



REVERE® Deformity Stabilization System





Life moves us 🍃

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.



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REVERE® Deformity Stabilization System



The **REVERE**® Deformity System is a comprehensive stabilization system providing ease of use and a wide range of options to meet the needs of complex cases. With multiple screw, rod material, and rod reduction options, a proven locking mechanism and world-class instrumentation, surgeons have a complete system to treat thoracolumbar deformities. This system provides solutions to address various clinical issues in the operating room, and is designed to help the surgeon meet the needs of the patient and accomplish the surgical goal of providing long term spinal balance and stability.



REVERE® Deformity STABILIZATION SYSTEM

This premier deformity system was developed in conjunction with surgeons specializing in treating spinal deformities and is intended to complement the REVERE® Stabilization System. The REVERE® portfolio of products includes monoaxial and polyaxial screws, in addition to various types of hooks and cross connectors. Supplemental implants include Reduction, Dual Outer Diameter (DOD), and Uniplanar Screws, along with lateral and in-line connectors, revision and sacral fixation components.

While maintaining the reliability and ease of use that is expected from Globus Medical products, this system offers many advantages over competitive deformity systems. The system is designed with multiple options to address complex, multi-level deformity cases and accommodate various patient anatomies. The REVERE® Deformity system is a 5.5mm rod-based system based on a proven non-threaded locking cap design that captures the rod with a 90° rotation. All implants are available in titanium or stainless steel.

System highlights include:

REVERE[®] Non-Threaded Locking Cap

Rod is securely captured, while still allowing optimal clearance for correction maneuvers



Uniplanar Screws

The versatility of a polyaxial screw with the correction capabilities of a monoaxial screw



Advanced Deformity Correction Instruments

Ideal for multiple correction maneuvers



Low Profile Cross Connectors

An easy to implant, low profile cross connector that virtually eliminates prominence in the thoracic spine



CONTENTS

| Implant Overview | 4 |
|--|----|
| Instrument Overview | 7 |
| Surgical Technique | |
| 1. Approach | 10 |
| 2. Monoaxial Screw Insertion | 10 |
| Loading the Monoaxial Screwdriver | 11 |
| 3. Hook Placement | 12 |
| Using Hook Holders | 13 |
| 4. Rod Insertion | 15 |
| 5. Rod Capture | 16 |
| Using the Locking Cap Guide | 18 |
| 6. Rod Reduction | 19 |
| Option A: Rod Lever | 19 |
| Option B: Ratcheting Rod Reducer | 20 |
| Option C: Reduction Tower Rod Reducer | 21 |
| 7. Deformity Correction | 23 |
| 8. Compression or Distraction | 32 |
| 9. Stabilizing the Construct | 33 |
| 10. Final Tightening | 33 |
| Optional Technique: Uniplanar Screws | 34 |
| REVERE [®] Deformity Implant Set | 36 |
| REVERE® Deformity Instrument Set | 38 |
| Additionally Available Deformity Implants | 40 |
| Stainless Steel REVERE [®] Deformity Implant Set | 44 |
| Additionally Available Stainless Steel REVERE® Deformity Implants | 46 |
| Additionally Available Stainless Steel REVERE [®] Implants | 49 |
| REVERE [®] Small Diameter Screws Supplemental Set | 50 |
| Stainless Steel REVERE [®] Small Diameter Screws Supplemental Set | 52 |
| REVERE [®] Uniplanar Supplemental Screw | 54 |
| Stainless Steel REVERE [®] Uniplanar Supplemental Screw Set | 55 |
| REVERE® Deformity Hook Dimensions | 56 |
| Pre-Operative Planning Guide | 58 |
| Important Information | 60 |

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

REVERE® Non-Threaded Locking Cap

- Non-threaded design eliminates cross-threading
- 90° rotation of locking cap captures the rod
- Preassembled set screw allows for easy insertion and tightening
- Optimal design decreases need for rod reduction

REVERE® Monoaxial Screws

- Low profile, top-loading screw design
- Instrument-screw connection avoids interference with bony anatomy
- Blunt tip for bicortical purchase
- Constant outer diameter
- Double lead thread for rapid insertion (up to 7.5mm diameter)
- Multiple sizes to accommodate patient anatomy
- Screw diameters 4.0, 4.5, 5.0, 5.5, 6.5, 7.5, and 8.5mm
- Lengths: 25–90mm in 5mm increments

REVERE® Uniplanar Screws

- Useful for deformity correction
- Combines the versatility of a polyaxial screw with the correction capability of a monoaxial screw
- Medial/lateral rigidity with cranial/caudal adjustability
- Low profile
- Screw diameters: 4.5, 5.0, 5.5, and 6.5mm
- Lengths: 25–55mm in 5mm increments
- Double lead thread for rapid insertion
- ±20° angulation in cranial-caudal direction







IMPLANT OVERVIEW

REVERE® Hooks

- Low profile, top-loading hook design
- 37 different hook configurations for the lamina, pedicle or transverse process
- Unique lamina hooks for thoracic or lumbar applications
- Hooks available in small, medium and large profiles
- Narrow, standard, and wide blade widths available



Pedicle Hook



Lamina Hook



Thoracic Lamina Hook



Angled Lamina

Hook

Narrow



Hook



Transverse Process Hook

Sizes

5

Small



Medium

5

Large

R I





Standard

Blade Widths

Wide

Multiple Profiles

IMPLANT OVERVIEW

REVERE[®] Rods

- 5.5mm diameter
- Available in lengths of 200, 300, 400, 500, and 600mm
- Manufactured in titanium alloy (TAV), commercially pure titanium (CP), stainless steel (SS), and cobalt chrome (CoCr)
- Also available with hex-end (4.5mm hex on both ends)



- Low profile
- Profile above the rod is 6.15mm
- Overall height is 12.5mm
- Six sizes:
 - 24–25mm
 - 26–28mm
 - 29–34mm
 - 35–47mm
 - 48–72mm
 - 73–97mm



INSTRUMENT OVERVIEW

Screw Insertion Instruments



Monoaxial Screwdriver, Spring-Loaded 624.320



Quick-Release 1/4" Ratchet Straight Handle 630.407



Monoaxial Screwdriver, Spring-Loaded 624.320 Quick-Release 1/4" Ratchet Straight Handle 630.407 (Assembled)

Pedicle Preparation Instruments



Pedicle Finder 624.302

Hook Instruments



Hook Positioner 624.306

Rod Manipulation Instruments

Rod Template, 300mm 602.517



Hex Rod Wrench 624.316

Correction Instruments



Coronal Plane Bender, Right 624.310 Coronal Plane Bender, Left 624.309



Monoaxial Screwdriver, Quick-Disconnect 624.315

REVERE® Deformity SURGICAL TECHNIQUE

Step 1 Approach

A preoperative plan should be developed to determine the optimal approach and implant construct. The appropriate implants must be selected based on patient anatomy, deformity type and method of correction.

Before the procedure, the patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate levels. Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct implant placement.

Please refer to the information printed at the back of this guide for complete description, indications, contraindications and warnings. Refer to the REVERE[®] Stabilization System Surgical Technique Guide (GMTGD17) for polyaxial screw insertion and transconnector insertion.

Step 2 Monoaxial Screw Insertion

Locate pedicles and remove bone and/or soft tissue, as needed, using standard instruments.

Using REVERE® Stabilization System instruments, prepare the pedicle for the screw insertion by perforating the pedicle cortex and opening the pedicle pathway. REVERE® Monoaxial Screws are self-tapping, however pedicles may be tapped if desired using taps from the REVERE® Instrument I set.

After confirming the screw size by checking the length and diameter markings on the screw head, load the REVERE[®] Monoaxial Screw onto the **Monoaxial Screwdriver, Spring-Loaded.**

Drive the screw into the prepared pedicle. Remove the screwdriver from the screw head.



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Loading the Monoaxial Screwdriver

Select the appropriate monoaxial screw diameter and length. Follow the steps below to load the screwdriver.



Step 3 Hook Placement

Pedicle Hook Placement

A pedicle hook is typically used at the T10 level and above. The hook blade is placed up-going and sits flush against the facet and pedicle. The **Pedicle Finder** is used to prepare the pedicle for hook placement. Use the instrument to open the facet capsule and locate the pedicle. If necessary, a portion of the inferior facet process may be removed to aid in pedicle hook insertion.

Using the Pedicle Finder

Once the pedicle is clearly identified, the appropriate hook is inserted using the **Hook Holder**. Insert the hook into the holder and place in the desired position.

The **Hook Positioner** may be used to aid in hook placement. Alternatively, the **Lateral Hook Holder** or the **Offset Hook Holder** can be used for insertion.

Pedicle hook insertion

Lamina Hook Placement

A lamina hook can be used as an up-going or down-going hook. In the thoracic spine, these hooks may be used independently as a down-going hook or in conjunction with an up-going lamina or pedicle hook to form a claw construct. In the lumbar spine, these hooks may be used independently as an up-going hook or in conjunction with a transverse process or down-going lamina hook to form a claw construct.

The **Lamina Finder** is utilized to separate the ligamentum flavum from the lamina.

