



Unity[®]

LUMBOSACRAL FIXATION SYSTEM



Lumbosacral Fixation System



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INTRODUCTION

The Unity® Lumbosacral Fixation System consists of the Unity 51® Lumbosacral Fixation Plate for lumbosacral fixation and the Unity LX® Lumbar Fixation Plate for anterior or anterolateral fixation above L5 - S1.

The Orthofix Unity 51 Lumbosacral Fixation Plate is designed specifically for supplemental fixation of anterior lumbar fusions at the L5 - S1 level. The plate is contoured to the unique anatomy of the L5 - S1 segment. The Unity 51 Plate is available in six heights: 17mm to 25mm in 2mm increments and one additional plate at 28mm.

The Orthofix Unity LX Lumbar Fixation Plate is designed for lumbar levels above L5 - S1 in 2 configurations – anterior and anterolateral. In the anterolateral configuration, the plate allows surgeons lateral-to-medial placement of the self-tapping screws to minimize the risk of great vessel injury and to mitigate aberrant screw placement into the contralateral neuro foramen. The Unity LX Plate is available in six heights: 19mm to 25mm in 2mm increments and two additional plates at 28mm and 31mm.

When fully secured, the cover plate of each construct prevents back-out of the self-tapping bone screws and a semi-constrained screw-plate design to allow for focal physiologic dynamization and interbody loading, thus avoiding stress shielding of the interbody device.

Both the Unity LX Plate and the Unity 51 Plate use the same set of instruments. The bone screws for both plates are identical: 6.0mm primary and 7.0mm rescue diameters in lengths of 25, 30, and 35mm.

The Unity LX Plate and the Unity 51 Plate are implanted with similar techniques. This technique manual primarily illustrates implantation of the Unity 51 Plate construct and, where necessary, the modifications required to implant the Unity LX Plate in either of its two configurations are described.

Unity®

LUMBOSACRAL FIXATION SYSTEM



Fig. 1

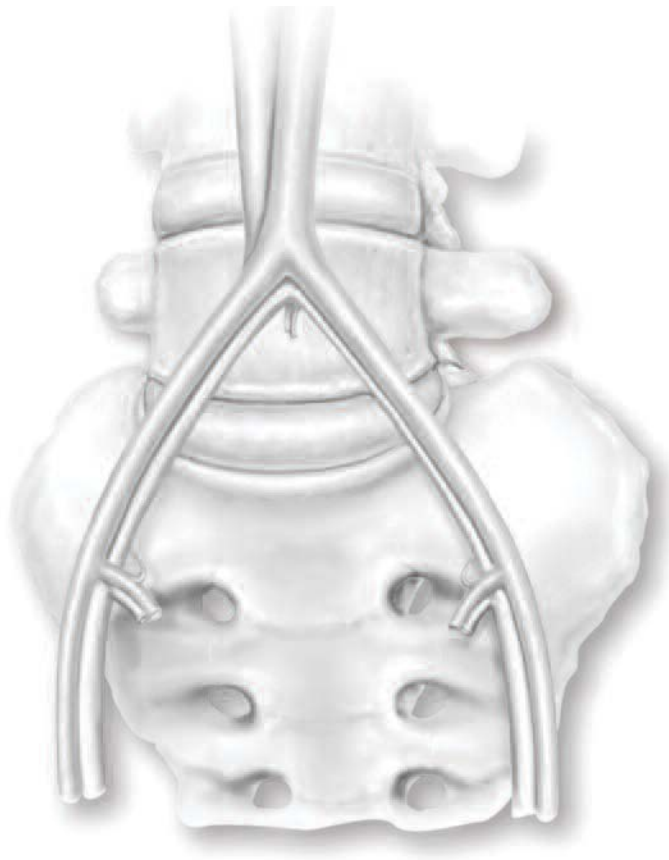
PREOPERATIVE PLANNING

As with any spine surgery, preoperative planning is essential to reduce the chances of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device and the plate and screw sizes.

PATIENT POSITIONING

The patient is placed in a supine position with all bony prominences padded. Placing a pillow beneath the knees to create a mild amount of hip flexion which aids in reducing tension across the iliopsoas muscle is recommended.

Additionally, when performing anterior lumbar interbody fusion with instrumentation at the L4 - L5 level or above, a pulse oximeter is placed onto the left great toe to assess lower extremity oxygenation as operating at this level has been shown to be associated with greater risks of thrombosis and injury due to vascular retraction. An A/P or a Ferguson view with fluoroscopic imaging is then taken to insure the lumbar spine is anatomic prior to prepping and draping the patient. **(Fig.1)**



1. ANTERIOR APPROACHES TO THE LUMBAR SPINE AND LUMBOSACRAL JUNCTION

Anterior access can be performed through a variety of approaches, including transperitoneal and right or left retroperitoneal, depending on surgeon preference and/or patient anatomy. However, a retroperitoneal approach is recommended to lessen the chance of retrograde ejaculation in males and improves exposure for easier and safer retraction of the peritoneal contents.

