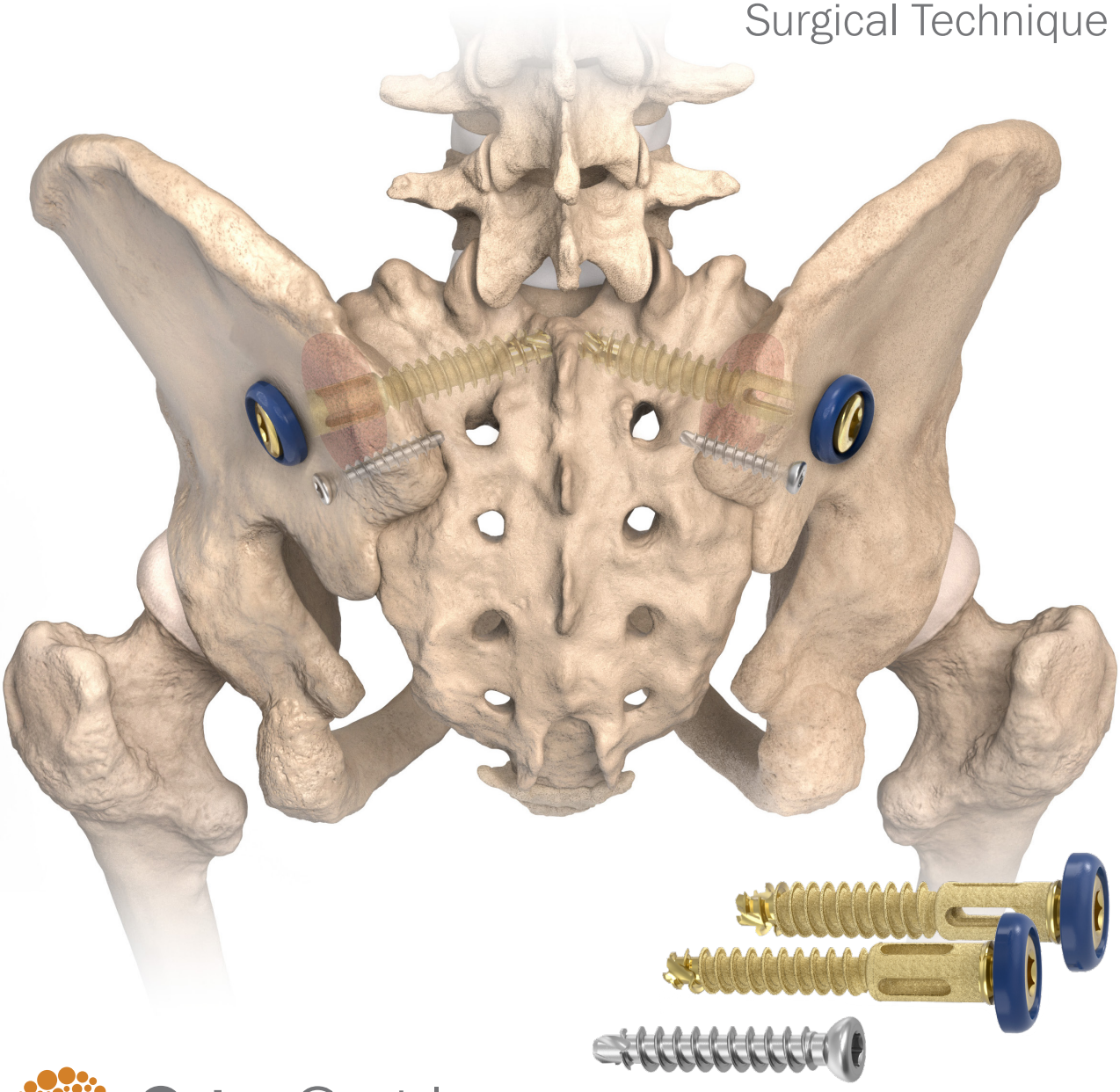
OsteoCentric Integrity-SI® Fusion System

Surgical Technique



OsteoCentric TECHNOLOGIES

Table of Contents

Unifi*MI*

An **Osteo**Centric Technology

Mechanical Integration (MI) is a revolutionary new method designed to instantly secure and stabilize implants to the patient's bone utilizing OsteoCentric's proprietary thread geometry called Unifi*MI*™ - providing improved primary stability of any implant in normal or compromised bone. Unique thread geometry instantly and circumferentially interlocks with bone by entrapping and containing bone between the thread form.

This mechanical interlocking creates a structural as well as functional connection between an implant and bone which is designed to perform similar to Biological Integration (Osseointegration). Unlike Biological Integration (Osseointegration), the Unifi*MI* connection to bone is instant vs. delayed, removable vs. permanent, mechanical vs. biological.

Blade*X*®

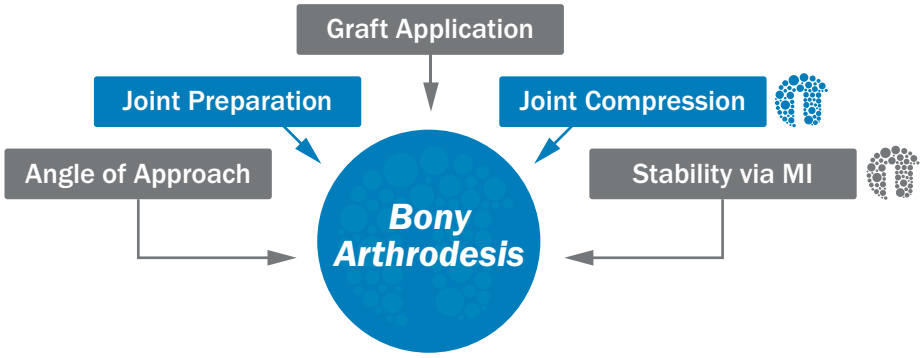
Blade*X* is a proprietary instrumentation system that enables the aggressive and precise joint preparation within the fusion zone. The robust design of BladeX allows for clear and aggressive decortication of both sides of the SI Joint, paving the way for the primary Integrity-SI implant to create an optimal fusion environment.

Blade*X* MIS Decorticator

Design Rationale and System Description

The Integrity-SI Fusion System was designed utilizing time-tested clinical principles of joint fusion. Throughout design the development team focused on these five clinically accepted principles of fusing a joint space: Angle of Approach, Joint Preparation, Graft Application, Joint Compression, and Stability via Mechanical Integration. As a result, the System provides unparalleled focus on creating fusion in the SI joint.

The Implants and Blades and 2.0mm Guide Wire item #202-80100 are for single-use only.



Enhanced by Mechanical Integration

10mm
Integrity-SI Fusion Implant

12mm
Integrity-SI Fusion Implant

6.5mm
Biomechanical Fastener

BladeX MIS Decorticator

Device Description

The Integrity-SI Fusion System consists of partially and fully threaded, self-tapping cannulated titanium implants designed to be inserted across sacroiliac joint providing stability for joint arthrodesis when used in conjunction with allograft or autograft. The surgical implants are available in various sizes to accommodate patient anatomy. The 10mm, and 12mm diameter fasteners are offered in partially and fully threaded version in lengths from 40-110mm, in 5mm increments. The 10mm, and 12mm fasteners also include a pre-assembled washer for improved joint compression. The fully threaded 6.5mm diameter, optional secondary fasteners are offered for additional rotational stability in lengths of 30–70 mm, in 5mm increments and are only intended for use in conjunction with a primary 10mm, or 12mm fastener. All implants as well as the Blade-X decortication instrument blades are provided non-sterile. See the appropriate Instructions for use. Non-Sterile implants as well as Blade-X decoration instrument blades are provided in a steam sterilization implant tray. The Integrity-SI Fusion surgical instruments are provided non-sterile in steam sterilization instrument tray. The Integrity-SI Fusion System is only intended for use with autograft or allograft material. The Integrity-SI Fusion implants are restricted by federal law (USA) to sale by or on the order of a physician only.

Indications For Use and Materials

The Integrity-SI Fusion System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

