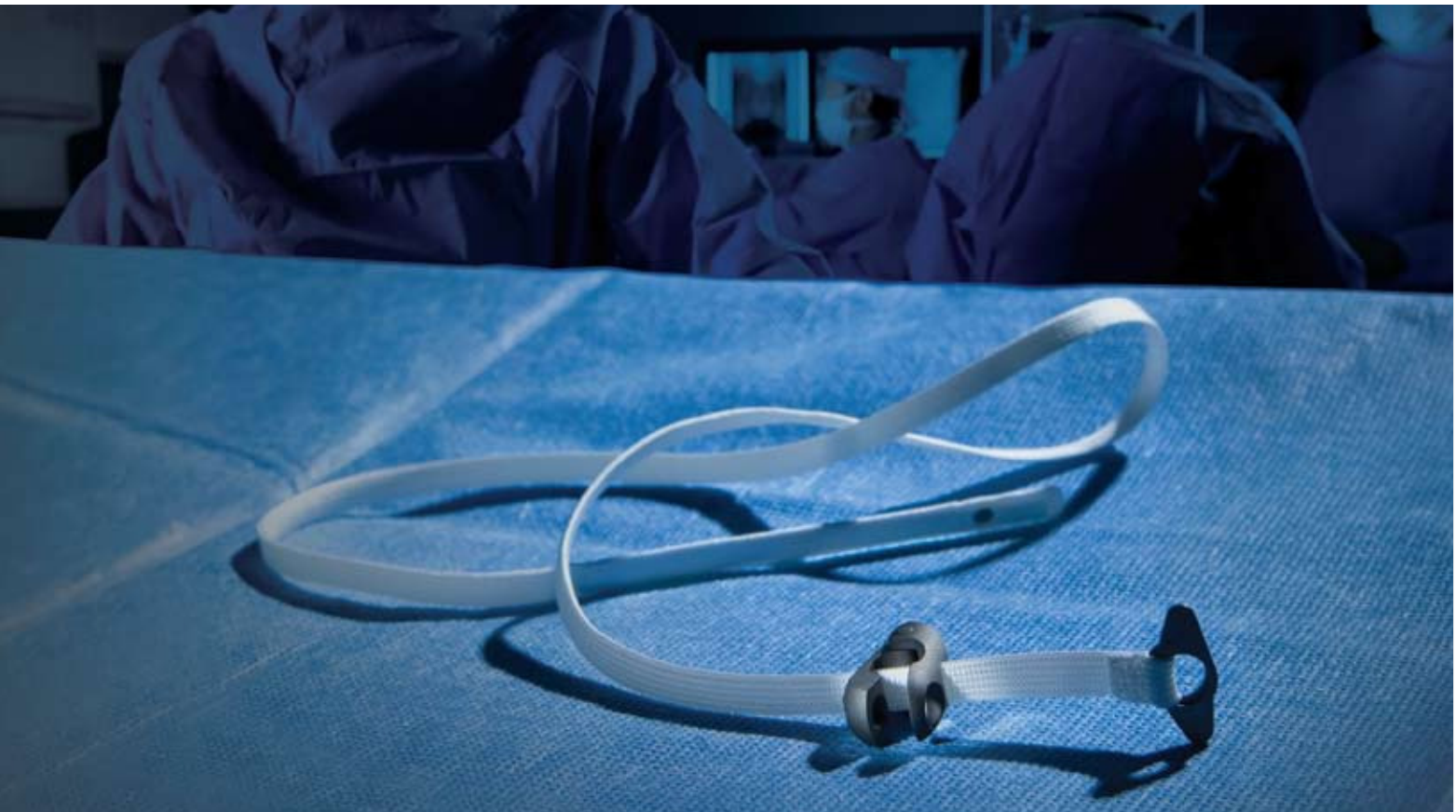
Universal Clamp®

Spinal Fixation System

Surgical Technique



You strive to simplify
the complex.
So do we.

Expertise at your side.

Abbott
A Promise for Life

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Introduction

Elegant Design. Complex Correction.

Our goal in designing the Universal Clamp was to produce a new implant by pooling the inherent advantages of implants currently on the market. Our research found surgeons were looking for an implant with the stability of screws, the adaptability of hooks and the simplicity of Luque-type instrumentation which optimized the strength of the implant/bone interface. The output of our project is the Universal Clamp – a proprietary implant and design we believe 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 provides a stable interface between spinal anatomy and the rod through a pedicle sparing band passage technique and combines the advantages of screws, hooks and sublaminar wires while avoiding their limitations. 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 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 is truly a universal implant for thoracolumbar stabilization.

Indications/Contraindications

Indications – Ti

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 bony fusion and aid in the repair of bone fractures. The indications for use include, but are not limited to, the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Universal Clamp System may also be used in conjunction with other medical implant grade implants made of titanium alloy whenever “wiring” may help secure the attachment of other implants.

