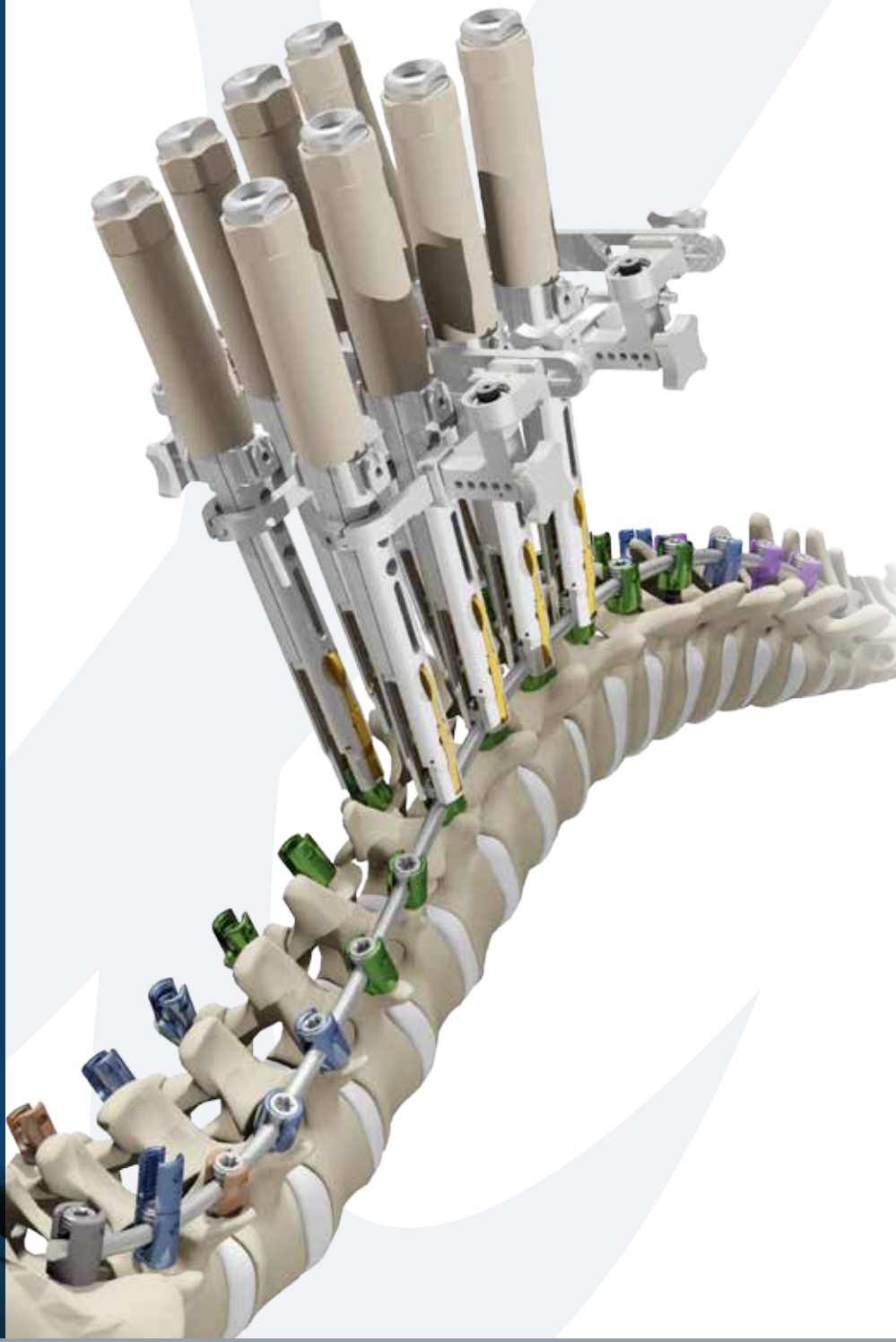
Alphatec Spine®

ZODIAC®

Reduction and Direct Vertebral Rotation System



Surgical Technique Guide

Zodiac Deformity Offering

Screws

- Polyaxial, Uniplanar, Monoaxial and Iliac
- 4.0mm through 8.5mm diameter
- 20mm through 80mm length

Hooks

- 26 Anatomical Hook Options

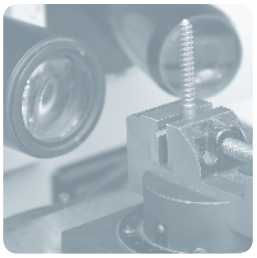
Deformity Rods

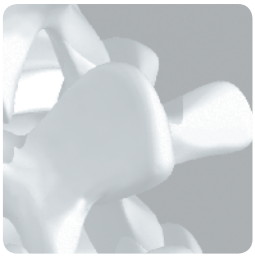
- Standard: CP Titanium, Titanium Alloy & Stainless Steel
- High Strength: Cobalt Chromium & High Strength Stainless Steel

Implants are available in Stainless Steel and Titanium Alloy

Comprehensive instrument selection including:

- Linkable reduction & derotation instruments for en bloc correction of axial deformity
- Thoracic screw preparation
- Hook preparation
- In situ rod benders





Preface

The Zodiac Direct Vertebral Rotation (DVR) System expands the capability of the Zodiac Deformity System for the correction of spinal deformities, including rod reduction and en bloc vertebral derotation, when used in conjunction with uniplanar screws.

The system is adaptable to familiar techniques including:

- Rod rotation
- Translation
- Derotation
- Sequential deformity reduction
- Compression & Distraction

Contents

Preface 3

ZODIAC DVR Surgical Technique 6

ZODIAC DVR Instruments 16

ZODIAC Cleaning Instructions 18

ZODIAC DVR Product Information 19

1. Reduction & Derotation capabilities

<5 turns to full reduction

2. 50mm reduction

3. Linkable for en bloc vertebral body rotation (VBR)

4. Squeeze tabs to remove

5. Drop & Lock engagement

Zodiac Direct Vertebral Rotation Instruments

The Zodiac DVR System provides reduction and deformity correction capability.

Simple – Fewer instruments and reduced procedural steps

Secure – Implant to instrument interface and rigid connection of linkable derotation components

Controlled – Correction of spinal deformity

Key Features & Benefits

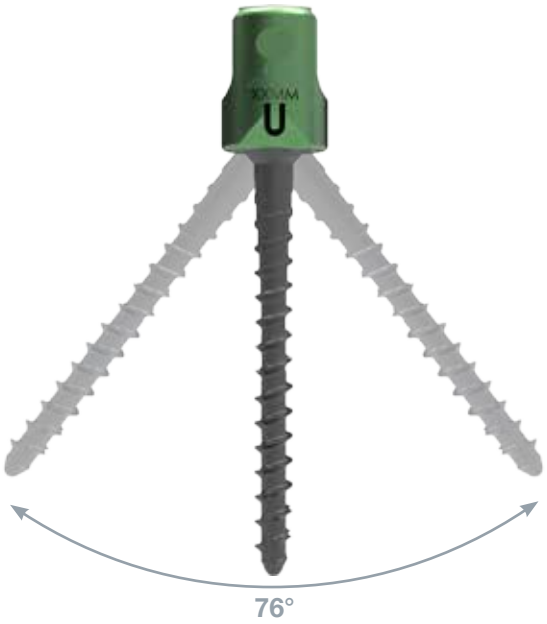
The Uniplanar Axial Reducer is a dual purpose instrument with 50mm of reduction capability, accommodating multiple deformity correction techniques, including derotation maneuvers.

