OPERATIVE TECHNIQUE

PHOENIX™
Minimally Invasive Spinal Fixation System

# Minimally Invasive Posterior Fixation

ORTHOFIX®

**Orthofix wishes to thank the following surgeon for his contribution to the development of this technique:**

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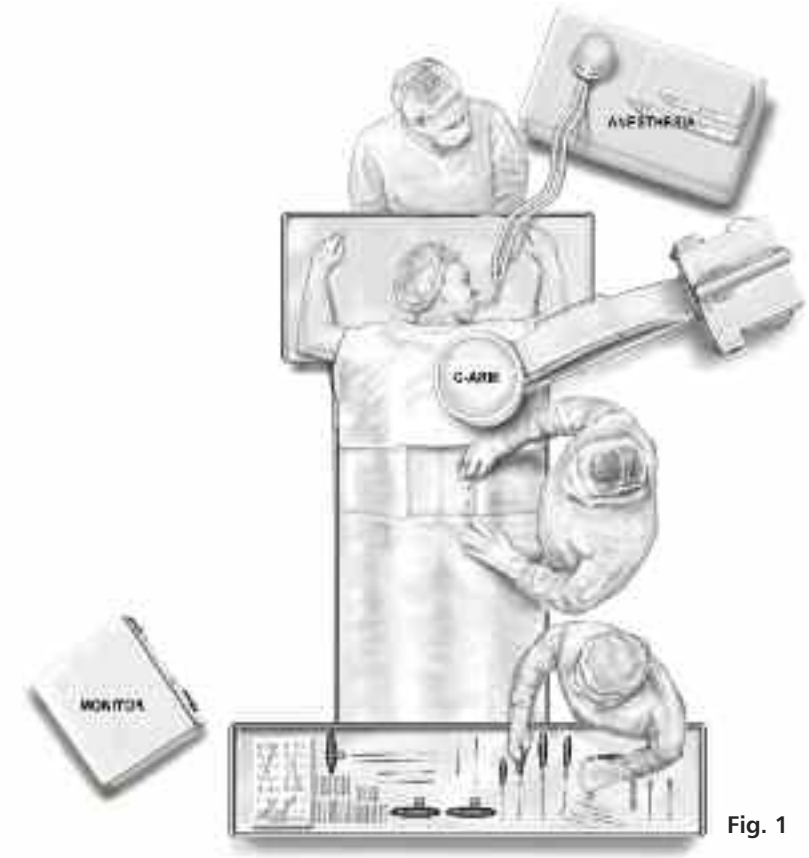


Fig. 1

## 1. PATIENT POSITIONING

Position the patient in the prone position. A/P and lateral fluoroscopy should be used to provide proper imaging. **(Fig. 1)**

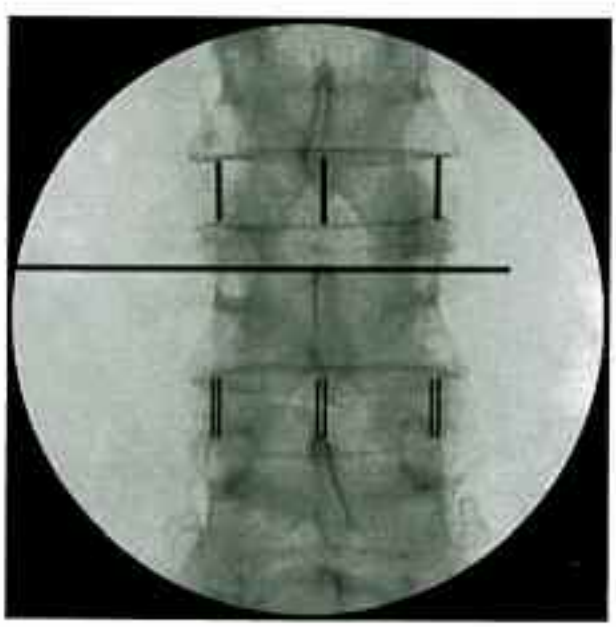

Fig. 2a

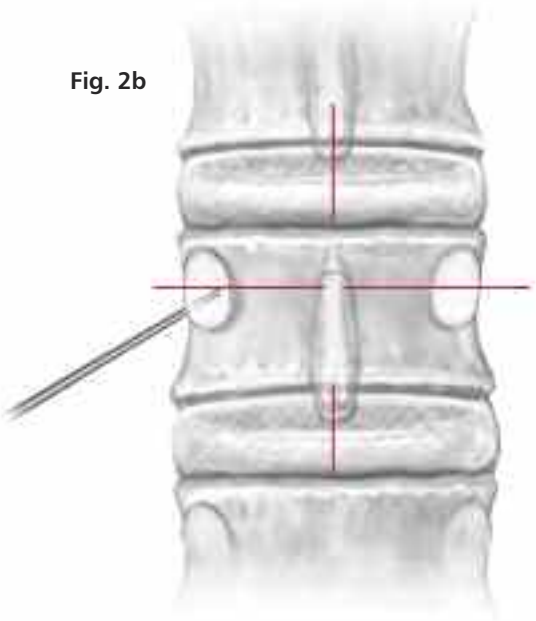

Fig. 2b

## 2. PEDICLE IDENTIFICATION AND INCISION PLANNING

Attain an A/P fluoro with spinous process aligned and end plates parallel to each other. **(Fig. 2a)**

Verify the lateral edge of the pedicle ovals are close to the lateral edge of the vertebral body. **(Fig. 2b)** The top of the ovals for both pedicles should be parallel and equidistant from the end plate. **(Fig. 2c)**

