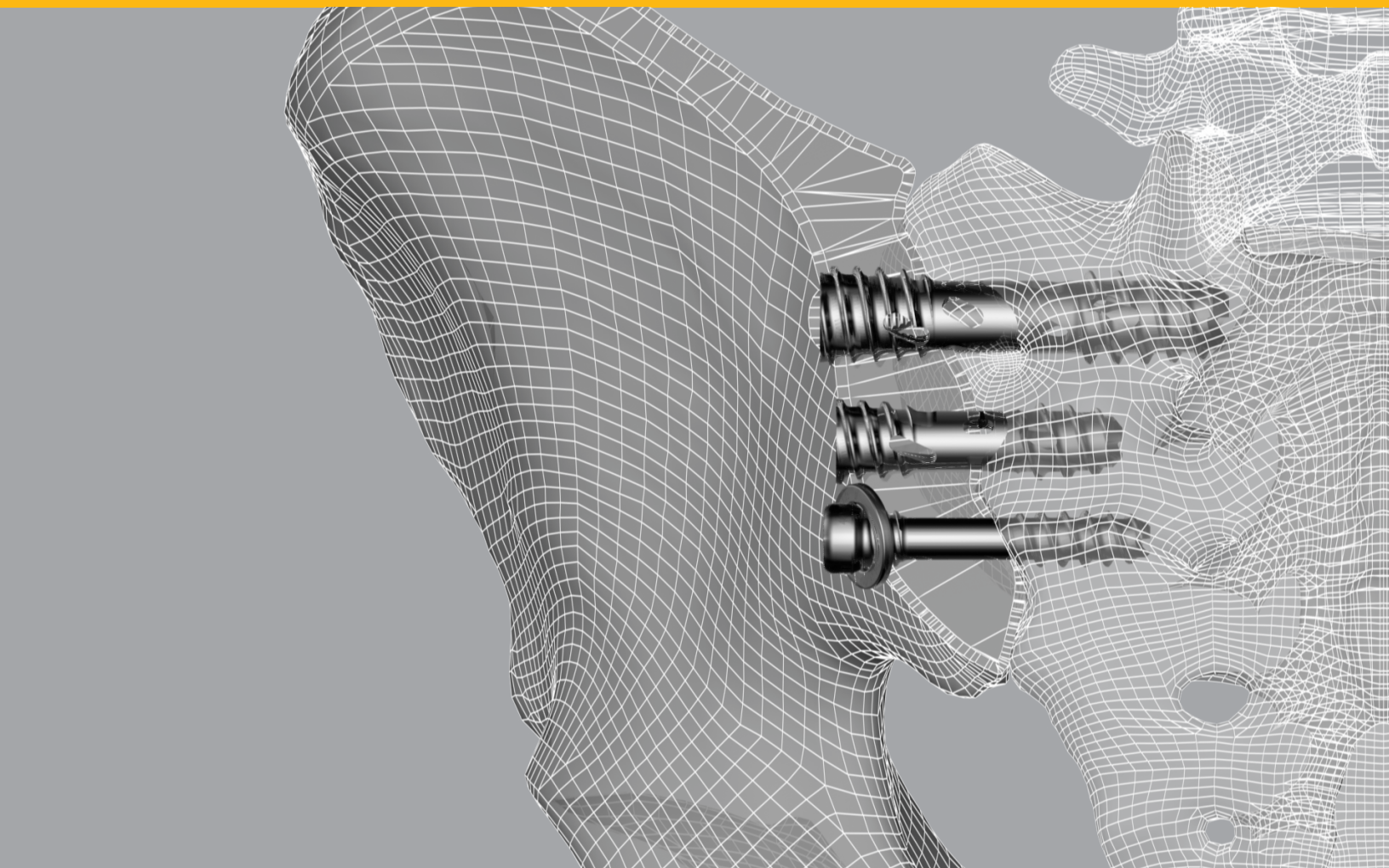
CoreLink
The Source for Spine™

CORELINK ENTASIS® SACROILIAC JOINT FUSION

Surgical Technique Guide



THE ENTASIS SI JOINT FUSION SYSTEM ADVANTAGE

The Entasis SI Joint Fusion System was designed to provide a faster and potentially safer SI joint fusion procedure with joint compression that the surgeon can feel.

The Entasis SI Joint Fusion System features ergonomic and intuitive instruments and an array of implants that are designed for:

Ease of Insertion
- Aggressive pitch threading
- "Easy-in" tip
- Streamlined technique

Joint Compression
- Up to 4.5mm of joint compression
- Pass-through fenestrations for straight-line fusion mass
- Self-harvesting and self-filling of autograft

TABLE OF CONTENTS

SYSTEM OVERVIEW

The Entasis Sacroiliac Joint Fusion System provides an array of joint stabilizing compression screw options in three diameters and nine length options, enabling surgeons to precisely fit varying patient anatomies.

SYSTEM FEATURES

- Self-drilling tip for easier introduction
- Helical fenestrations for self-harvesting of bone graft
- Dual-lead thread for faster implantation
- Dual-pitch threading provides compression
- Stackable Guide Wires allow constant proximal control, assisting with Guide Wire travel
- Easy-out removal instruments

IMPLANT SIZES

CoreLink offers screws in 7.0mm, 9.5mm, and 11.5mm diameters to tailor implant selection to patient anatomy while maximizing the number of points of fixation.

An optional 13mm Washer can be utilized with the 7.0mm diameter implant.

13MM
WASHER

SMALL IMPLANT — 7MM DIAMETER
30-70MM LENGTHS

MEDIUM IMPLANT — 9.5MM DIAMETER
30-70MM LENGTHS

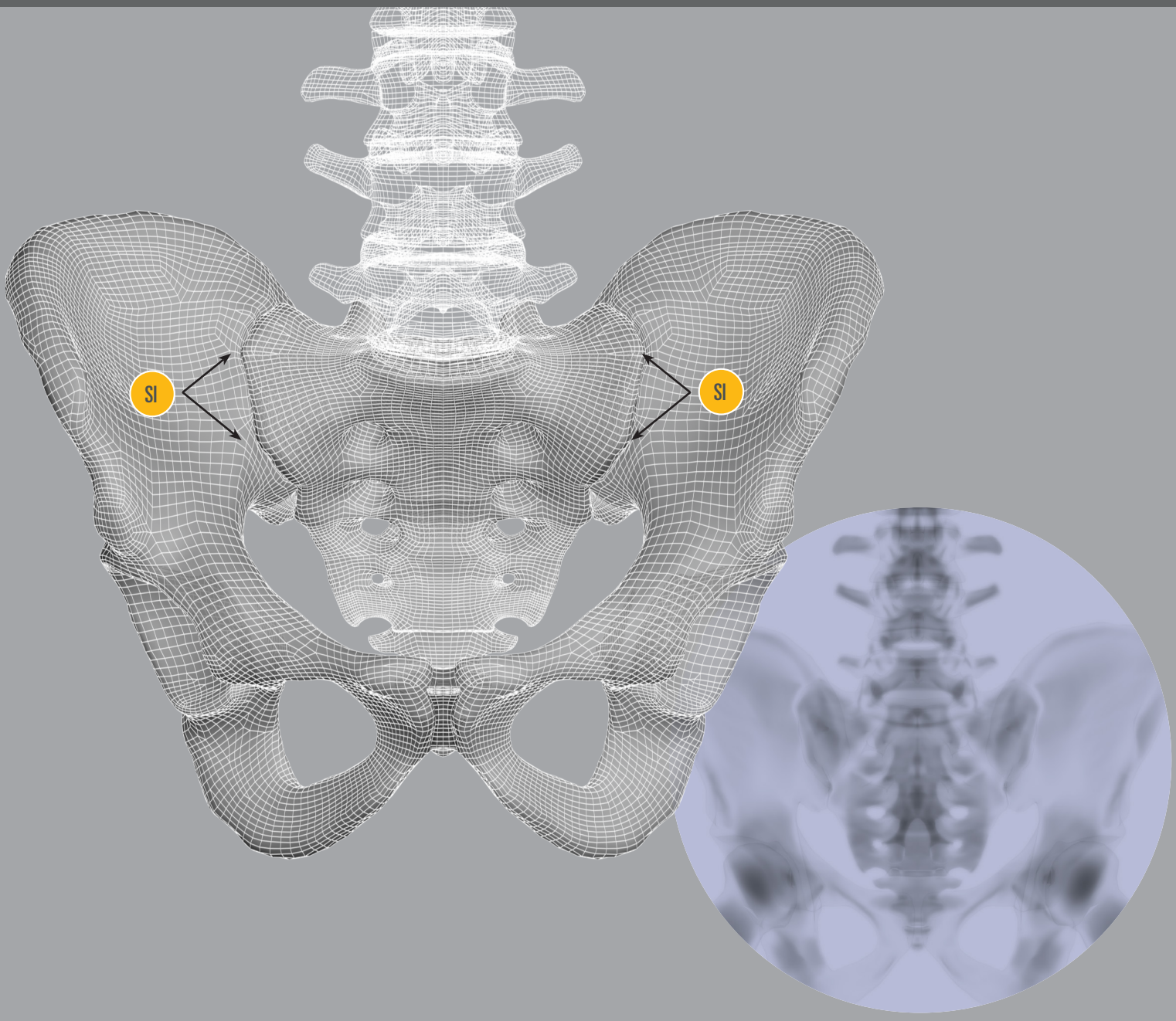
LARGE IMPLANT — 11.5MM DIAMETER
30-70MM LENGTHS

SI JOINT OVERVIEW

The sacroiliac (SI) joint is a bicondylar synovial joint which joins the sacrum into the ilium.

