Sequoia®
Pedicle Screw System

ZIMMER BIOMET
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Surgical Technique

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon 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 surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Description/Indications/Contraindications

Description

The Zimmer Biomet Spine *S*equoia Pedicle Screw System is designed to aid in the surgical correction of several types of spinal conditions. This system is intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass.

The Sequoia Pedicle Screw System consisting of open style polyaxial screws, titanium rods (varying lengths) and connectors is intended to provide temporary stabilization following surgery to fuse the spine. The polyaxial screw design allows the surgeon to use a top-loading technique for dropping the spinal rod down to the fixation components into a u-shaped opening.

This system offers a single package containing a wide array of implant styles, allowing the surgeon maximum flexibility to address patient needs.

SpeedLink II™ Transverse Connectors are provided to increase rotational stiffness to the final construct.

Components of the Sequoia Pedicle Screw System are offered in Titanium alloy Ti6Al4V ELI (ASTM F-136) and unalloyed Titanium (ASTM F67).

The Sequoia Pedicle Screw System instrumentation is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, and/or polymeric materials.

Indications

When intended for pedicle screw fixation from T1-S1, the Sequoia Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1- S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

When intended for anterolateral screw, rod and or cable fixation of the T6-L5 spine, the indications are degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

Contraindications

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Sequoia Implants

The Sequoia System features color-coded screws with a double-lead thread to improve intraoperative identification and reduce the number of turns required for full implantation. Importantly, Sequoia screws and closure tops feature a helical flange thread profile designed to reduce head splay and cross-threading. The Sequoia System also features point and rim geometry on the rod-contacting surface of all closure tops to improve resistance to rotation and axial slippage.

Polyaxial Screws (4.5 – 8.5mm)
3306-series

Closure Top
3301-1

Prebent Titanium Rods (30 – 100mm)
3313-series

Straight Titanium Rods (510mm)
3311-510

Adjustable *SpeedLink II*™ Transverse Connector System
3308-35 Small
3309-40 Medium
3310-50 Large

Sequoia Instruments

The Sequoia System features a range of flexible, ergonomic and intuitive instruments, each conceived with the purpose of improving simplicity and ease of use. The result is a series of instruments that provide the flexibility required for multiple approaches, pathologies, patient sizes and correction maneuvers. The Sequoia System includes drivers with low profile and antireflective surfaces that improve visualization through a port under intense light; lightweight overmolded, ergonomic handles; and smooth ratchets to help minimize fatigue. Sequoia instrumentation was designed with the user in mind.

Bone Awl
3350-1

Marks the pedicle entry point.

Pedicle Probes (Curved, Straight, Thoracic)
3352-series

Create a path through the pedicle and into the vertebral body.

Pedicle Sounders
3354-series

Ball-tipped to check pedicle integrity prior to tapping.

Sequoia Screwdriver
3363-1

Drives and adjusts Sequoia System polyaxial pedicle screws.

Non-Cannulated Bone Taps (4.0 – 7.5mm)
3360-040, 3361-045 to 3361-075

Non-cannulated, with a double-lead thread; tap the pedicle to prepare for polyaxial screw placement.

Cannulated Bone Taps (4.5 – 7.5mm)*
3360-045 to 3360-075

Cannulated, with a double-lead thread; tap the pedicle to prepare for polyaxial screw placement over a K-wire.

COLOR CODE	SCREW DIAMETER	ASSOCIATED TAP	ACTUAL TAP DIAMETER	TAP INCLUDED	OPTIONAL
Magenta	4.5mm	4.0mm	3.75mm	Non-Cannulated	N/A
Dark Blue	5.5mm	4.5mm	4.75mm	Non-Cannulated	Cannulated
Light Blue	6.5mm	5.5mm	5.75mm	Non-Cannulated	Cannulated
Green	7.5mm	6.5mm	6.75mm	Non-Cannulated	Cannulated
Gold	8.5mm	7.5mm	7.75mm	Non-Cannulated	Cannulated

** Available by separate order only*

Straight Non-Ratcheting Handle
3358-2

Straight Ratcheting Handle
3358-1

Ratcheting Torque Limiting Driver*
3356-1

Torque Limiting Driver
3356-2

Bi-Directional Ratcheting T-Handle
3357-1

** Available by separate order only*

Rod Holding Forceps

3369-1

Securely hold rod for placement and positioning in the construct.

Power Rod Gripper

3380-1

Alternative to Rod Holding Forceps for secure placement and positioning of the implant rod.

Head Adjuster

3366-1

Aligns polyaxial screw heads for rod placement.

Dorsal Height Adjuster / Revision Tool

3367-2

Backs out an implanted screw to adjust dorsal height or for revision / removal.

