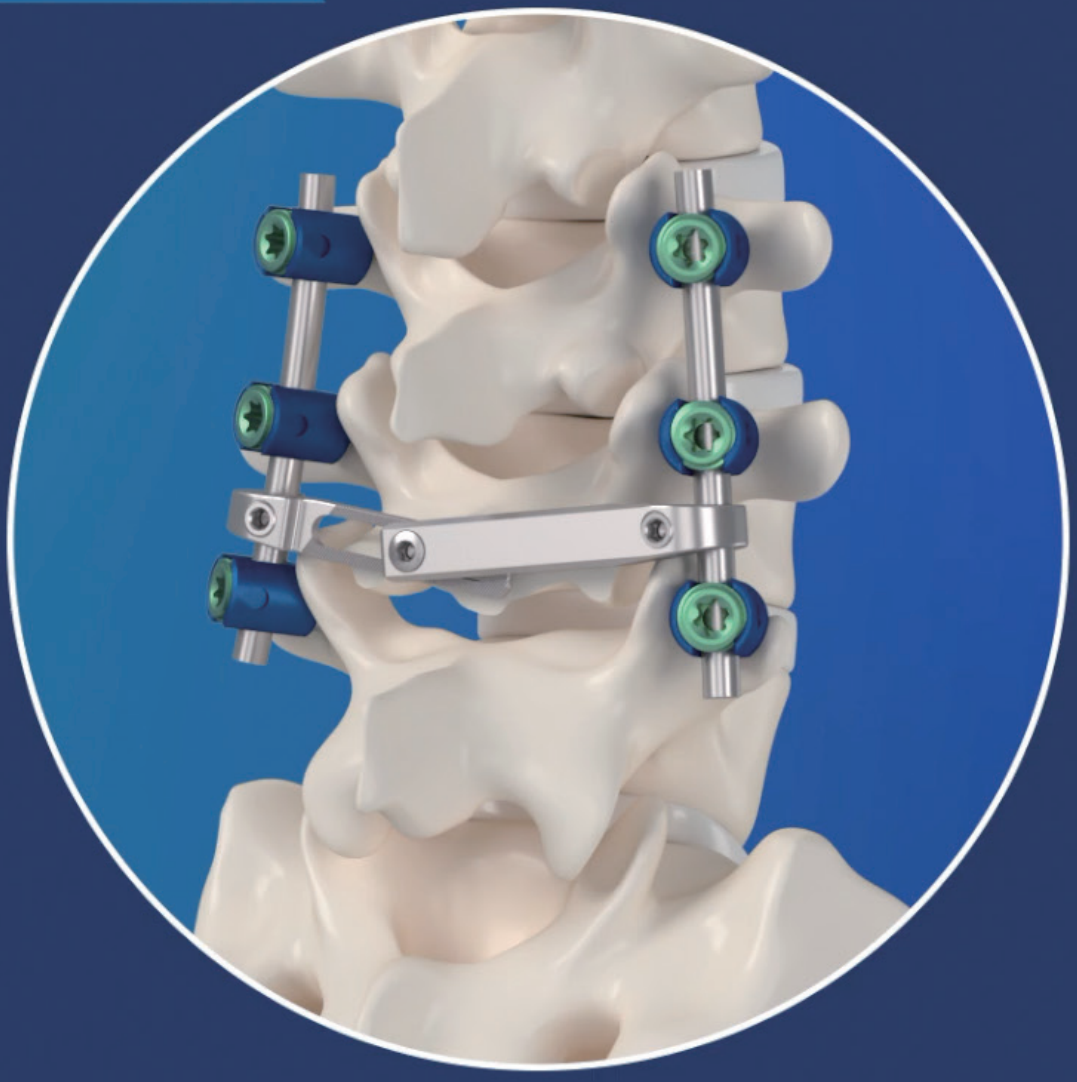
SOLCO.

4CIS®
CHIRON

Spinal Fixation System for 5.5mm Rod

SURGICAL TECHNIQUE



Medical & health care group with a history of 43 years

Established in 1974, SOLCO BIOMEDICAL is a medical & healthcare company that exports its products to 20 different countries overseas
It is also the first medical device manufacturer in Korea, and has developed implants for orthopedic surgery,
surgical instruments, and health care products for body temperature and antioxidation for 43 years.
Under our business philosophy, "make the world smile with health", we're devoted to improve the quality of life
for everyone by developing high-tech medical instruments and health products based on medical R&D and clinical researche.

Vision

To help cure as many patients as possible around the world.

Mission

Our Mission is to improve the health of our patients, by providing products and services,
that promote and maintain a quality long lasting lifestyle.

Purpose

We work hard everyday to uplift society, to make the world smile.

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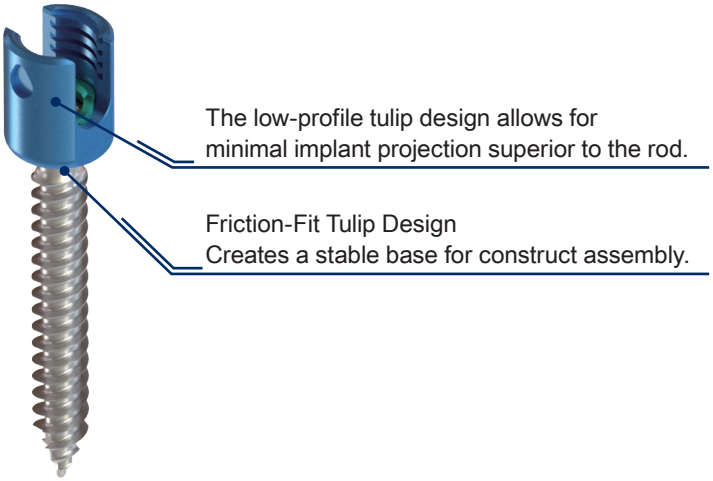
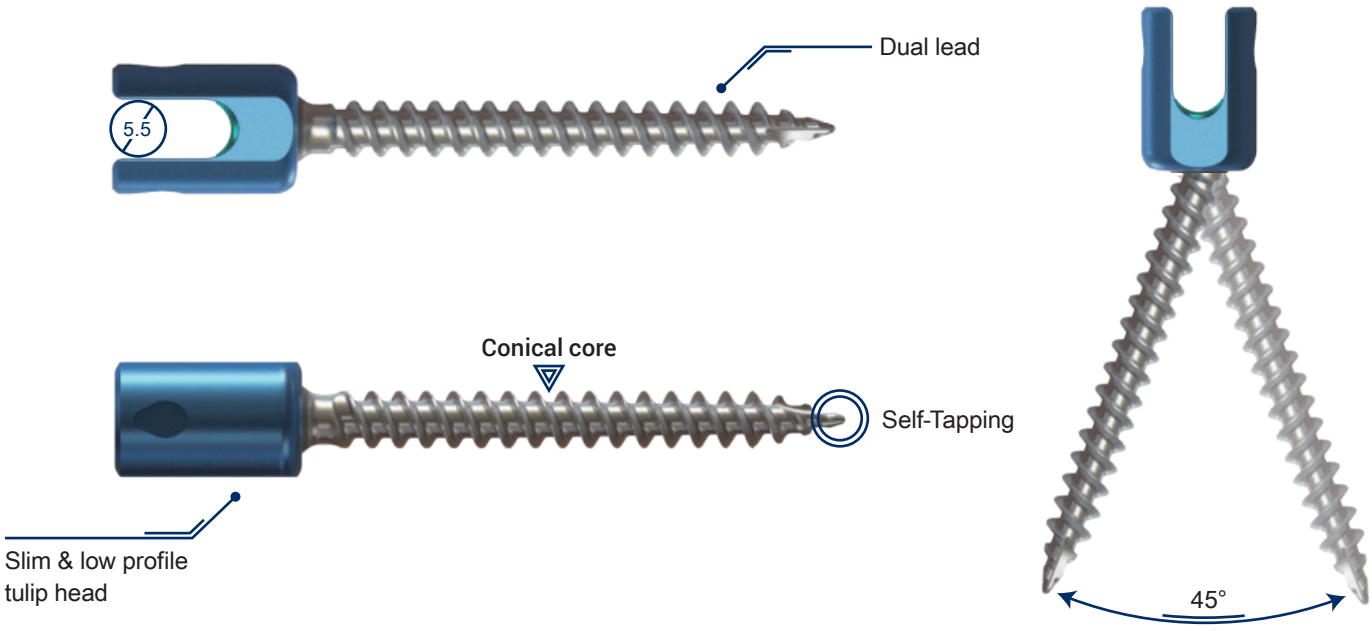
System Overview

