



# REVERE® 6.35 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's 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.



# REVERE® 6.35 Stabilization System





REVERE<sup>®</sup> 6.35 is a comprehensive thoracolumbar stabilization system providing surgeons all the flexibility and ease of use inherent in its predecessor, 5.5mm REVERE<sup>®</sup>, with the stiffness and strength of a 6.35mm diameter rod.

The system centers on the robust nonthreaded locking mechanism, with refined instrumentation and a wide range of implant options to meet the challenges of even the most complex cases. REVERE® 6.35 can be utilized for the complete range of posterior thoracolumbar procedures and includes various screw options, three material options and five reduction options.

Revere 6.35 is a comprehensive system for the treatment of degenerative spine conditions and spinal deformities.

# **REVERE® 6.35** STABILIZATION SYSTEM

## Screw Options

**Polyaxial** – provides intra-operative flexibility, double lead thread for rapid insertion and available in titanium alloy and stainless steel.

**Dual Outer Diameter** – designed to optimize purchase for both cancellous and cortical bone in the sacrum. **Also available** – monoaxial, reduction, uniplanar and uniplanar reduction.

## Material Options

#### Titanium Alloy (TAV)

- Strong titanium alloy
- More rigid than CP
- Allows for defined imaging

#### Commercially Pure Titanium (CP)

- Better metal memory less spring-back
- Industry standard for imaging

#### **Stainless Steel**

- Offers more rigid construct
- Stiffest of the three materials

## Reduction Options

**Tower Reducer** – Recommended when more reduction is required; allows up to 20mm of smooth, controlled reduction.

**Ratcheting Reducer** – Reduces the rod up to 10mm with simple scissor action (1mm per click)

Locking Cap Guide – Used to aid in small adjustments of the rod into the screw head

**Rod Lever** – Simple yet powerful rod reduction over shorter distances

**Rod Pusher** – Aids in small adjustments of the rod into the screw head



Titanium Alloy (TAV)

**Commercially Pure Titanium** 

**Stainless Steel** 





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REVERE® implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment. REVERE® implants are made from titanium alloy or commercially pure titanium, and are also available in stainless steel. Implants made from titanium alloy or commercially pure titanium have been shown to produce less artifact on CT or MRI than stainless steel implants.

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

## Non-threaded Locking Cap

- Non-threaded design eliminates cross-threading
- Low torque locking mechanism
- 90° rotation to capture the rod
- Optimal design decreases need for rod reduction
- Set screw pre-torqued in place to prevent any unintentional movement in shipping or handling
- Allows direct placement with the hex driver for easier assembly





## Screw Thread

- Self-tapping design
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase
- Double lead thread for rapid insertion (up to 7.5mm diameter)
- Taps are available, color-coded to screw size

## **Polyaxial Screws**

- ±30° angulation (60° total) provides intraoperative flexibility
- Low torque locking mechanism
- Double lead thread for rapid insertion (up to 7.5mm diameter)
- Screw diameters 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, 9.0mm
- Screw lengths 25–120mm
- Available in titanium alloy and stainless steel
- Color-coded screws





## Stainless Steel Polyaxial Screws

- Screw diameters 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, and 9.0mm
- Screw lengths 25-120mm
- Stainless steel monoaxial screws also available in 5.0–10.0mm diameters and the same lengths

## **Dual Outer Diameter Screws**

- Designed to optimize purchase for both cancellous and cortical bone
- Nominal diameter at distal end allows for deeper insertion into sacrum without perforation
- Designed for the sacrum and ilium, but can be used for the thoracic and lumbar
- ±30° angulation (60° total) provides intraoperative flexibility
- Available in distal/proximal outer diameters of 5.5/7.0, 6.0/7.5, 6.5/8.0, 7.0/8.5, and 7.5/9.0mm
- Screw lengths 30-120mm
- · Longer lengths designed for iliac placement and purchase
- Available in titanium alloy



THUNKING

Screw diameter measured distally

## Variable Cross Connectors

- · Optimized for profile and strength
- Unique design with fewer tightening steps
- Angular and medial-lateral adjustments provide secure fit
- Low profile, only 9.5mm above the rod
- Available in seven sizes with overlapping lengths
- Available in titanium alloy and stainless steel



# MATERIAL OPTIONS

### 6.35mm Diameter Rods

- Comprehensive selection of straight and curved rods available in a range of sizes up to 500mm
- Hex-ended rods (150mm and above) to aid in global derotation in deformity cases
- Manufactured in titanium alloy, commercially pure titanium and stainless steel



# **INSTRUMENT OVERVIEW**

# Pedicle Preparation Instruments

| -0                                   |          |
|--------------------------------------|----------|
| Pedicle Awl 602.104                  |          |
|                                      |          |
| Pedicle Probe, Straight 602.101      |          |
|                                      |          |
| Pedicle Probe, Curved 602.102        |          |
|                                      |          |
| Pedicle Probe, Thoracic 602.109      |          |
| Ball Tip Probe 602.105               |          |
|                                      |          |
| Ball Tip Probe, Curved 602.106       |          |
| Ball Tip Probe, Double Ended 624.110 | <b>P</b> |

## Pedicle Preparation Instruments (cont'd)



## Screw Insertion Instruments



Quick Release 1/4", Ratchet, Straight Handle 630.407



Quick Disconnect 1/4" Non-Ratcheting, Large Sport Handle 634.406 (alternative handle)

3.5mm Hex Driver Self-Retaining Shaft, 1/4" Connection 634.408

Ball End Hex Driver Shaft 630.411 3.5mm Hex Driver Rigid Shaft 634.703 6.35 Holding Sleeve Assembly 634.704 Rigid Driver Assembly (Assembled: Disassemble for cleaning)

## Rod Manipulation Instruments





# Rod Manipulation Instruments (cont'd)



T-Handle, Tower 624.801

## Screw Locking Instruments



6.35 Locking Cap Driver 634.601



## Cross Connector Instruments



## Other Instruments





6.35 Soft Tissue Retractor 634.514

## Additionally Available Instruments



3.5mm Torque Limiting Driver, Ratcheting, 1/4" Connect, SS 634.611 – to be used with 634.405 or 634.408

Quick Release 1/4", Ratchet, T-Handle 630.401 – to be used with 634.405 or 634.408 or all the taps



# **REVERE® 6.35** SURGICAL TECHNIQUE

## Step 1 Approach

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate level(s). Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct screw placement.