French Benders

3378-1

Contour the titanium implant rod to match patient anatomy.

Rod Pusher

3371-1

Manipulates the rod during construct assembly or anatomical correction.

Reduction Forceps

3372-1

Achieve spondylolisthesis reduction and rod approximation.

Power Rod Reducer

3373-1

Alternative means of spondylolisthesis reduction and rod approximation.

Compressor
3374-1

Compresses implants axially along the rod.

Distractor
3376-1

Distracts implants axially along the rod.

Closure Top Starter
3370-2

Initiates closure tops' locking mechanism and retains the closure top for easy and safe implantation.

Counter Torque Tube
3382-1

Provides counter torque leverage for final tightening or closure top removal.

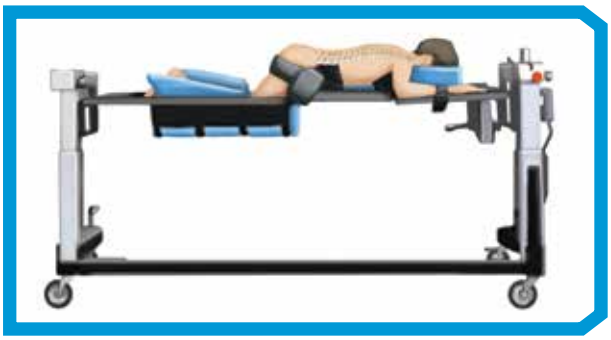
Final Driver
3384-3

Final tightens closure tops and the *SpeedLink II* System.
4.0mm diameter hex.

Surgical Technique

Patient Positioning

Step 1

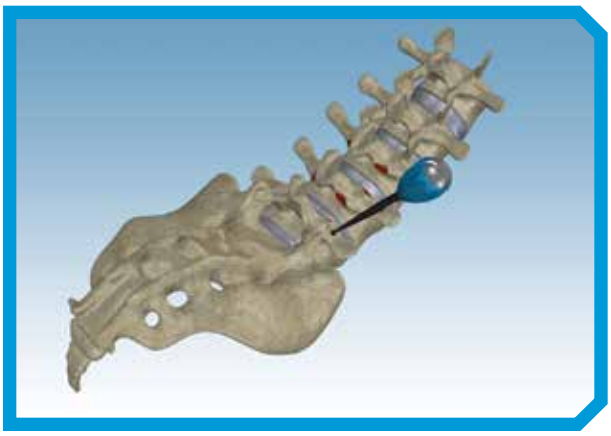


Patient Positioning

Place the patient on a radiolucent operating table in the prone position. Drape the patient for posterior spinal fusion.

Pedicle Preparation

Step 2

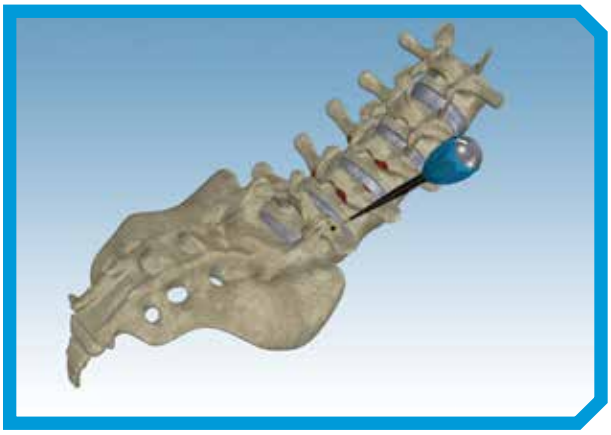


Prepare the Pedicle

Clean the facet joints and remove the inferior facet and the articular cartilage on the superior facet. Identify the intersection of the mid-portion of the transverse process and the pars interarticularis to locate a starting point for each pedicle screw.

At each starting point, use a high-speed burr or the supplied Bone Awl to breach the cortical exterior of the instrumented vertebrae.

Step 3

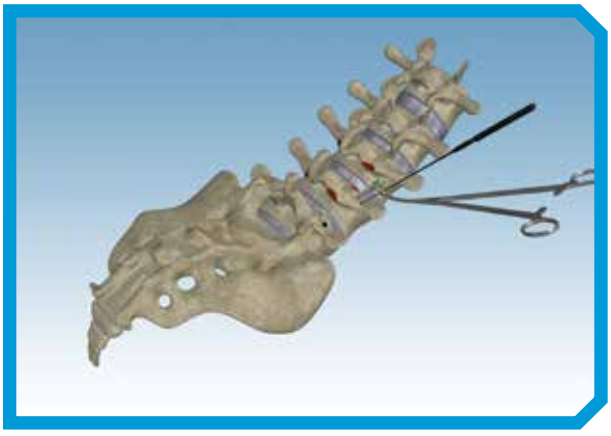


Create Intrapedicular Path

Use a Pedicle Probe to create a path through intrapedicular cancellous bone. If a curved probe is selected, initially orient the curve laterally away from the canal.

