Surgical Technique

Dynesys® Top-Loading System

The Dynamic Stabilization System

zimmer
Personal Fit. Renewed Life.®

Dynesys Top-Loading Spinal System
Surgical Technique

The Dynamic Stabilization System

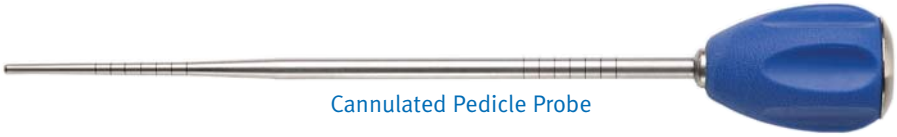
Please refer to the *Dynesys*® Spinal System and *Zimmer*® *DTO*™ Implant package insert for the Instructions for Use, indications, device description, contraindications, precautions, warnings and potential risks associated with the *Dynesys*® Top-Loading Spinal System.

Dynesys TL Instruments


Implant Trial


Cannulated Bone Awl


Solid Bone Awl


Cannulated Pedicle Probe


Solid Pedicle Probe


Pedicle Probe Sleeve


Pedicle Sound


Tap T-Handle

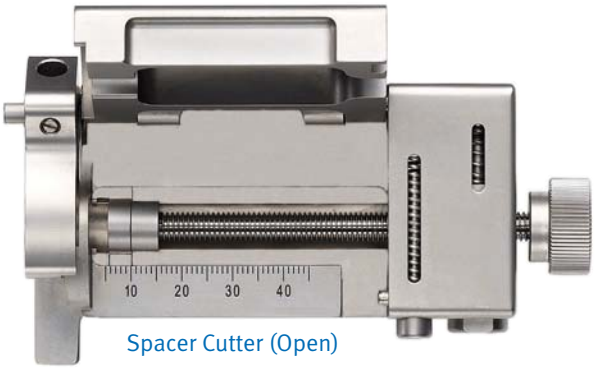

Cannulated Bone Taps


Pedicle Screw Driver


Ratcheting Handles

Pedicle Distance Gauge

Guide Pin Wrench



Spacer Cutter (Open)

Spacer Cutter Lever

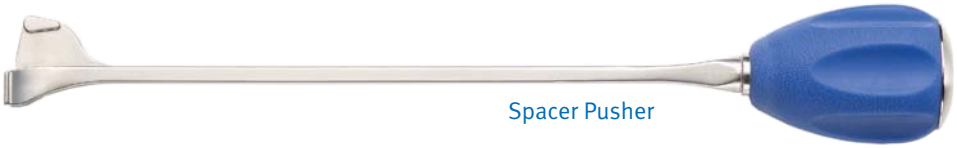
Guide Pin

Dynesys Glide™ Instruments

Set Screw Guide

7° Cord Guide

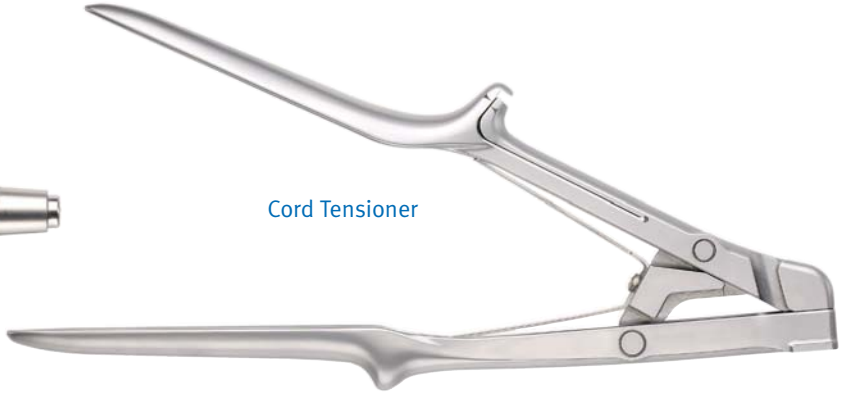
Spacer Holder



Spacer Pusher

Set Screw Driver with retaining feature (two options available)

Set Screw Torque Indicating Handle



Cord Tensioner

Dynesys TL Implants

The *Dynesys* TL Spinal System is composed of pedicle screws, universal spacers and cords.

Pedicle Screws: The screws anchor the *Dynesys* TL System into the spine. Hydroxyapatite (HA-coated) and standard screws are provided.

Note: The HA-coated screw threads have a white appearance.

Pedicle Screw:
PROTASUL®-100 (Titanium alloy)

HA-Coated Pedicle Screw:
PROTASUL®-100

Twenty-five screw sizes are available:

5.2 mm Diameter	6.0 mm Diameter	6.4 mm Diameter	7.2 mm Diameter	8.0 mm Diameter
5.2 x 35 mm	6.0 x 35 mm	6.4 x 35 mm	7.2 x 35 mm	8.0 x 35 mm
5.2 x 40 mm*	6.0 x 40 mm	6.4 x 40 mm	7.2 x 40 mm	8.0 x 40 mm
5.2 x 45 mm*	6.0 x 45 mm	6.4 x 45 mm	7.2 x 45 mm	8.0 x 45 mm
5.2 x 50 mm*	6.0 x 50 mm	6.4 x 50 mm	7.2 x 50 mm	8.0 x 50 mm
5.2 x 55 mm*	6.0 x 55 mm*	6.4 x 55 mm	7.2 x 55 mm	8.0 x 55 mm

*Optional; available upon request.

Note: A screw with a diameter greater than 6.0 mm is recommended for good anchorage in the sacrum.

Note: 8.0 mm screws should be used for revisions only.

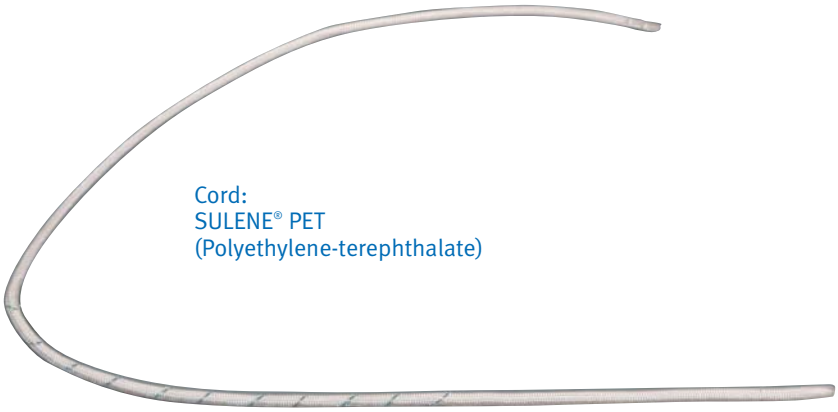
Use the largest diameter and longest length screw possible according to the patient's anatomy. Consider the individual patient's case when selecting a screw.

Universal Spacers: The spacers are used to hold the segments in a more natural anatomical position and to control the spine in extension.

Universal Spacers:
SULENE® PCU
(Polycarbonate-urethane)

Cords: The cord controls forward flexion movements.

Note: Use only the Dynesys *stabilizing cord.*



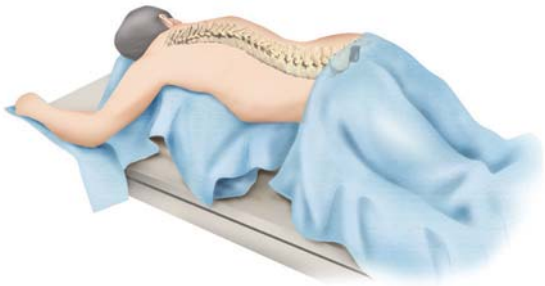
Cord:
SULENE® PET
(Polyethylene-terephthalate)

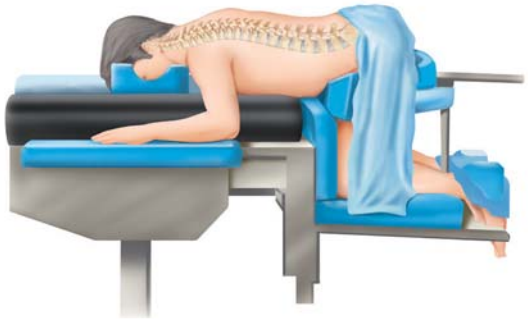
Patient Positioning

Prone or Knee-Chest positions are acceptable provided that care is taken to preserve the natural lordosis of the lumbar spine. Avoid any pressure on the abdominal cavity that might result in excessive bleeding.

The use of fluoroscopy for placement of the screws is strongly recommended.

Other valid computer-aided surgical navigation techniques may also be used.





Incision

Two Options:

Paraspinal Approach:
The Paraspinal Intermuscular Approach is the preferred minimally invasive technique to be used (when desired bone decompression can be accomplished).

Incision Choices:
Use a midline incision over the spinous processes of the vertebrae.

OR

Make two cuts lateral from the spinous processes of the vertebrae.

Open the dorsal fascia.

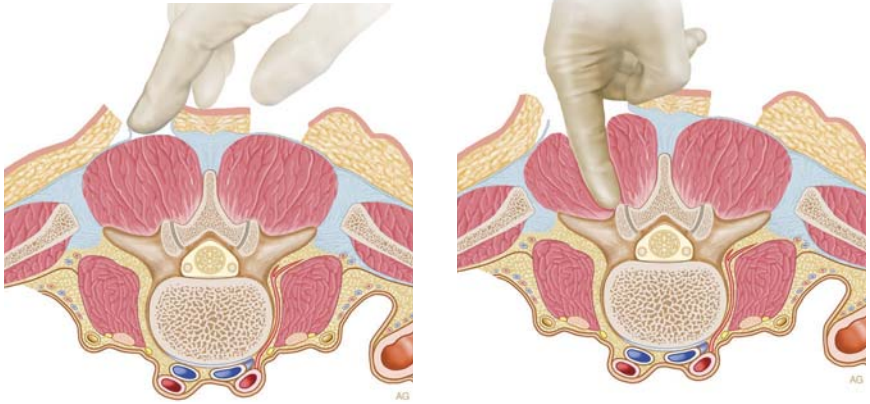
Split up the muscles (L1–L3 between Multifidus and Longissimus; L4–S1 between Iliocostalis and Longissimus).

Midline Approach:
Make a lumbar median incision over the spinous processes of the vertebrae.

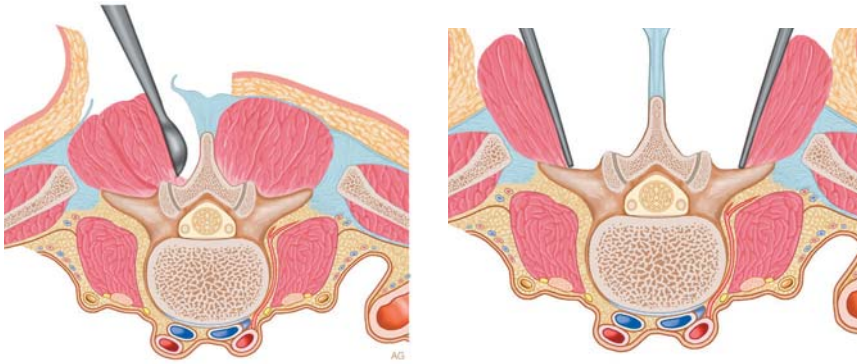
Make the incision one segment longer (proximal and distal) than the planned operative level(s).

Move the musculature aside from the spinous process.

Paraspinal Approach



Midline Approach



Preparation Before the Placement of the Pedicle Screws

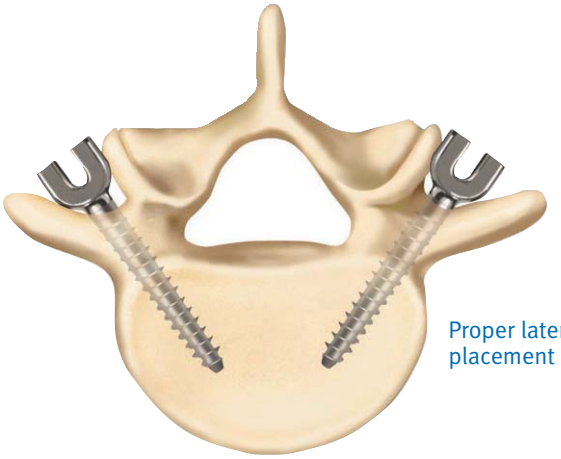
Place the screws lateral to the facet joints.

Correct screw placement is absolutely necessary for optimal functioning of the system and for long term anchorage of the screws.

Use the Implant Trial to determine the correct position of the screws.

Note: The facet joints must remain intact.

Note: If there is not adequate room for the spacer, remove bone from the lateral aspect of the articular process while preserving the capsule.



Proper lateral screw placement

Option 1: Pedicle Preparation and Screw Placement with K-wires

Pedicle Preparation with K-wires

The *Dynesys* TL System is designed for use with 1.6 mm K-wires with blunt ends.

Prepare the pedicle for K-wire placement. Place the K-wire into the vertebral body.

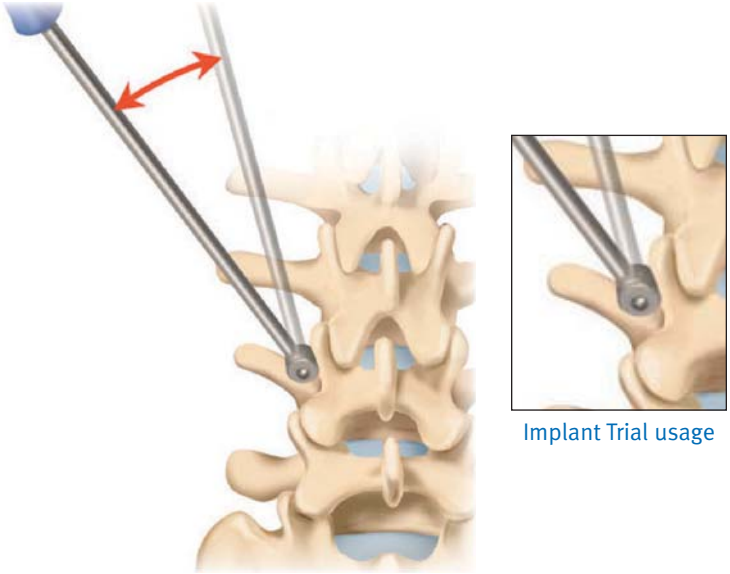
Caution: X-ray use is recommended when using K-wires and cannulated instrumentation to ensure proper positioning within the pedicle and vertebral body.

Note: Inspect the Cannulated Bone Awl, Cannulated Pedicle Probe, Cannulated Taps, and Pedicle Screw Driver prior to use to ensure that the cannula is not occluded.

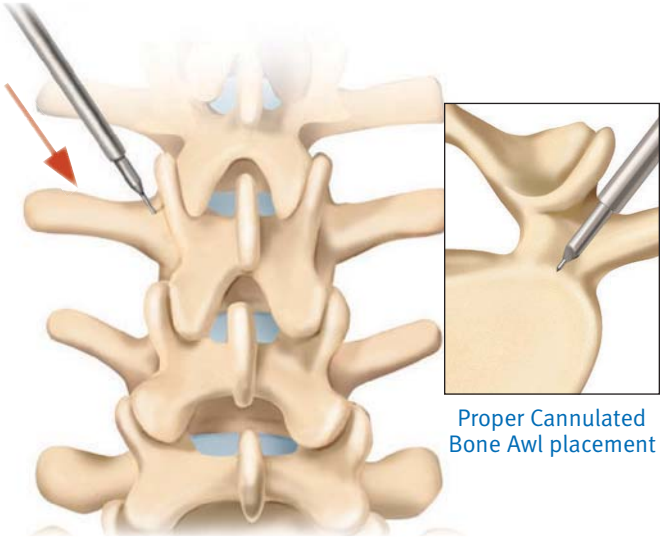
Place the Cannulated Bone Awl over the K-wire and open the pedicle with the Cannulated Bone Awl.

Note: The Cannulated Bone Awl is intended for use over a K-wire only.

Remove the Cannulated Bone Awl, leaving the K-wire in desired position.



Implant Trial usage



Proper Cannulated Bone Awl placement

Place the Cannulated Pedicle Probe over the K-wire and advance to create the channel for the screw.

