Daytona™ Deformity System

Surgical Technique

SeaSpine™

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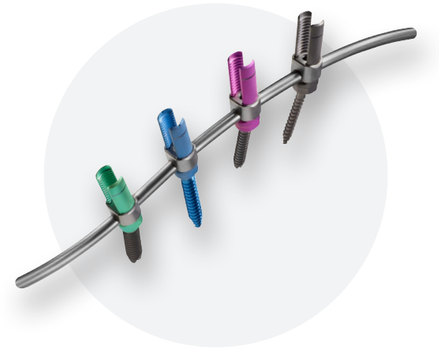
Daytona™ Deformity System

Design Rationale

The Daytona™ Deformity System, which utilizes Malibu™ technology is designed to address standard to complex deformity cases patients. It combines unique implant designs, materials and innovative instrumentation to create a highly flexible and intuitive system.



System Features

Daytona screws feature extended travel housings with 30mm of built in rod reduction

- Screw Options
  - Polyaxial
  - Uniplanar
- Rod Options
  - TI
  - ESS

ESS (Enhanced Strength and Stiffness) feature higher strength and stiffness than stainless steel rods and has minimal spring back during contouring

Surgical Technique

STEP 1 Site Preparation

Prepare the pedicle by first creating an entry hole for the screw using the sharp **Awl**. At the entry hole location, typically the intersection of the superior articular facet and the midline of the transverse process, apply a downward, twisting force until the sharp tip of the **Awl** enters the pedicle. The **Awl** tip limits penetration to 10mm.

The screw path through the pedicle and into the vertebral body is created using the **Bone Probe**. The **Probes**, offered in both a straight and curved version, come in two diameters for the thoracic and lumbar pedicles. The Probes are marked for measurement in 10mm increments beginning at the tip of the instrument.

Check the integrity of the pedicle walls for any cortical disruptions using either the **Straight** or **Curved Ball Tipped Pedicle Sounder**.

Although the Daytona™ System features self-tapping pedicle screws, 0.5mm undersized modular **Taps** are included for 4.5mm, 5.5mm, 6.5mm and 7.5mm screw diameters.

Select the appropriate **Tap** and attach to the **Ratcheting Handle** by pulling back on the outer handle connection and inserting the proximal end of the **Tap** into the handle socket.

Tap to the desired depth. The **Taps** feature depth indicators on the distal neck of the shaft.

Note: The threaded portion of the **Tap** is 30mm.

STEP 2 Screw Placement

The eventual derotation technique will be predetermined by the **Uniplanar/Polyaxial Screw** configuration implanted at this step.

The Daytona™ **Driver** consists of modular **Shafts** and **Sleeves** in short and long configurations. After selecting the appropriate screw length, load a **Daytona Polyaxial** or **Uniplanar Screw** onto the assembled Daytona **Driver**.

Holding the screw threads, load the screw tulip into the **Sleeve** and advance the hex tip of the **Shaft** into the hex cavity located at the bottom of the screw tulip. Secure the screw on the **Driver** by threading the **Sleeve** clockwise into the tulip until the **Driver** is securely engaged with the screw.

Insert the screw into the site. To release the Daytona Driver, rotate the sleeve counterclockwise until it is free from the screw. Repeat this process for remaining vertebral levels until all screws have been implanted. The screw depth may be adjusted using the 3mm Screwdriver. Align the Daytona screw heads using the **Screw Head Adjuster**.

STEP 3 Rod Selection

Place the **Rod Template** in the tulips on each side to determine the appropriate length and sagittal contour of the spine.

The Daytona System is equipped with two rod configurations and multiple lengths:

- Titanium: 5.5mm straight rod and precontoured rods
- ESS (CoNiCr): 5.5mm straight and precontoured rods

Note: The precontoured rods have an indication line corresponding to the thoraco-lumbar junction.

STEP 4 External Rod Contouring

The Daytona™ System features two instrumentation techniques for rod contouring.

Option 1:

Place the **French Rod Bender** and contour the rod to the desired sagittal curvature.

Option 2:

Place **Bending Irons** bilaterally on the rod and contour to the desired radial curvature.

The **Rod Grippers** can be used to hold the rod, or alternately a **Combination Wrench** can be applied onto the hex end of the rod.

