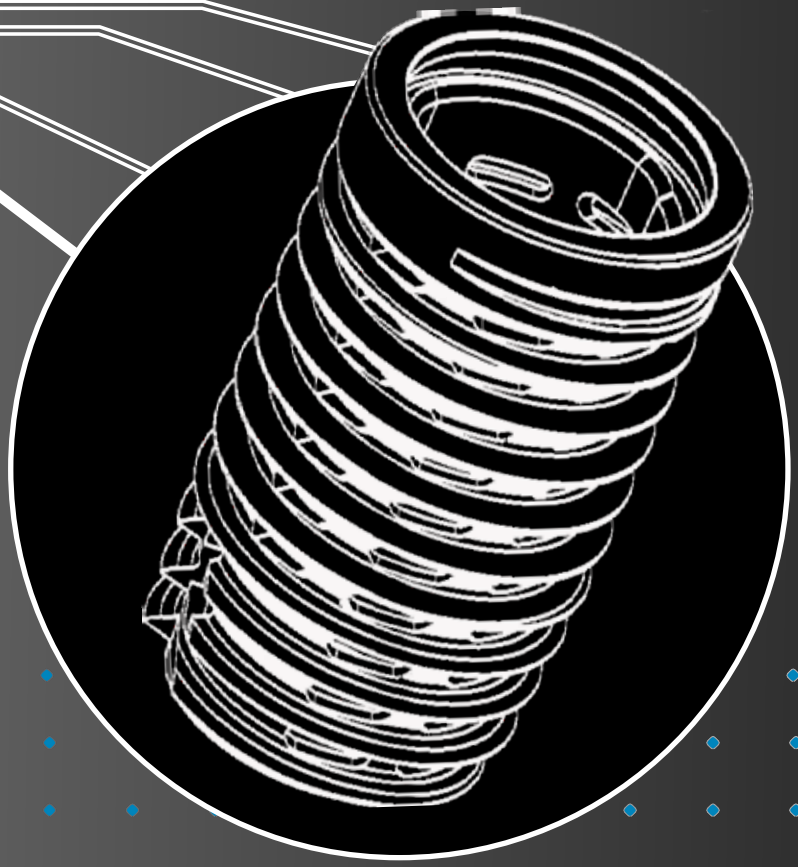
NADIA®

NeuroSafe® Surgical Bridging Technique

SACROILIAC JOINT ARTHRODESIS



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AN INVITATION TO A CHALLENGING PROBLEM

The sacroiliac joint (SIJ) remains a lingering challenge in spine surgery. Although the sacroiliac joint involvement in low back complaints has been suspected for many years, new means of diagnosis and more effective treatment have made it clear that the sacroiliac joint is a significant pain generator, whose severe symptoms often mimic pain of the hip or spine.[1] Failure to recognize the SIJ as the clinical problem will result in a misdiagnosis, eventually causing poor results or late patient dissatisfaction of an otherwise successful regional surgery. For these reasons the NADIA method of bridging the SIJ has been developed.

DIAGNOSIS

The diagnosis of sacroiliac disease should be made using a combination of clinical examination, radiographic imaging and provocative testing with injections. [1-2]

