DOMINION

EXPANDABLE CORPECTOMY SYSTEM

CERVICAL

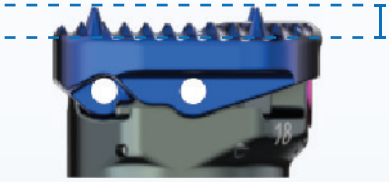
ASTURA MEDICAL

DESIGN RATIONALE

The Dominion Expandable Corpectomy System provides unparalleled precision with an innovative blend of implants and instruments tailored for the unique challenges associated with cervical procedures. The system features expandable columns with modular adjustable endplates, designed for an exact anatomical fit, ensuring each procedure is as unique as the patient it serves. Surgeons are empowered with multiple fixation options for endplates, providing the flexibility needed to navigate the distinct challenges of each surgery. Whether adapting to exposure constraints or specific biomechanical needs, the Dominion System offers intraoperative versatility, setting a new standard for surgical precision and patient-specific care.

SPECIFICATIONS

COLUMNS



0.5mm spikes

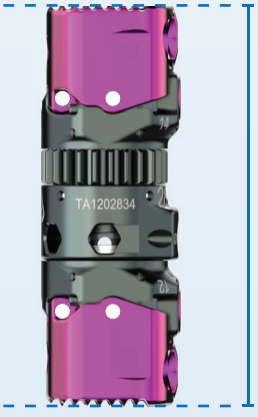
****Not included in table column height values.**

Standard Non-fixated Collapsed Height

Standard Non-fixated Collapsed Height

Full Plate Collapsed Height

Full Plate Expanded Height



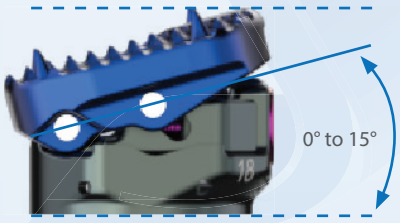
Zero Plate Collapsed Height

Zero Plate Expanded Height

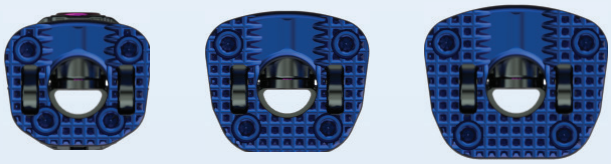
COLUMNS WITH NON-FIXATED OR FULL PLATE ENDPLATES				
COLUMN PART NUMBER	COLLAPSED HEIGHT (MM)	EXPANDED HEIGHT (MM)	MIN LORDOSIS	MAX LORDOSIS
TA1201520	15	20	7°	7°
TA1202025	20	25	3.5°	18.5°
TA1202329	23	29	3.5°	18.5°
TA1202834	28	34	0°	30°
TA1203242	32	42	0°	30°
TA1204160	41	60	0°	30°

COLUMNS WITH ZERO ENDPLATES				
COLUMN PART NUMBER	COLLAPSED HEIGHT (MM)	EXPANDED HEIGHT (MM)	MIN LORDOSIS	MAX LORDOSIS
TA1201520	N/A	N/A	N/A	N/A
TA1202025	N/A	N/A	N/A	N/A
TA1202329	28	34	7°	22°
TA1202834	38	40	0°	30°
TA1203242	44	54	0°	30°
TA1204160	53	72	0°	30°

LORDOSIS



FOOTPRINTS

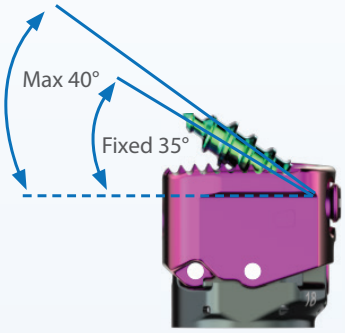


14x12mm 16x14mm 18x15mm

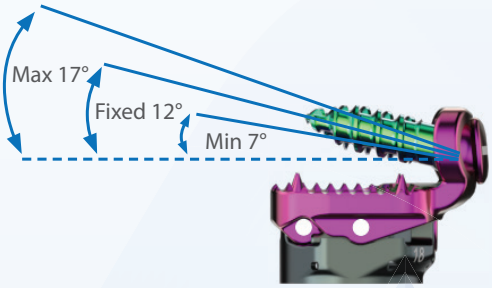
SPECIFICATIONS

SCREW ANGULATION

Zero Plate



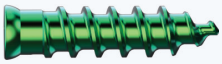
Full Plate



SCREWS

Ø3.5mm

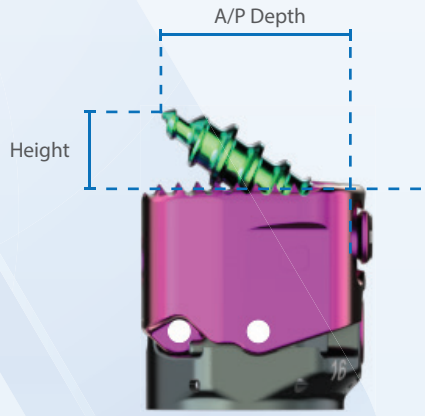
Ø4.0mm



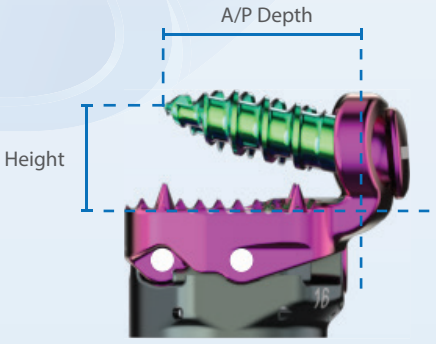
*Lengths available from 10-20mm in 2mm increments.

Warning: Screws not to exceed the max lengths for the sizes designated below.

