

SOLCO.

4CIS[®]
CHIRON XT

Mininnaly Invasive Spine Surgery system

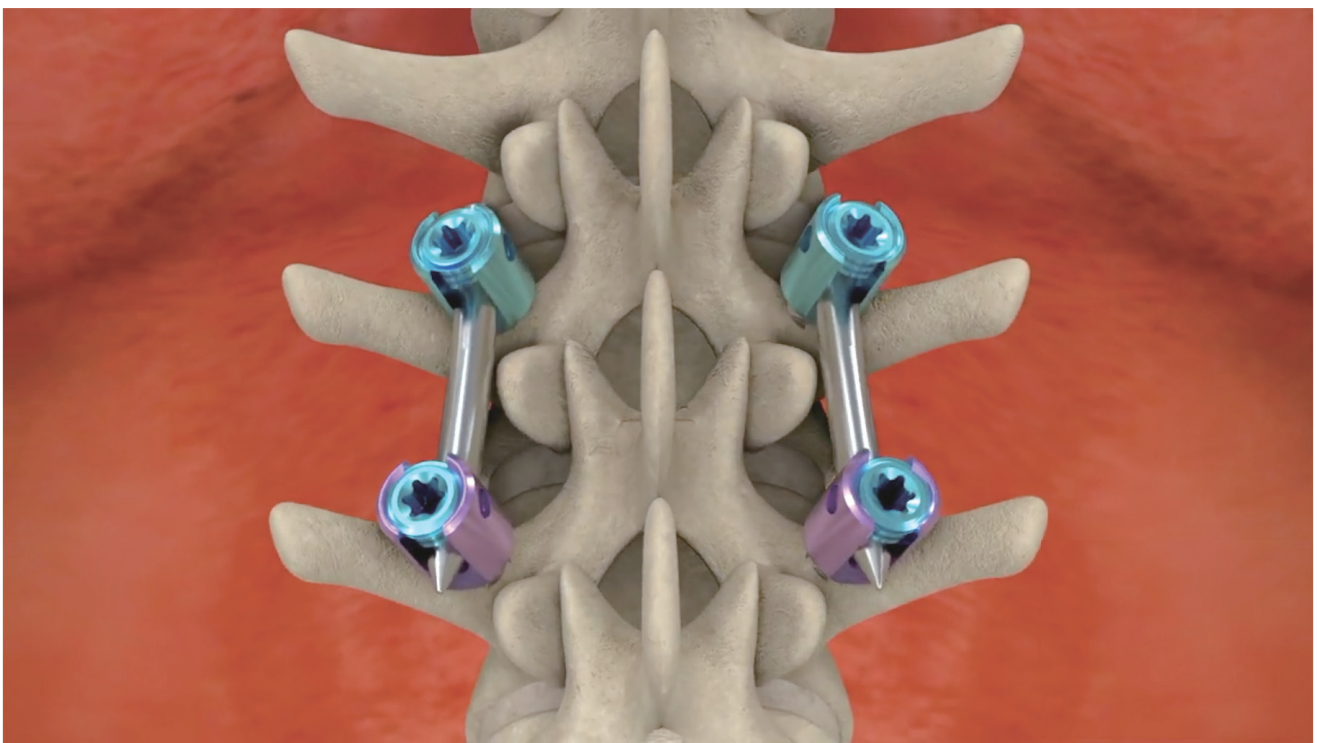
Surgical Technique





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

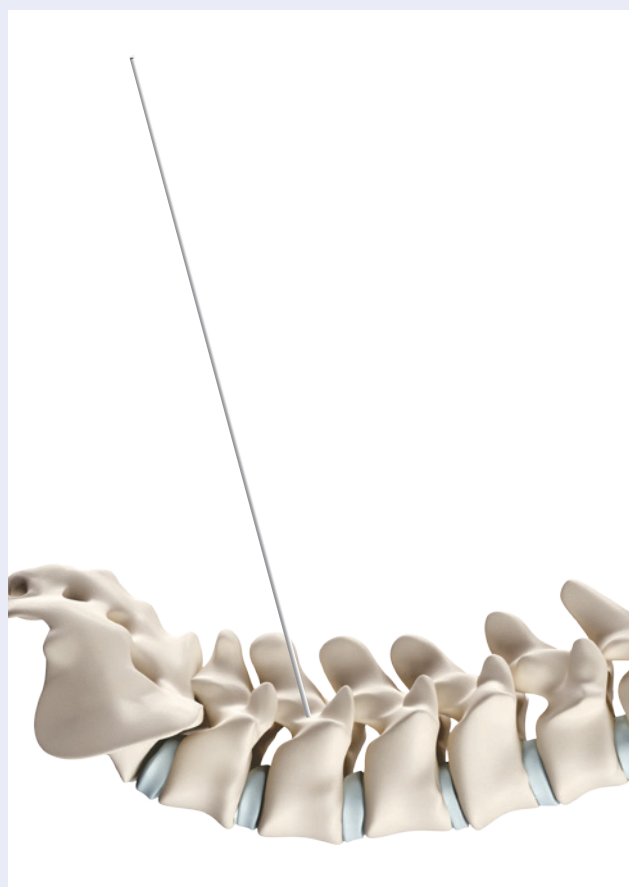