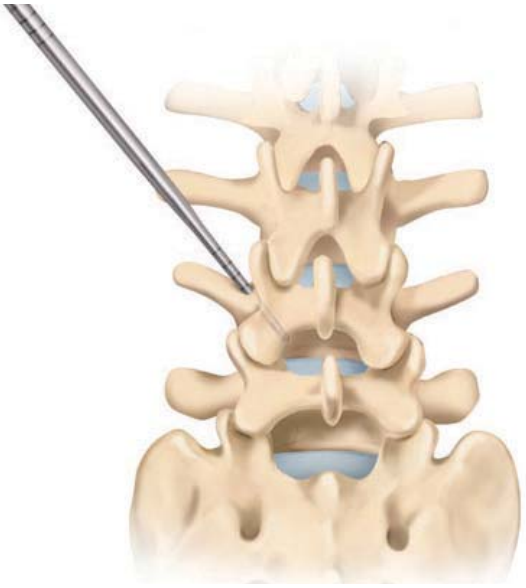
The marks on the Cannulated Pedicle Probe help determine the appropriate screw lengths (35, 40, 45, 50 or 55 mm).

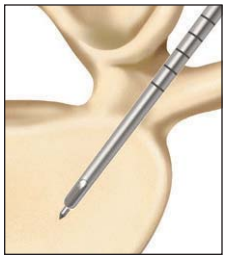
Note: Do not open the pedicle deeper than the length of the intended screw (maximum screw length is 55 mm). Screw length depends on patient morphology.

Note: X-ray use is recommended.

Remove the Cannulated Pedicle Probe, leaving the K-wire in desired position.

Note: Inspect the Cannulated Pedicle Probe after use to ensure that the cannula is not occluded.





The marks on the Cannulated Pedicle Probe will help determine the appropriate screw lengths (35, 40, 45, 50 or 55 mm).

OPTIONAL:
Depth Sleeve
If you have difficulty seeing the marks on the tip of the Cannulated Pedicle Probe, use the Depth Sleeve and the corresponding marks on the proximal end of the shaft.

Optional Pedicle Tapping with K-wires

Note: Dynesys *TL screws do not require tapping. Use of a Cannulated Bone Tap is optional.*

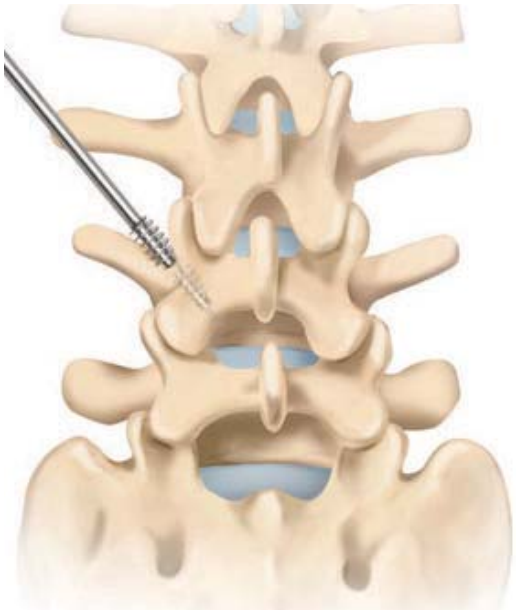
Select appropriate sized Cannulated Bone Tap.

Place over K-wire, advance to pedicle entrance point and tap to the appropriate depth.

Caution:
- **Always select the Bone Tap diameter that corresponds to the pedicle screw size to be implanted.**
- **Inspect cannulated Bone Taps prior to use to ensure that the cannula is not occluded.**
- **Do not tap beyond the length of the pedicle screw to be implanted.**
- **X-ray use is recommended when using Bone Taps.**

Remove Cannulated Bone Tap, leaving K-wire in desired position.

Note: Inspect the Cannulated Bone Tap after use to ensure that the cannula is not occluded.

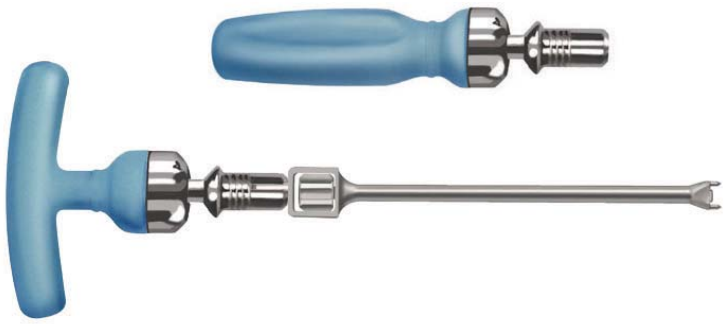


Placement of the Pedicle Screws with K-wires

Set Up of the Pedicle Screw

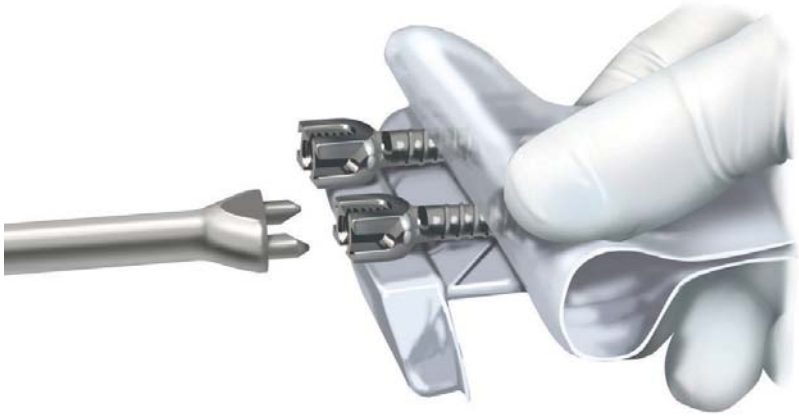
Engage the Pedicle Screw Driver with the desired Ratcheting Handle.

Note: Inspect to ensure that the components are fully engaged.



Insert the screw onto the Pedicle Screw Driver.

Caution: Avoid contact between glove and screw threads to ensure aseptic conditions.



Ensure that the Pedicle Screw Driver tangs are fully seated into the corresponding screw slots.

Advance thumbwheel, turning clockwise to secure the screw to the Pedicle Screw Driver.

Caution: Do not over-tighten.

Note the orientation of the Pedicle Screw Driver and the pedicle screw head.

Placement of the Pedicle Screws

Place desired screw and Pedicle Screw Driver over K-wire.

Note: You may choose to remove the K-wire once proper trajectory of the pedicle screw is identified.

Advance into the pedicle until the screw head or the polished portion of the screw is in contact with the bone.

Caution:
- **Inspect the Pedicle Screw Driver and Ratcheting Handle prior to use to ensure that the cannula is not occluded.**
- **Ensure that the K-wire is properly positioned in the cannulated portion of the Pedicle Screw Driver when advancing the screw.**

Caution: Upon insertion of the screw, do not reverse the screw to back it up.

The distance between the middle of the screw head and bone must be less than 10 mm.

Position the screws to allow for passage of the cord.

Caution: A torque and/or bending load that is too high can fracture the pedicle.

Turn the thumbwheel counterclockwise to release the pedicle screw from the Pedicle Screw Driver.

Remove the Pedicle Screw Driver.

After the first screw has been placed, use the Implant Trial to approximate the final position and orientation of the second screw head, and to ensure adequate room for the spacer.

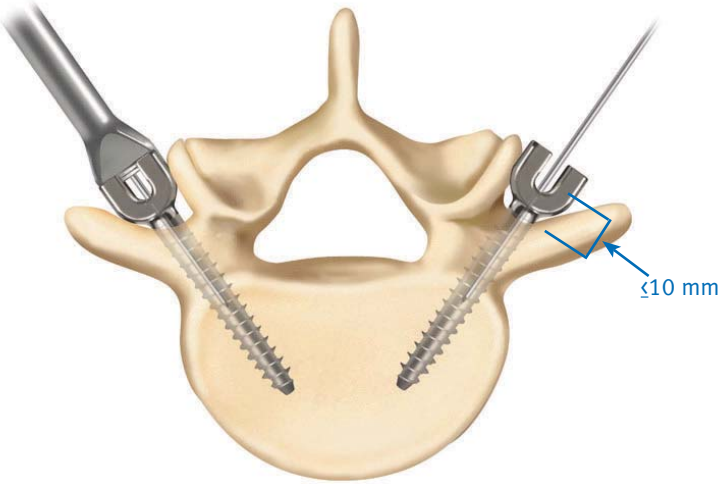
Place all screws.

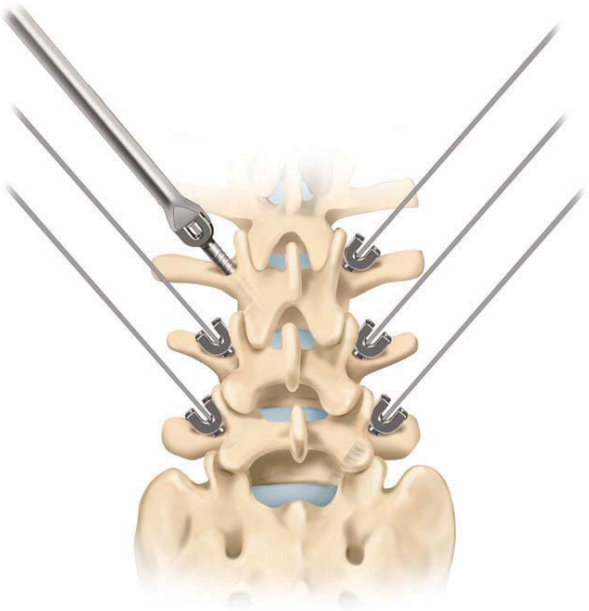
Check the screw placement with fluoroscopy, x-ray or other valid computer-aided surgical navigation techniques.

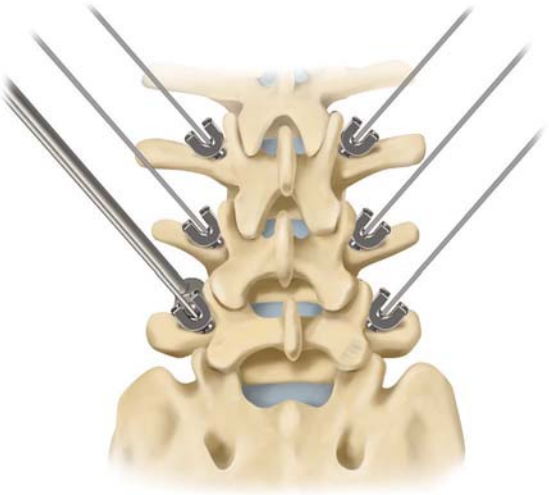
Use the Implant Trial to ensure adequate room for the spacer.

Note: If there is not enough room for the spacer, carefully remove bone from the lateral aspect of the articular process while preserving the facet capsule.

Proceed to the “Universal Spacer” section.







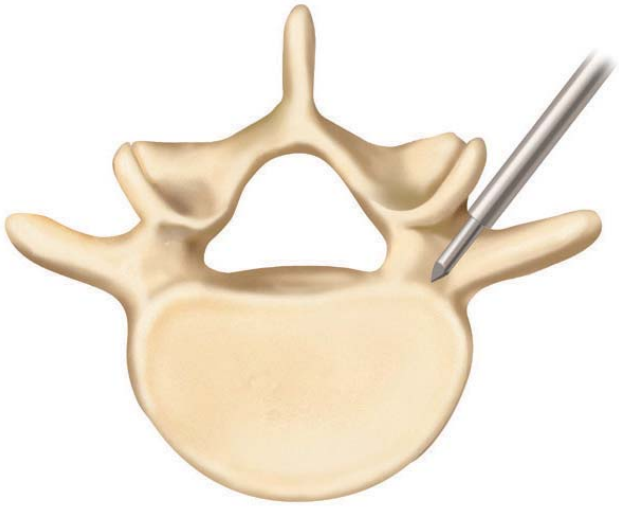
Option 2:

Pedicle Preparation and Screw Placement without K-wires

Pedicle Preparation without K-wires

Open the pedicle with the Bone Awl.

Caution: Do not use the Cannulated Bone Awl without K-wires.



Use the Solid Pedicle Probe to create the channel for the screw.

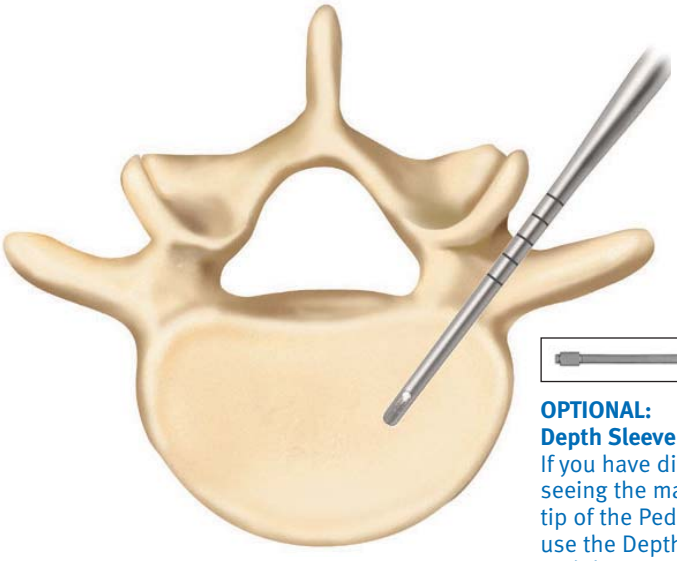
The marks on the Solid Pedicle Probe help determine the appropriate screw lengths (35, 40, 45, 50 or 55 mm).

Note: Do not open the pedicle deeper than the length of the intended screw (maximum length is 55 mm). Screw length depends on patient morphology.

Note: Do not use a curved pedicle probe, which may widen the bone channel.

Note: X-ray use is recommended.

Check with the Pedicle Sound to confirm that the pedicle wall is intact.



OPTIONAL:
Depth Sleeve
If you have difficulty seeing the marks on the tip of the Pedicle Probe, use the Depth Sleeve and the corresponding marks on the proximal end of the shaft.

Optional Pedicle Tapping

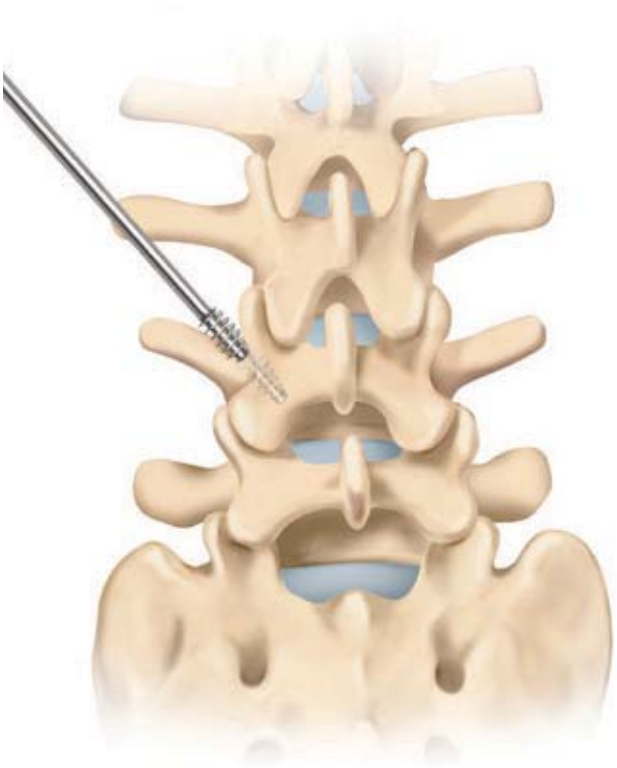
Note: Dynesys *TL screws do not require tapping. Use of a Cannulated Bone Tap is optional.*

Select the appropriate size Cannulated Bone Tap.

Advance to pedicle entrance point and tap to the appropriate depth.

Caution:
- **Always select the Bone Tap diameter that corresponds to the pedicle screw size to be implanted.**
- **Inspect cannulated Bone Taps before and after use to ensure that the cannula is not occluded.**
- **Do not tap beyond the length of the pedicle screw to be implanted.**
- **X-ray is recommended when using Bone Taps.**

Remove the Cannulated Bone Tap.

