SURGICAL TECHNIQUE

EVOLSI®

Sacroiliac Joint Fusion System

By Cutting Edge Spine
Distributed By Precision Spine

PRECISION SPINE®

Discover the Difference

Made in the USA

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EVOL® SI System Overview

DEVICE DESCRIPTION

The EVOL-SI Joint Fusion System is intended to treat dysfunctions of the sacroiliac joint. It includes titanium alloy screws and optional washers as well as a full complement of instruments to place them in the body. The basis of the implant design is a bone screw with a poly-axial washer. It is designed to cross the sacroiliac joint anchoring the sacrum to the pelvis thereby preventing motion of the sacroiliac joint. Screws and Washers are made from a titanium alloy Ti-6Al-4V ELI per ASTM F136-13. Each screw is treated with a hydroxyapatite (HA) surface treatment that is approximately 20 nanometers thick.

INDICATIONS

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

Please refer to package insert for complete system description, indications and warnings.

DESIGN FEATURES

CANNULATED
Provides ability to use a guide wire for more accurately placed screws.

FENESTRATED
Provides ability to place autograft and/or allograft within the screw to increase the opportunity for fusion.

OPEN BODY CANNULATION
Allows more bone graft within the screw.

DOUBLE LEAD THREAD
Lessens the time required to place screw.

TWO THREAD REGIONS
Cortical thread for purchase in ilium; Cancellous thread for purchase in sacrum.

HA*nano* SURFACE TREATMENT
Crystalline HA, all the benefits of conventional HA without the thickness.

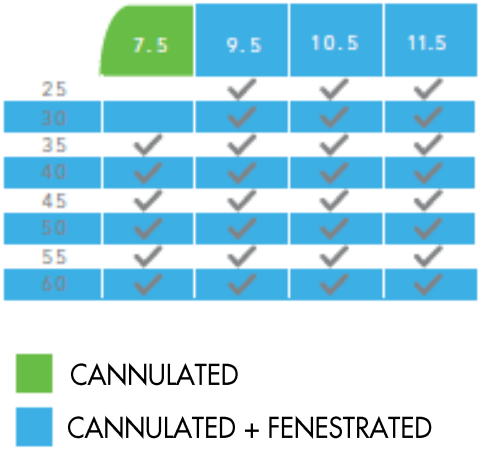
WASHER
Distributes load about a larger area of the pelvis.

CONICAL THREAD CONNECTION TO DRIVER
Provides paramount trajectory control over screw during insertion as well as unprecedented tactile feedback.

SELF-TAPPING FLUTES
Allows user to skip tapping step.

WIDE VARIETY OF SIZES AVAILABLE*
30 different sizes available from 7.5x35mm to 11.5x60mm

***Some sizes may require advance orders**



INSTRUMENTS

CES-284 – 2.4mm Sharp, Short, 350mm K-Wire

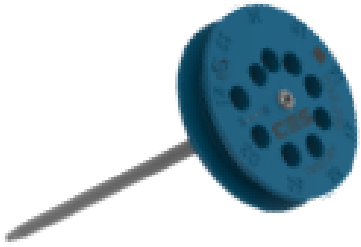
CES-285 – 2.4mm Sharp, Long, 480mm K-Wire

CES-286 – 2.4mm Blunt, Long, 480mm K-Wire

CES-287 – Fixed Wire Guide, 14mm

CES-288 – Fixed Wire Guide, 17mm

CES-289 – Fixed Wire Guide, 20mm



CES-290 – Adjustable Wire Guide

CES-290-02 – Second Wire Guide
(Removable component of the Adjustable Wire Guide)

CES-291 – Depth Gauge

CES-292 – Dilator

CES-293 – Fixed Port, 22 x 100mm

CES-294 – Fixed Port, 22 x 140mm

INSTRUMENTS
(CONTINUED)

CES-302 – 7.5mm Cannulated Drill

CES-304 – 9.5mm Cannulated Drill

CES-305 – 10.5mm Cannulated Drill

CES-306 – 11.5mm Cannulated Drill

CES-312 – 7.5mm Cannulated Tap

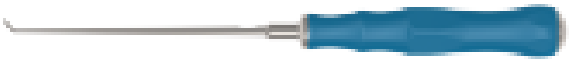
CES-314 – 9.5mm Cannulated Tap

CES-315 – 10.5mm Cannulated Tap

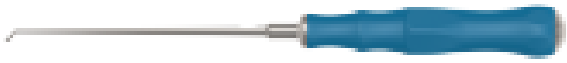
CES-316 – 11.5mm Cannulated Tap

CES-323 – T40 Cannulated Screw Driver

CES-324 – T40 Solid Screw Driver*
*Additionally available



CES-326 – Up-biting Curette



CES-327 – Down-biting Curette

CES-332 – Large Insertion Sleeve

CES-336 – Bone Funnel

CES-337 – Bone Pusher

CES-342 – 2.4mm Temporary K-Wire

INSTRUMENTS
(CONTINUED)

