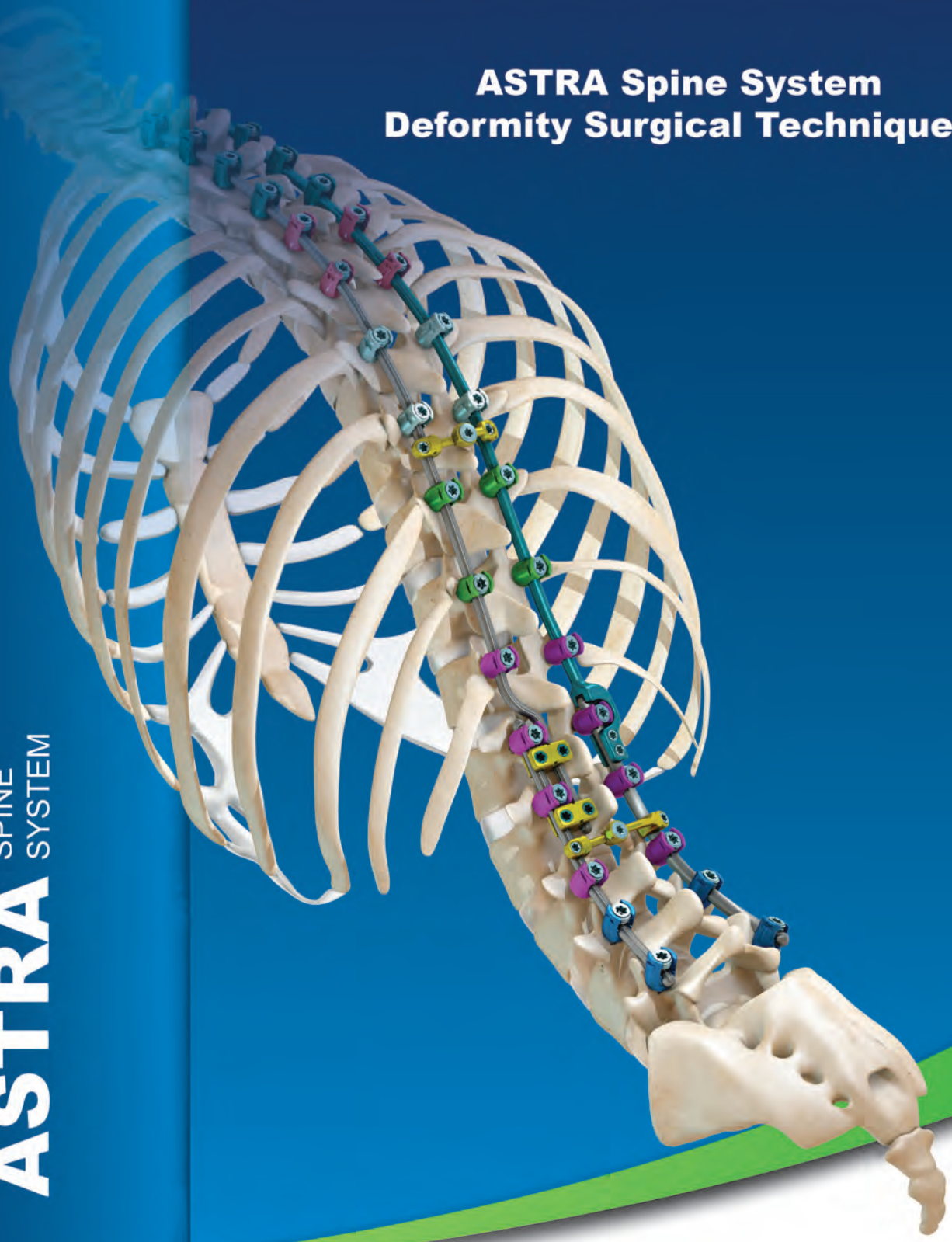
ASTRA Spine System
Deformity Surgical Techniques



ASTRA SPINE SYSTEM

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ASTRA SPINE SYSTEM

DEFORMITY SURGICAL TECHNIQUES

Disclaimer

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In the event that this document could be construed as an offer at any time, such offer shall not be binding in any event and shall require subsequent confirmation in writing.

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01. Introduction

Dear Colleagues,

The ASTRA Spine System, when used as a top-loading, top-tightening system, answers spine surgeons' pursuit for optimal deformity correction.

Deformity correction requires a comprehensive selection of implants and well-designed instruments; the ASTRA Spine System was designed to provide both.

The ASTRA Spine System allows for different techniques of rod reduction, with wide selection of rod manipulation instruments, various pedicle screws, reduction screws, hooks, and cross connectors.

The ASTRA Spine System is a comprehensive universal system that offers significant performance and ease of use benefits and brings innovation, versatility, and reliability to various spine surgery procedures.

Sincerely,

Kamal Ibrahim, MD
Elmhurst, Illinois

Steve Mardjetko, MD
Morton Grove, Illinois

Khaled Kebaish, MD
Baltimore, Maryland

02. Description

The ASTRA Spine System is a screw/hook and rod system for stabilization of the lumbar and thoracic spine. It utilizes Ø6.00mm & Ø5.50mm titanium alloy or cobalt chrome alloy rods, polyaxial and uniplanar double lead thread screws with standard or reduction heads, cross connectors, lateral Iliac connectors, rod-to-rod connectors, screw washers, and hooks.

ASTRA Spine System Key Features:

- The system employs a Ø6.0mm or Ø5.5mm rod diameter made of titanium alloy or cobalt chrome alloy.
- All standard polyaxial screws, uniplanar screws, and hooks are very compact, yet strong, for optimum performance with different rod material choices.
- All screws are designed with Dual Core Technology and Double Lead Thread.
- All ASTRA screws have a double lead thread design with optimized cortical and cancellous zones.
- Polyaxial screws and uniplanar screws are available in Ø4.50mm diameter and start from 25mm length. Reduction screws are also available in different diameters and lengths. This makes the system particularly suitable for deformity correction.
- All screws are available as self-tapping.
- ASTRA polyaxial screws have a friction-fit head designed to facilitate rod placement in deformity and complex spine procedures.
- The ASTRA Spine System includes a cross connector design, which provides very low profile and versatile connection between the two rods, regardless of their orientation or level.
- ASTRA titanium hooks & screws are color-coded by screw diameter/hook throat size.

03. Implant Ordering Information

ASTRA implant closure technology has been developed using advanced CAD techniques and has considered the latest in material and spine dynamics studies. ASTRA screws & hooks are color-coded by screw diameter/hook throat size.

Uniplanar Screws	Catalog n°
Ti Uniplanar Screw Ø4.50 x 25mm	A5U-4525
Ti Uniplanar Screw Ø4.50 x 30mm	A5U-4530
Ti Uniplanar Screw Ø4.50 x 35mm	A5U-4535
Ti Uniplanar Screw Ø4.50 x 40mm	A5U-4540
Ti Uniplanar Screw Ø5.00 x 25mm	A5U-5025
Ti Uniplanar Screw Ø5.00 x 30mm	A5U-5030
Ti Uniplanar Screw Ø5.00 x 35mm	A5U-5035
Ti Uniplanar Screw Ø5.00 x 40mm	A5U-5040
Ti Uniplanar Screw Ø5.50 x 30mm	A5U-5530
Ti Uniplanar Screw Ø5.50 x 35mm	A5U-5535
Ti Uniplanar Screw Ø5.50 x 40mm	A5U-5540
Ti Uniplanar Screw Ø5.50 x 45mm	A5U-5545
Ti Uniplanar Screw Ø6.00 x 35mm	A5U-6035
Ti Uniplanar Screw Ø6.00 x 40mm	A5U-6040
Ti Uniplanar Screw Ø6.00 x 45mm	A5U-6045
Ti Uniplanar Screw Ø6.00 x 50mm	A5U-6050
Ti Uniplanar Screw Ø6.50 x 35mm	A65U-6535
Ti Uniplanar Screw Ø6.50 x 40mm	A65U-6540
Ti Uniplanar Screw Ø6.50 x 45mm	A65U-6545
Ti Uniplanar Screw Ø6.50 x 50mm	A65U-6550
Ti Uniplanar Screw Ø7.00 x 30mm	A5U-7030
Ti Uniplanar Screw Ø7.00 x 35mm	A5U-7035
Ti Uniplanar Screw Ø7.00 x 40mm	A5U-7040
Ti Uniplanar Screw Ø7.00 x 45mm	A5U-7045
Ti Uniplanar Screw Ø7.00 x 50mm	A5U-7050

Polyaxial Screws	Catalog n°
Ti Poly Screw Ø4.50 x 25mm, Favored Angle & Friction Head	A5P-4525
Ti Poly Screw Ø4.50 x 30mm, Favored Angle & Friction Head	A5P-4530
Ti Poly Screw Ø4.50 x 35mm, Favored Angle & Friction Head	A5P-4535
Ti Poly Screw Ø4.50 x 40mm, Favored Angle & Friction Head	A5P-4540
Ti Poly Screw Ø5.00 x 25mm, Favored Angle & Friction Head	A5P-5025
Ti Poly Screw Ø5.00 x 30mm, Favored Angle & Friction Head	A5P-5030
Ti Poly Screw Ø5.00 x 35mm, Favored Angle & Friction Head	A5P-5035
Ti Poly Screw Ø5.00 x 40mm, Favored Angle & Friction Head	A5P-5040
Ti Poly Screw Ø5.50 x 30mm, Favored Angle & Friction Head	A5P-5530
Ti Poly Screw Ø5.50 x 35mm, Favored Angle & Friction Head	A5P-5535
Ti Poly Screw Ø5.50 x 40mm, Favored Angle & Friction Head	A5P-5540
Ti Poly Screw Ø5.50 x 45mm, Favored Angle & Friction Head	A5P-5545
Ti Poly Screw Ø6.00 x 35mm, Favored Angle & Friction Head	A5P-6035
Ti Poly Screw Ø6.00 x 40mm, Favored Angle & Friction Head	A5P-6040
Ti Poly Screw Ø6.00 x 45mm, Favored Angle & Friction Head	A5P-6045
Ti Poly Screw Ø6.00 x 50mm, Favored Angle & Friction Head	A5P-6050
Ti Poly Screw Ø6.50 x 35mm, Favored Angle & Friction Head	A5P-6535
Ti Poly Screw Ø6.50 x 40mm, Favored Angle & Friction Head	A5P-6540
Ti Poly Screw Ø6.50 x 45mm, Favored Angle & Friction Head	A5P-6545
Ti Poly Screw Ø6.50 x 50mm, Favored Angle & Friction Head	A5P-6550
Ti Poly Screw Ø6.50 x 55mm, Favored Angle & Friction Head	A5P-6555
Ti Poly Screw Ø7.00 x 35mm, Favored Angle & Friction Head	A5P-7035
Ti Poly Screw Ø7.00 x 40mm, Favored Angle & Friction Head	A5P-7040
Ti Poly Screw Ø7.00 x 45mm, Favored Angle & Friction Head	A5P-7045
Ti Poly Screw Ø7.00 x 50mm, Favored Angle & Friction Head	A5P-7050
Ti Poly Screw Ø7.00 x 55mm, Favored Angle & Friction Head	A5P-7055
Ti Poly Screw Ø7.00 x 60mm, Favored Angle & Friction Head	A5P-7060
Ti Poly Screw Ø7.50 x 35mm	A5P-7535
Ti Poly Screw Ø7.50 x 40mm	A5P-7540
Ti Poly Screw Ø7.50 x 45mm	A5P-7545
Ti Poly Screw Ø7.50 x 50mm	A5P-7550
Ti Poly Screw Ø7.50 x 45mm	A5P-7555
Ti Poly Screw Ø7.50 x 60mm	A5P-7560
Ti Poly Screw Ø8.50 x 35mm	A5P-8535
Ti Poly Screw Ø8.50 x 40mm	A5P-8540
Ti Poly Screw Ø8.50 x 45mm	A5P-8545
Ti Poly Screw Ø8.50 x 50mm	A5P-8550
Ti Poly Screw Ø8.50 x 55mm	A5P-8555
Ti Poly Screw Ø8.50 x 60mm	A5P-8560
Ti Poly Screw Ø8.50 x 70mm	A5P-8570
Ti Poly Screw Ø8.50 x 80mm	A5P-8580
Ti Poly Screw Ø8.50 x 90mm	A5P-8590
Ti Poly Screw Ø8.50 x 100mm	A5P-85100
Ti Poly Screw Ø9.50 x 70mm	A5P-9570
Ti Poly Screw Ø9.50 x 80mm	A5P-9580
Ti Poly Screw Ø9.50 x 90mm	A5P-9590
Ti Poly Screw Ø9.50 x 100mm	A5P-95100

Reduction Screws

Polyaxial Reduction Screws	Catalog n°
Ti Poly Reduction Screw Ø4.50 x 25mm, Favored Angle & Friction Head	A5P-4525R
Ti Poly Reduction Screw Ø4.50 x 30mm, Favored Angle & Friction Head	A5P-4530R
Ti Poly Reduction Screw Ø4.50 x 35mm, Favored Angle & Friction Head	A5P-4535R
Ti Poly Reduction Screw Ø4.50 x 40mm, Favored Angle & Friction Head	A5P-4540R
Ti Poly Reduction Screw Ø5.00 x 30mm, Favored Angle & Friction Head	A5P-5030R
Ti Poly Reduction Screw Ø5.00 x 35mm, Favored Angle & Friction Head	A5P-5035R
Ti Poly Reduction Screw Ø5.00 x 40mm, Favored Angle & Friction Head	A5P-5040R
Ti Poly Reduction Screw Ø5.00 x 45mm, Favored Angle & Friction Head	A5P-5045R
Ti Poly Reduction Screw Ø5.50 x 30mm, Favored Angle & Friction Head	A5P-5530R
Ti Poly Reduction Screw Ø5.50 x 35mm, Favored Angle & Friction Head	A5P-5535R
Ti Poly Reduction Screw Ø5.50 x 40mm, Favored Angle & Friction Head	A5P-5540R
Ti Poly Reduction Screw Ø5.50 x 45mm, Favored Angle & Friction Head	A5P-5545R
Ti Poly Reduction Screw Ø6.00 x 30mm, Favored Angle & Friction Head	A5P-6030R
Ti Poly Reduction Screw Ø6.00 x 35mm, Favored Angle & Friction Head	A5P-6035R
Ti Poly Reduction Screw Ø6.00 x 40mm, Favored Angle & Friction Head	A5P-6040R
Ti Poly Reduction Screw Ø6.00 x 45mm, Favored Angle & Friction Head	A5P-6045R
Ti Poly Reduction Screw Ø6.00 x 50mm, Favored Angle & Friction Head	A5P-6050R
Ti Poly Reduction Screw Ø6.50 x 40mm, Favored Angle & Friction Head	A5P-6540R
Ti Poly Reduction Screw Ø6.50 x 45mm, Favored Angle & Friction Head	A5P-6545R
Ti Poly Reduction Screw Ø6.50 x 50mm, Favored Angle & Friction Head	A5P-6550R
Ti Poly Reduction Screw Ø7.00 x 35mm, Favored Angle & Friction Head	A5P-7035R
Ti Poly Reduction Screw Ø7.00 x 40mm, Favored Angle & Friction Head	A5P-7040R
Ti Poly Reduction Screw Ø7.00 x 45mm, Favored Angle & Friction Head	A5P-7045R
Ti Poly Reduction Screw Ø7.00 x 50mm, Favored Angle & Friction Head	A5P-7050R
Ti Poly Reduction Screw Ø7.50 x 45mm	A5P-7545R
Ti Poly Reduction Screw Ø7.50 x 50mm	A5P-7550R
Ti Poly Reduction Screw Ø7.50 x 55mm	A5P-7555R
Ti Poly Reduction Screw Ø7.50 x 60mm	A5P-7560R
Ti Poly Reduction Screw Ø8.50 x 45mm	A5P-8545R
Ti Poly Reduction Screw Ø8.50 x 50mm	A5P-8550R
Ti Poly Reduction Screw Ø8.50 x 55mm	A5P-8555R
Ti Poly Reduction Screw Ø8.50 x 60mm	A5P-8560R
Ti Poly Reduction Screw Ø8.50 x 70mm	A5P-8570R

