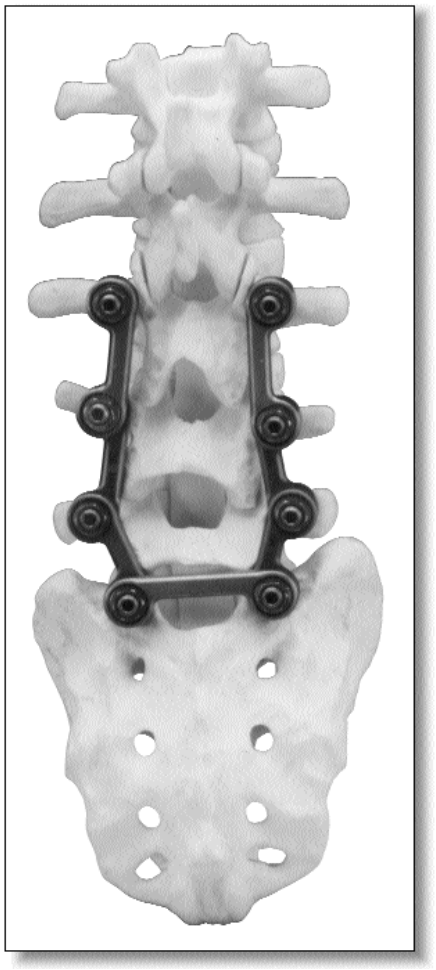
THORACOLUMBAR

EBI SPINE SYSTEMS



EBI

SpineLink™

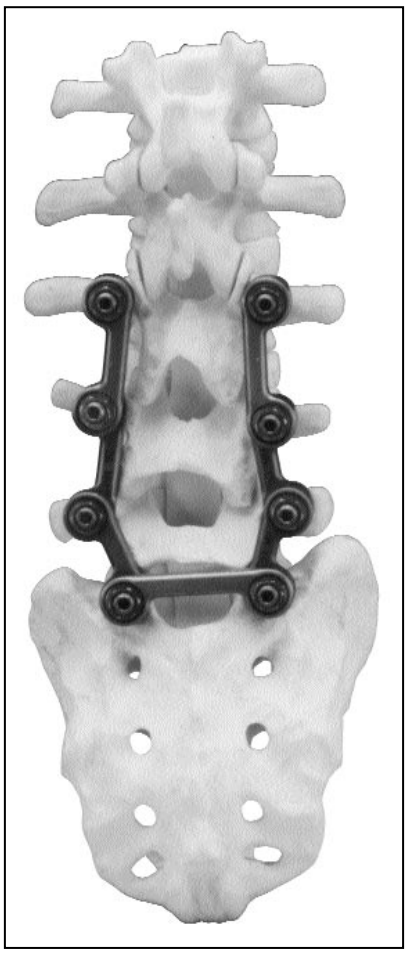
Spinal Fixation System

SURGICAL TECHNIQUE

EBI

SpineLink™

Spinal Fixation System



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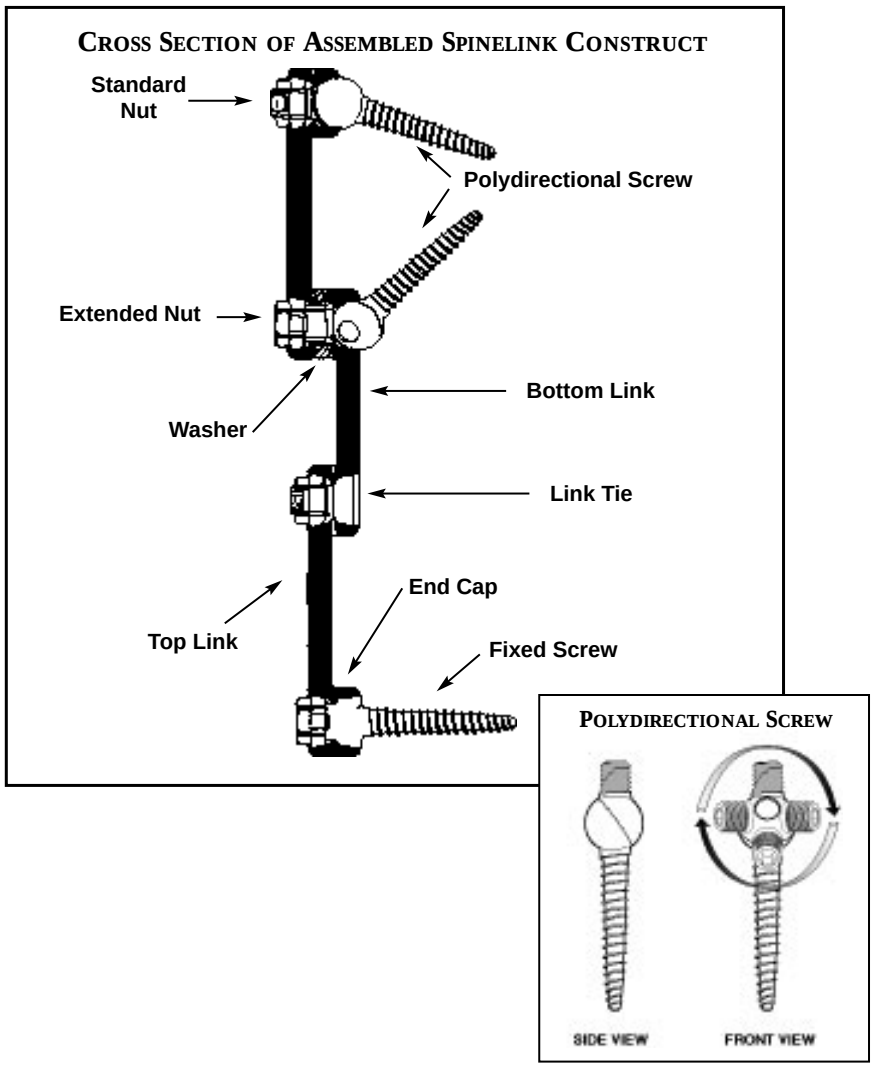


INTRODUCTION

Spinal fixation is frequently complicated by the inherently non-linear nature of the spine, and can be further complicated by trauma and disease processes which may further alter spine anatomy. Traditional rod systems can traverse several vertebra, and therefore require complicated intraoperative contouring to achieve precise fixation between the rod attachment members and the spine. Such adjustments can be time-consuming, and final implantation may not reconstitute the spine alignment or achieve the desired degree of correction.

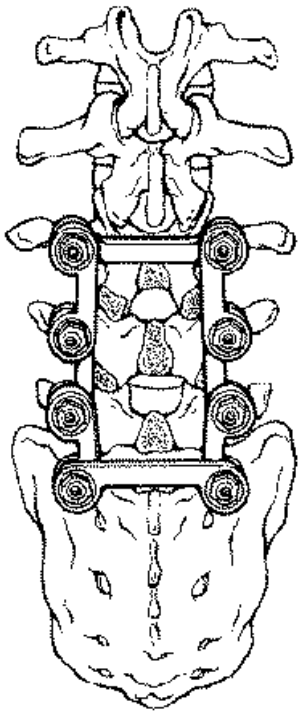
The EBI SpineLink™ System offers spine surgeons simplicity, efficiency and versatility. It's segmental construction assures conformity to each patient's unique anatomic needs, enabling surgeons to achieve reproducible results under all clinical conditions.

