INFUSE™ BONE GRAFT/
LT-CAGE™ LUMBAR TAPERED FUSION DEVICE
Open Surgical Technique
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Important Medical Information
Once the appropriate spinal level has been identified, the proper size device must be selected. Templates are available to facilitate proper device selection from plain radiographs, CT or MRI scans. These templates are available in appropriate reduction or magnification ratios for radiographs and CT or MRI scans (Figure 1). To determine the magnification of a CT or MRI scan, match the scale on the template with the scale on the CT or MRI scan. Example templates are shown below.

These templates allow the surgeon to measure normal, adjacent disc space height and determine intraoperative distraction height. In using the templates, the physician must ensure that the devices remain within the lateral borders of the intervertebral disc space. Device length, reaming depth and countersink may also be assessed preoperatively using the templates.

Once the implant size is determined, note the diameter of the leading end. This diameter is used to reference the corresponding instrumentation. A color-coding system is used to differentiate each of the leading diameters.

14mm – Red
16mm – Green
18mm – Blue
Intraoperatively, the patient is placed on the operating table in a supine position. Compression stockings should be placed on the patient. General anesthesia with endotracheal intubation is administered.

The lumbar spine may be approached through either a transperitoneal or an anterior retroperitoneal exposure (Figure 2). The amount of great vessel release and retraction should be limited to that required for insertion of the instruments and devices. At the L4-L5 level, the iliolumbar and segmental vessels should be identified and ligated if necessary in order to achieve adequate mobilization of the great vessels. At L5-S1, the middle sacral artery is typically ligated and divided. Care should be taken at L5-S1 to only use blunt dissection in order to minimize injury to the presacral neural plexus.
The center of the disc should be located and marked with the assistance of both A/P and lateral fluoroscopy. Accurate identification of the midline is essential for the successful implantation of two LT-CAGE™ Device components.

Attach the Centering Pin to the Centering Pin/Template Shaft and place at the center of the disc (Figure 3). The position is checked with A/P fluoroscopy and adjusted as needed. Since a block discectomy is to be performed, marks are placed at midline on the vertebral bodies both cephalad and caudal to the Centering Pin (Figure 3A). A lateral fluoroscopic check is helpful in confirming the targeted lumbar level (Figure 3B).

**Tip:** Mark the vertebral bodies both cephalad and caudal to the centering pin.

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**Figure 3**

**Figure 3A**

**Figure 3B**
An en bloc discectomy is typically performed. This provides adequate space for insertion of the Distractors, ensuring that the disc is not displaced during insertion. The disc removal instrumentation will simultaneously remove the required volume of remaining disc and prepare the adjacent vertebral bodies for the threaded device. Anterior osteophytes should be removed to ensure accurate seating of the instrumentation against the vertebral bodies.

Remove the Centering Pin from the Centering Pin Shaft and attach the appropriate size colored Template (14mm, 16mm, 18mm). Position the colored Template so the central notch is aligned with the midline.

Holding the appropriate colored Template against the disc space, identify and mark the lateral margins of the block discectomy (Figure 4). Incise the annulus sharply. Use a pituitary rongeur to remove the nucleus pulposus.

The instrumentation used to implant the LT-CAGE™ Device component centralizes within the annular window. Therefore, it is extremely important to properly create the annular window by centering the Template on the midline markings and incising the annulus along the lateral edges of the Template.

**Tip:** Remove any anterior osteophytes to ensure the instrumentation seats flush against the vertebral bodies.
Curettes are used to remove the cartilaginous endplates. These steps are performed under direct visualization, taking care not to perforate posteriorly or laterally. Lateral fluoroscopy may be used to confirm the extent of the posterior disc removal through visualization of discectomy instruments. Use care to avoid exceeding the lateral margins defined by the block discectomy Template annulus anterolaterally (Figure 5).

After completion of the block discectomy, the anterolateral annulus remains intact and acts to enhance device stability (Figure 6).

The procedure continues utilizing specific instrumentation for the appropriate diameter devices.
Sequential distraction is carried out using the Starter Distractor Driver and sized Distractor Tips (Figure 7). The Starter Distractors are sequentially driven into the disc space at midline, acting to develop the disc space height in preparation for the placement of the Distractor Assembly.

Starter Distractor sizes included in the general instrument tray are:

- 6mm
- 8mm
- 10mm
- 12mm

Mating Distractor Shafts (Figure 8) are located in the size specific trays.

The following distraction heights are provided with the corresponding instrument sets:

- 14mm instruments = 10mm Distraction
- 16mm instruments = 12mm Distraction
- 18mm instruments = 14mm Distraction

**Tip:** In addition to sequential distraction of the disc space, the Starter Distractors can help confirm the final distraction height.
If appropriate, the Starter Distraction step may be eliminated. Final distraction to the selected height follows.

The radiolucent Distractors are intended to provide contact with the endplates, resulting in uniform annular tensioning and disc space height restoration.

Mate the Cylindrical and C-Style Distractors and slide into the Double Barrel Sleeve. With the proximal end of the Distraction Shafts slightly proud, slide the Distraction Driver Cap along the slot in the Outer Sleeve; capturing the Distraction Shafts.

Insert the radiolucent Distractor Tips into the disc space. Verify midline placement by referencing the marks created in Step 1. Impact the Distractor Driver Cap until the Distractor Tips are fully seated (Figure 9). Radiographic markers in the Distractor Tips will help determine the position of the Distractors while seating. Remain parallel to the endplates during insertion and verify with lateral fluoroscopy. The intact anterolateral annulus will act to center the Distractors and reduce the lateral migration during impaction. Remove the Distractor Driver Cap by sliding the cap off the proximal end of the Distractors and Outer Sleeve.

Tip: Make sure the Distractor Driver Cap captures both the Distractors and the Outer Sleeve.
Place the Driver Cap and impact the Outer Sleeve until fully seated (Figure 10).

Fluoroscopic control is helpful in assessing distraction height and orientation of the Distractors. The Distractors act as a centering and alignment guide for the procedure, it is essential that they are located properly.