The Linkable Derotation Instruments allow distribution of corrective forces over multiple implants during global deformity correction.

Complementary Implants

Uniplanar Screws

- The Zodiac Uniplanar Screw is a top-loading, low profile pedicle screw that restricts motion in the medial-lateral plane while allowing up to 76° of sagittal (cranial-caudal) variability, making it highly useful in deformity surgery.
- The uniplanar screw allows for easier engagement of the rod and improved sagittal plane restoration, minimizing hypokyphosis while maintaining the ability to derotate the spine.
- Variability in the sagittal plane allows for straight forward or anatomic screw insertion.



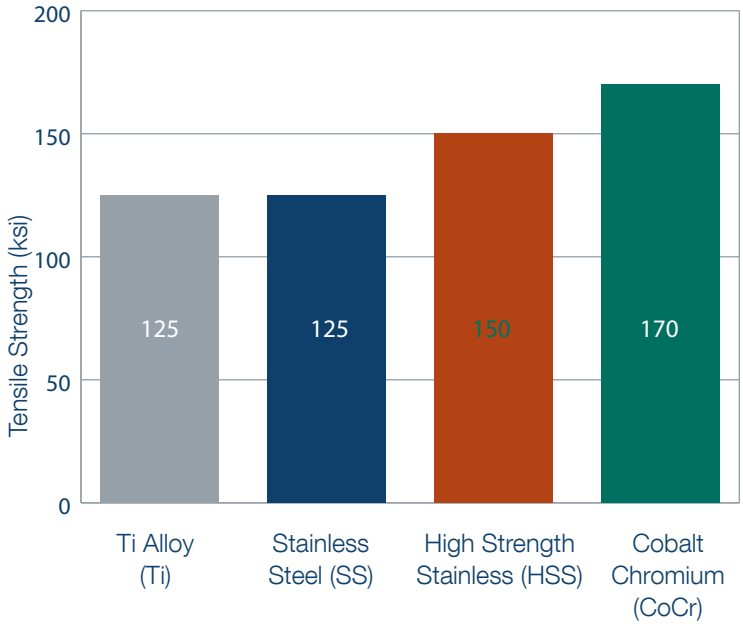
High Strength Rod options

Cobalt Chrome Alloy Rods

- 36% stronger than a Zodiac stainless steel rod[1]
- Inherent stiffness and strength characteristics maintain sagittal and coronal deformity correction
- Stiffness of 5.5mm Cobalt Chrome Alloy rod is similar to 6.35 Ti rod[1]

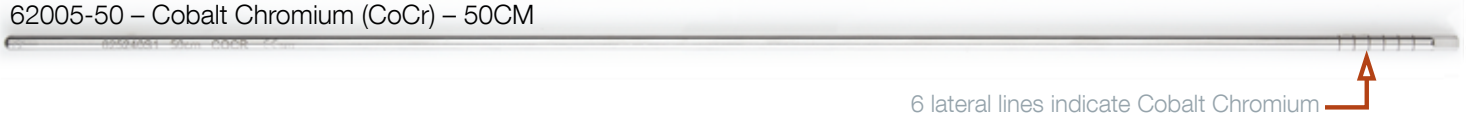
High-Strength SS Rods

- 25% stronger than a Zodiac stainless steel rod[1]
- Providing a more rigid construct in a lower profile 5.5mm screw system



Rod Identification

62005-50 – Cobalt Chromium (CoCr) – 50CM



82002-50 – High-Strength SS (HSS) – 50CM

[1]Data on File

Figure 1.

DVR Surgical Technique

The Zodiac DVR System can be arranged unilaterally or bilaterally to correct the curvature of the spine by application of derotation forces applied to the Uniplanar Axial Reducers and Alignment Clips. The Zodiac DVR system can also be cross linked for en bloc reduction and derotation, with the addition of the Crosslink Bracket and Crosslink Bar. The Zodiac DVR System is only compatible with Zodiac Uniplanar Screws for vertebral body derotation maneuvers.

Note: During derotation maneuvers, it is recommended to translate the load evenly over multiple fixation points.

Pedicle Preparation

Following thorough exposure of the posterior elements the pedicles will be prepared for screw placement as indicated by preoperative radiographic assessment and surgical planning. For apical derotation of scoliosis it is recommended to place screws bilaterally in each vertebrae of the deformity. Typically four apical vertebrae are used. Although both fixed and polyaxial pedicle screws may be utilized, Zodiac Uniplanar screws are preferred at the apex to maximize derotation forces. Zodiac Polyaxial screws may be used at the cephalad and caudal ends of the construct.

Tip: Thoracic bone probes available in the Zodiac Deformity instrument set may be utilized for thoracic pedicle preparation. **Figure 1.**

Note: the Zodiac DVR Surgical Technique Guide is intended as a supplement to the Zodiac Deformity Surgical Technique Guide (LIT-83111).

Uniplanar Screw Insertion

Attach a quick connect axial or T-handle to a polyaxial screwdriver. Select an appropriate size Uniplanar Screw. Place the screwdriver assembly over the selected screw and engage the hex tip with the recessed hex of the screw. Push the knurled knob down to advance the sleeve and rotate clockwise to engage the screwdriver with the screw. Verify screw length and diameter using the screw template. **Figure 2.**

Note: Uniplanar screws can be differentiated from standard polyaxial screws by the "U" on the side of the screw head. **Figure 3.**

Figure 3.

Note: Alphatec screws are measured from the tip of the screw to the proximal thread. Therefore there is an additional 2.85mm length from the undersurface of the screw body to the most proximal thread. For example, when verifying a 55mm screw in the gauge on the screw caddy, the length from distal tip to the undersurface of the head is actually 57.85mm. The clinician must be aware of this difference to avoid over advancing the screw tip.

Figure 2.