Figure 5

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

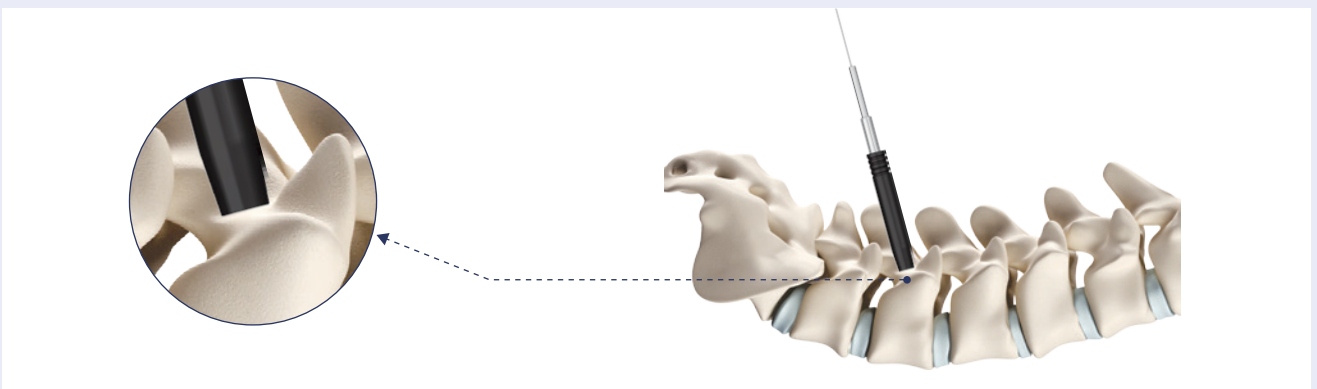


Figure 8

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 guidewire advancement during tapping.