There are various techniques for pedicle screw and rod insertion. For the purposes of this technique guide, a Wiltse paramedial approach and building of an L4-L5-S1 construct are shown.

Note: Please refer to product insert for complete description, indications, contraindications and warnings.

# Step 2 Polyaxial Screw Insertion

#### **Pedicle Preparation**

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

Use the **Pedicle Awl** to perforate the pedicle cortex.

Use a **Pedicle Probe** to open the pedicle pathway. Demarcations every 10mm on the probe indicate the depth of the pathway and help determine proper screw length.



Preparing pedicle pathway

Use a **Ball Tip Probe** to verify that the walls of the prepared pedicle pathway are not violated. Demarcations every 10mm on the probe indicate the depth of the pathway and can also help determine proper screw length.

REVERE<sup>®</sup> 6.35 pedicle screws are self-tapping, however pedicles may be tapped if desired. Insert the **Tap** of the desired diameter into the **Quick Release Ratchet Handle**. Tap the pedicle to the determined depth.

#### **Screwdriver Assembly**

Select the appropriate pedicle screw diameter and length. Assemble the **3.5mm Hex Screwdriver Rigid Shaft** to the Quick Release Ratchet Handle. Slide the Holding Sleeve Assembly over the shaft. Turn the knurled knob until the indication line (groove) on the shaft is visible. Insert the screwdriver into the screw body. Once engaged, turn the knurled knob counterclockwise (LOCK) until the screw is firmly in place, holding the threaded portion of the screw straight to engage the hex. The thread on the driver should not be visible when the hex is fully engaged.

To disengage, turn the ratcheting mechanism on the handle to neutral or reverse. Turn the knurled knob clockwise (UNLOCK) until the line on the shaft is visible. Pull up and disengage the driver from the screw.



REVERE® 6.35 polyaxial screw loaded onto 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 Disconnect Non-Ratcheting Handle** may be used for screw insertion. Simply insert the hex tip into the hexagonal screw head until the indicator line on the shaft is flush (see arrow below).



Self-Retaining 3.5mm Hex Screwdriver Shaft attached to the Quick Disconnect Non-Ratcheting Handle



Self-Retaining 3.5mm Hex Screwdriver Shaft attached to the Quick Release Ratchet Handle



#### **Inserting Screws**

Drive the screws into the prepared pedicles. When complete, 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.



Screw insertion



Screws inserted

#### Using the Screw Head Positioner

Once the screws are fully inserted, the screw heads can be oriented to better receive the rod using the **Screw Head Positioner**, as shown below. Insert the Screw Head Positioner into the screw head and rotate to the desired position.



Positioning screw heads using Screw Head Positioner

## Step3Rod Insertion and Locking Cap Delivery

#### **Rod Preparation**

Determine the appropriate length and contour of the rod using the **Rod Template**. Straight and curved rods are available in a variety of lengths. Alternatively, rods may be cut to length using the **Rod Cutter**. Rods may also be contoured using the **Power Bender**. There are three radius options for bending (small, medium, large) in the center dial. To change, pull and rotate.







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

The construct is not completely locked until final tightening. See step 5, page 26.



#### Loading Cap Driver

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



Load Locking Cap Driver from module



Align cap driver with the locking cap



Cap driver loaded

#### Using the Locking Cap Guide

To adjust the Locking Cap Guide to a parallel position, 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.

#### Locking Cap Guide

The Locking Cap Guide is used to aid in small adjustments of the rod into the screw head and acts as a guide for the **Locking Cap Driver**. Place the Locking Cap Guide over the rod and screw head, and apply downward pressure. The Locking Cap Guide handle can be adjusted to a parallel position, as shown at left.



Using the Rod Pusher

If greater visualization is desired, the **Rod Holder**, **Rod Gripper** or **Rod Pusher** may be used. The Rod Pusher aids in small adjustments of the rod into the screw head. Place the Rod Pusher over the rod and apply downward pressure. Once the rod is seated within the screw head, load the Locking Cap Driver and install the locking cap, as shown.



Using the Rod Holder

![](_page_21_Picture_8.jpeg)

![](_page_22_Picture_0.jpeg)

#### **Rod Reduction**

The REVERE® 6.35 system has five options for rod reduction:

- Locking Cap Guide
- Rod Pusher
- Rod Lever
- Ratcheted Rod Reducer
- Tower Reducer

The rod reduction instruments are designed to seat the rod into the screw head, not to bend the rod. Ensure that the rod is properly contoured prior to reduction.

#### **Option 1: Locking Cap Guide**

The **Locking Cap Guide** may be used for rod reduction. The instrument aids in small adjustments of the rod into the screw head.

#### **Option 2: Rod Pusher**

The **Rod Pusher** aids in direct manual reduction of the rod. This instrument aids in small adjustments of the rod into the screw head.

![](_page_22_Picture_13.jpeg)

Option 1: Rod reduction using the Locking Cap Guide

Option 2: Rod reduction using the Rod Pusher

![](_page_22_Picture_16.jpeg)

#### **Option 3: Rod Lever**

The **Rod Lever** can be used to maneuver the rod into position. This instrument is useful when the rod is slightly above the screw. Slide the Rod Lever into the reduction slots on the screw head. Lever the rod down, sliding it into the screw head.

![](_page_23_Picture_2.jpeg)

Rod reduction using the Rod Lever

**Rod Lever** 

#### **Option 4: Ratcheted Rod Reducer**

The **Ratcheted Rod Reducer** provides up to 10mm of reduction (1mm per click) and can be used to reduce the rod into position. Ensure it is fully open, then place the Ratcheted Rod Reducer squarely over the screw head and push down until it is fully seated. Compress the handles to engage and reduce the rod. The groove on the proximal end of the internal shaft is exposed when the rod is fully reduced. The Locking Cap Driver is inserted through the Reducer.

![](_page_24_Picture_2.jpeg)

Rod reduction using the Ratcheted Rod Reducer

#### **Option 5: Tower Reducer**

The **Tower Reducer** provides up to 20mm of continuous reduction and can be used to reduce the rod into position.

Ensure the reducer is in the starting position by fully backing it up counter clockwise until stop (do not over-tighten). Place the Tower Reducer squarely over the screw head and push down until it is completely flush with the screw head. Turn the reducer clockwise and continue until the horizontal etchings align, as shown at right.