ZERO PLATE WITH SCREWS		
SCREW LENGTH (MM)	**A/P DEPTH (MM)**	**HEIGHT (MM)**
10	11.44	1.97
12	13.27	2.78
14	15.10	3.59
16	16.93	4.40
18	18.75	5.21
20	20.58	6.03
PLATE SIZE (MM)	**MAX SCREW LENGTH (MM)**	
14x12	10	
16x14	12	
18x15	14	



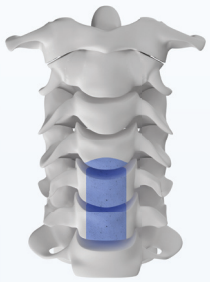
FULL PLATE WITH SCREWS		
SCREW LENGTH (MM)	**A/P DEPTH (MM)**	**HEIGHT (MM)**
10	8.48	2.05
12	10.31	2.86
14	12.14	3.67
16	13.97	4.48
18	15.80	5.29
20	17.62	6.10
PLATE SIZE (MM)	**MAX SCREW LENGTH (MM)**	
14x12	14	
16x14	16	
18x15	16	



1.0 EXPOSURE

1.1 Use a surgical pen to mark the incision location using a combination of palpation and fluoroscopy.

1.2 Incise the skin and dissect down to the desired level and maintain exposure using general surgical instrumentation.



2.0 VERTEBRAL RESECTION

2.1 Utilize general surgical instrumentation and techniques to remove the desired vertebral segments and adjacent discs. Preserve all autograft bone for use within the Column.

3.0 IDENTIFICATION OF COLUMN SIZE

3.1 Identification of Starting Height

3.1.1 Place the distal tips of the Height Caliper (TZBA03000) on the two opposing end plates ensuring the recessed portion of the tips are fully seated on the proximal cortex and end plate junction. Record the size shown within the window of the device. Warning: Do not force the caliper against the endplates, this will result in an inacurate measurement.

4.0 TRIAL ASSEMBLY (OPTIONAL)

4.1 Identify the largest height Expandable Trial Column (TZBA0100X) from the table on page 3 that is less than the height recorded with the Height Caliper (TZBA03000) in the sequence above.

4.1.1 Note that the selected endplates will affect the starting height of the selected Column Assembly.

4.2 Identify the desired Trial Endplate: footprint (TZBA02BX0).

4.3 Obtain the Assembly Guide (TZBA2002) and place it on a level surface. Position the first Trial Endplate (TZBA02BXX) on the assembly guide with the contact surface facing downwards. Rotate the Trial Endplate on the guide until it drops into its "keyed" location, ensuring that the endplate cannot rotate with respect to the guide.

4.4 Obtain the previously selected Expandable Trial Column (TZBA0100X) and locate the orientation lasermark on its end. Align this mark with the lasermark on the bottom side of the Expandable Trial Endplate (TZBA02BX0) to ensure correct orientation. Apply downward force on the Expandable Trial Column until you hear an audible click, confirming proper attachment. Repeat these steps to attach the opposite Expandable Trial Endplate.

4.4.1 If an alternative approach angle is desired, match the alignment lasermarking on the Expandable Trial Column (TZBA0100X) to the markings on the Assembly Guide (TZBA2002).

4.4.2 Optional: Utilize the Implant Assembly Instrument (TZBC20002) to apply the assembly force.

4.4.3 Once the endplates are attached, their lordotic angle can be adjusted using the Lordosis Driver (TZBB12000) with the desired Modular Handle (Egg EDDEATAAZ or Axial EABEASADZ). Insert the distal Torx end of the Lordosis Driver into the female Torx and rotate clockwise until the desired lordosis is achieved. This adjustment is self-locking and does not require an additional locking sequence.

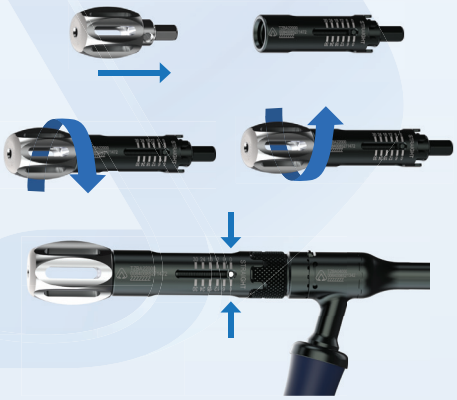
Warning: Stop rotating the handle when the endplates are fully collapsed or expanded to avoid damaging the instruments or implant.

4.5 Attach the desired Inserter (Straight TZBA04000 or Articulating TZBA06000) to the Column Trial by first securing the Black Inserter Assembly Knob (TZB007000) to the proximal end of the Inserter. Once the Assembly Knob is in place, align the threads on the distal end of the Inserter with those on the Column Trial. Rotate the locking knob clockwise until you can visually confirm that the Inserter is fully seated on the Column Trial. Finally, remove the Assembly Knob by pulling it off the Inserter.

4.6 Attach the distal end of the Silver Inserter Expansion Knob (TZB008000) to the proximal end of the Expansion Indicator (TZBB22000).

4.6.1 If using the Straight Inserter (TZBB04000), rotate the Inserter Expansion Knob (TZB008000) clockwise until the indicator is in the "0" location.

4.6.2 If using the Articulating Inserter (TZBB06000), rotate the Inserter Expansion Knob counter-clockwise until the indicator is in the "0" location.

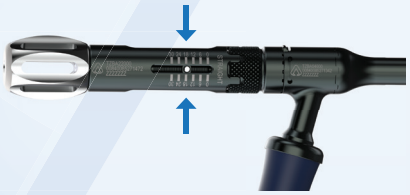


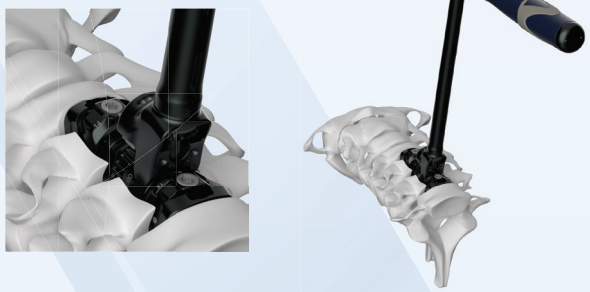
4.7 Attach the Expansion Indicator (TZBB22000) and Inserter Expansion Knob (TZB008000) Assembly onto the Inserter by inserting the proximal end of the Expansion Gauge (TZBC22000) into the proximal end of the Inserter.

5.0 TRIALING

5.1 Once assembly of the Expandable Trial has been completed, place the distal end of the device into the previously created vertebral void and confirm the location using fluoroscopy.

5.2 Once the Expandable Trial is in the desired location, rotate the knob until the desired height is achieved and record the value from the Expansion Indicator (TZBC22000).

