ORTHOFIX
Connector System

Operative Technique

ORTHOFIX® | SPINE

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

ORTHOFIX
Connector System

INTRODUCTION

The Connector System is a comprehensive system designed to reduce the complexity of revising and extending existing spinal constructs. The system includes a variety of Rod-to-Rod Connectors, Bypass Connectors, Axial In-Line Connectors and Z Rods as well as unique instrumentation intended to facilitate the removal of bony anatomy. The Connector System eliminates the need to remove existing hardware while providing stability at adjacent levels.

IMPLANT OVERVIEW

A variety of implants are available which accommodate simple to more complex revision surgeries. An understanding of the implant's specifications is an important consideration when selecting the appropriate implant. All implants are made from implantable grade titanium alloy.

Side/Top Loading Connector:

Side interface will accommodate 4.75mm to 6.35mm rod diameters; Top interface will accommodate 5.5mm to 6.0mm rod diameters

- Side loading on one end and top loading on the other end
- Side interface is assembled over the rod
- Top interface side is inserted from under the rod
- 12mm, 16mm, and 18mm rod to rod spacing
- 1x small set screw is required for the side interface
- 1x large set screw is required for the top interface
- Blue anodization

Side/Side Loading Connector:

Side interface(s) will accommodate 4.75mm to 6.35mm rod diameters

- Side interface on both ends
- Side interface is assembled over the rod
- 12mm, 16mm, and 18mm rod to rod spacing
- 2x small set screws are required for the side interfaces
- Green anodization

Side/Front Loading Connector:

Side and front interfaces will accommodate 4.75mm to 6.35mm rod diameters

- Side interface on one end and front loading on the other end
- Side interface is assembled over the rod
- Rod inserted through front interface
- 12mm, 16mm, and 18mm rod to rod spacing
- 1x small set screw is required for the side interface
- 1x small set screw is required for the front interface
- Gold anodization

Front/Front Loading Connector:

Front interface(s) will accommodate 4.75mm to 6.35mm rod diameters

- Front interface on both ends
- Rod inserted through front interface
- 12mm, 16mm, and 18mm rod to rod spacing
- 2x small set screws are required for the front interfaces
- Magenta anodization

Small Side/Front Loading Connector:

Side interface will accommodate 4.75mm to 6.35mm rod diameters; Front interface will accommodate 3.0mm to 3.5mm rod diameters

- Side loading on one end and front loading on the other end
- Side interface is assembled over the rod
- Front interface inserted through front
- 12mm rod to rod spacing
- 1x small set screw is required for the side interface
- 1x small set screw is required for the front interface
- Natural anodization

16mm Bypass Connector (79-212X)

Accepts 4.75mm to 6.35mm rod diameters

- Bypass allows a construct to navigate around a pedicle screw to extend a construct
- 16mm bypass length and 13mm bypass depth
- Incorporates a 5.5 x 200mm in-line rod extension
- 1x small set screw is required

U-Style, 16mm Bypass Connector (79-216X)

Accepts 4.75mm to 6.35mm rod diameters

- Bypass allows a construct to navigate around a pedicle screw to extend a construct
- 16mm bypass length and 13mm bypass depth
- Incorporates a 5.5 x 200mm offset rod extension
- 2x small set screws are required

Axial In-Line Connector with Rod (79-2140)

Accepts 4.75mm to 6.35mm rod diameters

- Allows an in-line connection for construct extension
- Incorporates a 5.5mm x 200mm rod extension
- Blue anodized line to assist with rod bending and alignment
- 1x small set screw is required

Z Rod

Two lengths available, 150mm x 150mm (standard) and 150mm x 300mm (optional)

- Z Rod offset provides flexibility to maneuver around existing hardware
- 5.5mm diameter rod
- 12mm, 16mm, and 18mm rod offset
- Blue anodized line to assist with rod bending and alignment

34mm Bypass Connector (79-213X)

Accepts 4.75mm to 6.35mm rod diameters ordered by request only (optional)

- Bypass allows a construct to navigate around one or two pedicle screws to extend a construct
- 34mm bypass length and 13.5mm bypass depth
- Incorporates a 5.5 x 200mm in-line extension rod
- 1x small set screw is required

Large Set Screw

Small Set Screw

Set Screws (Large 79-2002, Small 79-2003)

- Both set screws incorporate a 3.7mm hex interface and 60 in. lbs. torque value
- Large Set Screw only used with Side/Top Rod-to-Rod Connector (Top Interface)
- Large screw features a buttress thread design to minimize cross threading

NOTE: The Connector System is compatible with posterior spinal fixation systems (e.g. Firebird® Spinal Fixation Systems, Spinal Fixation System (SFS), Centurion POCT System, and Ascent POCT System). Refer to the respective operative technique for instructions regarding pedicle screw insertion, rod cutting and rod contouring.

BONE PREPARATION INSTRUMENTS

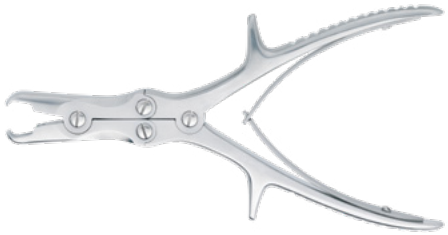
The Connector System features unique bone-preparation instruments specifically designed to facilitate fusion mass removal commonly associated with revision procedures.

Bone Chisel (79-1012)

The distal end incorporates a chisel designed to remove bone around the previously implanted rod. The proximal end features a flat end to facilitate instrument impaction.

