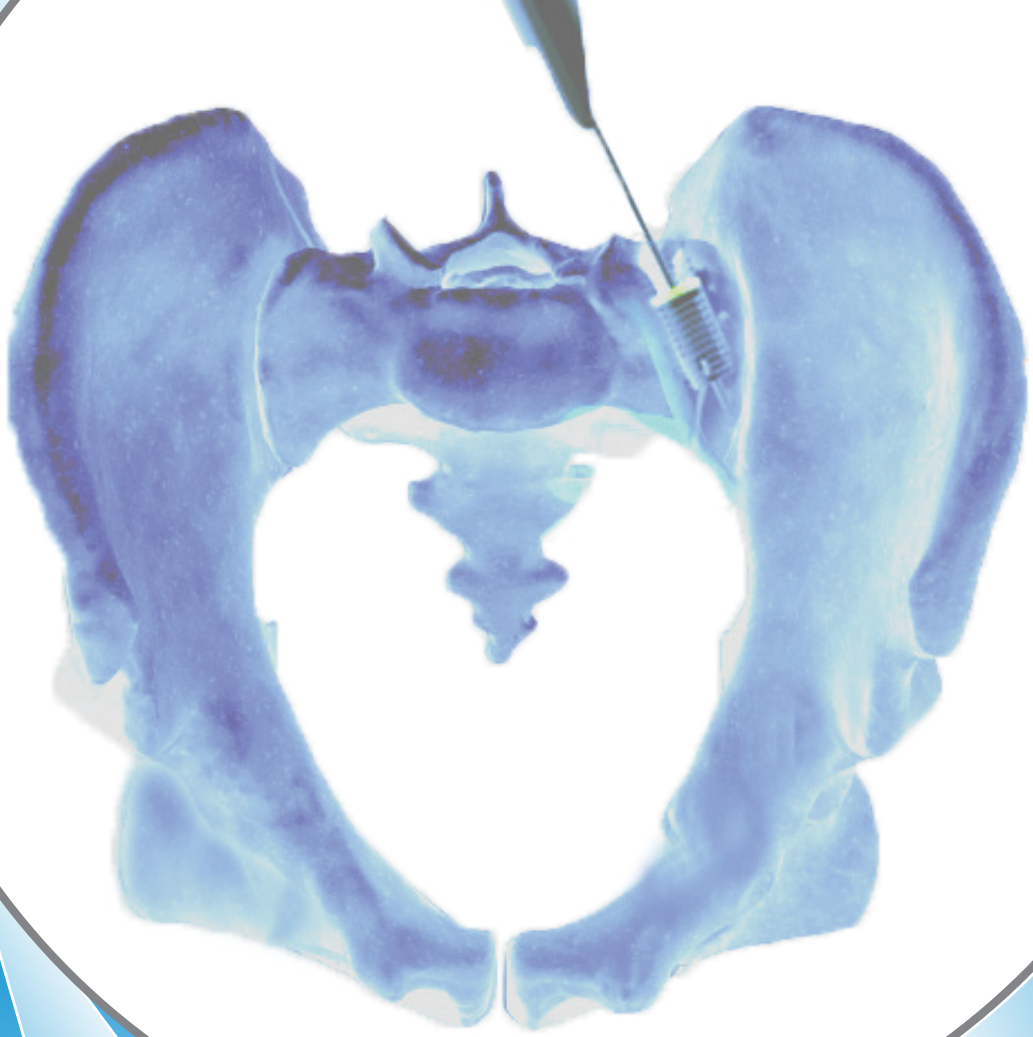

NADIA®

SURGICAL MANUAL
NEUROSAFE® SACROILIAC FUSION

ILIONMEDICAL

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AN INVITATION TO A CHALLENGING PROBLEM

The sacroiliac joint (SIJ) remains a lingering challenge in spine surgery. The involvement of the SIJ in low back complaints has been suspected for many years. It was not until recently, that the means of diagnosis and more effective treatment have made it clear that the SIJ is a significant pain generator which often mimics the pain of the hip or spine. Failure to recognize the SIJ as the clinical problem will result in misdiagnosis, poor results of otherwise successful regional surgery. For these reasons, the NADIA method of bridging the painful SIJ has been developed.

DIAGNOSIS

The diagnosis of sacroiliac disease is established by a process of inclusion (sacroiliac-type findings such as regional posterior hemipelvic pain and imaging changes), and exclusion (ruling out similar complaints of pain of the hip or spine).

PAIN GENERATOR

The pain of the sacroiliac joint is most well understood as following an osteoarthritis model. The great majority of painful sacroiliac joints demonstrate visible manifestations of degenerative change including cartilage loss, sclerosis, and osteophyte formation. Subluxation, osteophyte formation, and capsular distention may compress the nerves or cause irritation of the overlying lumbar plexus. These symptoms often resemble radicular symptoms from lumbar spine or hip related causes. Correction of the deformity by bridging arthrodesis methods may address some components of the nerve encroachment.

ANATOMICAL FEATURES

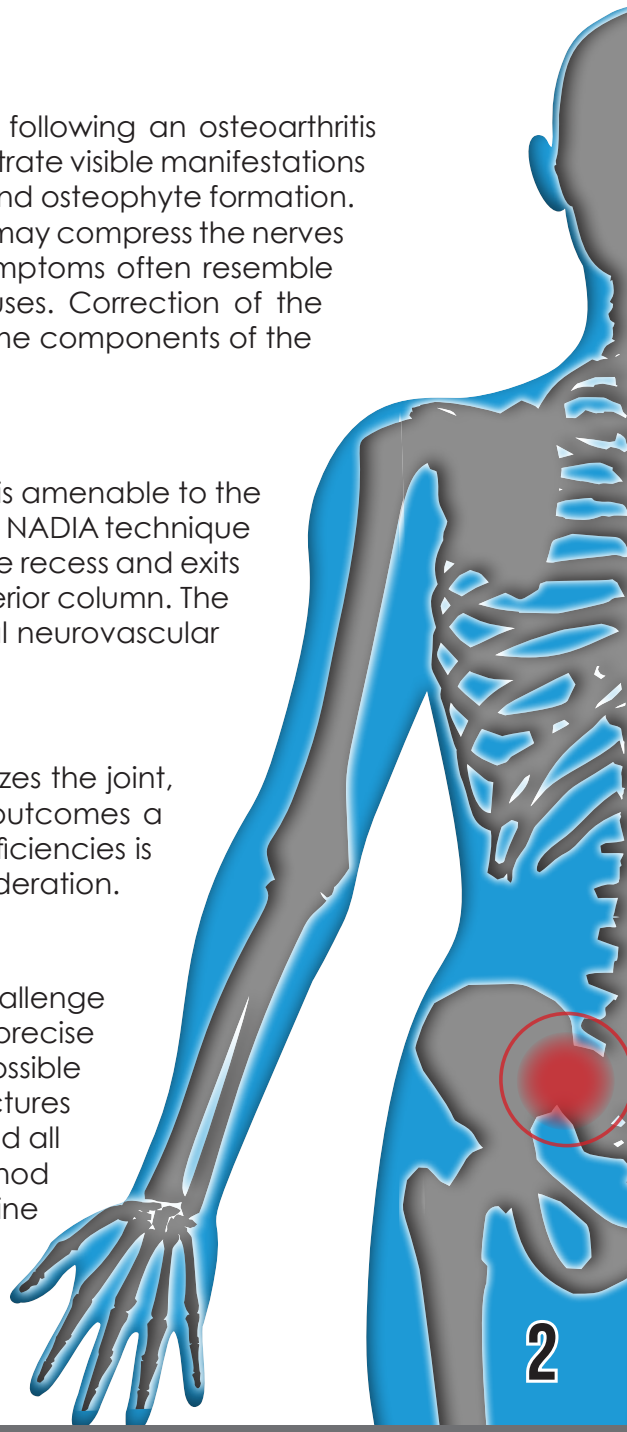
The neurovascular anatomy surrounding the sacroiliac joint is amenable to the proper surgical approach. For this reason, the guide pin of the NADIA technique approaches the sacroiliac articulation within the safety of the recess and exits into the safety of the intramedullary canal of the pelvic anterior column. The NADIA NeuroSafe® posterior approach never crosses critical neurovascular anatomy. Safety is planned into every step.

SURGERY AND HEALING CONDITIONS

The tapered implant serves to create a bridge which stabilizes the joint, support fusion, and facilitate bone healing. To maximize outcomes a full consideration of endocrine, metabolic, or nutritional deficiencies is necessary. Adequate systemic vitamin D is a special consideration.

CHALLENGING TREATMENT

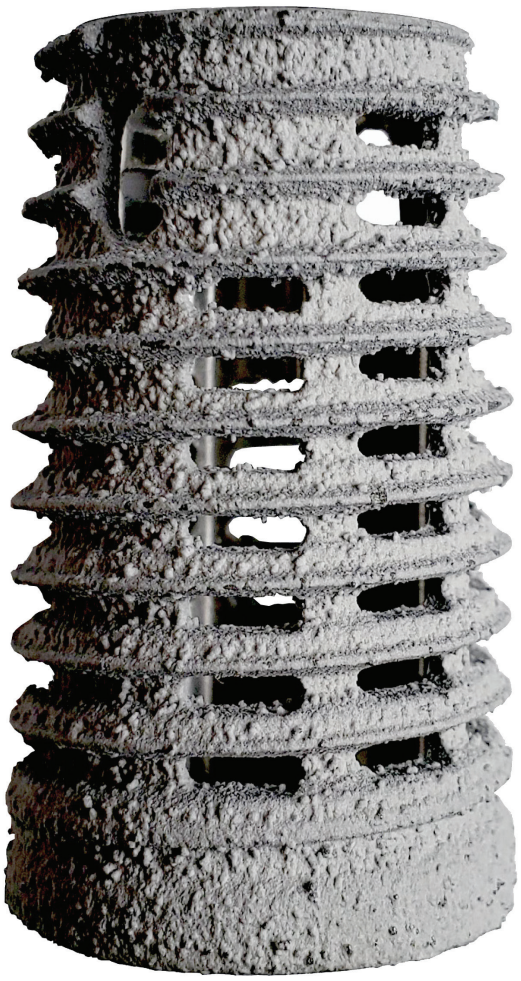
Surgical treatment of the sacroiliac joint is a worthy challenge for any spine surgeon. The NADIA method requires a precise diagnosis which also considers the hip and the spine as possible pain generators. Treatment of any of these individual structures requires a full understanding of all the possible diagnoses and all respective treatment options. A reliable, safe SIJ fusion method fulfills an important need in orthopedic and neurosurgical spine surgery.



FEATURES OF THE NADIA SIJ BRIDGING IMPLANT

TAPERED HEADLESS DESIGN

The implant is tapered to allow tightening over the course of the insertion. The headless design results in a low profile which fits within the recess.

