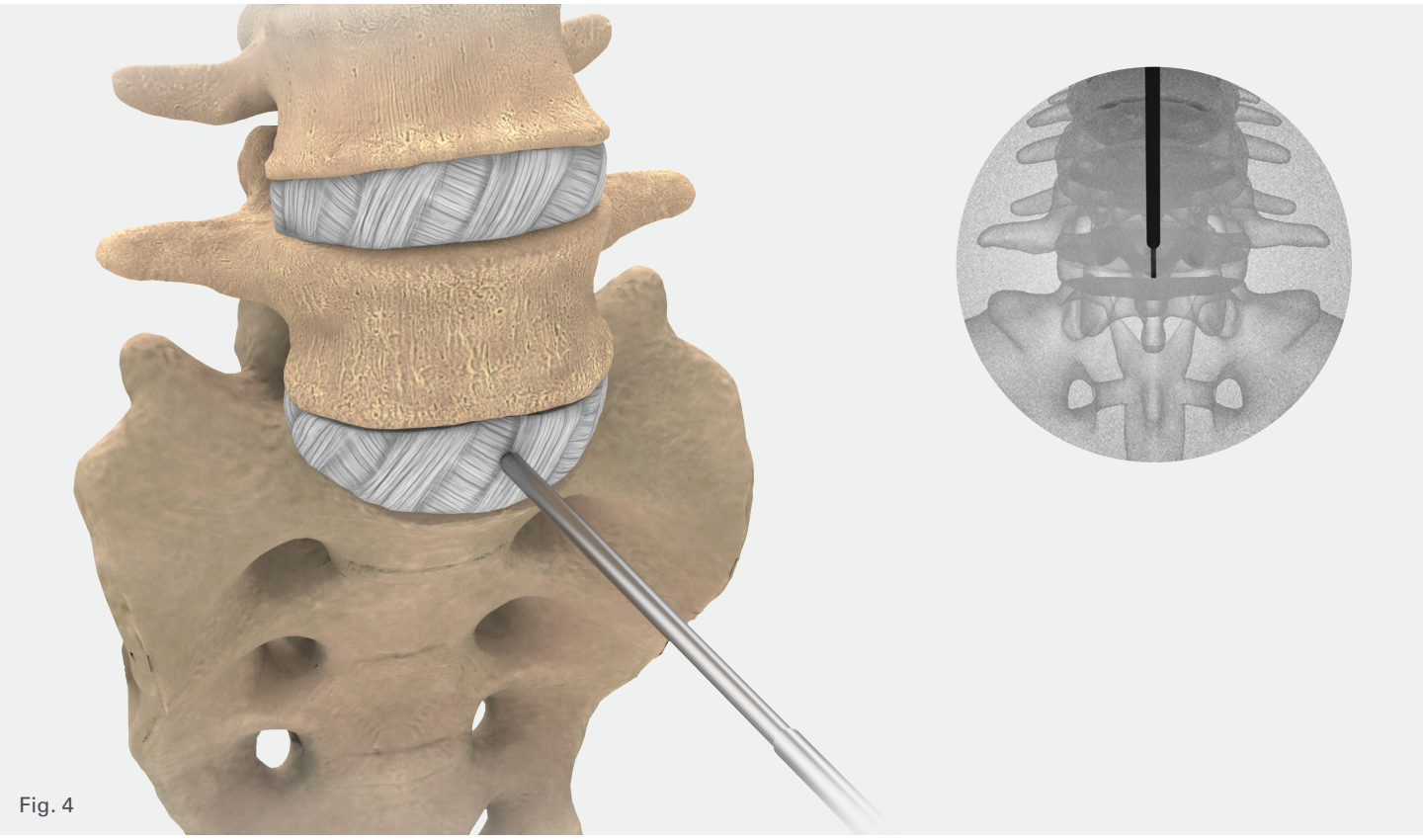


Fig. 4

Step 4

Trial and Implant Selection

Attach the selected trial to the inserter by engaging the bolt threads and aligning the pattern at the distal end of the inserter *(Fig. 5)* with the cruciform cutout on the trial. Thread the trial into a secure fit. Under lateral fluoroscopy, gently impact the trial into the disc space *(Fig. 6)*. Use sequential trialing within the disc space to help prevent endplate damage. Proper midline positioning of final trial placement should be verified using A/P fluoroscopy. Trialing is used to determine the appropriately sized Brigade Lateral implant from the portfolio of footprint and lordotic options.

