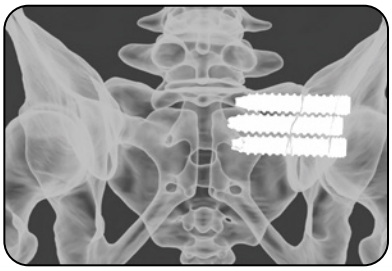
Nexxt Spine

Surgical Technique Guide

HELIXX



Lateral Technique

Sacroiliac Joint Fusion
Pelvic Fracture Fixation
Removal

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71-053-01, Rev A

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INTRODUCTION

The NEXXT MATRIXX® HELIXX Sacroiliac Joint Stabilization System is intended for sacroiliac joint fixation for conditions including degenerative sacroiliitis and sacroiliac joint disruption. NEXXT MATRIXX® HELIXX is a titanium 3D manufactured and machined cannulated implant with open and porous graft windows offering various lengths and diameters to accommodate different patient anatomies.

DISCLAIMER

This document is intended exclusively for physicians and is not intended for laypersons. Information on the product and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or reccomendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examanation and/or advice in whole or in part.

Instructions for Use

GENERAL DESCRIPTION

NEXXT MATRIXX® is a collection of additively manufactured implants. The SI System includes additively manufactured implants, traditionally manufactured washers, and traditionally machined instruments. The implants are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient.

The basic shapes of the implants are a structural cylinder with ridges to prevent and minimize motion / micromotion of the sacroiliac (SI) joint or a cannulated screw that is either fully threaded or with a lag design provided with optional washers. The implant design allows for fixation, stabilization and fusion fully of the joint or fracture. The washers are intended to add additional support under the head of the screw in situations where bone quality is poor. Each implant comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have 300-700µm pores. The implants can be packed with autograft and allograft materials. NEXXT MATRIXX SI System implants are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The washers are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F136.

INDICATIONS FOR USE

The NEXXT MATRIXX® SI System is indicated for sacroiliac joint fusion for:

• Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.

• Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. The NEXXT MATRIXX® SI System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

CONTRAINDICATIONS

The SI System contraindications include, but are not limited to:

1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Bone tumor involving the site of operation.
4. Unstable fracture of sacrum and or ilium involving the sacroiliac joint.
5. Any condition not described in the Indications for Use.

WARNINGS AND PRECAUTIONS

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion.
2. Individuals with comorbidities may have inferior clinical outcomes.
3. The NEXXT MATRIXX® SI System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
4. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. The NEXXT MATRIXX® SI System is used to augment the development of a SI joint or fracture fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
7. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
8. Use sterile technique when handling the implant and during the procedure to maintain sterility and minimize risk of infection.
9. Use of NEXXT MATRIXX SI implants has not been studied in patients with osteopenia / osteoporosis.
10. Patient adherence to post-operative instructions may affect outcomes.
11. In hard bone, adequately prepare the bone channel for implant delivery by drilling and tapping.
12. Avoid placement close to other spinopelvic hardware, which may make placement and/or removal difficult.
13. When removing an implant, make sure to adequately separate the implant from surrounding bone prior to use of the driver.
14. Patients with previous spinal surgery at the operative site(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
15. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, bony fracture, neurologic, vascular or visceral injury.

Instructions for Use

POTENTIAL ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other SI joint fusion and/or pelvic fracturing fixation systems and include, but are not limited to: pseudarthrosis, insufficient bone stock, painful bursa, pressure necrosis, palpable components, early or late loosening of the components; disassembly, bending or breakage of any or all of the components; foreign body (allergic) reaction to the implants; infections possible requiring removal of devices; loss of neurological function, including paralysis, spinal cord impingement or damage, injury to intra-pelvic structures; potential difficulty in delivery fetus vaginally due to device-related restriction of the SI joint stretching; fracture of ilium and/or the sacrum.

MRI SAFETY INFORMATION

The NEXXT MATRIXX® SI System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the NEXXT MATRIXX® SI System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLEANING AND DECONTAMINATION

All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine Reprocessing Instructions for Reusable Instruments document available at www.NexxtSpine.com or by calling 317-436-7801 for the detailed cleaning instructions.

STERILIZATION

The NEXXT MATRIXX® SI System implants are supplied STERILE. All sterile products are supplied in protective sterile barrier packaging. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants.

Non-sterile implants and instruments are supplied clean and NON-STERILE. All non-sterile components must cleaned and sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). AORN recommended practices for in hospital sterilization should be followed. The use of an FDA cleared sterilization wrap is recommended.

Sterilization testing of components has shown the following recommendations for sterilization are effective to an SAL of 10-6:

Method:	Steam
Cycle:	Prevaccum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	60 minutes

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

MANUFACTURED BY:

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NEXXT MATRIXX® Technology

NEXXT MATRIXX® is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral, and thoracolumbar implantation. Each device comprises an external structural frame with a roughened surface and is shaped as a structural column to provide surgical stabilization of the spine.

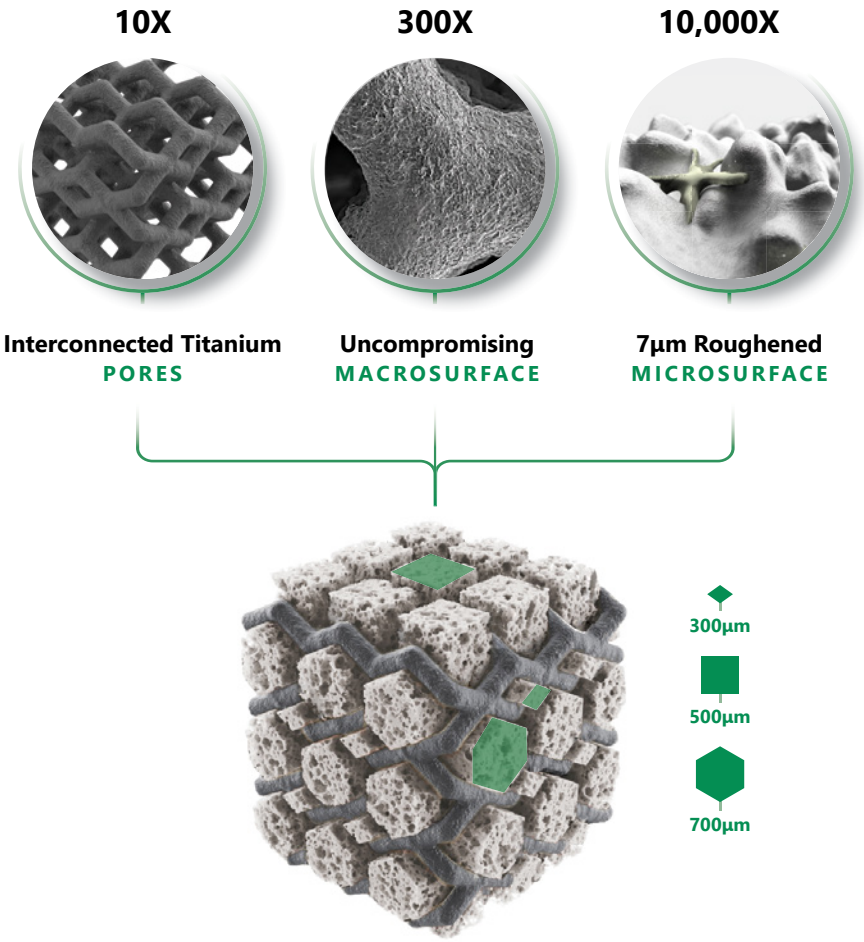


Image represents potential boney ingrowth

TI PORES

- NEXXT MATRIXX® exhibits three pore sizes of 300, 500, and 700µm.
- Minimized titanium material resulting in a 75% open porous architecture.

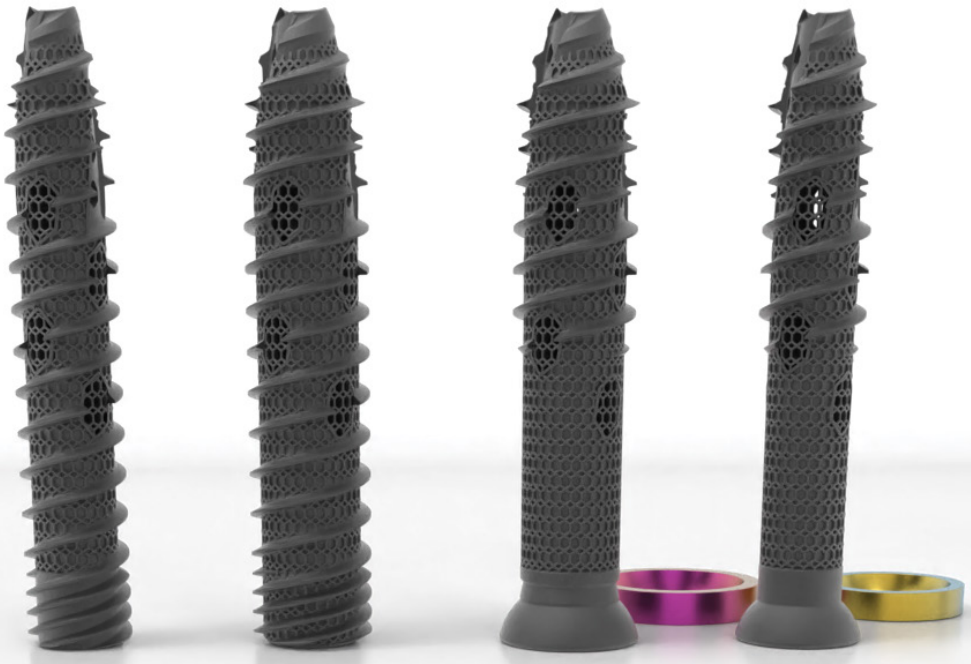
MATERIAL

- NEXXT MATRIXX® implants are manufactured from Titanium Alloy (Ti-6Al-4V) as described by ASTM F3001.