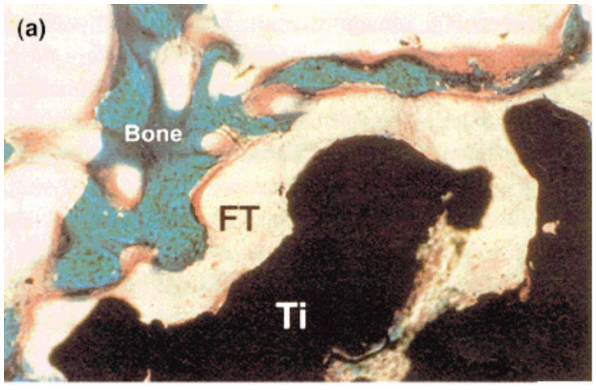


THREAD DESIGN

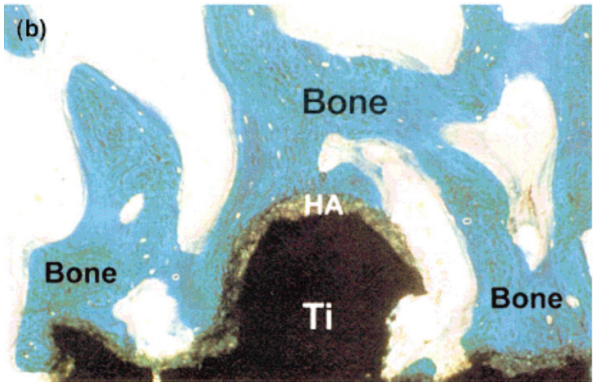
Sharp outer threads engage the harder bone's cortical elements. The patented smaller shoulder thread, within the primary cortical thread, progressively fills the core diameter over the length of the implant. The smaller shoulder threads, featured throughout the length of the implant, are designed to resist subsidence.

HA-COATED POROUS TITANIUM

NADIA implants are coated with a combination of titanium plasma spray and hydroxyapatite (HA) to enhance bone ingrowth. In a study by Mouzin et. al. 2011, their tests concluded that titanium plasma spray **and** hydroxyapatite together have at least 5.5-fold more bone ingrowth than titanium plasma spray alone.



(a) Photomicrograph of a representative, uncoated titanium implant from Mouzin et. al. 2000. Magnification X100. Titanium (Ti) alone without hydroxyapatite coating displays several areas without direct bone-implant apposition and many areas with interposition of fibrous tissue (FT).(Mouzin, et. al. 2011)

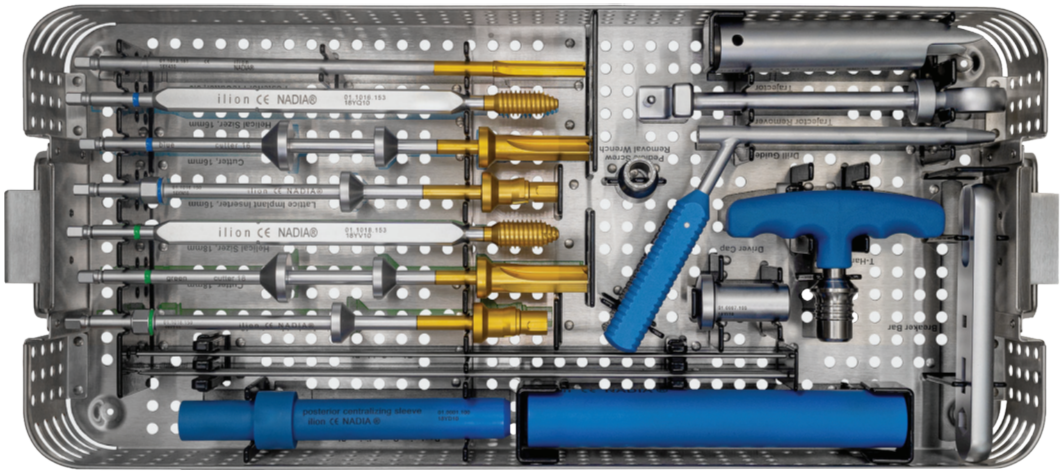


(b) Photomicrograph of a representative hydroxyapatite-coated (HA) porous titanium surface (Ti) implant from Mouzin et. al. 2000. Magnification X100. Surface coatings encourage intimate contact of bone tissue without interposition of fibrous tissue.

NADIA SURGICAL TRAY

The NADIA® NeuroSafe® technique uses an intuitive single tray design; these instruments allow for placement mechanical stabilization and alignment of the anatomic structures. The instruments are color coded to match implant sizes for ease of use. They feature hardened, treated surfaces for enhanced durability. The instrument set also includes a pedicle screw extraction tool.

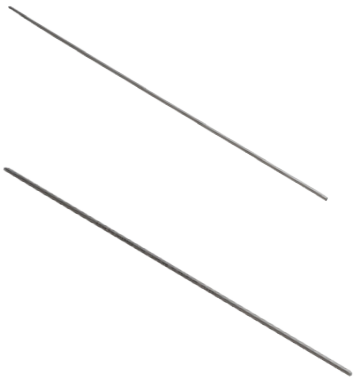
DESCRIPTION	ARTICLE NO.
T-HANDLE	01.0010.100
DRIVER CAP	01.0007.100
BREAKER BAR	01.0006.100
DRILL GUIDE	01.0005.100
GUIDE PIN BLUNT	01.0008.100
GUIDE PIN THREADED	01.0003.100
PRE-CUTTER 9.0 MM	01.0013.151
PRE-CUTTER 11.0 MM (OPTIONAL)	01.0014.151
HELICAL SIZER 16 - BLUE	01.0016.153
HELICAL SIZER 18 - GREEN	01.0018.153
POSTERIOR CENTRALIZING SLEEVE	01.0001.100
POSTERIOR IMPACTING SLEEVE	01.0002.100
TRAJECTOR	01.0016.152
TRAJECTOR REMOVER	01.0009.100
CUTTER 16 - BLUE	01.0016.151
CUTTER 18 - GREEN	01.0018.151
LATTICE IMPLANT INSERTER 16	01.0016.150
LATTICE IMPLANT INSERTER 18	01.0018.150
PEDICLE SCREW REMOVAL WRENCH	01.0011.100



FEATURES OF THE INSTRUMENTS

BLUNT GUIDE PIN

The blunt guide pin is used to establish correct position for the drill guide for insertion of the threaded guide pin. The blunt guide pin requires fingertip placement for safety.



THREADED GUIDE PIN

The sharp threaded guide pin follows the blunt guide pin. X-ray confirmation provides the axis for the subsequent distraction and preparation steps.

DRILL GUIDE

The drill guide allows for holding the correct position established by the blunt guide for simpler subsitution of the sharp threaded guide pin.

T-HANDLE

The T-handle features a rubber grip handle and features a locking bearings for easy of use while changing instruments.

PRECUTTER

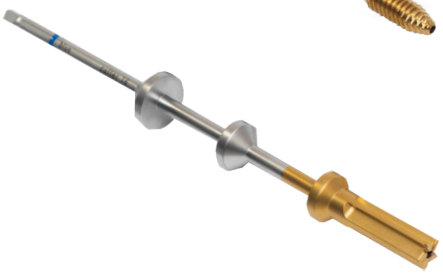
The 9mm precutter begins the process of preparing the hard bone of the SIJ recess for acceptance of the implant.

HELICAL SIZER

The helical sizer distracts the joint by pushing outward on the ligaments therefore restoring the anatomy. It is thought that the restorative element addresses the factors which cause adjacent neural compression.

FINAL CUTTER

The final cutter used after placement of the threaded guidepin and trajector to cut the surfaces of the sacrum and ilium assymetrically, preparing the recess for implant insertion.



IMPLANT INSERTER

The implant inserter advances the implant deep in the prepared channel. A 20mm inserter is available for revision procedures.

TRAJECTOR ASSEMBLY

The trajector is asymmetrically shaped to prepare and protect the softer sacral bone. The trajector, the impacting sleeve, the centralizing sleeve and the driver cap assemble together to hold the distraction after the helical sizer is removed. The trajector assembly allows for the final cutting and placement steps.

TRAJECTOR REMOVER

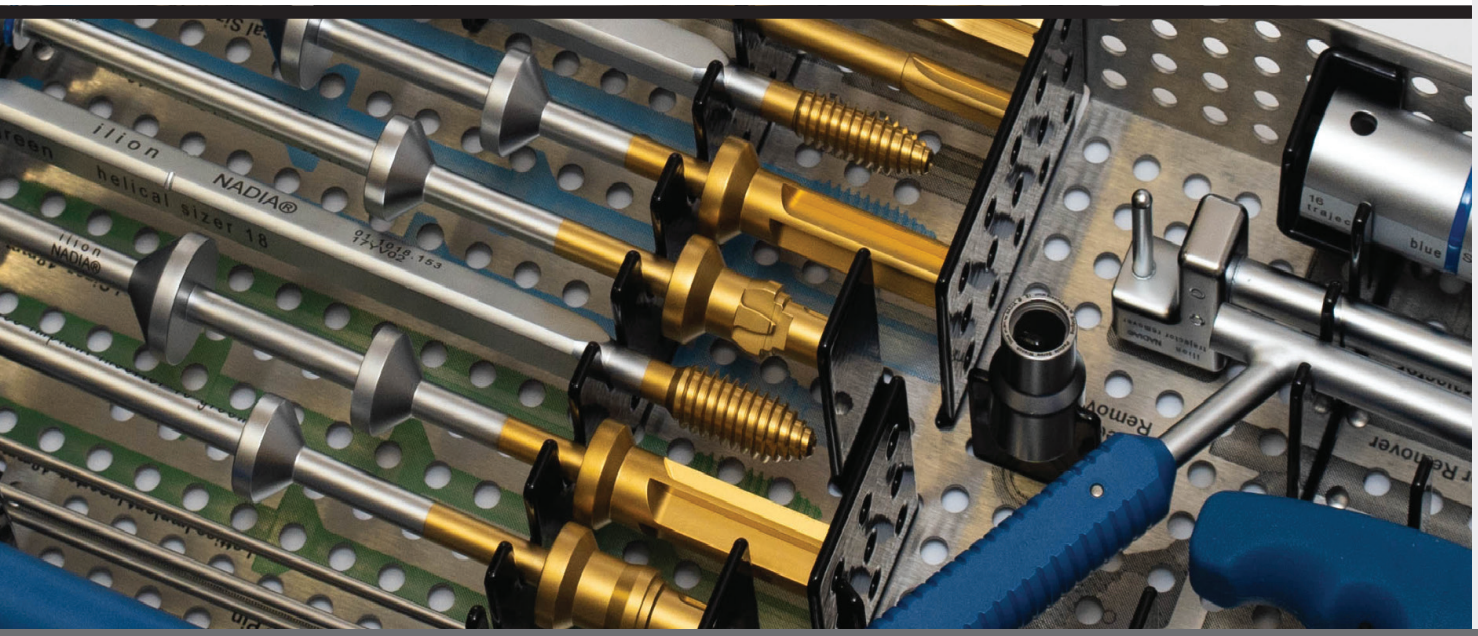
The trajector remover is supplied to assist in the removal of the trajector. It can be used in conjunction with breaker bar for additional removal control.

PEDICLE SCREW REMOVAL WRENCH

The pedicle screw removal wrench can be assembled with the NADIA 16 inserter and T-handle. After the connecting rod is transected above the pedicle screw to be removed, the removal wrench assembly can be placed over the tulip of the pedicle screw and the screw can then be backed out by turns.

