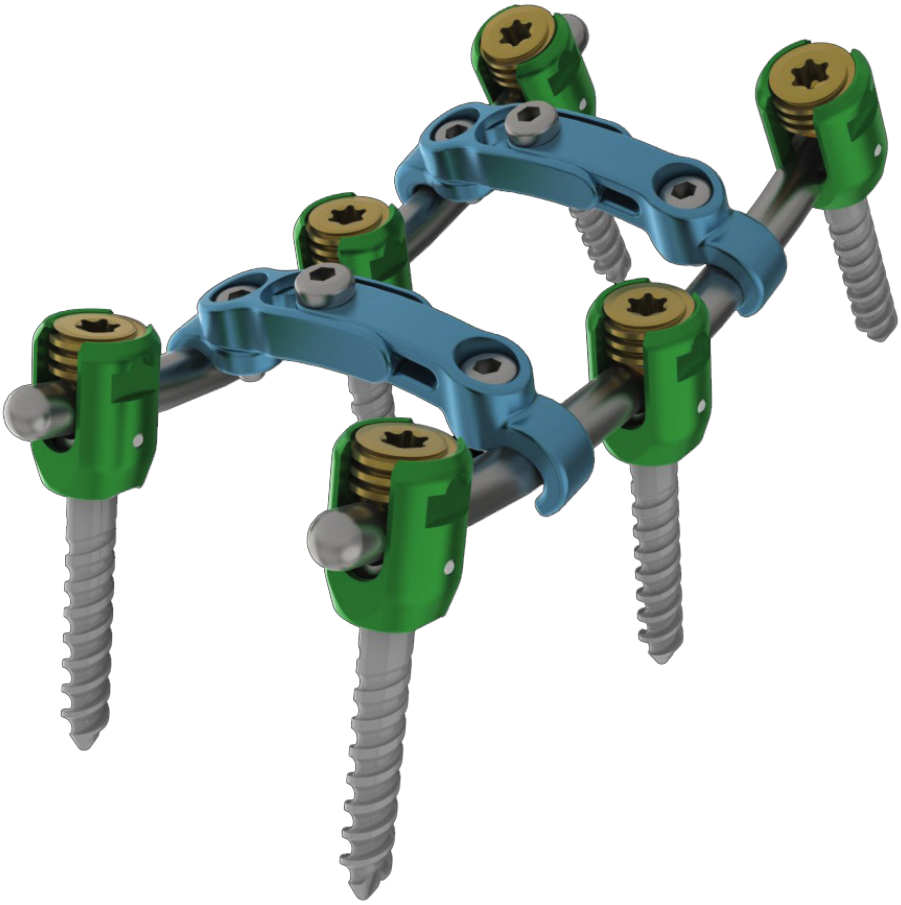
InSource Ortho LLC



Leucadia

Pedicle Screw System
Surgical Technique Guide

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Pedicle Screw System

Surgical Technique Guide

Preface

The Leucadia Pedicle Screw System is a posterior spinal fixation system consisting of implants and instrumentation. It represents the culmination of a development process with a focus on reliability, safety, ease of use, flexibility and simplicity.

This document is intended as a general guide for the use and implantation of the Leucadia Pedicle Screw System. It is expected that the surgeon is already familiar with the fundamentals of spinal fusion and instrumentation surgery.

Each patient represents an individual case that may require the surgeon to modify his technique according to the clinical requirements of the case. Please refer to the Instructions For Use for device description, intended use, indications for use, contraindications, precautions, warnings and potential risks associated with the use of this product.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

**Actual product appearance may vary*

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Leucadia

Pedicle Screw System

Surgical Technique Guide

Table of Contents

69002_J

Leucadia

Pedicle Screw System

Surgical Technique Guide

Introduction

The Leucadia Pedicle Screw System was designed by InSource Ortho's spine product engineers in collaboration with highly experienced and reputable spine surgeons. The system is uniquely designed for easy and reliable stabilization, combining ease of use with one of the lowest profiles and durable pedicle screw designs in the industry.

Key Features

- Low profile design
- Reduction & Non-Reduction Polyaxial heads
- Double lead screw shank
- Pre-cut, contoured rods
- MRI compatible Titanium Alloy
- Self-tapping screws
- Color coding for size differentiation
- Custom instrumentation

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Pedicle Screw System

Surgical Technique Guide

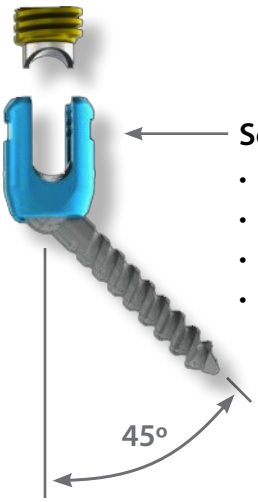
Pedicle Screw

Locking Nut / Set Screw

- Single size
- Stable thread profile
- Unique design

Screw Shaft

- Self-tapping design
- Diameters are from 5mm to 8mm
- Lengths 30-80mm
- Increased pull-out strength
- MRI compatible titanium alloy
- ~60° multiaxial angulation
- 45° angulation in the transverse plane only



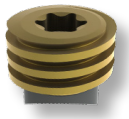
Screw Head

- Unique thread design
- Low profil
- Color coded by size
- Reduction & Non-Reduction Polyaxial

Non-Reduction Polyaxial head

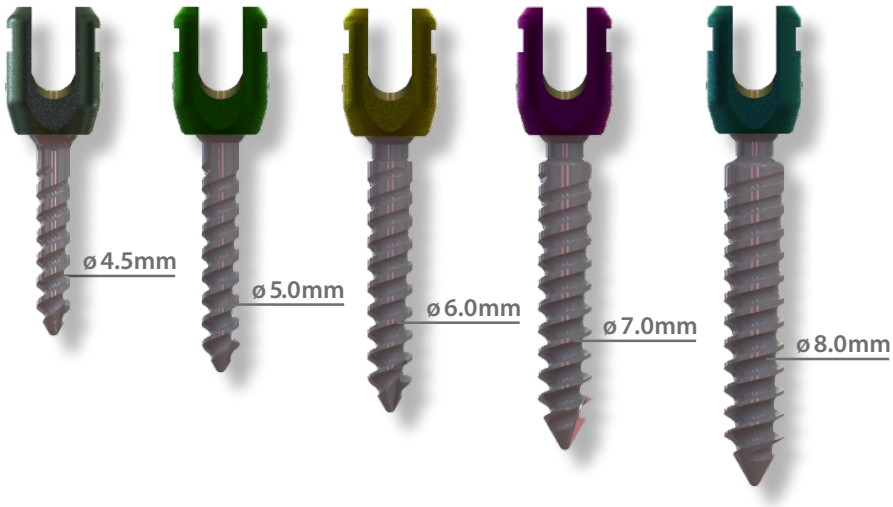
Reduction Polyaxial head

Locking Nut



Single Piece Set Screw (Optional)

