Surgical Technique
Elegant Design. Complex Correction.
From the people of Zimmer Spine.

Our goal in designing the Universal Clamp System was to produce a new implant by pooling the inherent advantages of technologies utilized in the market today. Our research and development team developed an implant with the benefits of screws, the adaptability of hooks and the simplicity of Luque-type instrumentation which optimized the strength of the implant/bone interface. The Universal Clamp’s System proprietary design closely mimics the benefits of its screw, wire and hook predecessors, while providing optimal bone/implant interface strength, simplicity in use and flexibility in placement.

The Universal Clamp System provides a stable interface between spinal anatomy and the rod through a pedicle-sparing band passage technique. The result is an implant that provides segmental stability, allows compression, distraction, derotation and translation while sparing the pedicles and reducing implant/bone contact stress.

The Universal Clamp System can be used to correct a wide variety of complex spinal pathologies including sagittal and coronal misalignment as well as degenerative conditions.

The Universal Clamp System. Truly a universal solution for thoracolumbar stabilization. From the people of Zimmer Spine.
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Indications

The *Universal Clamp* System is a temporary implant for use in orthopaedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid intervertebral fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques.

2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis.

3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The *Universal Clamp* System may also be used in conjunction with other medical implants made of similar metals whenever “wiring” may help secure the attachment of the other implants.

After solid fusion occurs, this device serves no functional purpose and may be removed. In most cases, removal is indicated because the implant is not intended to transfer or support forces developed during normal activities after several months. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.
Contraindications

The *Universal Clamp* System is not designed or sold for any use except as indicated. Do not use *Universal Clamp* implants in the presence of any contraindications.

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

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

3. Severe osteoporosis is a contraindication because it may prevent adequate fixation.

4. Suspected or documented metal allergy or intolerance.

5. Inadequate tissue coverage over the operative site.

6. In any situation where implant utilization would interfere with anatomical structures or expected physiological performance, such as impinging on vital structures.

7. Severe fractures such that segments may not be maintained in satisfactory proximate reduction.

8. Physical contact of the *Universal Clamp* System with dissimilar metals. The titanium clamp should only be used with titanium implants and the stainless steel clamp should only be used with stainless steel implants.

9. Any entity or condition that compromises the possibility of fusion, i.e. such as cancer, kidney dialysis or osteopenia.

10. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient’s occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.
Universal Clamp Implants

The Universal Clamp System provides the user with the adaptability of hooks and the simplicity of sublaminar instrumentation. Elegantly simple, Universal Clamp instrumentation allows surgeons to leverage the strengths of this versatile implant to correct a variety of spinal pathologies.

The Universal Clamp implant consists of three sterile parts furnished together in the same box:

- one clamp
- one woven polyester band
- one locking screw

5.5mm Universal Clamp
Titanium SNA027-0-20055
Stainless Steel SNA027-0-30055

6.0mm Universal Clamp
Titanium SNA027-0-20060
Stainless Steel SNA027-0-30060

6.35mm (1/4”) Universal Clamp
Stainless Steel SNA027-0-30063
Zimmer Spine made the development of easy-to-use instrumentation one of the major priorities of the *Universal Clamp* project with the goal of making it as simple, flexible and intuitive as the *Universal Clamp* System itself. With this goal in mind, we tried to limit the amount of required instrumentation, in order to reduce the potential for clutter in the surgical field and potentially improve surgical flow. The result is the suite of elegantly simple yet comprehensive implants and instruments that comprise the *Universal Clamp* System.

**Elevators**

*Note: Elevators and Band Passers are only used with the Figure 8 technique to facilitate passage around the transverse process. Elevators and Band Passers should not be used for sublaminar passage. Only included in Universal Clamp Instrument Module SNA027-0008-PL.*

Prepare a pathway around the transverse process through which to pass the *Universal Clamp*’s polyester band.

**Elevator 45 Degree Right**

SN2027-1-02102

**Elevator 90 Degree Right**

SN2027-1-02100

**Elevator Straight**

SN2027-1-02104

**Elevator 45 Degree Left**

SN2027-1-02103

**Elevator 90 Degree Left**

SN2027-1-02101
Band Passers

Note: Elevators and Band Passers are only used with the Figure 8 technique to facilitate passage around the transverse process. Elevators and Band Passers should not be used for sublaminar passage. Only included in Universal Clamp Instrument Module SNA027-0008-PL.

Draw the Universal Clamp System’s polyester band through the prepared pathway around the transverse process.

Band Passer 45 Degree Right
SN2027-1-02112

Band Passer 90 Degree Right
SN2027-1-02110

Band Passer 45 Degree Left
SN2027-1-02113

Band Passer 90 Degree Left
SN2027-1-02111
Additional Instrumentation

**Implant Positioner**  
SN2027-1-02600  
Loads and positions the implant on the rod after the bands have been attached.

**Final Screwdriver**  
SN2027-1-02570  
Final tightens the locking screw to complete the construct.

**Tapered Screw Starter**  
SN2027-1-02512  
Assembles the Universal Clamp System to the rod by introducing a locking screw.