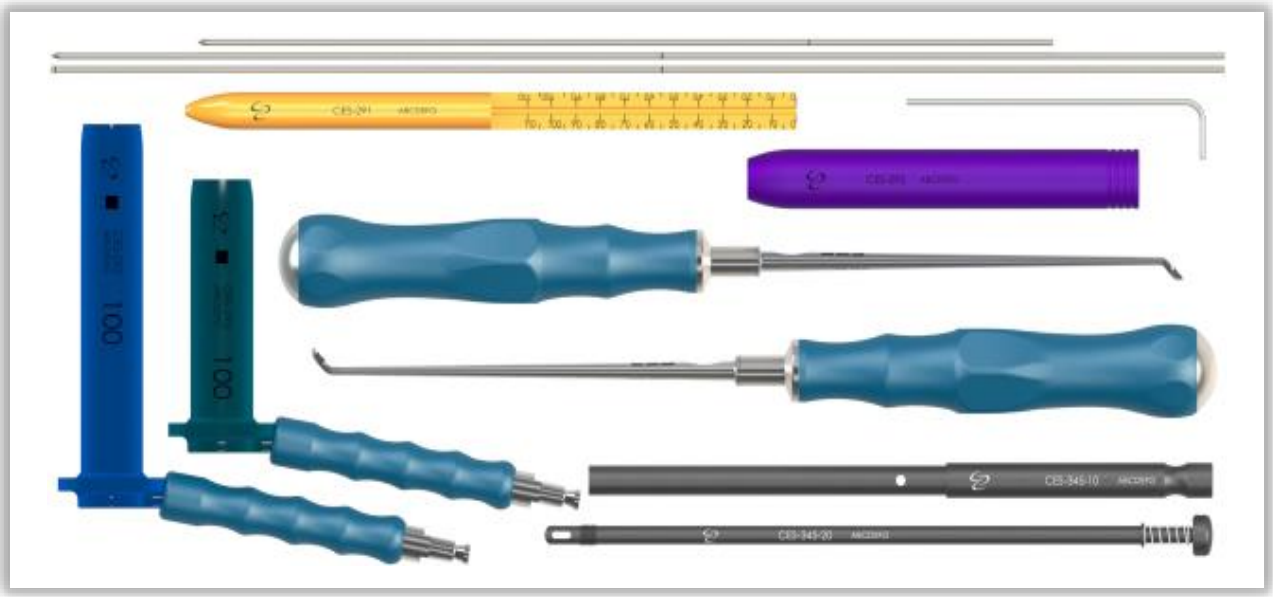
CES-345 – Radiolucent Wire Clamp

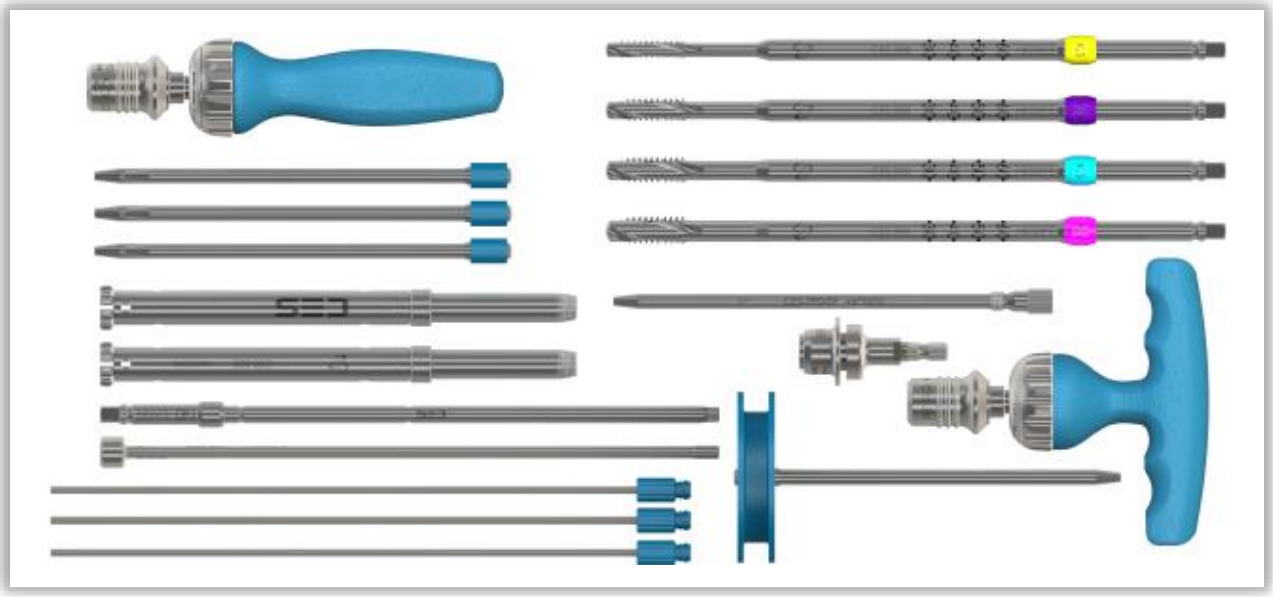
CES-351 – T-Handle, Ratchet, ¼" Square

CES-352 – Axial Handle, Ratchet, ¼" Square

CES-353 – Power Adaptor, ¼" Square to Jacobs Chuck

INSTRUMENT CASES





IMPLANT & ACCESSORY PART NUMBERS

Part #	Description
5002-035T	7.5mm x 035mm EVOL®SI Screw
5002-040T	7.5mm x 040mm EVOL®SI Screw
5002-045T	7.5mm x 045mm EVOL®SI Screw
5002-050T	7.5mm x 050mm EVOL®SI Screw
5002-055T	7.5mm x 055mm EVOL®SI Screw
5002-060T	7.5mm x 060mm EVOL®SI Screw
5004-025T	9.5mm x 025mm EVOL®SI Screw
5004-030T	9.5mm x 030mm EVOL®SI Screw
5004-035T	9.5mm x 035mm EVOL®SI Screw
5004-040T	9.5mm x 040mm EVOL®SI Screw
5004-045T	9.5mm x 045mm EVOL®SI Screw
5004-050T	9.5mm x 050mm EVOL®SI Screw
5004-055T	9.5mm x 055mm EVOL®SI Screw
5004-060T	9.5mm x 060mm EVOL®SI Screw
5005-025T	10.5mm x 025mm EVOL®SI Screw
5005-030T	10.5mm x 030mm EVOL®SI Screw
5005-035T	10.5mm x 035mm EVOL®SI Screw
5005-040T	10.5mm x 040mm EVOL®SI Screw
5005-045T	10.5mm x 045mm EVOL®SI Screw
5005-050T	10.5mm x 050mm EVOL®SI Screw
5005-055T	10.5mm x 055mm EVOL®SI Screw
5005-060T	10.5mm x 060mm EVOL®SI Screw
5006-025T	11.5mm x 025mm EVOL®SI Screw
5006-030T	11.5mm x 030mm EVOL®SI Screw