Curved Rasp (79-1003)

Features a chamfered tip and pyramidal teeth to remove bone both underneath the rod and around the corresponding screw construct.



Underbite Rongeur (79-1004)

A bone removal tool designed to navigate around an existing rod and remove bone underneath the construct.

IMPLANT INSERTION/TRIALING INSTRUMENTS

The Connector System features unique instrumentation designed to assist with inserting and positioning the implants.

Straight Implant Inserter (79-1001)

Engages the side of Rod-to-Rod Connectors to assist with implant insertion.

Threaded Implant Inserter (79-1002)

Threads into the set screw hole of Rod-to-Rod Connectors. Can also be used to rotate/reposition connectors for optimal placement.

Set Screw Inserter (79-1005)

Features a 3.7mm hex drive to provisionally tighten both large and small set screws.

Tamp (79-1014)

Assists with the positioning of various Bypass Connectors as well as seating the rod within various connectors and screw bodies.

IMPLANT INSERTION/TRIALING INSTRUMENTS (Cont.)

Trial Rod, 200mm (52-1041)

A 200mm trial rod that assesses rod length and configuration.

Rod Pliers/Holder (79-1008)

Assists with manipulating/holding the rod.

FINAL TIGHTENING INSTRUMENTS

Set Screw Driver (79-1006)

Features a 3.7mm hex driving end and a 7mm hex end that mates with the Connector Torque Limiting Handle for final tightening.

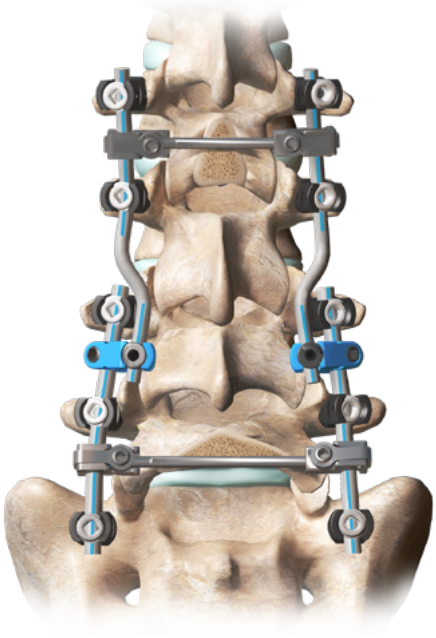
Connector Torque Limiting Handle (79-1010)

Mates with the Set Screw Driver via a 7mm female hex interface; locks both large and small set screws at 60 in. lbs.

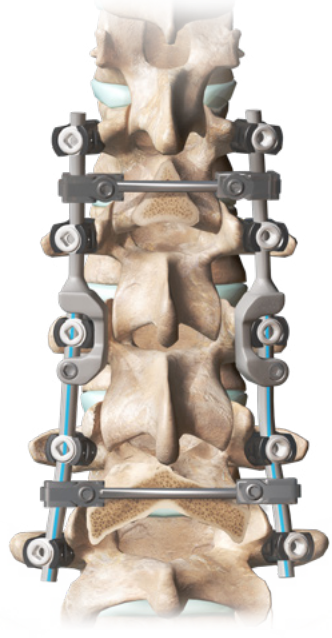
Connector Counter Torque Wrench (79-1007)

Used in conjunction with the Set Screw Driver to provide additional stability during final tightening.