BREAKER BAR

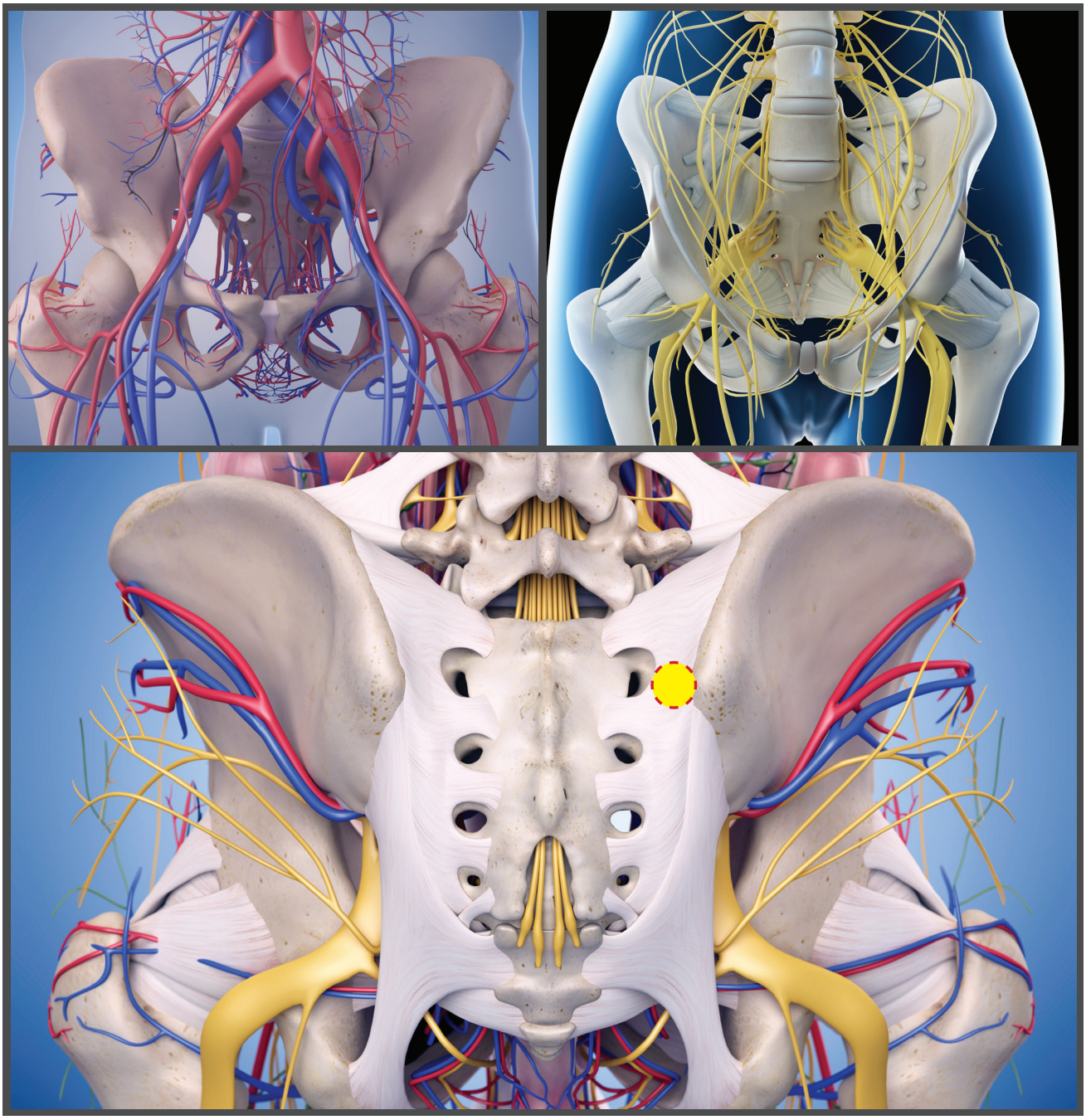
The breaker bar is a multi-functional tool. It works as a slide hammer when used with the trajector remover and can also be used as a T-Handle. All the drilling and placement instruments are fitted with extra engagement areas (hex or square), to work with the breaker bar.



FEATURES OF THE APPROACH

The NADIA implant system utilizes a posterior medial approach to bridge the sacroiliac joint. This unique approach works within the lines of tissue tension to avoid and protect nerves, blood vessels, fascial tissue and muscle structure. It has firm intraoperative surgical and radiologic landmarks which are recognizable by trained spine surgeons. The surgical approach is reproducible and revision-friendly; preserving the anatomy is a priority.

The midline incision allows access to the biomechanical weightbearing axis. When previously placed implants are present, a single midline surgical incision allows for exposure and removal of previously placed pedicle screws. The method of closure is similarly cautious, closing fascia along its lines of tension while respecting and protecting the nearby critical motor and skeletal anatomy.



The NADIA procedure is a major operation and requires careful medical evaluation. The health of the patient, psychosocial circumstances comorbidities, and bone health, all require cautious consideration through preoperative study. Proper communication is critical. The patient must understand the risks and benefits of SIJ fusion and participate in the decision for surgery. Other pain generators may be present and interfere with the outcome; all sources of pain must be understood so that reasonable patient expectations can be established. This is likely to lead to higher patient satisfaction. The patient must understand the diagnostic and surgical prioritization which led the surgeon to advocate for SIJ fusion surgery.

INDICATIONS FOR USE

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

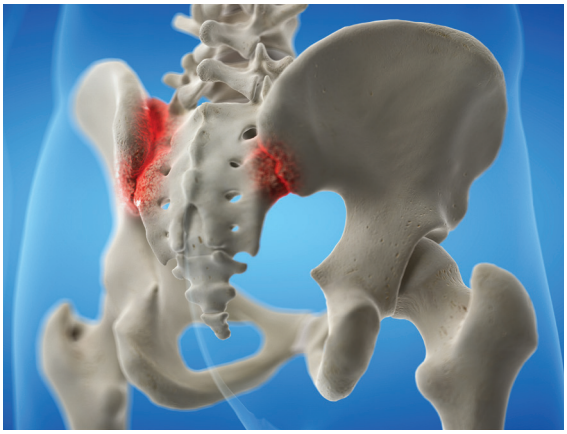
CONTRAINDICATIONS

- Acute or chronic infection of the SIJ
- Hypersensitivity or allergy to implant material
- Deformity, post traumatic or developmental, which will not accept the device
- Inadequate bone density, osteoporosis or osteomalacia, which may cause an inability to hold the device
- Compromised metabolic or nutritional status that will impair postoperative healing
- Inadequate skin or soft tissue coverage
- Primary sacroiliac instability, ligamentous laxity or inadequacy
- Inadequate bone surface area to accept a bone grafting procedure
- Inadequate ability to visualize with proper imaging equipment/bone landmarks
- Inadequate surgical training and experience with the technique by surgeon or staff
- Inadequate or inappropriate bone graft to accomplish the grafting/arthrodesis procedure successfully
- Incomplete set of the necessary instruments, including proper guide pins and tools for the distracting, alignment, drilling, preparation and implantation steps
- Very small or very large stature outside the suggested range for available surgical tools and implants
- Surgical conditions that preclude the possible benefits of sacroiliac surgery (e.g. severe damage to bony structures at the implant site, or severely deformed anatomy due to anomalies)
- Medical conditions that could be an obstacle to successful implantation (e.g. obesity, mental illness, pregnancy, pediatric cases, poor general health, lack of cooperation on the part of the patient, unstable psychosocial circumstance)
- Inadequate physical proximity to medical care for evaluation, re-evaluation and support/revision of the procedure
- Pelvic pain or instability due to neoplasia, primary or metastatic cases not included in the indications.
- Cases not included in the indications

The NADIA technique is designed to be anatomically and physiologically safe in the normal circumstance, but it remains incumbent on the surgeon and supporting specialists to confirm that the NADIA method can be safely applied in any given case.

PREOPERATIVE CONSIDERATIONS

Minimum preoperative evaluation:



1. General Physical Examination to Check for Competing Regional Complaint
    a. Abdomen
    b. Spine
    c. Hip
2. Imaging
    a. Plain X-ray - AP pelvis, lateral pelvis
    b. Lumbar MRI
    c. Pelvic/SIJ CT
    d. Pelvic Brim MRI (elective)
3. Laboratory Studies
    a. Standard preoperative preparation for a major skeletal procedure
    b. Vitamin D levels
    c. Bone density studies (recommended in at-risk populations)

4. Examine and rule out lumbar spine pathology, pelvic pathology, anomalous or complicating anatomy. Complicating anatomy, bone healing problems, metabolic or constitutional factors may cause inability to benefit from surgery. An understanding of existing internal fixation, bone deformity, bone disease and bone quality is important.

5. Plan for the evaluation and follow-up of problems and complications; have adequate backup and resources to study and address problems.

PREOPERATIVE DECISION

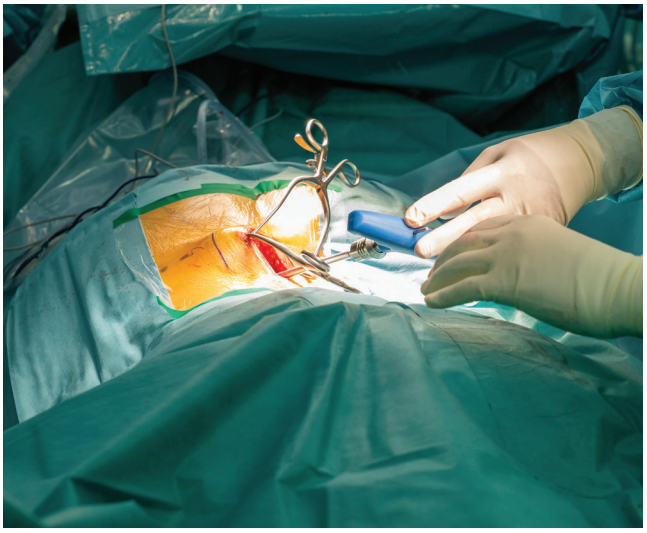
Surgery shall not be performed under the following circumstances:

- If the surgeon does not understand the technique, do not attempt to approach the recess and joint by this method
- If the patients cannot understand the risks and benefits; if they cannot assume the risks; if they cannot participate fully in the follow-up program
- If the surgical facilities and imaging will not support necessary major joint surgery
- If there is bony insufficiency, or questions of bone metabolism or of healing or ligamentous insufficiency
- If the extraarticular fusion shall not or cannot be performed to the required extent and quality. The implant must support a technically excellent fusion of the recess.

The procedure will take between **50 minutes and two hours under standard conditions,** however this time is influenced significantly by the preparation steps, adjustment of the C-Arm, and preparation of bone surfaces for bone graft.