Using Hook Holders

The REVERE® Deformity System has several instruments to aid in hook placement.





Hook Holder

Offset Hook Holder

The Hook Holder and the Offset Hook Holder engage into the reduction slots on the side of the implant. The Hook Positioner may be used with the standard Hook Holder to facilitate hook insertion.

The Offset Hook Holder allows for introduction of a cap without disengaging the instrument.

Alternatively, the Lateral Hook Holder may be used for insertion. This holder engages into the slots on the cranial and caudal sides of the hook and allows for introduction of the rod and cap without disengaging the instrument.



Lateral Hook Holder

Using the Lamina Finder



Lamina hook insertion

Hook Placement (cont'd)

Transverse Process Hook Placement

A transverse process hook is usually placed down-going. Typically it is used at the top of a construct. Transverse process hooks can be used with an up-going pedicle hook to form a claw construct, typically placed one level superior to the pedicle hook. The Lamina Finder can be used to separate the ligamentous attachment between the transverse process and posterior arch of the rib medial to the rib-transverse joint.

Insert the appropriate transverse process hook into the Hook Holder and place the hook in the desired location. Use the positioner to seat the hook.

Repeat hook insertion for each site as determined by preoperative planning.

Note: Hook position should be continuously checked during the procedure, ensuring that the hooks remain in the correct position throughout the procedure.



Transverse process hook insertion



Hook placement

Step 4 Rod Insertion

Rod Preparation

Once the hooks and screws are placed in the correct locations, the **Rod Template, 300mm** may be used to determine the length and contour of the rod. Alternatively, the rod may be contoured to the desired sagittal alignment without the use of the rod template.



Using the Rod Template

Rod Contouring

Select the appropriate rod length. If the rod needs to be cut, the additionally available Rod Cutter can be used to modify the rod length.

The rod is contoured to match the rod template using the Power Bender. To achieve the correct contour, the rod should be bent in small incremental steps so as not to damage the rod. The rods have orientation lines to assist in maintaining same plane orientation during contouring.



Rod Insertion (cont'd)

Rod Insertion

The contoured rod is inserted into the implants beginning from either end of the construct, depending on where the rod can most easily be introduced. The **Rod Grippers** are used to hold the rod during insertion.





Locking caps are introduced into the implants using the Locking Cap Driver. Caps are introduced first into implants where the rod seats well in the implant and little to no reduction is required. Subsequent caps are typically introduced in the order of difficulty, with the caps requiring small reduction first to the more difficult reductions last. The Rod Pusher may be used to push the rod down to make locking cap placement easier. The locking cap may be inserted using the free-hand technique or through the Locking Cap Guide.

Locking cap insertion

Loading Cap Driver

Align the slots on the Locking Cap Driver with the etched lines on the locking cap module. Push the driver down over the locking cap until fully seated.

Note: Ensure that the locking cap is properly seated in the driver before insertion.



Driver loaded

Locking Cap Insertion

With a loaded Locking Cap Driver, insert the locking cap into the screw head and rotate the driver clockwise 90° to capture the rod.

Note: Locking cap insertion requires minimal effort. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction or rod contouring is required.

Remove the Locking Cap Driver and the Locking Cap Guide. The rod is now captured by the screw and the cap. The construct is not completely locked until final tightening (Step 10).



Loaded cap driver inserted into screw head





Locking Cap INSERTED

Locking Cap LOCKED

Rod Capture (cont'd)

Locking Cap Delivery

The Locking Cap Guide acts as a guide for the Locking Cap Driver and is used to aid in small adjustments of the rod into the implant head. Place the guide over the rod and implant head and apply downward pressure. The Locking Cap Guide may be changed into a Parallel Locking Cap Guide, as shown below.

Once the rod is well seated within the implant, insert the loaded driver into the guide and insert the locking cap, as shown right. Repeat for all implants.

Using the Locking Cap Guide

To change the Locking Cap Guide into a Parallel Locking Cap Guide, loosen the set screw using the Torque Limiting 2.5mm Hex Driver and rotate the handle on the Locking Cap Guide 90°. Secure the handle by tightening the set screw.



If greater visualization of the locking cap insertion into the implant head is desired, the Rod Pusher may be used. This instrument aids in small adjustments of the rod into the implant head. Place the Rod Pusher over the rod and apply downward pressure. Once the rod is well seated within the implant head, load the driver and insert the locking cap, as shown on page 17.

The construct is not completely locked until final tightening (Step 10).



Locking cap insertion through the Locking Cap Guide



Using the Rod Pusher

Step 6 Rod Reduction

The REVERE® system has five options for rod reduction. The rod reduction instruments are designed to seat the rod into the implant head, not to bend the rod. Ensure that the rod is properly contoured prior to reduction. The Rod Pusher and the Locking Cap Guide may be used for smaller, incremental reduction. If greater reduction is needed, the following three instruments may be used to aid in reduction.

Option A: Rod Lever

The Rod Lever may be used to maneuver the rod into position. This instrument is useful when the rod is slightly above the implant. Slide the Rod Lever into the reduction slots on the implant head. Lever the rod down to reduce it into the screw head.

Once the rod is well seated within the implant head, use the loaded Locking Cap Driver to insert the locking cap, as shown on page 17.

The construct is not completely locked until final tightening (Step 10).





Rod Reduction using the Rod Lever

Locking cap insertion while using the Rod Lever

Rod Reduction (cont'd)

Option B: Ratcheting Rod Reducer

The Ratcheting Rod Reducer may be used to reduce the rod into position. Place the Ratcheting Rod Reducer over the implant head and compress the handle slightly to capture the implant. Continue compressing the handle to reduce the rod into the implant head. This instrument provides up to 10mm of reduction.



Rod reduction using Ratcheting Rod Reducer

Locking cap insertion through Ratcheting Rod Reducer

Once the rod is well seated into the implant head, insert the loaded driver into the rod reducer and insert the locking cap, as described on page 17.

The construct is not fully locked until final tightening (Step 10).

Option C: Reduction Tower Rod Reducer

The Reduction Tower Rod Reducer may be used to reduce the rod into position. With the retaining sleeve positioned proximally on the instrument, push the reduction tabs onto the implant. Twist the handle slightly, as described below, to capture the implant. Continue rotating to reduce the rod. This instrument provides up to 20mm of reduction.

Ensure that the instrument is in the "open" position such that the threaded top cannot be turned any further in the counterclockwise direction. Place the instrument over the top of the screw head and push downward onto the screw head. Begin rotating the threaded portion (a) of the instrument in the clockwise direction. The instrument is now engaged with the screw head. Reduce the rod by slowly rotating the threaded portion of the Reduction Tower in a clockwise direction. The rod is fully reduced when the black lines on the instrument align (b).

Note: Use the T-Handle (624.801) if more control and/or power is desired.



Reduction Tower



Locking cap insertion using the Reduction Tower Rod Reducer

Rod Reduction (cont'd)

Option C: Reduction Tower Rod Reducer (cont'd)

Once the rod is fully reduced, a loaded Locking Cap Driver is placed into the top of the Reduction Tower and used to position the locking cap in place.

After the locking cap is in place, remove the Locking Cap Driver from the Reduction Tower. Next, remove the tower by rotating the threaded portion in a counterclockwise direction until it is disengaged from the screw head.

Set screws are provisionally tightened utilizing the 3.5mm Torque Limiting Hex Driver, as shown below right. The construct is not completely locked until final tightening (Step 10).





Positioning the locking cap with the Locking Cap Driver

Set screws provisionally tightened using the Hex Driver

Step 7 Deformity Correction

Deformity correction can be accomplished using multiple techniques, including translation, rod rotation, *in situ* rod bending and direct vertebral body derotation, depending on the type and rigidity of the curve.

Segmental Translation

Translation maneuvers are frequently used while introducing the rod to the implants. This facilitates easier rod introduction and locking cap placement. Translational correction may be achieved by applying a lateral external force to the patient's torso at the apex of the scoliotic curve to straighten the spine or through the use of the additionally available Deformity Vertebral Derotation Instrument Set.



Deformity Correction (cont'd)

Segmental Translation (cont'd)

The rod is seated in the proximal and distal ends of the construct, and locking caps are inserted to hold the ends in place. The Vertebral Derotation Instruments are placed onto several levels at the apex of the curve and the spine is carefully pushed (translated) to the rod. As each level is translated to the rod, a locking cap is introduced to hold the rod in place. This is repeated for each level until the spine aligns with the rod and the rod is captured with locking caps.

As the correction is held, the rod is introduced into the implants and locking caps are placed. A fully captured rod partially holds the correction once the external translational force is removed.



Global Derotation

Global derotation maneuvers are used to translate a coronal plane deformity into the naturally curved sagittal plane by rotating the rod up to 90° in the construct.

After the rod is positioned in the implants and the locking caps are inserted, the rod may be rotated into its final position. To rotate the rod, two Rod Grippers are used. Position the Rod Grippers at the desired locations and rotate the rod. Rotation should be performed slowly to avoid neurological injury and maintain proper rod placement.

Alternatively, if using the hex end rods, the additionally available **Hex Rod Wrench** may be used to aid rod rotation.