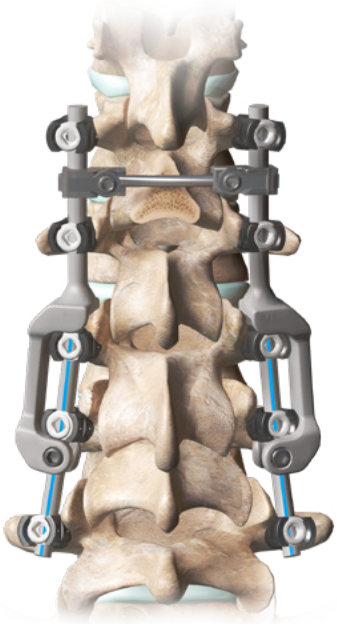
REVISION CONSTRUCTS



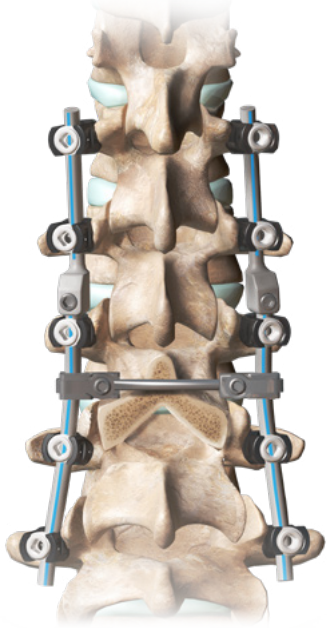
Side/Top and Z Rod Connector Construct



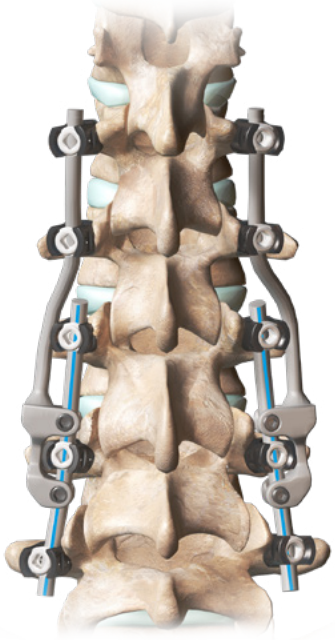
16mm Bypass Connector Construct



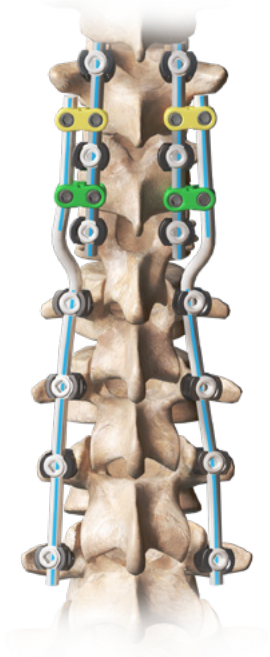
34mm Bypass Connector Construct



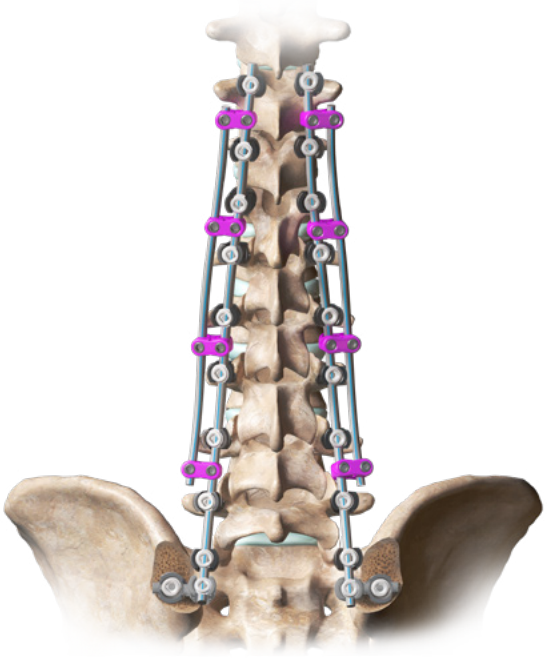
Axial In-Line Connector Construct



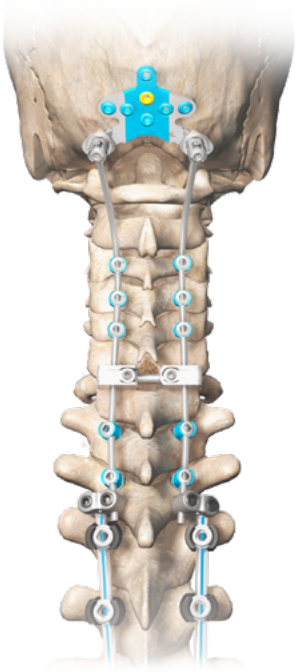
U-Style
Connector Construct



Side/Front, Side/Side and Z Rod
Connector Construct



Front/Front
Connector Construct



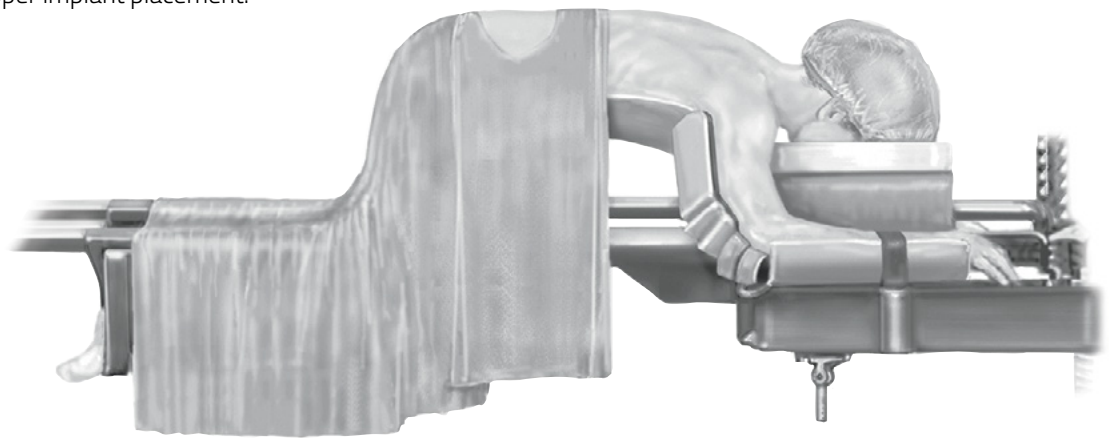
Small Side/Front
Connector Construct

1. PREOPERATIVE PLANNING

Preoperative planning, knowledge of the existing construct and proper implant selection and placement are important considerations when using the Orthofix Connector System. Lateral and AP imaging can assist with surgical planning and help determine the desired revision method as well as corresponding implants.

2. SURGICAL APPROACH

The patient is placed under anesthesia and placed in the prone position. An incision is made with care to ensure proper exposure of the target levels. Intra-operative imaging may be used to assist with proper implant placement.



3. BONE PREPARATION

The **Underbite Rongeur (79-1004) (Fig. 1a), Curved Rasp (79-1003) (Fig. 1b)** and **Bone Chisel (79-1012) (Fig. 1c)** are available to remove any bony material. Both the Underbite Rongeur and the Bone Chisel can remove bony material while accommodating any previously implanted rod.

Note: The Bone Chisel accommodates up to 6.35mm diameter rods.

Note: The parallel connectors require a 9.9mm wide channel to accommodate the implant.

Note: Thorough removal of the fusion mass or bony material is an important consideration in order to have a reliable connection for corresponding connectors and set screws.