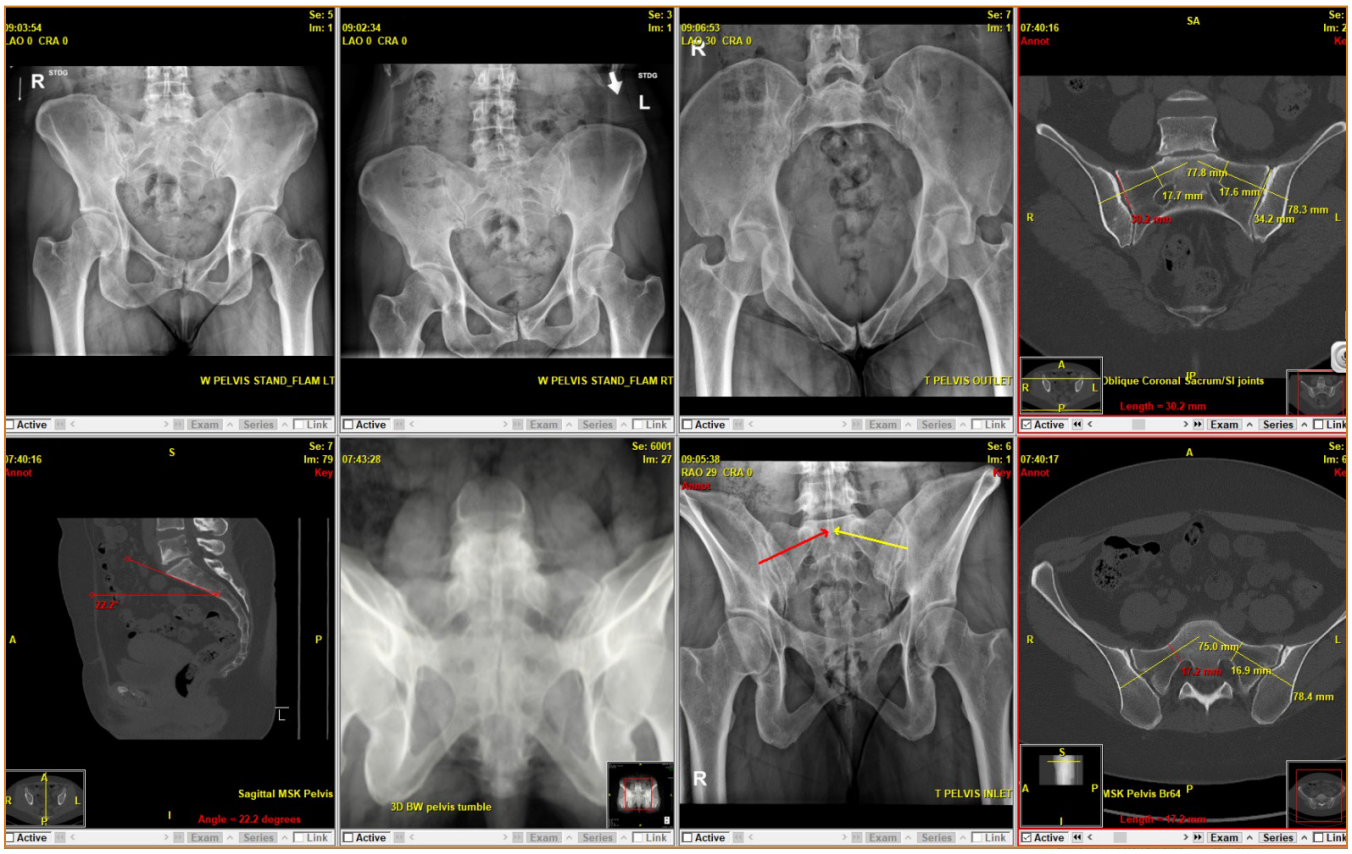
The Integrity-SI Fusion System is only intended for use with autograft or allograft.

The Integrity-SI Fusion implants are manufactured from Ti-6Al-4V ELI (ASTM F136).

Preoperative Templating and Imaging

Preoperative Templating and Inlet and Outlet imaging for implant placement into the upper sacral segment

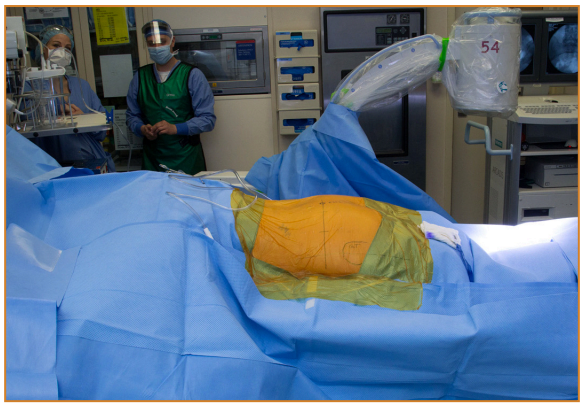
Standard preoperative template. Note the ‘safe zones’ of implant passage above and anterior to the S1 neural foramen and caudal and posterior to the L5 traversing nerve root. Also note the perpendicular positioning of the procedural approach as it relates to the SI joint angle.



Patient Positioning and Incision Planning

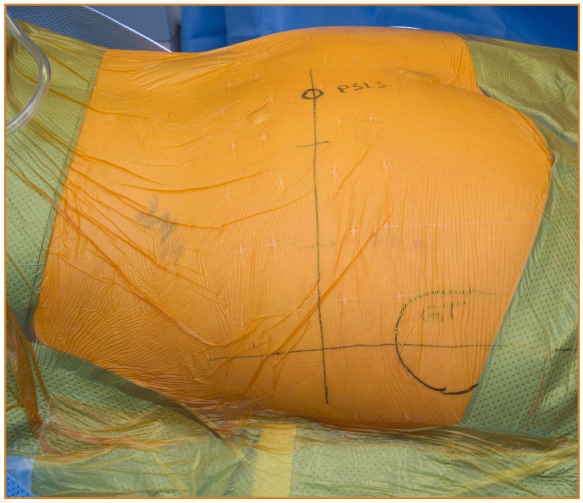
Starting Point Tip

Trace the lines of the image beams to create a grid showing your inlet and outlet beams. When moving your trajectory, strict attention must be paid to making ‘uniplanar’ corrections. For example, when moving cranial or caudal on the outlet view, move your guide pin along the trajectory of the inlet beam. This will ensure the greatest chance of uniplanar corrections.



Patient Positioning: Prone

The patient is placed prone with chest rolls or per surgeon preference. Fluoroscopy is brought in from the opposite side of surgery and the monitor is placed at the foot-end of the patient.

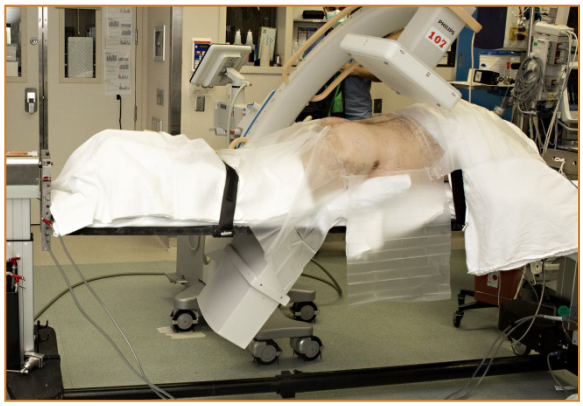


Incision Planning

The incision is planned by marking the PSIS and the axis of the femur. Two lines are drawn down the axis of the two marks creating an intersection. The line from the PSIS is drawn into 1/3rds. The starting point will be in the vicinity of the intersection of posterior and middle thirds.

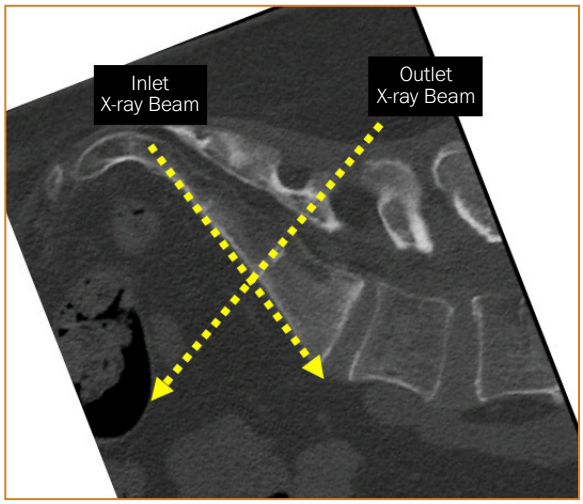
This will avoid the potential error of placing the guide in the direct vicinity of the greater sciatic notch and corresponding vascular structures.

Fluoroscopic Guidance



Outlet Imaging

Patient example (in prone position) of outlet imaging.



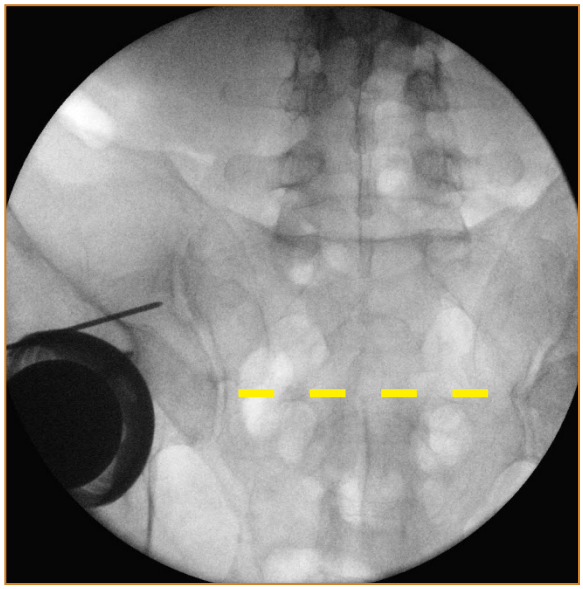
Patient in Prone Position

Outlet Imaging

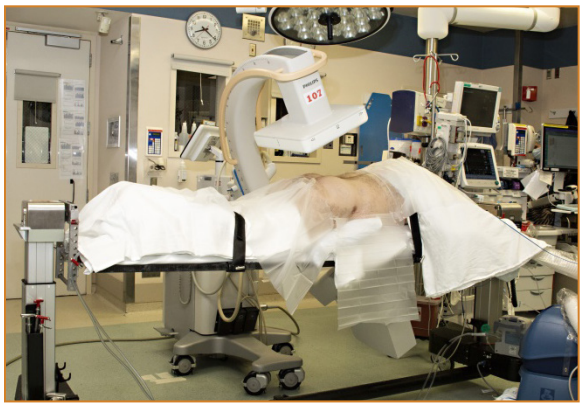
Basic definition for implant placement: A pelvis radiograph placing the pubic symphysis over the body the lower sacral segment (typically S2) or the neural foramen of the lower sacral segment.

Correct orientation allows the surgeon to adjust the implant placement in the cranial/caudal direction.

The fluoroscopy unit should be oriented in the AP direction and continually tilted with the image intensifier tilted towards the head to offer ideal imaging.

