

**SOLCO.**

# 4CIS<sup>®</sup> CHIRON-XT

MINIMALLY INVASIVE SURGERY

*Surgical Technique*

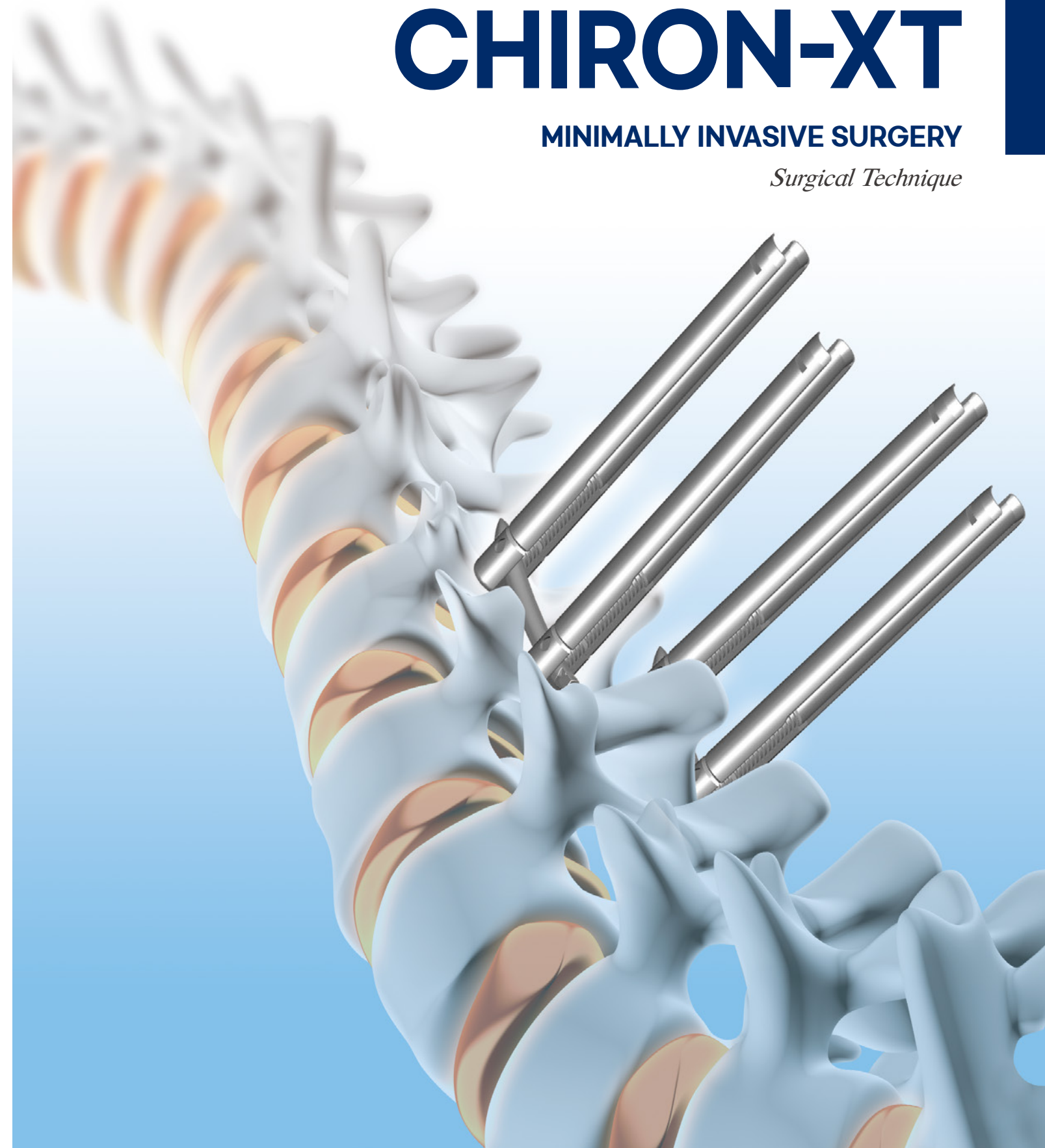


**FG Corp.**

Add : 5072 W Plano Pkwy, Suite 210, Plano Texas 75093

Tel : 972-247-2486 E-mail : [info@fg-solco.com](mailto:info@fg-solco.com)

