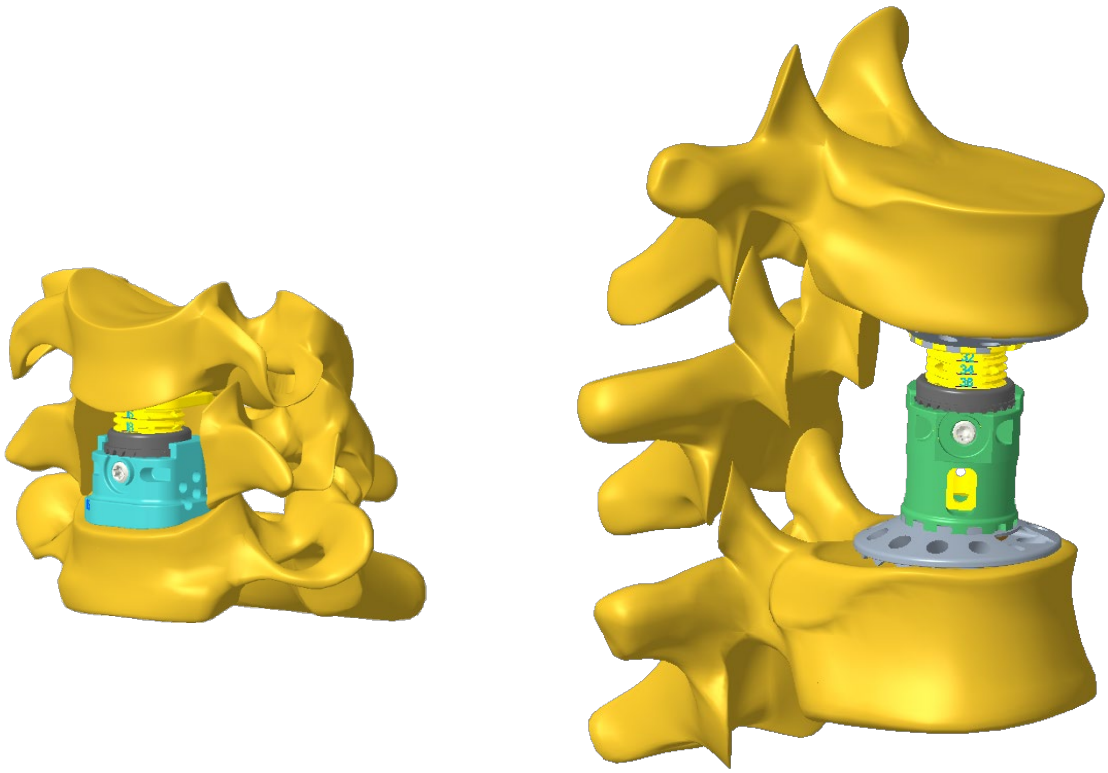
Normandy VBR™ System

Surgical Technique Guide



Normandy VBR™ System

Device Description: The Normandy VBR™ System is an adjustable height vertebral body replacement device that is implanted into the vertebral body space to provide structural stability in skeletally mature patients following corpectomy or vertebrectomy. The system is comprised of spacers of various sizes and options to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. The device is mechanically locked at the required height by means of a locking screw. Each spacer has an axial hole to allow autograft or allograft to be packed inside each spacer. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Components are manufactured from titanium alloy (Ti-6AL-4V) per ASTM F-136. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Intended Use: The Normandy VBR™ System is indicated for use in the cervical spine (C2-C7) and thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Normandy VBR™ System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Normandy VBR™ System is also 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Normandy VBR™ System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, and anterior plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Materials: The Normandy VBR™ System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

Contraindications:
-The Normandy VBR™ System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice
-Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
-This device is not intended for use except as indicated

Potential Adverse Events:
Potential adverse events include, but are not limited to:
-Pseudoarthrosis
-Early or late loosening of the components
-Bending, and/or breakage of the components
-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, straining, tumor formation, and/or auto-immune disease
-Post-operative change in spinal curvature, loss of correction, height, and/or reduction
-Infection
-Vertebral body fracture at, above, or below the level of surgery
-Loss of neurological function, including paralysis (complete or incomplete)
-Non-union, delayed union
-Pain, discomfort, or abnormal sensations due to the presence of the device
-Hemorrhage
-Cessation of any potential growth of the operated portion of the spine

-Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:
-A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful.
-Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
-Non-sterile, the Normandy VBR™ System implants are sold non-sterile, and therefore, must be sterilized before each use
-Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
-Do not reuse implants; discard used, damaged, or otherwise suspect implants
-Single use only
-The Normandy VBR™ System components should not be used with components of any other system or manufacturer.
-The Normandy VBR™ System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Normandy VBR™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
-Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Other preoperative, intraoperative, and postoperative warnings are as followed:

Implant Selection:
The selection of the implant for each patient is crucial to the success of the procedure. Metallic 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 metal fatigue and consequent breakage, bending 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.

Preoperative:
-Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
-Carefully screen the patient, choosing only those that fit the indications described above
-Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
-An adequate inventory should be available at surgery than those expected to be used
-All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:
-Instructions should be carefully followed
-Extreme caution should be used around the spinal cord and nerve roots
-The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct
-To assure proper fusion below and around the location of the fusion, autogenous bone graft should be used.
-Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

Postoperative:
-Detailed instructions should be given to the patient regarding care and limitations if any

-To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
-The patient should be advised or their limitations and taught to compensate for this permanent physical restriction in body motion
-If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.
-Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):
For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays if the inspection criteria provided below are acceptable for the tray.

<table>
<tr><td colspan="2">Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.</td></tr>
<tr><td colspan="2">Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.</td></tr>
<tr><td colspan="2">1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.</td></tr>
<tr><td colspan="2">2-Containment and transportation: Avoid damage and minimize time before cleaning</td></tr>
<tr><td colspan="2">3-Preparation for cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills, taps and awl that are left in the drill guides. (Note that these items are normally stored in their dedicated tray already disassembled).</td></tr>
<tr><td colspan="2">4 Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><td>Manual</td><td>Automated</td></tr>
<tr><td>4.1 Pre-Cleaning-Manual:
Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer.
Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
Change the soak solution if the solution becomes visibly soiled.</td><td>4.1 Pre-Cleaning-Automated:

Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Wash 45ºC 4 minutes dose pump 4 (detergent) 5mL
Wash 60ºC 3 minutes
Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water 1 minute.
Rinse 60ºC 1 minute</td></tr>
</table>

<table>
<tr><td>While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen.
Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear</td><td></td></tr>
<tr><td>4.2 Cleaning-Manual:
Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under running critical water, such as reverse osmosis, distilled, and/or deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear.
Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.</td><td>4.2 Washer Disinfector:
Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Thermal Disinfection A_0 93ºC
A_0 value: $A_0$3000
Dry 123ºC air 14 minutes</td></tr>
<tr><td colspan="2">Inspection:
Visually inspect each disassembled device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean.
Check disassembled instruments with long slender features for distortion.
Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration</td></tr>
<tr><td colspan="2">Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</td></tr>
<tr><td colspan="2">Sterilization: See sterilization procedure</td></tr>
<tr><td colspan="2">Storage: Control environment</td></tr>
<tr><td colspan="2">Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded.</td></tr>
<tr><td colspan="2">Manufacturer contact: Contact local representative or call customer service at 601-919-1119</td></tr>
</table>

Sterilization: The Normandy VBR™ System should be sterilized by the hospital using the recommended cycle: Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products, LLC, 3670 Flowood Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

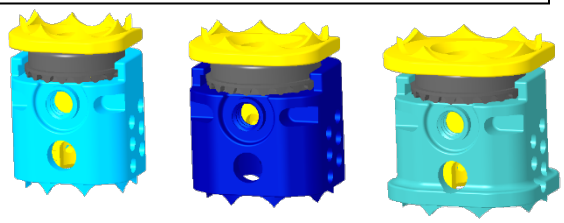
Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products, LLC, 3670 Flowood Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Normandy VBR™ System

12x14, 14x16, 16x18mm Cage

Cervical Spine (C2-C7)



Step 1 – Corpectomy

Access the targeted anatomy from an anterior approach and perform a complete or partial corpectomy as required by the pathology.

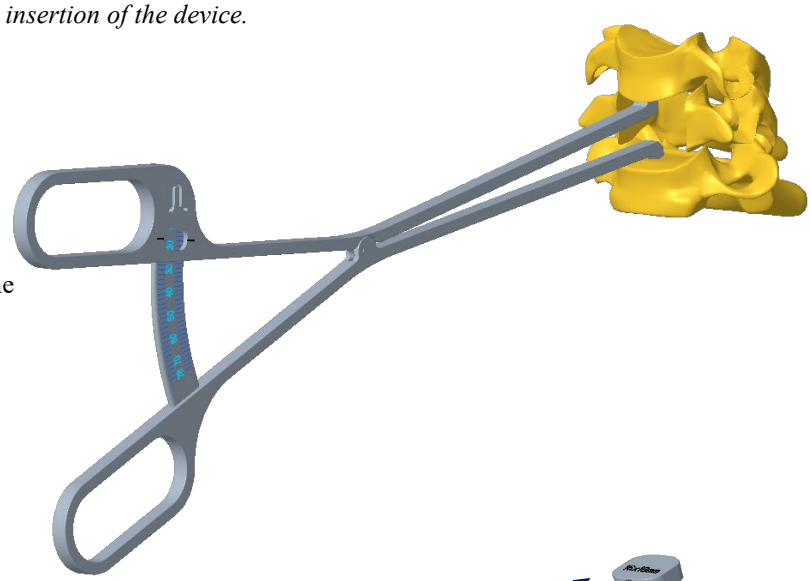
Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedure is recommended.