LUMBOSACRAL SPINE, L5 - S1 INTERSPACE

Exposure can be achieved in the majority of patients just below the bifurcation of the great vessels. However, should the bifurcation be unusually low, the vessels may require additional mobilization to allow visualization and safe placement of the Unity 51 Plate at the midline.

LUMBAR SPINE, L4 - L5 INTERSPACE (OR LEVELS ABOVE)

In most patients, it is crucial to ligate the iliolumbar vein and/or local segmental vessels to sufficiently retract the great vessels from left to right. Additionally, the sympathetic chain should be protected along the left lateral gutter medial to the iliopsoas musculature. The assistance of a general or vascular surgeon well-skilled in anterior approaches to the lumbar spine, while not mandatory, is commonly used for access.

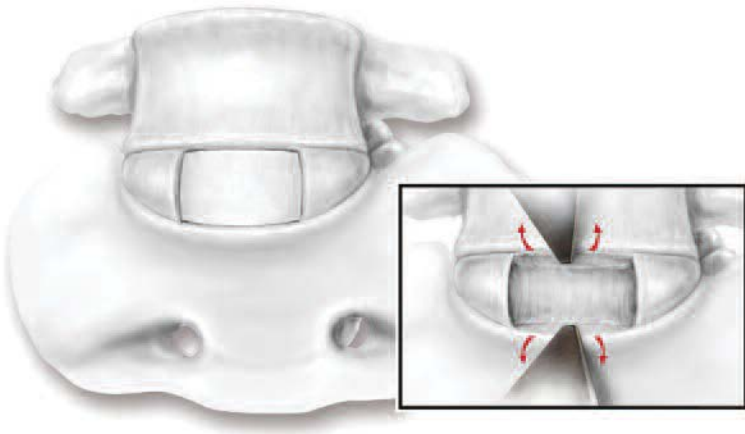


Fig. 2

2. DISC SPACE PREPARATION

After ensuring the correct lumbar level has been exposed using X-ray or C-arm localization, a box-cut annulotomy is performed with partial vertebrectomy, as needed, depending on the underlying pathology and surgeon preference. Similarly, once the disc space has been decompressed, the appropriate intervertebral device is then placed prior to plate fixation. (Fig. 2)

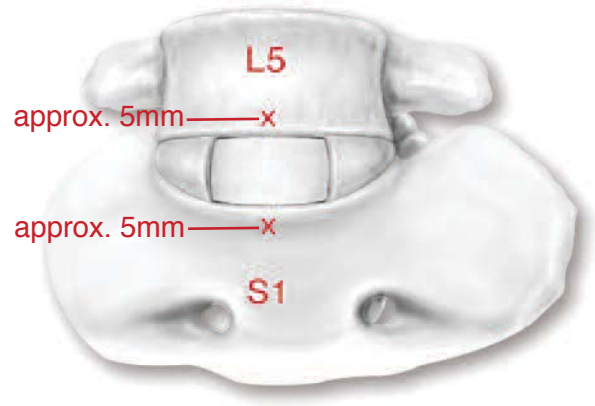


Fig. 3

3. SELECT THE CORRECT PLATE

Plate height is determined intra-operatively. The ideal screw starting points are determined when the sacral bone screw holes situate approximately 5mm caudal to the sacral promontory, and the lumbar bone screw holes situate approximately 5mm cephalad to the inferior L5 endplate. (Fig. 3)

For the lumbar levels above L5 – S1, the Unity LX plate is placed anteriorly or anterolaterally, approximately 5mm caudal to the inferior vertebral body endplate and 5mm cephalad to the superior vertebral body endplate.



Fig. 4



Fig. 5

4. ASSEMBLE BASE PLATE AND BASE PLATE HOLDER

Two base plate holders (Long, 43-0099 or Short, 43-0100) are available in the Unity Lumbar Fixation System. The longer of the two is designed to facilitate base plate placement in larger patients. Align the locating pin on the tip of the base plate holder to the corresponding slot on the base plate. Advance the base plate holder screw into the base plate's threaded central hole. Tighten the base plate holder with the hex driver. (**Fig. 4**)

5. TRIAL THE BASE PLATE ON THE L5 - S1 MOTION SEGMENT

The base plate should be placed at the L5 - S1 midline. The plate's posterior sagittal contours will closely accommodate most patients' L5 - S1 anatomy. Removal of osteophytes facilitates optimal base plate fit. (**Fig. 5**)

For the lumbar levels above L5 - S1, the Unity LX base plate can be placed either directly anterior as noted for the Unity 51 base plate or anterolaterally.

Note: The longitudinal arrow located on the face of the Unity LX Base Plate should be directed cephalad.