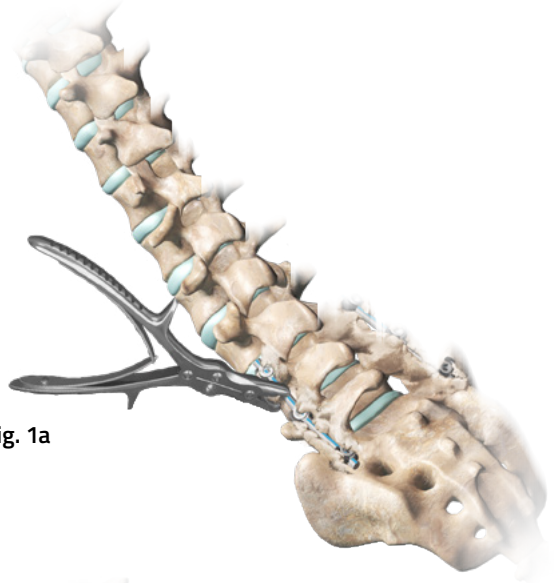


Fig. 1a

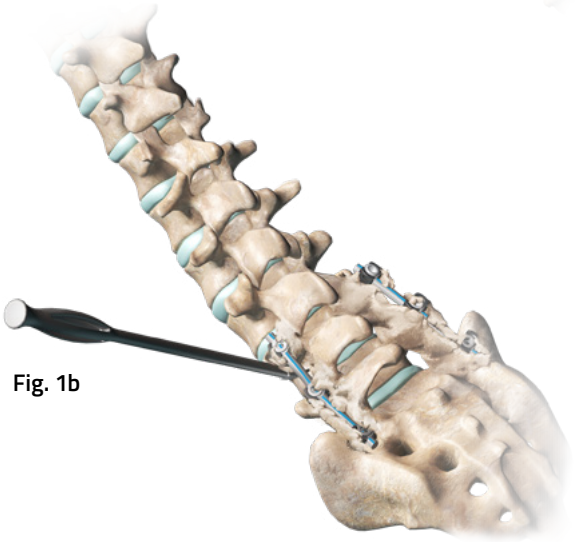


Fig. 1b

4. IMPLANT SELECTION

Lateral and AP imaging can assist with surgical planning and help determine the desired revision method as well as corresponding implants.

Utilize the appropriate rod to rod connector size or Z Rod offset for the construct to ensure the rod can be fully seated in the connector slot. Rod contouring may be required in order to have a reliable connection for corresponding connectors and set screws. Ensure the rods are contoured to fully seat them into the connector interface without applying excessive lateral compression.

The Rod to Rod Connectors (Side/Top, Side/Side, Side/Front, and Front/Front) are available with 12mm, 16mm, and 18mm rod spacing. The Small Side/Front connector is available in 12mm rod spacing.

The Z Rods are available with 12mm, 16mm and 18mm offsets.

WARNING: The correct handling of the implant is extremely important. Implants should not be excessively or repeatedly bent, notched or scratched. These operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.

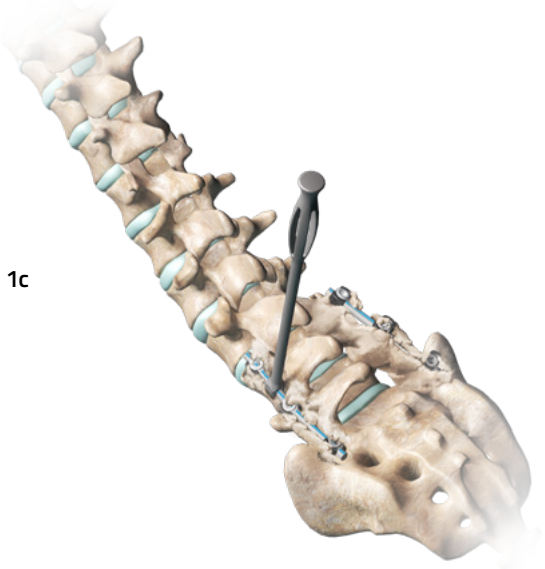


Fig. 1c

5. CONNECTOR INSERTION

A **Threaded Implant Inserter (79-1002)** and a **Straight Implant Inserter (79-1001)** are available to assist with implantation of the appropriate connector. The Threaded Implant Inserter is attached by inserting the distal tip into the small set screw hole and rotating clockwise until the inserter is fully engaged. Care should be taken to not over tighten the Threaded Implant Inserter **(Fig. 2)**.

The Straight Implant Inserter can be used to implant Rod-to-Rod Connectors by attaching the inserter to the engagement slots on the side of the desired connector. Ensure the inserter is fully engaged prior to implant insertion. **(Fig. 3)**

Note: The straight implant inserter is not compatible with Bypass or Axial In-Line Connectors.