Titanium screw heads are color coded by screw diameter



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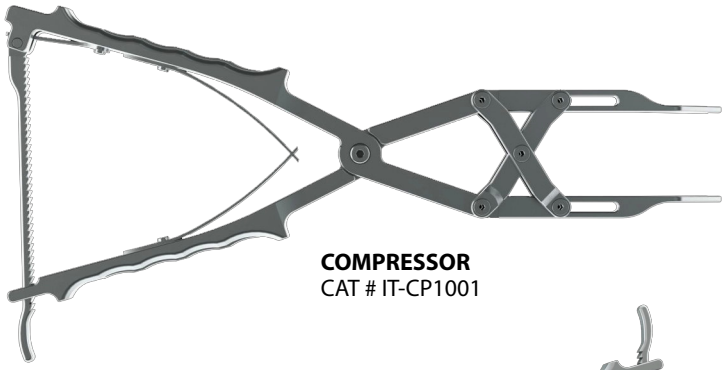
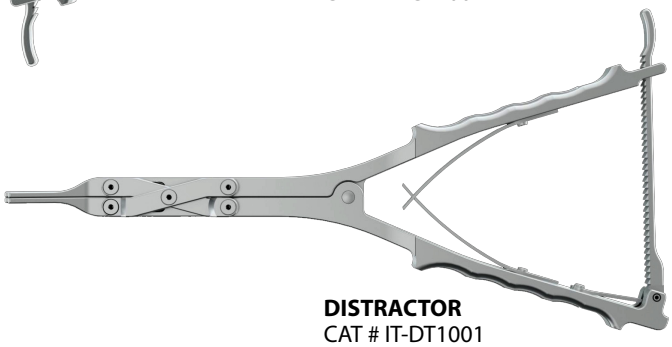
Pedicle Screw System

Surgical Technique Guide

Instrumentation



COMPRESSOR
CAT # IT-CP1001



DISTRACTOR
CAT # IT-DT1001

FRENCH ROD BENDER
CAT # IT-FB1001

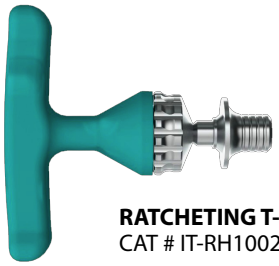
BALL TIP PROBE
CAT # IT-SP1001

CURVED BONE PROBE WITH BALL HANDLE
CAT # IT-BP1001

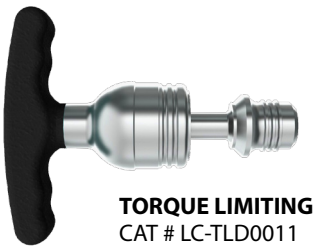
STRAIGHT BONE PROBE WITH BALL HANDLE
CAT # IT-BP1002

RETAINING RING
CAT # IT-RR1001

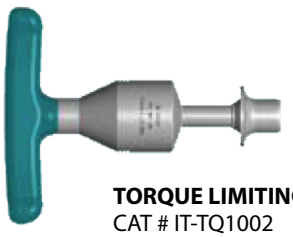
QUICK CONNECT RATCHETING HANDLE
CAT# IT-RH1003



RATCHETING T-HANDLE
CAT # IT-RH1002



TORQUE LIMITING DRIVER (12 Nm)
CAT # LC-TLD0011
* Use with set screw CO-HSS1011 only



TORQUE LIMITING DRIVER (10.16 Nm)
CAT # IT-TQ1002
* Use with locking nut LG-LN1004 only
* Available upon request

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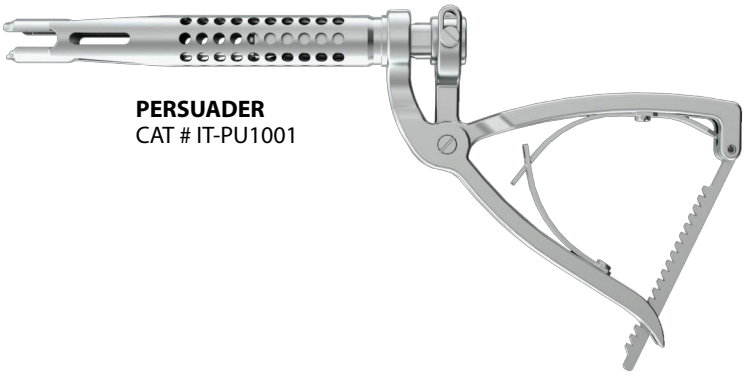
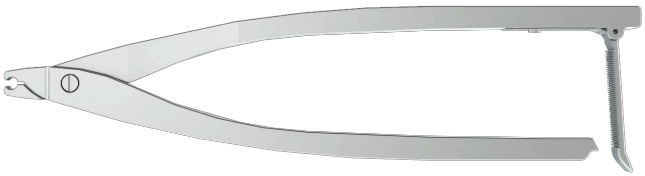
Pedicle Screw System

Surgical Technique Guide

Instrumentation



PERSUADER
CAT # IT-PU1001



ROD GRIPPER
CAT # IT-RG1002

LOCKING NUT HEXALOBE DRIVER
CAT # IT-SD1010 (LONG)
CAT # IT-SD1009 (SHORT)

TRIAL ROD
CAT # IT-TR1001

EXTENSION REMOVER
CAT # IT-XR1001

TAP, SIZE 5
CAT # LC-ST0005

TAP, SIZE 6
CAT # LC-ST0006

TAP, SIZE 7
CAT # LC-ST0007

TAP, SIZE 8
CAT # LC-ST0008

Instrumentation

NEWPORT AWL
CAT # IT-BA1001

VAMPIRE AWL
CAT # IT-BA1002

ROCKER
CAT # IT-RK1001

ROD PUSHER
CAT # IT-RP1001

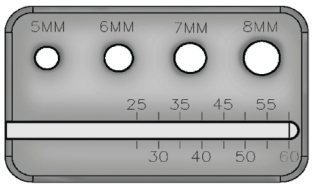
POLYAXIAL HEAD POSITIONER
CAT # IT-HP1002

IN-SITU BENDER, LEFT
CAT # IT-NS1001

IN-SITU BENDER, RIGHT
CAT # IT-NS1002

MULTIAXIAL SCREWDRIVER
CAT # IT-SD1006

COUNTER TORQUE WRENCH
CAT # IT-CT1002



SCREW GAUGE BLOCK
CAT # IT-SG1001

Surgical Exposure andApproach

Patient Positioning andExposure

The patient should be placed in a prone position on a radiolucent surgical table following all necessary safety protocols. The table used should be designed for posterior spine surgery and accommodate the use of a C-arm image intensifier that can be placed under the patient. It is recommended that the surgeon confirm patient positioning and surgical site prior to sterile prepping and draping.

