ZIMMER BIOMET
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Cervical Solutions

Lineum® OCT
Spine System

Surgical Technique Guide

Designed to encourage optimal screw placement and procedural efficiency

TABLE OF CONTENTS

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spine surgery should attempt to use the Lineum OCT Spine System. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

Zimmer Biomet Spine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

Refer to the package insert for a complete list of prescribing information, including indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information. This technique guide was developed in conjunction with health care professionals.

LINEUM OCT SPINE SYSTEM OVERVIEW

The Lineum OCT (Occipito-Cervico-Thoracic) Spine System is a universal system designed to facilitate reconstruction of the cervical and upper thoracic spine. The Lineum OCT Spine System features the Translation™ Screw—which offers 3.0mm of medial/lateral translation in the screw head to accommodate unique patient anatomy—a broad range of construct options and procedurally efficient instrumentation to support surgeons' needs.

The Lineum OCT Spine System also provides optimal screw placement. Screw placement no longer needs to be compromised to accommodate rod insertion. Translation Screw Technology allows screws to be placed in the surgeon's preferred anatomic location.

The Lineum OCT Spine System provides reliable Helical Flange® Technology, which enhances the strength of the locking mechanism. The contact between the upward facing flange of the plug and the downward facing flange of the seat minimizes cross threading and seat splay.

Key features of the system include:

Translation Screw

- Less rod manipulation and simplifies rod introduction
- 40° of angulation in the preferred direction

Adjustable Depth Drill and Tap Guides

- A truly unique drill guide allows surgeons to easily shift drill depth gears 2mm at a time
- Provides quick adjustment and easy confirmation of desired depth

Rocket™ Rod Reducers

- Utilize spring loaded tips for secure screw engagement and tactile feedback
- Support controlled, sequential rod reduction

Cobalt Chrome Alloy and Titanium Alloy Rods

- 3.5mm rod options offer strength and flexibility
- Cobalt chrome alloy rods have high-strength material that is wear resistant and corrosion resistant; stiffness and strength similar to stainless steel

PATIENT POSITIONING

Availability of appropriate imaging equipment should be confirmed prior to beginning surgery in order to properly identify the anatomic variability of individual patients.

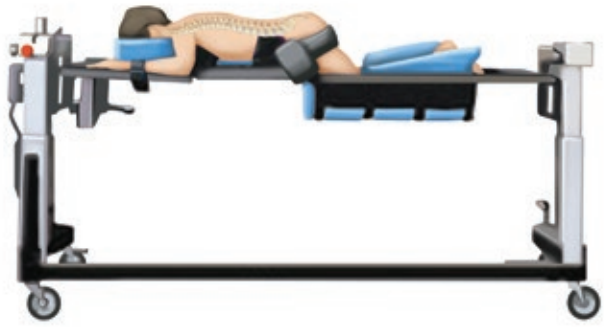


Figure 1
Patient positioning

SCREW HOLE PREPARATION

Figure 2
Awl

STEP 1

- The patient should be placed in the prone position and, when possible, in physiological alignment. Alignment should be confirmed with imaging and direct visualization prior to beginning site preparation.
- A standard midline approach may be used to expose the spinous processes and laminae of the vertebrae to be fused. If the procedure includes occipito-cervical fusion, the exposure may be extended to the external occipital protuberance (EOP).

  Note: *Care must be taken to avoid vital structures including, but not limited to, the vertebral arteries, nerve roots and the spinal cord.*

STEP 2

- Following preparation of the relevant posterior spinal elements, determine the entry point and trajectory of the screw into the cervical and upper thoracic spine. Optionally, the entry point may be marked using a burr or the included awl to penetrate the cortical bone. The screw hole is then prepared to the appropriate depth using the appropriate diameter drill bit and the drill guide oriented at the desired trajectory.
- The awl has a hard stop that limits insertion to 8.0mm.

  Note: *Creating a pilot hole with the awl or burr will help prevent movement of the drill and drill guide during drilling. Repeat for all screw placement sites.*

SCREW HOLE PREPARATION *(continued)*

Figure 3
Drill guides

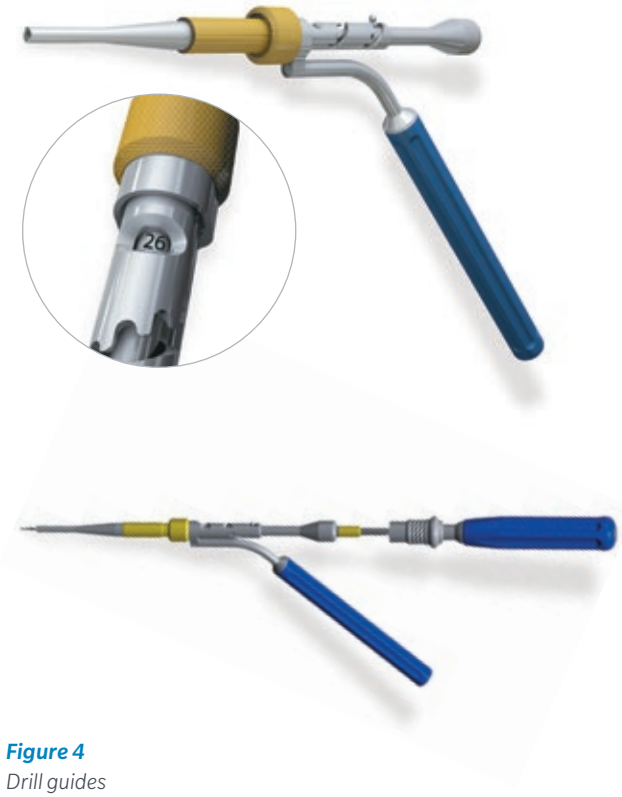


Figure 4
Drill guides

STEP 3

OPTION A: Drills

- To prepare the screw holes, choose the appropriate diameter drill and appropriate length drill guide. Confirm distal portion of guide is threaded completely into the collar.

  Note: *The 6.0mm–32mm drill guide is GOLD and the 32mm–50mm drill guide is BLACK.*

- Hold the drill guide handle with the drill guide tip oriented vertically (so the numbers are upright and readable), and adjust the drill depth by pulling back on the knurled knob and then turning it right or left to lock the drill guide and set the desired depth. The depth is set correctly when the pin on the guide is seated in the appropriate notch and the desired depth is visible in the window.

  Note: *Turn counterclockwise to decrease depth. Turn clockwise to increase depth.*

- Connect a quick-connect handle to the desired drill and insert through the drill guide. Orient the drill guide and drill at the desired trajectory and drill until reaching the positive stop. The positive stop is reached when the drill sleeve contacts the top of the knurled knob of the drill guide. This prevents the drill from penetrating any deeper.

  Note: *The 3.5mm drill has a GOLD titanium sleeve to match the GOLD 3.5mm screw and will drill a 2.0mm diameter hole. The 4.0mm drill has a GREEN titanium sleeve to match the GREEN 4.0mm screw and will drill a 2.5mm diameter hole (see page 33).*

- Once the positive stop is reached, gently remove the drill guide and drill from the site.

- A pedicle sound may be used to confirm that the drill hole remains within the confines of the bone.

- Repeat for all screw placement sites.

  Note: *The pedicle sound has depth markings every 10mm.*

Figure 5
Curved probe

Figure 6
Tap guide and taps

OPTION B: Probes

- If desired, one of the two included pedicle probes (straight and curved) may be used to prepare the hole. Advance the probe to the desired depth at the desired trajectory, using the depth marking as a guide.

  Note: *The curved probe is colored GOLD up to the 18mm mark.*

STEP 4

- If desired, the screw hole may be tapped using the tap guide and the appropriate diameter tap. Hold the tap guide handle with the tap guide tip oriented vertically (so the numbers are upright and readable), and adjust the tap depth by pulling back on the knurled knob and then turning it right or left to lock the tap guide and set the desired depth. The depth is set correctly when the pin on the guide is seated in the appropriate notch and the desired depth is visible in the window.

  Note: *Turn counterclockwise to decrease depth. Turn clockwise to increase depth.*

SCREW PLACEMENT

Figure 7
Taps

Figure 8
Screw selection

STEP 4 *(continued)*

- Connect a quick-connect handle to the desired tap and insert through the tap guide at the desired trajectory (rotate clockwise while advancing), to tap the hole until reaching the positive stop. The positive stop is reached when the tap sleeve contacts the knurled knob on the tap guide. This prevents the tap from penetrating any deeper.
- Remove the tap by rotating the shaft counterclockwise.

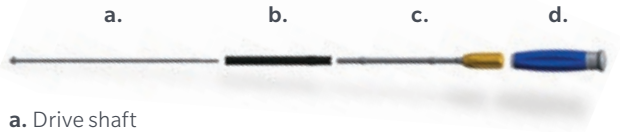
  Note: *The 3.0mm tap has a BRONZE titanium sleeve and can be used to undersize the tapped hole for a 3.5mm screw. The 3.5mm tap has a GOLD titanium sleeve to match the GOLD 3.5mm screw. The 4.0mm tap has a GREEN titanium sleeve to match the GREEN 4.0mm screw.*
- Repeat for all screw placement sites.

  Note: *Manual tapping may not be necessary since the Lineum Translation Screws are self-tapping.*

STEP 5

The Translation Screw offers the surgeon a great deal of flexibility when determining where to place the screw. Like a typical multi-axial screw, the screw shank can angulate relative to the screw head. However, Translation Screws allow the screw head to translate up to 3.0mm medial/lateral relative to the screw shaft for ease of rod insertion and less rod manipulation. These screws also offer up to 40° of angulation in the cephalad/caudal preferred direction.