Tip: *It is recommended to use the non-ratcheting T-handle for trial inserter, implant inserter, and awl.*

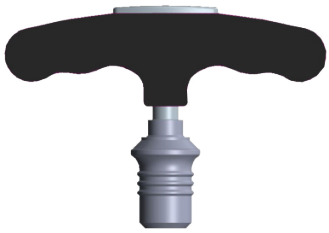


Fig. 5

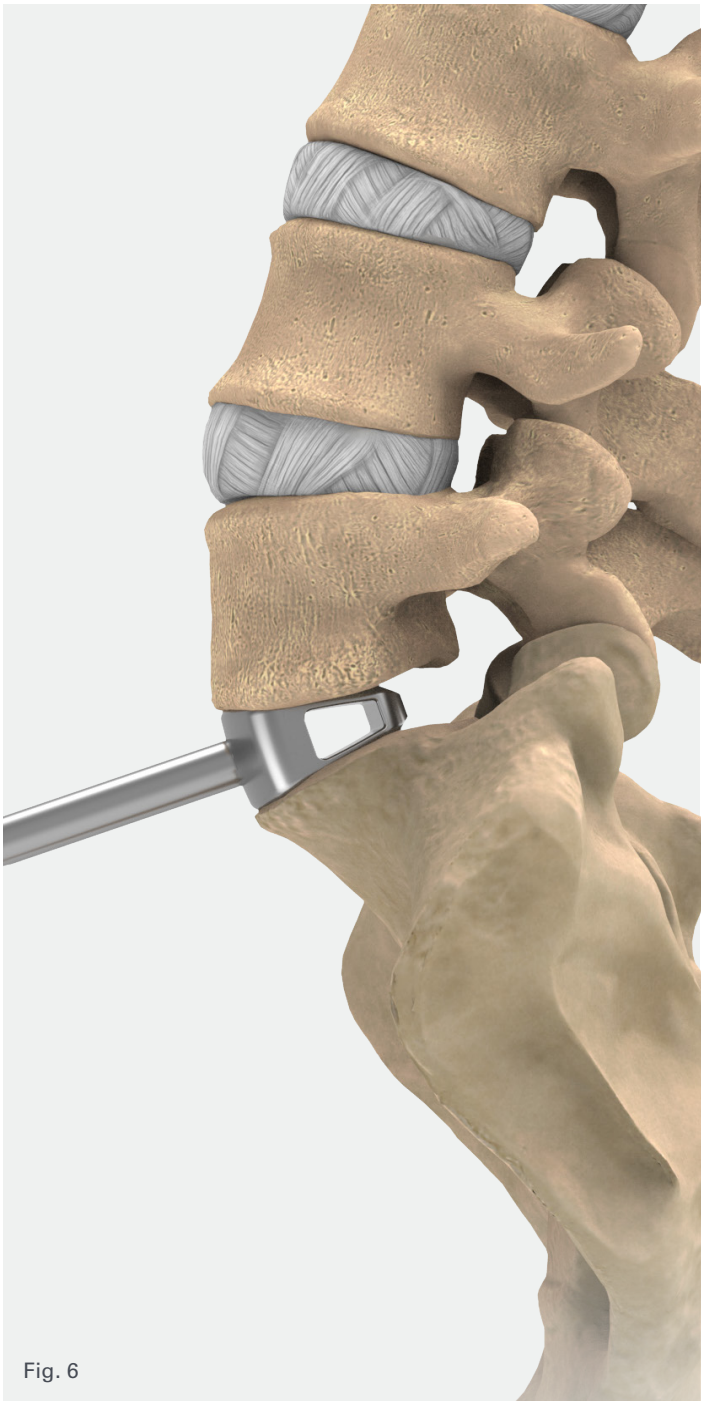


Fig. 6

Step 5

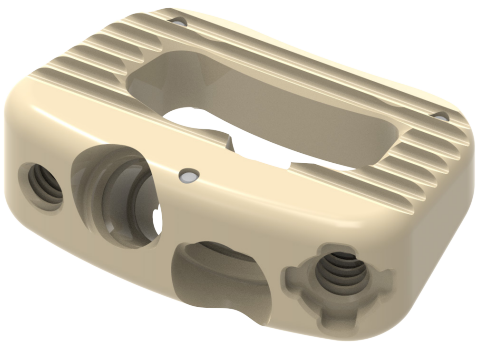
Implant Placement

Attach the Brigade Lateral implant to the desired inserter and gently impact the implant into the disc space. If using the anterolateral inserter, attach the implant by aligning the cruciform pattern at the distal end of the inserter with the cutout on the implant and thread it into a secure fit *(Fig. 7)*.