Once surgical exposure is obtained, a lateral radiograph or C-arm image (together with clinical verification) should be taken to assist in determining levels exposed and the orientation of the pedicles (see Figure 1).

Figure 1

Pedicle Preparation

After the soft tissue has been retracted, the transverse process is identified. The cortex is prepared and fenestrated with the awl where the ridge of the pars interarticularis joins the mid portion of the transverse process (see Figure 2).

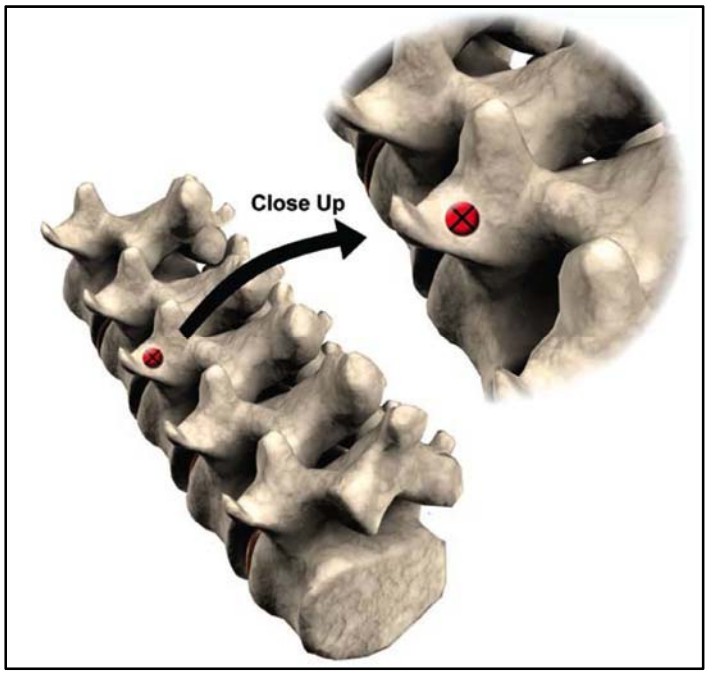


Figure 2

After a starting hole is created by fenestrating the cortex using either the newport awl or vampire awl, based on anatomy and surgeon preference (see Figure 3), a straight or curved pedicle probe is gently pushed down the core of the pedicle into the cancellous bone of the vertebral body. This maneuver creates a controlled channel for the insertion of a tap or pedicle screw.

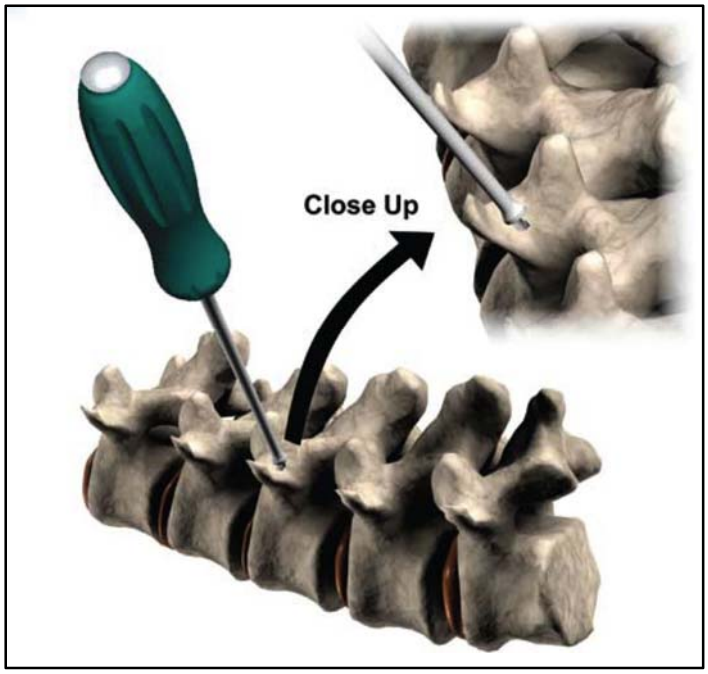


Figure 3

Pedicle Preparation

Once the initial channel is created using the appropriate pedicle probe, a ball tipped probe (feeler probe) should be inserted to verify that the pathway is entirely inside the parameters of the vertebral body at all depths (see Figure 4). The ball tipped probe is relatively malleable and may be gently angled prior to use per the surgeons preference and/or the patient's anatomy.

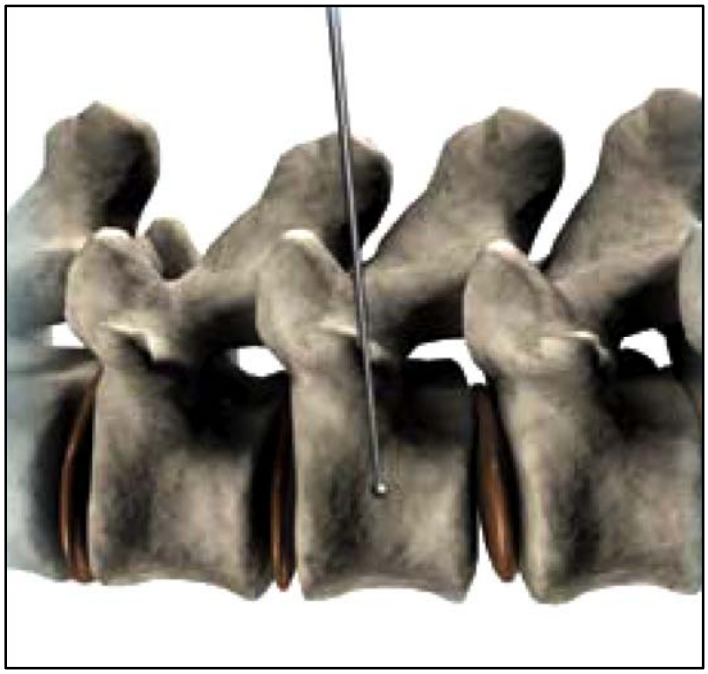


Figure 4

After the channel through the pedicle into the vertebral body is created, checked and measured, the appropriate size screw may be inserted. The Leucadia Pedicle Screws are designed to be self-tapping; however, if the bone is dense or sclerotic, a separate corresponding size tap may be required. Carefully advance the tap through the pedicle into the vertebral body to the desired depth (see Figure 5). Use a ball tipped probe to detect any perforations in the pedicle and vertebral body walls before spinal screw insertion.