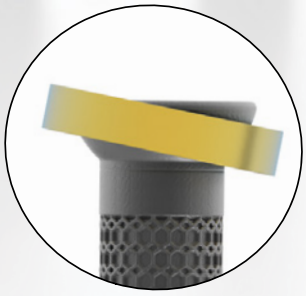
SURFACE

- Nexxt Spine has developed a proprietary, residue-free, micro-roughening process that creates a highly cohesive 7µm roughened topography.
- Due to the micro-roughened porous structure of the NEXXT MATRIXX® titanium, the implants exhibit up to 4X more surface area for bone apposition and potential bony integration than conventional spinal implants.

PRODUCT FEATURES



Bone-gathering channels designed to aid harvesting of nutrient-rich autologous bone

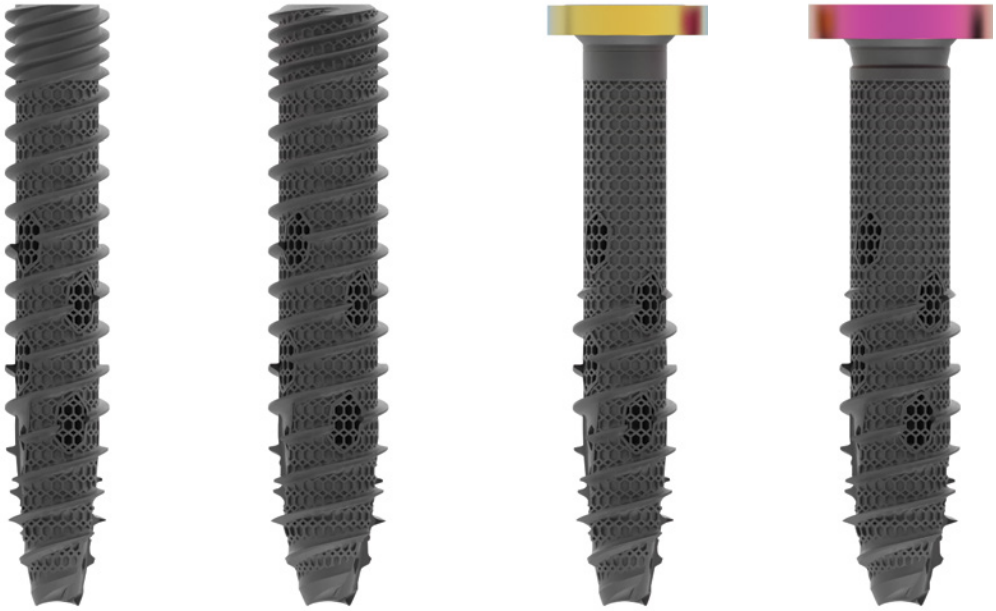


Polyaxial washer assists compression and seating during final placement

Aggressive distal tip geometry to aid in Implant advancement

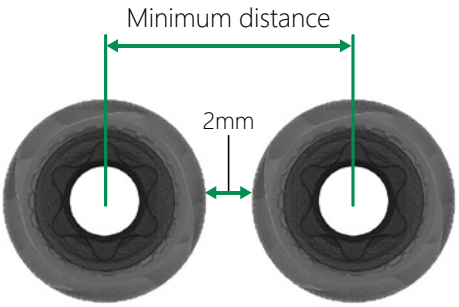
- Proprietary 3D printed NEXXT MATRIXX technology designed to be an active participant in the fusion process
- Dual thread profile designed to provide greater MATRIXX surface area and compression distally, while increasing fixation proximally in the cortical layer
- Engineered fenestrations allow for bony ingrowth as well as ports for targeting flowable allograft
- Instruments designed to reduce steps, minimize working corridors, facilitate implant placement, and support post-packing with flowable graft extenders and demineralized bone matrix..
- 3.2mm Steinmann Pin designed to reduce crimping or bending

PRODUCT SPECIFICATIONS

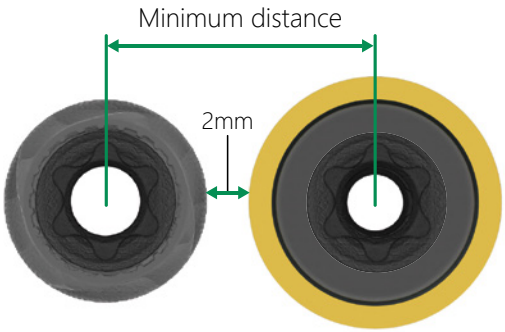


	HELIXX Fully Threaded	and	HELIXX Lag Implant	
Part Number	64-HE-10XX-SP	64-HE-12XX-SP	64-LB-10XX-SP	64-LB-12XX-SP
Major Ø	Ø10.4	Ø12.0	Ø10.4	Ø12.0
Minor Ø	Ø8.4	Ø10.0	Ø8.4	Ø10.0
Inner Ø	Ø3.5	Ø3.5	Ø3.5	Ø3.5
Head Ø	Ø10.4	Ø12.0	Ø12.6	Ø14.1
Lengths	35-80mm	35-80mm	35-80mm	35-80mm
Drill Ø	Ø7	Ø9	Ø7	Ø9
Tap Ø	Ø10	Ø12	Ø10	Ø12
Washer Ø	N/A	N/A	16mm	18mm
Washer Height	N/A	N/A	3mm	3mm
Washer Angle	N/A	N/A	25° Cone	25° Cone
Thread length	Full-length	Full-length	20-32mm	20-32mm

MULTIPLE IMPLANT SPACING



Ø10mm HELIXX Fully Threaded Implants



Ø10mm HELIXX Fully Threaded Implant
Ø10mm HELIXX Lag with Washer

Minimum Implant Distance (mm)	HELIXX Fully Threaded (H)		HELIXX Lag Implant (L) and Washer (W)			
	Ø10 H	Ø12 H	Ø10 L	Ø12 L	Ø10 LW	Ø12 LW
Ø10 H	12.4	13.2	13.6	14.4	15.2	16.2
Ø12 H	13.2	14.0	14.4	15.2	16.0	17.0
Ø10 L	13.6	14.4	14.7	15.5	16.4	17.4
Ø12 L	14.4	15.2	15.5	16.3	17.2	18.2
Ø10 LW	15.2	16.0	16.4	17.2	18.0	19.0
Ø12 LW	16.2	17.0	17.4	18.2	19.0	20.0

Minimum distance measurements can be verified with the Variable Pin Guide.

SURGICAL STEPS

The surgical technique shown in this document is for illustrative and demonstrative purposes only. The technique actually employed will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important information concerning the use and guidance of the NEXXT MATRIXX® HELIXX Sacroiliac Joint Stabilization System.

1. TARGETING INSTRUCTIONS

With the patient in the prone position, place the C-Arm in a lateral orientation and identify both Alar lines (Figure 1.1, 1.2).

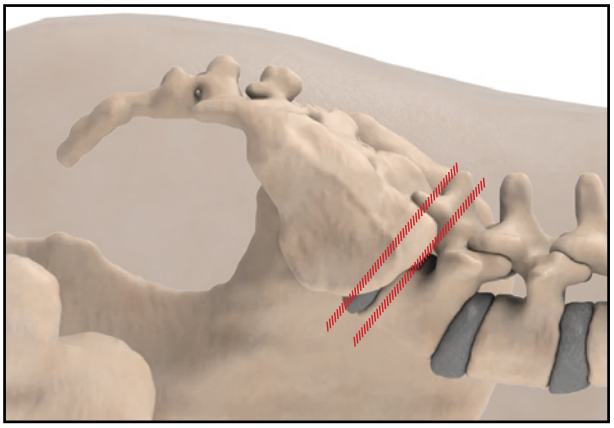


Figure 1.1

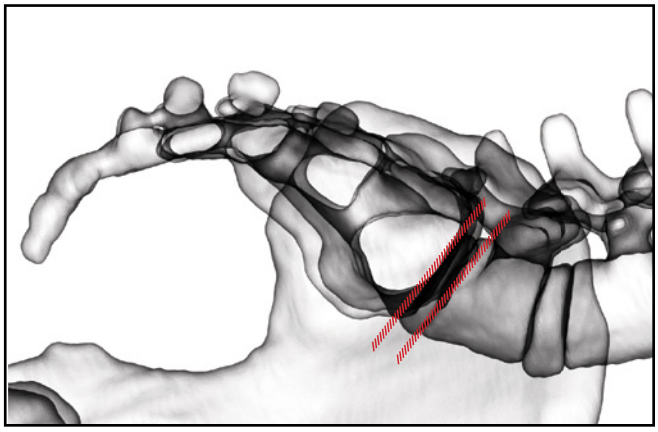


Figure 1.2

The C-Arm operator may have to swivel the C-Arm to achieve a superimposed image of the Alar lines to define a "True Lateral" view (Figure 1.3).