Remove the superficial layers of the entire cartilaginous endplates and expose bleeding bone while preserving the integrity of the endplates.

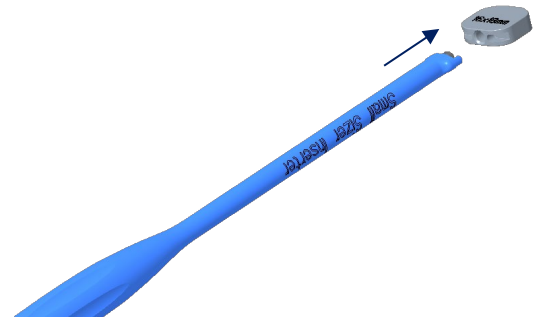
Incorrect preparation of the endplates increases the risk factor of subsidence, careful attention should be given to endplate preparation prior to insertion of the device.

Step 2 – Implant Height Measurement

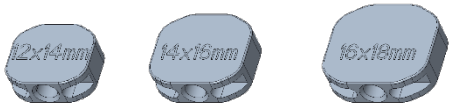
Use the caliper to determine the implant height taking the height correction into account.

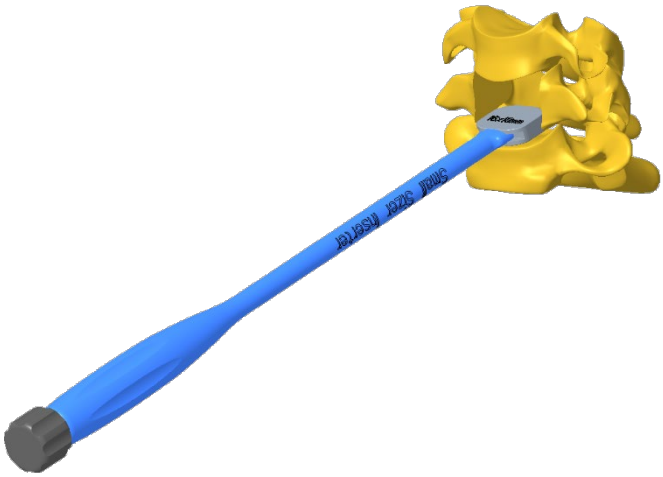


Step 3 – Implant Footprint Measurement



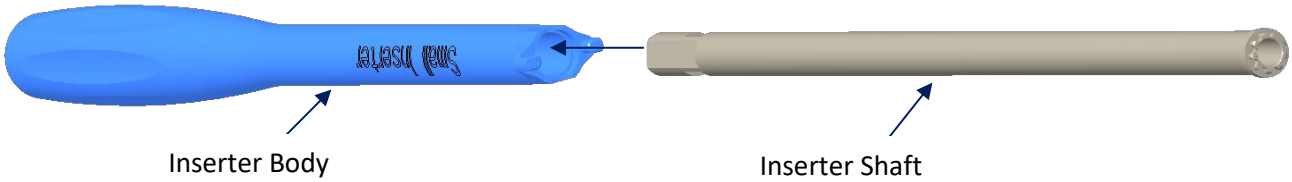
Use the trials to determine the footprint size of the cage. Connect the trail to the trial inserter by threading the center connector shaft into the sizer plate.



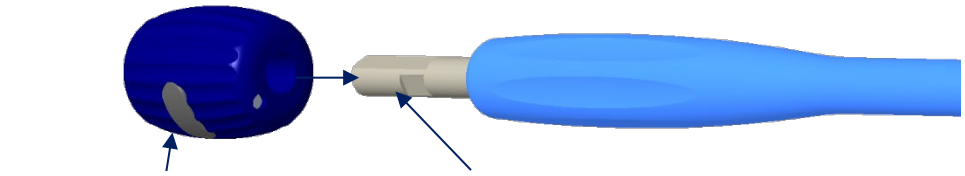


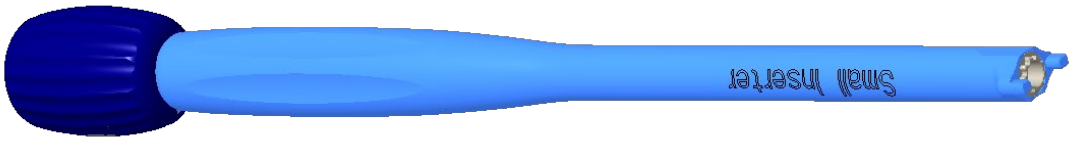
Step 4 – Inserter Assembly

Fully insert the inserter shaft into the distal end of the inserter body.



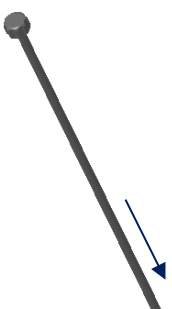
Insert the expander knob onto the proximal end of the inserter shaft by pressing the expander knob button while aligning the button 90 degrees to the flats on the shaft. Hold the distal end of the shaft to prevent it from sliding out of the inserter body while installing the knob onto the shaft.



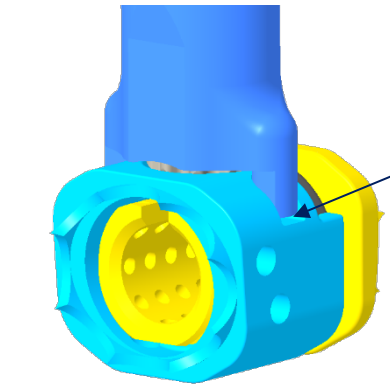


Step 5 – Implant Attachment

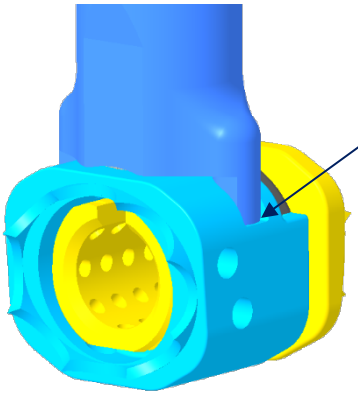
Align the prongs on the distal end of the inserter to the slots on the implant. Turn the expander know to align the teeth of the inserter instrument to the teeth of the implant.



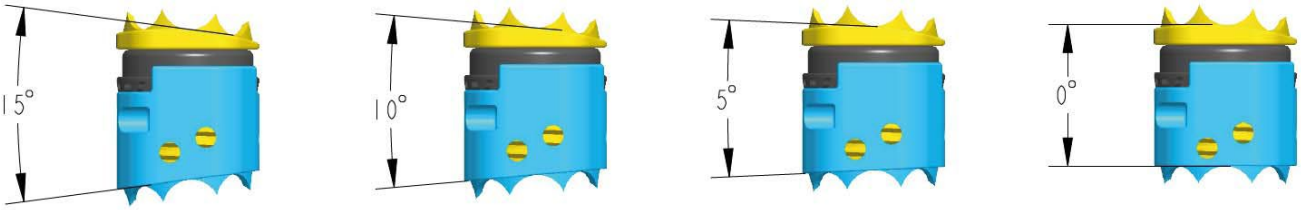
When the teeth are aligned the tips of the prongs will be fully engaged into the slots of the implant as shown in the image below. After verifying the teeth are aligned, insert the inserter attachment shaft through the center cannula and thread the shaft into the implant until the head of the shaft sits against the expander knob.



Gap indicates the gear teeth are not aligned

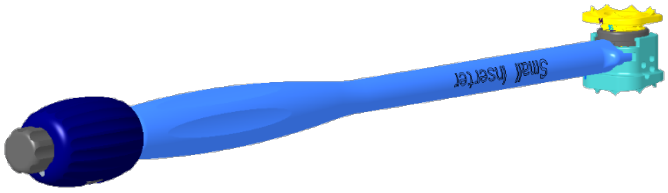


No gap indicates the gear teeth are aligned and the inserter is fully seated against the implant



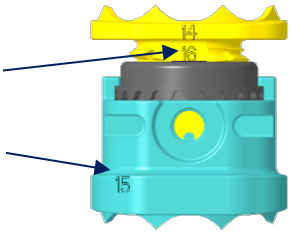
ANGLE OPTIONS

Step 6 – Cage Height Adjustment



Rotate the large expander knob of the inserter instrument to expand the implant to 2mm less than the height measured in step 2.