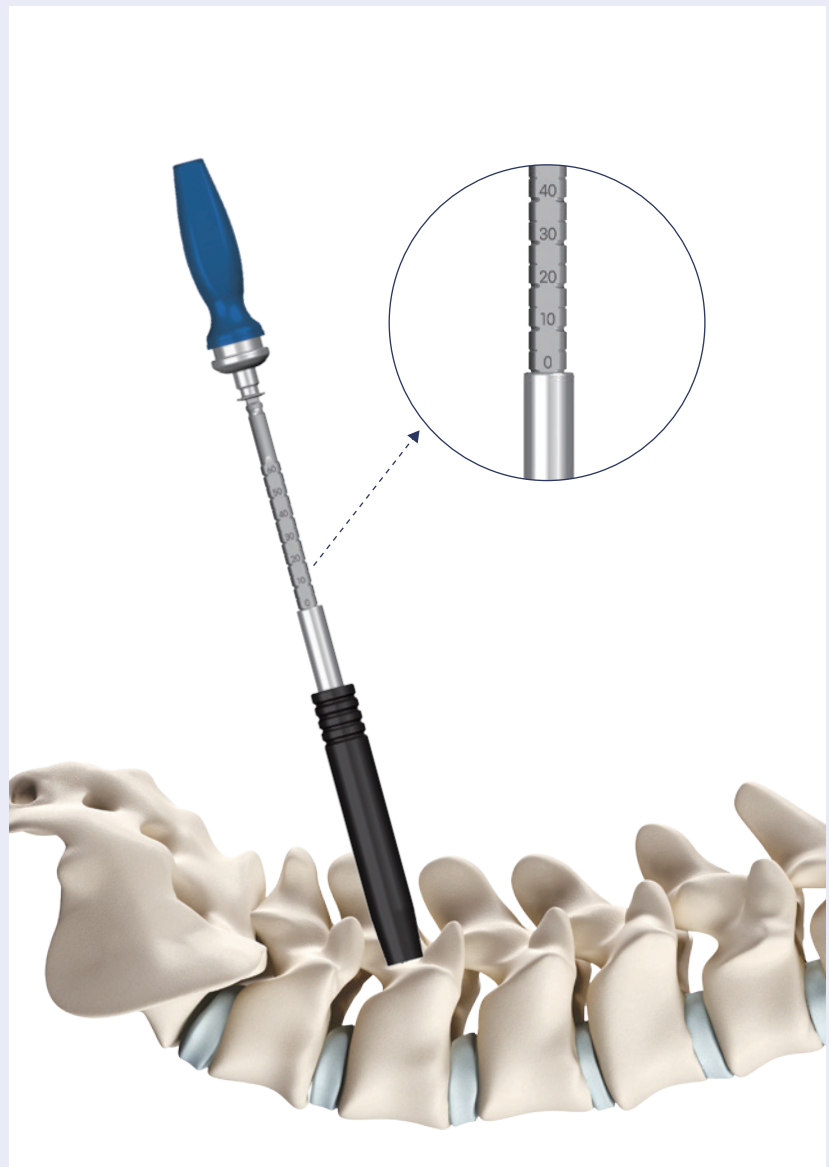


Figure 9

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.

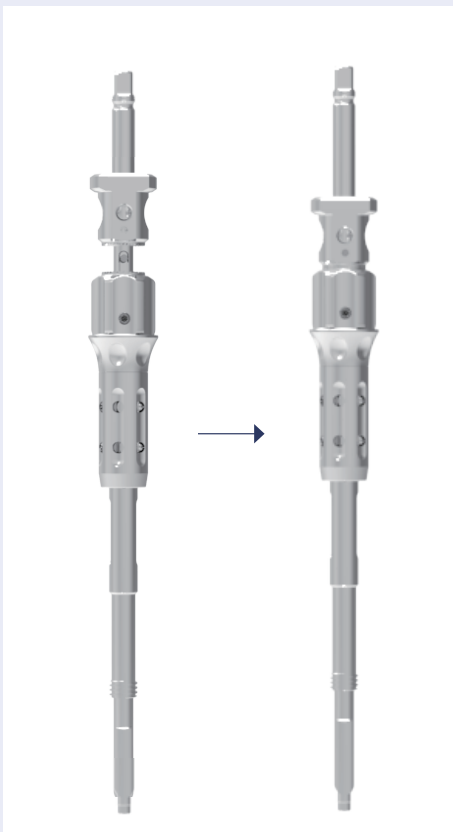


Figure 10



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 Tightening

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® Chiron-XT Poly Cannulated Screw and apply another Fixing Sleeve over a blade of adjacent 4CIS® 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.