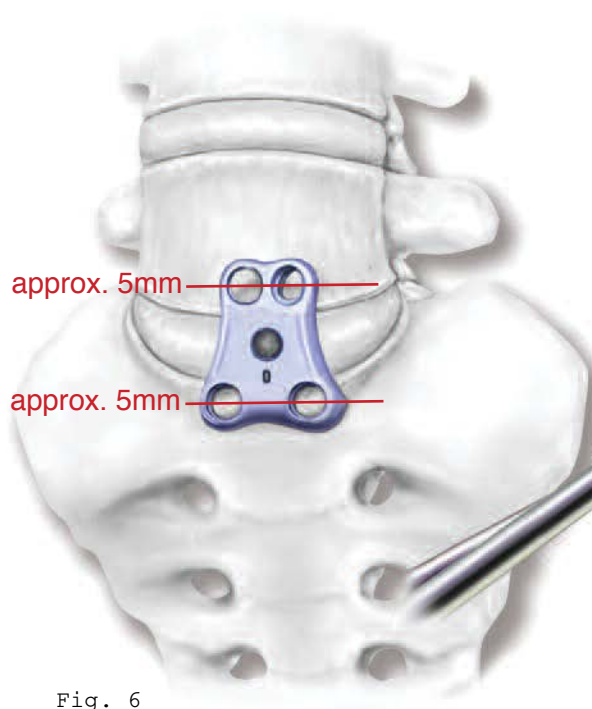


Fig. 6

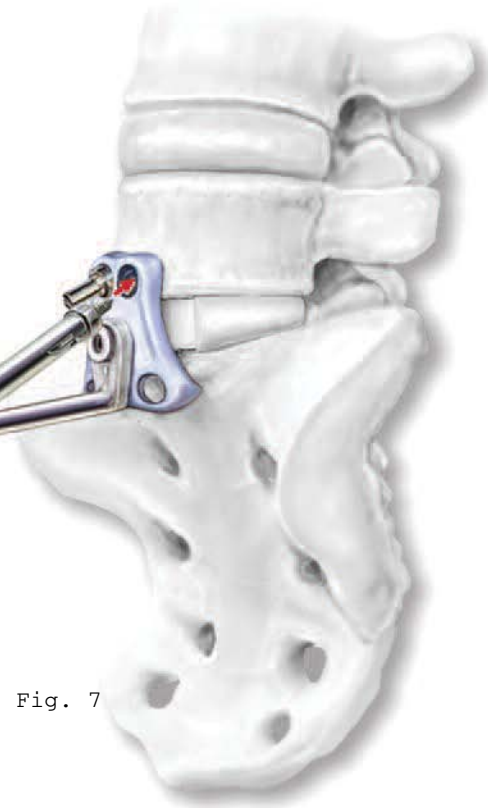


Fig. 7

6. CONFIRM BASE PLATE SIZE

Verify that the base plate is sized and positioned in accordance with the description provided in **Figure 6**. Fluoroscopic imaging to confirm midline placement may be helpful.

If the Unity LX base plate is placed anteriorly, then fluoroscopic imaging to confirm midline placement of the Unity LX base plate may be useful.

7. PROVISIONAL BASE PLATE FIXATION (OPTIONAL)

Load a tack (43-0104) onto the tack holder/driver (43-0103). Screw in or impact a tack into each of the two cephalad bone screw holes. (**Fig. 7**)

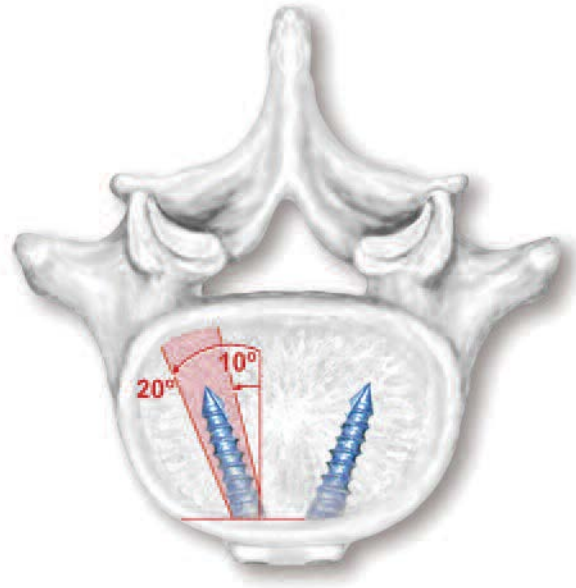


Fig. 8a

GUIDE AND SCREW ORIENTATION

Use the guide (43-0105) to assure proper bone screw placement in a variety of anatomical situations. When drilling and tapping, soft tissue or vascular structure impingement may be avoided with the appropriate use of the guide. Do not attempt to angle the bone screw in any plane beyond what the guide allows. Do not place any instruments down the guide without confirming that the guide is firmly inserted directly into one of the four base plate screw holes.

Note: The guide accommodates preparation of the bone screw hole in conjunction with the awl, drill, probe and tap. The bone screws cannot be implanted through the guide.

8A. UNITY 51 LUMBOSACRAL FIXATION PLATE BONE SCREW ORIENTATION

Relative to the parasagittal line in Figures 8a and 8b, the bone screws can be inserted at variable angles within the limits of the red shade, as depicted.