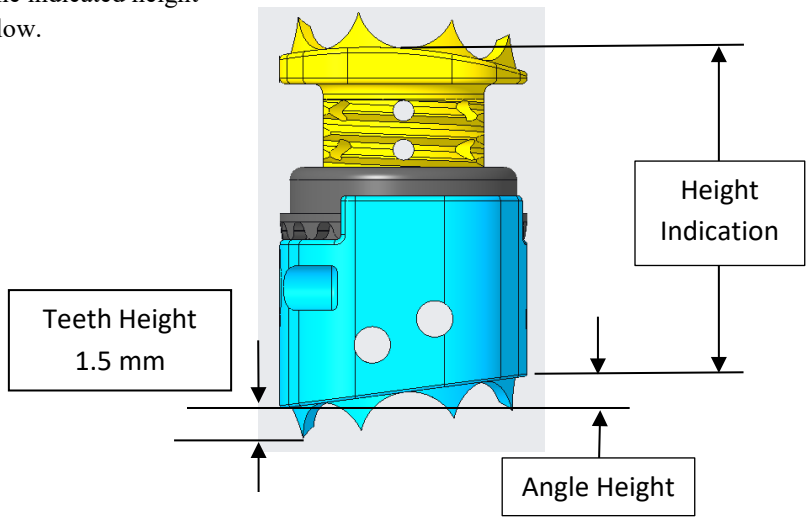
Height is shown on the post of the expandable implant.



Implant Overall Height Determination

Overall height is determined by adding the indicated height to the angle height shown in the table below.

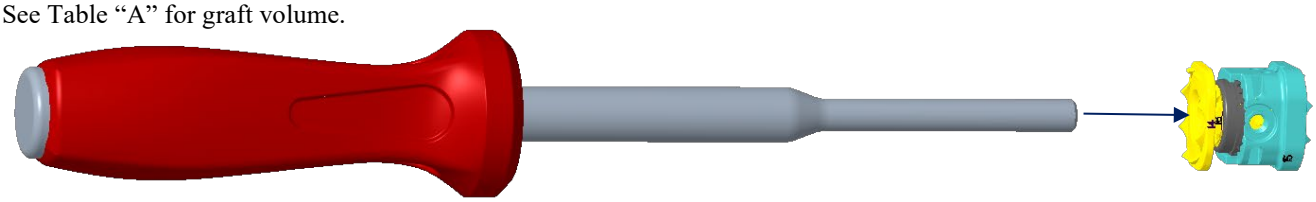
Size	Angle	Angle Height (mm)
12x14mm	0°	0.0
	5°	0.5
	10°	1.0
	15°	1.5
14x16mm	0°	0.0
	5°	0.6
	10°	1.2
	15°	1.8
16x18mm	0°	0.0
	5°	0.9
	10°	1.4
	15°	2.1



Step 7 – Bone Graft Packing

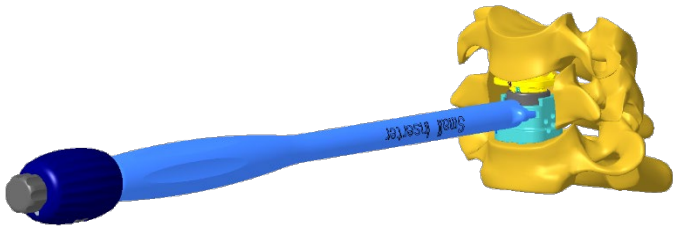
Use the graft tamp to fill the implant with autograft or allograft material if necessary.

See Table “A” for graft volume.



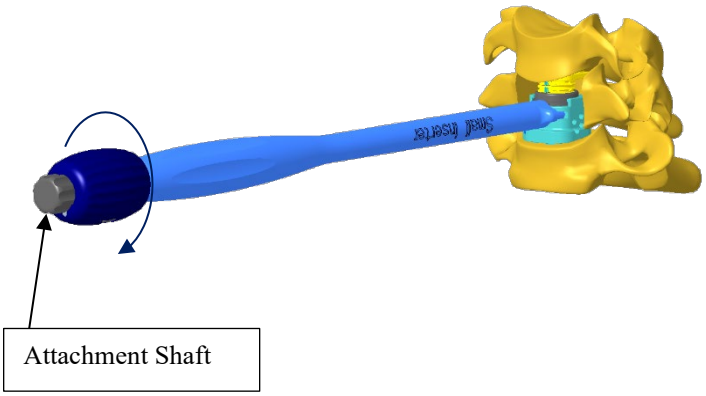
Step 8 – Implant Insertion and Expansion

Insert the implant into the prepared space and center to the endplates of the adjacent vertebral bodies.



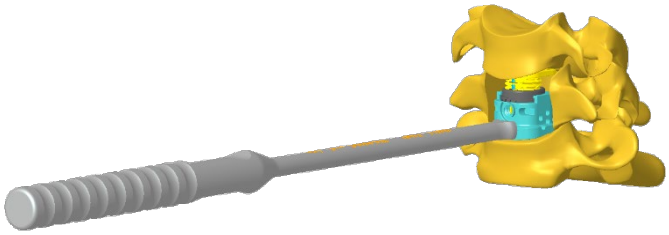
Rotate the large expander knob of the inserter instrument to expand the implant to the desired amount of distraction. Height is shown on the post of the expandable implant.

Remove the inserter instrument by unthreading the attachment shaft from the implant by rotating the shaft counterclockwise.

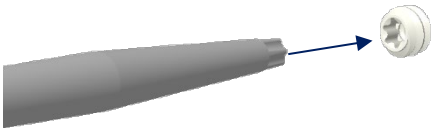


Step 9 – Implant Positioning

Implant position can be adjusted by use of the tamp. To prevent damage to the endplates, reduce the height of the implant until the teeth disengage the endplates, reposition the implant and then re-expand the cage.

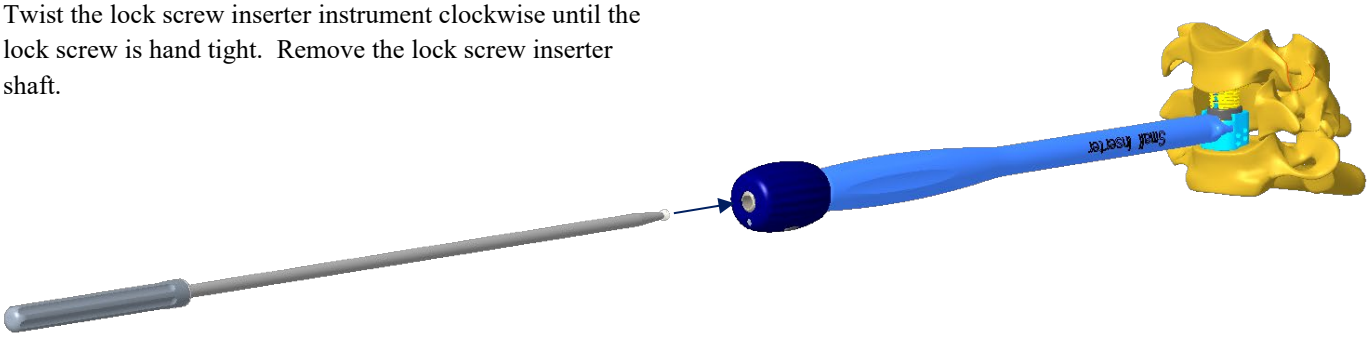


Step 10 – Lock Screw Insertion

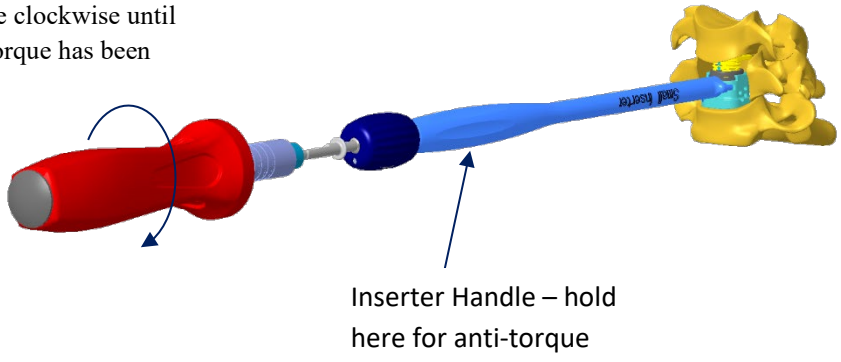


Press the self-retaining distal tip of the lock screw inserter instrument into the lock screw.

Position the implant inserter instrument, without the attachment shaft, into the implant attachment slots. Using the implant inserter instrument as an alignment guide, insert the lock screw through the cannula of the implant inserter until the lock screw rests against the implant. Twist the lock screw inserter instrument clockwise until the lock screw is hand tight. Remove the lock screw inserter shaft.



Attach the lock screw torque shaft to the torque limiting handle Z-1018 (7.5 in-lbs.). Insert the torque shaft through the implant inserter cannula and rotate until the torx tip of the torque shaft aligns to the torx drive of the lock screw. The torque shaft will advance into the lock screw when properly aligned. Using the implant inserter instrument as an anti-torque, hold the inserter handle (not the expander knob) and rotate the torque limiting handle clockwise until the handle clicks indicating the required torque has been placed on the lock screw.



Step 11 – Supplemental Fixation

Implant FDA- cleared supplemental spinal fixation (i.e., posterior screw and rod systems, and anterior plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Removal Process

The removal of the Normandy VBR™ System is accomplished by reversing the order of the implant procedure.