Reduction Screws

Uniplanar Reduction Screws	Catalog n°
Ti Uniplanar Reduction Screw Ø4.50 x 25mm	A5U-4525R
Ti Uniplanar Reduction Screw Ø4.50 x 30mm	A5U-4530R
Ti Uniplanar Reduction Screw Ø4.50 x 35mm	A5U-4535R
Ti Uniplanar Reduction Screw Ø4.50 x 40mm	A5U-4540R
Ti Uniplanar Reduction Screw Ø4.50 x 45mm	A5U-4545R
Ti Uniplanar Reduction Screw Ø5.00 x 25mm	A5U-5025R
Ti Uniplanar Reduction Screw Ø5.00 x 30mm	A5U-5030R
Ti Uniplanar Reduction Screw Ø5.00 x 35mm	A5U-5035R
Ti Uniplanar Reduction Screw Ø5.00 x 40mm	A5U-5040R
Ti Uniplanar Reduction Screw Ø5.00 x 45mm	A5U-5045R
Ti Uniplanar Reduction Screw Ø5.50 x 30mm	A5U-5530R
Ti Uniplanar Reduction Screw Ø5.50 x 35mm	A5U-5535R
Ti Uniplanar Reduction Screw Ø5.50 x 40mm	A5U-5540R
Ti Uniplanar Reduction Screw Ø5.50 x 45mm	A5U-5545R
Ti Uniplanar Reduction Screw Ø5.50 x 50mm	A5U-5550R
Ti Uniplanar Reduction Screw Ø6.00 x 35mm	A5U-6035R
Ti Uniplanar Reduction Screw Ø6.00 x 40mm	A5U-6040R
Ti Uniplanar Reduction Screw Ø6.00 x 45mm	A5U-6045R
Ti Uniplanar Reduction Screw Ø6.00 x 50mm	A5U-6050R

Cross Connectors

Adjustable Cross Connectors	Catalog n°
Ti Adjustable Cross Connector, 25-27mm	A5X-A2527
Ti Adjustable Cross Connector, 27-31mm	A5X-A2731
Ti Adjustable Cross Connector, 31-39mm	A5X-A3139
Ti Adjustable Cross Connector, 39-50mm	A5X-A3950
Ti Adjustable Cross Connector, 50-75mm	A5X-A5075

Miscellaneous Implants	Catalog n°
C-Blocker, fitting Ø5.5 and Ø6.0mm	A5B

Rod Connectors

Rod-to-Rod Connectors	Catalog n°
Tandem, Closed, fitting Ø5.5 and Ø6.0mm, 22mm	A5T-C22
Tandem, Closed, fitting Ø5.5 and Ø6.0mm, 33mm	A5T-C33
Side-by-Side, Open, Side-Loading, fitting Ø5.5, Ø6.0, & Ø6.35mm, 10mm	A5D-OS
Side-by-Side, Open, Side-Loading, fitting Ø5.5, Ø6.0, & Ø6.35mm, 12mm	A5D-OS2
Side-by-Side, Open, Side-Loading, fitting Ø5.5, Ø6.0 & Ø6.35mm, 14mm	A5D-OS4
Side-by-Side, Closed, fitting Ø5.5 and Ø6.0mm	A5D-C
U-Clamp, fitting Ø5.5, Ø6.0mm, & Ø6.35mm	A5-1090-OCU

Iliac Connectors	Catalog n°
Open Top-loading Iliac Connector, 15mm	A5L-OT015
Open Top-loading Iliac Connector, 25mm	A5L-OT025
Open Top-loading Iliac Connector, 35mm	A5L-OT035
Open Top-loading Iliac Connector, 45mm	A5L-OT045
Open Top-loading Iliac Connector, 75mm	A5L-OT075
Closed Iliac Connector, 15mm	A5L-C015
Closed Iliac Connector, 25mm	A5L-C025
Closed Iliac Connector, 35mm	A5L-C035
Closed Iliac Connector, 45mm	A5L-C045
Closed Iliac Connector, 75mm	A5L-C075

ASTRA In-line Connector Module	Catalog n°
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 150mm, Left	A5RR-55L-150
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 300mm, Left	A5RR-55L-300
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 450mm, Left	A5RR-55L-450
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 150mm, Right	A5RR-55R-150
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 300mm, Right	A5RR-55R-300
ASTRA Ø5.5mm In-line Connector Module, with Ø5.5/Ø6 Connector, 450mm, Right	A5RR-55R-450
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 150mm, Left	A5RR-56L-150
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 300mm, Left	A5RR-56L-300
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 450mm, Left	A5RR-56L-450
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 150mm, Right	A5RR-56R-150
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 300mm, Right	A5RR-56R-300
ASTRA Ø6.0mm In-line Connector Module, with Ø5.5/Ø6 Connector, 450mm, Right	A5RR-56R-450

Set Screws & Washers

Set Screws	Catalog n°
T22 Set Screw, Flat	A5S-T22F
T22 Set Screw, Coned	A5S-T22C
T30 Set Screw	A5S-T30

Screw Washers	Catalog n°
ASTRA Washer, Closed	A5W-C
ASTRA Washer, Open	A5W-O

Laminar Hooks

Narrow Laminar Hooks	Catalog n°
Ti Narrow Laminar Hook - 5.0 mm	A5H-NL50
Ti Narrow Laminar Hook - 6.5 mm	A5H-NL65
Ti Narrow Laminar Hook - 8.0 mm	A5H-NL80
Ti Narrow Laminar Hook - 9.5 mm	A5H-NL95

Laminar Hooks	Catalog n°
Ti Laminar Hook - 5.0 mm	A5H-L50
Ti Laminar Hook - 6.5 mm	A5H-L65
Ti Laminar Hook - 8.0 mm	A5H-L80
Ti Laminar Hook - 9.5 mm	A5H-L95

Transverse Process Hooks

Transverse Process Right Hooks	Catalog n°
Ti Transverse Process Hook - 8.0 mm, Right	A5H-RTP80
Ti Transverse Process Hook - 9.0 mm, Right	A5H-RTP90
Ti Transverse Process Hook - 10.0 mm, Right	A5H-RTP100
Ti Transverse Process Hook - 11.0 mm, Right	A5H-RTP110

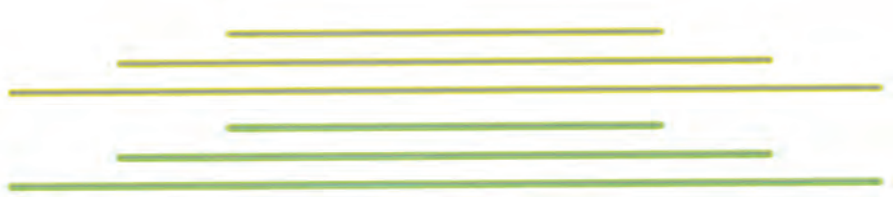
Transverse Process Left Hooks	Catalog n°
Ti Transverse Process Hook - 8.0 mm, Left	A5H-LTP80
Ti Transverse Process Hook - 9.0 mm, Left	A5H-LTP90
Ti Transverse Process Hook -10.0 mm, Left	A5H-LTP100
Ti Transverse Process Hook - 11.0 mm, Left	A5H-LTP110

Offset Hooks

Offset Left Hooks	Catalog n°
Ti 9mm Offset Left Hook - 6.5 mm	A5H-9LO65
Ti 9mm Offset Left Hook - 8.0 mm	A5H-9LO80
Ti 9mm Offset Left Hook - 9.5 mm	A5H-9LO95
Ti 12mm Offset Left Hook - 6.5 mm	A5H-12LO65
Ti 12mm Offset Left Hook - 8.0 mm	A5H-12LO80
Ti 12mm Offset Left Hook - 9.5 mm	A5H-12LO95
Ti 15mm Offset Left Hook - 6.5 mm	A5H-15LO65
Ti 15mm Offset Left Hook - 8.0 mm	A5H-15LO80
Ti 15mm Offset Left Hook - 9.5 mm	A5H-15LO95

Offset Right Hooks	Catalog n°
Ti 9mm Offset Right Hook - 6.5 mm	A5H-9RO65
Ti 9mm Offset Right Hook - 8.0 mm	A5H-9RO80
Ti 9mm Offset Right Hook - 9.5 mm	A5H-9RO95
Ti 12mm Offset Right Hook - 6.5 mm	A5H-12RO65
Ti 12mm Offset Right Hook - 8.0 mm	A5H-12RO80
Ti 12mm Offset Right Hook - 9.5 mm	A5H-12RO95
Ti 15mm Offset Right Hook - 6.5 mm	A5H-15RO65
Ti 15mm Offset Right Hook - 8.0 mm	A5H-15RO80
Ti 15mm Offset Right Hook - 9.5 mm	A5H-15RO95

Titanium Rods



Titanium Straight Rods	Catalog n°
Ti Straight Rod Ø5.50 x 300mm	A5R-55-300D
Ti Straight Rod Ø5.50 x 450mm	A5R-55-450D
Ti Straight Rod Ø5.50 x 600mm	A5R-55-600D
Ti Straight Rod Ø6.00 x 300mm	A5R-60-300D
Ti Straight Rod Ø6.00 x 450mm	A5R-60-450D
Ti Straight Rod Ø6.00 x 600mm	A5R-60-600D

Titanium Straight Rods w/ Hex End	Catalog n°
Ti Straight Rod Ø5.50 x 300mm, w/ hex end	A5R-55H-300
Ti Straight Rod Ø5.50 x 450mm, w/ hex end	A5R-55H-450
Ti Straight Rod Ø5.50 x 600mm, w/ hex end	A5R-55H-600
Ti Straight Rod Ø6.00 x 300mm, w/ hex end	A5R-60H-300
Ti Straight Rod Ø6.00 x 450mm, w/ hex end	A5R-60H-450
Ti Straight Rod Ø6.00 x 600mm, w/ hex end	A5R-60H-600

Titanium Contoured Rods	Catalog n°
Ti Contoured Rod Ø5.5mm, 55mm straight length, 300mm total length	A5R-55C55-300
Ti Contoured Rod Ø5.5mm, 55mm straight length, 450mm total length	A5R-55C55-450
Ti Contoured Rod Ø5.5mm, 55mm straight length, 600mm total length	A5R-55C55-600
Ti Contoured Rod Ø5.5mm, 70mm straight length, 300mm total length	A5R-55C70-300
Ti Contoured Rod Ø5.5mm, 70mm straight length, 450mm total length	A5R-55C70-450
Ti Contoured Rod Ø5.5mm, 70mm straight length, 600mm total length	A5R-55C70-600
Ti Contoured Rod Ø5.5mm, 85mm straight length, 300mm total length	A5R-55C85-300
Ti Contoured Rod Ø5.5mm, 85mm straight length, 450mm total length	A5R-55C85-450
Ti Contoured Rod Ø5.5mm, 85mm straight length, 600mm total length	A5R-55C85-600
Ti Contoured Rod Ø6.0mm, 55mm straight length, 300mm total length	A5R-60C55-300
Ti Contoured Rod Ø6.0mm, 55mm straight length, 450mm total length	A5R-60C55-450
Ti Contoured Rod Ø6.0mm, 55mm straight length, 600mm total length	A5R-60C55-600
Ti Contoured Rod Ø6.0mm, 70mm straight length, 300mm total length	A5R-60C70-300
Ti Contoured Rod Ø6.0mm, 70mm straight length, 450mm total length	A5R-60C70-450
Ti Contoured Rod Ø6.0mm, 70mm straight length, 600mm total length	A5R-60C70-600
Ti Contoured Rod Ø6.0mm, 85mm straight length, 300mm total length	A5R-60C85-300
Ti Contoured Rod Ø6.0mm, 85mm straight length, 450mm total length	A5R-60C85-450
Ti Contoured Rod Ø6.0mm, 85mm straight length, 600mm total length	A5R-60C85-600

Titanium Lordosed Rods	Catalog n°
Ti Lordosed Rod Ø5.50 x 30mm	A5R-55L-030
Ti Lordosed Rod Ø5.50 x 40mm	A5R-55L-040
Ti Lordosed Rod Ø5.50 x 50mm	A5R-55L-050
Ti Lordosed Rod Ø5.50 x 60mm	A5R-55L-060
Ti Lordosed Rod Ø5.50 x 70mm	A5R-55L-070
Ti Lordosed Rod Ø5.50 x 80mm	A5R-55L-080
Ti Lordosed Rod Ø5.50 x 90mm	A5R-55L-090
Ti Lordosed Rod Ø5.50 x 100mm	A5R-55L-100
Ti Lordosed Rod Ø6.00 x 30mm	A5R-60L-030
Ti Lordosed Rod Ø6.00 x 40mm	A5R-60L-040
Ti Lordosed Rod Ø6.00 x 50mm	A5R-60L-050
Ti Lordosed Rod Ø6.00 x 60mm	A5R-60L-060
Ti Lordosed Rod Ø6.00 x 70mm	A5R-60L-070
Ti Lordosed Rod Ø6.00 x 80mm	A5R-60L-080
Ti Lordosed Rod Ø6.00 x 90mm	A5R-60L-090
Ti Lordosed Rod Ø6.00 x 100mm	A5R-60L-100

Other rod sizes are available.

Cobalt Chrome Rods

Cobalt Chrome Straight Rods	Catalog n°
CoCr Straight Rod Ø5.50 x 300mm	A5R-55-300K
CoCr Straight Rod Ø5.50 x 450mm	A5R-55-450K
CoCr Straight Rod Ø5.50 x 600mm	A5R-55-600K
CoCr Straight Rod Ø6.00 x 300mm	A5R-60-300K
CoCr Straight Rod Ø6.00 x 450mm	A5R-60-450K
CoCr Straight Rod Ø6.00 x 600mm	A5R-60-600K

Cobalt Chrome Straight Rods w/ Hex End	Catalog n°
CoCr Straight Rod Ø5.50 x 300mm, w/ hex end	A5R-55H-300K
CoCr Straight Rod Ø5.50 x 450mm, w/ hex end	A5R-55H-450K
CoCr Straight Rod Ø5.50 x 600mm, w/ hex end	A5R-55H-600K
CoCr Straight Rod Ø6.00 x 300mm, w/ hex end	A5R-60H-300K
CoCr Straight Rod Ø6.00 x 450mm, w/ hex end	A5R-60H-450K
CoCr Straight Rod Ø6.00 x 600mm, w/ hex end	A5R-60H-600K

Cobalt Chrome Contoured Rods	Catalog n°
CoCr Contoured Rod Ø5.5mm, 55mm straight length, 300mm total length	A5R-55C55-300K
CoCr Contoured Rod Ø5.5mm, 55mm straight length, 450mm total length	A5R-55C55-450K
CoCr Contoured Rod Ø5.5mm, 55mm straight length, 600mm total length	A5R-55C55-600K
CoCr Contoured Rod Ø5.5mm, 70mm straight length, 300mm total length	A5R-55C70-300K
CoCr Contoured Rod Ø5.5mm, 70mm straight length, 450mm total length	A5R-55C70-450K
CoCr Contoured Rod Ø5.5mm, 70mm straight length, 600mm total length	A5R-55C70-600K
CoCr Contoured Rod Ø5.5mm, 85mm straight length, 300mm total length	A5R-55C85-300K
CoCr Contoured Rod Ø5.5mm, 85mm straight length, 450mm total length	A5R-55C85-450K
CoCr Contoured Rod Ø5.5mm, 85mm straight length, 600mm total length	A5R-55C85-600K
CoCr Contoured Rod Ø6.0mm, 55mm straight length, 300mm total length	A5R-60C55-300K
CoCr Contoured Rod Ø6.0mm, 55mm straight length, 450mm total length	A5R-60C55-450K
CoCr Contoured Rod Ø6.0mm, 55mm straight length, 600mm total length	A5R-60C55-600K
CoCr Contoured Rod Ø6.0mm, 70mm straight length, 300mm total length	A5R-60C70-300K
CoCr Contoured Rod Ø6.0mm, 70mm straight length, 450mm total length	A5R-60C70-450K
CoCr Contoured Rod Ø6.0mm, 70mm straight length, 600mm total length	A5R-60C70-600K
CoCr Contoured Rod Ø6.0mm, 85mm straight length, 300mm total length	A5R-60C85-300K
CoCr Contoured Rod Ø6.0mm, 85mm straight length, 450mm total length	A5R-60C85-450K
CoCr Contoured Rod Ø6.0mm, 85mm straight length, 600mm total length	A5R-60C85-600K

Other rod sizes are available.