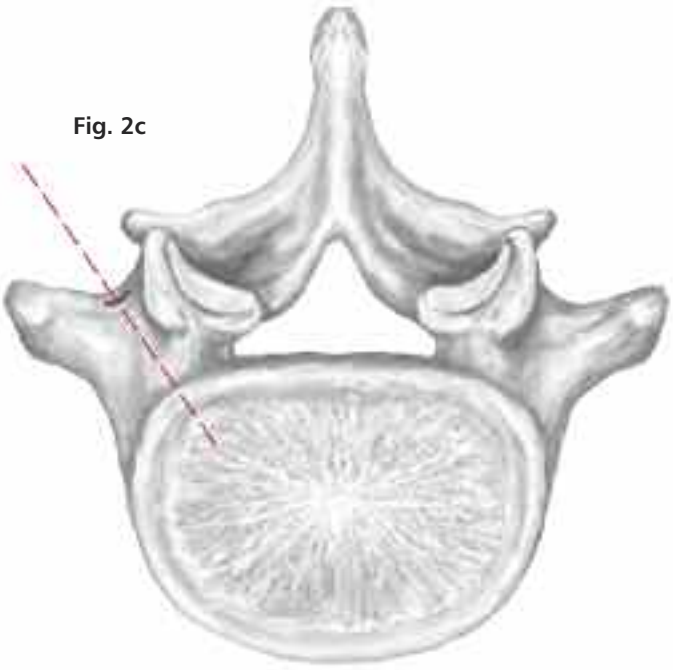

Fig. 2c

**Incision for Mini on both sides using TLIF**

**Incision for Mini on both sides using PLIF**

Incision placement will depend on the surgical approach and minimally invasive technique used to place the rod. The four figures provide common options when performing a single level fusion.

**Incision for Mini on left sides and percutaneous on right using TLIF**

**Incision for Mini on left sides using TLIF and percutaneous on right using TLIF**

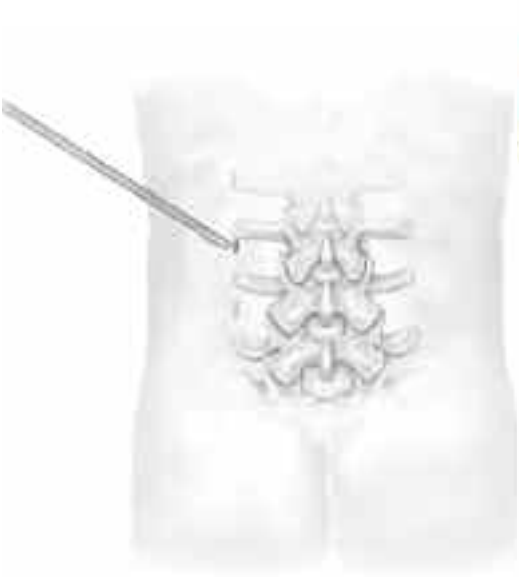

Fig. 3a

Fig. 3b

Fig. 3c

## 3. INCISION AND GUIDE WIRE INSERTION

Locate and make the first incision as defined in the incision planning step. The incision is approximately 14mm in length to match the diameter of the Phoenix Screw Body. **(Fig. 3a)**

Insert the Pedicle Targeting Needle into the pedicle entry point and advance under AP fluoro to ensure that the Pedicle Targeting Needle is not medial to the medial border of the pedicle prior to the entrance into the vertebral body. Multiple Pedicle Targeting Needles can be placed in succession prior to switching to lateral fluoro to check superior/inferior angulation. **(Fig. 3b)**

Remove the inner stylet of the pedicle targeting needle. Insert the Guidewire (20-0123, 20-0124) through the Pedicle Targeting Needle and place the Guidewire into the mid portion of the vertebral body on the lateral view. **(Fig. 3c)**

Fig. 4a

## 4. TISSUE DILATION AND PEDICLE TAPPING

**Assembly of Dilator/Awl/Tap Instrument**

Choose the appropriate diameter Tap, 5.5, 6.5 or 7.5mm (20-0155, 20-0165, 20-0175) based on surgeon preference and bone quality. Each Tap has a color band on the proximal end that corresponds the Tap diameter to the same color of the Screw. Assemble the T-Handle (52-1011) or a Straight Handle (52-1013) onto Tap. Next, assemble the Tap Sleeve Dilator (20-0275) onto the Tap until it lines up with the zero mark on the Tap. Advance the Tap Dilator until it engages the first groove on the Tap, this is your starting position for insertion into the incision. The Dilator will be retained in this position until the Release Button is depressed. A visual inspection is recommended to comfirm the awl portion of the Tap thread is protruding through the tip of the Tap sleeve. **(Fig. 4a)**

**NOTE:** If pedicle screw monitoring is to be performed, there is a non-conductive dilator (20-0218) that should be placed over Dilator/Awl/Tap instrument prior to use.