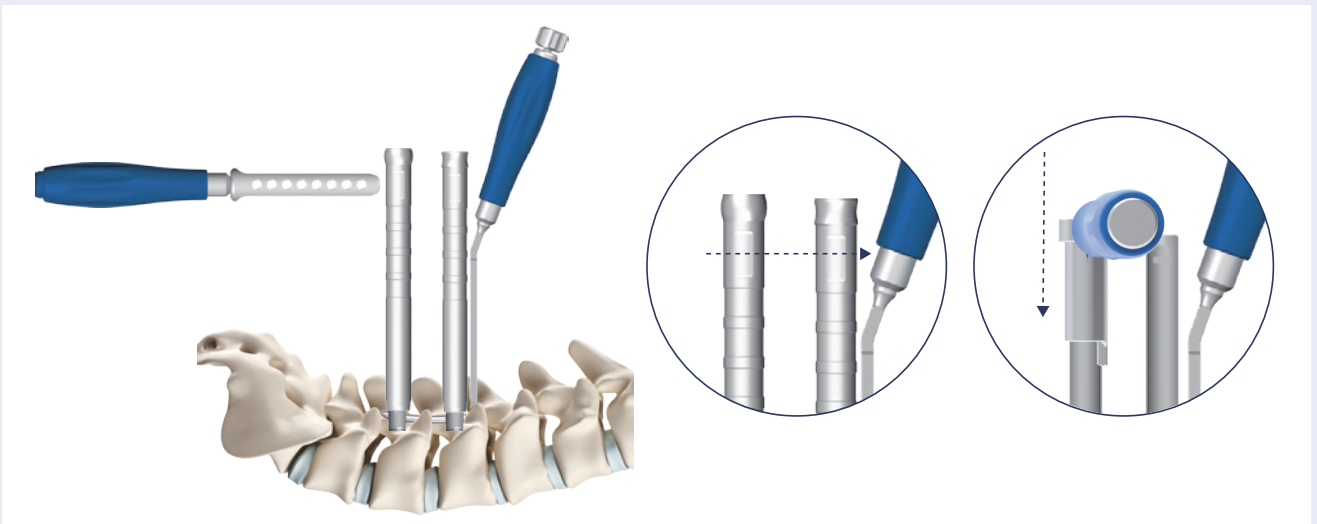


Figure 19



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.

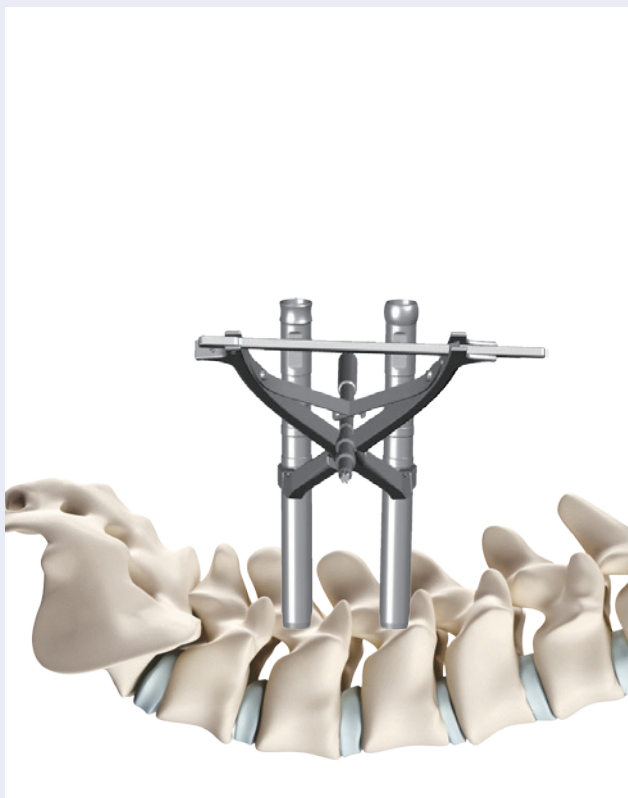


Figure 23



Figure 24

STEP 8 : Tap Removal

4CIS[®] 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[®] Screw Head Positioner on the tap of the 4CIS[®] Chiron-XT Poly Cannulated Screw after final tightening has taken place. Ensure the the 4CIS[®] 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.

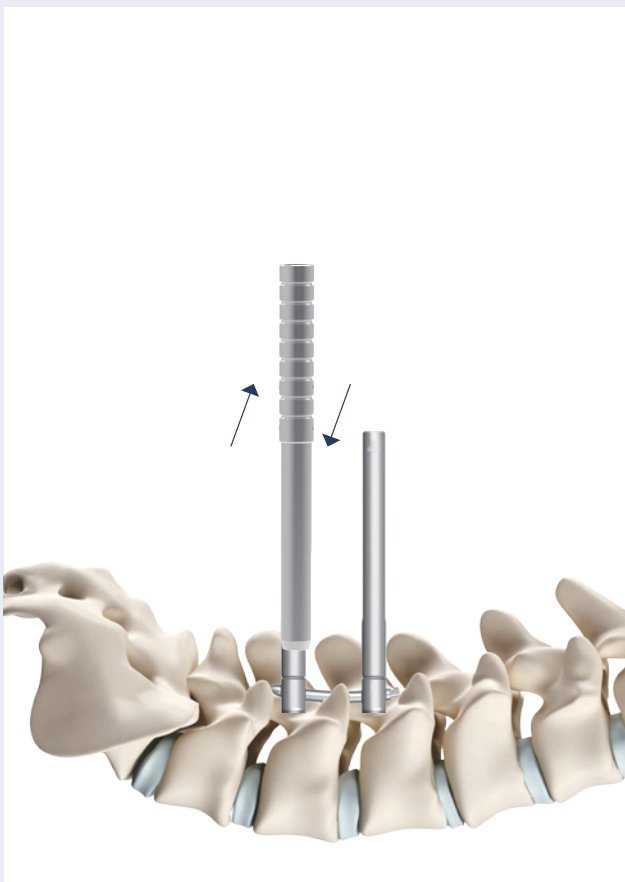
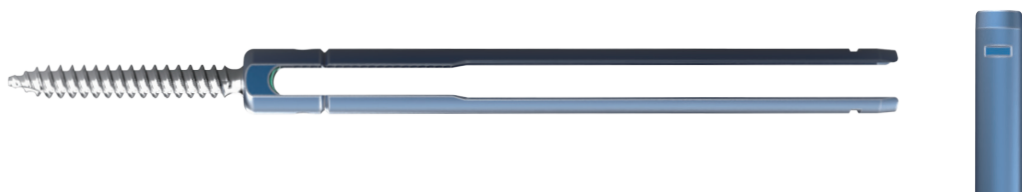