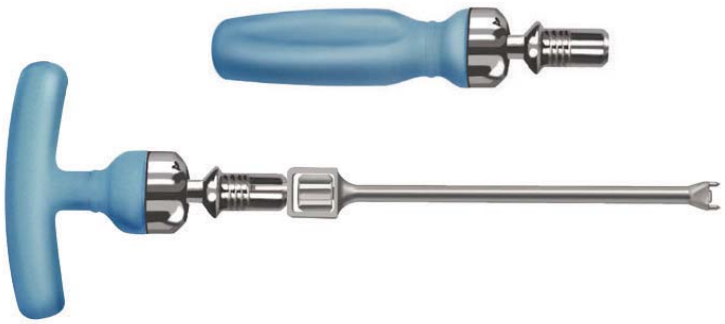


Placement of the Pedicle Screws without K-wires

Set Up of the Pedicle Screw

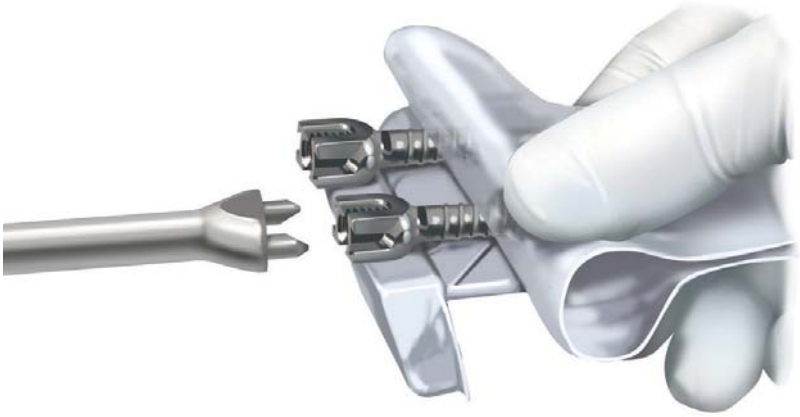
Engage the Pedicle Screw Driver with the desired Ratcheting Handle.

Note: Inspect to ensure that the components are fully engaged.



Insert the screw onto the Pedicle Screw Driver.

Caution: Avoid contact between glove and screw threads to ensure aseptic conditions.



Ensure that the Pedicle Screw Driver tangs are fully seated into the corresponding screw slots.

Advance the thumbwheel, turning clockwise to secure the screw to the Pedicle Screw Driver.

Caution: Do not over-tighten.

Note the orientation of the Pedicle Screw Driver and the pedicle screw head.

Placement of the Pedicle Screws

Insert the screws. It is important to place the screws lateral to the facets.

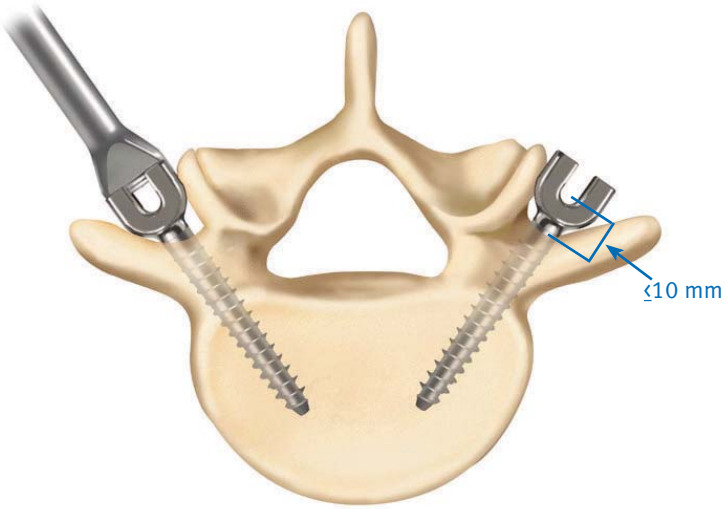
Advance the screw until the head or the polished portion of the screw is in contact with the bone.

Caution: Upon insertion of the screw, do not reverse the screw to back it up.

Position the screws to allow for passage of the cord.

Caution: A torque and/or bending load that is too high can fracture the pedicle.

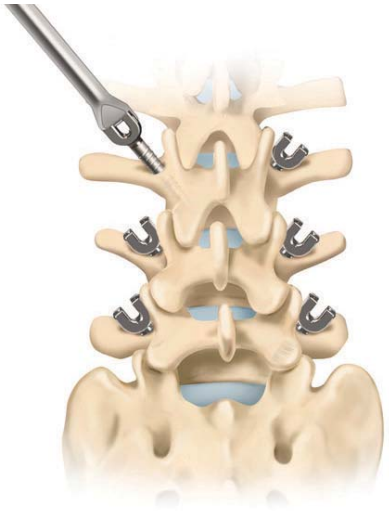
The distance between the middle of the screw head and bone must be less than 10 mm.



Turn the thumbwheel counterclockwise to release the screw from the Pedicle Screw Driver.

Remove the Pedicle Screw Driver.

After the first screw has been placed, use the Implant Trial to approximate the final position and orientation of the second screw head, and to ensure adequate room for the spacer.

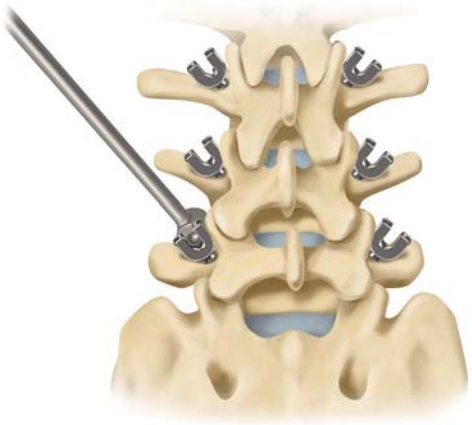


Place all screws.

Check the screw placement with fluoroscopy, x-ray or other valid computer-aided surgical navigation techniques.

Use the Implant Trial to ensure adequate room for the spacer.

Note: If there is not enough room for the spacer, carefully remove bone from the lateral aspect of the articular process while preserving the facet capsule.



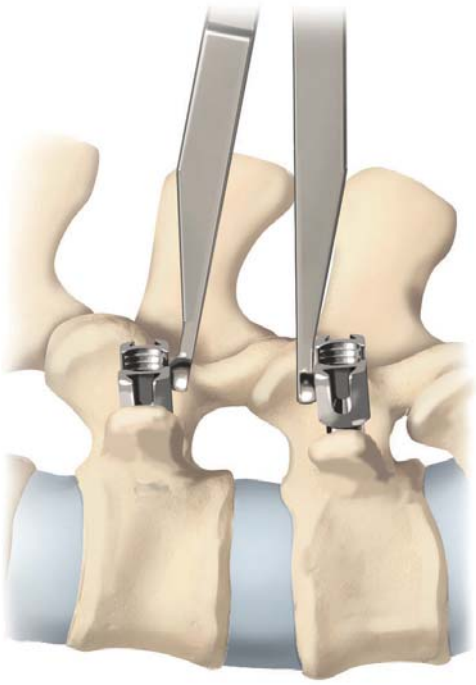
Universal Spacer

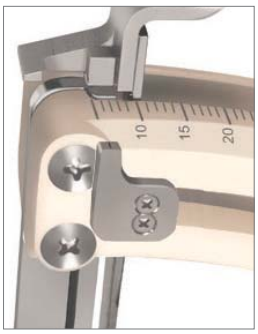
Measuring Spacer Length

Verify that the Drag Indicator on the Pedicle Distance Gauge is in the start position.

Place the Pedicle Distance Gauge between the screw heads at the bottom of the screw slots. Verify proper position and measure the appropriate spacer length.

Note: The Pedicle Distance Gauge allows measurement with or without the cord in place.





Drag Indicator start position

Assess the movement in the facets in distraction and compression.

Measure the distance (spacer length) with a slight distraction force.

Possible guidelines: Distract to create parallel endplates or distract to create neutral facet joint position.

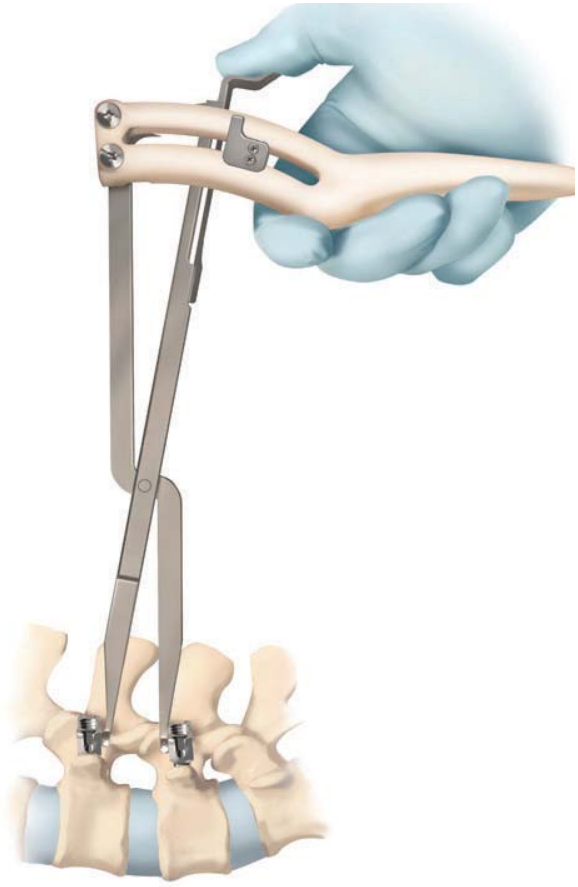
Caution: Do not induce kyphosis or scoliosis.

Note: Fluoroscopy usage is highly recommended while measuring the spacer length.

Considering patient position, determine the desired spacer length for each side with light distraction or compression.

Record the measured spacer length for all levels. Spacer length measurement must be done on both sides before the cord and spacer are implanted.

Note: Reset the Drag Indicator after each measurement. Failure to reset may lead to incorrect spacer measurement.



Cutting the Universal Spacer to Size

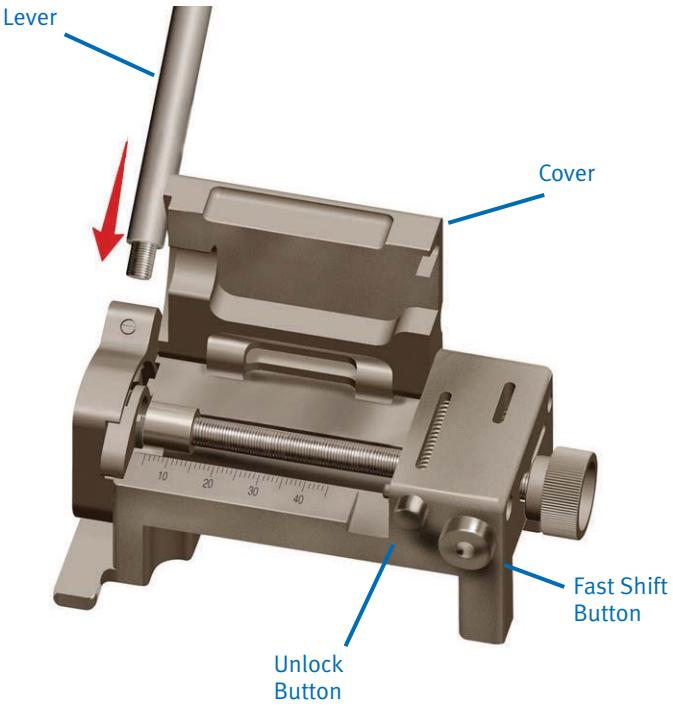
Use the Spacer Cutter to cut the spacer.

The spacer can only be cut once and is used only on one vertebral segment side.

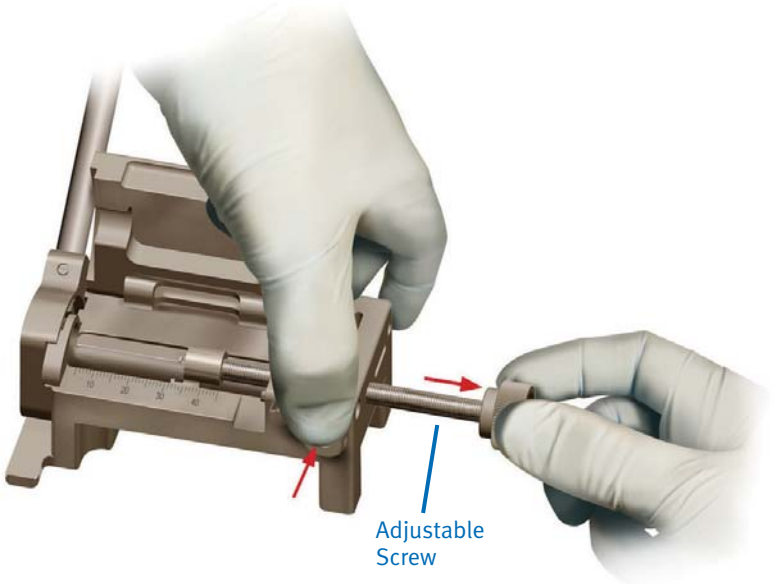
Spacer lengths can be cut from 6 mm to 45 mm.

The Cutter Blade must be replaced if the cutting edge has deteriorated (nicks on the cut surface of the spacer). Refer to Appendix A for instructions.

Remove the Lever from the tray. Put the Lever into the Blade Holder. Open the Cover while pressing the Unlock Button.



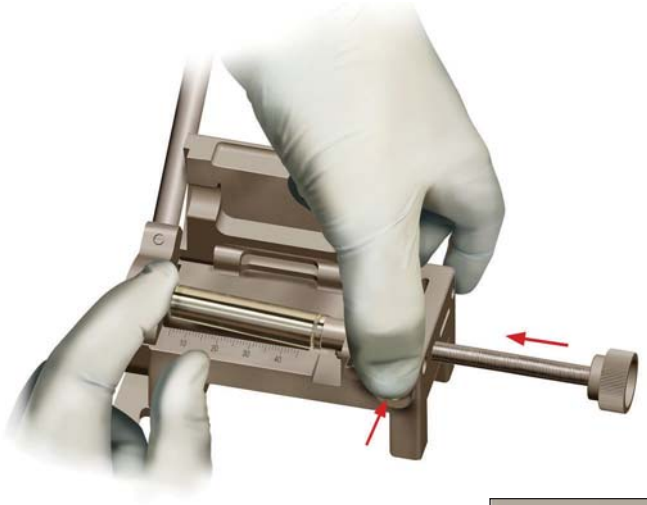
To open the channel for the spacer, press the Fast Shift Button and move the Adjustable Screw as far to the right as it will go.



Place the spacer groove into the slot provided on the Adjustable Screw.

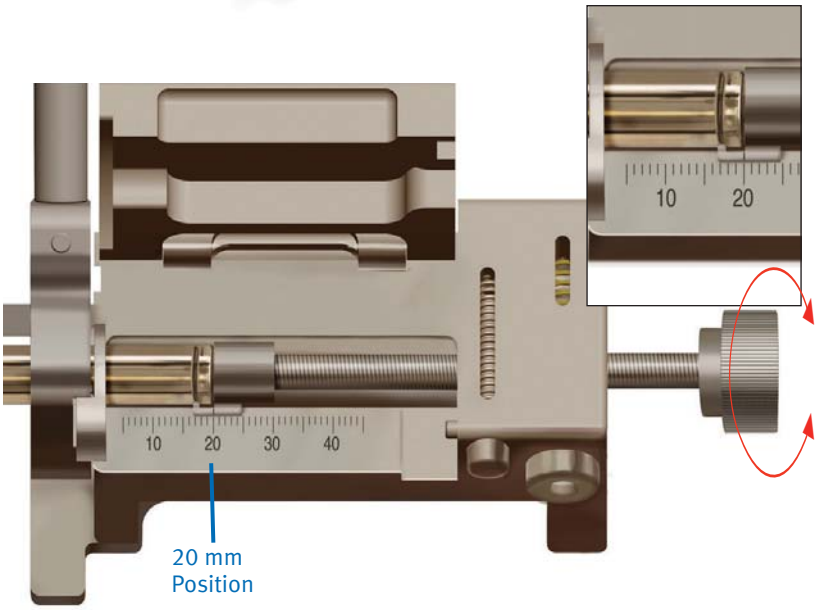
Hold down the Fast Shift Button and push the Adjustable Screw to the left for the initial adjustment.

Note: The Blade Holder must be in the backward (open) position to adjust the spacer.



Turn the Adjustable Screw to set the final desired length.

Alignment of the markers shows the actual size being cut.