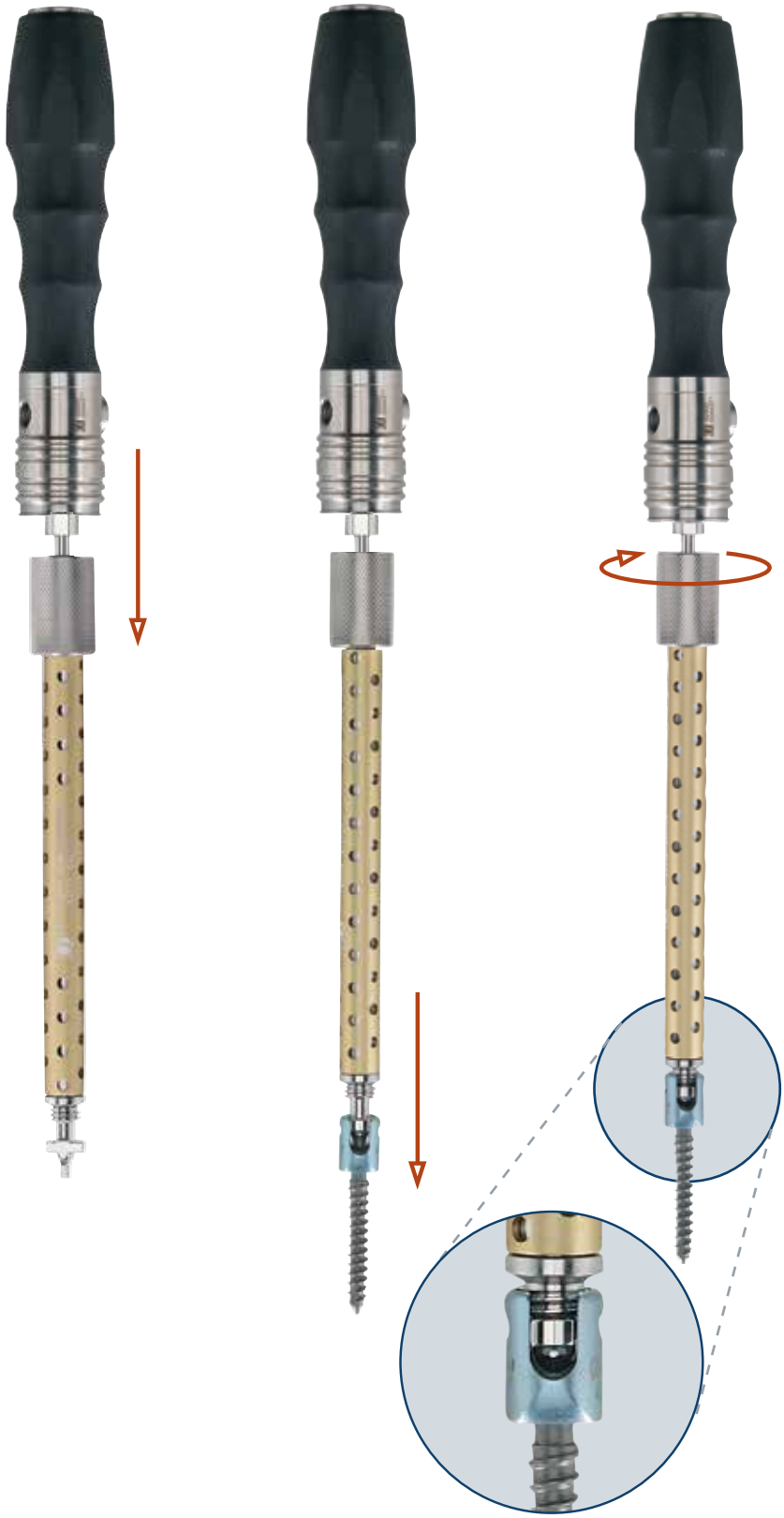
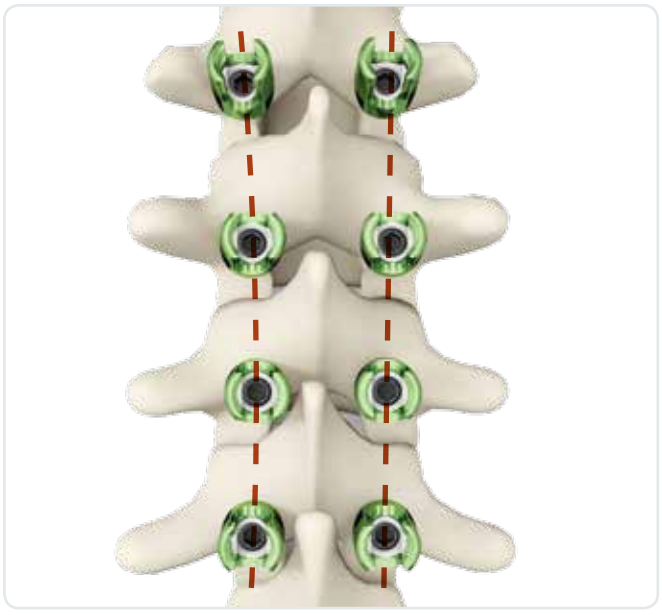


Figure 4.

Ensure the collar on the ratcheting handle is in the forward position then advance the screw into the prepared pedicle. To disengage the screw from the screwdriver, turn the knurled barrel counterclockwise and remove. Figure 4.

Note: It is recommended to leave the screw body slightly above the bony surface. This will facilitate screw variability and ease of Uniplanar Axial Reducer engagement.

Figure 5.

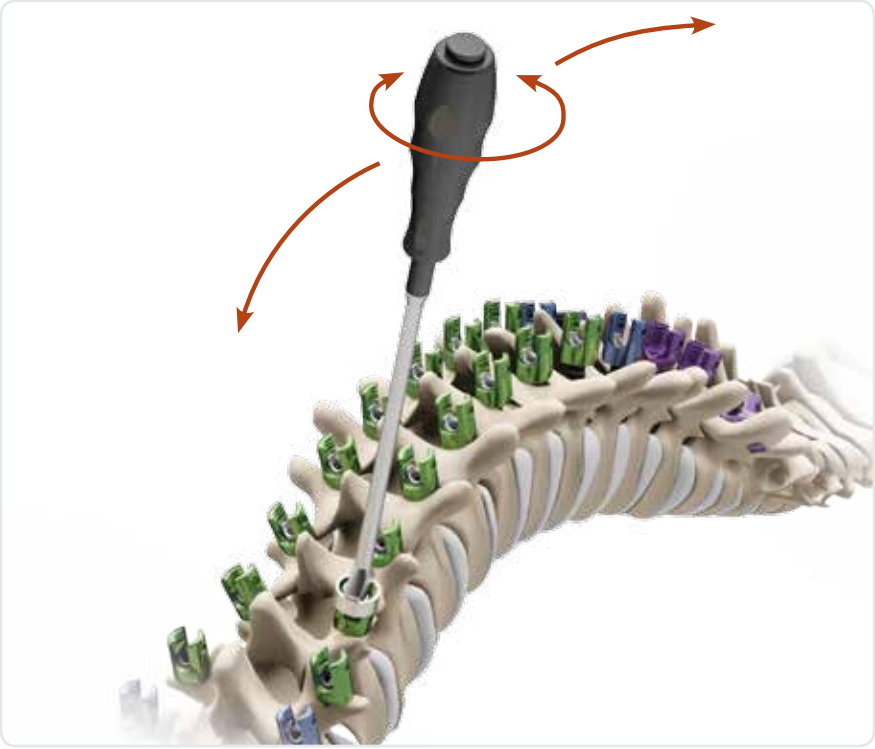


Following screw insertion and prior to removing the driver from the uniplanar screw, verify screw alignment to adjacent screws, assess the bone/screw interface and the ability to directly derotate the apical region of the scoliosis by moving the driver medial and lateral. Figure 5.