If using the direct anterior inserter, align the cruciform symbol (+) at the distal end with the matching cutout on the implant and slide the inserter tang into the corresponding hole *(Fig. 8)*. Thread the contralateral side of the inserter into the implant by spinning the inserter thumbwheel clockwise until the connection is secure.

Note: *When assembling the inserter, the arrow on the thumbwheel must point distally toward the implant for proper instrument function.*

During insertion of the implant, monitor its position under lateral and A/P fluoroscopy. Confirm that the interbody is fully seated into the disc space and positioned midline under lateral *(Fig. 9)* and A/P imaging *(Fig. 10)*.



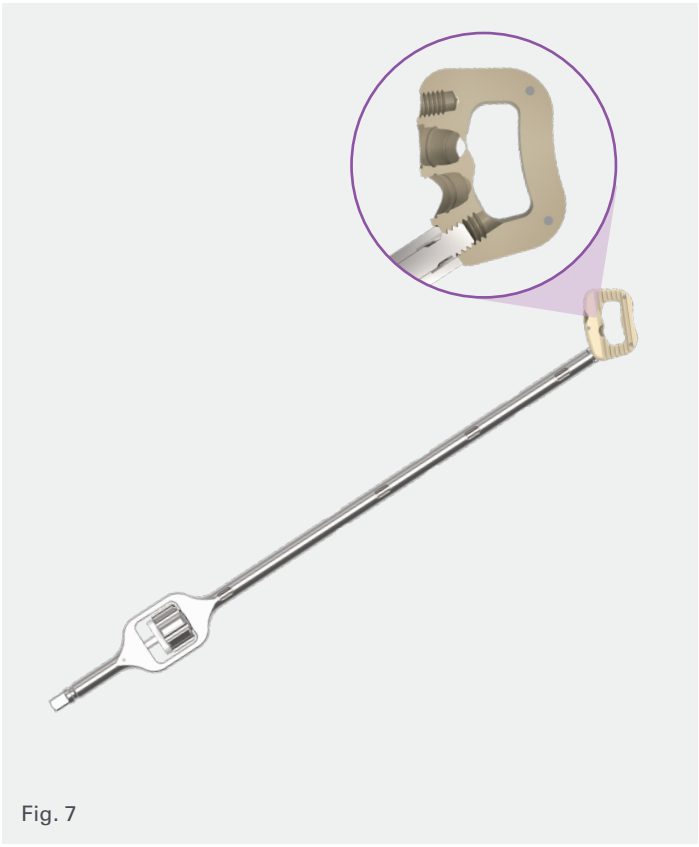


Fig. 7

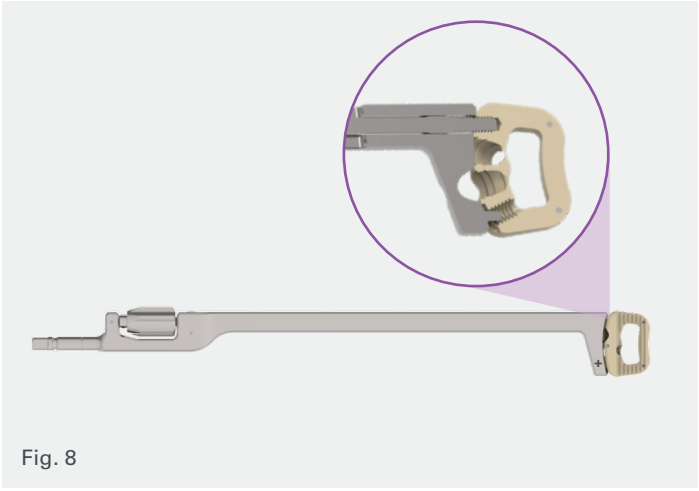


Fig. 8

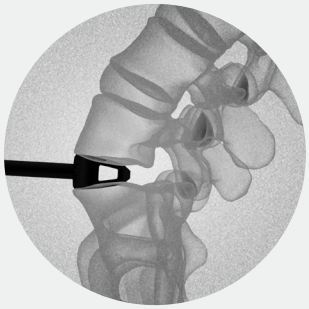


Fig. 9

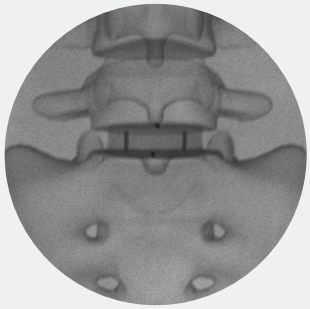


Fig. 10

Step 6

Screw Placement

Step 6A: Pilot Hole Preparation

Select the desired handle (straight or T) and awl (straight or angled) and place over the proximal end of the awl shaft. Set the awl depth stop to zero and spin the thumbwheel clockwise until tightened *(Fig. 11)*. The tip of the awl is placed directly into the screw hole on the implant. When engaged, it will sit firmly inside the implant. Once seated, slide the awl depth stop to 15mm. Advance the awl into the vertebral body until the desired depth is reached. Take a flouroscopy image to confirm.