SACROILIAC JUNCTION

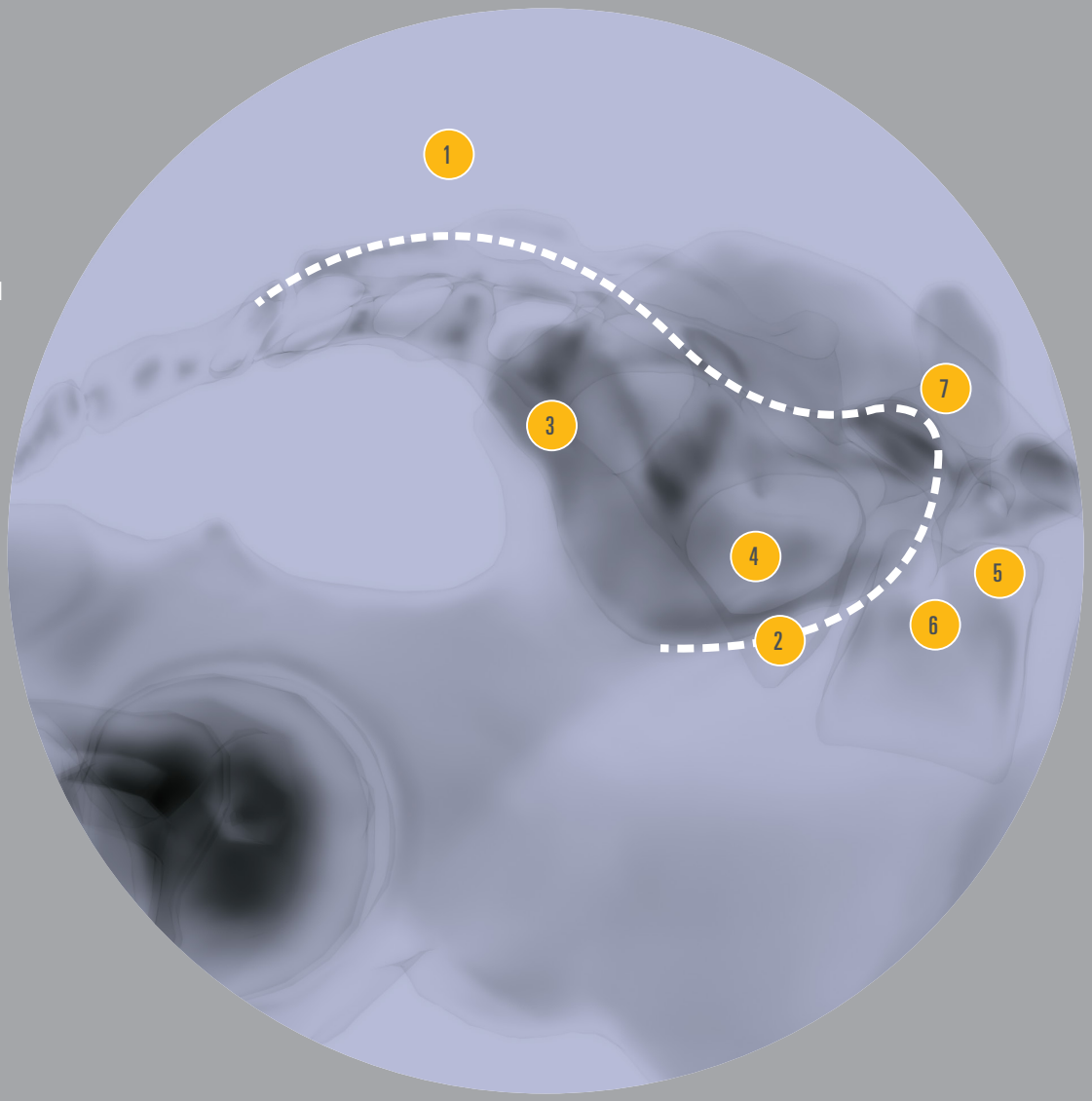
SACROILIAC FLUOROSCOPY (OUTLET VIEW)



The Entasis Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

SACROILIAC FLUOROSCOPY (LATERAL VIEW)

1. Posterior Sacral Wall
2. Sacral Ala
3. Anterior Sacral Wall
4. Sacroiliac Joint
5. Inferior Endplate – L5
6. Superior Endplate – S1
7. Greater Sciatic Notch



PATIENT POSITIONING AND APPROACH

The patient is put under anesthesia and positioned prone. The operative area is prepared and draped in the standard fashion.

Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of the implant(s).

INITIAL TARGETING

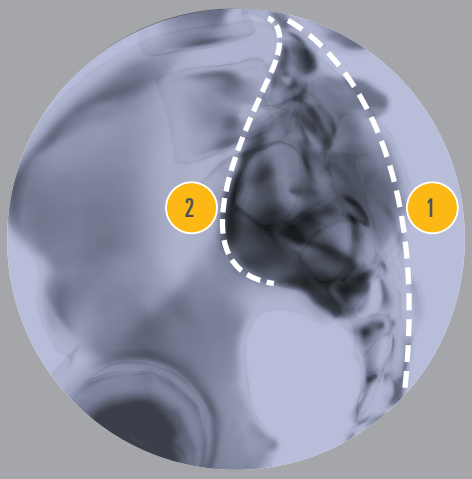
Using the Exchange Flat Pin (#5040-103) locate the Posterior Sacral Wall (1) and the Sacral Alar Line (2) via lateral fluoroscopy and demarcate on patient.

Make an incision along the posterior sacral wall of at least 3cm in length starting at the intersection with sacral alar skin marking. Using the Trocar Tip Guide Wire (#5040-100), create an initial target vector by inserting through the incision approximately 1cm anterior to the posterior sacral wall and 1cm inferior to the ala.

Using lateral, inlet, and outlet fluoroscopy, confirm that the Guide Wire is pointing to the middle of the sacrum. Return the fluoroscopic view to an outlet position.

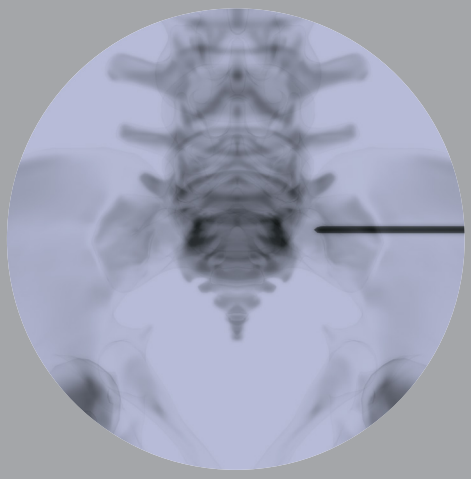
Confirm that the Guide Wire is parallel to the S1 endplate.

TARGETING UNDER FLUOROSCOPY



LATERAL FLUOROSCOPY

OUTLET FLUOROSCOPY



INLET FLUOROSCOPY

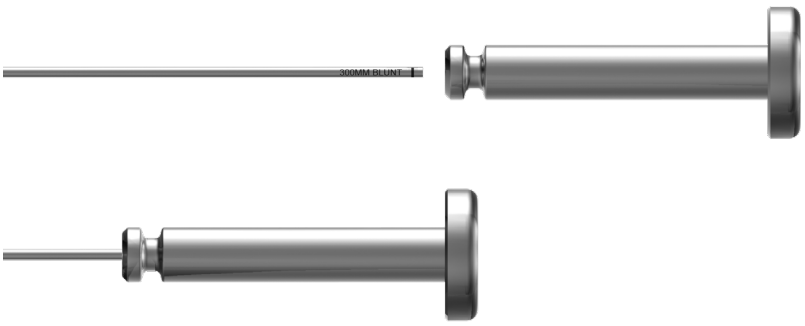
GUIDE WIRE POSITIONING

The distal end of the Guide Wire must be monitored at all times during surgery to ensure patient safety. This is critically important to monitor during drilling, tapping, and implantation.