▶ **Note:** Precontoured ESS rods alleviate need for extensive rod contouring.

STEP 5 Rod Placement – Coronal/Sagittal Correction

The following instruments may be used to assist in rod placement:

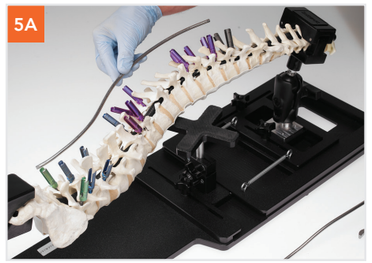
- **Rod Grippers**
- **Combination Wrench**
- **Rod Controllers (Left and Right handed)**
- **Head Turner/Translators (Left and Right handed)**

STEP 5 Rod Placement – Option 1

5A

Rod Cantilever Approach

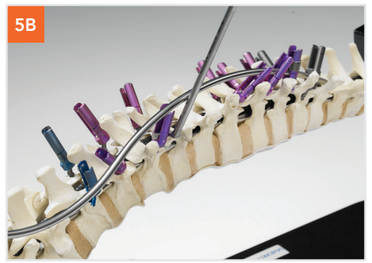
Starting at either the cephalad or caudad level of the construct, begin the rod reduction. At each vertebral level, reduce the rod onto the screw tulip, incrementally correcting the spine to sagittal and coronal balance until the rod is contained within the tulip.



5B

Method A:

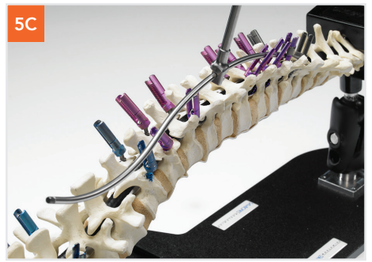
The **Rod Controller** may be utilized during rod placement to medially/laterally translate or elevate/depress the rod. Place the **Rod Controller** over the rod and twist to engage and secure the rod.



5C

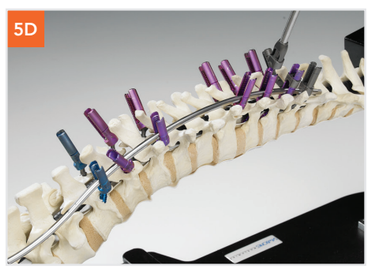
Method B:

The **Head Turner/Translators** may be utilized during rod placement to translate the rod medially/laterally.



5D

Provisionally secure the rod by placing **Locking Caps** using the **Cap Loader**. The **Locking Cap** captures the rod within the screw tulip while still allowing free movement of the rod. The design prevents tulip splay when the rod is finally reduced into the tulip seat.

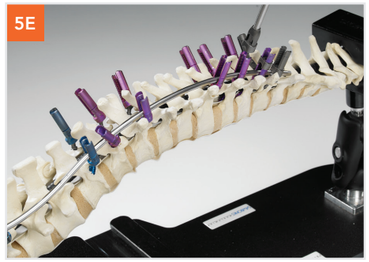


STEP 5 Rod Placement – Option 2

Rod Derotation Approach

Placing the contoured rod on its side, align the contours of the rod to match the patient's deformity as best as possible.

Any difference in rod contour is accommodated by the extended tabs of the Daytona™ screw tulips. **Polyaxial Screws** will further facilitate this, and some minor rod persuasion may be required when using **Uniplanar Screws**.



5E At each vertebral level, provisionally secure the rod using the **Cap Loader** and **Locking Caps**.

▶ **Note:** Leave the **Locking Caps** slightly proud on the tulips.

5F Using the **Rod Grippers** and/or **Combination Wrenches**, rotate the rod until the optimal correction is achieved in both the coronal and sagittal planes.

5G

STEP 6 Vertebral Derotational Maneuver – Intersegmental and En-Bloc Correction

Intersegmental derotation is performed on individual vertebral bodies to achieve axial alignment. En-Bloc derotation requires counterposed forces to correct the rotational deformity about the apex of a curve. In the case of a double curve, each curve is derotated against one another. For a single curve, the apex is derotated while the upper and lower ends of the construct are held neutral. The ends of the construct are typically held by two pairs of screws and constitute a **Foundation Cluster**. The apex of the curve is typically instrumented with three pairs of screws and constitutes an **Apical Cluster**.