Figure 9
Translation Screws



a. Drive shaft
b. Soft tissue sleeve
c. Outer sleeve
d. Handle or ratcheting handle

Figure 10
Fully assembled screw inserter

- After drilling/tapping the hole, choose the appropriate screw style and size. The depth gauge may be used to confirm the length of screw to be inserted. The length and diameter of the chosen screw may be confirmed using the gauges located on the screw caddies.

  Note: *The Lineum OCT Spine System offers Translation Screws in diameters of 3.5mm (GOLD screw head), 4.0mm (GREEN screw head) and 4.35mm (BLUE screw head). Also offered are 3.5mm smooth shank Translation Screws (GOLD screw head), which have approximately 9.25mm of smooth shaft.*

STEP 6

- To assemble the screw inserter, remove the screw inserter drive shaft, outer sleeve, soft tissue sleeve and screw inserter handle from the Lineum Standard Instrument Kit A.
- Slide the soft tissue sleeve groove side first onto the gold handle screw inserter outer sleeve until it snaps onto the outer sleeve at the base of the gold handle. The black soft tissue sleeve is optional and may be omitted depending on surgeon preference. Next, slide the screw inserter drive shaft, proximal end first, through the screw inserter outer sleeve.

  Note: *You may experience some slight resistance when you reach the base of the gold handle. Continue to push until the back end of the screw inserter drive shaft is completely through the gold handle.*

SCREW PLACEMENT *(continued)*

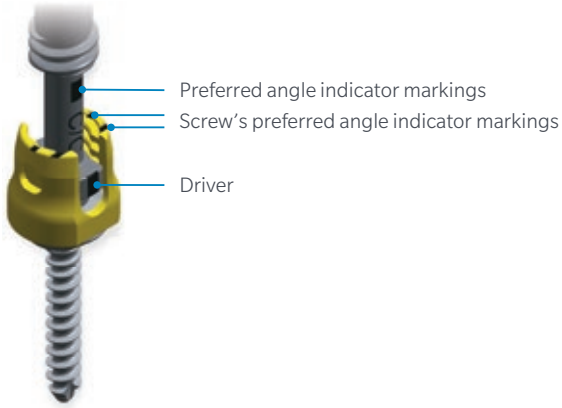


Figure 11
Screw

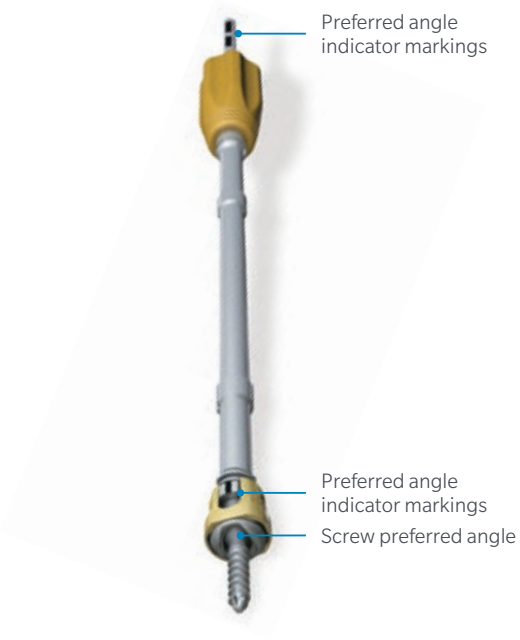


Figure 12
Screw inserter

STEP 6 *(continued)*

- While holding the distal end of the inserter, align the flat end of the inserter drive shaft with the flat edge at the base of the screw inserter handle or ratcheting screw inserter handle. Snap the screw inserter handle onto the screw inserter drive shaft by pushing them together. Ensure that the handle is securely attached by attempting to pull the assembly apart.
- While holding the head of the screw and screw shank, line up the dotted line on the distal end of the inserter with the black marking on the screw seat, which indicates the preferred angle direction of the screw. Load the Translation Screw onto the screw inserter by inserting the hex of the screw head into the distal tip of the screw inserter, taking care to ensure that the screw shaft is co-linear with the instrument shaft.
- Ensure that the driver is fully seated on the screw head, and then push on the screw inserter outer sleeve to begin engaging the threads on the inserter with the threads on the screw. Secure the Translation Screw to the screw inserter by turning the gold handle clockwise to tighten the screw inserter outer sleeve down the screw seat until the shaft is completely engaged with the seat of the screw.

  Note: *The inserter is completely and properly engaged with the seat of the screw when the screw and screw inserter form a solid, co-linear assembly.*

Figure 13
Screw placement site

- Insert the Translation Screw into the previously drilled/tapped hole by rotating the blue screw inserter handle clockwise to gently advance the screw to the desired depth. The preferred direction is noted by the black markings on the top of the screw seat and dotted line located between the gold handle and screw inserter handle. Once the screw is fully seated, disengage the screw inserter from the Translation Screw by turning the gold knob counterclockwise.
- Repeat for all screw placement sites.

FOR POSTERIOR CERVICAL SCREW PLACEMENT

Various surgical techniques exist for placing screws in the cervical spine. Most common techniques include lateral mass and pedicle screw placement. The level at which screws are being placed often dictates which technique is used, however individual patient anatomy must be considered. The common techniques based on level are described below:

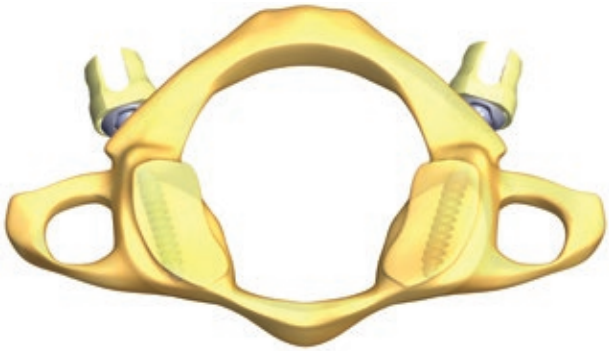


Figure 14
C1 lateral mass screws

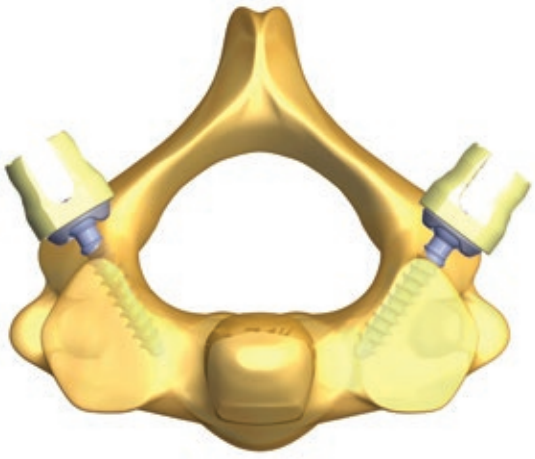


Figure 15
C2 pedicle screw placement

C1 Lateral Mass Screws

The starting point of C1 lateral mass screw placement is at the junction of the posterior arch and lateral mass, inferior to the arch. Smooth shank screws are available which may reduce the possibility of C2 nerve root irritation.

C2 Pedicle Screw Placement

The starting point of C2 pedicle screw placement is in the superior and medial portion of the C2 lateral mass. The medial angulation directs the screw away from the vertebral artery.

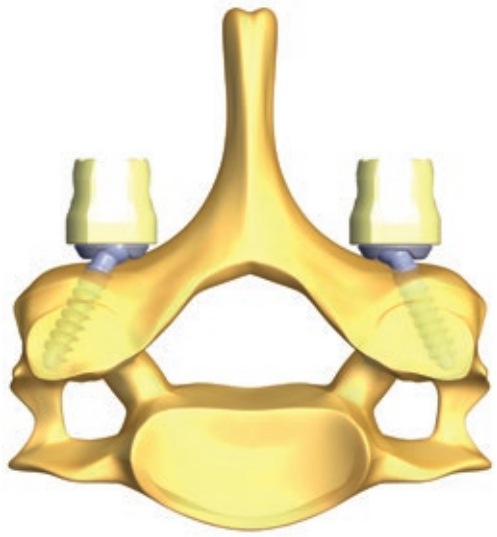


Figure 16
Placement of lateral mass screws (C3–C7)

Figure 17
Placement of pedicle screws at C7

Placement of Lateral Mass Screws (C3–C7)
The starting point for lateral mass screw placement should be near the center of the lateral mass. The tip of the screw should be directed cephalad and lateral, away from the nerve root, spinal cord and vertebral artery.

Note: *It is possible to place screws in the pedicles of C3–C6, but can be technically challenging due to the anatomical structure in this location. Careful consideration and pre-operative planning should be conducted with imaging studies to verify screws can be safely placed in the pedicle. Intra-operative imaging should also be utilized during pilot-hole preparation and screw insertion.*

Placement of Pedicle Screws at C7
The C7 pedicle is slightly larger than the C3–C6 pedicles, therefore in a majority of cases, C7 favors pedicle screw placement over lateral mass screw placement. The entry point for the screw should start lateral and superior to the center of the lateral mass.

Note: *In some instances, lateral mass and pedicle screw placement may not be appropriate due to inherent anatomic variability of the pedicles or other anatomical considerations such as proximity to vessels or nerve roots. Careful consideration should be given to patient anatomy prior to selecting the screw placement technique. Other available techniques include pars screws, translaminar screws and transarticular screw placement.*

LAMINAR HOOK PLACEMENT

a. Drive shaft
b. Outer sleeve
c. Handle or racheting handle

Figure 18
Hook inserter

Figure 19
Fully assembled hook inserter

The Lineum OCT Spine System offers left and right offset hooks in 4.5mm and 6.0mm throat openings. The hooks are top-loading and top-tightening for easy insertion and tightening.