SpineLink™ permits intrasegmental fixation, focusing on just two points of fixation at a time. The modular links are similar in concept to the links of a bicycle chain. The radial serrations interconnecting the links give the surgeon excellent coronal plane variability. In addition, a unique polydirectional screw permits 360° rotation of the screw head for optimal pedicular placement while maintaining a top loading orientation to facilitate application. The polydirectional screw compensates for sagittal plane variability, thereby reducing the need for contouring. The system also offers fixed screws which may require contouring of the links when necessary.

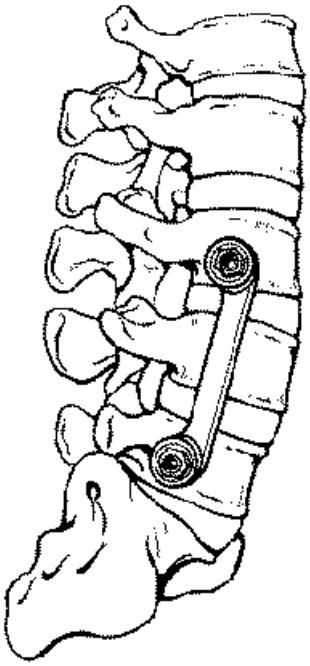
DESCRIPTION

The SpineLink™ System is a spinal fixation device made from titanium alloy (Ti-6A1-4V ELI). The system includes fixed, polydirectional pedicle/sacral screws (available in diameters from 5.5 to 8.5 mm), various types and sizes of interconnecting links, different styles of hooks, locking nuts, spacer washers and link tie's for connecting two links. The locking nuts along with serrations on the link's interface form a tightly locked construct. Various instruments are also available as part of the SpineLink™ System for use by the surgeon to facilitate implantation of the device.

POSTERIOR APPLICATION
with transverse links



ANTERIOR APPLICATION



SURGICAL TECHNIQUE
POSTERIOR SCREW APPLICATION

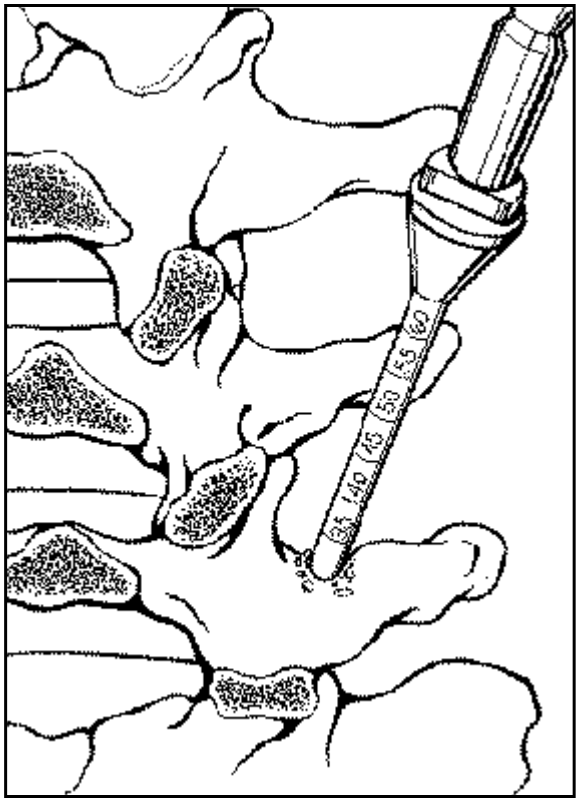
After positioning the patient in the customary manner, the spine is exposed via a midline or paraspinal incision. Paraspinal musculature is retracted laterally, and a discectomy or posterior decompression is performed if indicated.

1 Pedicle Preparation

After adequate exposure, the appropriate pedicle entry point is selected and the pedicle is prepared. The entrance to the pedicle is marked with an awl, burr, or currette. The cancellous bone within the cortical tube of the pedicle is sounded using a probe. A Steinmann pin can be placed into the pedicle, and its positioning confirmed on AP and lateral radiographs, ensuring proper orientation and trajectory.

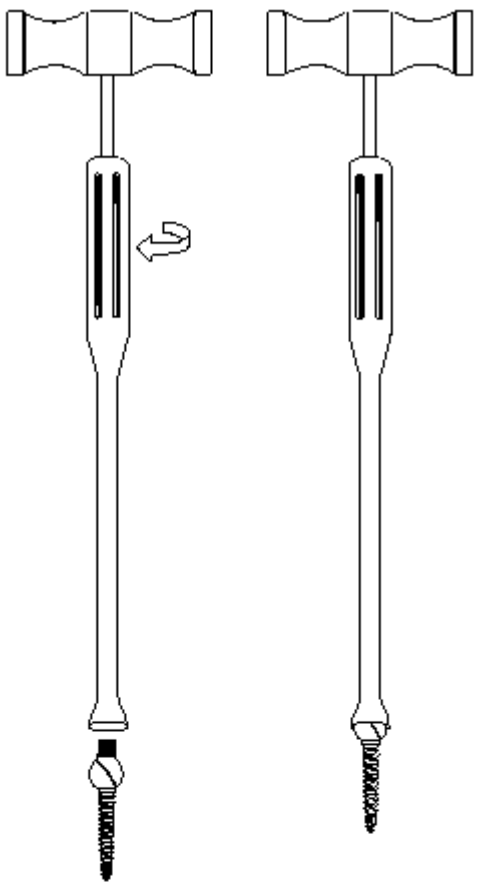
The appropriate diameter reamer is used to prepare the pedicle using a slow circular motion, allowing the reamer to center itself along the longitudinal axis of the pedicle. A 5.5mm reamer is used for the 5.5mm screw, a 6.5mm reamer is used for the 6.5mm screw and a 7.5mm/8.5mm reamer for the 7.5mm and 8.5mm screw. The reamer is initially advanced to a depth of approximately 30mm using the depth guide on the reamer. Once the appropriate depth has been attained, proper pedicle positioning can be confirmed radiographically before the reamer is removed. After removal of the reamer, pedicle wall integrity can be palpated using a flexible sound probe to confirm containment. Other confirmatory tests can also be used.

Instead of the reamer, a ball handle pedicle probe can also be used at this point. The diameter of the pedicle probe is 4.9mm, matching the minor diameter of the 6.5mm screw. The depth markings on the probe confirm appropriate screw length.



Insertion of reamer into pedicle.

SCREW INSERTER



2 Screw Selection

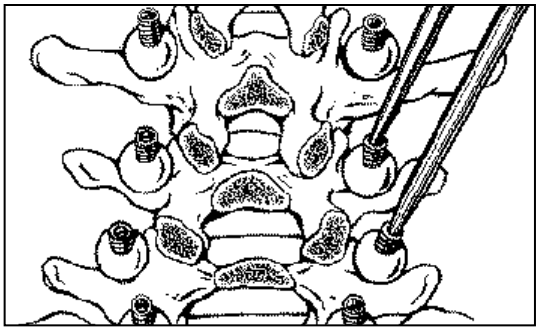
Polydirectional screws are available in 4 diameters (5.5mm, 6.5mm, 7.5mm and 8.5mm), ranging in length from 30mm to 60mm in 5mm increments. Fixed screws, with a truncated spherical head, may be used instead of polydirectional screws, and are available in the same range of sizes. Fixed screws do not offer sagittal plane variability, and may require the contouring of lordosis, kyphosis, and other spinal curvatures into the links.