The Chiron Spinal Fixation System consists of a variety of pedicle screws, rods, nuts, cross links, and rod connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the mature patient. All components are made of titanium alloy, per ASTM F136.
From the thoracic spine to the ilium, the Chiron Spinal System facilitates surgeon choice and flexibility across patient types with a variety of implant options for treating multiple spinal pathologies with one system.

FEATURES & BENEFITS

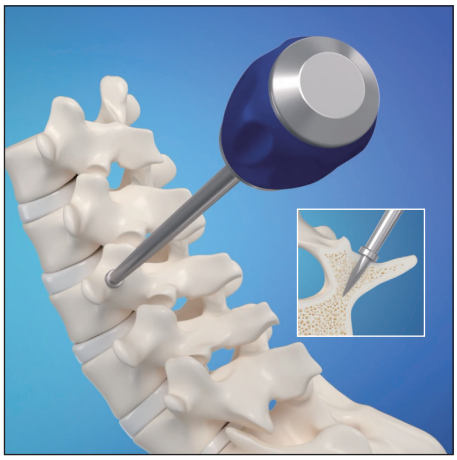


SPECIFICATION



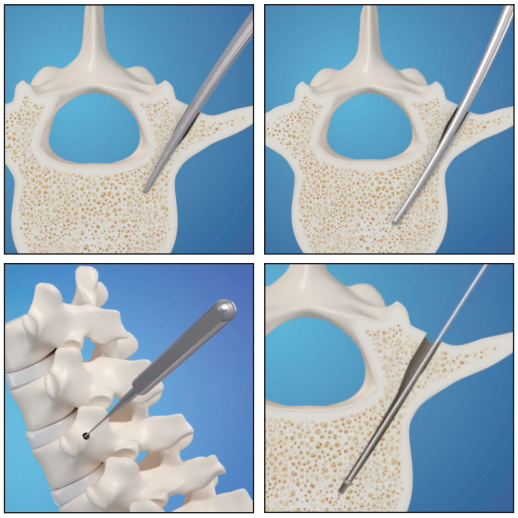
Operative Technique

Step 1
Pedicle Identification



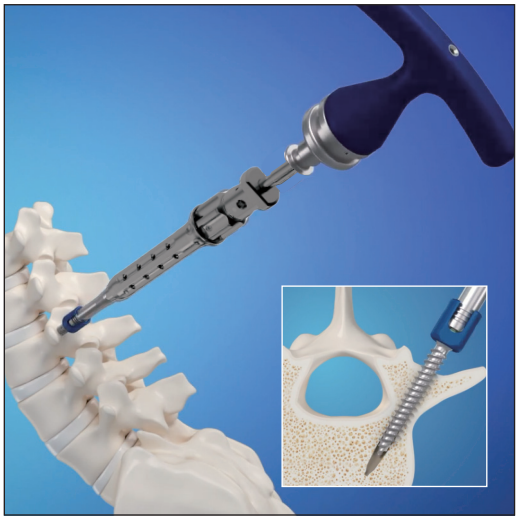
The pedicle entry point depends on the intersection techniques.
It involves drawing a line from the lateral aspect of the facet joint,which intersects a line that bisects the transverse process at a spot overlying the pedicle. However, because of the high variability in pedicle dimensions on each level of vertebra, intraoperative radiograph is checked to determine the exact position of the entry in the anteroposterior and lateral projection after inserting guide pins.

Step 2
Pedicle Preparation



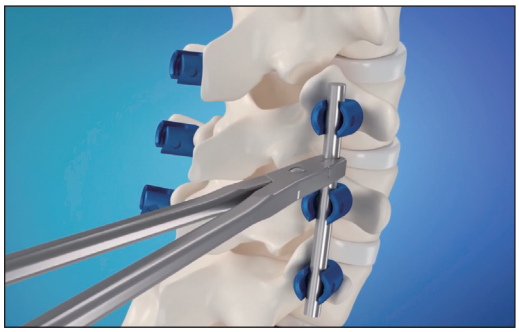
After the determination of the pedicle entry point, the entry hole is prepared by Awl.
A pathway is then opened up with a Pedicle Probe from a smaller to a larger sequentially. The Pedicle Probe is calibrated and marked with 1cm intervals to help determine proper screw length. A balltipped Pedicle Tester is utilized to palpate five distinct bony borders floor and four walls.

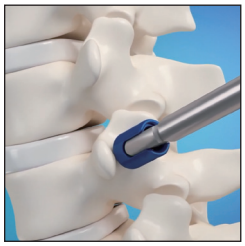
Step 3
Screw Insertion

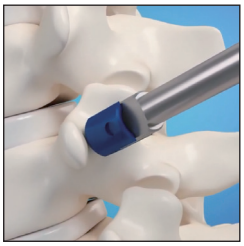


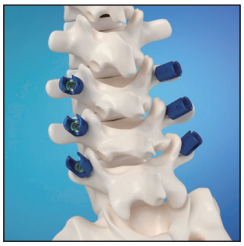
With the pedicle pathway prepared and proper screw length and diameter determined, the screw is ready for insertion. Place the screw slowly while checking proper trajectory using fluoroscopic x-ray.

