VySpine™

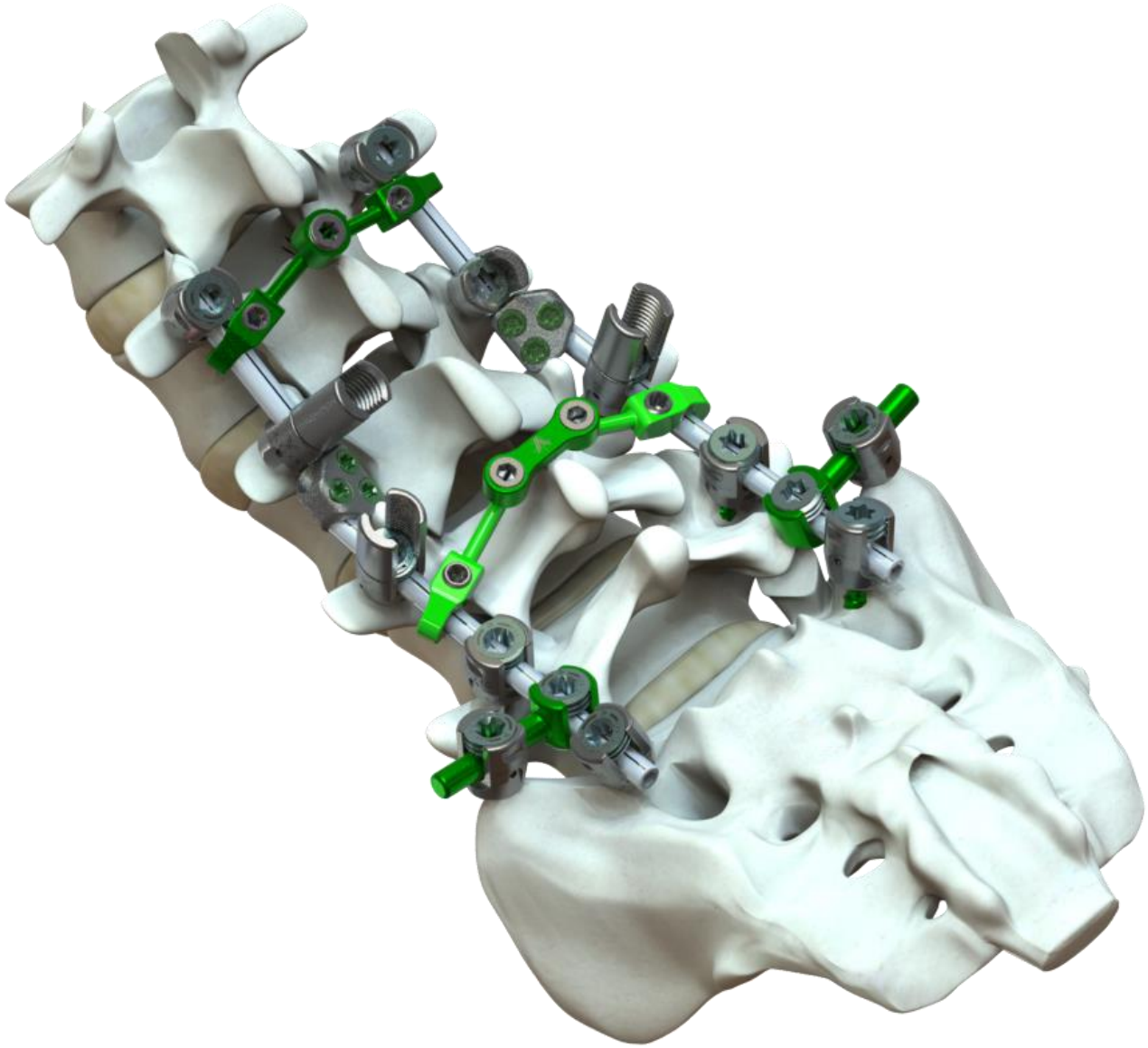
VyLink™
Spinal Screw System

Posterior Surgical Technique

VyLink™ System Overview

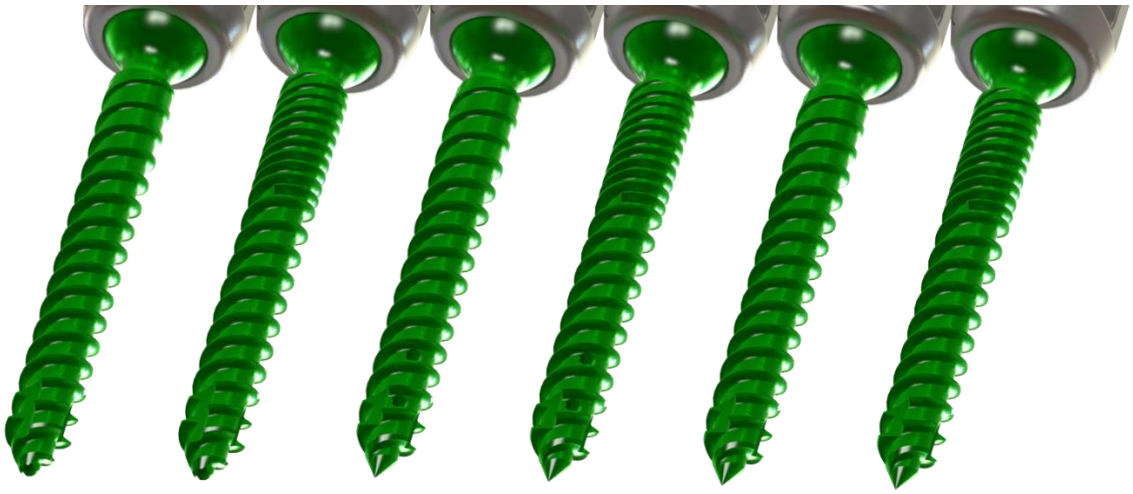
Description:

The Posterior VyLink™ Spinal Screw System consists of longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, cannulated poly axial screws, cannulated reduction screws, hooks, reduction hooks, set screws, and transverse connectors. The Anterior VyLink™ Spinal Screw System consists of two spinal rods, monoaxial screws, staples, and set screws. The Anterior staples, washers, and screws are intended to be attached to the lateral aspect of the vertebral bodies from T5 to L4, and SHOULD NOT be attached to the anterior aspect. Furthermore, only Titanium components should be used anteriorly. (See Precautions section of IFU)



VyLink™ System Overview

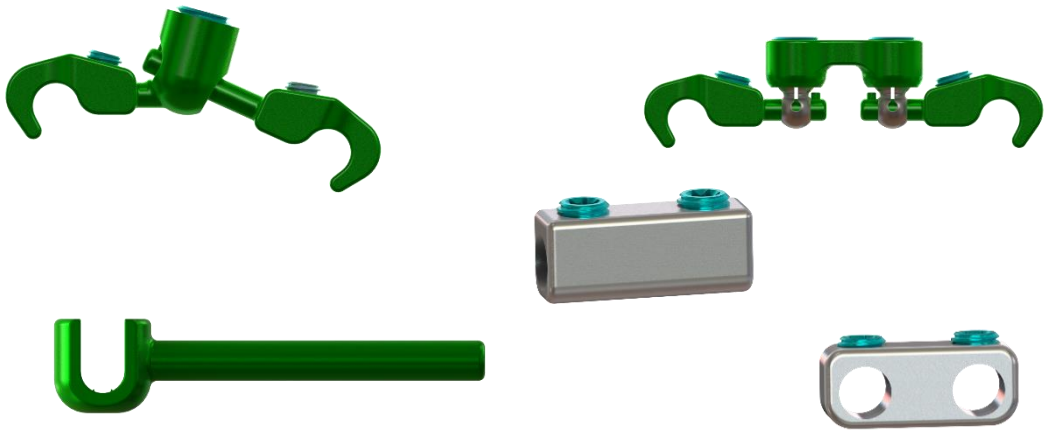
VyLink™ Screw System provides numerous screw options, including solid, cannulated, fenestrated, and uni-fenestrated. Additionally, there are standard cancellous threaded screws, cortical-cancellous threaded screws, and bi-cortical threaded screw options



VyLink™ Screw System pairs various head styles, including fixed angle, fixed angle reduction, poly-axial, and poly-axial reduction, all with the numerous screw types. Also, see the VyLink™ MIS System for MIS heads.

VyLink™ System Overview

VyLink™ Screw System offers complete spine care with a full array of components including crosslinks, rod to rod connectors, and offset connectors. From Deformity to Degen, the VyLink™ Screw System has the implant and instrument options necessary to meet any patient's needs. The VyLink™ Screw System can connect with the VySpan™ PCT System.



The VyLink™ Screw System features numerous rods to enhance the adaptability of the construct and aid in the overall usability and strength of the system. These include straight rods, pre-curved rods, barbell end rods, Titanium-alloy rods, and Cobalt Chrome rods. Additionally, all rods have a hex feature to aid in manipulation, as well as a laser etch line to help with visualization. The VyLink™ Screw System can connect with the VySpan™ PCT System with transitional rods. Also, see the VyLink™ MIS System for MIS rods.

