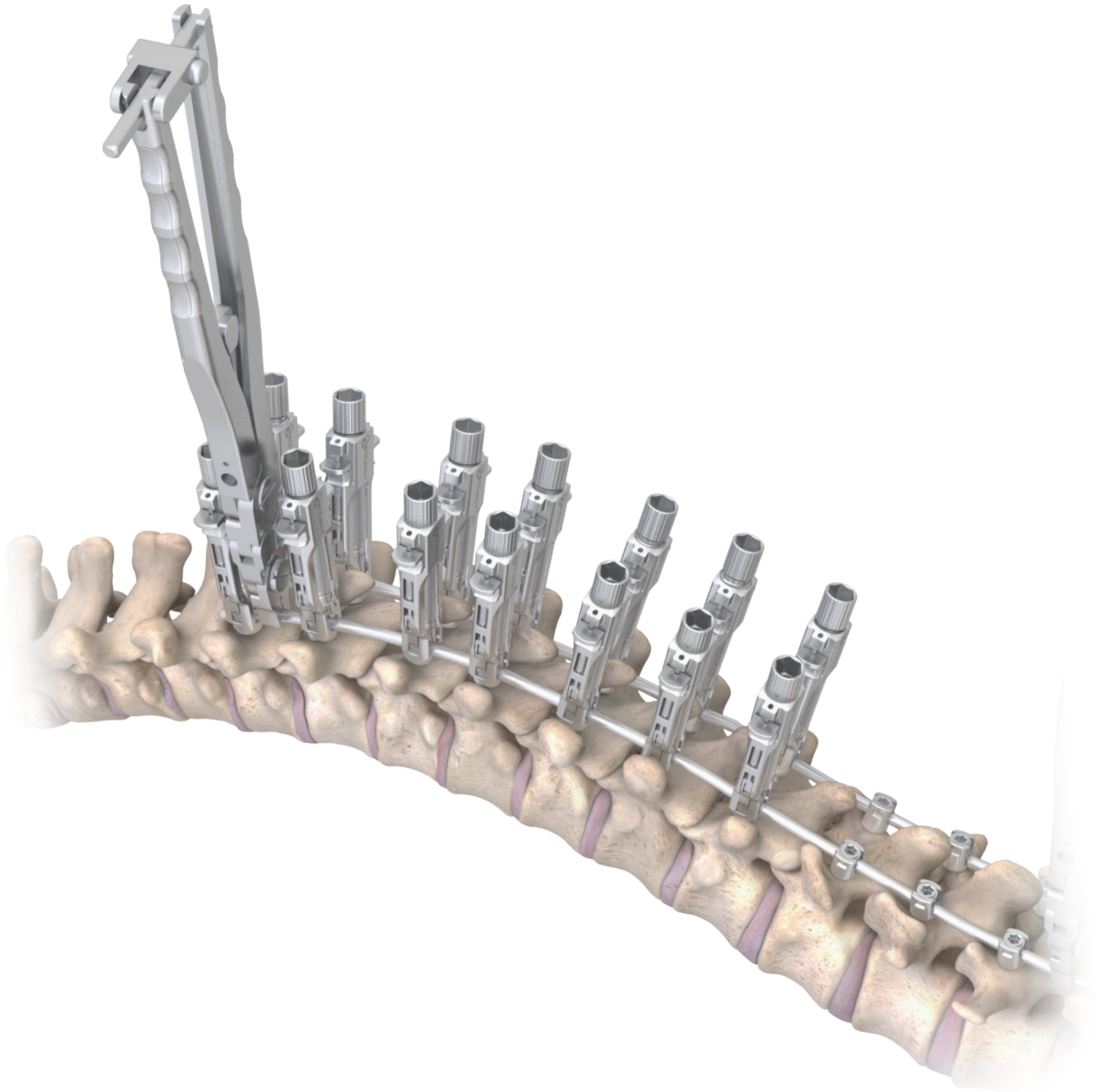


# RESPONSE™ Derotation System

DEROTATION SURGICAL TECHNIQUE





# TABLE OF CONTENTS

## System Overview

---

Indications.....	3
Instruments.....	4

## Surgical Technique

---

Rod Reduction - (Mini) Rod Reducer .....	8
Rod Reduction - Rod Reduction Tower .....	9
Provisionally Tighten Screws.....	10
Derotation - (Mini) Rod Reducer & (Universal) Derotation Handles .....	11
Derotation - Tower & Multi-Segmental Handles.....	12
Derotation - (Universal) Segmental Derotators .....	13
Derotation - Locking Tube Constructs.....	14
Post Derotation .....	15

## INDICATIONS

**Outside** of the United States - The **RESPONSE™ 4.5/5.0 and 5.5/6.0mm Spine Systems** are intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

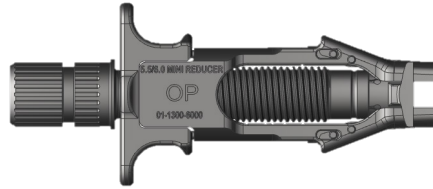
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the RESPONSE 4.5/5.0 and 5.5/6.0mm Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The RESPONSE 4.5/5.0 and 5.5/6.0mm Spine Systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

