

**BRECKENRIDGE™**  
Intervertebral Body/VBR Fusion System



ACDF Anterior Cervical Discectomy and Fusion

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™ ACDF 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™ ACDF INTERVERTEBRAL BODY FUSION SYSTEM

### Anterior Cervical Discectomy and Fusion System

The Breckenridge™ ACDF Intervertebral Body Fusion System is designed and engineered for ease of insertion and placement. It is intended to be used as a cervical intervertebral body fusion device at one level from the C2-C3 disc to the C7-T1 disc. The implant features three footprint options to fit the patient's unique anatomy. Each interbody implant is manufactured from radiolucent PEEK-OPTIMA® LT1 and contains tantalum makers for radiographic visualization.

#### Features:

- Three footprint options, two lordotic angles, and multiple height options to match anatomic conditions
- A very large graft space for autogenous bone graft in each footprint size
- A threaded inserter to allow for repositioning after placement
- A bullet-shaped nose for self-distraction and easy insertion
- Reverse angled teeth on the endplate surfaces to allow for easy insertion and prevention of retropulsion



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

## INDICATIONS FOR USE

When used as a cervical intervertebral body fusion device, the Breckenridge 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 spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Breckenridge device is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Anterior Cervical Plate System.

## 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).
- Implants and instruments are provided non-sterile and must be cleaned and sterilized prior use. Cleaning and decontamination instructions begin on page 6.
- Replace or add any needed components for the planned surgery.
- Primary surgeon must be fully experienced with the required spinal fusion techniques.

## SURGICAL EXPOSURE AND SITE PREPARATION

1. The patient is prepped, positioned and draped in the usual fashion.
2. Expose the affected level 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.
  - Use a combination of rongeurs, curettes, rasps, or osteotomes to remove the disc material and cartilage from the vertebral endplates.



Fig. 1

5. After preparing the intervertebral disc space, the **trials** (5°: 8842-15XX, -16XX, -17XX; 0°: 8842-11XX, -12XX, -13XX) are inserted, starting with smallest trial height and footprint. (Fig. 1)

The appropriate trial footprint (12x14, 13x16, or 14x18 mm) is selected using radiographic imaging to fit the anatomic conditions. Progressively insert the trials by increasing heights until the appropriate distraction is achieved.

**Note:** Use of trials is recommended to ensure usage of appropriate sized implant.

# INSERTING THE BRECKENRIDGE™ ACDF IMPLANT



Fig. 2

6. Once the appropriately sized trial has been chosen, select the corresponding sized Breckenridge ACDF implant from the implant caddy.

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

7. Assemble the ACDF implant to the **ACDF inserter (8840-1000)**. (Fig. 2)

- a. Assemble the draw rod of the ACDF inserter through the back end of the inserter shaft and secure by pressing until the snap ring engages.
- b. Push the draw rod slightly to expose the threaded tip, then load the desired implant and turn the thumb wheel clockwise until the implant is secured.



Fig. 3

8. Insert the ACDF implant into the disc space. (Fig. 3)

- a. 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 the implant position can be achieved using the **ACDF impactor (8841-1000)** until the implant is in its final position. (Fig. 4a-c)

Additional autogenous graft material may be inserted into the disc space at this time.



Fig. 4a



Fig. 4b



Fig. 4c

## CLOSURE

9. Compress vertebral bodies on the implant and secure with a Lanx Anterior Cervical Plate System (Snowcap™).
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™ ACDF IMPLANT

1. Attach the ACDF Inserter (8840-1000) or ACDF Removal Instrument (8844-1000) to the implant.
2. Pull the instrument until implant is removed from disc space.

# CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Presence of fever or infection (systemic, spinal, or localized).
- Pregnancy.
- Severe osteopenia.
- Prior fusion at the level to be treated.
- Any condition not described in the Indications for Use.

Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, patients with metal sensitivity or allergies to the implant materials, and patients unwilling or unable to cooperate with postoperative care instructions.

# RISKS

Potential risks identified with the use of this device system, which may require additional surgery include: device component failure (expulsion, loosening or breakage of the implant). Failure may occur as a result of implant stress, loss of fixation, non-union, infection, or subsequent fracture of the vertebra. Implant failure may result in neurological injury and vascular or visceral injury. These devices can break when subjected to increased loading associated with delayed union or non-union. Internal fixation appliances are load-sharing devices, which hold a fracture in alignment until healing occurs.

If healing is delayed or does not occur, the implant could eventually break due to material fatigue. The patient's weight, activity level, and compliance to weight bearing or activity restrictions can have an effect on the stresses to which the implant is subjected. Such stresses may affect the long term survival of the implant. The following warnings do not include all possible adverse effects, but are important considerations particular to spinal fixation devices.

# WARNINGS

Federal Law (USA) restricts this device to sale by or on the order of a licensed physician only. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery. The risk of a device expulsion and migration is higher without the use of supplemental fixation.