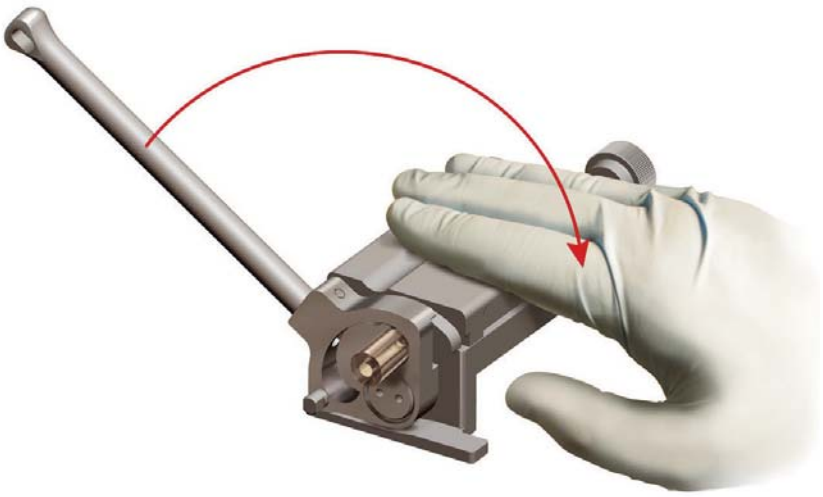


Close the Cover while pressing the Unlock Button.

Hold the Spacer Cutter with one hand and pull the Lever forward with the other hand until it stops.

Return the Lever to the initial position.

Open the Cover while pressing the Unlock Button.



Discard the cut off portion of the spacer.

Remove the sized spacer. Spacer length may be verified on the scale located on the top of the Spacer Cutter.

You may order an optional Spacer Organizer to organize cut spacers by placing them on a peg that corresponds to the correct level and side.

Note: Do not recut the spacer.

Note: Implant the spacer portion with the groove.

Cord

The cord is available in two sizes: 100 mm and 200 mm.

Note: Use the 100 mm length for one or two levels. Use the 200 mm length for two or more levels.

The cord is made up of three segments: the Introduction Zone, the Working Zone and the Functional Zone.

Note: The Introduction Zone is the thin part of the cord and should be positioned on the most cephalad side of the implant construct (100 mm length only).

Note: The Working Zone is wrapped in green thread and is intended to facilitate cord tensioning.

Note: With the Cord Tensioning Instrument, only work in the Working Zone.

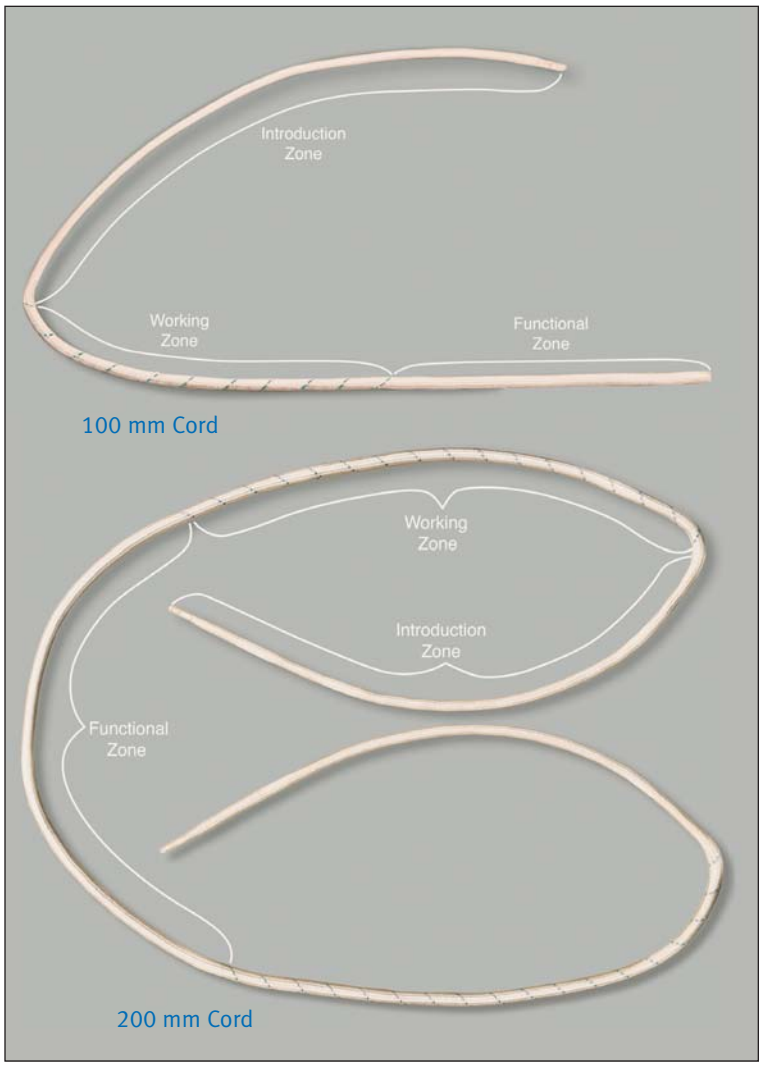
Note: The Functional Zone is the part implanted into the patient.

Do not work with the Cord Tensioning Instrument in the Functional Zone.

The 100 mm cord has one Introduction Zone, one Working Zone and one Functional Zone.

The 200 mm cord has two Introduction Zones (one on each end), two Working Zones (next to the Introduction Zones) and one Functional Zone (in the middle of the cord).

Note: Handle the cord carefully to ensure aseptic conditions.



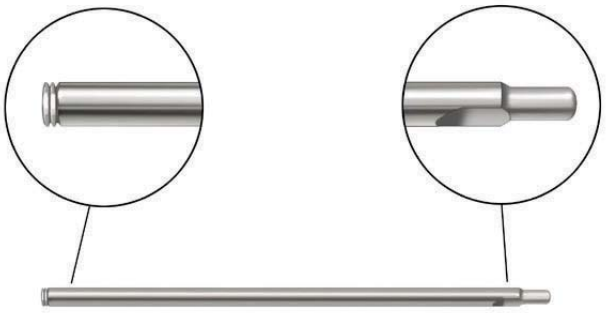
Guide Pin

Use the Guide Pin to dock *Dynesys Glide* Instruments. One end of the Guide Pin is terminated with threads to fix the Guide Pin to the screw. The opposite end of the Guide Pin is terminated with a blunt end that provides a floating engagement with the screw.

Note: If using the threaded end of the Guide Pin, do not over-tighten.

Use the Guide Pin Wrench to remove the Guide Pin from the screw.

Note: It may be necessary to compensate for tissue pressure when removing the Guide Pin.



Dynesys Glide Instrumentation

The *Dynesys Glide* Instruments are available in three angulations (0°, 7° and 15°) to accommodate various corresponding angles of screw convergence.

0° *Dynesys Glide* Instrument

7° *Dynesys Glide* Instrument

15° *Dynesys Glide* Instrument

Caution: Off-axis alignment between the Glide and pedicle screw can result in the docking of only one of side of the Glide. This may lead to excessive loading of the dovetail feature when a distractive force is applied to the Glide.

Note: A guide pin is necessary to assist with correct placement of the Glide.

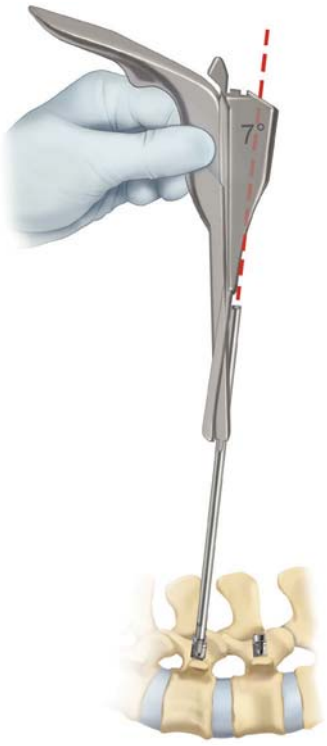
Incorrect alignment

Caution: Even with the use of the Guide Pin, off-axis alignment is still possible with the 7° and 15° Glides. This can occur when the Glide is not axially aligned with the Guide Pin due to side load being applied to the Glide.

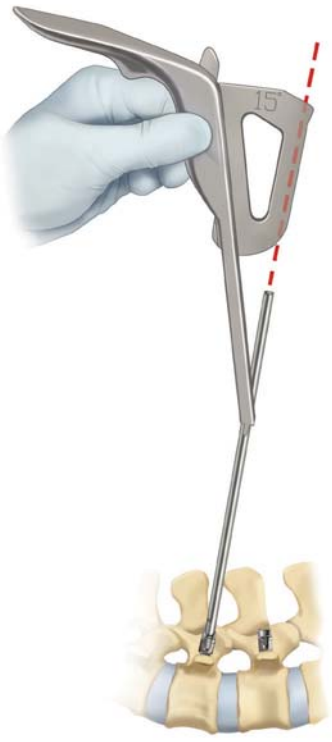
Note: Use of the Cord Guide with the 7° Glide, and of the Set Screw Driver Guide with the 15° Glide, will ensure proper alignment.

Incorrect alignment

0°



7°



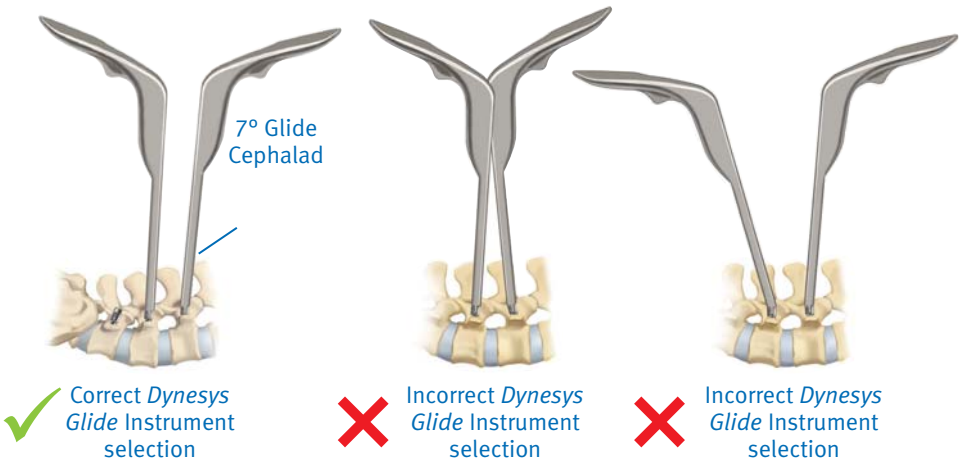
15°

Dynesys Glide Instrumentation: Primary Level

Using the Guide Pin, dock the 7° *Dynesys Glide* Instrument onto the cephelad screw.

Using the Guide Pin, dock the 0°, 7° or 15° *Dynesys Glide* Instrument to the caudal screw.

Note: When the appropriate angled Dynesys Glide *Instruments have been docked to the pedicle screws, the two instruments should be parallel or slightly divergent.*



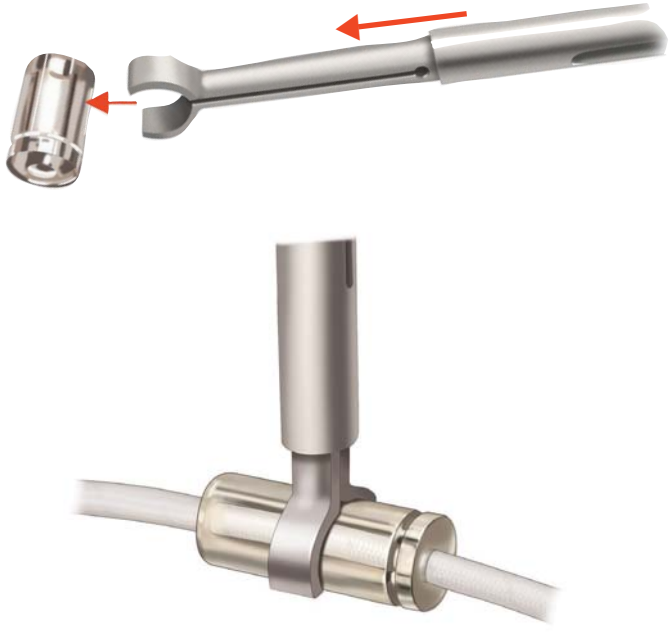
Reduction of the Cord and Spacer

Attach the appropriately sized spacer to the distal end of the Spacer Holder and advance the sleeve fully to lock the spacer into place.

Ensure that the Spacer Holder is centered on the spacer.

Thread a 100 or 200 mm cord through the spacer and position with the spacer in the Functional Zone.

Note: Handle the cord carefully to ensure aseptic conditions.

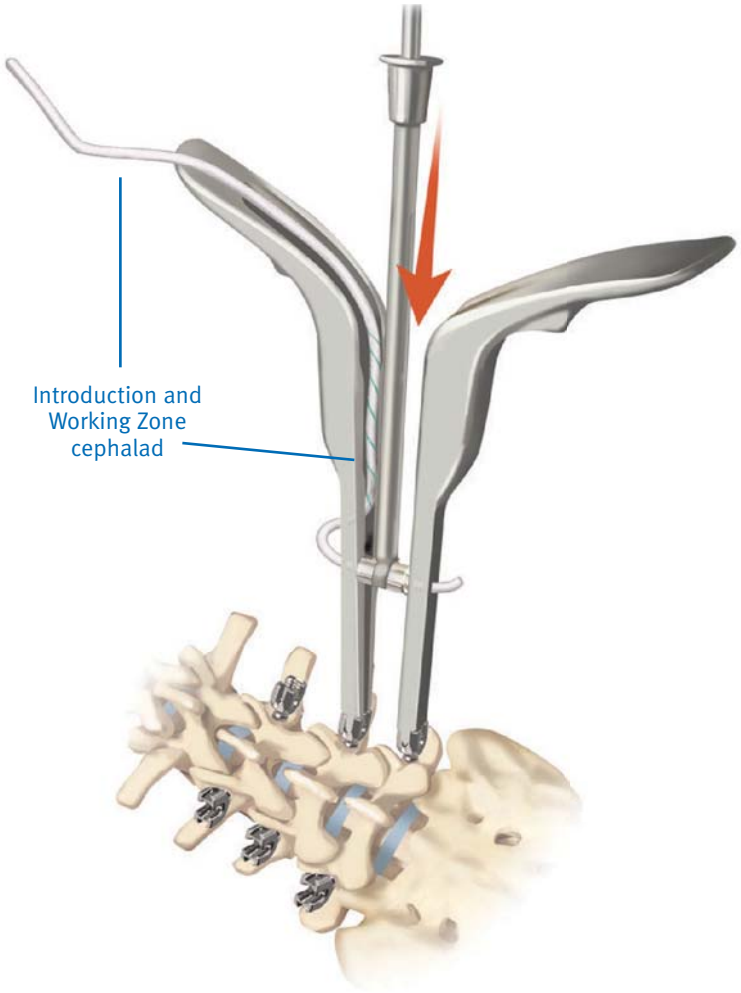


Ensure that a minimum of 20 mm of Functional Zone extends beyond the spacer on the caudal side.

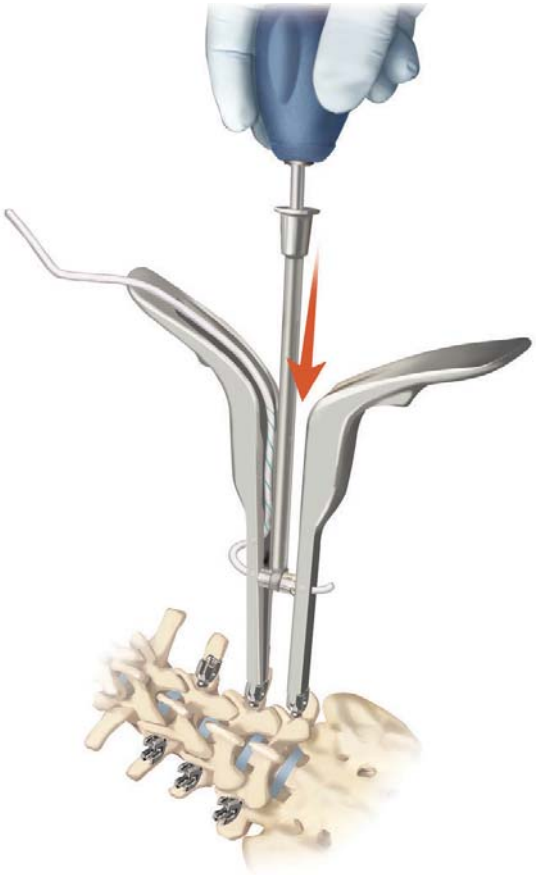
When using the 100 mm cord, the Introduction and Working Zones should be positioned cephalad.