**Tip:** Prior to fully seating the Outer Sleeve, all vascular structures should be accurately identified and adequately retracted. Intraoperative fluoroscopy is useful in confirming that the Outer Sleeve is fully seated against the vertebral bodies and properly oriented within the disc space. The Outer Sleeve Barrel extensions are intended to assist in keeping soft tissue and vascular structures from slipping under the lateral margin of the Outer Sleeve.
With the Double Barrel Outer Sleeve fully seated, use the Instrument Remover to carefully remove the Cylindrical Distractor to allow a cylindrical working channel (Figure 11). The C-Styled Distractor remains in place (Figure 11A and Figure 11B).

Tip: The Distractors are “keyed” so that the Cylindrical Distractor must be removed first.
The appropriately sized Hollow Reamer is used to prepare the disc space for placement of the LT-CAGE™ Device components.

Attach the Depth Stop to the Reamer. Hold the knurled sections of the Depth Stop and compress, allowing the Depth Stop to move freely over the depth grooves. Slide the Depth Stop and orient the square window to show the etched depth markings on the shaft of the Reamer (Figure 12). Release the proximal knurled portion of the Depth Stop allowing it to lock in position. Verify that the desired depth compression appears in the window.

NOTE: The Depth Stop may need to be rotated to view the depth setting in the window.

Tip: The appropriate Depth Stop setting should be chosen based on the preoperative templating using axial CT or MRI scans. The depth selected should reflect the length of the threaded device and the desired depth of countersinking.
The T-handle (Figure 13) is attached. The Reamer is inserted into the Outer Sleeve and advanced in a clockwise motion until the Depth Stop contacts the top of the Outer Sleeve (Figure 14). Several passes may be taken (cleaning the Reamer after each pass) increasing the depth of penetration during each pass until the Depth Stop makes contact with the top of the Outer Sleeve. Fluoroscopy should be used to verify depth of reaming (Figure 14A).

**Tip:** Any sensation of resistance to easy progression during reaming should prompt removal and cleaning of the Reamer. When removing the Reamer, a continued clockwise rotation should be performed to aid in debris removal. The Reamer may be cleaned by wiping with a moist lap sponge or by inserting the Reamer Clean Out Tool through the clean out hole in the distal end of the Reamer.
Once the initial reaming is complete, insert the Reaming Plug into the Outer Sleeve (Figure 15 and Figure 15A). Remove the C-Styled Distractor and ream the contralateral side to the same depth.

**Tip:** Make sure both sides of the endplate are reamed to the same depth.
Step 1: Observing proper sterile technique, open the outer ACS package and place the inner package containing the two 1" x 2" collagen sponges in the sterile field. Open and place one of the two 5 mL syringes/needles into the sterile field.

Step 2: Using one of the two remaining 5 mL syringe/needles, withdraw 3.2 mL of sterile water for injection.

Step 3: Reconstitute the rhBMP-2 with 3.2 mL of sterile water.

Step 4: Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 5 mL syringe/needle, repeat steps 2 & 3 with the remaining vial of sterile water and vial of rhBMP-2.

Step 2: Using the other 5 mL syringe/needle, withdraw 3.2 mL of sterile water for injection.

Step 3: Reconstitute the rhBMP-2 with 3.2 mL of sterile water.

Step 2: Using the other 10 mL syringe/needle, withdraw 8.4 mL of sterile water for injection.

Step 3: Reconstitute the rhBMP-2 with 8.4 mL of sterile water.

Step 2: Using the other 10 mL syringe/needle, withdraw 8.4 mL of sterile water for injection.

Step 3: Reconstitute the rhBMP-2 with 8.4 mL of sterile water.
**NON-STERILE FIELD**

**Step 4** Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

**STERILE FIELD**

**Step 5** Open the inner ACS package leaving all collagen sponges in the plastic tray.

**Step 6** In the sterile field use the 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

**STERILE FIELD**

**Step 5** Open the inner ACS package leaving all collagen sponges in the plastic tray.

**Step 7** Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on the first 1” x 2” collagen sponges.

**NON-STERILE FIELD**

**Step 5** Open the inner ACS package leaving all collagen sponges in the plastic tray.

**Step 6** In the sterile field use the 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

**NON-STERILE FIELD**

**Step 4** Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

**STERILE FIELD**

**Step 5** Open the inner ACS package leaving all collagen sponges in the plastic tray.

**Step 6** In the sterile field use the 10 mL syringe/needle to withdraw 4.0 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

**STERILE FIELD**

**Step 5** Open the inner ACS package.

**Step 6** In the sterile field use the 10 mL syringe/needle to withdraw 4.0 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.
Step 7 Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on one of the 1” x 2” collagen sponges.

Step 8 Using the same 5 mL syringe/needle, repeat steps 6 & 7 for the remaining 1” x 2” collagen sponge.

Before proceeding, let wetted collagen sponges stand for a minimum of 15 minutes. Use within 2 hours.

DO NOT use irrigation or suction near implanted device
Note: During handling avoid excessive squeezing of the wetted sponge.

Step 8 Using the same 5 mL syringe/needle, repeat steps 6 & 7 for the second 1” x 2” collagen sponge.

Step 10 Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on the third 1” x 2” collagen sponge.

Step 9 In the sterile field use the second 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

Step 11 Using the second 5 mL syringe/needle, repeat steps 9 & 10 for the fourth 1” x 2” collagen sponge.

Before proceeding, let wetted collagen sponges stand for a minimum of 15 minutes. Use within 2 hours.

DO NOT use irrigation or suction near implanted device
Note: During handling avoid excessive squeezing of the wetted sponge.

Step 7 Uniformly distribute 4.0 mL of reconstituted rhBMP-2 on three of the 1” x 2” collagen sponges.

Step 8 Using the same 10 mL syringe/needle, repeat steps 6 & 7 for the remaining three 1” x 2” collagen sponges.

Before proceeding, let wetted collagen sponges stand for a minimum of 15 minutes. Use within 2 hours.

