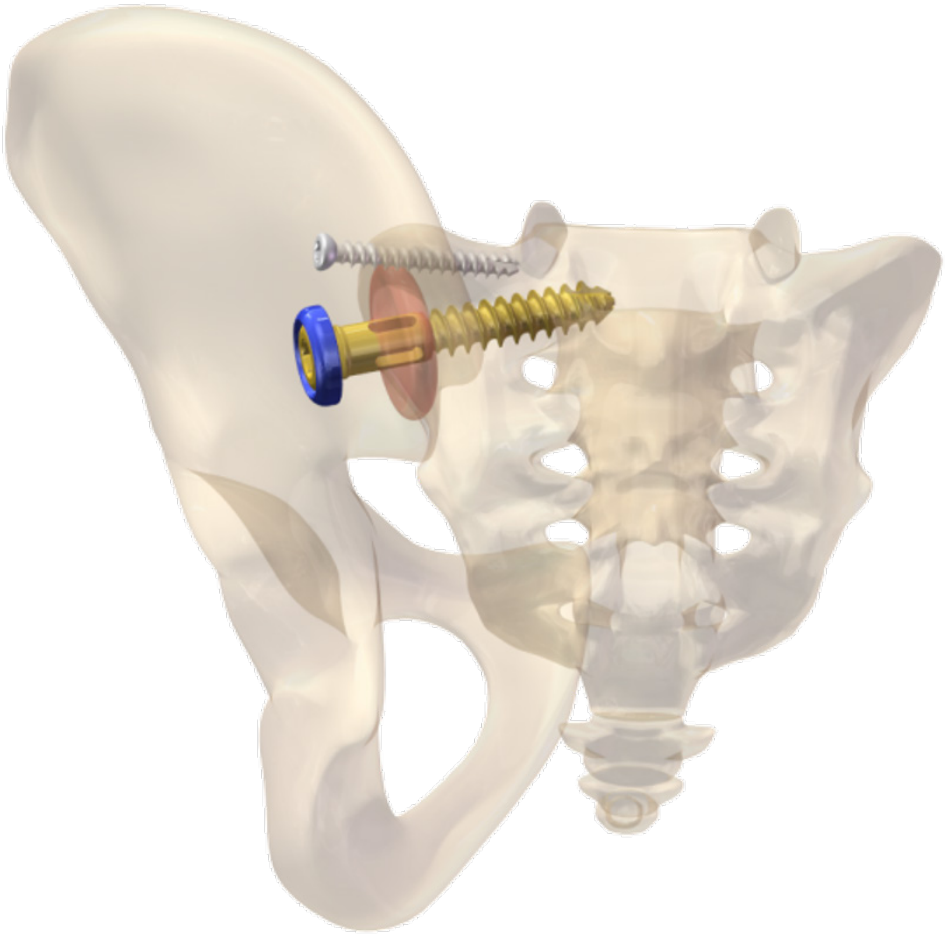
OsteoCentric Integrity-SI® Fusion System

Surgical Technique



OsteoCentric
TECHNOLOGIES

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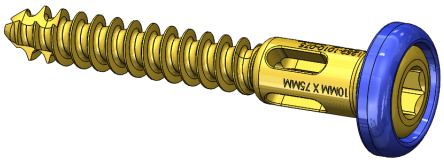
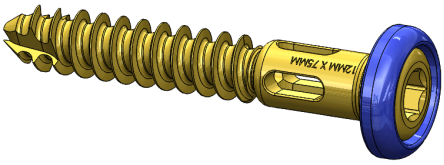
Description

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 screws are offered in partially threaded versions in lengths from 40 - 110mm, in 5mm increments. The 10mm and 12mm screws also include a pre-assembled washer for improved joint compression. The fully threaded 6.5mm diameter screws are offered from lengths of 30–70 mm, in 5mm increments and are intended to be used only in conjunction with either a 10mm or 12mm screw for additional rotational stability. The implants and cutter blades are provided non-sterile in a steam sterilization tray and must be sterilized at the hospital per the IFU.

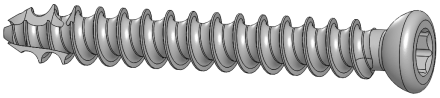
The Implants and Blades are for single-use only.



10mm Integrity-SI Fusion Implant



12mm Integrity-SI Fusion Implant



6.5mm Biomechanical Screw

BladeX® Cutter

Indications For Use

The Integrity-SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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

