UniLink and UniLink 5/1 Interspinous Fusion System
Surgical Technique

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UniLink Graft
Surgical Technique

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Description, Indications & Contraindications

DESCRIPTION
The UniLink and UniLink 5/1 Interspinous Fusion Systems of Zimmer Spine are internal fixation devices for spinal surgery. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patients. The device may consist of titanium alloy (per ASTM F136), or both titanium alloy and polyetheretherketone (PEEK-OPTIMA® Polymer) (per ASTM F2026). All implants are intended for single use only and should not be reused under any circumstances.

INDICATIONS
The UniLink Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondyloolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The UniLink and UniLink 5/1 Interspinous Fusion Systems are intended for use with bone graft material, and not for stand-alone use.

CONTRAINDICATIONS
Contraindications for the UniLink and UniLink 5/1 Interspinous Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).
13. Reuse or multiple uses.
14. Prior fusion at the level to be treated.
UniLink and UniLink 5/1 System

Surgical Technique

Patient Positioning and Approach

Step 1a
Position the patient in the prone position on the operating table.

Step 1b
Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging.

Step 1c
Make a midline incision about 3cm in length to expose the spinous processes at the correct level. (Fig. 1)

Step 1d
Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or removed entirely.

Step 1e
Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. When fusing through the spinous processes, a burr, ronguer or rasp may be used to remove the interspinous ligament. The interspinous ligament may optionally be incised/dilated without complete removal.

Step 1f
If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed, using care to leave the spinous process intact.

Step 1g
If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets may be trimmed.

NOTE: Do not perform a complete facetectomy. Preserving a sufficient portion of the facets to provide biomechanical stability for axial rotation and transverse shear loads is required.

This surgical technique applies to both the UniLink and UniLink 5/1 Systems. The UniLink 5/1 Device has angled spikes to allow for lower engagement on the spinous process and to be closer to the lamina for variations in spinal anatomy. See Step 13 for implant variation.
Initial Dilation of the Interspinous Ligament

Step 2
If the interspinous ligament has been left intact, insert the interspinous ligament Piercer-Rasp and puncture the interspinous ligament, placing it as far anterior as possible. (Fig. 2)

**WARNING:** Do not direct the Piercer-Rasp in a ventral direction which could result in damage to neurological elements.

**NOTE:** The Compressor-Piercer may be used in place of the Piercer-Rasp.

Determine Size of Implant

Step 3
Using the Spreader, insert into the interspinous ligament where the initial dilation was performed. Squeeze the handle until the desired distraction is achieved and insert size is determined. (Fig. 3)

**NOTE:** As a precaution, leave the ratcheting mechanism up until desired distraction is felt. Once the desired distraction is felt, drop the ratchet bar down to determine correct implant size.

Trial-Rasps

Step 4
Once the insert size has been determined, use the correlating Trial-Rasp to decorticate the spinous processes. Work the Trial-Rasp in a cephalad to caudad motion to achieve best results. (Fig. 4)

Instruments

- **Piercer-Rasp**
  - 07.02208.005 (X060-0307)
- **Compressor-Piercer**
  - 07.02208.011 (X060-0328)
- **Spreader**
  - 07.02208.015 (X060-0390)
- **Trial-Rasp (8 – 18mm)**
  - 07.02208.016 – 07.02208.021 (X060-0440 – X060-0445)
- **Fixed In-Line Handle, Square Connect**
  - 07.02208.010 (X060-0324)
Plate Sizing (Length)

**Step 5**
Place the Plate Sizer instrument laterally, (28mm, 32mm, 36mm, 40mm or 55mm) to visually determine the length of the plate. (Fig. 5)

**NOTE:** The UniLink 5/1 Implant is available in 32, 36 and 40mm sizes.

**Step 6**
Tilt the desired implant, bottom first, into the Cross Bar Plate Inserter while simultaneously squeezing the instrument until the implant is secured. (Fig. 6)

Instruments

- **Plate Sizer**
  - 07.02208.012 36 mm (X060-0336)
  - 0702208.013 40 mm (X060-0340)

- **Inserter, Cross Bar Plate**
  - 07.02208.006 (X060-0318)
Step 7
Press the insert firmly against a sterile table to lock the insert onto the cross bar plate. (Fig. 7)

**NOTE:** Visually inspect to make sure there is no space between the insert and the base of the cross bar plate. This will minimize the possibility of the insert slipping on the cross bar.