**20cm Bengolea Forceps**  
SN2027-1-02270  
Holds and stabilizes the tip of the band, assisting with its introduction to the lamina.

**26cm Bengolea Forceps**  
SN2027-1-02276

**Reduction Tool Barrel**  
SN2027-1-02200

**Reduction Tool Handle**  
SN2027-1-02201  
Together, they tighten the implant's polyester band to achieve anatomical reduction.
Surgical Technique

Implant Preassembly

Step 1

Thread the Band
Assemble the Universal Clamp implant by passing the malleable leader of the band first through the slot of the clamp’s upper jaw identified by an etched arrow, then through the slot in the lower jaw. Gently pull the band clamp until the clamp reaches the buckle end of the band.

Prepare the lamina for band passage by removing at least 5 mm of the ligamentum flavum on both the cephalad and caudal ends of the lamina.

Step 2 Option 1: Standard Band Passage

Standard Band Passage
Shape the band’s malleable leader to facilitate band passage under the lamina. Pass the band from the caudal margin of the lamina toward the cephalad laminar margin.

Caution: During band passage, maintain upward pressure on the malleable leader to ensure the band stays in contact with the anterior aspect of the lamina and does not push or bow into the dura.

Note: Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.
Band Advancement
When the band is visible at the cephalad margin of the lamina, hold and stabilize the tip of the band with the Bengolea Forceps. To avoid pushing the band into the dura, maintain upward pressure against the anterior aspect of the lamina by pulling up on the tip of the band while advancing the malleable leader under the lamina until its ends are of equal length.

Note: Periosteal Elevators are not used to prepare laminar anatomy prior to band passage. Band Passers are not used to pass the band under the lamina. Do not twist the band during band passage maneuvers and take care when passing the band near the thecal sac.

Step 2 Option 1b: Passage Around Transverse Process
To pass the band around the transverse process, first use an Elevator to create a pathway for the band. Introduce the Elevator from the cephalad margin of the transverse process, holding the handle lateral to the spine. With a rotating motion, turn the Elevator around the transverse process.

Step 2 Option 2: “Figure 8” Band Passage - For Use in Adult Patients
Requires Universal Clamp Instrument Module SNA027-0008-PL.

“Figure 8” band passage is warranted in boney situations or parts of a construct where additional boney fixation is desired. In this technique, transverse process passage will be followed by sublaminar passage, both in the down-going orientation.
Step 2 Option 2b

**Band Passer**
To pass the band, insert the Band Passer into the eyelet near the tip of the band. Contour the malleable leader to the Band Passer.

Step 2 Option 2c

**Band Threading**
Use the Band Passer with the handle lateralized in a rotating motion to thread the band through the passage created by the Elevator.

Step 2 Option 2d

**Band Pushing**
When its tip becomes visible at the caudal margin of the transverse process, hold and stabilize the band with the Bengolea Forceps. Using a pushing motion on the cephalad margin, guide the band from the caudal margin of the transverse process.
Passage Around Lamina

After passing the band around the transverse process, pass it around the lamina in the cephalad to caudal direction.

*Note:* Do not twist the band during band passage maneuvers and take care when passing the band near the thecal sac.

Final Locking

Final Locking

Once the band has been passed around the lamina, or the lamina and transverse process pass the tip first through the lower jaw and then the upper jaw of the clamp. Pass the band’s tip through both buckles and loop back through only one buckle; tighten to create a working loop. Use the buckle to adjust the working loop’s size as needed. Ensure reduction capability by having twice as much leader length in the soft band area between the buckle and leader.

*Note:* To reduce the risk of sepsis related to the band, bands may be placed in sterile plastic bags placed bilaterally along the incision prior to final tightening of the implant and cutting of the band.
Affix Implant to Rod

After Universal Clamp bands have been attached to the vertebral anatomy, the clamp can be attached to a rod contoured in the normal manner to reproduce native spinal curvature.

**Step 4**

Assemble Universal Clamp Implant to Rod
Load the Universal Clamp Implant onto the rod with the jaws in the open position and medial orientation.

*Note:* Verify that the rod diameter and rod material match those of the clamp and that the arrow etched on the Universal Clamp is visible and pointing toward the mid-line of the spinal column.

**Step 4b**

Lock Universal Clamp Implant
Ensure the jaw with the directional arrow is loaded in the “up” or dorsal orientation. Assemble the clamp to the rod by introducing a locking screw with the Tapered Screw Starter. Initiate the locking screw a few turns for implant stabilization.

*Note:* Do not tighten the locking screw at this time, as this may prevent reduction or distraction/compression capability.

