DOLOMITE

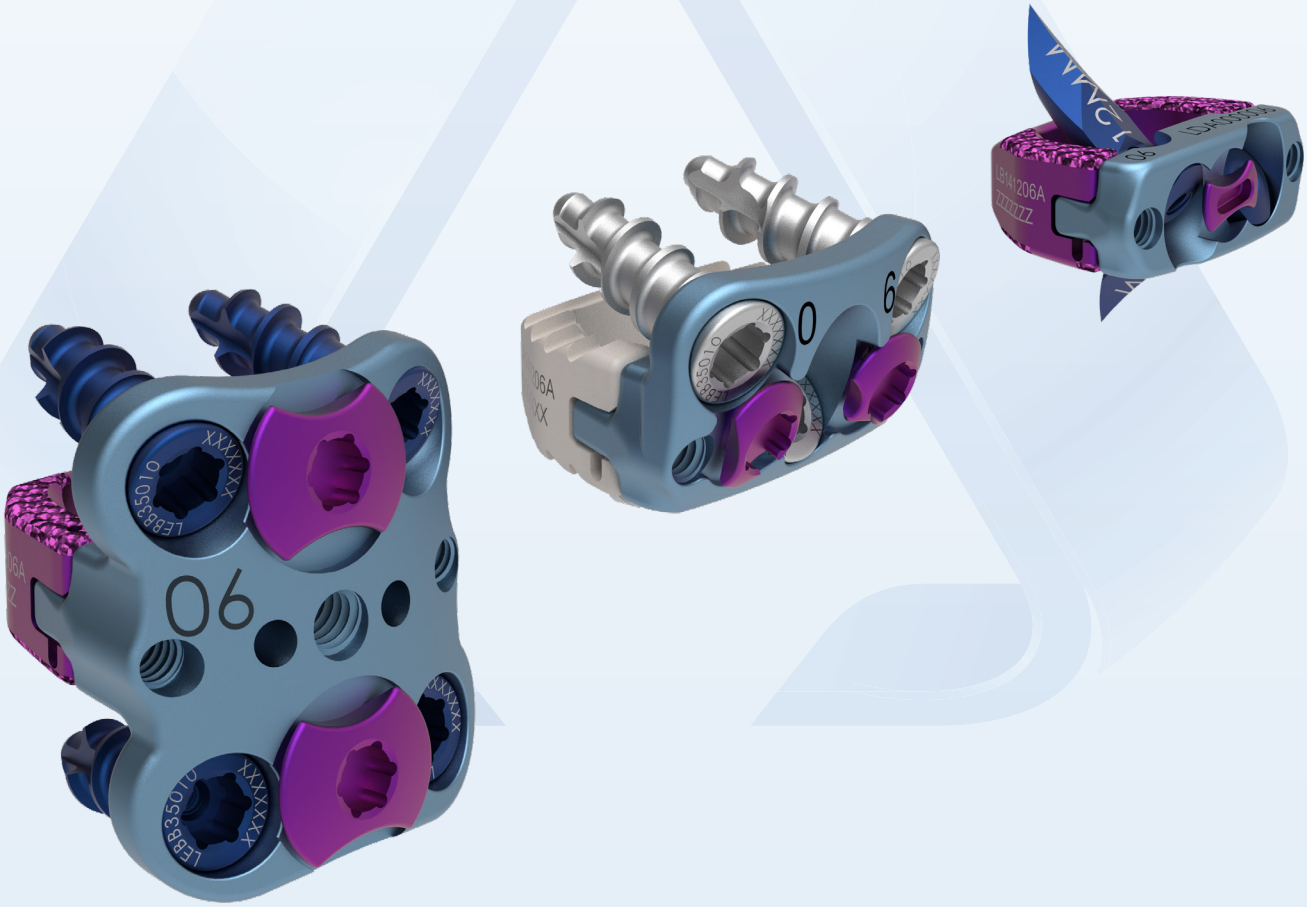
ANTERIOR CERVICAL STABILIZATION SYSTEM

ASTURA MEDICAL

DESIGN RATIONALE

The Dolomite Stand Alone Cervical System by ASTURA MEDICAL is a comprehensive system that provides a complete range of anatomic spacers and fixation options for ridged anterior stabilization. The intuitive design of the system provides the versatility to accommodate a wide array of anatomical challenges to ensure an efficient, streamlined procedural sequence.

- ***All DOLOMITE Spacers are available in Acid-Etched Titanium, or HA PEEK***
- ***Heights ranging from 5-12mm in 1mm increments***
- ***Footprint options; 14x12, 16x14, 18x15***
- ***Lordosis Options: 7°, 13°***
- ***Multiple Plating Options: Zero Plate, Half Plate, Full Plate***
- ***Multiple Fixation Options: Self Drilling and Self Tapping Screws, Impactable Nails***

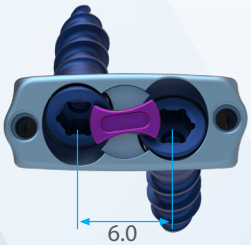


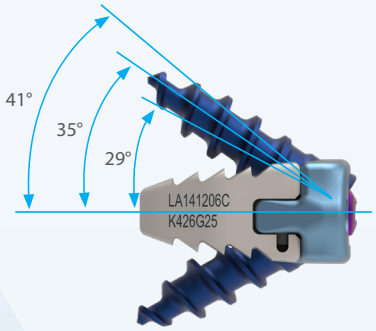
SPECIFICATIONS

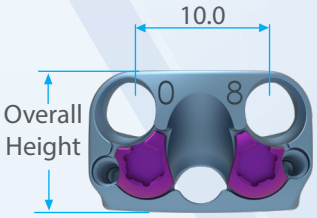
SPACER SIZING			
Type	Footprint (mm)	Heights (mm)	Lordosis (deg)
HA PEEK Spacer	14x12, 16x14, 18x15	5-12	7°, 13°
Titanium Spacer	14x12, 16x14, 18x15	5-12	7°, 13°

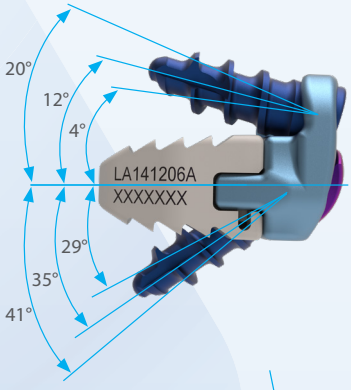
PLATE TYPES AND SIZING				
Type	Spacer Height (mm)	Overall Height (mm)	Width (mm)	Thickness (mm)
Zero	5-12	5-12	NA	NA
Half	5-12	8.4 - 15.4	15.2	2.3
Full	5-12	17-24	16	2.3

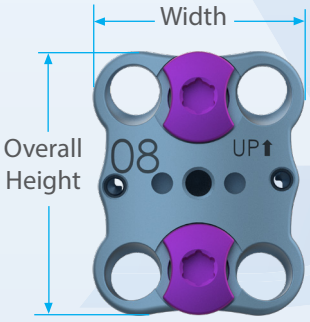
FIXATION TYPES AND SIZING			
Type	Constraint	Diameters (mm)	Lengths (mm) 2mm Increments
Self-Drilling / Self- Tapping Screws	Variable	3.5, 4.0	10-20
Nails	Variable	3.5	12-16

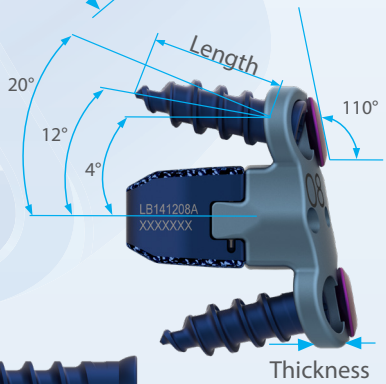












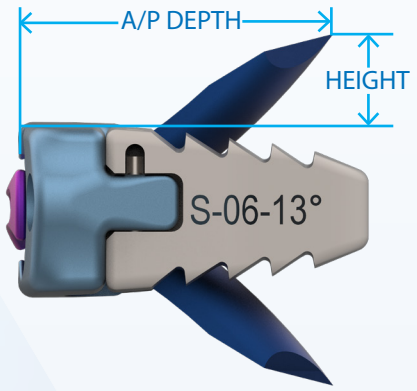
NAIL AND SCREW SIZING

Warning: Screws and Nails not to exceed the Max Lengths for the Sizes Designated Below