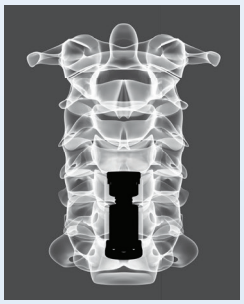


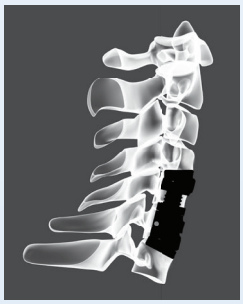


5.2.1 If additional input torque is required, you can replace the Inserter Expansion Knob with the Modular Egg Handle (EDDEATAAZ) by attaching it to the Inserter AO Expansion Adapter (TZBB09000) to gain additional mechanical advantage.

Warning: Be sure to stop rotating the handle when it is fully expanded to avoid damaging the instruments.

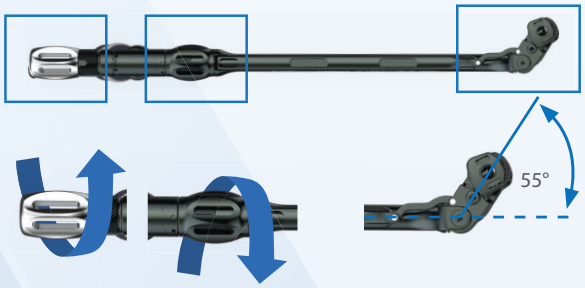
5.2.1.1 Verify Trial Column placement with fluoroscopy.





5.3 To remove the Expandable Trial, rotate the Inserter Expansion Knob (TZB008000) counterclockwise until the Column (TZBC0100X) is fully collapsed, then remove it from the patient.
Warning: Be sure stop rotating the handle when fully collapsed to avoid damaging the instruments.

5.4 If using the ML Articulating Inserter (TZBB06000), adjust the insertion angle by rotating the Distal Black Angulation Knob until the desired angle is achieved.
Warning: Column expansion for the ML Articulating Inserter requires counterclockwise rotation of the silver knob.



6.0 COLUMN ASSEMBLY

6.1 Identify the desired Column (TA120XXXX) based on the Caliper (TZBA03000) trialing performed above.

6.2 Identify the desired Endplate: footprint and fixation type (Standard TBB0XXXXX, Zero TBEAXXXXX, Full TBF0XXXXX).

6.3 Obtain the Column Assembly Guide (TZBA21002) and place it on a level surface. Position the first Endplate onto the Column Assembly Guide with the teeth facing downwards toward the table. Rotate the Endplate on the guide until it drops into a "keyed" location, ensuring that the endplate cannot rotate with respect to the guide.

6.4 Obtain the previously selected size Column (TA120XXXX) and locate the orientation lasermark on its end. Align this mark with the lasermark on the bottom side of the Endplate (Standard TBB0XXXXX, Zero TBEAXXXXX, Full TBF0XXXXX) to ensure correct orientation. Once properly aligned, apply downward force on the Column until you hear an audible click, confirming proper attachment. Repeat these steps to attach the opposite Endplate.

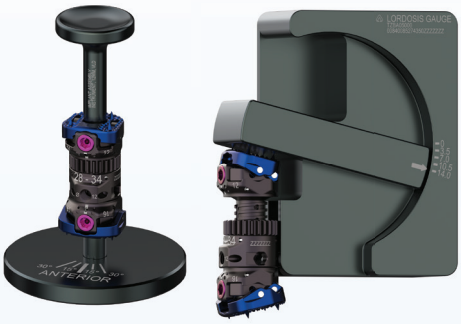
6.4.1 If an alternative approach angle is desired, match the alignment lasermarking on the Expandable Trial Column (TZBC0100X) to the markings on the Assembly Guide (TZBA21002).

6.4.2 Optional: Utilize the Implant Assembly Instrument (TZBA21002) to apply the assembly force.

7.0 PRE-INSERTION ENDPLATE ADJUSTMENT

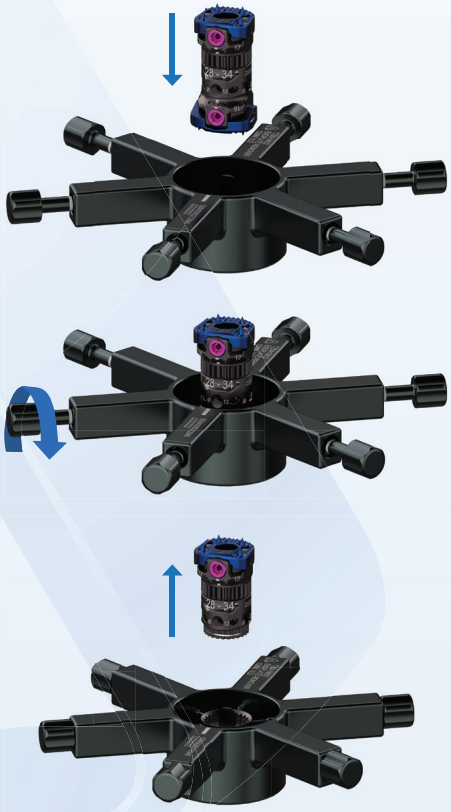
7.1 Once the endplates are attached, theri lordotic angle can be adjusted using the Lordosis Driver (TZBB12000) with the desired Modular Handle (Egg EDDEATAAZ or Axial EABEASADZ). Insert the distal Torx end of the Lordosis Driver into the femail Torx and rotate it clockwise until the desired lordosis is acheived. This adjustment is self-locking and does not require an additional locking sequence.

Warning: Be sure to stop rotating the handlewhen it is fully expanded to avoid damaging the instruments.



8.0 ENDPLATE DISASSEMBLY (OPTIONAL)

8.1 Obtain the Endplate Disassembly Tool (TZBB19002) and place it on a level surface. Ensure all threaded knobs are in their starting positions by rotating them counter-clockwise. Next, place the Endplate (Standard TBB0XXXXX, Zero TBEAXXXXX, Full TBF0XXXXX) being removed onto the center post and rotate until the alignment feature is engaged, creating torsional resistance. Thread all the knobs clockwise until they are fully tightened, then pull the Column (TAXXXXXX) upwards to separate it from the Endplate. Once the Column is removed, unthread all the knobs and remove the Endplate from the Endplate Disassembly Tool.



9.0 PRE-EXPANSION COLUMN GRAFTING

9.1 Once the Column and Inserter assembly has been completed, place graft in all voids within the Column except for the threaded hole and alignment pin holes for the inserter.