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# 4CIS® CHIRON-XT

## MINIMALLY INVASIVE SURGERY

*Surgical Technique*



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# SYSTEM OVERVIEW

## Introduction

Minimal invasive spine surgery has several advantages over traditional open techniques. Smaller incisions and minimal muscle resection, markedly decrease operating time, blood loss and postoperative pain. The 4CIS® Chiron-XT Poly Cannulated Screw System was created to offer a less invasive surgical option for pedicle screw placement. The system incorporates anatomically driven solutions such as self-tapping cannulated polyaxial screws and pre-lordosed rods. The instrumentation is ergonomically designed to allow for true percutaneous. The 4CIS® Chiron-XT Poly Cannulated Screw System offers a simple, precise and efficient solution to spinal fixation.

## Intended Use

When used as a posterior, non-cervical pedicle screw system, the 4CIS® Chiron-XT Poly Cannulated 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 of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
  - Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebrae
  - Degenerative spondylolisthesis
  - Trauma (i.e., fracture or dislocation)
- Spinal stenosis
  - Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
  - Tumor
  - Pseudoarthrosis
  - Failed previous fusion

## Preoperative Planning

When using the 4CIS® Chiron-XT Poly Cannulated Screw System, the patient should be positioned prone on a radiolucent table. Chest rolls may be used, but the knee-to-chest position should be avoided. Using fluoroscopic imaging, it should be verified that the true views of both anterior-posterior (A/P) and lateral images of the spine (views which adequately delineate pedicle morphology and geometry) are obtainable. It is also recommended that preoperative planning be used to help determine a proper entry point and trajectory. After identifying the pedicle entry point, a targeting needle and a guide should be used to initiate the starting entry point. Adjustments to the entry angle and the trajectory should be made as often as needed with the assistance of fluoroscopic imaging until the proper position is attained.

**Note.** This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Features & Benefits



- Integrated Rod Reduction**  
Ensures proper thread alignment while reducing and locking the rod in one simplified step.
- Minimized Muscle Disruption**  
Extended screw heads provide a minimized outer diameter to help reduce muscle disruption.
- Friction fit Poly-axial Screw Head**  
Chiron XT Screw head is designed to maintain position for rod placement.

Specification



Chiron-XT Poly Cannulated Screw



Chiron-XT Poly Cannulated Screw (Half Closed Type)

OPERATIVE TECHNIQUE

STEP 1 : Pedical Preparation

Pedicle Identification

It is recommended that preoperative planning is used to help determine the proper entry point and trajectory as the starting point is not usually at the point directly over the pedicle. Identify the operative levels using A/P and lateral fluoroscopy. Plan the entry point to target the pedicle from a transverse trajectory lateral to the facet. Make an incision through the skin and fascia. The typical starting point is 3-4cm off the midline. Insert the Targeting Needle and the Guide down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy. Adjustments to the entry angle and the trajectory should be made until the proper position is attained. Advance the Targeting Needle and the Guide down through the pedicle. Once proper placement is confirmed, remove the inner stylet of the targeting needle.



Figure 1



Figure 2



Figure 3



Guidewire Placement

Insert the Guidewire through the cannulated target needle and advance the Guidewire just past the tip of the Targeting Guide. Use caution when advancing the Guidewire under fluoroscopy ensure the location of the Guidewire. Once the Guidewire is in place remove the Targeting needle and leave the Guidewire in place.