CHECKLIST FOR SUCCESSFUL SURGERY

- ☐ Implants
- ☐ Bone Graft
- ☐ Radiolucent Operating Table
- ☐ Free Rotation of the C-Arm
- ☐ Tissue Rolls and Cushions
- ☐ Complete NADIA Instrument Set
- ☐ Spinal Needle
- ☐ Cobb Elevator
- ☐ Sharp Bone Currettes
- ☐ Micro-Burr (with a new, sharp bit)
- ☐ Cannulated Power Drill
- ☐ Surgical Mallet
- ☐ Self-Retaining Retractors (cerebellars or Gielpes)



SURGICAL STEPS

1. **Midline incision to the deep fascia**
2. **Paramedian incision of the lateral fascia to the recess**
3. **Preparation of the recess, decortication**
4. **Placement of the Guide Pins under direct vision and imaging, first blunt then threaded**
5. **Controlled pre-cutting**
6. **Controlled helical distraction**
7. **Maintenance of the distraction with Trajector**
8. **Preparation of the implant seat with the Final Cutter**
9. **Implantation/Insertion**
10. **Wound Closure**

INTRAOPERATIVE DECISION

Consider changing the plan intraoperatively when certain things may happen:

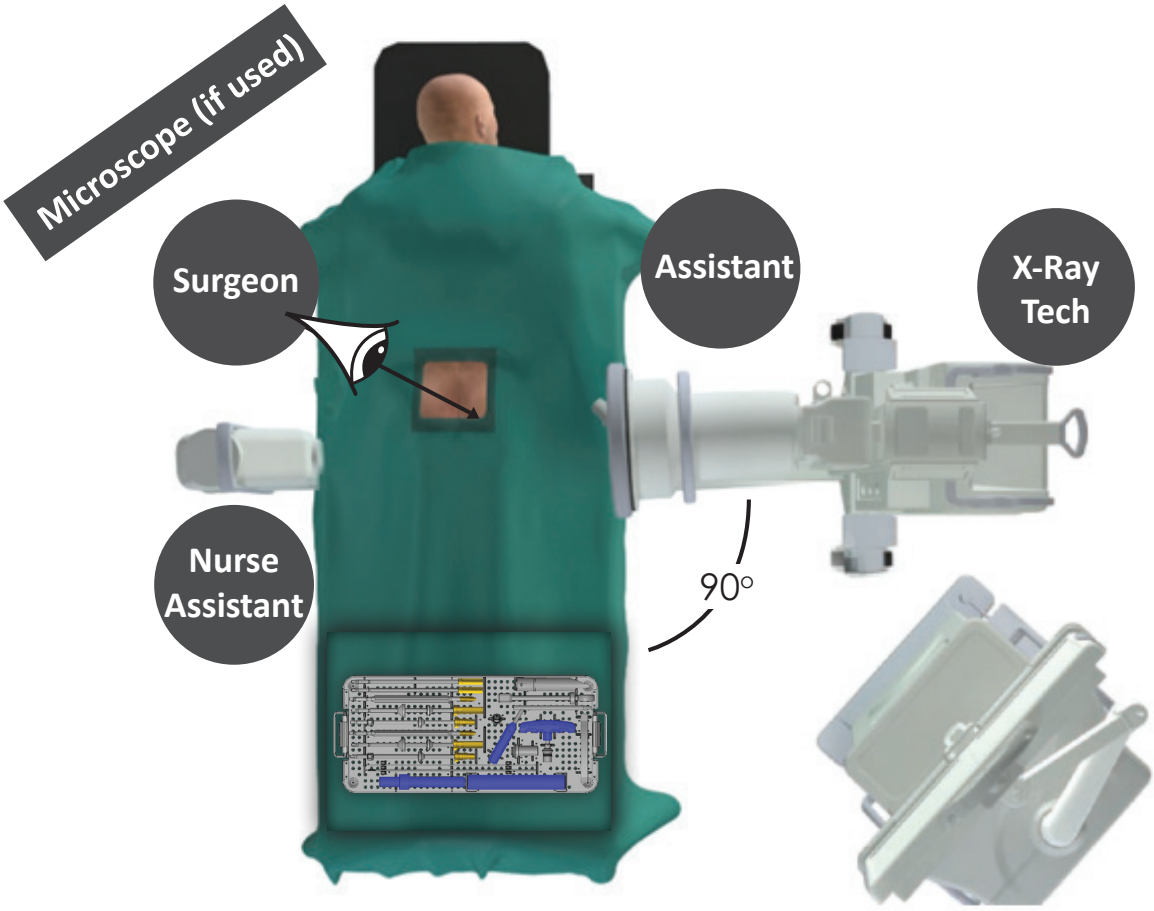
- If the radiologic criteria cannot be met
- If the bony anatomy is anomalous or of poor bone quality, do not drill or cut, or if in some other way it cannot accept the implant reliably
- If the instruments (Guide Pin, Helio(s), Trajector, Cutter) are not interfacing well, or the implant is improperly sized, or if the implant is seated without purchase

OPERATING ROOM SETUP

The patient is positioned prone over bolsters or positioning rolls on the radiolucent table. The patient is placed directly anterior-posterior, leaning neither to the right or left. The surgeon stands contralateral to the operative sacroiliac joint target. This position puts the surgeon's line of view down the extraarticular recess.

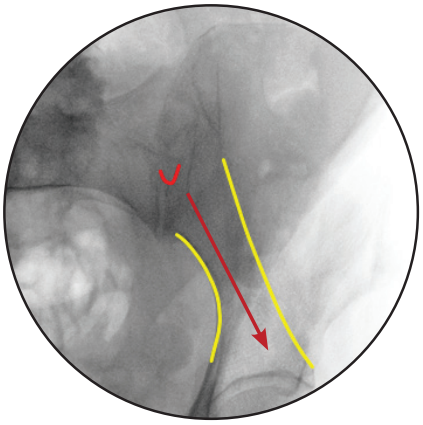
The base of the C-arm should be placed at 90° to the operative table. If the base is not at 90°, any movement of the arm (extension, rotation) will distort the field of view. Once at 90°, the C-arm should rotate freely around the table so that true AP, lateral, and vertical oblique images can be obtained.

If the C-arm image is misdirected or abnormally rotated, take the time to correct it. **The correct position of the C-arm should be preserved throughout the surgery. The surgeon and staff should take special care to maintain the position during the draping step**. Correct position of the C-arm is the best answer to a visualization problem.



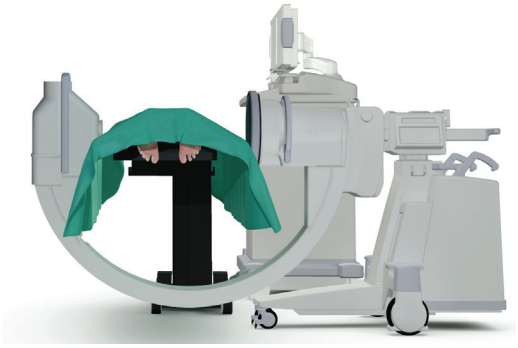
INITIAL AP IMAGES

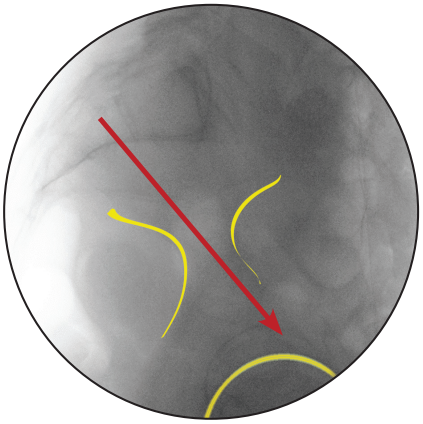
When properly positioned, the C-arm scope of view will be able to image the entire anterior column, from the superior acetabulum, across the SIJ, to the base of the L5-S1 disc space.



LATERAL IMAGES

After the AP image is satisfactory, the C-arm should be rotated into the lateral position to obtain a true lateral image of the pelvis, which is necessary for accurate placement of the Guide Pins. The sciatic notches (operative and contralateral) should be superimposed by a combination of wagging the C-arm and rolling the table. If the sciatic notches are indistinct because of bowel gas or soft tissue size, the hips can be used for orientation.

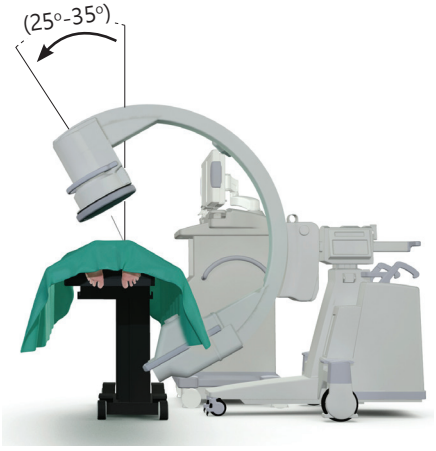


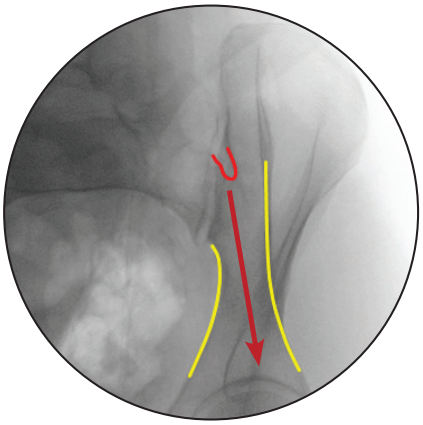


VERTICAL/OBLIQUE IMAGES

With AP and true lateral views established, the C-arm can then be positioned for the vertical oblique image. The vertical oblique image will be obtained by rotating the receiver over the top of the patient, in 5 to 10 degree increments from the AP view, until the SIJ joint recess comes into view.

Remember: The goal is to see the recess, which will appear as a "V" aligned with the anterior column.