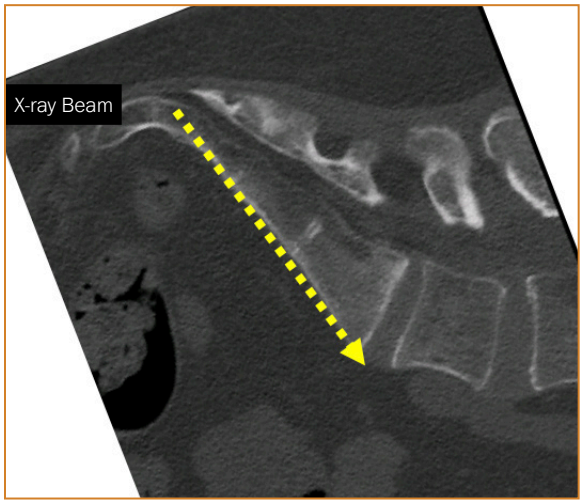


The yellow line is placed on top of the pubic symphysis at the caudal level of the S1 foramen.



Inlet Imaging

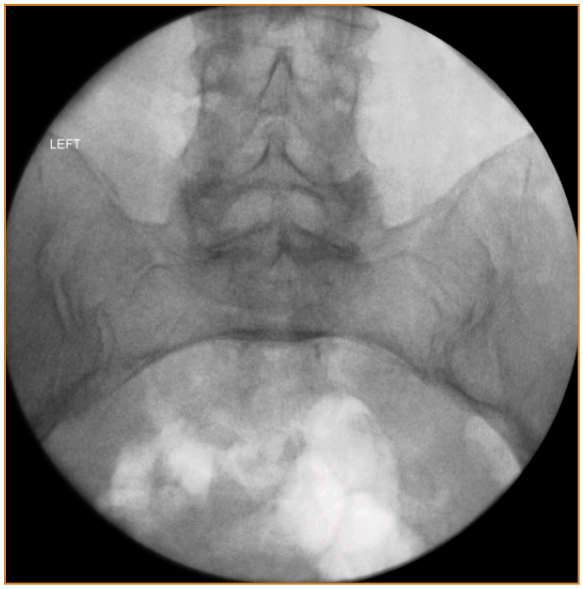
Patient example (in prone position) of inlet imaging.



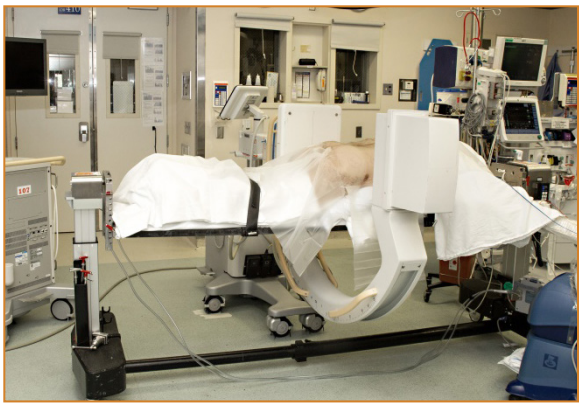
Patient in Prone position

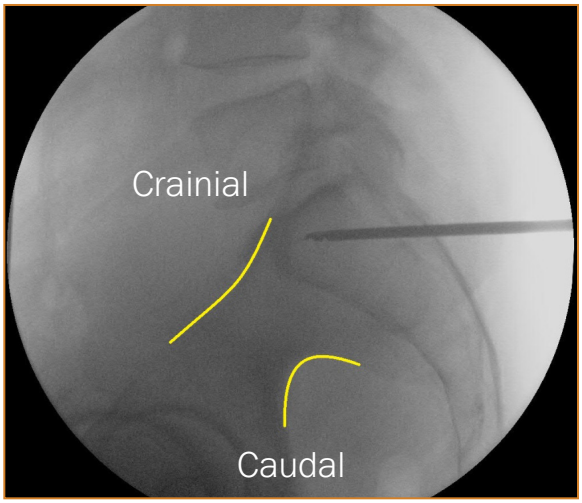
Inlet Imaging

Basic Definition for implant placement: A pelvis radiograph superimposing the upper 2 sacral segments on top of one another is utilized to ensure that guide wire placement is in the correct orientation in the Anterior-Posterior (AP) plane. This is orientation is based upon the premise that the vertebral bodies of the upper and lower sacral segments (most often presumed to be S1 and S2) are directly in-line with each other giving a double-density of the anterior rim of the vertebral bodies. The fluoroscopy unit is centered around the pelvis and then the image intensifier is tilted toward the legs until the image is optimized.



Intra-operative inlet view demonstrating a perfect hyper-dense zone representing the overlay of the anterior borders of S1 and S2.





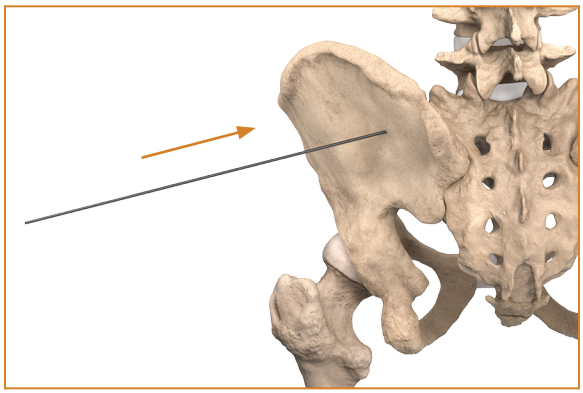
Lateral Imaging

Patient example (in prone position) of lateral imaging.

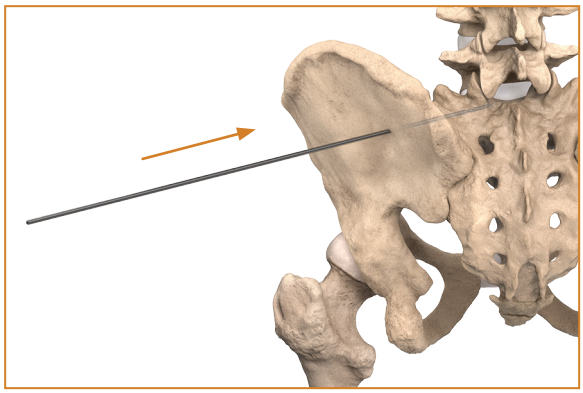
This is a safety step to ensure that the guide wire is not anterior to the iliac-cortical density, (a radiographic marker detailing the location of the L5 nerve root and vascular structures anterior to the sacral ala).

This image may be utilized to ensure that the implants are staying posterior to the Iliac-cortical density (ICD). This line, in non-dysmorphic sacra, represents the path of the L5 nerve root and any implant or guide wire placed anterior to the ICD may place the L5 nerve in danger of injury. In this image, the yellow lines represent the ICD cranially and the greater sciatic notch caudally.

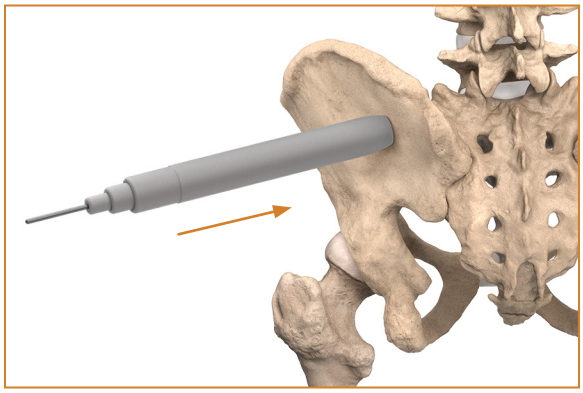
Surgical Technique



2.0mm Guide Wire



3.2mm Guide Wire



Dilators

Patient Prep and C-arm Alignment

As instructed previously, set up and align the c-arm lateral view, inlet view, and outlet view.

Step 1
2.0mm/3.2mm(long) Guide Wire Insertion

Manually insert the 2.0mm guide wire through the soft tissue until the tip contacts the lateral wall of the ilium. The ideal entry point is typically 6-8 centimeters anterior to the PSIS. The ideal trajectory is templated on axial and coronal CT imaging.

Surgical Pearl: A safe plan will direct the implant anterior and cranial to the S1 foramen posterior and caudal to the sacral ala and the L5 nerve root. This will be in the upper (S1 typically) or lower (S2 typically) sacral segment based on pre-operative templating. The goal is to position the guide wire safely in the perpendicular orientation to the SI Joint space

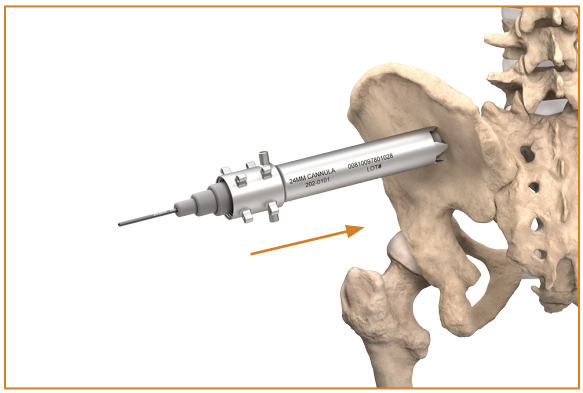
Take fluoroscopic images as necessary to verify the correct placement and trajectory. Once complete, make a 3-4cm skin incision at the desired location, with the wire being located just cranial of the incision.

Utilizing 2.0 guide wire as a guide, insert the 3.2mm guide wire manually right next to the 2.0 guide wire. Remove the 2.0mm guide wire. Verify the trajectory of the 3.2mm guide wire and fine-tune the starting point via fluoroscopic imaging, prior to impacting the wire into the lateral wall of the ilium a few millimeters. This prevents slippage of the wire on the lateral wall of the ilium. Utilizing a powered wire driver, insert the 3.2mm guide wire thru the sacroiliac joint space and embed it to its final position within the vertebral body using fluoroscopic guidance.