**NOTE:** The RESPONSE 4.5/5.0 System may not be available in all markets; please contact your local OP representative for availability.

**Inside** the United States - The **RESPONSE™ 4.5/5.0mm and 5.5/6.0mm Spine Systems** are intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the RESPONSE 4.5/5.0mm and 5.5/6.0mm Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis, neuromuscular scoliosis and congenital scoliosis. The RESPONSE 4.5/5.0mm and 5.5/6.0mm Spine Systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

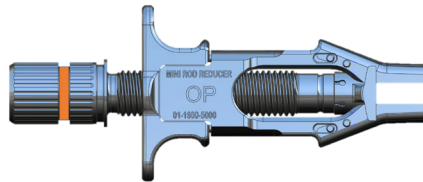
# INSTRUMENTATION



5.5/6.0 Mini Rod Reducer  
01-1300-6000



5.5/6.0 Rod Reduction Tower  
01-1003-9081



4.5/5.0 Mini Rod Reducer  
01-1600-5000



4.5/5.0 Rod Reduction Tower  
01-1600-9081



Axial Handle, Fixed  
01-1003-6299



Axial Handle, Ratcheting  
01-1003-6033



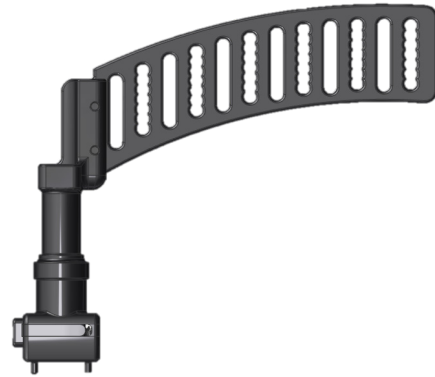
Palm Handle, Ratcheting  
01-1003-6034

# INSTRUMENTS

## Multi Segment Derotation Instruments



Multi Segment Rotation Handle  
01-1003-6100



Universal Locking Derotation Handle  
01-1300-5061



Multi Segment Comb  
01-1003-6279



Multi Segment Rotation Pin, Long  
01-1003-6116



Multi Segment Rotation Pin, Short  
01-1003-6117



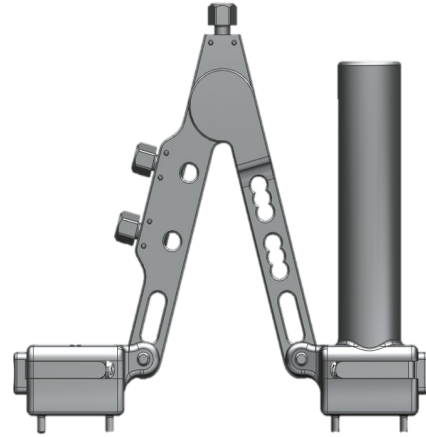
Multi Segment Rotation Pin, Extra Long  
01-1003-6305