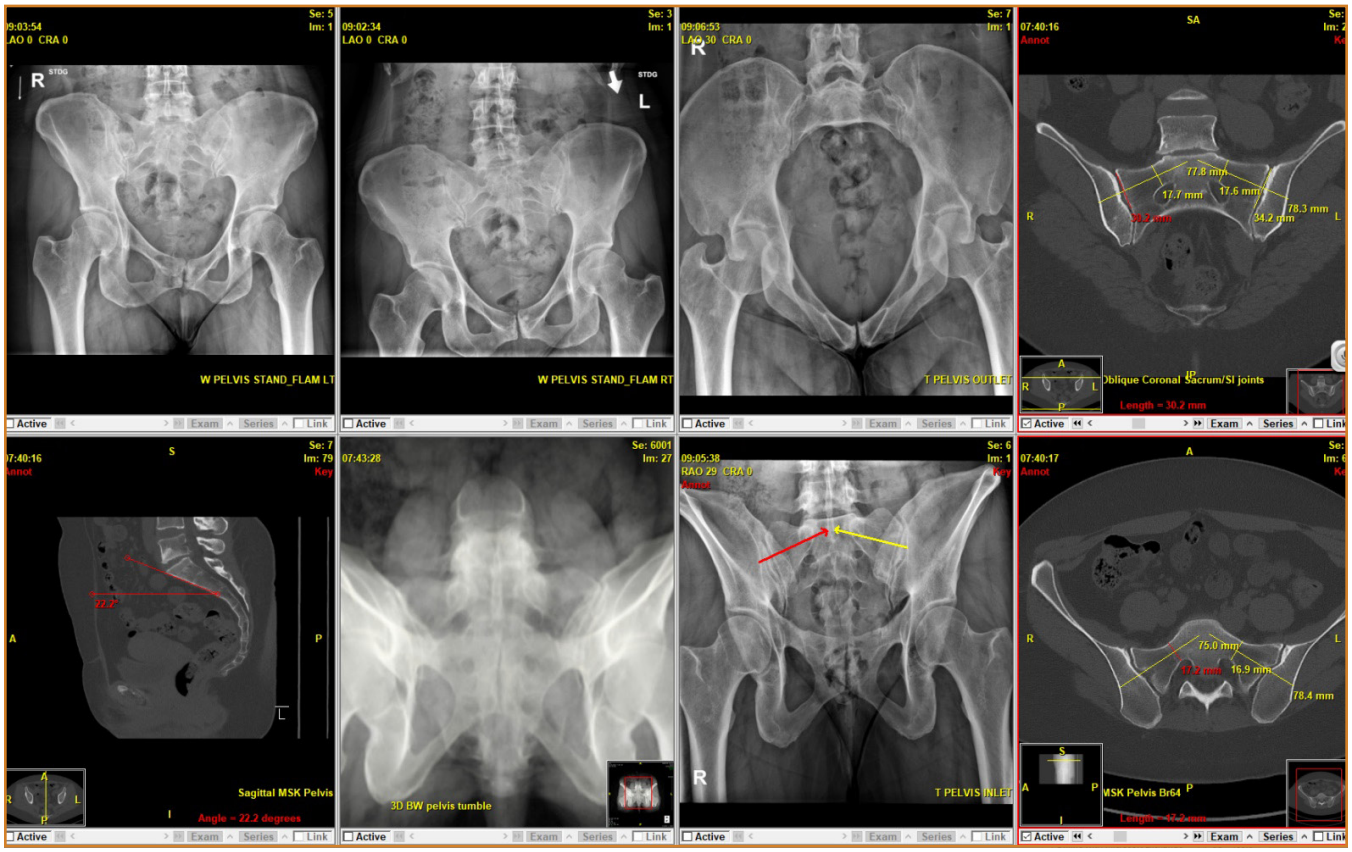
Materials

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

Preoperative Templating and Imaging

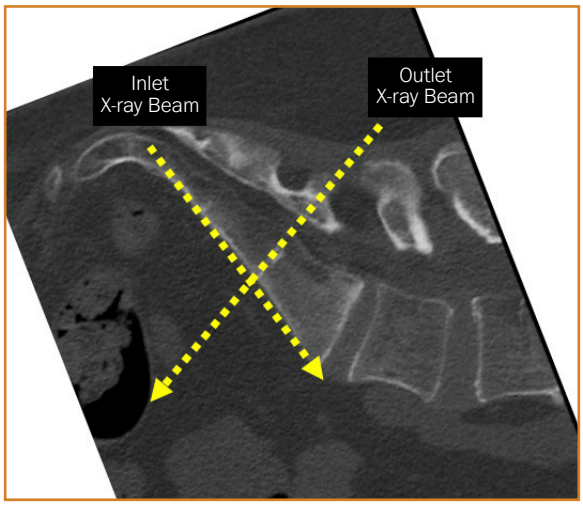
Preoperative Templating and Inlet and Outlet imaging for implant placement into the upper sacral segment

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 implant as it relates to the SI joint angle.



Outlet Imaging

Patient example (in prone position) of outlet imaging.



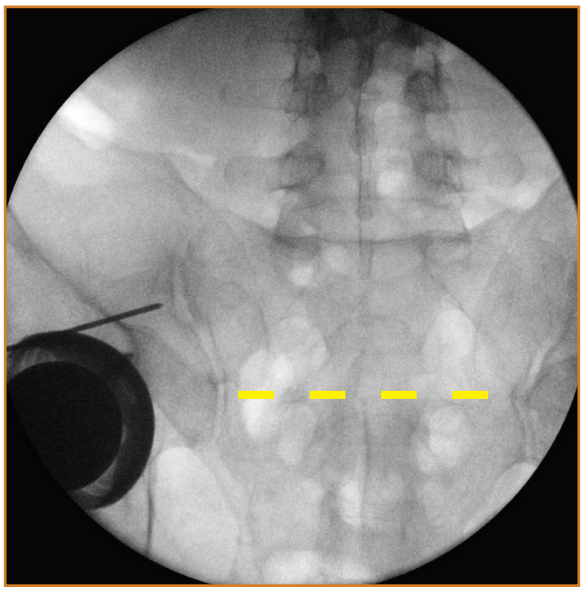
Patient in Prone position

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.

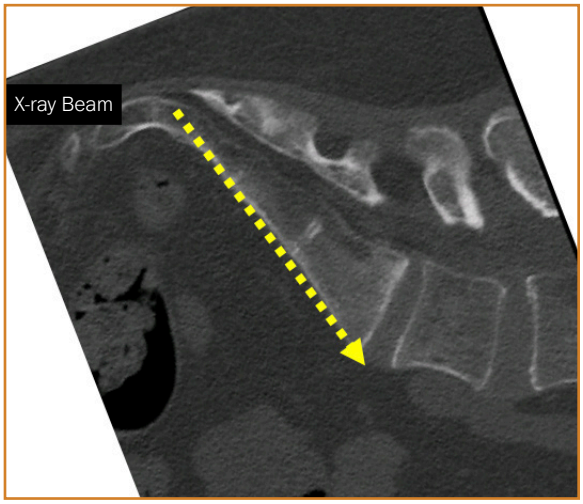
The fluoroscopy unit should be oriented in the AP direction and continually tilted with the image intensifier tilted towards the head to offer ideal imaging.



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

Inlet Imaging

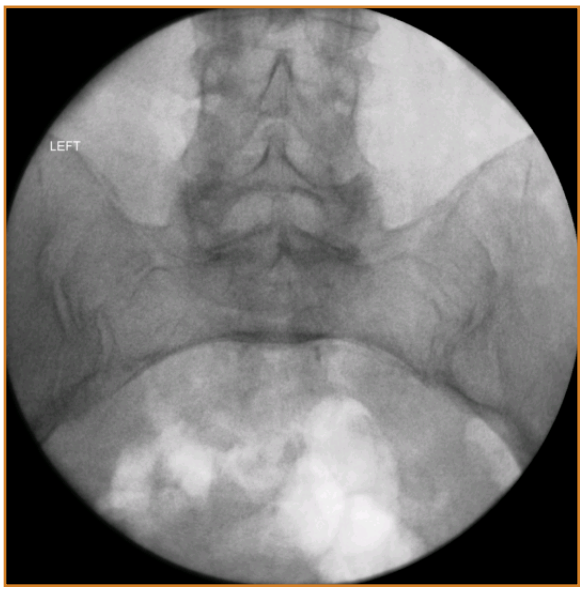
Patient example (in prone position) of inlet imaging.