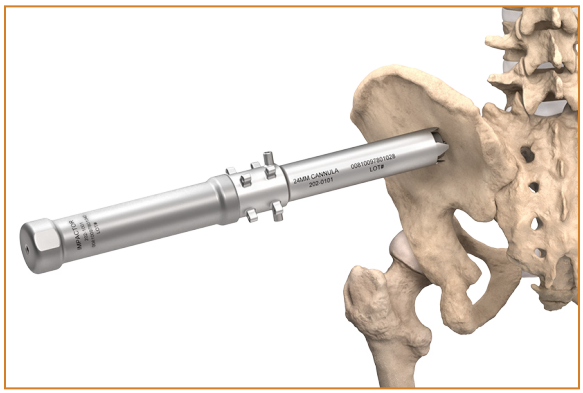
Step 2
Dilation

Using a #11 blade on a long handle, run this down the wire to incise the gluteal fascia away from the guide wire. Then, sequentially dilate over the 3.2mm guide wire starting with the 12mm dilator and working up to the 24mm.

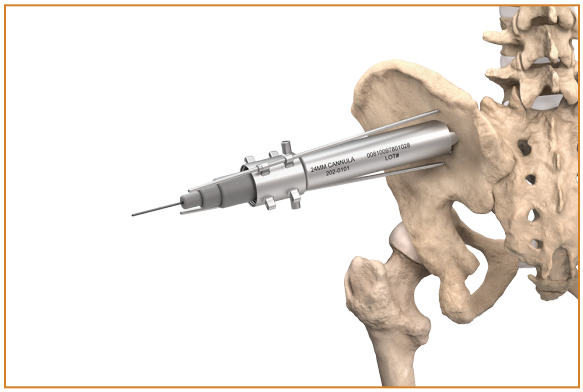
Surgical Pearl: It is often helpful for the surgeon to use their finger to stretch the fascial tissues to allow easier passage of the dilators.



Working Cannula



Impaction of Cannula



Stabilizing Pin

24mm Cannula

Impactor

Step 3
Cannula and Stabilization Pin Insertion

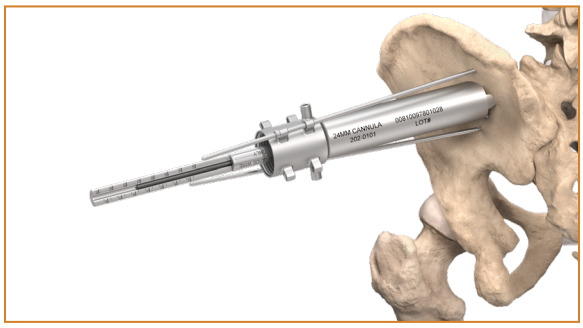
Insert the 24mm working Cannula over the 24mm Dilator until it contacts the lateral ilium wall.

Place the Impactor on the 24mm working Cannula and impact the end with a Mallet to embed the Cannula Fins into the ilium. Continue impacting until the fins are fully engaged. Typically, an audible pitch change during impaction will indicate a fully seated cannula.

***Surgical Pearl*:** Care should be taken to ensure that the impaction process does not change the trajectory of the either the guide wire or the 24mm cannula. The impaction is not always exactly perpendicular to the contour of the ilium. Take special care to ensure the working cannula base is at the lateral ilium wall following impaction.

If desired, stabilizing pins may be utilized to increase the stability of the working Cannula. To insert, utilize a powered wire driver and insert the stabilizing pin through the desired guide slots on the Cannula until the shoulder is flush with the top of the guide holes. Up to four Stabilizing pins may be used. Slow advancement is recommended.

Surgical Note: It is recommended that two stabilizing pins be placed on opposite sides of the 24mm cannula in nearly all patients, especially osteopenic patients, to aid in keeping the system stable. Care should be taken not to overtighten the pins as this can change the trajectory. In addition, these pins can provide minor changes to aid in straightening out the trajectory.



Step 4
Measure Implant Length

With the dilators inserted, place the Length Gauge over the guide wire so it is flush against the 24mm working Cannula. Read the length from the Gauge. (This step may be skipped if using Primary Depth Gauge.)

Surgical Pearl: Step 4 can happen with or without the dilators still inserted however it is recommended to measure with the dilators to ENSURE the guide wire is in the center of the Length Gauge when measuring for implant length. It must not be used with the 12mm sleeve inserted.

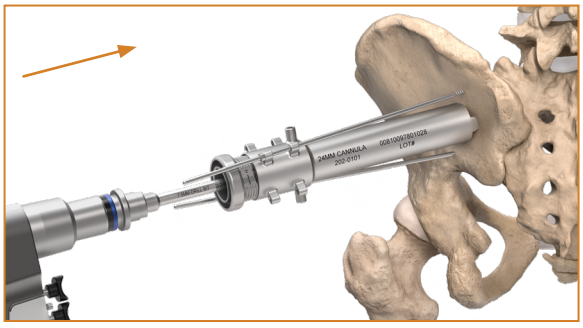
Step 5
12mm Sleeve Insertion and Primary Depth Gauge Measurement

After removing the Dilators and while leaving the 3.2mm guide wire in place, insert the 12mm Sleeve into the 24mm Cannula and rotating until the '0' line is flush with the top surface of the Cannula. Depth of the sleeve is not important at this step. Primary Depth Gauge may be used at this time based on surgeon preference.

Length Gauge

Primary Depth Gauge

12mm Sleeve



6.0mm drill (10mm primary implant)

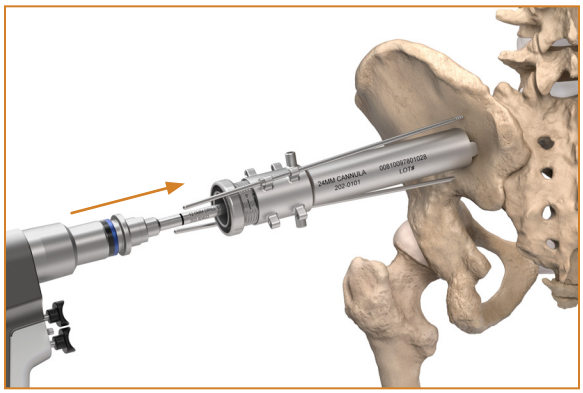
7.5mm drill (12mm primary implant)

Step 6
Drill Minor Diameter

Select the desired Implant diameter (10mm or 12mm). Connect the corresponding drill size to the Inline Ratcheting Handle or Power Driver.

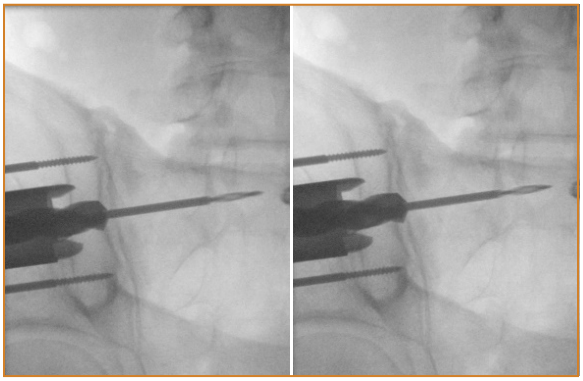
Primary Implant Diameter	Drill Diameter
10mm	6.0mm
12mm	7.5mm

Insert the desired Implant Inner Diameter Drill over the 3.2mm guide wire advance to the desired depth. Ensure the Long 3.2mm guide wire remains in place.



12mm Drill through 12mm Sleeve

12mm Drill



Note 12mm drill going just across the SI joint. Depth should be set once at the sacral side of the SI joint or just across it.

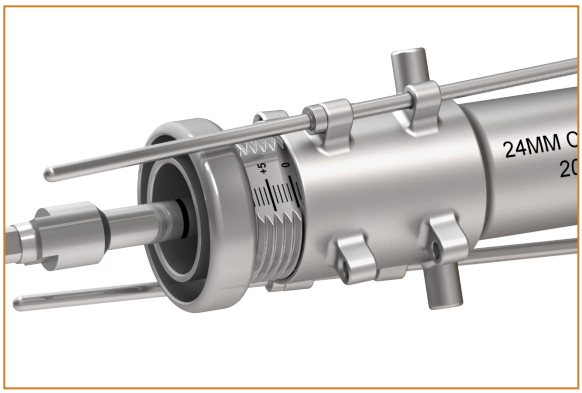
Step 7
Drill Across SI Joint

Connect the 12mm Drill to power of the Inline Ratcheting Handle. After manually inserting the Drill over the 3.2mm guide wire, continue drilling 6 to 7mm into the sacral ala. If contact with the 12mm sleeve is made before the drill tip is 6 to 7mm into the ala, decrease the height of the 12mm sleeve incrementally until the desired depth is achieved. Rotate counterclockwise to increase the height of the sleeve, and clockwise to decrease the height of the sleeve. Use tactile feedback in conjunction with fluoroscopy to identify the lateral border of the sacral ala prior to plunging thru the sacral cortex.

Once the depth is set, it is helpful to penetrate the sacral side of the SI joint to allow for minor changes with the 12mm sleeve should a deeper, more aggressive decortication be desired and collect autograft.

Surgical Pearl: When collecting autograft from the ala, rotate the drill slowly and remove slowly from the cannula to retain as much bone graft as possible.

Surgical Note: The 12mm Sleeve should now be adjusted to help prevent over penetration and plunging with subsequent preparation steps. (See Step 8 for details.) Great care should be taken at this step to assess the tactile-feedback from the ilial and sacral sides of the SI joint. This depth sets the decortication depth for the remainder of the case. Adjusting the sleeve depth can correct for initial under or over penetration.