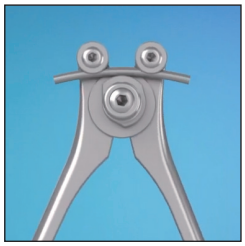
Step 4
Rod Insertion





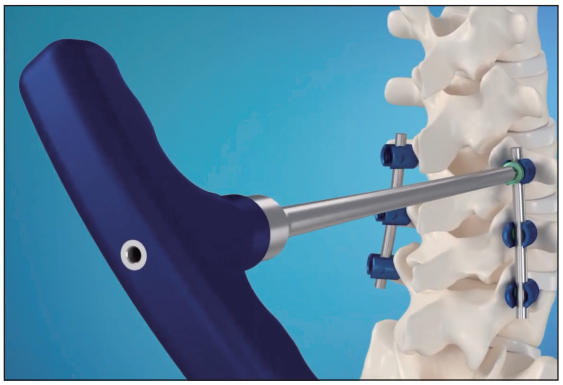






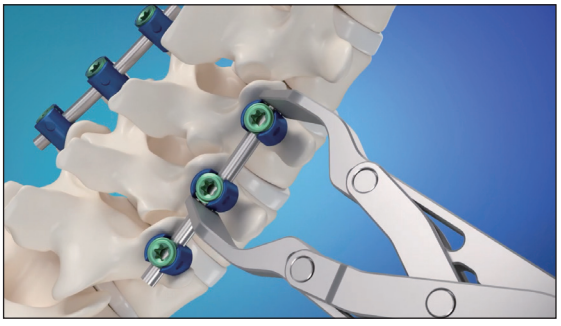
Cut the Rod to the appropriate length and bend the Rod with a French Rod Benderto fit the desired spinal contours. A Rod Holder can be used for optimal Rod insertion.

Step 5
Nut Application



After the Rod is loaded into the bottom of the he head of the screw, the Rod Introducer is preferred for reduction.
The Rod Introducer is then rotated clockwise levering the Rod inside of the screw head.
The Nut Starter is then used to insert the Nut.
If necessary, the Rod Pusher or Anti Torque Wrench is used to hold the Rod inside of screw head.

Step 6
Compression or Distraction

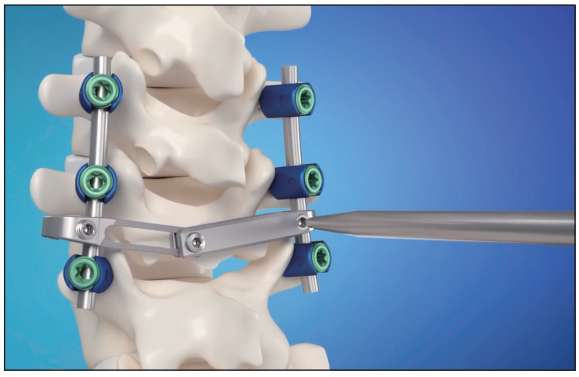


The compression or the distraction procedure may be performed if necessary. In that case, extra caution should be required when placing the nuts securely against the head of the screws. In either maneuver, the Nut on one side of the segment should be tightened provisionally, while the Nut on the other side remains loosened. The Compression or Distraction will occur against the provisionally tightened screws.

Step 7
Final Tightening

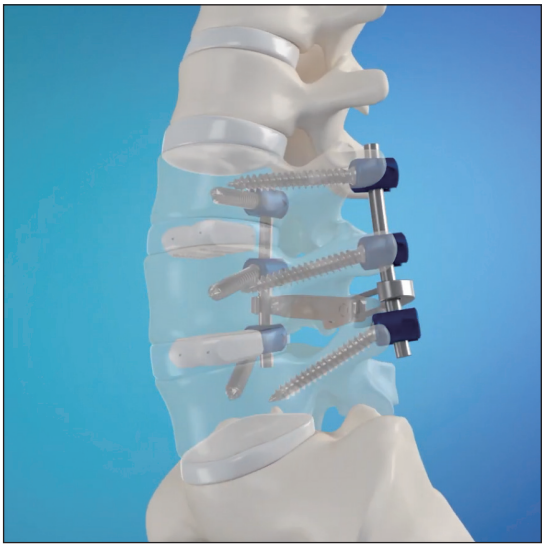
The final tightening is performed with the Nut Final Driver and the AntiTorque Wench. The AntiTorque Wench is placed to a screw and a Rod, while the nut final Driver is inserted through the cannulation of the Anti Torque Wench.
If necessary, the Nut Final Driver may be used to remove a nut after final tightening. Once a nut has been removed, it should be discarded and replaced with the new one.

Step 8
Cross Link Technique



After selection of cross link that corresponds in proper size for the distance between rods, the cross link is applied to the rods and tightened with two tightening screws.
If the size of cross link doesn't fit exactly, Compressor or Distractor can be used accordingly to adjust the distance between rods before final fixation.

Removal / Revision Technique:



Items needed :
Nut final driver, Screw Driver, Anti Torque Wrench
If a decision is made to remove the implants after fusion occurs, the following steps should be taken after the implant is exposed:

1. Clean debris and soft tissue from the nut.
2. Rotate the nuts counter-clockwise.
3. Remove the rod to expose the head of the screw.
4. Insert screw driver into screw head and to back screw out of the pedicle.

Description on driver instruments

Cat. No.	Description	Size
4901-8009	4CIS® Chiron Screw Driver	HEX 4.0
4901-5015	4CIS® Poly Axial Bone Screw Final Driver	HEX 4.0
4901-8018	4CIS® Chiron Reduction Screw Driver	HEX 4.0
4901-0030	Screw Driver 3HEX	HEX 3.0
4901-8013	4CIS® Nut Starter	TORX T30
4901-8014	4CIS® Nut Screw Final Driver Shaft	TORX T30
4901-8048	4CIS® Nut Starter	TORX T30

Implants

Poly Axial Pedicle Screw

Cat. No	Description	Size	
4144-4520	Poly Axial Pedicle Screw	Ø4.5	20mm
4144-4525	Poly Axial Pedicle Screw		25mm
4144-4530	Poly Axial Pedicle Screw		30mm
4144-4535	Poly Axial Pedicle Screw		35mm
4144-4540	Poly Axial Pedicle Screw		40mm
4144-4545	Poly Axial Pedicle Screw		45mm
4144-4550	Poly Axial Pedicle Screw		50mm
4144-5525	Poly Axial Pedicle Screw	Ø5.5	25mm
4144-5530	Poly Axial Pedicle Screw		30mm
4144-5535	Poly Axial Pedicle Screw		35mm
4144-5540	Poly Axial Pedicle Screw		40mm
4144-5545	Poly Axial Pedicle Screw		45mm
4144-5550	Poly Axial Pedicle Screw		50mm
4144-5555	Poly Axial Pedicle Screw		55mm
4144-5560	Poly Axial Pedicle Screw		60mm
4144-6530	Poly Axial Pedicle Screw	Ø6.5	30mm
4144-6535	Poly Axial Pedicle Screw		35mm
4144-6540	Poly Axial Pedicle Screw		40mm
4144-6545	Poly Axial Pedicle Screw		45mm
4144-6550	Poly Axial Pedicle Screw		50mm
4144-6555	Poly Axial Pedicle Screw		55mm
4144-6560	Poly Axial Pedicle Screw		60mm
4144-6565	Poly Axial Pedicle Screw		65mm
4144-6570	Poly Axial Pedicle Screw		70mm
4144-6575	Poly Axial Pedicle Screw		75mm
4144-6580	Poly Axial Pedicle Screw		80mm
4144-6585	Poly Axial Pedicle Screw		85mm
4144-6590	Poly Axial Pedicle Screw		90mm
4144-7530	Poly Axial Pedicle Screw	Ø7.5	30mm