Deformity Correction (cont'd)

Global Derotation (cont'd)

It is important to monitor the position of the hooks during the rotation process to verify that they have not been displaced. Once the rod is rotated into its final position, the set screws are provisionally tightened to maintain rod positioning.

After the first rod is secured in its final position, compression and/or distraction can be performed as outlined in Step 8. A second rod is then inserted to stabilize the construct, as described on page 33. Further compression and/or distraction can be performed if necessary. Verify the hook positions and make necessary adjustments, then final tighten the set screws to completely lock the rod (Step 8).



Direct Vertebral Body Derotation

The Deformity Vertebral Derotation Instruments Set may be used for correction of axial rotation in scoliosis surgery. This type of correction is used to axially align the vertebral bodies relative to each other, but does not necessarily affect the magnitude of the curve correction itself. This correction is achieved using one or several instruments and can be performed with one or both rods in place, depending on the type of correction.

Segmental Axial Derotation

This type of correction is typically performed with one rod in place to maximize correction. Derotation instruments are placed onto the screws on either side of the same vertebral body. The derotation instruments are then linked together to evenly distribute the force of the correction over the two screws and rotate the body around the true center of the spine. Several sets of instruments are used over multiple levels. Axial derotation of vertebral bodies relative to each other is achieved by holding one set of derotation instruments stationary, while the other set of derotation instruments is used to rotate the attached vertebral body relative to the stationary body.



Segmental axial rotation

Deformity Correction (cont'd)

Segmental Axial Derotation (cont'd)

Correction is held by tightening the set screws on the locking caps through the derotation instruments.

The second rod is inserted and captured with the locking caps, as described in Step 9. If no further correction is required, the construct is final tightened as described in Step 10.



En Bloc Derotation (Coupled Axial Derotation)

This type of correction is typically performed with one rod in place to maximize correction. Derotation instruments are placed onto the screws on either side of the same vertebral bodies and over multiple levels. The derotation instruments are then "boxed" together to evenly distribute the force of the correction over all coupled screws and rotate the segment of spine as one unit. Derotation is achieved by holding a section of the spine stationary while the coupled segment is rotated relative to the stationary section. Correction is held by tightening the set screws on the locking caps through the derotation instruments. This technique is commonly used to correct thoracic "rib hump".



Deformity Correction (cont'd)

En Bloc Derotation (Coupled Axial Derotation)

To achieve "rib hump" correction, apply downward pressure on the convex side of the rib cage and rotate the coupled axial derotation construct toward the convex side. Correction is held by tightening the set screws on the locking caps through the instruments. Careful attention should be made to ensure that the corrective forces applied in this maneuver are evenly distributed.

The second rod is inserted and captured with the locking caps. If no further correction is required, the construct is final tightened as described in Step 10.



In Situ Bending

In situ rod bending can be accomplished using *In Situ* **Benders** or **Coronal Plane Benders**. Rod bending is performed after the rod is fully seated into the implants and the locking caps are inserted.

In Situ Benders

In Situ Benders are used to make corrections to the rod curvature in the sagittal plane. Rod bending is accomplished with two benders (left and right) positioned close to one another. The rod is bent in small increments so as not to damage the rod.

Once the rod bending is complete, compression or distraction can be performed as described in Step 8.

Note: In Situ Benders are powerful instruments and care should be taken not to disrupt fixation of the implants.



Coronal Plane Benders

Coronal Plane Benders are used to make corrections to the rod curvature in the coronal plane. The rod bending is accomplished with two benders (left and right) positioned close to each other. Position the bender so the grooves on the inside of the left bender engage the grooves on the right bender. The rod is bent in small increments so as not to damage the rod.

Once rod bending is complete, compression or distraction can be performed as described in Step 8.



Step8Compression or Distraction

After the rod is secured in the implants, compression and/or distraction may be performed if necessary. REVERE[®] screws may be compressed or distracted along the rod using the Compressor or Distractor, respectively. Tighten one of the set screws, to establish a rigid point for compression or distraction. Once compression or distraction is completed, tighten the set screws using the 3.5mm Hex Driver.



Compression



Step9Stabilizing the Construct

Upon completion of the deformity correction and placement of the first rod, select a stabilizing rod and ensure rod length is appropriate. After determining rod length, contour the rod to match the curvature of the spine. Insert the rod into the implants and provisionally tighten the set screws. After the rod has been secured to the implants, compression and/or distraction may be performed as outlined above.

The construct can now be final tightened.

Step10Final Tightening

Final tightening of the set screws is necessary to secure the construct and is accomplished using the Torque Limiting 3.5mm Hex Driver and the Final Tightening Counter Torque.

While holding the Final Tightening counter torque in one hand, insert the Torque Limiting 3.5mm Hex Driver through the top of the Counter Torque. Engage the tip of the hex driver into the set screw and ensure that it is completely engaged, then slide the counter torque over the screw head and begin to rotate the hex driver until it reaches the torque limit (5.5Nm). Rotate until two audible clicks are heard. Repeat for all locking caps.





Optional Technique: Uniplanar Screws

Screwdriver Assembly

Select the appropriate uniplanar screw diameter and length. Assemble the 3.5mm Hex Screwdriver Rigid Shaft to the Quick-Release Ratchet Handle. Rotate the knurled knob until the line (groove) on the shaft is showing. Insert the screwdriver into the female hex in the screw body. Once engaged, rotate the knurled knob counterclockwise until tight and the threads are no longer visible.

To disengage, rotate the ratcheting mechanism on the handle to neutral or reverse. Rotate the knurled knob clockwise (UNLOCK) until the etched line on the shaft is visible. Pull up on the screwdriver to disengage it from the screw.



Knurled knob of screwdriver



Load the screw onto a screwdriver, as shown above. Verify the size by checking the length and diameter markings on the screw head in addition to using the gauge provided in the implant tray.

Alternatively, the Self-Retaining 3.5mm Hex Screwdriver Shaft attached to the Quick-Release Non-Ratchet Handle may be used for screw insertion. Insert the hex tip into the female hex in the screw body.



to the Quick-Release Non-Ratchet Handle

Drive the screws into the prepared pedicles. Remove the screwdriver from the screw head. If using the 3.5mm Hex Screwdriver Rigid Shaft and Holding Sleeve, rotate the knurled knob clockwise in the UNLOCK direction to disengage the screwdriver and remove. If the screws need to be removed or repositioned, the 3.5mm Self-Retaining Screwdriver may be used.



Note angulation of screw relative to the vertebral body



Allows the surgeon to utilize either the Straight Forward (SF) or Anatomical (AN) approach

With Uniplanar Screws:

- Screw heads pivot cranial-caudal to align with the rod
- Rod may be fully seated with no additional contouring needed



REVERE® DEFORMITY IMPLANT SET







5.5mm Diameter Monoaxial Screws

| Length | Part No. | Qty |
|--------|----------|-----|
| 25mm | 124.251 | 4 |
| 30mm | 124.252 | 8 |
| 35mm | 124.253 | 8 |
| 40mm | 124.254 | 8 |
| 45mm | 124.255 | 8 |
| 50mm | 124.256 | 4 |
| 55mm | 124.257 | 4 |

6.5mm Diameter Monoaxial Screws

| 25mm | 124.261 | 4 |
|------|---------|---|
| 30mm | 124.262 | 8 |
| 35mm | 124.263 | 8 |
| 40mm | 124.264 | 8 |
| 45mm | 124.265 | 8 |
| 50mm | 124.266 | 6 |
| 55mm | 124.267 | 2 |

5.5mm Straight Rods (TAV)

| 200mm | 124.517 | 2 |
|-------|---------|---|
| 300mm | 124.519 | 2 |
| 400mm | 124.520 | 2 |
| 500mm | 124.521 | 2 |

Hooks

| Part No. | Description | Qty |
|----------|--|-----|
| 124.891 | REVERE [®] Low Profile Pedicle Hook, Small | 2 |
| 124.892 | REVERE [®] Low Profile Pedicle Hook, Medium | n 2 |
| 124.893 | REVERE [®] Low Profile Pedicle Hook, Large | 2 |
| 124.924 | REVERE® Transverse Process Hook, Right | 2 |
| 124.925 | REVERE [®] Transverse Process Hook, Left | 2 |
| 124.944 | REVERE [®] Lamina Hook, Small | 2 |
| 124.945 | REVERE [®] Lamina Hook, Medium | 4 |
| 124.946 | REVERE [®] Lamina Hook, Large | 4 |

Other Implants

| 124.000 | REVERE [®] Locking Cap | 24 |
|---------|--|----|
| 124.012 | REVERE [®] Low Profile Adjustable T-Connector, 24–25mm | 2 |
| 124.013 | REVERE [®] Low Profile Adjustable T-Connector, 26–28mm | 2 |
| 124.014 | REVERE [®] Low Profile Adjustable T-Connector, 29–34mm | 2 |