Place the spacer and cord between the *Dynesys Glide* Instruments with the cord positioned into the *Dynesys Glide* Instrument slots.

Note: Handle the cord carefully to ensure aseptic conditions.



Using the Spacer Holder, carefully advance the spacer toward the pedicle screws until fully seated.



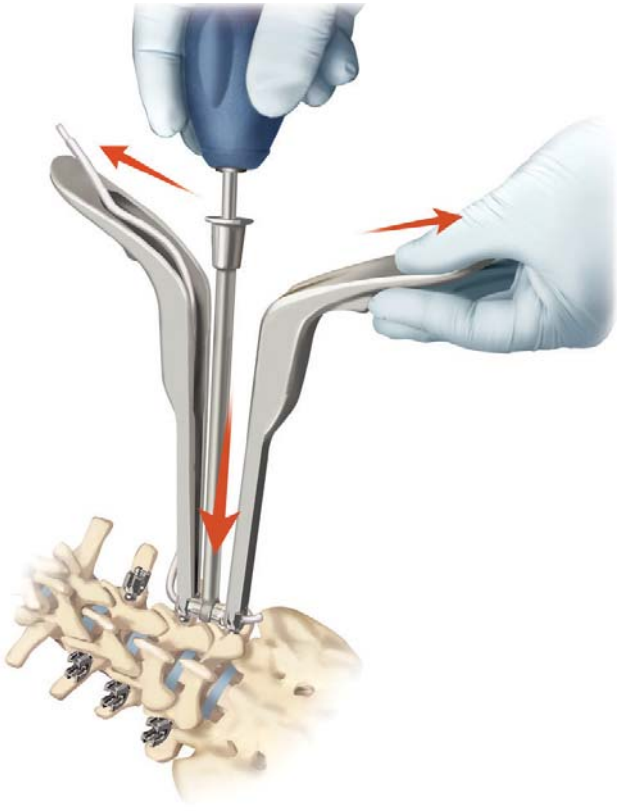
You may use a mallet to gently tap against the Spacer Holder handle if desired.

Note: While advancing the spacer, a slight distractive force may be applied with the Dynesys Glide *Instrument handles.*

Caution: A torque and/or bending load that is too high can fracture the pedicle.

Disengage and remove the Spacer Holder.

Ensure that the cord is placed properly into the *Dynesys Glide* Instrument slots and is fully seated in the pedicle screw saddle.



Placing and Tightening the First Set Screw with the 0° *Dynesys Glide* Instrument

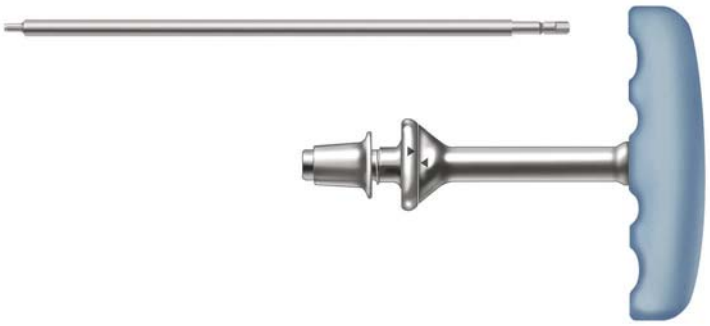
Reposition the cord as required, ensuring that a minimum of 10 mm extends beyond the most caudal screw.

Assemble a Set Screw Driver to the Set Screw Torque Indicating Handle.

Note: Two styles of Set Screw Driver are provided (see illustration) to accommodate surgeon preference.

Note: Inspect to ensure that the components are fully engaged.

Note: When using the Set Screw Driver with retaining ring, inspect the retaining feature before and after each use to ensure proper condition.



Two Set Screw Drivers are available:

Both Set Screw Drivers have a set screw retaining feature that will hold the set screw securely when the set screw is fully seated.

Insert the set screw onto the preferred Set Screw Driver tip and inspect to ensure that the screw is fully seated and secure.

Note: It may be necessary to rotate the set screw slightly to identify the optimal engagement position.

Caution: When using the Set Screw Driver with retaining ring, do not force the set screw onto the Set Screw Driver. Damage to the retaining feature may result.

Caution: Do not use bone wax to fix the screw to the Set Screw Drivers.

Advance the set screw through the 0° *Dynesys Glide* Instrument into the pedicle screw.

Note: Proper alignment is necessary to ensure that the set screw is properly engaged. Never force the set screw. Thread stripping may result.

Note: Ensure that the 0° Dynesys Glide *Instrument is properly seated on the pedicle screw.*

Note: Remove any soft tissue present that may impede set screw placement.

Place one hand on the 0° *Dynesys Glide* Instrument handle to provide anti-torque.

Tighten the set screw to final torque.

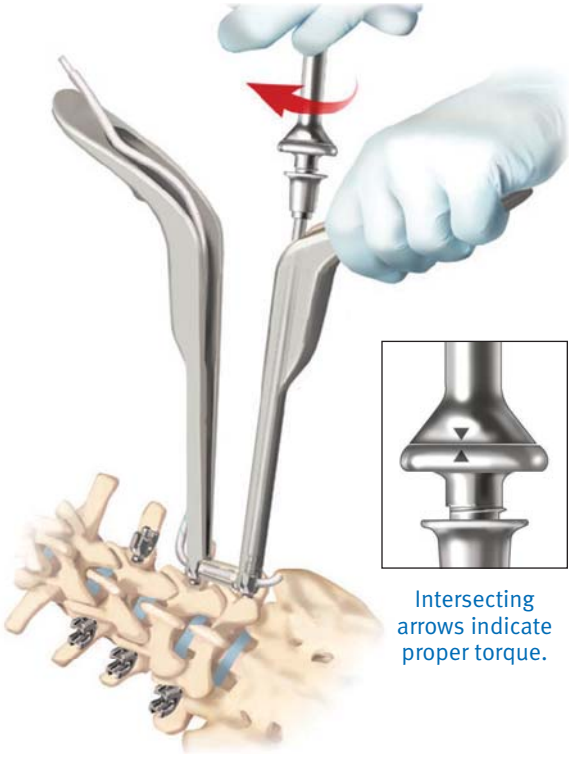
Proper torque has been reached when the two arrows on the Torque Indicating Handle intersect.

Caution: Do not over- or under-tighten the set screws.

Remove the Set Screw Driver assembly and 0° *Dynesys Glide* Instrument .

Note: It may be necessary to compensate for tissue pressure when removing the 0° Dynesys Glide *Instrument.*

Repeat contralateral side as desired.



Intersecting arrows indicate proper torque.

Placing and Tightening the First Set Screw with the 7° *Dynesys Glide* Instrument

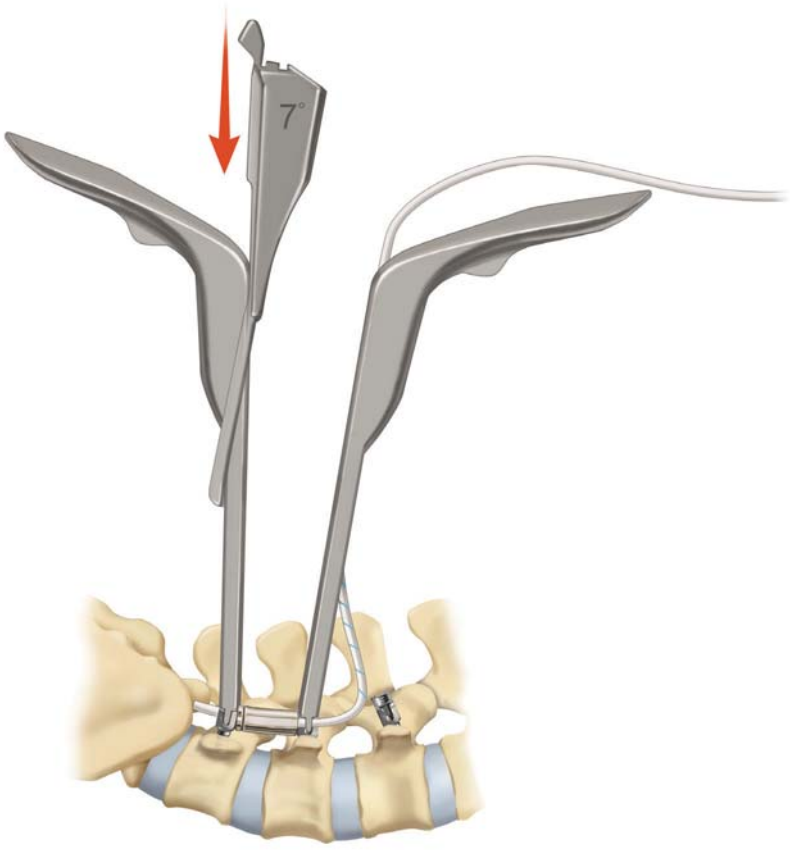
Reposition the cord as required, ensuring that 10 mm extends beyond the most caudal screw.

Place the 7° Cord Guide into the 7° *Dynesys Glide* Instrument and advance until locked in place.

Note: The 7° Cord Guide is designed for use only with the 7° Dynesys Glide *Instrument.*

Note: Advance the 7° Cord Guide until tactile feedback indicates proper locking has occurred.

Note: It may be necessary to temporarily remove the cephalad Dynesys Glide *Instrument to provide adequate clearance for the 7° Cord Guide.*

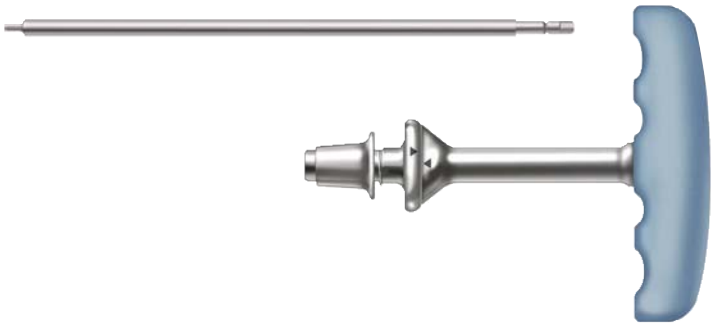


Assemble a Set Screw Driver to the Set Screw Torque Indicating Handle.

Note: Two styles of Set Screw Driver are provided (see illustration) to accommodate surgeon preference.

Note: Inspect to ensure that the components are fully engaged.

Note: When using the Set Screw Driver with retaining ring, inspect the retaining feature before and after each use to ensure proper condition.



Two Set Screw Drivers are available:

Both Set Screw Drivers have a set screw retaining feature that will hold the set screw securely when the set screw is fully seated.

Insert the set screw onto the preferred Set Screw Driver tip and inspect to ensure that the screw is fully seated and secure.

Note: It may be necessary to rotate the set screw slightly to identify the optimal engagement position.

Caution: When using the Set Screw Driver with retaining ring, do not force the set screw onto the Set Screw Driver. Damage to the retaining feature may result.

Caution: Do not use bone wax to fix the screw to the Set Screw Drivers.

Advance the set screw through the 7° Cord Guide into the pedicle screw.

Note: Proper alignment is necessary to ensure that the set screw is properly engaged. Never force the set screw. Thread stripping may result.

Note: Ensure that the 7° Dynesys Glide *Instrument is properly seated on the pedicle screw.*

Note: Remove any soft tissue present that may impede set screw placement.

Place one hand on the 7° *Dynesys Glide* Instrument handle to provide anti-torque.

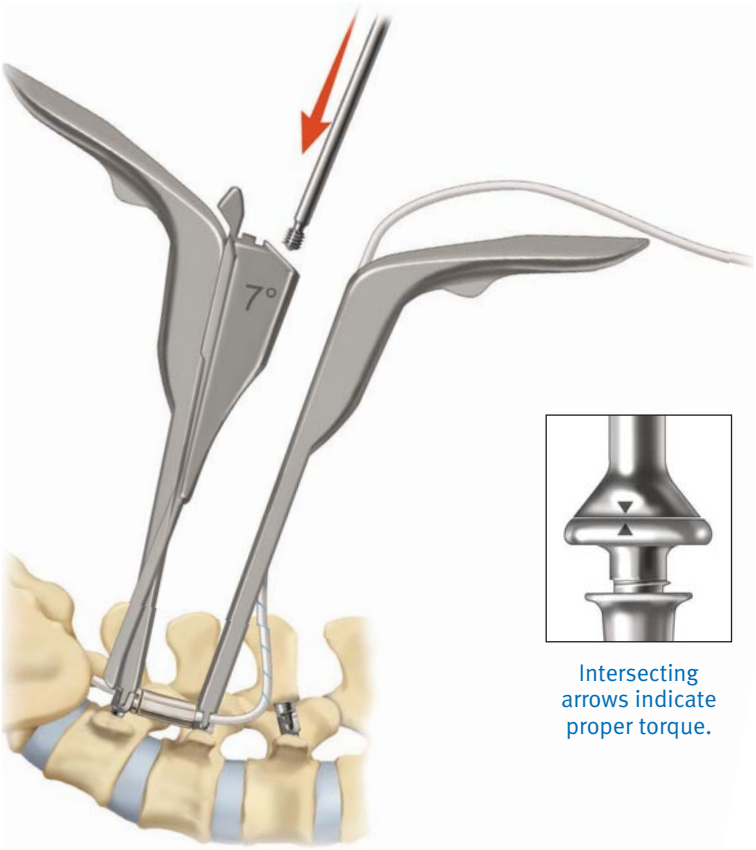
Tighten the set screw to final torque. Proper torque has been reached when the two arrows on the Torque Indicating Handle intersect.

Caution: Do not over- or under-tighten the set screw.

Remove the Set Screw Driver assembly and caudal 7° *Dynesys Glide* Instrument.

Note: It may be necessary to compensate for tissue pressure when removing the 7° Dynesys Glide *Instrument.*

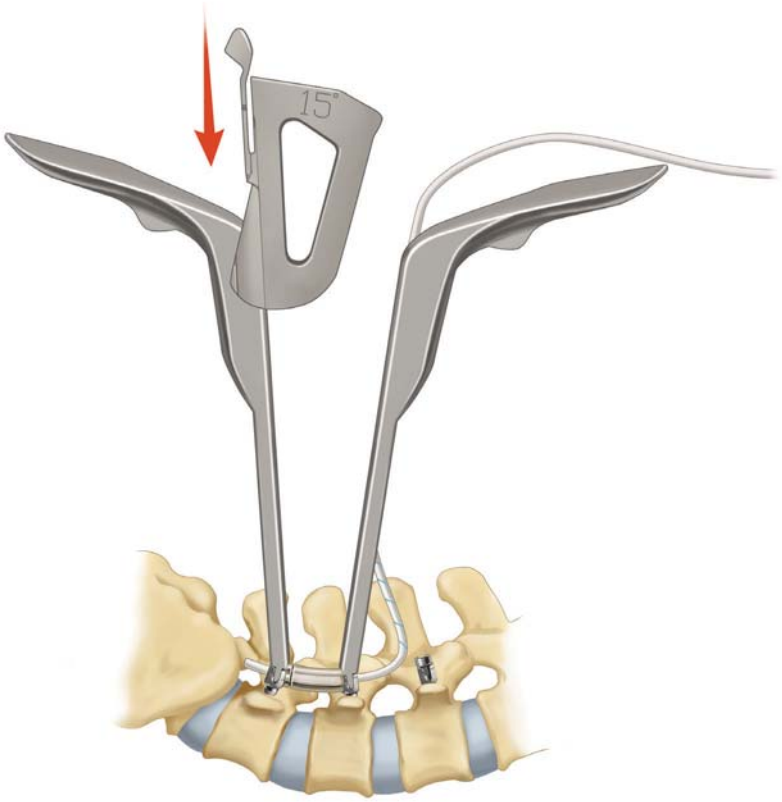
Repeat contralateral side as desired.



Intersecting arrows indicate proper torque.

Placing and Tightening the First Set Screw with the 15° *Dynesys Glide* Instrument

Reposition the cord as required, ensuring that a minimum of 10 mm extends beyond the most caudal screw.



Place the 15° Set Screw Guide into the 15° *Dynesys Glide* Instrument and advance until locked in place.

Note: The 15° Set Screw Guide is designed for use with the 15° Dynesys Glide *Instrument only.*

Note: Advance the 15° Set Screw Guide until tactile feedback indicates proper locking position.