The appropriate screw length is determined by using the depth gauge on the reamer.

3 Decortication and Screw Insertion

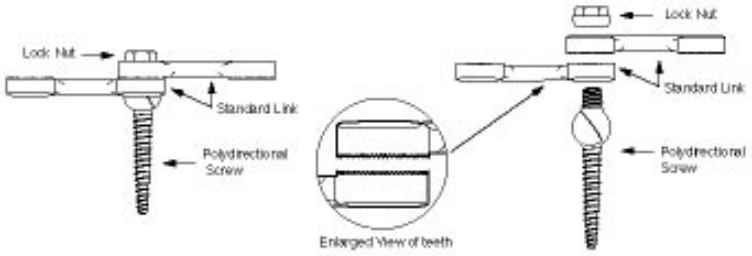
Decortication must be meticulously performed. Graft can be placed or packed into the posterolateral gutters either before or after the SpineLink System has been implanted.

To insert the screw, the machine-threaded end is turned into the inserter by rotating the ridged shaft on the inserter. When using polydirectional screws, lines on the top and bottom portions of the sphere should be aligned, thus ensuring a neutral position necessary for proper screw insertion. Using the screw inserter, the screw is advanced into the pedicle to the appropriate depth. The screw inserter is disengaged by rotating the ridged shaft the opposite way to loosen. Following screw insertion, the machine-threaded portion of the screw should be rotated until it is aligned perpendicular to the floor. A ball-handled allen wrench that fits into the top of the screw can be used to help align the machine portion of the screw. All screws are inserted in the manner as described above.

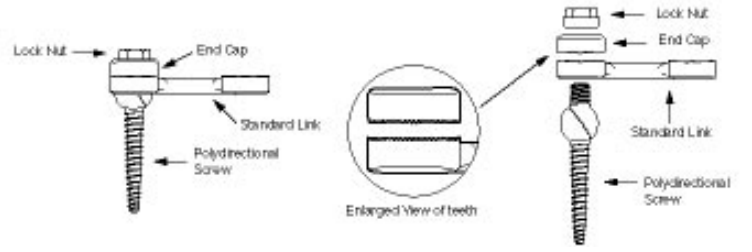


Measuring link size with calipers.

INTER CONNECTION BETWEEN POLYDIRECTIONAL SCREW, TWO STANDARD LINKS AND LOCK NUT.



INTER CONNECTION BETWEEN POLYDIRECTIONAL SCREW, END CAP, ONE STANDARD LINK AND LOCK NUT



4 Link Selection and Preparation with Planer

Link length selection is determined by the distance between two screws as measured with the measuring calipers. The tips of the caliper are placed at the top of the machine threaded portion of the screw for accurate link length measurement.

Prior to insertion of the links , a planer may be used to prepare the spine anatomy for the link and ensure proper placement of the link.

5 Link Application

The SpineLink™ link is a modular component featuring tapered recesses on one side and radial serrations on the other side. The tapered recess fits over the spherical surface of the polydirectional screw or fixed screw to facilitate tightening of the construct. The radial serrations interdigitate to secure two links together in a construct. The unique shape of the link medializes the system, facilitating bone grafting in the lateral gutter of the transverse processes.

When inserting the links at multiple levels, the second link should be placed with the radial serrations of the first link interdigitating with the serrations of the second link.

To secure the proximal and distal ends of the construct, either an end cap or a transverse link must be utilized. The end cap provides both a tapered recess and a radial serration to provide the interdigitation and compression necessary to secure the construct. An end cap holder can used to both position and hold the end cap in place during provisional and final torquing of the lock nut.

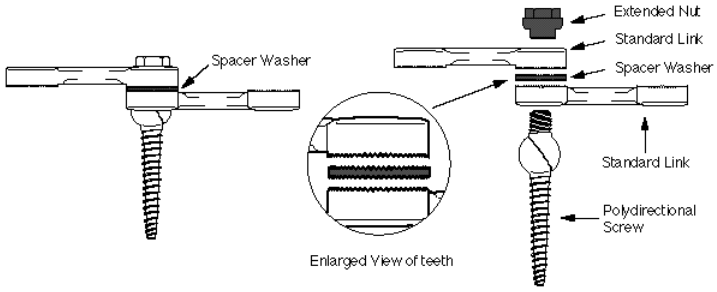
The transverse link may be used in place of an end cap to provide additional torsional stability. All links, end caps, and transverse links function similarly whether polydirectional screws, fixed screws, or a combination of polydirectional and fixed screws are used in a construct.

6 Compensating for Offset Screw Heights

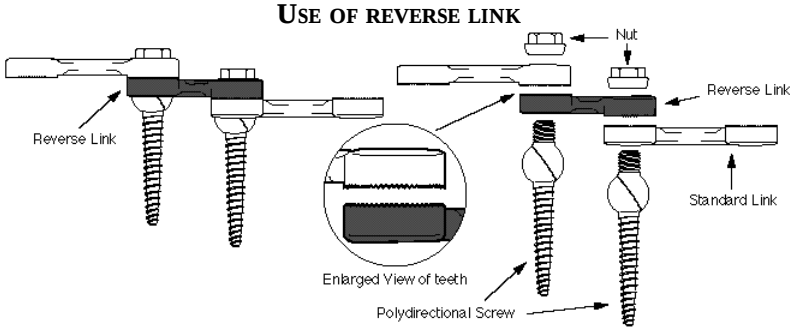
Offset screw heights are compensated for in the SpineLink™ System with the use of spacer washers, endcaps, or reverse links. The spacer washer has radial serrations on both sides for interdigitation between two links or between a link and an end cap or transverse link. The reverse link is similar to a standard link, with radial serrations on opposing sides. The reverse link is available in right and left styles.

When spacer washers are used to compensate for offset screw heights, the extended lock nut must be used to secure that portion of the construct. **The extended lock nut is only used when a spacer washer is used.**