Figure 25



Figure 26

IMPLANT



Poly Cannulated Screw

| Catalog No. | Description | Size | |
|-------------|-----------------------|-------|-------|
| 4150-4520 | Poly Cannulated Screw | Ø 4.5 | 20mm |
| 4150-4525 | Poly Cannulated Screw | | 25mm |
| 4150-4530 | Poly Cannulated Screw | | 30mm |
| 4150-4535 | Poly Cannulated Screw | | 35mm |
| 4150-4540 | Poly Cannulated Screw | | 40mm |
| 4150-4545 | Poly Cannulated Screw | | 45mm |
| 4150-4550 | Poly Cannulated Screw | | 50mm |
| 4150-5525 | Poly Cannulated Screw | | Ø 5.5 |
| 4150-5530 | Poly Cannulated Screw | 30mm | |
| 4150-5535 | Poly Cannulated Screw | 35mm | |
| 4150-5540 | Poly Cannulated Screw | 40mm | |
| 4150-5545 | Poly Cannulated Screw | 45mm | |
| 4150-5550 | Poly Cannulated Screw | 50mm | |
| 4150-5555 | Poly Cannulated Screw | 55mm | |
| 4150-5560 | Poly Cannulated Screw | 60mm | |
| 4150-6530 | Poly Cannulated Screw | Ø 6.5 | 30mm |
| 4150-6535 | Poly Cannulated Screw | | 35mm |
| 4150-6540 | Poly Cannulated Screw | | 40mm |
| 4150-6545 | Poly Cannulated Screw | | 45mm |
| 4150-6550 | Poly Cannulated Screw | | 50mm |
| 4150-6555 | Poly Cannulated Screw | | 55mm |
| 4150-6560 | Poly Cannulated Screw | | 60mm |
| 4150-6565 | Poly Cannulated Screw | | 65mm |
| 4150-6570 | Poly Cannulated Screw | 70mm | |
| 4150-6575 | Poly Cannulated Screw | 75mm | |
| 4150-6580 | Poly Cannulated Screw | 80mm | |
| 4150-7530 | Poly Cannulated Screw | Ø 7.5 | 30mm |
| 4150-7535 | Poly Cannulated Screw | | 35mm |
| 4150-7540 | Poly Cannulated Screw | | 40mm |
| 4150-7545 | Poly Cannulated Screw | | 45mm |
| 4150-7550 | Poly Cannulated Screw | | 50mm |
| 4150-7555 | Poly Cannulated Screw | | 55mm |
| 4150-7560 | Poly Cannulated Screw | | 60mm |
| 4150-7565 | Poly Cannulated Screw | | 65mm |
| 4150-7570 | Poly Cannulated Screw | 70mm | |
| 4150-7575 | Poly Cannulated Screw | 75mm | |
| 4150-7580 | Poly Cannulated Screw | 80mm | |

Poly Cannulated Screw

| Catalog No. | Description | Size | |
|-------------|-----------------------|-------|------|
| 4150-8535 | Poly Cannulated Screw | Ø 8.5 | 35mm |
| 4150-8540 | Poly Cannulated Screw | | 40mm |
| 4150-8545 | Poly Cannulated Screw | | 45mm |
| 4150-8550 | Poly Cannulated Screw | | 50mm |
| 4150-8555 | Poly Cannulated Screw | | 55mm |
| 4150-8560 | Poly Cannulated Screw | | 60mm |
| 4150-8565 | Poly Cannulated Screw | | 65mm |
| 4150-8570 | Poly Cannulated Screw | | 70mm |
| 4150-8575 | Poly Cannulated Screw | | 75mm |
| 4150-8580 | Poly Cannulated Screw | | 80mm |