Revision Rods

Z Rods	Catalog n°
Ti Ø5.5mm Z Rod, 150mm	A5RR-Z55-150
Ti Ø5.5mm Z Rod, 300mm	A5RR-Z55-300
Ti Ø5.5mm Z Rod, 450mm	A5RR-Z55-450
Ti Ø6.0mm Z Rod, 150mm	A5RR-Z60-150
Ti Ø6.0mm Z Rod, 300mm	A5RR-Z60-300
Ti Ø6.0mm Z Rod, 450mm	A5RR-Z60-450
CoCr Ø5.5mm Z Rod, 150mm	A5RR-ZK55-150K
CoCr Ø5.5mm Z Rod, 300mm	A5RR-ZK55-300K
CoCr Ø5.5mm Z Rod, 450mm	A5RR-ZK55-450K
CoCr Ø6.0mm Z Rod, 150mm	A5RR-ZK60-150K
CoCr Ø6.0mm Z Rod, 300mm	A5RR-ZK60-300K
CoCr Ø6.0mm Z Rod, 450mm	A5RR-ZK60-450K

04. Instruments

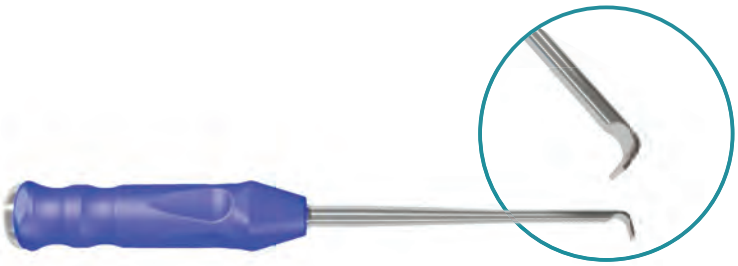
Instruments for Pedicle Preparation

Starter Awl
6000-45

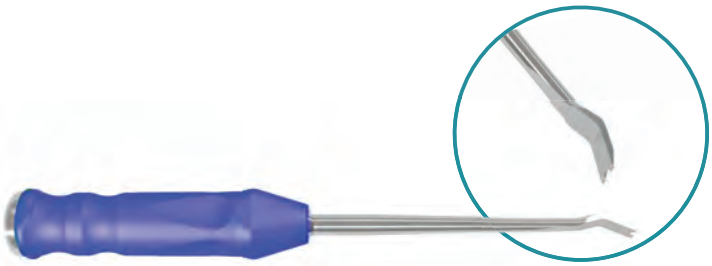
Small Sounding Probe, Straight (Hard Steel)
6000-44-1-H

Lumbar Pedicle Probe
6000-49

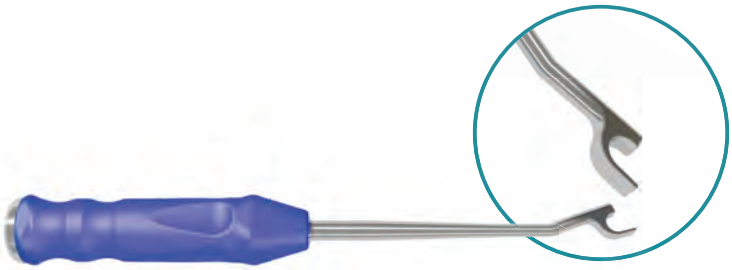
Thoracic Pedicle Probe
6000-48



Laminar Elevator/Finder
6000-31



Pedicle Elevator/Finder
6000-33

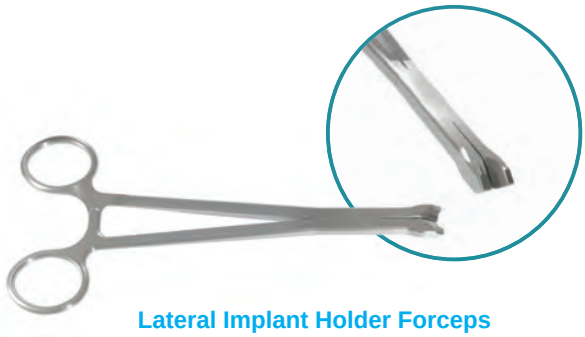


Hook Starter
6000-38

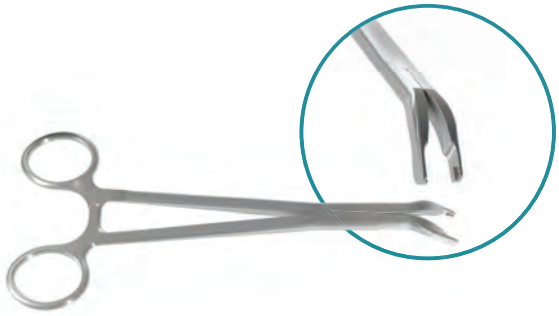
Double Lead Taps

Ø4.00mm	6300-71-40-NC	Ø6.50mm	6300-71-65-NC
Ø4.50mm	6300-71-45-NC	Ø7.00mm	6300-71-70-NC
Ø5.00mm	6300-71-50-NC	Ø7.50mm	6300-71-75-NC
Ø5.50mm	6300-71-55-NC	Ø8.50mm	6300-71-85-NC
Ø6.00mm	6300-71-60-NC	Ø9.50mm	6300-71-95-NC

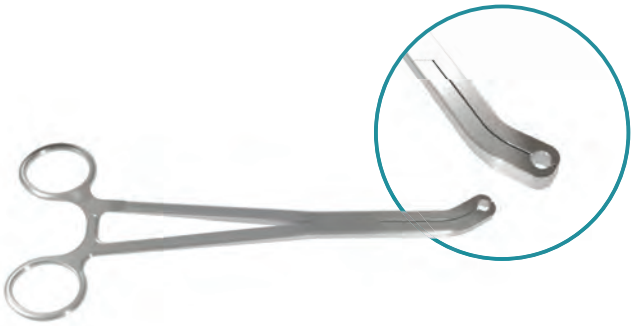
*cannulated taps also available



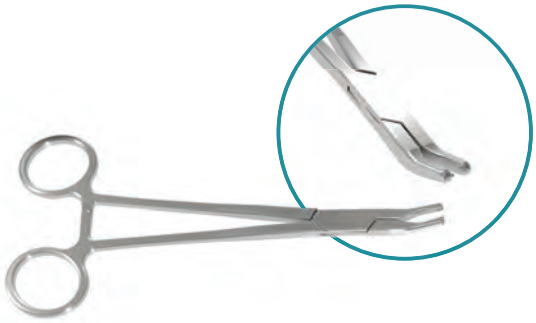
Lateral Implant Holder Forceps
6000-09



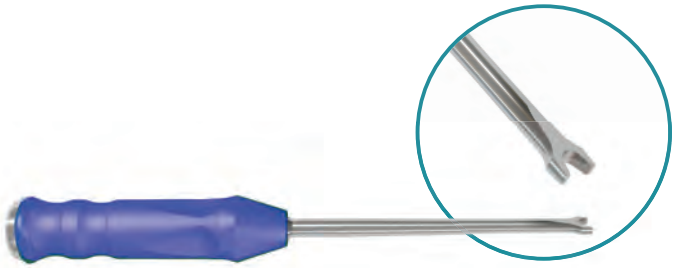
Curved Implant Holder Forceps
6300-08



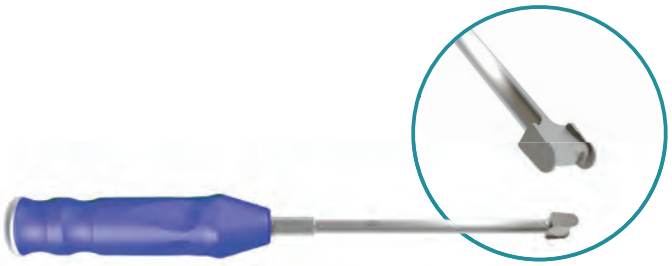
Rod Holder Forceps
6000-11



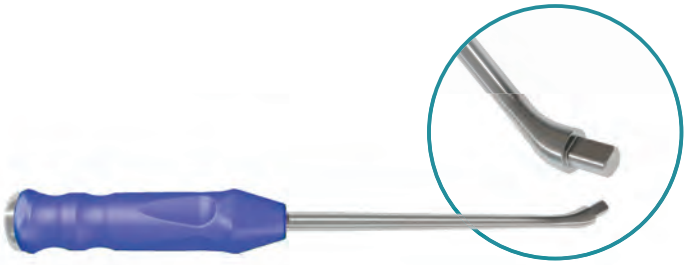
Cross Connector Holder Forceps
6300-10



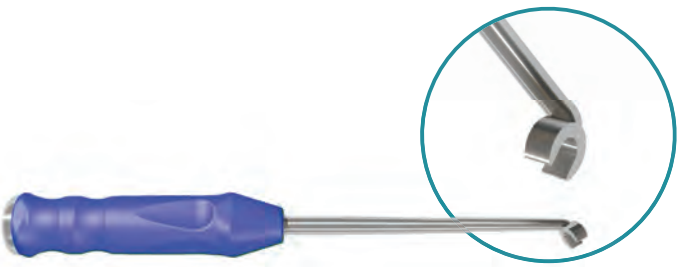
Rod Pusher
6000-34



Universal Head Adjuster
6000-75-U

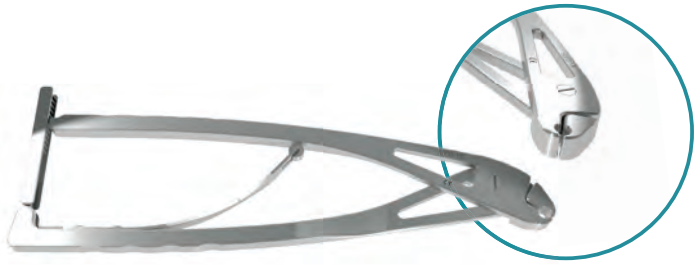


Implant Pusher Dual Purpose
6000-32

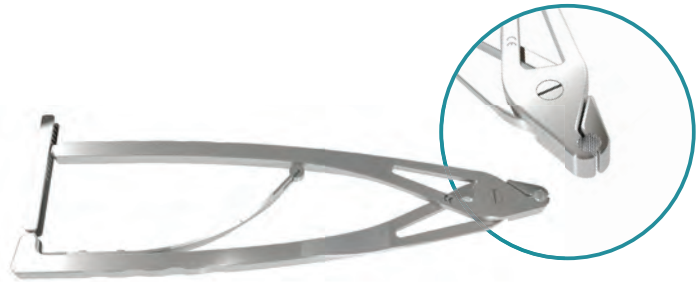


“C” Rod Pusher
6000-35

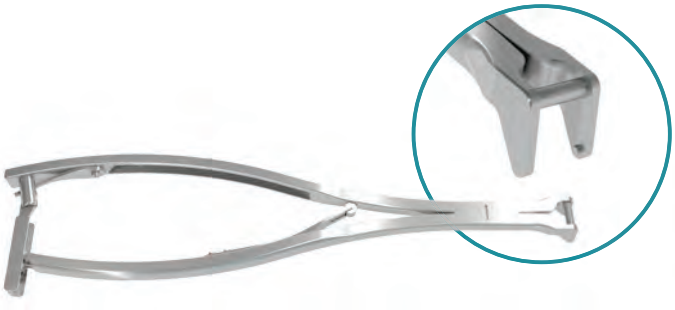
Instruments for Rod and Correction Maneuvers