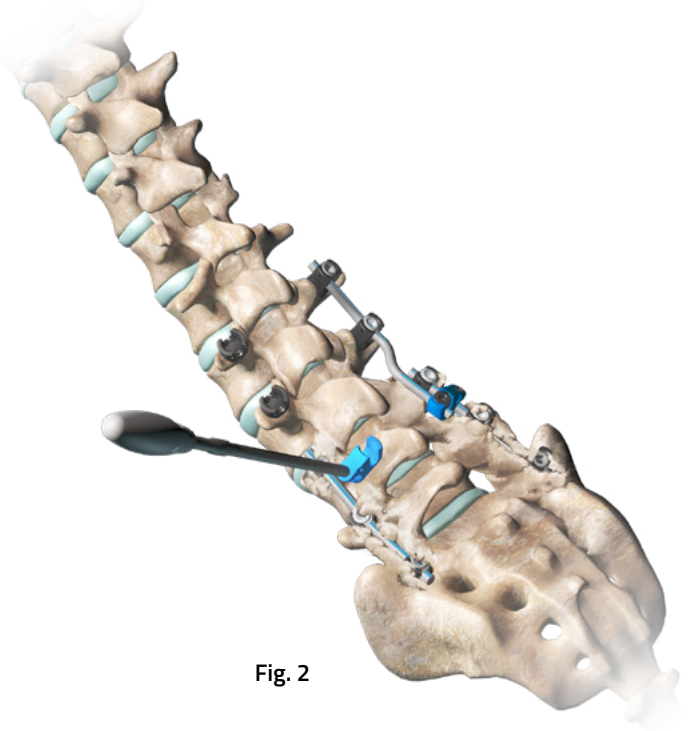


Fig. 2

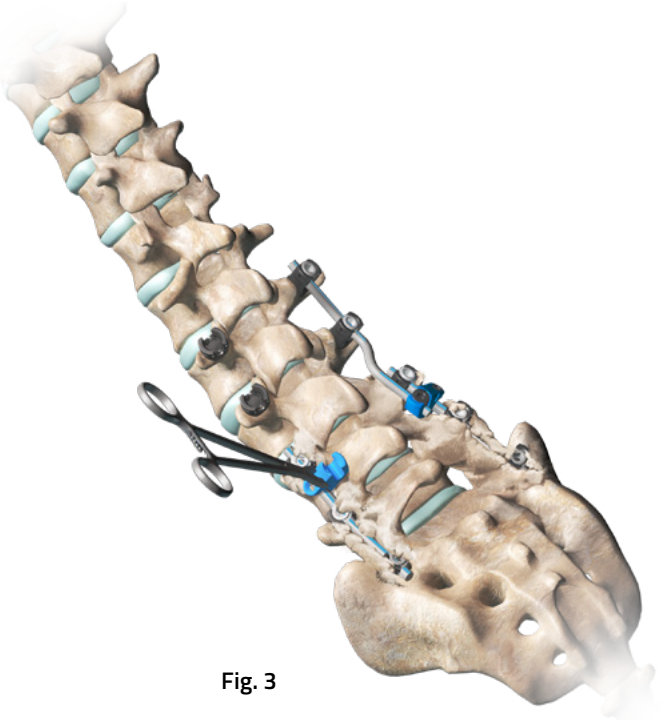


Fig. 3

6. ROD TRIALING

Rod trialing is an optional surgical step intended to determine the appropriate rod length and configuration. Place the trial rod within the screw bodies to determine the appropriate length and configuration. Rod overhang should also be considered when determining final rod length. **(Fig. 4)**

Note: Various coronal, In-situ and rod benders are available in both the Firebird and Firebird Deformity Systems and may be used to contour the rod to the desired configuration.

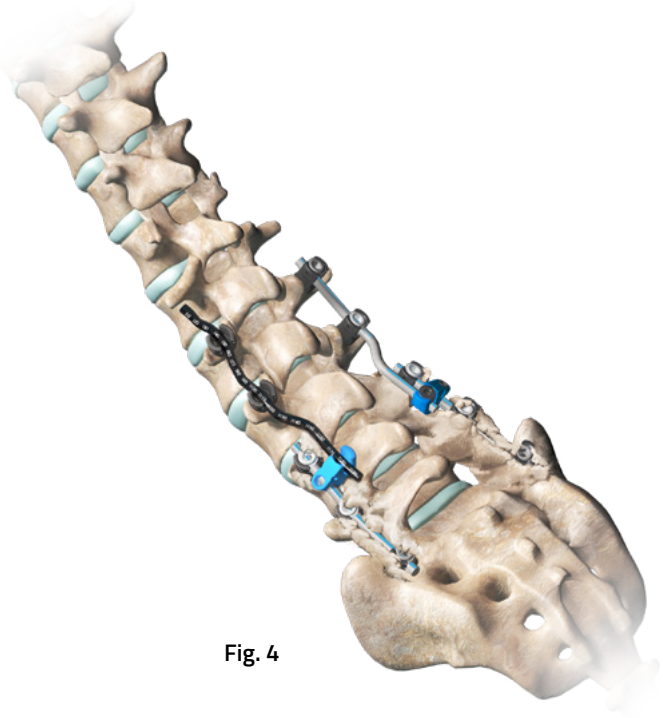


Fig. 4

7. PRELIMINARY TIGHTENING

For side loading connectors, set screw preliminary tightening should be completed while the rod is held laterally compressed into the connector slot using the Rod Pliers/Holder.

Select the appropriate set screw for the corresponding implant. Load the set screw onto the **Set Screw Inserter (79-1005)** and attach the set screw to the desired implant. Prior to advancing the set screw, turn it a quarter turn counter clockwise to align the set screw with the connector. Turn the Set Screw Inserter clockwise to thread set screw into the implant and provisionally tighten the set screw. **(Fig. 5)**

Note: Small Set Screw is not intended to reduce the rod laterally into the side loading connector slot.

Note: To obtain a reliable connection, ensure that the rod is fully inserted and seated in the connector slot prior to provisional tightening.