Step 8
Pack the implant with the desired bone graft by hand. (Fig. 8)

Step 9
Pull back the chuck on the Torque Limiting T-Handle, insert the Screwdriver shaft and release. (Fig. 9)

**NOTE:** The Torque Limiting T-Handle is calibrated to 40 in-lbs.

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**Instruments**

- **Torque Limiting T-Handle**
  - 07.02208.009
  - (X060-0322)

- **Screwdriver**
  - 07.02208.008
  - (X060-0320)
**Step 10**
Using the correlating locking plate based upon the predetermined insert size, squeeze the Locking Plate Inserter until there is no movement between the locking plate and inserter. (Fig. 10, 11)

**NOTE:** Visually verify the tip of the set screw is not protruding into the hole of the locking plate.

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**Cross Bar Plate Insertion**

**Step 11**

**Technique 1** (shown): Re-insert the Spreader into the interspinous space and ratchet to the previously determined implant size. Introduce the implant, via the Cross Bar Plate Inserter, into the Spreader until the implant insert has been fully pushed through the interspinous space. (Fig. 12)

**Technique 2** (not shown): Utilizing the Cross Bar Plate Inserter, press the implant through the previously dilated space until the bullet tip of the insert is fully through.

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**Instruments**

- **Spreader**
  - 07.02208.015 (X060-0390)

- **Inserter, Cross Bar Plate**
  - 07.02208.006 (X060-0318)
**Locking Plate Introduction**

**Step 12**
Using the corresponding locking plate based upon the predetermined insert size, slide the locking plate over the insert/cross bar plate until it comes in contact with the spinous processes. *(Fig. 13)*

**Compression of Plates**

**Step 13**
Align the spherical tips of the Compressors into the round lateral pockets in each UniLink or UniLink 5/1 Plate. Prior to applying compression, take a lateral X-ray to confirm proper positioning. Using the Compressors, clamp the plates against the spinous processes, driving the spikes into the bone. *(Fig. 14,15)*

**WARNING:** Placement of excessive force on the Compressors may result in spinous process failure.

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**Instruments**

Compressor
07.02208.014
(X060-0370)
Final Locking of Plates

Step 14
Slide the Torque Limiting T-Handle with the attached Screwdriver into the set screw of the locking plate and rotate clockwise until two audible clicks are heard. (Fig. 16)

Instruments

Torque Limiting T-Handle
07.02208.009 (X060-0322)

Screwdriver
07.02208.008 (X060-0320)
The UniLink System was designed with a 3° taper on the cross bar to allow the locking plate to be tightened into a provisionally locked position while fully removing the locking plate instrumentation. This allows the removal of the Locking Plate Inserter without having the plate disassemble while engaging the Compressors.

1. Securing the Locking Plate onto the Cross Bar Plate
After completing steps 1–9, insert the Screwdriver into the set screw of the Locking Plate and hand tighten until secure. Remove the Screwdriver from the Locking Plate. (Fig. 17)

2. Removal of Inserter
Flip the ratcheting mechanism up to release the Inserter from the implant and compress the plates. (Fig. 18)

NOTE: Turn the Torque Limiting T-Handle until hand-tight. Do not overturn.