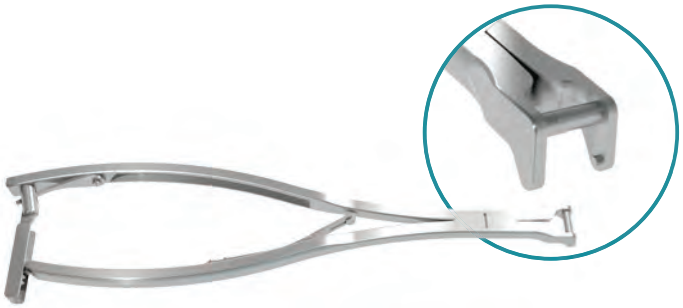
Rod Clamp, Offset (Optional)
6000-13



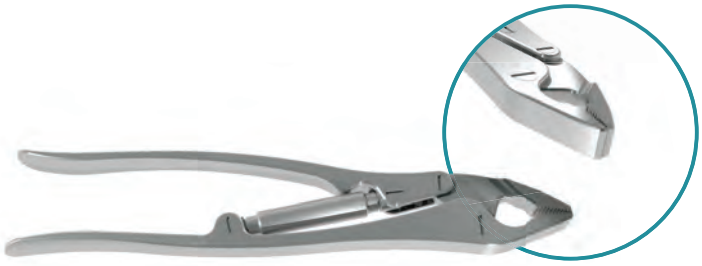
Rod Clamp, Straight
6000-12



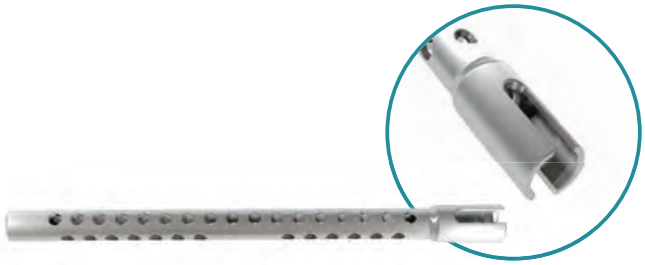
Long Forceps Rocker
6000-05



Short Forceps Rocker
6000-06

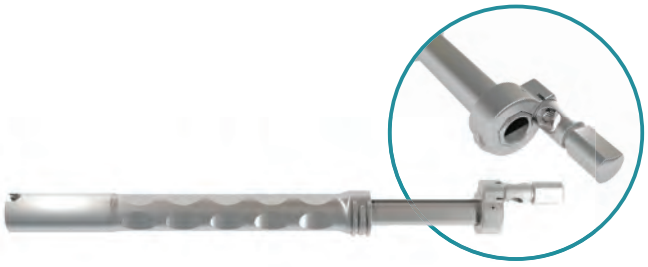


Rod Rotation Power Grip Holder
6000-18



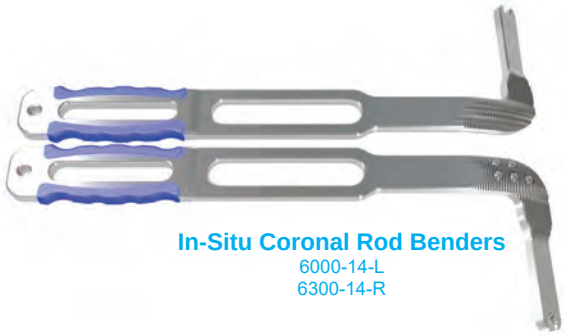
Derotation Tube (Optional)
6000-850

Dual Purpose Derotator Handle
6000-808



Derotator Post w/ Ring
6000-801

Instruments for Rod and Correction Maneuvers

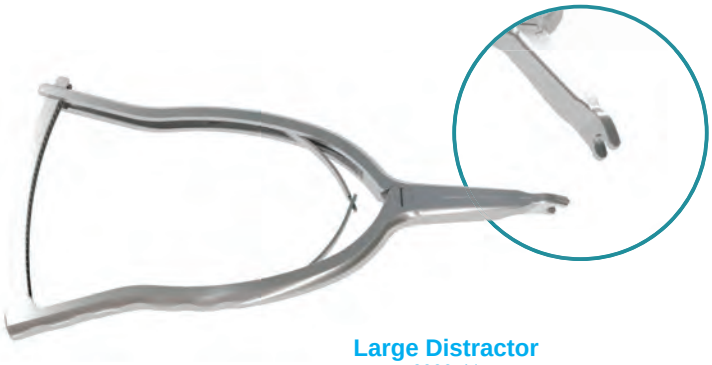


In-Situ Coronal Rod Benders
6000-14-L
6300-14-R

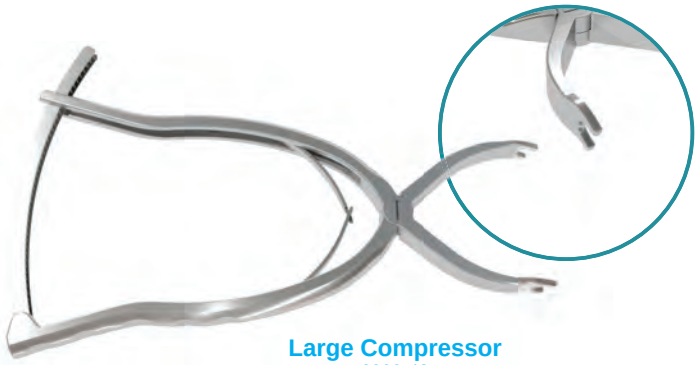
In-Situ Sagittal Rod Benders
6000-94ST-L
6000-94ST-R

French Rod Bender
6000-16-S

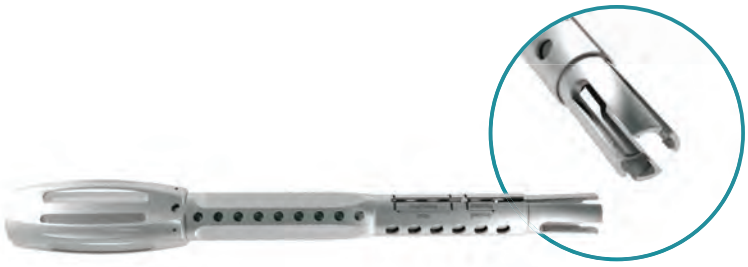
Flat Rod Benders
6000-15-A
6000-15-B



Large Distractor
6000-41



Large Compressor
6000-42



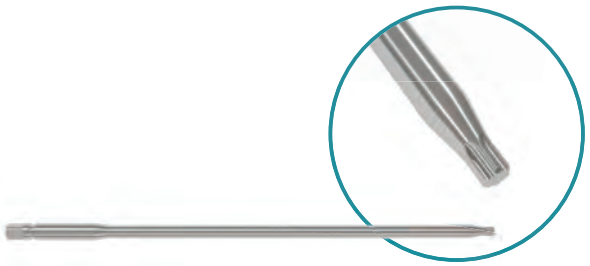
Axial Persuader
6000-01-A

***Handheld Rod Cutter**
6000-95

****Table-Top Rod Cutter** (Optional)
6000-96

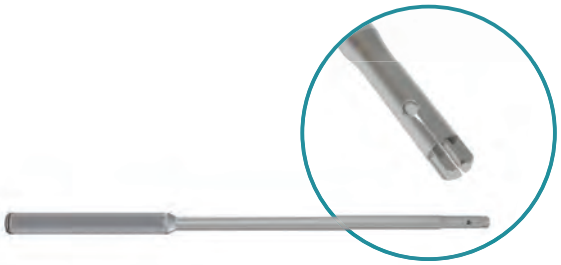
* Do not use the Handheld Rod Cutter for Cobalt Chrome rods.
** Due to the high stiffness of Cobalt Chrome rods, additional care must be taken when using the Table-Top Rod Cutter to avoid damage to the instrument. Careful inspection of the cutting mechanism should be performed before using the Table-Top Rod Cutter to cut Cobalt Chrome rods. The Table-Top Rod Cutter should not be used close to the patient.

T30 Hexalobe Driver
6000-30-M

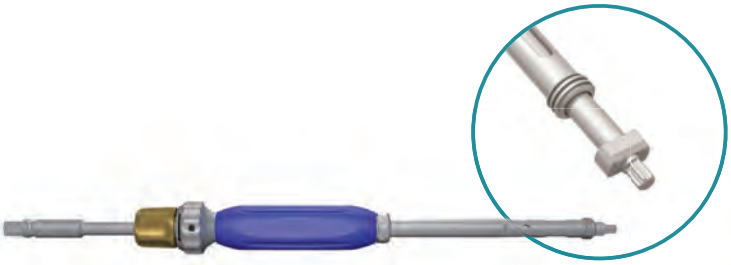


T22 Hexalobe Driver
6300-22

T30 Starter Driver
6000-30-2



T22 Self-Retaining Driver with Dedicated Handle
6300-22-3



Polyaxial Screwdriver
6300-89-PS

Dedicated Polyaxial Screwdriver
6300-89-DR

Instruments for Screws and Nuts

Torque-Limiting T-Handle 10.5Nm*
6300-02

* 6300-02 is for use with all Set Screws using a T30 Hexalobe Driver.

Torque-Limiting T-Handle 8.5Nm**
6000-02-C

** 6300-02-C is for use with all Set Screws using a T22 Hexalobe Driver.

Ratcheting Straight Handle (Optional)
6000-03-S

Ratcheting T-Handle
6000-03

Ratcheting Palm Handle
6000-03-P2

Regular Anti-Torque
6000-98

Regular Anti-Torque with Large Cannula (Optional)
6000-983

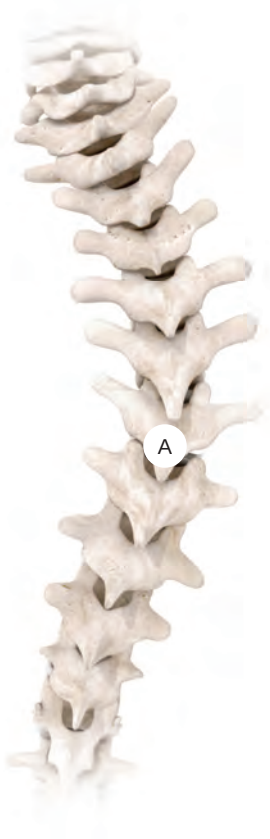
Cross Connector Anti-Torque
6300-99

05. Hook Correction Technique

Surgical Options

1

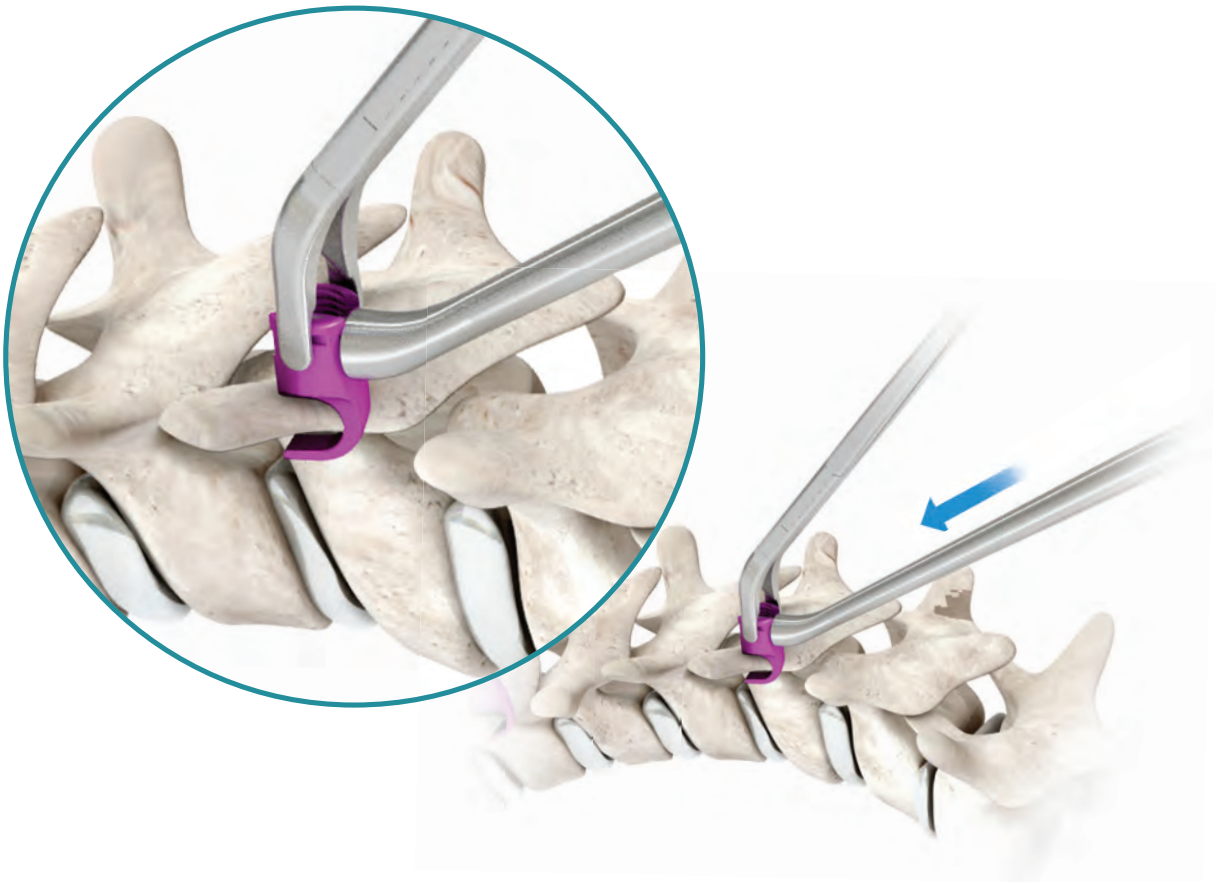
Preoperatively, any spinal surgery should be studied and a scheme of the construct defined. Shown below are examples of some typical hook constructs for a T4-L1 adolescent idiopathic scoliosis. These schemes, which are strictly for illustrative purposes, are examples of how to treat these types of scoliosis. This figure (A) shows a standard right thoracic curve (Lenke Type 1AN/King Type III) which can be instrumented with hooks from T4 to L1. This case can also be treated using a hybrid construct consisting of hooks and pedicle screws.



Hook Site Preparation

2

The ASTRA Spine System offers a number of top-loading hooks of different shapes and sizes. Any ASTRA Spine System Hook may be treated as a closed hook by simply placing the set screw into the hook prior to insertion of the rod. The surgeon must choose the appropriate hook based on the individual patient's anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants. The Curved or Lateral Implant Holder can be used for hook insertion and can be combined with the Implant Pusher as illustrated below.



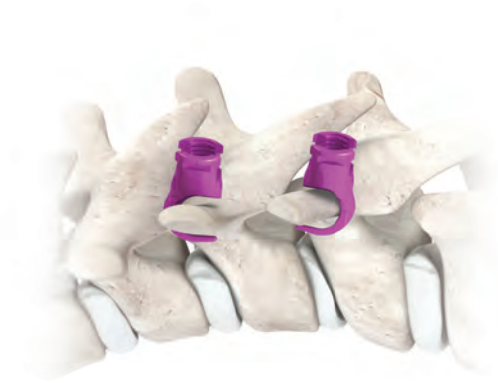
» TRANSVERSE PROCESS HOOKS

The transverse process hook is typically used in a transverse process claw construct as a caudal (down-going) hook. The Laminar Elevator or a transverse process elevator may be used to separate the ligamentous attachment between the undersurface of the transverse process and the posterior arch of the rib medial to the rib transverse joint. An Implant Holder is used to insert this hook.

» LAMINAR HOOKS:

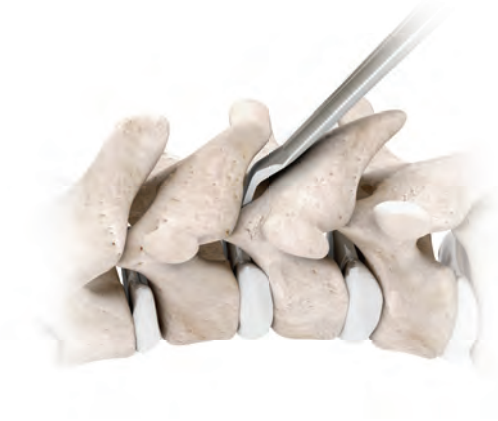
Thoracic Supralaminar Hooks

The direction of this hook is always caudal (down-going). A partial or total division of the spinous process directly above the vertebra to be instrumented (thoracic vertebra) may be performed. A division and/or partial removal of the ligamentum flavum and a small laminotomy are carried out on the superior lamina. The amount of bone removed from the lamina may vary depending on the size of the hook blade and throat angle chosen. The upper edge of the lamina below may be resected to ease the placement of this hook. The opening in the canal should not be too wide to avoid slippage of the hook body into the canal. The Laminar Elevator may be used to check the space between laminar and peridural structures.



Lumbar Infralaminar Hooks

This hook is always inserted in the cephalad direction (up-going) and is generally used at T10 or below. With this hook type, the ligamentum flavum is partially removed or separated from the inferior surface of the lamina using the Laminar Elevator, keeping the bone intact, if possible. An Implant Holder is used to insert the hook.



Narrow Laminar Hooks

The ASTRA Spine System also offers the “narrow” blade version, for use when smaller metal volume in the spinal canal is needed.

» OFFSET HOOKS

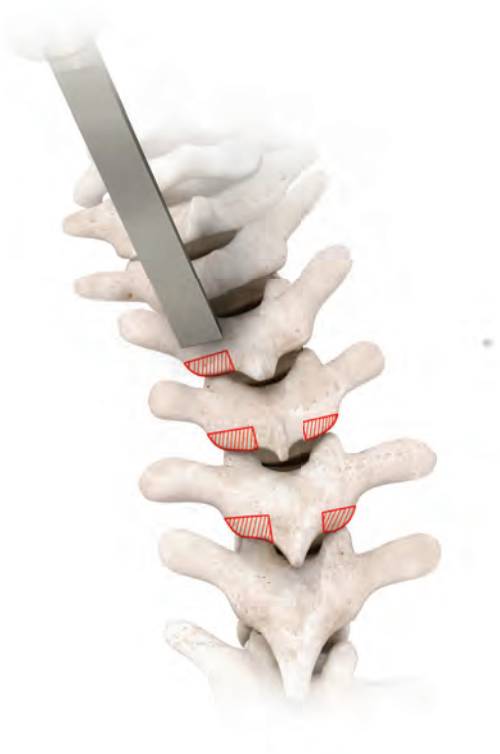
This hook is used in the thoraco-lumbar spine and is available in Left and Right versions. Offsets of 9, 12, and 15mm are offered.