ZERO PROFILE PLATE WITH NAILS

NAIL LENGTH	A/P DEPTH	HEIGHT
12MM	10.82	7.69
14MM	11.59	10.14
16MM	12.07	13.01

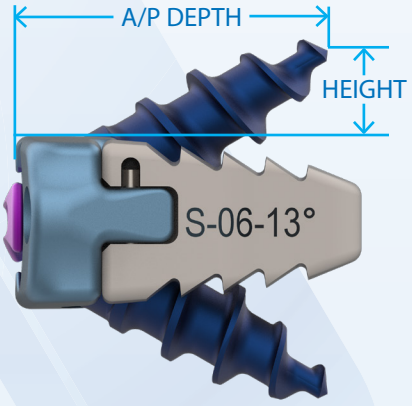
SPACER SIZE	MAX NAIL LENGTH
14X12	12MM
16X14	14MM
18X15	16MM



ZERO PROFILE PLATE WITH SCREW

SCREW LENGTH	A/P DEPTH	HEIGHT
10MM	10.49	3.68
12MM	12.12	4.82
14MM	13.76	5.97
16MM	15.40	7.12
18MM	17.04	8.27
20MM	18.68	9.41

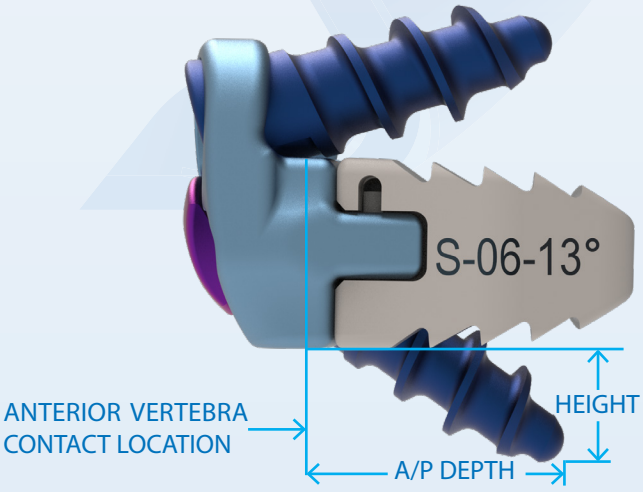
SPACER SIZE	MAX SCREW LENGTH
14X12	10MM
16X14	12MM
18X15	14MM



HALF PLATE WITH ZERO PROFILE SCREW

SCREW LENGTH	A/P DEPTH	HEIGHT
10MM	10.40	2.76
12MM	12.16	3.73
14MM	13.91	4.69
16MM	15.66	5.66
18MM	17.41	6.63
20MM	19.16	7.60

SPACER SIZE	MAX SCREW LENGTH
14X12	14MM
16X14	16MM
18X15	16MM



1.0 EXPOSURE

1.1 Identify the affected level using a combination of palpitation and fluoroscopy.
1.2 Select either a left or right-sided approach. Using a standard anterior cervical surgical technique, expose the midline of the affected site.
1.3 Use tissue retractors to perform a blunt dissection, then retract the trachea and esophagus accordingly.

2.0 DISTRACTION

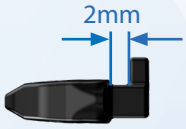
2.1 A variety of distraction techniques are available for the cervical spine. Based on surgeon's preferences, a selected technique will be used to distract the two adjacent vertebrae to provide sufficient access to the disc space

3.0 DISC PREPARATION

3.1 Perform an annulotomy and discectomy to remove the intervertebral disc.

4.0 ENDPLATE PREPARTION

4.1 Endplate preparation can be achieved by the use of the Straight Rasp (LZA090000). Prepare disc space by removing any remaining cartilaginous endplates to create a fusion bed of bleeding bone.



5.0 IMPLANT TRIALING

5.1 Select the Trial* (LZFXXXXXX) to match the desired Implant type and size.
5.2 Attach the Trial to the Trial Inserter (LZA010000) by placing the pegs into the Trial holes and threading on the inner shaft. Ensure the direction on the inserter matches the trial orientation.
5.3 Start with a Trial size less than the disc space height and sequentially increase the Trial size until the desired fitment is achieved. If necessary, utilize fluoroscopy to determine the desired fitment.

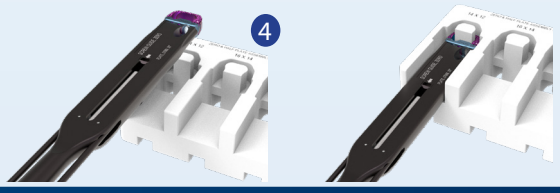
***Note: Trials are 1:1 true to size**

6.0 INSERTER AND IMPLANT ASSEMBLY

6.1 Inserter Assembly Zero Profile Construct
6.1.1 Obtain the Implant Inserter (LZA021000) and then select the fixation guide (Screw Guide, LZA032XXX / LZA0330XX or Nail Guide, LZE0110XX) that matches the size of the chosen trial. (1) Attach the fixation guide to the Implant Inserter by aligning the arrows of both devices and then sliding them together until audible click is heard.

6.2 Inserter Assembly Half and Full Construct
6.2.1 Utilize the Implant Inserter (LZA021000) for Half Plates or use the Simplified Inserter (LZA0220000) for Full Plates.
6.3 Identify the desired plate caddy. Open the caddy and then insert the distal alignment pins of the Inserter into the holes within the Plate** and then rotate proximal knob(s) clockwise until the Plate is attached to the Inserter. (2)
6.4 Identify the desired spacer caddy . Remove the desired Spacer** and place into the appropriate slot of the Implant Assembly Gauge (LZA110000). Use the Inserter to align the distal end of the plates with the selected Spacer and then place downward force on inserter until audible click is heard. (3)

6.5 Verify Implant is fully attached by placing the assembled Implant and Inserter into the Implant Assembly Gauge (LZA110000) until bottomed out. (4) If the construct doesn't bottom out, the spacer is not fully engaged with the plate. Utilize the top "ZERO AND HALF PLATE ASSEMBLY GAUGE" with the zero and half plate attached to the Implant Inserter, and use the bottom "FULL PLATE ASSEMBLY GAUGE" with the full plate attached to the Full Plate Inserter.



6.5.1 If necessary, the components can be removed by threading the Implant Disassembly Tools (LZA080000) into the threaded holes within the plate and then sliding the two components away from one another.

****Note: Spacer size and Plate size must match**

7.0 IMPLANT INSERTION, SCREWS

7.1 Insert the distal portion of the Implant into the disc space and impact using the Mallet until the desired depth is achieved. Confirm anatomic alignment using fluoroscopy.

7.2 If necessary, use the Straight Tamp (LZA040000) or Rotation Tamp (LZA050000) to impact the implant to the proper position.

7.3 Screw Preparation and Delivery

Dolomite drills are not disposable and will be charged back to the distributor if disposed

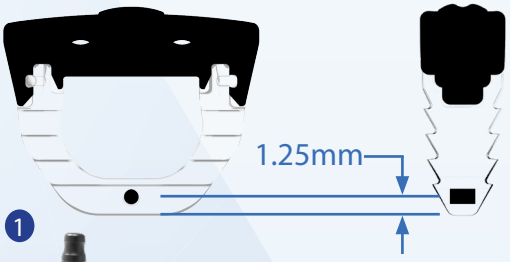
7.3.1 Straight 1

7.3.1.1 Attach the Self Centering Drill (LZB020000) to the Modular Axial Handle or Power Driver.

7.3.1.2 Place the distal end of the Drill into the Screw Guide and advance Drill until bottomed out (10mm).

7.3.1.3 Repeat steps above with Tap (LZB030000) if desired.

7.3.1.4 Attach Screwdriver (LZB040000) to Modular Axial Handle (EABEASADZ) then attach Screw by pressing tip of Screwdriver into Screw creating a "Stick Fit" then insert screw into prepared hole and advance until the screw is fully seated in the plate.



7.3.2 Variable Angle 2

7.3.2.1 Attach the Variable Angle Drill (LZC030000) to the Modular Axial Handle or Power Driver.

7.3.2.2 Place Variable Angle Drill into the Variable Angle Drill Guide (LZC010000) and place Variable Angle Drill Guide tip into the interbody until bottomed out.