- To assemble the hook inserter, remove the hook inserter drive shaft and outer sleeve from the Lineum Standard Instrument Kit B. Then remove the screw inserter handle or ratcheting screw inserter handle and slide the hook inserter drive shaft, proximal end first, through the hook inserter outer sleeve.

  Note: *You may experience some slight resistance when you reach the base of the gold handle. Continue to push until the back end of the inserter shaft is completely through the gold handle.*

- While holding the distal end of the inserter, align the flat end of the inserter with the flat edge at the base of the screw inserter handle. Snap the screw inserter handle or ratcheting screw inserter handle onto the hook inserter by pushing them together. Ensure that the handle is securely attached by attempting to pull the assembly apart.

Figure 20
4.5mm hook with hook inserter

Figure 21
Hook site elevator

- Determine the size and style of the hook required.
- While holding the base of the hook, load the hook onto the hook inserter by inserting the distal tip of the hook inserter into the U-shaped recess in the hook.
- Ensure that the driver is fully seated on the hook and then push on the gold handle hook inserter outer sleeve to begin engaging the threads on the inserter drive shaft with the threads on the hook. Secure the hook to the hook inserter by turning the gold handle clockwise to tighten the outer shaft down the hook until the hook is rigidly attached to the inserter.
- The hook site elevator may be used to elevate the lamina during hook insertion. The hook site elevator is attached to a quick connect handle. Insert the hook onto the lamina using the hook inserter.
- Once the hook is inserted, disengage the hook inserter from the hook by rotating the gold handle counterclockwise.
- Repeat for all hook placement sites.

ROD PREPARATION

Figure 22
Ratcheting rod cutter

Figure 23
Rod bender

STEP 7

- Use the rod template to determine the appropriate length and curvature of the rod.
- Choose the appropriate rod length, material and style.

  Note: *The titanium rods are colored blue and the cobalt chrome rods are silver. Titanium rods are available in 40mm, 80mm, 180mm and 240mm straight lengths and 40mm, 50mm, 60mm, 70mm, 80mm and 120mm curved lengths. Cobalt chrome rods are available in 80mm and 240mm straight lengths and 120mm curved lengths.*
- Cut the rod to the appropriate length using one of the available rod cutters.
- Spin the wheel until the two arrows are aligned. Insert the rod through the hole in the cutter.
- Ratchet until the rod cutter cuts the rod.

  Note: *Markings on the rod template are every 10mm. The "cutting line" marks the spot where the cutter will cut the rod. The "cutting line" is located 8.0mm from the face of the instrument.*
- Contour the rod to the appropriate shape using the rod bender or sagittal bending irons.

  Note: *The rod may be bent using either side of the rod bender. The markings on either side of the rod bender indicate the aggressiveness of the bend.*

  Note: *Do not straighten the rod or apply reverse bends after bending. Sagittal or coronal bending irons may be used after placement of the rod to enable in-situ bending.*

ROD INSERTION

Figure 24
Seat alignment tool and bone planer

Figure 25
Reducer with handle with Helical Flange plug starter

STEP 8

- The seat alignment tool may be used to translate and/or angulate the seat of each screw so that the rod channels of adjacent screws are aligned, minimizing the need to bend the rod.

  Note: *If the screw seats do not translate and/or angulate due to bone interference, the bone planer can be used to quickly and easily remove a small amount of bone around the screw seat. The bone planer is designed to accept a quick connect handle.*

- Insert the rod into the seat of each screw or hook with the rod holder.

STEP 9

The reducer with handle or Rocket™ Rod Reducer may be used if additional assistance is required to fully position the rod into the seat of the screw or hook.

Reducer with Handle

- Squeeze handle until the lines on the proximal end of the instrument are aligned and the arms move from open to parallel. With the arms in the parallel position, place the distal tip of the reducer around the seat of the screw or hook to mate the instrument with the reduction notches on the screw seat. Squeeze the handle of the reducer to advance the rod down into the seat as desired.
- Use one of the Helical Flange plug starters to insert and provisionally tighten the Helical Flange plugs before disengaging the reducer.
- To remove the reducer with handle from the screw, completely release the handle and gently disengage the reducer from the screw.

ROD INSERTION *(continued)*

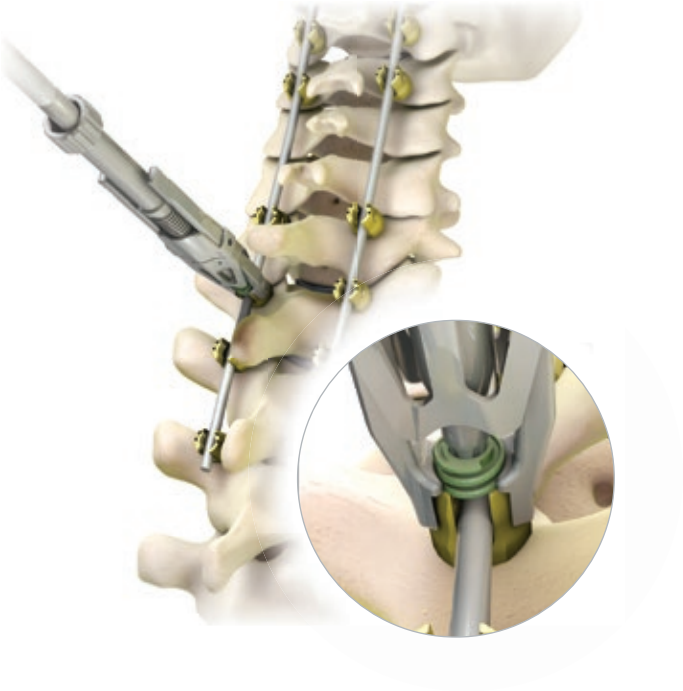


Figure 26
Rocket Rod Reducer

SCREW POSITIONING

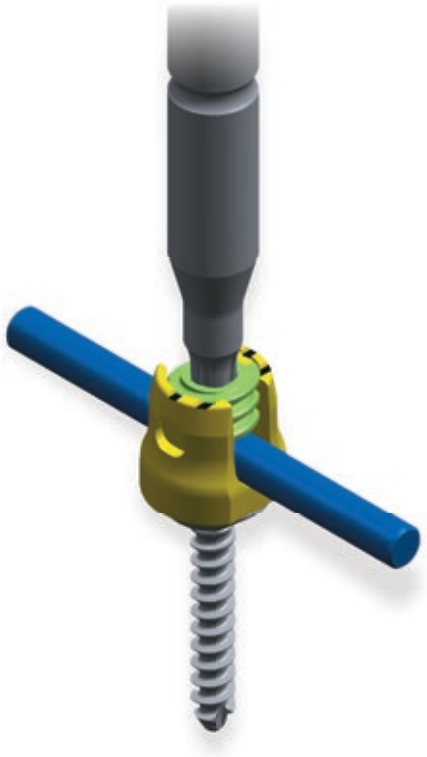


Figure 27
Helical Flange plug starter

STEP 9 *(continued)*

Rocket Rod Reducer

- Squeeze the tips to open the arms and seat the distal tips of the reducer around the seat of the screw or hook to mate the instrument with the reduction notches on the screw seat. Turn the knob clockwise, either by hand or with the included Rocket hex key, to persuade the rod into the screw or hook seat.

  Note: *Connect the Rocket hex key to a quick-connect handle prior to use.*

- Use one of the plug starters to insert and provisionally tighten the Helical Flange plugs before disengaging the reducer.

  Note: *To remove the Rocket Rod Reducer from the screw, turn the knob counterclockwise until it cannot be turned anymore and squeeze the handles to disengage the reducer from the screw or hook.*

Screw Positioning

The compressor or distractor may be used to perform minor screw adjustments prior to provisionally tightening the plugs.

- Seat the U-shaped openings over the rod and gently compress the handles.

Helical Flange Plug Application

- Insert the Helical Flange plug into the seat of the screw or hook using the Helical Flange plug starter and provisionally tighten.

FINAL TIGHTENING

Figure 28
Final tightening—Helical Flange plugs

STEP 10

Note: *The torque stabilizer must be used during final tightening of plugs for both screws and hooks to maintain torsional stability of the construct.*

- Slide the torque stabilizer over the seat of the screw or hook to be tightened.
- Attach the Helical Flange plug driver to the GREEN Helical Flange torque wrench handle or to the GREEN Helical Flange torque wrench T-handle and advance the shaft of the assembly down the torque stabilizer until it is fully inserted into the Helical Flange plug.
- Hold the torque stabilizer handle steady and rotate the handle of the torque wrench clockwise until an audible click is heard and tension is released within the handle.

Note: *The Helical Flange torque wrench will tighten the locking plug to a minimum of 36 in-lbs.*

ADDITIONAL SURGICAL OPTIONS

Titanium transitional rod

Cobalt chrome transitional rod

Rod connectors

Figure 29
Rods and connectors

Figure 30
Rod connector

Linkage to Other Zimmer Biomet Spinal Systems
The Lineum OCT Spine System can also be linked to the Polaris™ System via transitional rods or by using Altius™ Rod Connectors or Polaris™ Dominos.