Cat. No	Description	Size	
4144-7535	Poly Axial Pedicle Screw	Ø7.5	35mm
4144-7540	Poly Axial Pedicle Screw		40mm
4144-7545	Poly Axial Pedicle Screw		45mm
4144-7550	Poly Axial Pedicle Screw		50mm
4144-7555	Poly Axial Pedicle Screw		55mm
4144-7560	Poly Axial Pedicle Screw		60mm
4144-7565	Poly Axial Pedicle Screw		65mm
4144-7570	Poly Axial Pedicle Screw		70mm
4144-7575	Poly Axial Pedicle Screw		75mm
4144-7580	Poly Axial Pedicle Screw		80mm
4144-7585	Poly Axial Pedicle Screw		85mm
4144-7590	Poly Axial Pedicle Screw		90mm
4144-8535	Poly Axial Pedicle Screw	Ø8.5	35mm
4144-8540	Poly Axial Pedicle Screw		40mm
4144-8545	Poly Axial Pedicle Screw		45mm
4144-8550	Poly Axial Pedicle Screw		50mm
4144-8555	Poly Axial Pedicle Screw		55mm
4144-8560	Poly Axial Pedicle Screw		60mm
4144-8565	Poly Axial Pedicle Screw		65mm
4144-8570	Poly Axial Pedicle Screw		70mm
4144-8575	Poly Axial Pedicle Screw		75mm
4144-8580	Poly Axial Pedicle Screw		80mm
4144-8585	Poly Axial Pedicle Screw		85mm
4144-8590	Poly Axial Pedicle Screw		90mm

Implants

Poly Axial Reduction Screw

Cat. No	Description	Size	
4148-4520	Poly Reduction Pedicle Screw	Ø4.5	20mm
4148-4525	Poly Reduction Pedicle Screw		25mm
4148-4530	Poly Reduction Pedicle Screw		30mm
4148-4535	Poly Reduction Pedicle Screw		35mm
4148-4540	Poly Reduction Pedicle Screw		40mm
4148-4545	Poly Reduction Pedicle Screw		45mm
4148-4550	Poly Reduction Pedicle Screw		50mm
4148-5525	Poly Reduction Pedicle Screw	Ø5.5	25mm
4148-5530	Poly Reduction Pedicle Screw		30mm
4148-5535	Poly Reduction Pedicle Screw		35mm
4148-5540	Poly Reduction Pedicle Screw		40mm
4148-5545	Poly Reduction Pedicle Screw		45mm
4148-5550	Poly Reduction Pedicle Screw		50mm
4148-5555	Poly Reduction Pedicle Screw		55mm
4148-5560	Poly Reduction Pedicle Screw		60mm
4148-6530	Poly Reduction Pedicle Screw	Ø6.5	30mm
4148-6535	Poly Reduction Pedicle Screw		35mm
4148-6540	Poly Reduction Pedicle Screw		40mm
4148-6545	Poly Reduction Pedicle Screw		45mm
4148-6550	Poly Reduction Pedicle Screw		50mm
4148-6555	Poly Reduction Pedicle Screw		55mm
4148-6560	Poly Reduction Pedicle Screw		60mm
4148-6565	Poly Reduction Pedicle Screw		65mm
4148-6570	Poly Reduction Pedicle Screw		70mm
4148-6575	Poly Reduction Pedicle Screw		75mm
4148-6580	Poly Reduction Pedicle Screw		80mm
4148-6585	Poly Reduction Pedicle Screw		85mm
4148-6590	Poly Reduction Pedicle Screw		90mm
4148-7530	Poly Reduction Pedicle Screw	Ø7.5	30mm

Cat. No	Description	Size	
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4148-7540	Poly Reduction Pedicle Screw		40mm
4148-7545	Poly Reduction Pedicle Screw		45mm
4148-7550	Poly Reduction Pedicle Screw		50mm
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4148-7560	Poly Reduction Pedicle Screw		60mm
4148-7565	Poly Reduction Pedicle Screw		65mm
4148-7570	Poly Reduction Pedicle Screw		70mm
4148-7575	Poly Reduction Pedicle Screw		75mm
4148-7580	Poly Reduction Pedicle Screw		80mm
4148-7585	Poly Reduction Pedicle Screw		85mm
4148-7590	Poly Reduction Pedicle Screw		90mm
4148-8535	Poly Reduction Pedicle Screw	Ø8.5	35mm
4148-8540	Poly Reduction Pedicle Screw		40mm
4148-8545	Poly Reduction Pedicle Screw		45mm
4148-8550	Poly Reduction Pedicle Screw		50mm
4148-8555	Poly Reduction Pedicle Screw		55mm
4148-8560	Poly Reduction Pedicle Screw		60mm
4148-8565	Poly Reduction Pedicle Screw		65mm
4148-8570	Poly Reduction Pedicle Screw		70mm
4148-8575	Poly Reduction Pedicle Screw		75mm
4148-8580	Poly Reduction Pedicle Screw		80mm
4148-8585	Poly Reduction Pedicle Screw		85mm
4148-8590	Poly Reduction Pedicle Screw		90mm

Implants

Poly Axial Cannulated Screw

Cat. No	Description	Size	
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4146-4525	Poly Axial Cannulated Screw		25mm
4146-4530	Poly Axial Cannulated Screw		30mm
4146-4535	Poly Axial Cannulated Screw		35mm
4146-4540	Poly Axial Cannulated Screw		40mm
4146-4545	Poly Axial Cannulated Screw		45mm
4146-4550	Poly Axial Cannulated Screw		50mm
4146-5525	Poly Axial Cannulated Screw	Ø5.5	25mm
4146-5530	Poly Axial Cannulated Screw		30mm
4146-5535	Poly Axial Cannulated Screw		35mm
4146-5540	Poly Axial Cannulated Screw		40mm
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4146-5550	Poly Axial Cannulated Screw		50mm
4146-5555	Poly Axial Cannulated Screw		55mm
4146-5560	Poly Axial Cannulated Screw		60mm
4146-6530	Poly Axial Cannulated Screw	Ø6.5	30mm
4146-6535	Poly Axial Cannulated Screw		35mm
4146-6540	Poly Axial Cannulated Screw		40mm
4146-6545	Poly Axial Cannulated Screw		45mm
4146-6550	Poly Axial Cannulated Screw		50mm
4146-6555	Poly Axial Cannulated Screw		55mm
4146-6560	Poly Axial Cannulated Screw		60mm
4146-6565	Poly Axial Cannulated Screw		65mm
4146-6570	Poly Axial Cannulated Screw		70mm
4146-6575	Poly Axial Cannulated Screw		75mm
4146-6580	Poly Axial Cannulated Screw		80mm
4146-6585	Poly Axial Cannulated Screw		85mm
4146-6590	Poly Axial Cannulated Screw		90mm
4146-7530	Poly Axial Cannulated Screw	Ø7.5	30mm

Cat. No	Description	Size	
4146-7535	Poly Axial Cannulated Screw	Ø7.5	35mm
4146-7540	Poly Axial Cannulated Screw		40mm
4146-7545	Poly Axial Cannulated Screw		45mm
4146-7550	Poly Axial Cannulated Screw		50mm
4146-7555	Poly Axial Cannulated Screw		55mm
4146-7560	Poly Axial Cannulated Screw		60mm
4146-7565	Poly Axial Cannulated Screw		65mm
4146-7570	Poly Axial Cannulated Screw		70mm
4146-7575	Poly Axial Cannulated Screw		75mm
4146-7580	Poly Axial Cannulated Screw		80mm
4146-7585	Poly Axial Cannulated Screw		85mm
4146-7590	Poly Axial Cannulated Screw		90mm
4146-8535	Poly Axial Cannulated Screw	Ø8.5	35mm
4146-8540	Poly Axial Cannulated Screw		40mm
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4146-8550	Poly Axial Cannulated Screw		50mm
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4146-8565	Poly Axial Cannulated Screw		65mm
4146-8570	Poly Axial Cannulated Screw		70mm
4146-8575	Poly Axial Cannulated Screw		75mm
4146-8580	Poly Axial Cannulated Screw		80mm
4146-8585	Poly Axial Cannulated Screw		85mm
4146-8590	Poly Axial Cannulated Screw		90mm