Normandy VBR™ System

18mm Body, Modular End Plate Cage

Thoracolumbar Spine (T1-L5)

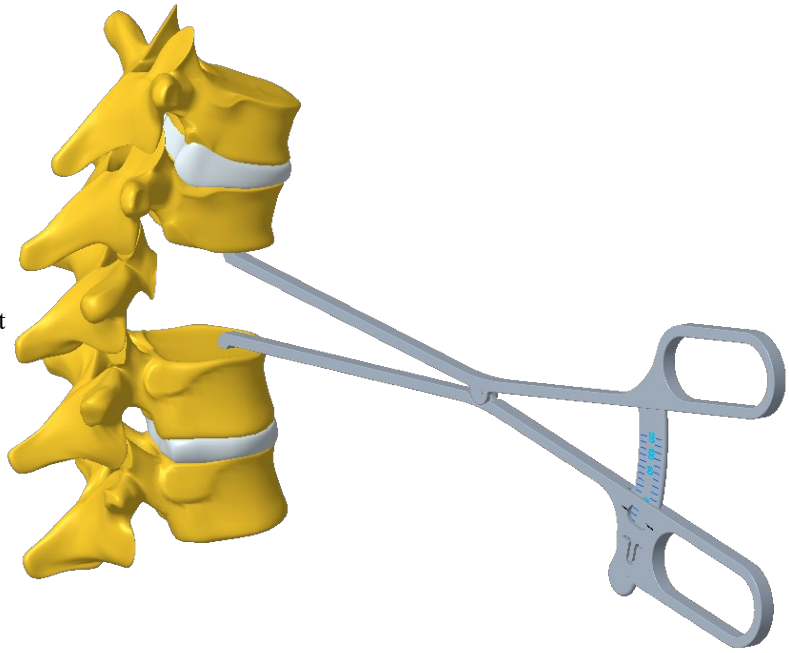
Step 1 – Corpectomy

Multiple approach options may be used including anterior, anterior lateral, lateral, posterior lateral, and posterior. Perform a complete or partial corpectomy as required by the pathology.

Remove the superficial layers of the entire cartilaginous endplates and expose bleeding bone while preserving the integrity of the endplates.

Incorrect preparation of the endplates increases the risk factor of subsidence, careful attention should be given to endplate preparation prior to insertion of the device.

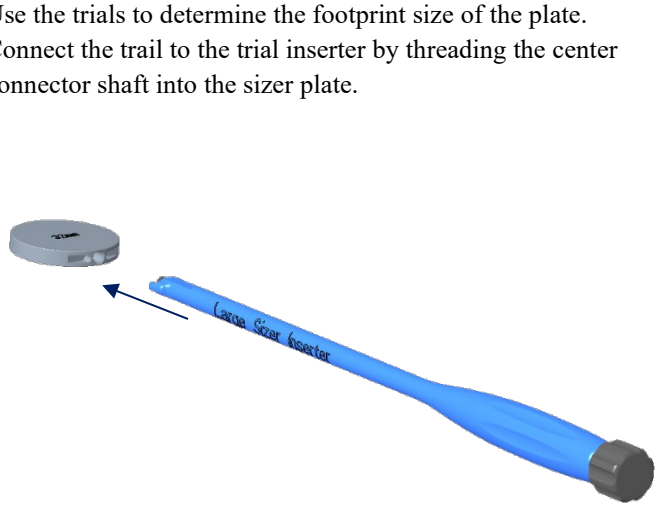
Step 2 – Implant Height Measurement

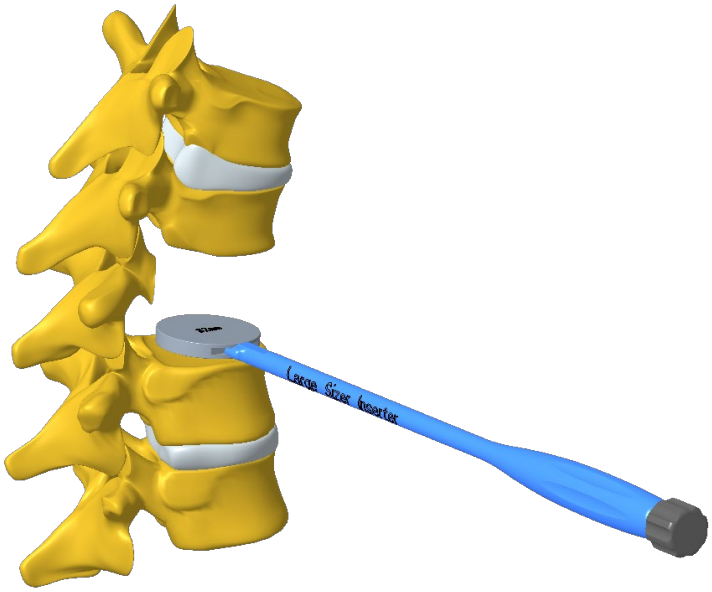


Use the caliper to determine the implant height taking the restored height correction into account. Take measurement between the closest points between the two vertebral bodies.

Step 3 – Implant Footprint Measurement

Use the trials to determine the footprint size of the plate. Connect the trail to the trial inserter by threading the center connector shaft into the sizer plate.





Step 4 – Implant Body Selection

Select the implant body with a height range that includes the measurement from Step 2. Five height range options are available.

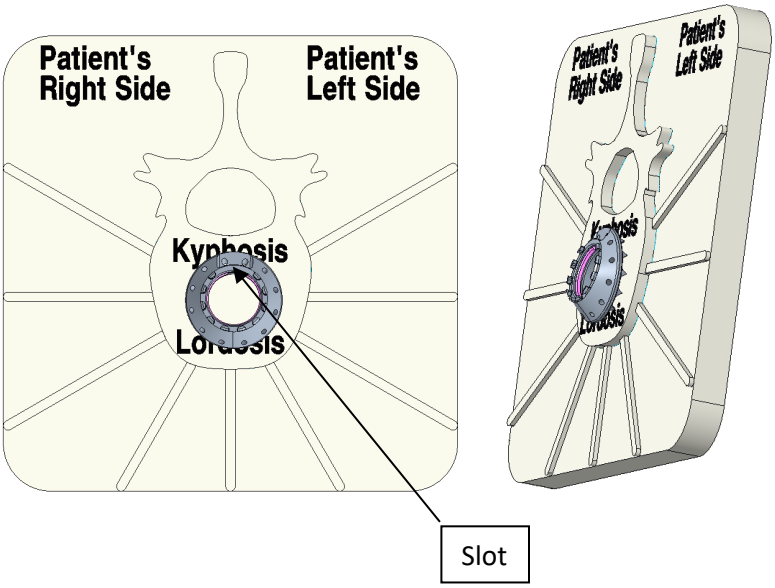
20-26mm
24-34mm
30-46mm
40-66mm
60-106mm

Step 5 – Inserter Attachment

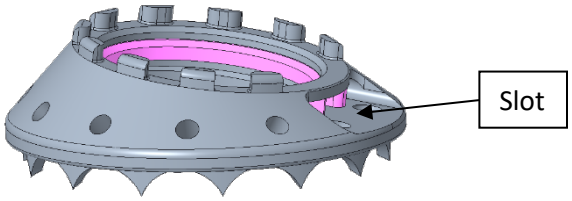
Align the prongs on the distal end of the inserter to the slots on the implant. Turn the expander know to align the teeth of the inserter instrument to the teeth of the implant. When the teeth are aligned the tips of the prongs will be fully engaged into the slots of the implant. After verifying the teeth are aligned, insert the inserter attachment shaft through the center cannula and thread the shaft into the implant until the head of the shaft sits against the expander knob.

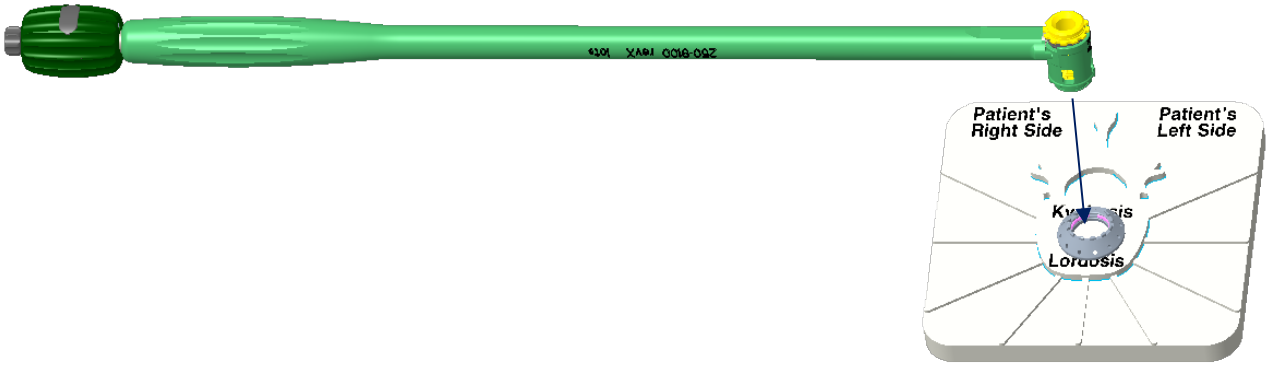
Step 6 – Endplate Attachment

Orientation of the endplates can induce lordosis or kyphosis. Position the caudal endplate with the spikes facing down on the template with the thickest side of the plate facing either lordosis or kyphosis. The slot in the endplate is opposite the thickness side of the plate. The slot in the endplate will face either anterior or posterior. The image to the right shows the thickest side of the plate facing lordosis therefore the final cage assembly will induce lordosis.