DO NOT use irrigation or suction near implanted device
Note: During handling avoid excessive squeezing of the wetted sponge.

Step 7 Uniformly distribute 4.0 mL of reconstituted rhBMP-2 on one of the 1½” x 4” collagen sponges.

Step 8 Using the 10 mL syringe/needle, repeat steps 6 & 7 for the remaining 1½” x 4” collagen sponge.

Before proceeding, let wetted collagen sponges stand for a minimum of 15 minutes. Use within 2 hours.

DO NOT use irrigation or suction near implanted device
Note: During handling avoid excessive squeezing of the wetted sponge.
The LT-CAGE™ Lumbar Tapered Fusion Device component has an interior chamber which can be packed with the appropriate size INFUSE™ Bone Graft component. Follow the specific directions for INFUSE™ Bone Graft component preparation and placement.

**Item 7510200 Small INFUSE™ Bone Graft Component Instructions for Preparation:**

The Small INFUSE™ Bone Graft Kit is designed specifically for use with the 14 x 20mm (8941420), 14 x 23mm (8941423) or 16 x 20mm (8941620) LT-CAGE™ Lumbar Tapered Fusion Device components.

Contents:
- One (1) Vial of Sterile rhBMP-2 (4.2mg)
- One (1) Package of 2 Sterile Absorbable Collagen Sponges (ACS) 1" x 2" (2.5cm x 5cm)
- One (1) Vial of Sterile Water for Injection (5mL)
- Two (2) Sterile 5mL Syringes with 20G 1 1/2" Needle
- One (1) Package Insert

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**Item 7510400 Medium INFUSE™ Bone Graft Component Instructions for Preparation:**

The Medium INFUSE™ Bone Graft Kit is designed specifically for use with the 16 x 23mm (8941623), 16 x 26mm (8941626) or 18 x 23mm (8941823) LT-CAGE™ Lumbar Tapered Fusion Device components.

Contents:
- Two (2) Vials of Sterile rhBMP-2 (4.2mg)
- One (1) Package of 4 Sterile Absorbable Collagen Sponges (ACS) 1" x 2" (2.5cm x 5cm)
- Two (2) Vials of Sterile Water for Injection (5mL)
- Four (4) Sterile 5mL Syringes with 20G 1 1/2" Needle
- One (1) Package Insert

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**Item 7510600 Large INFUSE™ Bone Graft Component Instructions for Preparation:**

The Large INFUSE™ Bone Graft Kit is designed specifically for use with the 18 x 26mm (8941826) LT-CAGE™ Lumbar Tapered Fusion Device components.

Contents:
- One (1) Vial of Sterile rhBMP-2 (12mg)
- One (1) Package of 6 Sterile Absorbable Collagen Sponges (ACS) 1" x 2" (2.5cm x 5cm)
- One (1) Vial of Sterile Water for Injection (10mL)
- Two (2) Sterile 10mL Syringes with 20G 1 1/2" Needle
- One (1) Package Insert

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**Item 7510800 Large-II INFUSE™ Bone Graft Component Instructions for Preparation:**

The Large-II INFUSE™ Bone Graft Kit is designed specifically for use with the 18 x 26mm (8941826) LT-CAGE™ Lumbar Tapered Fusion Device components.

Contents:
- One (1) Vial of Sterile rhBMP-2 (12mg)
- One (1) Package of 1 Sterile Absorbable Collagen Sponge (ACS) 3" x 4" (7.5cm x 10cm)
- One (1) Vial of Sterile Water for Injection (10mL)
- Two (2) Sterile 10mL Syringes with 20G 1 1/2" Needle
- One (1) Package Insert
Using forceps roll the wetted collagen sponges and place inside the LT-CAGE™ Device components (Figure 16A and B).

LT-CAGE™ Device components have specific Implant Holders located in the size specific tray. Select the correct Implant Holder for the device size. The distal end of the Implant Holder consists of two contact fingers. Hold the two contact fingers and pass the Implant Holder Shaft through the Implant Driver Sleeve. Thread the Holder to the Driver until finger tight. Connect a T-Handle to the proximal end of the Driver Assembly (Figure 17A).

After preparing the LT-CAGE™ Device component for implantation, fit the two contact fingers onto the two flat sides of the device (Figure 17B). While holding the device in place, turn the Implant Driver Sleeve clockwise to tighten the contact fingers around the device. The LT-CAGE™ Device component is securely in place when there is no space between the tip of the Implant Holder and the Implant Driver Shaft.

**Tip:** Use the Implant Driver Wrench to fully tighten the LT-CAGE™ Device and the Implant Driver.
The LT-CAGE™ Device component is passed through the Outer Sleeve and inserted into the cylindrical, reamed feature (Figure 18). The proximal end of the device is flush with the anterior apex of the vertebral body when the first concentric ring on the Implant Driver is aligned with the top of the Outer Sleeve.

Each subsequent ring indicates 3mm of device countersink. Advance until the proper countersink level is reached (Figure 18A). Device insertion must be completed with the T-handle parallel to the disc space. A/P and lateral fluoroscopic checks are recommended to confirm device positioning (Figure 18B).

Tip: The final position of the devices should be slightly countersunk (2-5mm) from the anterior cortex of the vertebral body.

The Implant Driver is disengaged from the LT-CAGE™ Device component by unscrewing the Outer Sleeve of the Implant Driver in a counterclockwise fashion. If necessary, the Implant Driver Wrench may be used at the collar of the Outer Sleeve to provide additional leverage in loosening the Implant Driver.

The second LT-CAGE™ Device component is placed at the same depth as the first LT-CAGE™ Device component. To assure the placement is correct, confirm with a lateral C-arm view.
In the final position, the LT-CAGE™ and INFUSE™ Bone Graft Device component should be slightly countersunk (2 – 5mm) from the anterior surface and within the lateral margins of the vertebral bodies.

If necessary, an Implant Adjuster can be inserted into the proximal end of the device for alignment corrections. The T-handle should be placed parallel with the disc space when the final device depth is achieved.