Screw Head Adjustment

When a Uniplanar screw requires adjustment or alignment in situ, only use Head Positioner (73730) provided in the Zodiac DVR instrument tray. **Figure 6.**

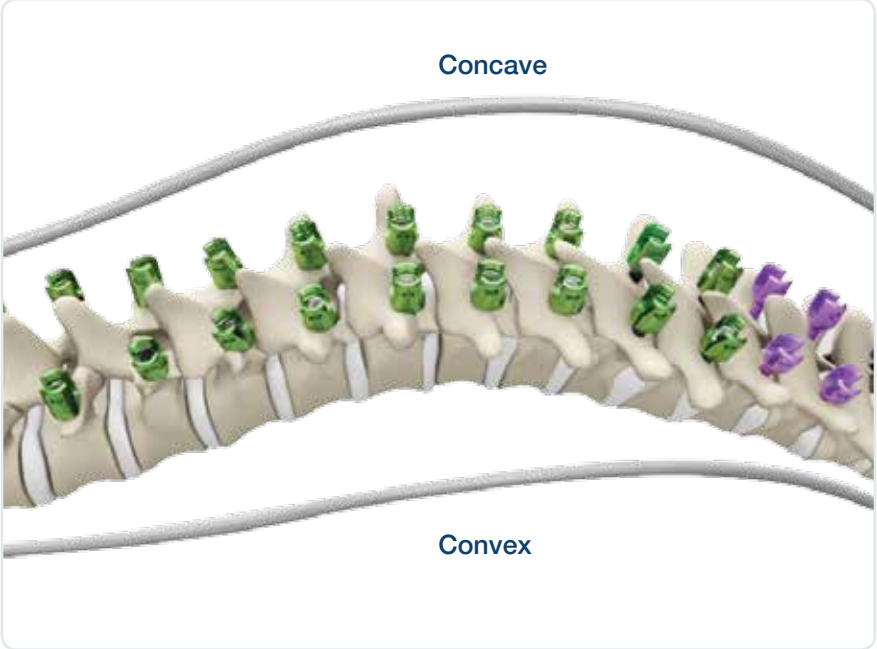
Figure 6.



Rod Contour

It has been noted that during reduction of scoliosis the concave rod may flatten. Extra kyphosis may be given to the concave rod in an effort to pull the apical vertebrae posterior. The convex rod may be given less thoracic kyphosis to push down on the convex side of the vertebral bodies in an effort to reduce the rib prominence. **Figure 7.**

Figure 7.



Note: Rod strength has an effect on the amount of kyphosis given to the rod: Zodiac Cobalt Chrome & High Strength SS rods may be bent to slightly more than normal kyphosis while standard SS and Ti rods may be contoured with additional kyphosis, anticipating a reduction of sagittal rod bend during correction.

Figure 8.

Figure 9.

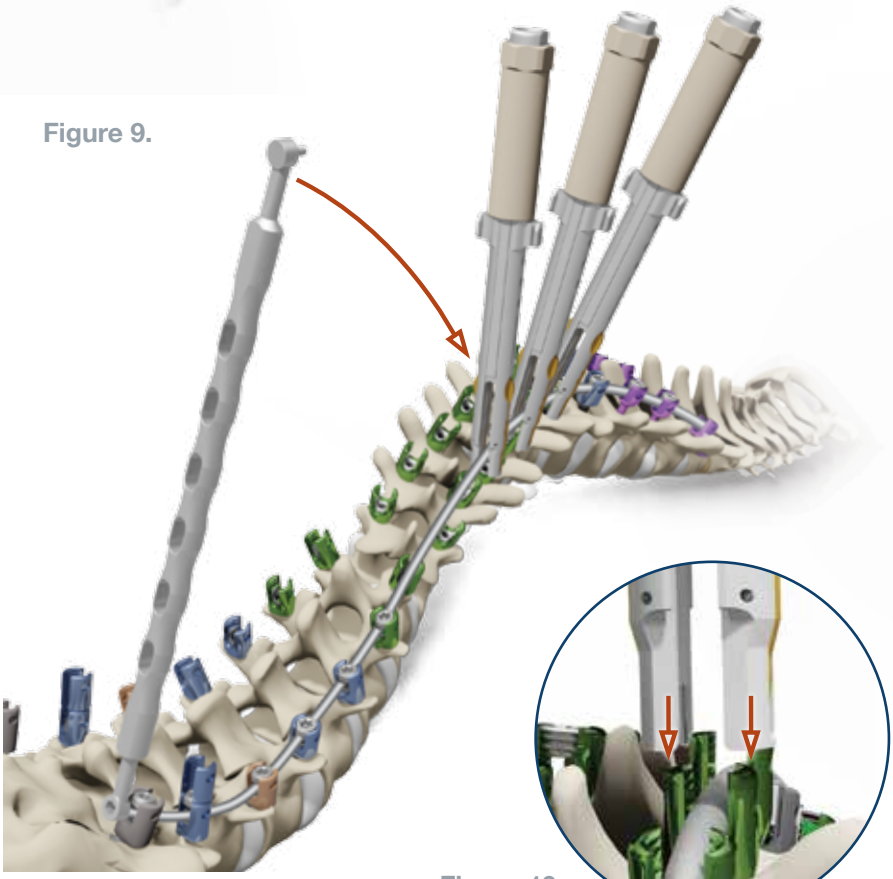


Figure 10.

Rod Placement

The concave rod is inserted first using either a translation technique or a traditional CD rod rotation technique.

- The translation technique is accomplished by inserting the rod into the proximal and distal screws. The rod should be oriented in the correct sagittal plane with the proximal and distal set screws locked. The apical segments can now be translated or reduced segmentally using the Uniplanar Axial Reducers. **Figure 8.**

Note: The Reduction Drive Adapter can be used in conjunction with standard Zodiac ratcheting handles to facilitate rod reduction.

- The rod rotation technique is accomplished by inserting the rod 90° to the final sagittal alignment. The rod is captured in the proximal and distal screws, with set screws loosely tightened. Use the Uniplanar Axial Reducers to capture the rod at the apical segments. The rod is rotated from the midline 90° laterally, using the Zodiac rod rotation wrench (92932) and/or rod grippers (92902), to correct the coronal alignment. Proximal and distal set screws should be provisionally tightened. The Uniplanar Axial Reducers can be used to segmentally reduce the rod to the apical segments. The apical set screws can now be inserted and loosely tightened. **Figure 9.**

Note: The Zodiac Uniplanar Axial Reducer may be attached to a uniplanar screw using a drop and lock technique. With the rod in place, position the Uniplanar Axial Reducer over a uniplanar screw and with light downward pressure the reducer will drop and automatically lock onto the screw. A light tug upward will confirm engagement. **Figure 10.**

En Block Direct Vertebral Rotation

With the concave rod engaged to all screws, attach the Uniplanar Axial Reducer to the screws on both concave and convex sides of the curve. **Figure 11.**

When a rod is not engaged to the uniplanar screw, Bushing Blockers must be inserted into each apical screw which will be used during derotation. The Bushing Blockers are inserted with the Long Set Screw Inserter. If required the Bushing Blockers can be inserted through the cannula of the Uniplanar Axial Reducer. **Figure 12.**

Figure 13. To derotate the spine, push down on the convex screws while simultaneously rotating the concave and convex screws. Lifting the concavity out of the chest is accomplished with the Uniplanar Axial Reducer locked on the Uniplanar Screws.