924.005 REVERE® Deformity Implant Graphic Case

REVERE® DEFORMITY INSTRUMENT SET



REVERE® Deformity Instrument Set 924.904

| | Part No. | Description | Qty |
|----|----------|---|-----|
| 1 | 602.517 | Rod Template, 300mm | 1 |
| 2 | 602.522 | Rod Gripper, 6.0mm | 1 |
| 3 | 624.301 | Lamina Finder | 1 |
| 4 | 624.302 | Pedicle Finder | 1 |
| 5 | 624.303 | In Situ Bender, Left | 1 |
| 6 | 624.304 | <i>In Situ</i> Bender, Right | 1 |
| 7 | 624.305 | Hook Holder | 2 |
| 8 | 624.306 | Hook Positioner | 1 |
| 9 | 624.307 | Lateral Hook Holder | 1 |
| 10 | 624.308 | Offset Hook Holder | 1 |
| 11 | 624.309 | Coronal Plane Bender, Left | 1 |
| 12 | 624.310 | Coronal Plane Bender, Right | 1 |
| 13 | 624.312 | Rotation Instrument | 4 |
| 14 | 624.320 | Monoaxial Screwdriver, Spring-Loaded | 2 |
| 15 | 624.315 | Monoaxial Screwdriver, Quick-Connect | 1 |
| 16 | 630.407 | Quick-Release 1/4" Ratchet, Straight Handle | e 1 |
| | 924.004 | REVERE® Deformity Instrument Graphic Case | e |

Additionally Available REVERE® Deformity Implants

5.5mm Diameter Monoaxial Screws

| Length | Part No. |
|--------|----------|
| 27mm | 124.111 |
| 32mm | 124.112 |
| 37mm | 124.113 |
| 42mm | 124.114 |
| 47mm | 124.115 |
| 60mm | 124.258 |
| 65mm | 124.259 |

7.5mm Diameter Monoaxial Screws (cont'd)

| Length | Part No. |
|--------|----------|
| 65mm | 124.279 |
| 70mm | 124.871 |
| 75mm | 124.872 |
| 80mm | 124.873 |
| 85mm | 124.874 |
| 90mm | 124.875 |

8.5mm Diameter Monoaxial Screws

6.5mm Diameter Monoaxial Screws

| 27mm | 124.121 |
|------|---------|
| 32mm | 124.122 |
| 37mm | 124.123 |
| 42mm | 124.124 |
| 47mm | 124.125 |
| 60mm | 124.268 |
| 65mm | 124.269 |

7.5mm Diameter Monoaxial Screws

| 25mm | 124.271 |
|------|---------|
| 27mm | 124.131 |
| 30mm | 124.272 |
| 32mm | 124.132 |
| 35mm | 124.273 |
| 37mm | 124.133 |
| 40mm | 124.274 |
| 42mm | 124.134 |
| 45mm | 124.275 |
| 47mm | 124.135 |
| 50mm | 124.276 |
| 55mm | 124.277 |
| 60mm | 124.278 |

| 25mm | 124.281 |
|------|---------|
| 30mm | 124.282 |
| 35mm | 124.283 |
| 40mm | 124.284 |
| 45mm | 124.285 |
| 50mm | 124.286 |
| 55mm | 124.287 |
| 60mm | 124.288 |
| 65mm | 124.289 |
| 70mm | 124.881 |
| 75mm | 124.882 |
| 80mm | 124.883 |
| 85mm | 124.884 |
| 90mm | 124.885 |

6.5mm Diameter Preferred Angle Monoaxial Screw

| 30mm | 124.801 |
|------|---------|
| 35mm | 124.802 |
| 40mm | 124.803 |
| 45mm | 124.804 |

Additionally Available REVERE® Deformity Implants (cont'd)

7.5mm Diameter Preferred Angle Monoaxial Screw

| Length | Part No. | |
|--------|----------|--|
| 30mm | 124.811 | |
| 35mm | 124.812 | |
| 40mm | 124.813 | |
| 45mm | 124.814 | |

Hooks

Part No. Description

| 124.901 | Thoracic Lamina Hook, Narrow, Small |
|---------|--------------------------------------|
| 124.902 | Thoracic Lamina Hook, Narrow, Medium |
| 124.904 | Thoracic Lamina Hook, Small |
| 124.905 | Thoracic Lamina Hook, Medium |
| 124.907 | Upgoing Thoracic Lamina Hook, Medium |
| 124.908 | Upgoing Thoracic Lamina Hook, Large |
| 124.921 | Offset Lamina Hook, Right |
| 124.922 | Offset Lamina Hook, Left |
| 124.927 | Pedicle Hook, Small |
| 124.928 | Pedicle Hook, Medium |
| 124.929 | Pedicle Hook, Large |
| 124.931 | Lamina Hook, Transverse, Small |
| 124.932 | Lamina Hook, Transverse, Medium |
| 124.933 | Lamina Hook, Transverse, Large |
| 124.935 | Pedicle Hook, Transverse, Small |
| 124.936 | Pedicle Hook, Transverse, Medium |
| 124.937 | Pedicle Hook, Transverse, Large |
| 124.940 | Lamina Hook, Narrow, Small |
| 124.941 | Lamina Hook, Narrow, Medium |
| 124.942 | Lamina Hook, Narrow, Large |
| 124.948 | Lamina Hook, Wide, Small |
| 124.949 | Lamina Hook, Wide, Medium |
| 124.950 | Lamina Hook, Wide, Large |

124.952 Lamina Hook, Tall Body, Small

Hooks (cont'd)

| Part No. | Description |
|----------|---------------------------------|
| 124.953 | Lamina Hook, Tall Body, Medium |
| 124.954 | Lamina Hook, Tall Body, Large |
| 124.955 | Angled Lamina Hook, Small |
| 124.956 | Angled Lamina Hook, Medium |
| 124.957 | Angled Lamina Hook, Large |
| 124.958 | Extra Offset Lamina Hook, Right |
| 124.959 | Extra Offset Lamina Hook, Left |

5.5mm Hex-End Straight Rods

| 524.001 | 5.5mm Straight Rod, Hex-End, CP Grade 4, 300mm |
|---------|--|
| 524.002 | 5.5mm Straight Rod, Hex-End, CP Grade 4, 400mm |
| 524.003 | 5.5mm Straight Rod, Hex-End, CP Grade 4, 500mm |
| 524.004 | 5.5mm Straight Rod, Hex-End, CP Grade 2, 300mm |
| 524.005 | 5.5mm Straight Rod, Hex-End, CP Grade 2, 400mm |
| 524.006 | 5.5mm Straight Rod, Hex-End, CP Grade 2, 500mm |
| 524.007 | 5.5mm Straight Rod, Hex-End w/Stop, 500mm |
| 524.008 | 5.5mm Straight Rod, Hex-End w/Stop, CP Grade 4, 500mm |
| 524.009 | 5.5mm Straight Rod, Hex-End w/Stop, CP Grade 2, 500mm |
| 524.010 | 5.5mm Straight Rod, Hex End, CP Grade 4, 600mm |
| 524.517 | 5.5mm Straight Rod, Hex-End, 200mm |
| 524.519 | 5.5mm Straight Rod, Hex-End, 300mm |
| 524.520 | 5.5mm Straight Rod, Hex-End, 400mm |
| 524.521 | 5.5mm Straight Rod, Hex-End, 500mm |
| | |

- 524.523 5.5mm Straight Rod, Hex-End, 600mm
 - REVERE® Deformity Stabilization System | 41

Additionally Available REVERE® Deformity Implants (cont'd)

Cobalt Chrome Specialty Rods

| Part No. | Description |
|----------|-------------------------------------|
| 724.400 | 5.5mm CoCr Pre-Contoured Rod, 450mm |
| 724.403 | 5.5mm CoCr Pre-Contoured Rod, 600mm |
| 724.406 | 5.5mm S-Rod, CoCr, 18mm, Right |
| 724.407 | 5.5mm S-Rod, CoCr, 18mm, Left |
| 724.408 | 5.5mm S-Rod, CoCr, 20mm, Right |
| 724.409 | 5.5mm S-Rod, CoCr, 20mm, Left |
| 724.410 | 5.5mm Unit Rod, CrCo, 250mm |
| 724.411 | 5.5mm Unit Rod, CoCr, 275mm |
| 724.412 | 5.5mm Unit Rod, CoCr, 300mm |
| 724.413 | 5.5mm Unit Rod, CoCr, 325mm |
| 724.414 | 5.5mm Unit Rod, CoCr, 350mm |
| 724.415 | 5.5mm Unit Rod, CoCr, 375mm |
| 724.416 | 5.5mm Unit Rod, CoCr, 400mm |
| 724.417 | 5.5mm Unit Rod, CoCr, 425mm |
| 724.418 | 5.5mm Unit Rod, CoCr, 450mm |
| 724.419 | 5.5mm Unit Rod, CoCr, 475mm |
| 724.420 | 5.5mm Unit Rod. CoCr. 500mm |

Specialty Rods

| 124.400 | 5.5mm | Pre-Contoured | Rod, | 450mm |
|---------|-------|---------------|------|-------|
| | | | | |

