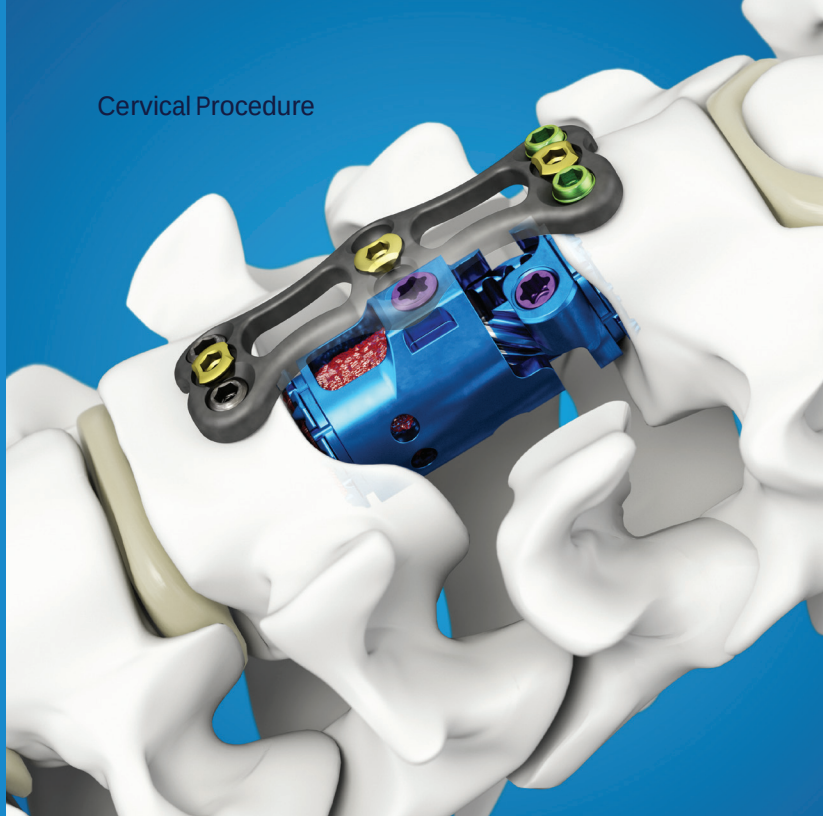
SURGICAL
TECHNIQUE

T2 Stratosphere™

Expandable Corpectomy System



Thoracolumbar Procedure

Medtronic
Further, Together

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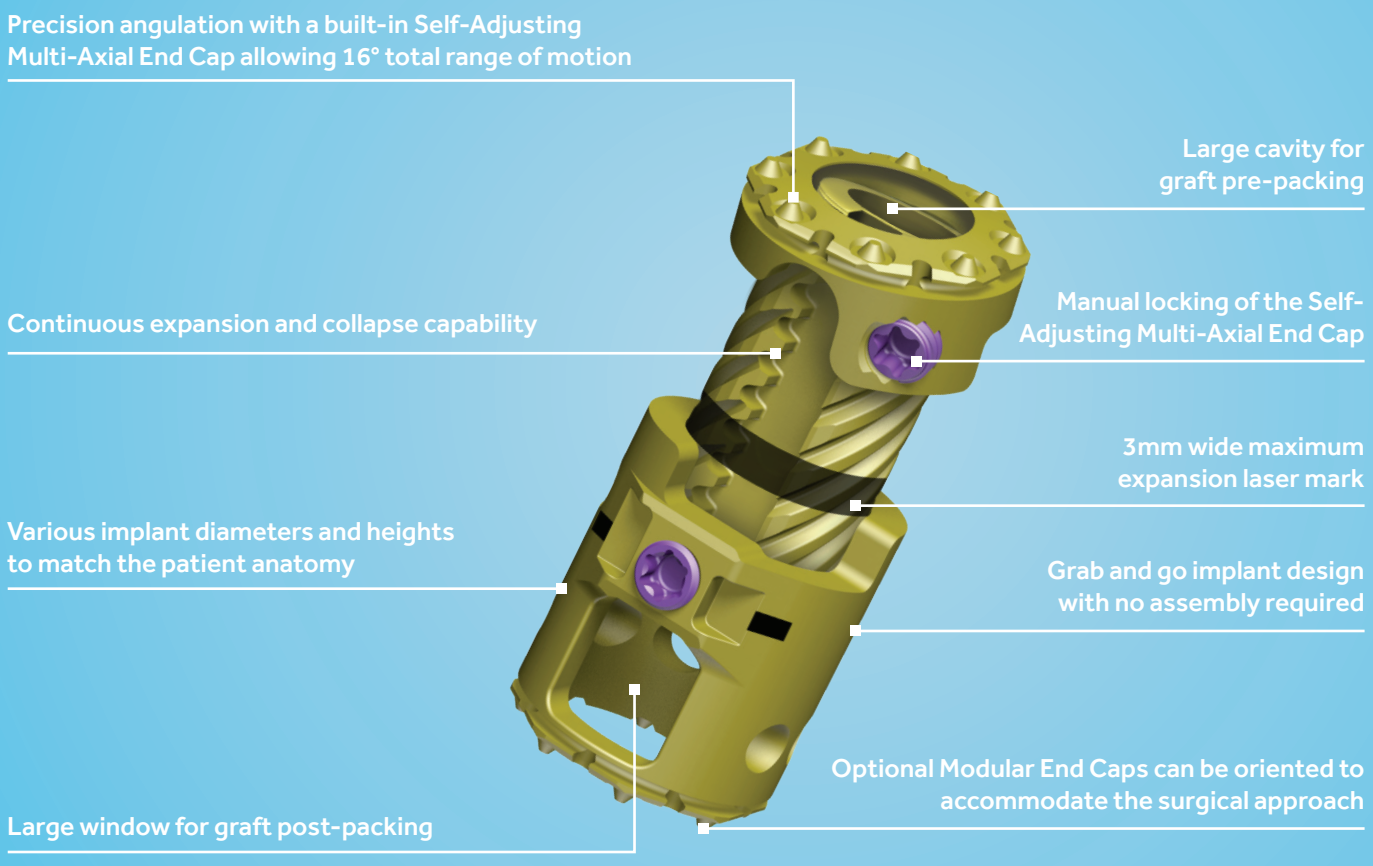
IMPLANT FEATURES

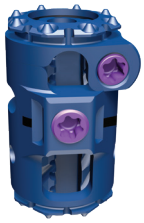
The T2 Stratosphere Expandable Corpectomy System is an adjustable vertebral body replacement implant intended for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-C7). When used in the thoracolumbar spine, the T2 Stratosphere Expandable Corpectomy System may be used to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma. For the cervical spine, the T2 Stratosphere Expandable Corpectomy System may be used to replace a collapsed, damaged, or unstable vertebral body due to tumor, trauma, or osteomyelitis or for reconstruction following corpectomy performed to achieve decompression of the spinal canal in cervical degenerative disorders. The T2 Stratosphere System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit the achievement of fusion.

The T2 Stratosphere System is available in three Centerpiece diameters – 13mm Centerpieces for the cervical and thoracolumbar spine and 20mm and 25mm Centerpieces for the thoracolumbar spine. The Centerpieces also feature a Self-Adjusting Multi-Axial End Cap to match the angulation between vertebral endplates. The system includes Modular End Caps for use in the thoracolumbar spine which are available in various angles and geometries.