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Instruments

- **Inserter, Locking Plate**
  - **Part Number**: 07.02208.007 (X060-0319)
  - **Inserter, Cross Bar Plate**
    - **Part Number**: 07.02208.006 (X060-0318)
  - **Screwdriver**
    - **Part Number**: 07.02208.008 (X060-0320)
  - **Compressor**
    - **Part Number**: 07.02208.014 (X060-0370)
  - **Torque Limiting T-Handle**
    - **Part Number**: 07.02208.009 (X060-0322)
Pre-Assembly

If desired, the UniLink Implant can be pre-assembled on the back table to allow for insertion. This technique includes the removal of the supraspinous and interspinous ligaments to allow the implant to be lowered into place with a single instrument.

1. Attach the appropriate insert to the pre-sized cross bar plate. (Fig. 19)

2. Using the corresponding locking plate based upon the predetermined insert size, slide the locking plate over the insert/cross bar plate until just the tip of the cross bar plate is showing.

3. Insert the Screwdriver and hand tighten until secure.

4. Tilt the implant, bottom first, into the Cross Bar Plate Inserter while simultaneously squeezing the instrument until the insert is secured.

Instruments

Compressor
07.02208.014
(X060-0370)

Inserter, Cross Bar Plate
07.02208.006
(X060-0318)

Screwdriver
07.02208.008
(X060-0320)

Torque Limiting T-Handle
07.02208.009
(X060-0322)
UniLink All-In-One Inserter – For 36 and 40mm Plates Only

The All-In-One Inserter is designed to insert, compress, and final tighten the implant without the need of additional instruments.

**NOTE:** For use with UniLink 36mm and 40mm plates only. Not for use with UniLink 5/1 plates.

1. **Exposure**
   Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. Using a ronguer, or similar instrument, remove both the supraspinous and interspinous ligament. If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed, using care to leave the spinous processes intact. (Fig. 20)

2. **Inserter Assembly**
   Position the All-In-One Inserter so that it is vertical. Place the cross bar plate onto the articulating arm; the oblong posts of the articulating arm go into the holes of the cross bar plate. While holding the cross bar plate firmly on the arm, use the Screwdriver to tighten the side set screw of the articulating arm to secure the cross bar plate to the arm; do not over tighten. Place the locking plate on the opposite arm; the oblong posts of the arm go into the holes of the locking plate. While holding the locking plate firmly on the arm, use the Screwdriver to turn the locking plate set screw counter-clockwise until the plate is secured. (Fig. 21, 22)

**Instruments**

- **All-In-One Inserter**
  - Model: 07.02210.008 (X060-0520)
- **Torque Limiting T-Handle**
  - Model: 07.02208.009 (X060-0322)
- **Screwdriver**
  - Model: 07.02208.008 (X060-0320)

*Optional Instrument; must be ordered separately*
**UniLink All-In-One Inserter, continued**

**3. Implant Insertion**

Once loaded, lower the instrument into the interspinous space and confirm placement via fluoroscopy. Once placement is confirmed, compress the plates onto the spinous processes by squeezing on the Inserter handles.

After the implant has been compressed onto the spinous processes, slowly guide the Screwdriver shaft through the instrument and into the recessed channel until the driver tip is fully seated into the set screw. Then rotate the Torque Limiting T-Handle clockwise until two audible clicks are heard confirming that the plate is secure. (Fig. 23)

*NOTE: When tightening on the cross bar, some initial tension could be encountered.*

**4. Removal of Instrument**

Loosen the side set screw of the articulating arm to disengage the cross bar plate from the instrument.

Open the ratcheting arm at the handle of the instrument to release the compression on both plates. Then slowly open both handles laterally to disengage the Inserter from the implant. Once visually confirmed that the implant and Inserter are fully disengaged, slowly remove the inserter. (Fig. 24)

**Instruments**
UniLink and UniLink 5/1 Removal

Surgical Technique

Step 1
Place a single Compressor onto the implant and compress until the spherical tips are fully seated into the round lateral pockets of the plate. (Fig. 25)

Step 2
Insert the Screwdriver into the set screw and, while maintaining compression on the single Compressor, turn the Torque Limiting T-Handle counter clockwise until the locking plate has been loosened.