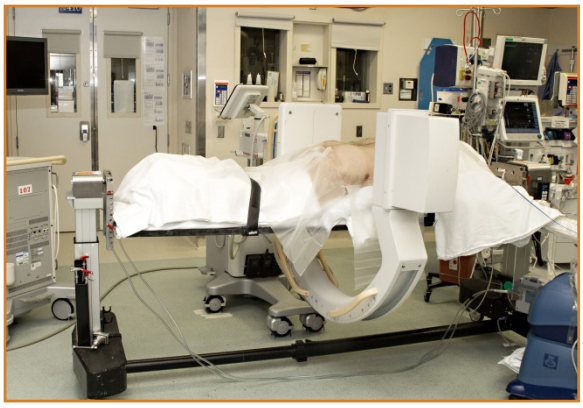
Patient in Prone position

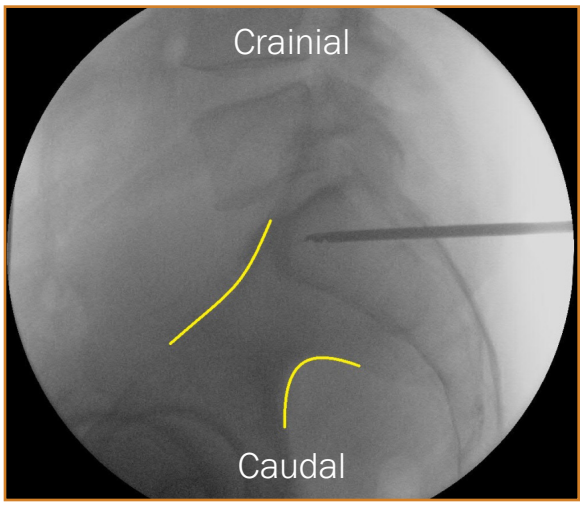
Inlet Imaging

Basic Definition for implant placement: A pelvis radiograph superimposing the upper 2 sacral segments on top of one another is utilized to ensure that guidewire 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.



Intraoperative 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 k-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 guidewire 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.

Positioning and 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

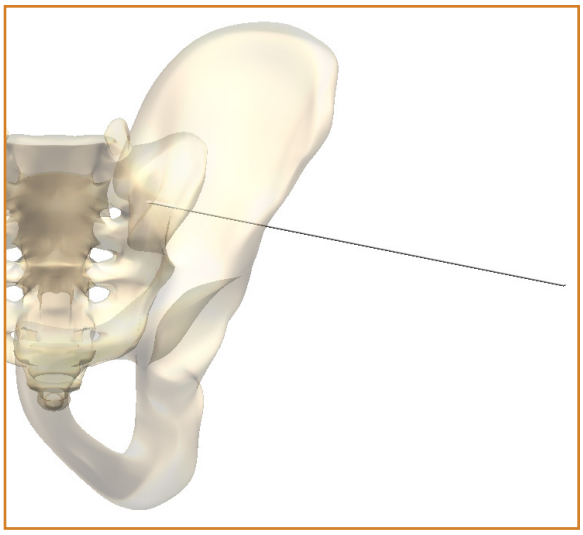
The patient is placed prone with chest rolls or per surgeon preference. Fluoroscopy is brought in from the opposite side of surgery and the monitor is placed at the foot-end of the patient.

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.

Surgical Technique



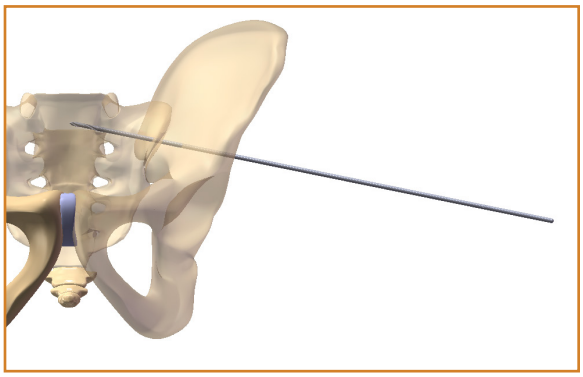
2.0mm k-wire

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 k-wire insertion (Optional)

Manually insert the 2.0mm k-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. 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. 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.

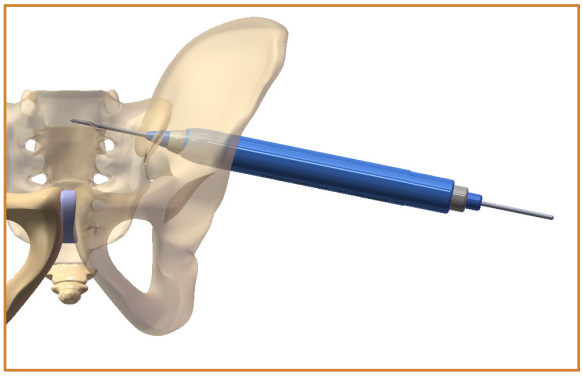


3.2mm k-wire

Step 1b
3.2mm k-wire (long) insertion

Utilizing 2.0 k-wire as a guide, insert the 3.2mm k-wire manually right next to the 2.0 k-wire. Remove the 2.0mm k-wire. Verify the trajectory of the 3.2mm k-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 k-wire thru the sacroiliac joint space and embed it to its final position within the vertebral body using fluoroscopic guidance.

Note: This will be in the upper (S1 typically) or lower (S2 typically) sacral segment based on pre-operative templating.