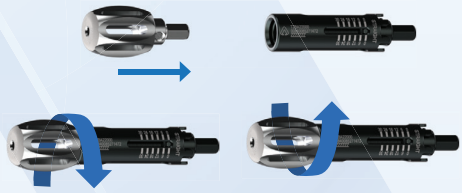
10.0 INSERTER ASSEMBLY

10.1 Attach the Inserter to the Column by first securing the Black Inserter Assembly Knob (TZB007000) to the proximal end of the Inserter. Once the Assembly Knob is attached, align the threads on the distal end of the Inserter with those on the Column (TAXXXXXX). Rotate the Inserter Assembly Knob clockwise until you visually confirm that the Inserter is fully seated on the Column.

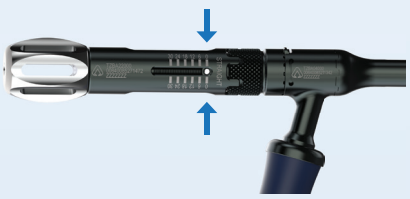
10.2 Attach the distal end of the Silver Inserter Expansion Knob (TZB008000) to the proximal end of the Expansion Indicator (TZBB22000).

10.2.1 If using the Straight Inserter (TZBB04000), rotate the Inserter Expansion Knob (TZB008000) clockwise until the indicator is in the "0" location.

10.2.2 If using the Articulating Inserter (TZBB06000), rotate the Inserter Expansion Knob (TZB008000) counterclockwise until the indicator is in the "0" location.



10.3 Attach the Expansion Indicator (TZBC22000) and Inserter Expansion Knob (TZB008000) Assembly onto the Inserter by inserting the proximal end of the Expansion Gauge into the proximal end of the Inserter.

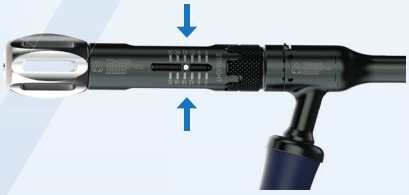


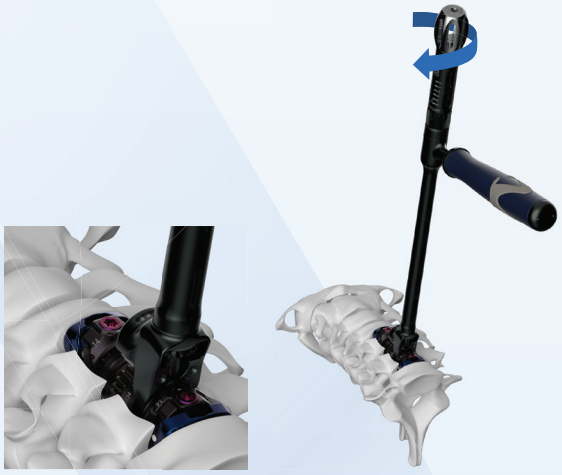
11.0 COLUMN INSERTION AND EXPANSION

11.1 Once the Column (TAXXXXXXX) and Inserter assembly has been completed, place the distal end of the device into the previously created vertebral void and confirm the location using fluoroscopy.

11.2 Once the Column (TAXXXXXX) is in the desired location, rotate the Inserter Expansion Knob (TZB008000) until the desired height is achieved. The device is self-locking and does not require a secondary locking sequence.

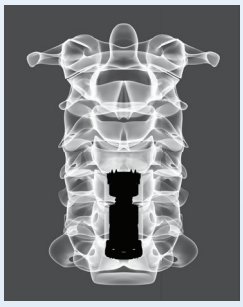
11.3 Verify the Column is in the correct final position and orientation by using fluoroscopy and clinical judgement.

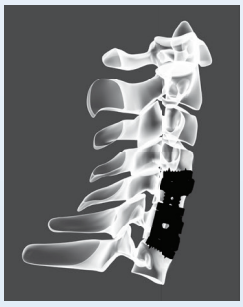




11.3.1 If additional input torque is required, replace the Inserter Expansion Knob with the Modular Egg Handle to the Inserter AO Expansion Adapter to provide additional mechanical advantage.
Warning: Be sure stop rotating the handle when fully expanded to avoid damaging the implant.

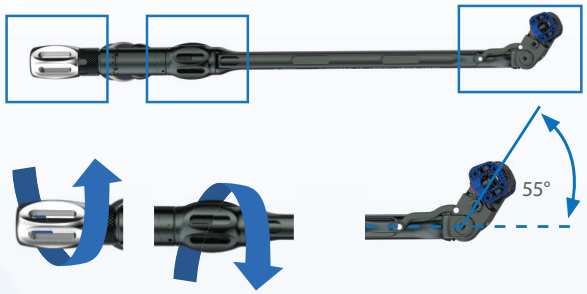
11.3.1.1 Verify Column placement with fluoroscopy.





11.3.3 If using the ML Articulating Inserter (TZBB06000), adjust the insertion angle by rotating the Distal Black Angulation Knob until the desired angle is achieved.

Warning: Column expansion for the ML Articulating Inserter requires counterclockwise rotation of the silver knob.



12.0 INSERTER REMOVAL

12.1 To remove the Column from the Inserter, first remove the Inserter Expansion Knob (TZB008000) and Inserter Expansion Indicator (TZBC22000). Next, attach the Inserter Assembly Knob (TZB007000) and rotate it counterclockwise until the Column is completely disengaged.

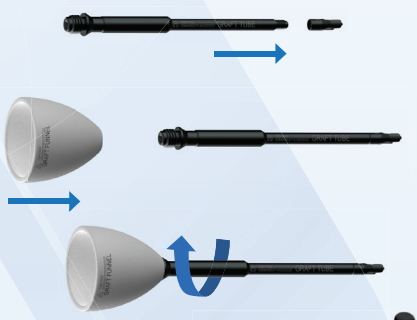
12.2 Post-Insertion Endplate Adjustment

12.2.1 If desired, the lordotic angle of the Endplate can be adjusted by attaching the Lordosis Driver (TZBB12000) to the desired Modular Handle (Egg EDDEATAAZ or Axial EABEASADZ). Insert the distal Torx end of the Lordosis Driver into the female Torx and rotate it clockwise until the desired lordosis is acheived. This adjustment is self-locking and does not require an additional locking sequence.