Figure 11.

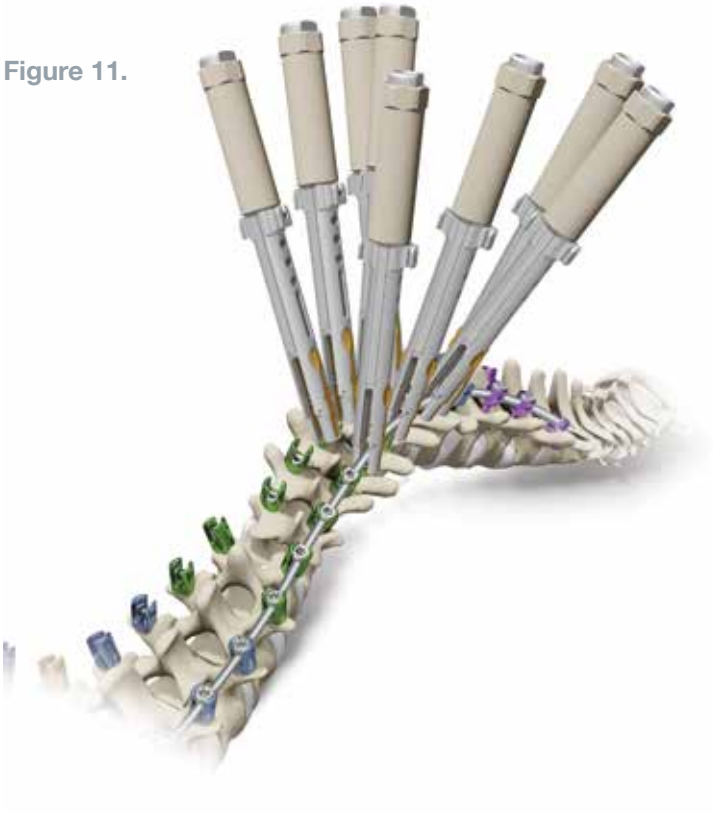


Figure 12.

Figure 13.

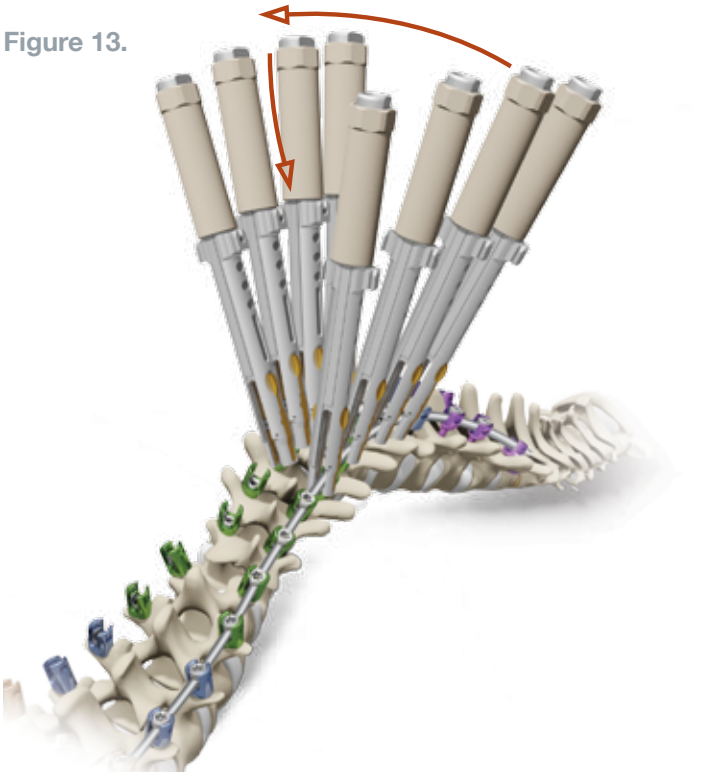


Figure 14a.

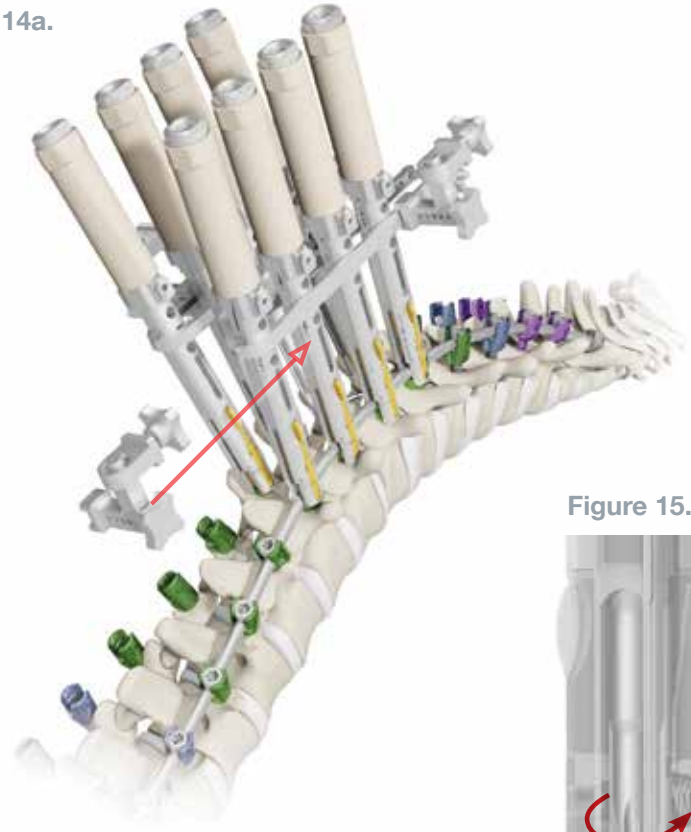


Figure 15.

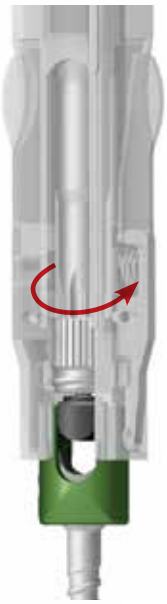


Figure 14b.