Based on fatigue testing results, 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.

# CAUTIONS

Only experienced spinal surgeons should perform the implantation of this system with specific training in the use of vertebral implants. The surgical procedure is technically demanding and presents a risk of serious injury to the patient.

- The Breckenridge device is intended to be used only by surgeons specialized in spinal surgery and having thorough knowledge of vertebral anatomy, regional vertebral morphology, and the biomechanical principles of the spine. It is advised that the surgeon also be thoroughly familiar with the surgical techniques relative to the use of the device.
- Risks associated with neurosurgery, general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using implants, as well as alternative treatment methods, are explained to the patient.
- Correct selection and placement of the implants is extremely important. Implant selection must be based upon the bone defect to be treated as well as the patient's weight, height, occupation, or degree of physical activity.
- Proper handling of the implant before and during the operation is crucial.
- The Breckenridge device must only be used with appropriate secondary stabilization instrumentation. The Breckenridge device must not be used with vertebral components or instruments from other manufacturers.
- Before use, inspect all instrumentation for possible damage, wear, or non-function. Damaged or defective instruments should not be used or processed. Contact your local Lanx representative or dealer for repair or replacement.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.
- Do not apply excessive force or stress. Misuse can damage instruments or implants.
- Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.
- The instrument components of the Breckenridge system should NOT be used with the instrument components from any other system or manufacturer.
- The implant components of the Breckenridge system are NOT compatible with implant systems from other manufacturers.
- The Breckenridge device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The Breckenridge device has not been tested for heating or migration in the MR environment.
- The Breckenridge device is for single use only. Reuse of the implant components may result in reduced mechanical performance, malfunction, or failure of the device.
- Mixing of dissimilar metals can accelerate or initiate the corrosion process. Titanium components must NOT be used together in building a construct that involves other implant materials. Titanium and cobalt chrome may be used together within the same construct.
- Federal law (USA) restricts this device to sale by or on the order of a physician.

## PACKAGING

Components are packaged in metal sterilization cases and/or sealed polyethylene bags. 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.

### 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 implants and instruments.

## BRECKENRIDGE ACFD STERILIZATION PROTOCOL

Method	Cycle	Temperature	Exposure Time	Minimum Dry Time
Steam	PreVacuum	132° C (270° F)	8 minutes	55 minutes
Steam	Gravity	132° C (270° F)	18 minutes	55 minutes

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

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

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 ACDF CERVICAL INTERBODY SYSTEM



Insertion | 8840-1000



Impactor | 8841-1000



Rasp | 8843-0105



### Trials 0° Parallel

8842-1105, 7, 9, 11 Trial 12x14 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm

8842-1205, 7, 9, 11 Trial 13x16 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm

8842-1305, 7, 9, 11 Trial 14x18 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm

### Trials 5° Lordotic

8842-1505, 7, 9, 11 Trial 12x14 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm

8842-1605, 7, 9, 11 Trial 13x16 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm

8842-1705, 7, 9, 11 Trial 14x18 by heights 5/6 mm, 7/8 mm, 9/10 mm, 11/12 mm



Mallet | 3300-1005



Removal Tool | 8844-1000

### 5° LORDOTIC IMPLANTS

Height	12x14 Footprint	13x16 Footprint	14x18 Footprint
5 mm	8824-4505	8824-4605	8824-4705
6 mm	8824-4506	8824-4606	8824-4706
7 mm	8824-4507	8824-4607	8824-4707
8 mm	8824-4508	8824-4608	8824-4708
9 mm	8824-4509	8824-4609	8824-4709
10 mm	8824-4510	8824-4610	8824-4710
11 mm	8824-4511	8824-4611	8824-4711
12 mm	8824-4512	8824-4612	8824-4712



12x14 Footprint



13x16 Footprint



14x18 Footprint

### 0° PARALLEL IMPLANTS

Height	12x14 Footprint	13x16 Footprint	14x18 Footprint
5 mm	8824-4105	8824-4205	8824-4305
6 mm	8824-4106	8824-4206	8824-4306
7 mm	8824-4107	8824-4207	8824-4307
8 mm	8824-4108	8824-4208	8824-4308
9 mm	8824-4109	8824-4209	8824-4309
10 mm	8824-4110	8824-4210	8824-4310
11 mm	8824-4111	8824-4211	8824-4311
12 mm	8824-4112	8824-4212	8824-4312