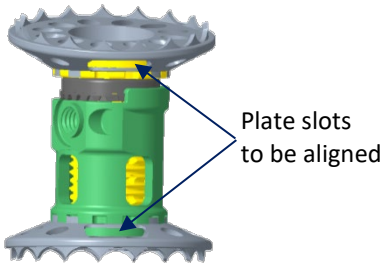


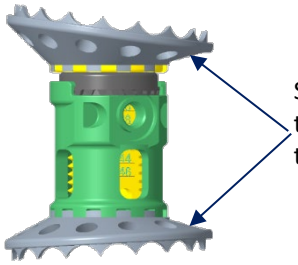
Endplates can be orientated in 30-degree increments according to the approach choice. Position the cage body above the endplate relative to the surgical approach. The image below shows a lateral approach from the patient's right side.

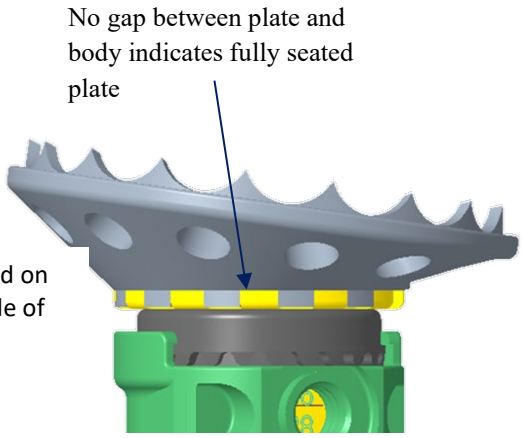




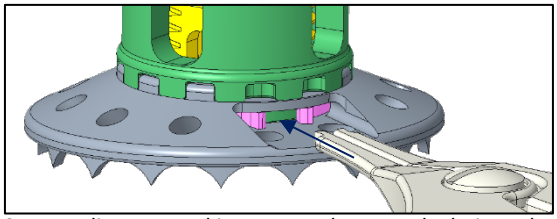
For proper orientation of the cephalad plate, align the plate slot of the attached caudal plate to that of the cephalad plate and press the body assembly into the center hole of the cephalad plate until fully seated. Use the glove guard to reduce the risk of the plate spikes puncturing gloves.



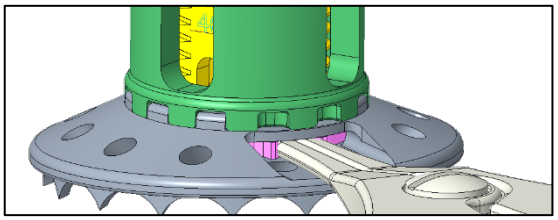




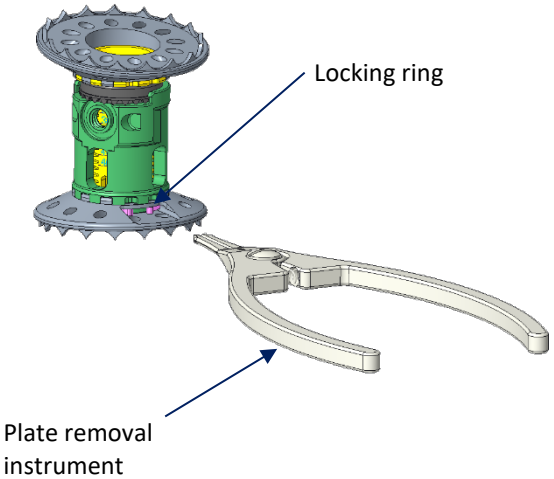
Use the plate removal instrument to remove or re-orientate the plate. Insert the tip of the removal instrument between the two ends of the plate locking ring (Step 1 & 2) and squeeze the handles together to spread the locking ring for plate removal (Step 3).

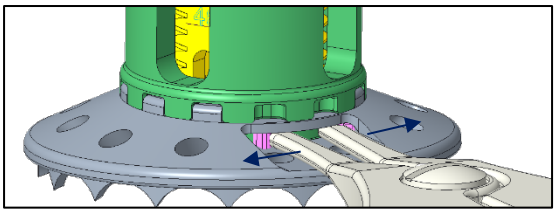


Step 1: Align removal instrument between lock ring tabs



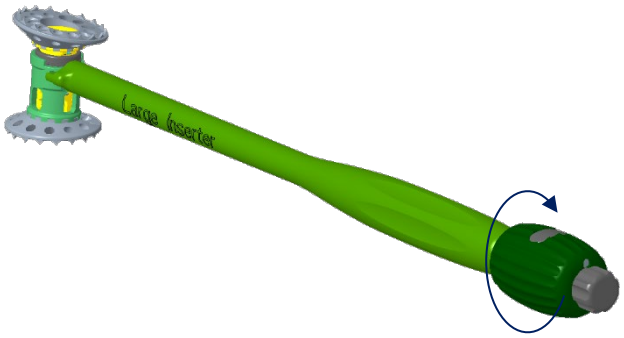
Step 2: Insert removal instrument between lock ring tabs





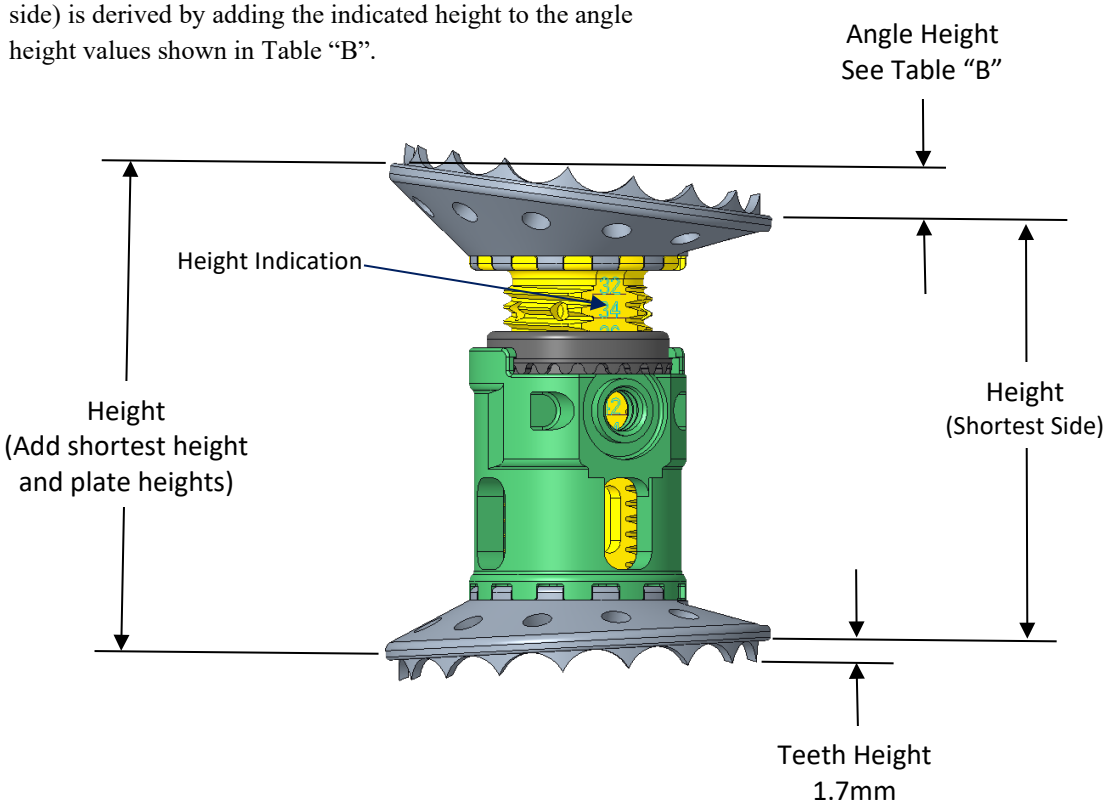
Step 3: Squeeze removal instrument handles to spread lock ring. Plate can now be removed from body.

Step 7 – Expanding VBR



Rotate the large expander knob of the inserter instrument to expand the implant to 2mm less than the height measured in step 2.

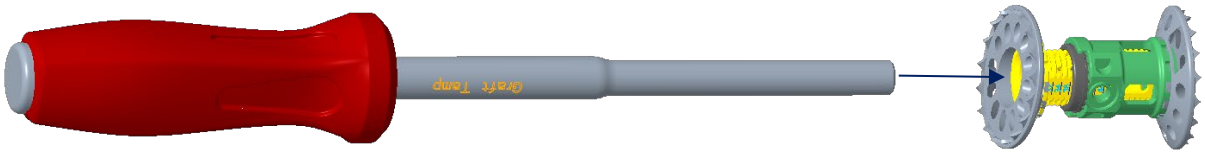
Height is shown on the post of the expandable implant body. The height indicated on the implant post is a measurement of the shortest side on the construct and does not include the teeth height as shown in the image below. The height of the construct on the opposite side (tallest side) is derived by adding the indicated height to the angle height values shown in Table “B”.