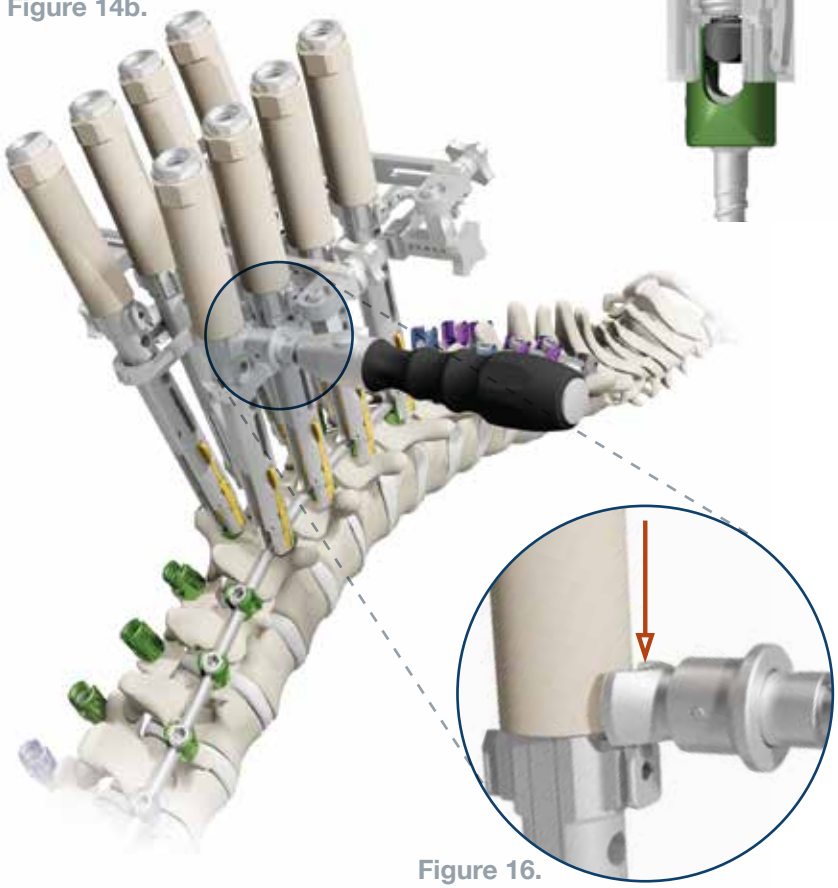


Figure 16.

Using the Alignment Clips, the Uniplanar Axial Reducers can be linked together and rotated in unison. The Alignment Clips also provide a base to which the Crosslink Brackets and Crosslink Bars are attached for en block derotation. **Figure 14a and 14b.**

Following derotation of the apical segment provisionally tighten all the set screws on the concave rod to hold the correction.

To complete the construct, remove the Bushing Blockers using the long set screw inserter. **Figure 15.**

The convex rod can now be inserted. Provisionally tighten the set screws on the convex side.

Note: During derotation the surgeon may find it useful to attach the anti-torque adapter and axial handle to the apical Uniplanar Axial Reducer to help lift the concave deformity out of the chest. **Figure 16.**

Segmental Vertebral Body Derotation

Derotation of individual spinal segments can also be accomplished with the Zodiac DVR System.

Implant both rods and capture them with the set screws. Tighten the set screws nearest the distal end of the construct. The remaining set screws should be left loose to allow spinal lengthening during the derotation maneuver.

Attach two Uniplanar Axial Reducers in the distal neutral vertebra to provide counter-rotation force during segmental derotation of the next proximal segment. **Figure 17.**

Attach Uniplanar Axial Reducers bilaterally at the next proximal vertebrae and derotate each proximal vertebral segment. Tighten the set screws once the vertebral segment has reached a neutral position relative to the distal vertebrae. Repeat the above steps, moving towards the apex of the deformity.

Figure 17.

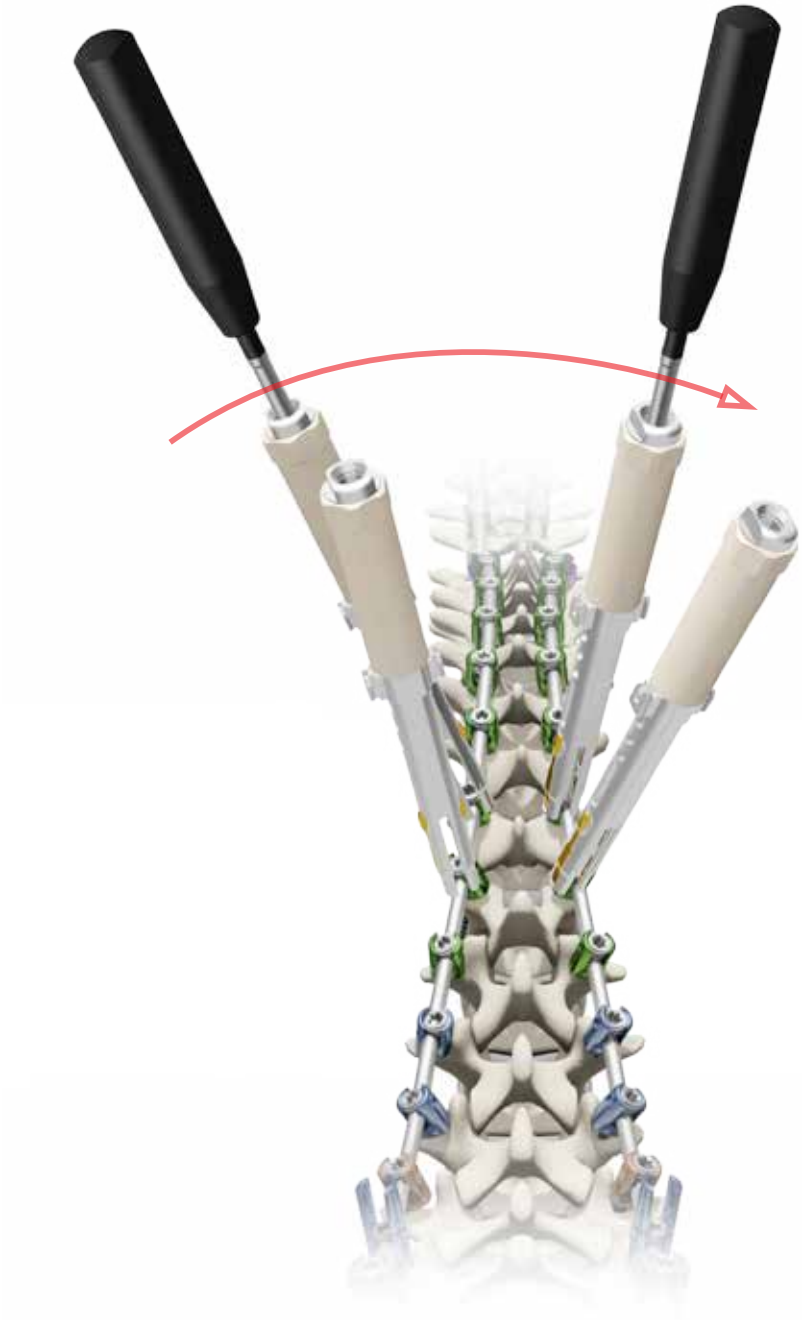
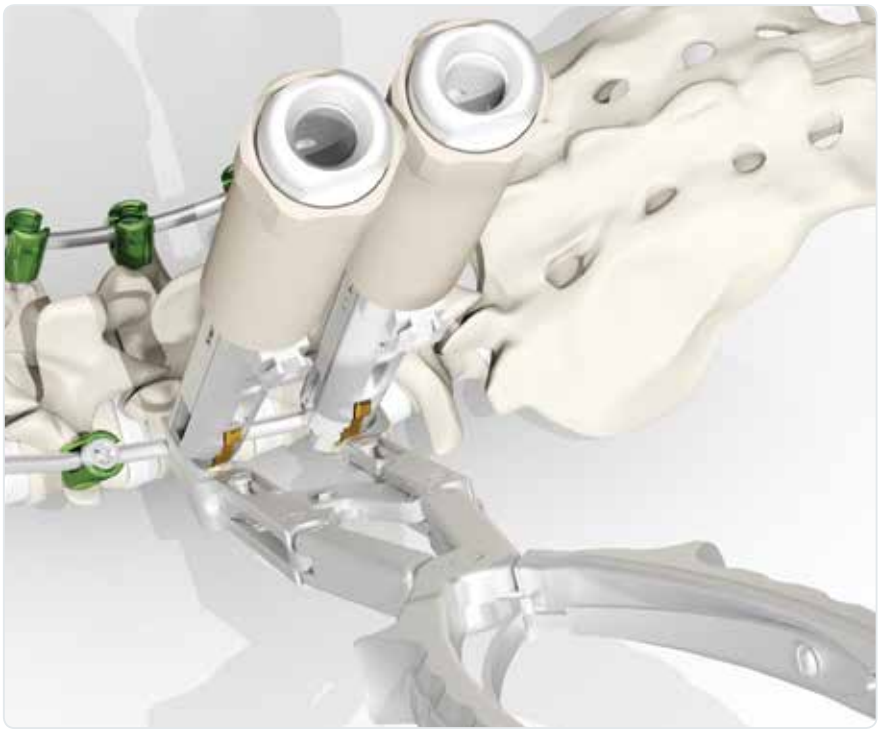