Note: *Titanium and cobalt chrome transitional rods are offered in a 3.5mm/5.5mm diameter. Connectors are available in 3.5mm/3.5mm, 3.5mm/5.5mm and 3.5mm/6.35mm. Please refer to the individual system's package insert for a list of indications for use for each system.*

Rod Connector/Domino Placement

- Approximate the size, length and contour of the rod to be extended with the rod to be joined.
- Slightly disengage the set screws from the rod connector by inserting the set screw driver and rotating it counterclockwise.
- Slide the rod connector onto the 3.5mm rod ensuring the rod passes completely through the 3.5mm rod connector hole and provisionally tighten using the set screw driver.
- Insert the rod to be connected to the 3.5mm rod through the remaining hole of the rod connector and provisionally tighten.
- Perform final tightening by attaching the set screw driver to the BLUE set screw torque wrench handle and by rotating clockwise until an audible click is heard and tension is released within the handle.

  Note: *The set screw torque wrench will tighten the locking plug to a minimum of 18 in-lbs.*

Figure 31
Lateral connector

Lateral Connector Placement

The Lineum OCT Spine System offers standard and long lateral connectors to provide additional medial/lateral screw placement flexibility. If necessary, the long lateral connector can be cut to length using the rod cutter. Ensure that the cut portion of the connector is removed from the rod cutter.

Note: *The lateral connectors can be attached to the rod after rod insertion.*

- Slide the open throat of the connector over the rod and drop the lateral portion of the connector into the seat of the screw or hook. Provisionally tighten the set screw with the set screw driver. Using the plug starter, provisionally tighten the rod end of the lateral connector in the screw or hook seat.
- Attach the set screw driver to the BLUE set screw torque wrench handle and perform final tightening of the set screw by rotating the handle clockwise until an audible click is heard and tension is released within the handle. Final tightening of the GREEN Helical Flange plug proceeds as previously described.

  Note: *The set screw torque wrench will tighten the locking plug to a minimum of 18 in-lbs.*

- Repeat for all lateral connector sites.

ADDITIONAL SURGICAL OPTIONS *(continued)*

Figure 32
Cross connector

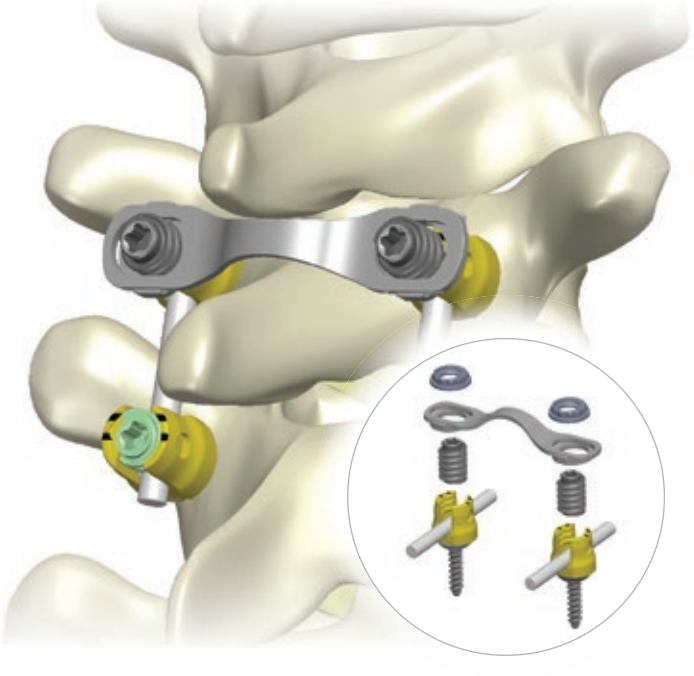


Figure 33
Head-to-head crossband

Rod-to-Rod Cross Connector Placement

In the event that additional torsional stability is required, a cross connector may be utilized. The cross connector should be applied after the construct has been assembled and the appropriate plugs have been tightened. The Lineum OCT Spine System comes complete with standard rod-to-rod cross connectors and head-to-head cross connectors in various sizes.

- Adjustable cross connectors are available in small (20mm–26mm), medium (25mm–38mm), large (37mm–62mm) and extra-large (46mm–80mm) lengths to maximize the flexibility of cross connector placement and sizing.
- Determine the appropriate size cross connector(s) required.
- Slightly disengage the set screws from the adjustable cross connector by inserting the set screw driver and rotating it counterclockwise.
- Slide the cross connector over the rods and provisionally tighten the set screws with the set screw driver.
- Attach the set screw driver to the BLUE set screw torque wrench handle and perform final tightening by rotating the handle clockwise until an audible click is heard and tension is released within the handle. Tighten the set screws that attach to the rod before tightening the center set screw. Place the cross connector stabilizer over the center set screw before tightening it.

Head-to-Head Cross Connectors*

Head-to-head cross connectors are used in situations where there is inadequate space between the screw heads to place a standard rod-to-rod connector. The Lineum OCT Spine System offers several crossband lengths with arched centers to better support patient anatomy. Head-to-head cross connectors are available in small (24mm–32mm), medium (31mm–39mm), large (38mm–46mm) and extra-large (45mm–53mm) lengths.

Note: *Head-to-head cross connectors must be utilized with the Helical Flange double plugs.*

**Head-to-head cross connectors may not be available in all geographic areas.*

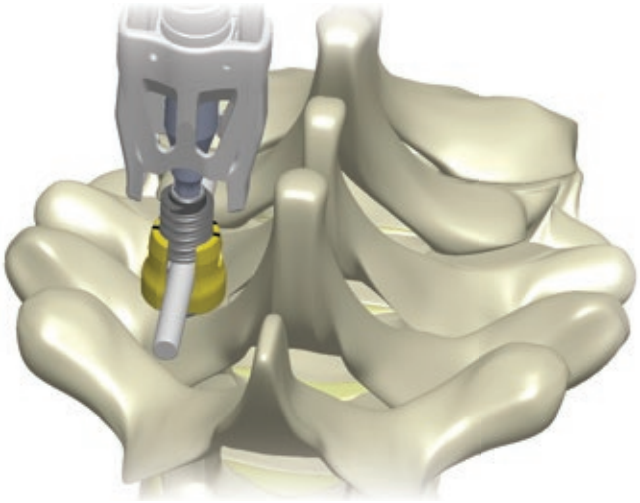


Figure 34
Translating screw with reducer

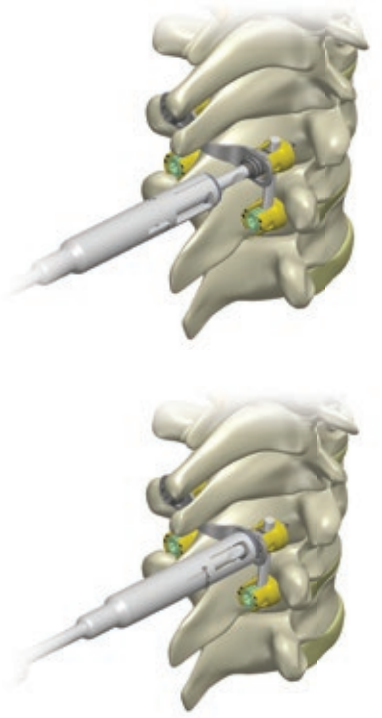


Figure 35
Cross connector nut tightening

Head-to-Head Cross Connector Placement

- Insert the Helical Flange double plug into the tulip head of the screws or hooks using the plug starter and provisionally tighten each one. Once the double plugs have been properly placed, slide the torque stabilizer over the seat of each screw and/or hook to be tightened.
- Attach the GREEN Helical Flange plug driver to the Helical Flange torque wrench handle or to the Helical Flange torque wrench T-handle and advance the shaft of the assembly down the torque stabilizer until it is fully inserted into the Helical Flange double plug.
- Hold the torque stabilizer handle steady and rotate the handle of the torque wrench clockwise until an audible click is heard and tension is released within the handle.
- Determine the appropriate size head-to-head cross connector(s) required.
- Place the head-to-head cross connector over the double plugs.

Note: *The seating on the head-to-head cross connector can accommodate medial/lateral translation for up to 3.5mm in either direction.*

- Attach the GREEN Helical Flange nut driver to the Helical Flange torque wrench handle or to the T-handle. The nut is removed directly from the caddy using the nut driver.
- Perform final tightening of the nut by rotating the handle clockwise until an audible click is heard and tension is released within the handle.
- Repeat for additional screws.