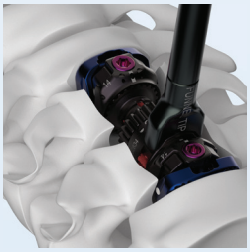
Warning: Be sure to stop rotating the handle when it is fully expanded or collapsed to avoid damaging the implant.

13.0 POST EXPANSION COLUMN GRAFTING

13.1 Thread the Bone Graft Funnel (TZBB16000) onto the Bone Graft Funnel Tube (TZBB17000) and place graft into the Bone Graft Funnel.



13.2 Insert the distal end of the Bone Graft Funnel Tube into the void of the Column, then use the Bone Graft Funnel Plunger (TZBB18000) to force the graft into the Column.

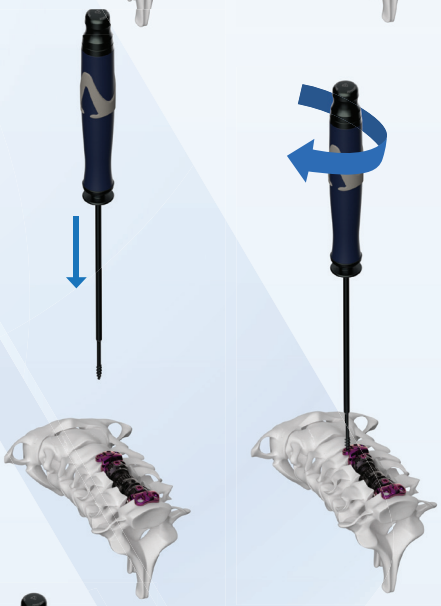


14.0 SCREW FIXATION (OPTIONAL)

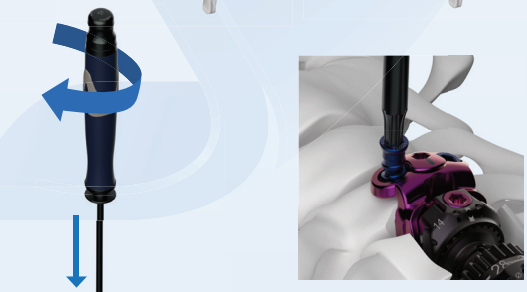
14.1 Straight Fixation Instruments

14.1.1 Drill: Attach the straight drill (LZB020020) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ) or power drill. Insert the distal end of the drill into the hole in the plate and drill until the depth stop engages, confirming a drill depth of 10mm.

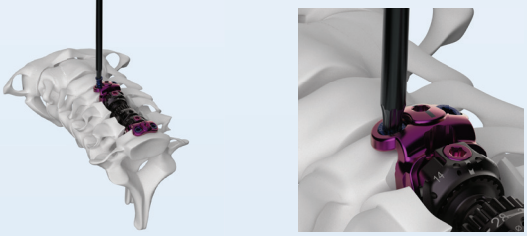
14.1.2 Tap: Attach the straight tap (LZB030000) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ). Place the distal end of the tap into the previously drilled hole and rotate clockwise until the desired depth is achieved.



14.1.3 Screwdriver: Attach the straight screwdriver (LZB040000) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ). Secure the screw (LEABXXXXX) to the driver by inserting the distal end of the screwdriver into the screw. Insert the distal end of the screw into the plate hole and rotate clockwise until the screw is fully seated.
Warning: Failure to fully seat the screw may caise damage to the plate locking mechanism.

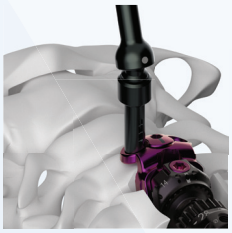


14.1.4 Lock Driver (KZC050000): Attach the straight Screwdriver to the desired Modular Handle (Egg EDDEATAAZ, Axial EABEASADZ). Insert the distal end of the Lock Driver into the Plate Locking Cam. Rotate the Cam 90 degrees until you feel a click, indicating that the cam covers both screws.

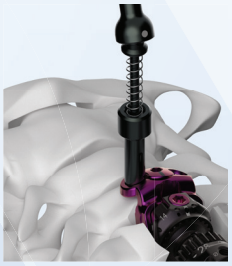


14.2 Variable Angle Fixation Instruments

14.2.1 Drill: Attach the Variable Angle Drill (LZC030000) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ) or power drill. Place the distal end of the drill into the hole in the plate and drill until the depth stop engages confirming 10mm of drill depth.

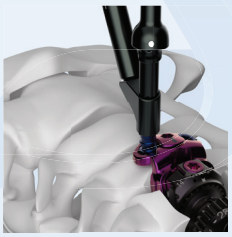


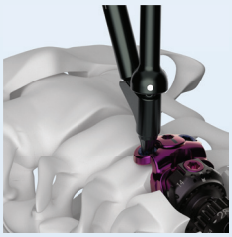
14.2.2 Tap: Attach the Variable Angle Tap (LZC040000) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ). Place the distal end of the tap into the previously drilled hole and rotate clockwise until the desired depth is achieved.



14.2.3 Screwdriver: Attach the Variable Angle Driver(LZC06000) to the desired modular handle (Egg EDDEATAAZ, Axial EABEASADZ). Secure the screw (LEABXXXXX) to the driver by inserting the distal end of the screwdriver into the screw and applying downward pressure until driver is firmly wedged into screw. Insert the Variable Angle Driver into the Variable Angle Driver Guide (LZC050000). Place the distal end of screw into the plate hole and rotate clockwise until the screw is fully seated.

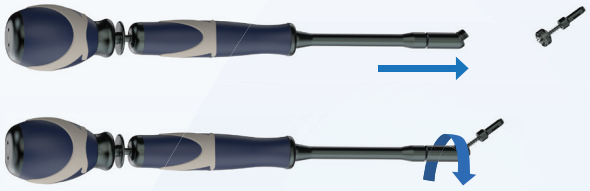
Warning: Failure to fully seat the screw may cause damage to the plate locking mechanism.



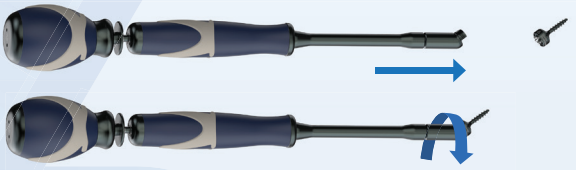


14.3 Fixed Angle Fixation Instruments

14.3.1 Drill: Attach the Fixed Angle Drill (LZD031000) to the Fixed Angle Driver (LZD021000). Then, secure the modular handle (Egg EDDEATAAZ, Axial EABEASADZ) to the proximal end of the Fixed Angle Driver. Insert the distal end of the drill into the hole in the plate and drill until the depth stop engages, confirming a drill depth of 10mm.