Decortication

4

Once inserted, laminar hooks are not very stable prior to rod insertion. Therefore, it is recommended to remove them.

At this point in the surgery, bilateral partial facetectomies are carried out. The intervening cartilage is denuded to allow exposure of the subchondral bone assisting in bone fusion. Decortication of the laminae, spinous processes, and transverse processes is done at this stage.



Rod Contouring

5

Once the hooks on the correction side of the deformity (concave in the thoracic area, convex in the lumbar area of the spine) are tested for fit and placement, a rod template may be used to determine the length and the curve. The correction rod is cut to the appropriate length (2 to 3cm longer than the overall hook-to-hook length). To achieve the correct sagittal plane contour, the rod is bent in small incremental steps using a French Rod Bender or Flat Rod Benders. It is important to maintain a same plane orientation of the rod to prevent a spiral-type bend down the rod.

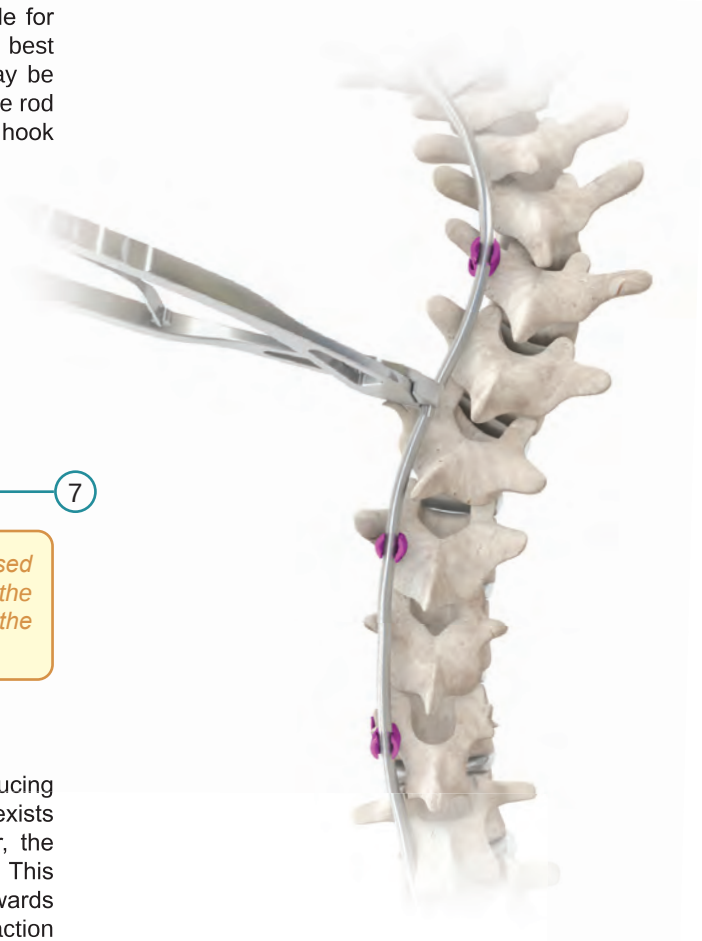
Note: In the case of a reducible scoliosis, the rod is bent according to the final postoperative planned correction to obtain a nice postoperative thoracic kyphosis and lumbar lordosis. In a case of stiff scoliosis, further in-situ contouring may be needed.

Note: When using CoCr Rods, the majority of bending should be performed before implantation with the Flat Rod Benders (6000-15 A & B). The In-Situ Coronal and Sagittal Rod Benders (6000-14 A & B and 6000-94ST-L & R) should only be used for minor corrections and only with SpineCraft-supplied rods.

Rod Insertion

6

The contoured rod is placed into the top-loading implants beginning from either the upper or lower part of the construct: there is no particular rule for rod insertion. One can start with the implants in which the rod seems to best position and facilitate the continuation of the insertion. A rod holder may be used to assist in placing the rod. The Rod Pusher may be used to push the rod down in order to place a set screw and/or, due to its C-shape, to push the hook into its correct position.



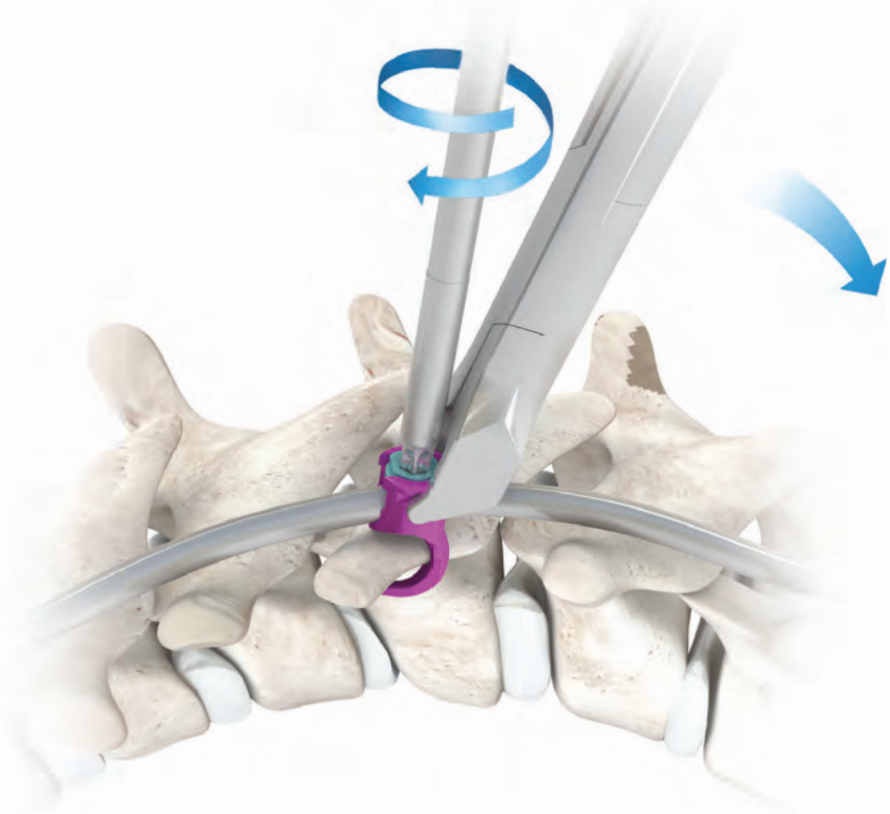
Rod Reduction

7

Note: There are several methods and instruments that may be used to facilitate rod reduction and to fully seat the rod into the saddle of the implants. Depending on the method and instruments used to reduce the rod, the set screws will be inserted with the T30 Starter Driver.

Forceps Rocker Method

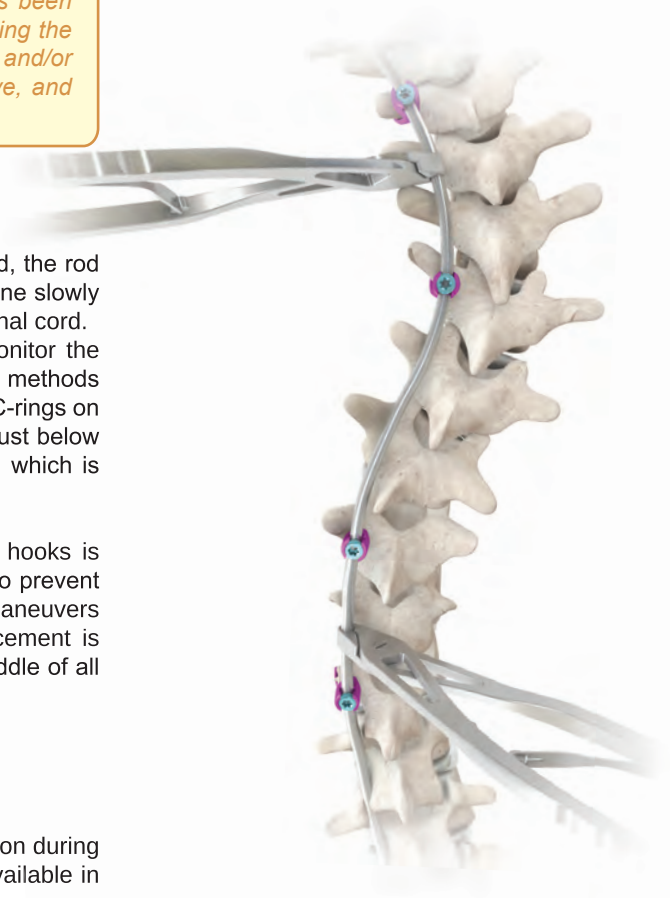
Use of the Forceps Rocker (Short or Long) is an effective method for reducing (or seating) the rod into the implant when only a slight height difference exists between the rod and the implant saddle. To use the Forceps Rocker, the Forceps tips should be facing in the same direction as the hook blade. This angle will avoid dislodgment of the hook. Lever the Forceps Rocker backwards over the rod to seat the rod into the saddle of the implant. The levering action allows the rod to be fully seated in the saddle of the implant.



Rod Rotation

8

Note: At this point of the surgery part of the correction has been achieved, mainly due to translation maneuvers used when inserting the rod. Further correction can be accomplished with rod rotation and/or in-situ bending, depending on the type and stiffness of the curve, and completed with compression/distraction maneuvers.



» ROD ROTATION

Once the contoured rod and all of the set screws have been placed, the rod is ready to be rotated into its final position. The rotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. The rotation is done using two Rod Clamps. It is important to monitor the interval hooks, which tend to back out during rod rotation. Several methods are proposed: use of the C- Shaped Rod Pusher, the placement of C-rings on the rod prior to rotation, placement of the Rod Clamps on the rod just below the hook to buttress it, or the use of a hook stabilizer instrument, which is available upon special ordering request.

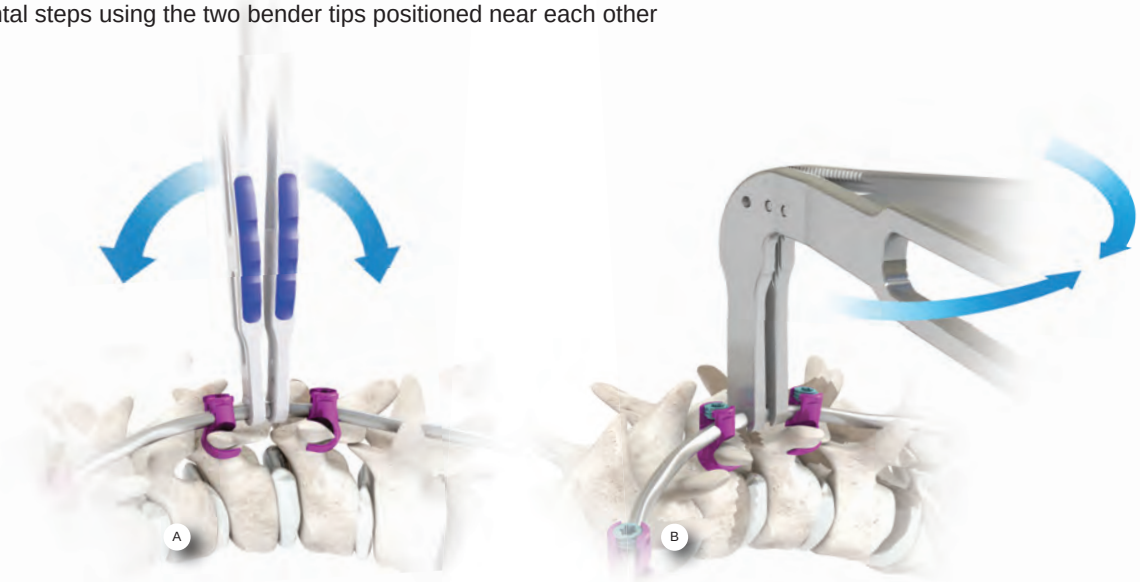
Once the rotation of the rod is complete and the position of the hooks is verified, the interval hooks' set screws are provisionally tightened to prevent rod derotation. The hooks should be checked following all rotation maneuvers and the necessary adjustments made to ensure that proper placement is maintained. At this point, the rod should be fully seated into the saddle of all of the implants.

Straight rod with hexagon end

The straight rod with hexagon end is designed to facilitate rod rotation during spine deformity correction. The straight rod with hexagon end is available in CoCr and Ti alloy material choices

» IN-SITU BENDING

In-Situ Sagittal Rod Benders may be used for correction and final adjustment of the rod in the sagittal plane (A) and the In-Situ Coronal Rod Benders may be used for correction of the rod in the coronal plane (B). The rod is bent in small incremental steps using the two bender tips positioned near each other on the rod.



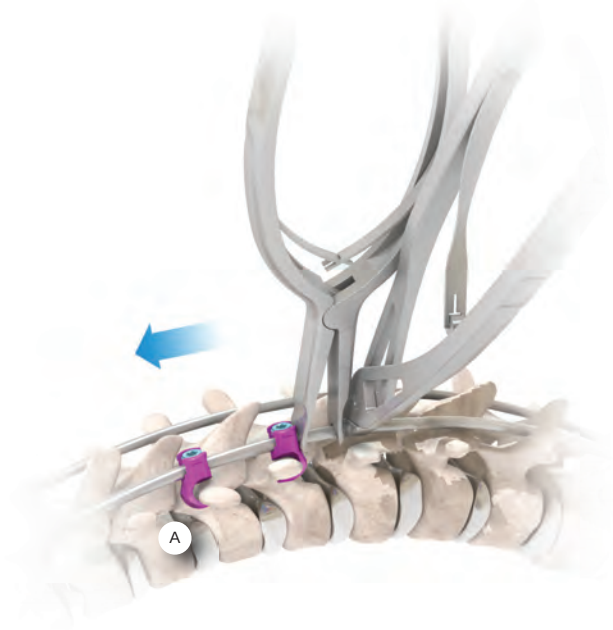
Correction in the sagittal plane

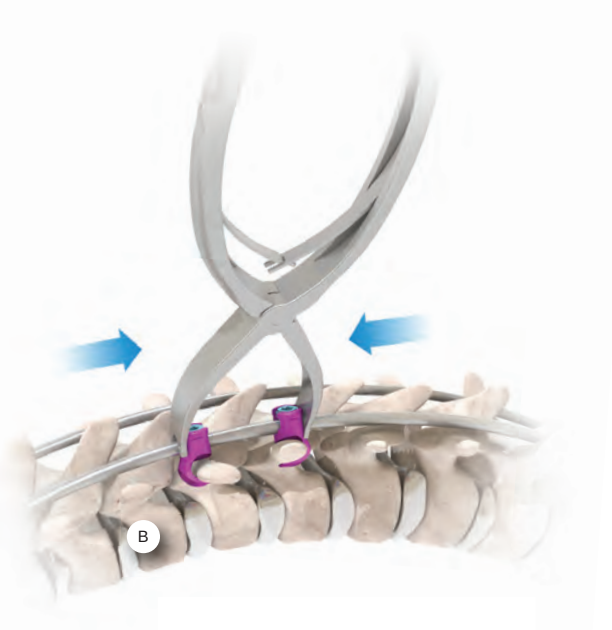
Correction in the coronal plane

Compression/Distraction

9

Once the rod is secured in the implants, distraction and/or compression are performed to place the hooks in their final position. The Compressor, Distractor, T30 Hexalobe Driver, and Rod Clamps are used to carry out these maneuvers. It is recommended to use the Rod Clamps as a stop for distraction maneuvers rather than the implant (A), with the exception of the inverted claw. Compression maneuvers are most often carried out directly on two hooks (B). Care should be taken to ensure that the foot of either instrument is placed against the implant body and not against the set screw. After these maneuvers are complete, the set screw is tightened.