- 124.403 5.5mm Pre-Contoured Rod, 600mm
- 124.406 5.5mm S-Rod, 18mm, Right
- 124.407 5.5mm S-Rod, 18mm, Left
- 124.408 5.5mm S-Rod, 20mm, Right
- 124.409 5.5mm S-Rod, 20mm, Left
- 124.410 5.5mm Unit Rod, 250mm
- 124.411 5.5mm Unit Rod, 275mm
- 124.412 5.5mm Unit Rod, 300mm
- 124.413 5.5mm Unit Rod, 325mm
- 124.414 5.5mm Unit Rod, 350mm
- 124.415 5.5mm Unit Rod, 375mm

Specialty Rods (cont'd)

| Part No. | Description |
|----------|---------------------------|
| 124.416 | 5.5mm Unit Rod, 400mm |
| 124.417 | 5.5mm Unit Rod, 425mm |
| 124.418 | 5.5mm Unit Rod, 450mm |
| 124.419 | 5.5mm Unit Rod, 475mm |
| 124.420 | 5.5mm Unit Rod, 500mm |
| 124.523 | 5.5mm Straight Rod, 600mm |

Cobalt Chrome 5.5 Hex-End Straight Rods

| 724.717 | 5.5mm Straight Rod, Hex Ended, CoCr, 200mm |
|---------|--|
| 724.719 | 5.5mm Straight Rod, Hex Ended, CoCr, 300mm |
| 724.720 | 5.5mm Straight Rod, Hex Ended, CoCr, 400mm |
| 724.721 | 5.5mm Straight Rod, Hex Ended, CoCr, 500mm |
| 724.723 | 5.5mm Straight Rod, Hex Ended, CoCr, 600mm |

CP Rods

| 124.001 | 5.5mm Straight Rod, CP, 300mm |
|---------|-------------------------------|
| 124.002 | 5.5mm Straight Rod, CP, 400mm |
| 124.003 | 5.5mm Straight Rod, CP, 500mm |
| 124.007 | 5.5mm Straight Rod, CP, 600mm |

CP2 Rods

| 124.004 5.5m | m Straight Rod, | CP2, 300mm |
|--------------|-----------------|------------|
|--------------|-----------------|------------|

- 124.005 5.5mm Straight Rod, CP2, 400mm
- 124.006 5.5mm Straight Rod, CP2, 500mm

Low-Profile Adjustable T-Connectors

- 124.016 Low-Profile Adjustable T-Connector, 48–72mm
- 124.017 Low-Profile Adjustable T-Connector, 73–97mm



Additionally Available REVERE® Deformity Implants (cont'd)

Connectors

Instruments

| Part No. | Description | Part No. |
|----------|--|----------|
| 124.960 | Parallel Connector, 5.5mm to 5.5mm | 602.519 |
| 124.961 | Parallel Connector, 5.5mm to 5.5mm, Wide | 602.526 |
| 124.966 | Parallel Connector, Double, 5.5mm to 5.5mm | 624.111 |
| 124.967 | Parallel Connector, Double, 5.5mm to 5.5mm, Wide | 624.112 |
| 124.970 | 5.5mm Offset Connector, 15mm | 624.113 |
| 124.971 | 5.5mm Offset Connector, 20mm | 624.114 |
| 124.972 | 5.5mm Offset Connector, 25mm | 624.313 |
| 124.976 | 5.5mm Offset Connector, 30mm | 624.316 |
| 124.977 | 5.5mm Offset Connector, 35mm | 624.322 |
| 124.980 | In-Line Connector, 5.5mm to 5.5mm | 624.323 |
| 124.990 | 5.5mm Closed Offset Connector, 5.5mm Rod, 15mm | 624.324 |
| 124.991 | 5.5mm Closed Offset Connector, 5.5mm Rod, 20mm | 624.325 |
| 124.992 | 5.5mm Closed Offset Connector, 5.5mm Rod, 25mm | 624.326 |
| 124.993 | 5.5mm Closed Offset Connector, 5.5mm Rod, 30mm | 624.450 |
| 124.994 | 5.5mm Closed Offset Connector, 5.5mm Rod, 35mm | 624.517 |
| 124.995 | 5.5mm Closed Offset Connector, 5.5mm Rod, 100mm | 624.607 |
| 124.996 | 5.5mm Closed Offset Connector, 5.5mm Rod, 120mm | 624.613 |
| 124.997 | 5.5mm Closed Offset Connector, 5.5mm Rod, 150mm | |
| | | |

| .526 | Vise-Style Rod Grip |
|------|-----------------------------------|
| .111 | Pedicle Probe, Small, Straight |
| .112 | Pedicle Probe, Small, Curved |
| .113 | Pedicle Probe, Thoracic, Curved |
| .114 | Pedicle Probe, Thoracic, Straight |
| .313 | Monoaxial Screwdriver |
| .316 | Hex Rod Wrench |
| .322 | Locking Cap Driver, Double Ended |
| .323 | Monoaxial Screw Head Positioner |
| .324 | Reduction Forceps |
| .325 | External Head Positioner |
| .326 | Rigid Monoaxial Screwdriver |
| .450 | Monoaxial Self Retaining Driver |
| .517 | Power Rod Gripper, 5.5mm |
| .607 | Rod Bender for 5.5 Rod |
| | |

REVERE® Power Bender

Description

Rod Template, 500mm

Clamps

| 124.962 | Rod-to-Rod Clamp, 5.5mm to 5.5mm |
|---------|--|
| 124.963 | Rod-to-Rod Clamp, 5.5mm to 5.5mm, Wide |
| 124.964 | Parallel Connector Clamp, 5.5mm to 5.5mm |
| 124.965 | Parallel Connector Clamp, 5.5mm to 5.5mm, Wide |
| 124.973 | 5.5mm Rod Clamp, 100mm |
| 124.974 | 5.5mm Rod Clamp, 120mm |
| | |

124.975 5.5mm Rod Clamp, 150mm

STAINLESS STEEL REVERE[®] DEFORMITY IMPLANT SET





Stainless Steel REVERE® Deformity Implant Set 924.910

Stainless Steel 5.5mm Straight Rod

| Length | Part No. | Qty |
|--------|----------|-----|
| 200mm | 224.517 | 2 |
| 300mm | 224.001 | 2 |
| 400mm | 224.002 | 2 |
| 500mm | 224.003 | 2 |

Stainless Steel 5.5mm Monoaxial Screws

| 25mm | 224.251 | 4 |
|------|---------|---|
| 30mm | 224.252 | 8 |
| 35mm | 224.253 | 8 |
| 40mm | 224.254 | 8 |
| 45mm | 224.255 | 8 |
| 50mm | 224.256 | 4 |
| 55mm | 224.257 | 4 |

Stainless Steel 6.5mm Monoaxial Screws

| 25mm | 224.261 | 4 |
|------|---------|---|
| 30mm | 224.262 | 8 |
| 35mm | 224.263 | 8 |
| 40mm | 224.264 | 8 |
| 45mm | 224.265 | 8 |
| 50mm | 224.266 | 6 |
| 55mm | 224.267 | 2 |

Stainless Steel Hooks

| Part No. | Description | Qty |
|----------|---|-----|
| 224.891 | Stainless Steel Low-Profile Pedicle Hook, Smal | 1 2 |
| 224.892 | Stainless Steel Low-Profile Pedicle Hook, Medium | 2 |
| 224.893 | Stainless Steel Low-Profile Pedicle Hook, Large | e 2 |
| 224.924 | Stainless Steel Transverse Process Hook, Righ | t 2 |
| 224.925 | Stainless Steel Transverse Process Hook, Left | 2 |
| 224.944 | Stainless Steel Lamina Hook, Small | 2 |
| 224.945 | Stainless Steel Lamina Hook, Medium | 4 |
| 224.946 | Stainless Steel Lamina Hook, Large | 2 |

Low Profile Adjustable T-Connectors

| 224.012 | Low Profile Adjustable T-Connector, 24–25mm | 2 |
|---------|---|---|
| 224.013 | Low Profile Adjustable T-Connector, 26–28mm | 2 |
| 224.014 | Low Profile Adjustable T-Connector, 29–34mm | 2 |

Locking Cap

| Part No. | Description | Qty |
|----------|--|-----|
| 224.000 | Stainless Steel REVERE® Locking Cap | 24 |
| 924.008 | Locking Cap Module | |
| 924.010 | Stainless Steel REVERE® Deformity Implant Graphic Case | |

Additionally Available Stainless Steel REVERE® Deformity Implants

Stainless Steel Hex-End Rods

| Part No. | Description |
|----------|---|
| 224.008 | 5.5mm Stainless Steel Straight Rod, Hex-End, 300mm |
| 224.009 | 5.5mm Stainless Steel Straight Rod, Hex-End, 400mm |
| 224.010 | 5.5mm Stainless Steel Straight Rod, Hex-End, 500mm |
| 224.011 | 5.5mm Stainless Steel Straight Rod, Hex-End, 600mm |

Stainless Steel Straight Rods

| 224.515 | 5.5mm Stainless Steel Straight Rod, 150mm |
|---------|---|
| 224.519 | 5.5mm Stainless Steel Straight Rod, 300mm |
| 224.520 | 5.5mm Stainless Steel Straight Rod, 400mm |
| 224.521 | 5.5mm Stainless Steel Straight Rod, 500mm |
| 224.523 | 5.5mm Stainless Steel Straight Rod, 600mm |