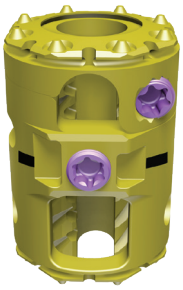


Fifteen Centerpiece Options

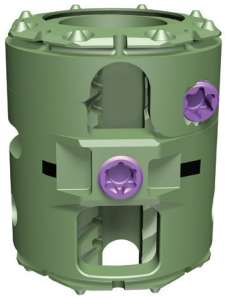
CENTERPIECE DIAMETER COMPARISON



Ø13mm Centerpiece

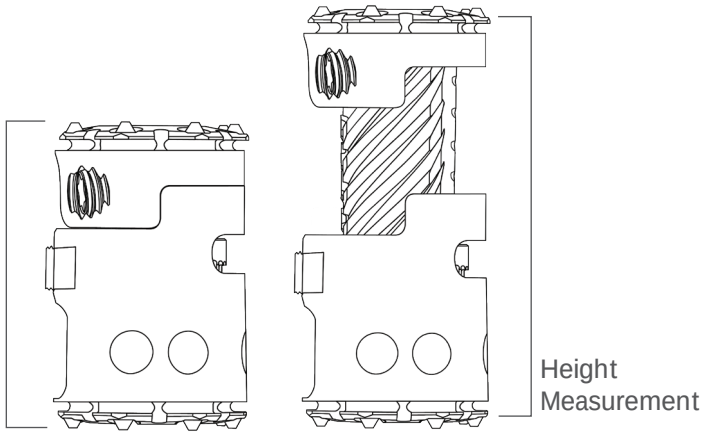


Ø20mm Centerpiece

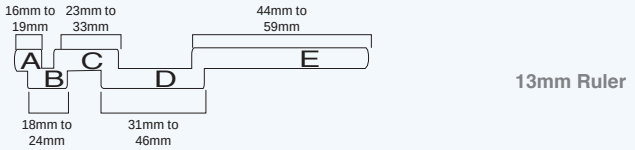


Ø25mm Centerpiece

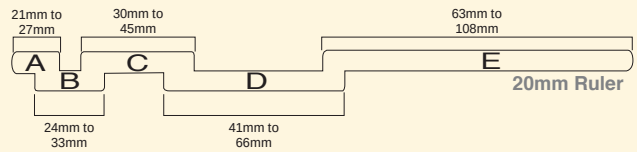
CENTERPIECE HEIGHT COMPARISON



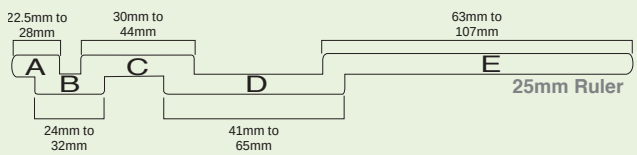
CENTERPIECE IMPLANT SELECTION



Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
13A	13	16	19	13mm & 16mm****
13B	13	18	24	13mm & 16mm****
13C	13	23	33	13mm & 16mm****
13D	13	31	46	13mm & 16mm****
13E	13	44	59	13mm & 16mm****



Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
20A	20	21	27	20mm & 22mm & 20mm Extended
20B	20	24	33	20mm & 22mm & 20mm Extended
20C	20	30	45	20mm & 22mm & 20mm Extended
20D	20	41	66	20mm & 22mm & 20mm Extended
20E***	20	63	108	20mm & 22mm & 20mm Extended



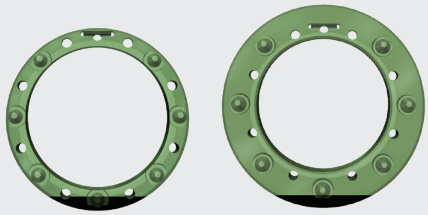
Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
25A	25	22.5	28	25mm & 30mm & 25mm Extended
25B	25	24	32	25mm & 30mm & 25mm Extended
25C	25	30	44	25mm & 30mm & 25mm Extended
25D	25	41	65	25mm & 30mm & 25mm Extended
25E***	25	63	107	25mm & 30mm & 25mm Extended

Note: The heights above are measured without End Caps attached to the Centerpiece.

*The collapsed height includes the spikes on the Centerpiece
**The expanded height does not include the spikes on the Centerpiece
***20E and 25E Centerpieces are not included in the set configuration
****For the 13mm Centerpieces, End Caps are cleared for use in the thoracolumbar spine only

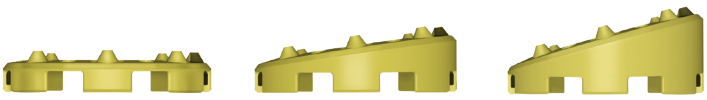
Twenty-Three Modular End Cap Options

END CAP DIAMETER COMPARISON



13mm 16mm 20mm 22mm 25mm 30mm

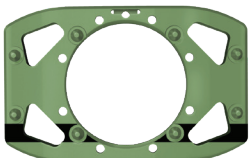
END CAP ANGLE COMPARISON



0 degrees* 8 degrees 15 degrees

*Only available in 16mm, 22mm, 30mm End Cap options.

EXTENDED END CAP WIDTH COMPARISON

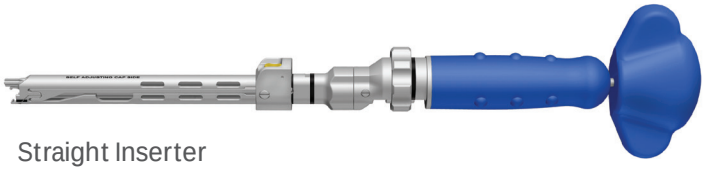


20mm 25mm

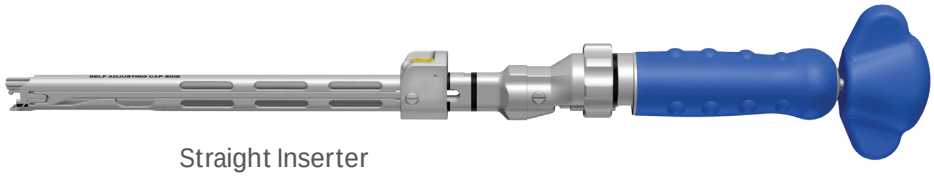
Lengths available = 30mm, 35mm, 40mm, 45mm
Extended End Caps are only offered in 0 degrees.

Note
Modular End Caps are cleared for use in the thoracolumbar spine only.