Utilize the T-Handle to reduce, if preferred.

Insert the loaded Cap Driver into the Tower Reducer.

Rotate the Cap Driver 90° clockwise to engage the locking cap.

Provisionally tighten the locking cap set screw.

Remove the Cap Driver and Tower Reducer by turning counterclockwise until stop .

Note: The Tower Reducer provides strong rod reduction (with a range up to 20mm).

Etch line indicates rod is fully reduced

**Tower Reducer** 

![](_page_25_Picture_11.jpeg)

Reduction using Tower Reducer

# Step4Compression or Distraction

REVERE® 6.35 pedicle screws can be compressed or distracted along the rod as necessary using the **Compressor** or **Distractor** respectively. REVERE® 6.35 screws allow for screw angulation to be free or locked under compression or distraction, as shown at right. Tighten one of the set screws, to establish a rigid point for compression or distraction. Once compression or distraction is completed, provisionally tighten the set screws using the **Torque Limiting 3.5mm Hex Driver.** 

![](_page_26_Picture_2.jpeg)

![](_page_26_Picture_3.jpeg)

#### **Free Angulation**

For free angulation, compress or distract the screws after Locking Cap insertion.

![](_page_26_Picture_6.jpeg)

Compression with free angulation

#### **Locked Angulation**

To lock the angulation of the screw and obtain parallel distraction, provisionally tighten the set screw(s) using the 3.5mm Hex Driver. Loosen at least one set screw by approximately one full turn (as shown on page 29) to allow the screw to slide along the rod without changing the polyaxial feature. Compress or distract the screws. Proceed to final tightening.

![](_page_26_Picture_10.jpeg)

Compression with locked angulation

## Step 5 Final Construct

#### **Final Tightening**

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

Insert the Torque Limiting 3.5mm Hex Driver into the Final Tightening Counter Torque and visually confirm the hex is fully engaged in the set screw. Then slide the FInal Tightening Counter Torque over the screw head, ensuring the instrument is fully seated. Rotate the Hex Driver (red handle) until it reaches the torque limit (6.5 N-m) and turn for two clicks. Repeat for all locking caps.

#### 3.5mm Ratcheting Torque–Limiting Driver

When final tightening:

![](_page_27_Picture_7.jpeg)

Use the RED 3.5mm Ratcheting Torque-Limiting Driver (634.604) (6.5 N-m) for titanium implants.

![](_page_27_Picture_9.jpeg)

Use the BLACK 3.5mm Ratcheting Torque-Limiting Driver (634.611) (8.0 N-m) for stainless steel implants.

![](_page_27_Picture_11.jpeg)

REVERE 6.35 Final Tightening Counter Torque with Torque Limiting Driver

# Step 6 Optional Techniques

#### Variable Cross Connector Insertion

To enhance construct stability, the Variable Cross Connector may be used as a transverse connector between two rods. The Variable Cross Connector Template can be used to estimate the length between the two rods.

![](_page_28_Picture_3.jpeg)

#### **Using Variable Cross Connector Template**

The **Variable Cross Connector Template** may be used to estimate the length between the two rods, as shown.

- Unlock the thumb screw of the Variable Cross Connector Template.
- Place the template between the rods at the desired level and lock the thumb screw.
- Read the span distance from the template handle indicated at the arrow.
- Use this measurement to determine the appropriate Variable Cross Connector size ranges, as shown below.

![](_page_28_Picture_10.jpeg)

Using Variable Cross Connector Template

![](_page_28_Picture_12.jpeg)

Variable Cross Connector Template (end view indicating 69mm)

#### Variable Cross Connector Insertion (cont'd)

Use the Variable Cross Connector Inserter to grasp the desired cross connector. Position the connector between the rods and provisionally tighten the set screws on the rods through the Variable Cross Connector Inserter. Adjust the connector position and provisionally tighten the set screws on the rods. Then tighten the center set screw. Final tighten the set screws bearing on the rods using the same Torque Limiting 2.5mm Hex Driver (2.5 N-m).

![](_page_29_Picture_2.jpeg)

![](_page_29_Picture_3.jpeg)

![](_page_29_Picture_4.jpeg)

#### **Implant Removal**

To remove a screw, begin by removing the locking cap. Insert the Self-Retaining 3.5mm Hex Screwdriver into the set screw of the locking cap. Rotate the Hex Driver counterclockwise until the set screw fully backs off from the rod and the locking cap becomes disengaged from the screw head (90° turn). Repeat for all desired screws. Remove the rod using the Rod Holder. Remove each screw using the self-retaining 3.5mm Hex Screwdriver or **Ball End Hex Driver**, if required. If the set screw strips, the locking cap can be released using the Locking Cap Driver (turning 90° counterclockwise).

![](_page_30_Picture_2.jpeg)

Removing the Locking Cap

![](_page_30_Picture_4.jpeg)

Pulling out the rod

![](_page_30_Picture_6.jpeg)

Removing a screw using the Self-Retaining Hex Screwdriver

![](_page_30_Picture_8.jpeg)

Removing a screw using the Ball End Hex Driver

## REVERE<sup>®</sup> 6.35 IMPLANT SET

![](_page_31_Picture_1.jpeg)

![](_page_31_Figure_2.jpeg)