7.3.2.3 Advance the Variable Angle Drill until bottomed out (10mm).

7.3.2.4 If desired, use Variable Angle Tap (LZC040000) by placing it directly into the drilled hole and advancing to the desired depth.

7.3.2.5 Attach Variable Angle Screwdriver (LZC060000) to Modular Axial Handle (EABEASADZ) then attach Screw by pressing tip of Variable Angle Screwdriver into Screw creating a "Stick Fit" then insert screw into prepared hole and advance until the screw is fully seated in the plate.

7.3.3 Variable Angle Guided 3

7.3.3.1 Attach Variable Angle Drill, Guided (LZC031000) to the Modular Axial Handle or Power Driver.

7.3.3.2 Place the distal end of the Variable Angle Drill, Guided into the Screw Guide (LZA03XXXX) and advance until bottomed out (10mm).

7.3.3.3 Repeat steps above with Variable Angle Tap, Guided (LZC041000) if desired.

7.3.3.4 Attach Variable Angle Screw Driver to Modular Axial Handle (EABEASADZ) then attach Screw by pressing tip of Variable Angle Screwdriver into Screw creating a "Stick Fit" then insert screw into prepared hole and advance until the screw is fully seated in the plate.

7.3.4 Fixed Angle (Awl) 4

7.3.4.1 Place the distal end of the Fixed Angle Awl (LZD010000) in the plate hole. Utilize the Mallet to impact the Fixed Angle Awl to advance the tip into the bone.

7.3.5 Fixed Angle (Drill, Tap, Screw) 5

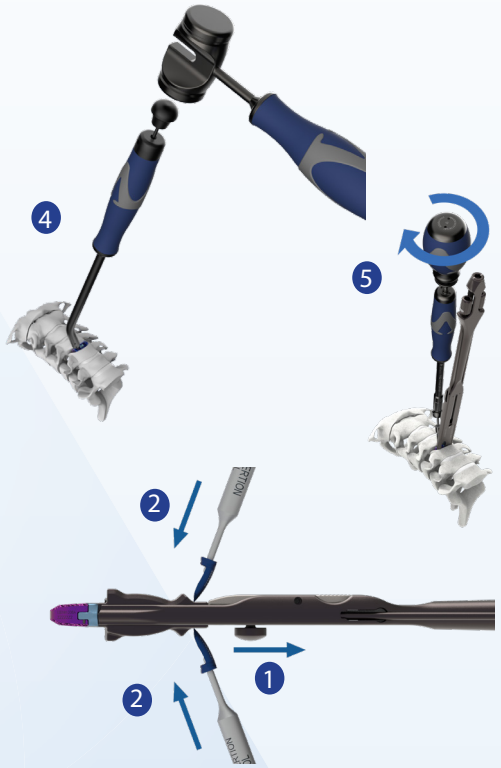
7.3.5.1 Attach the desired length Fixed Angle Drill Bit (LZD031000) to the distal end of the Fixed Angle Driver (LZD021000), then connect the Modular Egg Handle or Power Driver to the proximal end.

7.3.5.2 Place Fixed Angle Drill bit into the Screw Guide and advance the Fixed Angle Driver until the drill bit is bottomed out (10mm).

7.3.5.3 Repeat steps above with the Fixed Angle Tap (LZD041X35) if desired.

7.3.5.4 Attach the Fixed Angle Screwdriver bit to the distal end of the Fixed Angle Screwdriver (LZD051XXX), then connect the Modular Egg Handle to the proximal end. Attach the Screw by pressing the tip of the drive bit into the Screw creating a "Stick Fit," then insert the screw into the prepared hole and advance until the screw is bottomed out.

7.3.5.5 Unthread Implant Inserter (LZA021000 or LZA022000) from Spacer Plate and remove.



8.0 IMPLANT INSERTION, NAILS

8.1 Refer to section 6.0 for Implant Inserter (LZA021000) and Implant Assembly

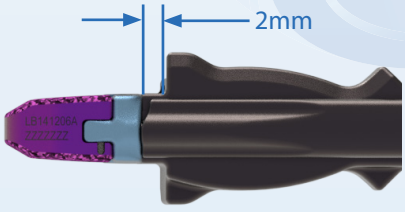
8.2 Once the Spacer is attached, pull the slide button back until the button locks into position. 1 Thread the Nail Insertion Tool (LZE040000) into the desired Nail and place a Nail in each of the one of the 2 channels. 2 Unthread the nail insertion tool from nail once it hs been place into the channel.

8.3 Insert the distal portion of the Spacer into the disc space and impact using the Mallet until the desired depth is achieved. 3

8.4 Once implant is in the desired location within the disc space, thread the Nail Impactor (LZE030000) into the proximal end of the Spacer Inserter. 4 Impact the Impaction Rod with the Mallet until bottomed out. 5

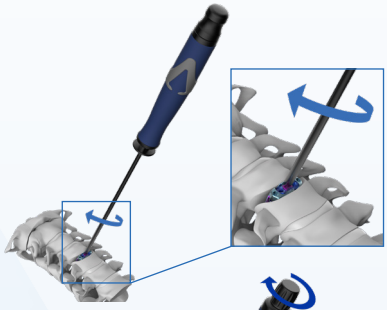
8.5 Remove the Nail Impactor from the Implant Inserter. 6

8.6 Unthread Implant Inserter from Spacer Plate and remove. 7 Use Implant Inserter Knob Driver (LZE050000) if necessary.



9.0 IMPLANT LOCKING

9.1 Attach the driver (LZA060000/Zero Plate, LZB040000 / Half and Full Plates) to the Modular Axial Handle then insert tip of Lockdriver into Spacer Cam component and rotate 90° or 45° degrees to the locked position.

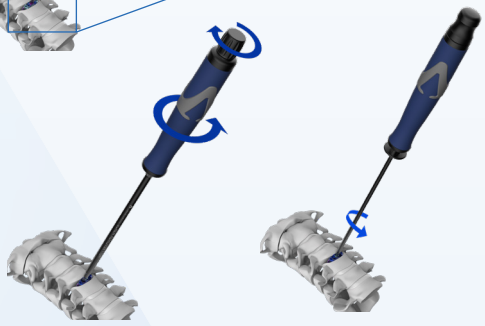


10.0 IMPLANT REMOVAL

10.1 Screw Removal

10.1.1 Attach the Lockdriver (LZA060000) to the Modular Axial Handle then insert tip of Lockdriver into Spacer Cam component and rotate 90° or 45° degrees to the unlocked position.

10.1.2 Attach the Screw Remover (LZB050000) to the screw by aligning the hexalobe feature and then threading the proximal knob clockwise until resistance is felt. Once securely attached, rotate silicone handle counter-clockwise with upward force until screw is removed

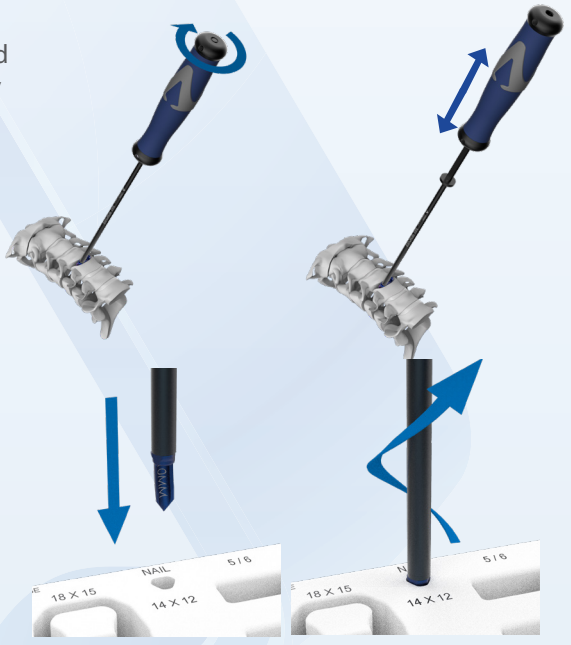


10.2 Nail Removal

10.2.1 Attach the Lockdriver to the Modular Ratcheting Axial Handle then insert tip of Lockdriver into Spacer Cam component and rotate 90 degrees to the unlocked position.

10.2.2 Attach the Nail Remover (LZE020000) to the Nail by threading the proximal end clockwise until resistance is felt. Once securely attached, remove the Nail by pulling the handle back in a radial motion, utilizing the built-in slap hammer, until the Nail is dislodged.