Stainless Steel REVERE® Low-Profile Adjustable T-Connectors

| 224.015 | Stainless Steel Low-Profile Adjustable T-Connector, 35–47mm |
|---------|--|
| 224.016 | Stainless Steel Low-Profile Adjustable T-Connector, 48–72mm |
| 224.017 | Stainless Steel Low-Profile Adjustable T-Connector, 73–97mm |

5.5mm Diameter Stainless Steel Monoaxial Screws

| Length | Part No. |
|--------|----------|
| 27mm | 224.111 |
| 32mm | 224.112 |
| 37mm | 224.113 |
| 42mm | 224.114 |
| 47mm | 224.115 |
| 60mm | 224.258 |
| 65mm | 224.259 |

6.5mm Diameter Stainless Steel Monoaxial Screws

| Length | Part No. |
|--------|----------|
| 27mm | 224.121 |
| 32mm | 224.122 |
| 37mm | 224.123 |
| 42mm | 224.124 |
| 47mm | 224.125 |
| 60mm | 224.268 |
| 65mm | 224.269 |

7.5mm Diameter Stainless Steel Monoaxial Screws

| 25mm | 224.271 |
|------|---------|
| 27mm | 224.131 |
| 30mm | 224.272 |
| 32mm | 224.132 |
| 35mm | 224.273 |
| 37mm | 224.133 |
| 40mm | 224.274 |
| 42mm | 224.134 |
| 45mm | 224.275 |
| 47mm | 224.135 |
| 50mm | 224.276 |
| 55mm | 224.277 |
| 60mm | 224.278 |
| 65mm | 224.279 |
| 70mm | 224.871 |
| 75mm | 224.872 |
| 80mm | 224.873 |
| 85mm | 224.874 |
| 90mm | 224.875 |

Additionally Available Stainless Steel REVERE® Deformity Implants (cont'd)

8.5mm Diameter Stainless Steel Monoaxial Screw

| Length | Part No. |
|--------|----------|
| 30mm | 224.282 |
| 35mm | 224.283 |
| 40mm | 224.284 |
| 45mm | 224.285 |
| 70mm | 224.881 |
| 75mm | 224.882 |
| 80mm | 224.883 |
| 85mm | 224.884 |
| 90mm | 224.885 |

Stainless Steel Hooks

Part No. **Description** 224.901 Stainless Steel REVERE® Thoracic Lamina Hook, Narrow, Small 224.902 Stainless Steel REVERE® Thoracic Lamina Hook, Narrow, Medium 224.904 Stainless Steel REVERE® Thoracic Lamina Hook, Small 224.905 Stainless Steel REVERE® Thoracic Lamina Hook, Medium 224.907 Stainless Steel REVERE® Upgoing Lamina Hook, Medium 224.908 Stainless Steel REVERE® Upgoing Lamina Hook, Large 224.921 Stainless Steel REVERE® Offset Lamina Hook, Right Stainless Steel REVERE® Offset Lamina Hook, Left 224.922 224.927 Stainless Steel REVERE® Pedicle Hook, Small 224.928 Stainless Steel REVERE® Pedicle Hook, Medium 224.929 Stainless Steel REVERE® Pedicle Hook, Large 224.931 Stainless Steel REVERE® Lamina Hook, Transverse, Small

224.932 Stainless Steel REVERE® Lamina Hook, Transverse, Medium

Stainless Steel Hooks (cont'd)

| Part No. | Description |
|----------|---|
| 224.933 | Stainless Steel REVERE® Lamina Hook, Transverse, Large |
| 224.935 | Stainless Steel REVERE® Pedicle Hook, Transverse, Small |
| 224.936 | Stainless Steel REVERE® Pedicle Hook, Transverse, Medium |
| 224.937 | Stainless Steel REVERE® Pedicle Hook, Transverse, Large |
| 224.940 | Stainless Steel REVERE® Lamina Hook, Narrow, Small |
| 224.941 | Stainless Steel REVERE® Lamina Hook, Narrow, Medium |
| 224.942 | Stainless Steel REVERE® Lamina Hook, Narrow, Large |
| 224.948 | Stainless Steel REVERE® Lamina Hook, Wide, Small |
| 224.949 | Stainless Steel REVERE® Lamina Hook, Wide, Medium |
| 224.950 | Stainless Steel REVERE® Lamina Hook, Wide, Large |
| 224.952 | Stainless Steel REVERE® Lamina Hook, Tall Body, Small |
| 224.953 | Stainless Steel REVERE Lamina Hook, Tall Body, Medium |
| 224.954 | Stainless Steel REVERE® Lamina Hook, Tall Body, Large |
| 224.955 | Stainless Steel REVERE® Angled Lamina Hook, Small |
| 224.956 | Stainless Steel REVERE® Angled Lamina Hook, Medium |
| 224.957 | Stainless Steel REVERE® Angled Lamina Hook, Large |

Additionally Available Stainless Steel REVERE® Deformity Implants (cont'd)

Stainless Steel Connectors

| Part No. | Description | Pa |
|----------|---|----------|
| 224.960 | Stainless Steel Parallel Connector, 5.5mm to 5.5mm | 22 |
| 224.961 | Stainless Steel Parallel Connector, 5.5mm to 5.5mm, Wide | 22 |
| 224.966 | Stainless Steel Parallel Connector, Double, 5.5mm to 5.5mm | 22 |
| 224.967 | Stainless Steel Parallel Connector, Double, 5.5mm to 5.5mm, Wide | 22 |
| 224.970 | 5.5mm Stainless Steel Offset Connector, 15mm | 22 |
| 224.971 | 5.5mmm Stainless Steel Offset Connector, 20mm | 22 |
| 224.972 | 5.5mm Stainless Steel Offset Connector, 25mm | 22 |
| 224.976 | 5.5mm Stainless Steel Offset Connector, 30mm | ~~~ |
| 224.977 | 5.5mm Stainless Steel Offset Connector, 35mm | 5. |
| 224.980 | Stainless Steel In-line Connector, 5.5mm to 5.5mm | Le |
| 224.990 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 15mm | 25 |
| 224.991 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 20mm | 27 30 |
| 224.992 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 25mm | 32 |
| 224.993 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 30mm | 35 37 |
| 224.994 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 35mm | 40 |
| 224.995 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 100mm | 42 45 |
| 224.996 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 120mm | 47 |
| 224.997 | SS 5.5mm Closed Offset Connector, 5.5mm Rod, 150mm | 50 |

Stainless Steel Clamps

| Part No. | Description |
|----------|---|
| 224.962 | Stainless Steel Rod-to-Rod Clamp, 5.5mm to 5.5mm |
| 224.963 | Stainless Steel Rod-to-Rod Clamp, 5.5mm to 5.5mm, Wide |
| 224.964 | Stainless Steel Parallel Connector Clamp, 5.5mm to 5.5mm |
| 224.965 | Stainless Steel Parallel Connector Clamp, 5.5mm to 5.5mm, Wide |
| 224.973 | 5.5mm Stainless Steel Rod Clamp, 100mm |
| 224.974 | 5.5mm Stainless Steel Rod Clamp, 120mm |
| 224.975 | 5.5mm Stainless Steel Rod Clamp, 150mm |

5.5mm Stainless Steel Unit Rod

| 5.5mm | Length | Part No. |
|-------|--------|----------|
| | 250mm | 224.410 |
| | 275mm | 224.411 |
| | 300mm | 224.412 |
| | 325mm | 224.413 |
| | 350mm | 224.414 |
| | 375mm | 224.415 |
| | 400mm | 224.416 |
| | 425mm | 224.417 |
| | 450mm | 224.418 |
| | 475mm | 224.419 |
| | 500mm | 224.420 |
| | | |

Additionally Available Stainless Steel REVERE® Implants

5.5mm Stainless Steel REVERE[®] Solid Pedicle Screw

 Length
 Part No.