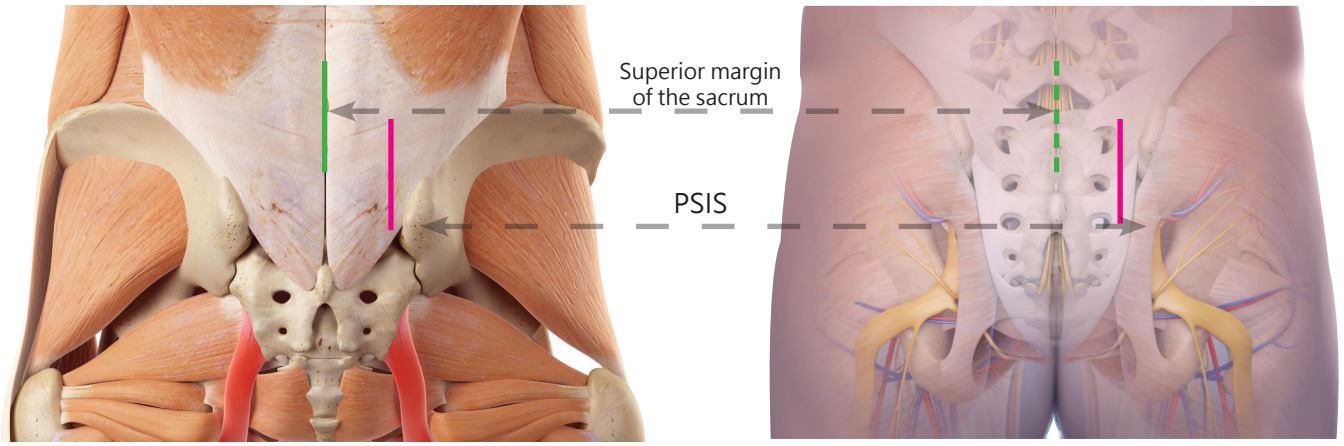




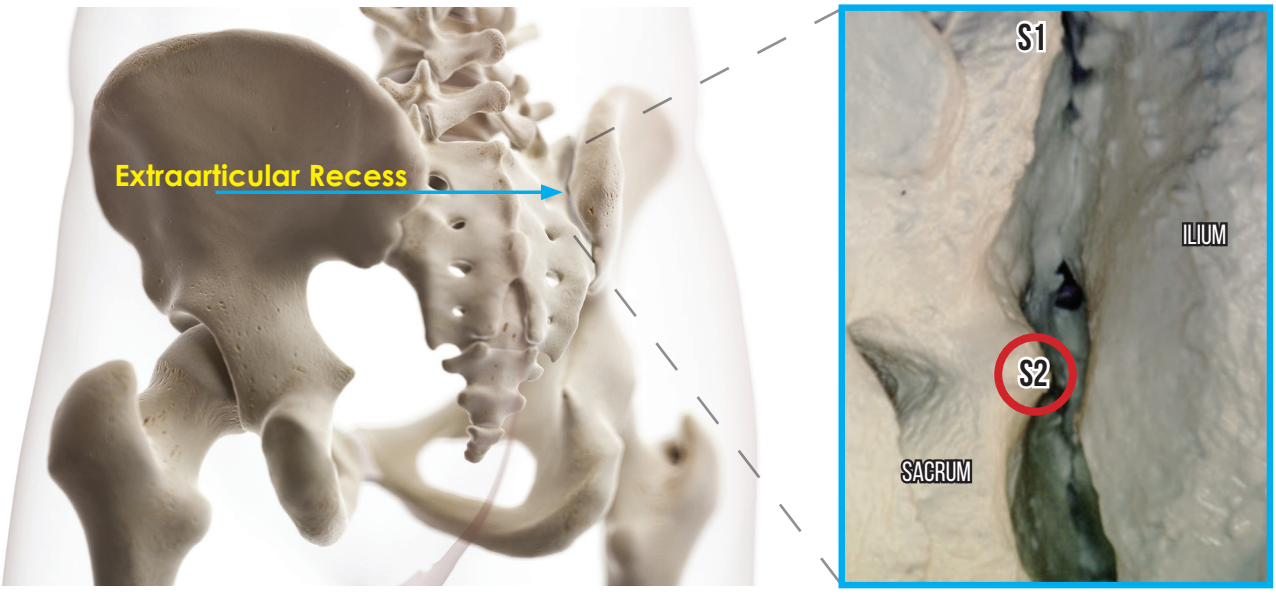
THE SURGICAL INCISION

While standing on the contra-lateral side, the surgeon makes a 4-6cm incision in the skin which is equidistant proximally and distally, centered at the superior margin of the sacrum (green line). The incision and the subcutaneous tissues are followed deep until the fascia is met. The dissection then turns laterally over the fascia until just 2cm medial to the PSIS (pink line).

Once below the subcutaneous layer, the PSIS can usually be palpated through the fascia easily. Protect the PSIS and the important muscle attachments. A longitudinal incision, approximately the same length (4-6cm) as the skin incision, is made in the fascia medial to the PSIS.



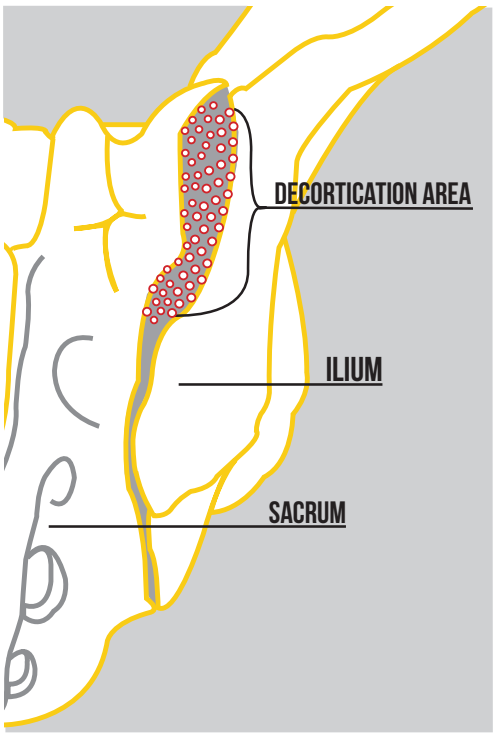
The paramedian fascial incision, when lined up with the skin and the surgeon's position, puts the recess directly in the line of sight. Self-retaining retractors are inserted obliquely. Follow the bone margins and recheck alignment, palpating for important landmarks (medial ilium and adjacent dorsal sacrum). It is best to identify the vertical ilial wall beneath the fascia and follow it to the recess; this will help ensure a safer margin away from the foramina or midline structures. Once below dorsal fascia, the recess may be approached with a large curette. Before entering the recess, it will be necessary to remove the soft tissues within the intersection, where the horizontal sacrum meets the vertical ilium.



CURETTING AND DECORTICATION

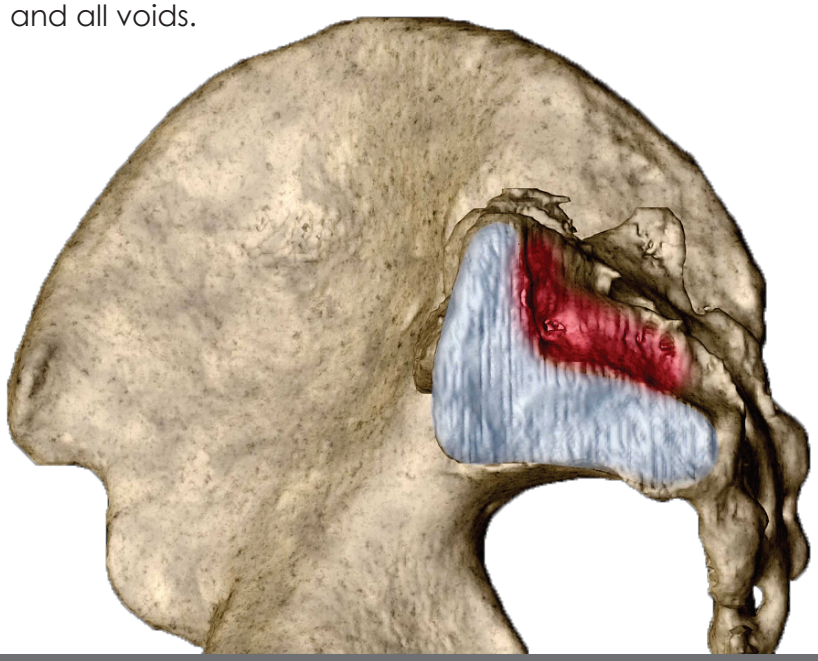
The extraarticular recess is ordinarily easily found (see the red area in figure below). It may be confused, at times, with the soft adjacent bone surface on the sacral side. Special attention should be given to removing the soft tissues from the recess, so that the bony margins are preserved. This step ordinarily involves cautious use of either a sharp curette or a pituitary rongeur.

The process for preparing the recess begins at the medial ilial wall working down to the recess bottom. Curettes of appropriate size (usually number 4 and number 2) are used to remove the sacralis muscle from the medial ilium and dorsal sacrum. Care should be taken that the dissection does not involve the iliac crest itself or long spinal extensors which originate along the iliac crest dorsally. The dorsal sacrum and adjacent foramina are also protected.



Be deliberate with bone preparation. Start with the ilium, work along the ilium to the bottom of the recess, and then come up from the bottom, of the sacral side. Protect the edges and corners of the sacral anatomy. Violation of the sacral margins will sacrifice useful bony anatomy and introduce confusion while undergoing pin placement. A new high-speed burr (toothed or "rose burr" cutting bit) can be used to complete the bone surface preparation, whisking the soft tissues before and during the formal decortication step.

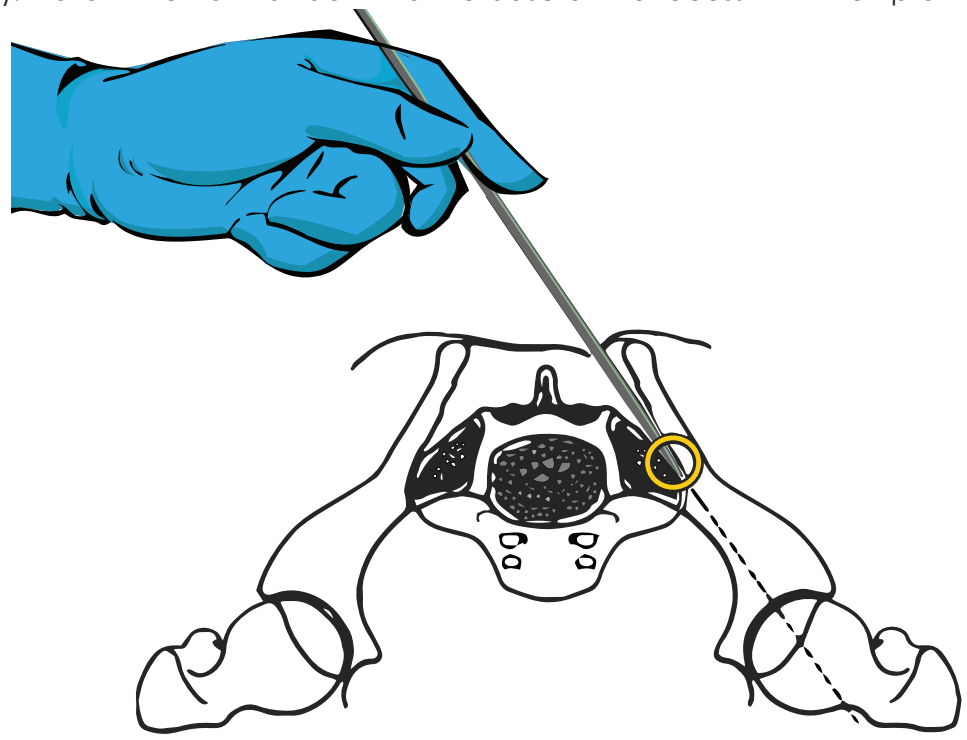
Respect and preserve the cortical margins during the decortication step (red circles, right). When ready to decorticate, perforate the surface under direct vision with a high-speed burr. Remove any soft tissue debris but leave any residual bone debris from the decortication step. Make a mental note of recess landmarks, since the graft material is now placed over decorticated surfaces and will obscure the view. Place the graft now, fill the recess and all voids.



Left: A medial view of the ilium is shown with the extraarticular recess is shown in red. The actual sacroiliac joint is shown in white. In the next step the pin will be placed in the recess at the level of the S2 transverse process (page 13, bottom right). The ilial wall forms a firmer line of resistance as the pin is advanced. The sacroiliac joint line is usually seen at the base of the recess, but it is not violated.