Note: *The nut driver will final tighten the nut to a minimum of 36 in-lbs.*

Note: *The rod template can be used as a guide to aid in the selection of the appropriate cross connector size.* *See page 22 for available cross connector sizes.*

OCCIPITAL FIXATION

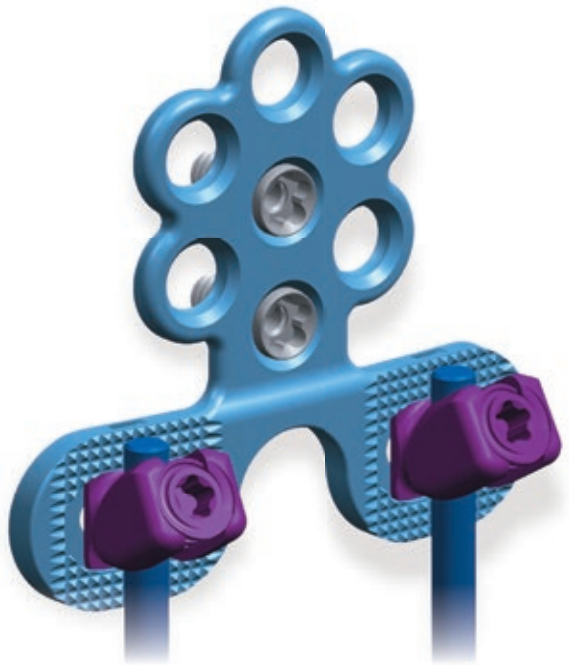


Figure 36
Lineum Occipital Plate

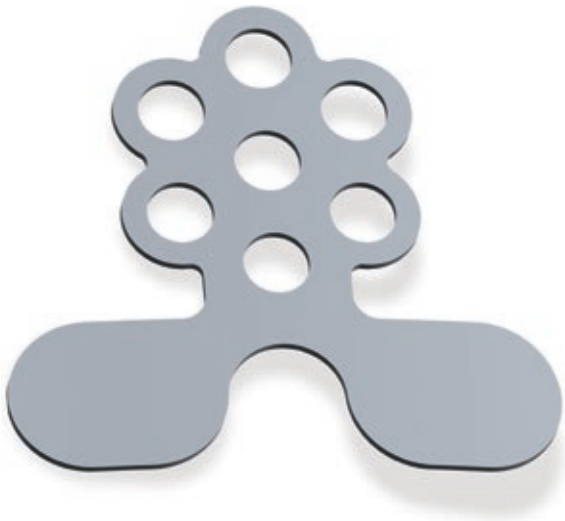


Figure 37
Lineum Occipital Plate template

The Lineum Occipital Plate offers low-profile fixation along the midline of the occiput, where the most bone purchase can be obtained. The occipital screws have a spherical head allowing them to be placed within a 20° cone of angulation relative to the plate. The plate features three midline fixation points and seven total points of fixation and contains a machined radius to conform to the contour of the skull. The rod seats are angled at 30° and translate up to 10mm to ease plug insertion.

Occipital Plate and Screw Selection

- Use the occipital plate templates to determine the appropriate occipital plate size based on anatomy *(see page 36 for plate sizes)*.

  Note: *If contouring is necessary, the occipital plate templates can be easily bent to help determine the required curvature of the plate. This should minimize the incidence of over-contouring of the occipital plate.*

- Once an appropriate plate has been selected, the plate may be gently contoured, if needed, using the occipital hole cover bender and the occipital plate bender. If the rod seat pads (knurled area of plate) need to be bent downward in the sagittal plane, slide the occipital hole cover over the honeycomb portion of the plate such that the handle extends vertically upward (use the bottom slot in the occipital hole cover bender). Slide the occipital plate bender around one of the rod seats such that the handle is parallel to the occipital hole cover handle. Gently apply pressure to bend the plate to the appropriate angle. Repeat for the second rod seat.

Figure 38
Lineum Occipital Plate bender and hole cover

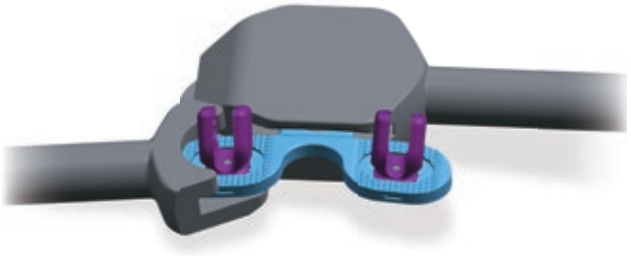


Figure 39
Lineum Occipital Plate bender and hole cover

- If the rod seat pads need to be bent downward in the transverse plane, slide the occipital hole cover over the honeycomb portion of the plate such that the handle extends sideways from the plate (use the top slot in the occipital hole cover bender). Slide the occipital plate bender around one of the rod seats such that the handle is parallel to the occipital hole cover handle. Gently apply pressure to bend the plate to the appropriate angle. Repeat for the second rod seat.

  Warning: *Do not bend the plate in the knurled area near the sliding connectors or in the honeycomb portion of the plate. Take care to ensure that the screw holes and the rod seat pads have not been distorted by the bending process. Do not straighten the plate after bending.*

- After the appropriate size plate has been selected, mark the entry points where the occipital bone screws will be inserted through the holes in the occipital plate. Ensure that the occipital plate is flush against the occiput.
- Determine the appropriate lengths of occipital bone screws required via preoperative planning or fluoroscopy. The 4.5mm diameter screw is the primary screw. The 5.0mm diameter screw is the rescue screw.

  Note: *It may be necessary to remove small amounts of occipital bone to optimize the plate-to-bone interface.*

  Caution: *Do not remove bone near areas of screw placement.*

OCCIPITAL FIXATION *(continued)*

Figure 40
Occipital drill/tap guide

Figure 41
Occipital drill/tap guide

Occipital Drilling and Tapping

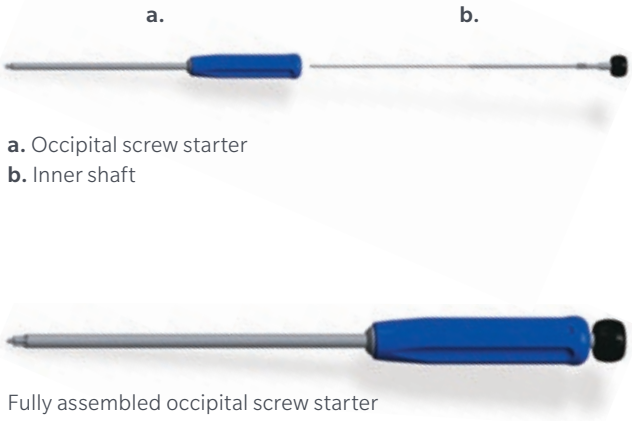
- Choose the occipital drill/tap guide.

  Note: *The occipital drill/tap guide is BRONZE and ranges from 6.0mm–20mm.*

- Hold the drill/tap guide handle with the tip oriented vertically (so the numbers are upright and readable), and adjust the drill/tap depth by pulling back on the knurled knob and then turning it clockwise or counterclockwise to lock the drill guide and set the desired depth. The depth is set correctly when the pin on the guide is seated in the appropriate notch and the desired depth is visible in the window.
- Connect a quick connect handle or quick connect T-handle to the desired drill bit or tap shaft and insert through the drill/tap guide. Orient the drill/tap guide and drill bit or tap at the desired trajectory and drill or tap until reaching the positive stop. The positive stop is reached when the drill bit or tap contacts the top of the knurled knob of the drill/tap guide. This prevents the drill or tap from penetrating any deeper.
- Once the positive stop is reached, gently remove the drill/tap guide and drill/tap from the site.
- Repeat for all screw placement sites.

  Warning: *Drill/tap guide must be used through the occipital plate.*

  Note: *Flexible drills and taps may be used through the occipital drill/tap guide if the anatomy will not accommodate the rigid drill or tap.*



a. Occipital screw starter
b. Inner shaft

Fully assembled occipital screw starter

Figure 42
Occipital screw starter

Occipital Screw Insertion

- Remove the occipital screw starter and inner shaft, from the Lineum Occipital Instrument Kit.
- Slide the inner shaft through the occipital screw starter and thread it into the occipital screw starter by turning the black knob clockwise until the inner shaft is captured within the starter and the inner threads are no longer engaged.

  Note: *The inner shaft is correctly inserted into the occipital screw starter when there is a small amount of linear play between the two components, but the inner shaft cannot be pulled out.*
- Place the occipital screw starter into the pentalobe of the desired occipital screw and turn the black knob clockwise to securely attach the occipital screw starter to the screw.
- Using the plate holder, align the plate with the drilled/tapped holes.
- Insert the screws through the plate into the drilled/tapped holes by rotating the occipital screw starter clockwise to gently advance the screw until it is fully seated against the plate.
- Repeat for all screw placement sites.
- A non-retaining, occipital screw driver can be used for final tightening of the occipital screws.

  Note: *If the anatomy will not accommodate the rigid instruments, the 90° occipital screw driver may be used to place the screws. The screw is attached to these instruments in the same manner as the occipital screw starter.*

OCCIPITAL FIXATION *(continued)*

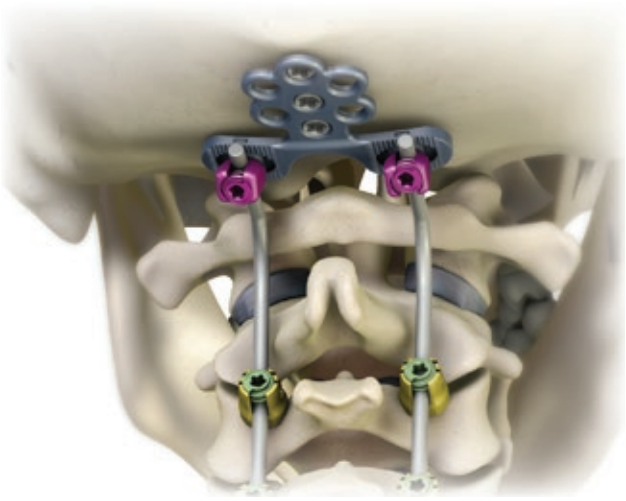


Figure 43
Occipital rod preparation and insertion

Figure 44
Helical Flange occipital plug

Occipital Rod Preparation and Insertion

- If desired, the rod template may be used to determine the appropriate length and curvature of the rod.
- Cut the rod to the appropriate length using the rod cutter and contour the rod to the appropriate shape using the rod bender or sagittal bending irons.

  Caution: *Do not straighten the rod or apply reverse bends after initial bending.*
- Insert the rod into the rod seats of the occipital plate so that the straight section of the rod rests against the knurled surface of the plate (approximately 3.0mm–4.0mm of the rod should extend above the channel).
- Repeat for second rod.