EMG monitoring for verification of the absence of pedicular wall penetration may be employed at this time.

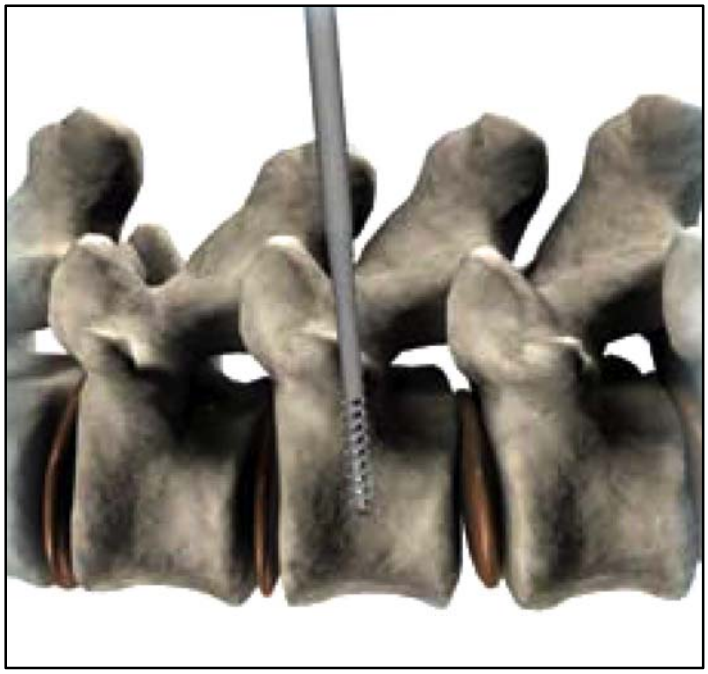
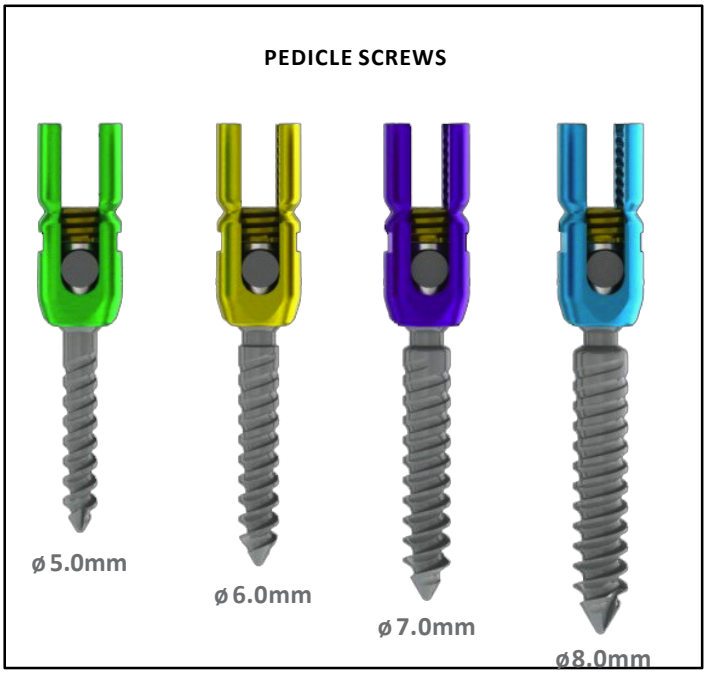


Figure 5

Pedicle Preparation

The Leucadia taps sizes 4, 5, 6 and 7mm allow the surgeon to select the appropriate size tap for the corresponding pedicle screw. The 1mm increments allow for precise under-tapping in relation to the selected pedicle screw diameters of (5mm, 6mm, 7mm or 8mm) facilitating proper screw purchase after tapping.

The Leucadia System includes two styles of taps with differing features, offering the surgeon added choice and flexibility. The key difference between the Taps are the thread profile, penetration depths and cutting flutes.



Polyaxial Screw Insertion

After determining the proper screw diameter and length, insert the hex end of the multi-axial screwdriver into the screw head (see Figure 6a). Then, thread the screwdriver sleeve into the screw head. Make sure that the hex end is fully engaged in the bone screw so that the "T" is completely seated into the saddle of the screw assembly (see Figures 6b and 6c). This allows the surgeon to grasp the screw head securely and firmly control the angle of screw insertion.

Once the screw has been securely seated into the pedicle, disengage the instrument sleeve and remove the screwdriver. The same screwdriver may be used for polyaxial and monoaxial screws.

Repeat all these steps for each screw.

In order to evaluate the position of the screws, a lateral radiograph should be taken. When fully inserted, the screws should extend 50 to 80% into the vertebral body (see Figure 7). Bicortical purchase can be used for sacral fixation particularly if the bone is osteopenic. For optimum fixation of the S1 pedicle screw, some surgeons suggest directing the screw toward the anterior–superior angle of the vertebral body.

Intraoperative EMG monitoring may be used based on availability and surgeondiscretion.