Sleeve Adjustment

Step 8
12mm Sleeve Height Adjustment

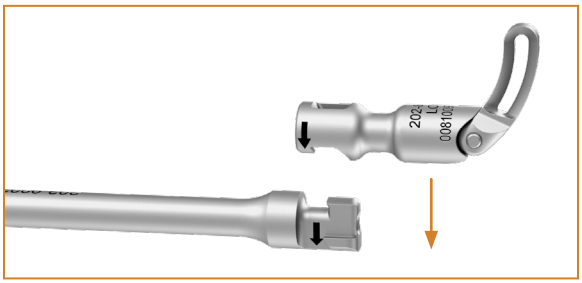
While the 12mm Drill is inserted to the appropriate depth, manually adjust the 12mm Sleeve by rotating it until the proximal surface is flush with the end of the Inline Ratcheting Handle or the T-handle. Rotate counterclockwise to increase the height of the sleeve, and clockwise to decrease the height of the sleeve. Each rotational 'click' on 12mm Sleeve corresponds to 1mm of axial travel (depth). This sleeve will now serve as a hard depth stop for subsequent instruments.

Remove the 12mm Drill and long 3.2mm guide wire, taking care to collect the autograft bone from the Drill flutes for subsequent graft application. Remove drill slowly to avoid losing the autograft from the flutes.

Surgical Note: The 12mm Sleeve provides the depth control for the remaining instruments by acting as a hard stop to prevent over-penetration or plunging. Intraoperative fluoroscopy can assist the surgeon in determining appropriate drill depth; just across the SI joint.

Surgical Note: Do not retract the 12mm Sleeve beyond the '-15mm' location.

38mm Blade



Blade Connection

BladeX® Handle

Central Shaft with Blade attached

Central Shaft insertion with "Blade" aligned

Step 9
Assembly of BladeX® Instrument

Connect the 38mm Blade to the Central Shaft. Insert the Central Shaft into the BladeX Handle Assembly and turn the knob clockwise to engage. Turn the Knob until the Gauge reads "12".

The BladeX blades are intended for single-use only.

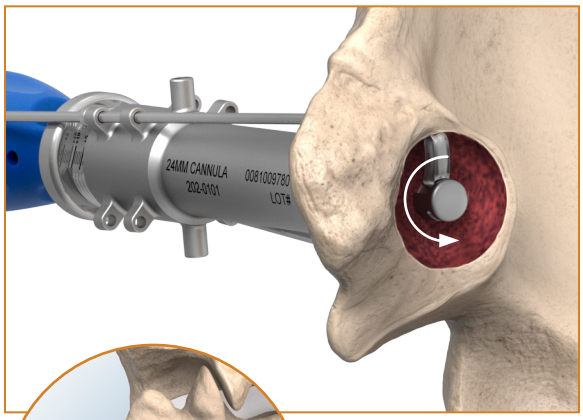
When installing the Blade on the Central Shaft, be sure to orient the laser marks (→) as shown. The Blade will click into place when properly installed.

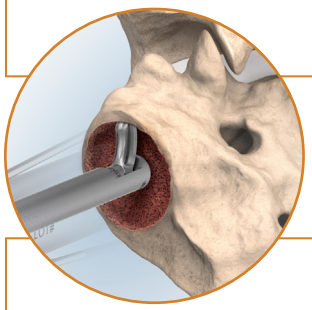
When installing the Central Shaft into the BladeX Handle Assembly, be sure to orient the Blade with the Handle by aligning the laser marks (BLADE →) as shown.

A new Blade is required for each surgery to ensure component sharpness for efficient bone resection.

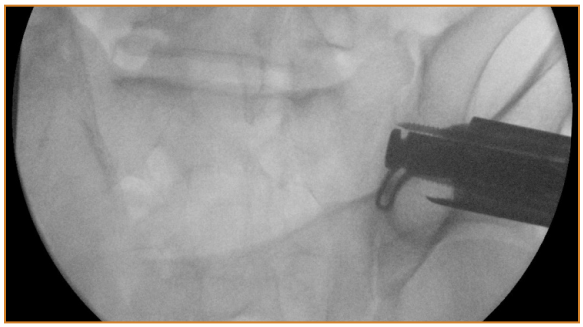
Surgical Pearl: The Gauge may be used as a visual indicator of Blade deployment. The readout corresponds to the diameter of the cut.

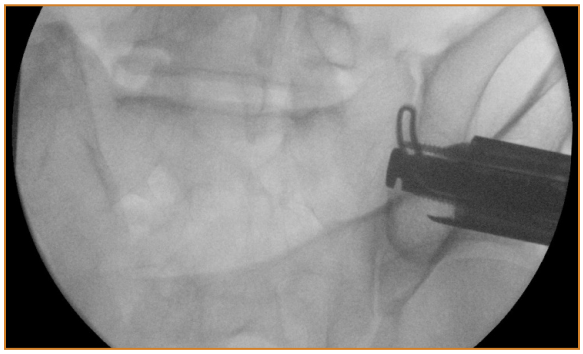
BladeX MIS Decorticator *showing blade deployed*





BladeX Cutting





Step 10
Aggressively Decorticate SI Joint Using Blade*X* MIS Decorticator

Insert the BladeX through the 12mm Sleeve until the Handle makes contact with the proximal end of the 12mm Sleeve. If the bottom of the BladeX handle is flush with the adjustment sleeve, resection will be performed at the proper depth. Fine adjustment to the resection depth may be made rotating the 12mm Sleeve incrementally to increase or decrease the depth stop if the surgeon desires to do so (See Step 10b for more detail).

The Alignment Slot on the distal tip of the BladeX provides the user a visual indicator of blade location when viewed under fluoroscopic imaging. The location of the Slot corresponds to the centerline of the Blade after it has reached full deployment.

Surgical Note: Each rotational 'click' on 12mm Sleeve corresponds to 1mm of axial travel (depth).

Rotate the BladeX Knob clockwise to extend the Blade until bone is contacted. Increased resistance when rotating the Knob serves as tactile feedback to the user that the Blade is in contact with bone. To start bone resection, rotate the entire BladeX Instrument a few turns (both clockwise or counterclockwise are acceptable and recommended). Continue alternating rotating the Knob clockwise (to further deploy the Blade) and rotating the Instrument assembly until the desired cutting diameter is achieved based on preoperative templating. When the Gauge reads "38", a 38mm diameter cavity has been created.

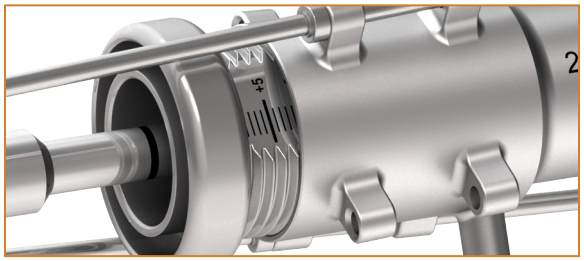
Surgical Note: The user may choose to cut less than the maximum diameter allowed by the chosen Blade size to accommodate patient anatomy based on preoperative templating.

Surgical Note: When the Blade is fully deployed, the Knob will not allow more rotation as the Blade has reached the full travel.

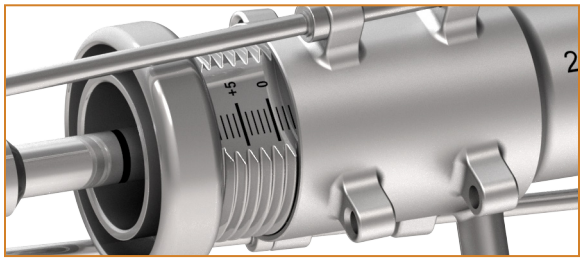
Surgical Note: Ensure that the BladeX handle remains in contact with the proximal surface of the 12mm sleeve during cutting.

Once the desired cavity has been created, turn the Knob counterclockwise until the Gauge reads "12" and then remove Instrument from the Cannula.

For cleaning, remove the central shaft of the cutter by rotating the knob counterclockwise and then pulling the shaft out. Dispose of the blade.



+2mm Sleeve Adjustment



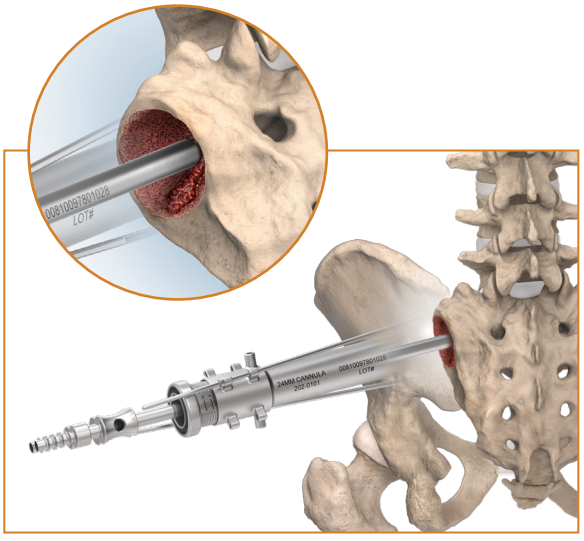
-2mm Sleeve Adjustment

Step 10b
(Optional) Depth Adjustment of BladeX MIS Decorticator

The resection depth may be increased or decreased by advancing the BladeX either further medial or more lateral. Precise control of the depth may be achieved by adjusting the 12mm Sleeve. Each rotational “click” of the 12mm Sleeve corresponds to 1mm of axial travel. Rotate the 12mm Sleeve counterclockwise to increase the height of the depth stop, and clockwise to decrease the height of the depth stop. Reset the BladeX gauge to read 12 and then redeploy to the new depth. Rotate the cutter to create a larger cavity.