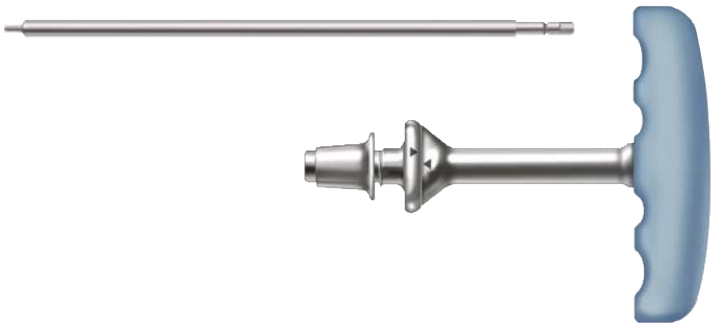
Note: It may be necessary to temporarily remove the cephalad Dynesys Glide *Instrument to provide adequate clearance for the 15° Set Screw guide.*

Assemble a Set Screw Driver to the Set Screw Torque Indicating Handle.

Note: Two styles of Set Screw Driver are provided (see illustration) to accommodate surgeon preference.

Note: Inspect to ensure that the components are fully engaged.

Note: When using the Set Screw Driver with retaining ring, inspect the retaining feature before and after each use to ensure proper condition.



Two Set Screw Drivers are available:

Set Screw Driver with retaining ring

Set Screw Driver with retention spring

Both Set Screw Drivers have a set screw retaining feature that will hold the set screw securely when the set screw is fully seated.

Insert the set screw onto the preferred Set Screw Driver tip and inspect to ensure that the screw is fully seated and secure.

Note: It may be necessary to rotate the set screw slightly to identify the optimal engagement position.

Caution: When using the Set Screw Driver with retaining ring, do not force the set screw onto the Set Screw Driver. Damage to the retaining feature may result.

Caution: Do not use bone wax to fix the screw to the Set Screw Drivers.

Advance the set screw through the 15° Cord Guide into the pedicle screw.

Note: Proper alignment is necessary to ensure that the set screw is properly engaged. Never force the set screw. Thread stripping may result.

Note: Ensure that the 15° Dynesys Glide *Instrument is properly seated on the pedicle screw.*

Note: Remove any soft tissue present that may impede set screw placement.

Place one hand on the 15° *Dynesys Glide* Instrument handle to provide anti-torque.

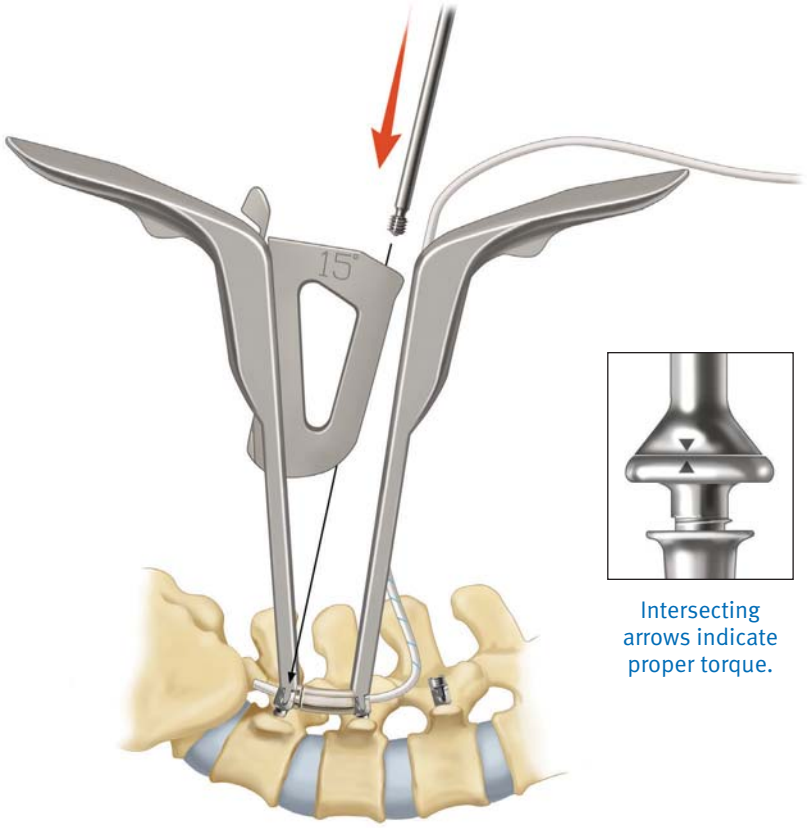
Tighten the set screw to final torque. Proper torque has been reached when the two arrows on the Torque Indicating Handle intersect.

Caution: Do not over- or under-tighten the set screw.

Remove the Set Screw Driver assembly and 15° *Dynesys Glide* Instrument.

Note: It may be necessary to compensate for tissue pressure when removing the 15° Dynesys Glide *Instrument.*

Repeat contralateral side as desired.



Intersecting arrows indicate proper torque.

Tension and Final Tighten Cephalad Set Screw

Place the 7° Cord Guide into the 7° *Dynesys Glide* Instrument and advance until locked in place.

Note: Advance the 7° Cord Guide until tactile feedback indicates proper locking has occurred.

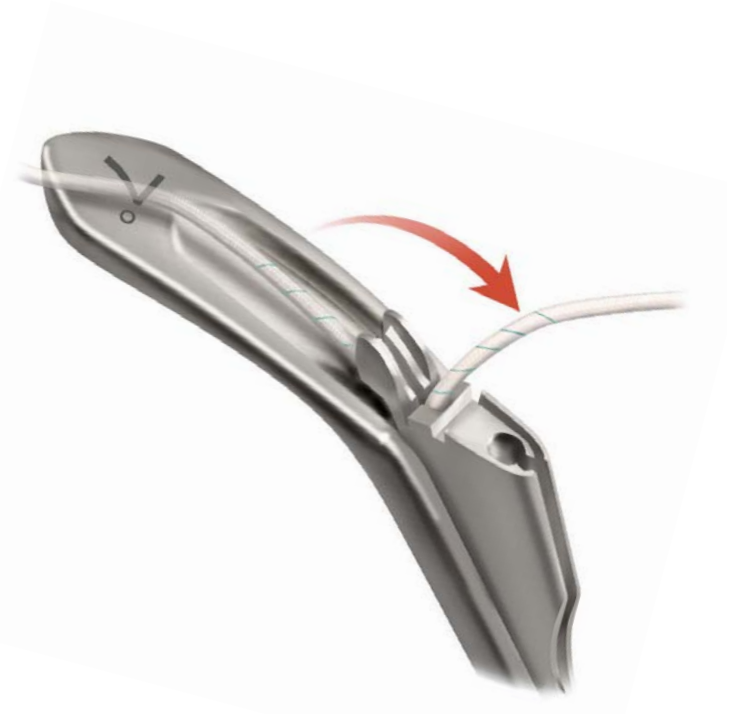
Ensure that the cord is captured properly in the Cord Guide distal end.

Place cord Working Zone through the Cord Guide slot.

Insert the set screw onto the Set Screw Driver tip and inspect to ensure that the screw is fully seated and secure.

Note: It may be necessary to rotate the set screw slightly to identify the optimal engagement position.

Caution: Do not use bone wax to fix the screw to the Set Screw Driver.

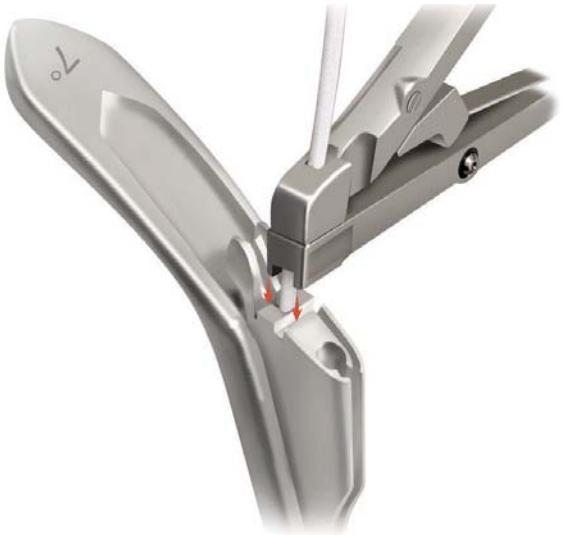


Feed the cord through the Cord Tensioner and place onto the 7° Cord Guide docking location.

Advance the set screw through the 7° Cord Guide into initial position on the pedicle screw. Do not tighten the screw at this time.

Note: Ensure that the 7° Dynesys Glide *Instrument is properly seated on the pedicle screw.*

Note: Remove any soft tissue present that may impede set screw placement.



Gently remove any slack from the cord. Squeeze the tensioner handles to the appropriate tension as indicated on the tensioner. While maintaining cord tension, advance and tighten the set screw to final torque.

Proper torque has been reached when the two arrows on the Torque Indicating Handle intersect.

Note: Proper alignment is necessary to ensure that the set screw is properly engaged. Never force the set screw. Thread stripping may result.

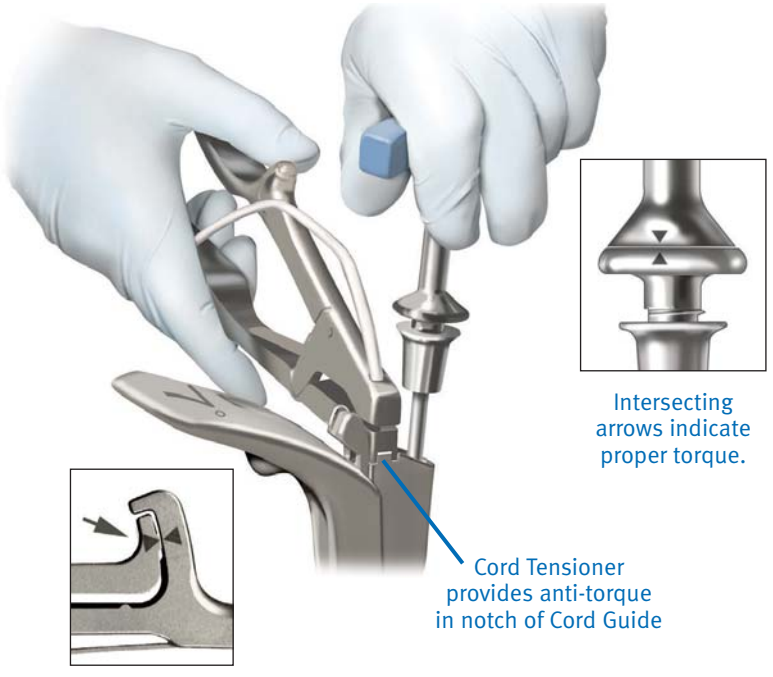
Note: When properly docked, the Cord Tensioner will provide anti-torque.

Caution: Do not over- or under-tighten the set screw.

Remove the Set Screw Driver assembly.

Remove the Cord Tensioner.

Remove the assembled 7° *Dynesys Glide* Instrument and Cord Guide.



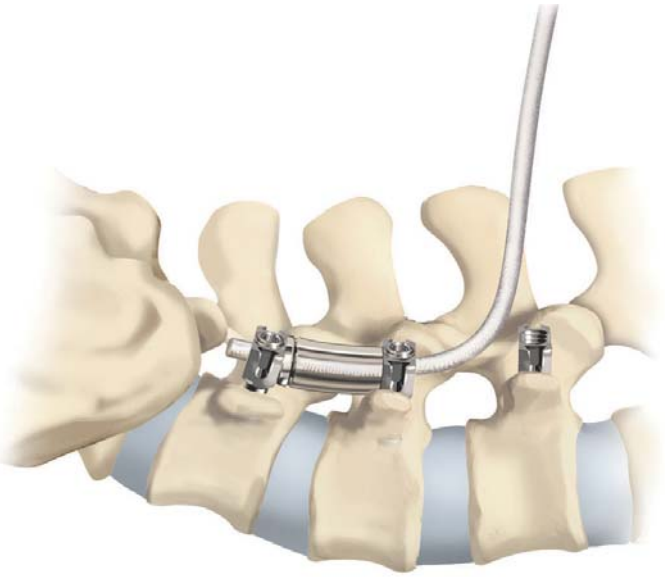
Repeat Contralateral Side
Adjacent Segment(s)

Refer to the *Dynesys Glide* Instrumentation: Adjacent Level section of this document to implant and tension additional segments.

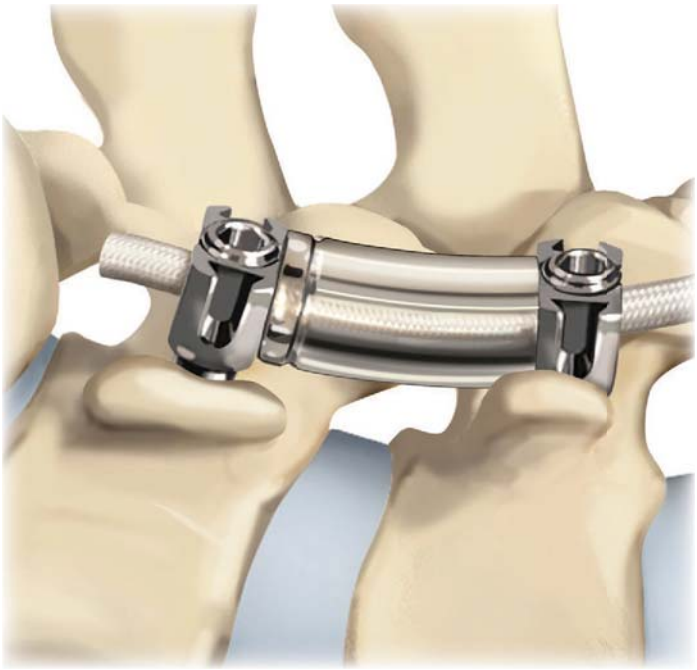
When the entire construct is complete and the system is fully tensioned, cut the cords, leaving 10 mm of cord out of the screw heads. Remove the cut ends.

Note: Only implant the Functional Zone of the cord.

Caution: Implantation of the Working or Introduction Zones in the patient could lead to cord failure.



Completed one level construct.



Dynesys Glide Instrumentation: Adjacent Level

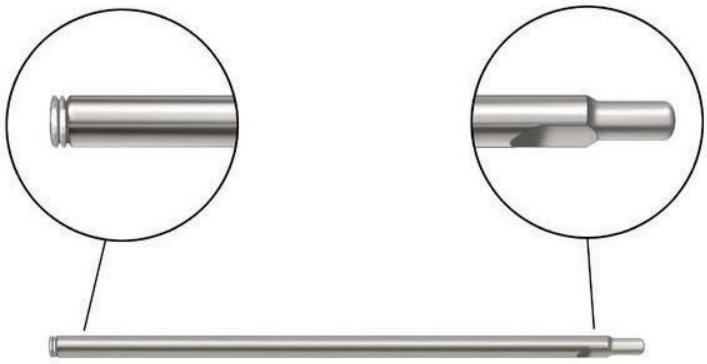
Guide Pin

Use the Guide Pin to dock *Dynesys Glide* Instruments. One end of the Guide Pin is terminated with threads to fix the Guide Pin to the screw. The opposite end of the Guide Pin is terminated with a blunt end that provides a floating engagement with the screw.

Note: If using the threaded end of the Guide Pin, do not over-tighten.

Use the Guide Pin Wrench to remove the Guide Pin from the screw.

Note: It may be necessary to compensate for tissue pressure when removing the Guide Pin.



Caution: Even with the use of the Guide Pin, off-axis alignment is still possible with the 7° and 15° Glides. This can occur when the Glide is not axially aligned with the Guide Pin due to side load being applied to the Glide.

Note: Use of the Cord Guide with the 7° Glide, and of the Set Screw Driver Guide with the 15° Glide, will ensure proper alignment.

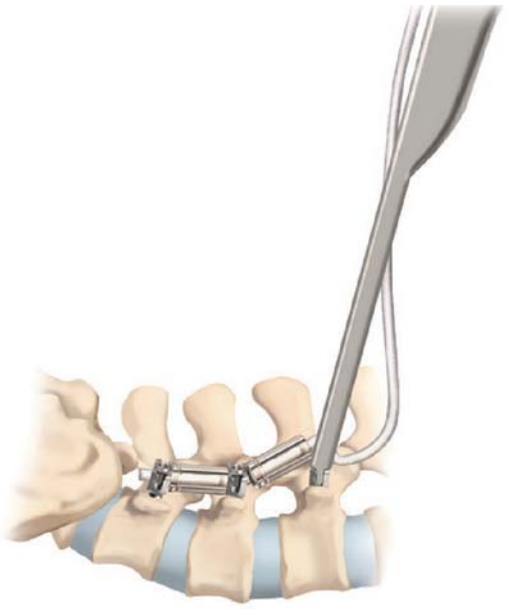
Incorrect alignment

Place Spacer

Using the Guide Pin, dock the 7° *Dynesys Glide* Instrument to the cephalad screw.