Driver Segmental Derotator, Short  
01-1300-5100



Driver Segmental Derotator, Medium  
01-1300-5102



Universal Segmental Derotator  
01-1300-0200



Driver Segmental Derotator, Long  
01-1300-5101

# INSTRUMENTS

## Multi Segment Derotation Instruments



Derotation Cross Bar - 150mm  
01-1300-0258

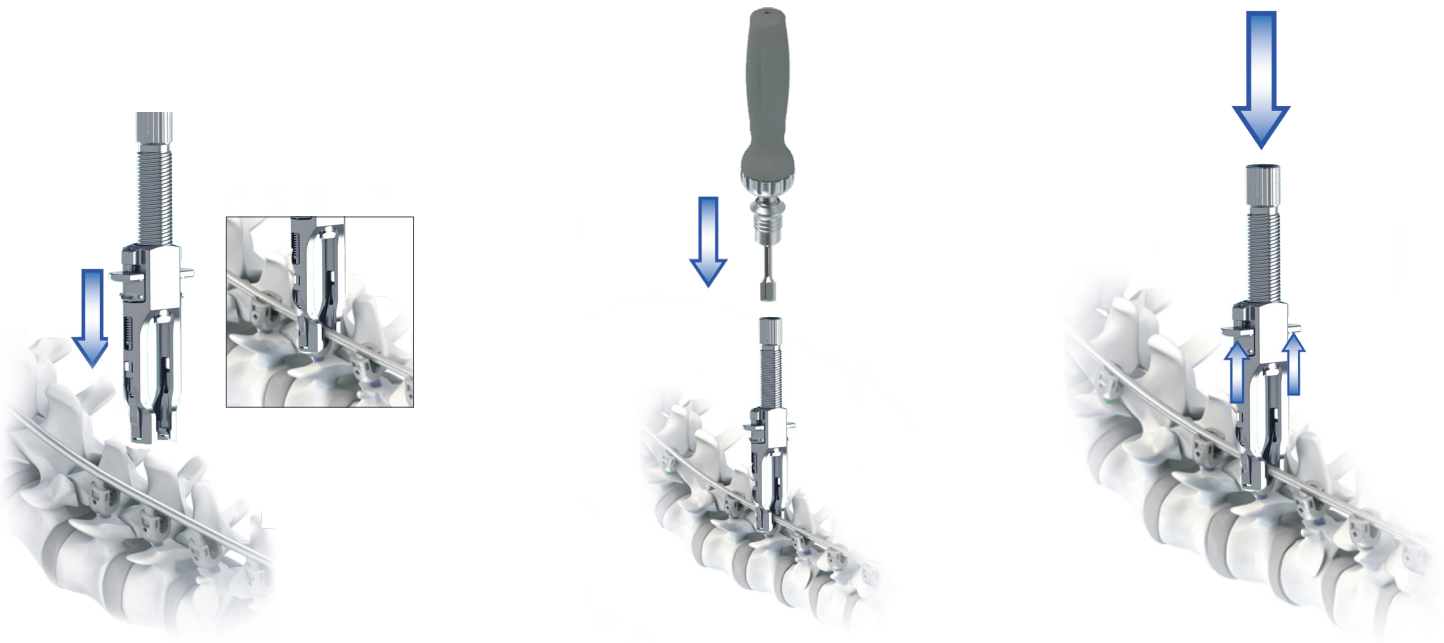


Derotation Cross Bar - 225mm  
01-1300-0257



Locking Tube  
01-1300-0250

## DEROTATION SURGICAL TECHNIQUE



### Rod Reduction – Mini Rod Reducer

Insert and affix Mini Rod Reducer by pushing down over the top of the screw head.