Trocar Tip Stackable Guide Wires (#5040-112) and Blunt Tip Stackable Guide Wires (#5040-113) are offered in the set and the Blunt Wire must be used to stack into the proximal end of the Trocar Wire.

Blunt, Non-stackable Guide Wires (#5040-101) and Trocar, Non-stackable Guide Wires (#5040-100) are offered as alternative options.

Impact the Guide Wire using the Mallet (#2040-219) provided in the set to advance the Guide Wire. Be sure to use the 3.2mm Guide Wire Impactor (pictured below). This will help retain the proximal end of the Guide Wire and prevent warping. Simply slide the Impactor down onto the proximal end of the wire and hammer on the round proximal end. Remove the Impactor to take fluoroscopy images and to begin drilling.



SCREW PLACEMENT PREPARATION

To expose a working channel, sequentially slide Dilators 1 (#2040-211), 2 (#2040-212), and 3 (#2040-213) over the Guide Wire. Should the surgeon want to test for impedence, Dilator #1 can be removed and replaced with the Plastic Tissue Shield (#2040-210).

Please note that the Dilator Handle (#2040-215) can be used if more leverage is required or a better field of view is desired.

Measure the correct implant size by fitting the end of the Implant Length Gauge (#5040-108) over the end of Dilator 3. Take note of the three ridges at proximal end of dilator. Be sure that the three ridges are fully seated in the #3 side notch of the Length Gauge.

DILATORS & TISSUE SHIELD

DILATORS TISSUE SHIELD

DILATOR HANDLE

DILATOR HANDLE

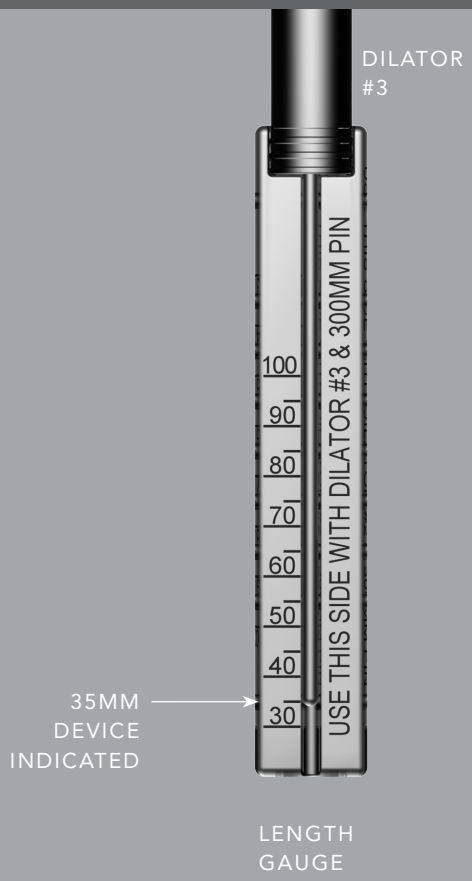
When using the 7mm implant without a washer, Dilator 2 is used with the Length Gauge (#2 Dilator side notch) to determine proper length. The Guide Wire will lie down the central channel of the Length Gauge. The implant size is indicated by the laser markings corresponding to the end of the Guide Wire.

STACKABLE GUIDE WIRE

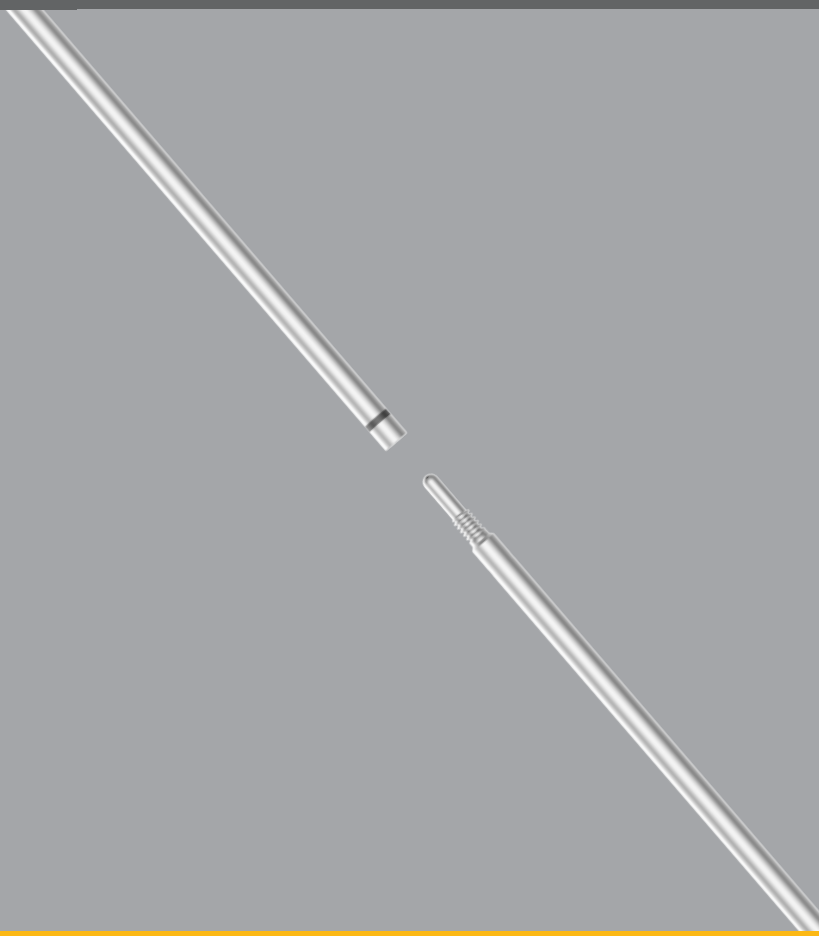
A second Blunt Guide Wire can be threaded into the proximal end of the Trocar Guide Wire once implant length is measured, prior to drilling. Take note of the reverse thread at the connection point to prevent unthreading while drilling, tapping, and inserting screws. This stackable feature allows constant proximal control of the Guide Wire. When using power, a third stacked Blunt Guide Wire can provide additional length, making the passing of the power drill down the Guide Wire easier.

CAUTION: Guide Wires should not be stacked when:
(1) the first wire is being advanced into the patient,
(2) when using the Implant Length Gauge, or
(3) when a lateral fluoroscopy image is being taken (due to the close nature of the fluoroscopy machine during a lateral image).

LENGTH GAUGE



STACKABLE GUIDE WIRE



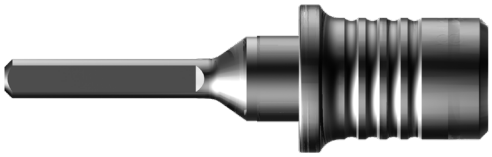
PILOT HOLE PREPARATION

Attach the appropriate drill (7.0mm, 9.5mm, or 11.5mm) to a ratcheting handle (Straight or T-handle). If desired, the Jacob's Chuck (#8100-105) enables use of a cordless power Drill. At this point, the wires can be stacked.

Place the Drill over the Guide Wire and advance until the ilium is reached. It is important to match the trajectory of the Guide Wire to minimize interference with the Guide Wire. (An outlet fluoroscopy view can be used to confirm this).

Continue advancing until the Drill crosses the sacroiliac joint. If desired, the Drill depth can match the desired implant size as was determined by the Length Gauge.

If using stackable wires, keep downward pressure and slide Drill toward proximal end of the wires.