Implants

Poly Axial Reduction Cannulated Screw

Cat. No	Description	Size	
4137-4520	Poly Axial Reduction Cannulated Screw	Ø4.5	20mm
4137-4525	Poly Axial Reduction Cannulated Screw		25mm
4137-4530	Poly Axial Reduction Cannulated Screw		30mm
4137-4535	Poly Axial Reduction Cannulated Screw		35mm
4137-4540	Poly Axial Reduction Cannulated Screw		40mm
4137-4545	Poly Axial Reduction Cannulated Screw		45mm
4137-4550	Poly Axial Reduction Cannulated Screw		50mm
4137-5525	Poly Axial Reduction Cannulated Screw	Ø5.5	25mm
4137-5530	Poly Axial Reduction Cannulated Screw		30mm
4137-5535	Poly Axial Reduction Cannulated Screw		35mm
4137-5540	Poly Axial Reduction Cannulated Screw		40mm
4137-5545	Poly Axial Reduction Cannulated Screw		45mm
4137-5550	Poly Axial Reduction Cannulated Screw		50mm
4137-5555	Poly Axial Reduction Cannulated Screw		55mm
4137-5560	Poly Axial Reduction Cannulated Screw		60mm
4137-6530	Poly Axial Reduction Cannulated Screw	Ø6.5	30mm
4137-6535	Poly Axial Reduction Cannulated Screw		35mm
4137-6540	Poly Axial Reduction Cannulated Screw		40mm
4137-6545	Poly Axial Reduction Cannulated Screw		45mm
4137-6550	Poly Axial Reduction Cannulated Screw		50mm
4137-6555	Poly Axial Reduction Cannulated Screw		55mm
4137-6560	Poly Axial Reduction Cannulated Screw		60mm
4137-6565	Poly Axial Reduction Cannulated Screw		65mm
4137-6570	Poly Axial Reduction Cannulated Screw		70mm
4137-6575	Poly Axial Reduction Cannulated Screw		75mm
4137-6580	Poly Axial Reduction Cannulated Screw		80mm
4137-6585	Poly Axial Reduction Cannulated Screw		85mm
4137-6590	Poly Axial Reduction Cannulated Screw		90mm
4137-7530	Poly Axial Reduction Cannulated Screw	Ø7.5	30mm
4137-7535	Poly Axial Reduction Cannulated Screw		35mm
4137-7540	Poly Axial Reduction Cannulated Screw		40mm
4137-7545	Poly Axial Reduction Cannulated Screw		45mm
4137-7550	Poly Axial Reduction Cannulated Screw		50mm
4137-7555	Poly Axial Reduction Cannulated Screw		55mm
4137-7560	Poly Axial Reduction Cannulated Screw		60mm
4137-7565	Poly Axial Reduction Cannulated Screw		65mm
4137-7570	Poly Axial Reduction Cannulated Screw		70mm
4137-7575	Poly Axial Reduction Cannulated Screw		75mm
4137-7580	Poly Axial Reduction Cannulated Screw		80mm
4137-7585	Poly Axial Reduction Cannulated Screw		85mm
4137-7590	Poly Axial Reduction Cannulated Screw		90mm
4137-8535	Poly Axial Reduction Cannulated Screw	Ø8.5	35mm
4137-8540	Poly Axial Reduction Cannulated Screw		40mm
4137-8545	Poly Axial Reduction Cannulated Screw		45mm
4137-8550	Poly Axial Reduction Cannulated Screw		50mm
4137-8555	Poly Axial Reduction Cannulated Screw		55mm
4137-8560	Poly Axial Reduction Cannulated Screw		60mm
4137-8565	Poly Axial Reduction Cannulated Screw		65mm
4137-8570	Poly Axial Reduction Cannulated Screw		70mm
4137-8575	Poly Axial Reduction Cannulated Screw		75mm
4137-8580	Poly Axial Reduction Cannulated Screw		80mm
4137-8585	Poly Axial Reduction Cannulated Screw		85mm
4137-8590	Poly Axial Reduction Cannulated Screw		90mm

Implants

Chiron Straight Rod

Cat. No	Description	Size	
4302-5531	Chiron Rod Straight Rod	Ø5.5	30mm
4302-5536	Chiron Rod Straight Rod		35mm
4302-5504	Chiron Rod Straight Rod		40mm
4302-5501	Chiron Rod Straight Rod		45mm
4302-5505	Chiron Rod Straight Rod		50mm
4302-5555	Chiron Rod Straight Rod		55mm
4302-5506	Chiron Rod Straight Rod		60mm
4302-5565	Chiron Rod Straight Rod		65mm
4302-5507	Chiron Rod Straight Rod		70mm
4302-5575	Chiron Rod Straight Rod		75mm
4302-5508	Chiron Rod Straight Rod		80mm
4302-5585	Chiron Rod Straight Rod		85mm
4302-5509	Chiron Rod Straight Rod		90mm
4302-5595	Chiron Rod Straight Rod		95mm
4302-5510	Chiron Rod Straight Rod		100mm
4302-5511	Chiron Rod Straight Rod		110mm
4302-5512	Chiron Rod Straight Rod		120mm
4302-5513	Chiron Rod Straight Rod		130mm
4302-5514	Chiron Rod Straight Rod		140mm
4302-5515	Chiron Rod Straight Rod		150mm
4302-5516	Chiron Rod Straight Rod		160mm
4302-5517	Chiron Rod Straight Rod		170mm
4302-5518	Chiron Rod Straight Rod		180mm
4302-5519	Chiron Rod Straight Rod		190mm
4302-5520	Chiron Rod Straight Rod		200mm
4302-5525	Chiron Rod Straight Rod		250mm
4302-5530	Chiron Rod Straight Rod		300mm
4302-5540	Chiron Rod Straight Rod		400mm
4302-5550	Chiron Rod Straight Rod		500mm

Chiron Pre-bend Rod

Cat. No	Description	Size	
4332-5531	Chiron Rod Pre-bend Rod	Ø5.5	30mm
4332-5536	Chiron Rod Pre-bend Rod		35mm
4332-5504	Chiron Rod Pre-bend Rod		40mm
4332-5545	Chiron Rod Pre-bend Rod		45mm
4332-5505	Chiron Rod Pre-bend Rod		50mm
4332-5555	Chiron Rod Pre-bend Rod		55mm
4332-5506	Chiron Rod Pre-bend Rod		60mm
4332-5565	Chiron Rod Pre-bend Rod		65mm
4332-5507	Chiron Rod Pre-bend Rod		70mm
4332-5575	Chiron Rod Pre-bend Rod		75mm
4332-5508	Chiron Rod Pre-bend Rod		80mm
4332-5509	Chiron Rod Pre-bend Rod		90mm
4332-5510	Chiron Rod Pre-bend Rod		100mm
4332-5511	Chiron Rod Pre-bend Rod		110mm
4332-5512	Chiron Rod Pre-bend Rod		120mm
4332-5513	Chiron Rod Pre-bend Rod		130mm
4332-5514	Chiron Rod Pre-bend Rod		140mm
4332-5515	Chiron Rod Pre-bend Rod		150mm
4332-5516	Chiron Rod Pre-bend Rod		160mm
4332-5517	Chiron Rod Pre-bend Rod		170mm
4332-5518	Chiron Rod Pre-bend Rod		180mm
4332-5519	Chiron Rod Pre-bend Rod		190mm
4332-5520	Chiron Rod Pre-bend Rod		200mm