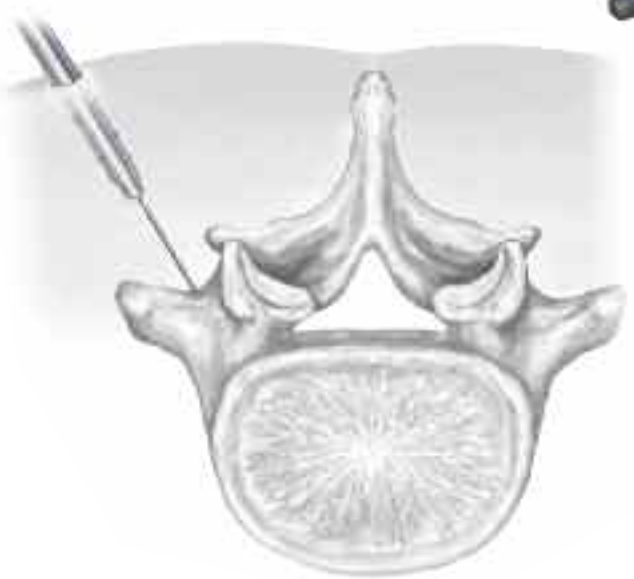

Fig. 4b

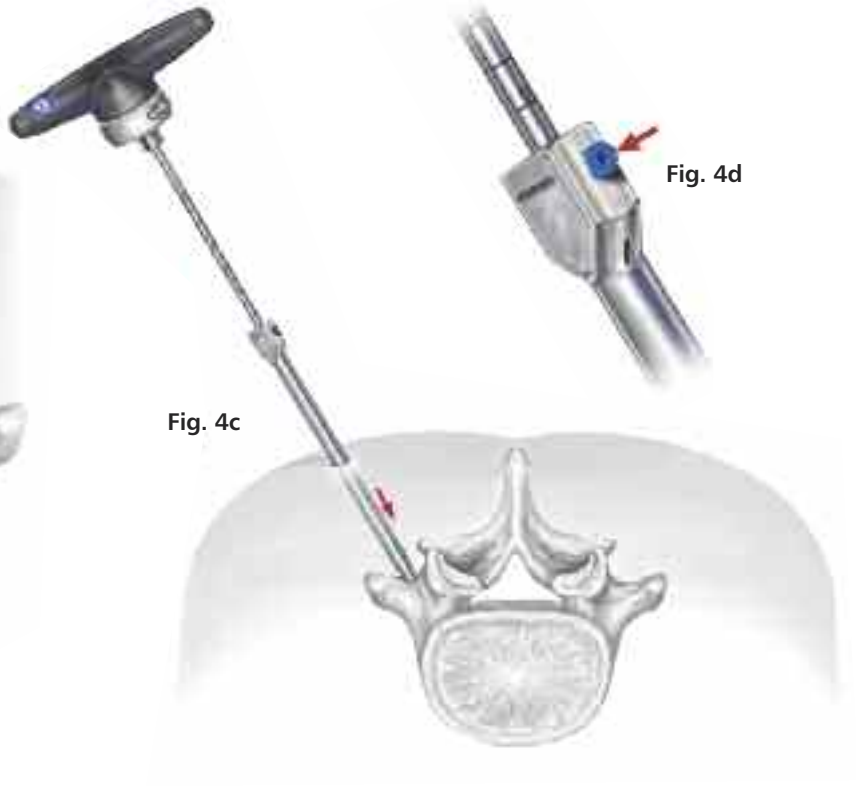

Fig. 4c

Fig. 4d

**Tissue Dilation**

Place Tap with assembled Dilator over the Guide Wire **(Fig. 4b)** and advance through the tissue using a twisting motion. **(Fig. 4c)** Once the Tap engages the bone, push the Release Button to allow the Tap Sleeve Dilator to move freely so the Awl and tapping can occur. **(Fig. 4d)**

The Tap Sleeve Dilator has measurements to indicate the appropriate length of Phoenix Screw Bodies to be used. **(Fig. 4e)** Generally, the Short is used for the thoracic region and Standard and Long are used in the lumbar region based on patient size. Sometimes a longer size may be preferred in a longer construct to reach the anterolisthesed segment of a spondylolisthesis.

It is ideal to have approximately 50% of the reduction head visible above the surface of the skin as indicated in the figure. **(Fig. 4e)**

A Non-Conductive Dilator (20-0218) can be placed on the Tap Sleeve Dilator if stimulation of the Tap is desired.

Fig. 4e

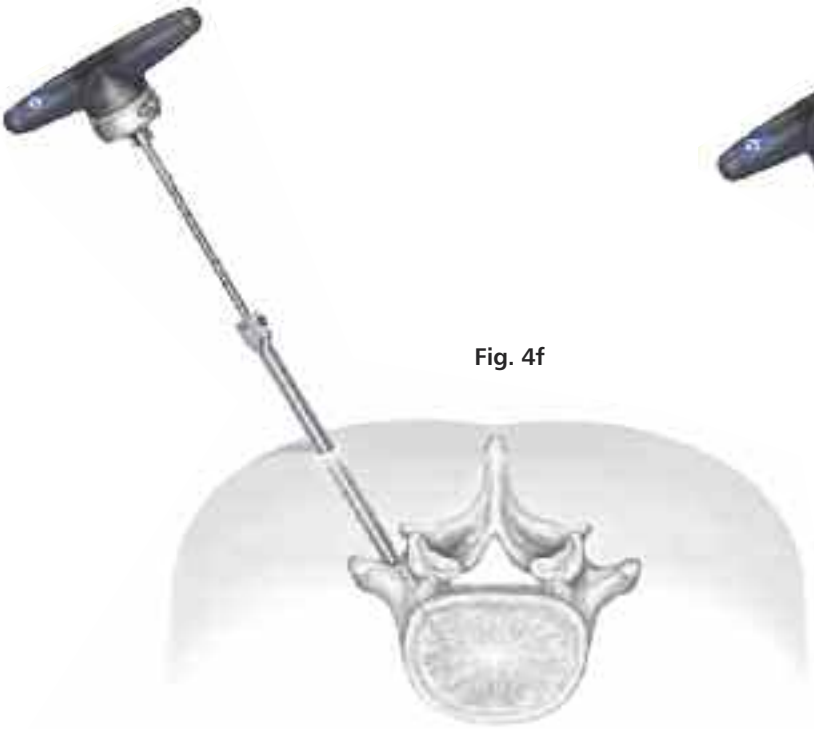

Fig. 4f



Fig. 4g

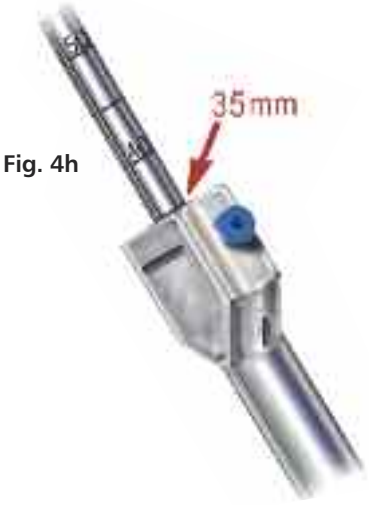


Fig. 4h

**Awl**

The instrument has a sharp tip design functioning as a Bone Awl to perforate the pedicle bone so tapping can occur. Use a clockwise twisting motion to break through the cortex. **(Fig. 4f)**

**Tapping**

Continue a clockwise motion for tapping the bone. **(Fig. 4g)** Use periodic fluoroscopy to check on depth and proper alignment. When the Tap is at the desired depth, the screw length is measured by reading the scale on the Tap. **(Fig. 4h)** The Dilator must be in contact with the pedicle bone surface to achieve accurate measurement.