Advance the probe through the pedicle and into the vertebral body. If using a curved probe, remove and reorient the probe such that the curve points medially once the tip of it has cleared the pedicle and entered the vertebral body. Carefully reinsert the reoriented probe into the same hole and advance the instrument to the desired screw depth.

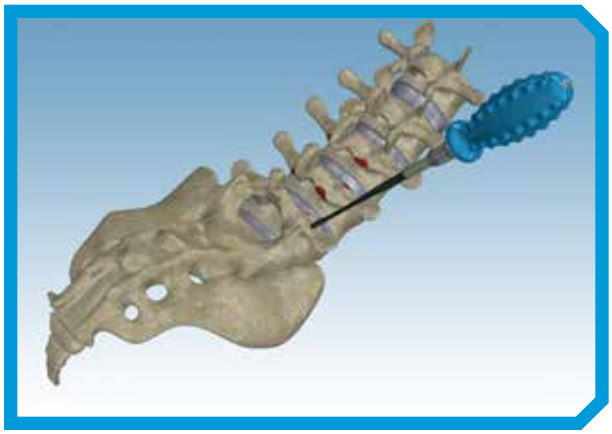
Step 4



Confirm Pedicle Integrity

Remove the Pedicle Probe and use the flexible ball tipped Pedicle Sounder to determine the integrity of the medial, lateral, anterior and posterior walls, as well as the base of the hole created by the probe. If observation reveals a breached pedicle, use the probe again, this time with a different trajectory to mitigate any further cortical breach. With the ball tipped Pedicle Sounder, confirm the integrity of the planned pedicle screw path. Clamp a forceps to the exposed shaft of the sounder to determine the length of the hole.

Step 5



Tap the Pedicle

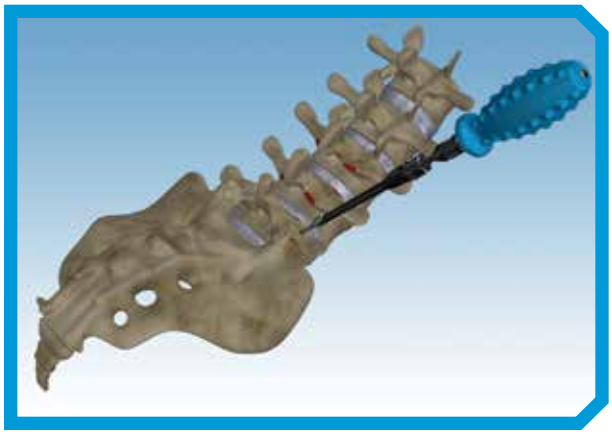
Appropriate screw diameter and length are determined by a combination of preoperative planning/measurement and intraoperative observation. Under-tap the pedicle approximately 0.75mm as compared to the appropriate screw diameter by rotating the tap clockwise. After reaching the desired depth, remove the tap by rotating counterclockwise, maintaining the integrity of the track prepared by the tap's threads. Next, use the pedicle sounder to confirm the integrity of the tapped threads in the interior of the pedicle. Select the proper screw length based on the size of the operatively tapped hole.

***Note:** The Sequoia System offers three styles of handles: Straight Non-Ratcheting, Straight Ratcheting, or Bi-Directional Ratcheting T-Handle.*

***Note:** Tapping with the appropriately sized tap (see table on page 6) is particularly important where larger diameter screws are used or in cases of hard bone.*

Construct Assembly

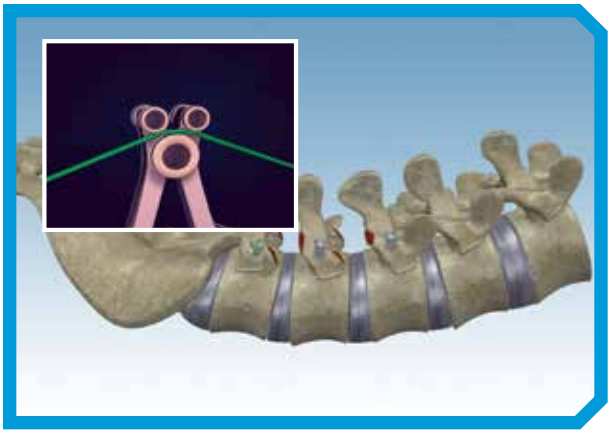
Step 6



Place the Pedicle Screw

Thread the appropriately sized polyaxial screw onto the Polyaxial Screwdriver by aligning the male hex of the screw with the female hex of the driver. Thread the retention shaft of the Polyaxial Screwdriver into the screw head and tighten to eliminate screw toggle. The retention shaft is locked by turning the collet clockwise. Advance the screw down the prepared pedicle until it is seated in the bone with the correct dorsal height. Release the driver from the polyaxial screw by turning the collet counterclockwise to unlock the retention shaft. Turn the retention shaft counterclockwise to release the driver from the screw. Instrument each level as needed and check screw positioning radiographically to ensure proper screw placement.