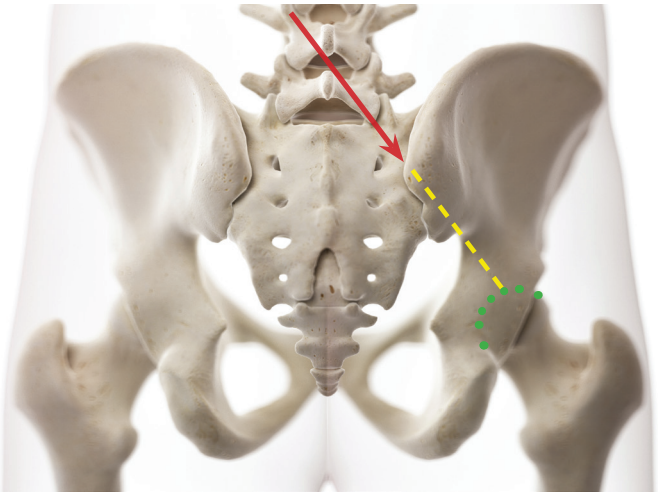
INSERTION OF THE BLUNT GUIDE PIN

Introduce the provisional blunt guide pin into the extraarticular recess at approximately the level of the S2 transverse process (***circled in red bottom right image, page 13***). **The provisional blunt pin is placed at the S2 transverse process, not within the bigger, more obvious bowl of the recess between S1 and S2.** The blunt guide pin is used to acquire the correct position before placing the threaded pin which has sharp edges. Initial application of the blunt pin is done with the fingertips. Work within the safety of the recess. Distinguish between the entry point (which is done with visible bony S2 landmarks) and the trajectory (which is done with C-arm imaging). Follow the ilial wall down to the base of the recess with the tip of the pin.



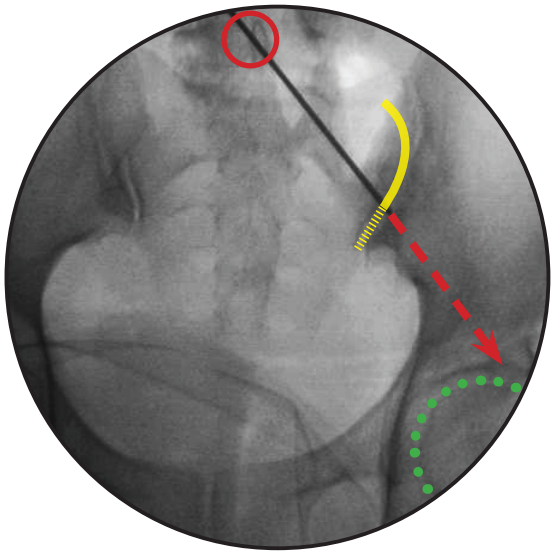
IMPORTANT

Preserve any acceptable elements of the guide pin placement (whether entry point or trajectory) while adjusting the remaining elements. Re-check frequently with imaging series. Remember that any changes in one plane of imaging may affect the other views.



AP VIEW

Start with the AP view when beginning to assess pin placement. Adjust the proximal distal entry point with the AP image. Once the pin is placed in the recess at the S2 transverse process, as a general rule when viewed externally, it should be directed distally and laterally approxmiately at the greater trochanter.

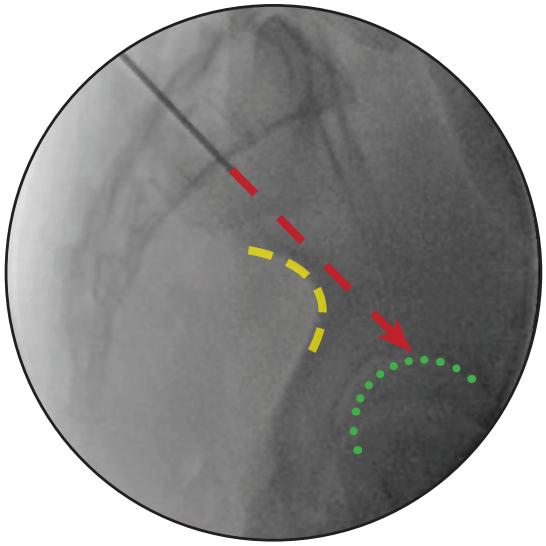


The AP X-ray should show the guide pin crossing three landmarks:

1. The midline at the L4-L5 disc (red circle)
2. The SIJ with 2/3 proximal (yellow) and 1/3 distal (dashed yellow).
3. The mid point of the superior dome of the acetabelum (green).

LATERAL VIEW

After the three landmarks in the AP view are confirmed the C-Arm is moved to the lateral position, The C-Arm will have to be comfirmed as providing a true lateral view.

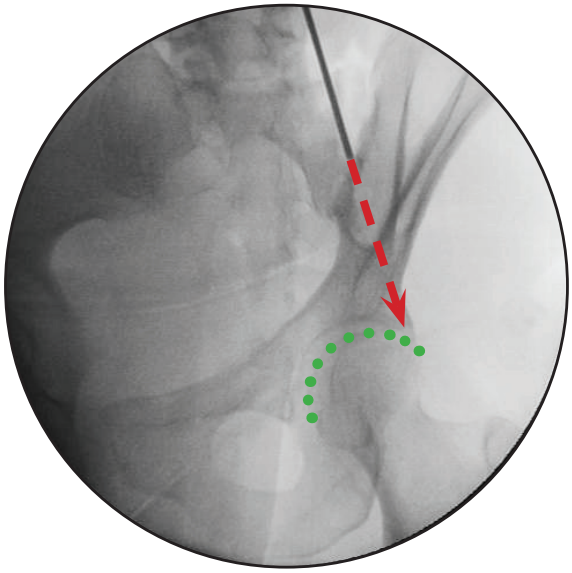


Ask and confirm on the lateral image:

1. Will the pin trajectory pass over the S2 pedicle?
2. Will the pin trajectory pass within bone, just over the notch? (yellow dashed line)
3. Will the pin trajectory intersect the superior femoral head? (green dotted line)

VERTICAL/OBLIQUE VIEW

The vertical oblique done with the C-arm rolled over the patient (bottom image, page 12) will bring the recess into view and in most cases, make the anterior column appear near vertical.



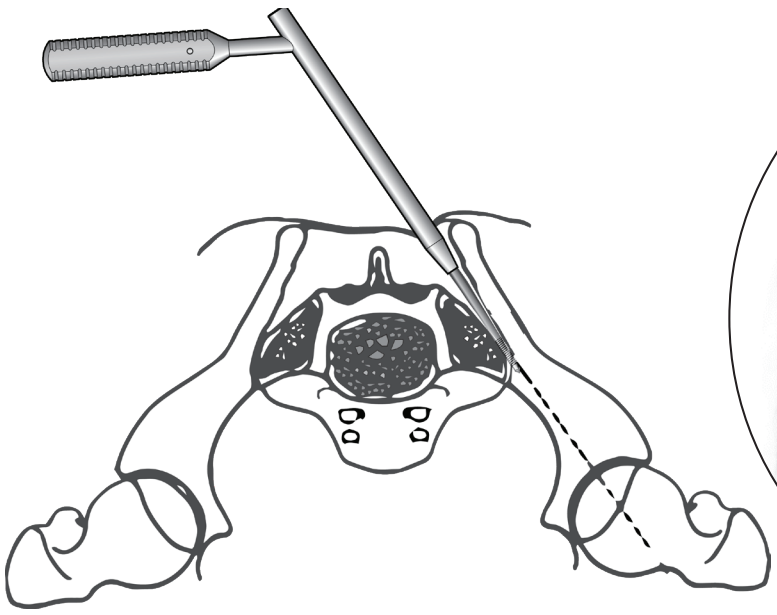
The properly placed guide pin will be near vertical, passing from recess through the anterior column toward the femoral head.

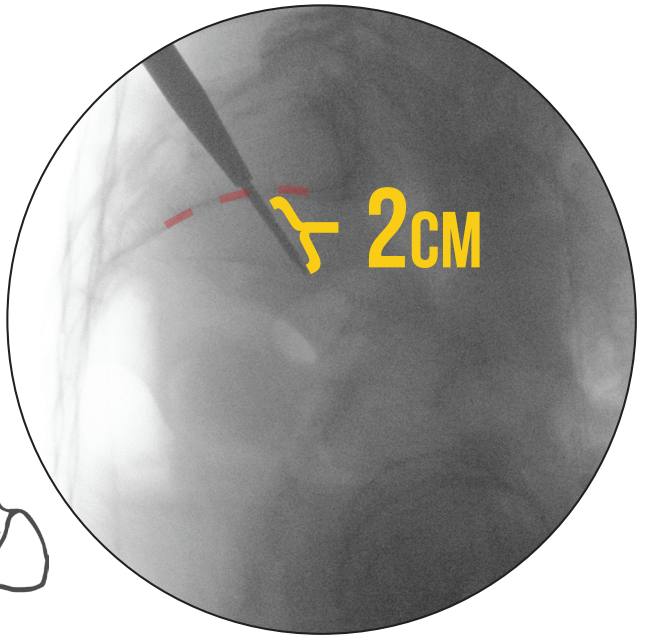
THE THREADED GUIDE PIN

Once the blunt pin is in an acceptable position, gently apply the drill guide over the pin. The drill guide protects the position while the blunt guide pin is replaced with the 3.2 mm threaded pin.

Holding the threaded pin firmly tap gently with a mallet. The pin should "bottom out" audibly and palpably, confirming contact with the floor of the recess. Listen for the properly placed pin to impact the floor of the recess. Check an image series.

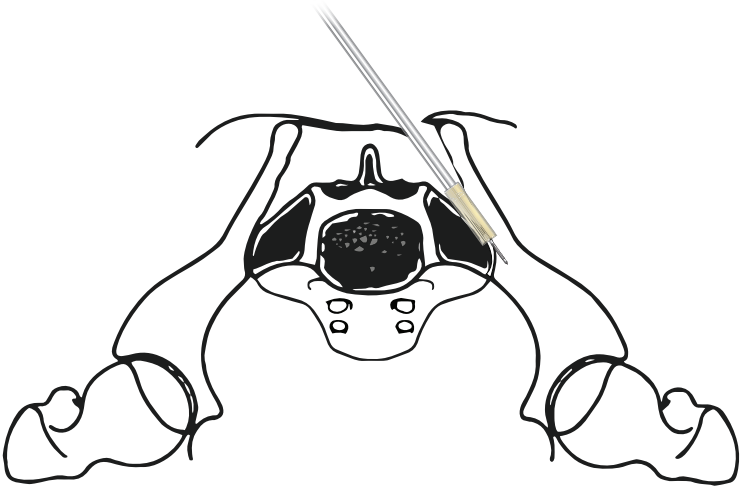
Apply the cannulated drill and advance under power while following on the lateral image. Confirm that the threads engage. The "bite" of the pin should suggest that the pin is within bone. If well placed and secure, advance under power a maximum of 2 cm beyond the anterior sacral line. This keeps the threaded portion of the pin within the subchondral bone on the ilial side which will hold better than the weaker or absent bone of the ilial intramedullary canal. Confirm final position with another image series.

