Insertion of a Posterior Spinal Motion Preservation Device

The TOPS™ System

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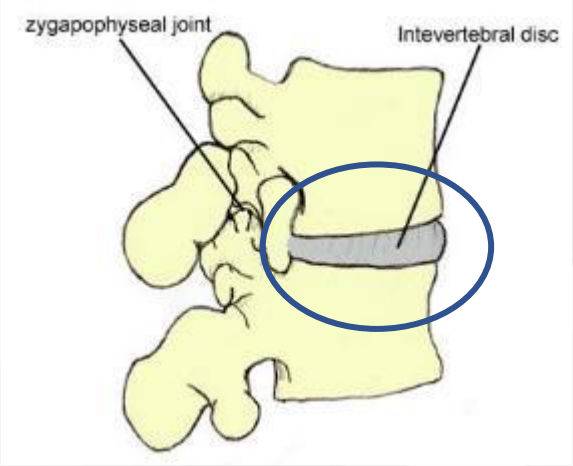
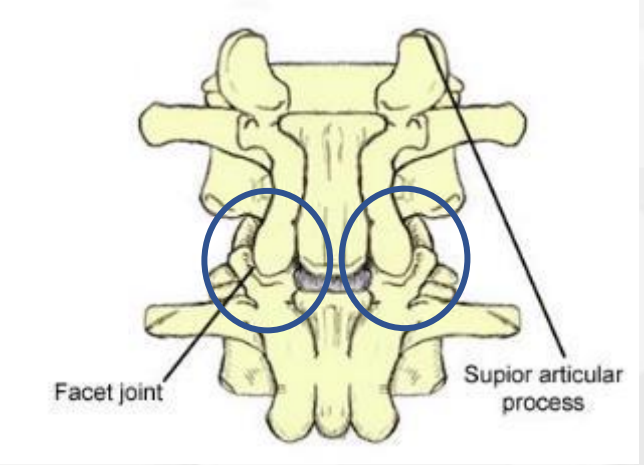
ICD-10 Coordination and Maintenance Committee Meeting

The Lumbar Vertebral Joint

- The lumbar vertebral joint is comprised of the intervertebral disc in the front and the two facet joints in the back of the spine
- The facet joints play a critical role in the function of the spine





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The Degenerative Cascade

- Lumbar facet joints degenerate over time like many other joints
- Osteoarthritis of the facet joints can contribute to:
  - **Spondylolisthesis**—the slip of one vertebra over another
  - **Spinal stenosis**—the narrowing of the central spinal canal or the foraminal exiting nerve roots

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Treatment for Spondylolisthesis & Stenosis

- Surgical treatment options for spondylolisthesis and stenosis are limited and have remained essentially the same for more than 50 years. These include:
  - Lumbar decompression without fusion
  - Lumbar decompression with instrumentation
- The determination of whether to add, for instance, a fusion construct is based on the surgeon's assessment of whether the patient requires instrumentation to restabilize the spine

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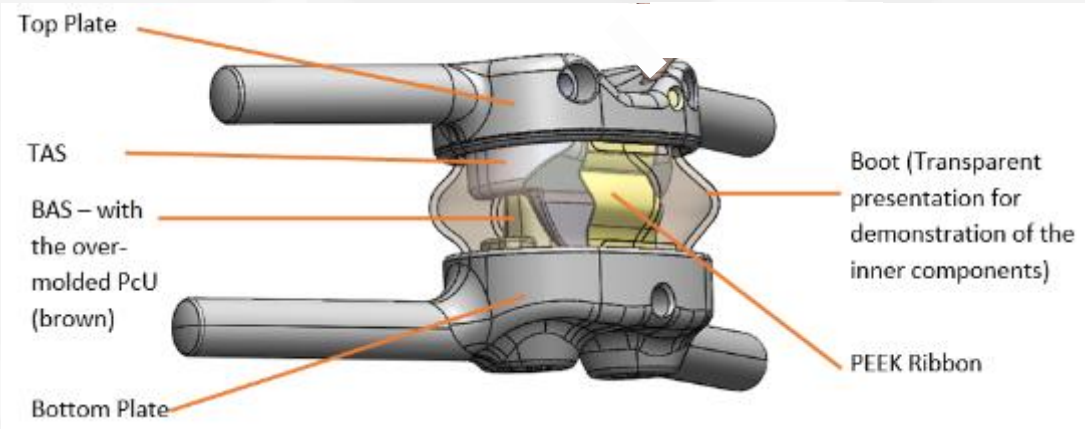
The TOPS™ System