USE OF SPACER WASHER WITH EXTENDED LOCK NUT

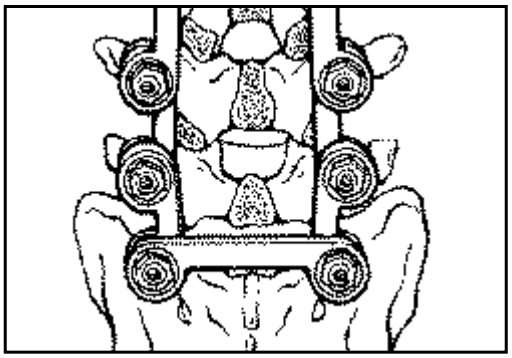


USE OF REVERSE LINK

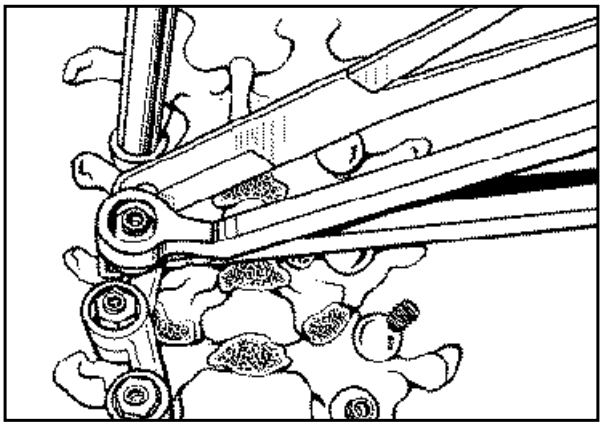


7 Transverse Linking

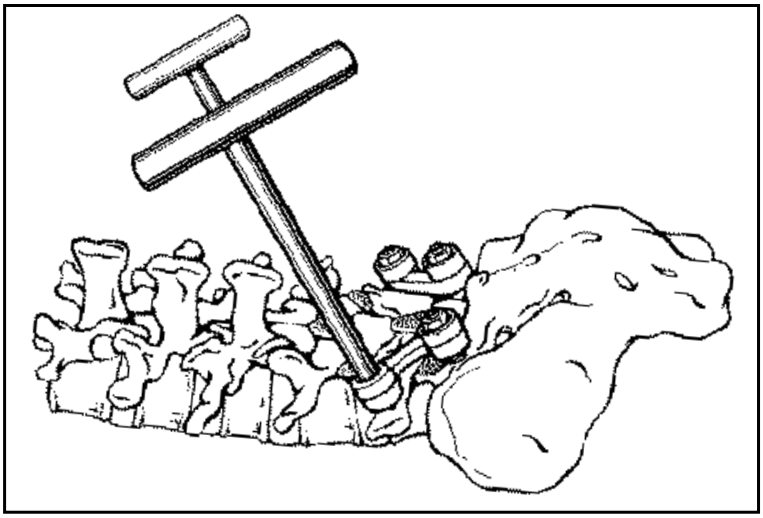
Transverse linking may be applied in two ways. A singular link can be placed after measuring for the appropriate inter screw traverse distance. If this distance does not match with an appropriate link size, a link tie can be used in combination with two links to exactly match the inter screw transverse distance.



Use of a Transverse Link.



Provisional tightening with the lock nut driver and link aligner.



Final torquing of the construct.

8 Securing the Construct

When all screws have been inserted and the corresponding links applied, fine adjustment of each screw is made with the ball handle allen wrench. The machine threaded portion of each polydirectional screw is oriented perpendicular to the floor to ensure that the shoulder at the base of the machine threaded portion snaps into the link ensuring proper screw and link alignment.

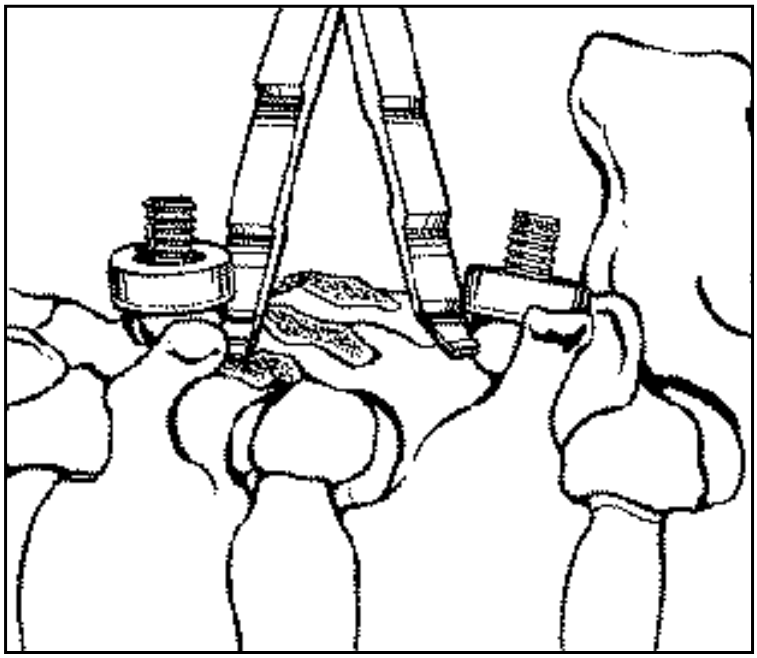
The construct is then secured using standard or extended lock nuts. Lock nuts are placed onto the machine threaded portion of each screw as it protrudes through the top link, end cap, or transverse link. Lock nuts should be placed in sequential order and provisionally tightened using a lock nut driver in combination with the counter rotation T-handle. (Surgical Note: The link holder helps to stabilize the link during tightening. The link aligner may be used to ensure complete interdigitation between the radial serrations of two connected links.)

After provisional tightening, proper implant and spinal positioning should be confirmed. The lock nuts can then be firmly tightened with the self-limited torque wrench in combination with the counter rotation T-handle. When fully tightened, the lock nuts apply compression to securely lock both the link and, when using polydirectional screws, the two halves of the sphere.

9 Additional Surgical Options

Applying Distraction

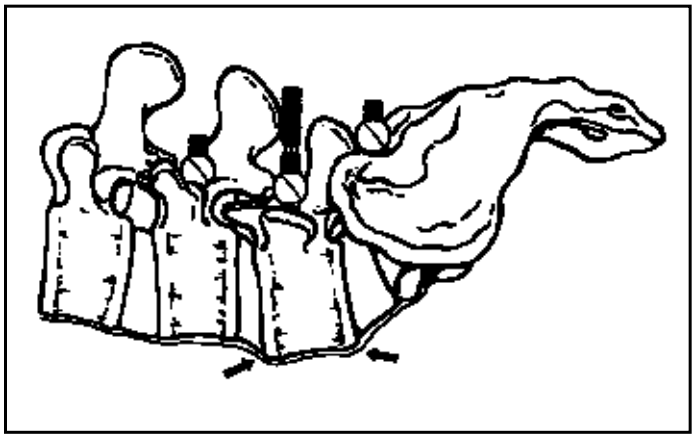
The SpineLink™ System distraction device permits the intraoperative application of distraction at any level. After two screws have been inserted proximal and distal to the site of desired manipulation, the tips of the distraction device are placed just below the spherical surface of the two screws and the desired degree of distraction is applied. The measuring calipers are then used to measure the distance between the two screws. The distraction device will maintain the position of the vertebra until the appropriate link is placed.



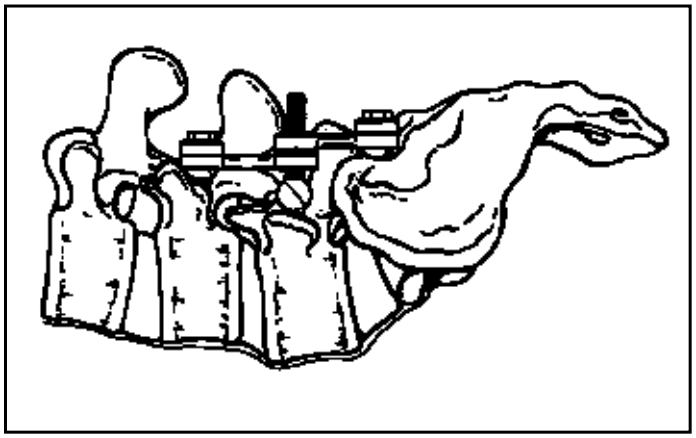
Use of distraction device.