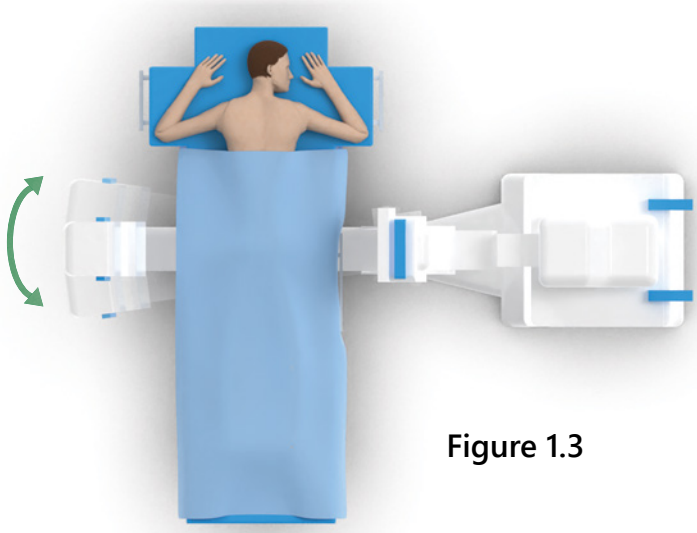


Figure 1.3

1. TARGETING INSTRUCTIONS (CONT.)

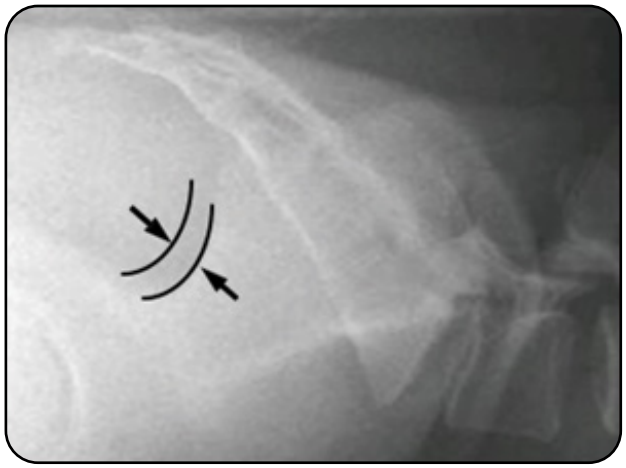


Figure 1.4

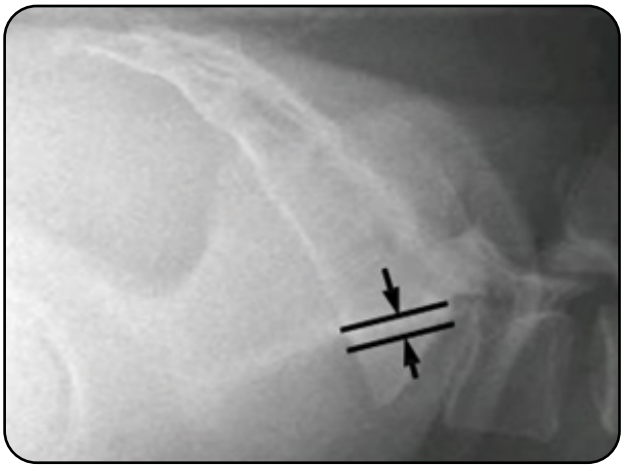


Figure 1.5

First, align the sciatic notches using the C-arm swivel (Figure 1.4). Adjusting patient position may be necessary for further alignment. Finalize alignment by superimposing the left and right alae (Figure 1.5).

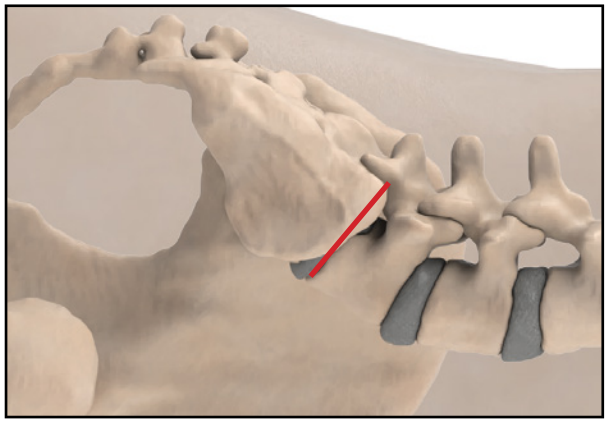


Figure 1.6

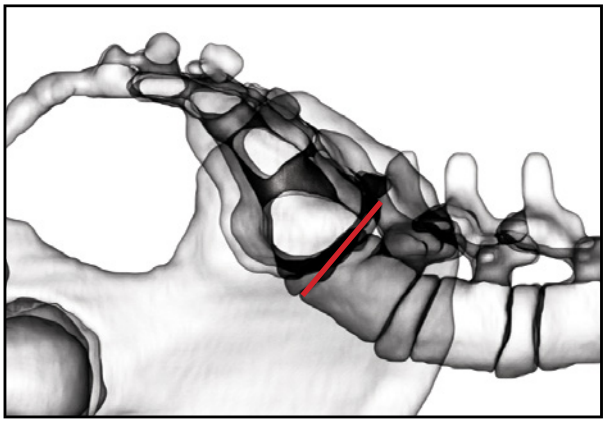


Figure 1.7

Once the C-Arm is positioned in a "True Lateral" view of the sacroiliac anatomy, mark the Alar line on the skin with a marker (Figure 1.6, 1.7). The Steinmann Pin can assist with marking and locating the Alar anatomy.

1. TARGETING INSTRUCTIONS (CONT.)

While the C-Arm is still in the "True Lateral" position, identify the Posterior Sacral Wall. Mark the Posterior Sacral Wall on the skin until it intersects with the Alar marking previously placed (Figure 1.8, 1.9).

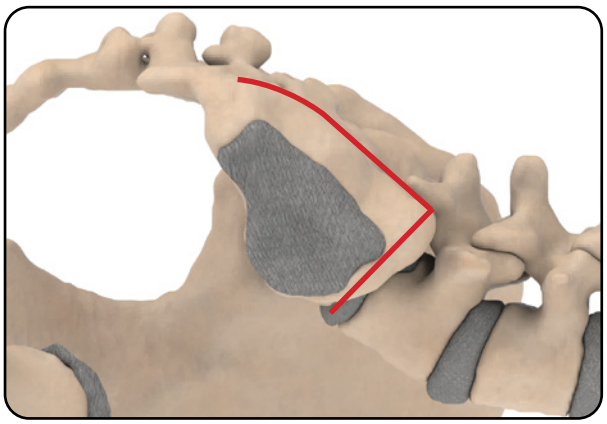


Figure 1.8

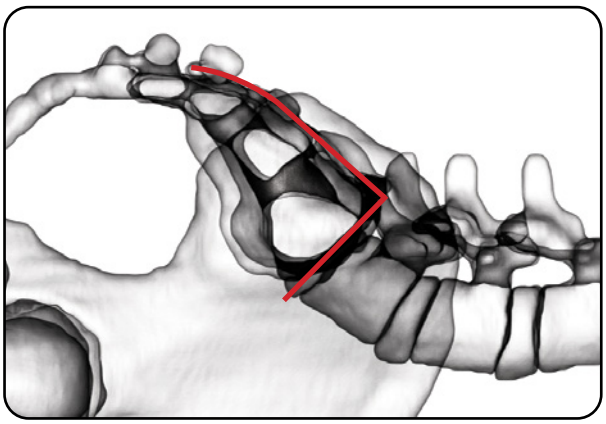


Figure 1.9

Create a 2 to 3-cm incision approximately 2cm anterior to the Posterior Sacral Wall and 1cm inferior to the Alar skin marking (Figure 1.10, 1.11).