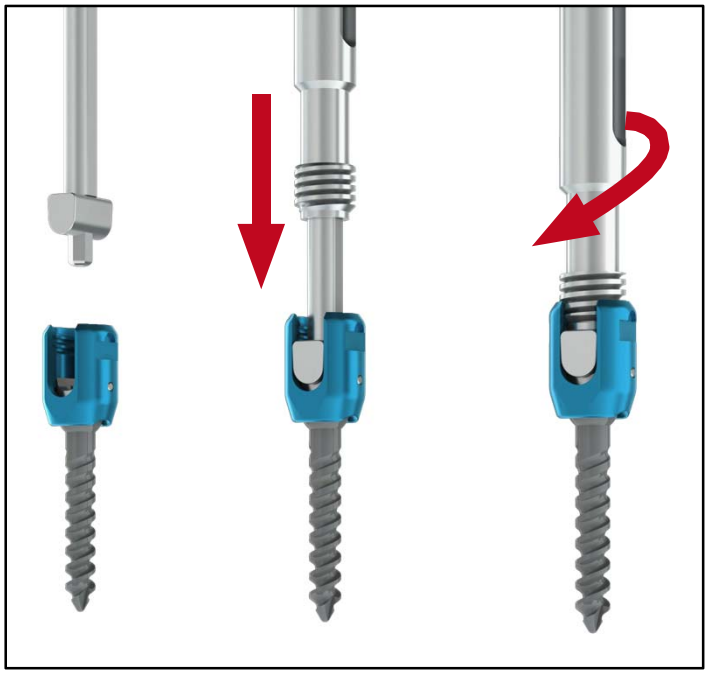


Figure 6a Figure 6b Figure 6c

Figure 7

Head Positioning

The operating table being used should allow for maximum lumbar lordosis in the prone position. The multi-axial screwdriver should be used to adjust the depth of the screws so that when the rod is seated in the screw heads, lumbar lordosis is preserved. The head positioner should be employed to align the heads of the polyaxial screws prior to insertion of the rod (see Figure 8).

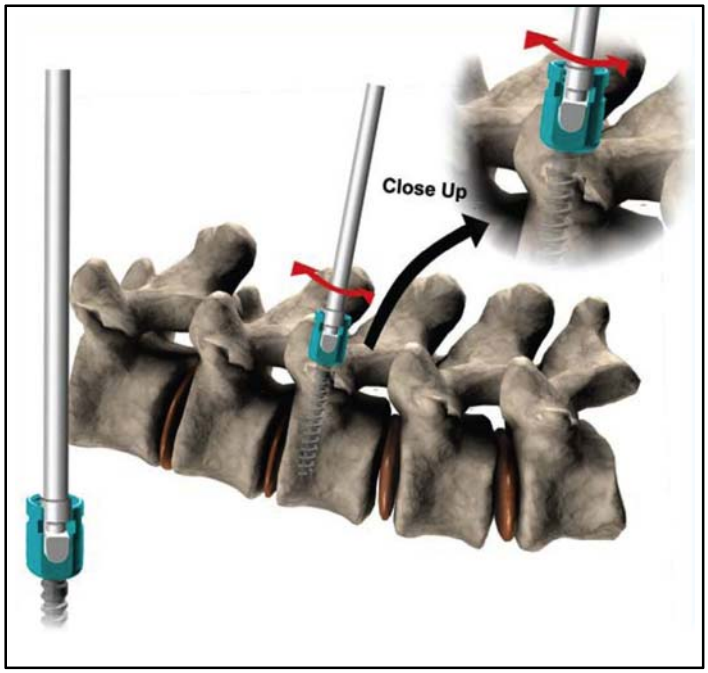


Figure 8

Rod Insertion

The Leucadia Pedicle Screw System provides a selection of pre-bent and straight rods. A malleable trial rod is also available in the set for use as a template to bending the rods before insertion. Using the rod gripper, insert the rod into the aligned screw heads (see Figure 9). If a straight rod is selected for physiological French rod a long construct, it should be bent into lordosis before insertion. Use the included bender to customize the curvature of a selected rod. A standard tabletop rod-cutting device may be used to customize the length of a selected rod (this instrument is not part of the Leucadia Pedicle Screw System).

Note: It is recommended that the rods be bent once and in one direction only as any other bending may cause weakening or failure of the rod.

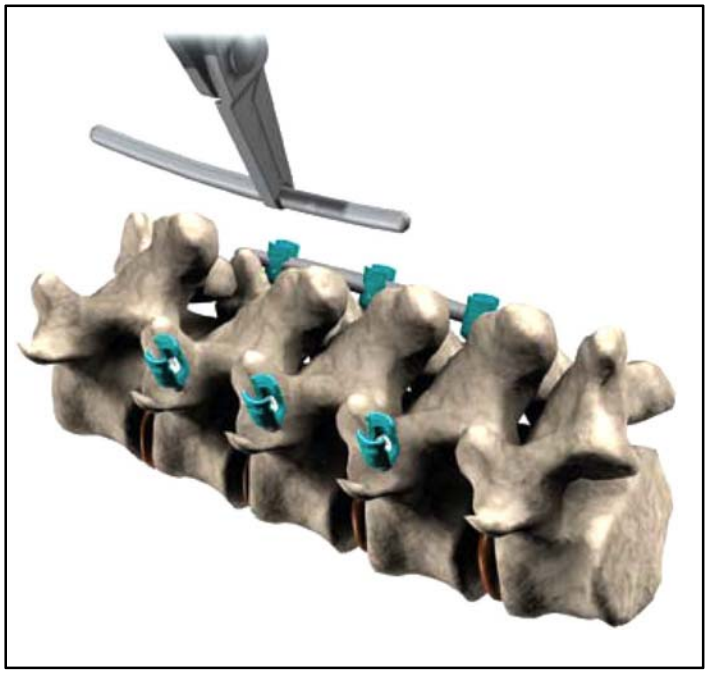


Figure 9

Locking Nut / Set Screw Insertion

Once the selected rod is appropriately positioned in the saddle of the screw head, the locking nut should be inserted into the head of the screw using the self-capturing hexalobe driver (see Figure 10). Correct alignment of the locking nut with the screw head is imperative for proper locking of the construct.

Confirm that the rod is fully reduced and seated against the bottom saddle of the screw head. If rod reduction is necessary, use the rocker or persuader to reduce rod (see "Rod Reduction" section for detailed instructions). If unable to visually confirm proper seating and alignment, always use a persuader.

WARNING: Failure to assure full rod reduction and proper rod alignment before final tightening may result in subsequent loosening of the construct.

Note: Do not fully tighten the locking nuts until geometry of construct is verified as acceptable. As necessary, perform vertebral body reduction, compression and distraction per instructions in the following sections. Perform final tightening of the locking nuts as per instructions in section, "Final Tightening".