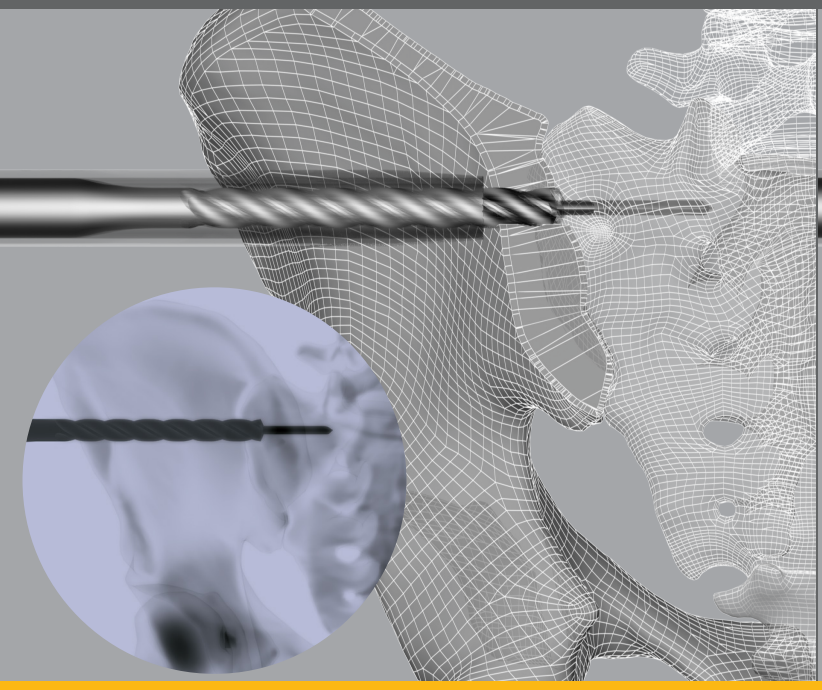
JACOB'S CHUCK ADAPTER

If using non-stackable wires, place the Exchange Pin (#5040-103) down the cannulated portion of the handle-drill interface until it presses on the proximal tip of the Guide Wire. Keep downward pressure on the Exchange Pin while removing the Drill to ensure the Guide Wire stays in place. Pull the Drill straight out without rotation. Retain the autograft from the Drill flutes to be packed inside the implant (all devices).

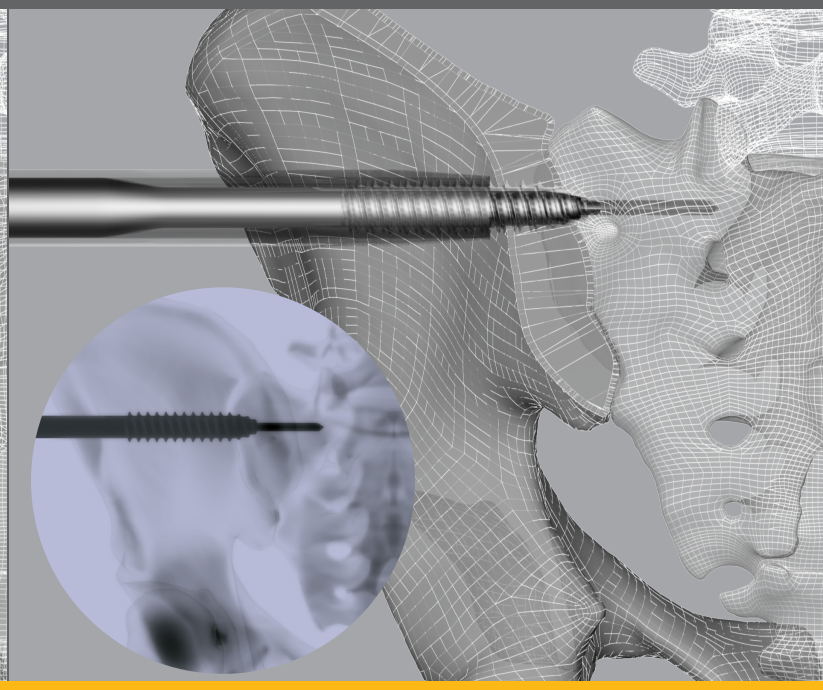
Bone graft may also be packed in the 11.5mm device after implantation via the bone funnel.

Place the appropriate Tap (#1041-070, 1041-095, 1041-115) on either the ratcheting Straight or T-handle. Advance the Tap over the Guide Wire in the same manner as the Drill. **Pay close attention to the Exchange Pin, assuring it keeps the Guide Wire in place during reverse rotation and removal of the Tap.**

DRILL AND GUIDE WIRE



TAP AND GUIDE WIRE



PREPARING THE JOINT FOR FUSION

Use the Decortication Tool (#5040-105) through the third Dilator to remove ligamentous tissue and prepare the joint for bony fusion. Verify Joint Locator is in joint with pelvic inlet view.

IMPLANT INSERTION

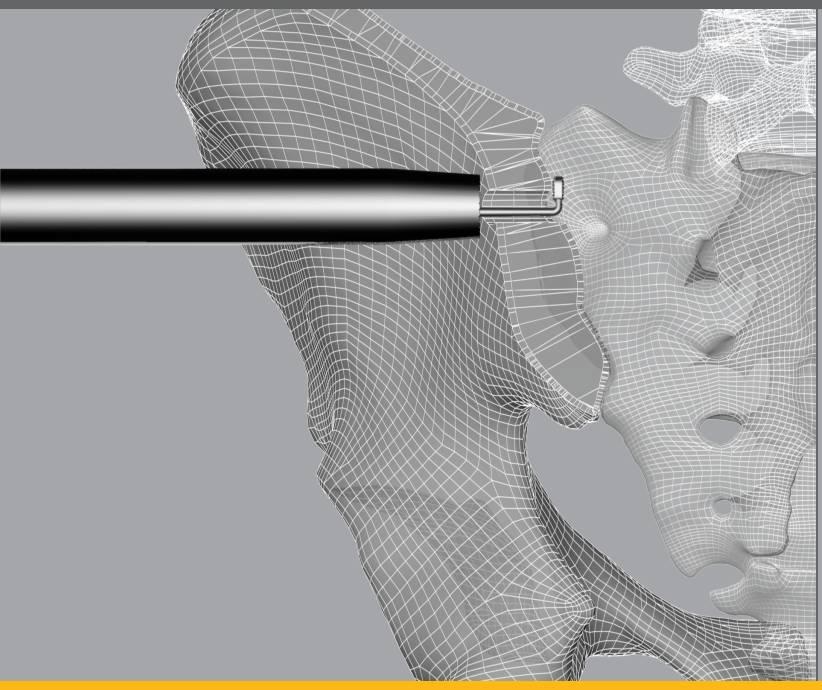
At the back table, insert a K-wire into the device being prepped for implantation. Pack harvested graft into device, around K-wire. Remove K-wire from implant, leaving a channel through the graft material. Place a ratcheting handle (Straight or T) onto the inserter corresponding to the diameter of the prepared hole.

Implants can also be inserted under power per surgeon choice utilizing the Jacob's Chuck Adapter (#8100-104).

INSERTERS

QTY	CATALOG NUMBER	HOLE SIZE
1	2040-200	7.0MM
1	2040-201	9.5MM
1	2040-202	11.5MM

DECORTICATION TOOL



INSERTER WITH T-HANDLE

IMPLANT INSERTION (CONTINUED)

An implant matching the diameter and depth of the prepared space is then chosen and placed onto the corresponding stab-and-grab Inserter.

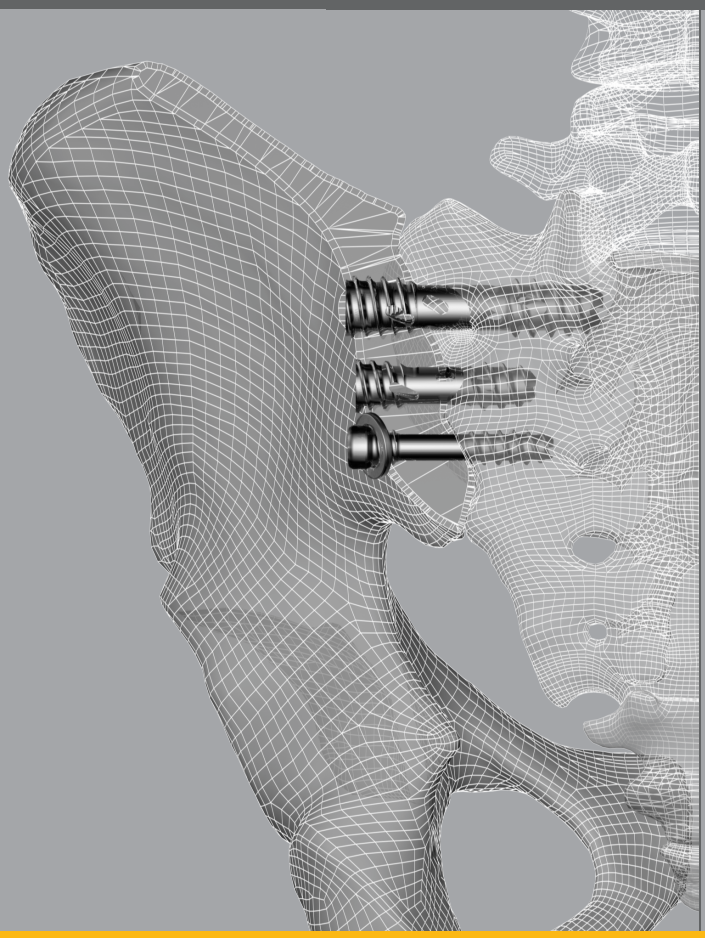
An optional 13mm Washer can be utilized with the 7.0mm diameter implant. The washer helps give tactile feedback regarding the correct depth of the insertion of the implant.