Step 8 – Bone Graft Packing

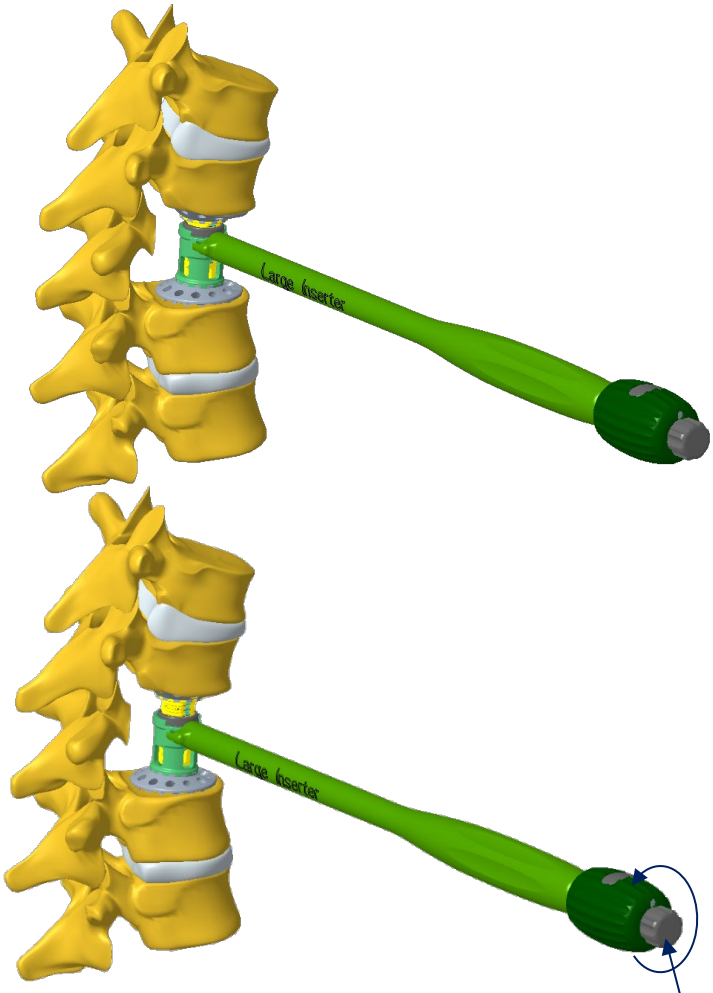
Use the graft tamp to fill the implant with autograft or allograft material if necessary.

See Table “A” for graft volume.



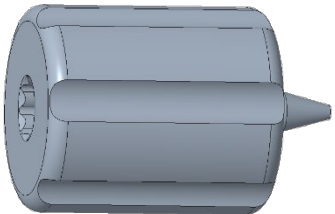
Step 9 – Implant Insertion and Expansion

Insert the implant into the prepared space and center to the endplates of the adjacent vertebral bodies.

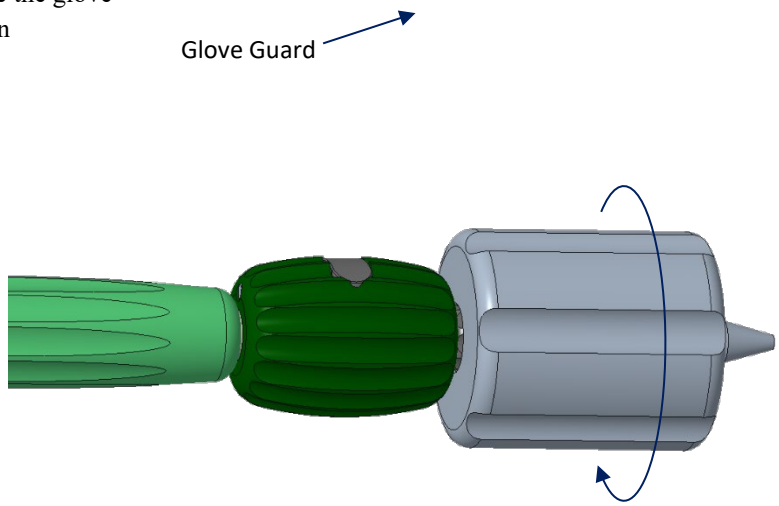


Rotate the large expander knob of the inserter instrument to expand the implant to the desired amount of distraction. Height is shown on the post of the expandable implant.

Remove the inserter instrument by unthreading the attachment shaft from the implant by rotating the shaft counterclockwise.

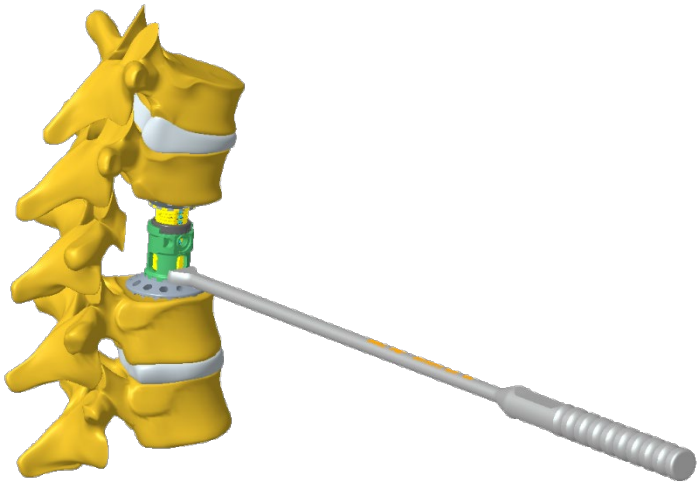


To aid in removing the inserter attachment shaft the glove guard can be used for additional leverage. Slide the glove guard over the inserter attachment shaft and turn counterclockwise.

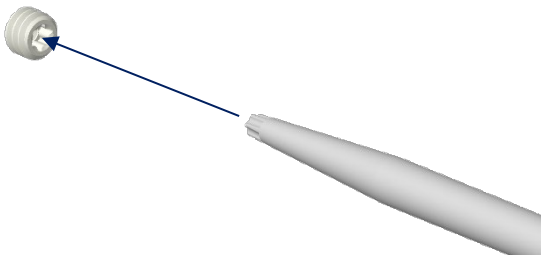


Step 10 – Implant Positioning

Implant position can be adjusted by use of the tamp.

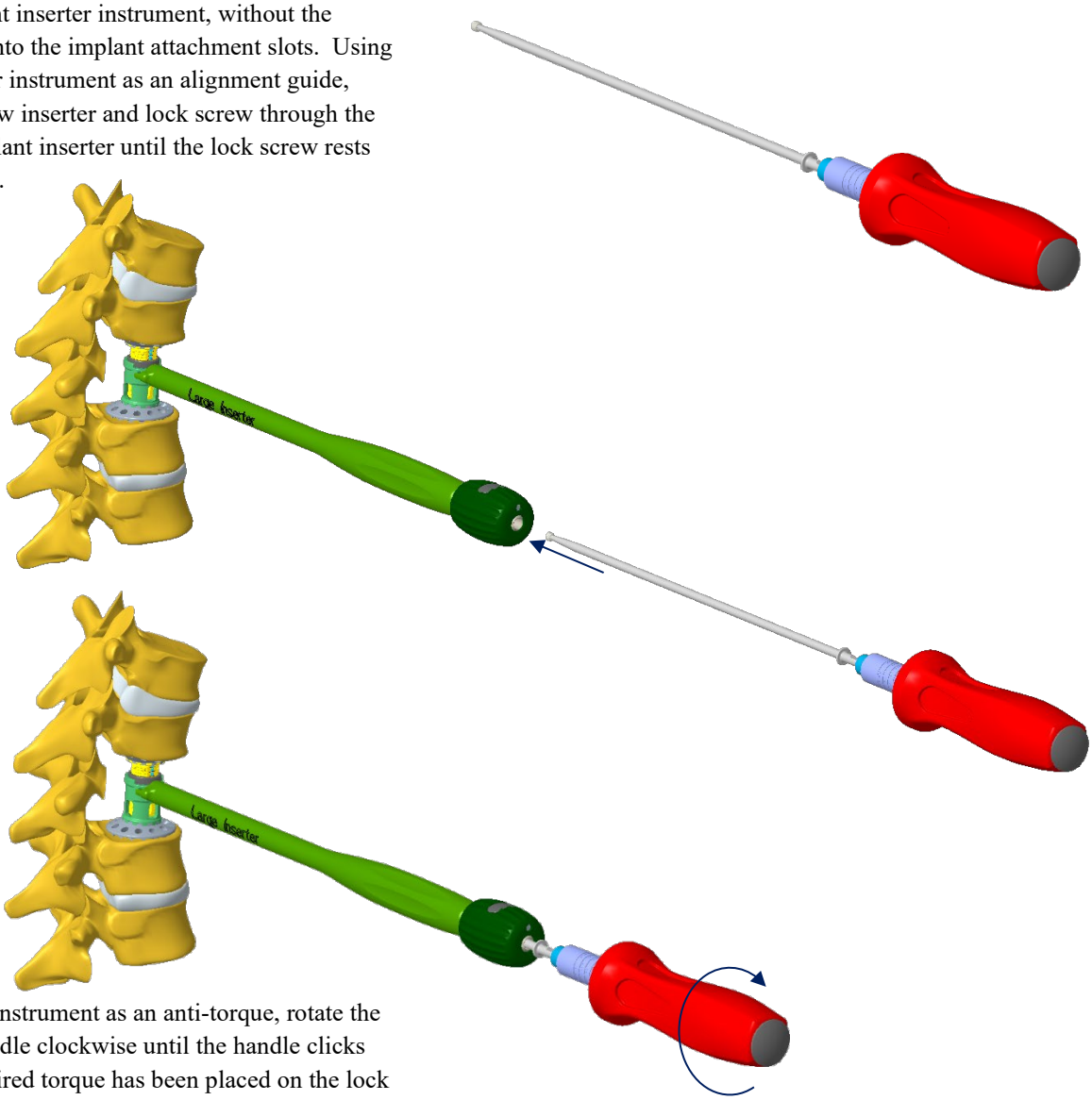


Step 11 – Lock Screw Insertion



Attach the torque limiting handle (Z-1017, 10 in-lbs.) to the lock screw insertion shaft and press the self-retaining distal tip of the shaft into the lock screw.