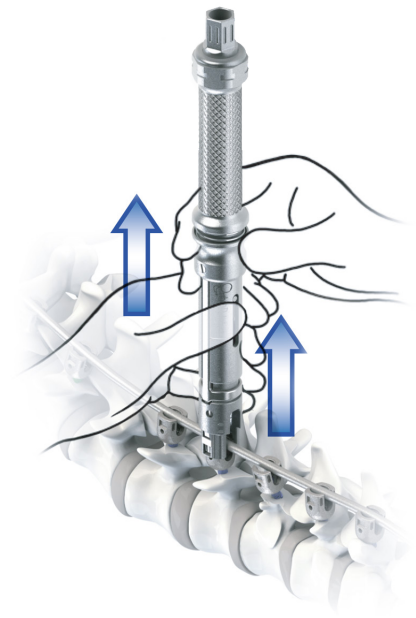
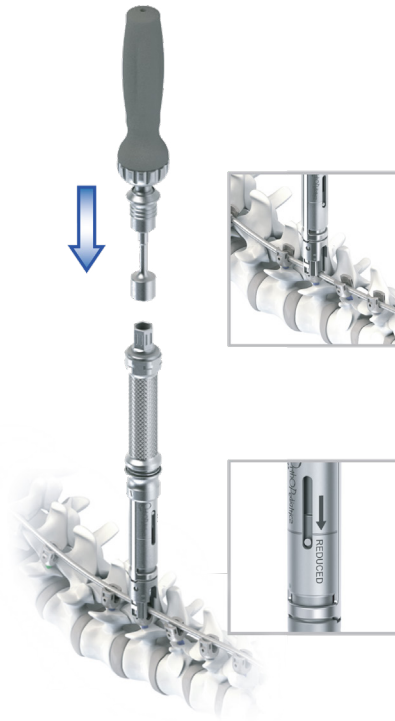
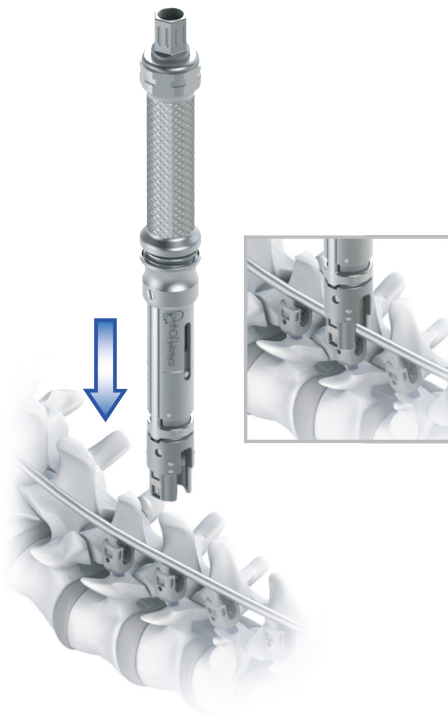
To reduce the Rod, use the short derotation driver and axial ratcheting handle to turn the knob clockwise.

While the Mini Rod Reducer is affixed to the screw head, derotation can be completed using any of the techniques demonstrated on page 10.

### Mini Rod Reducer Removal

See Mini Rod Reducer section of ST-1300-01-01 or ST-1600-01-01 for instructions on provisionally tightening set screws. After the rod has been reduced and the set screw has been provisionally tightened, the Mini Rod Reducer may be removed from the screw head. Turn the knob counter clockwise a few turns and then place downward pressure on the knob and pull up on the release tabs to disengage from the screw head.

**WARNING:** The Mini Rod Reducer does not fully seat the rod.



## Rod Reduction – Rod Reduction Tower

Insert and affix Rod Reduction Tower by pushing down over the top of the screw head.

To reduce the Rod, use the hex adapter and axial ratcheting handle to turn the hexagonal knob clockwise.