If user prefers using the washer, place it over the distal end of the cage and slide it toward the proximal portion of the implant.

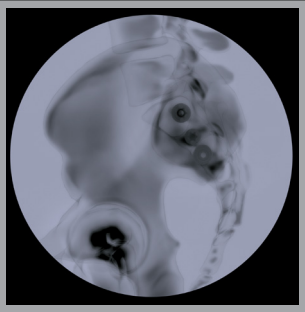
Under fluoroscopy, insert the implant to the desired depth.

Pay close attention to the relationship between the location of the devices and the sacral foramen, making sure the devices do not cross into the foramen, especially when inserting the second and third devices.

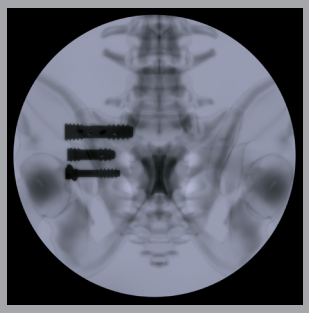
SACROILIAC CONSTRUCT



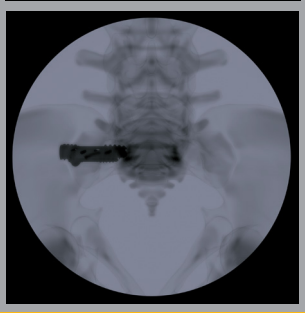
IMPLANT INSERTION UNDER FLUOROSCOPY



LATERAL VIEW



OUTLET VIEW



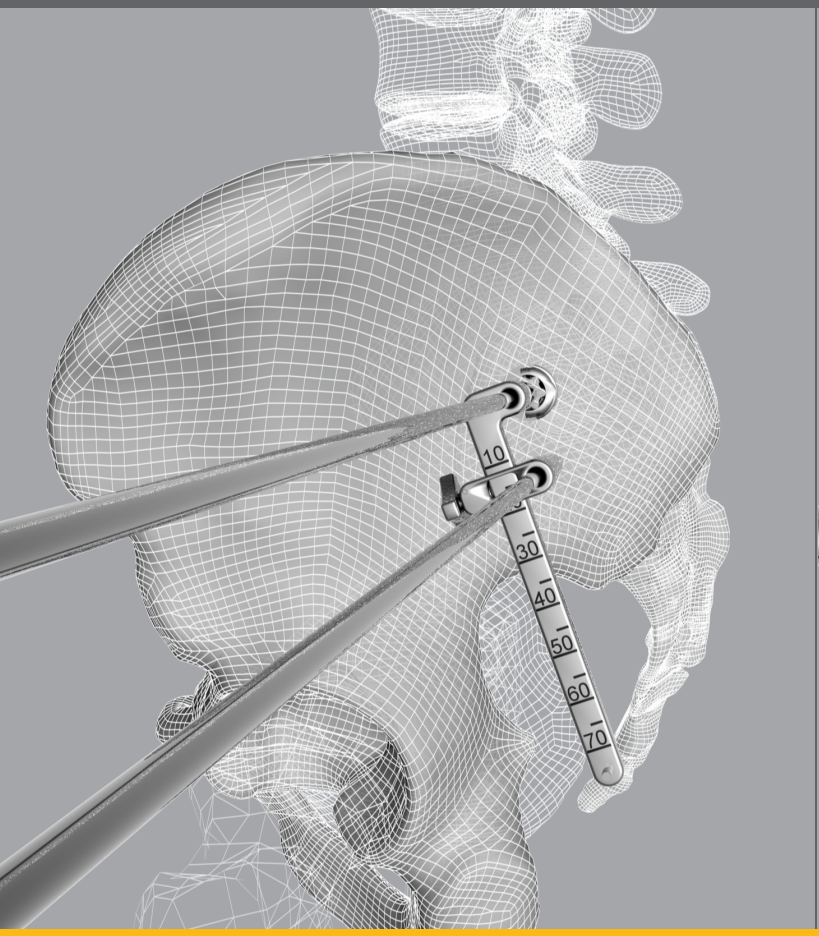
INLET VIEW

Slide the Variable Pin Guide (#5040-109) [or Implant Length Gauge (#5040-108)] over the Guide Wire at the 15mm marker. Following the sacral curve, place the second guide wire in the variable pinhole set at the 15mm marker. This is the starting point for the next Guide Wire placement.

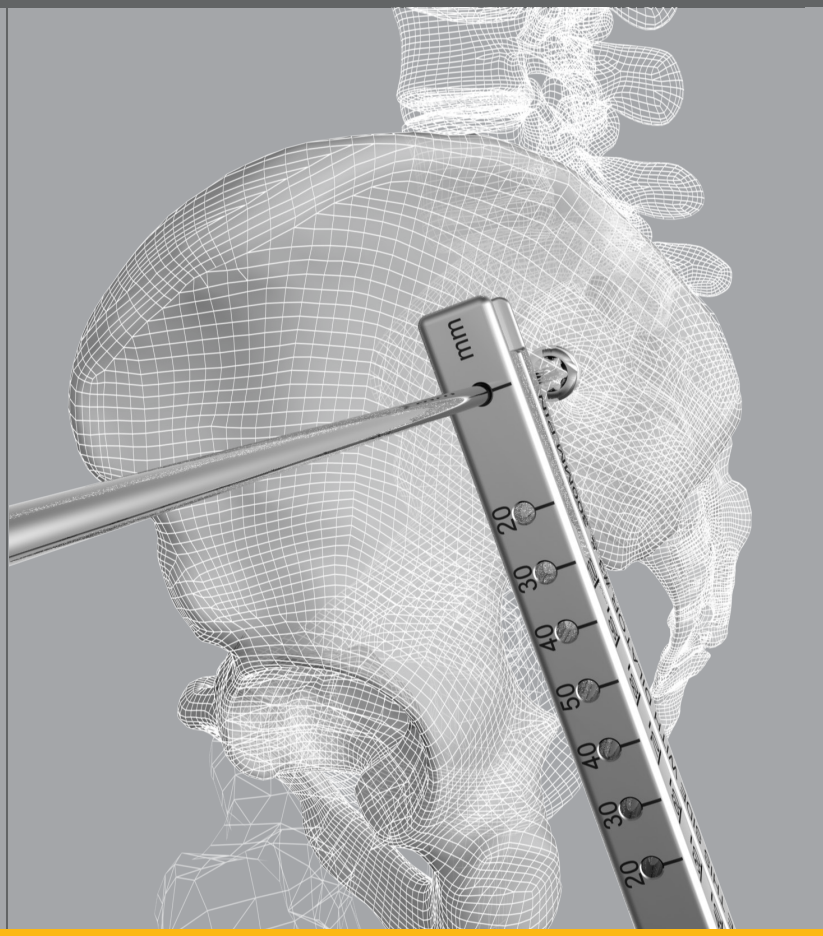
Repeat steps "Screw Placement Preparation" through "Implant Insertion" for the remaining two implants.

NOTE: The Bone Funnel (#5040-104) and Bone Tamp (#5040-107) can be utilized to post fill the large 11.5mm implant.