Figure 18.

Figure 19.



Distraction & Compression

Additional correction can be achieved by compressing the convexity and distracting the concavity during derotation maneuvers. Compression and distraction may be achieved using the Parallel Compressor or Distractor.

Distractor

Place the tips of the Distractor over the rod and between the Uniplanar Axial Reducers then squeeze handles to distract. **Figure 18.**

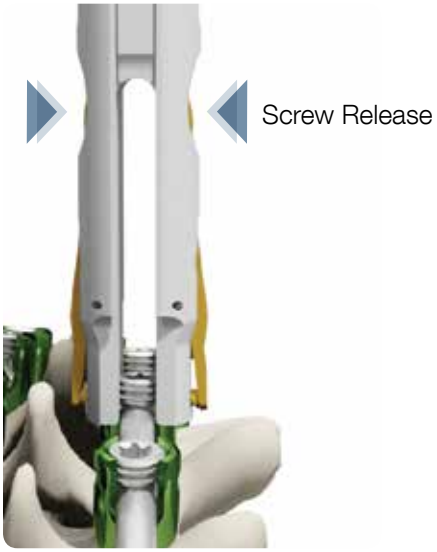
Compressor

Place the tips of the Compressor over the rod with the tips outside of the Uniplanar Axial Reducers then squeeze. **Figure 19.**

Use the long set screw inserter to provisionally tighten the set screws after desired compression or distraction is achieved.

Note: Zodiac Uniplanar Axial Reducers can be removed from the Uniplanar Screws after the set screws have been tightened. Squeeze the gold tabs and lift to release the Uniplanar Axial Reducer from the screw. It is not necessary to unthread the reduction handle prior to removal. **Figure 20.**

Figure 20.



Final Tightening

Assemble the 100in-lb T-Handle Torque Wrench with the Set Screwdriver Shaft. Insert the torque wrench assembly through the cannula of the Cannulated Anti-Torque. Engage the male tip portion of the set screwdriver into the female portion of the desired set screw. Slide the cannulated anti-torque down until the instrument is fully seated over the rod on each side of the screw head. Turn T-handle clockwise. Final tightening is achieved when the T-handle audibly clicks. **Figures 21, 22.**

Note: Make sure the male tip of the Set Screw Inserter is fully engaged with the female portion of the set screw.

Additional Correction:

Additional sagittal and coronal correction can be achieved with the use of Zodiac in-situ Benders. **Figures 23, 24.**

Figure 21.

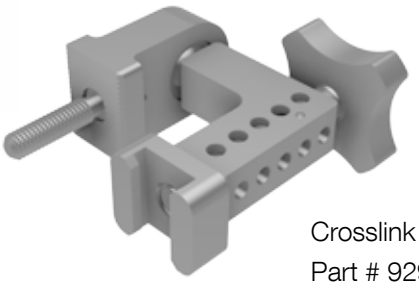
Figure 22.

Figure 23.

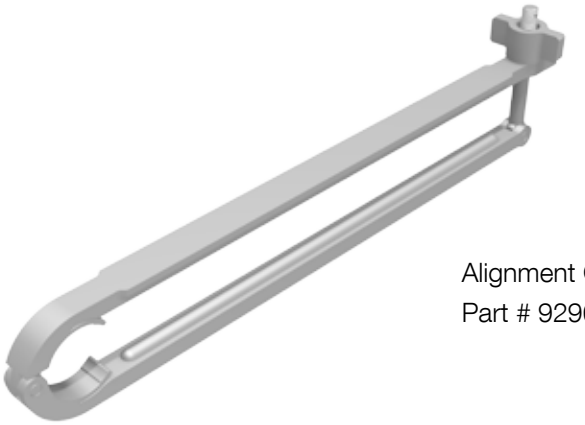
Figure 24.