VyLink™ Surgical Technique

Step 1. Prepare Spine

- VyLink™ Pedicle Screw Fixation

Locate pedicles and use the awl to perforate the cortex. Use the appropriate probe to open the pedicle canal. For selecting the appropriate length screw, the markings on the probe indicate the pedicle depth. All VyLink Spinal Screw System screws are self-tapping. However, if tapping is preferred, use the appropriate tap to tap the pedicle canal.

- VyLink™ Lamina Hook Fixation

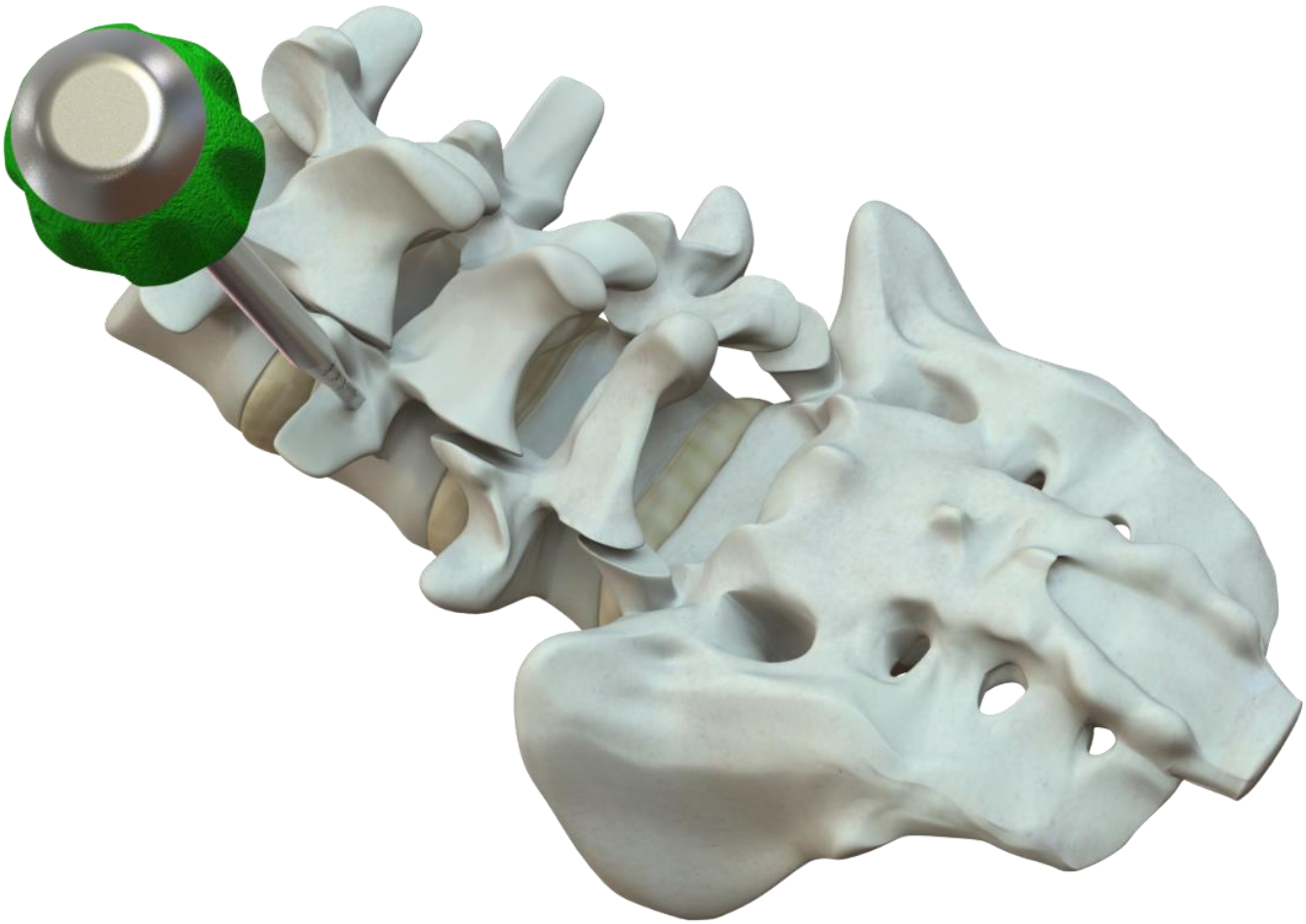
Using the appropriate size lamina finder, separate the ligamentum flavum from the underside of the lamina to ensure good bony contact with the lamina hook.

- VyLink™ Pedicle Hook Fixation

Using the Pedicle Finder, open the facet capsule and locate the pedicle. Remove a small piece of the inferior articular process to ensure proper seating of the pedicle hook. Pedicle hooks should be placed in an up-going direction only

- VyLink™ Transverse Process Hook Fixation

Use the transverse process finder to separate the ligamentum flavum from the underside of the transverse process



VyLink™ Surgical Technique

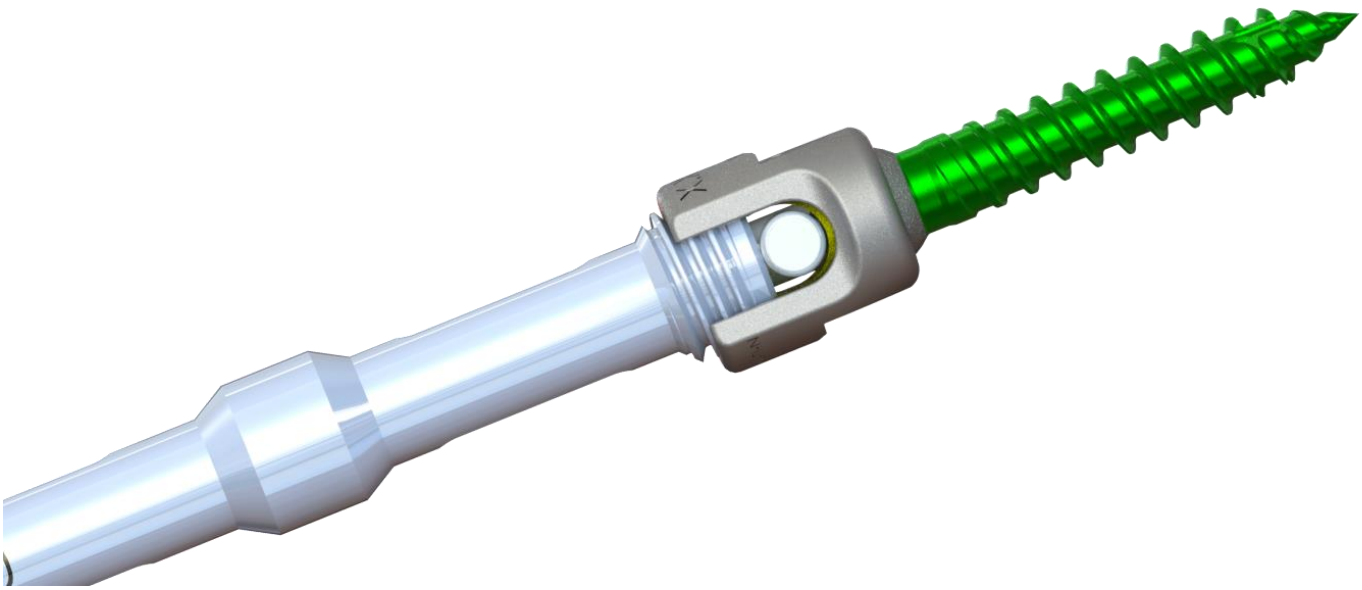
Step 2. Attach the Anchor to the Driver

- VyLink™ Pedicle Screw Fixation

Attach the appropriate screw to the screwdriver. For poly-axial screws, insert the hexalobe tip of the driver into bone screw head. The bone screw may have to be rotated in order for the hexalobe tip to fully seat. With the hexalobe seated, thread the outer sleeve of the driver into the poly-axial head of the screw while holding the handle in place. For fixed-angle screws, insert the head adjuster portion of the driver into the screw head. With the adjuster head seated, thread the outer sleeve of the driver into the threaded head of the screw while holding the handle in place.

- VyLink™ Hook Fixation

Attach the hook to the desired hook holding instrument. For hook holding forceps, grasp the sides of the hook. For screw driver, insert the head adjuster portion of the driver into the hook head. With the adjuster head seated, thread the outer sleeve of the driver into the threaded head of the hook while holding the handle in place.