Plug Insertion

The Lineum Occipital Plate has angled rod seats to ease insertion of the occipital Helical Flange plugs and to ease locking of the rods to the construct. Additionally, the seats translate up to 10mm medial/lateral for ease of rod insertion.

- Insert the MAGENTA Helical Flange occipital plugs into the MAGENTA seat(s) of the occipital plate using one of the plug starters from the Standard Instrument Kit A and provisionally tighten.
- Repeat for the contralateral side.

  Note: *The MAGENTA Helical Flange occipital plugs have a conical tip and must be used with the occipital plate.*

  Warning: *Do not use standard GREEN Helical Flange plugs with the occipital plate.*

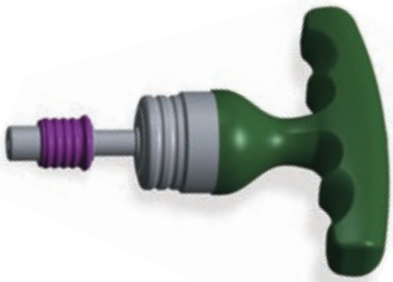
  Warning: *Do not use MAGENTA Helical Flange occipital plugs with the Translation Screws or hooks.*

Occipital torque stabilizer

Helical Flange plug driver

Figure 45
Occipital torque stabilizer and Helical Flange plug driver

Helical Flange torque wrench handle



Helical Flange torque wrench T-handle

Figure 46
Helical Flange torque wrench and T-handle

Final Tightening

Note: *The occipital torque stabilizer must be used during final tightening of MAGENTA Helical Flange occipital plugs in the occipital plate seats.*

Note: *The occipital torque stabilizer has a MAGENTA colored handle cap to match the MAGENTA colored seats and MAGENTA colored Helical Flange occipital plugs.*

- Slide the occipital torque stabilizer over the rod seat to be tightened.
- Attach the Helical Flange plug driver to the GREEN Helical Flange torque wrench handle or GREEN Helical Flange torque wrench T-handle and advance the shaft of the assembly down the occipital torque stabilizer until it is fully inserted into the Helical Flange occipital plug.

Note: *The GREEN Helical Flange torque wrench handle also has a MAGENTA sleeve to match the MAGENTA occipital plate seats and MAGENTA Helical Flange occipital plugs.*

- Hold the occipital torque stabilizer handle steady and rotate the handle of the Torque Wrench clockwise until an audible click is heard and tension is released within the handle.

Note: *The Helical Flange torque wrench will tighten the locking plug to a minimum of 36 in-lbs.*

IMPLANT REMOVAL

Removal of the Lineum OCT Spine System components is performed by reversing the order of the implant procedure.

Note: *The torque stabilizer should be used when removing screws to prevent unintended screw pullout. The torque stabilizer may be used either directly on the screw to be removed, or on the adjacent screws, to hold the construct in place during removal.*

KIT CONTENTS

Lineum Standard Implants, Kit Number: 14-525100

DESCRIPTION	QUANTITY	PART NUMBER
Rod Connector, 3.5mm/3.5mm, Single	2	1200-0020
Rod Connector, 3.5mm/3.5mm, Double	2	1200-0021
Rod Connector, 3.5mm/5.5mm	2	1200-0025
Rod Connector, 3.5mm/6.35mm	2	1200-0027
Arched Cross Connector, Small	2	1200-1220
Arched Cross Connector, Medium	2	1200-1221
Arched Cross Connector, Large	2	1200-1222
Arched Cross Connector, Extra Large	2	1200-1223
3.5mm x 40mm Ti Rod	4	14-524004
3.5mm x 80mm Ti Rod	4	14-524008
3.5mm x 80mm CoCr Rod	4	14-524009
3.5mm x 180mm Ti Rod	4	14-524018
3.5mm x 240mm Ti Rod	4	14-524024
3.5mm x 240mm CoCr Rod	4	14-524025
4.5mm Left Hand Hook	2	14-524034
4.5mm Right Hand Hook	2	14-524035
6.0mm Left Hand Hook	2	14-524036
6.0mm Right Hand Hook	2	14-524037
Helical Flange Plug	30	14-524038
Standard Lateral Connector	3	14-524039
3.5/5.5 Ti Transitional Rod	3	14-524046
3.5/5.5 CoCr Transitional Rod	3	14-524047
Long Lateral Connector	3	14-524053
3.5mm x 10mm Screw	14	14-524210
3.5mm x 12mm Screw	16	14-524212
3.5mm x 14mm Screw	16	14-524214
3.5mm x 16mm Screw	10	14-524216
3.5mm x 18mm Screw	6	14-524218
3.5mm x 20mm Screw	4	14-524220
3.5mm x 22mm Screw	2	14-524222
3.5mm x 24mm Screw	2	14-524224
3.5mm x 26mm Screw	2	14-524226
4.0mm x 10mm Screw	4	14-524510
4.0mm x 12mm Screw	8	14-524512
4.0mm x 14mm Screw	12	14-524514
4.0mm x 16mm Screw	8	14-524516
4.0mm x 18mm Screw	6	14-524518
4.0mm x 20mm Screw	4	14-524520
4.0mm x 22mm Screw	4	14-524522
4.0mm x 24mm Screw	4	14-524524

KIT CONTENTS *(continued)*

Lineum Standard Implants, Kit Number: 14-525100 *(continued)*

DESCRIPTION	QUANTITY	PART NUMBER
4.0mm x 26mm Screw	4	14-524526
4.0mm x 28mm Screw	4	14-524528
4.0mm x 30mm Screw	4	14-524530
4.0mm x 32mm Screw	4	14-524532
4.0mm x 34mm Screw	4	14-524534
4.35mm x 20mm Screw	6	14-524720
4.35mm x 24mm Screw	6	14-524724
4.35mm x 28mm Screw	6	14-524728
4.35mm x 32mm Screw	6	14-52732
4.35mm x 36mm Screw	6	14-524736
4.35mm x 40mm Screw	6	14-524740

Lineum Supplemental Implants and Instruments, Kit Number: 14-525101

DESCRIPTION	QUANTITY	PART NUMBER
Ratcheting Screw Inserter Handle	2	14-525064
Rod Cutter	1	1200-9032
Plug Starter with Handle	2	14-525031
Bone Planer	1	14-525034
Hook Site Elevator	1	14-525065
Curved 120mm Ti Rod	4	14-524946
Curved 120mm CoCr Rod	4	14-524947
3.5mm x 20mm Smooth Shank Screw	2	14-524370
3.5mm x 22mm Smooth Shank Screw	2	14-524372
3.5mm x 24mm Smooth Shank Screw	2	14-524374
3.5mm x 26mm Smooth Shank Screw	2	14-524376
3.5mm x 28mm Smooth Shank Screw	2	14-524378
3.5mm x 30mm Smooth Shank Screw	2	14-524380
3.5mm x 32mm Smooth Shank Screw	2	14-524382
3.5mm x 34mm Smooth Shank Screw	2	14-524384

Lineum Standard Instruments A, Kit Number: 14-524001

DESCRIPTION	QUANTITY	PART NUMBER
Awl with Stop, 8.0mm	1	1200-9004
Rod Template, 24cm/3.5mm	1	1200-9024
Rod Holder, 3.5mm	1	1200-9030
Probe, 2.3mm	1	14-500117
Quick Connect Handle	2	14-521004
3.5mm Drill*	2	14-525000
4.0mm Drill*	2	14-525001
6.0mm–32mm Drill Guide	1	14-525070
32mm–50mm Drill Guide	1	14-525071
Depth Gauge with Hook	1	14-525066
Pedicle Sound	1	14-525005
Curve Probe	1	14-525006
6.0mm–32mm Tap Guide	1	14-525072
3.5mm Tap*	1	14-525008
4.0mm Tap*	1	14-525009
Screw Inserter Drive Shaft and Outer Sleeve	2	14-525011
Soft Tissue Sleeve	2	14-525014
Two Radius Rod Bender	1	14-525015
Ratcheting Rod Cutter	1	14-525020
Helical Flange Plug Starter	2	14-525025
Dorsal Height Adjuster	1	14-525028
Torque Stabilizer	1	14-525030
Seat Alignment Tool	1	14-525032
Helical Flange Torque Handle Limit	1	14-525035
Helical Flange Torque T-Handle Limit	1	14-525036
Helical Flange Plug Driver	2	14-525037
3.0mm Tap*	1	14-525055
Screw Inserter Handle	2	14-525056

* Indicates a disposable instrument

KIT CONTENTS *(continued)*

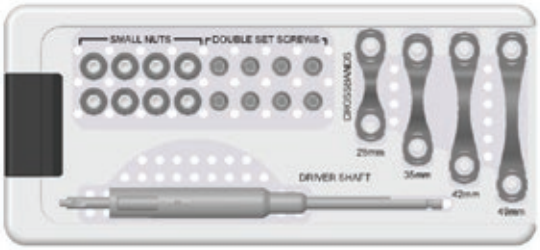
Lineum Standard Instrument B, Kit Number: 14-524002