FIRST AND SECOND PIN IN VARIABLE GUIDE



CLOSEUP OF PINS IN MEASURING BLOCK



IMPLANT REMOVAL

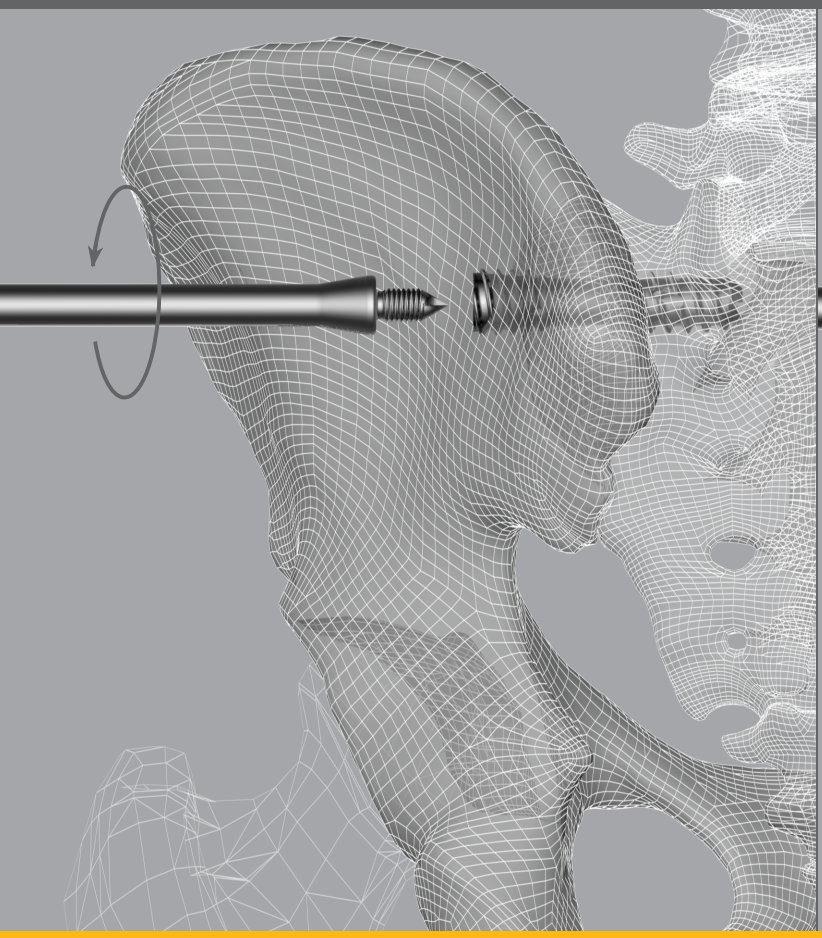
To remove the implant, use the Sacroiliac Implant Extractor which corresponds with the implant diameter.

- 7.0mm Extractor – #2040-216
- 9.5mm Extractor – #2040-217
- 11.5mm Extractor – #2040-218

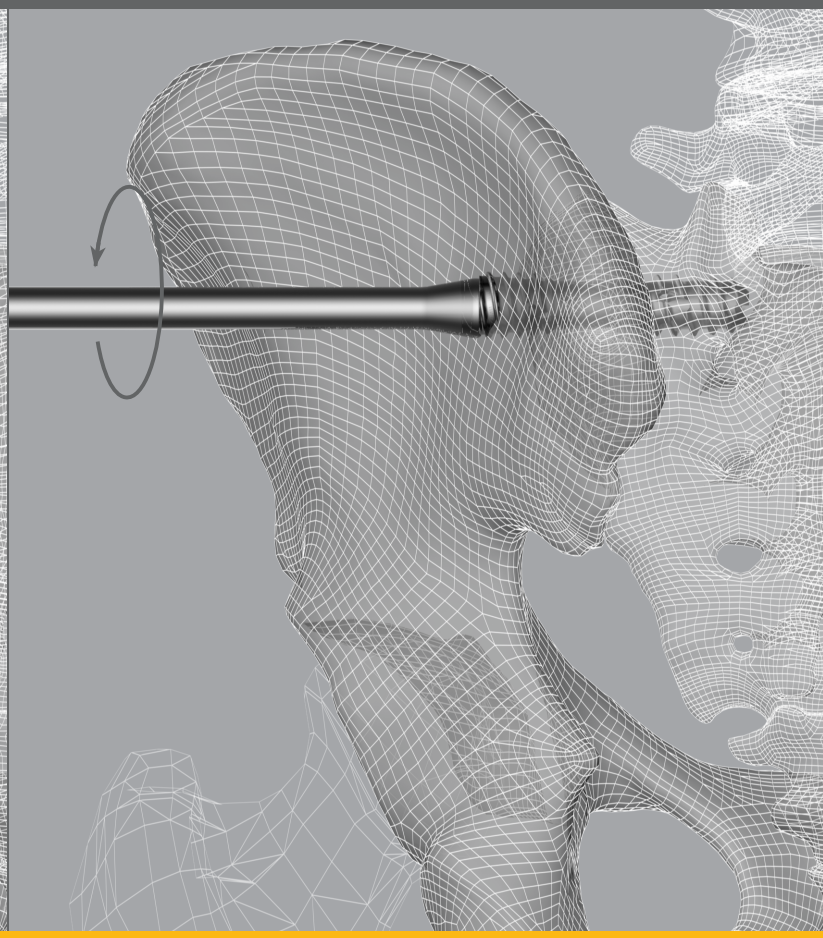
The proximal end of the 11.5mm implant has a counterclockwise thread. Attach the extractor to the preferred handle. Thread the Extractor into the implant by turning counterclockwise until tight. Ensure the ratchet is set to the left-most position and unthread the implant by continuing to rotate counterclockwise. Remove from the surgical site.

The 7.0mm and 9.5mm implants are specially designed "easy-out" style extractors that grab internal features of the cage. Firmly insert the appropriate extractor into the implant and rotate counterclockwise to back out the cage. Remove from the surgical site.

COUNTERCLOCKWISE ATTACHMENT OF EXTRACTOR TOOL



CONTINUED COUNTERCLOCKWISE ROTATION FOR IMPLANT EXTRACTION



INSTRUCTIONS FOR USE

ENTASIS® DUAL-LEAD SACROILLIAC IMPLANT SYSTEM

IMPORTANT NOTE: The user of this system must read and acknowledge the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision at corelinksurgical.com/ifu or by scanning the barcode on the product labeling.

DESCRIPTION

The Entasis Dual-Lead Sacroiliac Implant System is an implant system used for temporary immobilization of the sacroiliac spine while fusion occurs. The Entasis system includes screw-type implants in various sizes and configurations to accommodate patient anatomy and surgeon preference. The implants are provided with general and implant specific reusable manual surgical instruments for surgical site access, preparation, and implantation.

Implants in the Entasis Dual-Lead Sacroiliac Implant System are manufactured from medical grade titanium alloy (Ti6AL4V ELI as per ASTM F136).

Do not use any of the Entasis Dual-Lead Sacroiliac Implant System components with components from any other manufacturer or system unless specifically allowed to do so in this or other CoreLink document. Implants in this system must never be reused under any circumstance.

The Entasis Dual-Lead Sacroiliac Implant System includes a variety of manual surgical instruments manufactured from surgical grade stainless steel as per ASTM F899. The Entasis Dual-Lead Sacroiliac Implant System Navigation Instruments are nonsterile manual surgical instruments that are intended to be used with the Medtronic StealthStation® System to assist surgeons in precisely locating anatomical structures in either open or minimally invasive procedures for preparation and placement of sacroiliac fusion implants. This surgical imaging technology provides surgeons visualization for procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The Entasis Dual-Lead Sacroiliac Implant System Navigated Instruments are comprised of Drills, Taps, and Screw Drivers. The Entasis Navigated Instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S7 with software version 2.1.0, Violet, Orange, Green, and Gray Navlock Trackers (Part Numbers 9734682, 9734683, 9734734, and 9734590), Medtronic Navigation Instrument Drivers (Part Number NAV7426001), Drill (Part Number NAV7426002), and Tap (Part Number NAV7426002) and the Navlock Small Passive Reference Frame (Part Number (9731478).

Use of the Entasis Dual-Lead Sacroiliac Implant System with Navigated Instruments are limited to certain implant sizes. The Entasis Dual-Lead Sacroiliac Implants are limited to 11.5mm diameter with lengths ranging from 40mm to 60mm. The Entasis Navigation Driver is limited to the implant sizes 11.5mm in diameter.

INDICATIONS

The Entasis Dual-Lead Sacroiliac Implant System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliiitis and sacroiliac joint disruptions.

CoreLink Navigation Instruments are intended to be used during the preparation and placement of Entasis Dual-Lead Sacroiliac Implant System implants during sacroiliac surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Do not use the Entasis Dual-Lead Sacroiliac Implant System in the presence of an active or suspected latent systemic infection or infections localized to the site of the proposed implantation. Other relative contraindications include:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Severe osteoporosis as it may prevent adequate fixation of bone screws and thus preclude the use of this or any other sacroiliac instrumentation system.
- Tumor of sacral or iliac bone as it may present challenges in placement of implants due to size and location.
- Unstable fracture of sacrum and/or ilium involving the sacroiliac joint as they may reduce the effectiveness of the implants to temporarily stabilize the affected region for assistance in bony fusion.
- Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, osteopenia).
- Obesity, certain degenerative diseases, and foreign body sensitivity.
- Patient occupation, activity level, or mental capacity. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

Use of the Entasis Dual-Lead Sacroiliac Implant System Navigation Instruments and associated implants are contraindicated in any scenario that is contraindicated in the Medtronic StealthStation Instructions for Use. Use of the Entasis Dual-Lead Sacroiliac Implant System Navigation Instruments with implant systems other than those indicated in this document must not be performed.