Stabilization/Holding Rod Placement

10

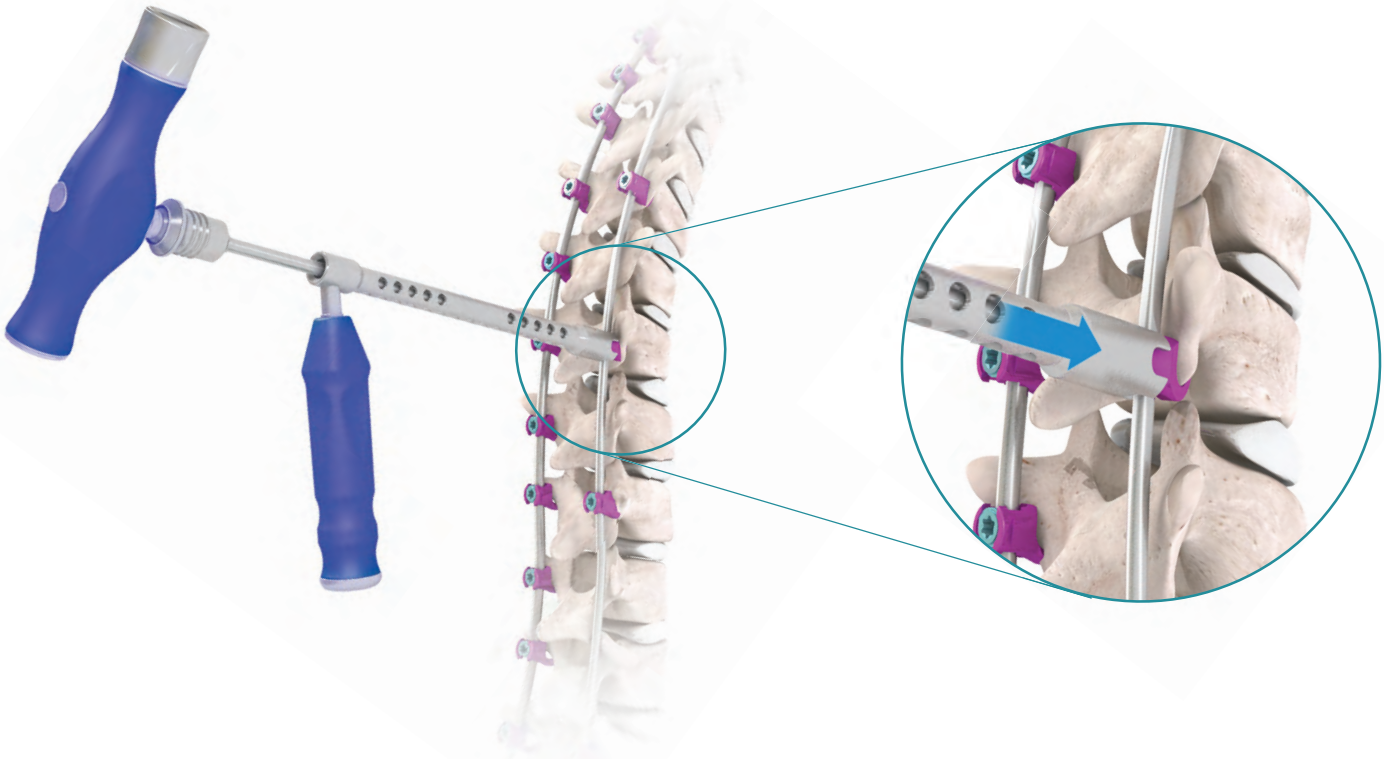
With the completion of the deformity correction and the seating of the correction rod, the opposite side of the construct is prepared. Measure the length for the stabilizing rod, then cut. Using the French Rod Bender, contour the rod according to the curvature of the spine and the residual position of alignment from the correction rod. Place the contoured rod into the hooks and provisionally secure the rod with set screws. Once the rod is secured to the implants, distraction and/or compression are performed to place the hooks in their final position. Refer to Step 9 to ensure the appropriate steps are followed.

Note: The spine may be decorticated to carry out the bone fusion and morselized cancellous bone may be placed along the decorticated spine, extending out over the transverse processes.

Final Tightening

11

When all implants are securely in place and the rod fully seated, final tightening is performed. Set screws are tightened using the T30 Hexalobe Driver, the 10.5 Nm Torque-Limiting T-Handle, and the Anti-Torque.



Cross Connector & C-Blocker Placement/Closure

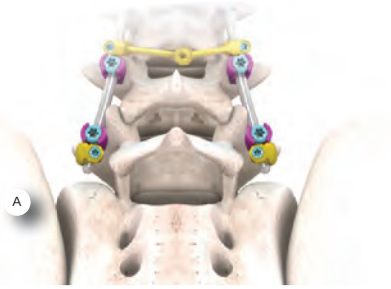
12

Once final tightening of the set screws is completed, it is mandatory that transverse connectors be placed to provide rotational stability to the construct. Final tightening of the cross connector should be done using the T22 Hexalobe Driver, the 8.5 Nm Torque-Limiting T-Handle and the Cross Connector Anti-Torque.

A framed construct resists rotational forces. Ideally, the cross connectors should be placed close to the construct extremities. The Multi-Span adjustable system is available.

The Multi-Span is a very flexible, highly adjustable system which is available in various sizes. Following cross connector placement, wound closure is performed in the customary manner.

The C-Blocker is a hook shaped implant that allows great flexibility in placement during surgery. It is designed to augment any anchor (e.g. pedicle screw) fixation during fusion, usually in complex cases at the end of the construct, as shown below (A).



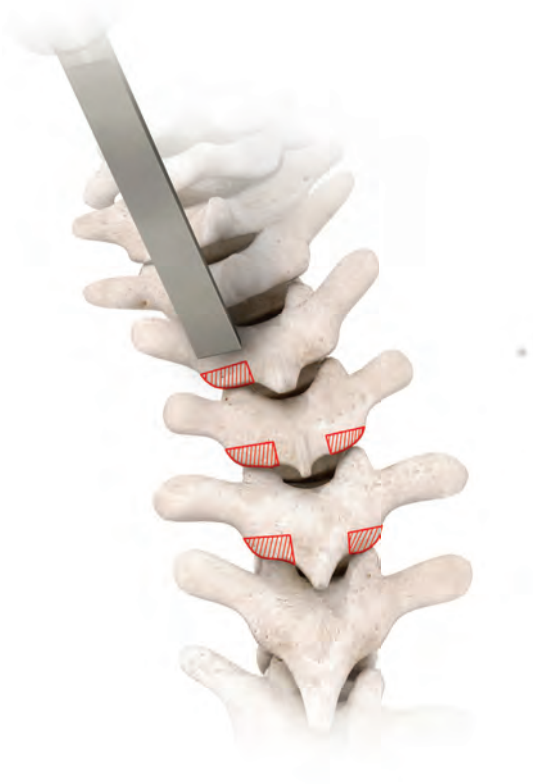
06. Pedicle Screw Correction Technique

Thoracic Facetectomy/Starting Points

1

Clean the facet joints and perform a partial inferior articular process osteotomy to enhance visualization and fusion. Remove 3mm to 5mm of the inferior facet and denude the articular cartilage on the superior facet, except for the lowest vertebra to be instrumented. This will allow for the intraoperative localization of the thoracic pedicle screw starting points.

Anatomic starting points vary by the posterior elements that can be observed intraoperatively. These include the transverse process, the lateral portion of the pars interarticularis, and the base of the superior articular process. After a thorough exposure, use as much anatomic information as possible by starting with a neutral, nonrotated vertebra. The lateral and posterior views shown below can be used as a guide for starting points and screw trajectory.



Thoracic Pedicle Screw Starting Points

2

Use or Polyaxial Screws for the straightforward approach (Purple Pins). Use Polyaxial Screws only for the anatomic approach (Green Pins).

Level	Cephalad-Caudal Starting Point	Medial-Lateral Starting Point
T1	Midpoint TP	Junction: TP-Lamina
T2	Midpoint TP	Junction: TP-Lamina
T3	Midpoint TP	Junction: TP-Lamina
T4	Junction: Proximal Third-Midpoint TP	Junction: TP-Lamina
T5	Proximal Third TP	Junction: TP-Lamina
T6	Junction: Proximal Edge Proximal Third TP	Junction: TP-Lamina-Facet
T7	Proximal TP	Midpoint Facet
T8	Proximal TP	Midpoint Facet
T9	Proximal TP	Midpoint Facet
T10	Junction: Proximal Edge-Proximal Third TP	Junction: TP-Lamina-Facet
T11	Proximal Third TP	Just medial to lateral pars

Pedicle Preparation

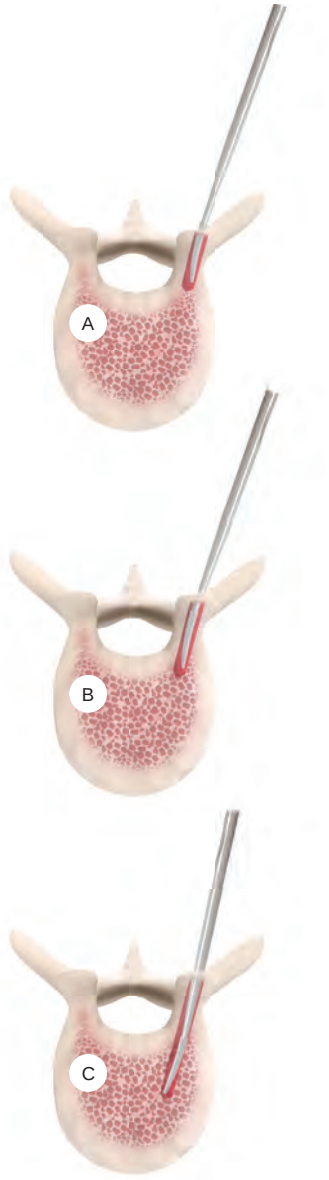
3

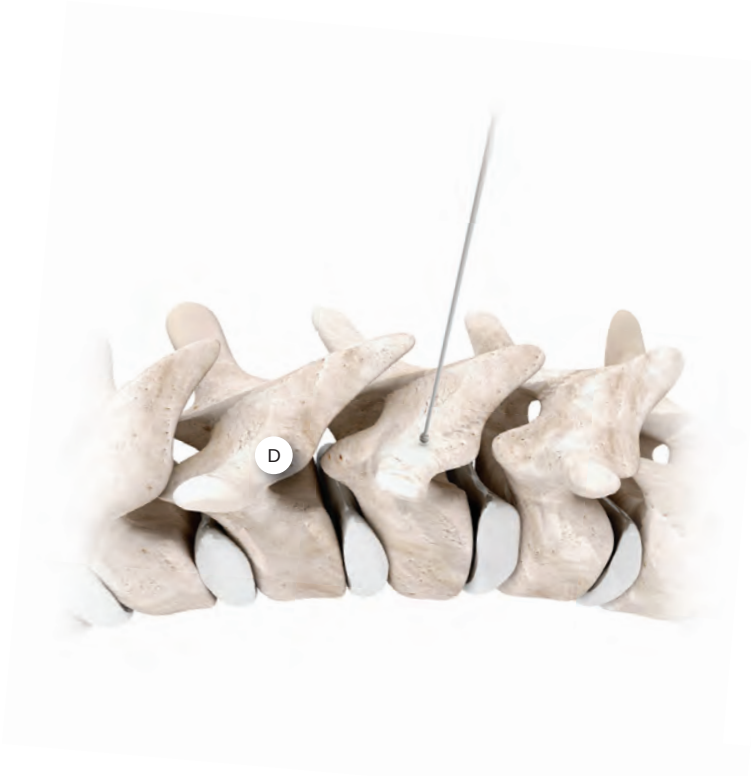
Create a 3mm deep posterior cortical breach with a high-speed burr. A pedicle “blush” may be visualized suggesting entrance into the cancellous bone at the base of the pedicle. Occasionally, when preparing small pedicles located at the apex of the curve, the blush will not be evident due to the limited intrapedicular cancellous bone. In this case, use the Thoracic Pedicle Probe to search in the burred cortical breach for the soft, funnel-shaped cancellous bone, which indicates the entrance to the pedicle. The tip should be pointed laterally to avoid perforation of the medial cortex (A).

Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm (B), and then remove the probe to reorient it so that the tip points medially. Carefully place the probe into the base of the prior hole and use the instrument markings to advance the probe to the desired depth (C). Rotate the probe 180° to ensure adequate room for the screw.

Check to ensure that only blood is coming out of the pedicle and that the bleeding is not excessive. Using a flexible ball tipped probe, advance a Sounding Probe (D) to the base (floor) of the hole to confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior). Give special care to the first 10 to 15mm of the track. Cortically breached pedicles may be salvageable. When necessary, place bone wax in the pedicle hole to limit bleeding, then reposition the probe with a more appropriate trajectory.

Next, undertap the pedicle by .75mm of the final screw diameter (E). Palpate the tapped pedicle tract with a flexible Sounding Probe (D). Clamp a hemostat to the exposed Sounding Probe and measure the length of the hole. Select the appropriate screw diameter and length by both preoperative measurement and intraoperative observation.





Screw Placement (Polyaxial and Uniplanar Screws) 4

» Polyaxial and Uniplanar Screws are inserted using a Polyaxial Screwdriver
» The Polyaxial Screwdriver is used in conjunction with the Ratcheting T-Handle

Uniplanar Screws are visibly distinguishable from the Polyaxial ASTRA tulips by the laser etched double-ended arrow on the upper part of the screws' tulips (A). Uniplanar Screws are designed to provide multiaxial freedom in the cephalad/caudal plane while remaining fixed in the medial/lateral plane (B).

To load a Polyaxial or Uniplanar Screw, insert the boss of the Screwdriver into the U-shaped slot of the screw tulip (C). Simultaneously rotate the screw shank to position the driver tip into the shank's hexalobe socket (polyaxial screws only). Slide down and turn the driver sleeve clockwise to engage the tulip thread, then tighten (D). Tighten the locking knob onto the sleeve to prevent inadvertent release of the screw (E). Once fully engaged, the screw can be inserted into the vertebral body (F)."

Implant the Polyaxial or Uniplanar Screw into the desired pedicle and advance to a depth where full angulation of the polyaxial head is maintained.

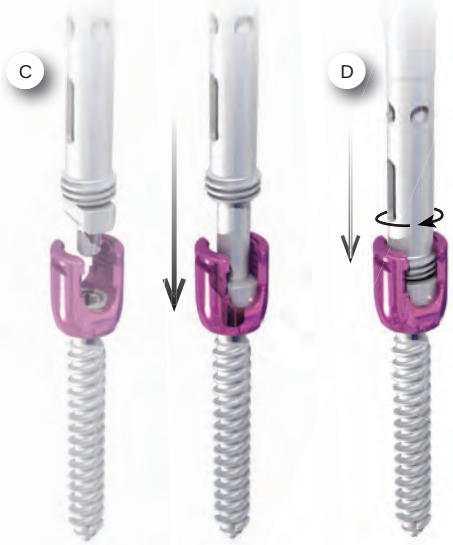
Note : Further advancement limits the angulation of the polyaxial and uniplanar screws.

Repeat the process until all polyaxial and uniplanar screws are placed.