VyLink™ Surgical Technique

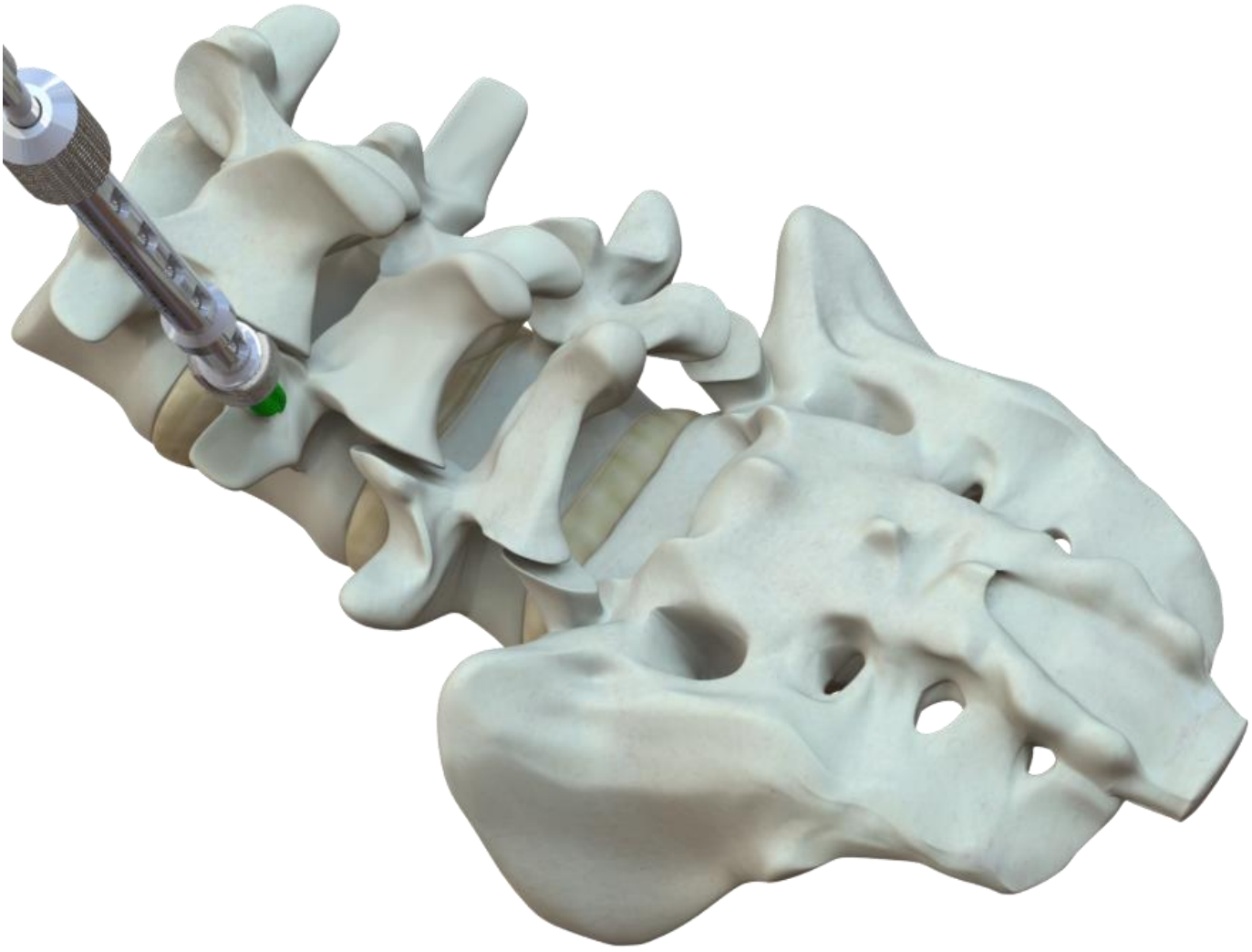
Step 3. Anchor Placement

- VyLink™ Pedicle Screw Fixation

Insert the screw into the prepared pedicle canal.
Disengage the screw from the driver by unthreading the outer sleeve while holding the handle in place.

- VyLink™ Hook Fixation

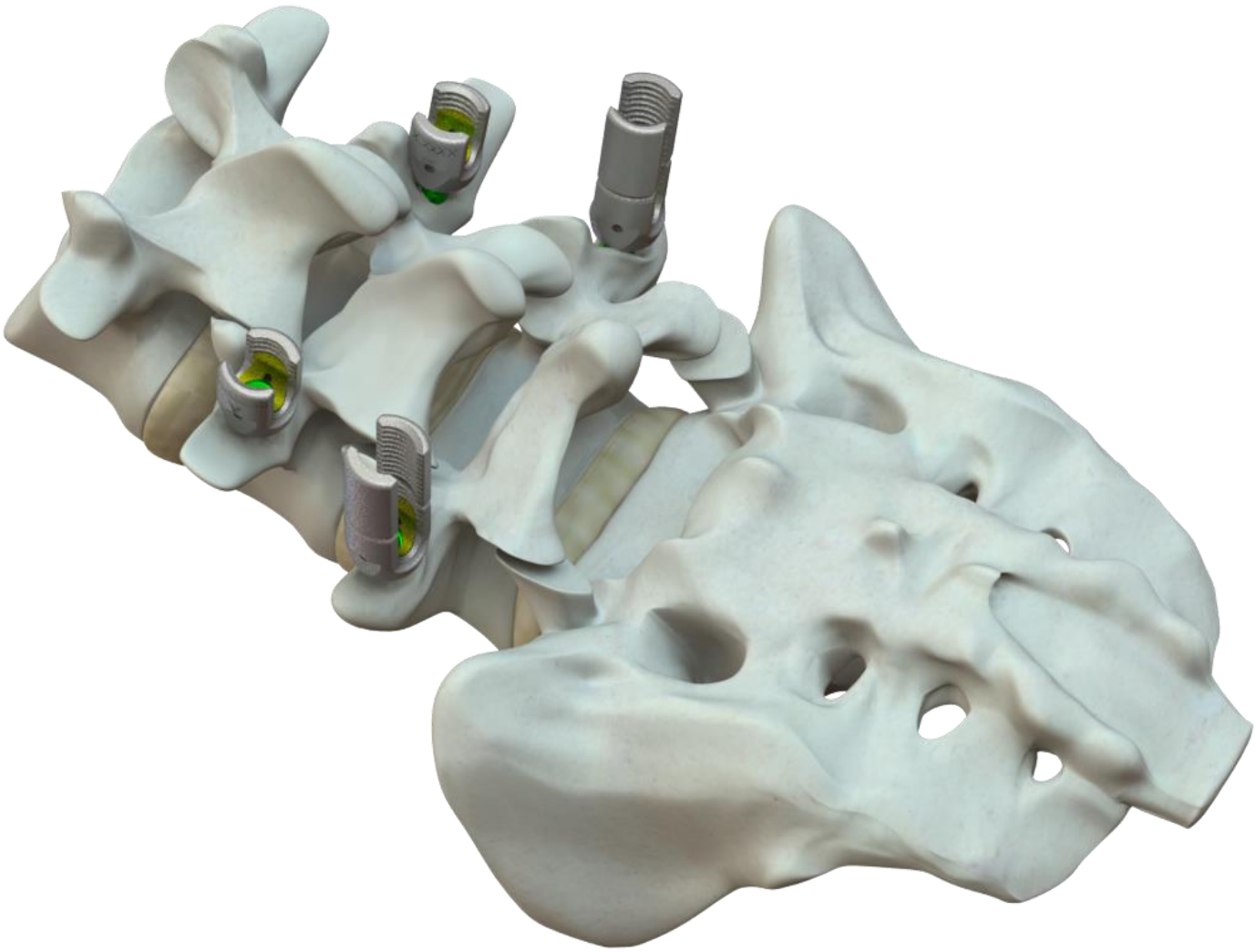
Place the hook in the desired location.
Disengage the hook holding instrument from the hook
For hook holding forceps, release the sides of the hook.
For screw driver, release the hook by unthreading the outer sleeve while holding the handle in place.



