The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon’s medical judgment as to the best treatment for each patient. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential. Only those individuals with specialized training and experience in spinal surgery should attempt to use the Breckenridge Intervertebral body/VBR Fusion System. Refer to the Instructions for Use for a more complete description of indications, contraindications, warnings, cautions and other information about the system.

THE BRECKENRIDGE™ OLIF INTERVERTEBRAL BODY FUSION SYSTEM

Oblique Lumbar Interbody Fusion

The Breckenridge™ OLIF Intervertebral Body System represents another Surgeon Driven Innovation™ from Lanx. The Breckenridge OLIF system is designed and engineered for ease of insertion and placement. It can be placed into the disc space through a Posterior Lumbar Interbody Fusion (PLIF) or a Transforaminal Lumbar Interbody Fusion (TLIF) approach. For a TLIF procedure, there is no need to turn the implant inside the disc space, as it is designed to be positioned obliquely across the midline. Breckenridge OLIF is manufactured from radiolucent PEEK-OPTIMA® and contains tantalum markers for radiographic visualization.

Features:

- A bullet shaped nose for self-distraction and easy insertion
- Curved endplate surfaces to match endplate anatomy and distribute load.
- Angled teeth on the endplate surfaces to allow for easy insertion and prevention of retropulsion
- 3 footprint options and multiple height options to match anatomic conditions
- A large graft space for autogenous bone graft
- Low profile for visualization during less invasive procedures
- Straight or bayonetted instruments for open or MIS procedures
- Compatible for use with the Descent™ Guided PEEK Interbody System and the Telluride™ Port System

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

When used as a lumbar intervertebral body fusion device, the Breckenridge OLIF implant is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Breckenridge device is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Spinal Fixation Systems (Aspen™, Silverton™, Silverton-D™ and Telluride™).
PRE-SURGERY PREPARATION

- Review and inspect all instrumentation and implants prior to sterilization.
  
  **Caution:** Special attention should be given to the inspection of the threads on the Draw Rod (if damaged – return to Lanx and use the second Draw Rod supplied in the surgical case).

- Replace or add any needed components for the planned surgery.

- Primary surgeon must be fully experienced with the required spinal fusion techniques.

- Please read the Instructions for Use (IFU) for a list of warnings, cautions, contraindications, risks and product description.

SURGICAL EXPOSURE AND SITE PREPARATION

1. The patient is prepped, positioned and draped in the usual fashion.

2. Expose the affected levels via a standard incision and tissue dissection.

3. Perform any necessary bone and tissue removal.

4. Remove disc material and prepare endplates at the appropriate level using Lanx Disc Prep Instruments.
   - Use a combination of curettes, rasps, osteotomes, disc shavers or box chisels to remove the disc material and cartilage from the vertebral endplates.
   - Sequentially larger instruments are used until debridement is complete.

5. After preparing the intervertebral disc space, the **bayoneted trials** (8800-65XX, 66XX, 67XX) or **straight trials** (8800-62XX, 63XX, 64XX) are inserted using the **t-handle** (2200-1112), starting with smallest trial height and length. (Fig. 1)

Select the appropriate length of trial (23 mm, 28 mm or 32 mm) using radiographic imaging to fit the anatomic conditions, and insert progressively increasing height of the trials until the appropriate height distraction is achieved.

**Note:** Use of trials is recommended to ensure usage of appropriate sized implant.
6. Once the appropriately sized trial has been chosen, select the corresponding sized Breckenridge OLIF implant from the implant caddy.

Note: It is recommended to pack the central graft cavity of the implant with autogenous bone graft prior to assembly to the graft inserter.

7. Assemble the OLIF implant to the **OLIF inserter**, which comes in two styles for optimal visualization during implant placement: with a **side handle** (8800-6105), or with a **palm handle** (8800-6106) which must be ordered separately. (Fig. 2)

   a. Assemble the **OLIF inserter draw rod** (8800-6106-13) through the center of the implant inserter and secure by retracting the quick connect thumb wheel of the inserter handle, fully inserting the draw rod, and then releasing the quick connect thumb wheel. (Fig. 3)

   b. The desired implant is loaded by threading onto the inserter assembly (turn the quick connect thumb wheel in a clockwise rotation).
8. Insert the OLIF implant into the disc space with the teeth oriented in the cranio-caudal direction. (Fig. 4)

**Caution:** The implant should be inserted with the teeth in direct contact with the endplates and is not intended for rotation within the disc space.

a. Slight impaction on the inserter can be used to gently advance the implant into the prepared disc space. Radiographically confirm the position and placement of the implant.

b. Remove the inserter by turning the thumb wheel counter-clockwise.

c. Optional fine tuning of implant position can be achieved using the *straight impactor* (8800-2016) until the implant is in its final position. (Fig. 5)

Additional graft material can be inserted into the disc space at this time.
CLOSURE


10. Close wound and dress in the usual fashion.

POSTOPERATIVE CARE

An appropriate analgesic, antibiotic, immobilization, and home care regimen must be followed. Using appropriate surgical dressings while the soft tissues are healing can help prevent injury to the related neural structures, and ultimately achieve fusion. The patient must be warned to avoid falls or sudden jolts.