Nut Screw

| Catalog No. | Description | |
|-------------|------------------|--|
| 4205-0001 | 4CIS® Chiron Nut | |

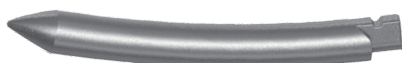


Poly Cannulated Screw(Half Closed Type)

| Catalog No. | Description | Size | | |
|-------------|---------------------------------------------|-------|-------|------|
| 4151-4520 | Poly Cannulated Screw (Half Closed Type) | Ø 4.5 | 20mm | |
| 4151-4525 | Poly Cannulated Screw (Half Closed Type) | | 25mm | |
| 4151-4530 | Poly Cannulated Screw (Half Closed Type) | | 30mm | |
| 4151-4535 | Poly Cannulated Screw (Half Closed Type) | | 35mm | |
| 4151-4540 | Poly Cannulated Screw (Half Closed Type) | | 40mm | |
| 4151-4545 | Poly Cannulated Screw (Half Closed Type) | | 45mm | |
| 4151-4550 | Poly Cannulated Screw (Half Closed Type) | | 50mm | |
| 4151-5525 | Poly Cannulated Screw (Half Closed Type) | Ø 5.5 | 25mm | |
| 4151-5530 | Poly Cannulated Screw (Half Closed Type) | | 30mm | |
| 4151-5535 | Poly Cannulated Screw (Half Closed Type) | | 35mm | |
| 4151-5540 | Poly Cannulated Screw (Half Closed Type) | | 40mm | |
| 4151-5545 | Poly Cannulated Screw (Half Closed Type) | | 45mm | |
| 4151-5550 | Poly Cannulated Screw (Half Closed Type) | | 50mm | |
| 4151-5555 | Poly Cannulated Screw (Half Closed Type) | | 55mm | |
| 4151-5560 | Poly Cannulated Screw (Half Closed Type) | | 60mm | |
| 4151-6530 | Poly Cannulated Screw (Half Closed Type) | | Ø 6.5 | 30mm |
| 4151-6535 | Poly Cannulated Screw (Half Closed Type) | | | 35mm |
| 4151-6540 | Poly Cannulated Screw (Half Closed Type) | 40mm | | |
| 4151-6545 | Poly Cannulated Screw (Half Closed Type) | 45mm | | |
| 4151-6550 | Poly Cannulated Screw (Half Closed Type) | 50mm | | |
| 4151-6555 | Poly Cannulated Screw (Half Closed Type) | 55mm | | |
| 4151-6560 | Poly Cannulated Screw (Half Closed Type) | 60mm | | |
| 4151-6565 | Poly Cannulated Screw (Half Closed Type) | 65mm | | |
| 4151-6570 | Poly Cannulated Screw (Half Closed Type) | 70mm | | |
| 4151-6575 | Poly Cannulated Screw (Half Closed Type) | 75mm | | |
| 4151-6580 | Poly Cannulated Screw (Half Closed Type) | 80mm | | |

Poly Cannulated Screw(Half Closed Type)