10.2.3 Detach the Nail from the Nail Remover by placing the Nail into the Implant Assembly Gauge (LZA110000) and unthreading the proximal end counterclockwise until the two are separated.



10.3 Spacer Removal (Assembled Construct)

10.3.1 Obtain the Implant Inserter then identify the corresponding Screw Guide that matches the chosen implant height. Attach the Screw Guide to the Implant Inserter by sliding the two components together.

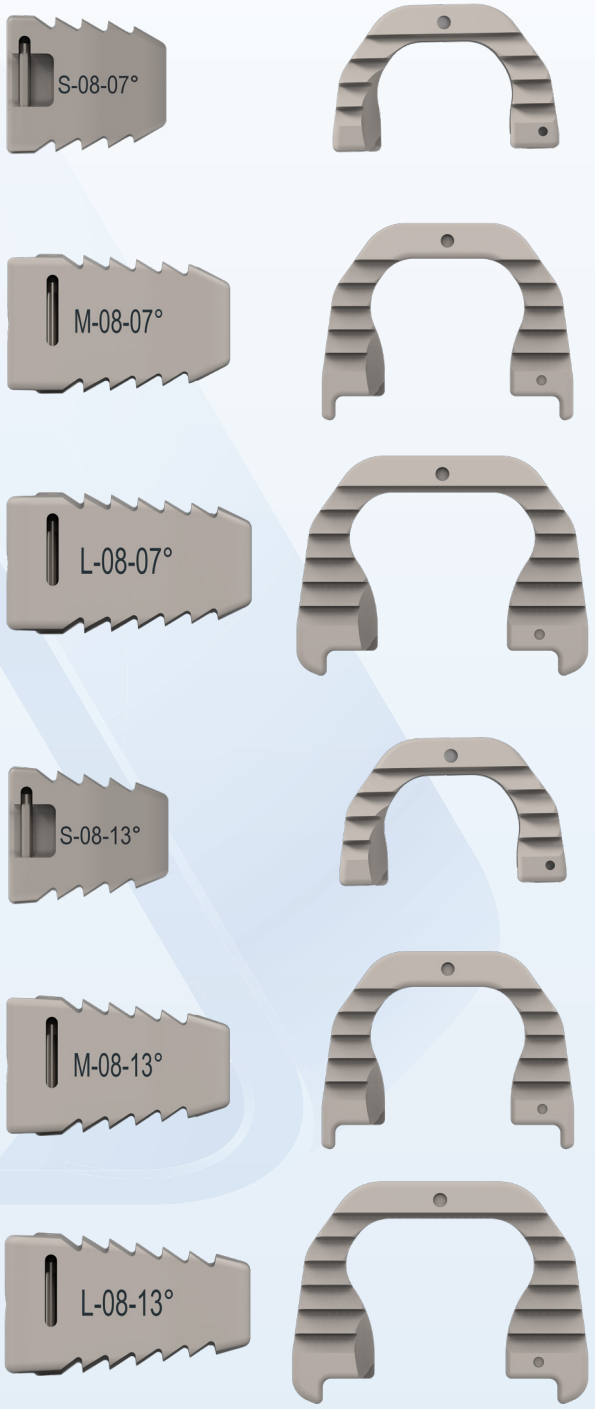
10.3.2 Once the Screw Guide is assembled to the Implant Inserter, align the implant to the inserter and thread the proximal knob(s) until the Implant is secure.

10.3.3 Remove the spacer by pulling the Implant Inserter in a linear motion until the spacer is dislodged.

ANTERIOR CERVICAL STABILIZATION SYSTEM
HA PEEK OFFERING

ACSS SPACERS, HA PEEK

Part Number	Description	Qty
LA141205A	ACSS SPACER, HA PEEK, 14MM-12MM-5MM, 7°, NON-STERILE	2
LA141206A	ACSS SPACER, HA PEEK, 14MM-12MM-6MM, 7°, NON-STERILE	3
LA141207A	ACSS SPACER, HA PEEK, 14MM-12MM-7MM, 7°, NON-STERILE	3
LA141208A	ACSS SPACER, HA PEEK, 14MM-12MM-8MM, 7°, NON-STERILE	3
LA141209A	ACSS SPACER, HA PEEK, 14MM-12MM-9MM, 7°, NON-STERILE	2
LA141210A	ACSS SPACER, HA PEEK, 14MM-12MM-10MM, 7°, NON-STERILE	2
LA141211A	ACSS SPACER, HA PEEK, 14MM-12MM-11MM, 7°, NON-STERILE	1
LA141212A	ACSS SPACER, HA PEEK, 14MM-12MM-12MM, 7°, NON-STERILE	1
LA161405A	ACSS SPACER, HA PEEK, 16MM-14MM-5MM, 7°, NON-STERILE	2
LA161406A	ACSS SPACER, HA PEEK, 16MM-14MM-6MM, 7°, NON-STERILE	3
LA161407A	ACSS SPACER, HA PEEK, 16MM-14MM-7MM, 7°, NON-STERILE	3
LA161408A	ACSS SPACER, HA PEEK, 16MM-14MM-8MM, 7°, NON-STERILE	3
LA161409A	ACSS SPACER, HA PEEK, 16MM-14MM-9MM, 7°, NON-STERILE	2
LA161410A	ACSS SPACER, HA PEEK, 16MM-14MM-10MM, 7°, NON-STERILE	2
LA161411A	ACSS SPACER, HA PEEK, 16MM-14MM-11MM, 7°, NON-STERILE	1
LA161412A	ACSS SPACER, HA PEEK, 16MM-14MM-12MM, 7°, NON-STERILE	1
LA181505A	ACSS SPACER, HA PEEK, 18MM-15MM-5MM, 7°, NON-STERILE	2
LA181506A	ACSS SPACER, HA PEEK, 18MM-15MM-6MM, 7°, NON-STERILE	3
LA181507A	ACSS SPACER, HA PEEK, 18MM-15MM-7MM, 7°, NON-STERILE	3
LA181508A	ACSS SPACER, HA PEEK, 18MM-15MM-8MM, 7°, NON-STERILE	3
LA181509A	ACSS SPACER, HA PEEK, 18MM-15MM-9MM, 7°, NON-STERILE	2
LA181510A	ACSS SPACER, HA PEEK, 18MM-15MM-10MM, 7°, NON-STERILE	2
LA181511A	ACSS SPACER, HA PEEK, 18MM-15MM-11MM, 7°, NON-STERILE	1
LA181512A	ACSS SPACER, HA PEEK, 18MM-15MM-12MM, 7°, NON-STERILE	1
LA141205C	ACSS SPACER, HA PEEK, 14MM-12MM-5MM, 13°, NON-STERILE	2
LA141206C	ACSS SPACER, HA PEEK, 14MM-12MM-6MM, 13°, NON-STERILE	3
LA141207C	ACSS SPACER, HA PEEK, 14MM-12MM-7MM, 13°, NON-STERILE	3
LA141208C	ACSS SPACER, HA PEEK, 14MM-12MM-8MM, 13°, NON-STERILE	3
LA141209C	ACSS SPACER, HA PEEK, 14MM-12MM-9MM, 13°, NON-STERILE	2
LA141210C	ACSS SPACER, HA PEEK, 14MM-12MM-10MM, 13°, NON-STERILE	2
LA141211C	ACSS SPACER, HA PEEK, 14MM-12MM-11MM, 13°, NON-STERILE	1
LA141212C	ACSS SPACER, HA PEEK, 14MM-12MM-12MM, 13°, NON-STERILE	1
LA161405C	ACSS SPACER, HA PEEK, 16MM-14MM-5MM, 13°, NON-STERILE	2
LA161406C	ACSS SPACER, HA PEEK, 16MM-14MM-6MM, 13°, NON-STERILE	3
LA161407C	ACSS SPACER, HA PEEK, 16MM-14MM-7MM, 13°, NON-STERILE	3
LA161408C	ACSS SPACER, HA PEEK, 16MM-14MM-8MM, 13°, NON-STERILE	3
LA161409C	ACSS SPACER, HA PEEK, 16MM-14MM-9MM, 13°, NON-STERILE	2
LA161410C	ACSS SPACER, HA PEEK, 16MM-14MM-10MM, 13°, NON-STERILE	2
LA161411C	ACSS SPACER, HA PEEK, 16MM-14MM-11MM, 13°, NON-STERILE	1
LA161412C	ACSS SPACER, HA PEEK, 16MM-14MM-12MM, 13°, NON-STERILE	1
LA181505C	ACSS SPACER, HA PEEK, 18MM-15MM-5MM, 13°, NON-STERILE	2
LA181506C	ACSS SPACER, HA PEEK, 18MM-15MM-6MM, 13°, NON-STERILE	3
LA181507C	ACSS SPACER, HA PEEK, 18MM-15MM-7MM, 13°, NON-STERILE	3
LA181508C	ACSS SPACER, HA PEEK, 18MM-15MM-8MM, 13°, NON-STERILE	3
LA181509C	ACSS SPACER, HA PEEK, 18MM-15MM-9MM, 13°, NON-STERILE	2
LA181510C	ACSS SPACER, HA PEEK, 18MM-15MM-10MM, 13°, NON-STERILE	2
LA181511C	ACSS SPACER, HA PEEK, 18MM-15MM-11MM, 13°, NON-STERILE	1
LA181512C	ACSS SPACER, HA PEEK, 18MM-15MM-12MM, 13°, NON-STERILE	1