Option 1:

Single Rod Derotation

This derotation technique suggests a screw assembly consisting of **Uniplanar Screws** implanted ipsilaterally to the rod side. **Polyaxial Screws** may be placed at top and bottom most levels of the rod side. The side which contains the rod shall be referred to as the Reduction Side, whereas the other shall be referred to as the Holding Side. Rod placement on the left or right side of the spine is dependent on the characteristics of the deformity and surgeon preference and typically on the concave side of the deformity.

6A

Holding Side Instrumentation:

Driver Shafts - Short and Long to accommodate differences in working height due to the sagittal contour of the spine.

Derotation Sleeves - Short and Long to match the appropriate **Driver Shafts**.

Reduction Side Instrumentation:

6B

Derotation Tubes - Short and Long to accommodate differences in working height due to the sagittal contour of the spine.

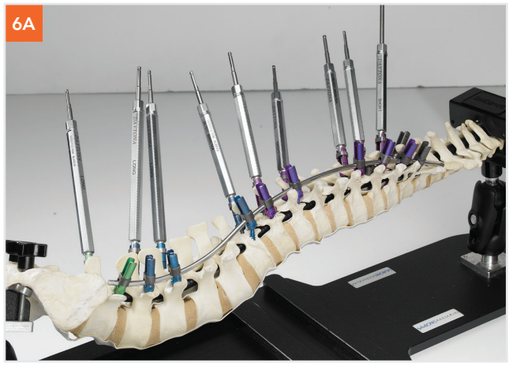
Derotation Tube Anchors - Short and Long to match the appropriate **Derotation Tubes**.

▶ **Note:** The **Derotation Tubes, Anchors** and **Sleeves** have been color coded to confirm instrument pairing.

STEP 6 Vertebral Derotational Maneuver: Option 1 continued

6A Holding Side

Refer to **Screw Placement** (Step 2) of this technique for the proper placement of the implants. Once the **Polyaxial Screws** are implanted to proper depth, disconnect the **Ratchet Handle** from the **Driver Shaft** and corresponding **Derotation Sleeve** so they remain intact with the screw. This rigidly constrains the head of a pedicle screw; the screw now acts as a monoaxial screw. Repeat ipsilaterally at the levels of construct that will be manipulated during the derotational maneuver.



6B Reduction Side

Refer to **Screw Placement** (Step 2) of this technique for the proper placement of the implant. As mentioned above, the implant of choice on the reduction side will most likely be a **Uniplanar Screw**. Once the screws are in place, refer to the **Rod Selection** and **Rod Placement** sections of this technique (Step 3-5) for the proper placement of the rod. Once the rod is in place, it may be secured at each desired level with a locking cap. Advance the **Locking Caps** using the 4mm **Driver** until the Indication Line on the tulip is seen above the cap. This will allow for adequate purchase of the **Derotation Tube Anchors**.

STEP 6 Vertebral Derotational Maneuver: Option 1 continued

6C Reduction Side Instrument Assembly

Select the appropriate **Derotation Tube** and corresponding **Tube Anchor**. Place the **Derotation Tube** onto the screw construct.

6D

Next, insert the **Tube Anchor** through the **Derotation Tube** and thread into the available reduction threads on the tulip. Repeat ipsilaterally at the levels of construct that will be manipulated during the derotational maneuver.

▶ **Note:** During this step, it is important to only hand tighten the **Tube Anchor** to avoid damaging the screw tulips.

If the rods have acquired a scoliotic bend, they should be straightened with the In-situ **Rod Benders**. Do not attempt to derotate around a crooked rod.

6E Single Construct Assembly

On the Reduction Side, attach a **Modular Handle** to the proximal hex end of the Derotation Tube and tighten the locking knob. On the Holding Side, attach a second Modular Handle to the proximal hex end of the Derotation Sleeve and tighten the locking knob.

Attach a **Derotation Clip** transversely across each desired level – connecting together the **Derotation Tube/Anchor** to its corresponding **Driver Shaft/Sleeve** to form a single construct. **Clips** are available in Short, Medium and Long lengths. This creates a triangulated construct which allows for powerful rotational manipulation of the vertebral level. The **Box Wrench** or **Socket Adapter** will allow for additional tightening of the knobs.