**NOTE:** When the black line is visible, it identifies the rod is fully reduced.

While the Mini Rod Reducer is affixed to the screw head, derotation can be completed using the technique demonstrated on page 11.

## Tower Removal

See Tower Removal section in ST-1300-01-01 or ST-1600-01-01 for instructions on provisionally tightening set screws. After the rod has been reduced and the set screw has been provisionally tightened, the Rod Reduction Tower may be removed from the screw head. Turn the hexagonal knob counter clockwise a few turns, then pull up on the medial collar to disengage from the screw head.



Rod Reducer

## Provisionally Tighten Set Screws

Capture the appropriate set screw onto the hexalobe feature of the Large Set Screw Driver.

Use the Large Set Screw Driver to introduce the Set Screw. Send the Set Screw down the Tower Rod Reducer or (Mini) Rod Reducer until it bottoms out on the screw threads. To avoid cross threading of

the Set Screw, turn the set screw counterclockwise until a click is felt, ensuring that the set screw is lined up correctly. Then proceed with clockwise tightening of the Set Screw.

**NOTE:** Set Screws can be introduced through the derotation instrumentation.

## PERFORM DEROTATION

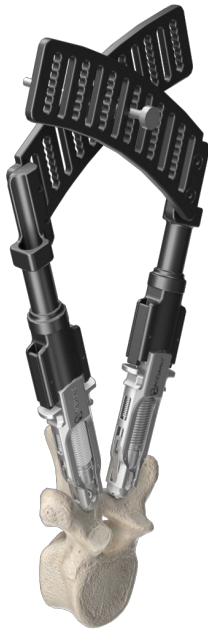


Figure 1



Figure 2

### Deformity Correction - Derotation Using the (Mini) Rod Reducers & (Universal) Derotation Handles

The following text and illustrations refer to the Rod Reducer (01-1003-5000) and Locking Derotation Handles (01-1003-5061). An alternative option using different instruments is provided below.

Attach either the Rod Reducer Extension Handle (non-locking option) or the Locking Derotation Handle to each of the Rod Reducers that will be employed for derotation. It is suggested that two Rod Reducers and Handles be used on each vertebra involved to balance the load on the pedicle screws.

**WARNING:** Derotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. Be aware that the Derotation Handles provide additional leverage and thus magnify the applied force as it is transferred to the pedicle screws. Care should be taken to avoid bone damage and/or screw failure.

Handles may be oriented with the flat flags facing inward and overlapping (Figure 1). In this scenario,

Multi Segment Rotation Pin(s) of the appropriate length can be used to connect Handles on the same and/or different vertebrae.

Alternatively, the Handles may be oriented with the flat flags facing outward (Figure 2). In this scenario, Multi Segment Rotation Pin(s) of the appropriate length can be used to link Handles on either side of the body. If desired, the Multi Segment Comb can be used to connect the constructs on either side of the body.

Perform sensory and motor evoked potential monitoring for the early detection of a spinal cord deficit during surgical manipulation of the spine.

Alternative Option: The same technique can be completed by attaching the Universal Locking Derotation Handles (01-1300-5061) to either the 4.5/5.0 Mini Rod Reducer (01-1600-5000) or the 5.5/6.0 Mini Rod Reducer (01-1300-6000). While the connection mechanism between the devices is different, the technique and resulting constructs are similar.