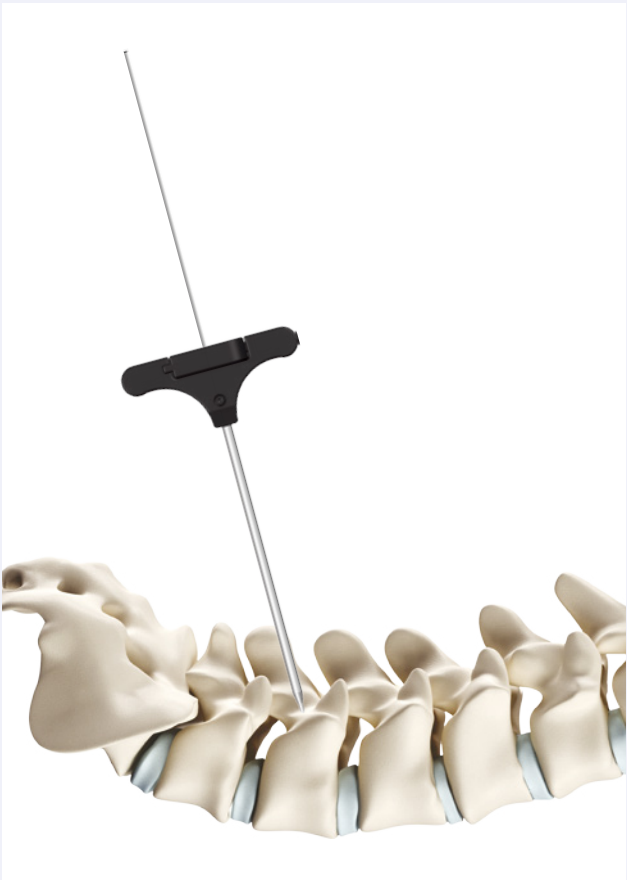


Figure 4



Figure 5

Tissue Dilation

A longitudinal incision about 1.5cm is made through the skin and fascia. An incision of 1.5cm will facilitate the insertion of the Dilators used later in the procedure. Prepare a pathway to the pedicle by sequentially using dilators 1,2 and 3. Once the Large Dilator is placed remove the inner Dilators and place them over the adjacent Guidewire. Leave the Large Dilator in place to protect the soft tissue while tapping.



Figure 6



Figure 7

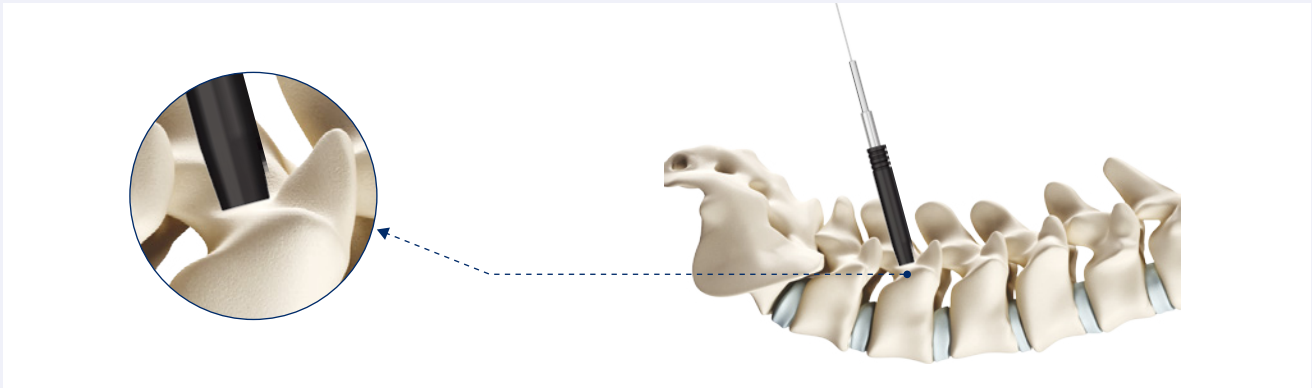


Figure 8

## Tapping

Attach the appropriate Tap size to the preferred handle. Place the tap over the Guidewire and through the Large Dilator to the surface of the pedicle. The depth markers on the Tap shaft where the Tap shaft meets the top of the Large Dilator are used to monitor insertion. They can also be used to determine screw length. Once desired depth has been achieved remove tap while maintaining control of guidewire.

**Caution:** Use fluoroscopy to monitor advancement during tapping.



Figure 9

## STEP 2 : Screw Insertion

### Screw driver assembly

Insert the screwdriver with the preferred handle through the blades of The 4CIS® Chiron-XT Poly Cannulated Screw System and engage the tip of the screwdriver with Hexalobe head of the screw. Rotate the screwdriver knob in a clockwise to assemble the tip of screw driver into the head of the screw. Ensure the screw is firmly attached to the screw driver.

### Screw implanting

Guide the screwdriver assembly over the guide wire and into pedicle. advance the screw to the desired depth and verify placement under fluoroscopy. After screw placement, remove the screwdriver and the guidewire. Rotate the screwdriver knob in a counter clockwise and gently pull out the screwdriver through the blade of the screw.