ASTRA Polyaxial and Uniplanar Screw Diameters	Standard Lengths
Ø4.50 mm	25 to 40 mm
Ø5.00 mm	30 to 45 mm
Ø5.50 mm	35 to 50 mm
Ø6.00 mm	35 to 50 mm
Ø6.50mm	35 to 50 mm
Ø7.00mm	40 to 90 mm

ASTRA LG Polyaxial Screw Diameters	Standard Lengths
Ø7.50 mm	40 to 90 mm
Ø8.50 mm	40 to 90 mm
Ø9.50 mm	40 to 90 mm

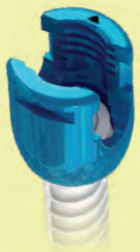
Uniplanar Screw
up to 45° ROM
cephalad/caudal

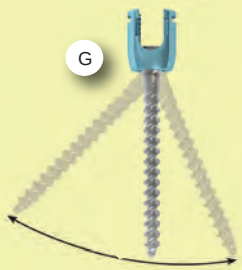


FAVORED ANGLE POLYAXIAL SCREWS

Polyaxial screws Ø4.5 - Ø7.0 are available with favored angle feature (medial/lateral). This feature, combined with the polyaxial feature, simplifies rod placement. The favored angle technology in the ASTRA Spine System allows for up to 67.5° total angulation based on the screw diameter (G). The added favored angle angulation of the screw head helps in capturing the rod at the apex of the curve during deformity correction. Using the ASTRA Favored Angle Screw at each level spreads the strain forces throughout the construct during reduction maneuvers, which reduces the risk of screw pullout.

Laser etched arrow denotes favored angle direction





Favored Angle Screw
up to 67.5° ROM
medial/lateral

Rod Contouring/Placement

5

Once correct screw placement has been verified radiographically, measure and contour rods in the sagittal and coronal planes. Clamping the rod with Rod Clamps at both ends helps prevent the rod from rotating during contouring.

CONTOURED ROD

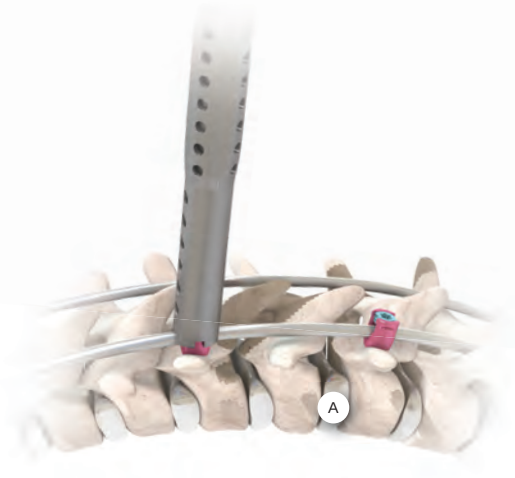
The contoured rod is pre-bent to match the kyphotic and lordotic curvature of the spine in order to save time during surgery. The contoured rod has a straight length transition between the kyphotic and lordotic sections which approximates the distance between T10 and L2. The contoured rod is available in CoCr and Ti alloy material choices.

Rod Reduction

6

Note: For non-hyperkyphotic deformities, place the rod on the concavity first. The contoured rod is placed into the previously placed screws. There are several methods and instruments that can facilitate fully seating the rod into the saddle of the implant.

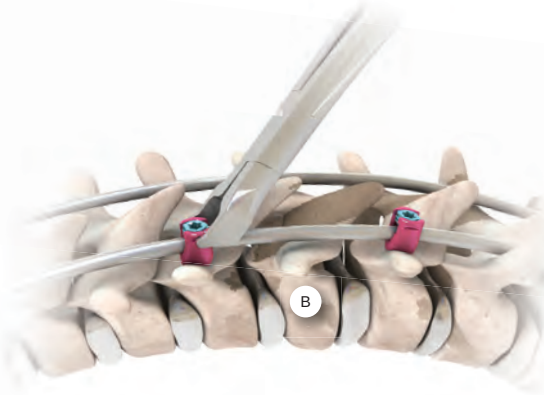
Care should be taken with any of the following reduction methods. Improper instrument use may loosen implants or damage the residual facets and other bony anatomy.



If the rod is not fully seated into the bottom of the screw head, one of the Rod Persuaders (Axial or Pistol-Grip) or one of the two Forceps Rockers (Short or Long) can be used to fully seat the rod and simplify the set screw insertion.

PERSUDER METHOD

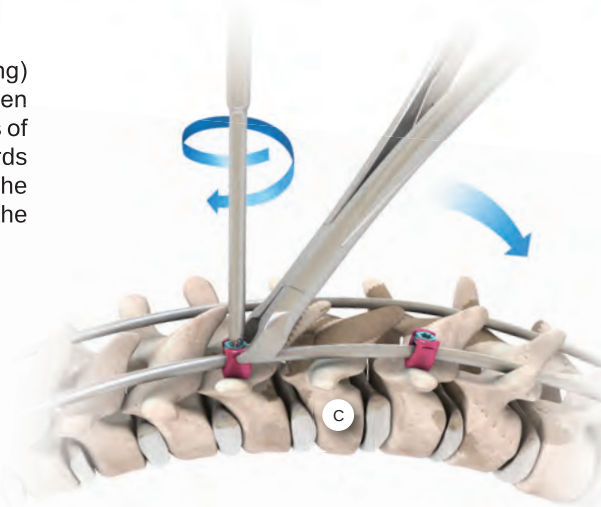
Use of the Persuaders is an effective method for reducing (or seating) the rod into the implant up to 25mm. Slide the Persuader over the implant, aligning the rod slot of the instrument with the implants. Activate the Persuader to securely capture the four recesses on the tulip and begin to reduce the rod to the fully seated position (A). The T30 Starter Driver is then used to introduce the set screw.



NOTE: Care should be taken with any rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony anatomy.

ROCKER METHOD

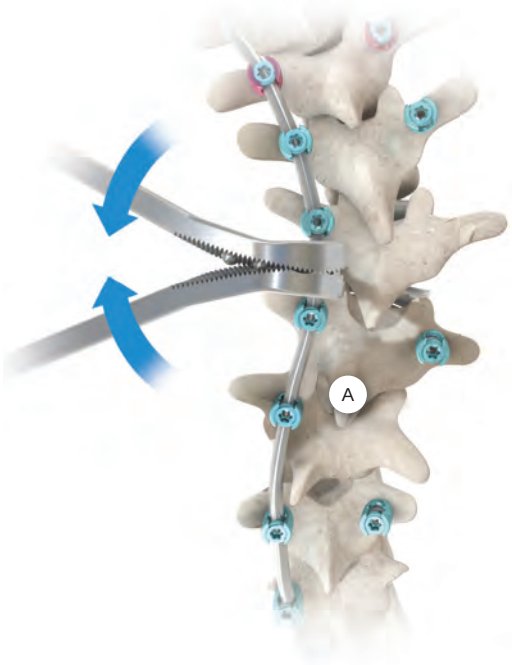
Use of the Forceps Rocker is an effective method for reducing (or seating) the rod into the implant when only a slight height difference exists between the rod and the implant saddle. To use the Forceps Rocker, grasp the sides of the implant with the rocker cam above the rod (B) and then lever backwards over the rod. The levering action allows the rod to be fully seated into the saddle of the implant. The T30 Starter Driver is then used to introduce the set screw (C).

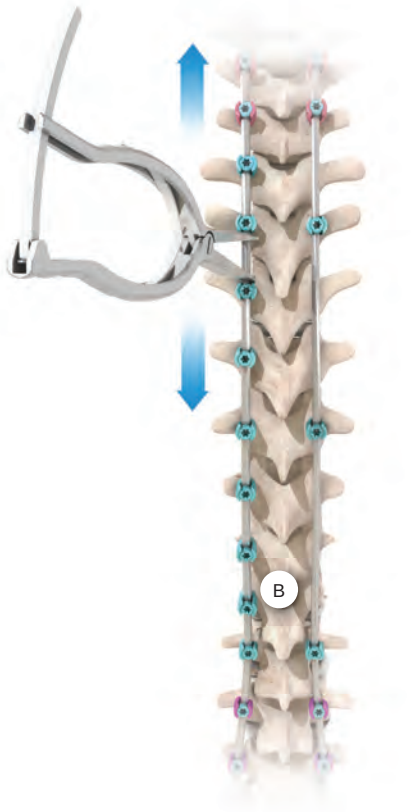


Deformity Correction

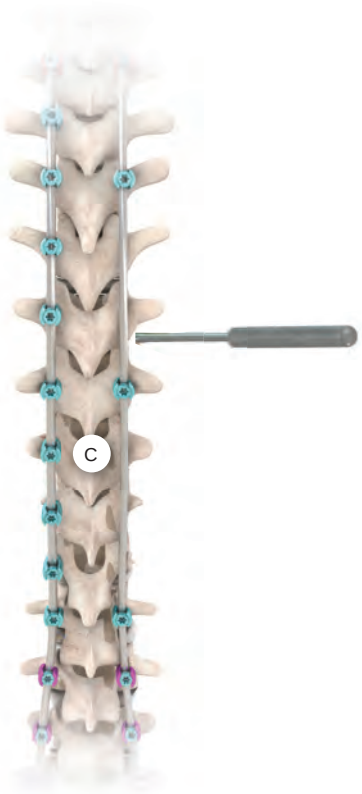
7

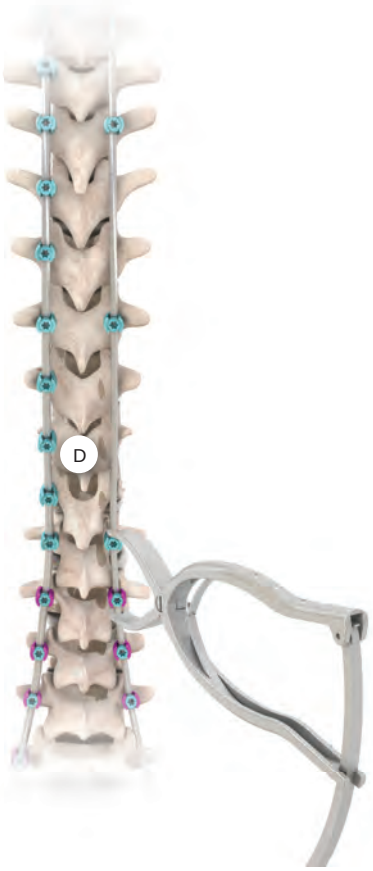
The set screws are kept loose (or only locked at one end), then the concave rod is slowly straightened with the In-Situ Coronal Benders. Each straightening of the concave rod is performed over a pedicle screw. Several passes may be required in order for viscoelastic relaxation with subsequent curve correction to occur (A). Tighten the apical set screws and perform the appropriate compression or distraction (B). Watch the screw/bone interface with all correction maneuvers.





Following placement of the second rod and set screws (C), convex compressive forces are placed on the segments using the Large Compressor to horizontalize the lowest instrumented vertebra and mildly compress the convexity of the deformity (D). NMEP and/or SSEP monitoring are performed to detect slow progressions of neurologic deficits. Fixation is verified with A/P and lateral x-rays to confirm spinal correction and alignment.





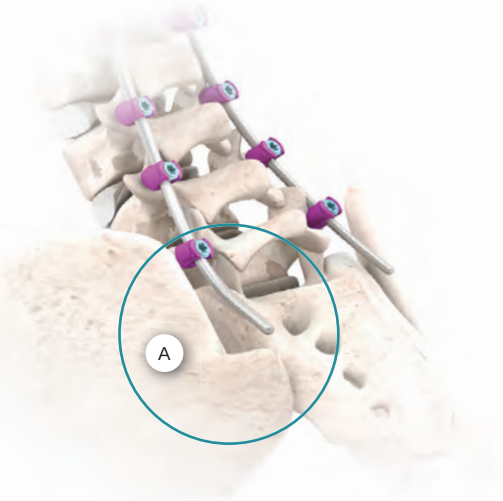
Iliac Fixation and Iliac Connector Placement

8

1. Prepare the Ilium

Exposure of the postero-lateral aspect of the iliac wing is done as per the surgeon's standard technique. The iliac wing is typically exposed enough to orient the path of the iliac wing and to avoid violation of the iliac cortex during placement of the Iliac screw.

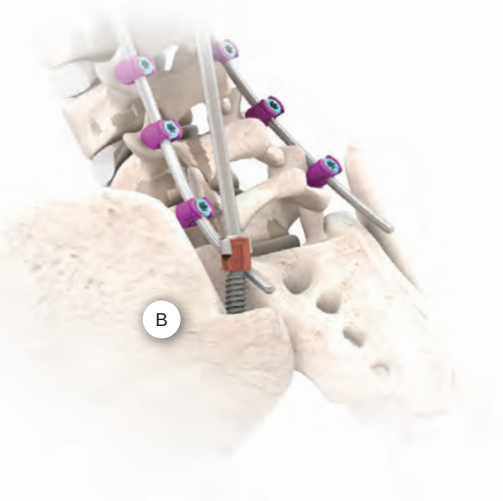
Rongeur-off the starting point for the Iliac screw - typically located 1 cm inferior to the PSIS - to the depth of about 1.5 cm to sink the Iliac Screw head in order to prevent prominence (A).



Place the iliac probe down between the iliac tables in a manner that places the path about 1cm to 1.5cm above the sciatic notch. With the iliac probe tip facing medially and with a trajectory of 45° caudally and 35° laterally as measured on preoperative CT scan, tunnel down an intraosseous pathway into the distal ilium, between the inner and outer tables.

In general, it is best to place the largest Iliac Screw diameter possible. The Screw is placed after the inner and outer tables are felt with a pedicle sound and the iliac walls and floors are noted to be intact.

Insert the Iliac Screw into the iliac wing (B).



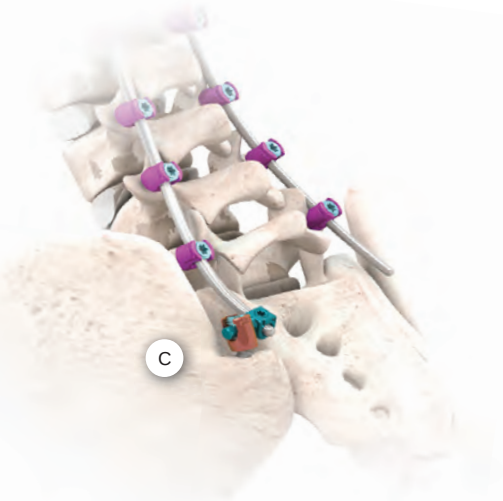
Gauge the required length of the Iliac Connector.

2. Applying the Iliac Connector

Insert/Preload the Iliac Connector onto the Longitudinal Spine Rod.
The roded part of the Iliac Connector may be cut and contoured as necessary.
Apply & align the roded part of the Iliac Connector to the head of the Iliac screw (C).

3. Provisional and Final Tightening

Tighten the Set Screw at the Iliac Connector/Longitudinal Spine Rod interface. All Set Screws must be final tightened with the T30 Hexalobe Driver coupled with the 10.5 Nm Torque-Limiting T-Handle in combination with the appropriate size Anti-Torque.



Warning: When placing screws in the ilium it is recommended to use tap size equal to the screw diameter. Using the same size tap and screw will prevent premature screwdriver breakage failure. Example: If placing an 8.5 mm iliac screw use the 8.5 mm tap.

Rod-to-Rod Connectors

9

The ASTRA Spine System offers different sizes of **Rod-to-Rod Connectors** to extend or revise constructs which use the same or different rod diameters.

Closed, Open, Side-loading and Tandem Rod-to-Rod Connectors are provided to allow connecting to an existing construct for construct extension and revision procedures. They are available to connect rods in multiple diameters (Ø5.5mm and Ø6.0mm). Open Side-loading Connectors can connect rods in Ø5.5mm, Ø6.0mm, and Ø6.35mm for revision purposes.

They can also be used to connect two rods when using three, four, or multiple rod techniques for complex surgeries. The Rod-to-Rod Connectors provide the ability for modular connection, adding to an existing construct.

Closed and Open, Side-loading Rod-to-Rod Connectors should be utilized in succession when connecting two rods side-by-side together, with a minimum of two per side. The connectors should also be spaced apart, between levels, to increase the overall strength of the construct and avoid the possibility of a pivot point between the two connected rods.