## Deformity Correction - Derotation Using the Rod Reduction Towers & Multi Segment Rotation Handles

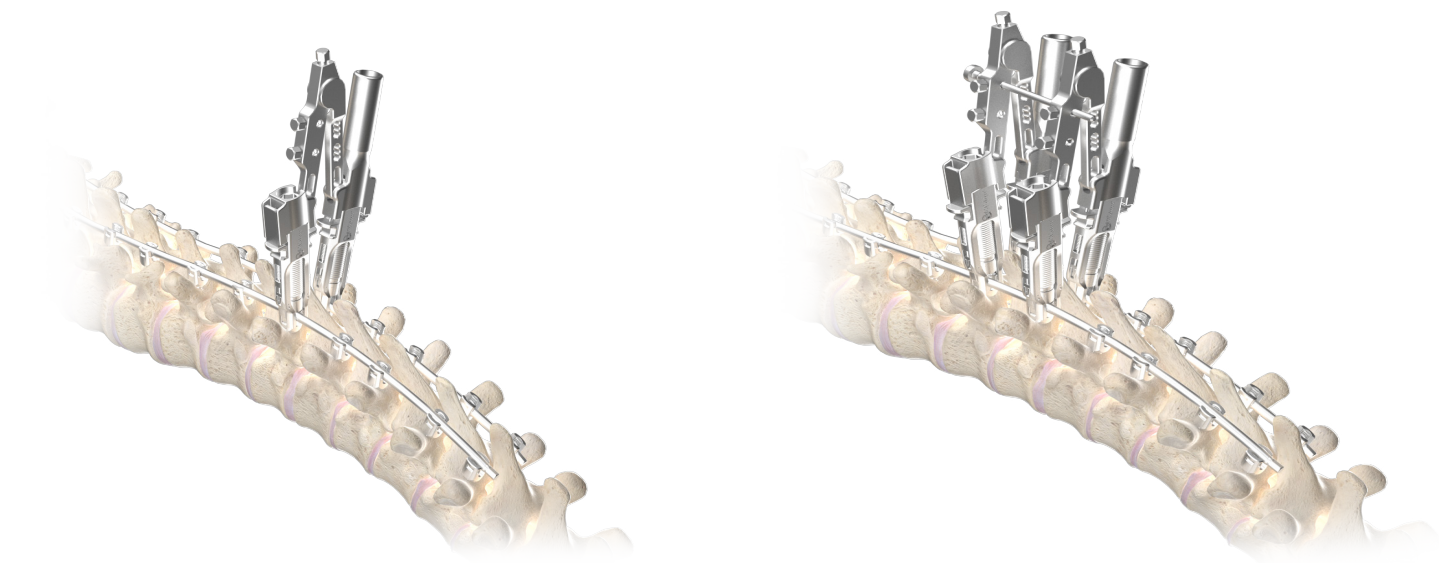
Attach a Multi Segment Rotation Handle to each of the Rod Reduction Towers that will be employed in the derotation. It is suggested that two Rod Reduction Towers and Handles be used on each vertebra to balance the load on the pedicle screws.

**WARNING:** Derotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. Be aware that the Derotation Handles provide additional leverage and thus magnify the applied force as it is transferred to the pedicle screws. Care should be taken to avoid bone damage and/or screw failure.

Handles may be oriented with the flat flags facing inward and overlapping. In this scenario, Multi Segment Rotation Pin(s) of the appropriate length can be used to connect Handles on the same and/or different vertebrae.

Alternatively, the Handles may be oriented with the flat flags facing outward. In this scenario, Multi Segment Rotation Pin(s) of the appropriate length can be used to link Handles on either side of the body. If desired, the Multi Segment Comb can be used to connect the constructs on either side of the body.

Perform sensory and motor evoked potential monitoring for the early detection of a spinal cord deficit during surgical manipulation of the spine.



## Deformity Correction - Derotation with the Segmental Derotator

The following text and illustrations refer to the Rod Reducer (01-1003-5000) and Segmental Derotators (01-1300-0100). An alternative option using different instruments is provided below.

The Segmental Derotator is intended to be used with a Rod Reducer attached to each pedicle screw on the vertebra to be rotated.

Loosen the Locking Screw at the hinge of the Segmental Derotator with either the Rod Reduction Driver. Note the internal hex socket of these drivers interfaces with the Locking Screws on the Segmental Derotator while the external hex driver interfaces with the Rod Reducer.