5006-035T	11.5mm x 035mm EVOL®SI Screw
5006-040T	11.5mm x 040mm EVOL®SI Screw
5006-045T	11.5mm x 045mm EVOL®SI Screw
5006-050T	11.5mm x 050mm EVOL®SI Screw
5006-055T	11.5mm x 055mm EVOL®SI Screw
5006-060T	11.5mm x 060mm EVOL®SI Screw
CES-284	EVOL®SI, 2.4mm x 350mm Sharp, Short K-Wire
CES-285	EVOL®SI, 2.4mm x 480mm Sharp, Long K-Wire
CES-286	EVOL®SI, 2.4mm x 480mm Blunt, Long K-Wire
CES-299	EVOL®SI, Steinmann Pin, Stackable Blunt End, 2.4 x 250mm
CES-298	EVOL®SI, Steinmann Pin, Stackable Trocar, 2.4 x 350mm

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1 PREOPERATIVE PLANNING

Ensure that adequate imaging is available. This procedure should not be performed if one cannot obtain clear imaging. It is essential to have a Lateral image of the sacrum with a clear, distinct sacral alar line (Figure 1), an Inlet view of the pelvis with distinct anterior margin of the sacrum and an Outlet view of pelvis with clearly-defined S1 pedicles and S1, S2 neuroforamina.

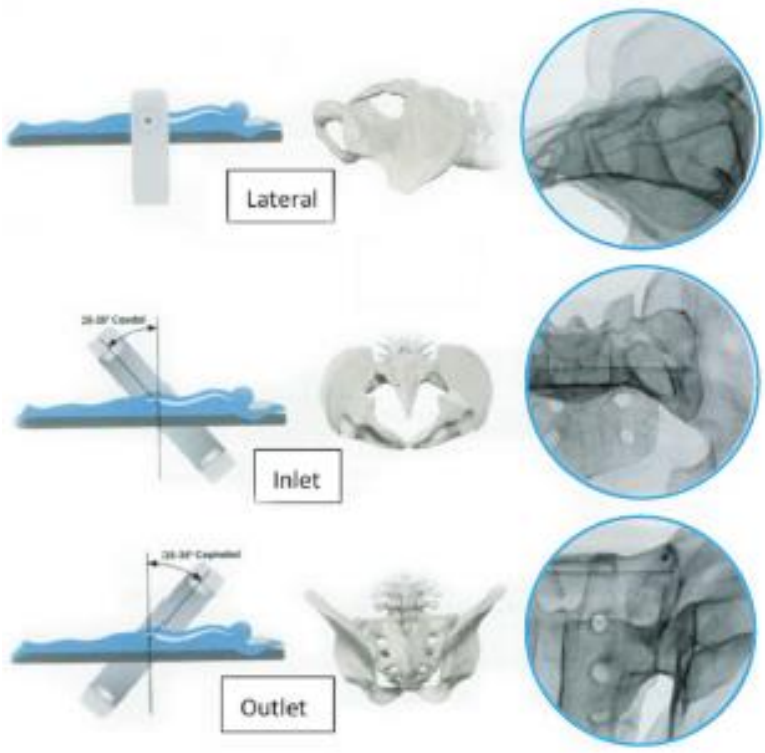

Figure 1

2 POSITION PATIENT

Position the patient in the prone position as shown in Figure 2.

Figure 2

3 LANDMARK IDENTIFICATION

Once the patient is safely positioned, use fluoroscopic imaging to ensure that Inlet, Outlet and Lateral sacral views can be obtained.