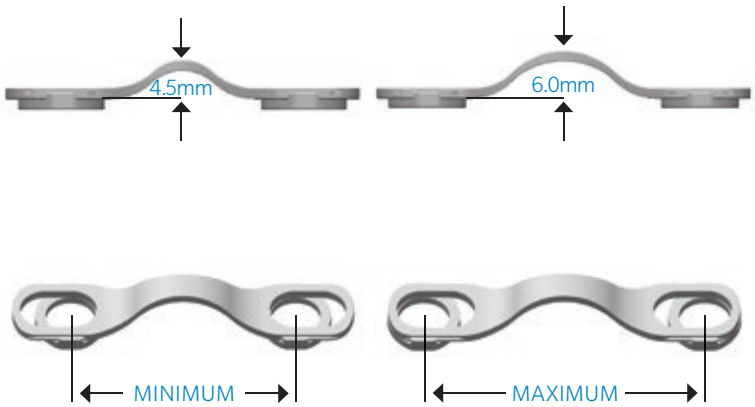
DESCRIPTION	QUANTITY	PART NUMBER
Set Screw Torque Wrench	1	1200-9027
Cross Connector Stabilizer	1	1200-9232
Hook Inserter Drive Shaft and Outer Sleeve	1	14-525012
Right Hand Coronal Bend Iron	1	14-525016
Left Hand Coronal Bend Iron	1	14-525017
Left Hand Sagittal Bend Iron	1	14-525018
Right Hand Sagittal Bend Iron	1	14-525019
3.5mm Rocket Hex Key	1	14-525022
3.5mm Rocket Rod Reducer	2	14-525023
3.5mm Reducer with Handle	1	14-525024
Distractor	1	14-525026
Compressor	1	14-525027
Set Screw Driver	2	14-525029
Quick Connect T-Handle	1	14-525033
Double Action Rod Gripper	1	14-525059

Head-to-Head Caddy, Kit Number: 14-524100

DESCRIPTION	ADJUSTMENT	QUANTITY	PART NUMBER
4.5mm Head-to-Head Cross Band, 28mm Width	24.5mm–31.5mm	1	14-525128
6.0mm Head-to-Head Cross Band, 35mm Width	31.5mm–38.5mm	1	14-525135
6.0mm Head-to-Head Cross Band, 42mm Width	38.5mm–45.5mm	1	14-525142
6.0mm Head-to-Head Cross Band, 49mm Width	45.5mm–52.5mm	1	14-525149
Head-to-Head Cross Connector Double Set Screw	N/A	8	14-525110
Head-to-Head Cross Connector Nut	N/A	8	14-525111
Head-to-Head Nut Driver	N/A	1	14-525306

Head-to-head cross connectors may not be available in all geographic areas.





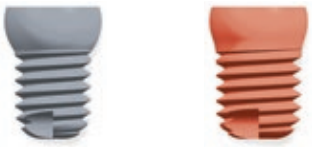
Lineum Occipital, Kit Number: 14-524003

DESCRIPTION	QUANTITY	PART NUMBER
Occipital Helical Flange Plug	4	14-524045
75° Ti Occipital Rod	3	14-524058
75° CoCr Occipital Rod	3	14-524059
90° Ti Occipital Rod	3	14-524060
90° CoCr Occipital Rod	3	14-524061
4.5mm x 6.0mm Occipital Screw	6	14-524806
4.5mm x 8.0mm Occipital Screw	6	14-524808
4.5mm x 10mm Occipital Screw	6	14-524810
4.5mm x 12mm Occipital Screw	6	14-524812
4.5mm x 14mm Occipital Screw	2	14-524814
Small Occipital Plate	2	14-524825
Medium Occipital Plate	2	14-524830
Large Occipital Plate	2	14-524835
5.0mm x 6.0mm Occipital Screw	6	14-524906
5.0mm x 8.0mm Occipital Screw	6	14-524908
5.0mm x 10mm Occipital Screw	6	14-524910
5.0mm x 12mm Occipital Screw	6	14-524912
5.0mm x 14mm Occipital Screw	2	14-524914
Occipital Torque Stabilizer	1	14-525038
Occipital Plate Template, Small	1	14-525039
Occipital Plate Template, Medium	1	14-525040
Occipital Plate Template, Large	1	14-525041
Occipital Plate Holder	1	14-525043
Occipital Drill Rigid	2	14-525044
Occipital Drill Flexible	1	14-525045
Occipital Drill/Tap Guide	1	14-525046
Occipital Tap Rigid	1	14-525047
Occipital Tap Flexible	1	14-525048
Occipital Screw Starter	2	14-525049
Occipital Screw Driver	1	14-525051
Occipital Screw Driver 90°	1	14-525052
Occipital Plate Bender	1	14-525053
Occipital Plate Hole Cover	1	14-525054
Occipital Inner Shaft Sub Assembly	2	14-525058
Occipital Rod Template	1	14-525061

IMPLANTS

All implants in the Lineum OCT Spine System (except the rods) are manufactured from Titanium Alloy (Ti 6Al-4V). Rods are available in two different materials, Titanium Alloy (Ti 6Al-4V) and Cobalt Chrome Alloy (Co-28Cr-6Mo).

Occipital Plates	PART NUMBER
Small	14-524825
Medium	14-524830
Large	14-524835



Occipital Screws	PART NUMBER
4.5mm x 6.0mm	14-524806
4.5mm x 8.0mm	14-524808
4.5mm x 10mm	14-524810
4.5mm x 12mm	14-524812
4.5mm x 14mm	14-524814
5.0mm x 6.0mm	14-524906
5.0mm x 8.0mm	14-524908
5.0mm x 10mm	14-524910
5.0mm x 12mm	14-524912
5.0mm x 14mm	14-524914

Translation Screws	PART NUMBER
3.5mm x 10mm	14-524210
3.5mm x 12mm	14-524212
3.5mm x 14mm	14-524214
3.5mm x 16mm	14-524216
3.5mm x 18mm	14-524218
3.5mm x 20mm	14-524220
3.5mm x 22mm	14-524222
3.5mm x 24mm	14-524224
3.5mm x 26mm	14-524226
4.0mm x 10mm	14-524510
4.0mm x 12mm	14-524512
4.0mm x 14mm	14-524514
4.0mm x 16mm	14-524516
4.0mm x 18mm	14-524518
4.0mm x 20mm	14-524520
4.0mm x 22mm	14-524522
4.0mm x 24mm	14-524524
4.0mm x 26mm	14-524526
4.0mm x 28mm	14-524528
4.0mm x 30mm	14-524530
4.0mm x 32mm	14-524532
4.0mm x 34mm	14-524534
4.35mm x 20mm	14-524720
4.35mm x 24mm	14-524724
4.35mm x 28mm	14-524728
4.35mm x 32mm	14-524732
4.35mm x 36mm	14-524736
4.35mm x 40mm	14-524740
3.5mm x 20mm, Smooth Shank	14-524370
3.5mm x 22mm, Smooth Shank	14-524372
3.5mm x 24mm, Smooth Shank	14-524374
3.5mm x 26mm, Smooth Shank	14-524376
3.5mm x 28mm, Smooth Shank	14-524378
3.5mm x 30mm, Smooth Shank	14-524380
3.5mm x 32mm, Smooth Shank	14-524382
3.5mm x 34mm, Smooth Shank	14-524384

Titanium Alloy Rods	PART NUMBER
3.5mm x 40mm Ti Rod	14-524004
3.5mm x 80mm Ti Rod	14-524008
3.5mm x 180mm Ti Rod	14-524018
3.5mm x 240mm Ti Rod	14-524024

Cobalt Chrome Alloy Rods	PART NUMBER
3.5mm x 80mm CoCr Rod	14-524009
3.5mm x 240mm CoCr Rod	14-524025

Pre-curved Titanium Alloy Rod	PART NUMBER
Curved 120mm Ti Rod	14-524946

Pre-curved Cobalt Chrome Alloy Rod	PART NUMBER
Curved 120mm CoCr Rod	14-524947

Transitional Rods	PART NUMBER
3.5/5.5 Ti Transitional Rod	14-524046
3.5/5.5 CoCr Transitional Rod	14-524047

Occipital Rods	PART NUMBER
75° Ti Occipital Rod	14-524058
75° CoCr Occipital Rod	14-524059
90° Ti Occipital Rod	14-524060
90° CoCr Occipital Rod	14-524061

Helical Flange Plugs	PART NUMBER
Helical Flange Plug	14-524038
Occipital Helical Flange Plug	14-524045

IMPLANTS *(continued)*

Offset Hooks	PART NUMBER
4.5mm Left Hand Hook	14-524034
4.5mm Right Hand Hook	14-524035
6.0mm Left Hand Hook	14-524036
6.0mm Right Hand Hook	14-524037

Rod Connectors	PART NUMBER
3.5mm/3.5mm, Single	1200–0020
3.5mm/3.5mm, Double	1200–0021
3.5mm/5.5mm	1200–0025
3.5mm/6.35mm	1200–0027

Adjustable Arched Cross Connectors	PART NUMBER
Small	1200–1220
Medium	1200–1221
Large	1200–1222
Extra Large	1200–1223

Head-to-Head Cross Bands	PART NUMBER
4.5mm, 28mm Width	14-525128
6.0mm, 35mm Width	14-525135
6.0mm, 42mm Width	14-525142
6.0mm, 49mm Width	14-525149

Lateral Connectors	PART NUMBER
Standard	14-524039
Long	14-524053

Head-to-Head Cross Connector	PART NUMBER
Double Set Screw	14-525110
Cross Connector Nut	14-525111

INSTRUMENT VISUAL GUIDE

Awl	PART NUMBER
	1200-9004

Depth Gauge with Hook	PART NUMBER
	14-525066

Drill Guide	PART NUMBER
6.0mm–32mm Drill Guide (Shown)	14-525070
32mm–50mm Drill Guide	14-525071