Attach the Segmental Derotator to the Rod Reducer by pushing downward. The latches will automatically engage and must be depressed to disengage.

Tighten the Locking Screw with the Rod Reduction Driver; the Segmental Derotator will now be locked. In the locked state, the two Rod Reducers, and thus the vertebra, can be rotated as a single unit by applying manual leverage to the handle.

**WARNING:** Derotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. Be aware that the Derotation Handles provide additional leverage and thus magnify the applied force as it is transferred to the pedicle screws. Care should be taken to avoid bone damage and/or screw failure.

If segmental derotation is performed on multiple levels, multiple Segmental Derotators can be attached to sequential vertebrae. Multi Segment Rotational Pin(s) of appropriate length can be inserted through either the Locking or Non-Locking Holes to help stabilize the construct. If the Locking Holes are used, the Driver Segmental Derotator can be used to engage the Locking Screws.

**NOTE:** The Locking Screws are intentionally captured to avoid full removal. Do not over-torque in the counter-clockwise direction.



## Deformity Correction - Derotation with the Segmental Derotator (cont.)

**Alternative Option:** The same technique can be completed by attaching the Universal Segmental Derotator (01-1300-0200 to either the 4.5/5.0 Mini Rod Reducer (01-1600-5000) or the 5.5/6.0 Mini Rod Reducer (01-1300-6000). While the connection mechanism between the devices is different, the technique and resulting constructs are similar.

As an alternative, the Universal Segmental Derotators can be attached to the 4.5/5.0 Quick Grab Pliers and/or the 5.5/6.0 Quick Grab Pliers to create a similar construct.

## Deformity Correction with Locking Tube Constructs

**Alternative Option:** The same techniques presented above can be completed by utilizing the Locking Tube and Cross Bar Assembly instruments.



Figure 1



Figure 2

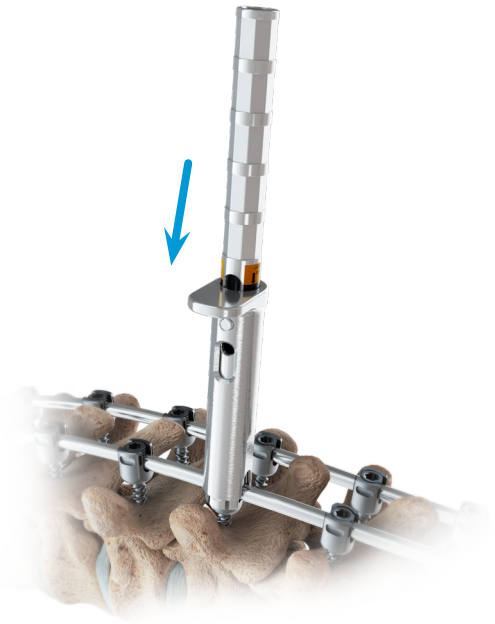


Figure 3

## Attaching Locking Tubes to Construct

Slide the outer sleeve of the Locking Tube fully into the up position (Figure 1). While maintaining the raised position of the outer tube, push the distal tip of the Locking Tube on the desired pedicle screw (Figure 2). When the Locking Tube snaps onto the pedicle screw, push down on the outer sleeve until the instrument is securely attached to the pedicle screw (Figure 3).

**NOTE:** The Locking Tube has a “Locked Zone” indication band. Visibility of this black band verifies that the instrument is properly seated on the pedicle screw.

**CAUTION:** The Locking Tube instrument is not intended for use with reduction pedicle screws.



Figure 4

## Creating Derotation Construct

Once both Locking Tubes are placed on the desired pedicle screws, attach the Cross Bar Assembly to them by pushing the opened claws onto their corresponding octagon slots of the locking tube (Figure 4). To lock the construct; turn the wing nut on the backside of the Cross Bar Assembly 1 full revolution (Figure 5). This same process can be repeated in the cephalad and caudad direction to create an En-Bloc style construct.