Contouring (with fixed screws and hooks only)

The bender contouring tool can be used to contour the link in the sagittal plane and axial planes, depending upon the spine anatomy. When contouring a link, the link must be properly positioned in the bender with the radial serrations of the bender interdigitated with the link. The link is then contoured to the appropriate curve.



Once positioned, the standard Surgical Technique is used for implanting the pedicle screws



At L4 and at S1, the standard polydirectional screws are used. At L5, the pedicle is fixed with an extended polydirectional screw.

SURGICAL TECHNIQUE

SPONDYLOLISTHESIS REDUCTION TECHNIQUE UTILIZING EXTENDED POLYDIRECTIONAL SCREWS

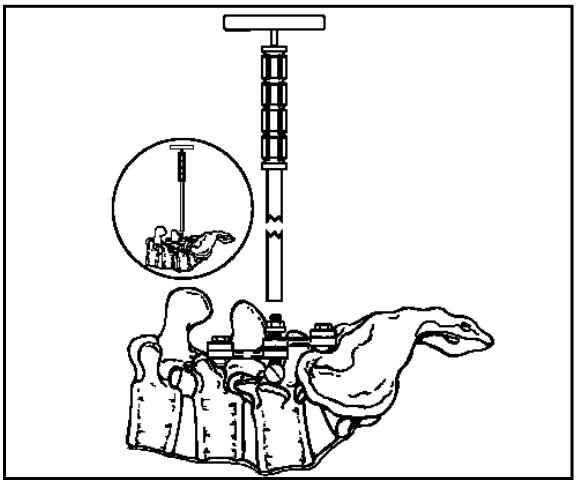
1

The patient is positioned pre-operatively according to the surgeon's customary manner. Once positioned, the standard SpineLink Spinal Fixation System Surgical Technique is used for implanting the pedicle screws (See Page 4).

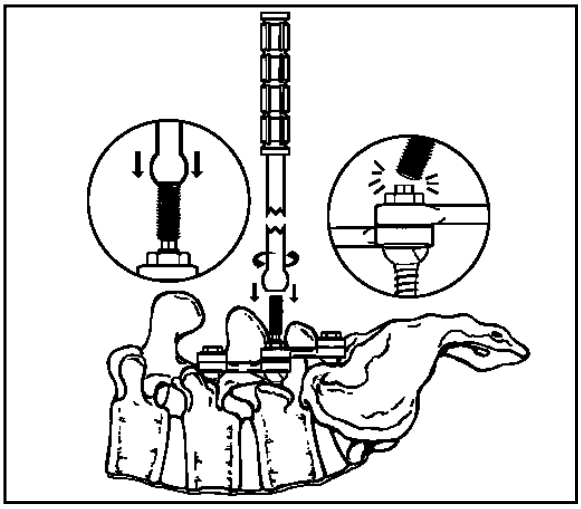
As an example, a fusion from L4 to the sacrum with reduction of an L5-S1 spondylolisthesis will be described. At L4 and at S1, the standard polydirectional screws are used. At L5, the pedicle is fixed with an extended polydirectional screw. This screw differs from the standard polydirectional screw by having a locking bolt in the central pivot and an extended machine portion. Choosing the approximate length link is performed in the standard manner using a caliper to determine the intrasegmental distance.

Link placement is performed in the following manner. The chosen link is used to connect the L4 and L5 screws. This is done bilaterally. The L4 and L5 screws are oriented perpendicular to the floor. Once these links have been applied, an appropriate length transverse link is placed connecting the right and left L4 screws. This transverse link is firmly affixed using lock nuts (See Page 8).

Attention is now directed towards instrumenting the L5-S1 segment. Once again, an appropriate length link is chosen to span the intrasegmental distance between L5 and S1. This is done bilaterally. A transverse link is used to interconnect the right



As the surgeon advances the lock nut onto the threads, the vertebral body will slide back into alignment.



Once fully engaged, the breakaway manipulator handle is cantilevered and the extended machine portion is sheared off.

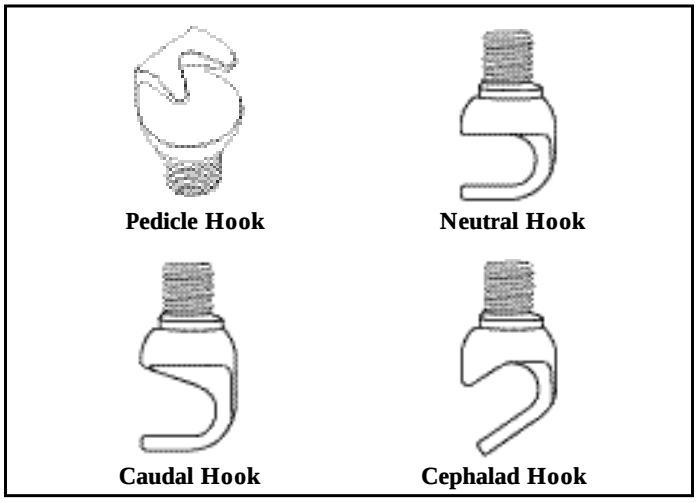
and left S1 screws and the link is locked and tightened with lock nuts.

The reduction maneuver is performed in the following manner. Lock nuts are applied to the extended machine portion of the L5 screws and tightened simultaneously on the right and left. This is done until the head of each polydirectional screw is fully engaged in the recess taper of the link. All lock nuts are tightened with a torque wrench and the counter rotation T-handle in place (See Page 8).

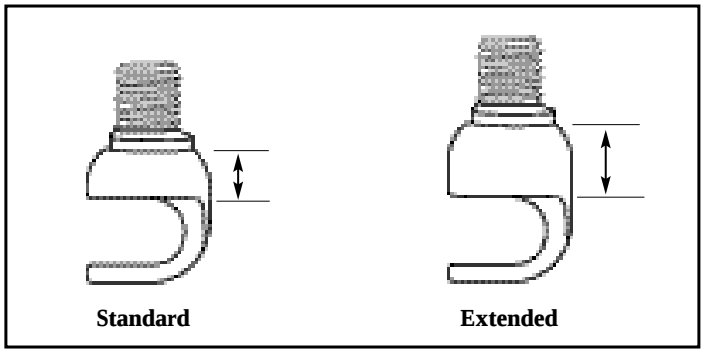
Once final torquing is complete, the extended machine portion on all the Extended Screws is removed with the Extended Screw Breakaway/ Manipulator (which is applied to the threads of the screw similar to a lock nut). Once fully engaged, the manipulator handle is cantilevered and the extended machine portion is sheared off. Closure and postoperative management is performed in the surgeon's standard method.

Note: The Locking bolt in the spherical head of the extended polydirectional screw is pre-set and should not be adjusted.

Hooks are available in four (4) different designs.



All hook designs and sizes are also available in two styles, (standard and extended).



The extended hook provides an additional 3mm of height compared to the standard hook.

SURGICAL TECHNIQUE
POSTERIOR HOOK APPLICATION

1

Hook Selection

Hooks are available in four (4) different designs; neutral, caudal, cephalad, and pedicle. Each hook is available in the following sizes to accommodate for anatomical variations of the lamina. The size refers to the hook aperture dimension.