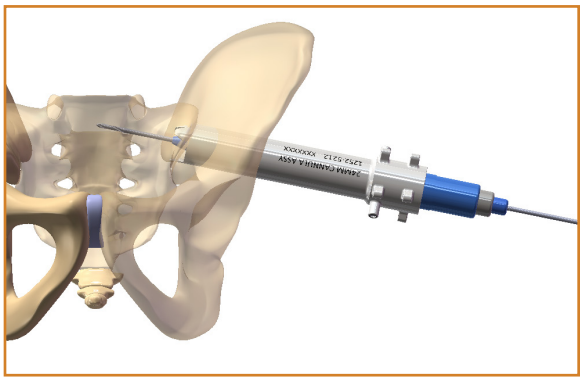


Dilators

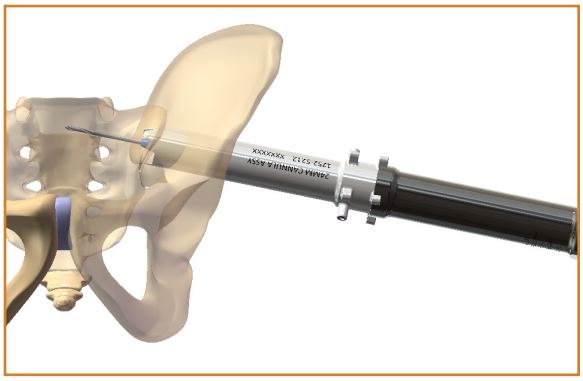
Step 2
Dilation

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

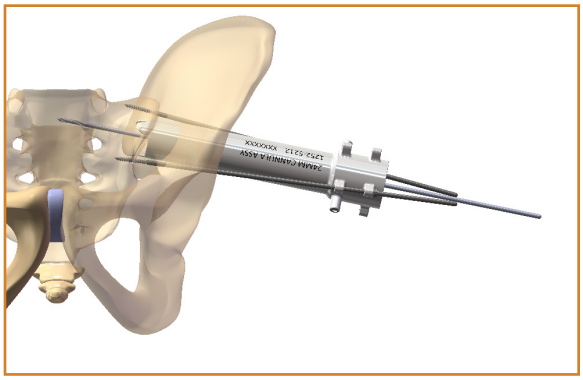
Note: It is often helpful for the surgeon to use their finger to stretch the fascial tissues to allow easier passage of the dilators.



Working Cannula



Impaction of Cannula



Stabilizing k-wire

24mm Cannula

Impactor

Step 3
Working Cannula Insertion

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

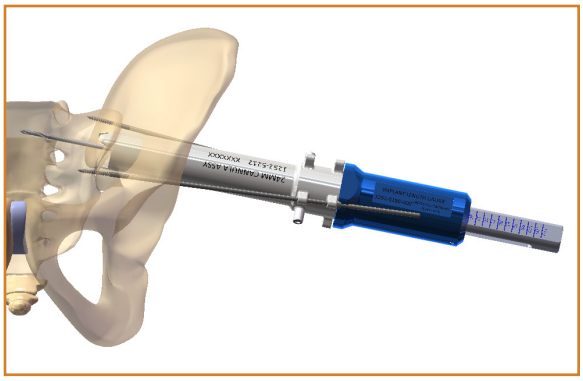
Place the Impactor on the 24mm working Cannula and impact the end with a Mallet to embed the Cannula Fins into the ilium. Continue impacting until the fins are fully engaged. Typically, an audible pitch change during impaction will indicate a fully seated cannula.

Note: Care should be taken to ensure that the impaction process does not change the trajectory of the either the guide pin or the working cannulas. The impaction is not always exactly perpendicular to the outer table of the ilium.

Step 3b
Stabilizing k-wire Insertion (Optional)

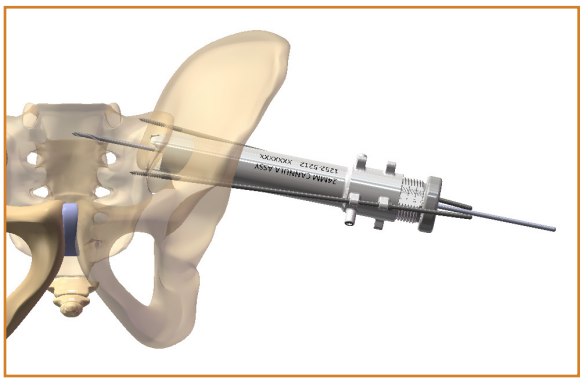
If desired, stabilizing k-wires may be utilized to increase the stability of the working Cannula. To insert, utilize a powered wire driver and insert the stabilizing k-wire through the desired guide slots on the Cannula until the shoulder is flush with the top of the guide holes. Up to four Stabilizing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

Note: It is recommended that two stabilizing wires 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.



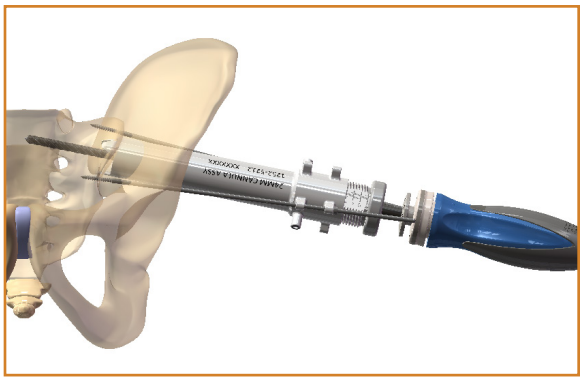
Step 4
Measure Implant Length

After removing the inner dilators, from the 24mm working Cannula, place the Depth Gauge over the K-wire so it is flush against the 24mm working Cannula. Read the length from the Gauge.



Step 5
12mm Sleeve Insertion

After removing the Dilators and while leaving the 3.2mm k-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.



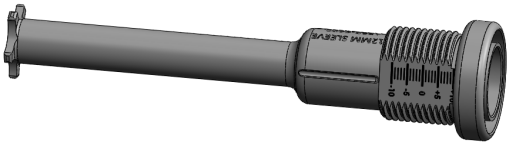
Step 6
Implant Inner Diameter Drill

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 k-wire advance to the desired depth. Ensure the Long 3.2mm k-wire remains in place.

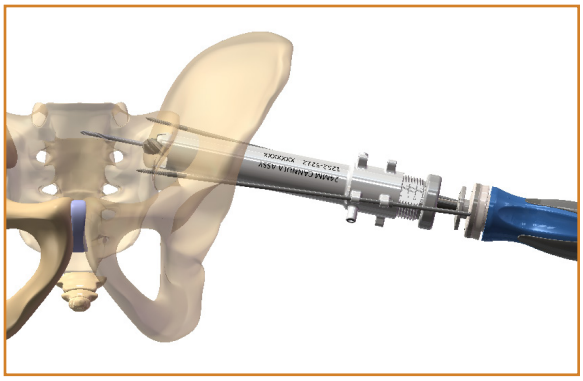
Length Gage



12mm Sleeve

Step 6b
Implant drill with Power adapter (Optional)

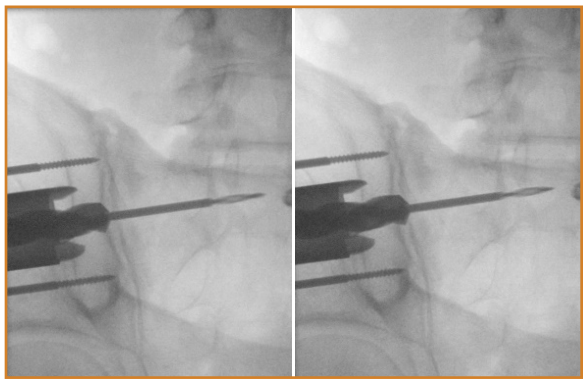
If desired, the Implant Drill may be connected into the power adapter and then power may be utilized to insert the Implant Drill to the correct depth. This is only recommended for experienced users.