REMOVING THE BRECKENRIDGE OLIF IMPLANT

1. Attach the OLIF inserter with either the side handle (8800-6105) or the palm handle (8800-6106), or the OLIF removal instrument (8800-6104) to the implant.

2. Attach the slap hammer (2200-1013) to the instrument or use a mallet to tap the instrument until the implant is removed from disc space.

PACKAGING

Check packages to ensure all components are intact upon receipt. Check all sets and confirm that all instruments and implants are present. Inspect all set components for functionality to ensure there is no damage prior to use. Immediately return any damaged packages or products to Lanx without using them.

HANDLING AND STORAGE

Breckenridge implants and instruments must be handled, stored, and opened in such a way that they are protected from inadvertent damage or contamination. The Breckenridge device does not have a labeled shelf life. The aging process has no observed affect on the mechanical performance of the materials. Verify the proper function of the specialized surgical instruments needed for the Breckenridge procedure prior to every surgical procedure.
CLEANING AND DECONTAMINATION

Breckenridge implants and instruments are not supplied sterile. Before sterilization, implants and instruments must be cleaned using the following procedures.

Caution: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used.

Note: Some instruments may require disassembly prior to cleaning.

Note: Special attention should be given to the draw rod. Avoid the use of pliers to disassemble the draw rod. This action will cause damage to the draw rod threads.

Machine Cleaning Instructions (Recommended)

1. Prepare cleaning detergent
   a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. Prepare devices for soaking
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. Clean and soak in bath
   a. Immerse devices in prepared bath.
   b. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in water, ensuring that all visible soil is removed.
   c. Whenever applicable:
      i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
      ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
      iii. Repeatedly operate/bend/articulate movable joints while cleaning.
      iv. Brush the inside of hollow spaces along their entire length.
   d. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.

4. Load devices into washer
   a. Place devices so they do not collide during operation.
   b. Place heavy items at the bottom and hollow objects in the washing machine baskets.
   c. Ensure no part is obstructed by large objects.
   d. Place articulating instruments in the fully open position and cannulated instruments horizontally.
   e. Place disassembled instruments in the washing machine baskets.
5. **Washing and drying cycles**
   a. 2 minutes: Prewash with cold water; drain.
   b. 5 minutes: Detergent wash with hot water; drain.
   c. 2 minutes: Neutralize with neutral pH detergent; drain.
   d. 2 minutes: Rinse with hot water; drain.
   e. Dry with hot air at a maximum of 115°C.

6. **Inspect**
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.

**Manual Cleaning Instructions**

1. **Prepare cleaning detergent**
   a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. **Prepare devices for soaking**
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. **Clean and soak in bath**
   a. Immerse devices in prepared bath.
   b. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in water, ensuring that all visible soil is removed.
   c. Whenever applicable:
      i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
      ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
      iii. Repeatedly operate/bend/articulate movable joints while cleaning.
      iv. Brush the inside of hollow spaces along their entire length.
   d. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.

4. **Rinse**
   a. Remove the devices from the soak bath.
   b. Thoroughly rinse the devices under running water for a minimum of 1 minute.
   c. Thoroughly flush cannulae, lumens and holes.
5. Ultrasonic bath
   a. Prepare an ultrasonic bath containing a blood-dissolving detergent, following the manufacturer’s instructions for preparation and use.
   b. Cover/seal the devices during transport from the rinse to the ultrasonic bath to prevent contamination.
   c. Place devices in the ultrasonic bath.
   d. Ensure that the devices are completely submerged and do not overlap.
   e. Sonicate for 15 minutes. To avoid corrosion, do not exceed 15 minutes.

6. Rinse in sterile water
   a. Thoroughly rinse the devices with sterile purified water (i.e., RO or DI) for a minimum of 3 minutes.

7. Dry
   a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g., interiors of cannulae).
   b. Be sure to completely dry the devices immediately after rinse to inhibit corrosion.