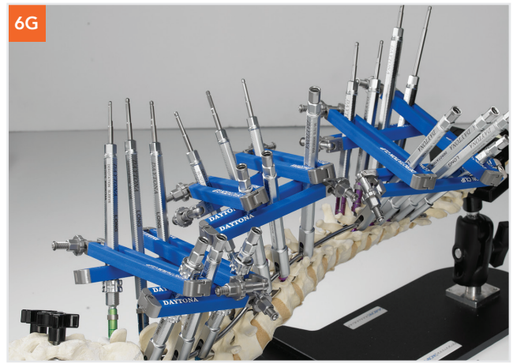
STEP 6 Vertebral Derotational Maneuver: Option 1 continued

6F Method A: Intersegmental Derotation

Segmentally derotate each instrumented vertebral body until axial alignment has been achieved. Provisionally yet securely tighten the **Locking Caps** at each vertebral level on the reduction side to maintain correction during the procedure. Another **Derotation Clip** can be applied longitudinally across several levels to maintain the intersegmental correction as the **Locking Caps** are provisionally tightened to maintain correction.

6G Method B: Cluster Assembly

The **Derotation Clips** can be applied longitudinally or transversely to provide rigidity within a segment as well as across multiple adjacent segments. Short, Medium and Long **Derotation Clips** are standard instruments in the set, which, when fixed to the **Derotation Tubes** and Sleeves, create a single rigid cluster. Not all **Screws** in the construct need to be included in a cluster. Since derotation requires the clusters to remain mobile, other methods must be used to keep the **Rods** in the proper sagittal orientation during the maneuver. Alternately, non-cluster **Screws** can be fully tightened to hold the **Rod** in position.



STEP 6 Vertebral Derotational Maneuver: Option 1 continued

6G Cluster Assembly

Attach the Modular Handle(s) for added leverage to the proximal end of the **Derotation Tubes/Sleeves**. Utilize one or more Modular Handle per cluster. The handles can be used to either lift or depress. Unilateral depression of the vertebral body creates a lordosis in the spine, whereas lifting will enhance kyphosis. This should be considered when the addressing the sagittal alignment of the spine.

▶ **Note:** The notched recess on the end of the handle can be used to assist in derotation. A long length of roll gauze is looped about the recess and the surgeon's foot is placed on the lower end of the loop to depress the handle and derotate or support the spine during the procedure.

6H Derotation

Loosen each **Locking Cap** along the reduction side and axially derotate the clusters until anatomical alignment has been achieved. Long **Derotation Clips** may be used to longitudinally hold the alignment by connecting multiple clusters together.

After the derotational maneuver has been completed, slowly tighten each **Locking Cap** on the reduction side incrementally along the entire construct to reduce the spine to the **Rods**. This will allow stress sharing and minimize screw pull out. When the reduction **Rod** is fully seated, firmly hand-tighten the corresponding **Locking Caps** to hold the correction.

With the spine axially balanced, remove the **Derotation Clips** and all instrumentation on the holding side. Place the second **Rod** into the **Screws** on the holding side and secure with **Locking Caps**.

STEP 6 Vertebral Derotational Maneuver – Option 2

Option 2:

Rod Derotation Approach

This rotation technique suggests a screw assembly consisting mainly of **Uniplanar Screws** implanted bilaterally. **Polyaxial Screws** may be placed at top and bottom most levels of the rod. Since both sides of the construct contain a rod, distinction between the holding side and reduction side of the spine does not apply.

Instrumentation:

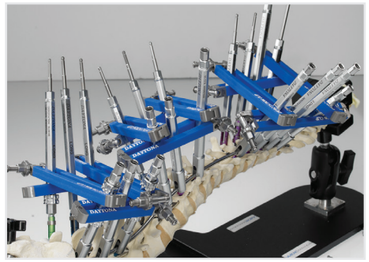
Derotation Tubes - Short and Long to accommodate differences in working height due to the sagittal contour of the spine.