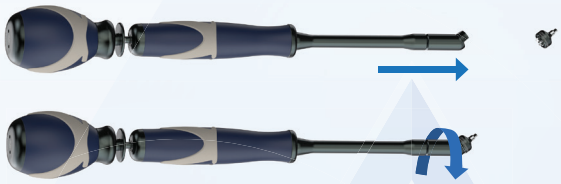


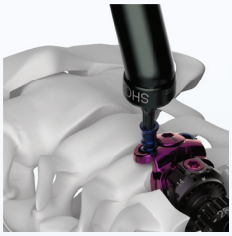
14.3.2 Tap: Attach the Fixed Angle Tap (Short LZD041035 or Long LZD041135) to the Fixed Angle Driver (LZD021000). Secure the modular handle (Egg EDDEATAAZ or Axial EABEASADZ) to the proximal end of the Fixed Angle Driver. Insert the distal end of the tap into the previously drilled hole and rotate clockwise until the desired depth is reached.



14.3.3 Screwdriver: Attach the Fixed Angle Screwdriver (Short LZD051010 or Long LZD051110) to the Fixed Angle Driver (LZD021000). Secure the modular handle (Egg EDDEATAAZ or Axial EABEASADZ) to the proximal end of the Fixed Angle Driver. Insert the distal end of the screwdriver into the screw (LEABXXXXX) and apply downward pressure until the driver is firmly wedged into the screw. Insert the distal end of the screw into the plate hole and rotate the Modular Egg Handle (EDDEATAAZ) clockwise until the screw is fully seated.

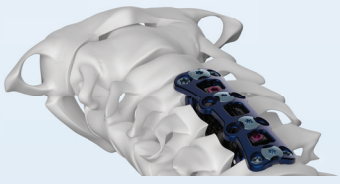
Warning: Failure to fully seat the screw may cause damage to the plate locking mechanism.





15.0 SUPPLEMENTAL FIXATION

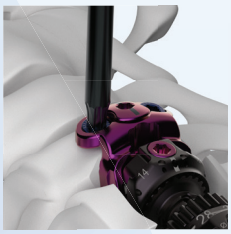
15.1 Approved supplemental fixation, such as the Zion Anterior Cervical Plating System or Bridalveil Posterior Cervical Fixation System, must be used in combination with the Dominion Columns to provide sufficient stabilization.

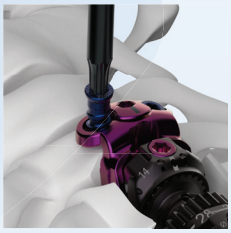


16.0 REVISION/REMOVAL

16.1 Screw Removal (If Applicable)

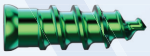
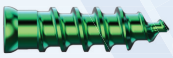
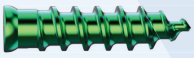
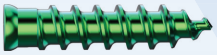
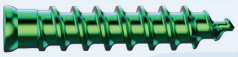
16.1.1 Rotate the cam 90 degrees. Then, attach the desired Screwdriver (Straight LZB040000, Variable Angle LZC060000, or Fixed Angle LZD051XXX) to the Screw (LEABXXXXX) and rotate it counterclockwise until the screw is completely unthreaded from the bone.





16.2 Column Removal

16.2.1 Inserter Technique: Obtain the desired inserter (Straight TZBA04000 or ML Articulating TZBA06000) and attach the Attachment Knob (TZB007000) to its proximal end. Insert the distal end of the inserter into the mating features on the Column (TAXXXXXXX) and thread the Attachment Knob clockwise until the device is fully seated. Remove the Attachment Knob and replace it with the Expansion Knob (TZB0080000). Rotate Expansion Knob counterclockwise until Column is fully collapsed, then remove it from patient.

Part Number	Description	Qty	
LEAB35012	ACSS Screw, Self-drilling Variable, Ø3.5mm X 12mm	8	
LEAB35014	AACS Screw, Self-drilling Variable, Ø3.5mm X 14mm	8	
LEAB35016	ACSS Screw, Self-drilling Variable, Ø3.5mm X 16mm	8	
LEAB35018	ACSS Screw, Self-drillingg Variable, Ø3.5mm X 18mm	8	
LEAB35020	ACSS Screw, Self-drilling Variable, Ø3.5mm X 20mm	8	
LEAB40010	ACSS Screw, Self-drilling Variable, Ø4.0mm X 10mm	8	
LEAB40012	ACSS Screw, Self-drilling Variable, Ø4.0mm X 12mm	8	
LEAB40014	ACSS Screw, Self-drilling Variable, Ø4.0mm X 14mm	8	
LEAB40016	ACSS Screw, Self Drilling Variable, Ø4.0mm X 16mm	8	
LEAB40018	ACSS Screw, Self-drilling Variable, Ø4.0mm X 18mm	8	
LEAB40020	ACSS Screw, Self-drilling Variable, Ø4.0mm X 20mm	8	

TRIAL COLUMNS

Part Number	Description	Qty
TZBA0100A	Trial Column, 12mm, 15-20mm	1
TZBA0100B	Trial Column, 12mm, 20-25mm	1
TZBA0100C	Trial Column, 12mm, 23-29mm	1
TZBA0100D	Trial Column, 12mm, 28-34mm	1
TZBA0100F	Trial Column, 12mm, 32-42mm	1
TZBA0100H	Trial Column, 12mm, 41-60mm	1

TRIAL ENDPLATES

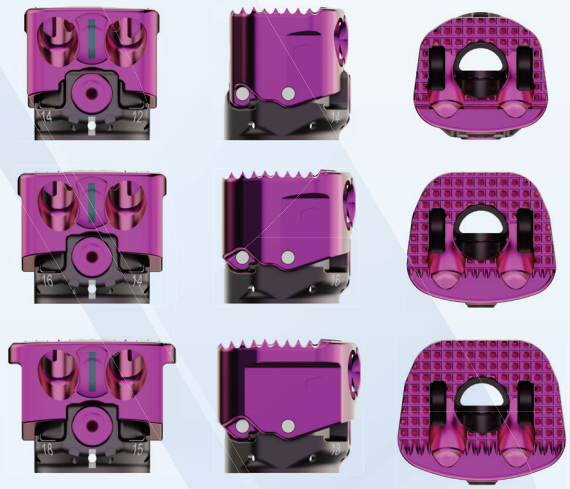
Part Number	Description	Qty
TZBA02BB0	Trial Endplate, 12mm, 14x12mm	2
TZBA02BC0	Trial Endplate, 12mm, 16x14mm	2
TZBA02BD0	Trial Endplate, 12mm, 18x15mm	2