VyLink™ Surgical Technique

Step 4. Anchor Placement

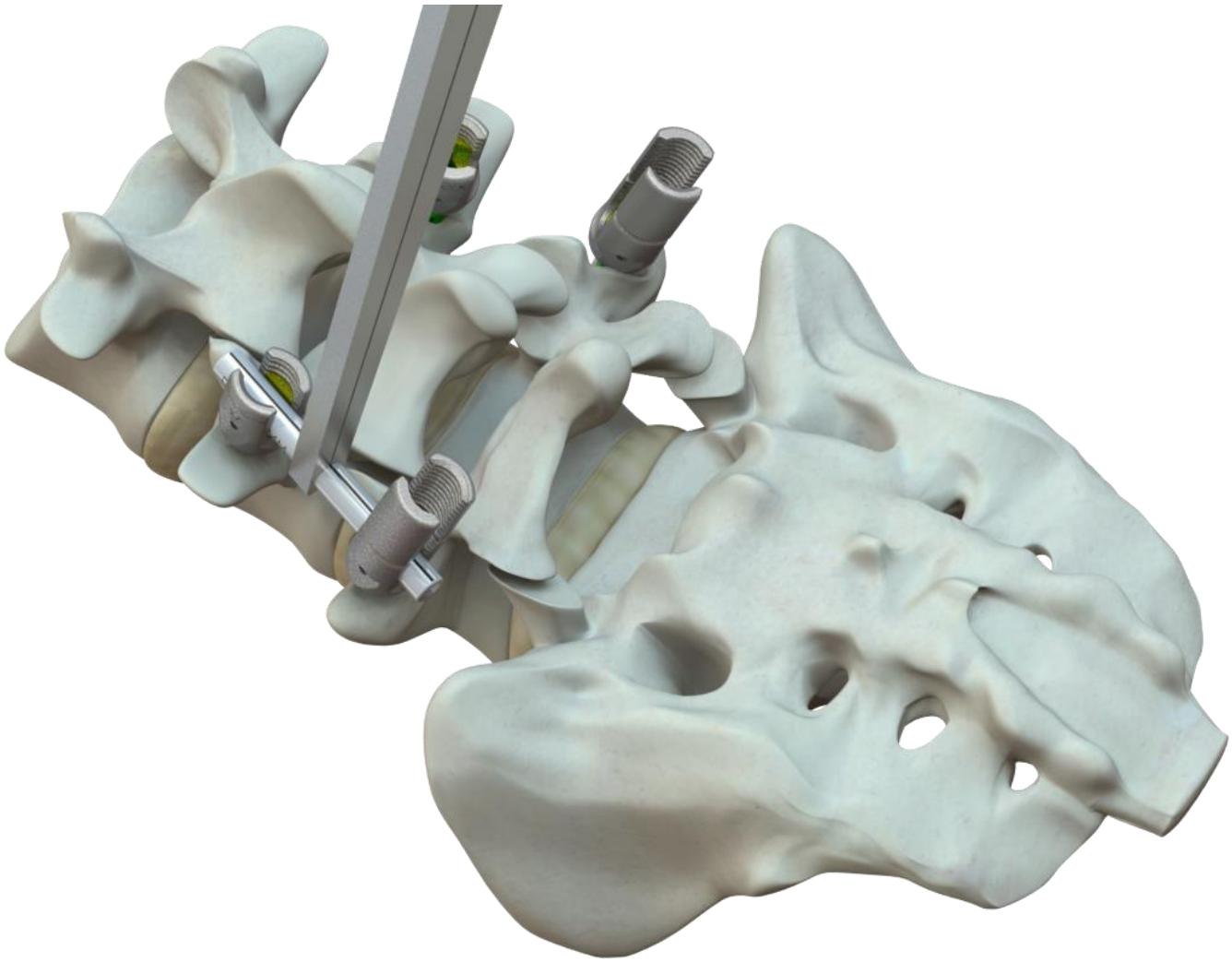
Repeat Step 3 for remaining VyLink™ anchors



VyLink™ Surgical Technique

Step 5. Rod Placement

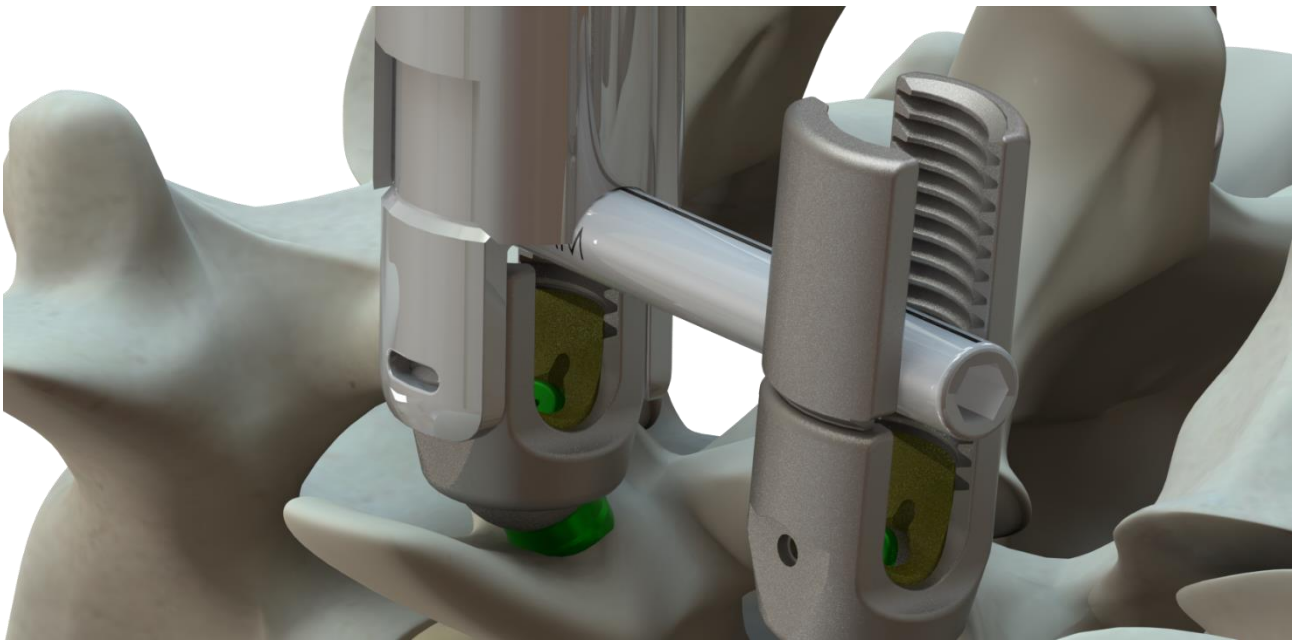
Determine VyLink™ rod contour by placing rod template into the heads of the VyLink™ anchors. The rod length may also be determined from the markings on the rod template.
Cut the VyLink™ rod to the appropriate length using rod cutters.
Contour the VyLink™ rod to match the rod template using the rod bender.
Align the VyLink™ rod to seat inside the heads of the VyLink™anchors.



VyLink™ Surgical Technique

Step 6. Rod Reduction (Optional)

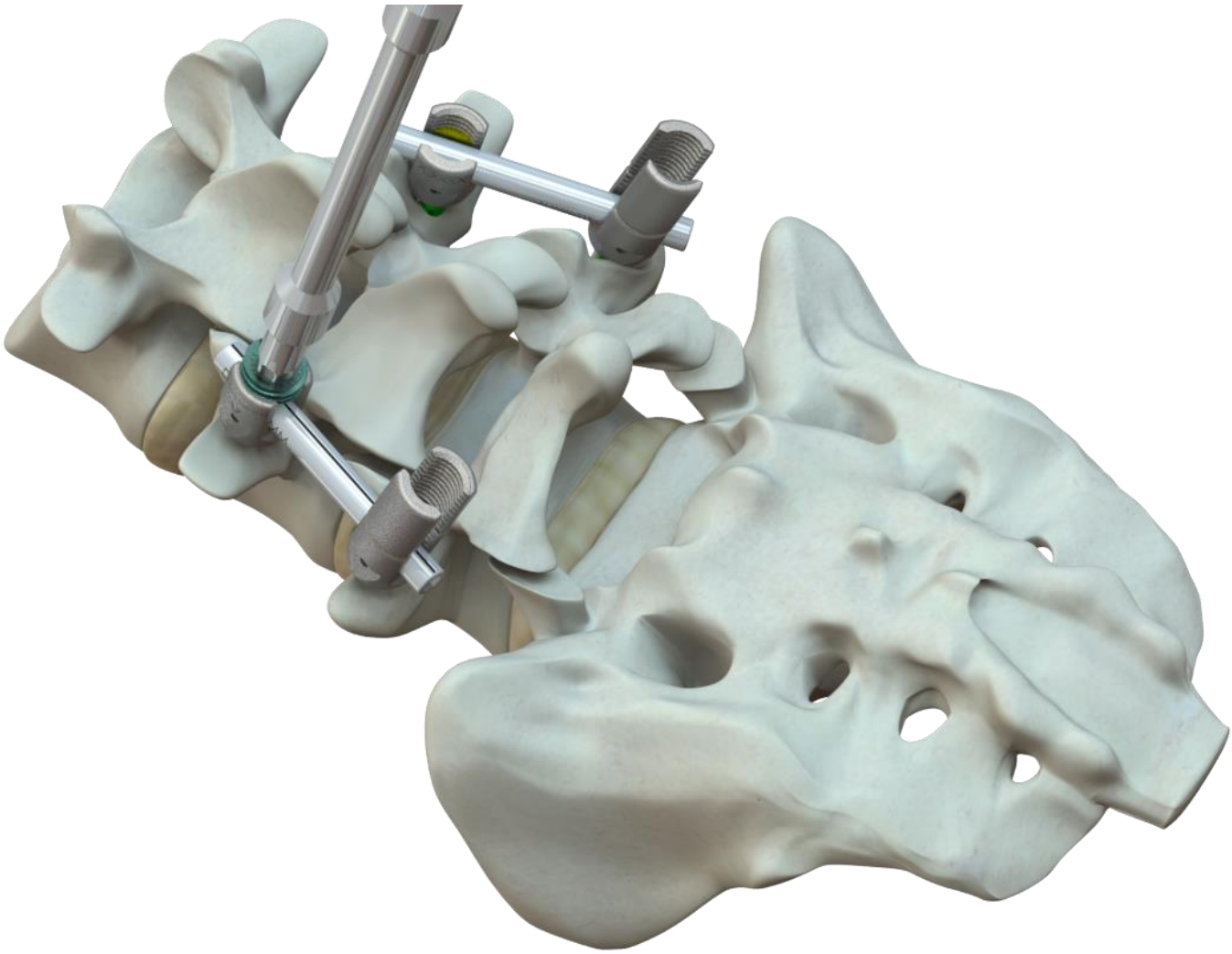
- Attach Reducer to the head of the VyLink™ Screw ensuring the interior tabs seat into the notches on the sides of the head. Use the Reducer to push the rod into the head of the VyLink™ Screw. Once Rod is seated, place a VyLink™ Set Screw onto a Final Driver or Swivel Stick, and insert the VyLink™ Set Screw into the Reducer. Finger tighten the Set Screw into the VyLink™ Screw head.
  If necessary, the rod made be persuading into the head of the anchor by using the rod pusher, rod forks, or rod persuaders.