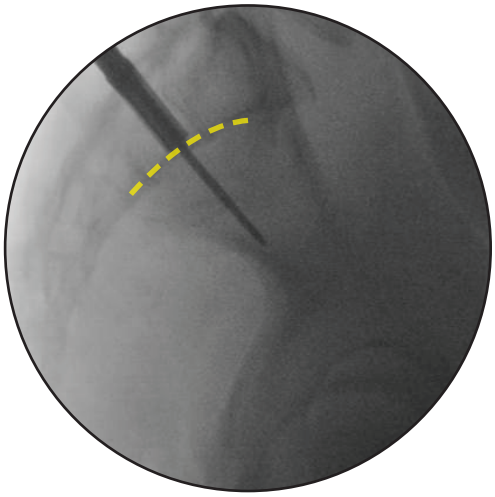




PRE-CUTTING

Pass the 9mm pre-cutter down the threaded guide pin. Twisting gently, **the pre-cutter should advanced cautiously. At its deepest, the pre-cutter should reach the anterior sacral line on the lateral x-ray (yellow line).** The channel created by the pre-cutter allows the entry and passage of the helical sizers.

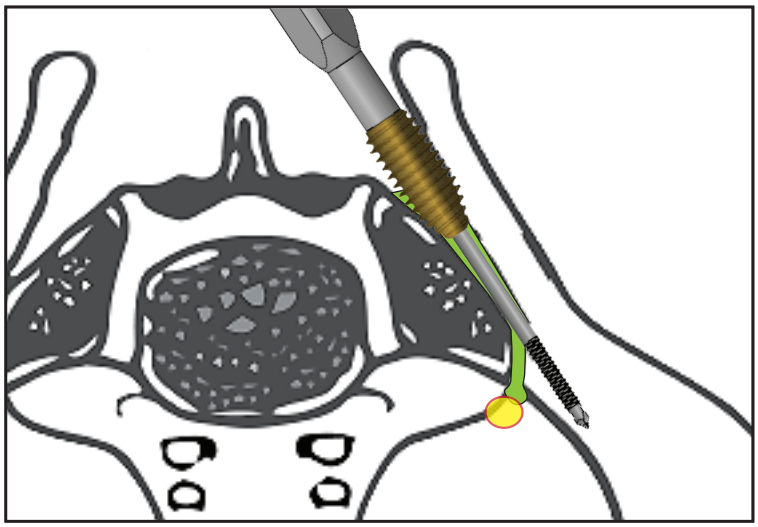


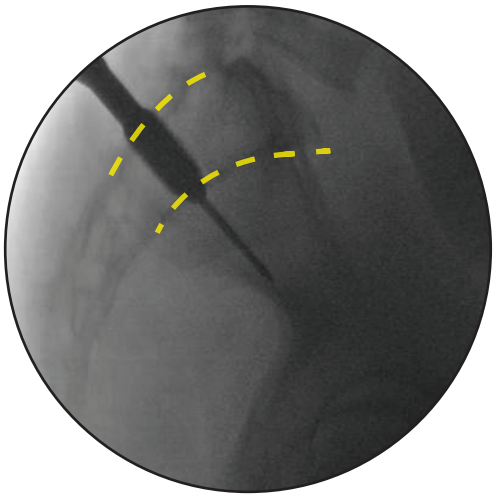


SIZING

Use the helical sizer. **Begin with the blue (16mm) helical sizer, this should fit tightly in the great majority of cases**. The threads of the sizer should extend to the level reached by the pre-cutter (the anterior sacral line). As it is placed, it should be followed by lateral x-ray. Ideally, the implant will rest in the position defined by the sizer threads, between the anterior and posterior margins of the sacrum (yellow dashed lines, parallel to the disc endplate, at the level of the S2 pedicle).

If the NADIA 16 helical sizer (blue) does not fit tightly, remove the blue sizer and insert the NADIA 18 helical sizer (green). The implant to be used will correspond with the color/size of the helical sizer which fits tightly.

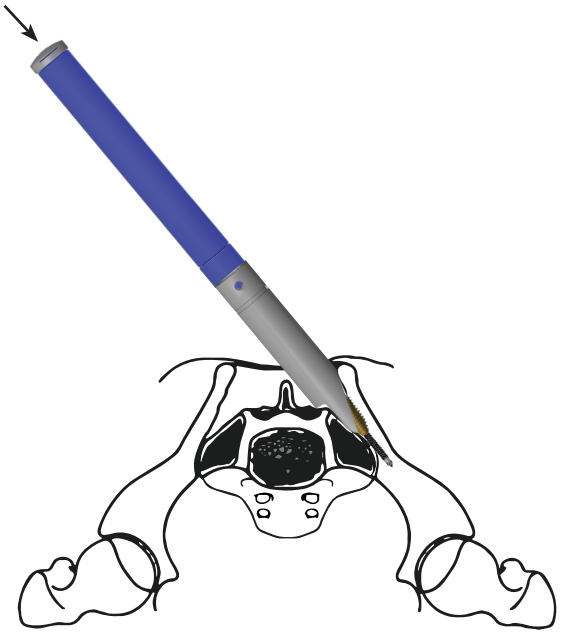


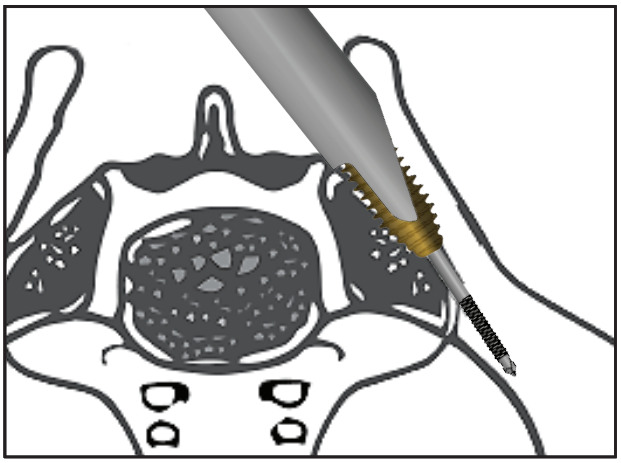


HOLDING THE DISTRACTION

Remove the T-handle, exposing the shaft of the helical sizer. The trajector, the centralizing sleeve, the impacting sleeve and the driver cap should be assembled, then handed ***carefully*** as unit to the surgeon, who steadies it and places it over the shaft of the helical sizer. The trajector is used to maintain the position achieved by the helical sizer and to protect the soft bone of the sacrum during the final cutting step.

As necessary, rotate it slightly into position; **the flat surface should lie against the sacrum**. The teeth, vertically directed into the recess, should follow the trajectory of the guide pin/sizer construct. After provisional placement, confirm with imaging that the teeth are placed within the recess; once confirmed, a hammer should be used to gently strike the impacting cap to seat the assembly firmly into the recess.

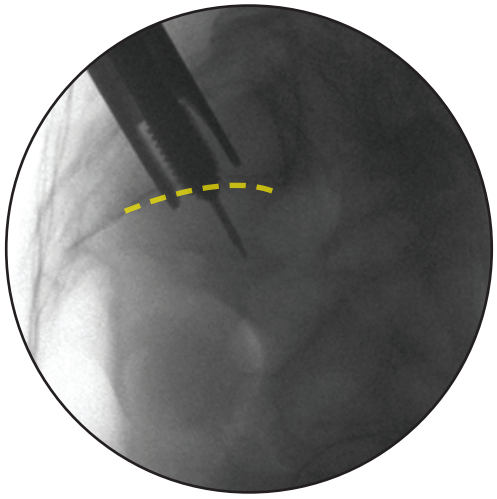




With the trajector in place, the impacting cap, impacting sleeve, the centralizing sleeve and the sizer are removed, leaving the guide pin and trajector. The guide pin and the trajector remain to provide the necessary control to direct the final cutting step and implant insertion. Both are used together, though sometimes the guide pin is slightly in a different trajectory than the seated trajector.

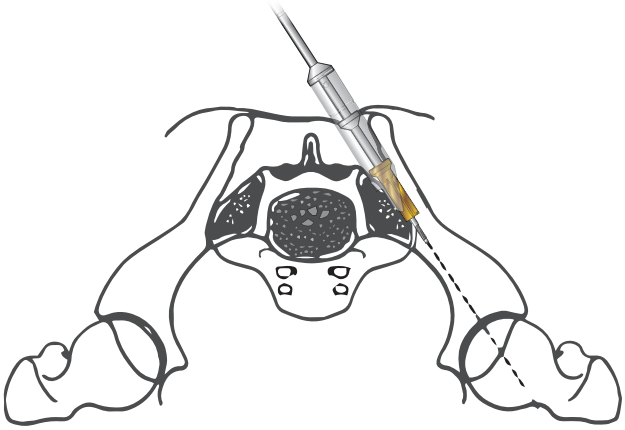
IMPORTANT

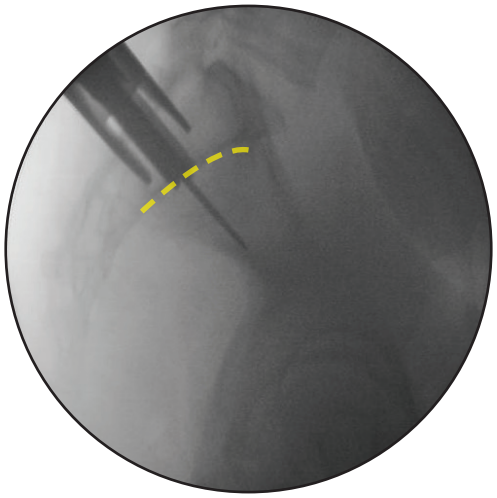
Slightly different trajectories may be observed between the guide pin and trajector tube, this does not interfere with the correct use of the two instruments together. Both are necessary for control of the cutting and implantation steps. Neither the pin nor the trajector alone can control these steps. Do not remove either until both the final cutting steps and the implant placement step are completed.



FINAL CUTTING

Place the appropriate cutter (blue or green) over the guide pin (within the Trajector) and ream to the anterior sacral line on the lateral X-ray. As a safety measure, the cutter is blocked from extending beyond 20mm from the end of the trajector teeth to prevent over cutting.

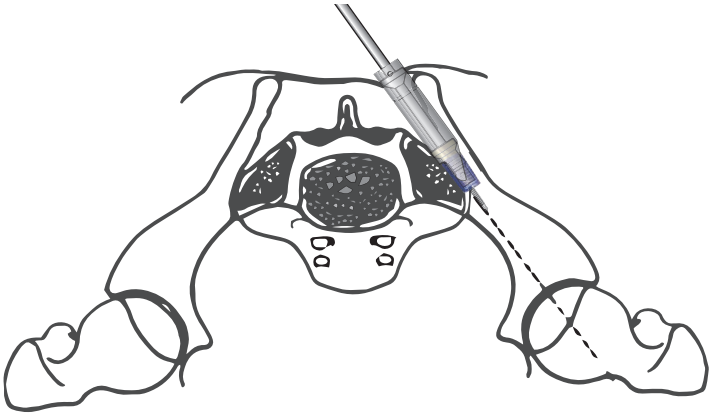


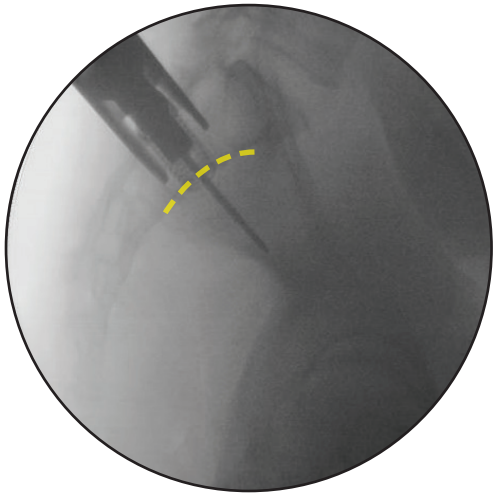


IMPLANT INSERTION

The implant is placed on the inserter and guided down the guide pin. Advance the appropriate implant by turns into the receiving site until it stops firmly at the extent of the prepared channel. The implant should come to a snug fit at the anterior margin of the sacrum. **Multiple lateral X-ray images should be used to follow the progress of the implant.**

If the implant does not easily advance to the landmark on the anterior sacrum, this may be due to debris in the front of the instrument, such as bone. Inelastic ligaments or/and, high bone density may also cause unexpected resistance. If this occurs, the surgeon will need to carefully make the decision to either to leave the implant short of the anterior sacral line or, if necessary, back the implant out and use the next largest available cutter.