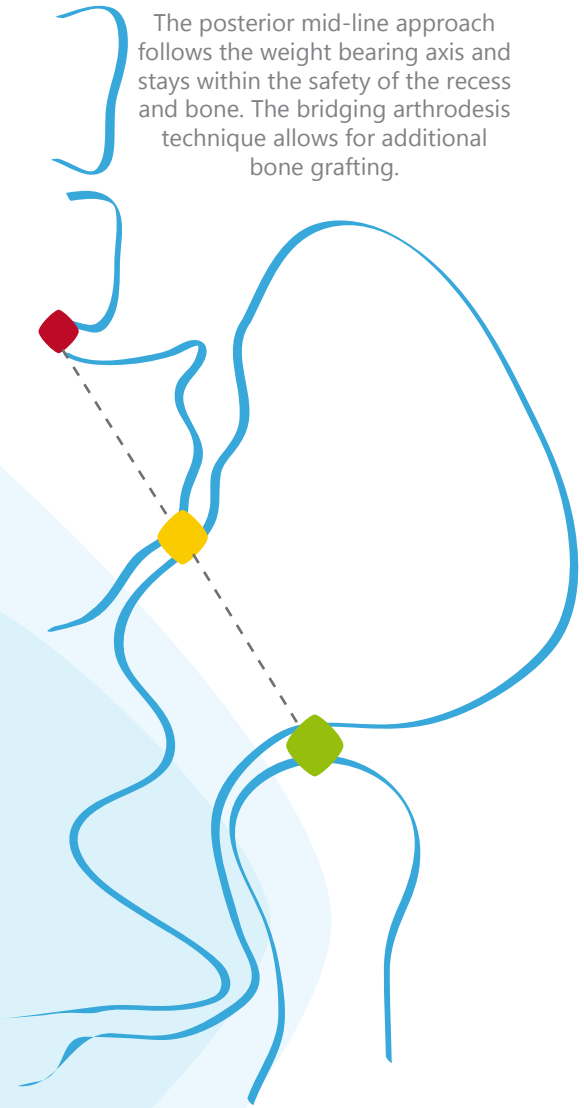
PAIN GENERATOR

SIJ pain has been suggested to be caused by motion, painful force concentrations, or osteoarthritis. Osteoarthritis is a common explanation for pain originating from the SIJ.[1] Surgical fusion or fixation has been used to address these suspected pain generators. [1,3]

1 "The diagnosis and treatment of sacroiliac joint abnormalities" John G. Stark (Current Orthopaedic Practice Volume 21 Number 4 July/August 2010)

2 Osteophyte at the sacroiliac joint as a cause of sciatica: A report of four cases. Bhaskaranand Kumar, K.G. Sriram, Chacko George, Kasturba Medical College, Manipal, Karnataka, India. Journal of Orthopaedic Surgery 2002, 10(1): 73–76. Idemmili, Meyer. ©2011

3 "The history of sacroiliac joint arthrodesis: a critical review and introduction of a new technique." John G. Stark et al. (Current Orthopaedic Practice Volume 22 Number 6 November 2011)



The posterior mid-line approach follows the weight bearing axis and stays within the safety of the recess and bone. The bridging arthrodesis technique allows for additional bone grafting.

ANATOMICAL FEATURES

The neurovascular anatomy surrounding the sacroiliac joint is amenable by a proper surgical approach. For this reason, the guide pin of the NADIA posterior 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 patented posterior approach of the NADIA technique never crosses critical neurovascular anatomy. Safety is planned into every step.

SURGERY AND HEALING CONDITIONS

The tapered NADIA implant serves only as a bridge to stabilize the joint and to support arthrodesis and bone healing. The NADIA implant is designed to restore the anatomical relationships through a small amount of distraction. To maximize outcomes a full consideration of endocrine, metabolic, or nutritional deficiencies is necessary.

CHALLENGING TREATMENT

In the light of increasing published numbers of adverse events with laterally based techniques, surgical treatment of the sacroiliac joint is a worthy challenge for any spine surgeon. Any SIJ surgical method, including the NADIA procedure, requires a precise diagnosis for optimal results. Treatment of any of these individual structures requires a full understanding of the diagnosis and all respective treatment options.

A reliable, safe SIJ surgical treatment method fulfills an important need in spine surgery.

- John G. Stark, MD

FEATURES THE OF NADIA IMPLANTS

Reliable. Pin-guided instrumentation follows radiologic landmarks and allows for consistent safe placement of the implant.

Multi-capacity thread. Cortical and cancellous threads combined into the same construct.

Tapered design. Tapered slightly, 1 mm over its 30-mm length, providing increased engagement as the implant is advanced.

Porous coating. The proprietary surface topography resulting from a combination titanium plasma spray and hydroxyapatite coating engages the bone at the microscopic and macroscopic levels.

Implant design concept. The implant is designed to bridge the space between the ilium and the sacrum.

Material. The implants are made from medical grade titanium alloy (TiAl6V4) according to ASTM F-136 and ISO 5832-3, and are provided with hydroxyapatite coating.