VyLink™ Surgical Technique

Step 7. Place Set Screws

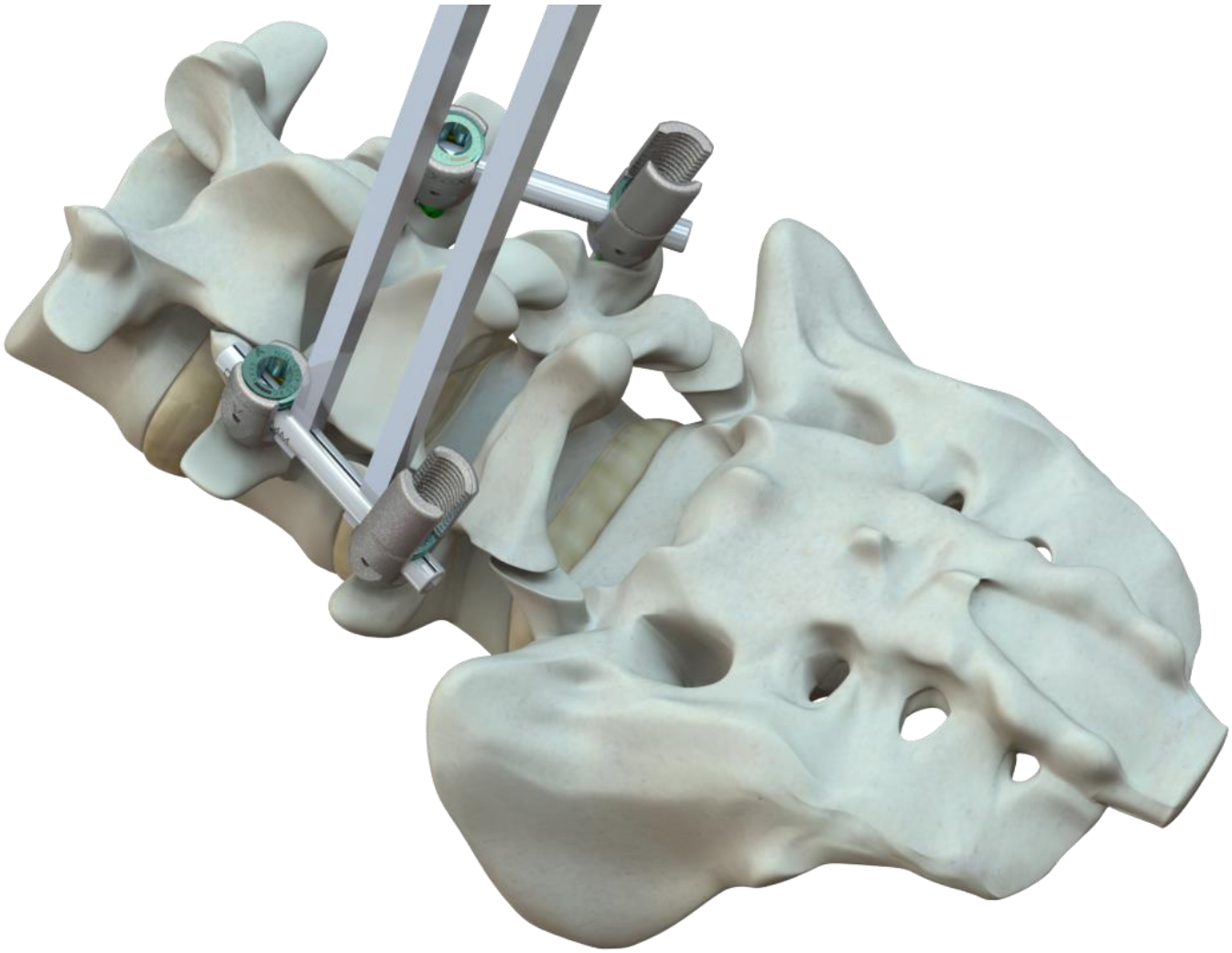
If a Reducer and VyLink™ Set Screw were not utilized in Step 6, place a VyLink™ Set Screw onto a Final Driver or Swivel Stick. Thread the VyLink™ Set Screw into the head of the VyLink™ Screw or Hook. Repeat as needed for remaining screws and hooks.



VyLink™ Surgical Technique

Step 8. Manipulate the Spine (Optional)

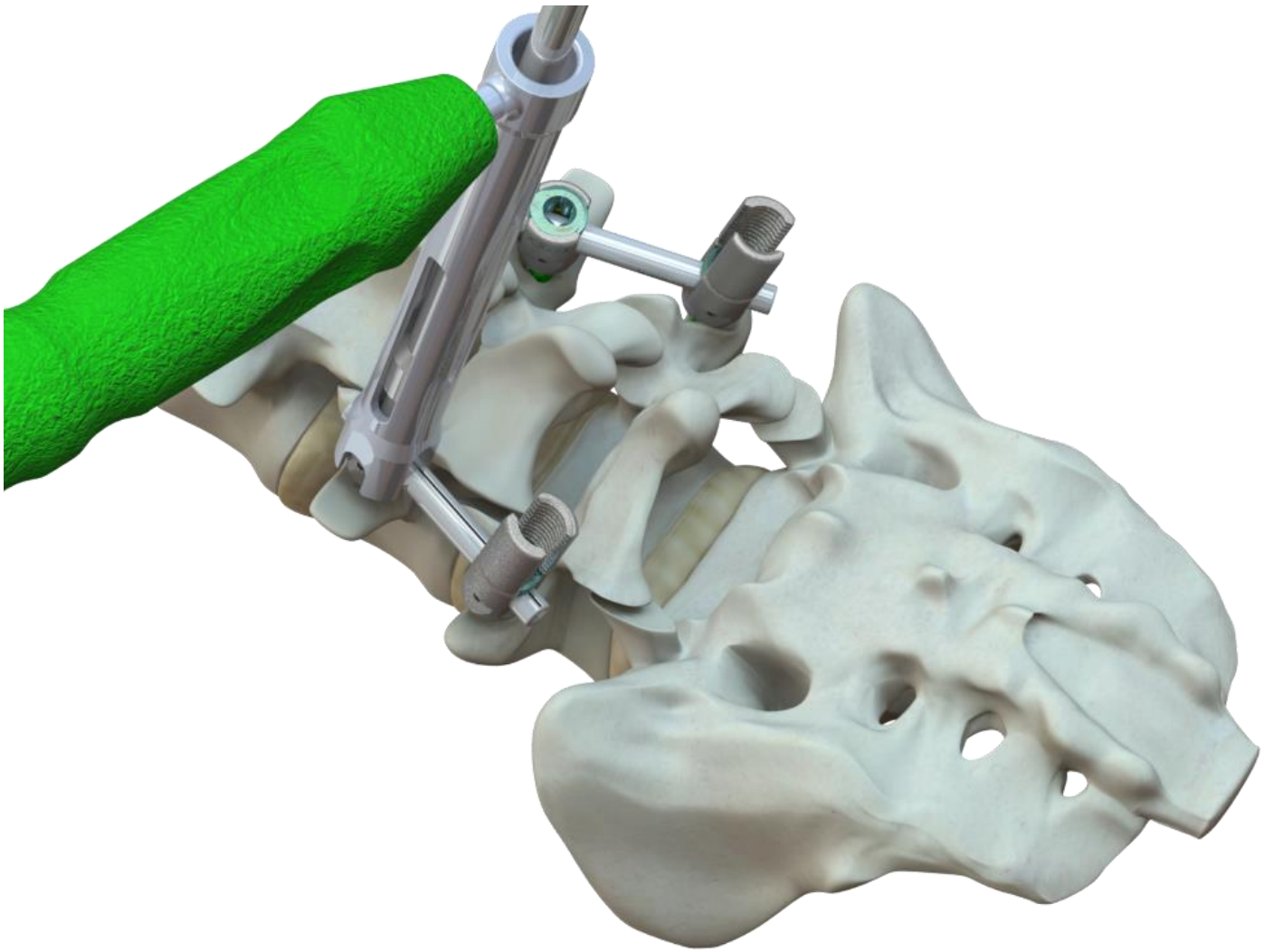
Manipulate the spinal anatomy as needed using distractors, compressors, in-situ benders, and/or rod derotators.