COMPLICATIONS AND ADVERSE EFFECTS

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Loosening of any or all components including screw back requiring surgical intervention.
- Disassembly, bending and/or breakage of any or all components.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Pain, skin penetration, bruising, swelling, irritation, and fibrosis caused by skin pressure by implant components.
- Bursitis.
- Fracture, microfracture, resorption, damage, impingement, or penetration of any spinal bone at and above the level of surgery.
- Injury to intra-pelvic structures
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological and/or gastrointestinal systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, consumption, etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, Phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. Pulmonary embolism, bronchitis, pneumonia, etc.
- Difficulty in delivering fetus vaginally due to device-related restrictions of sacroiliac joint stretching.
- Death.

Additional surgery may be required to correct these potential adverse events and/or outcomes.

USE OF IMPLANT COMPONENTS

WARNING: The safety and effectiveness of sacroiliac fixation and fusion systems has only been established for degenerative sacroiliiitis and sacroiliac joint disruptions. This system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. The safety and effectiveness of these devices for any other conditions are unknown.

Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following sacroiliac joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while fusion about the implant is developing. This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which

INSTRUCTIONS FOR USE (CONTINUED)

implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used or if a pseudarthrosis develops.

Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implants and the development of the fusion mass about the implants. Instruct the patient that implants may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

Spinal implants of this type may be removed after sufficient bone fusion develops. However, please inform the patient that a second surgical procedure may be necessary and that there are risks associated with a second surgical procedure. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

In addition to the warnings and precautions discussed above, the patient must be informed about general surgical risks prior to surgery.

Refer to the Surgical Technique Manual for additional important information about this system, in addition to the information described herein.

PRECAUTIONS: The implantation of sacroiliac fusion systems is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this sacroiliac fusion system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant components. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique Manual can be requested from CoreLink by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the Entasis Dual-Lead Sacroiliac Implant System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by CoreLink.

The Entasis Dual-Lead Sacroiliac Implant System has not been evaluated for safety and compatibility in the MR environment. The Entasis Dual-Lead Sacroiliac Implant System has not been tested for heating migration, or image artifact in the MR environment. The safety of the Entasis Dual-Lead Sacroiliac Implant System is unknown. Scanning a patient who has this device may result in patient injury.

USE OF NAVIGATED INSTRUMENTS

CAUTION: CoreLink is not a navigation provider. The navigation system must be set up per the manufacturer's instructions. The Entasis Dual-Lead Sacroiliac Implant System Navigated Instruments have been validated for use with the third-party Medtronic StealthStation navigation system and software version 2.1.0. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for calibration and navigation guidance. Compatible third-party navigation clamps, reference frames, and arrays are listed in the Surgical Technique Guide. Ensure the hospital has the appropriate third-party navigation equipment prior to the surgical case. It is recommended to setup the operating room and instrument arrays such that camera view of all arrays remain uninterrupted at all times. A field assessment should be performed by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed.

WARNING: Navigated instruments are highly accurate and sensitive medical devices that must be handled with extreme care. If you drop or otherwise damage it, do not use it in a surgical case. Any instrument that is suspected of being damaged, inaccurate, or cannot be registered or verified must not be used in a surgical case and must be returned to CoreLink immediately. Failure to do so may lead to serious injury to the patient. Additionally, all navigated instruments and StealthStation tracking instruments must be continuously verified for correct registration with the StealthStation software. Positional accuracy must be continuously monitored intraoperatively. Immediately discontinue use of the navigated instruments if an inaccuracy is detected. Inaccuracy may also occur if bending or other alteration of the instruments occurs.

Note: For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guide.

PREPARATION AT THE POINT OF USE

The implants and instruments of the Entasis Dual-Lead Sacroiliac Implant System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using the following validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual devices may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments in the Entasis Dual-Lead Sacroiliac Implant System must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. Drills and Taps must be inspected for wear and cutting flute damage. Drivers must be inspected to ensure correct and full engagement of implants. Dilators must allow for free passage of any instrument or implant. All navigated instruments must allow for free connection and rotation of any Navlock tracker. If you suspect an instrument is damaged, please contact CoreLink for a replacement.

Follow the Cleaning and Sterilization procedures below.

CLEANING AND STERILIZATION

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments should not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments.)

Manual Cleaning Instructions:

1. Completely submerge the instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices.
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.

5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

NOTE: Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

Automated Cleaning Instructions:

1. Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
2. Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection.

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	1-minute prewash with cold tap water
2	1-minute enzyme spray with hot tap water
3	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
4	1-minute hot tap water rinse
5	2-minute thermal rinse (80°–93°C/176°–200°F)
6	10-second purified water rinse (64°–66°C/146°–150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:

- The washer manufacturer's instructions should be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the implant surface or configuration.
- Pay attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions

Implants and instruments of the Entasis Dual-Lead Sacroiliac Implant System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, independent testing has shown that effective sterilization to a 10-6 sterility assurance level (SAL) may be achieved as follows:

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	4
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

Instruments and implants must be sterilized in the steam sterilization cases provided by CoreLink. Instrument and implant sets must be wrapped in in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used. Do not stack instrument cases during sterilization.

REUSABLE RIGID STERILIZATION CONTAINERS

The Entasis Dual-Lead Sacroiliac Implant System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10-6 sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the Entasis Dual-Lead Sacroiliac Implant System is not recommended.

IMPORTANT CONSIDERATIONS AND WARNINGS

1. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain alignment until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
2. **Implant Selection.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.
3. **Patient Considerations.** The following must be considered when evaluating whether a patient is a candidate for such a procedure.
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, drug abuse or mental conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **Degenerative diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.

INSTRUCTIONS FOR USE (CONTINUED)

- **Implant sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
- **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

1. **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Inform the patient that improper activities may cause the implants to become displaced or damaged and cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
2. **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (1) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (2) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
3. **Implant Removal.** Spinal implants of this type may require removal if the desired clinical and surgical outcomes are not obtained. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon should provide 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 risks involved with a second surgery. Although uncommon, permanent implantation of this device may result in the following: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury; and (7) Risk of additional injury from postoperative trauma.
4. **Do Not Reuse Implants.** An implant previously implanted must never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

POSTOPERATIVE IMMOBILIZATION

Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

CAUTION: Under federal law, this device may only be sold by or on the order of a physician.

LIMITED WARRANTY AND DISCLAIMER

CORELINK PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

For further information contact:

CoreLink, LLC
2072 Fenton Logistics Park
St. Louis, MO 63026
corelinksurgical.com | p: (888) 349–7808

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Lot Number – Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacturer's catalogue number so that the medical device can be identified	5.1.6
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	5.4.4

STANDARD IMPLANT AND INSTRUMENT SET PRODUCT LISTING

KIT ORDER #K5000169

DUAL-LEAD SACROILIAC IMPLANTS		
QTY	CATALOG NUMBER	DESCRIPTION
2	40070-30	7.0MM X 30MM
3	40070-35	7.0MM X 35MM
3	40070-40	7.0MM X 40MM
3	40070-45	7.0MM X 45MM
3	40070-50	7.0MM X 50MM
2	40070-55	7.0MM X 55MM
2	40070-60	7.0MM X 60MM
2	40070-65	7.0MM X 65MM
2	40070-70	7.0MM X 70MM
2	40095-30	9.5MM X 30MM
2	40095-35	9.5MM X 35MM
3	40095-40	9.5MM X 40MM
3	40095-45	9.5MM X 45MM
3	40095-50	9.5MM X 50MM
3	40095-55	9.5MM X 55MM
3	40095-60	9.5MM X 60MM
2	40095-65	9.5MM X 65MM
2	40095-70	9.5MM X 70MM
2	40115-30	11.5MM X 30MM
2	40115-35	11.5MM X 35MM
3	40115-40	11.5MM X 40MM
3	40115-45	11.5MM X 45MM
3	40115-50	11.5MM X 50MM
3	40115-55	11.5MM X 55MM
3	40115-60	11.5MM X 60MM
2	40115-65	11.5MM X 65MM
2	40115-70	11.5MM X 70MM
4	41070-13	WASHER – 13MM