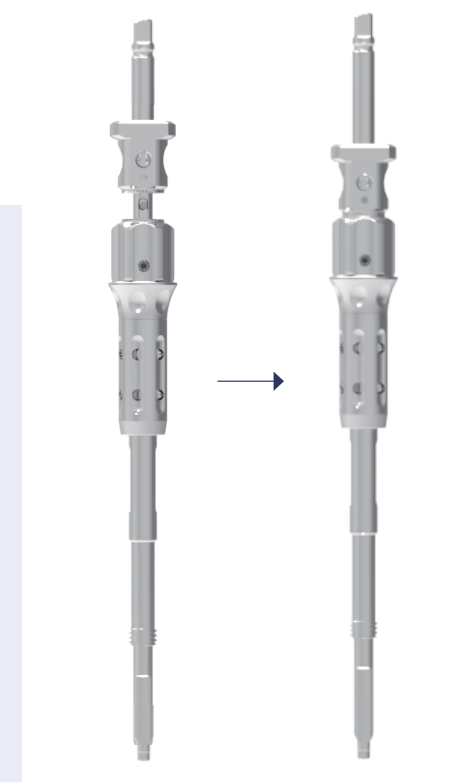


Figure 10



Figure 11



Figure 12



Figure 13

## STEP 3 : Rod Measurement

Align the screws and the Rod Length Gauge will allow you to measure the exact length of the Rod needed. Assemble the Rod Length Gauge to the proximal end of the screws. Based on the Screw positions the pointer will indicate the appropriate Rod length on the Gauge. Read rod measurement length from size marking on caliper, if the pointer falls between measurements the measurement should be rounded up to the next rod length. After determining the Rod length, remove the rod gauge.

### *Rod Bending & Guide*

*The French Rod Bender is allowed to contour the pre-determined rod if necessary.*



Figure 14



Figure 15

## STEP 4 : Rod Insertion

Place an appropriate length of the pre-bent rod at the end tip of the Rod holder and and rotate the handle on the top of the Rod Holder clock-wise.

This will securely lock the rod in the insertion position.

Pass the pre-bent rod through the window of the first screw blade. When the tip of the rod reaches the top of the screw head, advance the rod through the muscle to the top of the next screw and confirm the rod position using fluoroscopy.

At the position of the Rod Holder for the angle of 90 degrees, pushing downward the rod through the Rod Holder will be achieved to seat the rod into the pedicle screw heads.



Figure 16

STEP 5 : Initial Tightenting

Fixing Sleeve Insertion

After the rod is loaded into the bottom of the head of the screw, put a Fixing Sleeve over a blade of 4CIS<sup>®</sup> Chiron-XT Poly Cannulated Screw and apply another Fixing Sleeve over a blade of adjacent 4CIS<sup>®</sup> Chiron-XT Poly Cannulated Screw.

Nut Insertion

Load the Nut on the Nut Starter, and the Nut is inserted into the each screw head until it is fully seated.



Figure 17



Figure 18

STEP 6 : Final Tightening

Fit Torque Stabilizer over the exterior of the fixing sleeve and secure the screw with the Torque Stabilizer.  
Attach the Torque Limit Handle to the Nut final Driver.  
With the Driver, tighten the nut inserted into the each screw.



Figure 19



Figure 20



Figure 21



Figure 22

STEP 7 : Compression & Distraction

The Compression-Distraction tool will allow you to compress or distract the operable level and maintaining position.

Compression

Attach the tool as close as possible to the surface of the skin. The bar, which acts as a fulcrum, is inserted and above the pivot point between the two sleeve.

Distraction

Attach the tool as close as possible to the surface of the skin. The bar, which acts as a fulcrum, is inserted and below the pivot point between the two sleeves. Provisionally tighten one of the set screws and then apply force to the handle of the Compression-Distraction tool.



Figure 23



Figure 24

STEP 8 : Tap Removal

4CIS<sup>®</sup> Chiron-XT Poly Cannulated Screw is designed with breakaway features for easy removal after locking the construct. First, Remove the Fixing Sleeve and Rod Inserter. Then, gently position the 4CIS<sup>®</sup> Screw Head Positioner on the top of the 4CIS<sup>®</sup> Chiron-XT Poly Cannulated Screw after final tightening has taken place. Ensure the 4CIS<sup>®</sup> Screw Head Positioner is firmly seated in the extended tap. Rock the Breaker in a back and forth motion until tabs away from the screw and it may be required a repeated procedure a few times to ensure the breakage.