In order to countersink the device, adequate reaming depth must have been achieved. For example, if a 23mm length device is being inserted, the reaming depth must be greater than 23mm to allow the device to be countersunk. Trying to countersink in the setting of inadequate reaming may result in stripping and the potential loss/damage to the device/host interface.

A lateral fluoroscopic image may be taken to ensure proper final placement.

Tip: Re-attach the Implant Driver if the final depth of the device needs to be adjusted.
**Single Barrel Technique Steps**

1. Use the Centering Pin to identify and mark midline.

2. Use the appropriate sized Template to determine the width of the block discectomy. Complete the block discectomy as described in this technique Step 1.

3. Insert the Single Barrel Distractor in Side A. Use the Single Barrel Distractor Driver Cap to seat the Distractor Tip in place.


5. Placing the Impactor Cap over the Outer Sleeve, seat the Outer Sleeve so that it engages the disc space. Use the Single Barrel Driver Cap to fully seat the Outer Sleeve. Remove the Single Barrel Distractor.

6. Fit the Reamer with the Depth Stop and ream to the desired depth.

7. Remove the Reamer, insert the Reaming Plug within the Outer Sleeve and seat in the disc space. Remove the Reaming Plug Shaft and the Outer Sleeve.

8. Repeat Steps 3 through 7 to Side B.

9. Utilizing the assembled Inserter, attach the LT-CAGE™ Device component and insert into Side B.

10. After implanting the first LT-CAGE™ Device component into Side B, remove the Reaming Plug from Side A and seat the Outer Sleeve to aid in vessel protection.

11. Insert the second LT-CAGE™ Device component into Side A using the technique described in Step 9.
**GENERAL INSTRUMENTS**

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<th>Description</th>
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<td>One (1) Package Insert</td>
</tr>
<tr>
<td>7510400</td>
<td>INFUSE BONE GRAFT MEDIUM KIT</td>
</tr>
<tr>
<td></td>
<td>Two (2) Vials of Sterile rhBMP-P-2 (4.2mg)</td>
</tr>
<tr>
<td></td>
<td>One (1) Package of 4 Sterile Absorbable Collagen Sponges (ACS) 1&quot; x 2&quot; (2.5cm x 5cm)</td>
</tr>
<tr>
<td></td>
<td>Two (2) Vials of Sterile Water for Injection (5mL)</td>
</tr>
<tr>
<td></td>
<td>Four (4) Sterile 5mL Syringes with 20G 1½&quot; Needle</td>
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<tr>
<td></td>
<td>One (1) Package Insert</td>
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<tr>
<td>7510600</td>
<td>INFUSE BONE GRAFT LARGE KIT</td>
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<tr>
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<td>One (1) Vial of Sterile rhBMP-P-2 (12mg)</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>One (1) Vial of Sterile Water for Injection (10mL)</td>
</tr>
<tr>
<td></td>
<td>Two (2) Sterile 10mL Syringes with 20G 1½&quot; Needle</td>
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<td>7510800</td>
<td>INFUSE BONE GRAFT LARGE-II KIT</td>
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<td>One (1) Package of 1 Sterile Absorbable Collagen Sponges (ACS) 1&quot; x 2&quot; (2.5cm x 5cm)</td>
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<tr>
<td></td>
<td>One (1) Vial of Sterile Water for Injection (10mL)</td>
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<tr>
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<td>Two (2) Sterile 10mL Syringes with 20G 1½&quot; Needle</td>
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<tr>
<td></td>
<td>One (1) Package Insert</td>
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</tbody>
</table>
INFUSE™ BONE GRAFT/LT-CAGE™ LUMBAR TAPERED FUSION DEVICE

IMPORTANT MEDICAL INFORMATION

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

DESCRIPTION:
The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device consists of two components containing three parts– a tapered metallic spiral fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. The INFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. These components must be used as a system. The INFUSE™ Bone Graft component must not be used without the LT-CAGE™ Lumbar Tapered Fusion Device component.

LT-CAGE™ LUMBAR TAPERED FUSION DEVICE COMPONENT

The LT-CAGE™ device consists of a hollow, perforated, machined cylinder with opposing flat sides. The cage has a tapered design with an angle of 8.8° and is available in diameters ranging from 14mm to 19mm at the narrow end of the taper, 17mm to 22 mm at the wide end of the taper and in lengths ranging from 20mm to 26mm. There are two holes on each of the two flat sides. On each of the two rounded aspects, there is a single rounded slot. The implants have a helical screw thread on the outer surface. One end of the device is closed. The other end is open to be filled with the INFUSE™ Bone Graft component.

The LT-CAGE™ implants are made from implant grade titanium alloy (Ti-6Al-4V) described by such standards as ASTM F136 or its ISO equivalent.

The LT-CAGE™ Lumbar Tapered Fusion Device component is sold separately from the INFUSE™ Bone Graft component, however, these two components must be used together. The package labeling for the LT-CAGE™ Lumbar Tapered Fusion Device contains complete product information for this component.

INFUSE™ BONE GRAFT COMPONENT

INFUSE™ Bone Graft consists of recombinant human Bone Morphogenetic Protein-2 (rhBMP-2, known as dibotermin alfa) placed on an absorbable collagen sponge (ACS). The INFUSE™ Bone Graft component induces new bone tissue at the site of implantation. Based on data from non-clinical studies, the bone formation process develops from the outside of the implant towards the center until the entire INFUSE™ Bone Graft component is replaced by trabecular bone. rhBMP-2 is the active agent in the INFUSE™ Bone Graft component. rhBMP-2 is a disulfide-linked dimeric protein molecule with two major subunit species of 114 and 131 amino acids. Each subunit is glycosylated at one site with high-mannose type glycans. rhBMP-2 is produced by a genetically engineered Chinese hamster ovary cell line.

rhBMP-2 and exsipients are lyophilized. Upon reconstitution, each milliliter of rhBMP-2 solution contains: 1.5 mg of rhBMP-2; 5.0 mg sucrose; MF 25 mg glycerin; USP, 1.37 g L-glutamic acid; FCC, 0.1 mg sodium chloride; USP, 0.1 mg polysorbate 80; NF, and 1.0 mL of sterile water. The reconstituted rhBMP-2 solution has a pH of 4.5, and is colorless, colorless and essentially free from plainly visible particulate matter.