Each L5 bone screw can be placed divergent from 10° to 20° in the axial plane. (**Fig. 8a**)

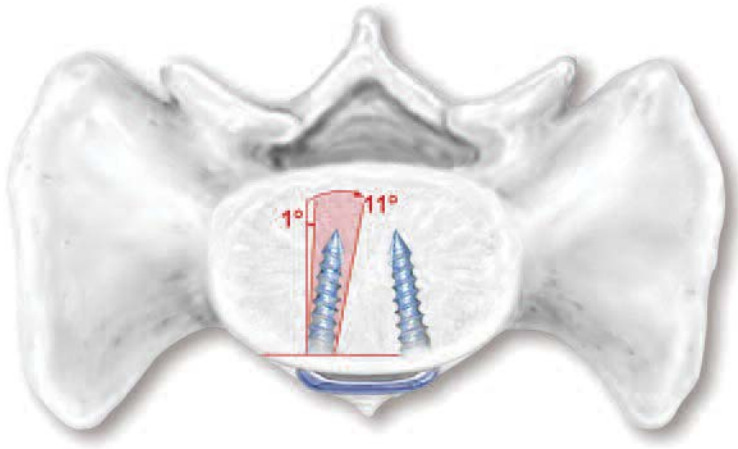


Fig. 8b



Fig. 8c

8B. UNITY 51 LUMBOSACRAL FIXATION PLATE BONE SCREW ORIENTATION

Each S1 bone screw can be placed convergent from 1° to 11° in the axial plane. (**Fig. 8b**)

8C. UNITY 51 LUMBOSACRAL FIXATION PLATE BONE SCREW ORIENTATION

In the sagittal plane, the L5 bone screws can be inserted at angles from 5° to 15° cephalad and the S1 bone screws can be inserted at angles from 0° to 10° caudal. (**Fig. 8c**)

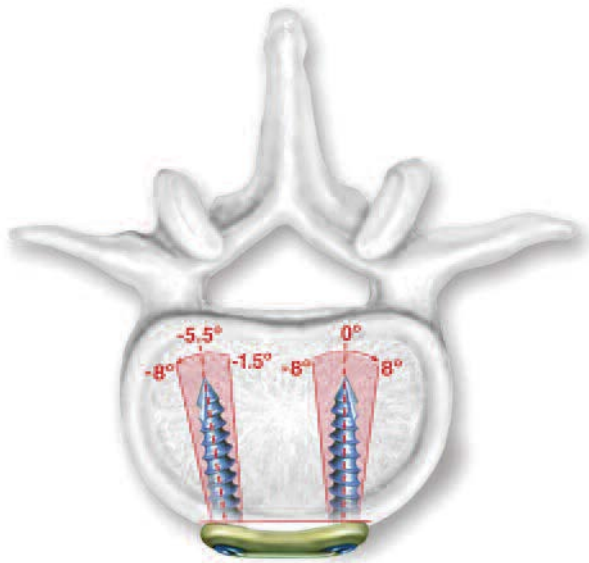


Fig. 8d

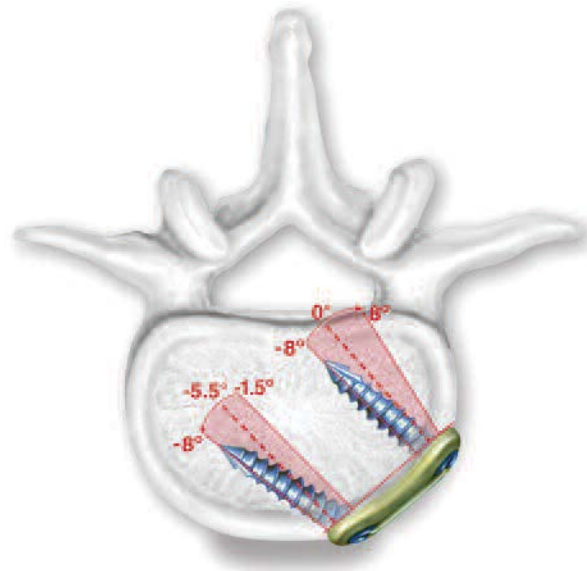


Fig. 8e

8D. UNITY LX LUMBAR FIXATION PLATE BONE SCREW ORIENTATION

Relative to the parasagittal lines in **Figures 8d** and **8e**, the bone screws can be inserted at variable angles within the limits of the red shade, as depicted. The guide accommodates preparation of the bone screw hole in conjunction with the awl, drill, probe and tap. The bone screws cannot be implanted through the guide.

The construct affords surgeons lateral-to-medial placement of the self-tapping bone screws to mitigate the possibility of great vessel injury. In the axial plane, the right-side bone screw can be placed from -8° divergent to 8° convergent and the left-side bone screw can be placed divergent from -8° to -1.5° .

8E. UNITY LX LUMBAR FIXATION PLATE BONE SCREW ORIENTATION

Strategically oriented bone screws are exhibited in the anterolateral construct placement in **Figure 8e**. By placing the bone screws in the orientation in **Figure 8e**, the surgeon minimizes the risk of aberrant screw placement into the left L4 - L5 foramen or any of the cephalad lumbar levels.