INSERTER FEATURES

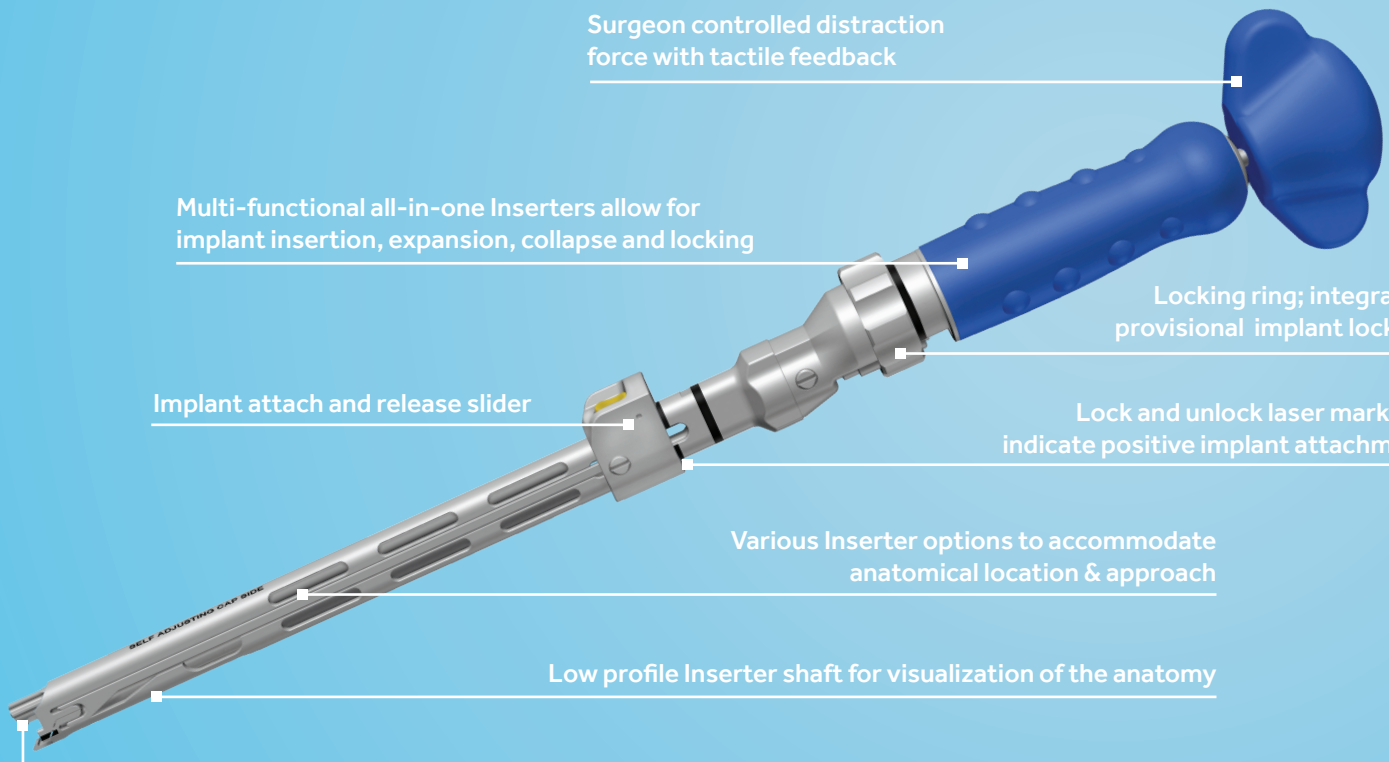


Straight Inserter
13mm, 4360113



Straight Inserter
20/25mm, 4360120

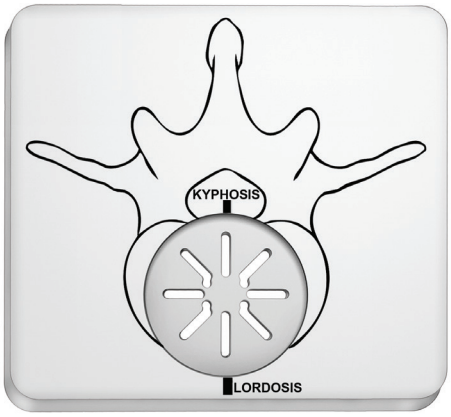
Angled Inserter
20/25mm, 4360221



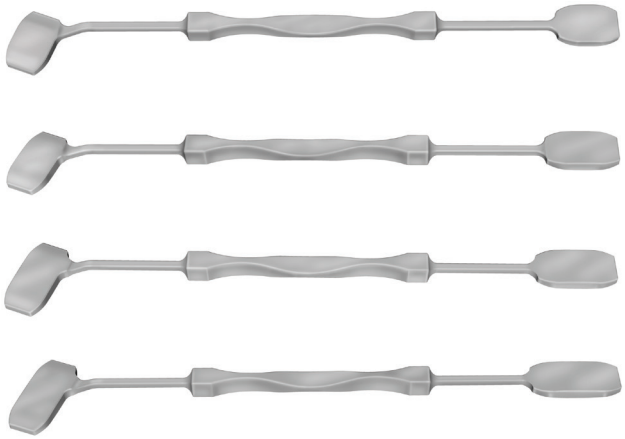
ADDITIONAL INSTRUMENTS

Template
13/16mm, 4361316
20/25mm, 4362025
22/30mm, 4362230

Caliper
13mm, 4360713
20/25mm, 4360720



Loading Block
7975116



Extended Template
20mm × 30mm, 4360030
20mm × 35mm, 4360035
20mm × 40mm, 4360040
20mm × 45mm, 4360045

Bone Tamp
Small 9359003
Large 9359904

Torque Limiting Handle
T10, SC335010-J
T17, SC230020-J

Driver
T10, 4360513
T17, 4360520

End Cap Removal Tool
4360002

Implant Removal Tool
4360320

HEIGHT MEASUREMENT

Select the appropriate Caliper for the implant diameter. Rotate the readout rack to the desired display **(Figure 2)**.

To rotate the readout rack to the desired display, lift the readout rack out of the Caliper fork **(Figure 3)**. Push the readout rack down and rotate to the desired display measuring option **(Figure 4 and 5)**.

Large Caliper for 20mm and 25mm Centerpieces.

The three sides of the readout rack on the large Caliper display:

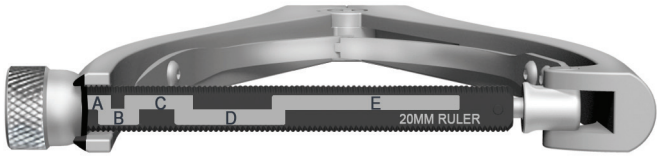
1. the height ranges of the 20mm Centerpieces
2. the height ranges of the 25mm Centerpieces and
3. the incremental height in millimeters

Small Caliper for 13mm Centerpieces.

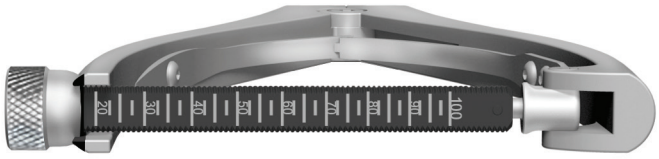
The three sides of the readout rack on the small Caliper display:

1. the height ranges of the 13mm Centerpieces
2. the height ranges of the 13mm Centerpieces with two 16mm 0 degree End Caps, and
3. the incremental height in millimeters

Once the rack is turned to the desired readout display, pull out the readout rack and position between the forks **(Figure 6)**. The desired readout display should be positioned between the two forks as shown in Figure 2.



Collapsed & Expanded Centerpiece Measurement



Incremental Height Measurement

Figure 2

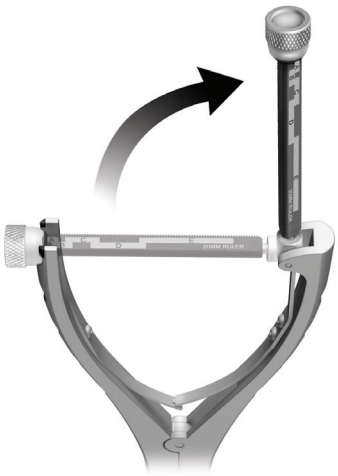


Figure 3

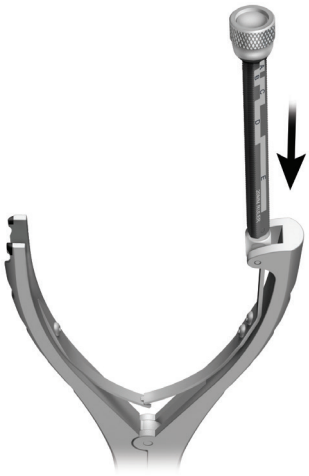


Figure 4

Figure 5

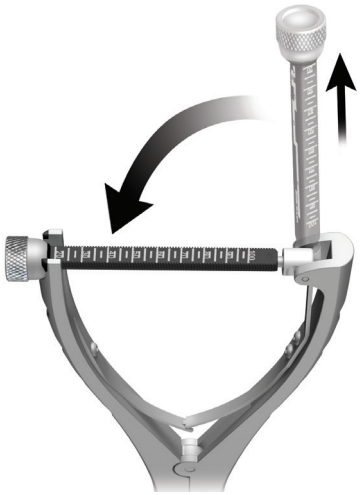


Figure 6

Position the Caliper in the defect. Squeeze the Caliper and measure from the black laser mark on the fork of the Caliper **(Figure 7)**. Alternatively, to get a more accurate reading the nut on the end of the readout rack can be screwed down and the height can be measured from the black laser mark on the end of the nut **(Figure 8)**.