| Catalog No. | Description | Size | |
|-------------|---------------------------------------------|-------|------|
| 4151-7530 | Poly Cannulated Screw (Half Closed Type) | Ø 7.5 | 30mm |
| 4151-7535 | Poly Cannulated Screw (Half Closed Type) | | 35mm |
| 4151-7540 | Poly Cannulated Screw (Half Closed Type) | | 40mm |
| 4151-7545 | Poly Cannulated Screw (Half Closed Type) | | 45mm |
| 4151-7550 | Poly Cannulated Screw (Half Closed Type) | | 50mm |
| 4151-7555 | Poly Cannulated Screw (Half Closed Type) | | 55mm |
| 4151-7560 | Poly Cannulated Screw (Half Closed Type) | | 60mm |
| 4151-7565 | Poly Cannulated Screw (Half Closed Type) | | 65mm |
| 4151-7570 | Poly Cannulated Screw (Half Closed Type) | | 70mm |
| 4151-7575 | Poly Cannulated Screw (Half Closed Type) | | 75mm |
| 4151-7580 | Poly Cannulated Screw (Half Closed Type) | Ø 8.5 | 80mm |
| 4151-8535 | Poly Cannulated Screw (Half Closed Type) | | 35mm |
| 4151-8540 | Poly Cannulated Screw (Half Closed Type) | | 40mm |
| 4151-8545 | Poly Cannulated Screw (Half Closed Type) | | 45mm |
| 4151-8550 | Poly Cannulated Screw (Half Closed Type) | | 50mm |
| 4151-8555 | Poly Cannulated Screw (Half Closed Type) | | 55mm |
| 4151-8560 | Poly Cannulated Screw (Half Closed Type) | | 60mm |
| 4151-8565 | Poly Cannulated Screw (Half Closed Type) | | 65mm |
| 4151-8570 | Poly Cannulated Screw (Half Closed Type) | | 70mm |
| 4151-8575 | Poly Cannulated Screw (Half Closed Type) | | 75mm |
| 4151-8580 | Poly Cannulated Screw (Half Closed Type) | 80mm | |



| Sharp Tip Pre-bend Rod | | | |
|------------------------|------------------------|-------|-------|
| Catalog No. | Description | Size | |
| 4343-5515 | Sharp Tip Pre-bend Rod | Ø 5.5 | 15mm |
| 4343-5520 | Sharp Tip Pre-bend Rod | | 20mm |
| 4343-5525 | Sharp Tip Pre-bend Rod | | 25mm |
| 4343-5530 | Sharp Tip Pre-bend Rod | | 30mm |
| 4343-5535 | Sharp Tip Pre-bend Rod | | 35mm |
| 4343-5540 | Sharp Tip Pre-bend Rod | | 40mm |
| 4343-5545 | Sharp Tip Pre-bend Rod | | 45mm |
| 4343-5550 | Sharp Tip Pre-bend Rod | | 50mm |
| 4343-5555 | Sharp Tip Pre-bend Rod | | 55mm |
| 4343-5560 | Sharp Tip Pre-bend Rod | | 60mm |
| 4343-5565 | Sharp Tip Pre-bend Rod | | 65mm |
| 4343-5570 | Sharp Tip Pre-bend Rod | | 70mm |
| 4343-5575 | Sharp Tip Pre-bend Rod | | 75mm |
| 4343-5580 | Sharp Tip Pre-bend Rod | | 80mm |
| 4343-5585 | Sharp Tip Pre-bend Rod | | 85mm |
| 4343-5590 | Sharp Tip Pre-bend Rod | | 90mm |
| 4343-5595 | Sharp Tip Pre-bend Rod | | 95mm |
| 4343-5100 | Sharp Tip Pre-bend Rod | | 100mm |
| 4343-5110 | Sharp Tip Pre-bend Rod | | 110mm |
| 4343-5120 | Sharp Tip Pre-bend Rod | | 120mm |
| 4343-5130 | Sharp Tip Pre-bend Rod | | 130mm |
| 4343-5140 | Sharp Tip Pre-bend Rod | | 140mm |
| 4343-5150 | Sharp Tip Pre-bend Rod | | 150mm |
| 4343-5160 | Sharp Tip Pre-bend Rod | | 160mm |
| 4343-5170 | Sharp Tip Pre-bend Rod | | 170mm |
| 4343-5180 | Sharp Tip Pre-bend Rod | 180mm | |
| 4343-5190 | Sharp Tip Pre-bend Rod | 190mm | |
| 4343-5200 | Sharp Tip Pre-bend Rod | 200mm | |
| 4343-5250 | Sharp Tip Pre-bend Rod | 250mm | |