The ACS is a soft, white, pliable implantable matrix for rhBMP-2. ACS is made from bovine Type I collagen obtained from the deep flexor (Achilles) tendon. The ACS acts as a carrier for the rhBMP-2 and acts as a scaffold for the bone morphogenetic protein and resulting bone. The INFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. The INFUSE™ Bone Graft component induces new bone tissue with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device are indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

Three sizes of the INFUSE™ Bone Graft component are available based on the internal volume of the LT-CAGE™ Lumbar Tapered Fusion Device component that is selected. The table below lists the appropriate INFUSE™ Bone Graft kit for the corresponding LT-CAGE™ Lumbar Tapered Fusion Device component size:

### INFUSE™ BONE GRAFT/LT-CAGE™ LUMBAR TAPERED FUSION DEVICE COMBINATIONS

<table>
<thead>
<tr>
<th>INFUSE™ Lumbar Tapered Fusion Device</th>
<th>Appropriate INFUSE™ Bone Graft Kit</th>
<th>Reconstituted rhBMP-2/ACS Graft Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part #</td>
<td>Size (lead diameter, mm x length, mm)</td>
<td>Part #</td>
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<tr>
<td>8941823</td>
<td>18x26</td>
<td>7510800</td>
</tr>
</tbody>
</table>

Each kit contains all the components necessary to prepare the INFUSE™ Bone Graft component: the rhBMP-2 which must be reconstituted, sterile water, absorbable collagen sponges, syringes with needles, this package insert and instructions for preparation. The number of each item may vary depending on the size of the kit.

The rhBMP-2 is provided as a lyophilized powder in vials delivering either 4.2 mg or 12 mg of protein. After appropriate reconstitution, both configurations result in the same formulation and concentration (1.5 mg/mL) of rhBMP-2. The solution is then applied to the provided absorbable collagen sponge(s). The INFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. The INFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. The INFUSE™ Bone Graft component induces new bone tissue with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used without the LT-CAGE™ Lumbar Tapered Fusion Device component.

The LT-CAGE™ device is provided with a helical screw thread on the outer surface. One end of the device is closed. The other end is open to be filled with the INFUSE™ Bone Graft component.

The LT-CAGE™ implants are made from implant grade titanium alloy (Ti-6Al-4V) described by such standards as ASTM F136 or its ISO equivalent.

The LT-CAGE™ Lumbar Tapered Fusion Device component is sold separately from the INFUSE™ Bone Graft component, however, these two components must be used together. The package labeling for the LT-CAGE™ Lumbar Tapered Fusion Device contains complete product information for this component.

INDICATIONS:
The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be implanted via an anterior open or an anterior laparoscopic approach.

CONTRAINDICATIONS:
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2; bovine Type I collagen or to other components of the formulation.
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used in the vicinity of a resected or extant tumor.
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be used in pregnant women. The potential effects of rhBMP-2 on the human fetus have not been evaluated.
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should not be implanted in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.
The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. 2/277 (0.7%) patients treated with INFUSE™ Bone Graft component and 1/127 (0.8%) patients treated with autograft bone developed antibodies to rhBMP-2. The effect of maternal antibodies to rhBMP-2, as might be present for several months following device implantation, on the unborn fetus is unknown. Additionally, it is unknown whether fetal expression of BMP-2 could re-expose mothers who were previously antibody positive, thereby eliciting a more powerful immune response to BMP-2 with adverse consequences for the fetus. Studies in genetically altered mice indicate that BMP-2 is critical to fetal development and that lack of BMP-2 activity, as might be induced by antibody formation, may cause neonatal death or birth defects.

The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device in nursing mothers has not been established. It is not known if BMP-2 is excreted in human milk.

Women of childbearing potential should be advised to avoid becoming pregnant for one year following treatment with the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device.

Women of childbearing potential should be advised not to become pregnant for one year following treatment with the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device.

The implantation of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device using an anterior laparoscopic surgical approach is associated with a higher incidence of retrograde ejaculation when compared to implantation using the anterior open surgical approach.

**PRECAUTIONS:**

**GENERAL**

- The safety and effectiveness of repeat applications of the INFUSE™ Bone Graft component has not been established.
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device should only be used by surgeons who are experienced in spinal fusion procedures and have undergone adequate training with this device, for anterior laparoscopic and/or anterior open procedures.
- Two LT-CAGE™ Lumbar Tapered Fusion Device components should be implanted side by side at the surgical level whenever possible.
- The LT-CAGE™ Lumbar Tapered Fusion Device components and instruments must be sterilized prior to use according to the sterilization instructions provided in the package insert for that component, unless supplied sterile and clearly labeled as such.
- The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is intended for single use only. Discard unused product and use a new device for subsequent applications.
- Prior to use, inspect the packaging, vials and stoppers for visible damage. If damage is visible, do not use the product. Retain the packaging and vials and contact the Medtronic Sofamor Danek representative.
- Do not use after the printed expiration date on the label.

**HEPATIC AND RENAL IMPAIRMENT**

- The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device in patients with hepatic or renal impairment has not been established. Pharmacokinetic studies of rhBMP-2 indicate that the renal and hepatic systems are involved with its clearance.

**GERIATRICS**

- Clinical studies of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device did not include sufficient numbers of patients 65 years and older to determine whether they respond differently from younger subjects.

**BONE FORMATION**

- The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device has not been demonstrated in patients with metabolic bone diseases.
- While not specifically observed in the clinical study, the potential for ectopic, heterotopic or undesirable exuberant bone formation exists.

**ANTIBODY FORMATION/ALLERGIC REACTIONS**

- The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device has not been demonstrated in patients with autoimmune disease.
- The safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device has not been demonstrated in patients with immunosuppressive disease or suppressed immune systems resulting from radiation therapy, chemotherapy, steroid therapy, or other treatments.