Remove the Tap Assembly leaving Guide Wire and Dilator (non-conductive) if desired behind.

Fig. 5a

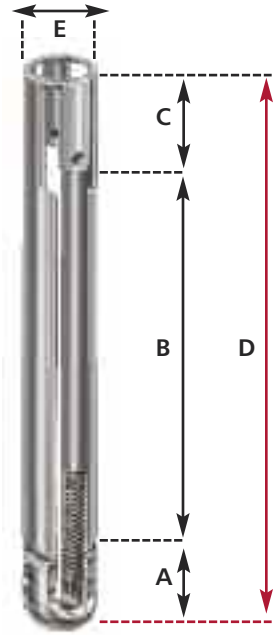


Fig. 5b

## 5. MULTI-AXIAL SCREW PLACEMENT

### Implant Selection

There are two Phoenix Body styles to accommodate different rod passing techniques. The closed (magenta) Phoenix Bodies are only used at the end of a construct and are optional based on surgeon preference. The closed style can also be used to guide the Rod into place for mini-open techniques.

The open (green) Phoenix Bodies are used in multi-level constructs and can also be used at the end of constructs based on surgeon preference.

See Step 4 – The Dilator has measurements to indicate the appropriate length of Phoenix Bodies to be used. Generally, the Short is used for thoracic region and Standard and Tall are used for lumbar based on patient size.

Sometimes a longer size may be preferred in a longer construct to reach the anterolisthesed segment of a spondylolisthesis.

It is ideal to have approximately 50% of the reduction head visible above the surface of the skin. **(Fig. 4e and 5b)**

| Phoenix Screw Body Styles | Dimension A Height of Saddle | Dimension B From Top of Saddle to Bottom of Tab | Dimension C Height of Tab | Dimension D Overall Phoenix Length | Dimension E Diameter |
|---|---|---|---|---|---|
| **Short** | 16mm | 70mm | 18mm | 104mm | 14mm |
| **Standard** | 16mm | 90mm | 18mm | 124mm | 14mm |
| **Tall** | 16mm | 120mm | 18mm | 154mm | 14mm |

Fig. 5b chart

Fig. 5c

Fig. 5d

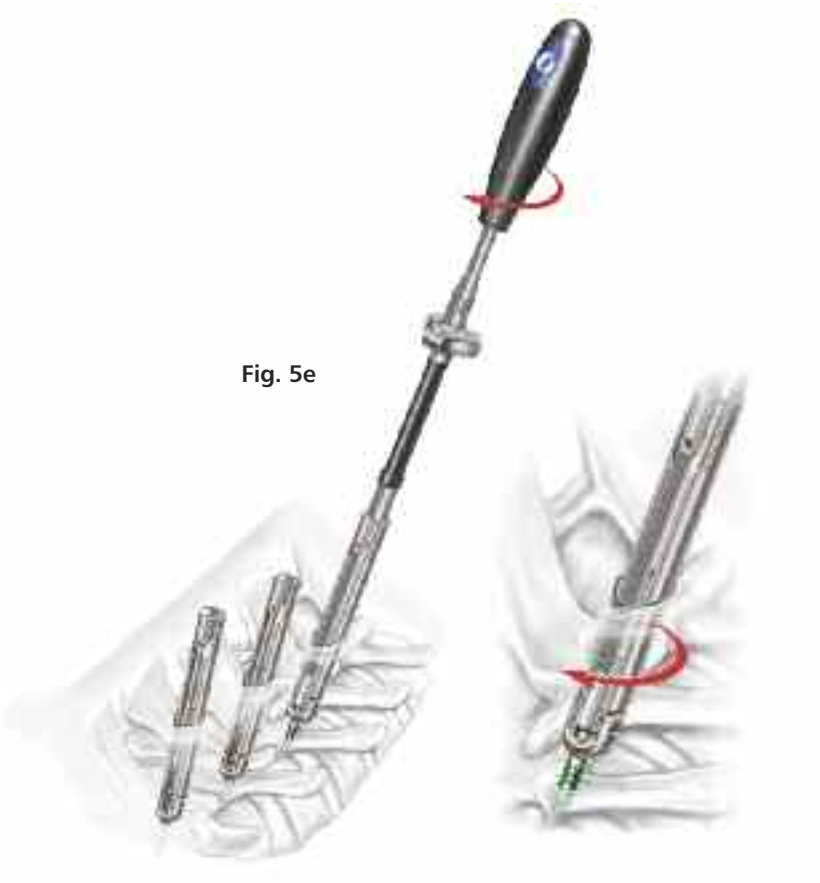

Fig. 5e

**Screw Driver Assembly**

Attach the appropriate modular Phoenix Screw Body onto to the desired Firebird™ Modular Screw. Confirm a secure connection by pulling on the Screw.

Insert the Screwdriver (20-0200) with either the Straight Handle (52-1013) or the T-Handle (52-1011) into Phoenix Screw Body and engage the tip of the Screwdriver with the hex of the Modular Screw. **(Fig. 5c)** Rotate the knob on a Screwdriver in a clockwise direction to assemble the Head of the Screw onto the Screwdriver Tip. **(Fig. 5d)** Confirm the Screw is solidly attached to the Screwdriver and do not overtighten.

Using the Screwdriver, drive the Multi-Axial Screw of appropriate length over the Guide Wire into the prepared Pedicle. Remove the Guide Wire after the Screw enters the vertebral body. **(Fig. 5e)** Periodically check with fluoro to ensure proper Screw placement based on surgeon preference. Over-insertion of Screw may limit poly-axial motion of the Reduction Head. Once the Screw is seated to the appropriate level, turn the Knob in a counter-clockwise direction and remove the Screwdriver.

