ORTHOFIX
Connector System
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 Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.
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 (79-2100):
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
- 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 (79-2115):
Side interface(s) will accommodate 4.75mm to 6.35mm rod diameters
- Side interface on both ends
- Side interface is assembled over the rod
- 2x small set screws are required for the side interfaces
- Green anodization

Side/Front Loading Connector (79-2105):
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
- 1x small set screw is required for the side interface
- 1x small set screw is required for the front interface
- Gold anodization

Small Side/Front Loading Connector (79-2100):
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
- 1x small set screw is required for the side interface
- 1x small set screw is required for the front interface
- Natural anodization

Front/Front Loading Connector (79-2155):
Front interface(s) will accommodate 4.75mm to 6.35mm rod diameters
- Front interface on both ends
- Rod inserted through front interface
- 2x small set screws are required for the front interfaces
- Magenta 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

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, (150mm x 150mm 79-2150, 150mm x 300mm 79-2300)
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 with a 12mm 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

• 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: Refer to the Firebird NXG Operative Technique Guide 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 Plier/Holder (79-1008)
Assists with manipulating/holding the rod (optional).

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.
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 are 9.9mm wide. This is the minimum width required to make a successful connection.

**Note:** Thorough removal of the fusion mass is an important consideration in order to have a reliable connection for corresponding connectors and set screws.
4. 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 a 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 inserter is not compatible with Bypass or Axial In-Line Connectors.

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.
5. IMPLANT 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.

6. PRELIMINARY TIGHTENING

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: To obtain a reliable connection, ensure that the rod is fully inserted and seated in the connector slot prior to provisional tightening.
7. 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 60in-lbs as indicated by the tactile feedback. (Fig. 6)

8. IMPLANT REMOVAL

To remove the large and small set screws, fully seat the set screw driver 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.
12 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
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## Instruments

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Set Configuration (79-9091)

### Implants

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### Instruments

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### Cases & Trays

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Note: The Case (79-1090) includes all case and tray items excluding the Ancillary Implant Caddy (79-8309)
Description:
The Connector System is designed to reduce the complexity of revising and extending existing constructs from the Occiput to the Ilium. The Connector System includes a variety of non-sterile implants manufactured from Titanium alloy comprised of bypass connectors, rod to rod connectors, Z rods, and an axial in-line connector with an attached rod. The Connector System implant options offered eliminate the need to remove existing hardware while providing stability to adjacent levels. The Connector System is compatible with posterior spinal fixation systems (e.g Firebird Spinal Fixation/Phoenix MIS Spinal Fixation System, Spinal Fixation System, Centurion POCT System, Ascent POCT System) which offer titanium and/or cobalt chrome rods ranging in sizes of 3.0mm to 6.35mm.

Indications for Use:
When used with the Centurion POCT System or Ascent POCT System for Posterior Occipital-Cervical-Thoracic (Occ – T3):
The Connector System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Connector System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

When used with the Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System or Spinal Fixation System (SFS) for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Ilium):
The Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:
1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation),
4. Spinal stenosis,
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

When used for posterior pedicle screw fixation in pediatric patients, the Connector System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach. The Connector System is intended to be used with autograft or allograft.

Contraindications:
Contraindications include, but are not limited to:
1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Use of the offset connectors for fixation to the ilium is contraindicated when the sacrum is absent or insufficient for implantation of pedicle screws at the S1 or S2 spinal level.
9. Any circumstances not listed under the heading indications.
Warnings and Precautions:

1. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

2. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection of placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

3. The selection of proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

5. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

6. Single use only

7. Non-sterile; the connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.

8. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.

9. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.

10. Excessive torque applied to the screws may strip the threads in the bone.

11. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.

12. The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of spinal systems.

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

14. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the titanium alloy or cobalt chrome alloy components of this system with implants of other material composition or components from different manufacturers unless specifically stated.

15. The Connector System has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

16. Reuse of the devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.

17. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

18. Other adverse effects related to pedicle screw fixation, such as rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.

19. 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.

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

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