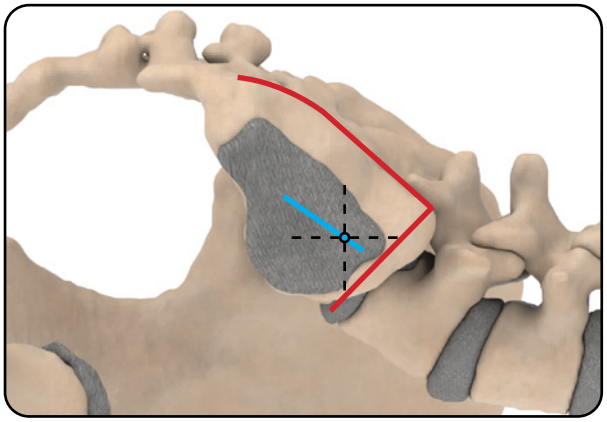


Figure 1.10

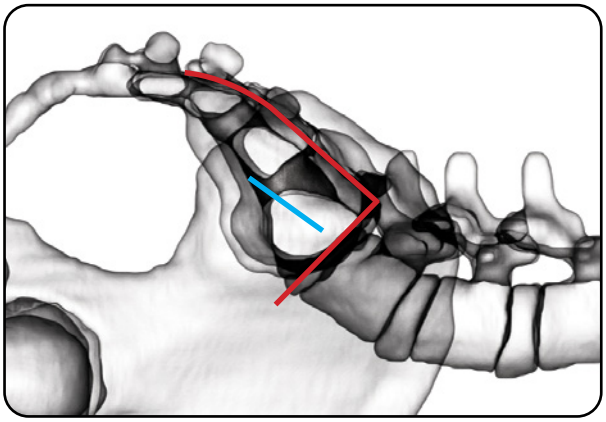


Figure 1.11

2. STEINMANN PIN PLACEMENT

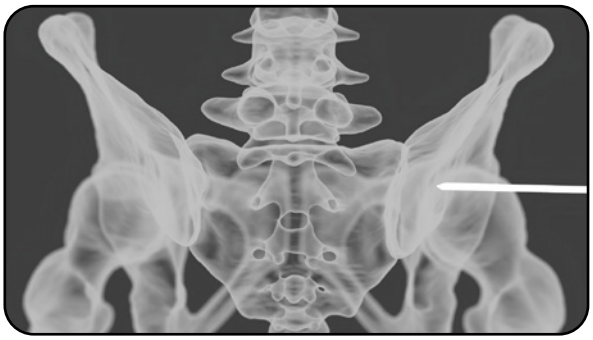


Figure 2.1

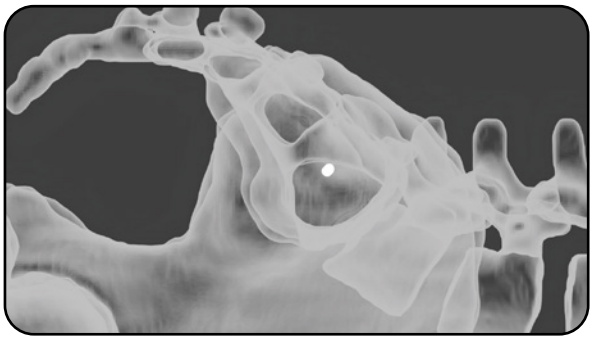


Figure 2.2

Position the first Steinmann Pin approximately 2cm anterior to the Posterior Sacral Wall and 1cm inferior to the Alar line (Figure 2.1). Maintaining the Steinmann Pin parallel to the floor is essential to prevent misplacement or breaching of the Sacrum or Ilium (Figure 2.2).

Imaging should be used to ensure that the Steinmann Pin is pointed just above the S1 nerve root foramen in the Outlet view. Additionally, the Steinmann Pin should be directed toward the middle of the Sacrum on the Inlet view.

Impact the Steinmann Pin through the Ilium and into the Sacrum at the desired trajectory to the desired depth.

The Radiolucent Forceps can be utilized to limit C-Arm exposure and assist with stabilizing the Steinmann Pin.

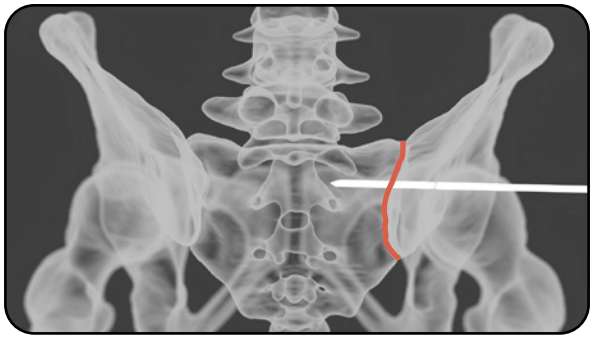


Figure 2.3

NOTE: *For fracture repair, confirm that the Steinmann Pin has crossed the fracture line (Figure 2.3).*

NOTE: *The system provides both Trocar and Blunt Steinmann Pin options. The Blunt option may also be used as a transfer pin during the following surgical steps.*

NOTE: *If placing the second and third Steinmann pin BEFORE the first implant insertion, please skip to MULTIPLE STEINMANN PIN INSERTION.*

2A. RADIOLUCENT FORCEPS (OPTIONAL)

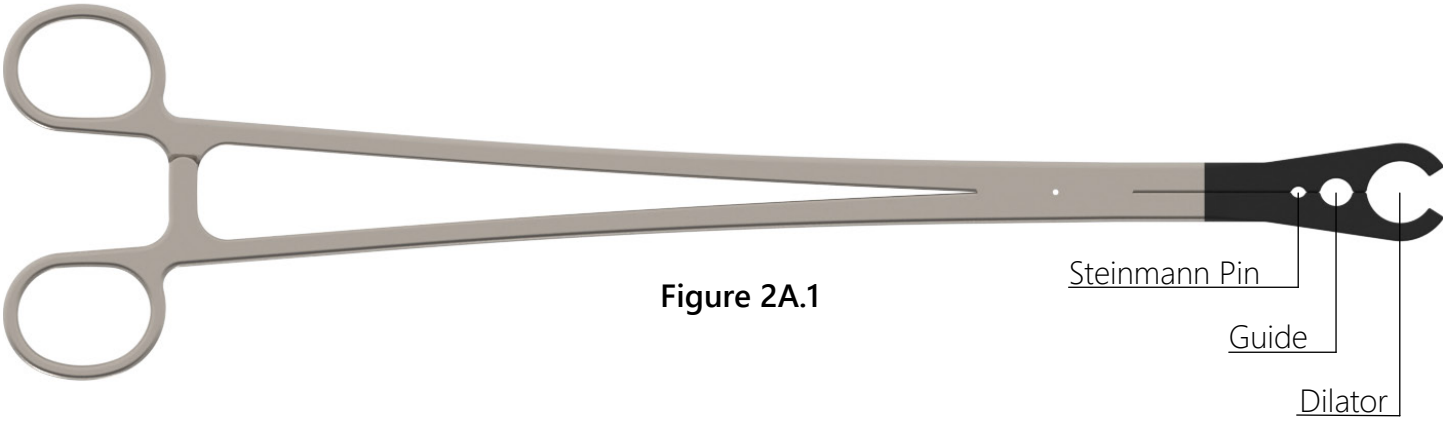


Figure 2A.1

The Radiolucent Forceps have been designed to stabilize the Steinmann Pin, Fixed and Variable Guides, or Dilator during fluoroscopic imaging (Figure 2A.1). The distal clamp of the Radiolucent Forceps allows for visualization of the instrument and pertinent anatomy, while keeping the surgeon's hand at a distance from the radiation source (Figure 2A.2).

The Radiolucent Forceps should be clamped to the Steinmann Pin approximately 2 inches from the proximal portion of the pin to assist with stability (Figure 2A.3).

Forceps placement should allow for perpendicular placement of the Steinmann Pin to the fluoroscopy emitter.

Figure 2A.2

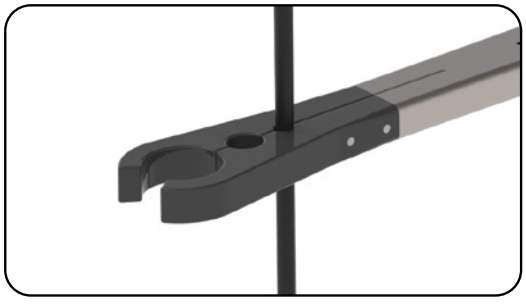


Figure 2A.3

NOTE: *Avoid trying to alter the course of the Steinmann Pin if it is securely positioned in the bone, as this could result in bending and increase the risk of damage in subsequent procedures.*

NOTE: *Refrain from securing any object with the Radiolucent Forceps that it is not explicitly designed to hold.*

3. TISSUE DILATION

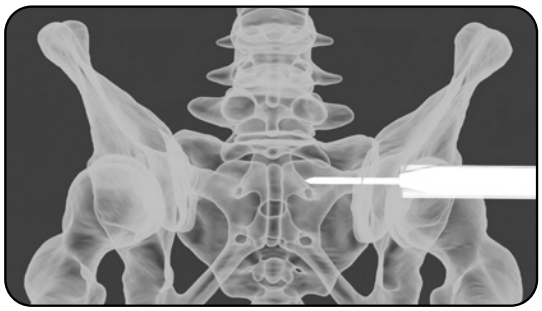


Figure 3.1

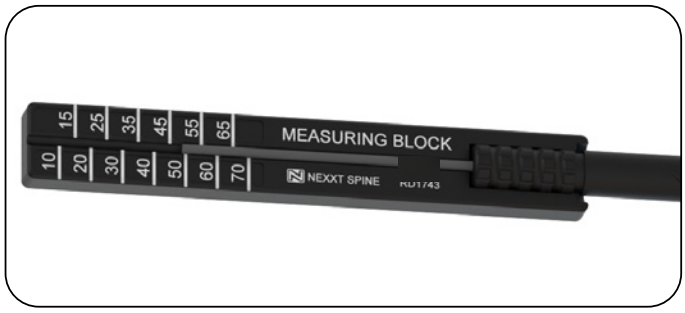


Figure 3.2

Small and Large Dilators provide the access corridor for the Small or Large Working Portal (Figure 3.1). Before inserting the desired Working Portal, utilize the Measuring Block. Place the Measuring Block onto the proximal end of either sized Dilator.

Select an appropriate Implant length by reading the proximal location of the Steinmann Pin and the markings on the Measuring Block (Figure 3.2). If the Steinmann Pin does not directly align with the Measuring Block markings, selecting a shorter Implant length is recommended.

The Measuring Block has been designed to be used with the Small and Large Dilator.