Note
If the Caliper is used for vertebral distraction, accuracy of the measurement could be impacted.

Important
In the cervical spine excessive distraction can cause potential neurologic injury and should be avoided.

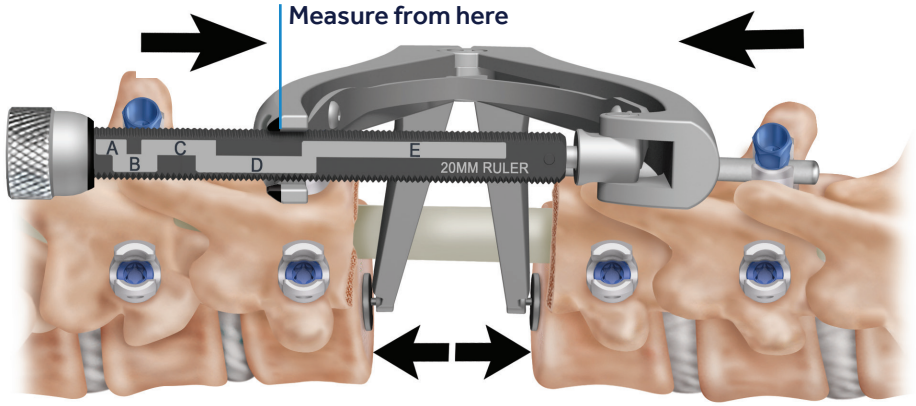


Figure 7

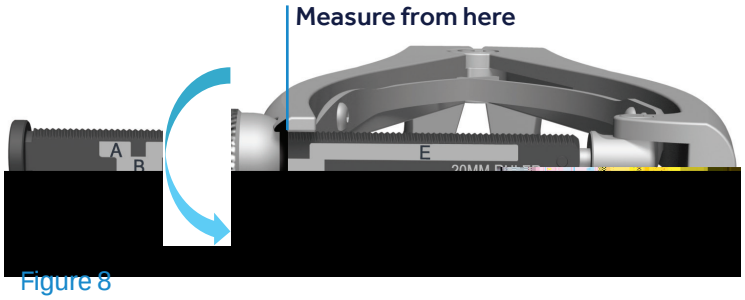


Figure 8

Caudal End Cap Orientation

Place the appropriately angled End Cap into the Loading Block with the spikes facing down and the holes facing up. Rotate the End Cap so that its tallest point is facing the word, "Lordosis" **(Figures 11a and 11b)**. If kyphosis is required, rotate the End Cap so that its tallest point is facing the word, "Kyphosis".

Centerpiece Orientation

Using the vertebral sketch on the Loading Block, orient the Centerpiece above the caudal End Cap relative to the surgical approach. The Centerpieces have 8 orientation options to attach the End Caps (**Figure 9a**). Locate the laser mark on the End Cap. Center one of the Centerpiece orientation options over the End Cap laser mark.

Caudal End Cap Attachment to the Centerpiece

Once the Centerpiece is positioned over the caudal End Cap, dock the groove on the edge of the Centerpiece on the black laser mark side of the End Cap (**Figure 11c**). Rotate the Centerpiece down onto the End Cap and press on the top side of the Centerpiece to snap together (**Figure 11d**).

Cephalad End Cap Attachment to the Centerpiece

If you need to add another End Cap, without removing the Centerpiece from the Loading Block, align the tallest point of the cephalad End Cap with the tallest point of the caudal End Cap. Dock the End Cap laser mark in the groove on the edge of the Centerpiece (**Figure 11e**). Rotate the End Cap down onto the Centerpiece and press on the top side of the End Cap to snap together (**Figure 11f**).

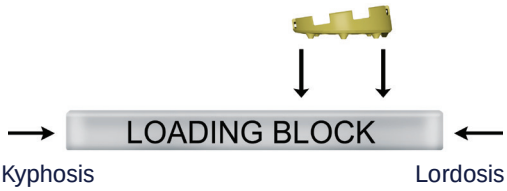


Figure 11a

Figure 11b

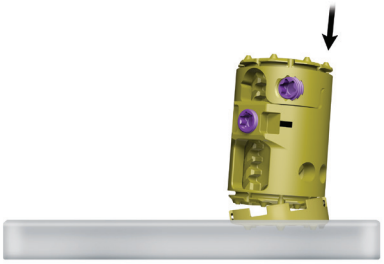


Figure 11c

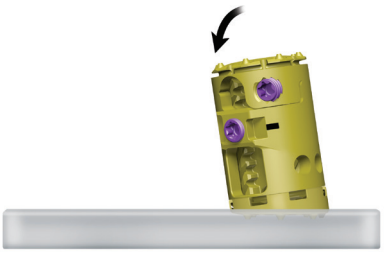


Figure 11d

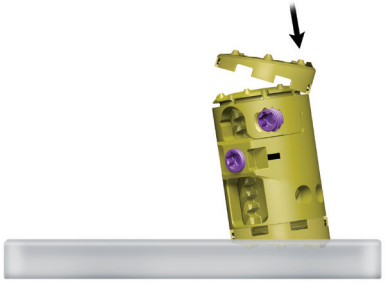


Figure 11e

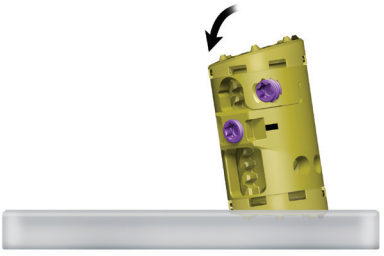


Figure 11f

GRAFT PRE-PACKING

Once you have assembled the implant, prepack the Centerpiece with bone graft using a Bone Tamp **(Figures 12a and 12b)**.

Cervical (C2-C7) - 13mm Centerpiece Only

In the cervical spine the system is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Medtronic offers Grafton Demineralized Bone Matrix (DBM) that can be combined with autograft for use in the cervical spine.

Cervical Allograft Options

*UDIWRQw
HPLQHUDOL]HGRQH
0DWUL[%

Thoracolumbar (T1-L5) - All Implants

In the thoracolumbar spine the system is intended to be used with autograft or allograft material. Medtronic offers Grafton Demineralized Bone Matrix (DBM) as an allograft option that can be used in the thoracolumbar spine

Important
When packing bone graft, ensure that graft does not come in contact with the expansion ring area (**Figure 12c**). Do not over pack the implant with graft.

Thoracolumbar Allograft Options

UDIWRw
HPLHUDOLHGRH
0DWUL[

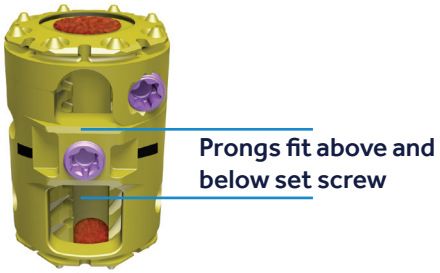
No Graft in Expansion Ring Area

Figure 12a

Figure 12b

Figure 12c

Align the prongs on the Inserter with the slots on the implant above and below the set screw (**Figure 16**). Push the implant onto the prongs of the Inserter (**Figure 17**). The black laser marks on the side of the Inserter and implant can also be used to align the tabs. Press the gold slider button and push the slider forward past the black lock laser mark **(Figure 18)**. Push the locking ring forward so that the black locking ring laser mark is visible **(Figure 19)**. Push the blue T-handle in and the implant is now connected to the Inserter **(Figures 20a and 20b)**.