**IMMUNOGENICITY**

- As with all therapeutic proteins, there is a potential for immune responses to be generated to rhBMP-2 or its influence on fetal development has not been assessed. In the clinical trial supporting the safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, 2/277 (0.7%) patients treated with INFUSE™ Bone Graft component and 1/127 (0.8%) patients treated with autograft bone developed antibodies to rhBMP-2. The effect of maternal antibodies to rhBMP-2, as might be present for several months following device implantation, on the unborn fetus is unknown. Additionally, it is unknown whether fetal expression of BMP-2 could re-expose mothers who were previously antibody positive, thereby eliciting a more powerful immune response to BMP-2 with adverse consequences for the fetus. Studies in genetically altered mice indicate that BMP-2 is critical to fetal development and that lack of BMP-2 activity, as might be induced by antibody formation, may cause neonatal death or birth defects.

- The incidence of antibody detection is highly dependent on the sensitivity and specificity of the assay. Additionally, the incidence of antibody detection may be influenced by several factors including sample handling, concomitant medications and underlying disease. For these reasons, comparison of the incidence of antibodies to the INFUSE™ Bone Graft component with the incidence of antibodies to other products may be misleading.

**ADVERSE EVENTS:**

The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device was implanted in 288 investigational patients and compared to 139 control patients who received an LT-CAGE™ Lumbar Tapered Fusion Device filled with iliac crest autograft. The investigational patients were implanted with the device via an open anterior surgical approach or a laparoscopic anterior surgical approach. The control patients were implanted only via the open anterior surgical approach.

Adverse event rates presented are based on the number of patients having at least one occurrence for a particular adverse event divided by the total number of patients in that treatment group.
**ADVERSE EVENTS**

(INFUSE™ Bone Graft/LT-CAGE™ Device Data Combined From All Experience with the Device)

<table>
<thead>
<tr>
<th>Complication</th>
<th>Inves.</th>
<th>Control</th>
<th>Inves.</th>
<th>Control</th>
<th>Inves.</th>
<th>Control</th>
<th>Inves.</th>
<th>Control</th>
<th>Inves.</th>
<th>Control</th>
<th># of Patients Reporting &amp; Total Adverse Events</th>
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</thead>
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<td>Anatomical/Technical Difficulty</td>
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<td>0</td>
<td>0</td>
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<td>1</td>
<td>4</td>
<td>11</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>14</td>
<td>4</td>
<td>20 / 7 / 6 / 8 / 65 (22.9) / 72 (21.6)</td>
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<td>4</td>
<td>5</td>
<td>6</td>
<td>2</td>
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<td>3</td>
<td>2</td>
<td>1</td>
<td>3 / 2 / 0 / 0 / 15 (5.2) / 12 (8.6)</td>
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<td>7</td>
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<td>8</td>
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<td>4</td>
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<td>5</td>
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<td>10 / 3 / 5 / 7 / 36 (12.5) / 39 (15.1)</td>
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<td>0</td>
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<td>1 / 1 / 1 / 1 / 5 (1.7) / 5 (3.1)</td>
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<tr>
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<td>8</td>
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<td>5</td>
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<td>11</td>
<td>6</td>
<td>14</td>
<td>5</td>
<td>27 / 9 / 11 / 7 / 60 (20.8) / 72 (29.0)</td>
</tr>
<tr>
<td>Urinary</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>2 / 1 / 4 / 2 / 33 (11.5) / 37 (10.7)</td>
</tr>
<tr>
<td>Vascular Intra-Qp</td>
<td>15</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 / 0 / 0 / 0 / 14 (4.9) / 15 (5.3)</td>
</tr>
<tr>
<td>Vertebral Fracture</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 / 0 / 0 / 0 / 1 (0.3) / 0 (0.0)</td>
</tr>
</tbody>
</table>

* Percent of 140 males.
** Percent of 70 males.

The reported rates of several adverse events were high, but similar, in both the investigational and control groups. These events included back and leg pain, neurological events, gastrointestinal events, spine events, cardiovascular events and infection.

Some of the reported adverse events required surgical interventions subsequent to the initial surgery. The number of subjects requiring a second surgical intervention was 10.4% (30/288) in the investigational groups and 13.7% (19/139) in the control group. The majority of supplemental fixations were due to painful nonunion.

Urgentential events occurred with greater frequency in the investigational groups (11.5%) compared to the control group (7%). Retrograde ejaculation rates were greater in the investigational groups (11 subjects) compared to the control group (1 subject) with the majority of events occurring in the early postoperative period.

The incidence of adverse events that were considered device related, including implant displacement/loosening, implant malposition and subsidence were all greater in the investigational groups compared to the control group. The rates of these events were low, however, and may be partially attributed to a learning curve associated with the laparoscopic surgical approach. The rate of nonunion requiring secondary surgery in the investigational groups was comparable to that of the control group. One death was reported - a control group subject with cardiovascular disease.
IMPORTANT MEDICAL INFORMATION

POTENTIAL ADVERSE EVENTS:
The following is a list of potential adverse events which may occur with spinal fusion surgery with the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. Some of these adverse events may have been previously reported in the adverse events table.

- Bone fracture.
- Bowel or bladder problems.
- Gastrointestinal complications.
- Incisional complications.
- Infection.
- Insufflation complications.
- Neurological system compromise.
- Nonunion (or pseudarthrosis), delayed union, mal-union.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Retrograde ejaculation.
- Scar formation.
- Tissue or nerve damage.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

CLINICAL RESULTS:
Clinical data to support the safety and effectiveness of the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device were collected as part of a prospective, multi-center pivotal study that consisted of randomized and non-randomized arms. The randomized arm contained two groups, one investigational and one control. The control group was implanted with the LT-CAGE™ Lumbar Tapered Fusion Device filled with iliac crest autograft bone, while the investigational group was implanted with the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. In both cases, the surgical approach was an open anterior approach. The non-randomized arm contained only an investigational group, where subjects were implanted with the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device through a laparoscopic anterior approach. The control group from the randomized arm was used as the control for the non-randomized arm.