ANTERIOR CERVICAL STABILIZATION SYSTEM
ACID-ETCHED TITANIUM OFFERING

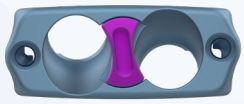
ACSS SPACERS, ACID-ETCHED TITANIUM

Part Number	Description	Qty
LB141205A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-5MM, 7°, NON-STERILE	2
LB141206A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-6MM, 7°, NON-STERILE	3
LB141207A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-7MM, 7°, NON-STERILE	3
LB141208A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-8MM, 7°, NON-STERILE	3
LB141209A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-9MM, 7°, NON-STERILE	2
LB141210A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-10MM, 7°, NON-STERILE	2
LB141211A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-11MM, 7°, NON-STERILE	1
LB141212A	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-12MM, 7°, NON-STERILE	1
LB161405A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-5MM, 7°, NON-STERILE	2
LB161406A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-6MM, 7°, NON-STERILE	3
LB161407A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-7MM, 7°, NON-STERILE	3
LB161408A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-8MM, 7°, NON-STERILE	3
LB161409A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-9MM, 7°, NON-STERILE	2
LB161410A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-10MM, 7°, NON-STERILE	2
LB161411A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-11MM, 7°, NON-STERILE	1
LB161412A	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-12MM, 7°, NON-STERILE	1
LB181505A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-5MM, 7°, NON-STERILE	2
LB181506A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-6MM, 7°, NON-STERILE	3
LB181507A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-7MM, 7°, NON-STERILE	3
LB181508A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-8MM, 7°, NON-STERILE	3
LB181509A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-9MM, 7°, NON-STERILE	2
LB181510A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-10MM, 7°, NON-STERILE	2
LB181511A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-11MM, 7°, NON-STERILE	1
LB181512A	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-12MM, 7°, NON-STERILE	1
LB141205C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-5MM, 13°, NON-STERILE	2
LB141206C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-6MM, 13°, NON-STERILE	3
LB141207C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-7MM, 13°, NON-STERILE	3
LB141208C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-8MM, 13°, NON-STERILE	3
LB141209C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-9MM, 13°, NON-STERILE	2
LB141210C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-10MM, 13°, NON-STERILE	2
LB141211C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-11MM, 13°, NON-STERILE	1
LB141212C	ACSS SPACER, ACID-ETCHED TITANIUM, 14MM-12MM-12MM, 13°, NON-STERILE	1
LB161405C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-5MM, 13°, NON-STERILE	2
LB161406C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-6MM, 13°, NON-STERILE	3
LB161407C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-7MM, 13°, NON-STERILE	3
LB161408C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-8MM, 13°, NON-STERILE	3
LB161409C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-9MM, 13°, NON-STERILE	2
LB161410C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-10MM, 13°, NON-STERILE	2
LB161411C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-11MM, 13°, NON-STERILE	1
LB161412C	ACSS SPACER, ACID-ETCHED TITANIUM, 16MM-14MM-12MM, 13°, NON-STERILE	1
LB181505C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-5MM, 13°, NON-STERILE	2
LB181506C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-6MM, 13°, NON-STERILE	3
LB181507C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-7MM, 13°, NON-STERILE	3
LB181508C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-8MM, 13°, NON-STERILE	3
LB181509C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-9MM, 13°, NON-STERILE	2
LB181510C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-10MM, 13°, NON-STERILE	2
LB181511C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-11MM, 13°, NON-STERILE	1
LB181512C	ACSS SPACER, ACID-ETCHED TITANIUM, 18MM-15MM-12MM, 13°, NON-STERILE	1

ANTERIOR CERVICAL STABILIZATION SYSTEM
PLATE OFFERING

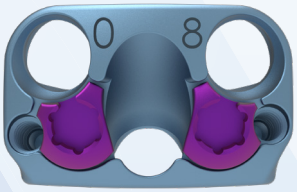
ACSS ZERO PLATE

Part Number	Description	Qty
LDA000005	ACSS ZERO PLATE, 5MM	2
LDA000006	ACSS ZERO PLATE, 6MM	3
LDA000007	ACSS ZERO PLATE, 7MM	3
LDA000008	ACSS ZERO PLATE, 8MM	3
LDA000009	ACSS ZERO PLATE, 9MM	2
LDA000010	ACSS ZERO PLATE, 10MM	2
LDA000011	ACSS ZERO PLATE, 11MM	1
LDA000012	ACSS ZERO PLATE, 12MM	1



ACSS HALF PLATE

Part Number	Description	Qty
LDB000005	ACSS HALF PLATE, 5MM	2
LDB000006	ACSS HALF PLATE, 6MM	3
LDB000007	ACSS HALF PLATE, 7MM	3
LDB000008	ACSS HALF PLATE, 8MM	3
LDB000009	ACSS HALF PLATE, 9MM	2
LDB000010	ACSS HALF PLATE, 10MM	2
LDB000011	ACSS HALF PLATE, 11MM	1
LDB000012	ACSS HALF PLATE, 12MM	1

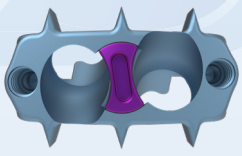


ACSS FULL PLATE

Part Number	Description	Qty
LDC000005	ACSS FULL PLATE, 5MM	2
LDC000006	ACSS FULL PLATE, 6MM	3
LDC000007	ACSS FULL PLATE, 7MM	3
LDC000008	ACSS FULL PLATE, 8MM	3
LDC000009	ACSS FULL PLATE, 9MM	2
LDC000010	ACSS FULL PLATE, 10MM	2
LDC000011	ACSS FULL PLATE, 11MM	1
LDC000012	ACSS FULL PLATE, 12MM	1

ACSS ZERO PLATE, SPIKE

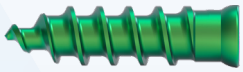
Part Number	Description	Qty
LDD000005	ACSS ZERO PLATE, SPIKE, 5MM	2
LDD000006	ACSS ZERO PLATE, SPIKE, 6MM	3
LDD000007	ACSS ZERO PLATE, SPIKE, 7MM	3
LDD000008	ACSS ZERO PLATE, SPIKE, 8MM	3
LDD000009	ACSS ZERO PLATE, SPIKE, 9MM	2
LDD000010	ACSS ZERO PLATE, SPIKE, 10MM	2
LDD000011	ACSS ZERO PLATE, SPIKE, 11MM	1
LDD000012	ACSS ZERO PLATE, SPIKE, 12MM	1



ANTERIOR CERVICAL STABILIZATION SYSTEM
PLATE SCREWS AND NAIL OFFERING

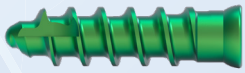
ACSS SCREW, SELF DRILLING VARIABLE

Part Number	Description	
LEAB35010	ACSS SCREW, SELF DRILLING VARIABLE, Ø3.5MM X 10MM	8
LEAB35012	ACSS SCREW, SELF DRILLING VARIABLE, Ø3.5MM X 12MM	8
LEAB35014	ACSS SCREW, SELF DRILLING VARIABLE, Ø3.5MM X 14MM	8
LEAB35016	ACSS SCREW, SELF DRILLING VARIABLE, Ø3.5MM X 16MM	8
LEAB35018	ACSS SCREW, SELF DRILLING 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