The Small Dilator provides the access corridor for the Small Working Portal. These instruments are used with all Helixx Implants WITHOUT the Modular Washer (Figure 3.3).

Small Working Portal and Small Dilator.
Do not use with Washer.

Figure 3.3

The Large Dilator is required for the access corridor for the Large Working Portal. The instruments are used with the HELIXX Lag Implant WITH the Modular Washer (Figure 3.4). See Step 6: Implant Insertion - Helixx Lag With Modular Washer for additional instrument requirements.

Large Working Portal and Large Dilator.
Use with Washer.

Figure 3.4

Place the chosen Working Portal over the placed Steinmann pin and Dilator until the distal tip is flush with the Iliac cortex. Remove the Dilator while leaving the Steinmann Pin and the Working Portal in place.

4. IMPLANT CORRIDOR PREPARATION

Multiple instruments are available for Implant hole preparation which can be utilized based on surgeon preference. The Drills are undersized by 3mm to the corresponding Implant diameters, while Taps are 1:1 in diameter.

Attach the Drill to the Ratcheting T-Handle or power drill using the provided Power Adapter (Figure 4.1). Under fluoroscopy in the inlet view drill, through the ilium (Figure 4.2). The Drill should pass across the SI joint and the cortex of the sacrum. Do not drill more than 2-3mm medial to the sacral cortex.

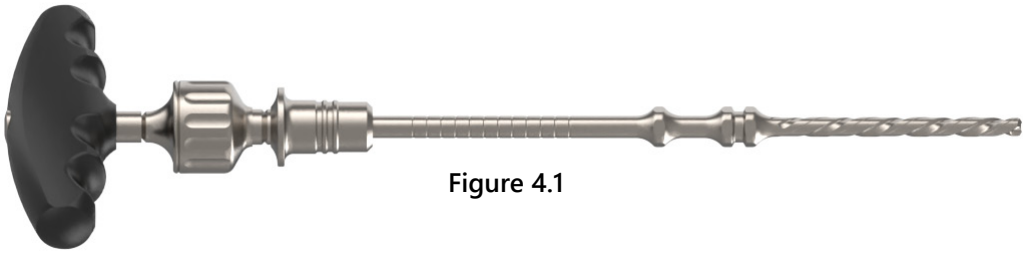


Figure 4.1

Drilling and tapping should be accomplished under fluoroscopy, ensuring that there is no unwanted Steinmann Pin advancement. Drill depth markings can be used to determine final depth and implant selection (Figure 4.3).

NOTE: *Make sure the flat portion of the Power Adapter attachment fits flush to the walls of the cordless power drill if using a cordless power drill.*

NOTE: *The Drill flutes are designed to capture the autogenous bone graft for augmenting the implant.*

NOTE: *The Steinmann Pin has the potential to be inadvertently withdrawn while removing the Drill. Utilize a transfer (Blunt) Steinmann Pin to retain the previously placed pin by placing the transfer Pin through the cannula of the Handle and Drill while removing the Drill. If the Drill appears to be advancing the Trocar Steinmann Pin while drilling the pilot hole, the surgeon can replace the Trocar Steinmann Pin with the Blunt option.*

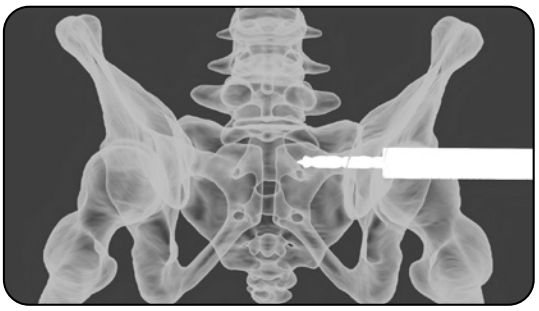


Figure 4.2

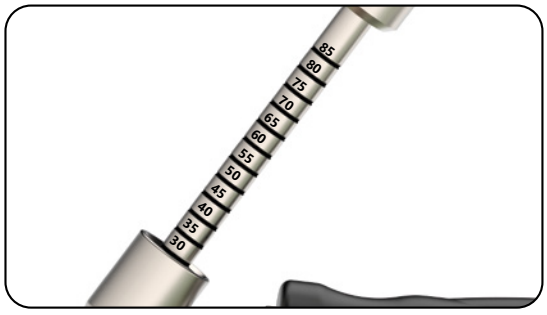


Figure 4.3

4A. OPTIONAL TAPPING

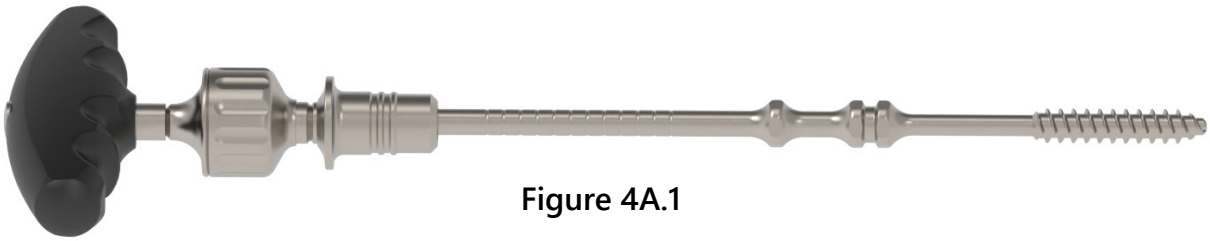


Figure 4A.1

The 10mm and 12mm Cannulated Tap can be utilized with the Ratcheting T-Handle if the surgeon prefers due to bone density or pathology (Figure 4A.1). The HELIXX Implants are designed with a self-tapping feature, so the procedure can be performed without tapping if preferred.

Assemble the appropriate Tap (10mm or 12mm) to the Ratcheting T-Handle. Insert the Tap over the Steinmann Pin and into the Working Portal (Figure 4A.2). The HELIXX Washer Sleeve is required if using HELIXX Lag Implant with Modular Washer.

NOTE: *Ensure that the Tap can move easily down the length of the Steinmann Pin to avoid Pin advancement. The Blunt Steinmann Pin may be used if the pin is close to a foramen or if advancement of the pin is noted.*

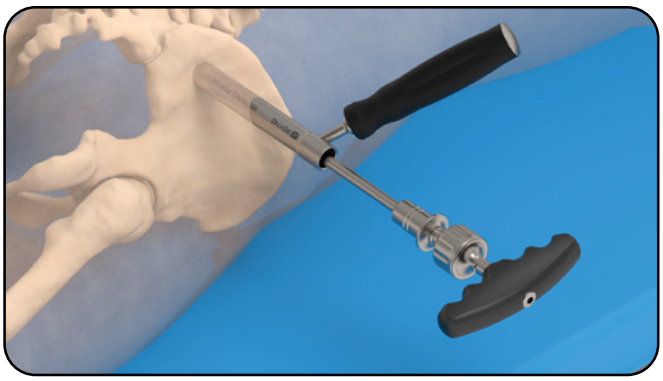


Figure 4A.2

Monitor Tap depth with fluoroscopy in the inlet view and measurement markings on the proximal end of the tap. Tap the placement hole to full depth through the lateral cortex of the sacrum (Figure 4A.3).

NOTE: *Do not drill more than 2-3mm medial to the sacral cortex.*

Utilize the Blunt Steinmann Pin when removing the tap to prevent the Trocar Steinmann Pin from withdrawing.

Fracture Repair: Surgeon should evaluate tapping past the fracture zone to minimize risk of fracture displacement during HELIXX Implant (Figure 4A.3).

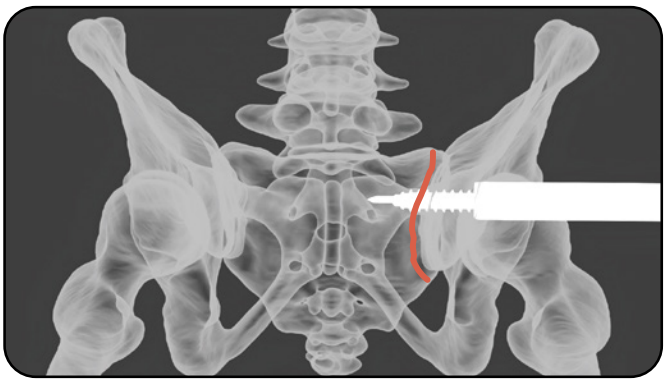


Figure 4A.3

5. PRIMARY IMPLANT INSERTION

Attach the Ratcheting T-Handle to the HELIXX Inserter. Select the appropriately sized Implant and secure it to the distal end of the Implant Inserter (Figure 5.1). Assembly is accomplished by inserting the distal tip of the Inserter into the hexalobe of the implant. Final tightening is done by rotating the grooved knob of the inserter clockwise to thread into the proximal end of the implant.