30 |Life moves us 🍃

## REVERE® 6.35 Implant Set List 934.901

### REVERE® 6.35 Polyaxial Pedicle Screws

|   | Length<br>25mm*<br>30mm<br>35mm<br>40mm<br>45mm<br>50mm<br>55mm | Ø5.5mm<br>134.451<br>134.452<br>134.453<br>134.454<br>134.455<br>134.456<br>134.457 | Qty<br>0<br>4<br>6<br>6<br>4<br>2 | V  | Length<br>25mm<br>30mm<br>35mm<br>40mm<br>45mm<br>50mm<br>55mm<br>60mm<br>65mm | Ø6.5mm<br>134.461<br>134.462<br>134.463<br>134.464<br>134.465<br>134.466<br>134.467<br>134.468<br>134.469 | Qty<br>0<br>4<br>10<br>10<br>8<br>4<br>2<br>2 | Y | Length<br>25mm<br>30mm<br>35mm<br>40mm<br>45mm<br>50mm<br>55mm<br>60mm<br>65mm<br>70mm | Ø7.5mm<br>134.471<br>134.472<br>134.473<br>134.474<br>134.475<br>134.476<br>134.477<br>134.478<br>134.479<br>134.071<br>134.072 | Qty<br>0<br>2<br>4<br>6<br>6<br>4<br>2<br>2<br>2<br>0<br>0 |
|---|---|---|-----------------------------------|--|--|---|---|---|--|---|--|
|   | Length  | Ø8 5mm  | Otv                               | <b>6</b> B   | Length   | Ø9 0mm  | Otv   |   | 75mm<br>80mm   | 134.072   | 0  |
| U | 25mm  | 134 481   | 0                                 | U  | 25mm   | 134 491   | 0   |   | 85mm   | 134 074   | 0  |
| - | 30mm  | 134.482   | 0                                 | -  | 30mm   | 134.492   | 0   |   | 90mm   | 134.075   | 0  |
|   | 35mm  | 134.483   | 0                                 |  | 35mm   | 134.493   | 0   |   | , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,  |   |  |
|   | 40mm  | 134.484   | 0                                 |  | 40mm   | 134.494   | 0   |   |  |   |  |
|   | 45mm  | 134.485   | 0                                 |  | 45mm   | 134.495   | 0   |   |  |   |  |
|   | 50mm  | 134.486   | 0                                 |  | 50mm   | 134.496   | 0   |   |  |   |  |
|   | 55mm  | 134.487   | 0                                 |  | 55mm   | 134.497   | 0   |   |  |   |  |
|   | 60mm  | 134.488   | 0                                 |  | 60mm   | 134.498   | 0   |   |  |   |  |
|   | 65mm  | 134.489   | 0                                 | and the second s | 65mm   | 134.499   | 0   |   |  |   |  |
|   | 70mm  | 134.081   | 0                                 |  | 70mm   | 134.091   | 0   |   |  |   |  |
|   | 75mm  | 134.082   | 0                                 |  | 75mm   | 134.092   | 0   |   |  |   |  |
|   | 80mm  | 134.083   | 0                                 |  | 80mm   | 134.093   | 0   |   |  |   |  |
|   | 85mm  | 134.084   | 0                                 |  | 85mm   | 134.094   | 0   |   |  |   |  |
|   | 90mm  | 134.085   | 0                                 |  | 90mm   | 134.095   | 0   |   |  |   |  |
|   | 95mm  | 134.086   | 0                                 |  | 95mm   | 134.096   | 0   |   |  |   |  |
|   | 100mm   | 134.087   | 0                                 |  | 100mm  | 134.097   | 0   |   |  |   |  |
|   | 110mm   | 134.088   | 0                                 |  | 110mm  | 134.098   | 0   |   |  |   |  |
|   | 120mm   | 134.089   | 0                                 |  | 120mm  | 134.099   | 0   |   |  |   |  |

#### Instruments

#### Qty

| (1) | 630.407 | Quick Release 1/4", Ratchet, Straight Handle             | 2 |
|-----|---------|--|---|
| 2   | 634.406 | Quick Disconnect 1/4" Non-Ratcheting, Large Sport Handle | 1 |
| 3   | 634.408 | 3.5mm Hex Driver Self-Retaining Shaft, 1/4" Connection   | 2 |
| 4   | 634.703 | 3.5mm Hex Driver Rigid Shaft                             | 2 |
| 5   | 634.704 | 6.35 Holding Sleeve Assembly                             | 2 |

#### 934.001 REVERE® 6.35 Implant Graphic Case

\*Items highlighted in gray are additionally available.

## REVERE® 6.35 Implant Set List 934.901 (cont'd)

Qty

Qty

### 6.35mm Rods

| Str | aio | ht | Rod | s – | Ti |
|-----|-----|----|-----|-----|----|
|     |     |    |     |     |    |

| 155.530 | 6.35mm   | Straight | Rod, | 30mm  | 0 |
|---------|----------|----------|------|-------|---|
| 155.535 | 6.35mm   | Straight | Rod, | 35mm  | 0 |
| 155.540 | 6.35mm   | Straight | Rod, | 40mm  | 0 |
| 155.545 | 6.35mm   | Straight | Rod, | 45mm  | 4 |
| 155.550 | 6.35mm   | Straight | Rod, | 50mm  | 0 |
| 155.555 | 6.35mm   | Straight | Rod, | 55mm  | 4 |
| 155.560 | 6.35mm   | Straight | Rod, | 60mm  | 0 |
| 155.565 | 6.35mm   | Straight | Rod, | 65mm  | 4 |
| 155.570 | 6.35mm   | Straight | Rod, | 70mm  | 0 |
| 155.575 | 6.35mm   | Straight | Rod, | 75mm  | 4 |
| 155.580 | 6.35mm   | Straight | Rod, | 80mm  | 0 |
| 155.585 | 6.35mm   | Straight | Rod, | 85mm  | 4 |
| 155.510 | 6.35mm   | Straight | Rod, | 100mm | 4 |
| 155.512 | 6.35mm   | Straight | Rod, | 125mm | 4 |
| 155.515 | 6.35mm   | Straight | Rod, |       |   |
|         | Hex End, | 150mm    |      |       | 4 |
|         |          |          |      |       |   |

### Straight Rods – CP

| 134.530 | 6.35mm Straight Rod CP, 30mm  | 0 |
|---------|-------------------------------|---|
| 134.535 | 6.35mm Straight Rod CP, 35mm  | 0 |
| 134.540 | 6.35mm Straight Rod CP, 40mm  | 0 |
| 134.545 | 6.35mm Straight Rod CP, 45mm  | 0 |
| 134.550 | 6.35mm Straight Rod CP, 50mm  | 0 |
| 134.555 | 6.35mm Straight Rod CP, 55mm  | 0 |
| 134.560 | 6.35mm Straight Rod CP, 60mm  | 0 |
| 134.565 | 6.35mm Straight Rod CP, 65mm  | 0 |
| 134.570 | 6.35mm Straight Rod CP, 70mm  | 0 |
| 134.575 | 6.35mm Straight Rod CP, 75mm  | 0 |
| 134.580 | 6.35mm Straight Rod CP, 80mm  | 0 |
| 134.585 | 6.35mm Straight Rod CP, 85mm  | 0 |
| 134.510 | 6.35mm Straight Rod CP, 100mm | 0 |
| 134.512 | 6.35mm Straight Rod CP, 125mm | 0 |
| 134.515 | 6.35mm Straight Rod CP,       |   |
|         | Hex End, 150mm                | 0 |