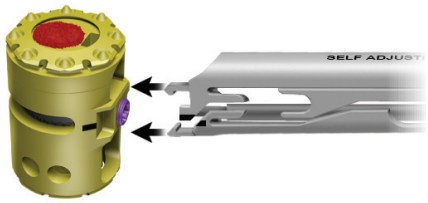
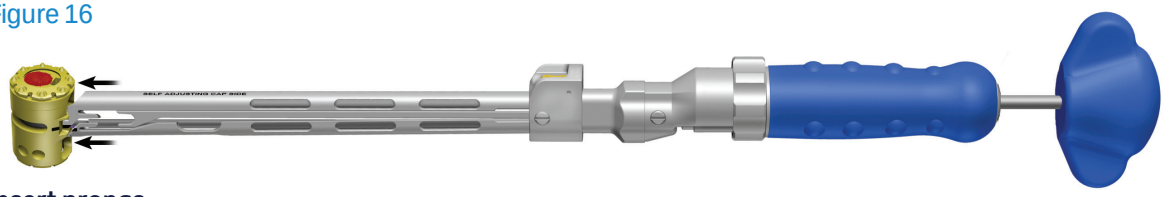


Figure 16



Insert prongs

Figure 17

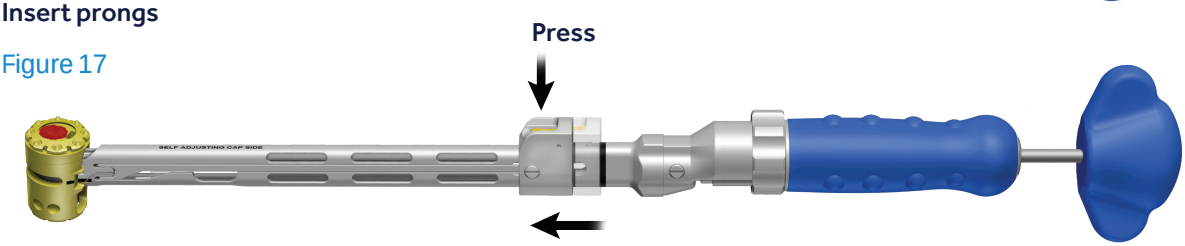


Figure 18

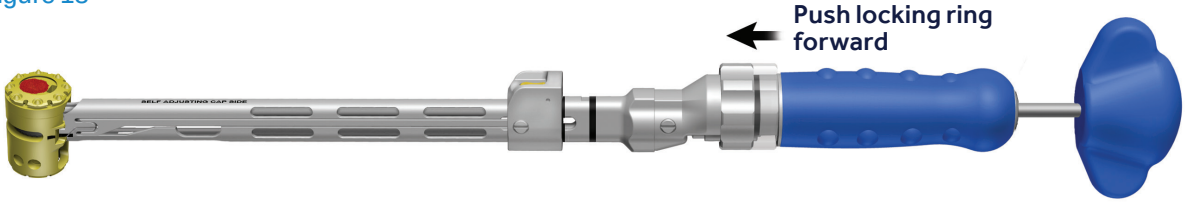


Figure 19

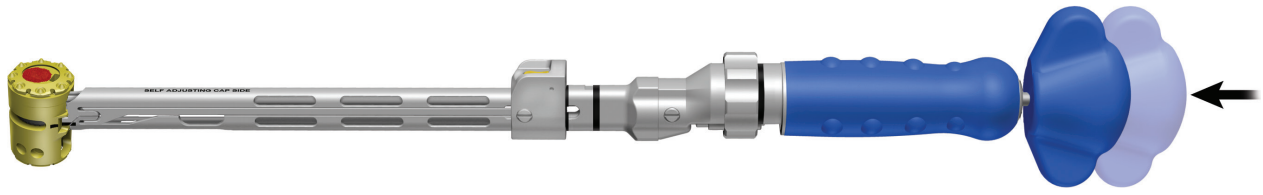
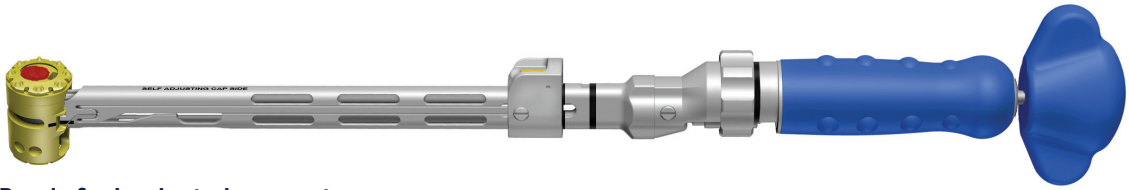


Figure 20a



Ready for implant placement

Figure 20b

Position the implant in the corpectomy defect and rotate the blue T-handle clockwise to expand the implant **(Figures 21a and 22)**. The Self-Adjusting Multi-Axial End Cap will self-align to the endplate surface as you expand. The implant can be positioned to expand either cephalad or caudal based on patient anatomy considerations **(Figures 21a and 21b)**. The blue T-handle can be turned counterclockwise to collapse the implant if repositioning is necessary. The implant is at the maximum expansion when the silver (13mm Centerpiece) or black (20mm and 25mm Centerpiece) line is fully visible on the implant. The maximum expansion laser mark is 3mm wide to indicate the implant is reaching its full expansion.

Note
If it is necessary to mallet the implant into the defect, the blue T-handle can be removed from the Inserter to access the impactor cap for malleting.

Important
In the cervical spine excessive distraction could cause potential neurological injury and should be avoided.

Important
When expanding the implant, always push down on the blue T-handle to ensure it is fully engaged with the implant. If at any time a clicking sound is heard during expansion, stop expanding and inspect the implant prior to proceeding.