Step 3
Using an elevator or forceps, gently push the insert through the interspinous space and remove the locking plate, cross bar plate, and insert.

Instruments
## Tray Layouts

**UniLink Interspinous Fusion System Set**

**Catalog Number** | **Description** | **Kit Quantity**
--- | --- | ---
07.02208.002 | 36 mm Plate Implant Caddy | 1
07.02207.001 | 36 mm Cross Bar Plate | 4
07.02207.003 | 36 x 8 mm Locking Plate | 3
07.02207.004 | 36 x 10 mm Locking Plate | 3
07.02207.005 | 36 x 12 mm Locking Plate | 3
07.02207.006 | 36 x 14 mm Locking Plate | 2
07.02207.007 | 36 x 16 mm Locking Plate | 2
07.02207.014 | 36 mm No Insert Locking Plate | 2
07.02208.003 | 40 mm Plate Implant Caddy | 1
07.02207.002 | 40 mm Cross Bar Plate | 4
07.02207.008 | 40 x 8 mm Locking Plate | 3
07.02207.009 | 40 x 10 mm Locking Plate | 3
07.02207.010 | 40 x 12 mm Locking Plate | 3
07.02207.011 | 40 x 14 mm Locking Plate | 2
07.02207.012 | 40 x 16 mm Locking Plate | 2
07.02207.013 | 40 x 18 mm Locking Plate | 2
07.02207.015 | 40 mm No Insert Locking Plate | 2
07.02208.027 | PEEK Insert Caddy | 1
07.02207.016 | PEEK, 8mm Insert | 3
07.02207.017 | PEEK, 10mm Insert | 3
07.02207.018 | PEEK, 12mm Insert | 3
07.02207.019 | PEEK, 14mm Insert | 2
07.02207.020 | PEEK, 16mm Insert | 2
07.02207.021 | PEEK, 18mm Insert | 2
07.02208.004 | Titanium Insert Caddy | 1
07.02207.022 | Titanium, 8 mm Insert | 3
07.02207.023 | Titanium, 10 mm Insert | 3
07.02207.024 | Titanium, 12 mm Insert | 3
07.02207.025 | Titanium, 14 mm Insert | 2
07.02207.026 | Titanium, 16 mm Insert | 2
07.02207.027 | Titanium, 18 mm Insert | 2
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UniLink Interspinous Fusion System Additions Set
07.02208.412

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UniLink 5/1 Interspinous Fusion System Set
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UniLink & UniLink 5/1 Systems Instrument Visual Guide

- **Piercer-Rasp**
  - 07.02208.005
  - 07.02208.011
  - (X060-0307)

- **Plate Sizers**
  - 07.02208.012 36 mm
  - 07.02208.013 40 mm
  - (X060-0336)

- **Screwdriver**
  - 07.02208.008
  - (X060-0320)

- **Trial-Rasps (8 – 18mm)**
  - 07.02208.016 – 07.02208.021
  - (X060-0440 – X060-0445)

- **Inserter, Cross Bar Plate**
  - 07.02208.006
  - (X060-0318)

- **Inserter, Locking Plate**
  - 07.02208.007
  - (X060-0319)

- **Compressor-Piercer**
  - 07.02208.010
  - (X060-0328)

- **Compressor**
  - 07.02208.014
  - (X060-0370)

- **Spreader**
  - 07.02208.015
  - (X060-0390)

- **Torque Limiting T-Handle**
  - 07.02208.009
  - (X060-0322)

- **Fixed In-Line Handle, Square Connect**
  - 07.02208.010
  - (X060-0324)

- **All-In-One Inserter (optional)**
  - 07.02210.008
  - (X060-0520)