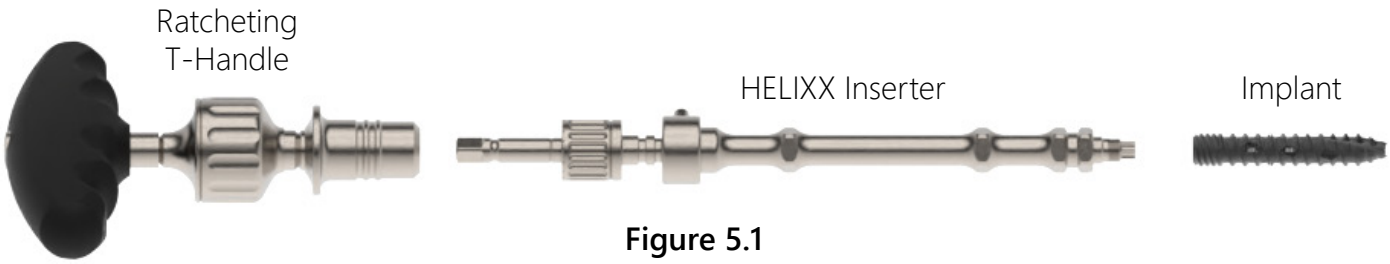


Figure 5.1

Depending on surgical preference and tissue coverage, the surgeon may want to countersink the Implant. The HELIXX Inserter provides the ability to place the Implant from 0mm/flush with the ilium to countersunk 5mm or 10mm deep.

Depress the PRESS button and translate depth stop until the desired depth is indicated. Implant depth can be modified while inserting the Implant (Figure 5.2).

NOTE: *Always check the setting before inserting the Implant, as the depth setting may change with cleaning and processing.*

Figure 5.2

5. PRIMARY IMPLANT INSERTION (CONT.)

Insert the Implant and HELIXX Inserter construct through the Working Portal and over the Steinmann Pin. Under fluoroscopic guidance, advance the Implant through the Ilium and into the Sacrum by rotating the T-Handle clockwise (Figure 5.3, 5.4).

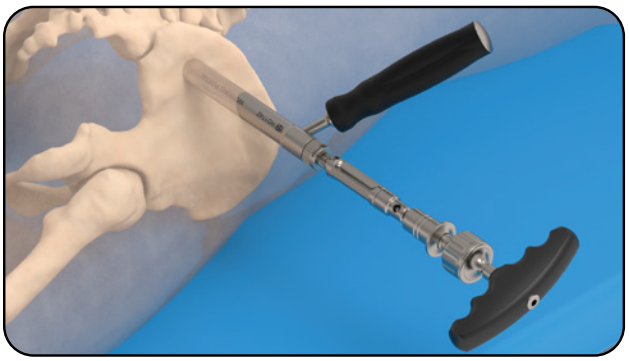


Figure 5.3

It is recommended to maintain the Quad Thread (where present) of the proximal end of the HELIXX Implant within the cortical layer of the ilium to aid in fixation and stability.

If post packing is desired, refer to instructions in Step 7: Implant Post Packing. Otherwise, proceed below.

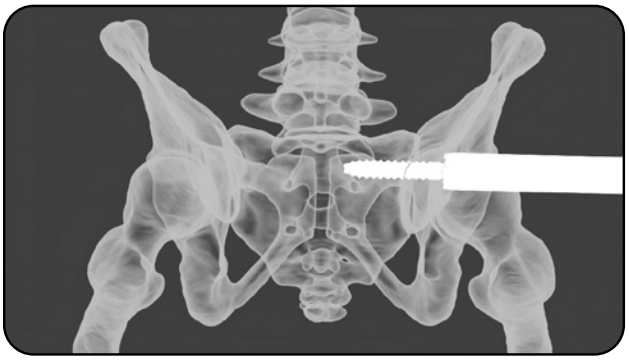


Figure 5.4

Rotate the Helixx Inserter grooved knob counter-clockwise to disengage the Helixx Inserter from the implant and remove the Inserter from the Working Portal.

NOTE: *Ensure that the Steinmann pin does not advance when inserting the Implant.*

Fracture Repair: Surgeon should evaluate that the Implant has extended through and past the fracture zone to minimize risk of fracture displacement during HELIXX Implant placement (Figure 5.5).

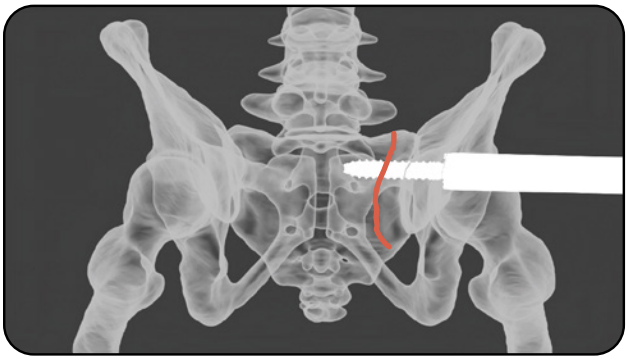


Figure 5.5

NOTE: *If Inserter is difficult to remove from the Implant, the Release Tool may be utilized by engaging the teeth of the Release Tool with the ratchet teeth of the Inserter knob and rotating counter-clockwise.*

6. IMPLANT INSERTION - HELIXX LAG WITH MODULAR WASHER

Placement of the Steinmann Pin, creating the working corridor, and assembly to the HELIXX Inserter follow the same surgical steps as the HELIXX Fully Threaded Implant if no Modular Washer is to be utilized.

The Helixx Lag Implant with Modular Washer is designed to prevent over-insertion of the implant and to aid in compression (Figure 6.1). If the Modular Washer is utilized, the Washer Sleeve must be attached to the HELIXX Drills, Taps, and the Inserter (Figure 6.2).

Additionally, when implanting with the Modular Washer, the Large Dilator and Large Working Portal must be utilized in place of the Small sized instruments.

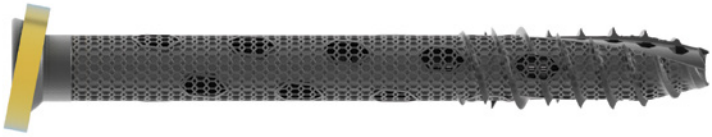


Figure 6.1

Figure 6.2

NOTE: *When using the Lag Implant, the Helixx Inserter depth stop will NOT sit flush with the Working Portal when the implant is fully seated.*

Attach the Ratcheting T-Handle to the HELIXX Inserter (Figure 6.3). Select the appropriately sized Implant and secure it to the distal end of the Helixx Inserter. Assembly is accomplished by inserting the distal tip of the Inserter into the hexalobe of the implant and rotating the grooved knob of the inserter clockwise to thread into the implant.

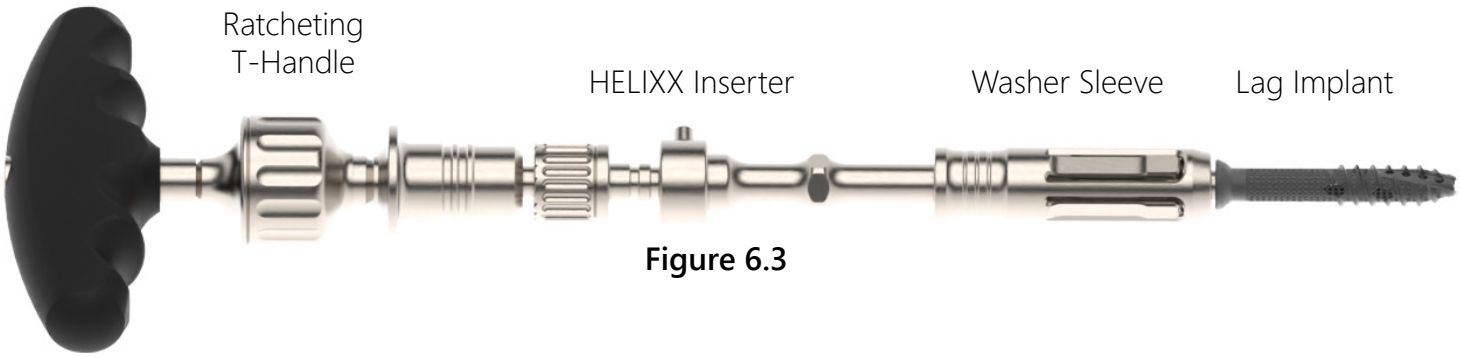


Figure 6.3

6. IMPLANT INSERTION - HELIXX LAG WITH MODULAR WASHER (CONT.)

Remove the desired washer from the caddy and assemble to the HELIXX Lag Implant by sliding up from the distal end (Figure 6.4, 6.5).

Figure 6.4

NOTE: *The markings on the Washer should be facing toward the hexalobe end of the Lag Implant to ensure polyaxial toggle.*

The surgeon should visualize the final placement of the Lag Implant via fluoroscopy in the Oblique Outlet view to ensure that the polyaxial washer of the Lag Implant is sitting flush on the ilium and that compression has been achieved.