**NOTE:** If for any reason the Phoenix Screw needs to be adjusted after the Screwdriver is removed, there is modular Multi-Axial Adjustment Screw Driver (20-0201) that mates with the Straight Handle (52-1013) to easily advance or withdraw the Screw.

Place the remaining Screws using the same technique by repeating Steps 3 to 6.

**NOTE:** Preparation of disc space may occur before or after Screw placement based on surgeon preference.

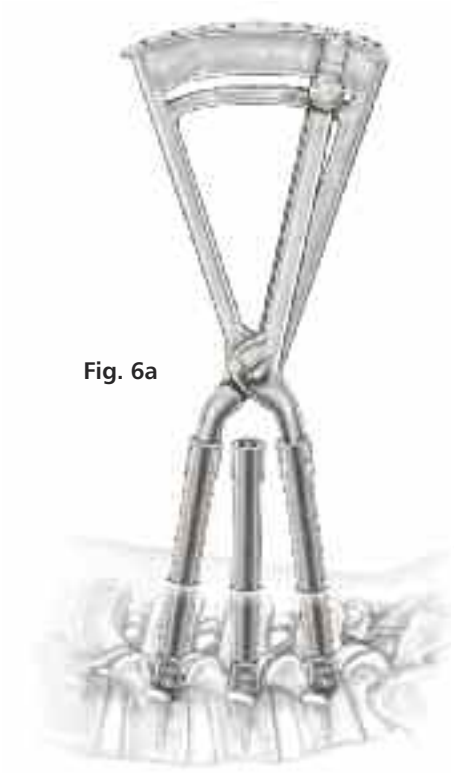

Fig. 6a

Fig. 6b

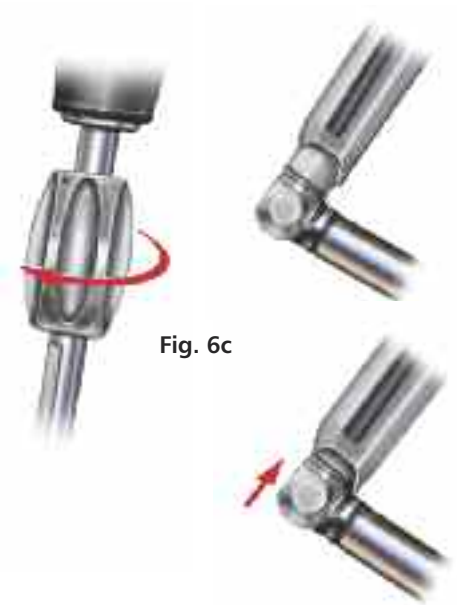

Fig. 6c

## 6. ROD INSERTION – ROD LENGTH

**Determination**

The Rod Sizing Tool (20-0205) is inserted into the most proximal and distal Phoenix Screw Body and the reading is taken from the markings on the scale. **(Fig. 6a)** This is a direct measurement and no additional numeric addition is necessary to determine proper length. Example: if the measurement tool reads 100mm, then select a 100mm Lordoctic Hex Rod. Both ends of the Caliper must be inserted until they contact the screw head to ensure an accurate measurement. This technique works up to a maximum of 150mm. The option exists to cut and bend Rods as required.

**Rod Inserter Assembly**

Align the Hex end of the Rod with the Hex mating features of the Rod Holder (20-0214). Check to make sure the black etch line is positioned facing upward as shown. Firmly push the Hex into the Rod Inserter until it is fully seated. **(Fig. 6b)** Rotate the knob on the Inserter in a clockwise motion to draw the Rod upwards until the front surface of the tip aligns and is engaged in the undercut feature of the Rod. **(Fig. 6c)** This will prevent the Rod from becoming disengaged during insertion.

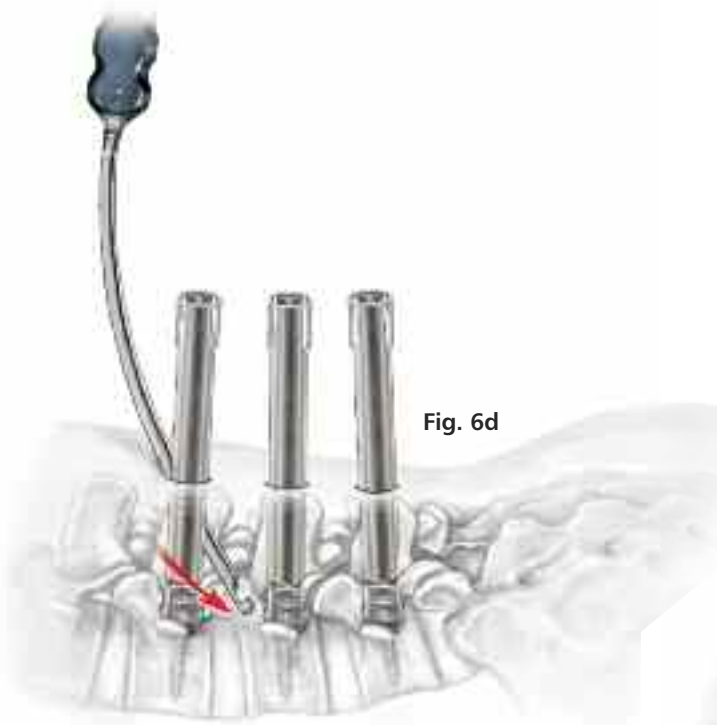

Fig. 6d

Fig. 6e

Fig. 6f

**Option: Creating a Tunnel for Rod**

The Tissue Dissector (20-0283) may be used to create a tunnel for passing the Rod into position. The distal tip of the Tissue Dissector is passed through the end of the construct with the hook facing down or towards the spine. **(Fig. 6d)** Advance the instrument through each Phoenix Screw Saddle until it passes to the opposite end of the construct. Slowly pull the instrument back which will dissect the tissue with distal hook of the instrument.