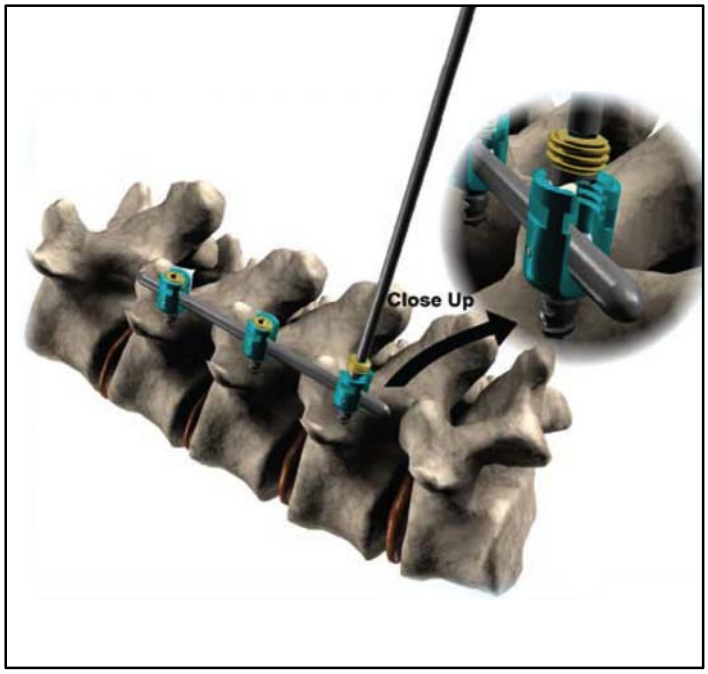


Figure 10

Do not torque down the locking nut at this time.

** "Set Screw" may be used wherever "Locking Nut" is mentioned above.*

Rod Reduction

In order to achieve proper locking of the construct, the rod must be completely and symmetrically seated against the bottom saddle of the screw head prior to tightening the locking nut. Improper seating of the rod may lead to increased resistance of the rod against the locking nut during tightening, and incomplete locking of the construct. If the rod is not fully seated into the saddle of the screw head, the rocker can be used to seat it. Use of the rocker is recommended when only minimal rod reduction is required. If greater force is necessary to properly seat the rod, the persuader should be used prior to locking the construct with the locking nut (see Figure 12a & b). The locking nut should not be used to reduce the Rod into proper position.

Be sure the rod is bent to the appropriate curvature. Engage the slots on the sides of the screw head with the nipples on the jaws of the rocker so that the rocker cam is positioned above the rod (see Figure 11a). Bring the rocker carefully down toward the rod pushing it into the saddle of the screw head (see Figure 11b).

Caution: The use of excessive force in the reduction may pull the screw out of the bone or shift the vertebral body.

Note: Use only the recommended instrumentation for this procedure to avoid dislodgement of the implants and/or damage to the bony anatomy.

** "Set Screw" may be used wherever "Locking Nut" is mentioned above.*

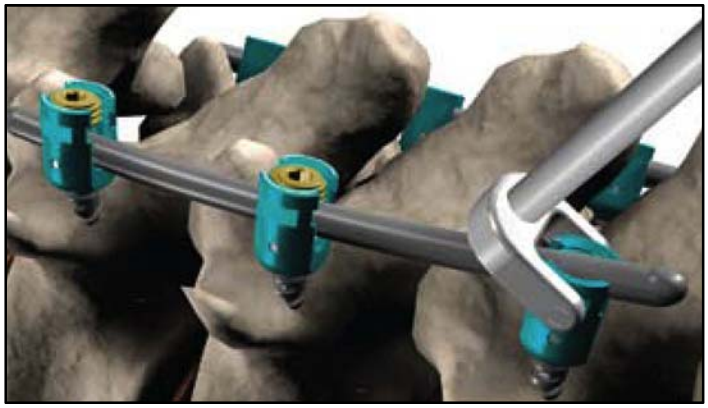


Figure 11a

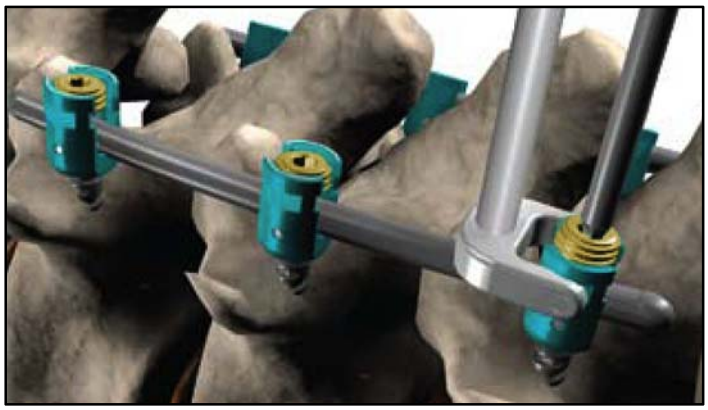


Figure 11b

Rod Reduction

If the rod protrudes beyond the top of the implanted screw head, use the persuader instrument to reduce it. Grasp the screw head in the jaws of the persuader by partially compressing the handles. Once the screw head is engaged, slowly compress the handles completely in order to reduce the rod into the saddle of the screw head. The persuader may be locked into position by engaging its ratcheting arm (see Figure 12a &12b).

Figure 12a

Figure 12b

Rod Reduction

Insert the screwdriver with locking nut attached through the center of the persuader and advance into the screw head (see Figure 13). Do not over-tighten the locking nut as this will preclude and adjustments during compression or distraction prior to final tightening.

Figure 13

Vertebral Body Reduction

In the case of anterolisthesis where the surgeon may want to move one vertebral body posteriorly on another, a winged reduction screw may be necessary. After the screw is inserted into the pedicle to the desired depth, and the rod has been placed between the wings of the screw head, a retaining ring should be temporarily inserted over the screw head until it is resting on the rod (see Figure 14). A locking nut is then threaded down to the rod, while the retaining ring is held in position, thereby pulling the pedicle screw back towards the rod. Once the surgeon has achieved a satisfactory reduction and the locking nut is securely seated in the screw head, the retaining ring must be removed.

** "Set Screw" may be used wherever "Locking Nut" is mentioned above.*

Figure 14

Tab Removal

After the reduction has been completed and verified, the wings (tabs) on the reduction screw head should be removed with the extension remover instrument (see Figures 15a & 15b).