*Optional Instrument; must be ordered separately*
Warnings and Precautions

WARNINGS
The implantation of spinal implant systems should be performed only by experienced spinal surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, none of the UniLink Interspinous Fusion System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The UniLink Interspinous Fusion System has not been evaluated for safety and compatibility in the MR environment. The UniLink Interspinous Fusion System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and Zimmer Spine cannot make any claims regarding the safety of Zimmer Spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

PREOPERATIVE MANAGEMENT
1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device’s indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
6. Implants should not be reused under any circumstances.
UniLink Graft Interspinous Allograft – Surgical Technique

Step 1
Position the patient in the prone position on the operating table.
Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging.
Make a midline incision from 3 to 5cm in length to expose the spinous processes at the correct level. Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and laminae to the medial border of the facet joints. Use a rongeur to fully remove the supraspinous/interspinous ligaments between the appropriate levels and any connective or soft tissue. (Fig. 1G)

Step 2
Load the Distraction Screwdriver with the appropriately sized Distraction Screw by inserting the Distraction Screw into the Screwdriver shaft. (Fig. 2G)

The UniLink Graft Interspinous allograft spacer is to be used in conjunction with the UniLink and UniLink 5/1 Interspinous Fusion System. Various implant sizes are available to adapt to different patient pathologies. All implants are intended for single use only and should not be reused under any circumstances.

Instruments

Distraction Screwdriver (Caspar Pin Screw Driver)
07.02222.008
(X078-0075)

Distraction Screw (12, 14, 16, 18mm)
07.02222.010 – 07.02222.013
(X078-0082 – X078-0088)
UniLink Graft Interspinous Allograft – Surgical Technique

**Step 3**

Target the dorsal midpoint of the identified spinous process then press firmly and rotate clockwise to advance the Distraction Screw until the base of the Distraction Screw is firmly against the dorsal portion of the spinous process.

Repeat for the adjacent spinous process. *(Fig. 3G)*

**CAUTION:** Placement of excessive force on the Distraction Screw may result in spinous process fracture and/or neurological injury.

**Step 4**

With both Distraction Screws secured to the dorsal portion of the spinous process, slip the Distraction Screw Sleeves over the Distraction Screws. Then place the Spinous Process Distractor over the Distractor Screw Sleeves and rotate the ratcheting key clockwise.

Use caution not to over-distract the interspinous space. *(Fig. 4G)*

**Step 5**

Decompression and decortication is performed using standard surgical techniques. *(Fig. 5G)*

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**Instruments**

| Distraction Screw Sleeve | 07.02222.009  
(X078-0080) |
|--------------------------|-----------------|
| Spinous Process Distractor | 07.02222.006  
(X078-0070) |
**Step 6**
After the interspinous space has been prepared, select the Spreader and insert to determine the size of the space. (Fig. 6G)

**Step 7**
Once the interspinous space is sized, select the appropriate Trial Block and place it into the interspinous space and release the distractor assembly to confirm proper fit on both the inferior and superior spinous processes as well as a level position with both the inferior and superior lamina. (Fig. 7G)

**NOTE:** When placing the Trial Block into place make sure the larger recessed notch of the Trial Block is on the inferior spinous process and the smaller recessed notch is placed on the superior spinous process.

**Step 8**
After the Trial Block size has been confirmed, turn the ratcheting key drive clockwise to distract and remove the Trial Block from the interspinous space. (Fig. 8G)

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**Instruments**

- **Spreader**
  - 07.02208.015 (X060-0390)

- **Trial Block (8 – 20mm)**
  - 07.02222.015 – 07.02222.021 (X078-0108 – X078-0120)

- **Trial Shaft**
  - 07.02222.014 (X078-0100)

*Included in the UniLink Interspinous Fusion System Set (07.02207.400)
Step 9
Load the corresponding UniLink Graft onto the desired UniLink Graft Inserter, Dorsal or Lateral. (Fig. 9G)

**NOTE:** When placing the UniLink Graft implant into place make sure the larger recessed notch of the implant is on the inferior spinous process and the smaller recessed notch is placed on the superior spinous process.