Neither the investigators nor the subjects were blinded to the treatment. Subject blinding was not possible due to the second surgical site resulting from the need to collect the iliac crest grafts. The potential for investigator bias in the clinical outcome parameters was reduced by having the subjects rate their outcome using objective self-assessments. The radiographic outcome parameters were performed by independent radiologists who were blinded to treatment.

These were the only radiographic evaluations used for determining radiographic success.

The indication studied was degenerative disc disease (DDD) accompanied by back pain with or without leg pain at a single level between L4 and S1 confirmed by history and radiographic studies.

CLINICAL AND RADIOGRAPHIC EFFECTIVENESS PARAMETERS
Patients were evaluated preoperatively (within 6 months of surgery), intraoperatively, and postoperatively at 6 weeks, 3, 6, 12 and 24 months, and biannually thereafter until the last subject enrolled in the study had been seen for their 24 month evaluation. Complications and adverse events, device-related or not, were evaluated over the course of the clinical trial. At each evaluation timepoint, the primary and secondary clinical and radiographic outcome parameters were evaluated. Success was determined from data collected during the initial 24 months of follow-up. Antibodies to rhBMP-2 and bovine Type I collagen were assessed preoperatively and at 3 months post-operatively. Antibodies to human Type I collagen were assessed if the antibody response to bovine Type I collagen was positive.

Primary and secondary clinical and radiographic effectiveness outcome parameters were evaluated for all treated subjects at all follow-up evaluation timepoints identified above. The primary clinical parameters assessed were pain, function and neurological status. The secondary clinical outcome parameters assessed were general health status, back and leg pain, donor site pain (control subjects only), patient satisfaction and patient global perceived effect of the treatment. The primary radiographic outcome parameter consisted of evaluations of fusion, while the secondary radiographic assessment was disc height.

Fusion was evaluated at 6, 12 and 24 months post-op using plain radiographs (AP, lateral and flexion/extension films) and high resolution thin-slice CT scans (1mm slices with 1mm index on axial, sagittal and coronal reconstructions). Fusion was defined as the presence of bridging bone connecting the inferior and superior vertebral bodies; a lack of motion on flexion/extension (<3mm of translation and <5° of angulation); and no evidence of radiolucencies over more than 50% of either implant. Fusion success was defined as the presence of all of these parameters plus the lack of a second surgical intervention resulting from a non-union. All assessments were made from the plain films except for the assessment of bridging bone, which was made using the CT scans only if bridging bone could not be visualized on the plain film.

Pain and function were measured using the Oswestry Low Back Pain Disability Questionnaire. Success was defined as a 15 point improvement in the Oswestry score from the pre-op baseline score.

Neurological status consisted of measurements of four parameters - motor, sensory, reflexes, and straight leg raise (SLR). Neurological status success was defined as maintenance or improvement of the pre-op baseline score for each parameter. Overall neurological status success required that each individual parameter be a success for that subject to be counted as a success.

PATIENT DEMOGRAPHICS AND ACCOUNTABILITY
A total of 143 open approach investigational and 136 control patients were enrolled in the randomized arm of the study and received the device. A total of 134 subjects were enrolled in the non-randomized arm of the study and received the device. For the majority of the demographic parameters, there were no differences in pre-op demographics across the three populations.

SURGICAL RESULTS AND HOSPITALIZATION

<table>
<thead>
<tr>
<th>SURGICAL AND HOSPITALIZATION INFORMATION</th>
<th>Investigational Open Surgical Approach</th>
<th>Control Open Surgical Approach</th>
<th>Investigational Laparoscopic Surgical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean operative time (hrs)</td>
<td>1.6*</td>
<td>2.0</td>
<td>1.9</td>
</tr>
<tr>
<td>mean EBL (ml)</td>
<td>109.8*</td>
<td>153.1</td>
<td>146.1</td>
</tr>
<tr>
<td>hospitalization (days)</td>
<td>3.1</td>
<td>3.3</td>
<td>1.2*</td>
</tr>
</tbody>
</table>

* statistically different from control
CLINICAL AND RADIOGRAPHIC EFFECTIVENESS EVALUATION

Individual subject success was defined as success in each of the primary clinical and radiographic outcome parameters. Success for these parameters included:

1. the presence of radiographic fusion;
2. an improvement of at least 15 points from the baseline Oswestry score;
3. maintenance or improvement in neurological status;
4. the presence of no serious adverse event classified as implant-associated or implant/surgical procedure-associated; and
5. no additional surgical procedure classified as “Failure.”

Study success was expressed as the number of individual subjects categorized as a success divided by the total number of subjects evaluated. The table below describes the success rates for the individual primary outcome parameters and overall success. All success rates were based on the data from the 24 month follow-up evaluation and posterior probabilities of success were calculated using Bayesian statistical methods.

<table>
<thead>
<tr>
<th>Primary Outcome Variable</th>
<th>Investigational Open Surgical Approach</th>
<th>Control Open Surgical Approach</th>
<th>Investigational Laparoscopic Surgical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusion</td>
<td>92.8% (88.5%, 96.9%)</td>
<td>88.1% (82.6%, 99.3%)</td>
<td>93.0% (87.9%, 97.5%)</td>
</tr>
<tr>
<td>Oswestry</td>
<td>71.0% (63.4%, 78.7%)</td>
<td>70.9% (63.1%, 79.1%)</td>
<td>83.0% (75.6%, 90.5%)</td>
</tr>
<tr>
<td>Neurologic</td>
<td>81.0% (74.5%, 87.9%)</td>
<td>81.7% (74.9%, 88.7%)</td>
<td>89.0% (83.1%, 94.8%)</td>
</tr>
<tr>
<td>Overall Success</td>
<td>57.1% (49.2%, 65.7%)</td>
<td>56.7% (48.3%, 65.0%)</td>
<td>68.0% (59.3%, 76.5%)</td>
</tr>
</tbody>
</table>

The probability (also called the posterior probability) that the 24 month overall success rate for the investigational groups was equivalent to the 24 month success rate for the control group was 99.4% for the open surgical approach investigational group and almost 100% for the laparoscopic surgical approach investigational group.