Surgical Note: Do not retract the 12mm Sleeve beyond the ‘-15mm’ location and ensure that the BladeX handle remains in contact with the proximal surface of the 12mm Sleeve during cutting.

Surgical Pearl: When fully deployed, the cutting blade matches the alignment slot. These images demonstrate decortication at the maximal blade deployment. If further debridement is desired modification of the 12mm cannula depth can be completed here. The cutting blade would need to be retracted prior to decorticating deeper or shallower.



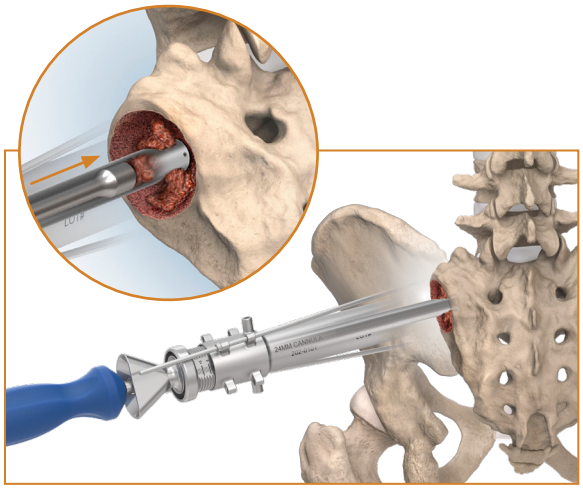
BladeX Cutting

Suction Tube

Step 11
Suction of Joint

Remove resected tissue by irrigating the joint and then using the Suction Tube. Irrigant can be flushed directly into the working portal or injected into the tube using the thumb-hole on the handle and pinching of the suction hose.

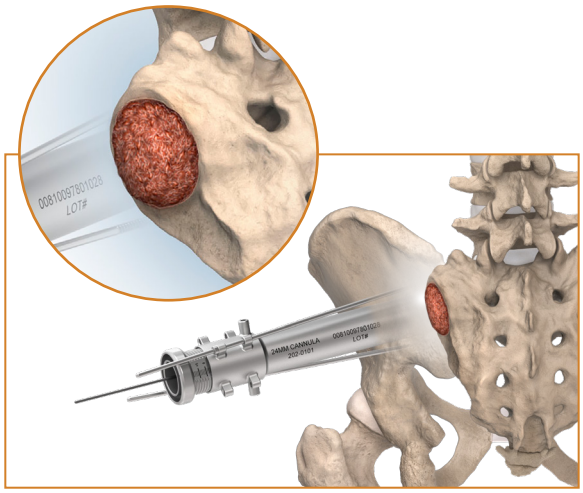
Surgical Note: Ensure that the tubing or connections do not get clogged with debris. Slow advancement of the suction tube into the cannula can help prevent this clogging. Use the long 3.2 guide wire to unclog suction tubing if clogging occurs.



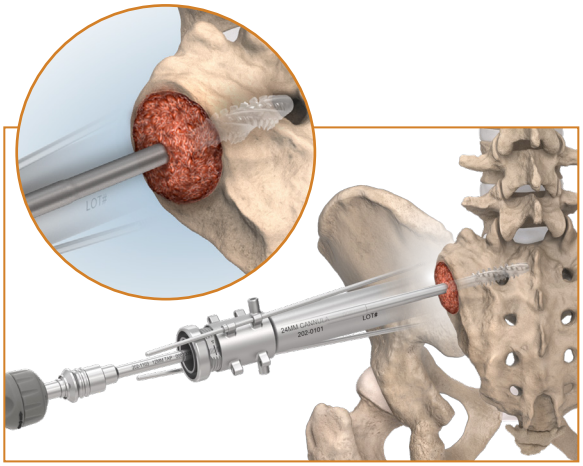
Graft Tube with Graft Ram inserted

Graft Tube

Graft Ram



3.2mm Long Guide Wire insertion



Optional tapping

Step 12
Allograft/Autograft Insertion

Load the Graft Inserter with the selected amount of allograft or autograft material.

Surgical Note: The Integrity-SI system and implants is only intended for use with autograft or allograft.

Cutter Blade Size	Minimum Cut Volume (cc)
38mm blade	6.5

Graft component	Volume Capacity (cc)
Graft Tube	17
Graft Funnel	12.5

Insert the loaded Graft Funnel through the 12mm Sleeve until the rim is flush with the proximal surface of the 12mm Sleeve, establishing the appropriate depth. This will align the distal opening of the Graft Tube with the cut cavity space. Insert the Graft Ram through the Graft Tube until bottoming out.

Step 13
Long 3.2mm Guide Wire Re-Insertion

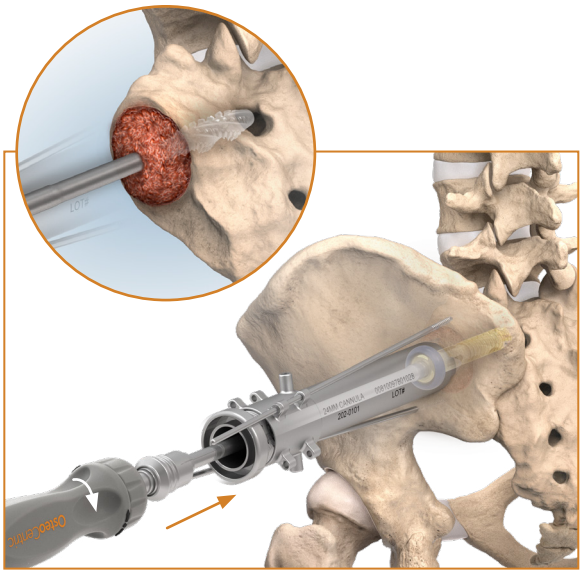
Re-insert the 12mm Dilator through the 12mm Sleeve. Insert the Long 3.2mm guide wire through the Dilator. Utilizing c-arm images, ensure the wire trajectory is correct and safe. Advance to the desired depth to match the initial guide wire placement depth. It is recommended to confirm placement with fluoroscopy using inlet and outlet images.

Once confirmed, the 12mm cannula and stabilization pins can be removed. The only remaining instrumentation should be the 24mm working cannula and the 3.2 mm guide wire.

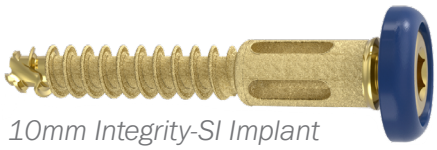
Surgical Note: This should follow the initial trajectory as long as the cannula has not shifted from decortication.

Tap

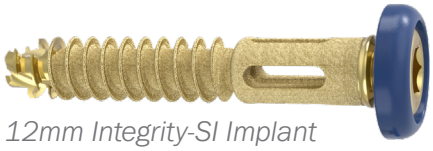
Prior to implant insertion, if tap is deemed necessary based on patient anatomy and bone quality, a tap can be utilized.



Integrity-SI implant insertion



10mm Integrity-SI Implant



12mm Integrity-SI Implant

Hex Driver

Step 14
Implant Insertion

Select Implant size and remove the desired implant from the sterilization tray. Connect the Large Hex Driver to the Inline Ratcheting Handle. Engage the Implant and insert over the long 3.2 guide wire. Insert the implant until it is near (<1.5cm) fully seated against the ilium bone. Remove the Driver but do not remove the long 3.2 guide wire. Remove the 24mm cannula. Then clear any gluteal fascia entrapped under the washer before final seating. Leave the long guide wire in place if the surgeon is planning on placing the biomechanical fastener (anti-rotation fastener).

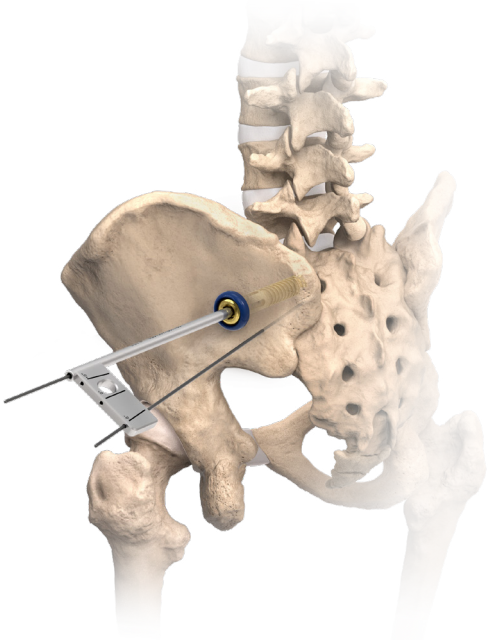
Surgical Pearl: When selecting implant length, ensure that a length is selected that is within 3mm of the measurement made by the Length Guide. This will ensure ideal fixation at the distal portion of the implant. If performing Bi-lateral getting as close to, but not passing mid-line, of the sacrum is recommended. The large hex driver fits all three implant offerings.

Surgical Note: After removing the cannula, seat the implant against the outer cortex of the ilium. Check with an AP view with a 20°- 30° degree rollback tilt to view the lateral table in profile to ensure the implant is flush with the outer cortex of the ilium. Also ensure to not intrude the lateral wall of the ilium or strip the implant's torque.

Surgical Pearl: It is helpful for the surgeon to use their finger to clear gluteal fascial tissues from the undersurface of the washer to prevent entrapment of the gluteal tissues against the lateral wall of the ilium.

6.5 Biomechanical Fastener Wire Guide & 2.0 Guide Wire Insertion

If a secondary biomechanical fastener is desired to add additional rotational support, then follow the remaining steps.