Note: The Rod Pliers/Holder assists with manipulating/holding the rod when slight compression is necessary. Avoid applying unnecessary lateral compression force. Ensure that the rod is pre bent to the desired contour.

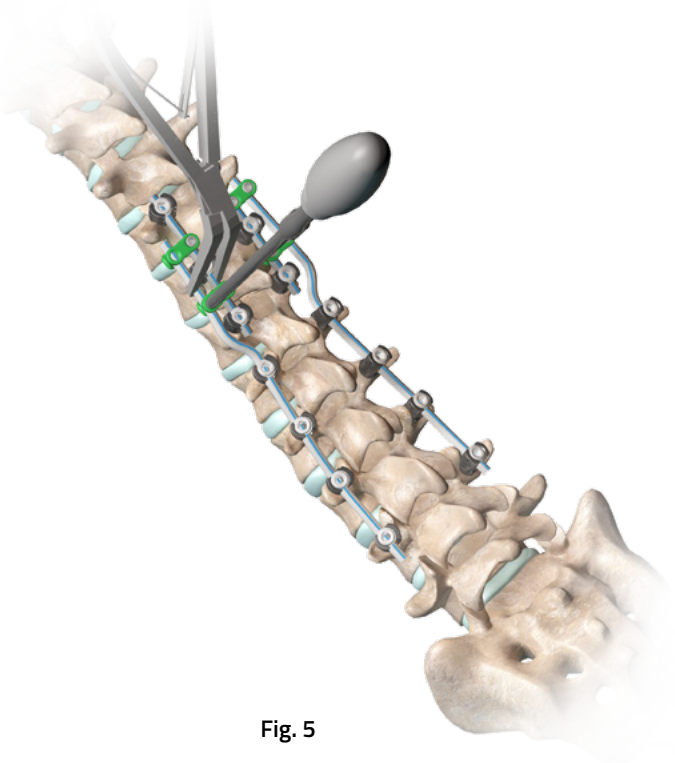


Fig. 5

8. FINAL TIGHTENING

To attach the Connector Torque Limiting Handle **(79-1010)** to the Set Screw Driver **(79-1006)**, retract the connector sleeve of the torque limiting handle and insert the hex end of the screw driver into the handle. If necessary, rotate the driver shaft to ensure the driver is fully engaged. Pull the driver shaft to confirm a secure connection. To disengage the screw driver from the torque limiting handle, retract the connector sleeve and remove the driver from the handle.

Position the Connector Counter Torque Wrench over the connector and rod. Ensure the notched counter torque wrench tip is fully engaged with the rod. Place the set screw driver construct through the cannulation of the counter torque wrench and fully seat into the hex drive of the set screw. Turn the connector torque limiting handle clockwise to tighten the set screw. The construct will lock at 60 in. lbs. **(Fig. 6)**

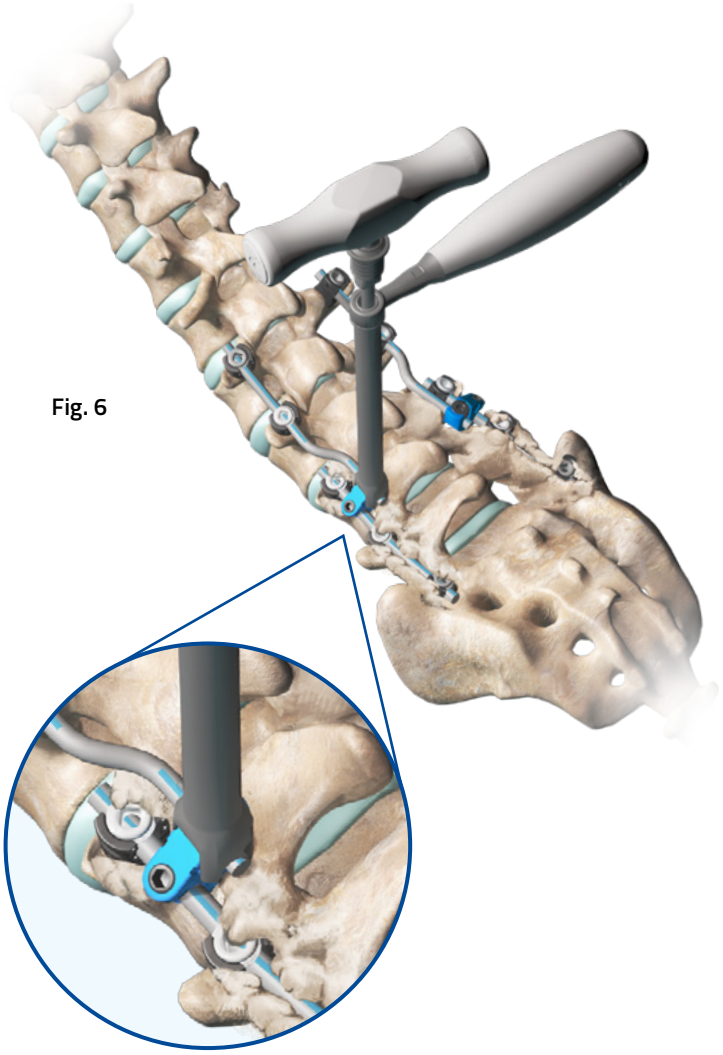


Fig. 6

9. IMPLANT REMOVAL

To remove the large and small set screws, fully seat the set screw driver attached to Modular T-Handle 27-5004 into the set screw and turn counter clockwise to loosen the set screw. Use of the connector counter torque wrench is recommended. Carefully remove set screws. The straight or threaded implant inserter can be attached to the connectors for removal from the construct.