12mm Drill trough 12mm Sleeve

Step 7
12mm Drill Insertion

Connect the 12mm Drill to the Inline Ratcheting Handle. After manually inserting the Drill over the 3.2mm k-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.



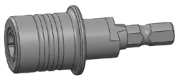
Note 12mm drill going just across the SI joint. Depth should be set once at the sacral side of the SI joint or just across it.

NOTE: 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.

NOTE: The 12mm Sleeve should now be adjusted to help prevent over penetration and plunging with subsequent preparation steps. (*See Step 8 for details.)*

NOTE: 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.

12mm Drill



Power Adapter

Step 7b
12mm Drill with Power (Optional)

If desired, the 12mm Drill may be connected to a powered hand-piece utilizing the Power Adapter. Take care not to over-drill the depth into the sacral ala. This is only recommended for experienced users.

12mm Sleeve adjustment

Step 8
12mm Sleeve Height Adjustment

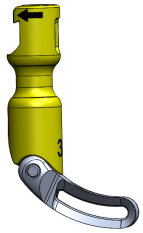
While the 12mm Drill is inserted to the appropriate depth, manually adjust the 12mm Sleeve by rotating it until the proximal surface is flush with the end of the Inline Ratcheting Handle or the Ratcheting T-handle. Rotate counterclockwise to increase the height of the sleeve, and clockwise to decrease 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.

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.

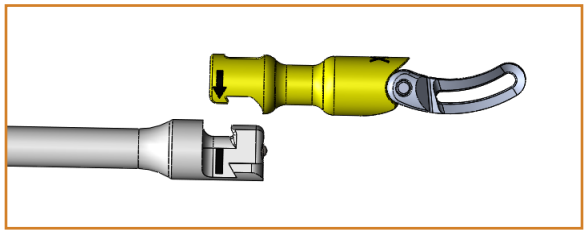
Note: Do not retract the 12mm Sleeve beyond the '-10mm' location.

Remove the 12mm Drill and long 3.2mm k-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.

Note: If the power adapter is utilized rather than the inline handle, then adjust the 12mm Sleeve height to be flush with the bold black line on the 12mm Drill shaft to set the hard stop depth.



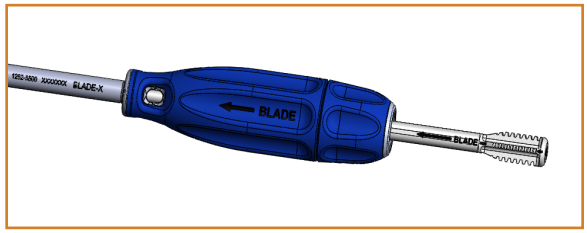
38mm Blade



Blade Connection

BladeX®

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".

Note: The BladeX blades are intended for single-use only.

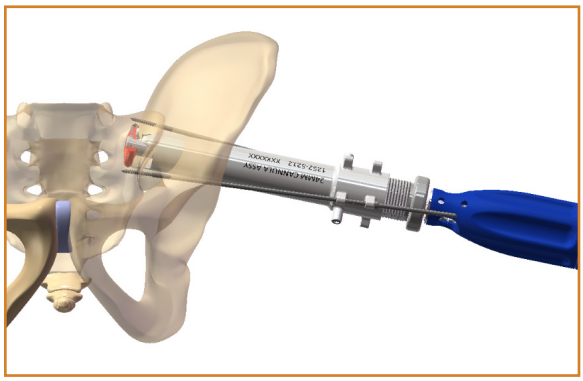
Note: When installing the Blade on the Central Shaft, be sure to orient the laser marks (→) as shown. The Blade will click into place when properly installed.

Note: 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.

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

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

BladeX Cutter showing blade deployed



BladeX Cutting

Step 10
Bone Resection using BladeX Instrument

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 11b for more detail).

Note: 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.

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.

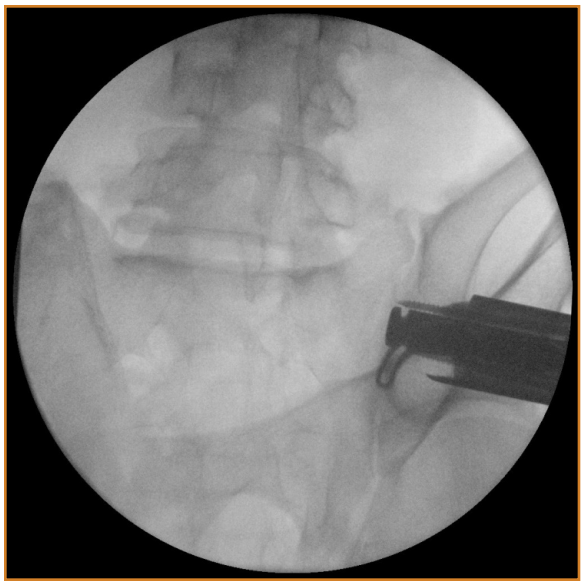
Note: The user may choose to cut less than the maximum diameter allowed by the chosen Blade size to accommodate patient anatomy based on preoperative templating.

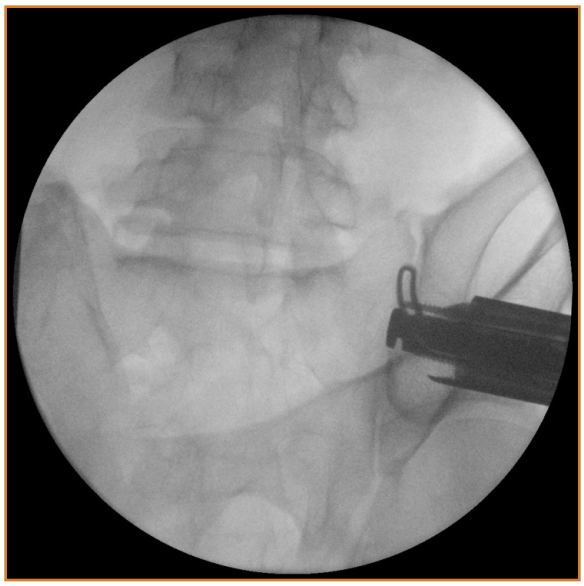
Note: When the Blade is fully deployed, the Knob will not allow more rotation as the Blade has reached the full travel.