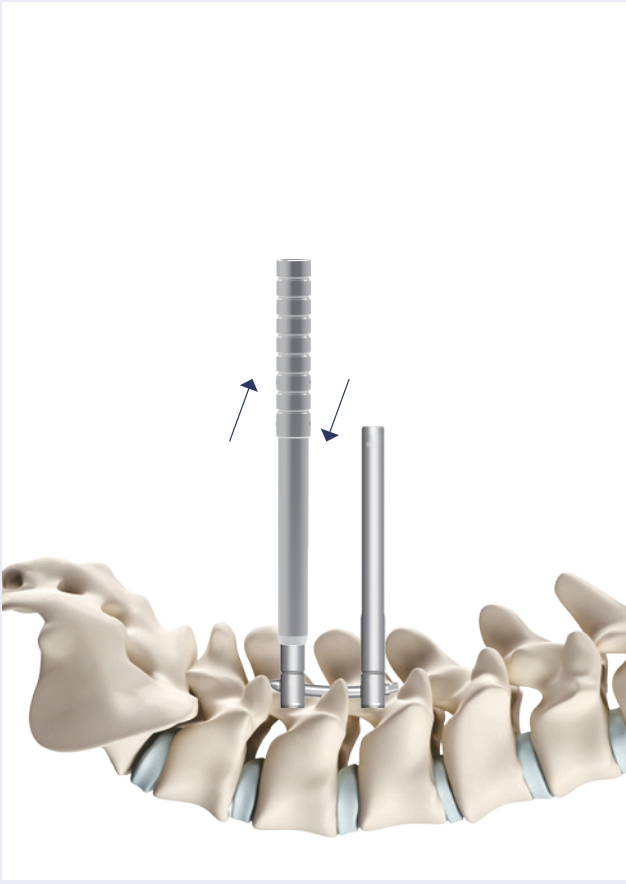


Figure 25



Figure 26









Poly Cannulated Screw (Half Closed Type)			
Catalog No.	Description	Size	
4151-9020	Poly Cannulated Screw (Half Closed Type)	Ø 9.0	145.45mm
4151-9025	Poly Cannulated Screw (Half Closed Type)		150.45mm
4151-9030	Poly Cannulated Screw (Half Closed Type)		155.45mm
4151-9035	Poly Cannulated Screw (Half Closed Type)		160.45mm
4151-9040	Poly Cannulated Screw (Half Closed Type)		165.45mm
4151-9045	Poly Cannulated Screw (Half Closed Type)		170.45mm
4151-9050	Poly Cannulated Screw (Half Closed Type)		175.45mm
4151-9055	Poly Cannulated Screw (Half Closed Type)		180.45mm
4151-9060	Poly Cannulated Screw (Half Closed Type)		185.45mm
4151-9065	Poly Cannulated Screw (Half Closed Type)		190.45mm
4151-9070	Poly Cannulated Screw (Half Closed Type)		195.45mm
4151-9075	Poly Cannulated Screw (Half Closed Type)		200.45mm
4151-9080	Poly Cannulated Screw (Half Closed Type)		205.45mm
4151-9520	Poly Cannulated Screw (Half Closed Type)	Ø 9.5	145.45mm
4151-9525	Poly Cannulated Screw (Half Closed Type)		150.45mm
4151-9530	Poly Cannulated Screw (Half Closed Type)		155.45mm
4151-9535	Poly Cannulated Screw (Half Closed Type)		160.45mm
4151-9540	Poly Cannulated Screw (Half Closed Type)		165.45mm
4151-9545	Poly Cannulated Screw (Half Closed Type)		170.45mm
4151-9550	Poly Cannulated Screw (Half Closed Type)		175.45mm
4151-9555	Poly Cannulated Screw (Half Closed Type)		180.45mm
4151-9560	Poly Cannulated Screw (Half Closed Type)		185.45mm
4151-9565	Poly Cannulated Screw (Half Closed Type)		190.45mm
4151-9570	Poly Cannulated Screw (Half Closed Type)		195.45mm
4151-9575	Poly Cannulated Screw (Half Closed Type)		200.45mm
4151-9580	Poly Cannulated Screw (Half Closed Type)		205.45mm