After placing the UniLink Graft onto either Inserter, rotate the screwcap clockwise until the screwcap stops advancing and is secure.

**CAUTION:** Over-tightening of the Inserter’s screwcap may result in damage to the UniLink Graft or instrumentation.

Step 10
Position the loaded Inserter as anterior as possible with the allograft resting on the superior and inferior spinous processes as well as both superior and inferior laminae. When the UniLink Graft has reached its desired position in the interspinous space, rotate the ratcheting key drive counterclockwise on the Spinous Process Distractor assembly to release the distraction. To remove the UniLink Graft from the Inserter, rotate the screwcap counterclockwise until the instrument releases from the UniLink Graft. (Fig. 10G)

**CAUTION:** Over-impaction of the Inserter may result in damage to the UniLink Graft or instrumentation.

Instruments

Dorsal Inserter
07.02222.004
(X078-0030)

Lateral Inserter
07.02222.005
(X078-0050)

Mallet
07.02222.003
(X078-0025)
Step 11 (recommended)
Reference the UniLink System surgical technique for implantation of the UniLink System. (Fig. 12G)

Instruments
### UniLink Graft Implant and Instrument Set

**Part Number** | **Description** | **Quantity**
---|---|---
07.02222.022 | Distraction Screw Caddy | 1
07.02222.010 | Distraction Screw, 12mm | 4
07.02222.011 | Distraction Screw, 14mm | 4
07.02222.012 | Distraction Screw, 16mm | 4
07.02222.013 | Distraction Screw, 18mm | 4
07.02222.001 | Graft Implant Carrying Case | 1
07.02221.008 | Interspinous Cortical Block 8mm | 3
07.02221.010 | Interspinous Cortical Block 10mm | 3
07.02221.012 | Interspinous Cortical Block 12mm | 3
07.02221.014 | Interspinous Cortical Block 14mm | 3
07.02221.016 | Interspinous Cortical Block 16mm | 2
07.02221.018 | Interspinous Cortical Block 18mm | 1
07.02221.020 | Interspinous Cortical Block 20mm | 1

### Part Number | **Description** | **Quantity**
---|---|---
07.02222.002 | Sterilization Case | 1
07.02222.003 | Mallet | 1
07.02222.004 | Dorsal Inserter | 1
07.02222.005 | Lateral Inserter | 1
07.02222.006 | Spinous Process Distractor | 1
07.02222.008 | Distraction Screwdriver | 2
07.02222.009 | Distraction Screw Sleeve | 4
07.02222.014 | Trial Shaft | 2
07.02222.015 | Trial Block, 8mm | 1
07.02222.016 | Trial Block, 10mm | 1
07.02222.017 | Trial Block, 12mm | 1
07.02222.018 | Trial Block, 14mm | 1
07.02222.019 | Trial Block, 16mm | 1
07.02222.020 | Trial Block, 18mm | 1
07.02222.021 | Trial Block, 20mm | 1
07.02222.023 | Trial Caddy | 1
UniLink Graft Instrument Visual Guide

Dorsal Inserter
07.02222.004
(X078-0030)

Lateral Inserter
07.02222.005
(X078-0050)

Trial Block (8 – 20mm) (shown with Trial Shaft)
07.02222.015 – 07.02222.021
(X078-0108 – X078-0120)

Trial Shaft (shown with Trial Block)
07.2222.014
(X078-0110)

Distraction Screwdriver
07.02222.008
(X078-0075)

Mallet
07.02222.003
(X078-0025)

Distraction Screw Sleeve
07.02222.009
(X078-0080)

Distraction Screw (12, 14, 16, 18mm)
07.02222.010 – 07.02222.013
(X078-0082 – X078-0088)

Spinous Process Distractor
07.02222.006
(X078-0070)
Disclaimer:
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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

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