AN EXPANDABLE INTERBODY DEVICE THAT PROVIDES CONTINUOUS APPosition OF BONE GRAFT-TO-ENDPLATE DURING EXPANSION
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The Elevate Expandable Interbody Device was developed as an implant for stabilization of the lumbar spinal column for PLIF, TLIF, and MAST® MIDLF® procedures. This surgical technique is designed to familiarize healthcare professionals with the surgical procedure. Please carefully read this surgical technique and its appendix prior to the use of the implant.

The aim of this development was an implant which fits the anatomical shape of the vertebral endplates and combines the following essential features:

- Two implant options available:
  - **Standard implant** – offers posterior expansion and up to 8 degrees of lordosis when fully expanded (for more information, see chart on page 28)
  - **Extra-lordotic implant** – offers fixed posterior height with various degrees of lordosis when fully expanded (for more information, see chart on page 28)
- Bullet tip device with continuous lordotic expansion
- MAST® Procedure compatible
- Continuous apposition of bone graft-to-endplate during expansion
- Open volume design for appropriate bone graft material
- 10mm width
- Teeth on the surface to reduce the likelihood of expulsion
- Bullet-tip design allows for self-distraction and ease of insertion
- Tantalum markers allow radiographic visualization

**Risks**

Potential risks associated with the device include, but are not limited to:

- Implant migration
- Loss of spinal curvature, correction, height, and/or reduction
- Bone fracture or stress shielding at, above, or below the level of surgery
- Bone graft donor site complication
- Loss of spinal mobility
- Endplate disruption
- Neurological impairment

See IFU for a full list of risks, warnings, and contraindications.
SIZE SPECIFICATIONS AND MARKER LOCATIONS

The diagrams on the left show the locations of the Tantalum x-ray markers as seen from a right-side TLIF approach as the view is rotated from a straight A/P to a lateral view. The diagrams on the right depict measurements for the available sizes.
**INSTRUMENT SET**

- **Distractor/Trial Driver**
  - G851200

- **Torque Handle**
  - G178101

- **Distractor/Trial**
  - Small Standard 8657005
  - Large Standard 8657006
  - Small Extra Lordotic 8657007
  - Large Extra Lordotic 8657008

- **Extractor Forceps**
  - 8657012

- **Slap Hammer**
  - 8657011

- **Leverage Tool**
  - 8657013

- **Inserter Drive Shaft**
  - 8657003

- **Inserter Inner Locking Tube**
  - 8657002

- **Inserter**
  - 8657001
Positioning

Prone patient positioning in kyphosis facilitates the approach to the spinal canal as well as to the disc space. The kyphotic positioning should be taken into consideration when confirming implant sizing and angle in order to avoid hyperlordosis. Imaging guidance is only possible in the lateral view.

The prone position will allow a free abdomen to dismiss abdominal pressure on the stomach vessels. This can be achieved by using a positioning frame or padding. Use a well-padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries. Furthermore, it allows intraoperative imaging guidance in the A/P and lateral views. The O-Arm® Imaging System can be used to provide imaging assistance.
Decompression / Discectomy

Mark the affected segment in the midline after imaging guidance. Make a skin incision 4cm lateral to the midline at the level of the affected segment. Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most of the cases, a resection of the spinous process is not required. The maintenance of the superior lamina is suggested to keep the interlaminar, as well as the interspinous, stability of the superior adjacent level and motion segment.

Open the annulus and resect the nucleus and the inner annulus as completely as possible. After discectomy, remove the endplate cartilage. Ensure that the bony endplates stay intact. Injuring bony endplates may lead to implant subsidence into the vertebrae.
Distraction / Implant Size Determination

Instruments for use with the Elevate Spinal System:

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<tr>
<th>Part Number</th>
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<tbody>
<tr>
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<td>Large Extra Lordotic Distractor/Trial</td>
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<tr>
<td>G851200</td>
<td>Distractor Driver</td>
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</table>

For all following steps, please use caution during retraction of the dura mater and the offbranching nerve root(s).