VyLink™ Surgical Technique

Step 9. Final Tighten Set Screws

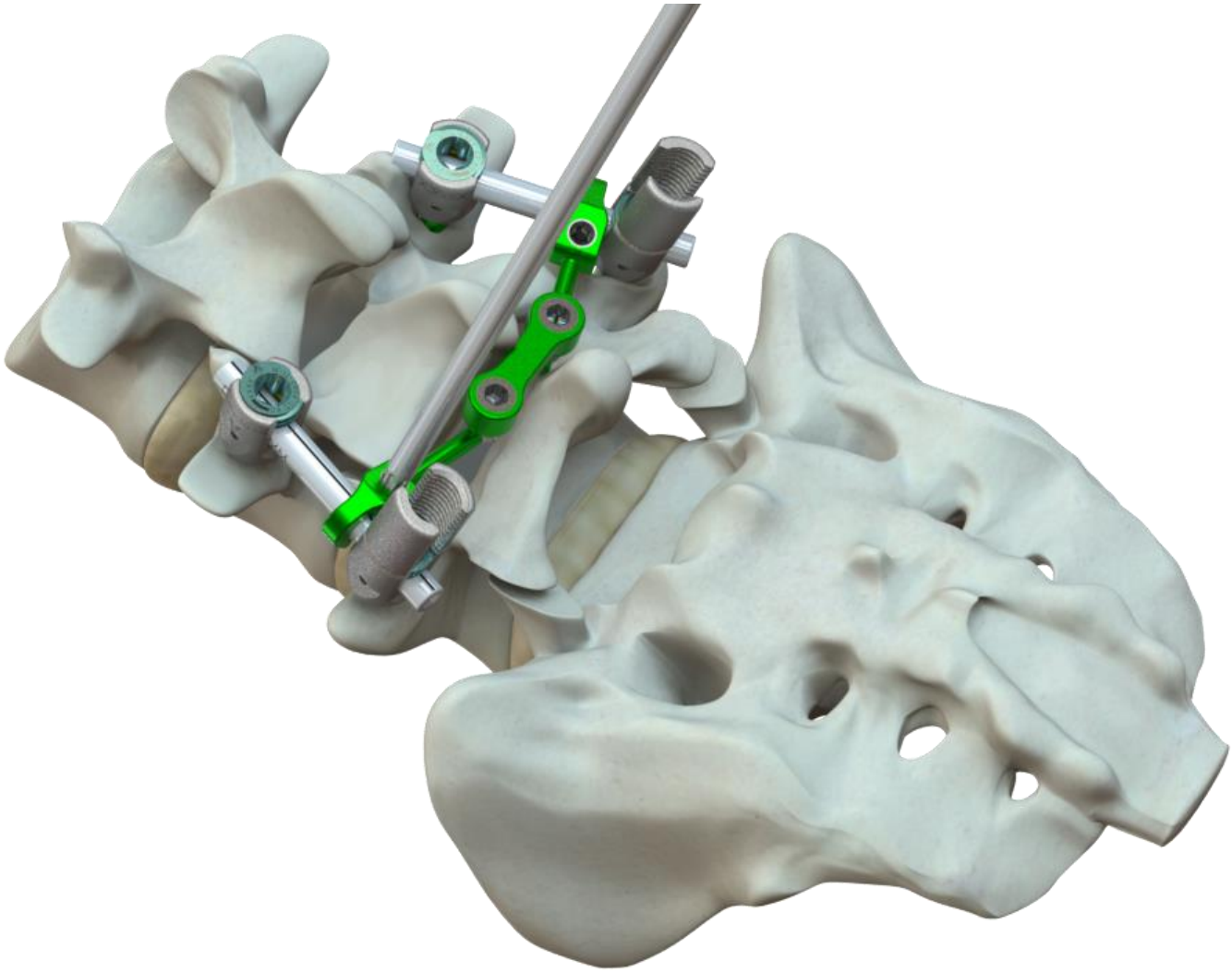
Prior to final tightening, ensure that the set screw is not resting on top of the capped portion of the rod, if capped rods are being used.
Place counter torque instrument over the head of the spine anchor.
Attach the 90 in-lb torque limiting handle (Lt Blue) to the locking driver.
Insert the tip of the Locking Driver into the hexalobe feature of the set screw.
Tighten until the 120 in-lb torque limiting handle clicks, indicating the proper torque has been applied.
Repeat for all set screws.
Remove any reduction tabs from the VyLink™ Reduction Screws, if used.



VyLink™ Surgical Technique

Step 10. Crosslink Placement (Optional)

Use calipers to measure the distance between the two rods.
Choose the appropriate connector.
Ensure that the set screws on the connector are not advanced.
Place the first hook end of the connector over the first rod.
Tighten the set screw of the first hook end using the crosslink driver and the 30 in-lb torque limiting handle (Grey). Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.
Place the second hook end of the connector over the second rod.
Tighten the set screw of the second hook end using the crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.
Tighten both set screws of the body portion using the crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.



VyLink™ Surgical Technique

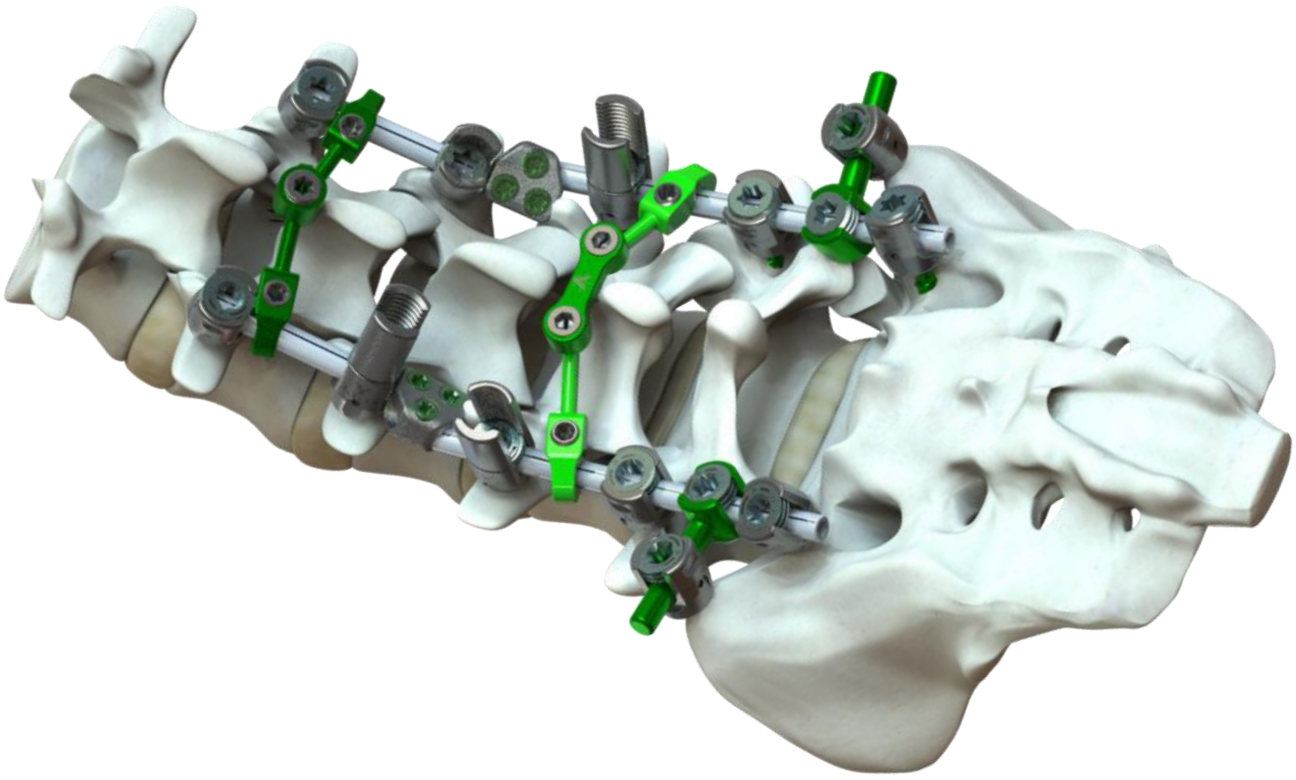
Step 11. Connector Placement (Optional)

- VyLink™ Rod to Rod Connectors

Choose the appropriate connector, if the rods line up, use the end-to-end connector, if they are offset, use the dual rod-to-rod, or open rod-to-rod connector.
Ensure that the set screws on the connector are not advanced.
Place the first end of the connector over the first rod.
Tighten the set screw of the first end using the crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle (Grey) clicks, indicating the proper torque has been applied.
Place the second end of the connector over the second rod.
Tighten the set screw of the second end using the crosslink driver and the 30 crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.
Tighten both set screws of the body portion using the crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.

- VyLink™ Lateral Offset Connector Placement

Use calipers to measure distance between rod and iliac screw to choose the appropriate connector.
Place the tulip end of the connector over the first rod.
Loosely secure the set screw on the tulip end using the final driver.
Place the rod end of the connector into the iliac screw.
Tighten the set screw of the second end using the crosslink driver and the 30 crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.
Tighten both set screws of the body portion using the crosslink driver and the 30 in-lb torque limiting handle. Tighten until the 30 in-lb torque limiting handle clicks, indicating the proper torque has been applied.