If necessary, spin the thumbwheel counterclockwise to disengage the awl from the vertebral body *(Fig. 12).*

Straight or angled awls are available for use. Select the appropriate instrument based on the access provided to the screw holes on the implant.

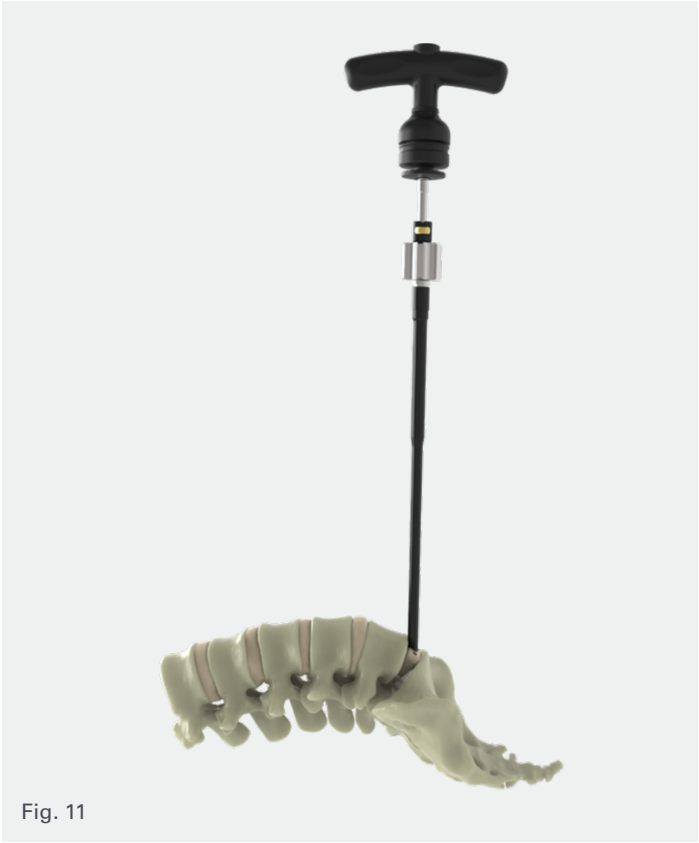


Fig. 11

Fig. 12

Step 6B: Screw Placement

Depending on surgeon preference and anatomical requirements, a variety of straight and angled drivers are available for screw placement. Select a ratcheting handle and slide it onto the proximal end of the desired screwdriver.

Next, select the appropriate length 4.5mm screw and insert the tip of the screwdriver into the engagement feature on the screw head *(Fig. 13)*. Screw length is determined using the interbody graft length and pilot hole depth for reference. 5.5mm rescue screws are available in the set if needed.

Place the screw through the pilot hole and begin advancement. Proper screw locking is confirmed using the visual indicators. The proximal head of the screw will pass visual indicator triangles to confirm proper seating depth. Full view of the triangle indicator confirms proper deployment *(Fig. 14)*.