Step 7



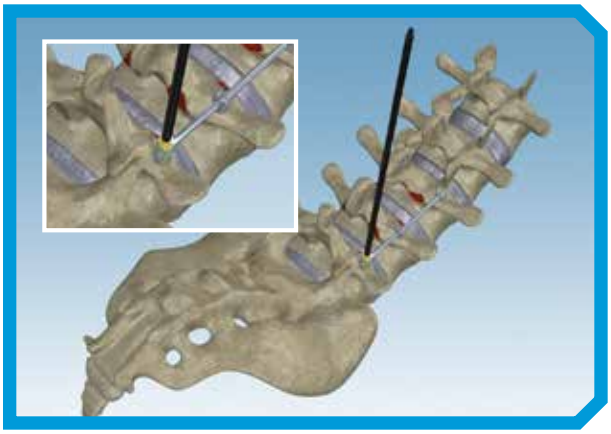
Prepare & Insert the Rod

Once all screws have been placed and their positions verified radiographically, use the supplied rod template to determine the appropriate lordosis and rod length required for optimal correction.

Use a rod cutter to cut the rod to length and the supplied French Benders to achieve the lordosis matching the rod template. Straight and pre-cut/pre-bent rods are available in the *Sequoia* implant tray.

Note: ***Reverse bending can weaken the rod and is not recommended.***

Step 8



Place Closure Tops

After contouring the rod, use the Screw Head Adjuster to ensure all screw heads are aligned. Place the rod into the aligned screw heads with the supplied Rod Holder Forceps. Turn the Closure Top Starter clockwise to introduce closure tops into the screw heads and provisionally tighten.

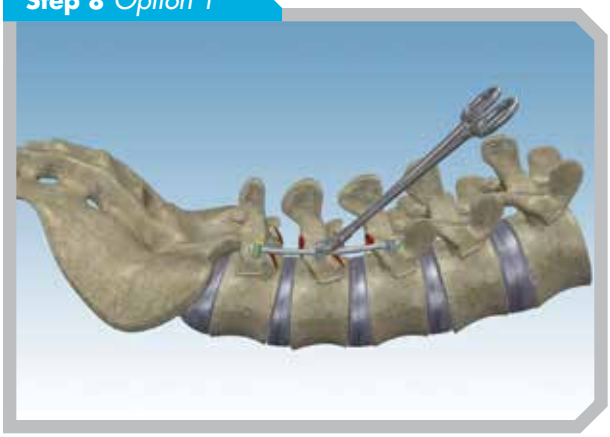
Note: ***Pay special attention to the alignment of the screw tulip relative to the closure top / closure top starter to ensure they are On Axis upon starting the closure top. To introduce the closure top, turn the closure top starter clockwise and provisionally tighten.***

Note: ***Provisional tightening is classified as hand tightening while not fully locking the screw head into place. Step 11 will discuss the final tightening phase of this surgical technique.***

Reduction Option

Step 9 ***Option 1:*** Rod Reduction (If Necessary)

Step 8 *Option 1*

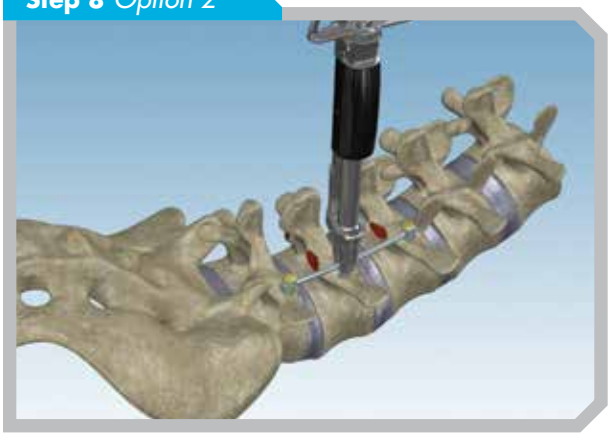


Reduction Forceps

Reduction Forceps can be used when there is only a slight difference between rod and screw saddle height. To use the Reduction Forceps, align the dimples in the side of the Sequoia screw head with the prongs at the end of the forceps. Use the rocker as a lever against the rod to fully seat the rod into the screw head. The Closure Top Starter can then be used to introduce the closure top into the screw head.