For a future patient receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device via the anterior laparoscopic surgical approach, the chance (the predictive probability) of overall success at 24 months would be 57.1% for the open surgical approach. Given the results of the trial, there is a 95% probability that the chance of success ranges from 49.2% to 65.7%. For a future patient receiving the INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device via the anterior laparoscopic surgical approach, the chance of overall success at 24 months would be 68.0%. Given the results of the trial, there is a 95% probability that the chance of success ranges from 59.3% to 76.5%. For a future patient receiving the control treatment, the chance of overall success at 24 months would be 56.7%. Given the results of the trial, there is a 95% probability that the chance of success ranges from 48.3% to 65.0%.

SAFETY AND IMMUNE RESPONSE EVALUATION

The assessment of safety consisted of an evaluation of the reported adverse events, as well as an evaluation of antibodies to rhBMP-2, bovine Type I collagen and human Type I collagen. The complete list of complications, adverse events and subsequent interventions is described in the Adverse Events section above. The presence of antibodies were assessed at the pre-op and 3 month post-op visits using ELISA. If there was a positive response to bovine Type I collagen, the serum was also tested for antibodies to human Type I collagen. The screening ELISA cutoff for positive antibody responses was set to 5 times the standard deviation of sera from normal human donors. Subjects were considered to have an elevated immune response if the preoperative test was negative (titer < 50) and postoperative test was positive (titer ≥ 50) or if the preoperative test was positive and the postoperative test was positive with a three-fold higher titer than the preoperative test.

There were 3 subjects who had positive antibody responses to rhBMP-2 – 1 subject in each of the study groups. The rates of positive antibody response to rhBMP-2 were 0.7% in the open surgical approach investigational group and 0.8% in the laparoscopic surgical approach investigational and open surgical approach control groups. While there is a theoretical possibility that antibodies to rhBMP-2 could neutralize endogenous BMP-2, thereby interfering with subsequent bone healing, this was not observed during the course of the study.

Sixty-six subjects were considered to have an authentic elevated antibody response to bovine Type I collagen - 18 open surgical approach investigational subjects, 32 laparoscopic surgical approach investigational subjects and 16 control subjects. No subjects had positive responses to human Type I collagen.

An evaluation was performed on the impact of a positive antibody response on overall success and fusion success. There was very little difference in overall and individual success when antibody status was taken into consideration.

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There were 3 subjects who had positive antibody responses to rhBMP-2 – 1 subject in each of the study groups. The rates of positive antibody response to rhBMP-2 were 0.7% in the open surgical approach investigational group and 0.8% in the laparoscopic surgical approach investigational and open surgical approach control groups. While there is a theoretical possibility that antibodies to rhBMP-2 could neutralize endogenous BMP-2, thereby interfering with subsequent bone healing, this was not observed during the course of the study.

Two cases of cancer were diagnosed during the course of the pivotal study – one in an investigational group and one in the control group. An investigational subject was found to have pancreatic cancer while a control subject was found to have breast cancer. No additional information is available on these subjects, e.g., BMP-2 receptor expression.

HOW SUPPLIED

INFUSE™ Bone Graft component is supplied in three kit sizes containing all the components necessary to prepare this portion of the device, i.e., the collagen sponge(s), a vial with the lyophilized growth factor, a vial with sterile water for reconstituting the growth factor, syringes and needles. The LT-CAGE™ Lumbar Tapered Fusion Device component is supplied in seven sizes which must be properly selected based on a specific patient’s anatomy.

STORAGE CONDITIONS

Store the INFUSE™ Bone Graft component at room temperature (15 – 25 degrees Centigrade (59 to 77° F). The LT-CAGE™ Lumbar Tapered Fusion Device component should also be stored at room temperature.

DOSEAGE AND ADMINISTRATION

INFUSE™ Bone Graft component is prepared immediately prior to use from a kit containing all necessary components. Once prepared, the INFUSE™ Bone Graft component contains rhBMP-2 at a concentration of 1.5 mg/mL.

The size of the INFUSE™ Bone Graft component kit and the volume of INFUSE™ Bone Graft component to be implanted are determined by the internal volume of the LT-CAGE™ Lumbar Tapered Fusion Device components which are utilized. The patient’s anatomy will determine the size of the LT-CAGE™ components to be used. The INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device surgical technique provides more information on templating to determine the appropriate size LT-CAGE™ Lumbar Tapered Fusion Device component.

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DIRECTIONS FOR USE

INFUSE™ Bone Graft component is prepared at the time of surgery in the surgical suite by reconstituting the lyophilized rhBMP-2 with sterile water (See Instructions for Preparation), and then uniformly applying the reconstituted rhBMP-2 solution to the ACS. The INFUSE™ Bone Graft component is then inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component. The complete device is then implanted through an anterior open or laparoscopic surgical approach (See the Surgical Technique manual). If the INFUSE™ Bone Graft component is not used within two hours after reconstitution, it must be discarded. The INFUSE™ Bone Graft component must not be sterilized by the hospital. The LT-CAGE™ Lumbar Tapered Fusion Device component, if not supplied sterile, should be sterilized before insertion of the INFUSE™ Bone Graft component. Refer to the package insert for the LT-CAGE™ Lumbar Tapered Fusion Device component for information on packaging, cleaning/decontamination and sterilization of this component and its instruments.

PRODUCT COMPLAINTS:

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the quality, identification, durability, reliability, safety, effectiveness and/or performance of this product, should notify the distributor, Medtronic Sofamor Danek. Further, if any of the implanted INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device components ever “malfunction” (i.e., do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately (1-800-933-2635). If any Medtronic Sofamor Danek product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component name and number, lot number, your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

DEVICE RETRIEVAL EFFORTS:

Should it be necessary to remove an INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, please call Medtronic Sofamor Danek prior to the scheduled surgery to receive instructions regarding data collection, including histopathological, mechanical and adverse event information.

IN USA

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