| Curved R | lods – Ti                | Qty |
|----------|--------------------------|-----|
| 155.635  | 6.35mm Curved Rod, 35mm  | 4   |
| 155.640  | 6.35mm Curved Rod, 40mm  | 4   |
| 155.645  | 6.35mm Curved Rod, 45mm  | 4   |
| 155.650  | 6.35mm Curved Rod, 50mm  | 4   |
| 155.655  | 6.35mm Curved Rod, 55mm  | 4   |
| 155.660  | 6.35mm Curved Rod, 60mm  | 0   |
| 155.665  | 6.35mm Curved Rod, 65mm  | 4   |
| 155.670  | 6.35mm Curved Rod, 70mm  | 0   |
| 155.675  | 6.35mm Curved Rod, 75mm  | 4   |
| 155.680  | 6.35mm Curved Rod, 80mm  | 0   |
| 155.685  | 6.35mm Curved Rod, 85mm  | 4   |
| 155.690  | 6.35mm Curved Rod, 90mm  | 0   |
| 155.695  | 6.35mm Curved Rod, 95mm  | 0   |
| 155.610  | 6.35mm Curved Rod, 100mm | 0   |
| 155.612  | 6.35mm Curved Rod, 125mm | 0   |
| 155.615  | 6.35mm Curved Rod, 150mm | 0   |
|          |                          |     |

#### Curved Rods – CP

## Qty

| 134.635 | 6.35mm Curved | Rod C | P, 35mm  | 0 |
|---------|---------------|-------|----------|---|
| 134.640 | 6.35mm Curved | Rod C | P, 40mm  | 0 |
| 134.645 | 6.35mm Curved | Rod C | P, 45mm  | 0 |
| 134.650 | 6.35mm Curved | Rod C | P, 50mm  | 0 |
| 134.655 | 6.35mm Curved | Rod C | P, 55mm  | 0 |
| 134.660 | 6.35mm Curved | Rod C | P, 60mm  | 0 |
| 134.665 | 6.35mm Curved | Rod C | P, 65mm  | 0 |
| 134.670 | 6.35mm Curved | Rod C | P, 70mm  | 0 |
| 134.675 | 6.35mm Curved | Rod C | P, 75mm  | 0 |
| 134.680 | 6.35mm Curved | Rod C | P, 80mm  | 0 |
| 134.685 | 6.35mm Curved | Rod C | P, 85mm  | 0 |
| 134.690 | 6.35mm Curved | Rod C | P, 90mm  | 0 |
| 134.695 | 6.35mm Curved | Rod C | P, 95mm  | 0 |
| 134.610 | 6.35mm Curved | Rod C | P, 100mm | 0 |
| 134.612 | 6.35mm Curved | Rod C | P, 125mm | 0 |
| 134.615 | 6.35mm Curved | Rod C | P, 150mm | 0 |

## REVERE® 6.35 Implant Set List 934.901 (cont'd)

#### REVERE® 6.35 Variable Cross Connectors

| 134.912 | REVERE® 6.35 Variable Cross Connector, 29mm-33mm             |
|---------|--|
| 134.913 | REVERE® 6.35 Variable Cross Connector, 32mm-40mm             |
| 134.914 | REVERE® 6.35 Variable Cross Connector, 38mm-50mm             |
| 134.915 | REVERE® 6.35 Variable Cross Connector, 48mm-60mm             |
| 134.916 | REVERE® 6.35 Variable Cross Connector, 58mm-70mm             |
| 134.917 | REVERE® 6.35 Variable Cross Connector, 68mm-80mm             |
| 134.918 | REVERE <sup>®</sup> 6.35 Variable Cross Connector, 78mm-90mm |

#### Qty

1

![](_page_34_Picture_4.jpeg)

#### Locking Cap

|         |                                      | Qty |
|---------|--------------------------------------|-----|
| 134.000 | REVERE <sup>®</sup> 6.35 Locking Cap | 24  |

![](_page_34_Picture_7.jpeg)

# REVERE® 6.35 INSTRUMENT I SET

![](_page_35_Figure_1.jpeg)

![](_page_35_Picture_2.jpeg)

## REVERE<sup>®</sup> 6.35 Instrument I Set List 934.902

| Pedicle F         | Preparation Instruments             | Qty    |
|-------------------|-------------------------------------|--------|
| 1 602.101         | Pedicle Probe, Straight             | 1      |
| 2 602.102         | Pedicle Probe, Curved               | 1      |
| 3 602.104         | Pedicle Awl                         | 1      |
| 4 602.105         | Ball Tip Probe                      | 1      |
| 5 602.106         | Ball Tip Probe, Curved              | 1      |
| 6 602.109         | Pedicle Probe, Thoracic             | 1      |
| 7 624.110         | Ball Tip Probe, Double Ended        | 1      |
| 8 602.107         | Pedicle Marker, Notched             | 4      |
| 9 602.108         | Pedicle Marker, Beaded              | 4      |
| 10 634.213        | 4.0mm Tap                           | 1      |
| 11 655.214        | 4.5mm Tap                           | 1      |
| 12 655.215        | 5.5mm Tap                           | 1      |
| 13 655.216        | 6.5mm Tap                           | 1      |
| 14 655.217        | 7.5mm Tap                           | 1      |
|                   |                                     |        |
| Screw In          | sertion Instruments                 | Qty    |
| 15 630.411        | Ball End Hex Driver Shaft           | 2      |
|                   |                                     |        |
| Rod Mar           | nipulation Instruments              | Qty    |
| <b>16</b> 602.521 | Rod Holder                          | 1      |
| (17) 634.511      | 6.35 Rod Lever                      | 1      |
| 18 634.513        | 6.35 Rod Pusher                     | 1      |
| 19 602.501        | Rod Template, 150mm                 | 1      |
|                   |                                     |        |
| Screw Lo          | ocking Instruments                  | Qty    |
| 20 634.601        | 6.35 Locking Cap Driver             | 2      |
| (21) 634.602      | 6.35 Locking Cap Guide              | 1      |
| Veriable          |                                     | 0.5    |
|                   | Veriable Cross Connector Instrument | Qty    |
| 2 034.006         | variable Cross Connector Inserter   | I      |
| Other In          | struments                           |        |
| 23 634 402        | 6 35 Screw Head Positioner          | 1      |
| 24 634 514        | 6 35 Soft Tissue Retractor          | י<br>1 |
|                   | 0.55 Soft HSuc Netractor            | I      |