**Percutaneous Rod Passing**

This technique requires use of the open body for the end of the construct where the Rod is to be introduced. Align the openings of the Phoenix Bodies by hand to facilitate easy passing of the Rod. A Body Alignment Tool (20-0212) is available to align the openings if tissue or bone prevents positioning by hand. The leading tapered end of the Rod is passed through the open channel in the Phoenix Screw Body until it passes below the surface of the skin directed toward the adjacent Screw Head. **(Fig. 6e)** The trailing edge is pushed down the open channel until both ends are seated within the Polyaxial Screw Heads.

The Rod Pusher (20-0210) can be inserted down the Phoenix Screw Body to seat the Rod into position. **(Fig. 6f)**

Fig. 7a

Fig. 7b

## 7a. SET SCREW INSERTION AND ROD REDUCTION

The Rod is brought into correct position and is stabilized with Rod Holder. The Set Screws are assembled onto the Set Screw Holders (20-0250, 20-0260) and held in place by depressing the button on the top of the handle. The Set Screws are inserted into each Phoenix Screw Body and are used to seat the Rod into the Impant Saddle. **(Fig. 7a)**

The instrument set contains two long Set Screw Holders and one short Set Screw Holder. The two different lengths of Inserters allow for simultaneous tightening of the Set Screws in tight working spaces as shown in figure. The round handle design eliminates the issues with the interference of using T-Handles side-by-side. A/P and lateral fluoroscopic views can be used to ensure proper Rod positioning and the extent of reduction. **(Fig. 7b)** There are two Round Handles (20-0211) that can be placed on the existing set screw handle, if a larger grip surface is desired. They can also be used to provide greater force when reducing a spondylolisthesis.

Fig. 7c

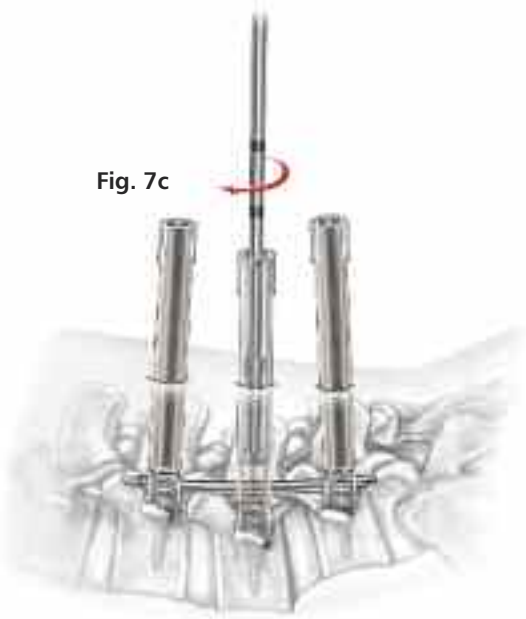

Fig. 7d

## 7b. ALTERNATIVE STEP FOR TREATMENT OF SPONDYLOLISTHESIS: SET SCREW INSERTION AND ROD REDUCTION

The built-in reduction capability is also useful for reducing a spondylolisthesis by first provisionally tightening one Set Screw followed by tightening of the anterolishesed segment to establish deformity correction.

Fully seat the set screws in the Phoenix Screw Bodies on either side of the vertebrae with the spondylolisthesis. Then insert the Set Screw on the vertebrae with spondylolisthesis. **(Fig. 7c)**

Advancing the Screw provides the reduction force to align the vertebrae. Make sure the black lines on the set screw holder shaft indicate the set screw is fully seated. **(Fig. 7d)** There are two Round Handles (20-0211) that can be placed on the existing set screw handle, if a larger grip surface is desired. They can also be used to provide greater force when reducing a spondylolisthesis.

**Compression**

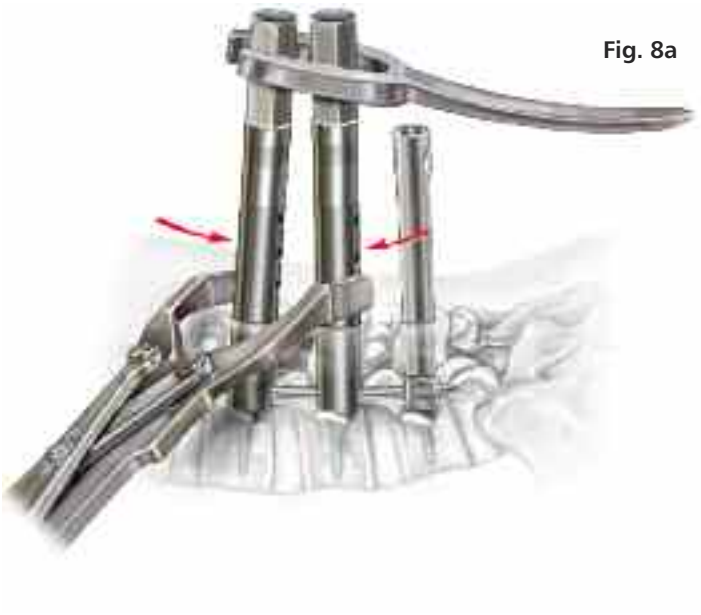

**Fig. 8a**

**Distraction**

**Fig. 8b**

## 8a. COMPRESSION

Slide the Torque Wrench Cannulas (20-0226) over each Phoenix Screw Body to which you are going to apply compression forces. Application of compression forces without use of the cannulas in not recommended. The slot in the end of the Cannula is aligned and engages the rod. Slide the Alignment Tool (70-3221) over the top of the cannulas and draw the cannulas together with either upward or downward force on the handle of the alignment tool. Alternative method – The compression/distraction fixture (20-0220) can be used in place of the alignment tool (70-3221). Adjust the fixture to the desired width
and lock the adjustment nut on the fixture. This is a surgeon preference.