In a Lateral view of the sacrum, ensure that a clear, crisp sacral alar line is visible. If there is rotation, adjust either the patient or the bed to get a good Lateral view. This is preferable to adjusting the lateral off-axis.

Place a K-Wire over the skin using the Radiolucent Wire Clamp at approximately the posterior border of the sacrum (Figure 3). Confirm with a Lateral view of the sacrum.

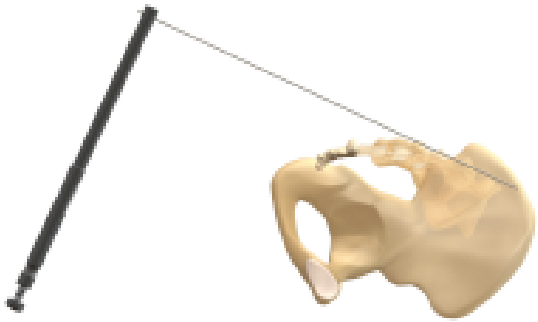

Figure 3

SURGICAL TECHNIQUE

3 LANDMARK IDENTIFICATION (continued)

It is often helpful to drop a "plumb" line by holding a K-Wire by its tip and letting it hang by gravity toward the floor. Take a Lateral image and rotate that image so that the K-Wire now shows true vertical. This will assist in making adjustments during placement of K-Wire.

MARK SKIN

Utilizing a skin marker, trace the posterior border of the sacrum on the patient's skin. Next, move the K-Wire over the sacral alar line and mark this trajectory on the skin. It should intersect with skin marking for the posterior sacrum.

INCISE SKIN

The skin incision should extend from this intersection point, distally along the posterior sacral trajectory line approximately 3-4cm (Figure 4). This incision may be adjusted depending on patient body habitus requirements or surgeon preference.

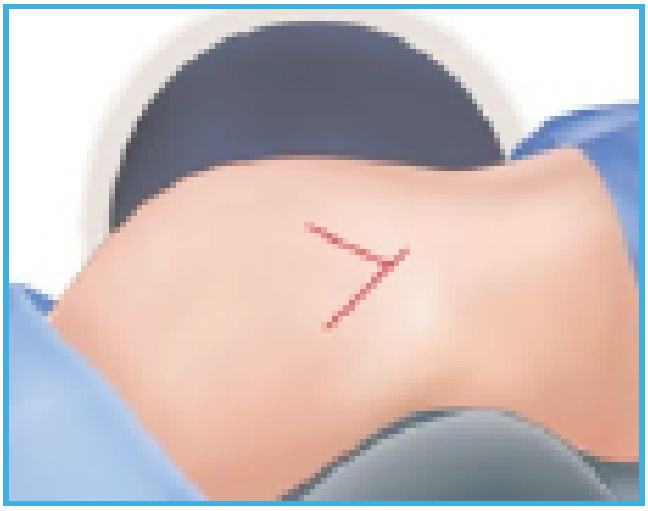

Figure 4

Dissect to the level of the gluteal fascia. If needed, place a K-Wire over your exposed gluteal fascia and utilize Lateral fluoroscopic imaging to confirm that your fascial incision is centered over the posterior aspect of sacrum.

Dissect through the gluteal musculature to the lateral ilium. Confirm correct trajectory with direct manual palpitation.

Once the outer table of the ilium is encountered, place a sharp K-Wire on the ilium at the desired entry point and take a Lateral fluoroscopic image.

NOTE: The following technique is for a "lateral" trajectory approach to the SI joint. If a more perpendicular approach is desired, wires can be placed at a starting point and trajectory per surgeon preference, as long as the same radiographic landmarks are utilized for safe wire placement as outlined in Step 4.

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4 PLACE INITIAL K-WIRE

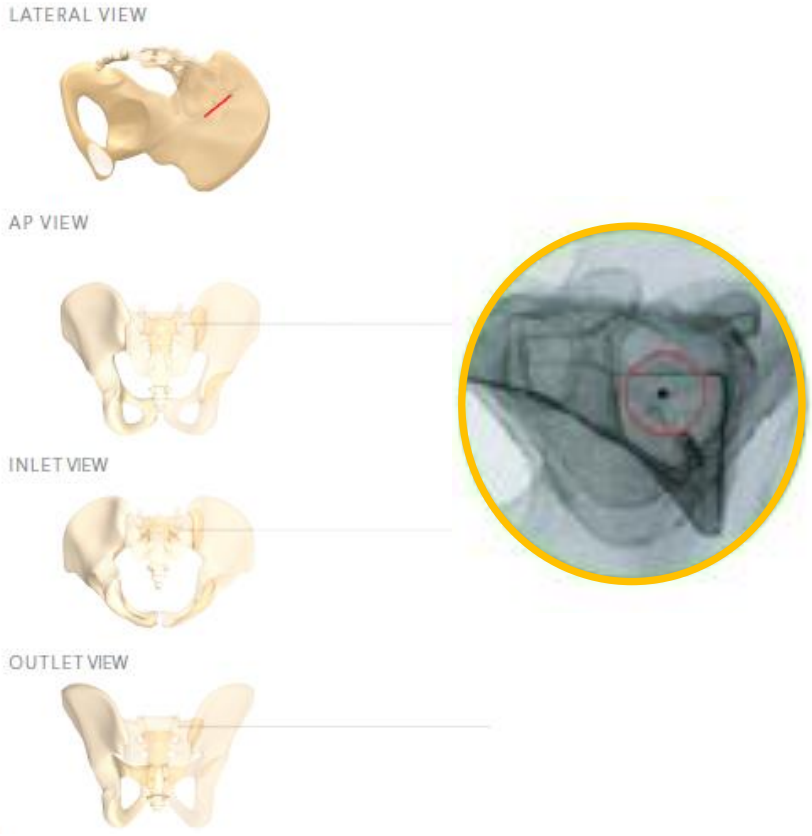
The ideal starting point for a first wire in the lateral trajectory approach is caudal to the sacral alar line, and in the mid to posterior ½ of the sacral body in the S1 segment.