Driver and Handle Options

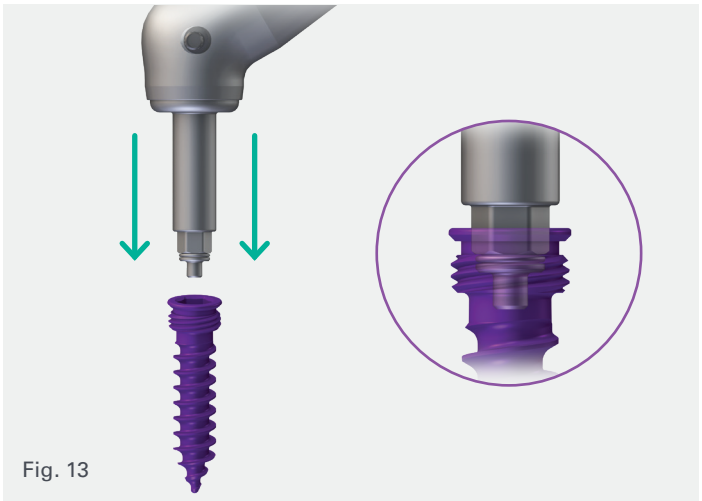


Fig. 13

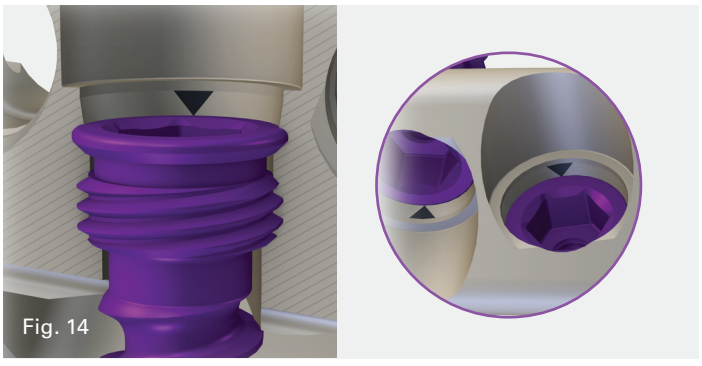


Fig. 14

Step 6C: Screw Placement Confirmation

Confirm final placement of screws with fluoroscopy. The implant should rest fully across the disc space under lateral fluoroscopy *(Fig. 15)* with the screws extending into the endplate either in the superior and/or inferior body. Under A/P fluoroscopy *(Fig. 16)*, the implant should be centered in the intervertebral space.

Note: *During screw placement, use lateral fluoro to confirm a nominal screw trajectory of 45° cranial or caudal.*