Sharp Tip Straight Rod			
Catalog No.	Description	Size	
4344-5515	Sharp Tip Straight Rod	Ø 5.5	25.0mm
4344-5520	Sharp Tip Straight Rod		30.0mm
4344-5525	Sharp Tip Straight Rod		35.0mm
4344-5530	Sharp Tip Straight Rod		40.0mm
4344-5535	Sharp Tip Straight Rod		45.0mm
4344-5540	Sharp Tip Straight Rod		50.0mm
4344-5545	Sharp Tip Straight Rod		55.0mm
4344-5550	Sharp Tip Straight Rod		60.0mm
4344-5555	Sharp Tip Straight Rod		65.0mm
4344-5560	Sharp Tip Straight Rod		70.0mm
4344-5565	Sharp Tip Straight Rod		75.0mm
4344-5570	Sharp Tip Straight Rod		80.0mm
4344-5575	Sharp Tip Straight Rod		85.0mm
4344-5580	Sharp Tip Straight Rod		90.0mm
4344-5585	Sharp Tip Straight Rod		95.0mm
4344-5590	Sharp Tip Straight Rod		100.0mm
4344-5595	Sharp Tip Straight Rod		105.0mm
4344-5100	Sharp Tip Straight Rod		110.0mm
4344-5110	Sharp Tip Straight Rod		120.0mm
4344-5120	Sharp Tip Straight Rod		130.0mm
4344-5130	Sharp Tip Straight Rod		140.0mm
4344-5140	Sharp Tip Straight Rod		150.0mm
4344-5150	Sharp Tip Straight Rod		160.0mm
4344-5160	Sharp Tip Straight Rod		170.0mm
4344-5170	Sharp Tip Straight Rod		180.0mm
4344-5180	Sharp Tip Straight Rod		190.0mm
4344-5190	Sharp Tip Straight Rod		200.0mm
4344-5200	Sharp Tip Straight Rod		210.0mm
4344-5250	Sharp Tip Straight Rod		160.0mm
4344-5300	Sharp Tip Straight Rod		310.0mm
4344-5350	Sharp Tip Straight Rod		360.0mm
4344-5400	Sharp Tip Straight Rod		410.0mm



Sharp Tip Pre-bend Rod			
Catalog No.	Description	Size	
4343-5515	Sharp Tip Pre-bend Rod	Ø 5.5	24.9mm
4343-5520	Sharp Tip Pre-bend Rod		29.9mm
4343-5525	Sharp Tip Pre-bend Rod		34.9mm
4343-5530	Sharp Tip Pre-bend Rod		39.9mm
4343-5535	Sharp Tip Pre-bend Rod		44.9mm
4343-5540	Sharp Tip Pre-bend Rod		49.9mm
4343-5545	Sharp Tip Pre-bend Rod		54.9mm
4343-5550	Sharp Tip Pre-bend Rod		59.8mm
4343-5555	Sharp Tip Pre-bend Rod		64.8mm
4343-5560	Sharp Tip Pre-bend Rod		69.8mm
4343-5565	Sharp Tip Pre-bend Rod		74.7mm
4343-5570	Sharp Tip Pre-bend Rod		79.7mm
4343-5575	Sharp Tip Pre-bend Rod		84.7mm
4343-5580	Sharp Tip Pre-bend Rod		89.6mm
4343-5585	Sharp Tip Pre-bend Rod		94.6mm
4343-5590	Sharp Tip Pre-bend Rod		99.5mm
4343-5595	Sharp Tip Pre-bend Rod		104.5mm
4343-5100	Sharp Tip Pre-bend Rod		109.4mm
4343-5110	Sharp Tip Pre-bend Rod		119.3mm
4343-5120	Sharp Tip Pre-bend Rod		129.1mm
4343-5130	Sharp Tip Pre-bend Rod		139.0mm
4343-5140	Sharp Tip Pre-bend Rod		148.8mm
4343-5150	Sharp Tip Pre-bend Rod		158.7mm