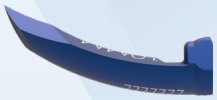
ACSS SCREW, SELF TAPPING VARIABLE

Part Number	Description	Qty
LEBB35010	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 10MM	8
LEBB35012	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 12MM	8
LEBB35014	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 14MM	8
LEBB35016	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 16MM	8
LEBB35018	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 18MM	8
LEBB35020	ACSS SCREW, SELF TAPPING VARIABLE, Ø3.5MM X 20MM	8
LEBB40010	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 10MM	8
LEBB40012	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 12MM	8
LEBB40014	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 14MM	8
LEBB40016	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 16MM	8
LEBB40018	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 18MM	8
LEBB40020	ACSS SCREW, SELF TAPPING VARIABLE, Ø4.0MM X 20MM	8



ACSS NAIL

Part Number	Description	Qty
LF0000012	ACSS NAIL, Ø3.5MM X 12MM	8
LF0000014	ACSS NAIL, Ø3.5MM X 14MM	8
LF0000016	ACSS NAIL, Ø3.5MM X 16MM	8



ACSS TRIAL, ZERO PLATE, SMALL, 7°

Part Number	Desctiption	QTY
LZFSAA05A	ACSS Trial, Zero Plate, Small, 5mm, 7°	1
LZFSAA06A	ACSS Trial, Zero Plate, Small, 6mm, 7°	1
LZFSAA07A	ACSS Trial, Zero Plate, Small, 7mm, 7°	1
LZFSAA08A	ACSS Trial, Zero Plate, Small, 8mm, 7°	1
LZFSAA09A	ACSS Trial, Zero Plate, Small, 9mm, 7°	1
LZFSAA10A	ACSS Trial, Zero Plate, Small, 10mm, 7°	1
LZFSAA11A	ACSS Trial, Zero Plate, Small, 11mm, 7°	1
LZFSAA12A	ACSS Trial, Zero Plate, Small, 12mm, 7°	1

ACSS TRIAL, ZERO PLATE, SMALL, 13°

Part Number	Desctiption	QTY
LZFSAA05C	ACSS Trial, Zero Plate, Small, 5mm, 13°	1
LZFSAA06C	ACSS Trial, Zero Plate, Small, 6mm, 13°	1
LZFSAA07C	ACSS Trial, Zero Plate, Small, 7mm, 13°	1
LZFSAA08C	ACSS Trial, Zero Plate, Small, 8mm, 13°	1
LZFSAA09C	ACSS Trial, Zero Plate, Small, 9mm, 13°	1
LZFSAA10C	ACSS Trial, Zero Plate, Small, 10mm, 13°	1
LZFSAA11C	ACSS Trial, Zero Plate, Small, 11mm, 13°	1
LZFSAA12C	ACSS Trial, Zero Plate, Small, 12mm, 13°	1

ACSS TRIAL, ZERO PLATE, MEDIUM, 7°

Part Number	Desctiption	QTY
LZFMAA05A	ACSS Trial, Zero Plate, Medium, 5mm, 7°	1
LZFMAA06A	ACSS Trial, Zero Plate, Medium, 6mm, 7°	1
LZFMAA07A	ACSS Trial, Zero Plate, Medium, 7mm, 7°	1
LZFMAA08A	ACSS Trial, Zero Plate, Medium, 8mm, 7°	1
LZFMAA09A	ACSS Trial, Zero Plate, Medium, 9mm, 7°	1
LZFMAA10A	ACSS Trial, Zero Plate, Medium, 10mm, 7°	1
LZFMAA11A	ACSS Trial, Zero Plate, Medium, 11mm, 7°	1
LZFMAA12A	ACSS Trial, Zero Plate, Medium, 12mm, 7°	1

ACSS TRIAL, ZERO PLATE, MEDIUM, 13°

Part Number	Desctiption	QTY
LZFMAA05C	ACSS Trial, Zero Plate, Medium, 5mm, 13°	1
LZFMAA06C	ACSS Trial, Zero Plate, Medium, 6mm, 13°	1
LZFMAA07C	ACSS Trial, Zero Plate, Medium, 7mm, 13°	1
LZFMAA08C	ACSS Trial, Zero Plate, Medium, 8mm, 13°	1
LZFMAA09C	ACSS Trial, Zero Plate, Medium, 9mm, 13°	1
LZFMAA10C	ACSS Trial, Zero Plate, Medium, 10mm, 13°	1
LZFMAA11C	ACSS Trial, Zero Plate, Medium, 11mm, 13°	1
LZFMAA12C	ACSS Trial, Zero Plate, Medium, 12mm, 13°	1

ACSS TRIAL, ZERO PLATE, LARGE, 7°

Part Number	Desctiption	QTY
LZFLAA05A	ACSS Trial, Zero Plate, Large, 5mm, 7°	1
LZFLAA06A	ACSS Trial, Zero Plate, Large, 6mm, 7°	1
LZFLAA07A	ACSS Trial, Zero Plate, Large, 7mm, 7°	1
LZFLAA08A	ACSS Trial, Zero Plate, Large, 8mm, 7°	1
LZFLAA09A	ACSS Trial, Zero Plate, Large, 9mm, 7°	1
LZFLAA10A	ACSS Trial, Zero Plate, Large, 10mm, 7°	1
LZFLAA11A	ACSS Trial, Zero Plate, Large, 11mm, 7°	1
LZFLAA12A	ACSS Trial, Zero Plate, Large, 12mm, 7°	1

ACSS TRIALS

ACSS TRIAL, ZERO PLATE, LARGE, 13°

Part Number	Desctiption	QTY
LZFLAA05C	ACSS Trial, Zero Plate, Large, 5mm, 13°	1
LZFLAA06C	ACSS Trial, Zero Plate, Large, 6mm, 13°	1
LZFLAA07C	ACSS Trial, Zero Plate, Large, 7mm, 13°	1
LZFLAA08C	ACSS Trial, Zero Plate, Large, 8mm, 13°	1
LZFLAA09C	ACSS Trial, Zero Plate, Large, 9mm, 13°	1
LZFLAA10C	ACSS Trial, Zero Plate, Large, 10mm, 13°	1
LZFLAA11C	ACSS Trial, Zero Plate, Large, 11mm, 13°	1
LZFLAA12C	ACSS Trial, Zero Plate, Large, 12mm, 13°	1

ACSS TRIAL, HALF PLATE, SMALL, 7°

Part Number	Desctiption	QTY
LZFSAB05A	ACSS Trial, Half Plate, Small, 5mm, 7°	1
LZFSAB06A	ACSS Trial, Half Plate, Small, 6mm, 7°	1
LZFSAB07A	ACSS Trial, Half Plate, Small, 7mm, 7°	1
LZFSAB08A	ACSS Trial, Half Plate, Small, 8mm, 7°	1
LZFSAB09A	ACSS Trial, Half Plate, Small, 9mm, 7°	1
LZFSAB10A	ACSS Trial, Half Plate, Small, 10mm, 7°	1
LZFSAB11A	ACSS Trial, Half Plate, Small, 11mm, 7°	1
LZFSAB12A	ACSS Trial, Half Plate, Small, 12mm, 7°	1

ACSS TRIAL, HALF PLATE, SMALL, 13°

Part Number	Desctiption	QTY
LZFSAB05C	ACSS Trial, Half Plate, Small, 5mm, 13°	1
LZFSAB06C	ACSS Trial, Half Plate, Small, 6mm, 13°	1
LZFSAB07C	ACSS Trial, Half Plate, Small, 7mm, 13°	1
LZFSAB08C	ACSS Trial, Half Plate, Small, 8mm, 13°	1
LZFSAB09C	ACSS Trial, Half Plate, Small, 9mm, 13°	1
LZFSAB10C	ACSS Trial, Half Plate, Small, 10mm, 13°	1
LZFSAB11C	ACSS Trial, Half Plate, Small, 11mm, 13°	1
LZFSAB12C	ACSS Trial, Half Plate, Small, 12mm, 13°	1

ACSS TRIAL, HALF PLATE, MEDIUM, 7°

Part Number	Desctiption	QTY
LZFMAB05A	ACSS Trial, Half Plate, Medium, 5mm, 7°	1
LZFMAB06A	ACSS Trial, Half Plate, Medium, 6mm, 7°	1
LZFMAB07A	ACSS Trial, Half Plate, Medium, 7mm, 7°	1
LZFMAB08A	ACSS Trial, Half Plate, Medium, 8mm, 7°	1
LZFMAB09A	ACSS Trial, Half Plate, Medium, 9mm, 7°	1
LZFMAB10A	ACSS Trial, Half Plate, Medium, 10mm, 7°	1
LZFMAB11A	ACSS Trial, Half Plate, Medium, 11mm, 7°	1
LZFMAB12A	ACSS Trial, Half Plate, MEdium, 12mm 7°	1