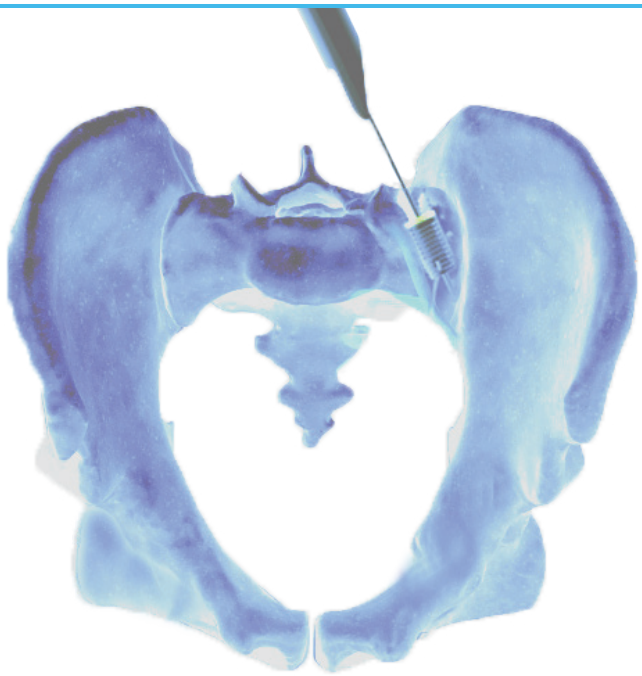




IMPORTANT

Hitting the T-handle may fracture bone or push the implant into vulnerable anatomy. **Do not hit the T-handle or T-handle instruments with a mallet** as you may damage the T-handle or the fittings of the instruments; instrument-to-instrument or instrument-to-plant instruments

INSTRUMENT REMOVAL AND WOUND CLOSURE



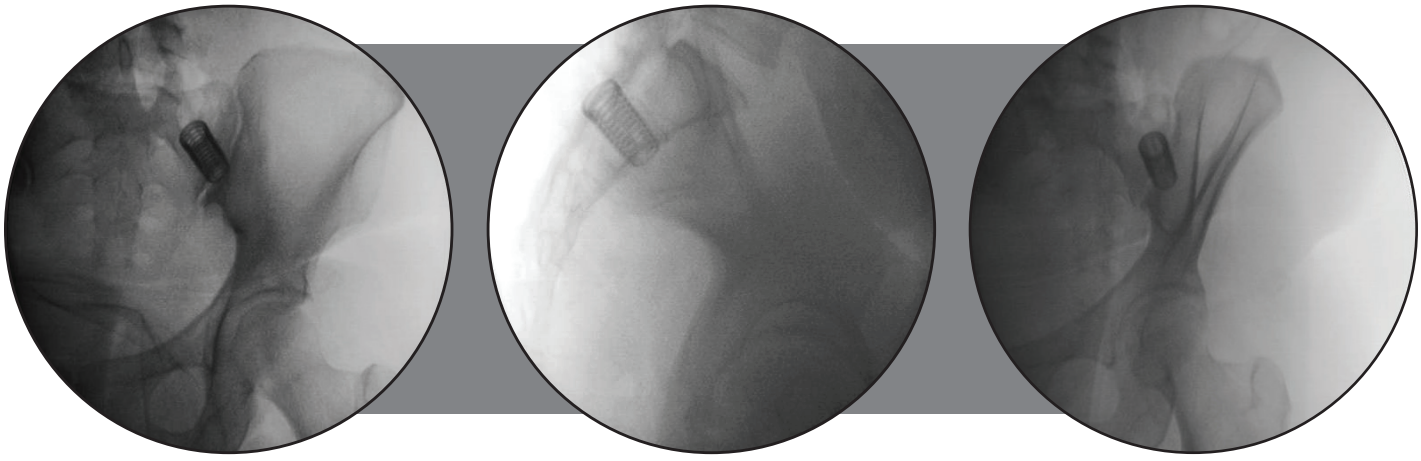
Remove the inserter by rotating and toggling it gently straight backward. Do not vigorously rock the inserter or the trajector as this may loosen the implant. The trajector should slip out easily, but if necessary engage the trajector remover and use the breaker bar as a slide hammer. Remove the guide pin. **Complete bone grafting, filling all voids of the recess and within the implant.**

Wound closure is performed with absorbable suture only. The fascia is subject to contracture secondary to overzealous fascial repair. **Large absorbable sutures are used, usually with a running stitch to control bleeding and isolate layer from layer.**

Avoid permanent suture in the fascial layer.
It can cause an uncomfortable contracture. It may become sensitive to the patient or be palpable subcutaneously. This may result in local pain or a tight sensation.

Overzealous fascial closure can result in an uncomfortable sensation of tightness. If absorbable suture is used, this usually resolves after the early postoperative period, beyond 6 to 12 weeks.

Obtain final confirming X-ray in AP, lateral, and vertical views. Save this final series as an element of the operative record.



AP LATERAL OBLIQUE/ VERTICAL

PROPHYLACTIC ANTIBIOTICS AND ANTICOAGULATION

Perioperative antibiotic selection and antithrombotic prophylaxis are generally exercised based on regional and local care norms. Following discharge, the surgeon and care team should follow local protocols.

PROTECTED WEIGHT BEARING

Patients are kept touch-down (toe touch) weight bearing on crutches or walker for six weeks. After six weeks, patients are cautiously encouraged to resume activities, respectful of balance, comfort and safety.

NSAIDS

Nonsteroidal anti-inflammatory drugs should be avoided. NSAIDS can interfere with or delay bone healing. A sacroiliac joint fusion is an operation where success depends on unecumbered bone health.

SMOKING

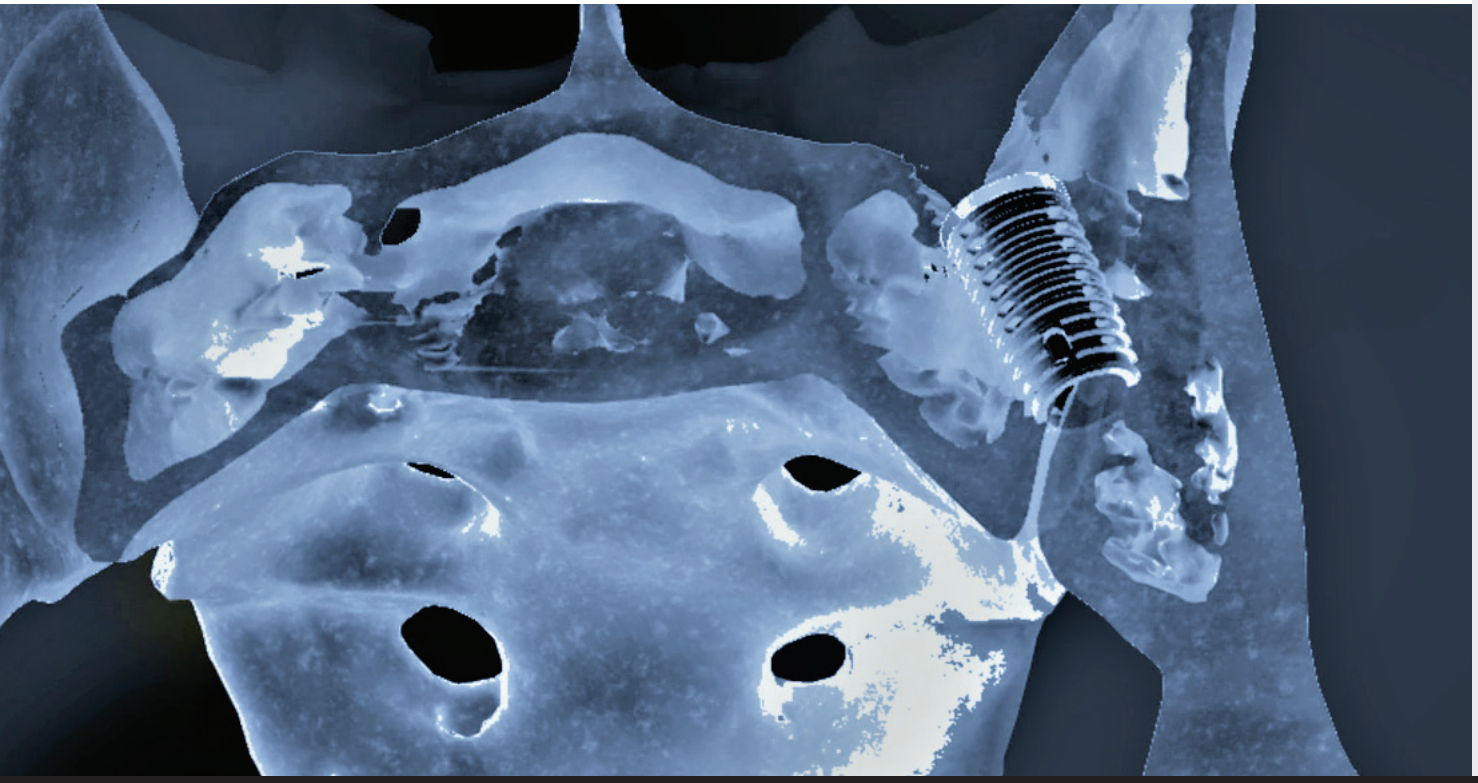
Patients should be encouraged to stop smoking. Smoking may cause healing delay or nonunion. Smoking also complicates the patient's use of narcotics.

PAIN CONTROL

Chronic pain syndromes are common within the SIJ population. Narcotics, antidepressants, and deconditioning all play a part in the patient with a severe problem or delayed diagnosis. Individually or collectively, these problems complicate or slow the patient's recovery. The patient may require additional support beyond a typical period of bone healing.

PATIENT SUPPORT

Encourage family involvement. Within the office, discuss the difficulties with the medical staff. Create a supportive environment for severely suffering patients.



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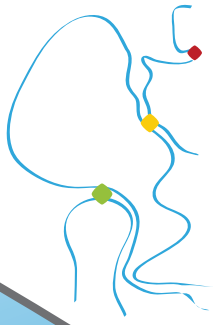

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US Patents:

7,648,509	8,454,618	8,734,456
9,808,346	10,149,764	2,117,479
9,668,781	8,740,912	9,314,232
10,682,150	2,262,433	5,438,694
9,345,589	1,274,593	1,500,130

Other Japanese and European Patents
Other Patents Pending

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REV: 2020-10