Step 9 ***Option 2:*** Rod Reduction (If Necessary)

Step 8 *Option 2*

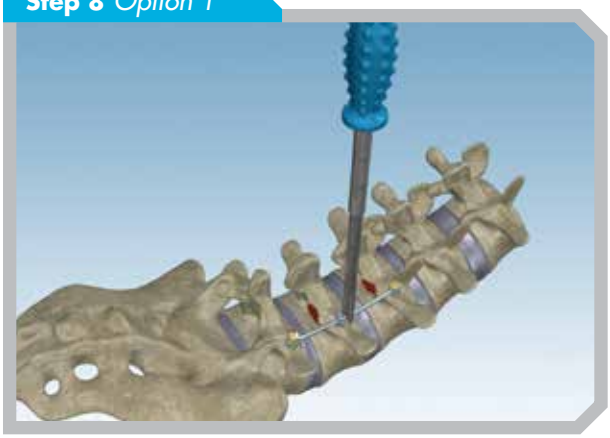


Power Rod Reducer

When the rod is above the implant the Power Rod Reducer may be used to seat the rod into the screw head. The reducer is locked in place over the screw head by matching the dimples on the Sequoia screw to the prongs at the distal end of the Power Rod Reducer. By slowly twisting the bowtie screw at the proximal end of the reducer, the rod may be persuaded into the screw head. A closure top can then be placed through the Power Rod Reducer using the Closure Top Starter.

Step 9 ***Option 3:*** Rod Reduction (If Necessary)

Step 8 *Option 1*



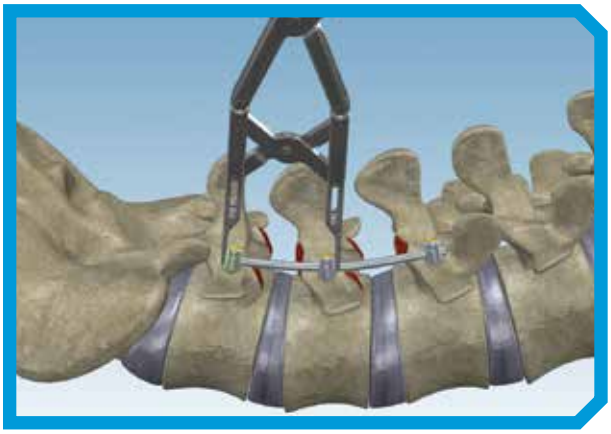
Persuade the Rod

The Rod Pusher may be used to persuade the rod into the screw head by applying force to the Rod Pusher. The distal end of the Rod Pusher has a semicircular recess that fits with the rod. When the rod has been seated into the screw head, a closure top may be introduced using the Closure Top Starter.

Compression and Distraction Options

After provisionally securing the rod to Sequoia implants, distraction and compression can be performed to translate implants axially along the rod.

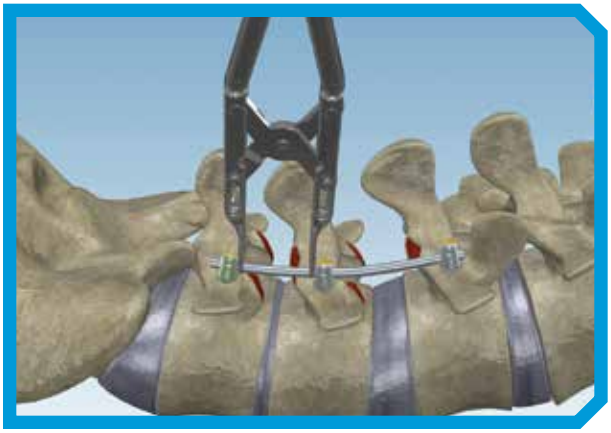
Step 10



Compression (If Necessary)

To compress two implants simultaneously, place the Compressor against the outerbody of the implants and squeeze its handles. Compression can also be performed serially by provisionally locking one implant using the Final Driver and compressing off the provisionally locked implant. When the compression maneuver is complete, provisionally lock the compressed implants with the Final Driver and release the Compressor.

Step 11

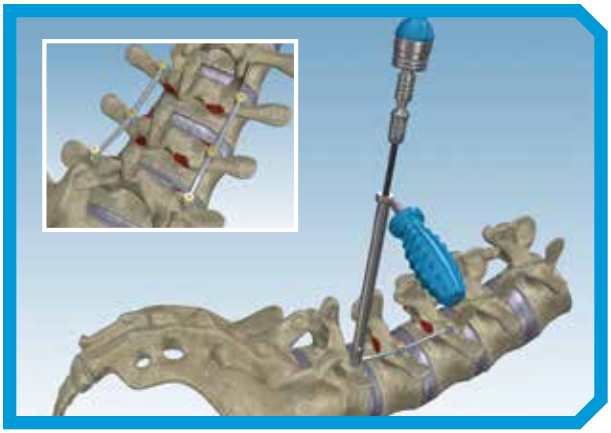


Distraction (If Necessary)

To distract two implants simultaneously, place the Distractor against the interior body of the implants and squeeze its handles. Distraction can also be performed serially by provisionally locking one implant using the Final Driver and distracting off the provisionally locked implant. When the distraction maneuver is complete, provisionally lock the distracted implants with the Final Driver and release the Distractor.