**GRAFT VOLUMES 5° LORDOTIC (CC)**

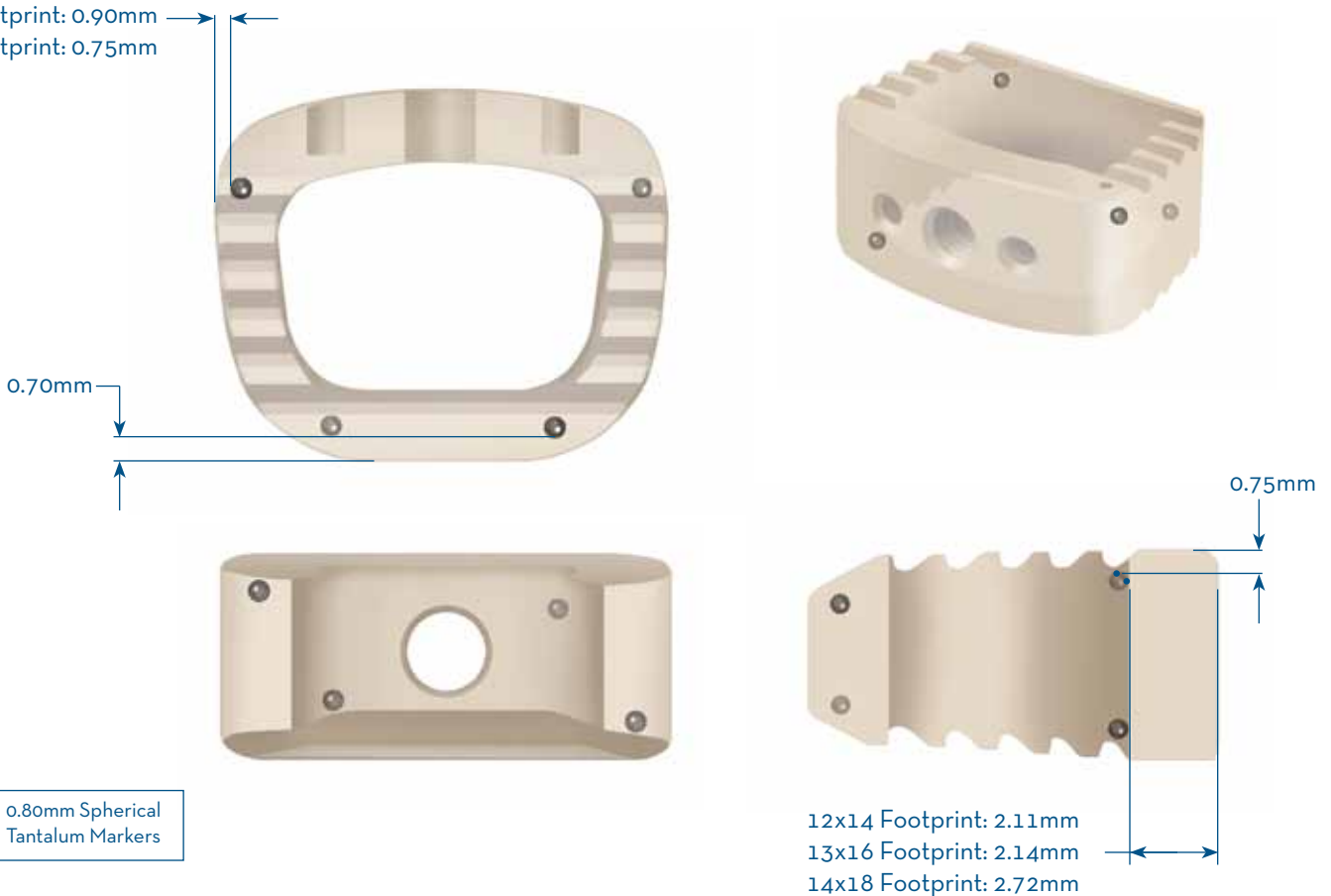
Height	12x14 Footprint	13x16 Footprint	14x18 Footprint
5 mm	0.29	0.39	0.49
6 mm	0.35	0.47	0.61
7 mm	0.41	0.56	0.72
8 mm	0.47	0.65	0.83
9 mm	0.54	0.73	0.94
10 mm	0.60	0.82	1.06
11 mm	0.67	0.91	1.17
12 mm	0.73	1.00	1.28

**GRAFT VOLUMES 0° PARALLEL (CC)**

Height	12x14 Footprint	13x16 Footprint	14x18 Footprint
5 mm	0.32	0.44	0.56
6 mm	0.38	0.52	0.68
7 mm	0.45	0.61	0.79
8 mm	0.51	0.70	0.90
9 mm	0.57	0.79	1.02
10 mm	0.64	0.87	1.13
11 mm	0.70	0.96	1.24
12 mm	0.76	1.05	1.36

**Radiographic Marker Positions**

12x14 Footprint: 0.72mm  
 13x16 Footprint: 0.90mm  
 14x18 Footprint: 0.75mm





## **PRODUCT COMPLAINTS**

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Lanx (email: [Complaints@lanx.com](mailto: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](mailto:CustomerSupport@lanx.com), Tel: 303.443.7500, Fax: 303.443.7501).

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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