NOTE: *HELIXX Lag Implants should not be countersunk either with or without the Modular Washer. Over-insertion may cause damage to the proximal cortex or limit ability to lag the joint spacing.*

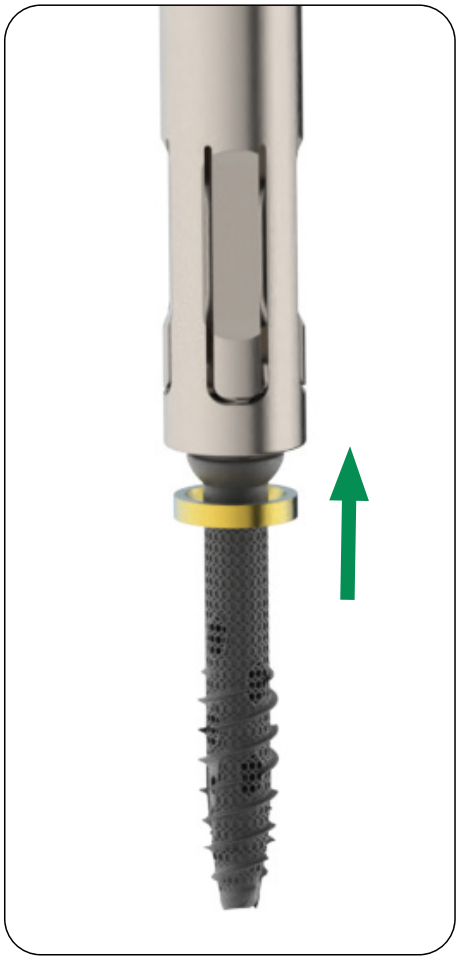


Figure 6.5

Fracture Repair: Surgeon should evaluate that the Lag Implant has extended through and past the fracture zone to minimize risk of fracture displacement during HELIXX Implant placement (Figure 6.6).

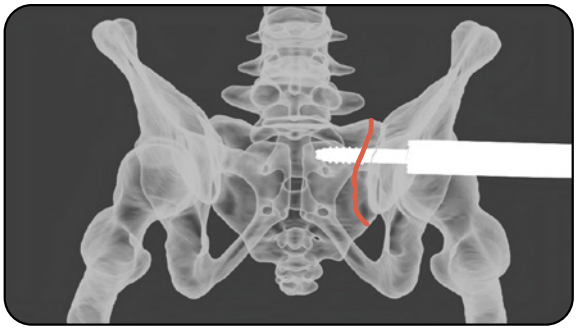


Figure 6.6

7. IMPLANT POST PACKING

If post-packing the joint and Implant is desired, the HELIXX Inserter may be utilized as the channel for placement without disengaging the Implant. Remove the Ratcheting T-Handle and follow one of the steps depending on preference.

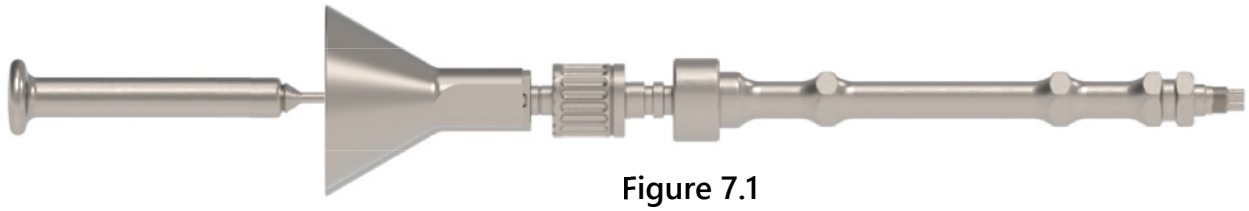


Figure 7.1

1. Autograft or non-syringe-based flowable allograft: Remove the Steinmann Pin and press the provided Bone Funnel onto the proximal end of the HELIXX Inserter (Figure 7.1). Using forceps or pickups, transfer the autograft/allograft to the Bone Funnel and tamp the material down the cannula of the HELIXX Inserter with the Plunger. The Plunger has been designed to extend past the tip of the HELIXX Inserter.

Figure 7.2

2. Syringe-based flowable allograft: Remove the Steinmann Pin and press on the provided Luer Lock Adapter to the proximal end of the HELIXX Inserter and attach syringe (Figure 7.2). Depress the Plunger to introduce the graft material down the cannula of the HELIXX Inserter. Remove the Syringe and tamp the material down the cannula of the HELIXX Inserter with the Plunger. The Plunger has been designed to extend past the tip of the HELIXX Inserter.

Repeat for additional implants.

NOTE: *The Luer taper is a standardized system for making leak-free connections between a male-taper fitting and its mating female part of the instrument. Luer Slip fittings are not recommended for dispensing because they will not attach to the HELIXX Inserter.*

NOTE: *Do not post-pack until all implants are placed.*

8. PLACING MULTIPLE STEINMANN PINS

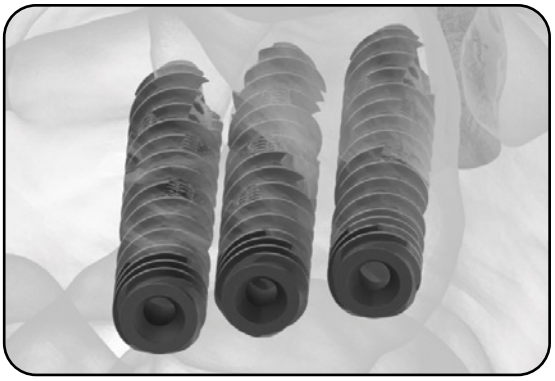


Figure 8.1

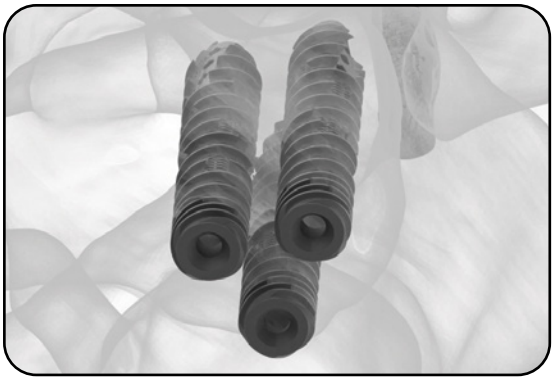


Figure 8.2

After placing the first Steinmann Pin, remove chosen Dilator, ensuring the Steinmann Pin remains in place. Determine the appropriate spacing required for placing the second and third implants (Figure 8.1, 8.2).

NOTE: *Minimum spacing should 12.4mm for Ø10mm implants and 14mm for the Ø12mm implants. Depending on the patient's anatomy, the surgeon should employ either linear or triangular placement.*

If using the Variable Guide, set the proper spacing by depressing the side button and slide the variable tube to the predetermined spacing (Figure 8.3). Release the button to secure the Variable Guide. A numerical gage is provided on the proximal surface of the Variable Guide for reference.

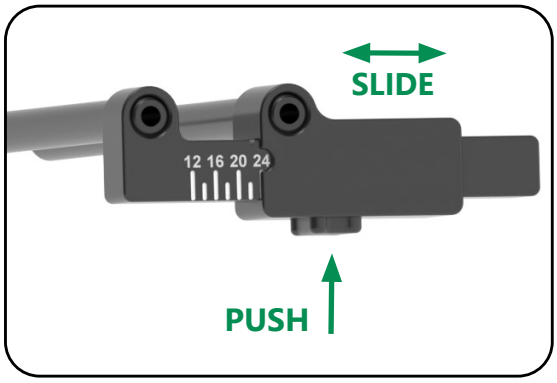


Figure 8.3

Slide the shorter tube of the Guide over the first Steinmann Pin. Rotate the Guide to position the second tube to the next Steinmann Pin location (Figure 8.4). Verify location and available space via lateral fluoroscopy.

Create a 2 – 3cm incision and slide the Guide down until the longer tube rests on the Ilium.

Place a Steinmann Pin into the Guide and secure it into the Sacrum and Ilium per the STEINMANN PIN PLACEMENT section of the surgical technique.

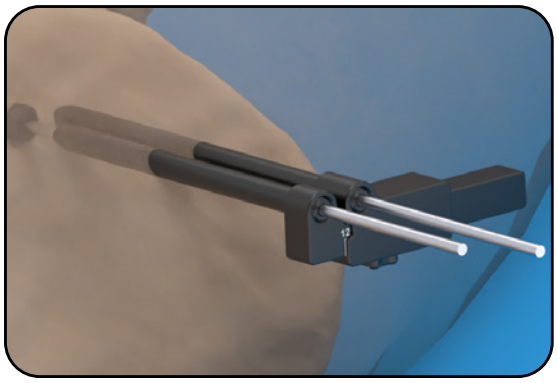
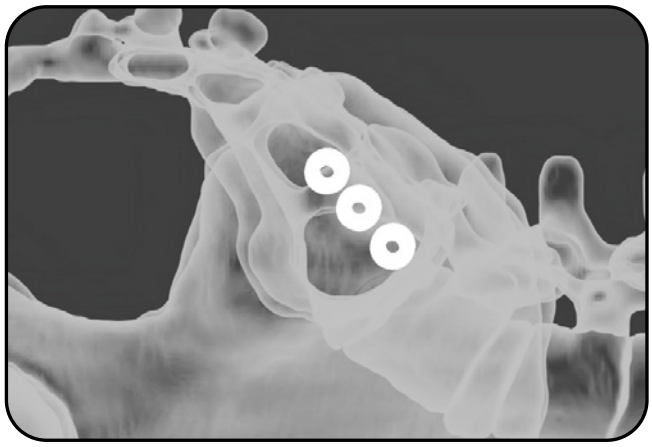