2.0mm Wire Guide and 2.0mm guide Wire insertion

2.0mm Wire Guide

Guide Wire Demonstration Parallel

Guide Wire Demonstration +8 degrees

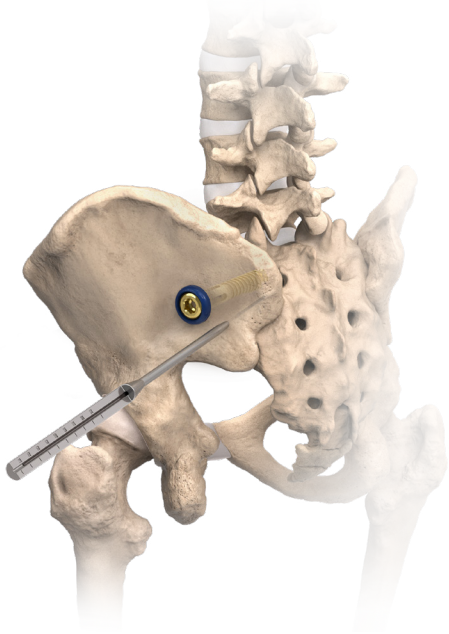
Guide Wire Demonstration -8 degrees

Step 15
2.0 Wire Insertion

Insert the 2.0mm Wire Guide over the Long 3.2mm guide wire and insert until the distal tip contacts the Implant surface. Maintain contact with the Implant and insert the 2.0mm guide wire through the desired hole of the 2.0 Wire Guide. Insert the 2.0mm guide wire to the desired depth of the screw. Remove the 3.2mm guide wire and then remove the 2.0 Wire Guide. Ensure to leave the 2.0mm guide wire in place.

Surgical Note: The 6.5mm Biomechanical Screw may not be used by itself and is only intended for use with either the 10mm, or 12mm Primary Implant.

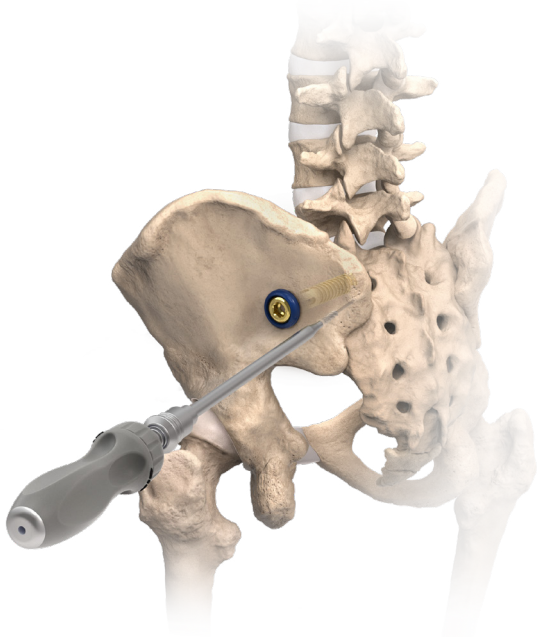
Surgical Note: It is recommended that the biomechanical screw implant be placed directly caudal to the primary implant when the primary implant is placed into the upper sacral segment. With this practice, the implant is directly under the primary implant on the inlet view and hidden on the image and directly caudal and convergent/parallel/divergent on the outlet view.



Depth Gauge

Step 16
Measure Length of Biomechanical Fastener

Measure the length of fastener by placing the Depth Gauge over the 2.0mm guide wire. The end of the wire indicates the length of implant needed.



6.5mm Biomechanical Fastener Drilling

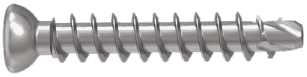
Step 17
6.5 Biomechanical Fastener Drill

Connect the 4.0mm drill to the Inline Ratcheting Handle or T-handle.

Insert the Drill over the 2.0mm guide wire and advance just through the outer ilial cortex. Ensure the 2.0mm guide wire does not advance and remains in place.

Surgical Pearl: Care must be taken to ensure the pin does not bind on the drill and come out. If this is noticed on the imaging, a 2nd guide wire can be used through the drill cannula to push out the guide wire to its original place. Often, simply drilling to the SI joint is far enough.

6.5mm Biomechanical Fastener



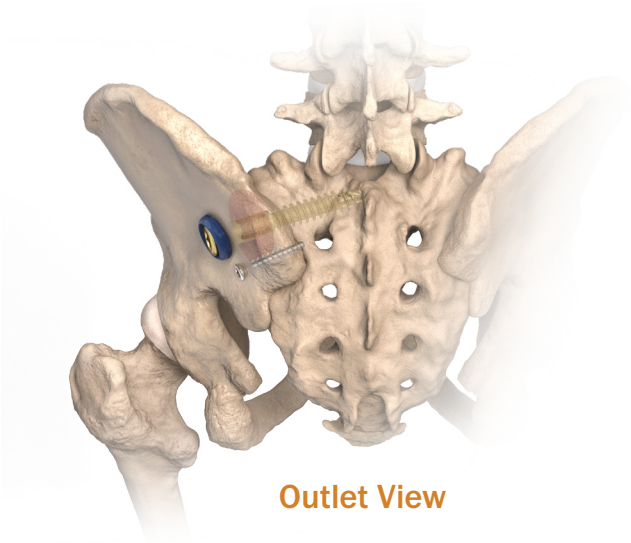
6.5mm Biomechanical Fastener Insertion

Step 18
6.5mm Biomechanical Fastener Insertion

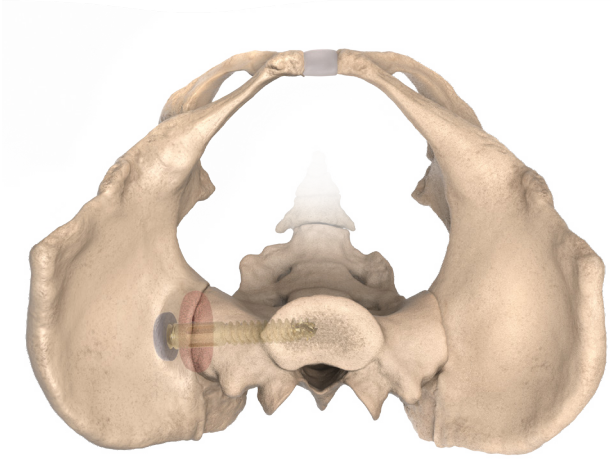
Connect the Small Hex Drive to the Inline Ratcheting Handle. Engage the 6.5mm Biomechanical fastener and insert over the 2.0mm guide wire. Advance until fully seated against the bone.

Surgical Pearl: Great care must be taken here to ensure that the guide wire does not inadvertently advance when inserting the screw. Following the fastener advancement with fluoroscopic guidance is recommended with this step.

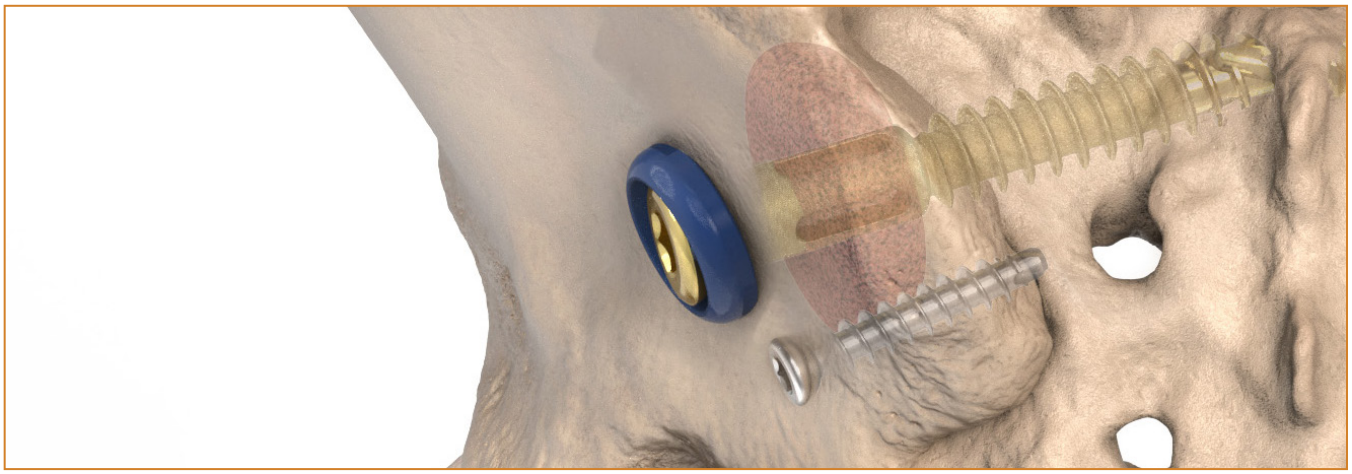
Ensure all Instruments Have Been Removed.



Outlet View



Inlet View



Installed Integrity-SI Implant and Biomechanical Fastener

Implant Removal

Removal Tool

Implant Removal

If either the 10mm, or 12mm Integrity–SI implants need removal then the Removal Tool may be utilized.

Utilizing the Dilators and Cannula, obtain access to the implant. Insert the Removal Tool through the Cannula and engage the hex of Removal Tool to the Implant.

Next, rotate the knob clockwise to thread into the implant ensuring that the implant is captured.

To remove the implant, rotate the Removal Tool handle counterclockwise to unscrew the Integrity-SI implant from the bone.

Surgical Pearl: It is often helpful to re-cannulate the implant with the 3.2 mm guide wire and partially remove the screw with the primary implant screwdriver. Typically 1-2 cm is sufficient. Then, remove the primary screw driver and long 3.2mm guide wire, and replace with the Implant Removal Tool. At this stage, the hex removal tool can be used as described above.