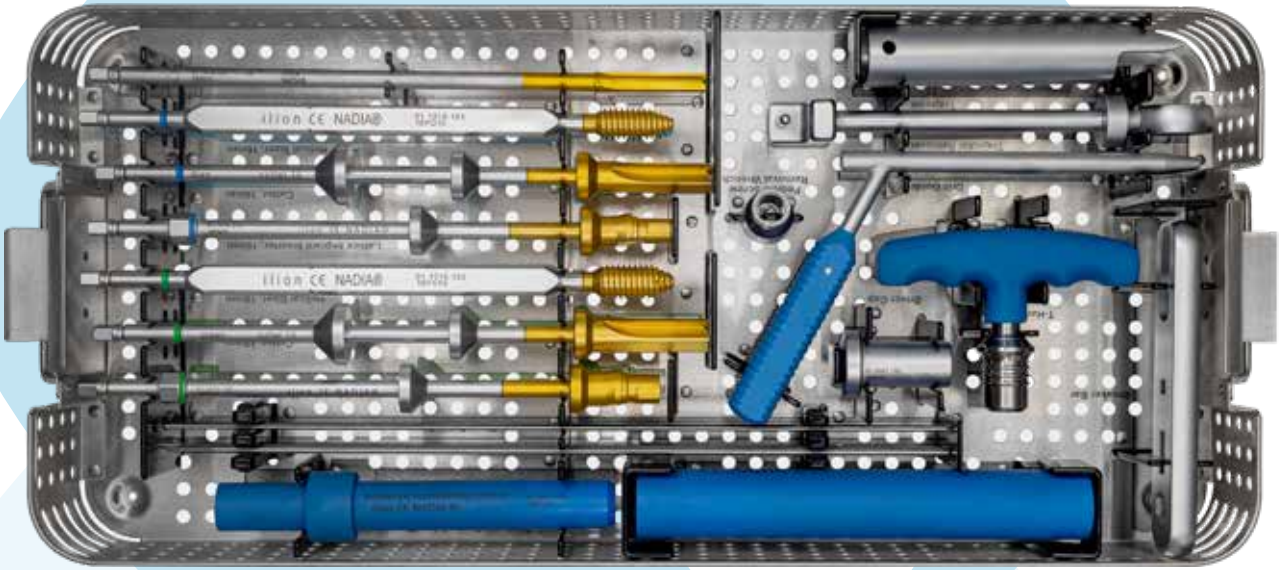
Implant sizes. Appropriate sizes are available for individual patient needs.

NADIA SIJ LATTICE IMPLANTS

DESCRIPTION	ARTICLE NO.	Ø	L
NADIA SIJ LATTICE	01.1016.030	16	30
NADIA SIJ LATTICE	01.1018.030	18	30

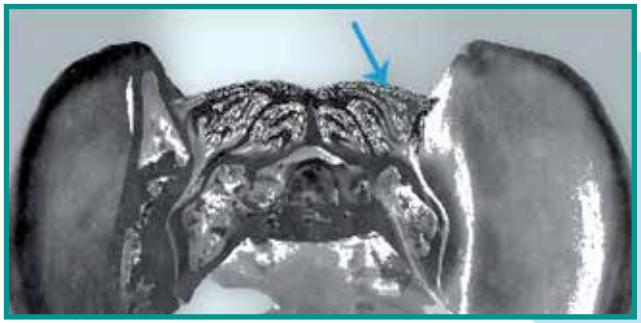
* The NADIA implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the NADIA implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

NADIA LATTICE INSTRUMENT SET



DESCRIPTION	ARTICLE NO.
T-HANDLE	01.0010.100
DRIVER CAP	01.007.100
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

The NADIA posterior technique emphasizes bone healing, mechanical stabilization and alignment of the anatomic structures. Following orthopedic principles, the familiar posterior approach allows for bridging the sacroiliac joint space through open bone grafting, preparing the recess for arthrodesis.
Review the patient's preoperative imaging studies for signs of previously placed implants in the lumbar spine area which may need to be removed if they interfere with the approach. A pedicle screw removal wrench is included with the instruments.



PATIENT SUPPORT AND POSITIONING

To perform the posterior approach, the patient is positioned prone on the radiolucent table and the surgeon stands contralateral to the operative sacroiliac target. This position puts the surgeon's line of view down the extraarticular recess.

The patient should be supported with bolsters on each side of the body and positioned in an anterior-posterior plane. For true AP and lateral views patient rotation must be corrected.

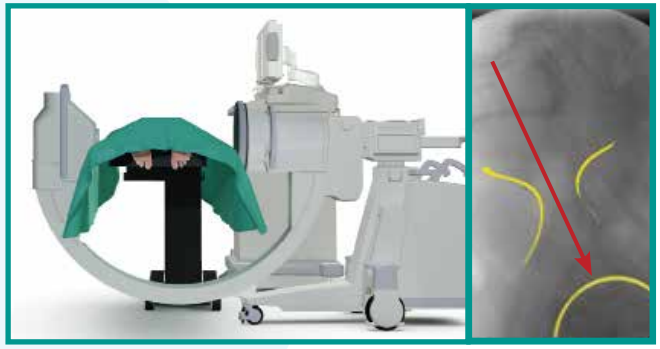
INTRAOPERATIVE C-ARM USE

Accurate placement of the Guide Pin requires excellent intraoperative imaging. To accomplish this, the C-arm base should be placed at a true right angle to the patient. The C-arm will then easily rotate freely around the table so that true AP, lateral, and vertical oblique films can be obtained. Minimal amounts of correction (wag of the C-arm, tilting of the table) will be necessary.