In order to choose the appropriate type and size of the Distractor/Trial, use preoperative planning to determine the appropriate height and lordosis.
Distraction / Implant Size Determination Continued

Insert the Distractor/Trial into the disc space. A mallet may be used to facilitate placement. It is desirable to position the Distractor/Trial on the apophyseal ring. Attach the Distractor Driver onto the Distractor/Trial (Figure 1). Rotate the Distractor Driver in order to expand the tip of the Distractor/Trial (Figure 2).

Once a desired fit of the Distractor/Trial in the intervertebral disc space is achieved, determine the implant size. The window of the Distractor/Trial will show the intradiscal height of expansion. The head of the Distractor/Trial has length markings that are visible under fluoroscopy to help the surgeon determine the appropriate length implant to use (Figure 2a). Use chart on page 28 to choose the appropriate implant size.
This expandable interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. In addition to filling the implant, the disc space may be filled with appropriate bone grafting material. Place anteriorly prior to implantation.

**Expandable Interbody Device Implantation**

Instruments for use with the Elevate Spinal System:

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<td>Inserter Drive Shaft</td>
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<tr>
<td>G178101</td>
<td>Torque Handle</td>
</tr>
<tr>
<td>8657013</td>
<td>Leverage Tool</td>
</tr>
</tbody>
</table>

Remove the correct size implant from the intact sterile packing. Pay attention to a correct implant size determination.

Thread the Inner Locking Tube into the Inserter in order to assemble the Inserter Assembly (Figure 3). Next attach the implant to the Inserter by turning the Inner Locking Tube clockwise (Figure 4).

It is recommended that the implant be attached to the Inserter so the PEEK portion of the implant with x-ray markers is superior during the insertion.
Expandable Interbody Device Implantation Continued

Carefully insert the implant into the disc space (Figure 5). A mallet may be used to facilitate placement.

Advance the implant anteriorly so that the leading tip of the implant rests on the anterior apophyseal ring.

**Note**
Ensure the screw on the back of the implant is fully retracted and the PEEK nose is fully recessed within the Titanium Alloy bottom.

**Figure 5**
Expandable Interbody Device Implantation Continued

In order to expand the implant inside the disc space, insert the Inserter Drive Shaft along with the attached Torque Handle inside the Inserter Assembly (Figure 6). Next, turn the Torque Handle clockwise to expand the implant (Figure 7). Verify the correct position using imaging.

Important
The Torque Handle has a maximum torque of 2.5Nm to help mitigate the potential risk of endplate and implant damage.

Important
Do not strike the Torque Handle with a mallet or damage to the implant may result.
Expandable Interbody Device Implantation Continued

After implantation is completed, remove the Torque Handle and the Inserter Drive Shaft from the Inserter Assembly (Figure 8).

Next, disengage the Inner Locking Tube from the implant (Figure 9) and remove the Inner Locking Tube and Inserter from the disc space (Figure 10). Disassemble the Inner Locking Tube from the Inserter for cleaning.

**Note**
The Leverage Tool can be used to disengage the Inner Locking Tube from the implant.
Expandable Interbody Device Implantation Continued

The implant can generate significant expansion forces. Care should be taken by the surgeon to avoid endplate damage caused by excessive expansion forces. If poor bone quality is suspected, the surgeon should limit the amount of torque that is delivered to the Torque Handle. Placement of the leading tip of the implant on the apophyseal ring is recommended.

The optimal position of the implant can be determined using the Tantalum x-ray markers in the implant (Figure 11).
Expandable Interbody Device Adjustment

If the implant must be repositioned or removed from the disc space, reattach the Inserter or use the Extraction Forceps. If the Inserter Assembly is used, collapse the implant by turning the Torque Handle counterclockwise (Figure 12). Attach a Slap Hammer to the Inserter Assembly to facilitate implant repositioning (Figure 13). If the implant will not collapse, the Extractor Forceps may be used to help facilitate implant adjustment (Figure 14).

Please consider the increased risk to the neural elements during implant explantation.
Supplemental Fixation / Postoperative Care

The Elevate Expandable Interbody Device is intended to be used with supplemental posterior fixation cleared for use in the lumbar spine.
Positioning

Prone patient positioning in kyphosis facilitates the approach to the spinal canal as well as to the disc space. The kyphotic positioning should be taken into consideration when confirming implant sizing and angle in order to avoid hyperlordosis. Imaging guidance is only possible in the lateral view.