ACSS TRIAL, HALF PLATE, MEDIUM, 13°

Part Number	Desctiption	QTY
LZFMAB05C	ACSS Trial, Half Plate, Medium, 5mm, 13°	1
LZFMAB06C	ACSS Trial, Half Plate, Medium, 6mm, 13°	1
LZFMAB07C	ACSS Trial, Half Plate, Medium, 7mm, 13°	1
LZFMAB08C	ACSS Trial, Half Plate, Medium, 8mm, 13°	1
LZFMAB09C	ACSS Trial, Half Plate, Medium, 9mm, 13°	1
LZFMAB10C	ACSS Trial, Half Plate, Medium, 10mm, 13°	1
LZFMAB11C	ACSS Trial, Half Plate, Medium, 11mm, 13°	1
LZFMAB12C	ACSS Trial, Half Plate, Medium, 12mm, 13°	1

ACSS TRIAL, HALF PLATE, LARGE, 7°

Part Number	Desctiption	QTY
LZFLAB05A	ACSS Trial, Half Plate, Large, 5mm, 7°	1
LZFLAB06A	ACSS Trial, Half Plate, Large, 6mm, 7°	1
LZFLAB07A	ACSS Trial, Half Plate, Large, 7mm, 7°	1
LZFLAB08A	ACSS Trial, Half Plate, Large, 8mm, 7°	1
LZFLAB09A	ACSS Trial, Half Plate, Large, 9mm, 7°	1
LZFLAB10A	ACSS Trial, Half Plate, Large, 10mm, 7°	1
LZFLAB11A	ACSS Trial, Half Plate, Large, 11mm, 7°	1
LZFLAB12A	ACSS Trial, Half Plate, Large, 12mm, 7°	1

ACSS TRIAL, HALF PLATE, LARGE, 13°

Part Number	Desctiption	QTY
LZFLAB05C	ACSS Trial, Half Plate, Large, 5mm, 13°	1
LZFLAB06C	ACSS Trial, Half Plate, Large, 6mm, 13°	1
LZFLAB07C	ACSS Trial, Half Plate, Large, 7mm, 13°	1
LZFLAB08C	ACSS Trial, Half Plate, Large, 8mm, 13°	1
LZFLAB09C	ACSS Trial, Half Plate, Large, 9mm, 13°	1
LZFLAB10C	ACSS Trial, Half Plate, Large, 10mm, 13°	1
LZFLAB11C	ACSS Trial, Half Plate, Large, 11mm, 13°	1
LZFLAB12C	ACSS Trial, Half Plate, Large, 12mm, 13°	1

ACSS TRIAL, FULL PLATE, SMALL, 7°

Part Number	Desctiption	QTY
LZFSAC05A	ACSS Trial, Full Plate, Small, 5mm, 7°	1
LZFSAC06A	ACSS Trial, Full Plate, Small, 6mm, 7°	1
LZFSAC07A	ACSS Trial, Full Plate, Small, 7mm, 7°	1
LZFSAC08A	ACSS Trial, Full Plate, Small, 8mm, 7°	1
LZFSAC09A	ACSS Trial, Full Plate, Small, 9mm, 7°	1
LZFSAC10A	ACSS Trial, Full Plate, Small, 10mm, 7°	1
LZFSAC11A	ACSS Trial, Full Plate, Small, 11mm, 7°	1
LZFSAC12A	ACSS Trial, Full Plate, Small, 12mm, 7°	1

ACSS TRIAL, FULL PLATE, SMALL, 13°

Part Number	Desctiption	QTY
LZFSAC05C	ACSS Trial, Full Plate, Small, 5mm, 13°	1
LZFSAC06C	ACSS Trial, Full Plate, Small, 6mm, 13°	1
LZFSAC07C	ACSS Trial, Full Plate, Small, 7mm, 13°	1
LZFSAC08C	ACSS Trial, Full Plate, Small, 8mm, 13°	1
LZFSAC09C	ACSS Trial, Full Plate, Small, 9mm, 13°	1
LZFSAC10C	ACSS Trial, Full Plate, Small, 10mm, 13°	1
LZFSAC11C	ACSS Trial, Full Plate, Small, 11mm, 13°	1
LZFSAC12C	ACSS Trial, Full Plate, Small, 12mm, 13°	1

ACSS TRIAL, FULL PLATE, MEDIUM, 7°

Part Number	Desctiption	QTY
LZFMAC05A	ACSS Trial, Full Plate, Medium, 5mm, 7°	1
LZFMAC06A	ACSS Trial, Full Plate, Medium, 6mm, 7°	1
LZFMAC07A	ACSS Trial, Full Plate, Medium, 7mm, 7°	1
LZFMAC08A	ACSS Trial, Full Plate, Medium, 8mm, 7°	1
LZFMAC09A	ACSS Trial, Full Plate, Medium, 9mm, 7°	1
LZFMAC10A	ACSS Trial, Full Plate, Medium, 10mm, 7°	1
LZFMAC11A	ACSS Trial, Full Plate, Medium, 11mm, 7°	1
LZFMAC12A	ACSS Trial, Full Plate, Medium, 12mm, 7°	1

ACSS TRIALS

ACSS TRIAL, FULL PLATE, MEDIUM, 13°

Part Number	Desctiption	QTY
LZFMAC05C	ACSS Trial, Full Plate, Medium, 5mm, 13°	1
LZFMAC06C	ACSS Trial, Full Plate, Medium, 6mm, 13°	1
LZFMAC07C	ACSS Trial, Full Plate, Medium, 7mm, 13°	1
LZFMAC08C	ACSS Trial, Full Plate, Medium, 8mm, 13°	1
LZFMAC09C	ACSS Trial, Full Plate, Medium, 9mm, 13°	1
LZFMAC10C	ACSS Trial, Full Plate, Medium, 10mm, 13°	1
LZFMAC11C	ACSS Trial, Full Plate, Medium, 11mm, 13°	1
LZFMAC12C	ACSS Trial, Full Plate, Medium, 12mm, 13°	1

ACSS TRIAL, FULL PLATE, LARGE, 7°

Part Number	Desctiption	QTY
LZFLAC05A	ACSS Trial, Full Plate, Large, 5mm, 7°	1
LZFLAC06A	ACSS Trial, Full Plate, Large, 6mm, 7°	1
LZFLAC07A	ACSS Trial, Full Plate, Large, 7mm, 7°	1
LZFLAC08A	ACSS Trial, Full Plate, Large, 8mm, 7°	1
LZFLAC09A	ACSS Trial, Full Plate, Large, 9mm, 7°	1
LZFLAC10A	ACSS Trial, Full Plate, Large, 10mm, 7°	1
LZFLAC11A	ACSS Trial, Full Plate, Large, 11mm, 7°	1
LZFLAC12A	ACSS Trial, Full Plate, Large, 12mm, 7°	1

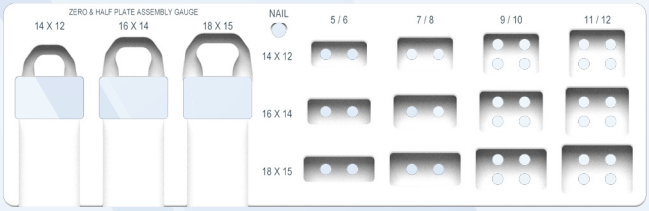
ACSS TRIAL, FULL PLATE, LARGE, 13°

Part Number	Desctiption	QTY
LZFLAC05C	ACSS Trial, Full Plate, Large, 5mm, 13°	1
LZFLAC06C	ACSS Trial, Full Plate, Large, 6mm, 13°	1
LZFLAC07C	ACSS Trial, Full Plate, Large, 7mm, 13°	1
LZFLAC08C	ACSS Trial, Full Plate, Large, 8mm, 13°	1
LZFLAC09C	ACSS Trial, Full Plate, Large, 9mm, 13°	1
LZFLAC10C	ACSS Trial, Full Plate, Large, 10mm, 13°	1
LZFLAC11C	ACSS Trial, Full Plate, Large, 11mm, 13°	1
LZFLAC12C	ACSS Trial, Full Plate, Large, 12mm, 13°	1