 25mm
 224.451

6.5mm Stainless Steel REVERE[®] Solid Pedicle Screw

25mm 224.461

7.5mm Stainless Steel REVERE® Solid Pedicle Screw

| 25mm | 224.471 |
|------|---------|
| 70mm | 224.071 |
| 75mm | 224.072 |
| 80mm | 224.073 |
| 85mm | 224.074 |
| 90mm | 224.075 |

8.5mm Stainless Steel REVERE[®] Solid Pedicle Screw

| 25mm | 224.481 |
|------|---------|
| 30mm | 224.482 |
| 35mm | 224.483 |
| 40mm | 224.484 |
| 45mm | 224.485 |
| 50mm | 224.486 |
| 55mm | 224.487 |
| 60mm | 224.488 |
| 65mm | 224.489 |
| 70mm | 224.081 |
| 75mm | 224.082 |
| 80mm | 224.083 |
| 85mm | 224.084 |
| 90mm | 224.085 |

5.5mm Stainless Steel Straight Rod Length Part No. 30mm 224.530 35mm 224.535 40mm 224.540 224.550 50mm 60mm 224.560 70mm 224.570 80mm 224.580 100mm 224.510

125mm224.512200mm224.517300mm224.519400mm224.520500mm224.521600mm224.523

5.5mm Stainless Steel Curved Rod

| 50mm | 224.650 |
|-------|---------|
| 60mm | 224.660 |
| 70mm | 224.670 |
| 80mm | 224.680 |
| 100mm | 224.610 |
| 125mm | 224.612 |
| 150mm | 224.615 |

REVERE[®] SMALL DIAMETER SCREWS SUPPLEMENTAL SET



REVERE® Small Diameter Pedicle Screws

| Length | Ø4.0mm | Qty |
|--------|---------|-----|
| 20mm | 124.430 | 0 |
| 25mm | 124.431 | 0 |
| 30mm | 124.432 | 0 |
| 35mm | 124.433 | 0 |
| 40mm | 124.434 | 0 |
| 45mm | 124.435 | 0 |
| | | |

REVERE® Small Diameter Monoaxial Screws

| Length | Ø4.0mm | Qty |
|--------|---------|-----|
| 20mm | 124.200 | 0 |
| 25mm | 124.201 | 2 |
| 30mm | 124.202 | 4 |
| 35mm | 124.203 | 4 |
| 40mm | 124.204 | 2 |

| Length | Ø4.5mm | Qty | Length | Ø4.5mm | Qty |
|--------|---------|-----|--------|---------|-----|
| 25mm | 124.441 | 2 | 25mm | 124.241 | 2 |
| 30mm | 124.442 | 2 | 30mm | 124.242 | 4 |
| 35mm | 124.443 | 4 | 35mm | 124.243 | 6 |
| 40mm | 124.444 | 4 | 40mm | 124.244 | 6 |
| 45mm | 124.445 | 2 | 45mm | 124.245 | 2 |

| Length | Ø5.0mm | Qty | Length | Ø5.0mm | Qty |
|--------|---------|-----|--------|---------|-----|
| 25mm | 124.051 | 2 | 25mm | 124.851 | 2 |
| 30mm | 124.052 | 2 | 30mm | 124.852 | 4 |
| 35mm | 124.053 | 4 | 35mm | 124.853 | 4 |
| 40mm | 124.054 | 4 | 40mm | 124.854 | 4 |
| 45mm | 124.055 | 4 | 45mm | 124.855 | 4 |
| 50mm | 124.056 | 2 | 50mm | 124.856 | 2 |
| 55mm | 124.057 | 2 | 55mm | 124.857 | 2 |

Locking Cap

| Part No. | Description | Qty |
|----------|--|-----|
| 124.000 | REVERE [®] Locking Cap | 10 |
| 924.006 | REVERE [®] Small Diameter Screw Implant Graphic Case | |

STAINLESS STEEL REVERE[®] SMALL DIAMETER SCREWS SUPPLEMENTAL SET



REVERE® Small Diameter Pedicle Screws

| Length | Ø4.0mm | Qty |
|--------|---------|-----|
| 20mm | 224.430 | 0 |
| 25mm | 224.431 | 0 |
| 30mm | 224.432 | 0 |
| 35mm | 224.433 | 0 |
| 40mm | 224.434 | 0 |
| 45mm | 224.435 | 0 |
| | | |

REVERE® Small Diameter Monoaxial Screws

| Length | Ø4.0mm | Qty |
|--------|---------|-----|
| 25mm | 224.201 | 2 |
| 30mm | 224.202 | 4 |
| 35mm | 224.203 | 4 |
| 40mm | 224.204 | 2 |

| Length | Ø4.5mm | Qty | Length | Ø4.5mm | Qty |
|--------|---------|-----|--------|---------|-----|
| 25mm | 224.441 | 2 | 25mm | 224.241 | 2 |
| 30mm | 224.442 | 2 | 30mm | 224.242 | 4 |
| 35mm | 224.443 | 4 | 35mm | 224.243 | 6 |
| 40mm | 224.444 | 4 | 40mm | 224.244 | 6 |
| 45mm | 224.445 | 2 | 45mm | 224.245 | 2 |

| Length | Ø5.0mm | Qty | Length | Ø5.0mm | Qty |
|--------|---------|-----|--------|---------|-----|
| 25mm | 224.051 | 2 | 25mm | 224.851 | 4 |
| 30mm | 224.052 | 2 | 30mm | 224.852 | 8 |
| 35mm | 224.053 | 4 | 35mm | 224.853 | 8 |
| 40mm | 224.054 | 4 | 40mm | 224.854 | 8 |
| 45mm | 224.055 | 4 | 45mm | 224.855 | 4 |
| 50mm | 224.056 | 2 | 50mm | 224.856 | 2 |
| 55mm | 224.057 | 2 | 55mm | 224.857 | 0 |

Locking Cap

| Part No. | Description | Qty |
|----------|--|-------|
| 224.000 | Stainless Steel REVERE® Locking Cap | 10 |
| 924.011 | Stainless Steel REVERE® Small Diameter S Implant Graphic Case | Screw |

REVERE[®] UNIPLANAR SUPPLEMENTAL SCREW SETS





REVERE® Uniplanar Supplemental Screw Sets

REVERE[®] Uniplanar Supplemental Screw Set 924.915

| Length | Ø4.5mm | Qty |
|---------|---------|-----|
| 25mm | 524.641 | 2 |
| 30mm | 524.642 | 4 |
| 35mm | 524.643 | 4 |
| 40mm | 524.644 | 2 |
| 45mm | 524.645 | 0 |
| 50mm | 524.646 | 0 |
| 55mm | 524.647 | 0 |
| Length | Ø5.0mm | Qty |
| 25mm | 524.651 | 4 |
| 30mm | 524.652 | 6 |
| 35mm | 524.653 | 6 |
| 40mm | 524.654 | 4 |
| 45mm | 524.655 | 4 |
| 50mm | 524.656 | 0 |
| 55mm | 524.657 | 0 |
| Length | Ø5.5mm | Qty |
| 25mm | 524.661 | 0 |
| 30mm | 524.662 | 6 |
| 35mm | 524.663 | 6 |
| 40mm | 524.664 | 4 |
| 45mm | 524.665 | 2 |
| 50mm | 524.666 | 0 |
| 55mm | 524.667 | 0 |
| Length | Ø6.5mm | Qty |
| 25mm | 524.671 | 0 |
| 30mm | 524.672 | 2 |
| 35mm | 524.673 | 4 |
| 40mm | 524.674 | 4 |
| 45mm | 524.675 | 2 |
| 50mm | 524.676 | 2 |
| 55mm | 524 677 | 0 |
| 5511111 | 324.077 | 0 |

Stainless Steel REVERE[®] Uniplanar Supplemental Screw Set 924.917

| Length | Ø4.5mm | Qty |
|---|--|---|
| 25mm | 224.801 | 2 |
| 30mm | 224.802 | 4 |
| 35mm | 224.803 | 4 |
| 40mm | 224.804 | 2 |
| 45mm | 224.805 | 0 |
| 50mm | 224.806 | 0 |
| 55mm | 224.807 | 0 |
| Length | Ø5.0mm | Qty |
| 25mm | 224.811 | 4 |
| 30mm | 224.812 | 6 |
| 35mm | 224.813 | 6 |
| 40mm | 224.814 | 4 |
| 45mm | 224.815 | 4 |
| 50mm | 224.816 | 0 |
| 55mm | 224.817 | 0 |
| Length | Ø5.5mm | Qty |
| 25mm | 224.821 | 0 |
| 30mm | 224.822 | 6 |
| 35mm | 224 823 | |
| | 224.025 | 6 |
| 40mm | 224.824 | 6 4 |
| 40mm 45mm | 224.823 224.824 224.825 | 6 4 2 |
| 40mm 45mm 50mm | 224.823 224.824 224.825 224.826 | 6 4 2 0 |
| 40mm 45mm 50mm 55mm | 224.823 224.824 224.825 224.826 224.827 | 6 4 2 0 0 |
| 40mm 45mm 50mm 55mm Length | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm | 6 4 2 0 0 0 |
| 40mm 45mm 50mm 55mm Length 25mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 | 6 4 2 0 0 0 Qty 0 |
| 40mm 45mm 50mm 55mm Length 25mm 30mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 224.832 | 6 4 2 0 0 0 Qty 0 2 |
| 40mm 45mm 50mm 55mm Length 25mm 30mm 35mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 224.832 224.833 | 6 4 2 0 0 0 Qty 0 2 4 |
| 40mm 45mm 50mm 55mm Length 25mm 30mm 35mm 40mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 224.832 224.833 224.833 | 6 4 2 0 0 Qty 0 2 4 4 |
| 40mm 45mm 50mm 55mm Length 25mm 30mm 35mm 40mm 45mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 224.832 224.833 224.833 224.834 224.835 | 6 4 2 0 0 Qty 0 2 4 4 4 2 |
| 40mm 45mm 50mm 55mm 25mm 30mm 35mm 40mm 45mm 50mm | 224.823 224.824 224.825 224.826 224.827 Ø6.5mm 224.831 224.832 224.833 224.833 224.833 224.834 224.835 224.836 | 6 4 2 0 0 2 4 4 2 2 |