Neutral	7, 9, & 11mm
Pedicle	7, 9, & 11mm
Caudal	5, 7, & 9mm
Cephalad	5, 7, & 9mm

All hook designs and sizes are also available in two styles, (standard and extended). The extended hook provides an additional 3mm of height compared to the standard hook. The height difference may be needed to facilitate link application.

Neutral Hook

The Neutral hook is a standard “U” shaped hook and is intended for the lamina or transverse process.

Cephalad Hook

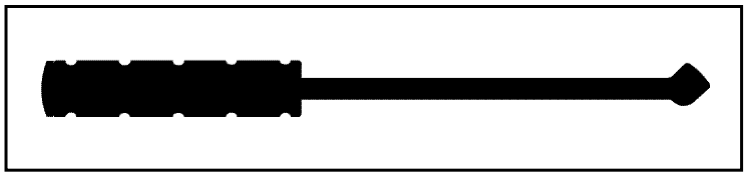
The Cephalad Hook is a down angled hook and is designed to accommodate for the anatomy of the inferior lamina. This hook is designed to engage and point in the cephalad direction.

Caudal Hook

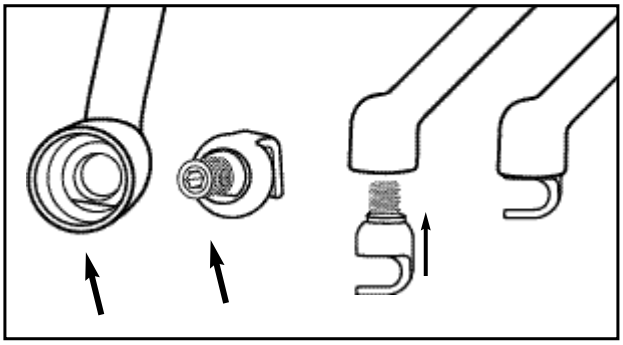
The Caudal hook is an up angled hook and is designed to accommodate for the anatomy of the superior lamina. This hook is designed to engage and point in a caudal direction.

Pedicle Hook

The Pedicle Hook is similar to the neutral hook as they are both a standard “U” shape. However, the pad of the hook is bifurcated for impacting the hook around the pedicle.

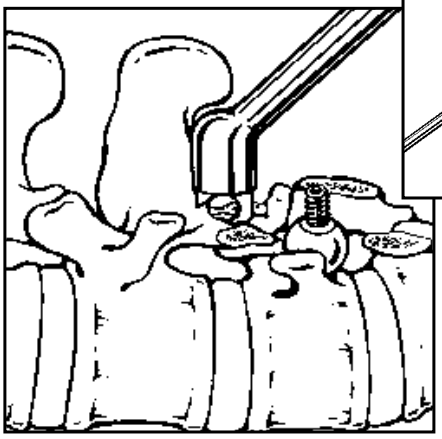


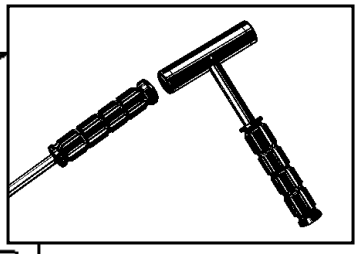
Dual Hook Inserter



Loading the Dual Hook Inserter.

Final positioning using the Dual Hook Inserter.





A mallet may be necessary to facilitate the impacting of the hook.

2 Lamina Preparation

After adequate exposure, the appropriate lamina is selected and prepared. To allow for proper seating, a sublaminar plane is prepared by reflecting the ligamentum flavum. Minor contouring of the laminar edge with a Kerrison rongeur may facilitate subsequent hook seating.

3 Hook Insertion

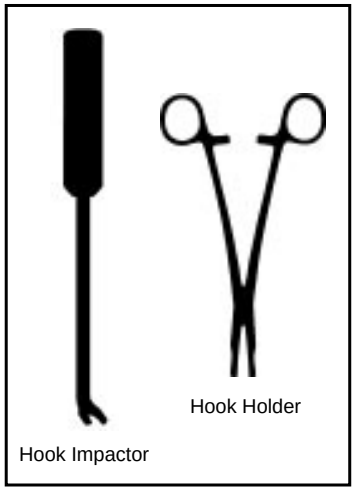
Evaluate the prepared lamina for size and orientation. Select the proper hook design and size.

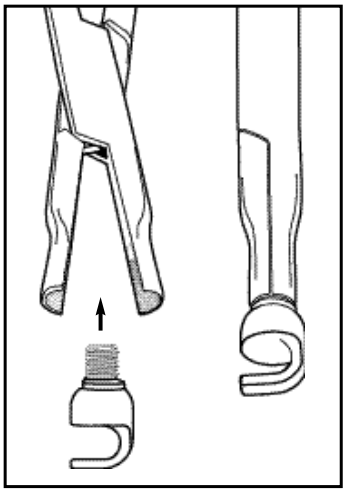
The Dual Hook Inserter or the Hook Holder and separate Hook Impacter can be used to insert any of the hooks.

3A Dual Hook Inserter

The Dual Hook Inserter allows the surgeon to hold, insert, and impact the hook without the help of an assistant.

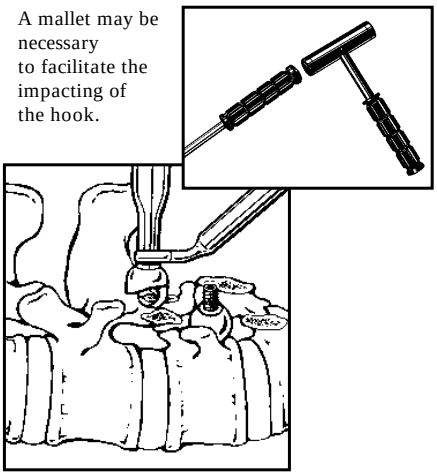
When utilizing the Dual Hook Inserter, the hook is loaded into the instrument by aligning the flat portion of the hook shoulder with the flat area inside the distal end of the instrument. The hook is now ready for positioning and insertion. The hook is gently manipulated under the lamina or around the pedicle using the Dual Hook Inserter. After the hook is properly seated, remove the Dual Hook Inserter.



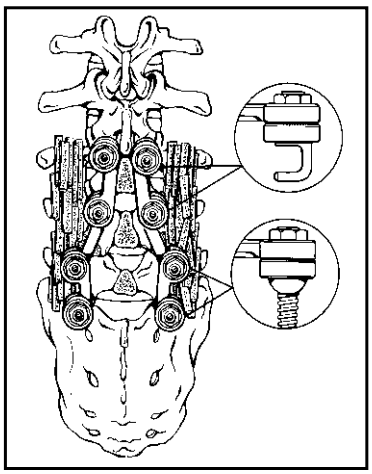


Loading the Hook Holder.

A mallet may be necessary to facilitate the impacting of the hook.



Final hook positioning with Hook Impactor.



Completed construct with hooks and screws.

3B Hook Holder and Hook Impactor

The Hook Holder allows the surgeon to apply an upward pull on the hook without disengaging the hook from the instrument. A Hook Impacter may be required to facilitate hook insertion.