Attach the compression instrument (70-3218) to the holes in the cannulas closet to the level of the skin. Compress the Cannulas to the desired level and proceed to final tightening of set screws. **(Fig.8a)**

## 8b. DISTRACTION

Slide the Torque Wrench Cannulas (20-0226) over each Phoenix Screw Body to which you are going to apply distraction forces. Application of distraction forces without use of the cannulas in not recommended. The slot in the end of the Cannula is aligned and engages the rod. Slide the compression/distraction fixture (20-0220) over the top of the cannulas. Adjust the fixture to the desired width and lock the adjustment nut on the fixture. Assemble the distraction tips (left 70-3220 & right 70-3222) on distraction instrument (70-3219) and attach to the holes in the cannulas closet to the level of the skin. Distract the Cannulas to the desired level and proceed to final tightening of set screws. **(Fig.8b)**

Fig. 9

Fig. 10a

Fig. 10b

## 9. FINAL TIGHTENING

The Torque Wrench Cannula slides over the Phoenix Screw Body and has two distal openings to engage the Rod. The Counter Torque Wrench Handle (20-0225) slides over the hex end of the Cannula. The Torque T-Handle (55-1068) attached to the Set Screw Driver (52-1061) is passed down the Phoenix Screw Body and mates with the Set Screw. **OPTIONAL – When the use of Compression or Distractioning is not desired, then a one piece Counter Torque Wrench (20-0224) can be used in place of the modular instruments.** Turn the Torque T-Handle (55-1068) clockwise to tighten the Set Screw to 100 in/lbs. The handle will reach its maximum torque and release at 100 in/lbs. **(Fig.9)**

## 10. TAB REMOVAL

Position the three claws on the small end of the Implant Tab Removal Tool (20-0280) below one of the small tabs on the Phoenix Screw Body and use an upward motion to engage the claws of the tool onto the tab. Rotate the handle downward causing the small end to rotate up and the small tab will break free of the Phoenix Screw Body. Perform the same steps on the opposite side. **(Fig.10a)** The small tabs can be discarded or recycled.

Slide the large opening of the Implant Tab Removal tool over the large tab on one side of the Phoenix Screw. Move the handle away from the midline and then back to midline until the large tab dissociates from the Phoenix Screw Head. Perform the same steps on the remaining tab. **(Fig.10b)** The larger tabs can be discarded or recycled.

## PHOENIX™ IMPLANT CASE, 20-0017

### Phoenix™ Implant Case

| Part Number | Description | Quantity |
|---|---|---|
| 20-0111 | Implant Case (Empty) | 1 |

### Phoenix™ Bodies

| Part Number | Description | Quantity |
|---|---|---|
| 20-2070 | Phoenix™ Open Body, Short | 18 |
| 20-2090 | Phoenix™ Open Body, Standard | 18 |
| 20-2120 | Phoenix™ Open Body, Tall | 18 |
| 20-3070 | Phoenix™ Closed Body, Short | 4 |
| 20-3090 | Phoenix™ Closed Body, Standard | 4 |
| 20-3120 | Phoenix™ Closed Body, Tall | 4 |

### Firebird™ Set Screws

| Part Number | Description | Quantity |
|---|---|---|
| 44-2001 | Set Screw | 30 |

### Firebird™ Cannulated Modular Screw/Self Tapping

| Part Number | Description | Quantity |
|---|---|---|
| 77-8535 | 5.5mm / 35mm | 6 |
| 77-8540 | 5.5mm / 40mm | 8 |
| 77-8545 | 5.5mm / 45mm | 8 |
| 77-8550 | 5.5mm / 50mm | 6 |
| 77-8555 | 5.5mm / 55mm | 4 |
| 77-8635 | 6.5mm / 35mm | 4 |
| 77-8640 | 6.5mm / 40mm | 10 |
| 77-8645 | 6.5mm / 45mm | 12 |
| 77-8650 | 6.5mm / 50mm | 10 |
| 77-8655 | 6.5mm / 55mm | 4 |
| 77-8740 | 7.5mm / 40mm | 4 |
| 77-8745 | 7.5mm / 45mm | 6 |
| 77-8750 | 7.5mm / 50mm | 6 |
| 77-8755 | 7.5mm / 55mm | 4 |
| 77-8840 | 8.5mm / 40mm | 2 |
| 77-8845 | 8.5mm / 45mm | 2 |

### Phoenix™ Lordotic Rods with Hex

| Part Number | Description | Quantity |
|---|---|---|
| 20-4035 | Pre-Lordosed Rod w/hex and taper, 35mm | 4 |
| 20-4040 | Pre-Lordosed Rod w/hex and taper, 40mm | 4 |
| 20-4045 | Pre-Lordosed Rod w/hex and taper, 45mm | 4 |
| 20-4050 | Pre-Lordosed Rod w/hex and taper, 50mm | 4 |
| 20-4055 | Pre-Lordosed Rod w/hex and taper, 55mm | 4 |
| 20-4060 | Pre-Lordosed Rod w/hex and taper, 60mm | 4 |
| 20-4065 | Pre-Lordosed Rod w/hex and taper, 65mm | 4 |
| 20-4070 | Pre-Lordosed Rod w/hex and taper, 70mm | 4 |
| 20-4075 | Pre-Lordosed Rod w/hex and taper, 75mm | 4 |
| 20-4080 | Pre-Lordosed Rod w/hex and taper, 80mm | 4 |
| 20-4090 | Pre-Lordosed Rod w/hex and taper, 90mm | 4 |
| 20-4100 | Pre-Lordosed Rod w/hex and taper, 100mm | 4 |
| 20-4110 | Pre-Lordosed Rod w/hex and taper, 110mm | 4 |
| 20-4120 | Pre-Lordosed Rod w/hex and taper, 120mm | 4 |
| 20-4130 | Pre-Lordosed Rod w/hex and taper, 130mm | 4 |
| 20-4140 | Pre-Lordosed Rod w/hex and taper, 140mm | 4 |
| 20-4150 | Pre-Lordosed Rod w/hex and taper, 150mm | 4 |