Implants

Chiron Nut Screw

Cat. No	Description	Size	
4205-0001	Chiron Nut Screw	M10	4.8mm

Chiron Crosslink

Cat. No	Description	Size
4412-3034	Crosslink	30~ 34mm
4412-3442	Crosslink	34~ 42mm
4412-4053	Crosslink	40~ 53mm
4412-5070	Crosslink	50~ 70mm

Chiron Rod Connector

Cat. No	Description	Size
4502-0011	Chiron Rod Connector	Axial
4502-1001	Chiron Rod Connector	Domino

Chiron Iliac Opened Connector

Cat. No.	Description	Size
4862-5515	Iliac Rod Connector	15mm
4862-5520	Iliac Rod Connector	20mm
4862-5525	Iliac Rod Connector	25mm
4862-5530	Iliac Rod Connector	30mm
4862-5540	Iliac Rod Connector	40mm
4862-5550	Iliac Rod Connector	50mm
4862-5560	Iliac Rod Connector	60mm

Chiron Iliac Opened Connector Variable

Cat. No.	Description	Size
4863-5515	Iliac Rod Connector Variable	15mm
4863-5520	Iliac Rod Connector Variable	20mm
4863-5525	Iliac Rod Connector Variable	25mm
4863-5530	Iliac Rod Connector Variable	30mm
4863-5540	Iliac Rod Connector Variable	40mm
4863-5550	Iliac Rod Connector Variable	50mm
4863-5560	Iliac Rod Connector Variable	60mm

Chiron Iliac Closed Connector

Cat. No.	Description	Size
4864-5515	Iliac Rod Colsed Connector	15mm
4864-5520	Iliac Rod Colsed Connector	20mm
4864-5525	Iliac Rod Colsed Connector	25mm
4864-5530	Iliac Rod Colsed Connector	30mm
4864-5540	Iliac Rod Colsed Connector	40mm
4864-5550	Iliac Rod Colsed Connector	50mm
4864-5560	Iliac Rod Colsed Connector	60mm

Chiron Iliac Closed Connector Variable

Cat. No.	Description	Size
4865-5515	Iliac Rod Colsed Connector Variable	15mm
4865-5520	Iliac Rod Colsed Connector Variable	20mm
4865-5525	Iliac Rod Colsed Connector Variable	25mm
4865-5530	Iliac Rod Colsed Connector Variable	30mm
4865-5540	Iliac Rod Colsed Connector Variable	40mm
4865-5550	Iliac Rod Colsed Connector Variable	50mm
4865-5560	Iliac Rod Colsed Connector Variable	60mm

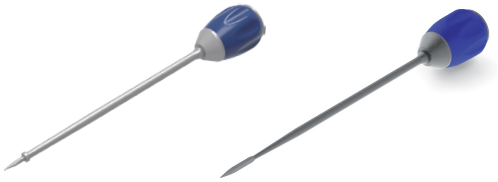
Chiron Iliac Closed Connector Variable (Curved)

Cat. No.	Description	Size
4866-5515	Iliac Rod Colsed Connector Variable (Curved)	15mm
4866-5520	Iliac Rod Colsed Connector Variable (Curved)	20mm
4866-5525	Iliac Rod Colsed Connector Variable (Curved)	25mm
4866-5530	Iliac Rod Colsed Connector Variable (Curved)	30mm
4866-5540	Iliac Rod Colsed Connector Variable (Curved)	40mm
4866-5550	Iliac Rod Colsed Connector Variable (Curved)	50mm
4866-5560	Iliac Rod Colsed Connector Variable (Curved)	60mm

Instruments

29-10015 Guide Pin Triangle
29-10016 Guide Pin Ellipse

4901-8028 Awl
9807-0038 Cannulated Awl
4901-0074 Guide Wire

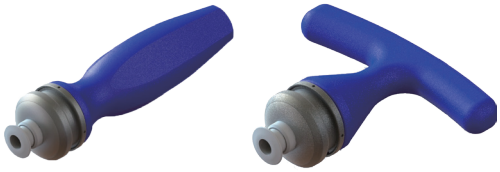


29-10012 Pedicle Probe for 5.5mm
4901-0041 Pedicle Probe, Curved 6.5mm
4901-8001 Pedicle Probe, Straight
4901-8002 Pedicle Probe, Curved

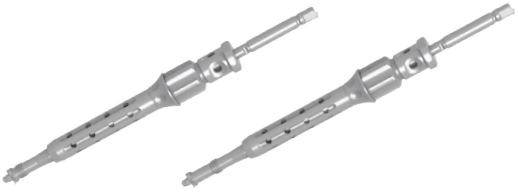
4901-8003 Sounder, Straight
4901-8004 Sounder, Angled

4901-8005 Tapper Ø 4.5mm
4901-8006 Tapper Ø 5.5mm
4901-8007 Tapper Ø 6.5mm
4901-8008 Tapper Ø 7.5mm
4901-8110 Tapper Ø 4.5mm (Cannulated)
4901-8073 Tapper Ø 5.5mm (Cannulated)
4901-8074 Tapper Ø 6.5mm (Cannulated)
4901-8075 Tapper Ø 7.5mm (Cannulated)

4901-8103 Ratcheting I-Handle
4901-8104 Ratcheting T-Handle



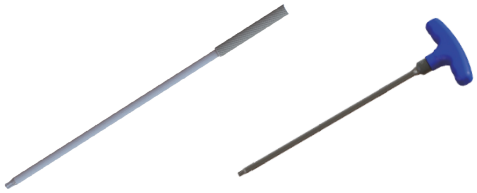
4901-8094 Chiron Screw Driver (HEX 4.0)
4901-8135 Chiron Reduction Screw Driver (HEX 4.0)



Instruments

4901-8032 Chiron Rod Holder A
4901-8049 Chiron Rod Holder B

4901-8048 Nut Starter (TORX T30)
4901-8013 Nut Starter T-Handle (TORX T30)



4901-8139 Anti Torque Wrench

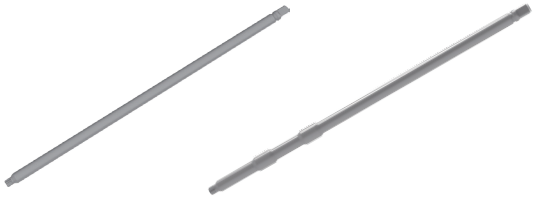
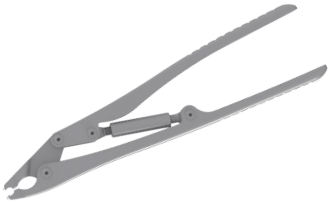
4901-8031 Screw Head Positoner