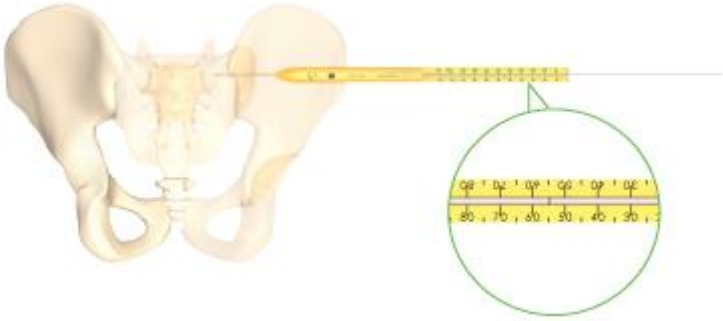
While holding the wire over the desired entry point, have fluoroscopy move to an Inlet and subsequent Outlet position. On an Inlet view, the trajectory of the wire should be towards the mid sacral body. On an Outlet view, it should be parallel to the S1 superior endplate. The wire can be advanced with power or by mallet*.

*Make any adjustments in trajectory PRIOR to advancing the wire; attempts to make adjustments after initial entry may result in bending the wire and potential hardware complication and/or patient injury.

Advance the K-Wire across the sacroiliac joint and into the sacrum with frequent fluoroscopic imaging until the surgeon's desired stopping point is achieved.

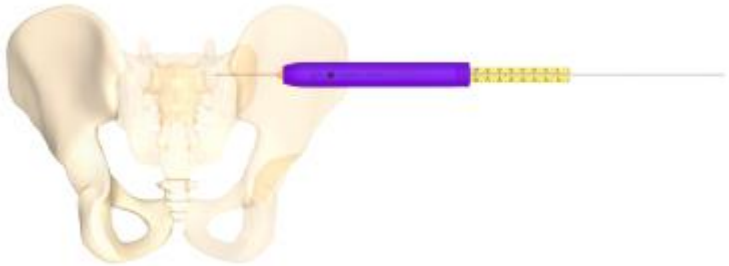
Once the K-Wire is placed to surgeon preference, a Lateral image should be taken to ensure the starting point is below the sacral ala.





5 DILATE AND DETERMINE SCREW LENGTH

Place the Depth Gauge over the K-Wire up to the ilium and use the mark on the K-Wire to indicate the appropriate screw length. Make adjustments to chosen length based on the desired stopping point of the screw.



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6 DILATE TISSUE

Insert the Dilator followed by the 100mm or 140mm Fixed Port into the soft tissue (Figure 4). If desired, attach the Fixed Port to a Table Clamp via the Hudson Connector on the handle.

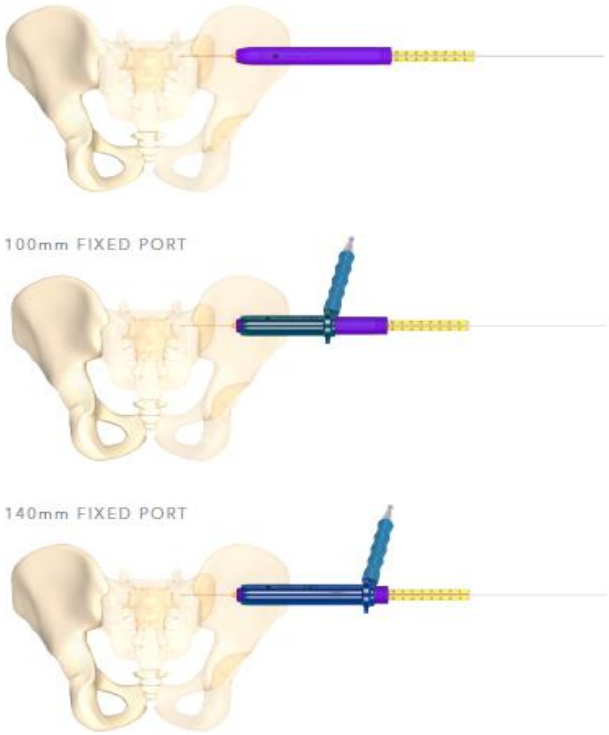

Figure 4

7 DRILL

Utilizing Inlet and Outlet views, advance the drill up to and just past the SI joint, with the goal being to decorticate the far side of the joint (near cortex of the sacrum) (Figure 5).