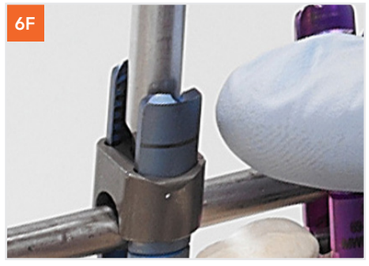
Derotation Tube Anchors - Short and Long to match the appropriate **Derotation Tubes**.

6F

Implantation

Refer to **Screw Placement** section (Step 2) of this technique for the proper placement of the implant. As mentioned above, the implant of choice will be a **Uniplanar Screw**, with the exception of the top and bottom of the construct. Once the screws are in place, refer to the **Rod Selection** and **Rod Placement** sections (Step 3-5) of this technique for the proper placement of the rods. Once the rods are in place, they may be secured at each desired level with a **Locking Cap**. Advance the **Locking Caps** using the 4mm **Driver** until the Indication Line on the tulip is seen above the cap. This will allow for adequate purchase of the **Derotation Tube Anchors**.

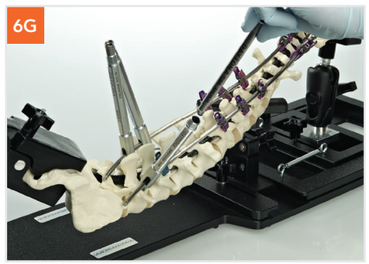




6G

Instrument Assembly

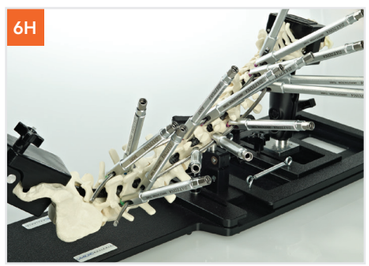
Select the appropriate **Derotation Tube** and corresponding **Tube Anchor**. Place the **Derotation Tube** onto the screw construct. Next, insert the Tube Anchor through the **Derotation Tube** and thread into the available reduction threads on the tulip. Repeat at the levels of construct that will be manipulated during the derotational maneuver.



6H

Note: During this step, it is important to only hand tighten the **Tube Anchor** to avoid damaging the screw tulips.

If the rods have acquired a scoliotic bend, they should be straightened with the In situ **Rod Benders**. Do not attempt to derotate around a crooked rod.

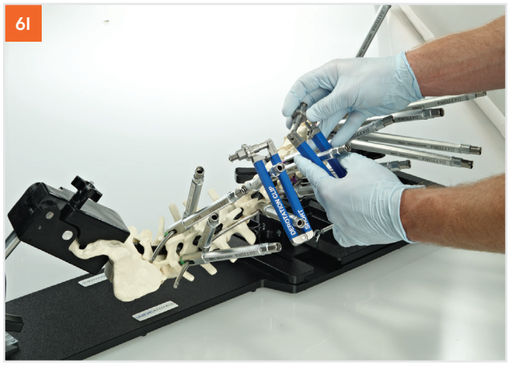


STEP 6 Vertebral Derotational Maneuver – Option 2 continued

6I

Single Construct Assembly

Attach a **Derotation Clip** transversely across each desired level – connecting together the **Derotation Tubes/Anchors** on both sides of the vertebral body to form a single construct. **Clips** are available in Short, Medium and Long lengths. This creates a triangulated construct which allows for powerful rotational manipulation of the vertebral level. The **Box Wrench** or **Socket Adapter** will allow for additional tightening of the knobs.



6J

Attach a **Modular Handle** to the proximal hex end of the **Derotation Tube** and tighten the locking knob. Attach a second **Modular Handle** to the opposite side of the construct to give additional leverage.

6K

Derotation

Segmentally derotate each instrumented vertebral body until axial alignment has been achieved. Provisionally yet securely tighten the locking caps at each vertebral level to maintain correction during the procedure. Another **Derotation Clip** can be applied longitudinally across several levels to maintain the intersegmental correction as the **Locking Caps** are provisionally tightened to maintain correction.