Position the implant inserter instrument, without the attachment shaft, into the implant attachment slots. Using the implant inserter instrument as an alignment guide, insert the lock screw inserter and lock screw through the cannula of the implant inserter until the lock screw rests against the implant.



Using the inserter instrument as an anti-torque, rotate the torque limiting handle clockwise until the handle clicks indicating the required torque has been placed on the lock screw.

Step 12 – Supplemental Fixation

Implant FDA- cleared supplemental spinal fixation (i.e., posterior screw and rod systems, and anterior or lateral

plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Removal Process

The removal of the Normandy VBR™ System is accomplished by reversing the order of the implant procedure.

Table “A” – Graft Volume

NORMANDY VBR PN	Expanded Height (mm)	Graft Volume (cc)
250-1214-12	12	0.32
	14	0.46
	16	0.60
250-1214-14	14	0.37
	16	0.51
	18	0.65
	20	0.79
250-1214-17	17	0.45
	19	0.59
	21	0.73
	23	0.87
	25	1.01
250-1214-22	22	0.59
	24	0.73
	26	0.87
	28	1.01
	30	1.15
	32	1.30
250-1214-30	30	0.80
	32	0.94
	34	1.08
	36	1.22
	38	1.36
	40	1.51
	42	1.65
	44	1.79
	46	1.93
	48	2.07
250-1214-44	44	1.18
	46	1.32
	48	1.46
	50	1.60
	52	1.74
	54	1.89
	56	2.03
	58	2.17
	60	2.31
	62	2.45
	64	2.59
	66	2.73
	68	2.87
	70	3.02
	72	3.16
	74	3.30
	76	3.44

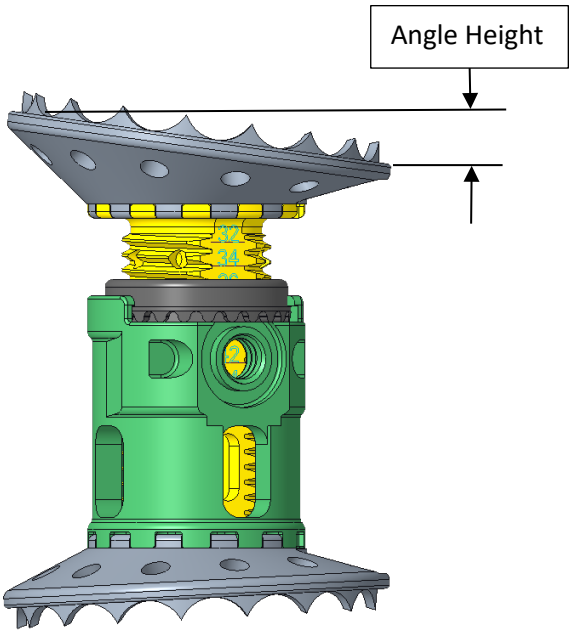
NORMANDY VBR PN	Expanded Height (mm)	Graft Volume (cc)
250-18-20	20	0.93
	22	1.18
	24	1.43
	26	1.67
250-18-24	24	1.11
	26	1.36
	28	1.61
	30	1.85
	32	2.10
	34	2.34
250-18-30	30	1.39
	32	1.64
	34	1.88
	36	2.13
	38	2.38
	40	2.62
	42	2.87
	44	3.11
	46	3.36
250-18-40	40	1.87
	42	2.11
	44	2.36
	46	2.61
	48	2.85
	50	3.10
	52	3.34
	54	3.59
	56	3.83
	58	4.08
	60	4.33
	62	4.57
	64	4.82
	66	5.06
250-1860	60	2.75
	62	3.00
	64	3.24
	66	3.49
	68	3.74
	70	3.98
	72	4.23
	74	4.47
	76	4.72
	78	4.97
	80	5.21
	82	5.46
	84	5.70
	86	5.95
	88	6.19
	90	6.44
	92	6.69
	94	6.93
	96	7.18
	98	7.42
	100	7.67
	102	7.91
	104	8.16
	106	8.41

Table “B” – Plate Heights

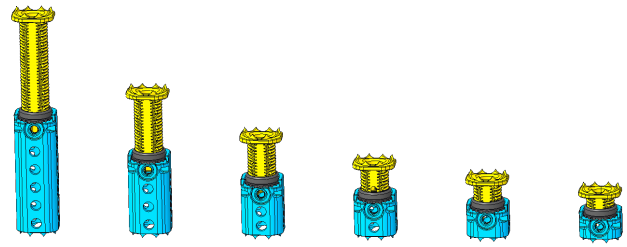
Shape	PN	Size	Angle	Additional Height (mm)
Round	250-P-18-0	18mm	0°	0.0
	250-P-18-3		3°	0.9
	250-P-18-8		8°	2.4
	250-P-18-15		15°	4.6
	250-P-20-0	20mm	0°	0.0
	250-P-20-3		3°	1.0
	250-P-20-8		8°	2.7
	250-P-20-15		15°	5.0
	250-P-22-0	22mm	0°	0.0
	250-P-22-3		3°	1.1
	250-P-22-8		8°	3.0
	250-P-22-15		15°	5.6
	250-P-24-0	24mm	0°	0.0
	250-P-24-3		3°	1.2
	250-P-24-8		8°	3.3
	250-P-24-15		15°	6.1
	250-P-26-0	26mm	0°	0.0
	250-P-26-3		3°	1.3
	250-P-26-8		8°	3.6
	250-P-26-15		15°	6.6
	250-P-28-0	28mm	0°	0.0
	250-P-28-3		3°	1.4
	250-P-28-8		8°	3.8
	250-P-28-15		15°	7.1
	250-P-30-0	30mm	0°	0.0
	250-P-30-3		3°	1.5
	250-P-30-8		8°	4.1
	250-P-30-15		15°	7.5
	250-P-32-0	32mm	0°	0.0
	250-P-32-3		3°	1.6
	250-P-32-8		8°	4.4
	250-P-32-15		15°	8.2

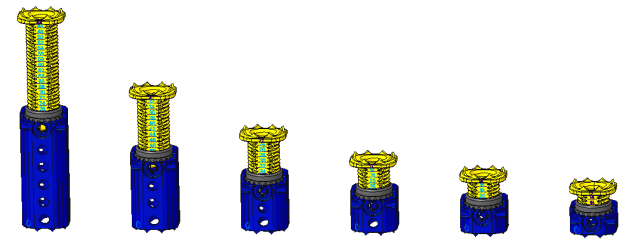
Shape	PN	Size	Angle	Additional Height (mm)
Oval	250-PO-1820-0	18x20mm	0°	0.0
	250-PO-1820-3		3°	0.9
	250-PO-1820-8		8°	2.4
	250-PO-1820-15		15°	4.5
	250-PO-2123-0	21x23mm	0°	0.0
	250-PO-2123-3		3°	1.1
	250-PO-2123-8		8°	2.8
	250-PO-2123-15		15°	5.2
	250-PO-2528-0	25x28mm	0°	0.0
	250-PO-2528-3		3°	1.3
	250-PO-2528-8		8°	3.4
	250-PO-2528-15		15°	6.3
	250-PO-2532-0	25x32mm	0°	0.0
	250-PO-2532-3		3°	1.3
	250-PO-2532-8		8°	3.4
	250-PO-2532-15		15°	6.3

Shape	PN	Size	Angle	Additional Height (mm)
Rectangular	250-PR-1830-0	18x30mm	0°	0.0
	250-PR-1830-3		3°	0.9
	250-PR-1830-8		8°	2.4
	250-PR-1830-15		15°	4.5
	250-PR-1840-0	18x40mm	0°	0.0
	250-PR-1840-3		3°	0.9
	250-PR-1840-8		8°	2.4
	250-PR-1840-15		15°	4.5
	250-PR-1850-0	18x50mm	0°	0.0
	250-PR-1850-3		3°	0.9
	250-PR-1850-8		8°	2.4
	250-PR-1850-15		15°	4.5
	250-PR-2240-0	22x40mm	0°	0.0
	250-PR-2240-3		3°	1.1
	250-PR-2240-8		8°	3.0
	250-PR-2240-15		15°	5.6
	250-PR-2250-0	22x50mm	0°	0.0
	250-PR-2250-3		3°	1.1
	250-PR-2250-8		8°	3.0
	250-PR-2250-15		15°	5.6
	250-PR-2260-0	22x60mm	0°	0.0
	250-PR-2260-3		3°	1.1
	250-PR-2260-8		8°	3.0
	250-PR-2260-15		15°	5.6