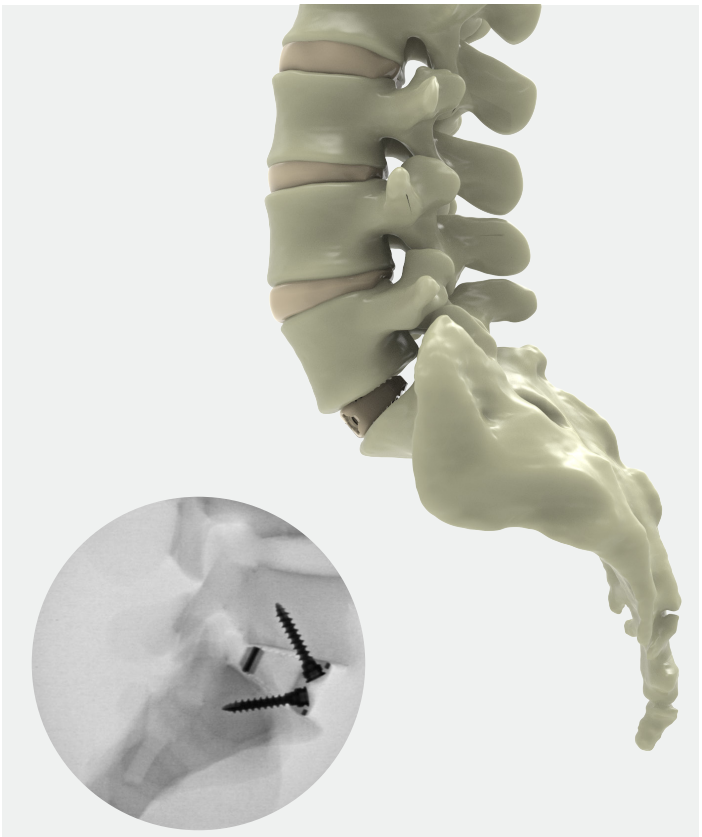


Fig. 15

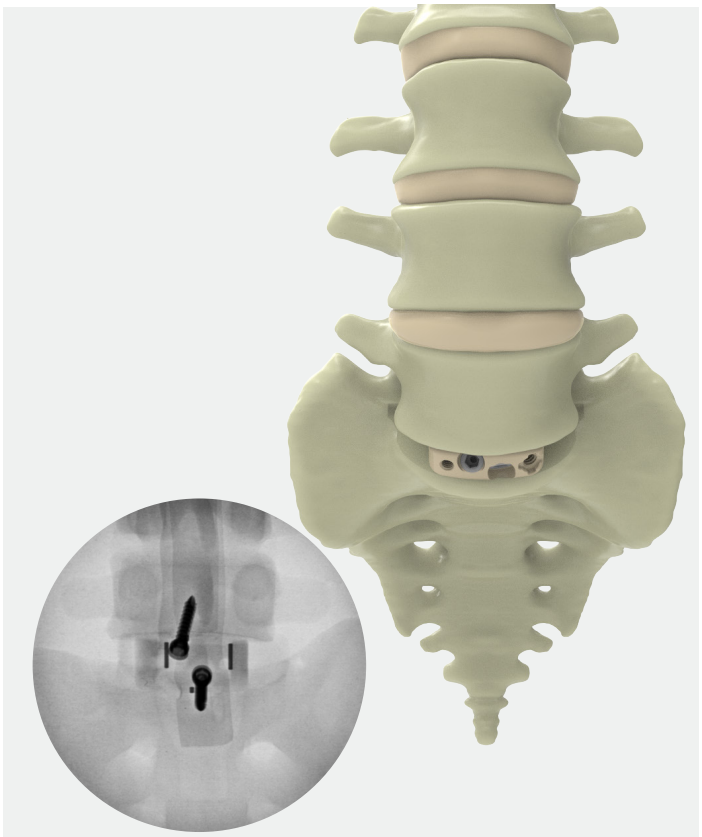


Fig. 16

Step 7

Supplemental Fixation

Complete the surgery with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine *(Fig. 17)*. See the system IFU and surgical technique for instructions.

Step 8

Screw Removal

Screw Removal: If screw removal is necessary, use the desired screwdriver to extract the screw from the implant and vertebral body.

Interbody Removal: Exposure is performed in the same fashion as the primary surgery. Once the implant has been accessed and the screws removed, reattach either inserter to the implant and remove gently. Care should be exercised to avoid neural and vascular elements during removal.