934.002 REVERE® 6.35 Instrument I Graphic Case

![](_page_37_Picture_1.jpeg)

![](_page_37_Picture_2.jpeg)

## REVERE® 6.35 Instrument II Set List 934.903

| Screw In  | sertion Instruments   | Qty         |
|-----------|---|-------------|
| 1 634.405 | 3.5mm Hex Screwdriver Shaft, 1/4" Connection                    | 2           |
| 2 634.604 | Quick Disconnect 1/4", 3.5mm<br>Ratcheting Torque Limiting T- H | 1<br>landle |
| Rod Man   | ipulation Instruments   | Qty         |
| 3 634.506 | Power Bender  | 1           |
| 4 634.522 | Rod Gripper, 6.35 Rod   | 1           |
| 5 624.503 | Parallel Compressor   | 1           |
| 6 624.504 | Parallel Distractor   | 1           |
| 7 634.505 | 6.35 Rod Reducer, Ratcheted                                     | 1           |
| 8 634.800 | 6.35 Tower Reducer  | 2           |
| 9 624.801 | T-Handle, Tower   | 1           |
| Screw Lo  | cking Instruments   | Qty         |
|           |   |             |

10 634.603 6.35 Final Tightening Counter Torque 1

#### Variable Cross Connector Instruments Qty

- 11 634.605 Variable Cross Connector Template 1
- 12 602.430 Torque Limiting 2.5mm Hex Driver 1

#### 934.003 REVERE® 6.35 Instrument II Graphic Case

Additionally Available Instruments

- 655.218 8.5mm Tap
- 634.219 9.0mm Tap
- 634.706 3.5mm Hex Driver, 1/4" Connect, Long
- 602.508 Rod Cutter
- 634.611 3.5mm Torque Limiting Driver Ratcheting 1/4" Connect, SS
- 630.401 Quick Release 1/4", Ratchet, T-Handle

## REVERE<sup>®</sup> 6.35 DUAL OUTER DIAMETER SCREW IMPLANT SET

![](_page_39_Picture_1.jpeg)

## REVERE<sup>®</sup> 6.35 Dual Outer Diameter Screw Implant Set List 934.912

#### REVERE® 6.35 Dual Outer Diameter Screws

| 0.0        | Length | Ø5.5mm  | Qty | - O D | Length | Ø6.0mm  | Qty | - 0 1   | Length | Ø6.5mm  | Qty |
|------------|--------|---------|-----|-------|--------|---------|-----|---------|--------|---------|-----|
| U          | 30mm*  | 134.751 | 0   |       | 30mm   | 134.761 | 0   | U       | 30mm   | 134.771 | 0   |
|            | 35mm   | 134.752 | 0   |       | 35mm   | 134.762 | 2   | Y       | 35mm   | 134.772 | 2   |
| 袋          | 40mm   | 134.753 | 0   | - 12  | 40mm   | 134.763 | 2   | 影       | 40mm   | 134.773 | 2   |
| 18         | 45mm   | 134.754 | 0   |       | 45mm   | 134.764 | 2   | 豊       | 45mm   | 134.774 | 2   |
| 服          | 50mm   | 134.755 | 0   |       | 50mm   | 134.765 | 2   | 整       | 50mm   | 134.775 | 2   |
| 招          | 55mm   | 134.756 | 0   | 1     | 55mm   | 134.766 | 2   | 「「「「「」」 | 55mm   | 134.776 | 2   |
| 10         | 60mm   | 134.757 | 0   | 吾     | 60mm   | 134.767 | 2   | 蠹       | 60mm   | 134.777 | 2   |
|            | 65mm   | 134.758 | 0   | 100   | 65mm   | 134.768 | 0   | 畫       | 65mm   | 134.778 | 0   |
|            |        |         |     | -     |        |         |     | 1       | 70mm   | 134.779 | 0   |
|            |        |         |     |       |        |         |     | 8       | 75mm   | 134.171 | 0   |
|            |        |         |     |       |        |         |     |         | 80mm   | 134.172 | 0   |
|            |        |         |     |       |        |         |     |         | 85mm   | 134.173 | 0   |
|            |        |         |     |       |        |         |     |         | 90mm   | 134.174 | 0   |
| <b>0</b> D | Length | Ø7.0mm  | Qty |       | Length | Ø7.5mm  | Qty |         | 95mm   | 134.175 | 0   |
| U          | 30mm   | 134.781 | 0   | U     | 30mm   | 134.791 | 0   |         | 100mm  | 134.176 | 0   |
|            | 35mm   | 134.782 | 2   |       | 35mm   | 134.792 | 0   |         |        |         |     |
| 鍲          | 40mm   | 134.783 | 2   | 静     | 40mm   | 134.793 | 0   |         |        |         |     |
| 邘          | 45mm   | 134.784 | 2   | 報     | 45mm   | 134.794 | 0   |         |        |         |     |
| 掍          | 50mm   | 134.785 | 2   | 报     | 50mm   | 134.795 | 0   |         |        |         |     |
| 报          | 55mm   | 134.786 | 2   | 报     | 55mm   | 134.796 | 0   |         |        |         |     |
| 長          | 60mm   | 134.787 | 2   | 靜     | 60mm   | 134.797 | 0   |         |        |         |     |
| 夏          | 65mm   | 134.788 | 0   | 11    | 65mm   | 134.798 | 0   |         |        |         |     |
| 髢          | 70mm   | 134.789 | 0   | 長     | 70mm   | 134.799 | 0   |         |        |         |     |
| 鸖          | 75mm   | 134.181 | 0   | 盤     | 75mm   | 134.191 | 0   |         |        |         |     |
| 18         | 80mm   | 134.182 | 0   | 臣     | 80mm   | 134.192 | 0   |         |        |         |     |
|            | 85mm   | 134.183 | 0   | 8     | 85mm   | 134.193 | 0   |         |        |         |     |
|            | 90mm   | 134.184 | 0   |       | 90mm   | 134.194 | 0   |         |        |         |     |
|            | 95mm   | 134.185 | 0   |       | 95mm   | 134.195 | 0   |         |        |         |     |
|            | 100mm  | 134.186 | 0   |       | 100mm  | 134.196 | 0   |         |        |         |     |
|            | 110mm  | 134.187 | 0   |       | 110mm  | 134.197 | 0   |         |        |         |     |
|            | 120mm  | 134.188 | 0   |       | 120mm  | 134.198 | 0   |         |        |         |     |

#### 934.012 REVERE® 6.35 Dual Outer Diameter Screw Graphic Case

\*Items highlighted in gray are additionally available.