29-10026 Rod Pusher
4901-8012 Rod Rocker

4901-0030 Screw Driver 3HEX (HEX 3.0)
4901-8058 Bone Screw Driver I Handle

4901-7003 Reduction Cutter

Instruments

4901-8105 4901-8140	4CIS® Nut Screw Final Driver Shaft 240mm 4CIS® Nut Screw Final Driver Shaft 240mm	
4901-8051	French Rod Bender	
4901-0055 4901-0056	Compressor Distractor	
4901-8109 4901-8117	4CIS® Chiron Persuader I type (Forceps) 4CIS® Chiron Persuader I type (Forceps)	
29-10022	Rod Gripper	
9807-0052	Torque Limit Handle 12Nm	

Important Product Information

Spinal Fixation System

4CIS® CHIRON Spinal Fixation System
4CIS® LOW-BACK Spinal Fixation System
4CIS® SOLAR Spinal Fixation System
4CIS® VANE Spinal Fixation System
4CIS® APOLLON Spinal Fixation System
4CIS® SOLAR3 Spinal Fixation System

A. DEVICE DESCRIPTION

The Spinal Fixation System consists of a variety of pedicle screws, rods, nuts, hooks, cross links, and rod connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the mature patient. All components are made of titanium alloy, per ASTM F136 and Co-28Cr-6Mo per ASTM F1537-11.

B. INDICATIONS

The spinal fixation system is intended to provide mature patient with immobilization and stabilization through fixation for solid fusion in the spinal segments which requires treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

1. Degenerative disc disease (as defined by discogenic pain originated from degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurological impairment
3. Severe spondylolisthesis (Grade 3 and 4) of the lumbosacral vertebrae objective evidence of neurological impairment
4. Fracture
5. Dislocation
6. Scoliosis
7. Kyphosis
8. Stenosis
9. Spinal tumor
   (tumor must be removed before using our system)
10. Failed previous fusion (pseudoarthrosis).

C. CONTRAINDICATIONS

1. Immature patient
2. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures.
3. Morbid obesity who can show abnormal reaction due to excess weight near surgery area.
4. Pregnancy.
5. Grossly distorted anatomy due to congenital abnormalities.
6. Any medical or surgical condition which would preclude the potential benefit of spinal surgery with implantation.
7. Rapid joint disease, bone absorption, osteopenia, osteomalacia, or severe osteoporosis, which may prevent this system from achieving adequate fixation to the bone of target segment. It also preclude the use of any other instrumentation system as well as our spinal instrument system.
8. Suspected or documented metal allergy or intolerance.
9. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
10. Old age, mental illness, alcohol/drug abuse, medicinal poisoned or neurological disc muscle disorder which may cause fail during surgery, complications after surgery or disability of following post-operative instructions.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.
12. Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of white blood cell count (WBC), or a left shift in the WBC differential count.

D. POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

The following potential complications and adverse events (singly or in combination) could also result from implantation of the Spinal System, those are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Discomfort or abnormal sensations due to the presence of the device.
2. Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.
3. Early or late loosening of the components.
4. Disassembly, bending or breakage of any or all of the components.
5. Foreign body (allergic) reaction to the implants or Infection.
6. non-Union(pseudoarthrosis)
7. Misalignment of anatomical structures or loss of spinal mobility.
8. Fracture, damage, degenerative changes or instability of segments at the adjacent level of surgery.
9. Decrease in bone density or bone loss due to bone resorption or stress shielding.
10. Cessation of any potential growth of the operated portion of the spine.
11. Bone graft donor complications including pain, fracture of bony structures or wound healing problems.
12. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, Spinal cord impingement or damage, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis.
13. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue and/or muscle Weakness.
14. Vascular damage resulting in catastrophic or fatal bleeding.
15. Hemorrhage, hematoma, Bursitis, seroma, embolism, edema, stroke, phlebitis, wound necrosis, or wound dehiscence.
16. Atelectasis.
17. Gastrointestinal system compromise.
18. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
19. Death

E. WARNINGS 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.

F. Surgical Procedure

1. Pre-operative preparations

a. This Instructions for Use has to be read with the related surgical technique before use these implants

b. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

c. All implants and instruments delivered are non-sterilized. Therefore, decontaminating, cleaning and sterilizing is required prior to surgical use as instructed by the manufacturer. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

d. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients must be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient must understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it.

e. Patients must be advised of all above potential complications and adverse side effects as risks. For example,
patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients must be advised of this fact and warned of the potential consequences.

f. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

g. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.