### Phoenix™ Straight Rods with Hex

| Part Number | Description | Quantity |
|---|---|---|
| 20-5040 | Straight Rod w/hex and taper, 40mm | 2 |
| 20-5050 | Straight Rod w/hex and taper, 50mm | 2 |
| 20-5060 | Straight Rod w/hex and taper, 60mm | 2 |
| 20-5070 | Straight Rod w/hex and taper, 70mm | 2 |
| 20-5080 | Straight Rod w/hex and taper, 80mm | 2 |
| 20-5090 | Straight Rod w/hex and taper, 90mm | 2 |
| 20-5100 | Straight Rod w/hex and taper, 100mm | 2 |
| 20-5110 | Straight Rod w/hex and taper, 110mm | 2 |
| 20-5120 | Straight Rod w/hex and taper, 120mm | 2 |
| 20-5140 | Straight Rod w/hex and taper, 140mm | 2 |
| 20-5160 | Straight Rod w/hex and taper, 160mm | 2 |
| 20-5180 | Straight Rod w/hex and taper, 180mm | 2 |
| 20-5200 | Straight Rod w/hex and taper, 200mm | 2 |
| 20-5450 | Straight Rod w/hex, 450mm | 2 |

## PHOENIX™ INSTRUMENT CASE 1, 20-0015

### Instruments

| Part Number | Description | Quantity |
|---|---|---|
| **20-0101** | Instrument Case 1 (Empty) | 1 |
| **20-0123** | Guide Wire Nitinol, 21 inch - Blunt (1.57mm Dia) | 10 |
| **20-0124** | Guide Wire Nitinol, 21 inch - Sharp (1.57mm Dia) | 10 |
| **20-0155** | 5.5mm Tap | 1 |
| **20-0165** | 6.5mm Tap | 1 |
| **20-0175** | 7.5mm Tap | 1 |
| **20-0200** | Screw Driver | 2 |
| **20-0201** | Modular Multi-axial Adjustment Screw Driver | 1 |
| **20-0205** | Rod Sizing Tool | 1 |
| **20-0210** | Rod Pusher | 1 |
| **20-0211** | Round Set Screw Inserter Handle | 2 |
| **20-0212** | Body Alignment Instrument | 1 |
| **20-0214** | Rod Holder/Inserter | 1 |

| Part Number | Description | Quantity |
|---|---|---|
| **20-0218** | Non-Conductive Dilator | 2 |
| **20-0224** | Counter Torque Wrench | 1 |
| **20-0250** | Set Screw Holder Long | 2 |
| **20-0251** | Set Screw Holder Long Insert | 2 |
| **20-0260** | Set Screw Holder Short | 1 |
| **20-0261** | Set Screw Holder Short Insert | 1 |
| **20-0275** | Tap Sleeve Dilator | 2 |
| **20-0280** | Implant Tab Removal Tool | 1 |
| **20-0283** | Tissue Dissector | 1 |
| **52-1011** | Cannulated Firebird T-handle | 2 |
| **52-1013** | Straight Ratcheting Handle, Small | 2 |
| **52-1061** | Set Screw Driver (adapter) | 2 |
| **70-3208** | Proview Rod Inserter | 1 |

## PHOENIX™ INSTRUMENT CASE 2, 20-0016

### Instruments

| Part Number | Description | Quantity |
|---|---|---|
| **20-0120** | Instrument Case 2 (Empty) | 1 |
| **20-0220** | Compression/Distraction Fixture | 1 |
| **20-0225** | Counter Torque Wrench Handle | 1 |
| **20-0226** | Counter Torque Cannula | 2 |
| **55-1068** | Torque T-Handle | 1 |

| Part Number | Description | Quantity |
|---|---|---|
| **70-3218** | Parallel Compressor | 1 |
| **70-3219** | Parallel Distractor | 1 |
| **70-3220** | Distractor Tip Left | 1 |
| **70-3221** | Alignment Tool | 1 |
| **70-3222** | Distractor Tip Right | 1 |

### Other Instruments

| Part Number | Description |
|---|---|
| **21-5000** | Bone Marrow Aspiration Needle Kit |

Description: The Phoenix MIS Multiaxial Extended Reduction Screw Bodies are used with the Firebird Spinal Fixation System, which is a temporary, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine. The Firebird Spinal Fixation System consists of an assortment of pedicle screws, set screws, lateral offsets, bone screws, and screw bodies. The Firebird Spinal Fixation System implants are not compatible with components or metal from any other manufacturer's system.

Indications: The Phoenix MIS Components and the Firebird Spinal Fixation System are intended for posterior, non-cervical pedicle fixation. The system is limited to use in skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

The Phoenix MIS Components and the Firebird Spinal Fixation System components are used with certain components of the SFS system, including rod connectors and cross-connectors.

Contraindications include, but are not limited to:
1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Any circumstances not listed under the heading indications.

Potential Adverse Events:
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:
1. Device component fracture
2. Loss of fixation
3. Non-union
4. Fracture of the vertebra
5. Neurological injury
6. Vascular or visceral injury
7. Early or late loosening of any or all of the components
8. Disassembly and/or bending of any or all components
9. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
10. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
12. Infection
13. Pain, discomfort, or abnormal sensations due to the presence of the device
14. Hemorrhage
15. Cessation of any potential growth of the operated portion of the spine
16. Death

Note: Potential risks identified with the use of the device system may require additional surgery.

Warnings and Precautions:
1. The safety and effectiveness of pedicle screw 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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
2. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
4. Single use only
5. Non-sterile; the screws, rods, dominos, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.
6. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
7. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
8. Excessive torque applied to the screws may strip the threads in the bone.
9. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
10. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
11. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
12. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the titanium alloy or cobalt chrome alloy components of this system with implants of other material composition or components from different manufacturers unless specifically stated.
13. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.

Instructions for Use: See actual package insert for Instructions for Use.

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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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