Note: The Modular T-Handle (27-5004) is not in the kit and needs to be ordered to facilitate removal surgery.

TECHNICAL INFORMATION

Revision Instruments	
79-1006	Set Screw Driver
79-1007	Connector Counter Torque Wrench
79-1010	Connector Torque Limiting Handle (60 in. lbs.)
79-1001	Straight Implant Inserter

Description	Drive Feature
Small Set Screw	3.7mm hex
Large Set Screw	3.7mm hex

Connector Description	Part Number	Rod Compatibility	Rod Compatibility	Set Screw
12mm Side/Top Loading Connector (Blue) 16mm Side/Top Loading Connector (Blue) 18mm Side/Top Loading Connector (Blue)	79-2100 79-2600 79-2800	Side Interface 4.75mm to 6.35mm rod diameters	Top interface 5.5mm to 6.0mm rod diameters	1 Large 1 Small
12mm Side/Front Loading Connector (Gold) 16mm Side/Front Loading Connector (Gold) 18mm Side/Front Loading Connector (Gold)	79-2105 79-2605 79-2805	Side Interface 4.75mm to 6.35mm rod diameters	Front Interface 4.75mm to 6.35mm rod diameters	2 Small
12mm Small Side/Front Loading Connector (Silver)	79-2110	Small side interface 3.0mm to 3.5mm rod diameters	Front Interface 4.75mm to 6.35mm rod diameters	2 Small
12mm Side/Side Loading Connector (Green) 16mm Side/Side Loading Connector (Green) 18mm Side/Side Loading Connector (Green)	79-2115 79-2615 79-2815	Side Interface 4.75mm to 6.35mm rod diameters	Side Interface 4.75mm to 6.35mm rod diameters	2 Small
12mm Front/Front Loading Connector (Magenta) 16mm Front/Front Loading Connector (Magenta) 18mm Front/Front Loading Connector (Magenta)	79-2155 79-2655 79-2855	Front Interface 4.75mm to 6.35mm rod diameters	Front Interface 4.75mm to 6.35mm rod diameters	2 Small

Connector/Rod Description	Part Number	Rod Diameter	Rod Length	Set Screw
16mm Bypass, Left	79-2120	5.5mm	200mm	1 Small
16mm Bypass, Right	79-2125	5.5mm	200mm	1 Small
34mm Bypass, Left	79-2130	5.5mm	200mm	1 Small
34mm Bypass, Right	79-2135	5.5mm	200mm	1 Small
U-Style, 16mm Bypass, Left	79-2160	5.5mm	200mm	2 Small
U-Style, 16mm Bypass, Right	79-2165	5.5mm	200mm	2 Small
12mm Offset Z Rod, 150mm x 150mm 16mm Offset Z Rod, 150mm x 150mm 18mm Offset Z Rod, 150mm x 150mm	79-2150 79-6150 79-8150	5.5mm	150mm x 150mm	N/A
12mm Offset Z Rod, 150mm x 300mm 16mm Offset Z Rod, 150mm x 300mm 18mm Offset Z Rod, 150mm x 300mm	79-2300 79-6300 79-8300	5.5mm	150mm x 150mm	N/A
Axial In-Line Connector with Rod	79-2140	5.5mm	200mm	1 Small

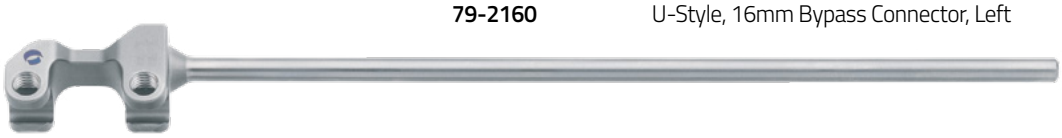
Trial Rod	Nitinol, Silicone
Implants	(Ti-6Al-4V)
Set Screws	(Ti-6Al-4V)
Bypasses and Rods	(Ti-6Al-4V)
Instruments	Stainless Steel, Silicone, Aluminum

KEY	
(Ti-6Al-4V)	Titanium Alloy

Implants

	Part #	Description	Qty
	**79-2100** **79-2600** **79-2800**	12mm Side/Top Loading Connector 16mm Side/Top Loading Connector 18mm Side/Top Loading Connector	4
	**79-2105** **79-2605** **79-2805**	12mm Side/Front Loading Connector 16mm Side/Front Loading Connector 18mm Side/Front Loading Connector	4
	**79-2110**	12mm Small Side/Front Loading Connector	4
	**79-2115** **79-2615** **79-2815**	12mm Side/Side Loading Connector 16mm Side/Side Loading Connector 18mm Side/Side Loading Connector	4
	**79-2155** **79-2655** **79-2855**	12mm Front/Front Loading Connector 16mm Front/Front Loading Connector 18mm Front/Front Loading Connector	4
	**79-2120**	16mm Bypass Connector, Left	2
	**79-2125**	16mm Bypass Connector, Right	2
	**79-2130**	34mm Bypass Connector, Left	Optional