924.015 REVERE® Uniplanar Screw Graphic Case

924.017 SS REVERE® Uniplanar Screw Graphic Case

REVERE® Deformity Hook Dimensions

Thoracic Lamina Hooks

| Part No. | L1 | L2 | L3 | L4 | L5 |
|----------|--------|-------|-----|-------|-------|
| 124.901 | 21.5mm | 3.5mm | 37° | 6.0mm | 8.5mm |
| 124.902 | 22.5mm | 4.0mm | 32° | 6.5mm | 9.0mm |
| 124.904 | 21.5mm | 5.0mm | 37° | 6.0mm | 8.5mm |
| 124.905 | 22.5mm | 5.5mm | 32° | 6.5mm | 9.0mm |



Upgoing Lamina Hooks

| Part No. | L1 | L2 | L3 | L4 |
|----------|--------|-------|-------|-------|
| 124.907 | 24.5mm | 5.5mm | 8.0mm | 8.0mm |
| 124.908 | 25.5mm | 6.0mm | 9.0mm | 9.0mm |



Pedicle Hooks

| Part No. | L1 | L2 | L3 |
|----------|--------|--------|-------|
| 124.927 | 23.0mm | 9.5mm | 7.5mm |
| 124.928 | 24.0mm | 11.0mm | 8.5mm |
| 124.929 | 25.0mm | 12.0mm | 9.5mm |





124.921





Part No. 124.924



Offset Lamina Hook, Left Part No. 124.922



Transverse Process Hook, Left Part No. 124.925

REVERE® Deformity Hook Dimensions

Transverse Lamina Hooks

| Part No. | L1 | L2 | L3 | L4 |
|----------|--------|-------|--------|-----|
| 124.931 | 21.5mm | 5.0mm | 8.5mm | 10° |
| 124.932 | 22.5mm | 5.5mm | 9.0mm | 11° |
| 124.933 | 23.5mm | 6.5mm | 10.0mm | 12° |



Transverse Pedicle Hooks

| Part No. | t No. L1 L2 | | L3 |
|----------|-------------|-------|--------|
| 124.935 | 23.0mm | 7.5mm | 9.5mm |
| 124.936 | 24.0mm | 8.5mm | 11.0mm |
| 124.937 | 25.0mm | 9.5mm | 12.0mm |



Lamina Hooks

| Part No. | L1 | L2 | L3 | L4 |
|----------|--------|-------|--------|-----|
| 124.940 | 21.5mm | 3.5mm | 8.5mm | 10° |
| 124.941 | 22.5mm | 4.0mm | 9.0mm | 11° |
| 124.942 | 23.5mm | 5.0mm | 10.0mm | 12° |
| 124.944 | 21.5mm | 5.0mm | 8.5mm | 10° |
| 124.945 | 22.5mm | 5.5mm | 9.0mm | 11° |
| 124.946 | 23.5mm | 6.5mm | 10.0mm | 12° |
| 124.948 | 21.5mm | 7.0mm | 8.5mm | 10° |
| 124.949 | 22.5mm | 7.5mm | 9.0mm | 11° |
| 124.950 | 23.5mm | 8.5mm | 10.0mm | 12° |
| 124.952 | 26.5mm | 5.0mm | 8.5mm | 10° |
| 124.953 | 27.5mm | 5.5mm | 9.0mm | 11° |
| 124.954 | 28.5mm | 6.5mm | 10.0mm | 12° |

Y.S

Angled Lamina Hooks

| Part No. | L1 | L2 | L3 | L4 |
|----------|--------|-------|--------|-----|
| 124.955 | 21.0mm | 5.0mm | 8.6mm | 17° |
| 124.956 | 22.0mm | 5.5mm | 9.1mm | 18° |
| 124.957 | 23.0mm | 6.0mm | 10.1mm | 20° |



Preoperative Planning Guide



Preoperative Planning Guide



Transverse Process Hooks

These hooks are commonly used in the upper thoracic spine and placed in a downgoing position on the transverse process.



Pedicle Hooks

These are used at an inferior level to the transverse process hook and are typically placed in an up-going position to form a claw like construct.



Uniplanar Screws

Commonly used at the apex of the scoliotic curve.

- Useful for deformity derotation
- Combines the versatility of a polyaxial screw with the stiff correction capability of a monoaxial screw



Lamina Hooks

These hooks are commonly used in the upper thoracic spine. Various blade orientation and widths are available increasing placement options.

Monoaxial Screws

May be used at any level.

- Instrument-screw connection avoids interference with bony anatomy
- Low profile to avoid external protuberance



Polyaxial Screws

These may be used at any level.

• Provide needed versatility, particularly in the lumbar spine



Dual Outer Diameter Screws These screws are typically used for sacroiliac fixation.

- Designed to optimize purchase for both cancellous and cortical sacral bone
- May also be used in the thoracic and lumbar spine





Reduction Screws: Polyaxial and Uniplanar

These screws may be used at any level.

- Provide reduction capability through extension tabs (28.5mm) and specialized instrumentation
- May be used in spondylolisthesis for at L5-S1



IMPORTANT INFORMATION ON THE REVERE® STABILIZATION SYSTEM

DESCRIPTION

The REVERE® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, offset housing clamps, head offset connectors, trans iliac connectors, sacral sacral and sacral-iliac plates, staples and staple plates, and associated manual surgical instruments. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy, REVERE® implants mate with 5.5mm diameter rods; REVERE® 6.35 implants mate with 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples and staple plates are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod, trans-iliac connectors and sacral-iliac plates

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. T-connectors from the PROTEX® system may be used with 6.5mm, 6.0mm or 5.5mm rod systems. REVERE® t-connectors may only be used with 5.5mm rods; REVERE® 6.35 t-connectors may only be used with 6.35mm rods. Additional connectors may be used to connect two rods, and are also secured using set screws.

REVERE® hooks and t-connectors, and 5.5mm or 6.35mm diameter rods may be used with the BEACON® Stabilization System.

REVERE® screws and locking caps may be used with the TRANSITION® Stabilization System. Specifically, REVERE® polyaxial (solid, cannulated and dual outer diameter) screws and monoaxial screws 6.5mm diameter and larger, and 35mm length and larger, may be used with the TRANSITION® implant assemblies.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. All other REVERE® implants are composed of titanium alloy or stainless steel, as specified in ASTM F136, F1295, and F138. The screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium molybdenum.

INDICATIONS

The REVERE® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVERE® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants

after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the REVERE® Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVERE® Stabilization System is intended for anterolateral screw (with or without staples or staple plates) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

WARNINGS

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 disc disease, 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.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation, • non-union,
- fracture of the vertebrae, • neurological injury, and
- · vascular or visceral injury.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy, commercially pure titanium, stainless steel and cobalt chromium molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The REVERE® Stabilization System includes 5.5mm REVERE® implants intended for use with a 5.5mm rod and REVERE® 6.35 implants intended for use with a 6.35mm rod.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The REVERE® Stabilization System has not been evaluated for safety and compatibility in the MR environment. The REVERE® Stabilization System has not been tested for heating or migration in the MR environment.

Based on fatigue testing results, when using the REVERE® Stabilization

IMPORTANT INFORMATION ON THE REVERE® STABILIZATION SYSTEM

System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

REVERE* implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness, and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the implants from the packaging using aseptic technique.

The instruments may be provided non-sterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehydefree solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

- 1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
- 2. Disassemble all instruments that can be disassembled.
- 3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
- 4. Prepare Enzol[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
- 5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
- 6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
- Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
- 8. Remove the instruments from the detergent and rinse them in running warm tap water.
- 9. Prepare Enzol[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.

- Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
- 11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
- 12. Dry instruments using a clean soft cloth and filtered pressurized air.
- 13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

REVERE® implants and instruments are provided sterile or non-sterile. REVERE® sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10.6. The expiration date is provided on the package label. Do not use if expired. These implants and instruments are considered sterile unless the packaging has been opened or damaged.

Non-sterile REVERE[®] implants and instruments have been validated to ensure an SAL of 10⁻⁶. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

The gravity displacement and pre-vacuum sterilization cycles are not considered by the FDA to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

Implants:

These devices may be supplied NONSTERILE. Sterilization is recommended as follows:

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|--------|-----------------------------------|---------------|------------------|----------------|
| Steam | Gravity Displacement (Wrapped) | 132°C (270°F) | 28 Minutes | 30 Minutes |
| Steam | Pre-vacuum (Wrapped) | 132°C (270°F) | 4 Minutes | 30 Minutes |

Instruments:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

| Method | Сусіе Туре | Temperature | Exposure Time | Drying Time |
|--------|-----------------------------------|---------------|------------------|----------------|
| Steam | Gravity Displacement (Wrapped) | 132°C (270°F) | 25 Minutes | 45 Minutes |
| Steam | Pre-vacuum (Wrapped) | 132°C (270°F) | 15 Minutes | 30 Minutes |

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.





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Customer Service: Phone 1-866-GLOBUS1 (or 1-866-456-2871) Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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