The prone position will allow a free abdomen to dismiss abdominal pressure on the stomach vessels. This can be achieved using a positioning frame or padding. Use a well padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries. Furthermore, it allows intraoperative imaging guidance in the A/P and lateral views. The O-Arm® Imaging System can be used to provide imaging assistance.

For complete labeling for the navigation products please contact Medtronic Navigation, General Business at 800-580-8860 or visit www.medtronic.com.
Decompression/Discectomy

Mark the affected segment in the midline after imaging guidance. Make a skin incision over midline or lateral to midline at the level of the affected segment. Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most of the cases, a resection of the spinous process is not required. The maintenance of the superior lamina is suggested to keep the interlaminar, as well as the interspinous, stability of the superior adjacent level and motion segment.

Open the annulus and resect the nucleus and the inner annulus as completely as possible. After discectomy, remove the endplate cartilage. Ensure that the bony endplates stay intact. Injuring bony endplates may lead to an implant subsidence into the vertebrae.
Distraction / Implant Size Determination

Instruments for use with the Elevate Spinal System:

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<tr>
<th>Part Number</th>
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</tr>
<tr>
<td>G851200</td>
<td>Distractor Driver</td>
</tr>
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</table>

For all following steps, please use caution during retraction of the dura mater and the offbranching nerve root(s).

In order to choose the appropriate type and size of the Distractor/Trial, use preoperative planning to determine the appropriate height and lordosis.
Distraction / Implant Size Determination Continued

Insert the Distractor/Trial into the disc space. A mallet may be used to facilitate placement. It is desirable to position the Distractor/Trial on the apophyseal ring. Attach the Distractor Driver onto the Distractor/Trial (Figure 15). Rotate the Distractor Driver in order to expand the tip of the Distractor/Trial (Figure 16).

Once a desired fit of the Distractor/Trial in the intervertebral disc space is achieved, determine the implant size. The window of the Distractor/Trial will show the intradiscal height of expansion. The head of the Distractor/Trial has length markings that are visible under fluoroscopy to help the surgeon determine the appropriate length implant to use (Figure 16a). Use chart on page 28 to choose the appropriate implant size.
This expandable interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. In addition to the filling of the implant, the disc space may be filled with appropriate bone grafting material. Place anteriorly prior to implantation.

**Expandable Interbody Device Implantation**

Instruments for use with the Elevate Spinal System:

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<td>Torque Handle</td>
</tr>
<tr>
<td>8657013</td>
<td>Leverage Tool</td>
</tr>
</tbody>
</table>

Remove the correct size implant from the intact sterile packing. Pay attention to a correct implant size determination.

Thread the Inner Locking Tube into the Inserter in order to assemble the Inserter Assembly (Figure 17). Next attach the implant to the Inserter by turning the Inner Locking Tube clockwise (Figure 18).

Ensure that the implant is attached to the Inserter so the PEEK portion of the implant with x-ray markers is superior during the insertion.
**Expandable Interbody Device Implantation Continued**

Carefully insert the implant into the disc space (Figure 19). A mallet may be used to facilitate placement.

Advance the implant anteriorly so that the leading tip of the implant rests on the anterior apophyseal ring.

**Note**

Ensure the screw on the back of the implant is fully retracted and the PEEK nose is fully recessed within the Titanium Alloy bottom.
**Expandable Interbody Device Implantation Continued**

In order to expand the implant inside the disc space, insert the Inserter Drive Shaft along with the attached Torque Handle inside the Inserter Assembly (Figure 20). Next, turn the Torque Handle clockwise to expand the implant (Figure 21). Verify the correct position using imaging.

**Important**
The Torque Handle has a maximum torque of 2.5Nm to help mitigate the potential risk of endplate and implant damage.

**Important**
Do not strike the Torque Handle with a mallet or damage to the implant may result.
Expandable Interbody Device Implantation Continued

After implantation is completed, remove the Torque Handle and the Inserter Drive Shaft from the Inserter Assembly (Figure 22).

Next, disengage the Inner Locking Tube from the implant (Figure 23) and remove the Inner Locking Tube and Inserter from the disc space (Figure 24). Disassemble the Inner Locking Tube from the Inserter for cleaning.