When utilizing the Hook Holder, the hook is loaded into the instrument by closing the clamps (at the distal end of the instrument) around the machine portion of the hook. The hook is now ready for positioning and insertion. The hook is gently manipulated under the lamina or around the pedicle using the hook Inserter. The separate Hook Impacter may be utilized for final positioning. After the hook is properly seated, remove the Hook Holder and separate Hook Impacter.

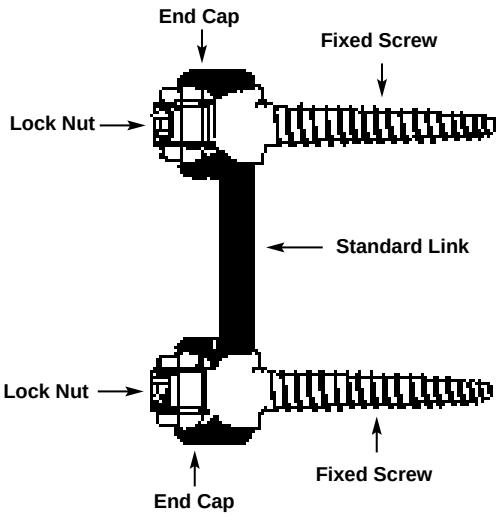
Repeat the hook placement procedure at each site. Once all hooks and/or screws have been inserted, link application may proceed.

4 Link Selection and Application

After hook and/or pedicle screw placement is completed, measuring calipers are used to measure the distance between the hooks or screws to determine the appropriate link length. This is described in detail on page 6 of the posterior screw technique. The tapered recesses of the link are placed over the spherical shoulder of the hooks. Before completing the construct, either an end cap or a transverse link must be placed at the proximal and distal ends of the construct.

Prior to insertion of the links, a Planer may be used to ensure proper placement of the link.

CROSSECTION OF ASSEMBLED SPINELINK ANTERIOR CONSTRUCT



SURGICAL TECHNIQUE
ANTERIOR SCREW

When using the SpineLink™ System for anterior spinal fixation, the spine may be exposed in customary fashion either through the thoracic, abdominal, or flank surgical approach.

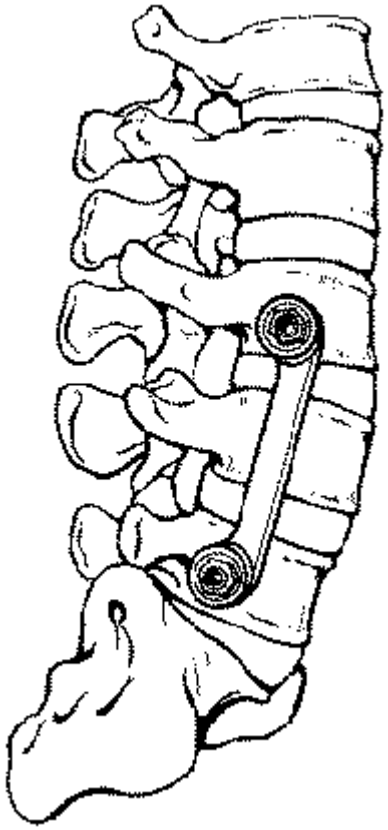
1 Vertebrae Preparation

After locating the desired screw position in the most proximal or distal vertebrae, a reamer is used to prepare the first screw hole. Depth can be gauged using the calibrated markings on the reamer. Precise trajectory and depth can be confirmed radiographically. Depth and perforation of the opposite cortex can be evaluated by removing the reamer and utilizing the flexible sound probe. Based on surgeon preference, one or two screws may be placed at each vertebral level.

2 Screw Selection and Insertion

In anterior applications, both polydirectional and fixed screws may be used to secure the construct. After the appropriate screw length has been determined using the depth gauge on the reamer, the machine-threaded end of the screw is mounted into the screw inserter and the screw inserted to the desired depth as described on page 5 of the Posterior Screw technique. Once the first screw(s) has been placed in the first vertebrae, the second screw(s) is implanted in the next vertebrae.

COMPLETED ANTERIOR CONSTRUCT



3 Link Selection and Application

After two screws have been placed, measuring calipers are used to measure the distance between the screws to determine the appropriate link length as described in page 6 of the Posterior Screw technique. The tapered recesses of the link are placed over the spherical surfaces of the screws. Additional screws and links are applied in the same fashion. Either an end cap or a transverse link must be placed at the proximal and distal ends of the construct.

4 Applying Compression and Distraction

Compression or distraction may be applied at any vertebral level after the screws proximal and distal to the desired level of manipulation have been inserted. As described on page 9 of the Posterior Screw technique, the tips of the compression/distraction device are placed just below the spherical surface of the two screws, and the desired degree of compression or distraction is applied. The caliper is then used to measure the distance between the two screws to facilitate link selection. The compression/distraction device can be used to maintain the position of the vertebra until the appropriate link has been applied.

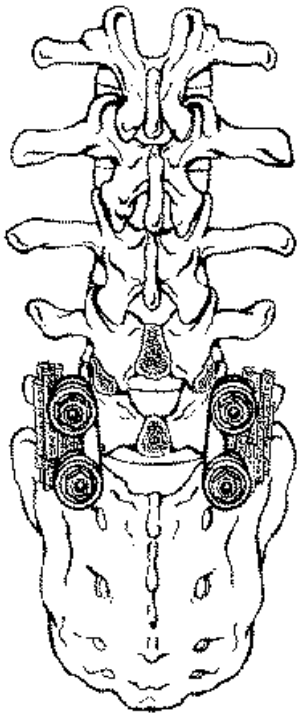
5 Compensating for Offset Screw Heights

Spacer washers or reverse links may be used to compensate for offset screw heights, as described on page 7 of the Posterior Screw technique. **Spacer washers require the use of extended locking nuts.**

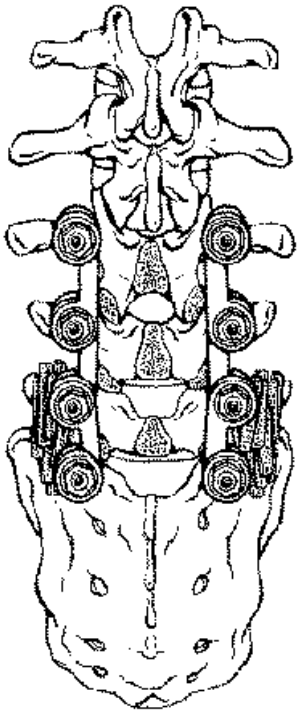
6 Securing the Construct

When all screws have been inserted and the corresponding links applied, the construct is secured using standard or extended lock nuts as described on page 8 of the Posterior Screw technique. When fully tightened, the lock nuts apply compression to securely lock both the link and, when using polydirectional screws, the two halves of the sphere.

1 Level Posterior Construct



3 Level Posterior Construct



Closure, Postoperative Care and Implant Removal

Closure

After implantation of the SpineLink™ System is complete, closure is performed in layers over drains according to standard protocol.

Postoperative Care

To enhance recovery following implantation of the SpineLink™ System, the patient should be mobilized after a few days. A TLSO brace may be used postoperatively to decrease excessive mobility. Walking-intensive activities should be restricted until otherwise advised by the surgeon. Postoperative radiographs should be taken periodically and reviewed to ensure fixation stability.