Sharp Tip Pre-bend Long Level Rod			
Catalog No.	Description	Size	
4343-5160	Sharp Tip Pre-bend Long Level Rod	Ø 5.5	169.4mm
4343-5170	Sharp Tip Pre-bend Long Level Rod		179.2mm
4343-5180	Sharp Tip Pre-bend Long Level Rod		189.1mm
4343-5190	Sharp Tip Pre-bend Long Level Rod		198.9mm
4343-5200	Sharp Tip Pre-bend Long Level Rod		208.8mm
4343-5250	Sharp Tip Pre-bend Long Level Rod		257.9mm

# INSTRUMENTS

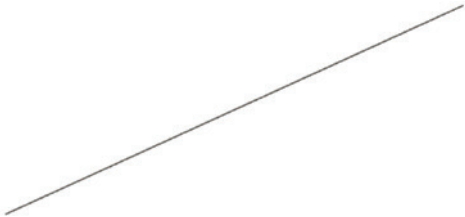
4901-3019 VP Needle



4901-8033 4CIS<sup>®</sup> Guide Wire Tool



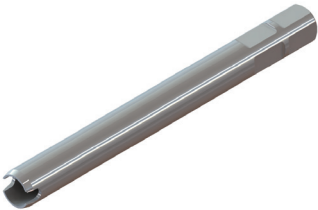
4901-3037 Guide Wire 400mm  
4901-3038 Guide Wire 450mm  
4901-3039 Guide Wire 500mm  
4901-3044 Guide Wire 550mm  
4901-0057 Guide Wire 400mm (Ni-Ti)  
4901-0058 Guide Wire 450mm (Ni-Ti)  
4901-0074 Guide Wire 480mm (Ni-Ti)  
4901-0059 Guide Wire 500mm (Ni-Ti)  
4901-0060 Guide Wire 550mm (Ni-Ti)



4901-8034 4CIS<sup>®</sup> Dilator 1  
4901-8035 4CIS<sup>®</sup> Dilator 2  
4901-8036 4CIS<sup>®</sup> Dilator 3



4901-8112 4CIS<sup>®</sup> Chiron XT Fixing Sleeve



4901-8038 4CIS<sup>®</sup> Chiron Tap 5.5mm (Cannulated)  
4901-8039 4CIS<sup>®</sup> Chiron Tap 6.5mm (Cannulated)  
4901-8040 4CIS<sup>®</sup> Chiron Tap 7.5mm (Cannulated)



4901-8026 4CIS<sup>®</sup> Chiron-XT Screw Driver



4901-8024 4CIS<sup>®</sup> Chiron-XT Rigid Rod Inserter



4901-8041 4CIS<sup>®</sup> Ring C type



4901-8042 4CIS<sup>®</sup> Closed Ring





4901-8059 4CIS<sup>®</sup> Chiron-XT Nut Starter



4901-8061 4CIS<sup>®</sup> Chiron-XT Nut Screw Final Driver



4901-8079 4CIS<sup>®</sup> Chiron XT Compressor & Distractor



4901-8113 4CIS<sup>®</sup> Chiron XT Anti Torque wrench



4901-8031 4CIS<sup>®</sup> Screw Head Positioner



4901-8058 Poly Axial Bone Screw Driver I-handle



4901-7050 4CIS<sup>®</sup> Ratcheting I-Handle



9807-0052 Torque Limit Handle



4901-8051 4CIS<sup>®</sup> French Rod Bender



9807-0038 Cannulated Awl



9807-0049 Counter Torque



4901-8046 Rod Holder Forceps type



4901-8025 4CIS® Chiron-XT Persuader



4901-8064 4CIS® Chiron-XT Rod Length Gauge



4901-8101 4CIS® Chiron XT Tab Breaker



Warning and Cautions

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. Thorough knowledge of spinal anatomy, biomechanics and surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
3. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect safety, effectiveness and service life of spine fixation system. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their safety, effectiveness and service life. Accordingly, strict adherence to the indications, contraindications, cautions, and warnings for this product is essential to potentially maximize the performance (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).
4. Experience with spinal fusion procedures and spinal fixation is required and hands-on training in the use of this device with proper surgical technique manual or operational literature is necessary.
5. The product must be used only for the patients who meet the criteria described in the above indications.
6. 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.
7. 4CIS® Spinal Fixation Systems has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of 4CIS® Spinal Fixation Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
8. The Spine Fixation System is not for sale to a physician but to a surgeon.