## STAINLESS STEEL REVERE® 6.35 IMPLANT SET 934.909

![](_page_41_Picture_1.jpeg)

![](_page_41_Picture_2.jpeg)

40 Life moves us

## Stainless Steel REVERE® 6.35 Implant Set List 934.909

#### SS REVERE® 6.35 Polyaxial Pedicle Screws

| 11        | Length | Ø5.5mm  | Qty      | 11                                      | Length | Ø6.5mm  | Qty | 11     | Length | Ø7.5mm  | Qty |
|-----------|--------|---------|----------|---|--------|---------|-----|--------|--------|---------|-----|
| Υ.        | 25mm*  | 234.451 | 0        |   | 25mm   | 234.461 | 0   | Ŷ      | 25mm   | 234.471 | 0   |
| - THE     | 30mm   | 234.452 | 4        | WW                                      | 30mm   | 234.462 | 4   | 000    | 30mm   | 234.472 | 2   |
| WW        | 35mm   | 234.453 | 4        |   | 35mm   | 234.463 | 4   | anne - | 35mm   | 234.473 | 4   |
| 889       | 40mm   | 234.454 | 6        | No.                                     | 40mm   | 234.464 | 10  | MMM    | 40mm   | 234.474 | 6   |
| MMM       | 45mm   | 234.455 | 6        |   | 45mm   | 234.465 | 10  | 88     | 45mm   | 234.475 | 6   |
| 000       | SUMM   | 234.456 | 4        | 999                                     | SUMM   | 234.466 | 8   |        | SUMM   | 234.476 | 4   |
| 8         | SSMM   | 234.457 | Ζ        | - A - A - A - A - A - A - A - A - A - A | SSMM   | 234.467 | 4   | 8      | SSMM   | 234.477 | 2   |
|           |        |         |          | ×                                       | 60mm   | 234.468 | 2   | - Mar  | 60mm   | 234.478 | 2   |
|           |        |         |          |   | 65MM   | 234.469 | Z   |        | 65mm   | 234.479 | 2   |
|           |        |         |          |   |        |         |     |        | 70mm   | 234.071 | 0   |
|           |        | ~~ F    | <b>.</b> |   |        | ~~~     |     |        | /Smm   | 234.072 | 0   |
| U         | Length | Ø8.5mm  | Qty      | - 11                                    | Length | Ø9.0mm  | Qty |        | 80mm   | 234.073 | 0   |
| N.        | 25mm   | 234.481 | 0        |   | 25mm   | 234.491 | 0   |        | 85mm   | 234.074 | 0   |
|           | 30mm   | 234.482 | 0        | 2                                       | 30mm   | 234.492 | 0   |        | 90mm   | 234.075 | 0   |
| <b>W</b>  | 35mm   | 234.483 | 0        | W                                       | 35mm   | 234.493 | 0   |        |        |         |     |
| AW I      | 40mm   | 234.484 | 0        |   | 40mm   | 234.494 | 0   |        |        |         |     |
| <b>HH</b> | 45mm   | 234.485 | 0        | H                                       | 45mm   | 234.495 | 0   |        |        |         |     |
|           | 50mm   | 234.486 | 0        |   | 50mm   | 234.496 | 0   |        |        |         |     |
| <b>WW</b> | 55mm   | 234.487 | 0        |   | 55mm   | 234.497 | 0   |        |        |         |     |
| <b>W</b>  | 60mm   | 234.488 | 0        | H                                       | 60mm   | 234.498 | 0   |        |        |         |     |
| \$        | 65mm   | 234.489 | 0        | Ŧ                                       | 65mm   | 234.499 | 0   |        |        |         |     |
|           | 70mm   | 234.081 | 0        | *                                       | 70mm   | 234.091 | 0   |        |        |         |     |
|           | 75mm   | 234.082 | 0        |   | 75mm   | 234.092 | 0   |        |        |         |     |
|           | 80mm   | 234.083 | 0        |   | 80mm   | 234.093 | 0   |        |        |         |     |
|           | 85mm   | 234.084 | 0        |   | 85mm   | 234.094 | 0   |        |        |         |     |
|           | 90mm   | 234.085 | 0        |   | 90mm   | 234.095 | 0   |        |        |         |     |
|           | 95mm   | 234.086 | 0        |   | 95mm   | 234.096 | 0   |        |        |         |     |
|           | 100mm  | 234.087 | 0        |   | 100mm  | 234.097 | 0   |        |        |         |     |
|           | 110mm  | 234.088 | 0        |   | 110mm  | 234.098 | 0   |        |        |         |     |
|           | 120mm  | 234.089 | 0        |   | 120mm  | 234.099 | 0   |        |        |         |     |

| _   | Instrum | ents   | Qty |
|-----|---------|--|-----|
| (1) | 630.407 | Quick Release 1/4", Ratchet, Straight Handle             | 2   |
| (2) | 634.406 | Quick Disconnect 1/4" Non-Ratcheting, Large Sport Handle | 1   |
| 3   | 634.408 | 3.5mm Hex Driver Self-Retaining Shaft, 1/4" Connection   | 2   |
| 4   | 634.703 | 3.5mm Hex Driver Rigid Shaft                             | 2   |
| 5   | 634.704 | 6.35 Holding Sleeve Assembly                             | 2   |
|     |         |  |     |