Indications – SS

The Universal Clamp Stainless Steel System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone factures. The indications for use include, but are not limited to, the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions;

The Universal Clamp Stainless Steel System may also be used in conjunction with other medical implants made of stainless steel whenever “wiring” may help secure the attachment of other implants.

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 which 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 relative 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 any dissimilar metals.
9. Any entity or condition that totally precludes the possibility of fusion, i.e. 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.

Key Instruments

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

Abbott 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 itself. In pushing toward this goal, 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 listed on the following pages.

Reduction Tool Barrel — SN2027-1-02200
Reduction Tool Handle — SN2027-1-02201

Elevator 45 Degree Right — SN2027-1-02102

Band Passer 45 Degree Right — SN2027-1-02112

Elevator 90 Degree Right — SN2027-1-02100

Band Passer 90 Degree Right — SN2027-1-02110

Key Instruments

Straight Elevator — SN2027-1-02104

Elevator 45 Degree Left — SN2027-1-02103

Band Passer 45 Degree Left — SN2027-1-02113

Elevator 90 Degree Left — SN2027-1-02101

Band Passer 90 Degree Left — SN2027-1-02111

Implant Positioner — SN2027-1-02600

Tapered Screw Starter — SN2027-1-02512

Bengolea Forceps, 20 cm — SN2027-1-02270

Bengolea Forceps, 26 cm — SN2027-1-02276

3.5 mm Screwdriver — SN2027-1-02570

Surgical Technique

Implant Preassembly

Figure 1

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

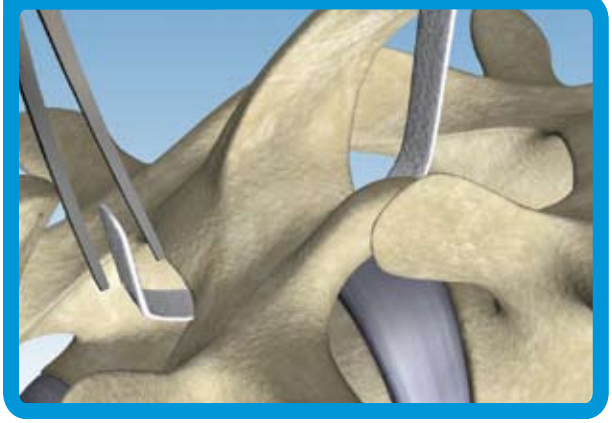
- one clamp
- one woven polyester band
- one locking screw

The Clamp is assembled by passing the malleable leader of the band first through the slot of the Clamp's upper, then through the slot in the lower jaw. The band is gently pulled through the Clamp until the Clamp reaches the buckle end of the band.

Surgical Technique

Figure 2

Figure 3



Band Passage Around the Lamina

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. When the band is visible at the cephalad margin of the lamina, hold and stabilize the tip of the band with Bengolea forceps. Use a pushing technique, while controlling the tip of the band, to advance the band under the lamina until the band ends are of equal length.

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.

Figure 4

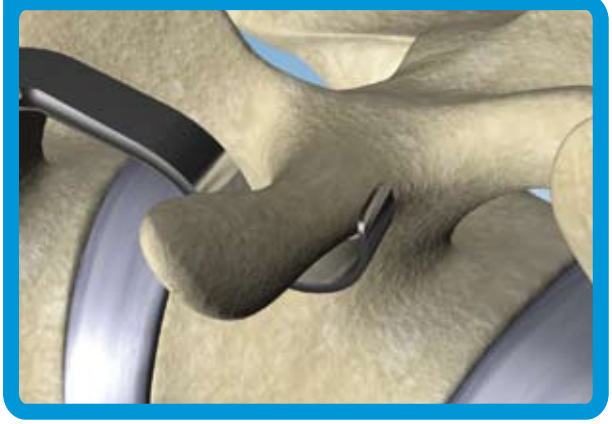


Figure 5

Figure 6

"Figure 8 style" Band Passage (Lamina & Transverse Process)

"Figure 8 style" band passage is warranted in situations or parts of a construct where a stronger bony base of fixation is required. In this technique, transverse process passage will be followed by sublaminar passage, both in the down-going orientation.

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.

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. Use the band passer with the handle lateralized in a rotating motion to thread the band through the passage created by the elevator.

Surgical Technique

Figure 7

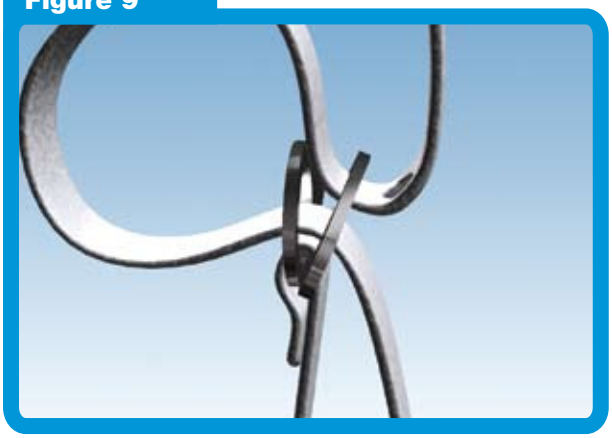
When the tip becomes visible at the caudal margin of the transverse process, hold and stabilize the band with forceps. Using a pushing motion on the cephalad margin, guide the band from the caudal margin of the transverse process.