Part Number	Description	Qty	
TA1201520	Expandable Column, 12mm, 15-20	2	
TA1202025	Expandable Column, 12mm, 20-25	2	
TA1202329	Expandable Column, 12mm, 23-29	2	
TA1202834	Expandable Column, 12mm, 28-34	2	
TA1203242	Expandable Column, 12mm, 32-42	2	
TA1204160	Expandable Column, 12mm, 41-60	1	

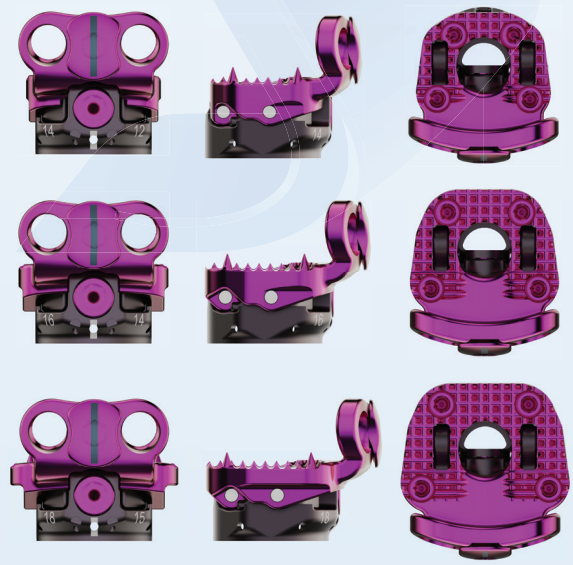
ENDPLATES

Part Number	Description	Qty
TBB014120	Endplate, 12mm, Variable Lordosis, 14-12	4
TBB016140	Endplate, 12mm, Variable Lordosis, 16-14	4
TBB018150	Endplate, 12mm, Variable Lordosis, 18-15	4

Part Number	Description	Qty
TBEA14120	Endplate, 12mm, Variable Lordosis, Fixated, Zero, 14-12	4
TBEA16140	Endplate, 12mm, Variable Lordosis, Fixated, Zero, 16-14	4
TBEA18150	Endplate, 12mm, Variable Lordosis, Fixated, Zero, 18-15	4



Part Number	Description	Qty
TBF014120	Endplate, 12mm, Variable Lordosis, Fixated, Full, 14-12	4
TBF016140	Endplate, 12mm, Variable Lordosis, Fixated, Full, 16-14	4
TBF018150	Endplate, 12mm, Variable Lordosis, Fixated, Full, 18-15	4



Part Number	Description	Qty
EABEASADZ	Axial, AO Quick Disconnect, Spin Top	2
EDDEATAAZ	Egg, Fixed Internal, Quick Disconnect	1
TZB007000	Inserter Assembly Knob, 12/16/20mm	1
TZB008000	Inserter Expansion Knob, 12/16/20mm	1
TZB024000	Knob Driver, 12/16/20mm	1
TZBA03000	Corpectomy Caliper, 12mm	1
TZBA04000	Inserter, Straight, 12mm	1
TZBA04000-14	Inserter, Straight, 12mm, Straight Handle	1
TZBA05000	Lordosis Gauge	1

Part Number	Description	Qty	
TZBA06000	Inserter, ML Articulating, 12mm	1/OPT	
TZBA09000	Inserter AO Expansion Adapter, 12mm	1	
TZBA12000	Lordosis Driver, T10A	1	
TZBA16000	Bone Graft Funnel, Body, 12mm	1	
TZBA17000	Bone Graft Funnel, Tube, 12mm	2	
TZBA17000-10	Bone Graft Funnel, Tube, 12mm, Inserter Hole Attatchment	1	
TZBA18000	Bone Graft Funnel, Plunger, 12mm	1	
TZBA19002	Endplate Remover, 12mm, Variable Lordosis	1	
TZBA20002	Implant Assembly Guide, Bottom, 12mm	1	
TZBA21002	Implant Assembly Guide, Top, 12mm	1	
TZBA22000	Expansion Indicator, 12mm	1	
LZB010000	Self-centering Awl	1	

Part Number	Description	Qty
LZB020010	Self-centering Drill Guide, Adjustable	1
LZB020020	Self-centering Drill, Adjustable	2
LZB030000	Tap	1
LZB040000	Screwdriver, T10A	2
LZB050000	Screw Remover, T10A	1
LZC010000	Drill Guide, Variable	1
LZC020000	Variable Angle Awl	1
LZC021000	Variable Angle Awl, Guided	1
LZC030000	Variable Angle Drill	1
LZC031000	Variable Angle Drill, Guided	1
LZC040000	Variable Angle Tap	1
LZC041000	Variable Angle Tap, Guided	1
LZC050000	Driver Guide, Variable	1

Part Number	Description	Qty	
LZC060000	Variable Angle Screwdriver T10A	1	
LZD010000	Fixed Angle Awl	1	
LZD021000	Fixed Angle Driver	1	
LZD031000	Fixed Angle Drill	1	
LZD041035	Fixed Angle Tap, Short	1	
LZD041135	Fixed Angle Tap, Long	1	
LZD051010	Fixed Angle Screwdriver. T10A, Short	1	
LZD051110	Fixed Angle Screwdriver. T10A, Long	1	
LZD071000	Fixed Angle Driver Cap Socket	1	

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The DOMINION Expandable Corpectomy System is a vertebral body replacement system manufactured from titanium alloy (Ti6Al4VELI) to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The devices have multiple footprint sizes and are capable of expanding in height to accommodate patient anatomy. The spacers have graft windows to help facilitate bony integration and teeth on both of their inferior and superior surfaces to prevent migration/expulsion.

2.0 MATERIALS: Titanium (ASTM F136), Nitinol #1(ASTM F2063)

3.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician. All implants are intended for single use only. The DOMINION Expandable Corpectomy System must not be reused under any circumstances. The DOMINION Expandable Corpectomy System is not a stand-alone device and must be utilized in conjunction with supplemental posterior fixation. These instructions for use are designed to assist in use of the DOMINION Expandable Corpectomy System and are not a reference for surgical techniques.