STANDARD IMPLANT AND INSTRUMENT SET (CONTINUED)

KIT ORDER #K5000169

INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION	TRAY POSITION
2	1040-070	DRILL – 7.0MM	1
2	1040-095	DRILL – 9.5MM	2
2	1040-115	DRILL – 11.5MM	3
1	1041-070	TAP – 7.0MM	4
1	1041-095	TAP – 9.5MM	5
1	1041-115	TAP – 11.5MM	6
2	2040-200	7.0MM INSERTER, #30 HEXALOBE	7
2	2040-201	9.5MM INSERTER, #40 HEXALOBE	8
2	2040-202	11.5MM INSERTER, #45 HEXALOBE	9
1	2040-210	TISSUE SHIELD	10
1	2040-211	#1 DILATOR	11
1	2040-212	#2 DILATOR	12
1	2040-213	#3 DILATOR	13
1	2040-215	DILATOR HANDLE	14
1	2040-216	7.0MM IMPLANT EXTRACTOR	15
1	2040-217	9.5MM IMPLANT EXTRACTOR	16
1	2040-218	11.5MM IMPLANT EXTRACTIOR	17
1	2040-219	MALLET	18
4	5040-100	300MM TROCAR GUIDE WIRE (3.2MM)	19
2	5040-101	300MM BLUNT GUIDE WIRE (3.2MM)	20
2	5040-112	300MM STACKABLE GUIDE WIRE, TROCAR (3.2MM)	21
4	5040-113	300MM STACKABLE GUIDE WIRE, BLUNT (3.2MM)	22
2	5040-103	500MM FLAT EXCHANGE PIN (3.2MM)	23
1	5040-104	CANNULATED AWL	24
1	5040-105	DECORTICATION TOOL	25
1	5040-106	GRAFT DELIVERY FUNNEL, 11.5MM	26

INSTRUMENTS (CONTINUED)

QTY	CATALOG NUMBER	DESCRIPTION	TRAY POSITION
1	5040-107	GRAFT TAMP	27
1	5040-108	IMPLANT LENGTH GAUGE AND PIN GUIDE	28
1	5040-109	VARIABLE PIN GUIDE	29
1	8040-101	3.2MM GUIDE WIRE IMPACTOR	30
1	8100-105	JACOBS CHUCK SQUARE POWER ADAPTER, .130 CANNULATION	31
1	5000-164	RADIOLUCENT GUIDE WIRE HOLDER – 3.2MM	32
2	8125-100	DRIVE MOLDED T-HANDLE – RATCHETING	33
0	8225-201	DRIVE MOLDED STRAIGHT HANDLE – RATCHETING (AM)*	34

CADDYS

QTY	CATALOG NUMBER	DESCRIPTION	TRAY POSITION
1	14G00305	7.0MM IMPLANT CADDY	35
1	14G00306	9.5MM IMPLANT CADDY	36
1	14G00307	11.5MM IMPLANT CADDY	37

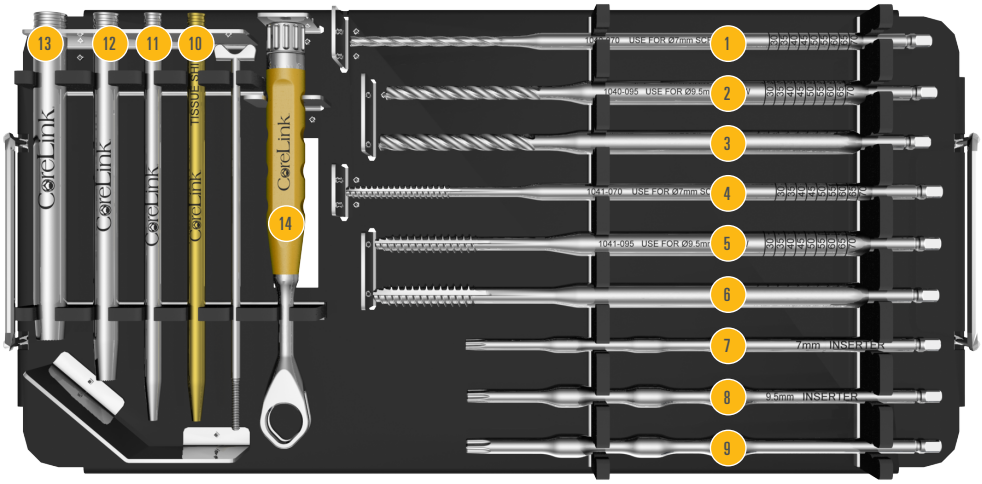
TRAYS

QTY	CATALOG NUMBER	DESCRIPTION
1	14G00308	IMPLANT AND INSTRUMENT TRAY
1	14G00309	BASE
1	14G00310	INNER TRAY 1
1	14G00311	INNER TRAY 2
1	14G00312	INNER TRAY 3

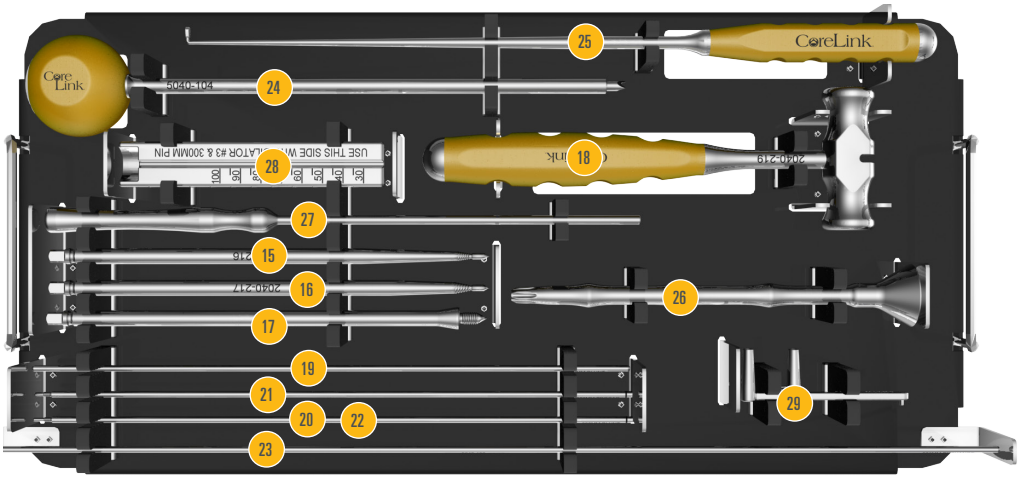
RADIOLUCENT GUIDE WIRE HOLDER
(EXTRA ITEM IN SET)

*Straight Handle available upon special request.

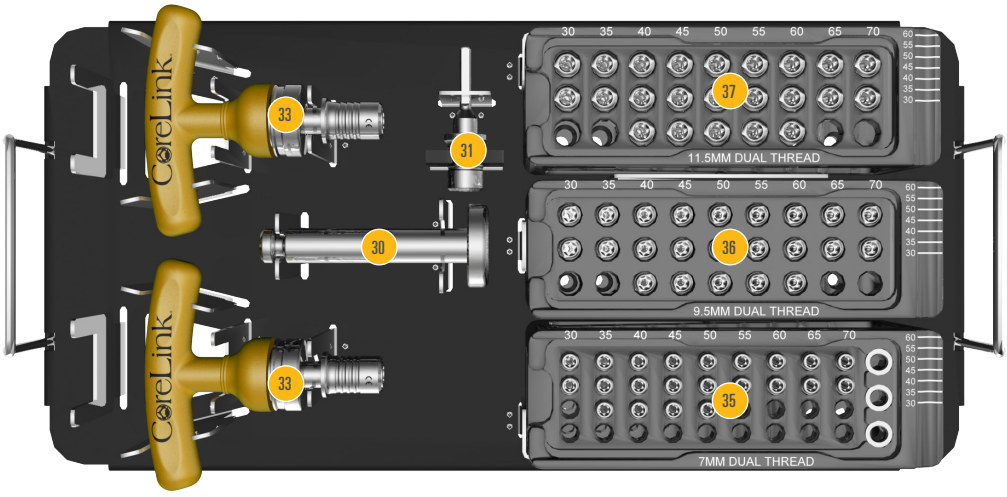
UPPER TRAY



MIDDLE TRAY



LOWER TRAY



NOTES

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The Source for Spine™

INSIGHT | PERFORMANCE | VALUE

CoreLinkSurgical.com 888.349.7808

Designed and manufactured in St. Louis, MO 63026

CL-FORM-206 Rev. 5