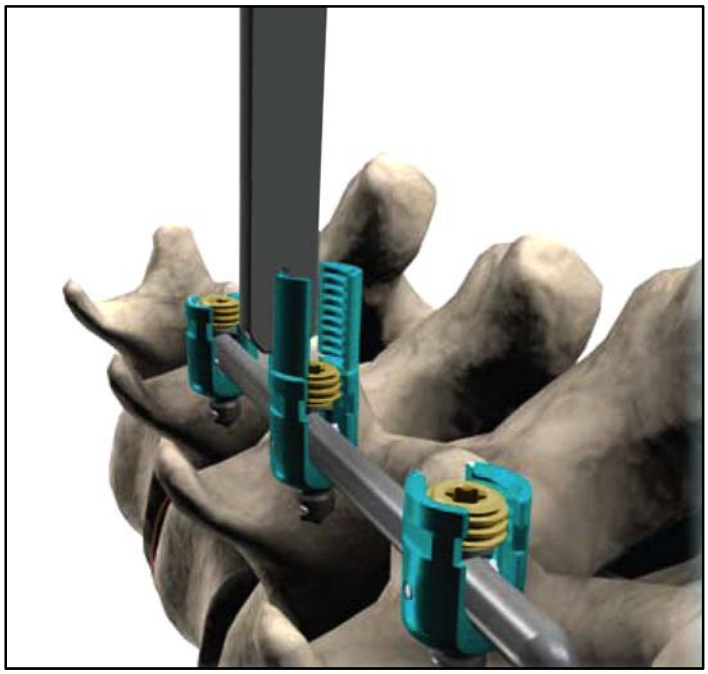


Figure 15a

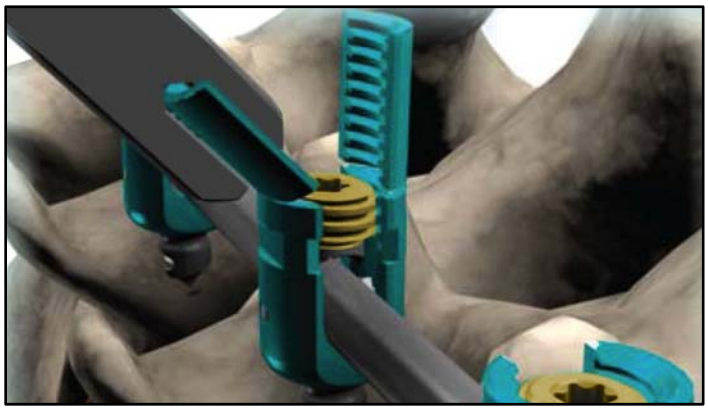


Figure 15b

Compression and Distraction

If compression or distraction is needed, use the screwdriver to provisionally tighten the locking nut on one side of the motion segment keeping the locking nut loose on the implant to be compressed or distracted (see Figure 16). Compression or distraction is achieved against the provisionally tightened screw assembly. Ensure that the feet of either the compressor or distracter are placed firmly against the base of the head of the implanted screw and not against the wings.

Failure to do this may cause the implant to slip and/or the wings to break off prematurely.

Rotational adjustment of the rod should be performed using the rod gripper, prior to tightening of the locking nut.

** "Set Screw" may be used wherever "Locking Nut" is mentioned above.*

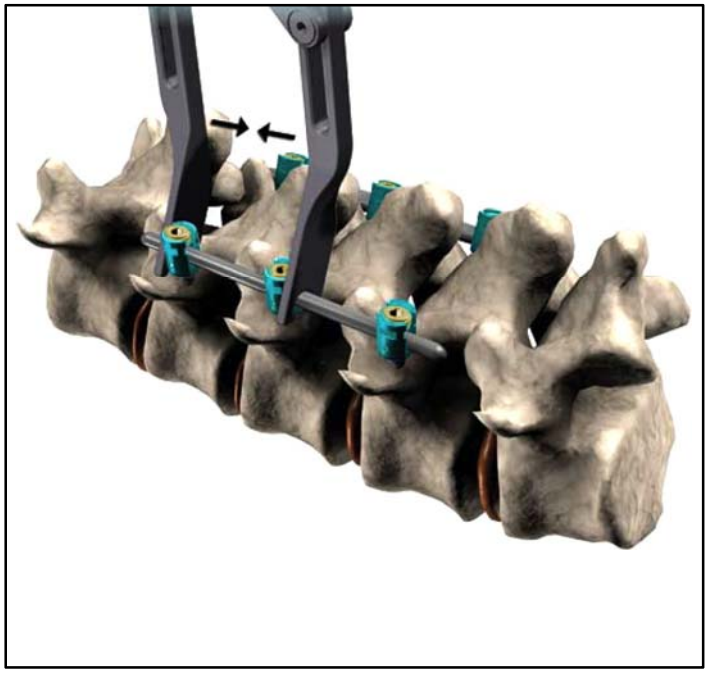


Figure 16

Final Tightening

After the surgeon has placed all the implants in a satisfactory position, only the preset torque handle must be used for final tightening of all the locking nuts. To prevent rod displacement and injury to the pedicle, the counter torque wrench should be placed over the screw head and seated on the rod. The counter torque wrench should be held securely in place to prevent torquing of the construct itself while the locking nut is being secured.

Attach the hexalobe driver to the preset torque handle and insert it through the center of the counter torque wrench, turning it slowly clockwise until it reaches maximum compression. Maximum compression is indicated by an audible "click" and tactile release of the mechanism within the preset torque handle. With this action final tightening of the locking nut is achieved. Repeat these steps for each pedicle screw (see Figure 17).

Note: For the two-piece locking nut (CAT# LG-LN1004), use Torque Handle CAT# IT-TQ1002 (10.16 Nm).
For the single piece set screw (CAT# CO-HSS1011), use Torque Handle CAT# LC-TLD0011 (12 Nm).

Important: Do not use any other instrument or handle for final tightening of the locking nuts. Doing so may compromise the security and stability of the construct.