Figure 21a

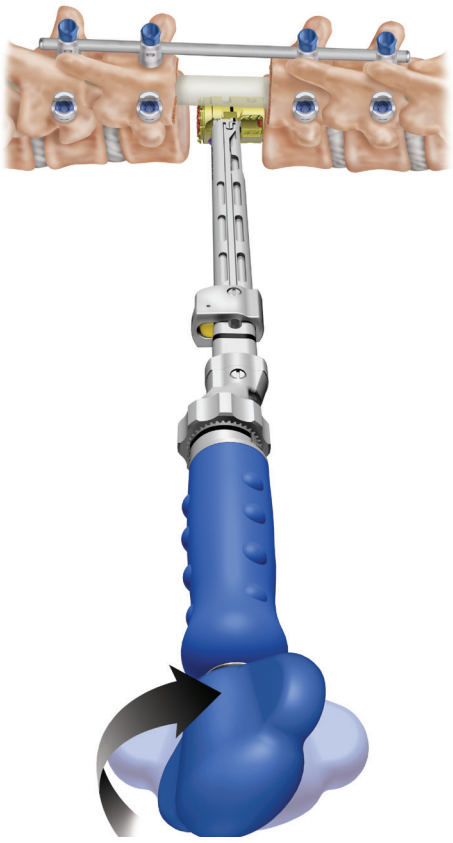


Figure 21b

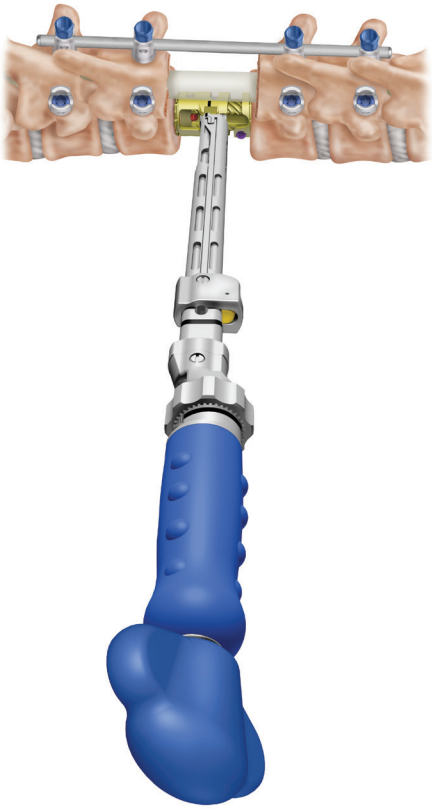


Figure 22

To confirm placement of the implant, the set screw can be provisionally tightened by pushing down on the locking ring, ensure the black laser mark is visible, and rotate the locking ring clockwise, approximately a 1/2 turn, to tighten the set screw **(Figure 23)**.

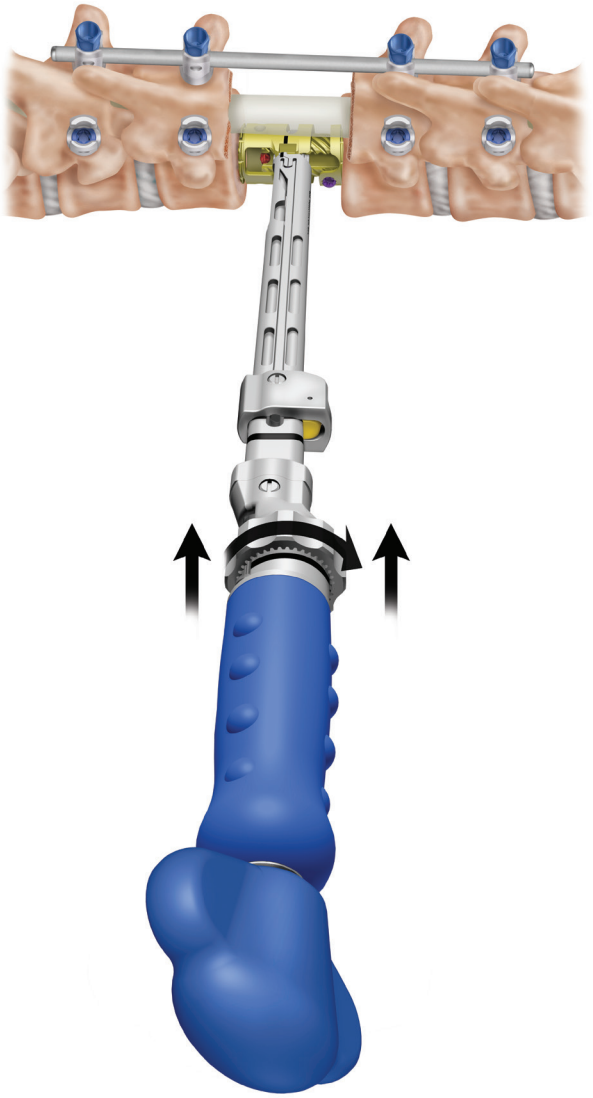


Figure 23

Note
If repositioning of the implant is necessary, the locking ring can be pushed down and rotated counterclockwise to release the set screw. The implant may be repositioned and reprovisionally tightened.

Note
When turning the locking ring only finger tightening is necessary to lock and unlock the set screw. Using excessive torque can make it difficult to subsequently loosen or tighten the set screw.

Final Locking

Once final placement of the implant is achieved, final lock the implant height by inserting the Driver into the hole on the Inserter handle, push down and turn clockwise until the Torque Limiting Handle clicks (**Figure 24**).

If desired, the Self-Adjusting Multi-Axial End Cap can be locked by placing the Driver in the set screw and turning the Driver clockwise until the Torque Limiting Handle clicks (**Figure 25**). Although not required, it is recommended to lock the Self-Adjusting Multi-Axial End Cap when possible.

Note
Once final locking is achieved with the Torque Limiting Handle, the implant cannot be re-used.

Note
If a posterior approach is utilized, the implant height may be locked and a posterior lordosis or kyphosis correction can be performed, if necessary. During this correction, the Self-Adjusting Multi-Axial End Cap will articulate with the endplate maintaining surface to surface contact and Multi-Axial End Cap load distribution. After the correction, the Self-Adjusting Multi-Axial End Cap set screw can be locked to maintain the position.

Note
If a lateral, oblique, or anterior approach is utilized, the Self-Adjusting Multi-Axial End Cap can be left unlocked prior to re-positioning the patient for posterior fixation. During posterior fixation a posterior lordosis or kyphosis correction can be performed. During this correction, the Self-Adjusting Multi-Axial End Cap will articulate with the endplate maintaining surface to surface contact and Multi-Axial End Cap load distribution. The Self-Adjusting Multi-Axial End Cap will remain unlocked after the correction.

Figure 24

Figure 25

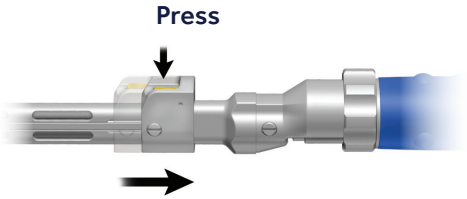
To remove the Inserter, pull back on or remove the blue T-handle and pull back on the locking ring to disengage them from the implant (**Figures 26 and 27**). Then press the gold slider button on the Inserter and pull the slider back past the black unlock laser mark and hold (**Figure 28**). Translate the Inserter slightly toward the Self-Adjusting Multi-Axial End Cap and pull back to disengage the Inserter from the implant (**Figure 29**).