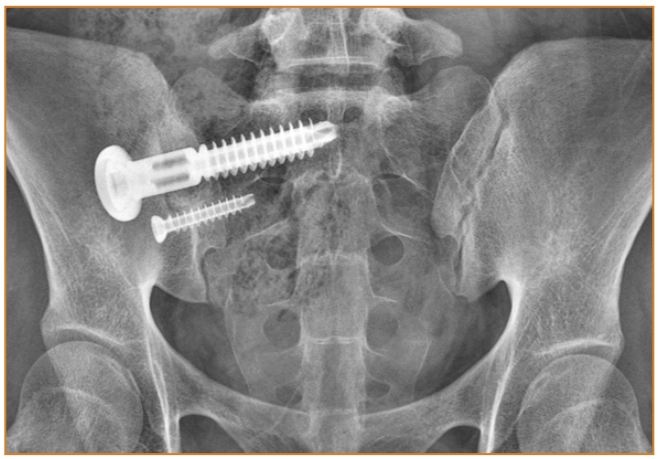
Contraindications:

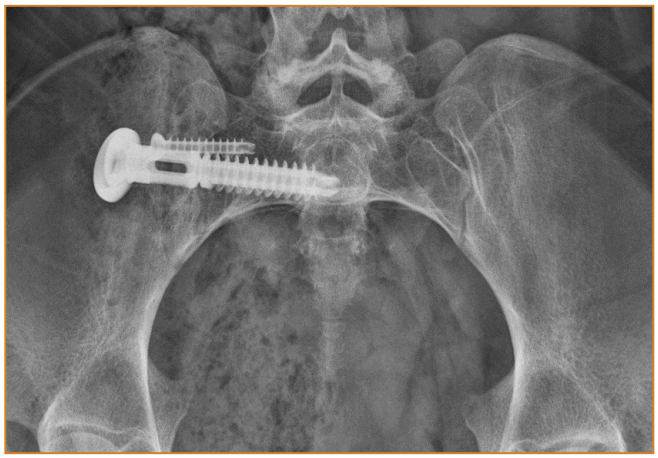
Contraindications for the Integrity-SI Fusion System include the following:

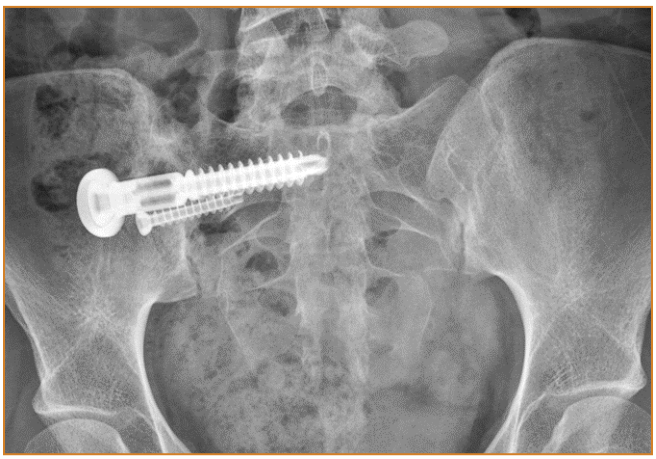
1. Deformities or anatomic variations that prevent or interfere with placement of the Integrity-SI Fusion implants
2. Tumor of sacral or ilial bone
3. Active infection at treatment site
4. Unstable fracture of the sacrum or ilium that involves the sacroiliac joint
5. Allergy to metal implants

Examples

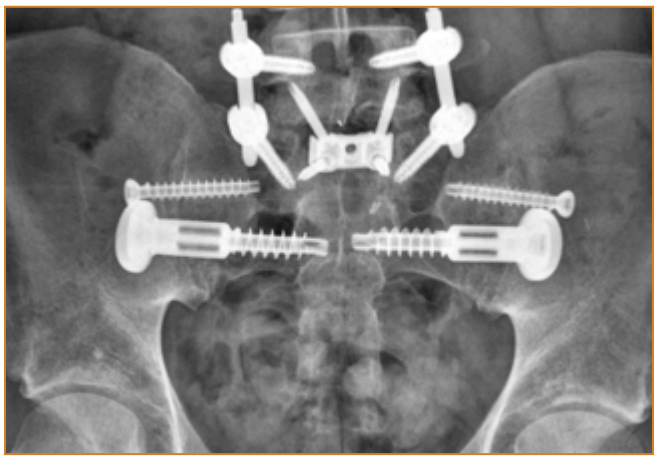
Example of patient with a unilateral implant with the additional biomechanical fastener.

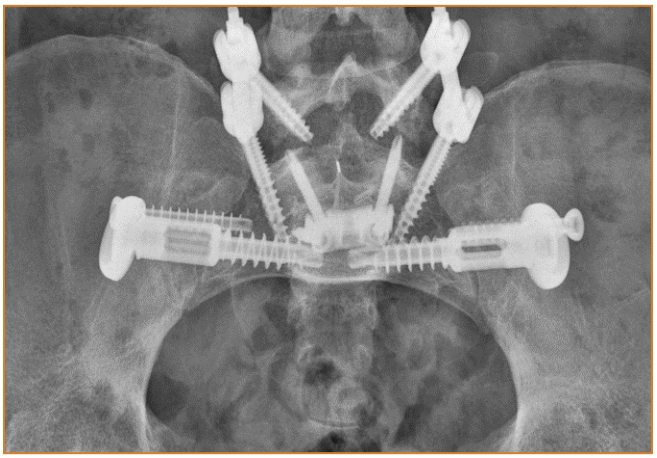


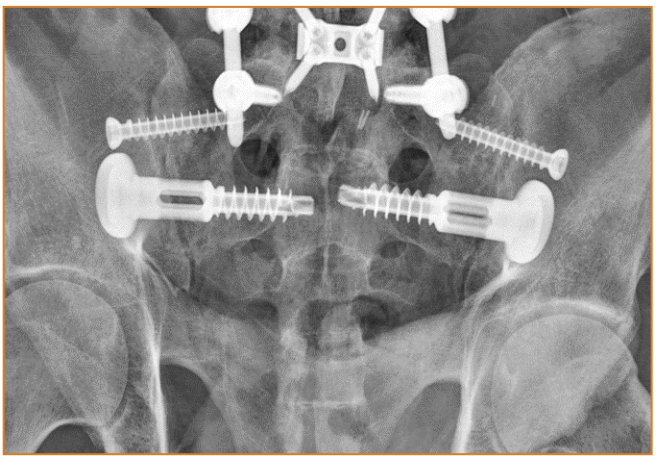




Example of patient with bilateral implants with the additional biomechanical fasteners.







Integrity-SI® Fusion System Instrument List

	Part number	Description
BladeX® MIS Decorticator	202-0001	BladeX Cutter
	202-0002	Central Shaft
	202-82038	Blade, 38mm
Guide Wires/Pins	202-80100	2.0mm Guide Wire
	202-80200	3.2mm Guide Wire - long
	202-80201	3.2mm Guide Wire - short
	202-80202	3.2mm Guide Wire - extra long
	202-80300	3.2mm Stabilizing Guide Pin
Drills	202-80403	12mm Drill
	202-80402	7.5mm Drill
	202-80401	6.0mm Drill
	202-80404	5.0mm Drill
	202-80400	4.0mm Drill
Taps	202-1101	6.5mm Tap
	202-1102	10mm Tap
	202-1103	12mm Tap
	202-1104	8.0mm Tap
Cannulas	202-0101	24mm Cannula
12mm Sleeve	202-0102	12mm Sleeve
Impactor	202-1002	Impactor
Dilators	202-0104	12mm Dilator
	202-0105	18mm Dilator
	202-0106	24mm Dilator
Implant Length Gauge	202-0201	Implant Length Gauge
Depth Gauge	202-0202	Depth Gauge
	202-0203	Primary Depth Gauge
Graft Inserter	202-0301	Graft Inserter
	202-0302	Graft Inserter Ram
Hex Driver	202-0401	Hex Driver - large
	202-0402	Hex Driver - small
Removal tool	202-0501	Removal Tool
Suction Tube	202-0601	Suction Tube
2.0 Wire Guide	202-0701	2.0 Wire Guide
Handles and Tray	202-0801	Inline Ratcheting Handle
	2004-0009	T-Handle
	202-90000	Instrument Tray
	1252-6001	Implant and Blade Tray

Integrity-SI Fusion System Implant List

	Part number	Length (mm)
12mm Anodized SI Implants	202-12050	50
	202-12055	55
	202-12060	60
	202-12065	65
	202-12067	67.5
	202-12070	70
	202-12072	72.5
	202-12075	75
	202-12077	77.5
	202-12080	80
	202-12082	82.5
	202-12085	85
	202-12090	90
	202-12095	95
	202-12100	100
	202-12105	105
	202-12110	110
10mm Anodized SI Implants	202-10050	50
	202-10055	55
	202-10060	60
	202-10065	65
	202-10067	67.5
	202-10070	70
	202-10072	72.5
	202-10075	75
	202-10078	78.5
	202-10080	80
	202-10082	82.5
	202-10085	85
	202-10090	90
	202-10095	95
	202-10100	100
	202-10105	105
	202-10110	110
Optional 6.5mm Biomechanical Fastener	202-65030	30
Note: The 6.5mm fastener	202-65035	35
can only be used in conjunction	202-65040	40
with a primary 10mm or 12mm fastener.	202-65045	45
	202-65050	50
	202-65055	55
	202-65060	60
	202-65065	65
	202-65070	70

Note:

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. 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 examination and/or advice.

OsteoCentric TECHNOLOGIES | UnifiMI An OsteoCentric Technology | BladeX®

75 West 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639
info@osteocentric.com
osteocentric.com

SI-002-LBL-0004 Rev 4