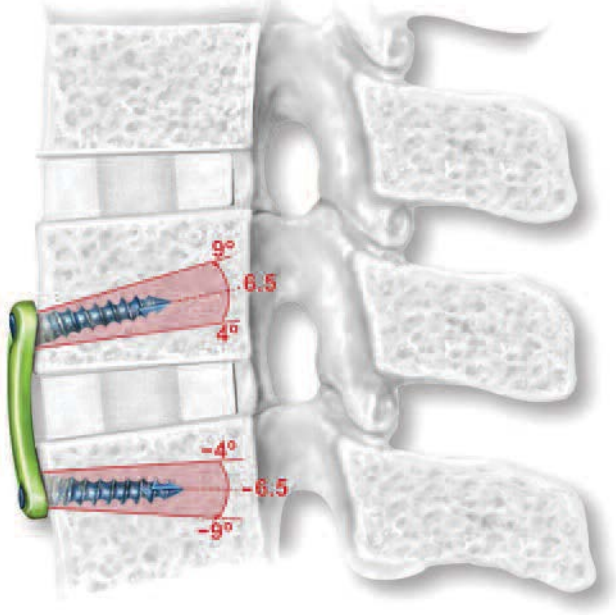


Fig. 8f

8F. UNITY LX LUMBAR FIXATION PLATE BONE SCREW ORIENTATION

In the sagittal plane, the cephalad bone screws can be inserted at angles from 4° to 9° cephalad (nominal angle, 6.5°) and the caudal bone screws can be inserted at angles from -4° to -9° caudal (nominal angle, -6.5°). (Fig. 8f)