Device View	Part #	Description
Implants		

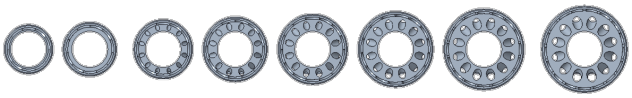
	250-1214-XX-XX	**12mm x 14mm VBR Cage**
		• Cervical Spine (C2-C7) Implant
		• 12mm x 14mm footprint
		• Six height range options
		  ○ 12-16mm
		  ○ 14-20mm
		  ○ 17-25mm
		  ○ 22-34mm
		  ○ 30-49mm
		  ○ 44-76mm
		• Four lordotic angle options
		  ○ 0°, 5°, 10°, 15°
		• Material: Titanium per ASTM F-136
		• Titanium color anodized
		• See attached drawing for additional detail

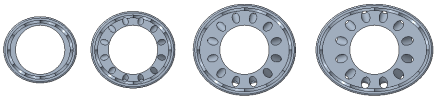
	250-1416-XX-XX	**14mm x 16mm VBR Cage**
		• Cervical Spine (C2-C7) Implant
		• 14mm x 16mm footprint
		• Six height range options
		  ○ 12-16mm
		  ○ 14-20mm
		  ○ 17-25mm
		  ○ 22-34mm
		  ○ 30-49mm
		  ○ 44-76mm
		• Four lordotic angle options
		  ○ 0°, 5°, 10°, 15°
		• Material: Titanium per ASTM F-136
		• Titanium color anodized
		• See attached drawing for additional detail

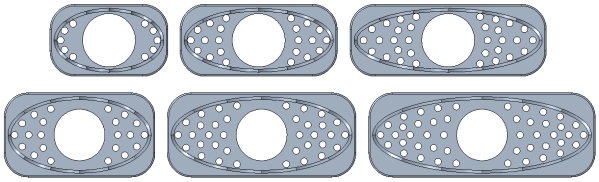
	250-1618-XX-XX	**16mm x 18mm VBR Cage**
		• Cervical Spine (C2-C7) Implant
		• 16mm x 18mm footprint
		• Six height range options
		  ○ 12-16mm
		  ○ 14-20mm
		  ○ 17-25mm
		  ○ 22-34mm
		  ○ 30-49mm
		  ○ 44-76mm
		• Four lordotic angle options
		  ○ 0°, 5°, 10°, 15°

Device View	Part #	Description
	250-1001-S	**Lock Screw** • Cervical Spine (C2-C7) Implant • T7 Hexalobe drive

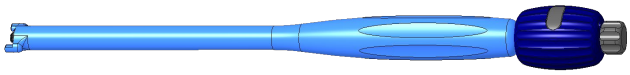
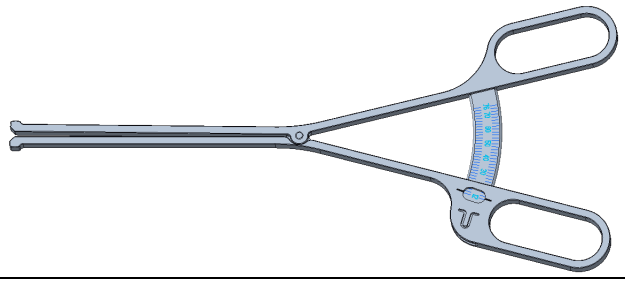
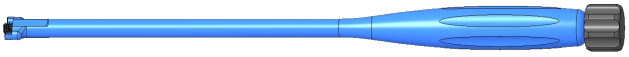
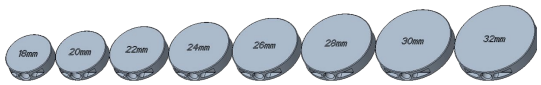
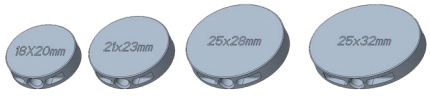
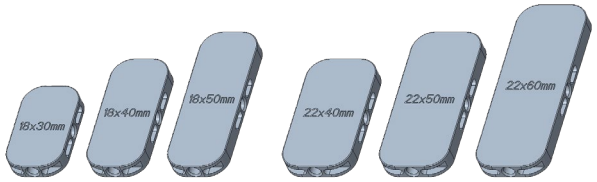
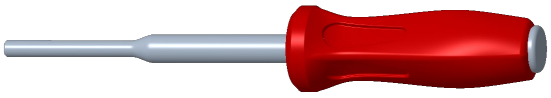
	250-18-XX	**18mm Body**
		• Thoracolumbar Spine (T1-L5) Implant
		• Five height range options
		  ○ 20-26mm
		  ○ 24-34mm
		  ○ 30-46mm
		  ○ 40-66mm
		  ○ 60-106mm
		• Attachable end plates allow for multiple footprint options, lordotic and kyphotic angles
		• Indexable plate orientation allows multiple surgical access approaches

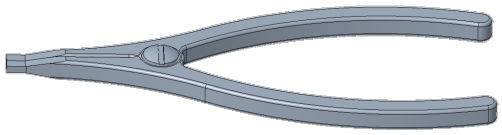
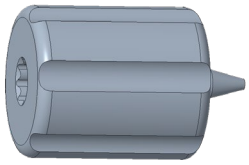
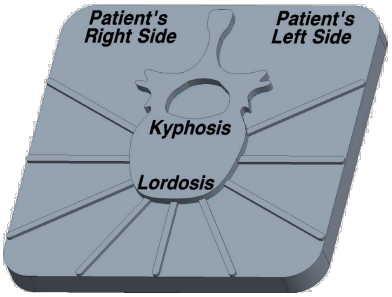
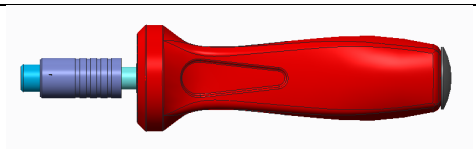
	250-P-XX-XX	**Round Plate**
		• Thoracolumbar Spine (T1-L5) Implant
		• Available diameters
		  ○ 18, 20, 22, 24, 26, 28, 30, 32mm
		• Angle options
		  ○ 0°, 3°, 8°, 15°

	250-PO-XXXX-XX	**Oval Plate:**
		• Thoracolumbar Spine (T1-L5) Implant
		• Available sizes
		  ○ 18x20, 21x23, 25x28, 25x32mm
		• Angle options
		  ○ 0°, 3°, 8°, 15°

	250-PR-XXXX-XX	**Rectangular Plate:**
		• Thoracolumbar Spine (T1-L5) Implant
		• Available sizes
		  ○ 18x30, 18x40, 18x50, 22x40, 22x50, 22x60mm
		• Angle options
		  ○ 0°, 3°, 8°, 15°

	250-1001-L	**Lock Screw - Large** • Thoracolumbar Spine (T1-L5) Implant • T8 Hexalobe drive

Device View	Part #	Description
Instruments		
	250-9000-S 250-9100	**Inserter:** • Holds and expands cage • Disassembles for cleaning
	250-9001-S 250-9001-L	**Tamp:** • Used to adjust position of cage
	250-9002-S 250-9102	**Lock Screw Torque Shaft:** • Used with torque limiting handle
	250-9002-SI	**Lock Screw Inserter:** • Used to insert the lock screw
	250-9003-S 250-9103	**Caliper:** • Measures the required cage height
	250-9004-1214 250-9004-1416 250-9004-1618	**Sizer - Small:** • Measures footprint required
	250-9005 250-9109	**Sizer Inserter** • Holds sizers
	250-9106-18 250-9106-20 250-9106-22 250-9106-22 250-9106-24 250-9106-26 250-9106-28 250-9106-30 250-9106-32	**Sizer, Round - Large:** • Measures footprint required
	250-9107-1820 250-9107-2123 250-9107-2528 250-9107-2532	**Sizer, Oval - Large:** • Measures footprint required
	250-9108-1830 250-9108-1840 250-9108-1850 250-9108-2240 250-9108-2250 250-9108-2260	**Sizer, Rectangular - Large:** • Measures footprint required
	250-9011 250-9112	**Graft Tamp - Small** • Used to pack graft into cage

Device View	Part #	Description
	250-9101	**Plate Release Instrument:** • Used to remove end plates
	250-9115	**Glove Guard:** • Used to protect gloves during plate assembly and to aid in removing the inserter attachment shaft.
	2509116	**Spine Plate:** • Used as a visual aid in assembling endplates to the expandable body
	Z-1017 (7.5 in-lbs.) Z-1018 (10 in-lbs.)	**Torque Limiting Handle:** • Used to apply torque to lock screw