Final Tightening

Step 12



Final Tighten

Final tightening of the construct is performed after all implants are in place, appropriately adjusted and provisionally tightened using the *Sequoia* Final Driver, Torque Limiting Handle and Counter Torque Tubes. To lock a screw, connect the Final Driver to a Torque Limiting Handle. Pass the assembly through the Counter Torque Tube and interface the Final Driver's hex with that of the closure top. Slide the Counter Torque Tube over the screw head, matching the recesses in the tube to the axis of the rod. To avoid construct torsion, use the Counter Torque Tube to tighten the closure top until the Torque Limiting Handle clicks once. The implant is then considered "locked". Repeat with all implants in the construct.

After all implants have been tightened and the construct completed, bone graft can be applied in the normal manner.

Note: ***The Bi-Directional Ratcheting T-Handle cannot be used for final closure top tightening.***

Note: ***Once the device has been fully tightened, it cannot be loosened and re-tightened. Loosening of the fully tightened device during implantation can damage the device and cause a reduction in strength based on the "single-lock" design of the implant. The device should only be provisionally tightened prior to performing intraoperative adjustments (i.e. compression, distraction, de-rotation, etc). This locking process is designed to prevent the device from inappropriately being re-used.***

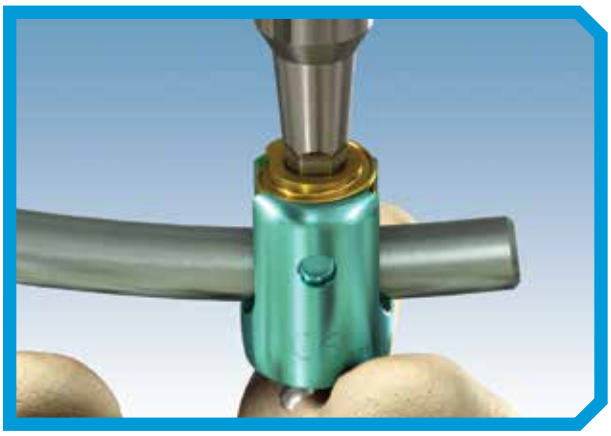
Seating Confirmation

Step 13

Off Axis/Incomplete Seating

The Final Driver may create a false positive that the instrument is fully seated into the closure top. This incorrect position can lead to stripping of the driver and implant.

Step 13b



On Axis/Fully Seated

To ensure proper seating each time, move the T-handle slightly from side to side while applying light downward pressure to establish complete engagement of the Final Driver into the closure top.

Cross Connectors Option

Step 14

Place the *SpeedLink II* System (If Necessary)

Prior to the *SpeedLink II* System placement onto the rod, ensure that the lateral cams are in the “start” or unlocked position. If cams are not in this position, use the *Sequoia* Final Driver with the Non-Ratcheting Straight Handle to unlock cams with a counterclockwise turn. Load the *SpeedLink II* System with the center set screw loose to allow free range of motion and neutral placement of the implant onto the rods.

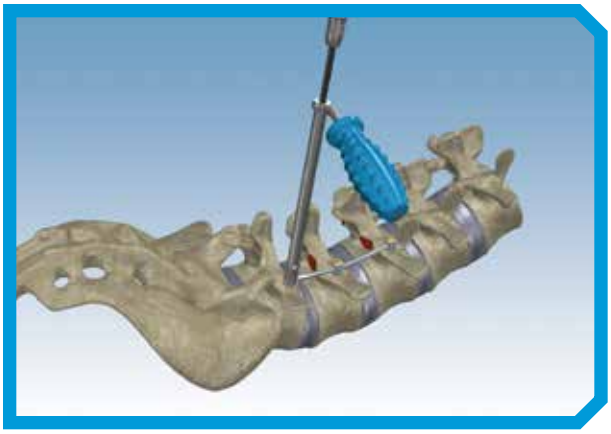
Step 15

Lock the *SpeedLink II* System (If Necessary)

Insert the *Sequoia* Final Driver with the Non-Ratcheting Straight Handle into the cam hex drive with the indicator line pointing in the medial direction. Rotate the driver to lock both lateral cams to the rods (Approximately 1/2 turn of each cam). Final tighten the center set screw using the *Sequoia* Final Driver. Re-insert the Final Driver and use tactile feedback to ensure both lateral cams are in the fully tightened position.