Pull blue T-handle back

Figure 26

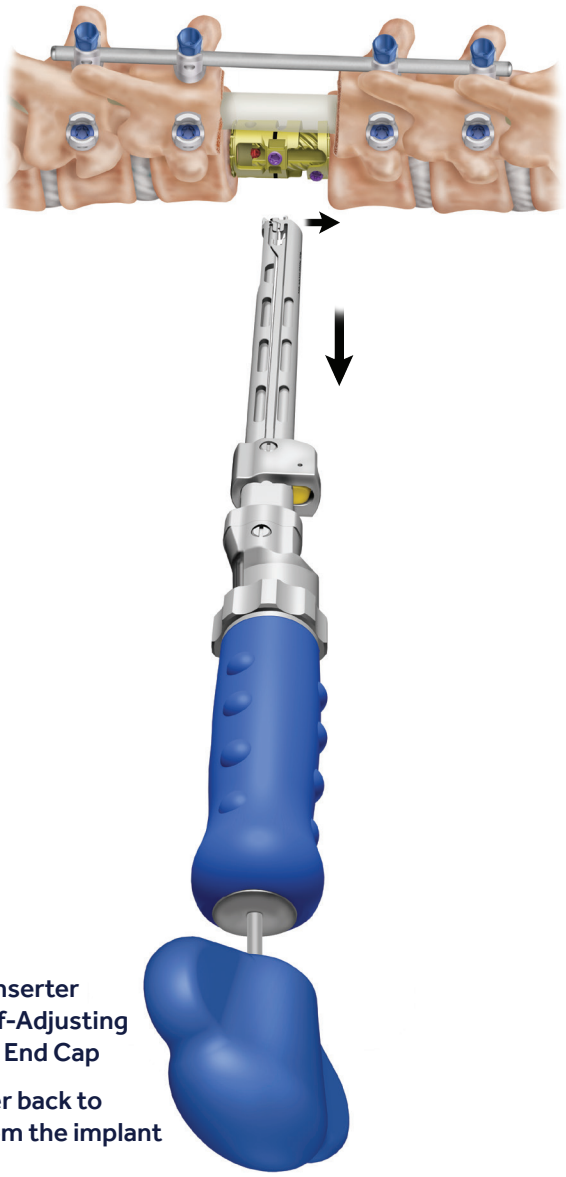
Pull locking ring back

Figure 27



Slide past unlock laser mark and hold

Figure 28



Translate Inserter toward Self-Adjusting Multi-Axial End Cap

Pull Inserter back to remove from the implant

Figure 29

FINAL PLACEMENT & GRAFT POST-PACKING

Obtain final imaging to ensure the implant is properly positioned. Pack additional bone graft inside and around the device (**Figure 30**).

In the cervical spine the system is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Medtronic offers allograft chips that can be combined with autograft for use in the cervical spine.

In the thoracolumbar spine the system is intended to be used with autograft or allograft material. Medtronic offers a number of allograft options that can be used in the thoracolumbar spine including **Grafton Demineralized Bone Matrix (DBM) .**

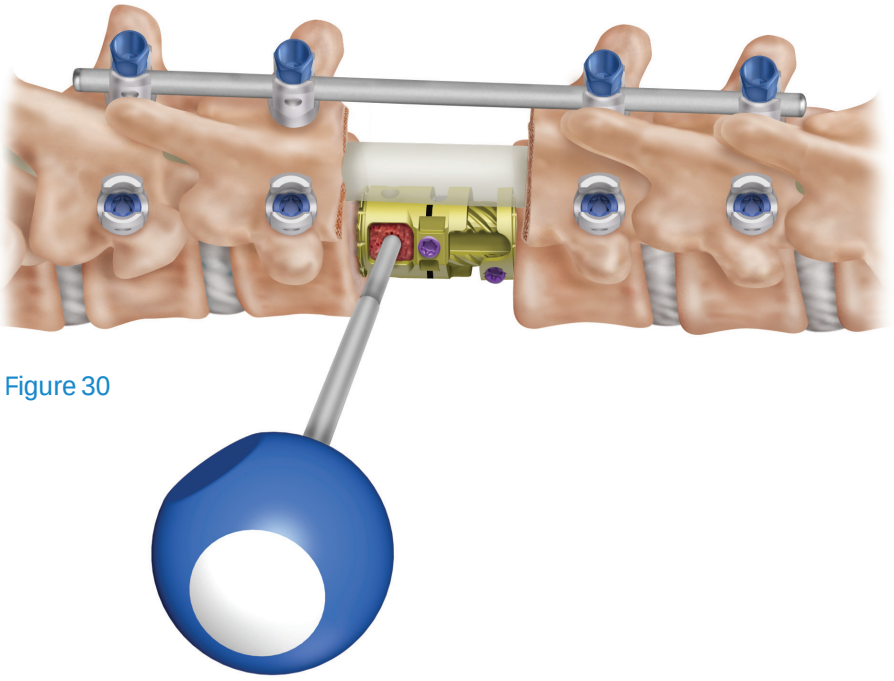
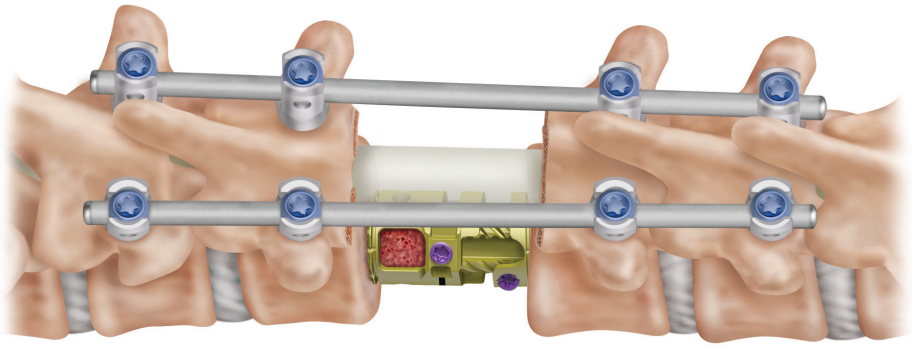


Figure 30



Final placement

EXPLANTATION

To explant the implant, grasp the implant with the Implant Removal Tool above and below the set screw (**Figure 31**).

Use the Driver to turn the implant set screw counterclockwise. The implant height will slightly collapse when it is unlocked. Remove the implant **(Figure 32)**.

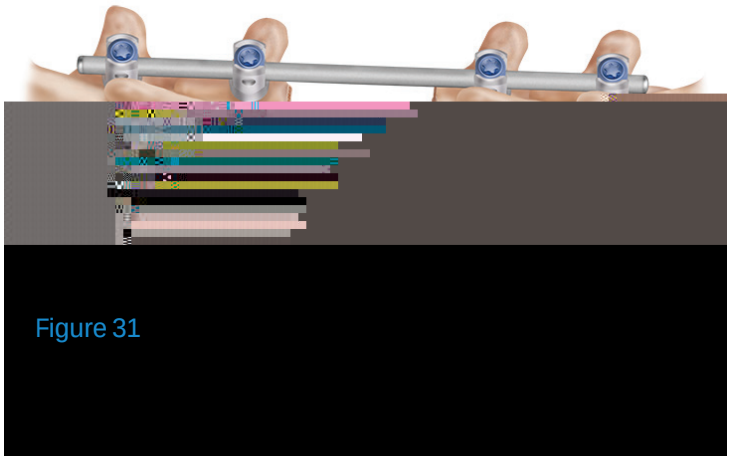


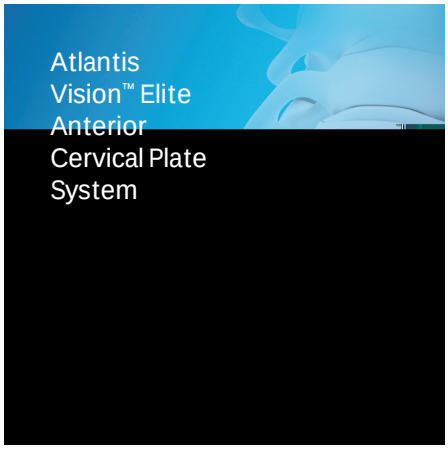
Figure 31

Figure 32

SUPPLEMENTAL FIXATION

Cervical Supplemental Fixation

When used in the cervical spine at one or two levels, apply anterior and/or posterior supplemental fixation cleared for use in the cervical spine such as Atlantis Vision™ Elite Anterior Cervical Plate System or Infinity™ Occipitocervical-Upper Thoracic System. When used at more than two levels, supplemental fixation must include posterior fixation cleared for use in the cervical spine. T2 Stratosphere Expandable Corpectomy System is NOT intended as a stand alone system.



Thoracolumbar Supplemental Fixation

When used in the thoracolumbar spine apply anterior and/or posterior supplemental fixation cleared for use in the thoracolumbar spine such as the Vantage™ Anterior Fixation System or the CD Horizon™ Spinal Systems. T2 Stratosphere Expandable Corpectomy System is NOT intended as a stand alone system.