934.009 SS REVERE® 6.35 Implant Graphic Case

## Stainless Steel REVERE® 6.35 Implant Set List 934.909 (cont'd)

#### SS 6.35mm Diameter Rods

| Straight | Rods – SS                                 |
|----------|---|
| 234.530  | 6.35mm Straight Rod SS, 30mm              |
| 234.535  | 6.35mm Straight Rod SS, 35mm              |
| 234.540  | 6.35mm Straight Rod SS, 40mm              |
| 234.545  | 6.35mm Straight Rod SS, 45mm              |
| 234.550  | 6.35mm Straight Rod SS, 50mm              |
| 234.555  | 6.35mm Straight Rod SS, 55mm              |
| 234.560  | 6.35mm Straight Rod SS, 60mm              |
| 234.565  | 6.35mm Straight Rod SS, 65mm              |
| 234.570  | 6.35mm Straight Rod SS, 70mm              |
| 234.575  | 6.35mm Straight Rod SS, 75mm              |
| 234.580  | 6.35mm Straight Rod SS, 80mm              |
| 234.585  | 6.35mm Straight Rod SS, 85mm              |
| 234.510  | 6.35mm Straight Rod SS, 100mm             |
| 234.512  | 6.35mm Straight Rod SS, 125mm             |
| 234.515  | 6.35mm Straight Rod SS,<br>Hex End, 150mm |

|     |          |                             | 9   |
|-----|----------|-----------------------------|-----|
| Qty | Curved F | Rods – SS                   | Qty |
| 0   | 234.635  | 6.35mm Curved Rod SS, 35mm  | 4   |
| 0   | 234.640  | 6.35mm Curved Rod SS, 40mm  | 4   |
| 0   | 234.645  | 6.35mm Curved Rod SS, 45mm  | 4   |
| 4   | 234.650  | 6.35mm Curved Rod SS, 50mm  | 4   |
| 0   | 234.655  | 6.35mm Curved Rod SS, 55mm  | 4   |
| 4   | 234.660  | 6.35mm Curved Rod SS, 60mm  | 0   |
| 0   | 234.665  | 6.35mm Curved Rod SS, 65mm  | 4   |
| 4   | 234.670  | 6.35mm Curved Rod SS, 70mm  | 0   |
| 0   | 234.675  | 6.35mm Curved Rod SS, 75mm  | 4   |
| 4   | 234.680  | 6.35mm Curved Rod SS, 80mm  | 0   |
| 0   | 234.685  | 6.35mm Curved Rod SS, 85mm  | 4   |
| 4   | 234.690  | 6.35mm Curved Rod SS, 90mm  | 0   |
| 4   | 234.695  | 6.35mm Curved Rod SS, 95mm  | 0   |
| 4   | 234.610  | 6.35mm Curved Rod SS, 100mm | 0   |
|     | 234.612  | 6.35mm Curved Rod SS, 125mm | 0   |
| 4   | 234.615  | 6.35mm Curved Rod SS, 150mm | 0   |

Qty

1

1

24

#### SS REVERE® 6.35 Variable Angle Cross Connectors

SS REVERE® 6.35 Variable Cross Connector, 29mm-33mm 234.912 234,913 SS REVERE® 6.35 Variable Cross Connector, 32mm-40mm 234.914 SS REVERE® 6.35 Variable Cross Connector, 38mm-50mm 234.915 SS REVERE® 6.35 Variable Cross Connector, 48mm-60mm SS REVERE® 6.35 Variable Cross Connector, 58mm-70mm 234.916 SS REVERE® 6.35 Variable Cross Connector, 68mm-80mm 234.917 234.918 SS REVERE® 6.35 Variable Cross Connector, 78mm-90mm

![](_page_43_Picture_6.jpeg)

SS Locking Cap

234.000 REVERE® 6.35 Locking Cap

\*Items highlighted in gray are additionally available.

![](_page_43_Picture_10.jpeg)

#### **IMPORTANT INFORMATION ON THE REVERE® 6.35 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, staples, 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 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 and trans iliac connectors.

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\* rods are composed of titanium alloy, commercially pure titanium, or stainless steel, as specified in ASTM F136, F1472, F1295, F67, and F138. All other REVERE\* implants are composed of titanium alloy or stainless steel, as specified in ASTM F136, F1472, F1295, and F138. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium or titanium alloy implants.

#### 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, kvohosis, 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 LS-51 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, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/lilium.

When used as an anterolateral thoracolumbar system, the REVERE<sup>®</sup> Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc discase (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.

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

#### 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.

#### ATTENTION

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled "Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices" for a complete list of potential risks.

#### 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.

#### CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

- Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
- Remove all traces of blood and other such residues immediately. Do not allow these to dry.
- The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
- 4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- 5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
- 6. Dry instruments immediately after cleaning.

#### 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 may be provided sterile or non-sterile. Sterile implants and instruments are sterilized by gamma radiation to ensure a sterility assurance level of 10<sup>-6</sup> SAL. The expiration date is provided in the package label. Sterile implants and instruments that are provided STERILE should be considered sterile unless the packaging has been opened or damaged.

Non-sterile REVERE\* implants and instruments have been validated to assure a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. 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.* 

#### Implants:

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

| Method | Cycle Type  | Temperature                     | Exposure Time | Drying Time |
|--------|---|---------------------------------|---------------|-------------|
| Steam  | Gravity Displacement<br>(Wrapped)                 | 132° - 135°C<br>(270° - 275° F) | 28 Minutes    | 0 Minutes   |
| Steam  | Pre-vacuum (Wrapped)<br>Preconditioning Pulses: 3 | 132° - 135°C<br>(270° - 275° F) | 4 Minutes     | 0 Minutes   |

#### Instruments:

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

| Method | Cycle Type  | Temperature                     | Exposure Time | Drying Time |
|--------|---|---------------------------------|---------------|-------------|
| Steam  | Gravity Displacement<br>(Wrapped)                 | 132° - 135°C<br>(270° - 275° F) | 25 Minutes    | 45 Minutes  |
| Steam  | Pre-vacuum (Wrapped)<br>Preconditioning Pulses: 3 | 132° - 135°C<br>(270° - 275° 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.

CAUTION: Federal (U.S.A) Law Restricts this Device to Sale by or on the order of a Physician.

# Notes

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![](_page_47_Picture_0.jpeg)

![](_page_47_Picture_1.jpeg)

Globus Medical Valley Forge Business Center 2560 General Armistead Avenue Audubon, PA 19403 www.globusmedical.com

 Customer Service:

 Phone
 1-866-GLOBUS1 (or 1-866-456-2871)

 Fax
 1-866-GLOBUS3 (or 1-866-456-2873)

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ECTREP: RMS – UK Limited 28 Trinity Road, Nailsea, Somerset, BS484NU England

![](_page_47_Picture_6.jpeg)