BE SURE THE WIRE DOES NOT ADVANCE!
If it is advancing, either adjust trajectory to ensure the wire and drill are in-line or remove and exchange the sharp wire for a long, blunt wire which can be held by an assistant to ensure it does not advance.

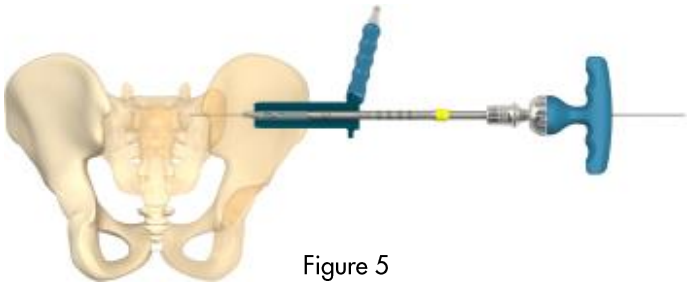

Figure 5

8 PLACE BONE GRAFT (AUTOGRAFT AND/OR ALLOGRAFT) IN SCREW

Place the Temporary K-Wire inside the cannula of the screw to maintain a clear path for the K-Wire during screw insertion (Figure 6). Salvage bone from the flutes of the drill with a small curette and place it into the cross holes.

NOTE: The Threads around the slots can be sharp. Use caution when handling the screw.

Figure 6

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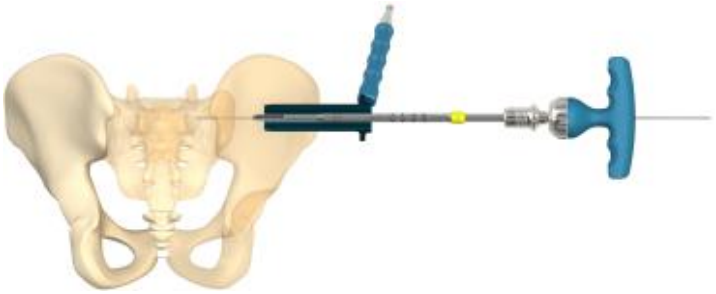
9 PREPARE JOINT SURFACES

Remove the K-Wire for SI joint decortication. Utilize fluoroscopy to ensure the curette is in the SI joint and carefully decorticate the ilium and sacrum circumferentially. Replace the K-Wire. Use the tip of the Depth Gauge to locate the hole if necessary.

10 TAP (OPTIONAL)

If hard bone is encountered, tapping is recommended for the ilium. Tapping the sacrum is generally not necessary and may diminish the purchase strength of the screw.

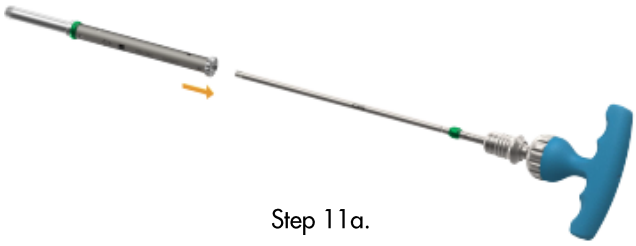


11 IMPLANT SCREW

While preparing the joint surface, a surgical assistant can prepare the screw on the screwdriver.

11a. LOAD THE INSERTION SLEEVE ONTO THE SCREW DRIVER

Push the appropriate size Insertion Sleeve onto the screw driver until it snaps into the groove.



Step 11a.

11b. LOAD THE SCREW ONTO THE INSERTION SLEEVE

1. Place the screw on the hexalobe driver.
2. Turn the knob clockwise to secure the screw. **Do NOT overtighten!**

NOTE: The threads around the slots can be sharp. Use caution when handling the screw.

Step 11b.

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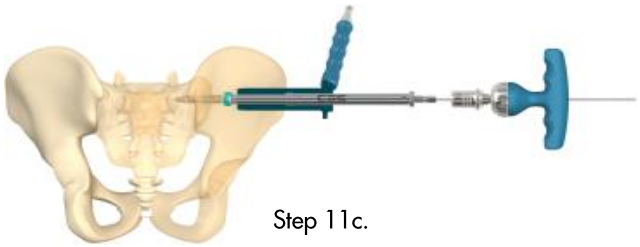
11 IMPLANT SCREW (continued)

11c. IMPLANT SCREW

Take care while placing the screw not to advance the K-Wire. If needed, take periodic fluoroscopic imaging.

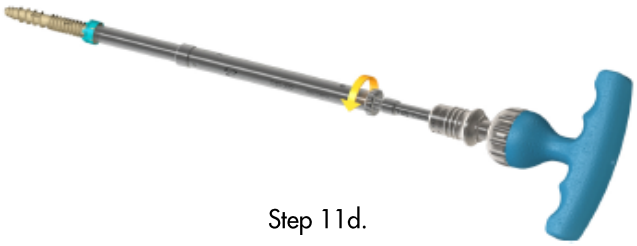
The screw should be advanced until the washer gains purchase into the outer border of the ilium. Take care to ensure the screw head does not advance into the ilium.