**WARNING:** Derotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. Be aware that the Derotation instruments provide additional leverage and thus magnify the applied force as it is transferred to the pedicle screws. Care should be taken to avoid bone damage and/or screw failure. Perform sensory and motor evoked potential monitoring for the early detection of a spinal cord deficit during surgical manipulation of the spine.

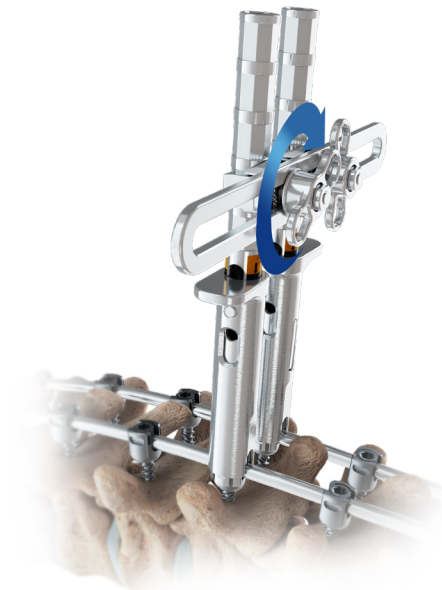


Figure 5

## Post Derotation

After the spine is sufficiently derotated, the set screws may be locked down to hold the construct in place following the steps in ST-1300-01-01 or ST-1600-01-01.

Set screws may be provisionally locked down through the derotation instruments and either the (Mini) Rod Reducer or the Rod Reduction Tower. For final tightening, see Final Tightening section in ST-1300-01-01 or ST-1600-01-01.





- CAUTION:** Federal law restricts this device to sale by or the order of a Physician.
- CAUTION:** Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.
- CAUTION:** Implants components are single-use. Do not reuse.
- CAUTION:** Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise noted.
- NOTE:** This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document is of general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

The information contained in this document was gathered and compiled by medical experts and qualified OrthoPediatics employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of the understanding of the information used and presented. OrthoPediatics does not practice medicine and does not recommend any particular orthopedic implant or surgical technique for use on a specific patient. The surgeon is responsible for determining the appropriate device(s) and technique(s) for each individual patient.

OrthoPediatics does not assume any liability, however, for the timeliness, accuracy, completeness or quality of the information and excludes any liability for tangible or intangible losses that may be caused by the use of this information.

Instructions For Use (IFU), cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

OrthoPediatics, ArmorLink, BandLoc Duo, Drive Rail, PediFlex, PediFoot, PediFrag, PediGraft, PediLoc, PediNail, PediPlates, PLEO, QuickPack, RESPONSE, Scwire, ShieldLoc, TorqLoc, PediPedal and the OP and Pedi logos are trademarks of OrthoPediatics Corp. ApiFix and Orthex are trademarks of wholly-owned subsidiaries of OrthoPediatics Corp.

OrthoPediatics is a registered trademark in Brazil, S.Korea, and the U.S.A. PediLoc and PediPlates are registered trademarks in Chile and the U.S.A. The OP logo is a registered trademark in Colombia, European Union, Japan, and the U.S.A. The Pedi logo is a registered trademark in Argentina, Australia, Brazil, Chile, Colombia, European Union, Israel, Mexico, New Zealand, S.Korea, Taiwan, Turkey, and the U.S.A. ApiFix is a registered trademark in the U.S.A. ArmorLink is a registered trademark in the U.S.A. Scwire is a registered trademark in the U.S.A. ShieldLoc is a registered trademark in the U.S.A. TorqLoc is a registered trademark in the U.S.A. BandLoc Duo is a registered trademark in the U.S.A. Orthex is a registered trademark in the U.S.A. QuickPack is a registered trademark in the U.S.A. .



2850 Frontier Drive | Warsaw, IN 46582  
ph: 574.268.6379 or 877.268.6339 | fax: 574.268.6302  
www.OrthoPediatics.com