4.0 INDICATIONS: The DOMINION Expandable Corpectomy System is indicated for vertebral body replacement in the cervical spine (C2-T1) and the thoracolumbar spine (T1-L5). The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the cervical spine (C2-T1), DOMINION spacers are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine.

When used in the thoracolumbar spine (T1-L5), DOMINION spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The system is intended to be used with supplemental fixation that has been cleared by the FDA for use in the thoracolumbar spine (i.e. posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

5.0 CONTRAINDICATIONS

5.1 Acute or chronic infectious diseases of any etiology and localization
5.2 Signs of local inflammation
5.3 Fever or leukocytosis
5.4 Morbid obesity
5.5 Pregnancy
5.6 Metal/polymer sensitivity/allergies to the implant materials
5.7 Mental illness, alcoholism, drug abuse
5.8 Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
5.9 Grossly distorted anatomy due to congenital abnormalities
5.10 Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
5.11 Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
5.12 Any case not needing a bone graft and fusion or where fracture healing is not required
5.13 Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
5.14 Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
5.15 Any case not described in the Indications.
5.16 Any patient unwilling to cooperate with the post-operative instructions.
5.17 Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
5.18 Symptomatic cardiac disease.
5.19 Systemic or terminal illness.
5.20 Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

6.0 POSSIBLE ADVERSE EVENTS:

6.1 A listing of possible adverse events includes, but is not limited to:
6.1.1 Bending or fracture of implant. Loosening of the implant.
6.1.2 Implant material sensitivity, or allergic reaction to a foreign body.
6.1.3 Infection, early or late.
6.1.4 Decrease in bone density due to stress shielding.
6.1.5 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.1.6 Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
6.1.7 Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6.1.8 Dural tears.
6.1.9 Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
6.1.10 Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
6.1.11 Loss of bowel and/or bladder control or other types of urological system compromise.
6.1.12 Scar formation possibly causing neurological compromise around nerves and/or pain.
6.1.13 Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
6.1.14 Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
6.1.15 Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
6.1.16 Graft donor site complications including pain, fracture, or wound healing problems.
6.1.17 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
6.1.18 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
6.1.19 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
6.1.20 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
6.1.21 Change in mental status.
6.1.22 Non-union (or pseudarthrosis). Delayed union. Mal-union.
6.1.23 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
6.1.24 Inability to perform the activities of daily living.
6.1.25 Paralysis.
6.1.26 Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

7.0 WARNINGS AND PRECAUTIONS: The DOMINION Expandable Corpectomy System is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the DOMINION Expandable Corpectomy System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the DOMINION Expandable Corpectomy System by the surgeon. 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

The implantation of the DOMINION Expandable Corpectomy System should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedures is recommended.

Incorrect preparation of the endplates may increase the risk factor for subsidence or vertebral body fracture, careful attention should be given to endplate preparation prior to insertion of the device.

Warning: This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Based on the fatigue testing results, the physician/surgeon should consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

CAUTION: Avoid over-distraction which can lead to neural injury.

INS-00018, DOMINION SYSTEM INSTRUCTIONS FOR USE, REVA
TEM-00041, PACKAGE INSERT TEMPLATE, REVC

The DOMINION Expandable Corpectomy System has not been evaluated for safety and compatibility in the MR environment. The DOMINION Expandable Corpectomy System has not been tested for heating or migration in the MR environment.

8.0 IMPLANT SELECTION: The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion. DOMINION Expandable Corpectomy System components should not be used with components from other manufacturers.

The 12mm column diameter implants are intended for cervical use only. While the 16mm and 20mm column diameter implants are intended for thoracolumbar use.

9.0 PREOPERATIVE:

9.1 Only patients that meet the criteria described in the indications should be selected.

9.2 Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

9.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

9.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

9.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.

9.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The DOMINION Expandable Corpectomy System components are not to be combined with components from another manufacturer.

9.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

9.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

9.9 A surgical technique manual may be obtained from ASTURA MEDICAL or from any of its representatives.

10.0 INTRAOPERATIVE

10.1 Any instruction manual should be carefully followed.

10.2 At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

10.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

10.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.

10.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.

10.6 Before closing the soft tissues, all of the devices should be securely seated.

10.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

11.0 POSTOPERATIVE: The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

11.1 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

11.2 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

11.3 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

11.4 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

11.5 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.

11.6 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved DOMINION Expandable Corpectomy System components should ever be reused under any circumstances.

12.0 PACKAGING: Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used and should be returned immediately to ASTURA MEDICAL.

13.0 CLEANING AND DECONTAMINATION: Instruments and implants of the DOMINION Expandable Corpectomy System are supplied clean and NOT STERILE and must be sterilized prior to use.

14.0 CLEANING: All instruments must first be thoroughly cleaned before sterilization and introduced into a sterile surgical field. All cleaning processes must conform to Advancement of Medical Instrumentation (AAMI) guideline TIR30 Section 5.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile or tap water and transport to a decontaminate environment. An enzymatic cleaner bath (soak) composed of lukewarm tap water and percent (%) volume of enzymatic cleaner per manufacturer's guidelines is effective in removing organic material from instruments. Instruments should be fully submerged for at least ten (10) minutes.

Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Once instruments are cleaned and disassembled, place instruments in an ultrasonic cleaner with an enzymatic cleaner mixture composed of lukewarm tap water and percent (%) volume of enzymatic cleaner per manufacturer's guidelines for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running tap water for at least one (1) minute to remove solutions. Drying methods are not necessary.

Instruments should never be exposed to cleaning agents containing any peroxides.

Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.

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

15.0 STERILIZATION: Instruments and implants of the DOMINION Expandable Corpectomy System are supplied clean and NOT STERILE and must be sterilized as specified below using the Astura provided sterilization container (Part #: DZ9900000). Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	30 minutes

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL. Instruments are to be in the assembled during sterilization.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

This statement is not required for the parameters listed above.

16.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted DOMINION Expandable Corpectomy System component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.

If any DOMINION Expandable Corpectomy System product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint.

If further information is needed or required, please contact using the company information listed below.

17.0 COMPANY INFORMATION

Astura Medical
4949 W Royal Ln.
Irving, TX 75063
Phone: (469) 501-5530
Email: info@asturamedical.com


ASTURA
MEDICAL