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.





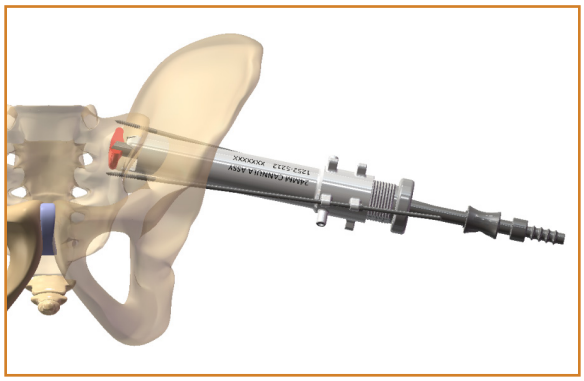
12mm Sleeve adjustment and Blade-X cutting

Step 11
Adjustment of BladeX Resection Depth (Optional)

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.

Note: Do not retract the 12mm Sleeve beyond the '-10mm' location and ensure that the BladeX handle remains in contact with the proximal surface of the 12mm Sleeve during cutting.

Note: 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 seating the cutter deeper or shallower.



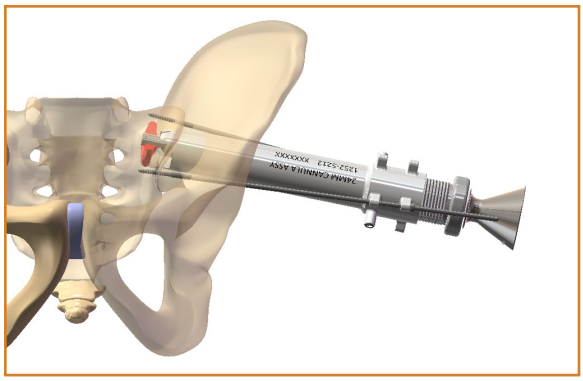
BladeX Cutting

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.

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 pin to unclog suction tubing if clogging occurs.



Graft Tube through 12mm Sleeve

Graft Tube

Graft Ram

Step 12
Allograft/Autograft Insertion

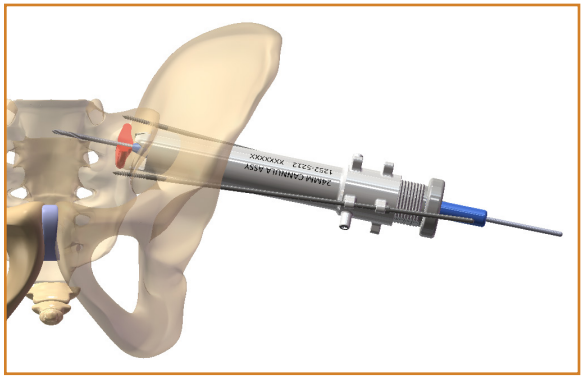
Load the Graft Inserter with the selected amount of allograft or autograft material.

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.



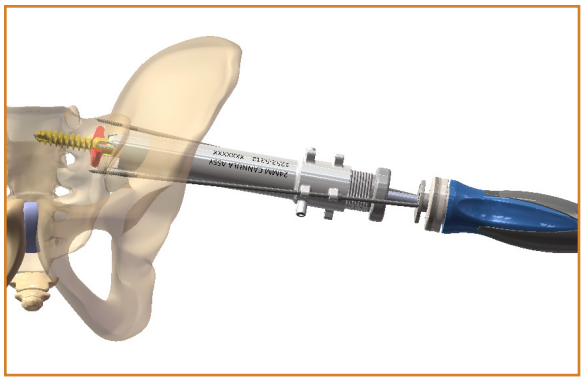
3.2mm Long k-wire insertion

Step 13
Long 3.2mm K-wire Re-Insertion

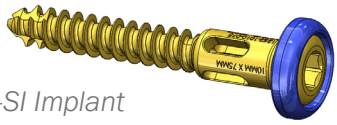
Re-insert the 12mm Dilator through the 12mm Sleeve. Insert the Long 3.2mm k-wire through the Dilator. Utilizing c-arm images, ensure the wire trajectory is correct and safe. Advance to the desired depth to match the initial guidewire placement depth. It is recommended to confirm placement with fluoroscopy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

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

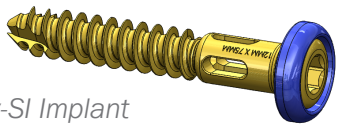
Note: This should follow the initial trajectory as long as the cannula has not shifted from decortication.



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 k-wire in place if the surgeon is planning on placing the biomechanical screw (anti-rotation screw).

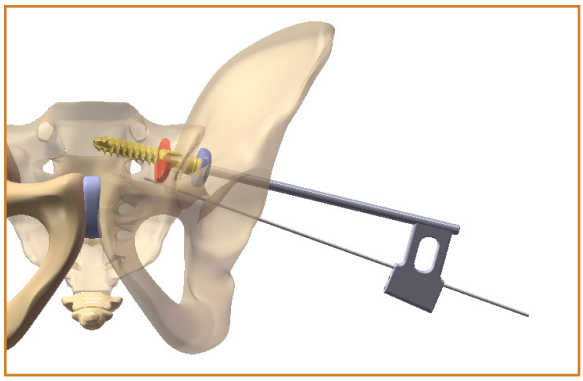
Note: The Large Hex Drive fits both the 10mm and 12mm Implants.

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.

Note: 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.

Optional Procedure:
6.5mm Biomechanical Screw

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



2.0 Wire Guide and 2.0mm

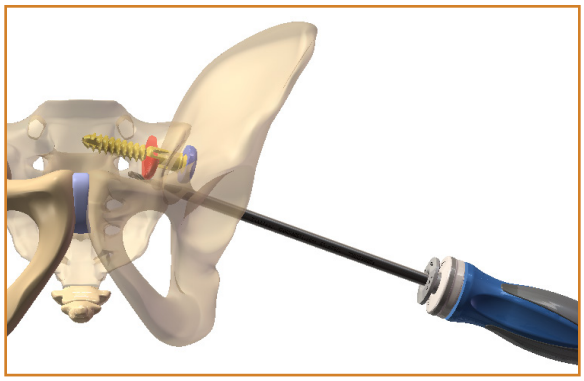
2.0mm Wire Guide

Step 15
2.0 Wire Insertion

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

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

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 on the outlet view.