STEP 1: AP

Once the C-arm is properly positioned and corrected, 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.

STEP 2: LATERAL



The C-arm should be rotated into the lateral position. A true lateral view of the pelvis is necessary at this stage. This means that the sciatic notches are superimposed. If the sciatic notches are indistinct because of bowel gas or soft tissue size, the hips can be used for orientation.

STEP 3: VERTICAL

With AP and true lateral established, the patient is properly positioned for the vertical oblique series. The vertical oblique series will be obtained by rotating the receiver over the top of the patient, in 10 degree increments from the AP view, until the SIJ joint line and the recess come into view.

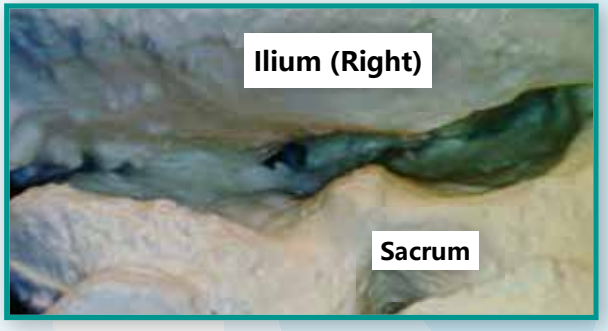
PREPARATION OF THE RECESS

Coronal cut showing the intraosseous ligaments (syndesmosis), recess, and SIJ

Skin incision and blunt dissection towards the medial wall of the ilium

The medial ilium and dorsal sacrum provide adequate surface area for extraarticular bridging fusion. These structures can be safely approached through a posterior incision. The incision is equidistant proximally and distally, centered at the superior margin of the sacrum. The incision and the subcutaneous tissues are followed deep to the fascia, which is then followed laterally. The PSIS can be palpated through the fascia easily, and medial to the PSIS, (approximately 2 cm) a paramedian fascial incision of approximately the same length is made. Self-retaining retractors are inserted obliquely so the skin incision and the paramedian incision are aligned, directing the surgeon and the surgical instruments into the intersection of the ilium and sacrum. Before entering the recess, remove the soft tissues of medial ilium and adjacent dorsal sacrum to define the area. The recess itself may be approached with a large curette or pituitary rongeur. Follow the bone margins and important landmarks.

Start curetting of the recess with the medial ilial wall and work down to the recess bottom. Curettes of appropriate size are used to remove the sacralis muscle from the medial ilium and dorsal sacrum. The dissection does not involve the iliac crest itself or long spinal extensors which originate along the iliac crest dorsally.



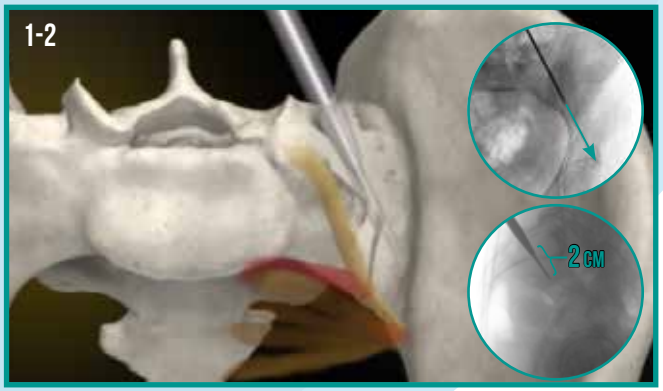
Caution:
The extraarticular recess is ordinarily easily found, but the adjacent bone surfaces may be soft on the sacral side. Attention should be directed toward removing the soft tissues from the recess, preserving bony margins.

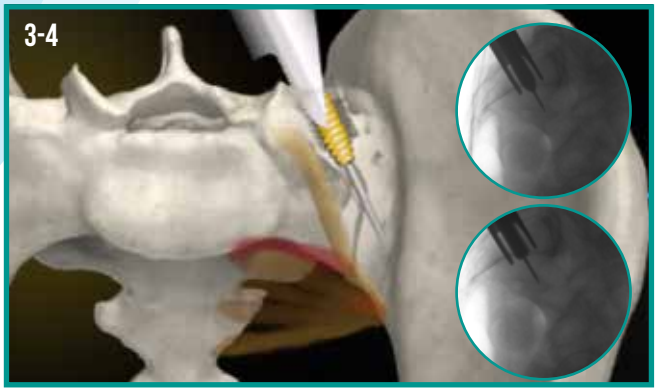
INDICATIONS FOR USE:

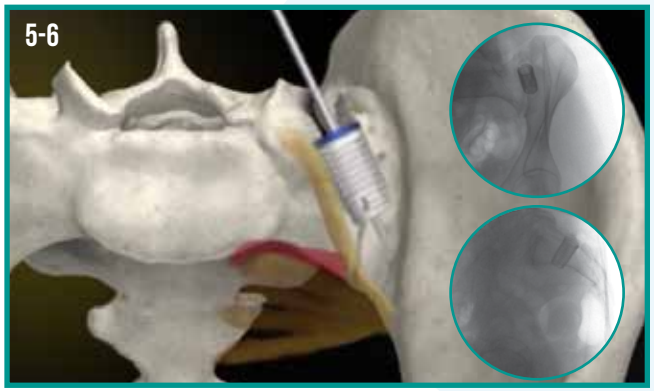
The NADIA SI Arthrodesis System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

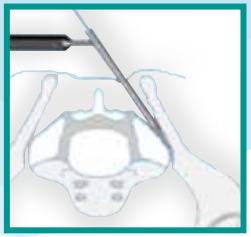
CONTRAINDICATIONS:

- Acute or chronic infection of bone or skin
- Hypersensitivity or allergy to implant material
- Deformity, post traumatic or developmental, which will not accept the device
- Inadequate bone density to hold the device (osteoporosis or osteomalacia)
- Compromised metabolic or nutritional status that will impair postoperative healing
- Inadequate skin or soft tissue coverage
- 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,
- 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 range of 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 psychosocial or psycho-emotional resources to undergo or recover from complex surgery
- Inadequate physical proximity to medical care, to undergo 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.

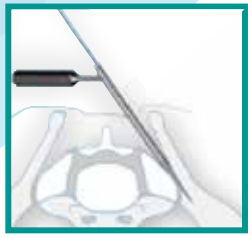








Drill Guide in position over the Blunt Guide Pin

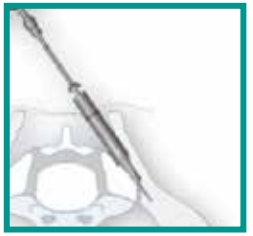


Threaded Guide Pin advanced to its final position

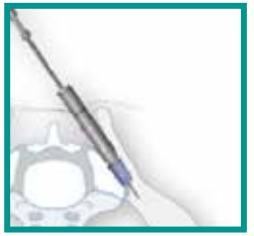
Starting position of the Helical Sizer

Helical Sizer in position

Trajector in position over the Helical Sizer



Cutter in position within the Trajector



Implant and Inserter in position

Bridging Implant in final position

1. Make a posterior incision, planning for a paramedian fascial incision. Stand contralateral to the operative side. The bone surfaces of the recess are cleaned of soft tissue. Decortication and bone grafting are generally accomplished before pin placement.

2. Introduce a small provisional Blunt Guide Pin into the extraarticular recess at approximately the level of the S2 transverse process. Obtain AP, oblique vertical and lateral X-ray, confirming that the provisional pin is in the recess, directed toward the hip on all views. The 3.2 mm Threaded Guide Pin is then substituted for the provisional pin and advanced under power into the safety of the iliac bone.

3. Use the Precutter to prepare for the purchase of the Helical Sizers. The Precutter should reach the anterior sacral line on the lateral X-ray. Begin with the 16 Sizer, and progress to the largest that will fit tightly; this will determine the size of the final implant. The tip of the Sizer should extend to the depth reached by the Precutter (anterior sacral line on the lateral X-ray).

4. Use the Trajector to maintain the position achieved by the Helical Sizer. Assemble the Impacting and Centralizing Tubes with the Trajector and place over the Sizer; impact gently into place with the mallet.

5. Remove the Helical Sizer. Place the Cutter over the Guide Pin within the Trajector; observe the progress on the lateral x-ray, advance the cutter to the anterior sacral line.

6. Attach the implant to the Inserter, place over the guide pin and follow with lateral X-ray. Advance it by turns into the receiving channel until it stops firmly at the deepest extent of the prepared channel. The implant will provide a tight fit, as it is slightly oversized to restore the anatomical position by providing approximately 1 to 2 mm of distraction. Remove the Inserter by pulling gently straight backwards. Complete bone grafting; fill all voids. Obtain final confirming X-ray in AP, lateral, and vertical oblique views. Wound closure in layers is performed with absorbable suture only.

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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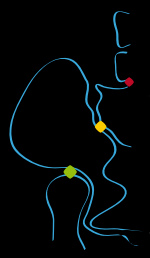

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