After passing the band around the transverse process, the band is passed around the lamina in the cephalad to caudal direction.

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

Figure 8

Figure 9



Preparation of Working Loop

Once the band has been passed around the lamina or 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 and tighten to create a working loop. Adjust the working loop size as needed with the buckle. Ensure reduction capability by having twice as much leader length in the soft band area between buckle and leader.

Figure 10

Figure 11

Connection 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.

Verify that the rod diameter and rod material match those of the clamp.

Load the Clamp onto the rod with the jaws in the open position and medial orientation. Implant placement can be accomplished freehand or using the implant positioner.

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.

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 the tapered driver 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 length of rod beyond the terminal universal clamp is 5 mm.

Figure 12

Modular Reduction Tool Assembly

The band is tightened using the Reduction Tool. The modular reduction tool is assembled by snapping the Kerrison Handle to the Reduction Barrel. The Reduction Tool can be disassembled by depressing the side button on the connection between Handle and Barrel.

Figure 13

Figure 14

Figure 15

Figure 16

Reduction

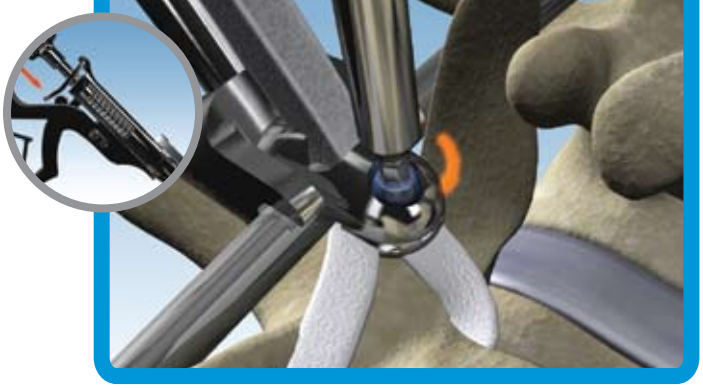
Place the tip of the Reduction Tool over the Universal Clamp and onto the rod. The working loop of the band is then wrapped around the capture post of the Reduction Tool and reduction is achieved by squeezing the Reduction Tool handle. This action lengthens the working loop and shortens the anatomical loop of the band.

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, 700 N of tension has been achieved. Tensioning prior to this indicator line is at surgeon discretion based on patient presentation, bone quality and surgical technique.

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

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

Figure 17



Final Tightening and Reduction Tool Release

When the intended correction or the maximal recommended tension reached, the Universal Clamp can be final tightened using the Final Driver. When the clamp has been final tightened, the Reduction Tool may be removed by depressing the button at the back of the Reduction Barrel.

Do not tighten the locking screw with the tapered screw starter, as the tapered driver 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.

Figure 18

Cutting the Band

When the desired correction has been achieved, all Clamps have been locked to the rod using the Final Driver and all Reduction Barrels removed from the construct, Universal Clamp bands may be cut 0.5-1.0 cm from the clamp and cauterized to eliminate frayed ends.

Wound closure is then performed in the usual manner.

Kit Contents

Part Number	Description	Standard Quantity
SN2027-1-02270	Bengolea Forceps, 20cm	1
SN2027-1-02276	Bengolea Forceps, 26cm	1
SN2027-1-02200	Reduction Tool Barrel	4
SN2027-1-02201	Reduction Tool Handle	2
SN2027-1-02600	Implant Positioner	1
SN2027-1-02512	Tapered Screw Starter	1
SN2027-1-02570	3.5 mm Screwdriver	1
SN2027-1-02104	Straight Elevator	1
SN2027-1-02102	Elevator 45 Degree Right	1
SN2027-1-02103	Elevator 45 Degree Left	1
SN2027-1-02100	Elevator 90 Degree Right	1
SN2027-1-02101	Elevator 90 Degree Left	1
SN2027-1-02110	Band Passer 90 Degree Right	1
SN2027-1-02111	Band Passer 90 Degree Left	1
SN2027-1-02112	Band Passer 45 Degree Right	1
SN2027-1-02113	Band Passer 45 Degree Left	1
SN2027-2-02001	Universal Clamp Metal Lid	1
SN2027-2-02002	Universal Clamp Instrument Base	1
SN2027-2-02003	Universal Clamp Tray - Upper	1
SN2027-2-02004	Universal Clamp Tray - Lower	1

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 increased 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.

Warnings

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 which can lead to failure of the appliance and the operation.

   b - The patient's occupation or activity. If the patient is involved in an occupation or activity which 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, orthopedic 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

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 risk 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 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 rehabilitation

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