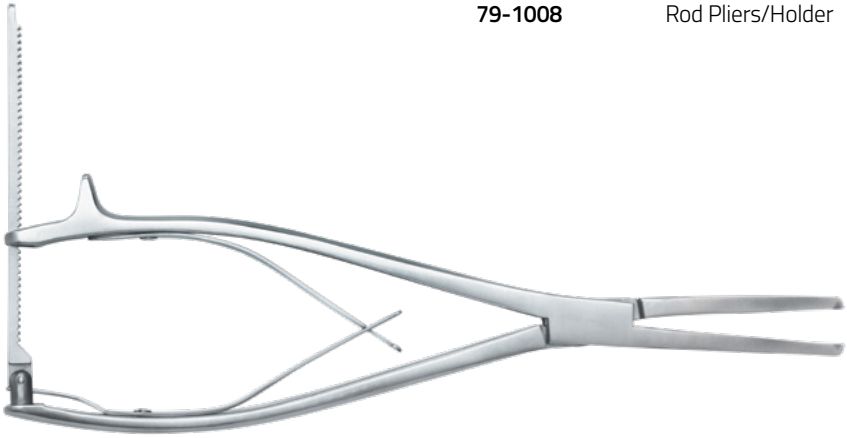
Implants

	Part #	Description	Qty Set
	**79-2135**	34mm Bypass Connector, Right	Optional
	**79-2160**	U-Style, 16mm Bypass Connector, Left	2
	**79-2165**	U-Style, 16mm Bypass Connector, Right	2
	**79-2140**	Axial In-Line Connector with Rod	4
	**79-2150** **79-6150** **79-8150**	12mm Offset Z Rod, 150mm x 150mm 16mm Offset Z Rod, 150mm x 150mm 18mm Offset Z Rod, 150mm x 150mm	4
	**79-2300** **79-6300** **79-8300**	12mm Offset Z Rod, 150mm x 300mm 16mm Offset Z Rod, 150mm x 300mm 18mm Offset Z Rod, 150mm x 300mm	Optional
	**79-2002**	Large Set Screw	10
	**79-2003**	Small Set Screw	20

Instruments

	Part #	Description	Qty Set
	52-1041	Trial Rod, 200mm	1
	79-1001	Straight Implant Inserter	1
	79-1002	Threaded Implant Inserter	1
	79-1003	Curved Rasp	1
	79-1004	Underbite Rongeur	1
	79-1005	Set Screw Inserter	2
	79-1006	Set Screw Driver	2

Instruments

	Part #	Description	Qty Set
	**79-1007**	Connector Counter Torque Wrench	1
	**79-1008**	Rod Pliers/Holder	1
	**79-1010**	Connector Torque Limiting Handle	1
	**79-1012**	Bone Chisel	1
	**79-1014**	Tamp	1

SET CONFIGURATION (79-9092)

Implants

Part #	Description	Qty
79-2002	Large Set Screw	10
79-2003	Small Set Screw	20
79-2100	12mm Side/Top Loading Connector	4
79-2105	12mm Side/Front Loading Connector	4
79-2115	12mm Side/Side Loading Connector	4
79-2155	12mm Front/Front Loading Connector	4
79-2110	12mm Small Side/Front Loading Connector	4
79-2600	16mm Side/Top Loading Connector	4
79-2605	16mm Side/Front Loading Connector	4
79-2615	16mm Side/Side Loading Connector	4
79-2655	16mm Front/Front Loading Connector	4
79-2800	18mm Side/Top Loading Connector	4
79-2805	18mm Side/Front Loading Connector	4
79-2815	18mm Side/Side Loading Connector	4
79-2855	18mm Front/Front Loading Connector	4

Part #	Description	Qty
79-2160	Single Bypass Connector, U-Style, Left	2
79-2165	Single Bypass Connector, U-Style, Right	2
79-2120	16mm Single Bypass Connector, Left	2
79-2125	16mm Single Bypass Connector, Right	2
79-2130	34mm Double Bypass Connector, Left	2
79-2135	34mm Double Bypass Connector, Right	2
79-2150	12mm Offset Z Rod, 150mm x 150mm	4
79-2300	12mm Offset Z Rod, 150mm x 300mm	0
79-6150	16mm Offset Z Rod, 150mm x 150mm	4
79-6300	16mm Offset Z Rod, 150mm x 300mm	0
79-8150	18mm Offset Z Rod, 150mm x 150mm	4
79-8300	18mm Offset Z Rod, 150mm x 300mm	0
79-2140	Axial In-Line Connector with Rod	4

Instruments

Part #	Description	Qty
52-1041	Trial Rod, 200mm	1
79-1001	Straight Implant Inserter	1
79-1002	Threaded Implant Inserter	1
79-1003	Curved Rasp	1
79-1004	Underbite Rongeur	1
79-1005	Set Screw Inserter	2

Part #	Description	Qty
79-1006	Set Screw Driver	2
79-1007	Connector Counter Torque Wrench	1
79-1008	Rod Pliers/Holder	1
79-1010	Connector Torque Limiting Handle	1
79-1012	Bone Chisel	1
79-1014	Tamp	1

Cases & Trays

Part #	Description	Qty
79-1091	Case	1
79-1091B	Base	1
20123806	Lid	1
79-8315	Middle Tray-Level	1
79-8317	Bottom Tray-Level	1
79-9301	Side Loading Connector Caddy	1
79-9302	Side/Front Loading Connector Caddy	1
79-9303	Front Loading Connector Caddy	1

Part #	Description	Qty
79-8310	16mm Front Loading Caddy	1
79-8311	18mm Front Loading Caddy	1
79-8312	16mm Side Loading Caddy	1
79-8313	18mm Side Loading Caddy	1
79-9304	Small Set Screw Caddy	1
79-9305	Large Set Screw Caddy	1
79-8314	Top Tray-Level	1
79-8316	Ancillary Implant Caddy	1

Notes

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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