| Sharp Tip Straight Rod | | | |
|------------------------|------------------------|-------|-------|
| Catalog No. | Description | Size | |
| 4344-5515 | Sharp Tip Straight Rod | Ø 5.5 | 15mm |
| 4344-5520 | Sharp Tip Straight Rod | | 20mm |
| 4344-5525 | Sharp Tip Straight Rod | | 25mm |
| 4344-5530 | Sharp Tip Straight Rod | | 30mm |
| 4344-5535 | Sharp Tip Straight Rod | | 35mm |
| 4344-5540 | Sharp Tip Straight Rod | | 40mm |
| 4344-5545 | Sharp Tip Straight Rod | | 45mm |
| 4344-5550 | Sharp Tip Straight Rod | | 50mm |
| 4344-5555 | Sharp Tip Straight Rod | | 55mm |
| 4344-5560 | Sharp Tip Straight Rod | | 60mm |
| 4344-5565 | Sharp Tip Straight Rod | | 65mm |
| 4344-5570 | Sharp Tip Straight Rod | | 70mm |
| 4344-5575 | Sharp Tip Straight Rod | | 75mm |
| 4344-5580 | Sharp Tip Straight Rod | | 80mm |
| 4344-5585 | Sharp Tip Straight Rod | | 85mm |
| 4344-5590 | Sharp Tip Straight Rod | | 90mm |
| 4344-5595 | Sharp Tip Straight Rod | | 95mm |
| 4344-5100 | Sharp Tip Straight Rod | | 100mm |
| 4344-5110 | Sharp Tip Straight Rod | | 110mm |
| 4344-5120 | Sharp Tip Straight Rod | | 120mm |
| 4344-5130 | Sharp Tip Straight Rod | | 130mm |
| 4344-5140 | Sharp Tip Straight Rod | | 140mm |
| 4344-5150 | Sharp Tip Straight Rod | | 150mm |
| 4344-5160 | Sharp Tip Straight Rod | | 160mm |
| 4344-5170 | Sharp Tip Straight Rod | | 170mm |
| 4344-5180 | Sharp Tip Straight Rod | 180mm | |
| 4344-5190 | Sharp Tip Straight Rod | 190mm | |
| 4344-5200 | Sharp Tip Straight Rod | 200mm | |
| 4344-5250 | Sharp Tip Straight Rod | 250mm | |
| 4344-5300 | Sharp Tip Straight Rod | 300mm | |
| 4344-5350 | Sharp Tip Straight Rod | 350mm | |
| 4344-5400 | Sharp Tip Straight Rod | 400mm | |

INSTRUMENT

4901-3019 VP Needle (Diamond ShortTip)
9807-0053 VP Needle (Diamond Long Tip)



4901-8033 4CIS® Guide Wire Tool



4901-0074 Guide Wire 480mm



4901-8034 4CIS® Dilator 1
4901-8035 4CIS® Dilator 2
4901-8036 4CIS® Dilator 3



4901-8080 4CIS® Chiron XT Fixing Sleeve 1
4901-8081 4CIS® Chiron XT Fixing Sleeve 2



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



4901-8095 4CIS® Chiron-XT Screw Driver



4901-8024 4CIS® Chiron-XT Rigid Rod Inserter



4901-8041 4CIS® Ring C type



4901-8042 4CIS® Closed Ring



4901-8059 4CIS® Chiron-XT Nut Starter
4901-8060 4CIS® Chiron-XT Nut Starter T-Handle
4901-8097 4CIS® Chiron-XT Nut Starter T-Handle Long-Type



4901-8061 4CIS® Chiron-XT Nut Screw Final Driver



4901-8079 4CIS® Chiron XT Compressor & Distractor
4901-8092 4CIS® Chiron XT Compression&Distraction Bar



4901-8044 4CIS® Torque Stabilizer



4901-8031 4CIS® Screw Head Positioner



4901-8058 4CIS® Poly Axial Bone Screw Driver I-handle



4901-8103 4CIS® Ratcheting I-Handle
4901-8104 4CIS® Ratcheting T-Handle



9807-0052 Torque Limit Handle



4901-8051 4CIS® French Rod Bender



9807-0038 Cannulated Awl



4901-8108 Counter Torque
4901-8082 Counter Torque (Half Closed)



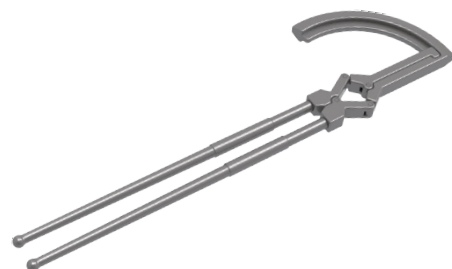
4901-8046 Rod Holder Forceps type



4901-8025 4CIS® Chiron-XT Persuader
4901-8065 4CIS® Chiron-XT Persuader (Half Closed)



4901-8107 4CIS® Chiron-XT Rod Length Gauge



4901-8101 4CIS® Chiron-XT Tab Breaker
4901-8111 4CIS® Ring Cutter



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.

4CIS[®] CHIRON XT

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