*

PRODUCT ORDERING INFORMATION

SPSXV300 -
T2 Stratosphere Expandable Corpectomy System 13mm Instrument & Implant Set

CFN	Description	QTY
436013A	13mm, A-size Centerpiece	1
436013B	13mm, B-size Centerpiece	1
436013C	13mm, C-size Centerpiece	1
436013D	13mm, D-size Centerpiece	1
436013E	13mm, E-size Centerpiece	1
4360160	End Cap 16mm, 0˚	2
4360138	End Cap 13mm, 8˚	2
4360168	End Cap 16mm, 8˚	2
4360135	End Cap 13mm, 15˚	2
4360165	End Cap 16mm, 15˚	2
4360113	13mm Inserter	1
4361316	13mm/16mm Template	1
4360713	13mm Caliper	1
7975116	Loading Block	1
4360320	Implant Removal Tool	1
4360513	T10 Driver	2
SC335010-J	T10 Torque Limiting Handle	1
4360002	End Cap Removal Tool	1
9359003	Small Bone Tamp	1

SPSXV400 -
T2 Stratosphere Expandable Corpectomy System Extended Templates & Extended End Caps Set

CFN	Description	QTY
4360030	30mm Extended Template	1
4360035	35mm Extended Template	1
4360040	40mm Extended Template	1
4360045	45mm Extended Template	1
436020300	Extended End Cap 20 x 30mm, 0˚	2
436020350	Extended End Cap 20 x 35mm, 0˚	2
436020400	Extended End Cap 20 x 40mm, 0˚	2
436020450	Extended End Cap 20 x 45mm, 0˚	2
436025300	Extended End Cap 25 x 30mm, 0˚	2
436025350	Extended End Cap 25 x 35mm, 0˚	2
436025400	Extended End Cap 25 x 40mm, 0˚	2
436025450	Extended End Cap 25 x 45mm, 0˚	2

SPSXV350 -
T2 Stratosphere Expandable Corpectomy System 20/25mm Instrument & Implant Set

CFN	Description	QTY
436020A	20mm, A-size Centerpiece	1
436020B	20mm, B-size Centerpiece	1
436020C	20mm, C-size Centerpiece	1
436020D	20mm, D-size Centerpiece	1
436025A	25mm, A-size Centerpiece	1
436025B	25mm, B-size Centerpiece	1
436025C	25mm, C-size Centerpiece	1
436025D	25mm, D-size Centerpiece	1
4360220	End Cap 22mm, 0˚	2
4360300	End Cap 30mm, 0˚	2
4360208	End Cap 20mm, 8˚	2
4360228	End Cap 22mm, 8˚	2
4360258	End Cap 25mm, 8˚	2
4360308	End Cap 30mm, 8˚	2
4360120	20mm/25mm Inserter	1
4362025	20mm/25mm Template	1
4362230	22mm/30mm Template	1
4360221	20mm/25mm Angled Inserter	1
4360720	20mm/25mm Caliper	1
7975116	Loading Block	1
4360520	T17 Driver	2
SC230020-J	T17 Torque Limiting Handle	1
4360002	End Cap Removal Tool	1
4360320	Implant Removal Tool	1
9359904	Large Bone Tamp	1

IMPORTANT INFORMATION ON THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM

PURPOSE

The T2 Stratosphere™ Expandable Corpectomy System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the thoracolumbar and cervical spine.

DESCRIPTION

The T2 Stratosphere™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self- adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements. The T2 Stratosphere™ Expandable Corpectomy devices for use in the thoracolumbar and cervical spine are restricted to the 13mm diameter centerpieces. The T2 Stratosphere™ Expandable Corpectomy System is made of titanium alloy and is provided sterile and non-sterile. This device is inserted between two vertebral bodies in the thoracolumbar or cervical spine and is expanded to aid in the surgical correction and stabilization of the spine. The centerpieces are available in multiple heights. The system also features modular end caps which are available in various angles and diameters, and are only for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

For Thoracolumbar Corpectomy with an Expandable Device

The device may be implanted through a lateral, oblique, or posterior approach using a minimally invasive technique or implanted through a lateral, oblique, posterior, or anterior approach through a traditional open technique. The device is indicated for single or two-level use in the thoracic and lumbar anterior spine.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the thoracolumbar spine.

For Cervical Corpectomy with an Expandable Device

The device may be implanted through an anterior approach using a traditional open technique.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation.

Do not use implant components from any other manufacturer with T2 Stratosphere™ Expandable Corpectomy System components. Never use titanium or titanium alloy implants with stainless steel in the same construct. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) and cervical spine (C2-C7). The T2 Stratosphere™ Expandable Corpectomy System is intended for use in skeletally mature patients.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at single or two levels, the T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine.

When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Corpectomy centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

CONTRAINDICATIONS

- The device is not intended to be implanted from a posterior cervical approach. Contraindications include:
- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any non-tumor cases where a bone graft and fusion are unnecessary or where fracture healing is not required.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Fever or leukocytosis.
- Infection (excluding osteomyelitis in the cervical spine) local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Suspected or documented metal allergy or intolerance.

These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POSSIBLE ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes:

- Early or late loosening of the components and implant migration.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density possibly caused by stress shielding.
- Subsidence of the device into vertebral body(ies).
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, cardiovascular system compromise, and wound necrosis or wound dehiscence.
- 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.
- Death.

Note: additional surgery may be necessary to correct some of these anticipated adverse events

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. This system is not intended to be the sole means of spinal support. The T2 Stratosphere™ Expandable Corpectomy System must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) could eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic because the combination with other instrumentation may be incompatible and may not be guaranteed.

A device that has been implanted should never be reprocessed or reused under any circumstances. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

IMPORTANT INFORMATION ON THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM

PURPOSE

The T2 Stratosphere™ Expandable Corpectomy System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine for tumor and trauma pathologies. This system is indicated for single and two-level use in the thoracic and lumbar anterior spine.

DESCRIPTION

The T2 Stratosphere™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self- adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements.

This device is inserted between two vertebral bodies in the thoracic and lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral, oblique, or posterior approach using a minimally invasive technique or implanted through a lateral, oblique, posterior, or anterior approach through a traditional open technique.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

The T2 Stratosphere™ Expandable Corpectomy System is made of titanium alloy and is provided sterile and non-sterile. The centerpieces are available in multiple diameters and heights. The system also features modular end caps which are available in various angles and geometries.

Do not use implant components from any other manufacturer with T2 Stratosphere™ Expandable Corpectomy System components. Never use titanium or titanium alloy implants with stainless steel in the same construct.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture).

The T2 Stratosphere™ Expandable Centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

The T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft, as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

CONTRAINDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is not intended for cervical surgical implantation. Contraindications include:

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Signs of local inflammation.
- Fever or leukocytosis.
- Infection local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Suspected or documented metal allergy or intolerance.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

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POSSIBLE ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes:

- Early or late loosening of the components and implant migration.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density possibly caused by stress shielding.
- Subsidence of the device into vertebral body(ies).
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Loss of spinal mobility or function.

- Inability to perform the activities of daily living.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, cardiovascular system compromise, and wound necrosis or wound dehiscence.
- 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.
- Death.

Note: additional surgery may be necessary to correct some of these anticipated adverse events

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. This system is not intended to be the sole means of spinal support. The T2 Stratosphere™ Expandable Corpectomy System must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) could eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic because the combination with other instrumentation may be incompatible and may not be guaranteed.

A device that has been implanted should never be reprocessed or reused under any circumstances. Sterile packaged devices should also never be resterilized. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

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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.

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