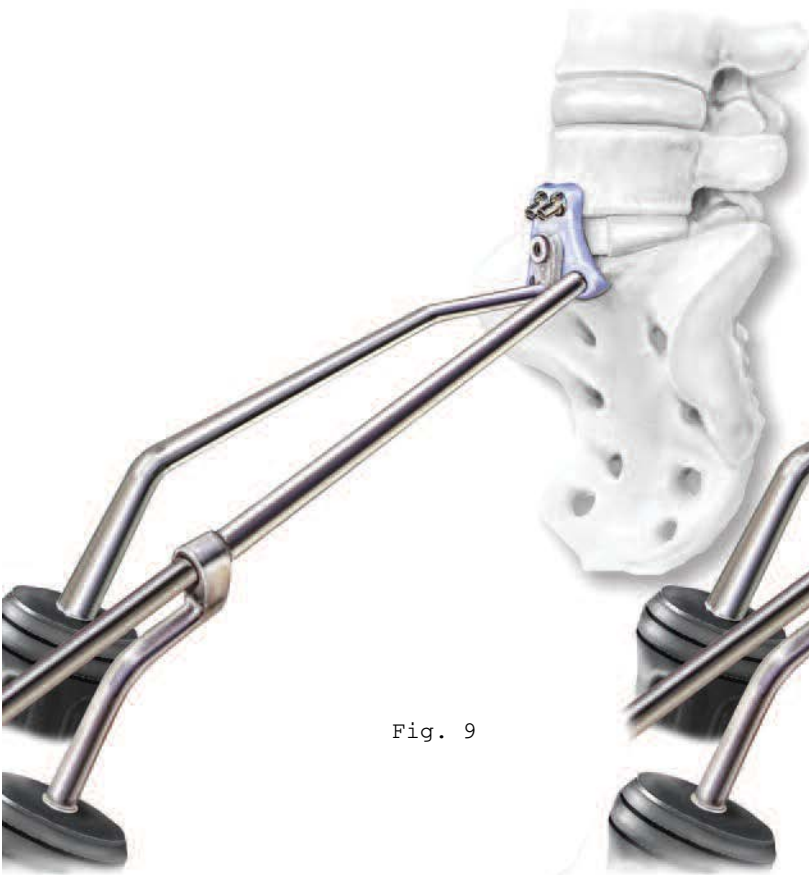


Fig. 9

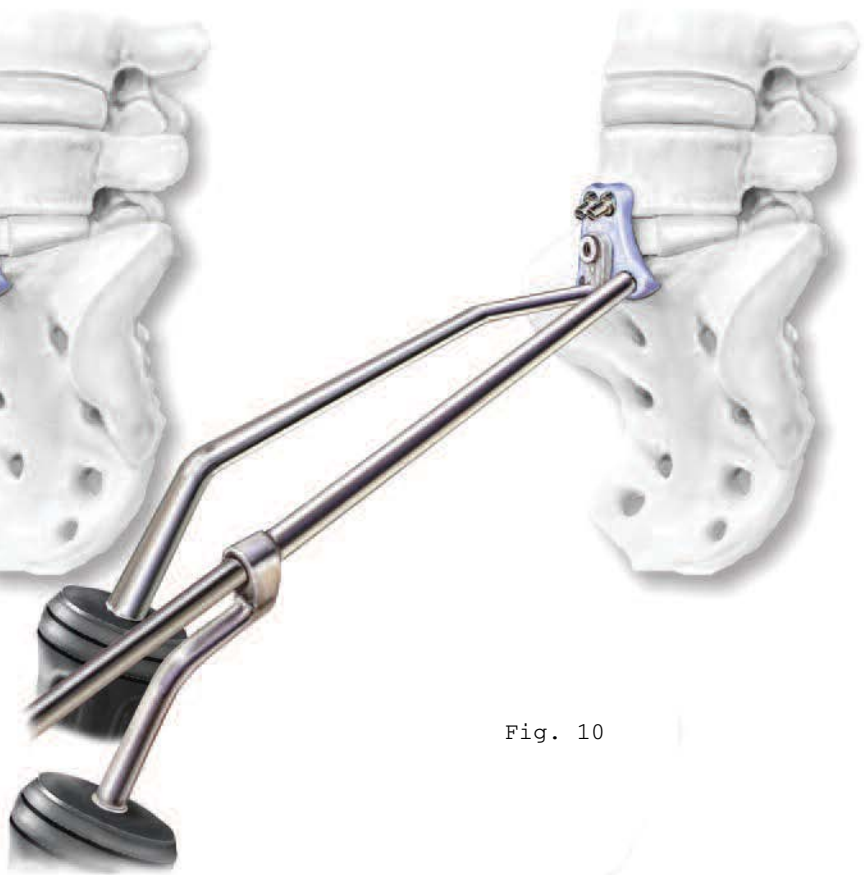
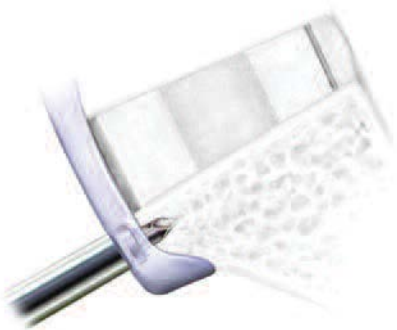


Fig. 10

9. AWL

Seat the guide completely into the bone screw holes. Insert the awl (43-0109) into the guide and penetrate the outer cortex of the vertebral body. (**Fig. 9**)



10. DRILL

Insert the drill (43-0106) into the guide. Drill until the collared-stop prevents advancement. (**Fig. 10**)





Fig. 11

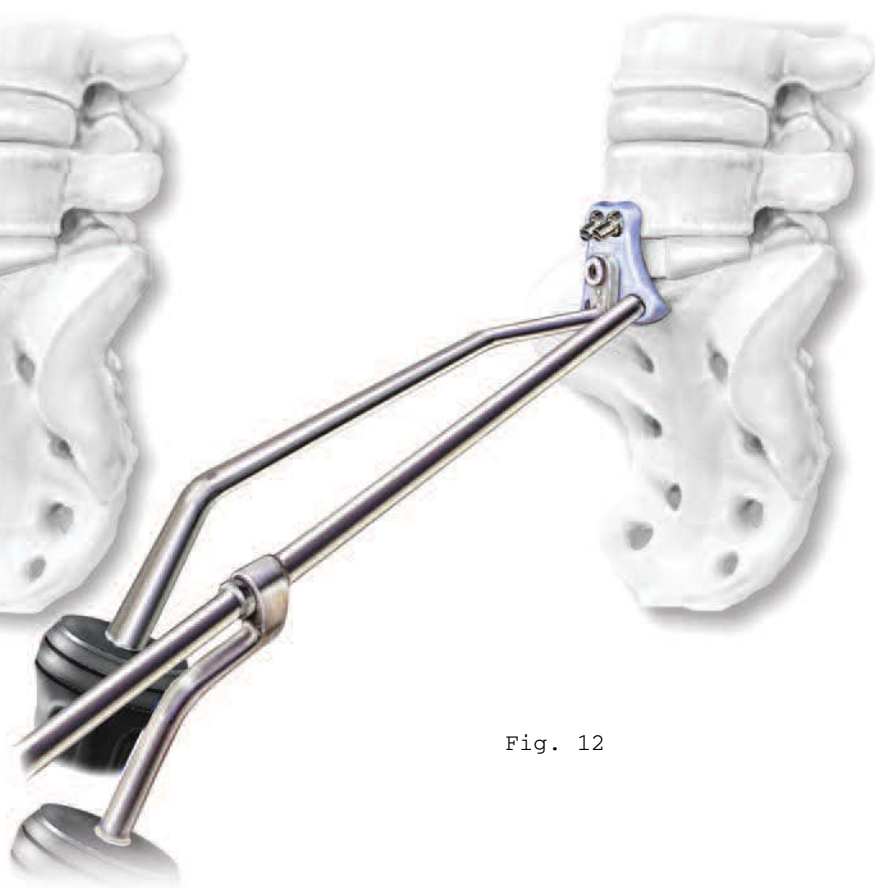


Fig. 12

11. PROBE (OPTIONAL)

Use the probe (43-0108) to verify location and depth of the drilled hole. X-ray confirmation of drill-hole position and direction can also be obtained with the probe in place. Intra-operative screw length can be facilitated using the probe and its gradient markers. (Fig. 11)



12. TAP (OPTIONAL)

A tap (43-0107) is provided, but not required, as the bone screws are self-tapping. Insert the tap into the guide. Tap until collared-stop prevents further rotation. (Fig. 12)

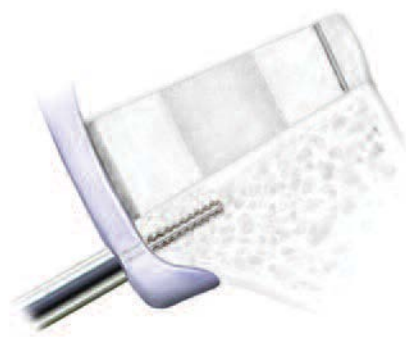




Fig. 13



Fig. 14

13. INITIAL BONE SCREW INSERTION

Remove the guide ahead of screw insertion. Assemble the self-retaining hex driver (long, 43-0112 or short, 43-0113) and the black ratchet handle, and insert the hex driver tip into the appropriate screw.