Step 11c.

11d. UNTHREAD THE INSERTION SLEEVE FROM THE SCREW

Hold the screwdriver and turn the knob on the Insertion Sleeve counterclockwise.



Step 11d.

12 USING WIRE GUIDES

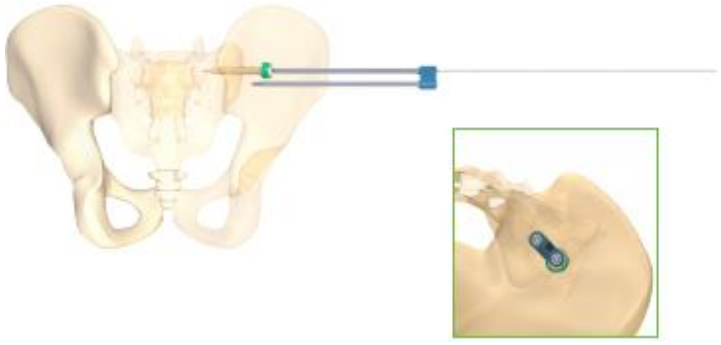
Choose one of the Drill Guides based on the screw diameter chosen and the spacing desired.

Screw Size	Min Screws Distance	Min Fixed Guide
7.5	14	14
9.5	15	14
10.5	16	17
11.5	17	17

(Option A) USING THE FIXED WIRE GUIDE TO PLACE SECOND K-WIRE

Place the short tube of the guide over the existing K-Wire and rotate the guide along the trajectory of the sacrum for placement of the second wire. Place the second K-Wire through the guide onto the surface of the ilium.

Advance the K-Wire across the sacroiliac joint and into the sacrum with frequent fluoroscopic imaging in both Inlet and Outlet views until the surgeon's desired stopping point is achieved.



(Option A)

12 USING WIRE GUIDES (continued)

(Option B)

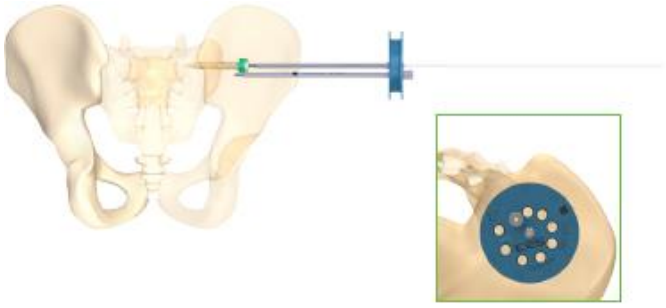
USING THE ADJUSTABLE WIRE GUIDE TO PLACE SECOND K-WIRE

The Adjustable Wire Guide provides more choices for spacing of the K-Wire. This may be advantageous in situations where: there is only sufficient sacrum for two screw purchase and maximum spread of screws is desired, or for surgeon preference in screw placement.

Place the center tube of the guide (with the disc) over the existing K-Wire.

The radiopaque markers (13-21) can be used to determine screw spacing. A Lateral image must be perfectly aligned along the axis of the first K-Wire to do so. Otherwise, the distance will be distorted.

Determine the appropriate spacing, rotate the appropriate hole into position and thread the Second Wire Guide into the hole. Place the second K-Wire through the Second Wire Guide onto the surface of the ilium. Advance the K-Wire across the sacroiliac joint and into the sacrum with frequent fluoroscopic imaging in both Inlet and Outlet views until the surgeon's desired stopping point is achieved.



(Option B)

13 ADDING AUTOGRAFT AND/OR ALLOGRAFT AFTER IMPLANTATION (OPTIONAL)

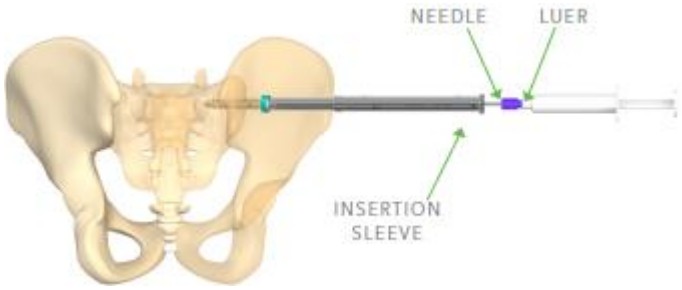
Once the K-Wire for the next screw is placed, additional autograft and/or allograft can be added to the screw if desired.

(Option A)
USING THE BONE FUNNEL

This option is intended for autograft and/or allograft materials that can flow through an 11 Gauge Needle.

A1. Reinsert the Insertion Sleeve into the screw head without the Screwdriver Shaft.
A2. Remove the K-Wire.
A3. Attach the Bone Funnel to your desired autograft and/or allograft material syringe using the Luer connector.
A4. Place the Bone Funnel through the Insertion Sleeve and into the screw.
A5. Dispense the desired amount of material. *The 2.4mm Blunt K-Wire can be used to clear the Bone Funnel of material. A full Bone Funnel contains approximately 1.25cc's of material.

CAUTION: DO NOT FORCE THICK MATERIALS THROUGH BONE FUNNEL. THE CONNECTION MAY DISCONNECT ABRUPTLY.