VyLink™ Ordering Information

Screw Options

All VyLink™ Screws use the same naming convention, as shown below. All VyLink Screw part numbers begin with 04, and end with TI-N, as they are all Titanium Alloy and provided Non-Sterile.

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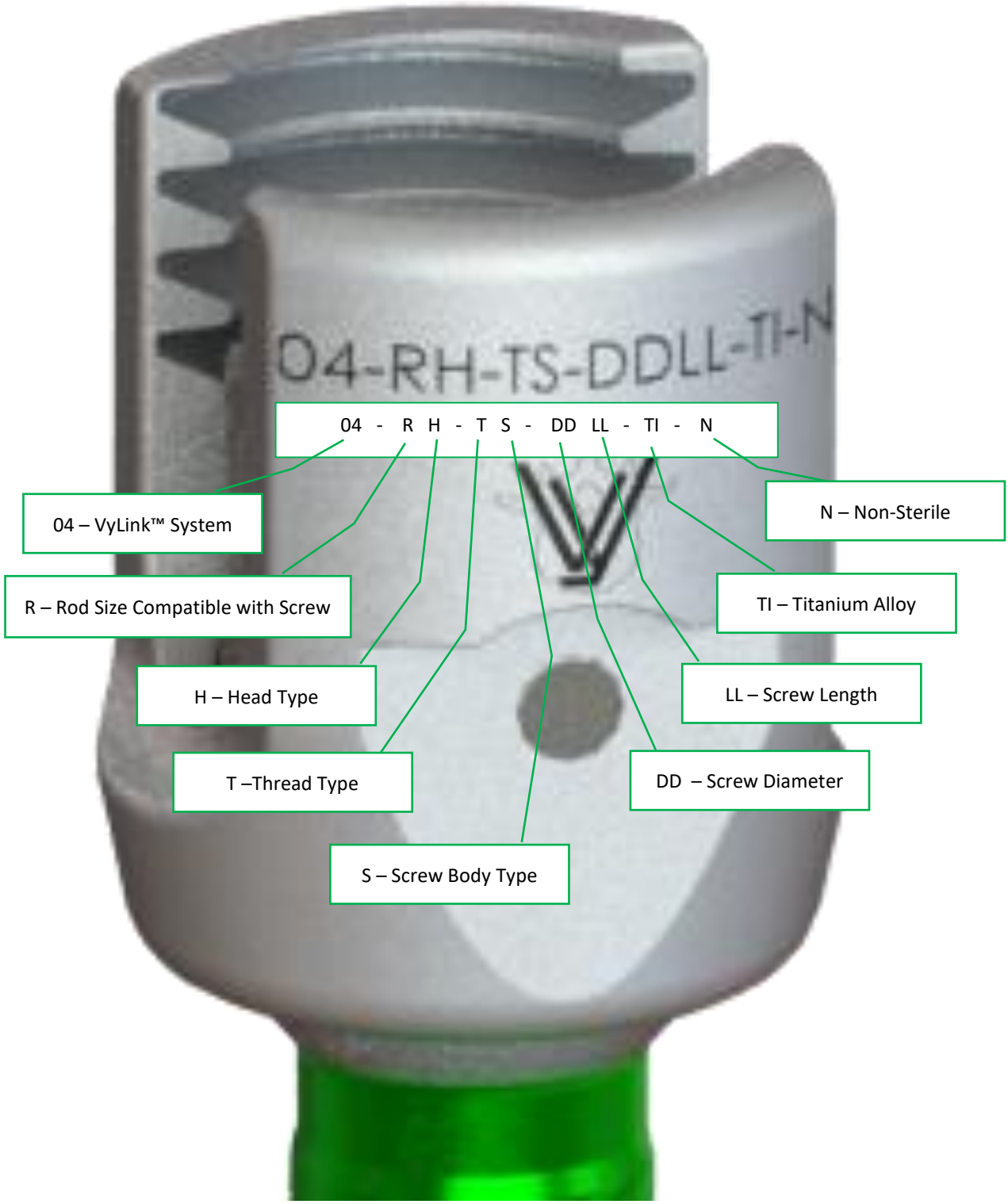


VyLink™ Ordering Information

Screw Options

Rod Size Compatibility

5 – Represents the 5.5 Rod (Silver Internal Collet)

6 – Represents the 6.0 Rod (Gold Internal Collet)

Head Type Offering

F – Fixed (Available upon Request)

FR – Fixed Reduction (Available upon Request)