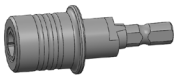


Step 16
6.5mm Biomechanical Screw Drill

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

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

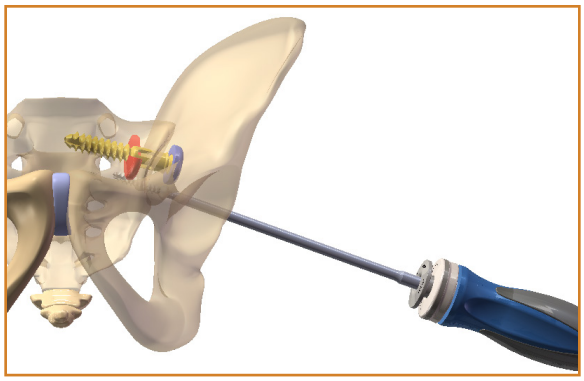
Note: Care must be taken to ensure the pin does not bind on the drill and come out. If this is noticed on the imaging, a 2nd pin can be used through the drill cannula to push out the pin to its original place. Often, simply drilling to the SI joint is far enough.



Power Adapter

Step 16b
6.5mm Biomechanical Screw drill with Power adapter (Optional)

If desired, the Biomechanical Screw Drill may be connected into the power adapter and then power may be utilized to insert the Biomechanical Screw Drill to the correct depth.

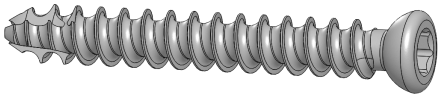


6.5mm Biomechanical Screw insertion

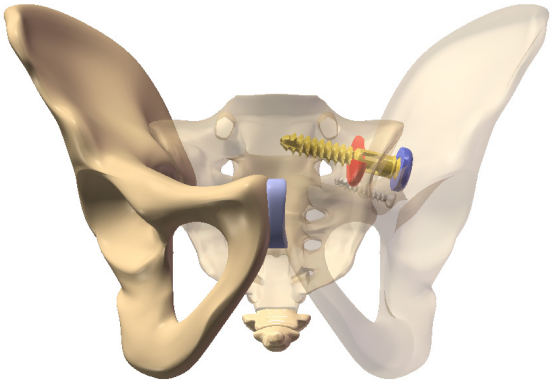
Step 17
6.5mm Biomechanical Screw Insertion

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

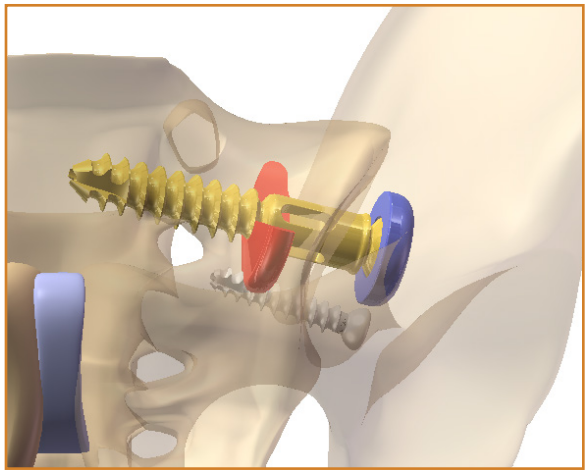
Note: Great care must be taken here to ensure that the guide pin does not inadvertently advance when inserting the screw. Following the screw advancement with fluoroscopic guidance is recommended with this step.



6.5mm Biomechanical Screw

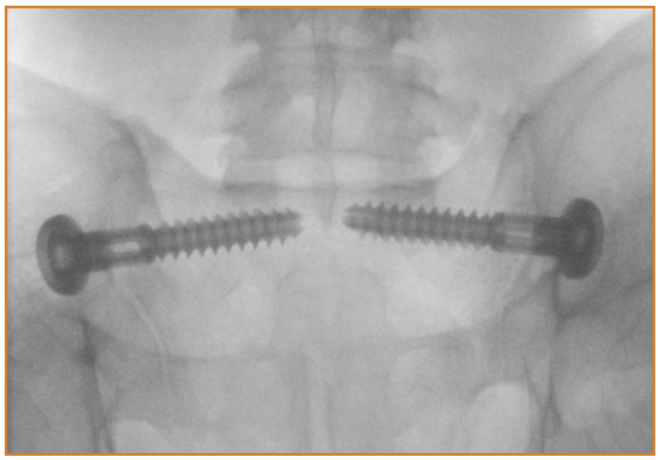


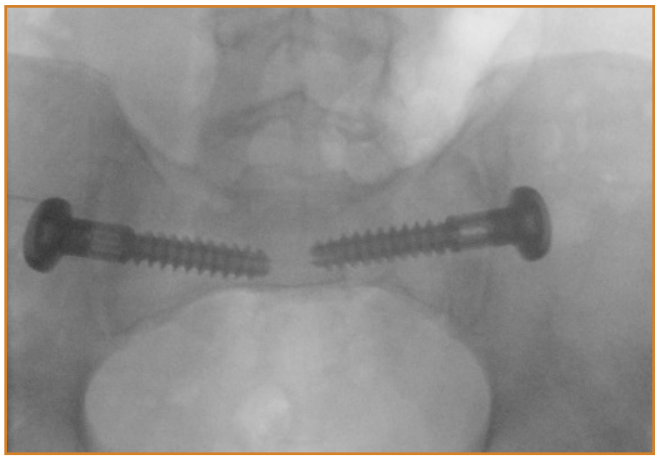
Ensure all instruments have been removed.