Drill	PART NUMBER
3.5mm Drill (Shown)	14-525000
4.0mm Drill	14-525001

Tap Guide	PART NUMBER
6.0mm–32mm	14-525072

Taps	PART NUMBER
3.0mm Tap	14-525055
3.5mm Tap (Shown)	14-525008
4.0mm Tap	14-525009

Probes	PART NUMBER
Curved Probe (Shown)	14-525006
Straight Probe	14-500117

Pedicle Sound	PART NUMBER
	14-525005

INSTRUMENT VISUAL GUIDE *(continued)*

Bone Planer	PART NUMBER
	14-525034

Screw Inserter	PART NUMBER
Screw Inserter Drive Shaft and Outer Sleeve	14-525011
Soft Tissue Sleeve	14-525014
Screw Inserter Handle	14-525056

Ratcheting Handle for Screw Inserter	PART NUMBER
	14-525067

Helical Flange Plug Starter	PART NUMBER
	14-525025

Helical Flange Plug Starter with Handle	PART NUMBER
	14-525031

Helical Flange Plug Driver	PART NUMBER
	14-525037

Dorsal Height Adjuster	PART NUMBER
	14-525028

Quick-Connect Handle	PART NUMBER
	14-521004

Quick-Connect T-Handle	PART NUMBER
	14-525033

Helical Flange Torque T-Handle	PART NUMBER
	14-525036

Helical Flange Torque Handle	PART NUMBER
	14-525035

Torque Stabilizer	PART NUMBER
	14-525030

Head-to-Head Nut Driver	PART NUMBER
	14-525306

Seat Alignment Tool	PART NUMBER
	14-525032

Hook Inserter Drive Shaft and Outer Sleeve	PART NUMBER
(Shown with 14-525056 Screw Inserter Handle)	14-525012

INSTRUMENT VISUAL GUIDE *(continued)*

Hook Site Elevator PART NUMBER

14-525065

Set Screw Driver PART NUMBER

14-525029

Set Screw Torque Wrench Handle PART NUMBER

1200-9027

Cross Connector Stabilizer PART NUMBER

1200-9232

Rod Template PART NUMBER

1200-9024

Ratcheting Rod Cuter PART NUMBER

14-525020

Rod Cuter PART NUMBER

1200-9032

Rod Bender	PART NUMBER
	14-525015

Rod Holder	PART NUMBER
	1200-9030

Rod Gripper	PART NUMBER
	14-525059

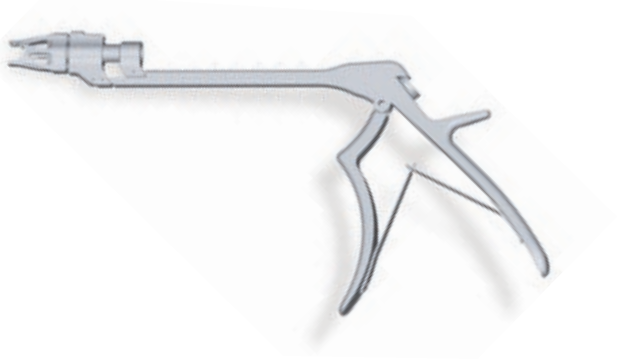
Coronal Bending Iron	PART NUMBER
Right Hand Coronal Bending Iron	14-525016
Left Hand Coronal Bending Iron (Shown)	14-525017

Sagittal Bending Iron	PART NUMBER
Right Hand Sagittal Bending Iron	14-525018
Left Hand Sagittal Bending Iron (Shown)	14-525019

Rocket Hex Key/Driver	PART NUMBER
	14-525022

Rocket Rod Reducer	PART NUMBER
	14-525023

INSTRUMENT VISUAL GUIDE *(continued)*



Reducer with Handle	PART NUMBER
	14-525024

Occipital Plate Templates	PART NUMBER
Small	14-525039
Medium	14-525040
Large	14-525041

Distracter	PART NUMBER
	14-525026

Occipital Drill/Tap Guide	PART NUMBER
	14-525046

Compressor	PART NUMBER
	14-525027

Rigid Occipital Drill	PART NUMBER
	14-525044

Flexible Occipital Drill PART NUMBER

14-525045

Rigid Occipital Tap PART NUMBER

14-525047

Flexible Occipital Tap PART NUMBER

14-525048

Occipital Screw Starter PART NUMBER

14-525049

Occipital Inner Shaft PART NUMBER

14-525058

Occipital Screw Driver PART NUMBER

14-525051

90° Occipital Screw Driver PART NUMBER

14-525052

Occipital Torque Stabilizer PART NUMBER

14-525038

Occipital Plate Bender PART NUMBER

14-525053

INSTRUMENT VISUAL GUIDE *(continued)*

Occipital Plate Hole Cover	PART NUMBER
	14-525054

Occipital Plate Holder	PART NUMBER
	14-525043

Occipital Rod Template	PART NUMBER
	14-525061

IMPORTANT INFORMATION ON LINEUM OCT SPINAL FIXATION SYSTEM

Description

The Lineum OCT Spine System is an occipito-cervico-thoracic spinal fixation system. The system includes screws, locking plugs, various types and styles of rods, hooks, lateral connectors, set screws, occipital plates, rod connectors/dominos and various cross connectors. For occipito-cervico-thoracic fusion, the occipital plate is fixed to the occiput with bone screws. Rods may be cut to the appropriate length. Bone screws are placed in the cervico-thoracic spine (Occiput–T3), and hooks are placed in the cervical spine. The rod is inserted and the construct is locked with plugs. Cross connectors can be added to the construct for additional stability.

The Surgical Technique outlines the recommended placement and use of Lineum OCT Spine System components. Actual selection of system implants may vary from those described in this technique depending on procedural and anatomical considerations.

Indications for Use

The Lineum OCT Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1–C7) and the thoracic spine (T1–T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Lineum OCT Spine 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 spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Lineum OCT Spine System can also be connected to the Zimmer Biomet Polaris System via transitional rods or using the Altius Rod Connectors or Polaris Dominoes. Please refer to the individual system's package insert for a list of indications for use for each system.

Contraindications

1. Active systemic infection or infection local to operative area
2. Morbid obesity
3. A patient who in the surgeon's opinion is not psychosocially, mentally or physically able to fully comply with the post-operative treatment regimen (e.g., mental illness, alcoholism, or drug abuse)
4. Pregnancy
5. Metal sensitivity/foreign body sensitivity
6. Patients with inadequate tissue coverage over the operative site
7. Open wounds local to the operative area

Warnings

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
- Implant Strength and Loading. The Lineum OCT Spine System is intended to assist healing and is not intended to replace normal bony structures. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue.
- Postoperative care is extremely important. Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be warned that noncompliance with postoperative instructions could lead to loosening or breakage of the implant and/or possible migration requiring revision surgery to remove the implant. The patient should be warned of these possibilities and instructed to limit and restrict physical activities especially lifting, twisting and any type of sport participation. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
- Selection of Implants. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present size limitations on the implants.
- Metabolic bone disease such as severe osteoporosis may adversely affect adequate fixation of the implants due to the poor quality of the bone.
- The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. They must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use. All non-sterile components and instruments must be cleaned and sterilized before use.

IMPORTANT INFORMATION ON LINEUM OCT SPINAL FIXATION SYSTEM *(continued)*

Warnings *(continued)*

- Zimmer Biomet spine implants should never be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics, and design.
- Corrosion. Contact of dissimilar metals accelerates the corrosion process, which could increase the possibility of fatigue fracture of the implants. Therefore, only use like or compatible metals for implants that are in contact with each other. Never use stainless steel and titanium implant components in the same construct. Cobalt Chrome Alloy rods should not be used with Stainless Steel Components. Cobalt Chrome Alloy rods are to be used ONLY with titanium implant components in the same construct.
- The Lineum OCT Spine System has not been evaluated for safety and compatibility in the MR environment. The Lineum OCT Spine System has not been tested for heating or migration in the MR environment.

Precautions

- Do Not Reuse Implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in or used on a different patient.
- Handling of Implants. If contouring of the rod is required, avoid sharp bends and reverse bends. Avoid notching or scratching of implants, which could increase internal stresses and lead to early breakage.
- Implant Removal After Healing. After healing is complete, the implant is intended to be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
- Adequate Patient Instructions. A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
- Surgical Techniques. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Please refer to the specific surgical technique for this device for more information. For a copy of the surgical technique, please contact your sales representative or customer service at the address provided below.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
- Bone grafts must be placed in the area to be fused and the graft must contact viable bone.
- The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.
- Pre-Op Planning—Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Possible Adverse Effects

Possible adverse effects include, but are not limited to:

- Bending, loosening or fracture of the implants or instruments, loss of fixation, sensitivity to a metallic foreign body, including possible tumor formation, skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications, nonunion or delayed union, infection, nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral spinal fluid leakage, pain or discomfort, bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra), hemorrhage of blood vessels and/or hematomas, malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height, bursitis, inability to resume activities of normal daily living, reoperation, or death.

Sterilization

Components provided non-sterile must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

U.S. Sterilization Parameters:

Cycle: *High Vacuum*
Temperature: *270°F/132°C*
Time: *4 minutes*
Drying Time: *30 minutes*
Note: *Allow for cooling*

Product Complaints

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Zimmer Biomet Spine.

NOTES

NOTES *(continued)*

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.*

Manufactured by:
Zimmer Biomet Spine, Inc.
10225 Westmoor Dr.
Westminster, CO 80021 USA
+1 800.447.3625

EC REP
Zimmer GmbH
Sulzerallee 8
CH-8404 Winterthur
Switzerland
+41 058.854.80.00

CE 0086

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800.447.3625/zimmerbiomet.com

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