Note
The Leverage Tool can be used to disengage the Inner Locking Tube from the implant.
Expandable Interbody Device Implantation
Continued

The implant can generate significant expansion forces. Care should be taken by the surgeon to avoid endplate damage caused by excessive expansion forces. If poor bone quality is suspected, the surgeon should limit the amount of torque that is delivered to the Torque Handle. Placement of the leading tip of the implant on the apophyseal ring is recommended.

The optimal position of the implant can be determined using the Tantalum x-ray markers in the implant (Figure 25).
Expandable Interbody Device Adjustment

If the implant must be repositioned or removed from the disc space, reattach the Inserter or use the Extraction Forceps. If the Inserter Assembly is used, collapse the implant by turning the Torque Handle counterclockwise (Figure 26). Then attach a Slap Hammer to the Inserter Assembly to facilitate implant repositioning (Figure 27). If the implant will not collapse, the Extractor Forceps may be used to help facilitate implant adjustment (Figure 28).

Please consider the increased risk to the neural elements during implant explantation.
Supplemental Fixation / Postoperative Care

The Elevate Expandable Interbody Device is to be used with supplemental posterior fixation cleared for use in the lumbar spine.
A MAST MIDLF Procedure is an approach to the spine medial and deep to the segmental back muscles with the screw construct placed along the spinous process. For Exposure, Cortical Screw Starting Point and Trajectory Reference, Pilot Hole Starting Point and Drilling, Drill Positioning and Trajectory Reference, Fluoroscopic Trajectory Reference, Tapping, and Discectomy, please refer to the MAST MIDLF Procedure surgical technique.
### Standard Implants: Approximately 1mm of Posterior Expansion

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<th>Length 28</th>
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<td>Max Lordosis (deg.)</td>
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### Extra-Lordotic Implants: No Posterior Expansion

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Expansion numbers are meant to give close approximations of specific implant’s expansion limitations taking into account an implant assembly at nominal geometry.
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### Elevate Spinal System Implants Standard and Extra-Lordotic 23 and 28mm

**SPS02710**

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**SPS02711**

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### Implants available for order as extra

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ELEVATE SPINAL SYSTEM

IMPORTANT INFORMATION ON THE ELEVATE SPINAL SYSTEM

PURPOSE
This device is a fusion device intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects, and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION
The ELEVATE™ Spinal System is an expandable PEEK, tantalum, and titanium alloy interbody device consisting of various lengths and starting heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The ELEVATE™ Spinal System expands for adjustable lordosis and height to match patient anatomy. The hollow geometry of the implants allows them to be packed with autologous or allogeneic bone graft comprised of cancellous and/or corticocancellous bone. The implants may be implanted via a posterior or transforaminal approach and the procedure may be open or minimally invasive. The ELEVATE™ Spinal System can be implanted unilaterally and bilaterally. The ELEVATE™ Spinal System is intended to be inserted with ELEVATE™ Spinal System reusable instruments. ELEVATE™ Spinal System implants are for single use only. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS
The ELEVATE™ Spinal System Expandable Interbody Fusion Device is intended for interbody fusion with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as degenerative back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS
This device is not intended for cervical spine use.

Contraindications include, but are not limited to:
- Infection local to the operative site.
- Signs of local infection.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as: the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone fragility or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

PLEASE NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:
- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

Take into consideration that the segmental stability can be affected by a variety of factors.

POTENTIAL ADVERSE EVENTS
Adverse effects may occur when the device is used either with or without associated instrumentation. The risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include, but are not limited to:
- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of nerve root tension.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury, and cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hemorrhatomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

Note: Additional surgery might become necessary to correct adverse effects.

WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Trial distractors enable a simple and safe size determination. Over-distraction is to be avoided. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

When used in deformity procedures, undersizing the implant may limit enplate engagement and potentially lead to implant migration and/or expulsion.

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

Document the used implants per patient with REF and LOT, so that the tracking, which is required by law, is guaranteed. The implants are only for single use. Do not re-process or re-use devices labeled as single use devices. Re-processing or re-use of single use devices may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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EC REP

Please contact your Sales Representative or Customer Service for the most up-to-date version of the package insert.
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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