Note: Make sure to use the black colored ratcheting handle for bone screw insertion.

Advance the bone screw into the S1 hole for provisional fixation, leaving the screw head approximately 1mm proud. This screw will be tightened to completion after the other three bone screws are inserted. (**Fig. 13**)

For the Unity LX bone screw insertion, follow a similar convention. Initiate bone screw placement into the inferior lumbar vertebral body, leaving the screw head about 1mm proud.

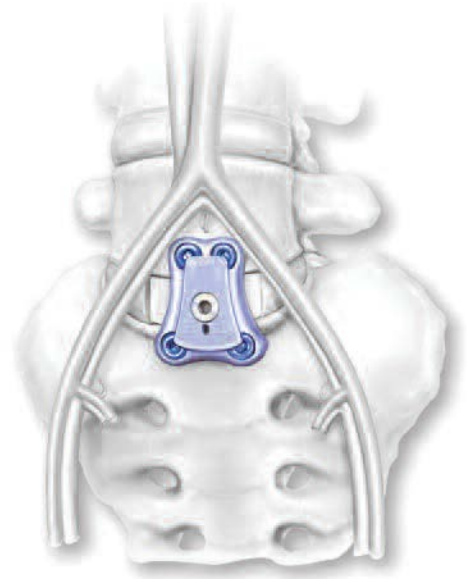
14. REMAINING SCREW INSERTION

On the opposite side of the base plate from the bone screw inserted into S1, remove the tack and provisionally insert a bone screw at L5. Proceed with screw insertion in a similar fashion.

For Unity LX bone screw insertion, follow a similar convention. On the opposite side of the base plate from the bone screw inserted into the inferior lumbar body, remove the tack and provisionally insert a bone screw into the superior lumbar body. (**Fig. 14**)



Fig. 15



Assembled Unity 51 Construct

15. COVER PLATE PLACEMENT

Assemble the gray torque-limiting t-handle (50in-lbs) (43-1065) to the cover plate holder/driver (43-0111). Secure the appropriately sized cover plate to the cover plate holder/driver. Align the cover plate onto the surface of the base plate, such that the cover plate screw settles into the threaded hole in the base plate's center and the keyed-feature slides into the base plate's corresponding hole. Advance the cover plate screw until audible and tactile feedback are achieved. (Fig. 15)

IMPLANT REMOVAL AND REVISIONS

In the case of construct revision or removal, follow the appropriate steps:

1. Stripped Screw – If it is determined that the fixation of the construct is inadequate due to a stripped bone screw, the bone screw should be removed and exchanged for a self-tapping 7.0mm rescue screw.
2. Late implant Removal or Revision – Caution should be exercised before deciding to reapproach the anterior lumbar spine as adhesions between and around the great vessels makes the approach hazardous. Once the the construct is completely exposed, simply reverse the insertion technique. Do not attempt to remove the construct unless it is completely exposed to avoid inadvertent injury to the great vessels.
 - a. Remove the cover plate with the cover plate holder/driver attached to a ratcheting t-handle (55-1031).
 - b. Affix the base plate holder to the exposed base plate.
 - c. Stabilize the base plate and remove the bone screws with hex driver/holder.

Note: The Ratcheting T-Handle (55-1031) is not in the kit and needs to be ordered to facilitate removal surgery.

CASE 1: UNITY 51 IMPLANTS AND ALL SYSTEM INSTRUMENTS**IMPLANTS**

43-1017*	Unity 51 Lumbar Sacral Fixation Base Plate, 17mm
43-1019	Unity 51 Lumbar Sacral Fixation Base Plate, 19mm
43-1021	Unity 51 Lumbar Sacral Fixation Base Plate, 21mm
43-1023	Unity 51 Lumbar Sacral Fixation Base Plate, 23mm
43-1025	Unity 51 Lumbar Sacral Fixation Base Plate, 25mm
43-1028	Unity 51 Lumbar Sacral Fixation Base Plate, 28mm
43-2017*	Unity 51 Lumbar Sacral Fixation Cover Plate, 17mm
43-2019	Unity 51 Lumbar Sacral Fixation Cover Plate, 19mm
43-2021	Unity 51 Lumbar Sacral Fixation Cover Plate, 21mm
43-2023	Unity 51 Lumbar Sacral Fixation Cover Plate, 23mm
43-2025	Unity 51 Lumbar Sacral Fixation Cover Plate, 25mm
43-2028	Unity 51 Lumbar Sacral Fixation Cover Plate, 28mm
43-6525	Bone Screw, Primary, 25mm
43-6530	Bone Screw, Primary, 30mm
43-6535	Bone Screw, Primary, 35mm
43-7525	Bone Screw, Rescue, 25mm
43-7530	Bone Screw, Rescue, 30mm
43-7535	Bone Screw, Rescue, 35mm
43-0104	Tack