STEP 6 Vertebral Derotational Maneuver – Option 2 continued

6L

Derotation

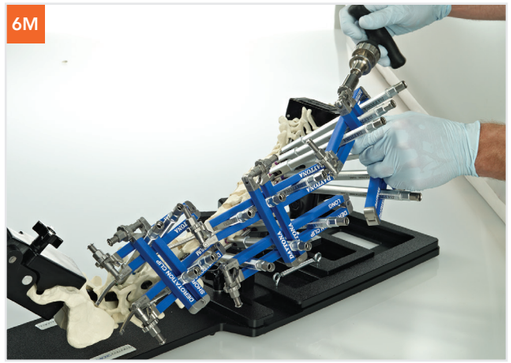
The **Derotation Clips** can be applied longitudinally or transversely to provide rigidity within a segment as well as across multiple adjacent segments. Short, Medium and Long

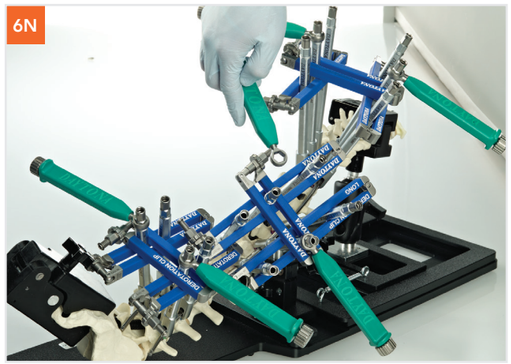
6M **Derotation Clips** are standard instruments in the set, which, when fixed to the **Derotation Tubes**, creates a single rigid cluster. Not all screws in the construct need to be included in a cluster. Since derotation requires the clusters to remain mobile, other methods must be used to keep the rods in the proper sagittal orientation during the maneuver. **CrossBars** may be used

6N to tie the rods together. Additionally, non-cluster screws can be fully tightened to hold the rod in position.

Attach the **Modular Handle(s)** for added leverage to the proximal end of the **Derotation Tubes**. Utilize one or more Modular Handle per cluster. The handles can be used to either lift or depress. Unilateral depression of the vertebral body creates a lordosis in the spine, whereas lifting will enhance kyphosis. This should be considered when the addressing the sagittal alignment of the spine.

▶ **Note:** The notched recess on the end of the handle can be used to assist in derotation. A long length of roll gauze is looped about the recess and the surgeon's foot is placed on the lower end of the loop to depress the handle and derotate or support the spine during the procedure.





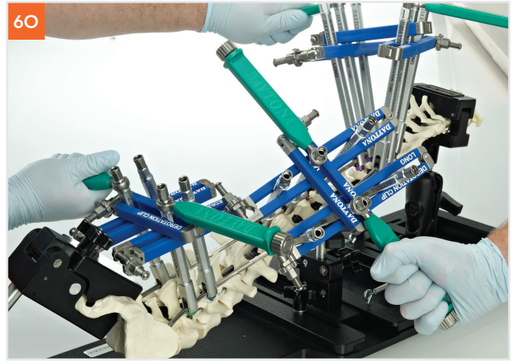
STEP 6 Vertebral Derotational Maneuver – Option 2 continued

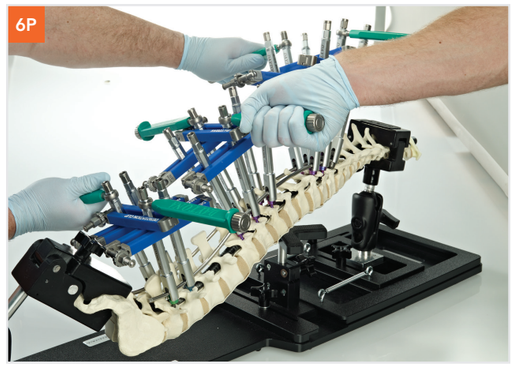
Derotation

6O Loosen each **Locking Cap** and axially derotate the clusters until anatomical alignment has

6P been achieved. **Long Derotation Clips** may be used to longitudinally hold the alignment by connecting multiple clusters together.

6Q After the derotational maneuver has been completed, slowly tighten each **Locking Cap** incrementally along the entire construct to reduce the spine to the rods. This will allow stress sharing and minimize screw pull out. When the rod is fully seated, firmly hand-tighten the corresponding **Locking Caps** to hold the correction.