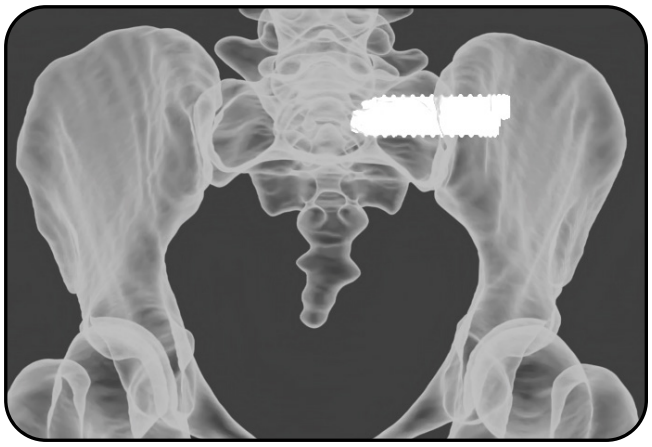
Figure 8.4

9. FINAL FLUOROSCOPIC VIEWS

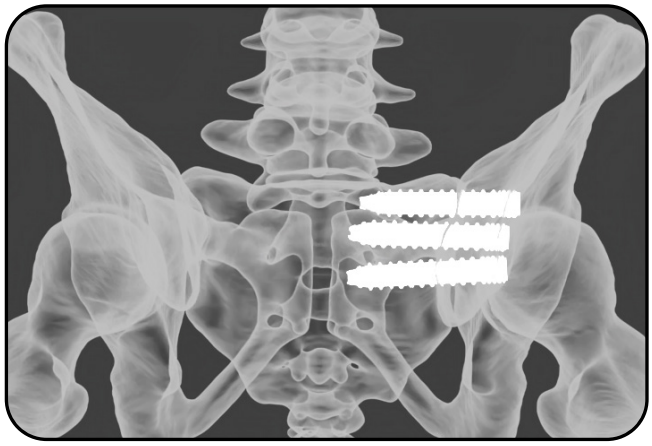
Always verify Lateral, Inlet, Outlet, and Outlet Oblique views to verify correct implant positioning, wall and foramen integrity, and maintenance of fracture reduction (Figure 9.1).



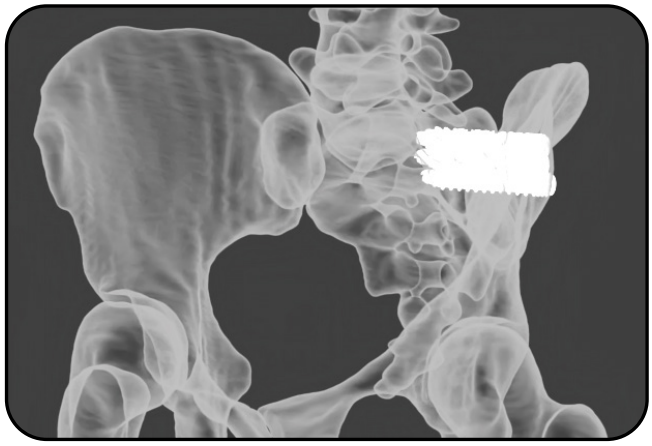
Lateral



Inlet



Outlet



Outlet Oblique

Figure 9.1

10. IMPLANT REMOVAL

Reattachment of the HELIXX Inserter should be the primary method of Implant removal. Clear tissue as necessary to access the Implant head. If necessary, introduce the Steinmann Pin into the cannulation of the Implant and place subsequent chosen Dilator and Working Portal to create an operative corridor and protect the soft tissue. Remove chosen Dilator, leaving Working Portal and the Steinmann Pin.

Attach the Ratcheting T-Handle to the HELIXX Inserter. Guide the HELIXX Inserter over the Steinmann Pin and seat the hexalobe of the HELIXX Inserter into the hexalobe of the Implant and rotate the grooved knob to thread the Helixx Inserter into the internal threads of the Implant (Figure 10.1). Rotate the HELIXX Inserter counterclockwise to remove the Implant from the surgical site. Fill the Implant site with bone graft to help with hemostasis.

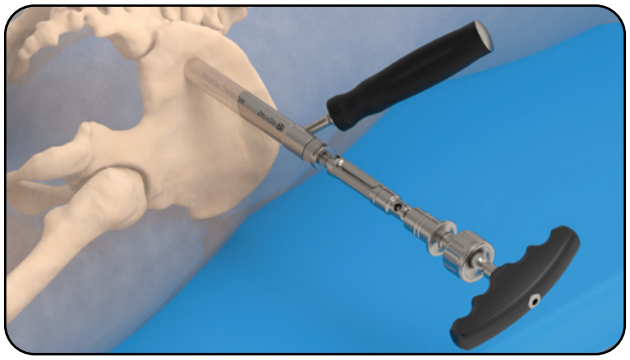


Figure 10.1

INSTRUMENT PART NUMBERS

Steinmann Pins

Standard P/N	Description
I64-05-01	12" Trocar Steinmann Pin
I64-05-02	9" Blunt Steinmann Pin
I64-05-03	12" Blunt Steinmann Pin*
I64-05-04	20" Blunt Steinmann Pin*

Dilators

Standard P/N	Description
I64-05-10	Small Dilator
I64-05-11	Large Dilator

HELIXX Inserter

Standard P/N	Description
I64-15-02	HELIXX SI Inserter

Helixx Washer Sleeve

Standard P/N	Description
I64-15-03	HELIXX SI Washer Sleeve

Working Portals

Standard P/N	Description
I64-05-12	Small Working Portal
I64-05-13	Large Working Portal

Release Tool

Standard P/N	Description
I64-15-05	Release Tool

*By Request, contact Info@NexxtSpine.com for full SKU offering

INSTRUMENT PART NUMBERS (CONT)

Variable Guide

Standard P/N	Description
I64-05-25	Variable Guide*

Measuring Block

Standard P/N	Description
I64-05-20	Measuring Block

Bone Funnel / Plunger

Standard P/N	Description
I64-20-01	Bone Funnel*
I64-20-02	Plunger

Fixed Guides

Standard P/N	Description
I64-05-27	16mm Fixed Guide
I64-05-28	20mm Fixed Guide

Modular Handle

Standard P/N	Description
I64-05-26	Modular Handle

SQR Ratchet T-Handle, Cannulated

Standard P/N	Description
I10-01-77	Sqr. Connection, Ratchet T-Handle, Cannulated

*By Request, contact Info@NexxtSpine.com for full SKU offering

INSTRUMENT PART NUMBERS (CONT)

Drills

Standard P/N	Description
I64-08-07	Ø7mm Drill
I64-08-09	Ø9mm Drill

Taps

Standard P/N	Description
I64-10-10	Ø10mm Tap
I64-10-12	Ø12mm Tap

Luer Lock Adapter

Standard P/N	Description
I64-20-03	Luer Lock Adapter

Radiolucent Forceps

Standard P/N	Description
I64-05-05	Radiolucent Forceps

Power Adapter

Standard P/N	Description
I92-10-14	SQR Power Adapter Ø3.4mm*

*By Request, contact Info@NexxtSpine.com for full SKU offering

IMPLANT PART NUMBERS

Standard P/N	Description
HELIXX Fully Threaded	
64-HE-1035-SP	Ø10 x 35mm
64-HE-1040-SP	Ø10 x 40mm
64-HE-1045-SP	Ø10 x 45mm
64-HE-1050-SP	Ø10 x 50mm
64-HE-1055-SP	Ø10 x 55mm
64-HE-1060-SP	Ø10 x 60mm
64-HE-1065-SP	Ø10 x 65mm
64-HE-1070-SP	Ø10 x 70mm
64-HE-1075-SP	Ø10 x 75mm
64-HE-1080-SP	Ø10 x 80mm
64-HE-1235-SP	Ø12 x 35mm
64-HE-1240-SP	Ø12 x 40mm
64-HE-1245-SP	Ø12 x 45mm
64-HE-1250-SP	Ø12 x 50mm
64-HE-1255-SP	Ø12 x 55mm
64-HE-1260-SP	Ø12 x 60mm
64-HE-1265-SP	Ø12 x 65mm
64-HE-1270-SP	Ø12 x 70mm
64-HE-1275-SP	Ø12 x 75mm
64-HE-1280-SP	Ø12 x 80mm

Standard P/N	Description
HELIXX Lag Implant	
64-LB-1035-SP	Ø10 x 35mm
64-LB-1040-SP	Ø10 x 40mm
64-LB-1045-SP	Ø10 x 45mm
64-LB-1050-SP	Ø10 x 50mm
64-LB-1055-SP	Ø10 x 55mm
64-LB-1060-SP	Ø10 x 60mm
64-LB-1065-SP	Ø10 x 65mm
64-LB-1070-SP	Ø10 x 70mm
64-LB-1075-SP	Ø10 x 75mm
64-LB-1080-SP	Ø10 x 80mm
64-LB-1235-SP	Ø12 x 35mm
64-LB-1240-SP	Ø12 x 40mm
64-LB-1245-SP	Ø12 x 45mm
64-LB-1250-SP	Ø12 x 50mm
64-LB-1255-SP	Ø12 x 55mm
64-LB-1260-SP	Ø12 x 60mm
64-LB-1265-SP	Ø12 x 65mm
64-LB-1270-SP	Ø12 x 70mm
64-LB-1275-SP	Ø12 x 75mm
64-LB-1280-SP	Ø12 x 80mm

Small Modular Washer

Standard P/N	Description	Qty
64-WA-10	Ø10mm Implant	12

Large Modular Washer

Standard P/N	Description	Qty
64-WA-12	Ø12mm Implant	12

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71-053-01, Rev A