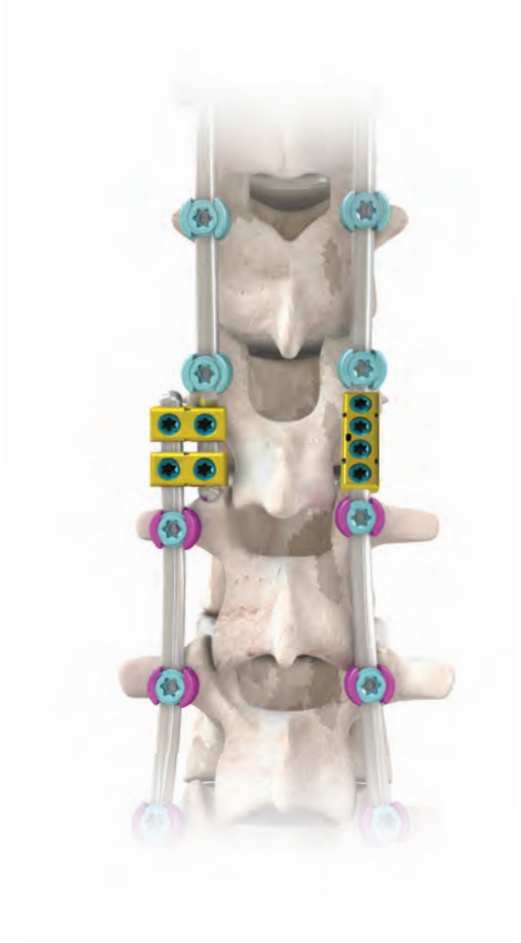
Tandem Rod-To-Rod Connectors are utilized to connect two rods axially together and can be particularly useful when space is limited and/or when the construct doesn't allow the use of the Open, Side-loading connectors.

Open Side-loading Rod-to-Rod Connectors are available to connect to Ø5.5mm, Ø6.0mm rods, and Ø6.35mm for revision purposes.

To utilize a Rod-to-Rod connector, select the appropriate type and size and insert the end of the rod into the corresponding-size opening of the connector and secure the rod provisionally.

Next, insert the other rod into the remaining opening on the connector, and secure the rod provisionally.

Use the appropriate size Hexalobe Driver with the appropriate size Torque-Limiting T-Handle to tighten all Set Screws until the Torque Handle audibly clicks.



Final Tightening/Decortication

10

After securing the rod within the implants, distraction and/or compression can be performed to place the screws in the final position. Compression is preferably released just before the final tightening. This will allow the implant head and rod to be normalized to each other and therefore allow the rod to be fully seated in the implant head during the final tightening.

Final tightening of the set screws is completed using the T30 Hexalobe Driver, the 10.5 Nm Torque-Limiting T-Handle, and the Anti-Torque. This locks the rods into place (A).

Final tightening of reduction screws requires use of the Regular Anti-Torque with Large Cannula. After final tightening is complete, Reduction Tabs can be removed using the Reduction Tab Remover (B).

Note: The Regular Anti-Torque with Large Cannula (6300-983) should always be made availalbe for use in the surgery when reduction screws are implanted.

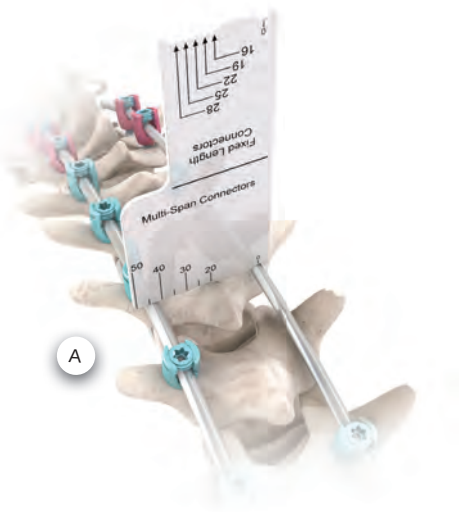
Placement of Cross Connector

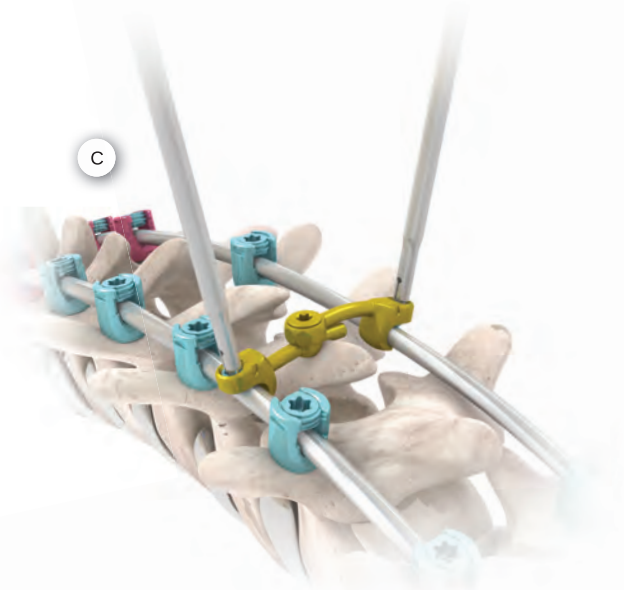
11

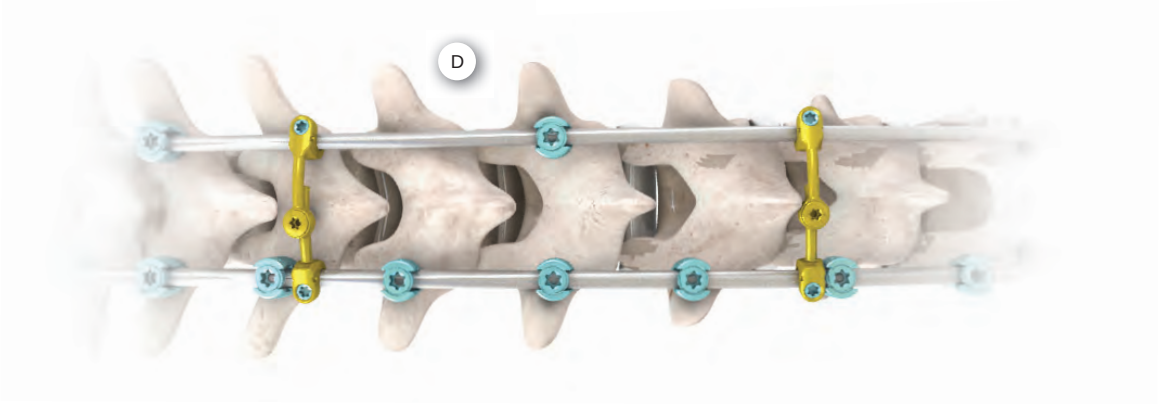
To place a Multi-Span Cross Connector, use the side of the X-C Size Selection Card labeled “Adjustable Length Connectors” (A). Place the semi-circular notch on one of the rods and estimate the distance of the span using the ruled portion of the card.

To insert a Multi-Span Cross Connector, the connector can be loaded directly from the caddy by inserting the tips of two of the T22 Self- Retaining Drivers with Dedicated Handles into the lateral gold-color set screws (B). Partially untighten the set screws while the connector is still in the caddy. Place the connector onto the rods and provisionally tighten the lateral set screws (C).

Final tightening of the connector should be done using the 8.5 Nm Torque-limiting T-Handle, the T22 Hexalobe Driver and the Cross Connector Anti-Torque (refer to the ASTRA Cross Connector Surgical Technique). Cross connectors should be placed at the proximal and distal ends of the construct (D).







07. Revision/Removal

Cross Connector Removal

To remove a Cross Connector, attach the Ratcheting T-Handle to a T22 Hexalobe Driver. Use the Cross Connector Anti-Torque and turn the T-Handle counterclockwise one full turn to loosen the central screw (MultiSpan Cross Connectors only). Use the T22 Hexalobe Driver to loosen and then remove the side set screws of the cross connector hooks.

Screw or Hook Set Screw Removal

To remove a set screw from a screw or a hook, attach the Ratcheting T-Handle to a T30 Hexalobe Driver and use with the Anti-Torque. Turn the handle counterclockwise to loosen and then remove the set screws completely. Remove the rod.

Tulip Remobilization

The polyaxial and uniplanar screw tulips can be remobilized with the Universal Head Adjuster. After removing the set screw and the rod, fit the Implant Head Adjuster into the tulip. Toggle the tool to manipulate the head without rotation.

Screw Removal

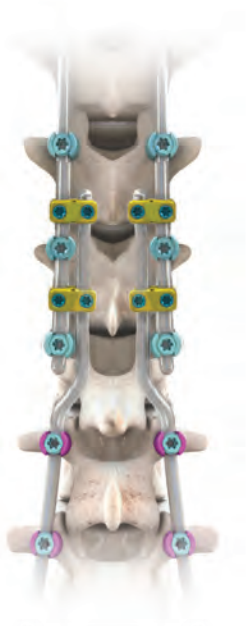
Use the T22 Hexalobe Driver or the Polyaxial Screwdriver with the Ratcheting T-Handle to remove a polyaxial screw.

Use the T22 Hexalobe Driver or the Polyaxial Screwdriver with the Ratcheting T-Handle or the Universal Head Adjuster to remove a uniplanar screw.

Revision Implant Insertion

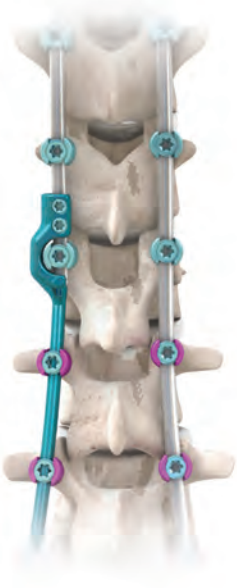
Z REVISION ROD

The Z Revision Rod is designed to extend and/or revise screw/hook-based spine fusion without the need to remove the existing implants. The Z Revision Rod design provides 10mm offset connection.



IN-LINE CONNECTOR MODULE

The In-Line Connector Module is designed to extend and/or revise screw/hook-based spine fusion without the need to remove the existing implants. Also, it is designed to enable connection from 5.5mm or 6.0mm rod diameters to 5.5 or 6.0mm rod diameters. The In-Line Connector Module is available in Left and Right versions.



08. Instructions for Use

ASTRA SPINE SYSTEM

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

ASTRA Spine System implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudo-arthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

The ASTRA Spine System consists of longitudinal, lordosed, contoured, and revision rods, pedicle screws (monoaxial, polyaxial, and uniplanar), cannulated pedicle screws (monoaxial, polyaxial and uniplanar), hooks, lateral iliac connectors, rod-to-rod connectors and transverse (cross) connectors.

The ASTRA Spine System components are available in titanium alloy conforming to ASTM F136 specifications. Rods are also available in Cobalt Chromium alloy conforming to ASTM F1537 specifications.

INDICATIONS

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: 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 (pseudo-arthrosis).

The ASTRA Spine System is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ASTRA Spine System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ASTRA Spine System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or rigid containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer's instructions. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface. Damaged packages or products should not be used, and should be returned to SpineCraft.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened SpineCraft package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineCraft. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all products must be sterilized prior to use.

INSPECTION

– SpineCraft implants should be inspected after processing, prior to sterilization.
– Any implant with corrosion, discoloration, excessive scratches, cracks, wear, residue or debris should be discarded.

STERILIZATION

Implants and instruments of the ASTRA Spine System are supplied clean and not sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ASTRA instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the steam pre-vacuum process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Blue Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Reuseable Rigid Sterilization Containers

Testing has demonstrated the ASTRA Spine System, when processed in Aesculap JN443 and JK445 rigid containers (with corresponding JK490 lid and Aesculap single use filters US751 or US994), can be sterilized to a 10-6 sterility assurance level (SAL) in a pre-vacuum steam sterilization cycle when processed using the required sterilization cycle.

Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization.

Aesculap rigid containers JN443 and JK445 have been validated ONLY with Aesculap single use filters US751 or US994. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Remove all packaging materials prior to sterilization. Use only sterile products in

the operative field.
It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

STORAGE

Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

USAGE

WARNING: 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 (pseudo-arthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: 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.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

Refer to the individual system surgical technique manuals for additional important information.

SpineCraft Spinal Systems components should not be used with components from other manufacturers.

During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

The implanting surgeon should consider carefully the size and type of implants most suitable for the patient's age, size and weight.

The ASTRA Spine System has not been evaluated for safety and compatibility in the MR environment. The ASTRA Spine System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ASTRA Spine System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE PLANNING AND POSTOPERATIVE CARE:

Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using ASTRA Spine System and should personally verify that all required implants sizes and necessary instruments are present before the surgery begins.

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
- ASTRA Spine System implants are internal fixation devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
- POSTOPERATIVE MOBILIZATION: Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.
- Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.

Any condition not described in the Indications for Use.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

Use of this type of surgical implant surgery in children or pediatric patients presents particular risks because of bone growth or physical movement. Subsequent re-intervention may be required.

Infants with a known hereditary or acquired bone friability or calcification problem, or those with a very short life expectancy, should not be considered for this type of surgery.

See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually

break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

B. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

C. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. Smoking. Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. SURGEON TRAINING AND EXPERIENCE. The implantation of pedicle screw fixation systems should be performed only by experienced spinal surgeons with specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.

2. DEVICE FIXATION. Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by SPINECRAFT. In the interests of patient safety, it is therefore recommended that SPINECRAFT implants are not used with devices from any other source. Never, under any circumstances, reuse an ASTRA Spine System implant.

3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

5. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

7. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT. Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

8. IMPLANTS FATIGUE. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

9. PREVIOUS SPINAL SURGERY. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Early or late loosening or movement of the implant.
3. Implant migration
4. Metal sensitivity or allergic reaction to a foreign body.
5. Infection, early or late.
6. Nonunion, delayed union.
7. Decrease in bone density due to stress shielding.
8. Pain, discomfort, or abnormal sensations due to the presence of the device.
9. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation in males, paraesthesia, or other types of serious injury.
10. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
11. Pressure on the surrounding tissues or organs.
12. Loss of proper spinal curvature, correction, height, and/or reduction.
13. Bursitis.
14. Paralysis temporary or permanent
15. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
16. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
17. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
18. Damage to lymphatic vessels and/or lymphatic fluid exudation.
19. Spinal cord impingement or damage.
20. Non-union (or pseudoarthrosis)
21. Degenerative changes or instability in segments adjacent to fused vertebral levels.
22. Fracture of bony structures or stress shielding at, above, or below the level of surgery.
23. Discitis, arachnoiditis, and/or other types of inflammation.
24. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
25. Spinal epidural hematoma.
26. Inability to resume activities of normal daily living.
27. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
28. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
29. Herniated nucleus pulposus, disc disruption or degeneration at, above, or

below the level of surgery.
30. Loss of or increase in spinal mobility or function.
31. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
32. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
33. Change in mental status.
34. Cessation of any potential growth of the operated portion of the spine.
35. Death.

Additional Possible Adverse Effects Specific to Pediatric Patients

1. Inability to use pedicle screw fixation due to anatomic limitations.
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Implant prominence (symptomatic or asymptomatic).
6. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
7. Post-operative change in spinal curvature, loss of correction, height or reduction.
8. Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).

PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or SpineCraft. Further, if any of the implanted ASTRA Spine System component(s) ever “malfunctions”, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any SpineCraft product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

LIMITED WARRANTY AND DISCLAIMER: ASTRA SPINE SYSTEM PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at +1 630-920-7300.

SURGICAL TECHNIQUE MANUAL COULD BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

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