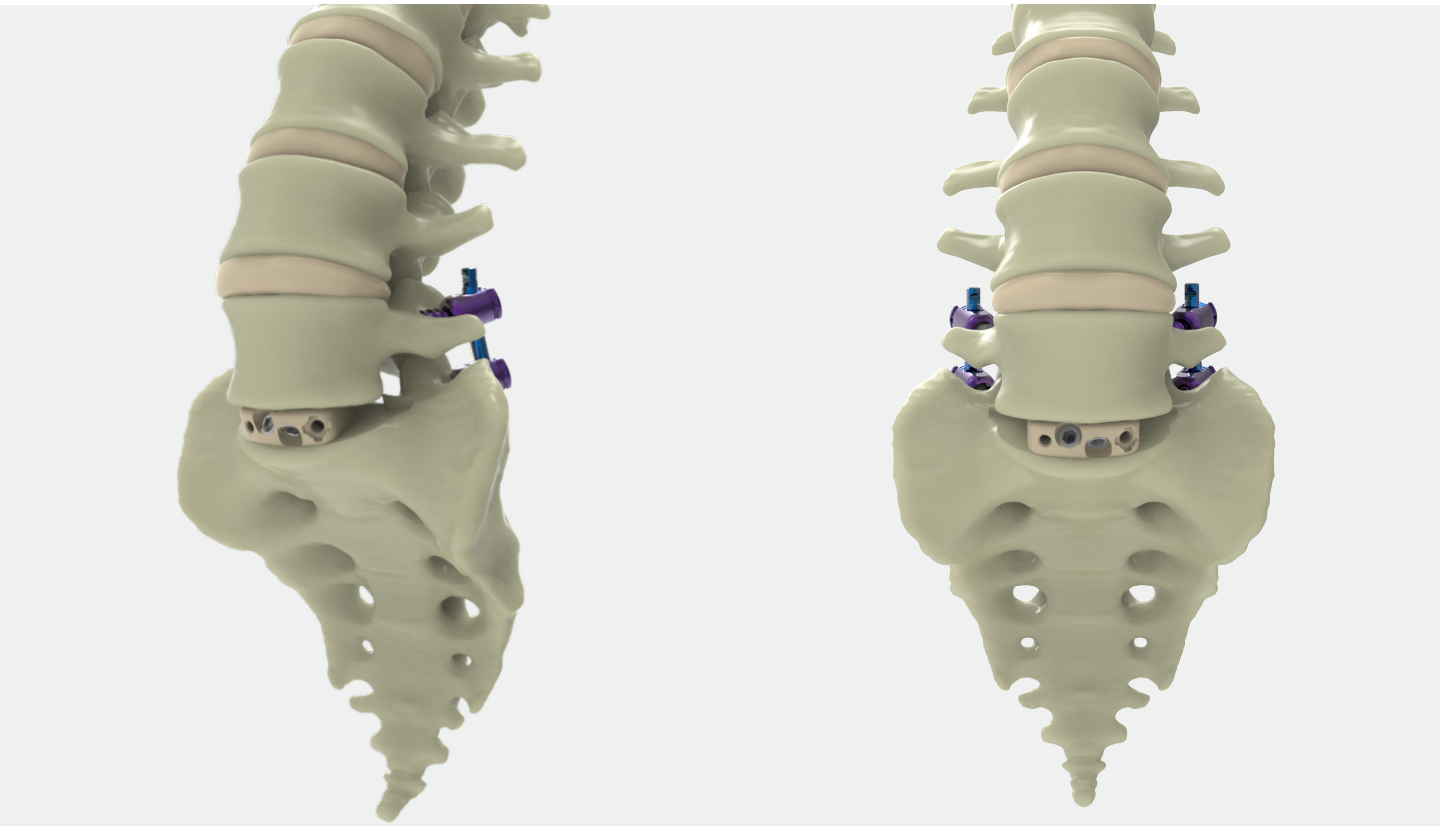


Fig. 17

Catalog

Brigade Lateral Implant Tray

Description	Part No.	QTY
NuVasive Generic Tray Lid	8801300	1
Brigade Lateral Caddy, Implant Tray	1791501	1
Brigade Lateral, 6x34x24mm 10°	6968439	1
Brigade Lateral, 8x34x24mm 10°	6968441	1
Brigade Lateral, 10x34x24mm 10°	6968443	1
Brigade Lateral, 6x34x24mm 15°	6982634	1
Brigade Lateral, 8x34x24mm 15°	6982834	1
Brigade Lateral, 10x34x24mm 15°	6983034	1
Brigade Lateral, 6x34x24mm 20°	6983634	1
Brigade Lateral, 8x34x24mm 20°	6983834	1
Brigade Lateral, 10x34x24mm 20°	6984034	1
Brigade Lateral, 6x34x24mm 25°	6984634	1
Brigade Lateral, 8x34x24mm 25°	6984834	1
Brigade Lateral, 10x34x24mm 25°	6985034	1
Brigade Lateral, 6x38x28mm 10°	6968466	1
Brigade Lateral, 8x38x28mm 10°	6968468	1
Brigade Lateral, 10x38x28mm 10°	6968470	1
Brigade Lateral, 6x38x28mm 15°	6982638	1

Description	Part No.	QTY
Brigade Lateral, 8x38x28mm 15°	6982838	1
Brigade Lateral, 10x38x28mm 15°	6983038	1
Brigade Lateral, 6x38x28mm 20°	6983638	1
Brigade Lateral, 8x38x28mm 20°	6983838	1
Brigade Lateral, 10x38x28mm 20°	6984038	1
Brigade Lateral, 6x38x28mm 25°	6984638	1
Brigade Lateral, 8x38x28mm 25°	6984838	1
Brigade Lateral, 10x38x28mm 25°	6985038	1
Brigade Caddy, Screw	1593451	1
CoRoent XLR-F Screw, 4.5x20mm	8594520	4
CoRoent XLR-F Screw, 4.5x22.5mm	8594522	4
CoRoent XLR-F Screw, 4.5x25mm	8594525	4
CoRoent XLR-F Screw, 5.5x20mm	8595520	4
CoRoent XLR-F Screw, 5.5x22.5mm	8595522	4
CoRoent XLR-F Screw, 5.5x25mm	8595525	4
Brigade Lateral Nipple Mat	1791502	1
Brigade Lateral Base, Implant Tray	1791500	1