Removal or Revision Option

Step 16



Remove Closure Tops (If Necessary)

Closure top removal can be accomplished by turning the closure top counterclockwise using the Final Driver. A Counter Torque Tube can be used to provide the additional leverage needed to loosen the closure top. When all closure tops have been removed, the rod may be removed manually or using the Rod Holder Forceps.

***Note:** As described in the IFU, the DEVICE is intended for single use and can be fully tightened only one time. Loosening of a fully tightened device during implantation can damage the device and cause reduced strength.*

Step 17

Remove Implanted Screw (If Necessary)

The Sequoia Dorsal Height Adjuster or the Sequoia Screwdriver can be used to remove an implanted screw. To remove a screw using the Dorsal Height Adjuster, align the Dorsal Height Adjuster coaxially with the shank of the screw and engage the adjuster's female hex with the male hex of the screw shank. Turn the Dorsal Height Adjuster counterclockwise to back out an implanted screw.

To remove a screw using the Sequoia Screwdriver, align the driver coaxially with the shank of the screw and engage the driver's female hex with the male hex of the screw. Turn the retention sleeve clockwise to fully engage the screw head. Lock the retention sleeve by turning the locking collet clockwise. Turn the driver counterclockwise to remove an implanted screw.

Sequoia Kit Contents

Kit Number 3300-0006-PL

Sequoia Gen 1 Revision Instrument Kit

Part Number	Description	Quantity
3358-2	Modular Straight, Non-Racheting Handle	1
3362-1	Gen 1 Revision Driver	2
3367-0	Gen 1 Revision Tool	1
3382-1	Counter-Torque Tube	1
3384-3	Sequoia Final Driver	2

Kit Number 3300-0008-PL

Sequoia Cannulated Taps Kit

Part Number	Description	Quantity
3360-045	Sequoia 4.5mm Cannulated Tap	1
3360-055	Sequoia 5.5mm Cannulated Tap	1
3360-065	Sequoia 6.5mm Cannulated Tap	1
3360-075	Sequoia 7.5mm Cannulated Tap	1

Kit Number 3300-0143-PL

Degenerative Implant Kit

Part Number	Description	Quantity
3306-4525	Sequoia Ti Poly Screw Assy 4.5 x 25	6
3306-4530	Sequoia Ti Poly Screw Assy 4.5 x 30	8
3306-4535	Sequoia Ti Poly Screw Assy 4.5 x 35	8
3306-4540	Sequoia Ti Poly Screw Assy 4.5 x 40	8
3306-4545	Sequoia Ti Poly Screw Assy 4.5 x 45	6
3306-5525	Sequoia Ti Poly Screw Assy 5.5 x 25	4
3306-5530	Sequoia Ti Poly Screw Assy 5.5 x 30	6
3306-5535	Sequoia Ti Poly Screw Assy 5.5 x 35	8
3306-5540	Sequoia Ti Poly Screw Assy 5.5 x 40	8
3306-5545	Sequoia Ti Poly Screw Assy 5.5 x 45	8
3306-5550	Sequoia Ti Poly Screw Assy 5.5 x 50	6
3306-5555	Sequoia Ti Poly Screw Assy 5.5 x 55	4

Degenerative Implant Kit (Continued)