2. The choice of Implants
a. Product's design and size must be selected by surgeon considering patient's weight, amount of exercise, and area of segment to be operated. Accurate decision to determine transplant size and operation techniques must be made by surgeon. Mistake to select wrong product may damage the product and cause unsuccessful surgery. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
b. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Therefore, cutting, contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced with new one.
c. Rods must only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
d. Solco spine fixation system is NOT compatible with implants from other manufacturers unless otherwise specified. If it is used with any other product, Solco biomedical Co., Ltd does not take any responsibility.
e. Discard all damaged or mishandled implants. Such implants must be handled by hospital personnel trained in the general procedures involving contaminant removal. Never reuse an implant, even though it may appear undamaged. If too much impact has been applied to the product or the product has been contacted to contaminated object or ground, then do not use the product and replace with the new one which is sterilized.
3. Intra-operative
a. Operation must be made by physician/surgeon depending on the patient's condition (Quality of bone, pathology, safety of spine).
b. It is advised to not to move patient from surgery area until bone is fully fixed by the product.
c. Patient Positioning - The patient is positioned on the operating table in the prone position. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excessive intraoperative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.
d. Exposure - The surgical approach is carried out though a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.
e. Decortication - Vertebral decortication and placement of bone grafts are usually done after pedicle screw preparation just prior to insertion of the pedicle screw. Meticulous fusion techniques are critical for success of the procedure.
f. Pedicle Probing - After confirmation of the position of the pedicle canal via radiography and creation of a cortical defect using the bone awl, the pedicle probe is gently pressed into the pedicle canal. The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars inter-articularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and noted on the preoperative radiographic images and on the intraoperative images. A small rongeur or a burr may be used to decorticate the pedicle entry point. The bone awl may be used to make an entry hole through the cortex at the pedicle entry point.
passed through the pedicle canal until the probe is 2/3rds of the distance to the anterior cortex of the vertebral body. The pedicle probe incorporates centimeter graduations and is used to determine the appropriate screw length. The length of the pedicle screw to be used can be determined relative to this measurement. Caution should be taken not to violate the anterior wall of the vertebral body or cortical walls.
g. Pedicle Testing - After use of the pedicle probe, the curved sounding probe is used to confirm continuity of the cortical walls of the pedicle. The straight sounding probe can also be used to palpate the inner surface of the pedicle canal to check for defects or perforations of the cortical walls.
h. Screw Driving - The pedicle screws are inserted using the Spinal Fixation System screw driver assembly. The screw driver head is inserted into the hexagonal opening and secured to the driver by engaging the locking outer slide into the screw head. The pedicle screw is inserted into the vertebral body to the desired depth. The pedicle screw should be parallel to the endplates and extend 50% to 80% into the vertebral body when fully seated. The distal tip of the Spinal Fixation System pedicle screw has a self-tapping flute and generally does not require tapping. Varying sizes of taps with quick connect capabilities are included for instances when tapping may be required due to high bone density.
i. Rod Selection - After the pedicle screws have been placed in the pedicles, the correct length of the rod is selected. The rods are provided in various pre-cut lengths. The rod should extend approximately 5 mm beyond the outer edges of the proximal screw bodies of the most superior and the most inferior pedicle screws.
j. Rod Bending - After the appropriate length of rod has been selected, lordosis may be bent into the rod via the rod bender. A simple lordosis bend is typically sufficient and the amount of lordosis is based on the patient's anatomy and the amount of reduction to be achieved.
k. Rod Placement and Loose Capture - After insertion of the Spinal Fixation System screws and rod bending, the rod is placed in the Spinal Fixation System screw housing. A rod gripper is provided for this purpose. The setscrew is placed by rotating clockwise using the cap-introducer instrument.
l. Rod Persuasion - A rod persuader instrument is included to assist in rod placement into the Spinal Fixation System screw housing. The persuader instrument slides over the collar of the Spinal Fixation System screw housing, where keyed tabs on the instrument engage with matching slots on the screw cup. Clockwise rotation of the persuader handle directs the rod downward into the Spinal Fixation System screw housing.
m. Distraction and Compression - Distraction is accomplished using the distractor, and compression is accomplished using the compressor. The spreader or compressor fit onto the rod adjacent to one or more loosely captured Spinal Fixation System screws. When the desired amount of distraction or compression has been achieved, final tightening of the Spinal Fixation System screw housing is performed. Screw unlocking, if desired, is the reversal of the locking procedure.
n. Final Tightening and Counter Torque - After desired distraction or compression has been performed, the anti-torque sleeve is used to stabilize the screw housing while rotating the setscrew clockwise using the final locking cap driver. Tightening should be confirmed by audible clicking of the torque handle.
o. Cross Bar Connector Placement - After final tightening of the Spinal Fixation System screws, a cross bar connector is used if desired. The cross bar connector assembly consists of one jointed transverse body and two integrated rod locking clamps. There are multiple sizes of cross bar connectors provided to allow for anatomic variation.
Once the desired location of the cross bar has been determined, the appropriate cross bar connector size is selected.The connector is placed with each clamp pressed lightly onto each rod. The cross bar connector hex driver and anti-torque sleeve, rotated clockwise, is used to tighten each locking clamp onto the rods.
4. Postoperative
a. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
b. Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
c. If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening or breakage of the device(s).
d. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Solco Spinal Fixation System components should ever be reused under any circumstances.
e. Internal fixation devices cannot always withstand activity and load levels equal to those placed on normal and healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result. Physician and/or surgeon are required to give a notice to the patient of this information as well as temporary restrictions such as limit on physical activities and few other restrictions to avoid re-surgery due to damage of product.
f. Cleaning and sterilizing of remained implants and instruments is required after surgical use as instructed by the manufacturer. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
5. Removal
a. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before attempted clinically.
b. Any decision by a surgeon to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Implant removal must be followed by adequate postoperative management to avoid fracture.

G. PACKAGING
1. The implants are delivered in packages. All they are non-sterilized and individually packed. These must be intact at the time of receipt.
2. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

H. CLEANING AND STERILIZATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE
In accordance with the reprocessing manual, Instrument should be cleaned and sterilized before use. Implant should not be cleaned and only non-sterilized implant should be sterilized before use. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

Important Product Information

1. Cleaning before sterilization
If the packing is not damaged, the product does not need to be washed. Otherwise, the product must be washed with a damp gauze pad or wipe to remove all gross visible soil. Surgical instruments must be also washed before sterilization; ultrasonic wash with water soluble neutral cleaner is advised. Cleaner's composition and cleaning method must follow by the cleaner company's. The solution must be within pH range 6-8.
2. Avoid cleaning the product in high temperature for long period.
3. Use of corrosive object including abrasive sponges and metal brushes must be avoided.
4. Verify that the product is in operating condition without any foreign substance in them after cleaning.
5. Unacceptable cleaning agents
It is inadequate to use strong acidic or basic cleaning solution such as sulphuric acid, nitric acid, or chloric acid. Sodium hydroxide (NaOH) is also prohibited.
6. Cautions when cleaning
Forbid using abrasion product or instrument. After cleaning, product's capability and condition, existence of foreign substance in implant should be checked. For this each hospital's cleaning instrument and method need to be verified.

I. DRYING
Surgical instrument and product must be dried without any water before sterilization.

J. STERILIZATION
All devices must be sterilized using FDA-cleared sterilization wraps. All non-sterilized implants and instruments must be free of packaging material and bio-contaminants prior to sterilization.
For storage before sterilization and surgery, use sterilized storage tray. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments must be autoclave sterilized using the following validated cycle parameter

- S.A.L(sterility assurance level) : 10^{-6}
- Minimum Cycle Times

The individual products are recommended to be steam sterilized by the hospital in a gravity displacement

Method	Cycle Type	Temperature	Exposure time	Drying Time
Steam	Gravity (Wrapped)	132°C(270°F)	15 min	30 min
Steam	Pre-vaccuum (Wrapped)	132°C(270°F)	4 min	30 min

It can use different sterilization method, however must verify if the sterilization method is valid before usage. Depend on sterilization method, hospital must check the certification and needs to check sterilization time and temperature regularly.
If sterilization is done with paper filter, filter must be changed every time it's used. If water is remained on sterilized tray and product you need to sterilize it again.

K. STORAGE

1. If non used product is exposed to waste, it must be sterilized and dried for storage. Product must be stored at a dry room temperature of 1 to 25° C and must be away from direct ray of light.

2. The product must be stored away from contact with metal or abrasive materials or corrosive environments to prevent damages such as cracks, scratches nick or notch. Also, the product maybe damaged from loads due to scratches not visible with naked eyes.

L. COMPLAINTS
If you are unsatisfied with the product or have complaints, please contact our representative. Especially if you suspect the product is having problems, please notify us immediately. If our products have caused damage, side effect, fatal injury to patient, please contact us immediately with the provider's information via fax, telephone, or letter. For all other complaints, please provide us product catalog number, lot number, your contact information including your name and telephone number, and detailed information about problems you are having. For more information, please contact us below.

Symbol	Description	Symbol	Description
	"DO NOT REUSE"		"MANUFACTURER"
LOT	"BATCH CODE" or "LOT NUMBER"		"DATE OF MANUFACTURE"
REF	"CATALOGUE NUMBER"		"WARNING"
	"NON STERILE"		"CAUTION, CONSULT ACCOMPANYING DOCUMENT"
Mat :	"MATERIAL"	QTY	"QUANTITY"
	"CONSULT INSTRUCTIONS FOR USE"	EC REP	"AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	"USED BY DATE"		"KEEP AWAY FROM SUNLIGHT"
CE	"ALLOWED BUSINESS ACTIVITY IN EEA"		"DO NOT USE IF PACKAGE IS DAMAGED"
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Solco Biomedical Corp.
5072 West Plano Parkway, Suite 210, Plano, TX 75093
Tel. 972-247-2486
Fax. 972-247-2413
E-mail: info@fg-solco.com
Website: www.solcospine.com