Brigade Lateral Instrument Tray

Description	Part No.	QTY
Generic NuVasive Tray Lid	1660362	1
Brigade Lateral Top, Instrument Tray	1791601	1
Brigade Lateral Trial Caddy, Ins Tray	1791603	1
Brigade Lateral Trial, 6x34x24mm 10°	1903310	1
Brigade Lateral Trial, 8x34x24mm 10°	1903312	1
Brigade Lateral Trial, 10x34x24mm 10°	1903314	1
Brigade Lateral Trial, 6x34x24mm 15°	1903328	1
Brigade Lateral Trial, 8x34x24mm 15°	1903330	1
Brigade Lateral Trial, 10x34x24mm 15°	1903332	1
Brigade Lateral Trial, 6x34x24mm 20°	1903337	1
Brigade Lateral Trial, 8x34x24mm 20°	1903339	1
Brigade Lateral Trial, 10x34x24mm 20°	1903341	1
Brigade Lateral Trial, 6x34x24mm 25°	1903346	1
Brigade Lateral Trial, 8x34x24mm 25°	1903348	1
Brigade Lateral Trial, 10x34x24mm 25°	1903350	1
Brigade Lateral Trial, 6x38x28mm 10°	1903499	1
Brigade Lateral Trial, 8x38x28mm 10°	1903501	1
Brigade Lateral Trial, 10x38x28mm 10°	1903503	1
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Brigade Lateral Trial, 8x38x28mm 15°	1903519	1
Brigade Lateral Trial, 10x38x28mm 15°	1903521	1
Brigade Lateral Trial, 6x38x28mm 20°	1903526	1
Brigade Lateral Trial, 8x38x28mm 20°	1903528	1
Brigade Lateral Trial, 10x38x28mm 20°	1903530	1

Description	Part No.	QTY
Brigade Lateral Trial, 6x38x28mm 25°	1903535	1
Brigade Lateral Trial, 8x38x28mm 25°	1903537	1
Brigade Lateral Trial, 10x38x28mm 25°	1903539	1
Brigade Hyperlordotic Inserter, Trial	7981213	2
Brigade Lateral Inserter, Direct Ant	D1859930	1
Brigade Lateral Tamp	1859970	1
Universal Handle, Straight	6180016	1
Brigade T-Handle	6180018	1
Brigade Lateral T-Handle, Non-Ratch	1859950	1
Brigade Driver, Solid Self-Retaining	7990008	1
Brigade Driver, Solid Ball End	7990011	1
Brigade Lateral Awl, 15mm Straight	D1859960	1
Brigade Driver, Angled Short	D7990001	1
Brigade Driver, Angled Retaining	D7990007	1
Brigade Lateral Driver, U-Joint Short	1859902	1
Brigade Lateral Driver, U-Joint Long	1859900	1
Brigade Lateral Driver, U-Joint Ball Hex	1859908	1
Brigade Awl, 15mm Angled	D6590229	1
Brigade Lateral Base w/ Bottom, Ins Tray	1791600	1

Instructions for Use

INDICATIONS FOR USE

The Brigade Lateral Interbody System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Lateral Interbody System lordotic cages must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Brigade Lateral Interbody System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The Brigade Lateral Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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.
- 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 that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal. The treatment of multilevel degenerative scoliosis may be associated with a lower interbody fusion rate compared to one- and two-level interbody fusions. 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
- Neurological, vascular or visceral injury
- 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
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS 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 specifictraining in the use of this spinal system because this is a technically demanding procedure presenting a riskof serious injury to the patient.

Correct selection of the implant is extremely important. The potential for success is increased by theselection of the proper size of the implant. While proper selection can minimize risks, the size and shape ofhuman 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.

It is important to select the appropriate length Brigade screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

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

During Screw placement, use lateral fluoroscopy to ensure proper Screw trajectory of 35° or 45° cranial or caudal.

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 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.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Based on fatigue testing results, when using the Brigade 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.

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.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

Additional care should be taken at the lower levels of the lumbar spine due to the obstruction of anatomical structures, such as the iliac crest and iliac vessels, surgical access for the subject device at the these levels may not be feasible.

Instructions for Use (cont.)

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/Do Not Re-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.

MRI Safety Information: The Brigade System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Brigade System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use Brigade System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system. All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

PRE-OPERATIVE WARNINGS

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementionedcontraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratchedor damaged. Implants and instruments should be protected during storage and from corrosiveenvironments.
- Refer to Cleaning and Sterilization Instructions in the Instructions for Use for all non-sterile parts.
- 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.

Please refer to the Instructions for Use for additional important labeling information.

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