Thread the cord through the appropriately sized spacer and place the spacer against the caudal screw head.

Ensure that the cord is placed properly into the 7° *Dynesys Glide* Instrument slot.



Place the Spacer Pusher into the 7° *Dynesys Glide* Instrument and advance until positioned in contact with the spacer.

Advance the Spacer Pusher until the spacer is in final position.

Note: The 15° Dynesys Glide *Instrument may be used in place of the 7° Glide Instrument to accommodate surgical scenarios such as highly convergent screws.*

You may use a mallet to gently tap against the Spacer Pusher handle if desired.

Note: Handle the cord carefully to ensure aseptic conditions.

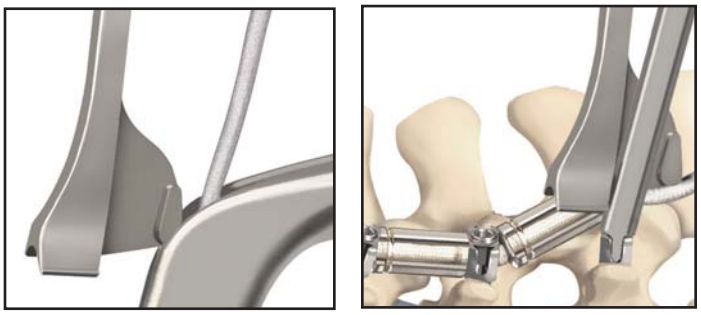
Note: A slight distractive force may be applied with the 7° Glide instrument handle if necessary while advancing.

Note: You may re-engage the caudal Dynesys Glide *Instrument and apply a slight distractive force with both handles if necessary while advancing.*

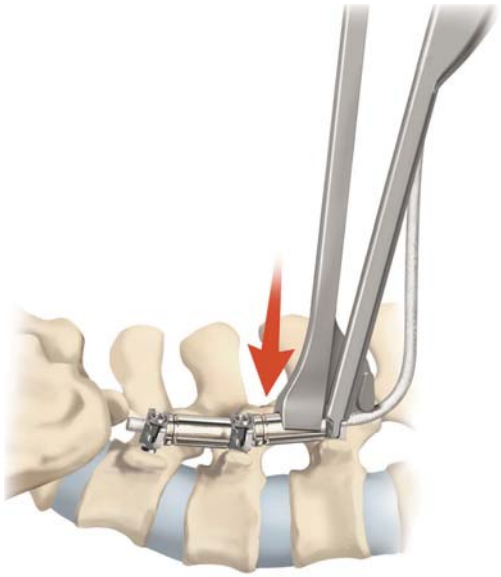
Caution: A torque and/or bending load that is too high can fracture the pedicle.

Remove the Spacer Pusher.

Note: If utilizing the 15° Dynesys Glide *Instrument, re-dock the 7° Glide Instrument, gently return the cord to the 7° Glide Instrument slot, and proceed to the "Tension and Final Tighten Cephalad Set Screw" section.*



Proper cord position when placing Spacer Pusher



Reducing a Spacer Less than 12 mm in Length

Advance the Spacer Pusher until the spacer is fully seated or the Spacer Pusher cannot be advanced further.

Caution: Carefully advance the Spacer Pusher when implanting a spacer less than 12 mm in length to avoid damaging the pedicle screw.

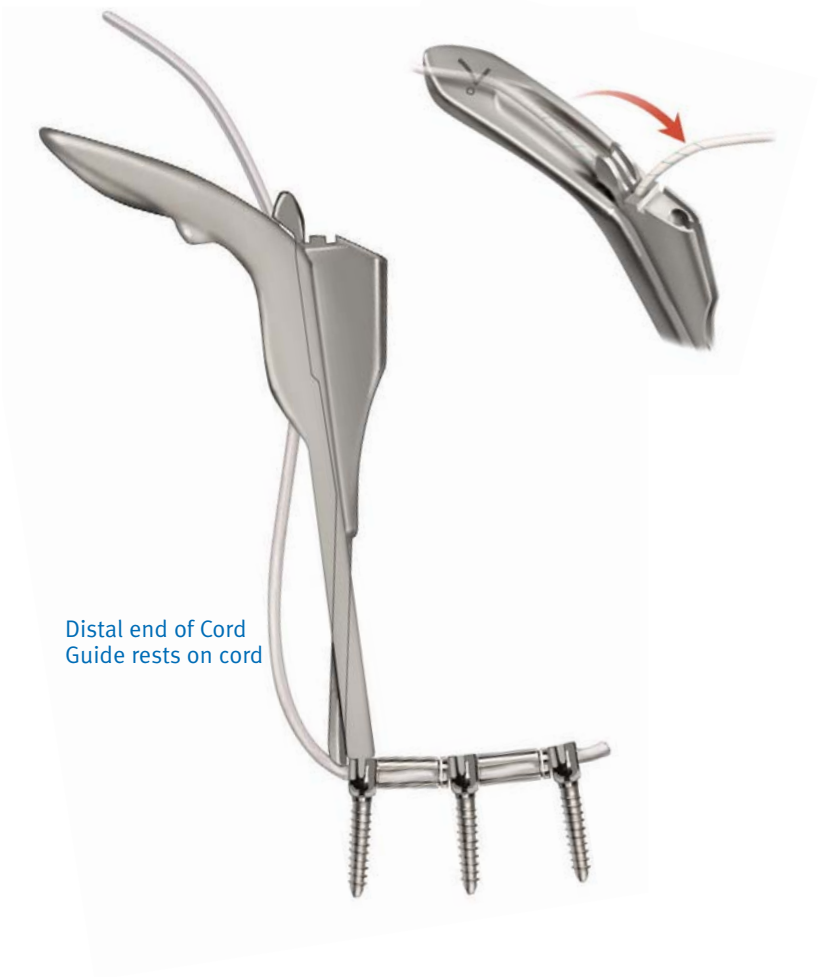
Remove the Spacer Pusher. Engage the distal end of the Spacer Holder and advance the sleeve to lock the spacer into place. Using the Spacer Holder, carefully advance the spacer until fully seated. Disengage and remove the Spacer Holder.

Tension and Final Tighten Cephalad Set Screw

Place the 7° Cord Guide into the 7° *Dynesys Glide* Instrument and advance until locked in place.

Note: The 7° Cord Guide will already be in place if utilizing the "Alternative Technique: Adjacent Level" section of this technique.

Ensure that the cord is captured properly in the Cord Guide distal end.



Place cord Working Zone through the Cord Guide slot.

Insert the set screw onto the Set Screw Driver tip and inspect to ensure that the screw is fully seated and secure.

Note: It may be necessary to rotate the set screw slightly to identify the optimal engagement position.

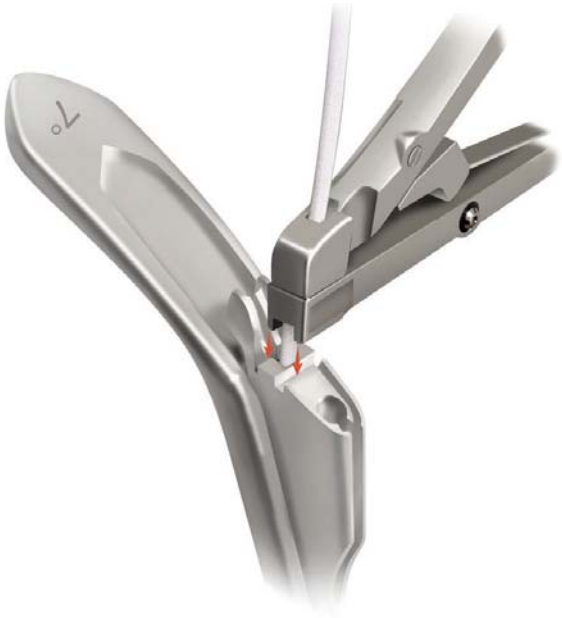
Caution: Do not use bone wax to fix the screw to the Set Screw Driver.

Feed the cord through the Cord Tensioner and place onto the 7° Cord Guide docking location.

Advance the set screw through the 7° Cord Guide into initial position on the pedicle screw. Do not tighten the screw at this time.

Note: Ensure that the 7° Dynesys Glide *Instrument is properly seated on the pedicle screw.*

Note: Remove any soft tissue present that may impede set screw placement.



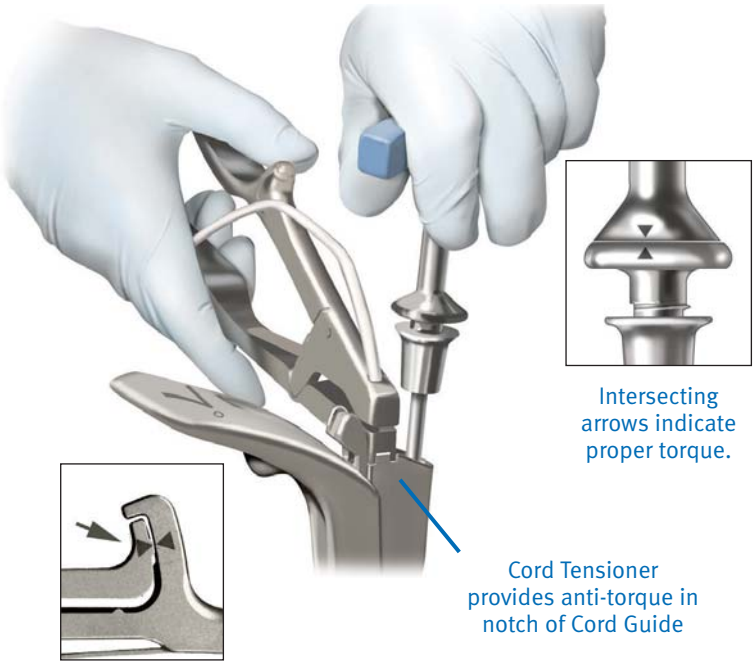
Squeeze the tensioner handles to the appropriate tension as indicated on the tensioner. While maintaining cord tension, tighten the set screw to final torque.

Proper torque has been reached when the two arrows on the Torque Indicating Handle intersect.

Note: Proper alignment is necessary to ensure that the set screw is properly engaged. Never force the set screw. Thread stripping may result.

Note: When properly docked, the Cord Tensioner will provide anti-torque.

Caution: Do not over- or under-tighten the set screw.



Remove the Set Screw Driver assembly.

Remove the Cord Tensioner.

Remove the assembled 7° *Dynesys Glide* Instrument and Cord Guide.

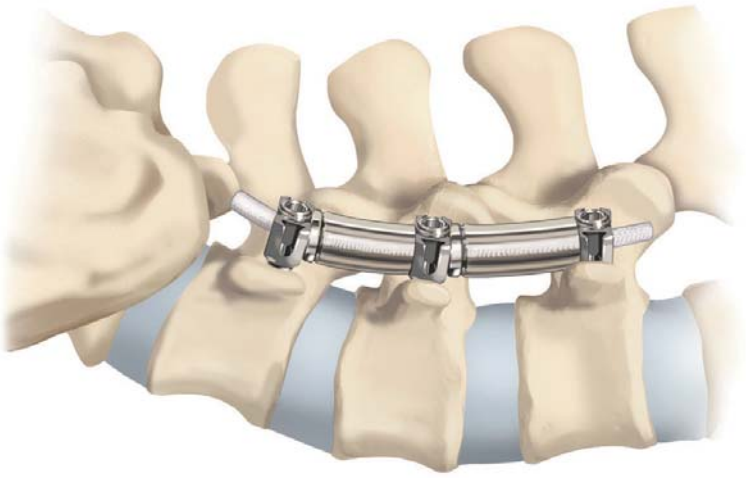
Repeat contralateral side and adjacent segment(s) as desired.

When the system is fully tensioned, cut the cords, leaving 10 mm of the Functional Zone out of the screw heads. Remove the cut ends.

Note: Only implant the Functional Zone of the cord.

Caution: Implantation of the Working or Introduction Zones in the patient could lead to cord failure.

Decorticate the posterior elements as necessary. Place bone graft to achieve the desired fusion.



Alternative Technique: Adjacent Level

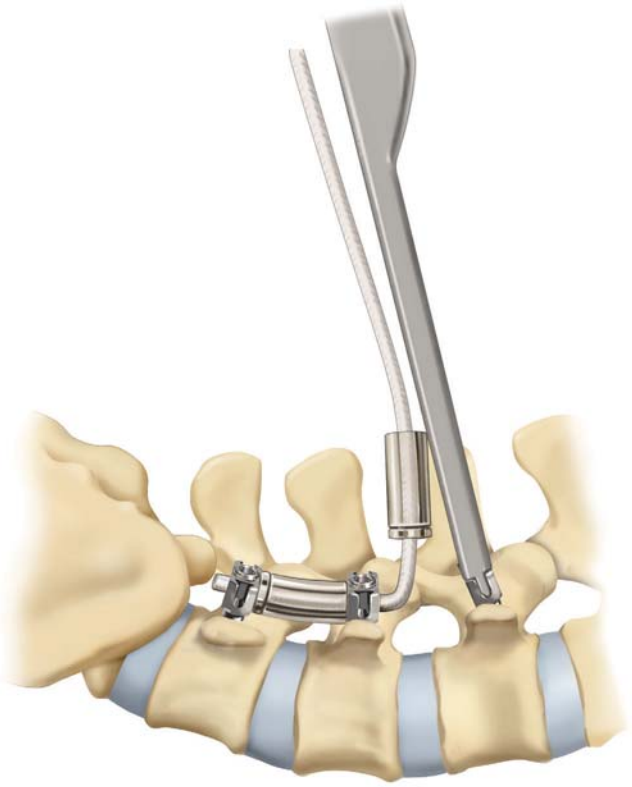
The surgeon may encounter surgical scenarios where an alternative technique may be useful to place the cord and spacer at an adjacent level. These scenarios could include:

- Pedicle or other anatomic anomalies
- Anatomic structures that obstruct spacer and cord placement
- Highly-convergent pedicle screw placement
- Short spacer length
- Spacers sized longer than measured with the Pedicle Distance Gauge
- Any combination of the aforementioned scenarios.

Using the Guide Pin, dock the 7° *Dynesys Glide* Instrument to the cephalad screw.

Thread the cord through an appropriately-sized spacer and place the spacer as shown in the illustration.

Note: Use caution to avoid twisting the cord.



Proper spacer placement

Place the 7° Cord Guide into the 7° *Dynesys Glide* Instrument and advance until locked in place. When the Cord Guide is fully advanced, the cephalad side of the spacer should be in contact with the distal portion of the Glide Instrument, and the cord should exit on the caudal side with a small S-curve visible between the spacer and pedicle screw.

Ensure that the cord is captured properly in the 7° Cord Guide distal end.

Place the cord Working Zone through the 7° Cord Guide slot.

Feed the cord through the Cord Tensioner and place it onto the 7° Cord Guide docking location. Place free hand on the 7° *Dynesys Glide* Instrument and hold it securely with a slight downward force applied to ensure that the instruments remain docked at all times.

Gently remove any slack from the cord. Use the Cord Tensioner to pull the spacer into position.

Note: It may be necessary for a surgical assistant to hold the free end of the cord with one hand.