8. Inspect
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.

STERILIZATION

The Breckenridge device is provided non-sterile and is intended for the user to be cleaned and sterilized by the user. The recommended sterilization process for the implants is steam autoclave sterilization. Implants must be sterilized prior to implantation. Use of a wrap FDA-cleared wrap is recommended to maintain sterility prior to use.

The following standard steam sterilization cycle must be used for the Breckenridge OLIF implants and instruments.

<p>| BRECKENRIDGE OLIF STERILIZATION PROTOCOL |
|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>PreVacuum</td>
<td>132 °C (270 °F)</td>
<td>8 minutes</td>
<td>55 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>132 °C (270 °F)</td>
<td>18 minutes</td>
<td>55 minutes</td>
</tr>
</tbody>
</table>

Instruments are supplied non-sterile and are designed to be reused, which is typical for surgical instruments.

<p>| BRECKENRIDGE INSTRUMENT STERILIZATION PROTOCOL |
|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>PreVacuum</td>
<td>132 °C (270 °F)</td>
<td>8 minutes</td>
<td>55 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>132 °C (270 °F)</td>
<td>24 minutes</td>
<td>55 minutes</td>
</tr>
</tbody>
</table>

The recommended sterilization cycles have been validated to assure a Sterility Assurance Level (SAL) of at least $10^{-6}$.

Alternative sterilization methods or cycles may be used for the instruments, but must be validated according to accepted laboratory practice. There is no validated flash sterilization method authorized.
### INSTRUMENTS FOR THE THE BRECKENRIDGE OLIF INTERVERTEBRAL BODY FUSION SYSTEM

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slap Hammer</td>
<td>2200-1013</td>
</tr>
<tr>
<td>T-Handle</td>
<td>2200-1112</td>
</tr>
<tr>
<td>Side Handle Inserter</td>
<td>8800-6105</td>
</tr>
<tr>
<td>Palm Handle Inserter*</td>
<td>8800-6106</td>
</tr>
<tr>
<td>Threaded Implant Removal Instrument</td>
<td>8800-6104</td>
</tr>
<tr>
<td>Inserter Draw Rod</td>
<td>8800-6106-13</td>
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<tr>
<td>Straight Impactor</td>
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<tr>
<td>Curved Impactor*</td>
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#### BAYONETED TRIALS

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<thead>
<tr>
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<th>10x23 Footprint</th>
<th>11x28 Footprint</th>
<th>13x32 Footprint</th>
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<tbody>
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<td>8800-6707</td>
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<td>8 mm</td>
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<td>8800-6608</td>
<td>8800-6708</td>
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<td>8800-6609</td>
<td>8800-6709</td>
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<td>8800-6710</td>
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<td>11 mm</td>
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<td>8800-6711</td>
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<td>12 mm</td>
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<td>8800-6712</td>
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<td>8800-6713</td>
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<tr>
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Available in Bayoneted case

#### STRAIGHT TRIALS

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<thead>
<tr>
<th>Height</th>
<th>10x23 Footprint</th>
<th>11x28 Footprint</th>
<th>13x32 Footprint</th>
</tr>
</thead>
<tbody>
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<td>7 mm</td>
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<td>8 mm</td>
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<td>8800-6408</td>
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<td>8800-6409</td>
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<tr>
<td>10 mm</td>
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<td>8800-6310</td>
<td>8800-6410</td>
</tr>
<tr>
<td>11 mm</td>
<td>8800-6211</td>
<td>8800-6311</td>
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<tr>
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<td>14 mm</td>
<td>8800-6214</td>
<td>8800-6314</td>
<td>8800-6414</td>
</tr>
</tbody>
</table>

Available in Straight case

*Special order Item
PRODUCT COMPLAINTS

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Lanx (email: Complaints@lanx.com Tel: 866.378.4195). When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint and patient case number. Sterilize and return all component(s) to your local Lanx representative. Notify Lanx immediately of an incident resulting in patient death or serious injury.

FURTHER INFORMATION

If further directions for use of this system are needed, contact Lanx Customer Service (email: CustomerSupport@lanx.com, Tel: 303.443.7500, Fax: 303.443.7501).
Implant Radiographic Marker Positions

23mm Length: 1.75mm
28mm Length: 2.0mm
32mm Length: 2.25mm

3.5mm 0.8mm

Tantalum Marker Dimensions
Diameter = 0.9mm
Length / Height = 1.6mm

With innovative solutions uniquely designed by surgeons for surgeons, Lanx specializes in devices and systems for all segments of spinal surgery. Integrating leading technology and state-of-the art engineering, our products have been created to meet the specific surgical needs of our customers and improve outcomes for their patients.

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Ph 303.443.7500 Fax 303.443.7501 www.lanx.com

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