Part Number	Description	Quantity
3306-5560	Sequoia Ti Poly Screw Assy 5.5 x 60	2
3306-6530	Sequoia Ti Poly Screw Assy 6.5 x 30	6
3306-6535	Sequoia Ti Poly Screw Assy 6.5 x 35	8
3306-6540	Sequoia Ti Poly Screw Assy 6.5 x 40	8
3306-6545	Sequoia Ti Poly Screw Assy 6.5 x 45	8
3306-6550	Sequoia Ti Poly Screw Assy 6.5 x 50	6
3306-6555	Sequoia Ti Poly Screw Assy 6.5 x 55	4
3306-6560	Sequoia Ti Poly Screw Assy 6.5 x 60	2
3306-7530	Sequoia Ti Poly Screw Assy 7.5 x 30	4
3306-7535	Sequoia Ti Poly Screw Assy 7.5 x 35	4
3306-7540	Sequoia Ti Poly Screw Assy 7.5 x 40	6
3306-7545	Sequoia Ti Poly Screw Assy 7.5 x 45	6
3306-7550	Sequoia Ti Poly Screw Assy 7.5 x 50	4
3306-7555	Sequoia Ti Poly Screw Assy 7.5 x 55	4
3306-7560	Sequoia Ti Poly Screw Assy 7.5 x 60	2
3306-8530	Sequoia Ti Poly Screw Assy 8.5 x 30	4
3306-8535	Sequoia Ti Poly Screw Assy 8.5 x 35	4
3306-8540	Sequoia Ti Poly Screw Assy 8.5 x 40	4
3306-8545	Sequoia Ti Poly Screw Assy 8.5 x 45	4
3306-8550	Sequoia Ti Poly Screw Assy 8.5 x 50	2
3306-8555	Sequoia Ti Poly Screw Assy 8.5 x 55	2
3306-8560	Sequoia Ti Poly Screw Assy 8.5 x 60	2
3301-1	Sequoia Closure Top	30
3313-030	Sequoia Prebent Rod CP Ti 30mm	2
3313-035	Sequoia Prebent Rod CP Ti 35mm	2
3313-040	Sequoia Prebent Rod CP Ti 40mm	2
3313-045	Sequoia Prebent Rod CP Ti 45mm	2
3313-050	Sequoia Prebent Rod CP Ti 50mm	2
3313-055	Sequoia Prebent Rod CP Ti 55mm	2
3313-060	Sequoia Prebent Rod CP Ti 60mm	2
3313-065	Sequoia Prebent Rod CP Ti 65mm	2
3313-070	Sequoia Prebent Rod CP Ti 70mm	2
3313-075	Sequoia Prebent Rod CP Ti 75mm	2
3313-080	Sequoia Prebent Rod CP Ti 80mm	2
3313-085	Sequoia Prebent Rod CP Ti 85mm	2
3313-090	Sequoia Prebent Rod CP Ti 90mm	2
3313-095	Sequoia Prebent Rod CP Ti 95mm	2

Degenerative Implant Kit (Continued)

Part Number	Description	Quantity
3313-100	Sequoia Prebent Rod CP Ti 100mm	2
3311-510	Sequoia Straight Rod CP Ti 510mm	2
3308-35	SpeedLink II Ti Small	2
3309-40	SpeedLink II Ti Medium	2
3310-50	SpeedLink II Ti Large	2

Kit Number 3300-0145-PL-A

Degenerative Instrument Kit A

Part Number	Description	Quantity
Tray 1		
3350-1	Bone Awl	1
3352-1	Pedicle Probe, Curved	1
3352-2	Pedicle Probe, Straight	1
3352-3	Pedicle Probe, Thoracic Curved	1
3354-1	Pedicle Sounder, Curved	1
3354-2	Pedicle Sounder, Straight	1
3354-3	Pedicle Sounder, Straight Stiff	1
3356-2	Modular Handle, T Non-Ratcheting Torque Limiting 90 in-lb	1
3358-1	Modular Handle, Straight Ratcheting	2
3358-2	Modular Handle, Straight Non-Ratcheting	1
3360-040	Sequoia Bone Tap. 4.0mm	1
3361-045	Sequoia Bone Tap. 4.5mm	1
3361-055	Sequoia Bone Tap. 5.5mm	1
3361-065	Sequoia Bone Tap. 6.5mm	1
3361-075	Sequoia Bone Tap. 7.5mm	1
3363-1	Sequoia Screw Driver	2
3366-1	Screw Head Adjuster	1
3367-2	Dorsal Height Adjuster	1
3369-1	Rod Forceps	1
3370-2	Closure Top Starter	2
3372-1	Reduction Forceps	1
3382-1	Counter Torque Tube	1
3384-3	Final Driver	2
857-150	Trial Rod, 150mm	1

Kit Number 3300-0146-PL-B

Degenerative Instrument Kit B

Part Number	Description	Quantity
Tray 2		
3371-1	Rod Pusher	1
3373-1	Sequoia Power Rod Reducer	1
3374-1	Compressor	1
3376-1	Distractor	1
3378-1	French Benders	1
3380-1	Power Rod Gripper	1
3357-1	Sequoia Bi-directional Ratcheting Handle	1

Warnings and Precautions

Warnings

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. 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 secondary to 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 is unknown.
3. BENEFIT OF SPINAL FUSIONS UTILIZING ANY PEDICLE SCREW FIXATION SYSTEM HAS NOT BEEN ADEQUATELY ESTABLISHED IN PATIENTS WITH STABLE SPINES. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a) Device component fracture
   b) Loss of fixation
   c) Non-union
   d) Fracture of the vertebra
   e) Neurological injury
   f) Vascular or visceral injury
4. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

6. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.

7. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

   b) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.

   c) A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

   d) Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.

   e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

   f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

Precautions

1. THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED 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.
2. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
3. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
4. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, and possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove implant thus eliminating the risk involved with a second surgery.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight- supporting devices may be particularly at risk during postoperative rehabilitation.

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. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.*

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