Implant Removal

Removal of the SpineLink™ System is performed by reversing the order of the implant procedure. The torque wrench, which is multidirectional, is used to remove the lock nuts.

Indications

The EBI SpineLink™ System is a spinal fixation device for pedicle screw fixation and a nonpedicle hook and sacral/iliac screw fixation system of the noncervical spine.

When used as a pedicle screw fixation system, in the non-cervical spine of skeletally mature patients,

STERILIZATION RECOMMENDATIONS

The EBI SpineLink™ Fixation System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle:	High Vacuum
Temperature:	270˚F / 132˚C
Time:	4 minutes

Note: Allow For Cooling

Individuals or hospitals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

the System is intended to provide immobilization and stabilization of spinal segments, 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor, and failed previous fusion (psuedarthrosis).

In addition, when used as a pedicle screw fixation system in skeletally mature patients, it is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior hook and sacral/iliac screw fixation system, the levels of attachment are the lumbar and thoracic spine, and screw fixation limited to the sacrum and ilium. The System is intended for the treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Psuedarthrosis; stenosis; scoliosis; spondylolisthesis, fracture; previous failed fusion; or tumor resection.

When used as an anterior fixation system, the levels of attachment are the anterolateral vertebral bodies of the lumbar and thoracic spine. The System is intended for the treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Psuedarthrosis, stenosis; scoliosis; spondylolisthesis, fracture; previous failed fusion; or tumor resection

SpineLink™ System Screw Part Numbers

Diameters - 5.5mm, 6.5mm, 7.5mm and 8.5mm
Lengths - 30mm to 60mm (5mm increments)

Polydirectional Screw		Fixed Screw		Extended Polydirectional Screw	
screw size	*part number*	*screw size*	*part number*	*screw size*	*part number*
5.5mm		**5.5mm**		**5.5mm**	
30mm	53530	30mm	52530	30mm	51530S
35mm	53535	35mm	52535	35mm	51535S
40mm	53540	40mm	52540	40mm	51540S
45mm	53545	45mm	52545	45mm	51545S
50mm	53550	50mm	52550	50mm	51550S
55mm	53555	55mm	52555	55mm	51555S
60mm	53560	60mm	52560	60mm	51560S
6.5mm		**6.5mm**		**6.5mm**	
30mm	51630	30mm	54630	30mm	51630S
35mm	51635	35mm	54635	35mm	51635S
40mm	51640	40mm	54640	40mm	51640S
45mm	51645	45mm	54645	45mm	51645S
50mm	51650	50mm	54650	50mm	51650S
55mm	51655	55mm	54655	55mm	51655S
60mm	51660	60mm	54660	60mm	51660S
7.5mm		**7.5mm**		**7.5mm**	
30mm	51730	30mm	54730	30mm	51730S
35mm	51735	35mm	54735	35mm	51735S
40mm	51740	40mm	54740	40mm	51740S
45mm	51745	45mm	54745	45mm	51745S
50mm	51750	50mm	54750	50mm	51750S
55mm	51755	55mm	54755	55mm	51755S
60mm	51760	60mm	54760	60mm	51760S
8.5mm		**8.5mm**		**8.5mm**	
30mm	51830	30mm	54830	30mm	51830S
35mm	51835	35mm	54835	35mm	51835S
40mm	51840	40mm	54840	40mm	51840S
45mm	51845	45mm	54845	45mm	51845S
50mm	51850	50mm	54850	50mm	51850S
55mm	51855	55mm	54855	55mm	51855S
60mm	51860	60mm	54860	60mm	51860S

CONTRAINDICATIONS

SpineLink is contraindicated in patients with spinal infection or inflammation; morbid obesity; mental illness; alcoholism or drug abuse; pregnancy; metal or foreign body sensitivity; inadequate tissue coverage over the operative site; or open wounds near 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 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 system, 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.

When using the link tie in an interconnected construct the interior interlink angle must be between 108˚ and 180˚.

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 system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

SpineLink™ System Part Numbers

STANDARD LINKS

link size		*part number*
18mm		70018
21mm		70021
24mm		70024
27mm		70027
30mm		70030
33mm		70033
36mm		70036
39mm		70039
42mm		70042
45mm		70045
48mm		70048
51mm		70051
54mm		70054
57mm		70057
60mm		70060
63mm		70063
66mm		70066
69mm		70069
72mm		70072
75mm		70075
78mm		70078

REVERSE LINKS

link size		*part number*
18mm		71018
21mm	left	71021
24mm	left	71024
27mm	left	71027
30mm	left	71030
33mm	left	71033
36mm	left	71036
39mm	left	71039
42mm	left	71042
21mm	right	72021
24mm	right	72024
27mm	right	72027
30mm	right	72030
33mm	right	72033
36mm	right	72036
39mm	right	72039
42mm	right	72042

LOCKING NUT

description	*part number*
Standard	53100
Extended	53200

COMPONENTS

	part number
Spacer Washer	73100
End Cap	74100
Link Tie	74200

STANDARD HOOKS

description	*part number*
7mm Neutral Hook	53007
9mm Neutral Hook	53009
11mm Neutral Hook	53011
5mm Cephalad Hook	53105
7mm Cephalad Hook	53107
9mm Cephalad Hook	53109
5mm Caudal Hook	53205
7mm Caudal Hook	53207
9mm Caudal Hook	53209
7mm Pedicle Hook	53307
9mm Pedicle Hook	53309
11mm Pedicle Hook	53311

EXTENDED HOOKS

description	*part number*
7mm Neutral Hook	54007
9mm Neutral Hook	64009
11mm Neutral Hook	54105
7mm Cephalad Hook	54107
9mm Cephalad Hook	54109
5mm Caudal Hook	54205
7mm Caudal Hook	54207
9mm Caudal Hook	54209
7mm Pedicle Hook	54307
9mm Pedicle Hook	54309
11mm Pedicle Hook	54311

INSTRUMENTATION

description	*part number*
Link Inserter	91000
Link Aligner	91015
Lock Nut Driver	91025
Torque Wrench	91030
Counter Rotation T-Wrench	91035
Measuring Calipers	91040
Compresser/Distractor	91045
Pedicle Sound	91055
Ball Handle Allen Wrench	91060
6.5mm Reamer	91065
7.5mm / 8.5mm Reamer	91070
5.5mm Reamer	91075
T-Handle Allen Wrench	91085
End Cap Holder	91095
Reamer Driver Handle	91100
Planer	91150
Gear Shift Pedicle Probe, 15 Degree	92040
Pedicle Probe, Straight	92045
Pedicle Awl	92050
Disassembled Screw Remover	92060
Screw Inserter	92070
Torque Stailizer	93030
Screw Inserter Inner Shaft	93061
Extended Screw Inserter Outer Sleeve	93062
Extended Screw Counter T-Wrench	93063
Extended Screw Breakaway/Manipulator	93040

See the Warnings, Precautions, and Possible Adverse Effects sections of the package insert for a complete list of potential risks.

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

This brochure is presented to demonstrate the surgical technique utilized by Steven Nagelberg, M.D. EBI as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. EBI is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

FURTHER INFORMATION

For further information, please contact the Customer Service Department at:

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THORACOLUMBAR

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