Do not tighten the locking screw with the Tapered Screw Starter, as its tapered tip may cause the internal hex of the screw to strip. Only use the Final Screwdriver for final tightening, as this driver is not tapered at the tip.

Adequate rod length beyond the terminal Universal Clamp Implant is 5mm.
Reduction

**Step 5**

*Modular Reduction Tool Assembly*

The band may be tightened using the Reduction Tool. The modular Reduction Tool is assembled by snapping the Kerrison Reduction Tool Handle to the Reduction Tool Barrel.

**Step 5b**

*Modular Reduction Tool Disassembly*

The Reduction Tool can be disassembled by depressing the side button on the connection between handle and barrel.
Step 6

Attach Reduction Tool
Place the tip of the Reduction Tool over the Universal Clamp Implant and onto the rod.

Step 6b

Reduction Maneuvers
Wrap the working loop of the Universal Clamp’s band around the capture post of the Reduction Tool; squeeze the Reduction Tool’s Handle. This action lengthens the working loop and shortens the anatomical loop of the band.

Note: Ensure that the buckle on the soft band does not contact the capture post during reduction. If it does, readjust the buckle until it is off of the capture post.

Step 6c

Tension Management
The Reduction Tool incorporates a tension gauge depicted by a line distal to the capture post. When the capture post slides to the indicator line (see inset), 700N of tension has been achieved. Tensioning prior to this indicator line is at the surgeon’s discretion based on the patient’s presentation and bone quality as well as the surgical technique.

Note: Tensioning beyond this point is not advised and may result in band breakage or bone fracture.

Line is engraved, orange highlighting added for illustrative purposes.

Note: Sequential tightening of multiple Universal Clamps in the construct is recommended to achieve a smooth correction.
Step 7

Final Tightening
When the intended correction or the maximal recommended tension is reached, use the Final Screwdriver to final tighten the Universal Clamp implant. The Reduction Tool may then be removed by depressing the button at the back of the Reduction Barrel.

*Note*: Do not tighten the locking screw with the Tapered Screw Starter, as its tapered tip may cause the internal hex of the screw to strip. Only use the Final Screwdriver for final tightening, as this driver is not tapered at the tip.

Ensure Final Screwdriver is axially aligned with the Universal Clamp locking screw during final tightening of the implant.

Finish the Construct

Step 8

Cutting the Band
When all Reduction Barrels have been removed from the construct, cut the Universal Clamp bands 0.5-1.0cm from the clamp and cauterize each band to eliminate frayed ends.

Perform wound closure in the usual manner.

Implant Removal

To remove the Universal Clamp, use the Final Screwdriver to loosen and remove the set screw and take the metal jaws off the rod. Cut the band close to the cephalad and caudal ends of the lamina. Gently massage the band back and forth a few millimeters to ensure no adherence with the lamina or dura. Gently pull the band from under the lamina in either direction.
# Universal Clamp Kit Contents

## 5.5mm Ti Implants Module

<table>
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<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
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<tbody>
<tr>
<td>SNA027-0-20055</td>
<td>Universal Clamp, 5.5mm Ti Sterile</td>
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## 6.0mm Ti Implants Module

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## 5.5mm SS Implants Module

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### 6.0mm SS Implants Module

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### Universal Clamp Instruments Module

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### Universal Clamp Instruments (Alternate) Module

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<tr>
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<td>Screwdriver</td>
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Warnings and Precautions

Warnings

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

1. In the U.S.A., this product has labeling limitations.

2. 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.
   - Vascular or visceral injury

3. Implants can break when subjected to the prolonged loading associated with delayed union or non-union. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Patients should be fully informed of the risks of implant failure.

4. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with the UNIVERSAL CLAMP System, must be made from like or compatible metals.
5. In selecting patients for internal fixation, the following factors can be of extreme importance to the eventual success of the procedure:

a. The patient’s weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the surgical treatment.

b. The patient’s occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.

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

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

e. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

f. The *Universal Clamp* System has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. The *Universal Clamp* System has not been tested for heating or migration in the MR environment.

g. Elevators and Band Passers should not be used for sublaminar passage. They should only be used for passage around the transverse process.
Precautions

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Refer to the UNIVERSAL CLAMP System Surgical Technique for instructions for implantation.

3. **REMOVAL OF THE IMPLANT AFTER HEALING.** Implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient’s ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in device failure. The patient should understand that a metallic or polyester implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative habilitation.

5. Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.
Solutions by the people of Zimmer Spine.

You are devoted to helping your patients reduce their pain and improve their lives. And the people of Zimmer Spine are devoted to you. We are dedicated to supporting you with best-in-class tools, instruments and implants. We are driven by the opportunity to share our unrivaled education and training. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. And we can be counted on always to act with integrity as ethical partners who are worthy of your trust. We are the people of Zimmer Spine.