*Available on request

INSTRUMENTATION

43-1090	Unity Lumbar Sacral Fixation System Case (Empty)
43-0099	Base Plate Holder, Long
43-0100	Base Plate Holder, Short
43-0103	Tack Holder/Driver
43-0104	Tack
43-0105	Fixed Guide
43-0106	Drill
43-0107	Tap
43-0108	Probe
43-0109	Awl
43-0111	Cover Plate Holder/Driver, Self-Retaining
43-0112	Hex Driver, Self-Retaining, Long
43-0113	Hex Driver, Self-Retaining, Short
43-1065	Gray Torque-Limiting T-Handle, 50 in-lbs
55-1030	Ratcheting Handle, Straight
55-1031*	Ratcheting Handle, T-Style
74-0050	Mallet

CASE 2: UNITY LX IMPLANTS, BONE SCREWS AND TACKS**INSTRUMENTATION**

43-1091	Unity LX Lumbar Fixation Plate Instrument/Implant Case (Empty)
43-3019	Unity LX Lumbar Fixation Base Plate, 19mm
43-3021	Unity LX Lumbar Fixation Base Plate, 21mm
43-3023	Unity LX Lumbar Fixation Base Plate, 23mm
43-3025	Unity LX Lumbar Fixation Base Plate, 25mm
43-3028	Unity LX Lumbar Fixation Base Plate, 28mm
43-3031	Unity LX Lumbar Fixation Base Plate, 31mm
43-4019	Unity LX Lumbar Fixation Cover Plate, 19mm
43-4021	Unity LX Lumbar Fixation Cover Plate, 21mm
43-4023	Unity LX Lumbar Fixation Cover Plate, 23mm
43-4025	Unity LX Lumbar Fixation Cover Plate, 25mm
43-4028	Unity LX Lumbar Fixation Cover Plate, 28mm
43-4031	Unity LX Lumbar Fixation Cover Plate, 31mm
43-6525	Bone Screw, Primary, 25mm
43-6530	Bone Screw, Primary, 30mm
43-6535	Bone Screw, Primary, 35mm
43-7525	Bone Screw, Rescue, 25mm
43-7530	Bone Screw, Rescue, 30mm
43-7535	Bone Screw, Rescue, 35mm
43-0104	Tack

Description: The Orthofix Unity™ Lumbosacral Fixation System is a supplemental fixation construct that consists of two implantable titanium alloy plates – the Unity LX™ Lumbar Fixation Plate and the Unity 51™ Lumbosacral Fixation Plate – and screws that are provided non-sterile.

Indications: The Orthofix Unity 51 Lumbosacral Fixation Plate is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures. The Orthofix Unity LX Lumbar Fixation Plate is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine above the bifurcation of the vascular structures. When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

- a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies)
- b) Pseudoarthrosis
- c) Spondylolysis
- d) Spondylolisthesis
- e) Fracture
- f) Neoplastic disease
- g) Unsuccessful previous fusion surgery
- h) Lordotic deformities of the spine
- i) Idiopathic thoracolumbar or lumbar scoliosis
- j) Deformities (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomeningocele
- k) Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity

Contraindications: The Orthofix Unity™ Lumbosacral Fixation System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:


- 1) Early or late loosening of any or all of the components
- 2) Disassembly, bending, and/or breakage of any or all of the components
- 3) Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
- 4) Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- 5) Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- 6) Infection
- 7) Vertebral body fracture at, above, or below the level of surgery
- 8) Loss of neurological function, including paralysis (complete or incomplete)
- 9) Non-union, delayed union
- 10) Pain, discomfort, or abnormal sensations due to the presence of the device
- 11) Hemorrhage
- 12) Cessation of any potential growth of the operated portion of the spine
- 13) Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:

- 1) Single use only
- 2) The Unity™ Lumbosacral Fixation System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- 3) Nonsterile; the plates, screws and instruments are sold nonsterile, and therefore, must be sterilized before each use.
- 4) When using the plate anteriorly, always orient the plate along the midline of the spine.
- 5) To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated.
- 6) To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
- 7) Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
- 8) Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- 9) Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
- 10) When choosing a metallic implant system, the physician/surgeon should consider factors such as: levels of implantation, patient weight, patient activity level, and other patient-specific conditions which may impact the performance of the system as it relates to fatigue of the implants.
- 11) Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not re-sterilize single-use implants that come in contact with body fluids.

Instructions for Use: See actual package insert for Instructions for Use.

 Orthofix Inc.
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Lewisville, Texas 75056 U.S.A.

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. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

Spinal Implants | Biologics | Spine Fusion Stimulation | MIS | Bracing

1.888.298.5700
www.orthofix.com

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