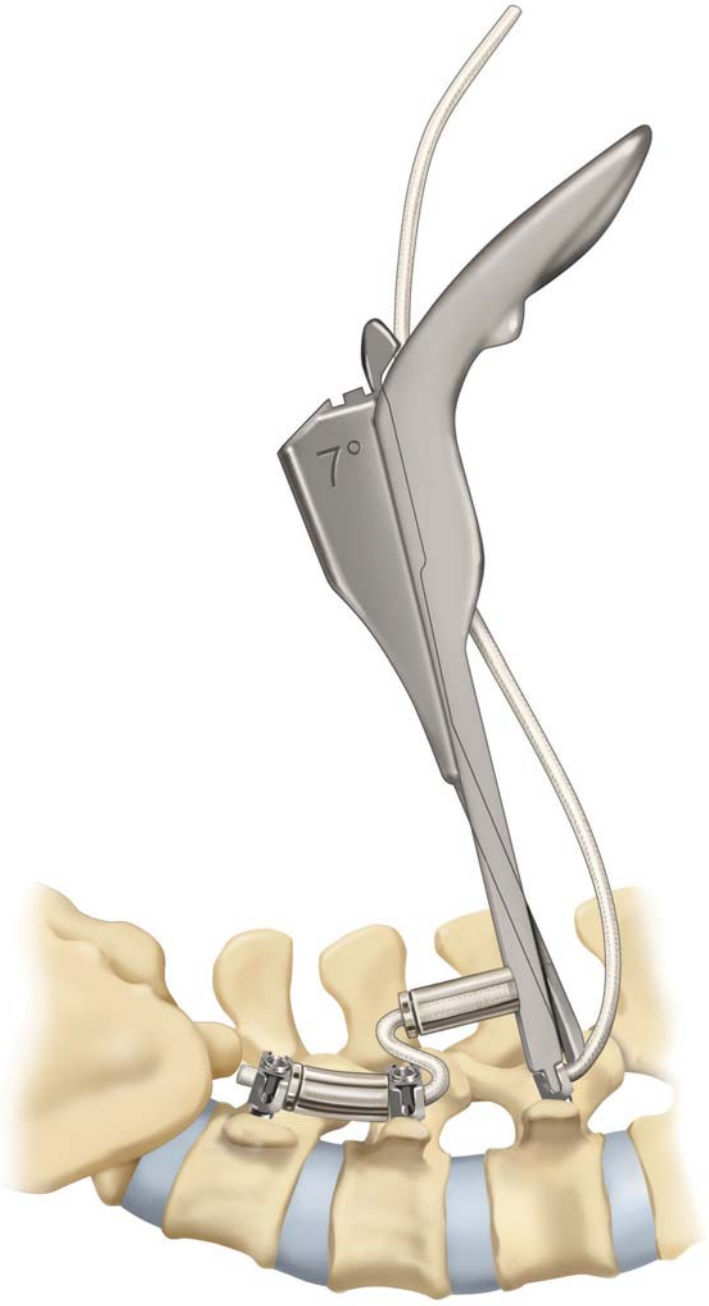
Note: Handle the cord carefully to ensure aseptic conditions.

Note: Avoid tensioning in the Introduction Zone of the cord.

Note: If necessary, a slight distractive force may be applied with the 7° Dynesys Glide *Instrument handle while advancing.*

Caution: A torque and/or bending load that is too high can fracture the pedicle.

If the spacer and cord are not fully seated, utilize the Spacer Holder instrument to complete placement.



Engage the distal end of the Spacer Holder onto the spacer and advance the sleeve fully to lock the spacer into place. Using the Spacer Holder, carefully advance the spacer until fully seated.

Disengage and remove the Spacer Holder.

Go to the "Tension and Final Cephalad Set Screw" section and complete the implantation.

Postoperative Treatment

It is the responsibility of the surgeon to assess the adequate postoperative treatment depending on the patient's condition.

- Analgesics
- Possible antibiotic prophylaxis against infection
- Possible prophylaxis against thromboembolism
- Early physiotherapy
- Limited activity is recommended for approximately six weeks
- A non-rigid brace should be considered during the period of limited activity
- A gradual resumption of activities can begin after approximately six weeks

Hardware Removal/Revision Instructions

Note: It may be necessary to use general surgical instrumentation to remove the implants.

Set Screw Removal

Engage the 0° *Dynesys Glide* Instrument with the pedicle screw head of the set screw to be removed. Fully seat the Torque Indicating Handle and Set Screw Driver into the set screw. While providing anti-torque with the 0° *Dynesys Glide* Instrument, turn the Set Screw Driver counterclockwise until the set screw is removed. Repeat for all set screws to be removed.

Spacer and Cord Removal

Slide the Spacer Holder sleeve into the open position and place onto the spacer to be removed. Carefully slide the Spacer Holder sleeve into the closed position and withdraw the spacer and cord. A slight rocking motion may be necessary to facilitate removal. Repeat for all spacers to be removed. Repeat on the contralateral side as desired.

Pedicle Screw Removal

Assemble the Ratcheting T-Handle and Pedicle Screw Driver and place onto the screw head using the marks located on the Pedicle Screw Driver to ensure proper orientation. Turn the Pedicle Screw Driver retainer nut clockwise and secure the screw to the Pedicle Screw Driver.

Once the screw is fully engaged on the driver, carefully turn the Pedicle Screw Driver counterclockwise until the screw is removed. Repeat for all pedicle screws to be removed.

Carefully examine the operative site and count implants to ensure that all hardware has been removed.

APPENDIX A

Changing the Cutter Blade

Rotate the Blade Holder clockwise into the forward (cut) position.

Loosen the screw on the Blade Holder using the Wrench Feature of the Spacer Cutter Lever.

Turn the Blade counterclockwise and pull it down, removing it from the Spacer Cutter.

Take the new Replacement Blade and insert it into the Spacer Cutter as far as it will go.

Rotate the Replacement Blade clockwise as far as it will go.

Verify that the hole of the blade is properly aligned with the screw.

Tighten the screw with the Wrench Feature of the Spacer Cutter Lever.

Note: Do not over-tighten the Spacer Cutter Blade Screw.

1.0 DESCRIPTION

When used as a pedicle screw fixation system, the *Dynesys* Spinal 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, and failed previous fusion (pseudoarthrosis). The *Dynesys* Spinal System is comprised of a variety of pedicle screws sizes, tensioning cords and longitudinal spacers that are uniquely fitted for each individual case. The pedicle screws are manufactured from medical grade titanium alloy conforming to ISO 5832-11. They are provided with or without hydroxyapatite coating conforming to ISO 13779-2. The tensioning cords are manufactured from Sulene-PET (polyethylene-terephthalate). The longitudinal spacers are manufactured from Sulene-PCU (polycarbonate-urethane).

The *Zimmer DTO* Implant is a cord-rod combination implant that is assembled intraoperatively by the final tightening of the fastening pin. The U & I Corporation *Optima*™ ZS Transition Screw is a transition pedicle screw that is part of the *Optima* ZS Spinal System. The *Zimmer DTO* Implant is used as an interface device when the *Dynesys* Spinal System and the *Optima* ZS Spinal System are implanted at adjacent levels. The tensioning cords are manufactured from Sulene-PET. The rod and pin are manufactured from Ti-6Al-4V conforming to ISO 5832-3. For information on the intended use, device description and materials for the *Optima* ZS Spinal System and the *Optima* ZS Transition Screw refer to the U & I Corporation's Instructions for Use for the *Optima* ZS Spinal System.

Before using the *Dynesys* Spinal System alone or in combination with the *Zimmer DTO* Implant the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information.

Any complications or other effects that may occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, sepsis, etc., fall within the responsibility of the operating surgeon; the manufacturer, the importers or the suppliers of Zimmer products cannot be held liable for same.

Zimmer products should be implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical technique.

Implants are always components of a system. They should only be combined with other components belonging to the same system or as defined in the surgical technique, and may be implanted only using original instruments also belonging to the same system unless otherwise indicated.

- Occasional exceptions to the above rules are pointed out in the description of the surgical technique or in the product description.
- Zimmer Companies implants and implant parts should never be combined with parts from other companies, unless otherwise indicated in the Instructions for Use and/or the Surgical Technique Manual. General use operating room instruments and/or other instruments described in the surgical technique are permitted for use. In addition, when using the *Zimmer DTO* Implant it is permitted to combine the *Dynesys* Spinal System with the *Optima* ZS Spinal System. Each system must be implanted using the appropriate instruments and surgical technique as defined in the respective Surgical Technique Manuals. The instruments for the different systems must not be commingled or used interchangeably.
- Spinal implants must not be machined or altered in any way, unless instructed to do so in the surgical technique.
- Implants or implant-parts that are contaminated, not sterile, damaged, scratched or have been improperly handled or altered without authorization may not be implanted under any circumstances.

2.0 INDICATIONS, CONTRAINDICATIONS AND POTENTIAL ADVERSE EVENTS

- An implant should only be considered if all other therapeutic possibilities have been carefully considered and found unsuitable or inappropriate.
- Any implant is subject to unavoidable wear and aging. In the course of time, an implant initially implanted in a stable manner can loosen or its functionality can become impaired. Wear, aging, loosening and so on can lead to the need for re-operation.
- The selection of patients depends to a great extent on the age of the patient, his/her general state of health, the condition of the existing bone, previous operations and anticipated further surgery. Normally speaking, pros¬thetic replacements are only indicated for patients whose skeleton is fully de-veloped.
- For the indications, contra-indications and potential adverse events of the *Optima* ZS Spinal System refer to the Instructions for Use for that system.

2.1 Indications

When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys* Spinal 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 im¬pairment, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the *Dynesys* Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

When the *Dynesys* Spinal System and the *Optima* ZS Spinal System are used on contiguous levels, they must be used with the *Zimmer DTO* Implant, rod-cord combination implant, and the U & I Corporation *Optima* ZS Transition Screw. The intended use for each level is as specified for each system.

2.2 Contraindications

Contraindications of the *Dynesys* Spinal System and the *Zimmer DTO* Implant are similar to other commercially available posterior spinal fixation systems. Contraindications include but are not limited to the following:

- Use in the cervical spine;
- Active systemic or local infection;
- Obesity;
- Pregnancy;
- Mental illness;
- Severe osteoporosis or osteopenia;
- Sensitivities/allergy to metals, polymers, polyethylene, polycarbonate urethane and polyethylene terephthalate;
- Alcohol or drug abuse;
- Patient unwilling or unable to follow postoperative instructions;
- Soft tissue deficit not allowing sound closure;
- Any medical or physical condition that would preclude the potential benefit of spinal implant surgery;
- Congenital abnormalities, tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device;
- Any medical or mental condition which would exclude the patient at high risk from surgery of this severity;
- For pedicle screw cases, inadequate pedicles of the thoracic, lumbar, and sacral vertebrae.

2.3 Complications and Possible Adverse Events

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential for additional surgery to correct these effects:

- Loosening, disassembly, bending or breakage of components;
- Tissue sensitivity to implant material;
- Potential for skin breakdown and/or wound complications;
- Non-union or delayed union;
- Infection;

- Nerve damage, including loss of neurologic function, dural tears, paralysis, paresthesia, and cerebral spinal fluid leakage;
- Fracture of vertebrae;
- Foreign body reaction (allergic) to components or debris;
- Loss of fixation;
- Vascular or visceral injury;
- Change of normal spinal curvature;
- Gastrointestinal, urological and/or reproductive system compromise;
- Pain or discomfort;
- Bursitis;
- Decrease in bone density due to stress shielding;
- Loss of bone or fracture of bone above or below the level of surgery;
- High removal torques may be encountered with the use of the hydroxyapatite coated screw;
- Bone graft donor site pain, fracture, and/or delayed wound healing;
- Restriction of activities;
- Lack of effective treatment of symptoms for which surgery was intended;
- Death.

3.0 WARNINGS

The safety and effectiveness of the *Dynesys* Spinal System and the *Zimmer DTO* Implant have not been established for spinal indications beyond those stated in the Indications section.

The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with bone graft is being performed at all instrumented levels.

For a complete list of Warnings and Precautions for the *Optima* ZS Spinal System, including the *Optima* ZS Transition Screw, refer to the Instructions for Use for that system.

3.1 Precautions

Only experienced spinal surgeons with specific training in the use of the *Dynesys* Spinal System, the *Zimmer DTO* Implant and the *Optima* ZS Spinal system should perform the implantation of these systems. This is due to the technically demanding procedure presenting a risk of serious injury to the patient. These systems should only be used with instrumentation specifically designed for each system. Refer to the respective surgical techniques to determine which instruments should be used for each step of the surgical procedure.

Unless the *Zimmer DTO* Implant is being used, components of spinal fixation systems other than Zimmer Companies should not be used with the components of the *Dynesys* Spinal System. Only the *Optima* ZS Spinal System, including the *Optima* ZS Transition Screw, may be used in combination with the *Zimmer DTO* Implant.

No component of the *Dynesys* Spinal System and the *Zimmer DTO* Implant should be reused or re-sterilized.

The *Dynesys* Spinal System and the *Zimmer DTO* Implant are intended to be used with bone graft, which is required to provide additional spinal support. A successful result is not always achieved in every surgical case.

The patients should be made aware that a successful result, as defined by reduced pain, increased function and the establishment of solid fusion, is not always achieved in every surgical case. Proper patient selection will greatly

affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be informed of this increased risk and counselled to discontinue tobacco use prior to and immediately after surgery. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spinal fusion. Patients with poor muscle tone and bone quality, and/or nerve paralysis are also poor candidates for spinal fusion. The use of autogenous bone graft has been shown to provide superior results compared to the use of allograft bone graft material.

In addition to the above specified warnings and precautions, general surgical risks should be explained to the patient prior to surgery.

3.2 Preoperative

- Only patients that meet the criteria described in Indications section and that do not have any conditions included in the Contraindications section of this package insert should be selected for surgery.
- Implants of this system must be handled and stored to avoid damage. Implants should be protected from damage including scratches, nicks and corrosive environments.
- The surgeon should be instructed on the proper use of instruments and implants.
- The doctor must explain the risks of a spinal implant to the patient, including the possible impact of the factors mentioned under Section 2.3 on the success of the operation and the possible side effects. The patient should also be informed as to what steps he/she can take in order to reduce the possible effects of these factors.

Note: The *Dynesys* Spinal System, the *Zimmer DTO* Implant and the *Optima* ZS Spinal System Surgical Technique Manuals should be followed carefully. Important information on the proper usage of implants and instrument are included.

3.3 Intraoperative

- The surgeon must follow the instructions provided in the surgical technique manual for the *Dynesys* Spinal System, the *Zimmer DTO* Implant and/or the *Optima* ZS Spinal System. Extreme caution must be used around the spinal cord and nerve root, especially during insertion of screws.
- A correct choice of the implant is extremely important. The appropriate type and size of an implant for the individual patient must be selected, taking anatomical and biomechanical factors into account.
- Aseptic handling is to be observed during the implantation. Implants removed from a patient should never be re-sterilized or reused.
- The *Zimmer DTO* Implant requires specific assembly; refer to the respective Surgical Technique Manual for the assembly instructions.
- When using the *Zimmer DTO* Implant, surgeon must be cautious about verifying that no component of the implant has become loose in the packaging, if the *Zimmer DTO* Implant components have become loose in the packaging please return the implant to Zimmer.
- Verify that the *Zimmer DTO* Implant is fully assembled prior to implantation.
- Remove any protective devices prior to implantation (i.e. protective caps or bags).
- The *Zimmer DTO* is supplied pre-bent and must not be further contoured.

3.4 Postoperative

- Implant removal should be considered after fusion has occurred. The risk and benefit of a second surgical procedure must be evaluated carefully. The surgeon is expected to supply postoperative care and management instructions to the patient. The patient should be advised that non-compliance with post-operative instructions could lead to poor results, including implant failure.
- The patient must be adequately instructed regarding the risks and limitations of this implant system. Additional surgeries may be required if fusion does not occur and implant failure occurs.
- Patient must be instructed on the physical limitations that are required to avoid placing excessive stress on the implant causing implant failure or delays in recovery.
- The patient must be informed that the risks of multiple complications do exist.
- Components of this system are only intended to support the spine during the period required to achieve solid spinal fusion.
- Regular X-ray checks are recommended in order to detect any changes in the position of the implant and signs of loosening or breakage of components.
- The patient should be urged to inform his doctor immediately of any unusual changes to the operated area.
- The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.
- An implant-bearer's card should also be made out for the patient

Disclaimer:

This documentation 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.

Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

Zimmer Spine is a non-exclusive distributor of the *OPTIMA*™ ZS Spinal System in South Korea and is the exclusive distributor of the *OPTIMA*™ ZS Spinal System throughout the rest of the world (except in Turkey and South America).

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***Dynesys*® Spinal System Implants and *Zimmer*® *DTO*® Implant Manufactured by:**

Zimmer GmbH
P.O. Box
Sulzer-Allee 8
CH-8404 Winterthur
Switzerland

Tel +41 (0)52 262 60 70
Fax+41 (0)52 262 01 39

www.zimmer.com

Distributed by:

Zimmer Spine
7375 Bush Lake Road
Minneapolis, MN 55439
800.655.2614

zimmerspine.com

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