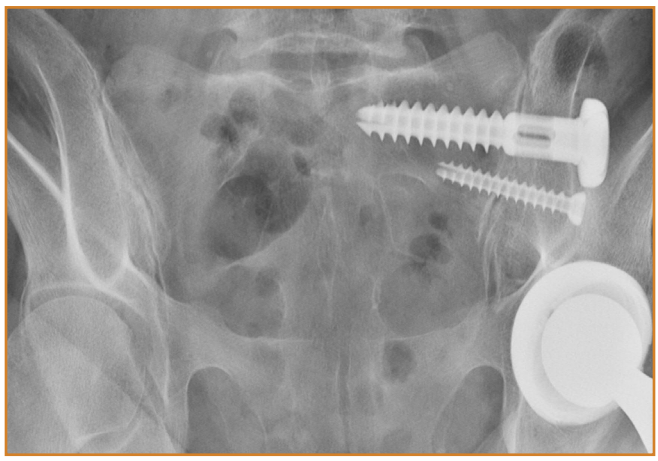
Installed Integrity-SI Implant and Biomechanical Screw

Examples

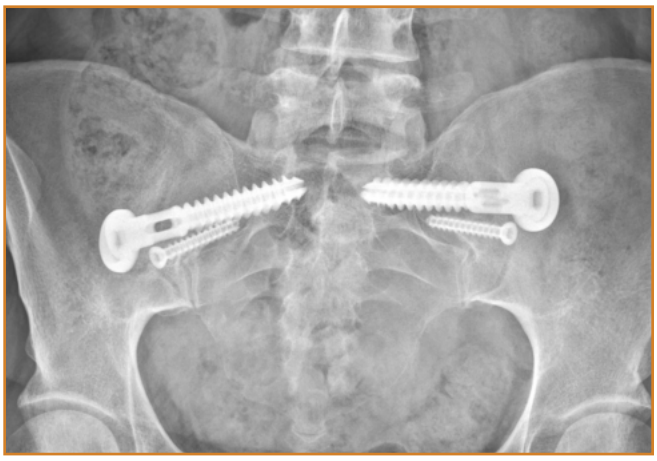


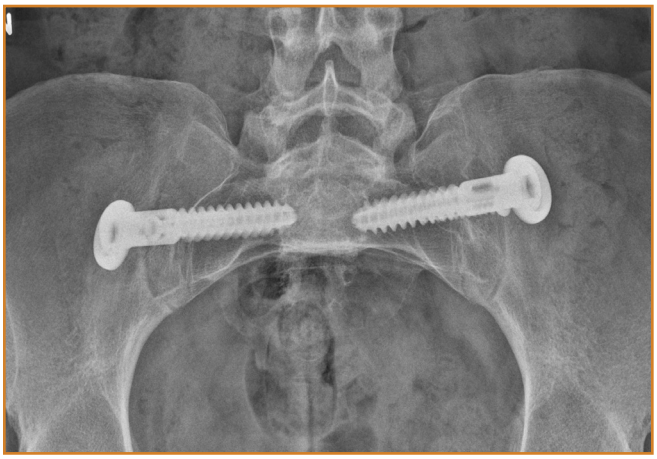


Example of patient with bilateral implants and no biomechanical screw.



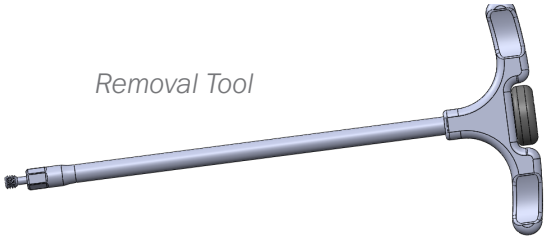
Example of patient with a unilateral implant with the additional biomechanical screw.





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

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.

Note: It is often helpful to re-cannulate the implant with the 3.2 mm k-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 k-wire, and replace with the Implant Removal Tool. At this stage, the hex removal tool can be used as described above.

Integrity-SI® Fusion System Instrument List

	Part number	Description
Cutter - BladeX®	1252-5500	BladeX Cutter
	1252-5510	Central Shaft
	1252-5520-232	Blade, 32mm
	1252-5520-238	Blade, 38mm
K-wires	1252-4100	2.0mm K-wire
	1252-4102-001	3.2mm K-wire - long
	1252-4102-002	3.2mm K-wire - short
	1252-4102-003	3.2mm K-wire - extra long
	1252-5103-000	3.2mm Stabilizing K-wire
Drill Bits	1252-4106	12mm Drill Bit
	1252-4107	7.5mm Drill Bit
	1252-4108	6.0mm Drill Bit
	1252-4109	4.0mm Drill Bit
Cannulas	1252-5212	24mm Cannula
12mm Sleeve	1252-4400	12mm Sleeve
Impactor	1252-4131	Impactor
Dilators	1252-4110	12mm Dilator
	1252-4120	18mm Dilator
	1252-4220	24mm Dilator
Implant Length Gauge	1252-5190-000	Implant Length Gauge
Graft Inserter	1252-5180-000	Graft Inserter
	1252-5186-000	Graft Inserter Ram
Hex Driver	1252-4140	Hex Driver - large
	1252-4135	Hex Driver - small
Removal tool	1252-5145-000	Removal Tool
Suction Tube	1252-5200-000	Suction Tube
2.0 Wire Guide	1252-5020-000	2.0 Wire Guide
Handles and Tray	1252-5260	Inline Ratcheting Handle
	1252-5265	Ratcheting T-Handle
	1252-5250	Power Adapter
	1252-6000	Instrument Tray
	1252-6001	Implant and Blade Tray

Integrity-SI Fusion System Implant List

	Part number	Length (mm)
12mm Anodized SI Implants	1252-1012-040	40
	1252-1012-045	45
	1252-1012-050	50
	1252-1012-055	55
	1252-1012-060	60
	1252-1012-065	65
	1252-1012-070	70
	1252-1012-075	75
	1252-1012-080	80
	1252-1012-085	85
	1252-1012-090	90
	1252-1012-095	95
	1252-1012-100	100
	1252-1012-105	105
	1252-1012-110	110
10mm Anodized SI Implants	1252-1010-040	40
	1252-1010-045	45
	1252-3110-050	50
	1252-1010-055	55
	1252-1010-060	60
	1252-1010-065	65
	1252-1010-070	70
	1252-1010-075	75
	1252-1010-080	80
	1252-1010-085	85
	1252-1010-090	90
	1252-1010-095	95
	1252-1010-100	100
	1252-1010-105	105
	1252-1010-110	110
Optional 6.5mm Biomechanical Screw	1252-0006-030	30
Note: The 6.5mm Screw	1252-0006-035	35
can only be used in conjunction	1252-0006-040	40
with a primary 10mm or 12mm screw.	1252-0006-045	45
	1252-0006-050	50
	1252-0006-055	55
	1252-0006-060	60
	1252-0006-065	65
	1252-0006-070	70

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SP-002-LBL-0004 Rev 5