ANTERIOR CERVICAL STABILIZATION SYSTEM
INSTRUMENT OFFERING

Part Number	Description	Qty
EABEASADZ	AXIAL, FIXED INTERNAL, QUICK DISCONNECT	2
EDDEATAAZ	EGG, FIXED INTERNAL, QUICK DISCONNECT	2
LZA010000	TRIAL INSERTER	2
LZA021000	IMPLANT INSERTER	1
LZA032X00	SCREW GUIDE, DUAL THREAD, ZERO PLATE, BLANK	1
LZA032C05	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 5MM, 35°	1
LZA032C06	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 6MM, 35°	1
LZA032C07	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 7MM, 35°	1
LZA032C08	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 8MM, 35°	1
LZA032C09	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 9MM, 35°	1
LZA032C10	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 10MM, 35°	1
LZA032C11	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 11MM, 35°	1
LZA032C12	SCREW GUIDE, DUAL THREAD, ZERO PLATE, 12MM, 35°	1
LZA0330XX	SCREW GUIDE, DUAL THREAD, HALF PLATE, BLANK	1
LZA033005	SCREW GUIDE, DUAL THREAD, HALF PLATE, 5MM	1
LZA033006	SCREW GUIDE, DUAL THREAD, HALF PLATE, 6MM	1
LZA033007	SCREW GUIDE, DUAL THREAD, HALF PLATE, 7MM	1
LZA033008	SCREW GUIDE, DUAL THREAD, HALF PLATE, 8MM	1
LZA033009	SCREW GUIDE, DUAL THREAD, HALF PLATE, 9MM	1
LZA033010	SCREW GUIDE, DUAL THREAD, HALF PLATE, 10MM	1
LZA033011	SCREW GUIDE, DUAL THREAD, HALF PLATE, 11MM	1
LZA033012	SCREW GUIDE, DUAL THREAD, HALF PLATE, 12MM	1

ANTERIOR CERVICAL STABILIZATION SYSTEM
INSTRUMENT OFFERING

Part Number	Description	Qty	
LZE011005	NAIL GUIDE, DUAL THREAD, 5MM	1	
LZE011006	NAIL GUIDE, DUAL THREAD, 6MM	1	
LZE011007	NAIL GUIDE, DUAL THREAD, 7MM	1	
LZE011008	NAIL GUIDE, DUAL THREAD, 8MM	1	
LZE011009	NAIL GUIDE, DUAL THREAD, 9MM	1	
LZE011010	NAIL GUIDE, DUAL THREAD, 10MM	1	
LZE011011	NAIL GUIDE, DUAL THREAD, 11MM	1	
LZE011012	NAIL GUIDE, DUAL THREAD, 12MM	1	
LZA110000	IMPLANT ASSEMBLY GAUGE	1	
LZA040000	STRAIGHT TAMP	1	
LZA050000	ROTATION TAMP	1	
LZA060000	LOCK DRIVER	2	
LZA080000	IMPLANT DISASSEBMLY TOOL	2	
LZA090000	STRAIGHT RASP	1	
LZB010000	SELF CENTERING AWL, 10MM	1	
LZB020000	SELF CENTERING DRILL, 10MM*	1	
LZB030000	TAP, 10MM*	1	
LZB040000	SCREWDRIVER, T10A	2	
LZB050000	SCREW REMOVER, T10A	1	
LZC020000	VARIABLE ANGLE AWL, 10MM*	1	

***NON-DISPOSABLE**

DOLOMITE STAND ALONE CERVICAL SYSTEM
INSTRUMENT OFFERING

Part Number	Description	QTY	
LZC021000	VARIABLE ANGLE AWL, GUIDED, 10MM*	1	
LZC030000	VARIABLE ANGLE DRILL, 10MM*	1	
LZC031000	VARIABLE ANGLE DRILL, GUIDED, 10MM*	1	
LZC040000	VARIABLE ANGLE TAP, 10MM*	1	
LZC041000	VARIABLE ANGLE TAP, GUIDED, 10MM*	1	
LZC010000	DRILL GUIDE, VARIABLE	1	
LZC050000	DRIVER GUIDE, VARIABLE	1	
LZC060000	VARIABLE ANGLE SCREWDRIVER T10A*	2	
LZD010000	FIXED ANGLE AWL, 10MM*	1	
LZD021000	FIXED ANGLE DRIVER	2	

***NON-DISPOSABLE**

ANTERIOR CERVICAL STABILIZATION SYSTEM
INSTRUMENT OFFERING

Part Number	Description	Qty	
LZD031000	FIXED ANGLE DRILL, 10MM*	2	
LZD041035	FIXED ANGLE TAP, SHORT*	1	
LZD041135	FIXED ANGLE TAP, LONG*	1	
LZD051010	FIXED ANGLE SCREWDRIVER. T10A, SHORT*	2	
LZD051110	FIXED ANGLE SCREWDRIVER. T10A, LONG*	2	
LZD061000	FIXED ANGLE LOCK DRIVER, SHORT*	2	
LZD061001	FIXED ANGLE LOCK DRIVER, LONG*	2	
LZE020000	NAIL REMOVER	1	
LZE030000	NAIL IMPACTOR*	1	
LZE030001	NAIL IMPACTOR*	1 /OPT	
LZE040000	NAIL INSERTION TOOL	1	
LZE050000	IMPLANT INSERTER, DUAL THREAD, KNOB DRIVER	1	

***NON-DISPOSABLE**

INSTRUCTIONS FOR USE

DOLOMITE
ANTERIOR CERVICAL STABILIZATION SYSTEM

INSTRUCTIONS FOR USE
1.0 DESCRIPTION: The DOLOMITE Anterior Cervical Stabilization System are implants developed for the stabilization of the cervical column. The spacers are a 2-piece modular design which allows for interchangeable plate and spacer components. The plate and spacer components contain interlocking features in addition to a locking mechanism which allows for intraoperative assembly prior to implantation. The spacer components are available in a range of footprints and heights in PEEK OPTIMA LT120HA or machined Titanium alloy. The plates are offered in multiple fixation types and sizes to suit the individual pathology and anatomical conditions of the patient in machined Titanium alloy. The implants have a hollow center to allow placement of autogenous bone graft. The superior and inferior surfaces are open to promote contact of the bone graft with the vertebral end plates to allow bone growth.
2.0 MATERIALS: VESTAKEEP® i4R PEEK (ASTM F2026), Tantalum (ASTM F560), Titanium (ASTM F136), PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced)
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 DOLOMITE Stand-Alone Cervical Interbody Spacer must not be reused under any circumstances. The DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer and are not a reference for surgical techniques
4.0 INDICATIONS: The DOLOMITE Stand-Alone Cervical Interbody Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at disc levels (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six weeks of nonoperative treatment prior to treatment with intervertebral cages. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.
The Dolomite Spacer is an interbody fusion device intended to be used with supplemental fixation for one or two levels of the cervical spine.
The DOLOMITE Spacer and Plate assembly are an integrated interbody fusion device intended for stand-alone use at one or two levels of the cervical spine (C2-T1) and used with titanium alloy screws. Multiple full plate assembly configurations can't be used in conjunction for two contiguous levels of the cervical spine. When used with anchors, the assembly is intended for use at one level of the cervical spine with additional supplemental fixation that has been cleared by the FDA for use in the cervical spine.
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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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.

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. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

The DOLOMITE Stand-Alone Cervical Interbody Spacer has not been evaluated for safety and compatibility in the MR environment. The DOLOMITE Stand-Alone Cervical Interbody Spacer 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. DOLOMITE Stand-Alone Cervical Interbody Spacer components should not be used with components from other manufacturers.
The following DOLOMITE plate combinations cannot be used in conjunction for two contiguous levels of the cervical spine: 2 Full plates together, a Full and Zero plate together
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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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. Reference LIT-00007 for disassembly and reassembly instructions. 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 DOLOMITE Stand-Alone Cervical Interbody Spacer 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 x 10-6, via the indicated methods. No claims of pyrogenicity are made.

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

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.
It has not been determined if reprocessing affects the chemical, phase, or structural properties of the hydroxyapatite on the HALF DOME Posterior Lumbar Interbody Spacer.
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 DOLOMITE Stand-Alone Cervical Interbody Spacer component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.
If any DOLOMITE Stand-Alone Cervical Interbody Spacer 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

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NOTES


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