STEP 7 In-Situ Rod Contouring

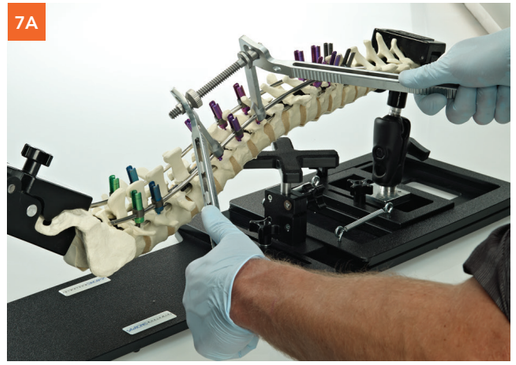
7A **Lordotic/Kyphotic:**

Place the **In-Situ Rod Benders** on the rod within the level to be contoured. Using a cephalad and caudad oriented force, bend the rod until the preferred lordosis/kyphosis is achieved.

Coronal:

The Daytona™ System features **L-shaped Coronal Rod Benders** which will provide sufficient rod contouring to adjust coronal balance. Place the **Coronal Benders** on the corresponding **Locking Cap**. Next, affix the appropriate Fulcrum and secure with the **Thumb Screw**. Utilizing the **Fulcrum**, rotate along the coronal plane until desired correction is achieved.

▶ **Note:** **Multiple Rod Controllers** may also be used in lieu of the **Benders**.



STEP 8 Compression and Distraction

8A Place the **Compressor/Distractor** on the rod so the instrument arms are fully engaged with the rod. The **Locking Cap** to be translated on the rod should not be tightened, this will prohibit vertebral articulation. The vertebral level(s) to remain fixed during this adjustment should be tightened enough to serve as a buttress for the instrument. Proceed with compression/ distraction until the desired vertebral tilt is attained.

8B

▶ **Note:** The strongest bone in the pedicle is on the caudal aspect. Therefore less force should be exercised when mobilizing a **Pedicle Screw** in the cephalad direction to avoid fracture.

STEP 9 Final Tightening

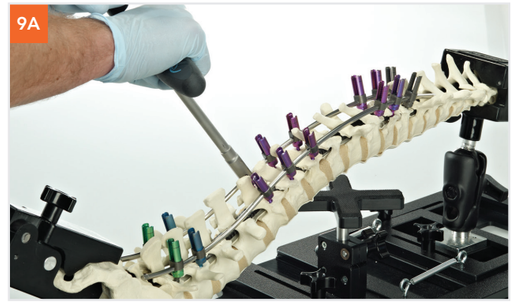
9A First, place the **Torque Limiting Driver** through the cannula of the **DLTA Counter Torque** until the male hex extrudes from the distal opening of the **DLTA Counter Torque**. Next, place the assembled instruments over the **Locking Cap** and insert the **Torque Limiting Driver** hex into the **Locking Cap** hex. Once the hex is engaged slide the **DLTA Counter Torque** down until the distal end recesses are flush with the rod.

Firmly turn the **Torque Limiting Driver** until an audible "click" is heard. This action may be repeated to ensure that the **Locking Cap** has been fully locked. Repeat this for the remaining **Locking Caps** in the construct.

9B **Tab Removal**

9C Using the **Tab Remover**, firmly grasp the lateral screw tulip and break the tab in a lateral direction. The **Medial Screw** tulip should be removed by breaking the tab in a medial direction. Repeat this for the remaining screw tulips in the construct.

9D



Indications for Use

The intended use of the Malibu™ system, when used as a Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System, is 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. The indications for use are as follows:

- Degenerative disc disease (DDD), as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion,
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Spinal tumor,
- Pseudoarthrosis, and/or
- Failed previous fusion.

Contraindications

The contraindications of this system are similar to those of other systems of similar design. Contraindications include the following conditions:

Absolute Contraindications

- Active posterior infection.
- Allergy to titanium.
- Allergy to nickel (Cobalt 35Ni-20Cr-10Mo for Malibu alloy rods and sublaminar wire only)

As the manufacturer of this device, SeaSpine Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

Caution: federal law restricts this device to sale by or on the order of a physician or practitioner.

SeaSpine

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Warning: Applicable laws restrict these products to sale by or on the order of a physician.

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