Zodiac DVR System Components

Uniplanar Axial Reducer (Qty 8)
Part # 92961

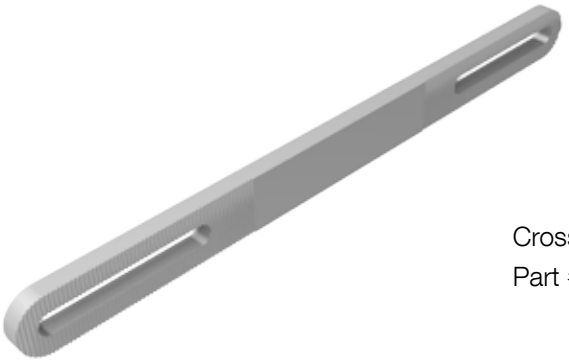


Crosslink Bracket (Qty 4)
Part # 92963



Alignment Clip (Qty 2)
Part # 92962

Crosslink Bracket Knob (Qty 4)
Part # 92964



Crosslink Bar (Qty 2)
Part # 92965

Zodiac DVR System Components

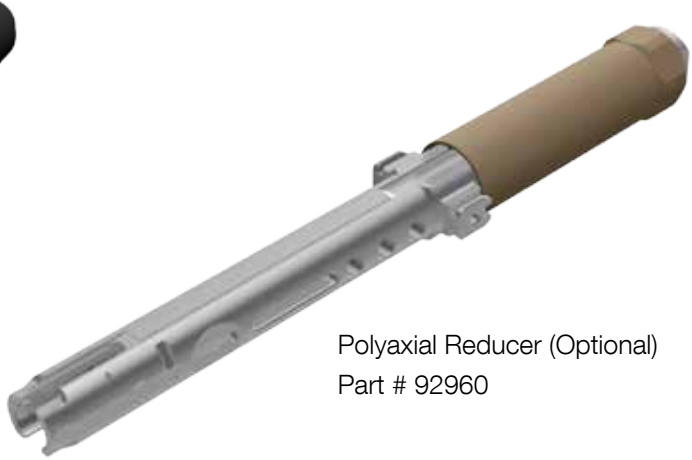
Reduction Drive
Adapter (Qty 1)
Part # 92966

Bushing Blocker (Qty 10)
Part # 92969

Counter Torque
Adapter (Qty 1)
Part # 92967

Long Set Screw Inserter (Qty 2)
Part # 92937

Head Positioner (Qty 1)
Part # 73730

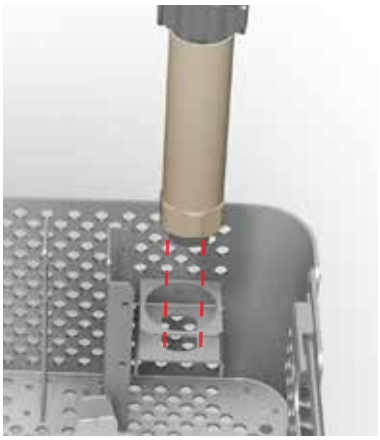


Polyaxial Reducer (Optional)
Part # 92960

Cleaning Instructions

Uniplanar and Polyaxial Axial Reducer Cleaning Instructions

- Disassemble for cleaning
- Reassemble
- Ready for use



Tray has a built in wrench for assembly and disassembly.

Note: Refer to Zodiac IFU (INS-025) for cleaning and sterilization instructions.

INSTRUCTIONS FOR USE
ZODIAC® POLYAXIAL SPINAL FIXATION SYSTEM

GENERAL INFORMATION:
The ZODIAC Polyaxial Spinal Fixation System facilitates the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI or Ti-6Al-4V) or stainless steel. Implant rods are also available in commercially pure titanium (Ti Grade 4) and cobalt chrome (CoCr). All hooks are intended for fixation/attachment to the posterior thoracic and lumbar spine only. It is intended that the implants be removed after successful fusion.

WARNINGS:
1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. The ZODIAC Polyaxial Spinal Fixation System implants are used only to provide temporary internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices.
3. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
4. **This implant is a single use device.** Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.
5. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient condition, which may impact on the performance of the system when using this device.
6. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
7. Based on testing results from these systems are significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants, proper reduction and complete compliance of the patient.
8. Potential risks identified with the use of these devices, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury.
9. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
10. Other significant risks to spinal surgery include alcohol abuse, obesity, and/or patients with poor bone, muscle and/or nerve quality.
11. It is critical that set screws are turned to the proper torque values as recommended in the surgical techniques, using the instruments provided.
12. The implants are provided non-sterile and must be cleaned and sterilized before use. ***REFER TO ZODIAC INSTRUCTIONS FOR USE, INS-025 FOR CLEANING AND STERILIZATION PROCEDURES.***
13. It is recommended that the implants of the ZODIAC Polyaxial Spinal Fixation System should not be used with any other spinal systems.

PRECAUTIONS:
1. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. The Zodiac System has not been evaluated for safety and compatibility in the MR environment. The Zodiac System has not been tested for heating or migration in the MR environment.
3. The uniplanar screws may be used in conjunction with the polyaxial screws and hooks contained within the Zodiac Polyaxial Spinal Fixation System or Alphatec Spine's monoaxial screws, iliac screws or adjustable bridges. The uniplanar screws are to be used in a multi-level instrumented construct to provide rigid internal stabilization of the spine until fusion is achieved.
4. The offset connectors may be used in conjunction with polyaxial screws and hooks contained within the Zodiac Polyaxial Spinal Fixation System or Alphatec Spine's monoaxial screws, iliac screws, uniplanar screws or adjustable bridges. The offset connectors may be used in a multi-level instrumented spinal fixation construct to provide rigid internal stabilization of the spine until fusion is achieved.

INDICATIONS FOR USE:
The Zodiac Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.
It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-Iliac screw indications are limited to the sacrum-iliac crest only.
1. The ZODIAC Polyaxial Spinal Fixation System, when used as a hook and sacral iliac screw fixation system (non-pedicle screw) is intended for:
   a. Patients having fractures of the thoracic and lumbar spine.
   b. Patients having deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
   c. Patient having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).
2. The ZODIAC Polyaxial Spinal Fixation System, when used as a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).
3. In addition, the ZODIAC Polyaxial Spinal Fixation System, when used as a pedicle screw fixation system is intended for:
   a. Patients receiving autograft or allograft bone graft.
   b. Patients having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis, grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.
4. The ZODIAC Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:
   a. Patients having fractures of thoracic and lumbar spine.
   b. Patients having thoracolumbar deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
   c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

CONTRAINDICATIONS:
The ZODIAC Polyaxial Spinal Fixation System is contraindicated for:
1. Use in the cervical spine.
2. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
3. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions, which would prohibit beneficial surgical outcome.
4. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
5. Use with bone cement.
6. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
7. Commingling of titanium and stainless steel components within the same construct.
8. Reuse, or multiple use.

POSSIBLE ADVERSE EFFECTS:
The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.
1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
3. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
5. Infection and/or hemorrhaging.
6. Bone graft, vertebral body and/or sacral fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level.
7. Non-union and/or pseudoarthrosis.
8. Neurological disorder, pain and/or abnormal sensations.
9. Revision surgery.
10. Death.

Excerpt from INS-025J

ALPHATEC SPINE, INC
5818 El Camino Real
Carlsbad, CA 92008 USA
(760) 431-9286
(800) 922-1356

EC REP

Emergo Europe
Molenstaat 15
2513 BH The Hague
The Netherlands

CE 0413

Alphatec Spine®

CORPORATE HEADQUARTERS
5818 El Camino Real
Carlsbad, California 92008

CUSTOMER SERVICE
Toll Free: 800.922.1356
Local: 760.431.9286
Fax: 800.431.1624

LIT-84415B | 2013/06/03