** "Set Screw" may be used wherever "Locking Nut" is mentioned above.*

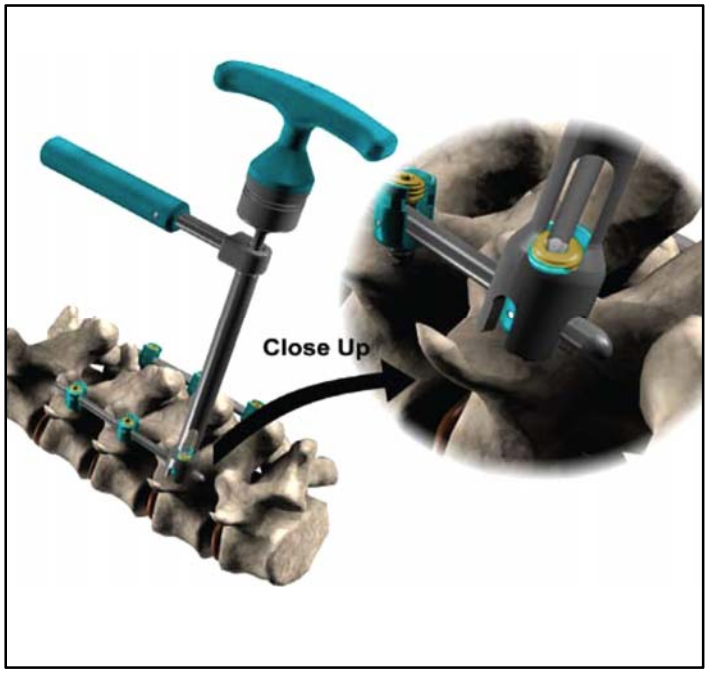


Figure 17

Revision and Extraction Procedure

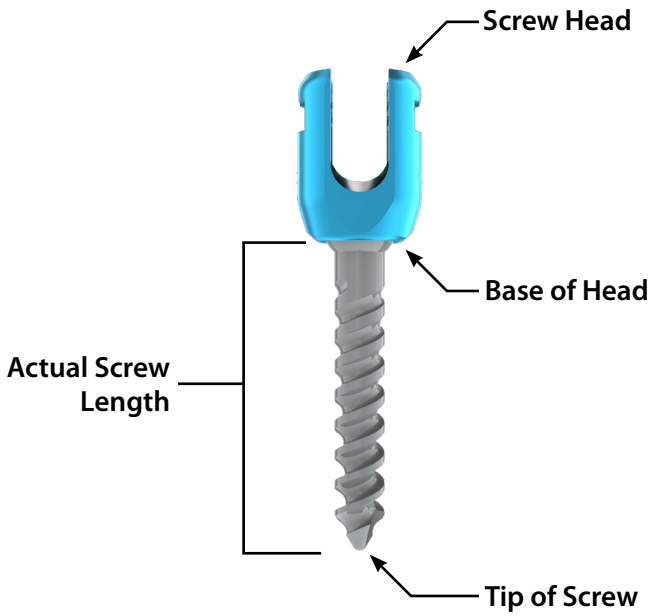
1. The patient should be positioned and exposed as described under "Patient Positioning and Exposure" section on page 6.
2. Insert the hexalobe portion of the hexalobe screwdriver shaft, either long or short depending on physician preference, into the locking nut(s) / set screw(s) of the pedicle screw(s) to be removed.
3. Attach the quick connect ratcheting handle to the opposite end of the hexalobe screwdriver shaft and adjust handle to permit the counter-clockwise rotation of the locking nut(s) / set screw(s).
4. Fully extract the locking nut(s) / set screw(s) by turning in a counter-clockwise direction.
5. Using the rod gripper, lift out the rod from the screw heads of all pedicle screws to be removed.
6. Insert the hex portion of the multi-axial screwdriver shaft Into base of the screw head, entering the hex portion of the screw shaft of the pedicle screw to be removed.
7. Be certain that the driver is fully seated.
8. Attach the quick connect ratcheting handle to the opposite end of the hex screwdriver shaft and adjust handle to permit the counter-clockwise rotation of the screw shaft(s).
9. Fully extract each screw shaft from the vertebral body by turning the screw shaft in a counter-clockwise direction.
10. A void filler of the surgeon's choice may be used to seal the extraction site in the vertebral body.
11. Take post-procedure radiographs to assure that all hardware has been removed.
12. Explanted components should be properly discarded and not used for re-implantation.

If in the judgment of the physician it is necessary to remove a Pedicle Screw from the vertebral body, the procedure described on this page is recommended.

Pedicle Screw Length Measurement

The screw length is measured from the tip of the screw to the base of the polyaxial head (see Figure 18). The screw length measurement is laser marked on the head of the Leucadia Pedicle Screw.

Figure 18



Leucadia

Pedicle Screw System

Surgical Technique Guide

Available Products

Leucadia Screws	Size
Polyaxial Sizes	
Product Code	**mm**
LC-PS4525	Ø4.5x25*
LC-PS4530	Ø4.5x30*
LC-PS4535	Ø4.5x35*
LC-PS4540	Ø4.5x40*
LC-PS4545	Ø4.5x45*
LC-PS4550	Ø4.5x50*
LC-PS4555	Ø4.5x55*
LC-PS0530	Ø5X30
LC-PS0535	Ø5X35
LC-PS0540	Ø5X40
LC-PS0545	Ø5X45
LC-PS0550	Ø5X50
LC-PS0630	Ø6X30
LC-PS0635	Ø6X35
LC-PS0640	Ø6X40
LC-PS0645	Ø6X45
LC-PS0650	Ø6X50
LC-PS0735	Ø7X35
LC-PS0740	Ø7X40
LC-PS0745	Ø7X45
LC-PS0750	Ø7X50
LC-PS0755	Ø7X55
LC-PS0835	Ø8X35
LC-PS0840	Ø8X40
LC-PS0845	Ø8X45
LC-PS0850	Ø8X50
LC-PS0855	Ø8X55
LC-PS0880	Ø8X80

Leucadia Rods	Size
Straight Rods	
Product Code	**mm**
LC-SR55400	400mm

Coronado Cross Connector	Size
Product Code	**mm**
LG-CC1001	30-37mm
LG-CC1002	37-50mm
LG-CC1003	50-80mm

Leucadia Rods	Size
Curved Rods	
Product Code	**mm**
LC-CR5530	Ø5.5X30*
LC-CR5540	Ø5.5X40
LC-CR5550	Ø5.5X50
LC-CR5560	Ø5.5X60
LC-CR5570	Ø5.5X70
LC-CR5580	Ø5.5X80
LC-CR5590	Ø5.5X90
LC-CR55100	Ø5.5X100
LC-CR55110	Ø5.5X110
LC-CR55120	Ø5.5X120
LC-CR55110	Ø5.5X110

Leucadia Screws	Size
Reduction Polyaxial Sizes*	
Product Code	**mm**
LC-PR0535	Ø5X35
LC-PR0540	Ø5X40
LC-PR0545	Ø5X45
LC-PR0635	Ø6X35
LC-PR0640	Ø6X40
LC-PR0645	Ø6X45
LC-PR0735	Ø7X35
LC-PR0740	Ø7X40
LC-PR0745	Ø7X45

Locking Nut/Set Screw
Product Code
LG-LN1004 (Saddle)
CO-HSS1011 (No Saddle)

**Available upon request*