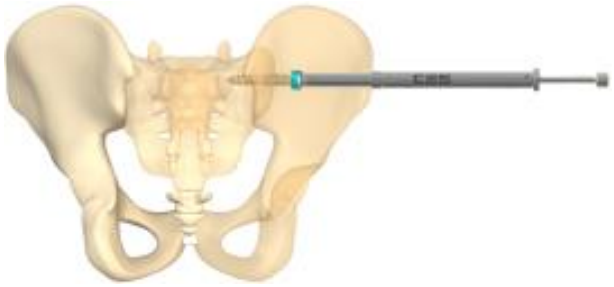


(Option A)

(Option B)
USING THE BONE PUSHER

This option is intended for autograft and other thicker allograft materials.

B1. Reinsert the Insertion Sleeve into the screw head without the Screwdriver Shaft.
B2. Remove the K-Wire.
B3. Place desired bone graft material into the Insertion Sleeve.
B4. Pack material into the screw using the Bone Pusher.



(Option B)

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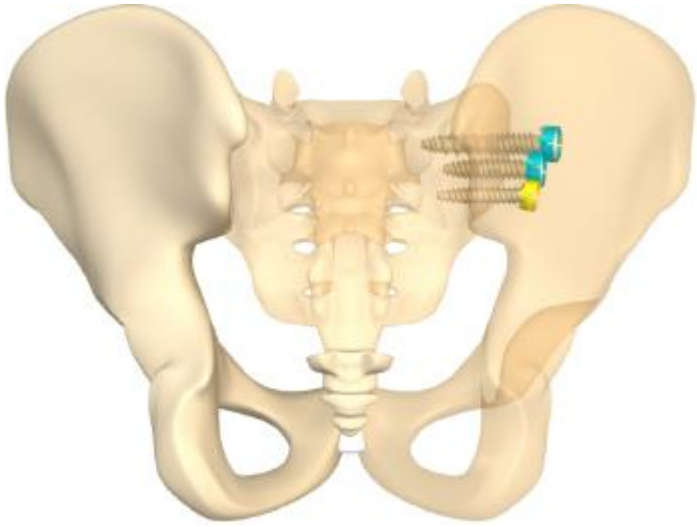
14 SECOND SCREW PLACEMENT

Repeat Steps 2-9. Frequent Fluoroscopic imaging will confirm safe placement of screws without wire migration. Generally, the second screw is in the S1 or S2 segment.

15 THIRD SCREW PLACEMENT

Repeat Steps 2-9. Take care to note the anterior-posterior thickness of the sacrum in the region of the starting point and desired ending point of the screw. If the sacrum is diminutive, consider a smaller-diameter screw or a two-screw construct, to avoid a situation of placement through ilium and missing sacrum, sacral canal violation or incomplete sacral purchase.



16 CONFIRM FINAL SCREW PLACEMENT

Final Inlet, Outlet and Lateral sacral views should be obtained to confirm acceptable screw placement. Additionally, 45-degree oblique views through SI joint can be obtained, if desired.

ADDITIONAL CONSIDERATIONS

If advanced imaging is not available, a CT scan through the pelvis prior to patient discharge is recommended to ensure acceptable placement of hardware. Other adjunctive considerations would be neuromonitoring.

17 HARDWARE REMOVAL OR REVISION

If required to remove or revise hardware, advance imaging (Computed Tomography) is recommended pre-operatively along with careful surgical planning. It is possible to have a screw loose in the sacrum and well-fixed in the ilium. Screws are removed by placing a blunt K-Wire inside the screw to be removed, followed by attachment of the screw driver and removal of the screw with the driver in reverse. If the screw does not easily remove from the ilium, adjunctive procedures to remove the screw may be necessary. After removal, Screw replacement, bone grafting or other fixation will be determined by clinical indication and surgeon preference.

(OPTIONAL SCREW REMOVAL)

Use the non-cannulated screw driver, which is available upon request.

INDICATIONS FOR USE

CONTRAINDICATIONS:

Contraindications for the EVOL®SI Joint Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple uses.

WARNINGS & PRECAUTIONS:

The following are warnings for this device.

1. The EVOL-SI Joint Fusion devices are provided STERILE packaged. Do not use if package has been opened, damaged or if the expiration date has passed. The EVOL-SI Joint Fusion device is intended for SINGLE USE ONLY.

2. The EVOL-SI Joint Fusion System components should not be used with components from another system or manufacturer.

3. As with any surgical system, the EVOL-SI Joint Fusion System should be used by experienced surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

4. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

5. Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

6. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

7. As with all orthopedic and neurosurgical implants, none of the EVOL-SI Joint Fusion System devices should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

8. Due to the presence of implants, interference with roentgenographic, C T and/or MR imaging may result. The EVOL-SI Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. The EVOL-SI Joint Fusion System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and neither Cutting Edge Spine nor Precision Spine can make any claims regarding the safety of Cutting Edge Spine implants and devices with any specific MR system.

9. Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

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Caution: Federal (USA) law restricts these devices to sale by, or on the order of, a physician.
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 P/N LBL-STG-046 Rev. A 08/2020