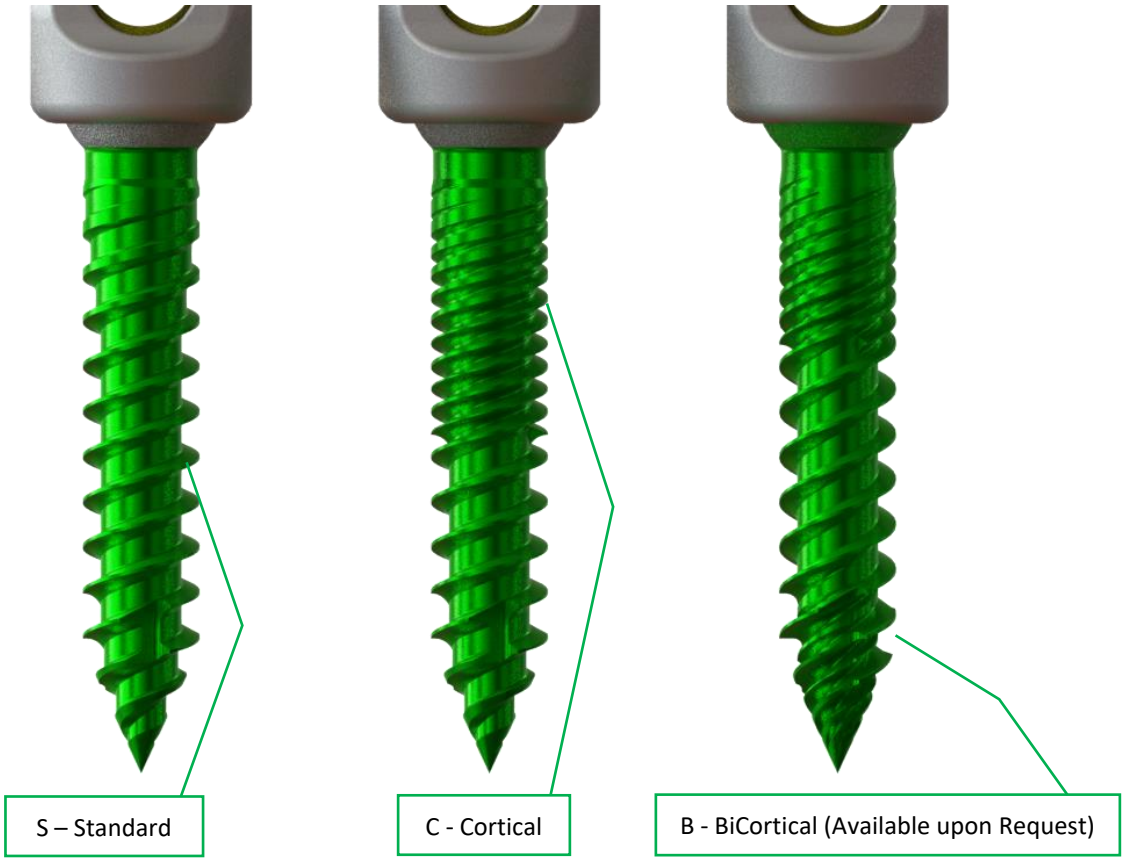
P – Polyaxial

PR – Polyaxial Reduction

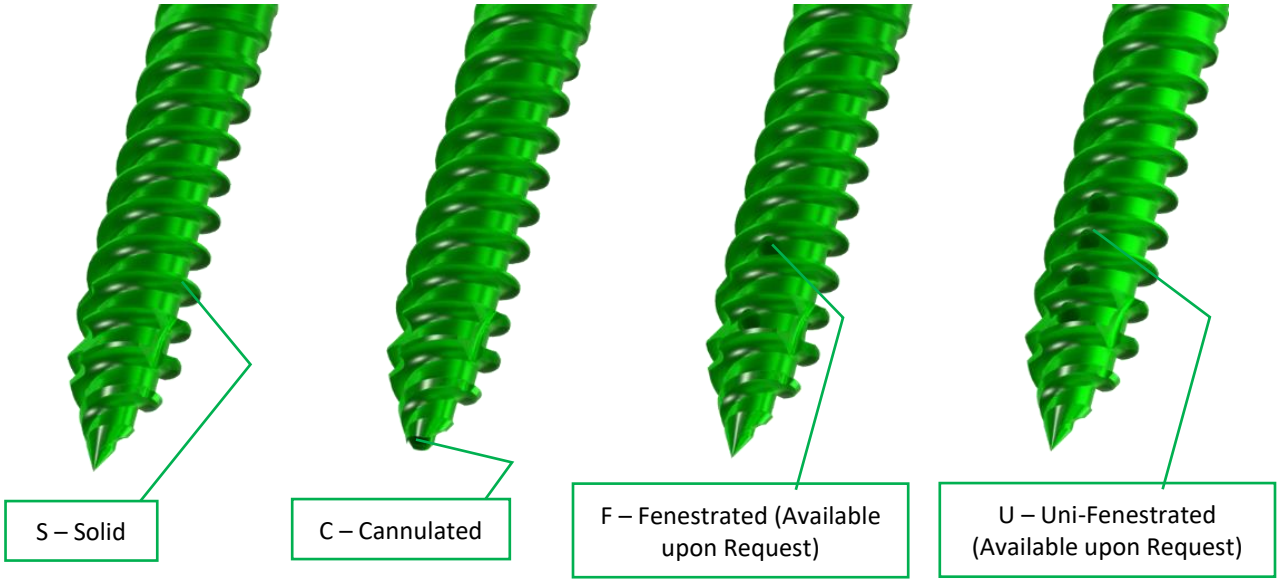
VyLink™ Ordering Information

Screw Options

Thread Type Offering



Screw Body Type Offering



VyLink™ Ordering Information

Screw Options

Diameter and Length Offering

Screw Diameter	Color	Lengths
Ø4.5mm	Yellow	25-45mm (50 – 100mm On Request)
Ø5.0mm (On Request)	Purple	25-45mm (50 – 100mm On Request)
Ø5.5mm	Green	25-55mm (60 – 100mm On Request)
Ø6.0mm (On Request)	Teal	25-55mm (60 – 100mm On Request)
Ø6.5mm	Magenta	25-70mm (75 – 100mm On Request)
Ø7.0mm (On Request)	Aqua	25-70mm (75 – 100mm On Request)
Ø7.5mm	Md Blue	25-70mm (75 – 100mm On Request)
Ø8.0mm (On Request)	Pink	25-70mm (75 – 100mm On Request)
Ø8.5mm	Dk Bronze	25-100mm
Ø9.0mm (On Request)	Dark Blue	25-100mm
Ø9.5mm (On Request)	Rose Gold	25-100mm
Ø10.0mm (On Request)	Lt Blue	25-100mm

VyLink™ Ordering Information

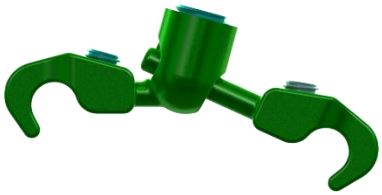
Rod Options

Part Number Series	Style	Material	Color	Diameter	Lengths
04-RC-55-LLL-CC-N	Curved	Cobalt Chrome	Silver	Ø5.5mm	25-600mm (On Request)
04-RC-55-LLL-TI-N	Curved	Titanium	Silver	Ø5.5mm	25-130mm (140-600mm On Request)
04-RCB-55-LLL-CC-N	Barbell	Cobalt Chrome	Silver	Ø5.5mm	25-600mm (On Request)
04-RCB-55-LLL-TI-N	Barbell	Titanium	Silver	Ø5.5mm	25-600mm (On Request)
04-RS-55-LLL-CC-N	Straight	Cobalt Chrome	Silver	Ø5.5mm	25-600mm (On Request)
04-RS-55-LLL-TI-N	Straight	Titanium	Silver	Ø5.5mm	400mm (25-600mm On Request)
04-RC-60-LLL-CC-N	Curved	Cobalt Chrome	Gold	Ø6.0mm	25-600mm (On Request)
04-RC-60-LLL-TI-N	Curved	Titanium	Gold	Ø6.0mm	25-130mm (140-600mm On Request)
04-RCB-60-LLL-CC-N	Barbell	Cobalt Chrome	Gold	Ø6.0mm	25-600mm (On Request)
04-RCB-60-LLL-TI-N	Barbell	Titanium	Gold	Ø6.0mm	25-600mm (On Request)
04-RS-60-LLL-CC-N	Straight	Cobalt Chrome	Gold	Ø6.0mm	25-600mm (On Request)
04-RS-60-LLL-TI-N	Straight	Titanium	Gold	Ø6.0mm	400mm (25-600mm On Request)

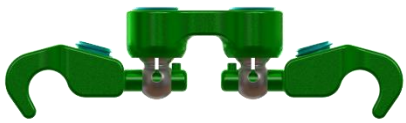
VyLink™ Ordering Information

Connector Options

Part Number	Product Size	Color
04-XS-6035-TI-N	35mm	Yellow
04-XS-6050-TI-N	50mm	Blue
04-XS-6075-TI-N	75mm	Green
04-XS-6090-TI-N	90mm	Brown

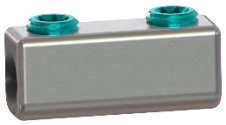


Part Number	Product Size	Color
04-XD-6035-TI-N	35mm	Yellow
04-XD-6050-TI-N	50mm	Blue
04-XD-6075-TI-N	75mm	Green
04-XD-6090-TI-N	90mm	Brown

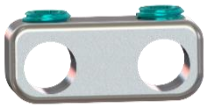


Part Number	Product Size	Color
04-CO-60050-TI-N	50mm	Blue
04-CO-60075-TI-N	75mm	Green
04-CO-60100-TI-N	100mm	Brown

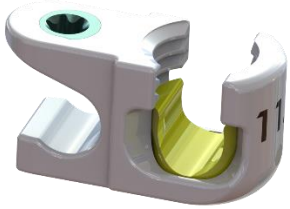
Part Number
04-CI-6001-TI-N



Part Number
04-CRR-6001-TI-N



Part Number	Product Size	Color
04-COR-5501-TI-N	5.5x12	Silver Collet
04-COR-5502-TI-N	5.5x14	Silver Collet
04-COR-6001-TI-N	6.0x12	Gold Collet
04-COR-6002-TI-N	6.0x14	Gold Collet



Part Number	Product Size	Color
04-COR-5512-TI-N	5.5x12	Silver Collet
04-COR-5514-TI-N	5.5x14	Silver Collet
04-COR-5516-TI-N	5.5x16	Silver Collet
04-COR-6012-TI-N	6.0x12	Gold Collet
04-COR-6014-TI-N	6.0x14	Gold Collet
04-COR-6016-TI-N	6.0x16	Gold Collet

Instrumentation Options

Part Number	Description	Size
04-ICC-001	Open Rod Connector Counter Torque	
04-ICC-002	Swivel Rod Connector Counter Torque	
04-ICT-001	Counter Torque	
04-IFD-001	Final Driver	
04-IFD-002	Final Driver - Long	
04-IHA-002	Head Adjuster 2	
04-ILP-001	Curved 465 Lenke Probe	
04-ILP-002	Straight 465 Lenke Probe	
04-INC-001	Open Connector Inserter	
04-INC-002	Threaded Open Connector Inserter	
04-IRD-001	Reducer	
04-IRD-002	Tower Reducer	
04-IRD-003	Tower Reducer Driver	
04-IRR-001	Rod Rotator	
04-ISC-001	Connector Driver	
04-ISD-001	Pedicle Screw Driver	
04-ISD-C01	Cannulated Pedicle Screw Driver	
04-ISD-C02	Cannulated Pedicle Screw Driver Hex	
04-ISD-R01	Reduction Pedicle Screw Driver	
04-ISD-R02	Reduction Pedicle Screw Driver Hex	
04-ISW-001	Swizzle Stick	
04-ISX-001	Crosslink Driver	
04-IT-C40	Cannulated Tap	4.0
04-IT-C50	Cannulated Tap	5.0
04-IT-C60	Cannulated Tap	6.0
04-IT-C70	Cannulated Tap	7.0
04-IT-C80	Cannulated Tap	8.0
BP301000-A	Awl (Black Handle)	
221300	Straight Fixed Handle	
692800	6.0mm Rod Holder	
673000	Rod Pusher	
TM145120-A	Torque Limiting, Driver (Cross Connector)	
PA712102-TI	Compresor	
PA712202-TI	Distractor	
SC224020-A	Torque-Limiting Screw Driver	

Indications:

The VyLink™ Spinal Screw System is a pedicle screw system 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The VyLink™ Spinal Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally-mature patients receiving fusion by autogenous bone graft and having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used posteriorly, the VyLink™ Spinal Screw System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for: spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

When used in a percutaneous, posterior approach with MIS instrumentation, the VyLink™ Spinal Screw System components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion in skeletally-mature patients.

The VyLink™ Spinal Screw System, when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous-failed fusion (pseudarthrosis).

The Vy Spine™ VySpan™ PCT System can also be linked to the Vy Spine™ VyLink™ Screw System using the dual diameter rods.

The Ø6.5mm and larger screws, including the hybrid screws, may be used for sacroiliac joint fusion. The VyLink™ Spinal Screw System when used in the sacroiliac joint is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

FOR ADDITIONAL INFORMATION INCLUDING PRECAUTIONS, WARNINGS, CONTRAINDICATIONS, CLEANING AND STERILIZATION, PLEASE REFER TO THE PACKAGE INSERT

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