- Pedicle screw-based device that is inserted into the lumbar vertebral joint
- Titanium construct with polycarbonate urethane (PcU) articulating core



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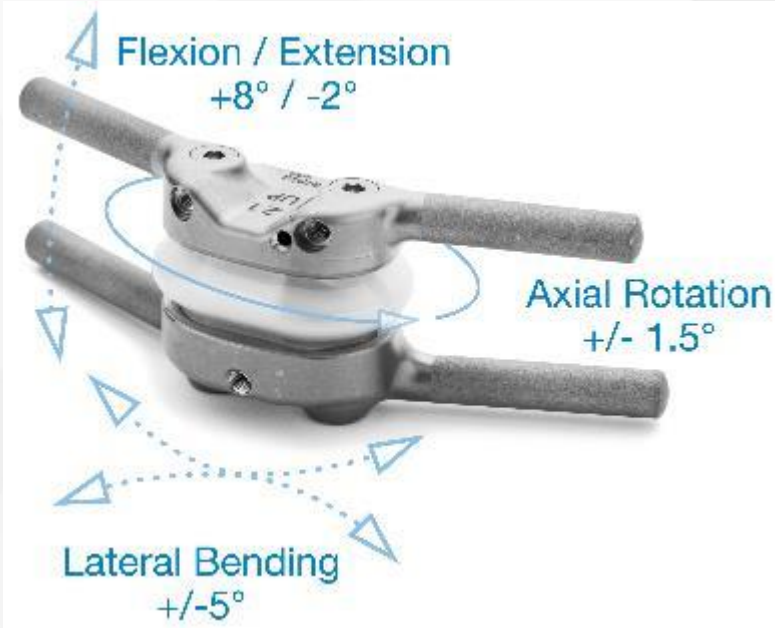
- Stabilizes the spine segment after a decompression
- Allows movement between the plates, simulating physiologic motion in axial rotation, lateral bending, extension, flexion and constrained sagittal translation



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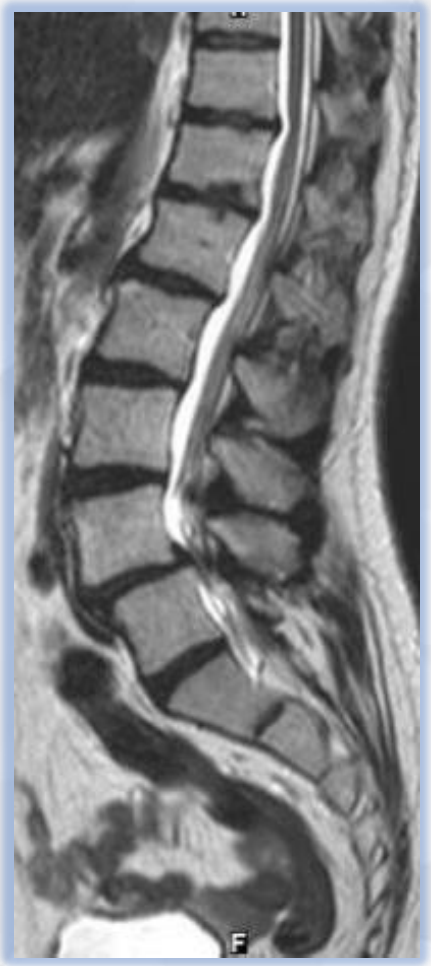
The TOPS™ System Indications

Primary Indications

Degenerative pathology at a single lumbar level between L2-L5 that includes:

- At least moderate spinal stenosis, and;
- Degenerative spondylolisthesis (up to Grade 1), and;
- Thickening of ligamentum flavum OR scarring of facet joint capsule



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Steps

1. Patient positioning and incision
2. Decompression
3. Screw position and orientation
4. TOPS™ Implant sizing and screw alignment
5. TOPS™ device preparation and insertion

Surgical Technique

Patient Positioning

- Neutral patient position
- No kyphosis or hyper-lordosis
- No mechanical reduction
- Legs straight or bent

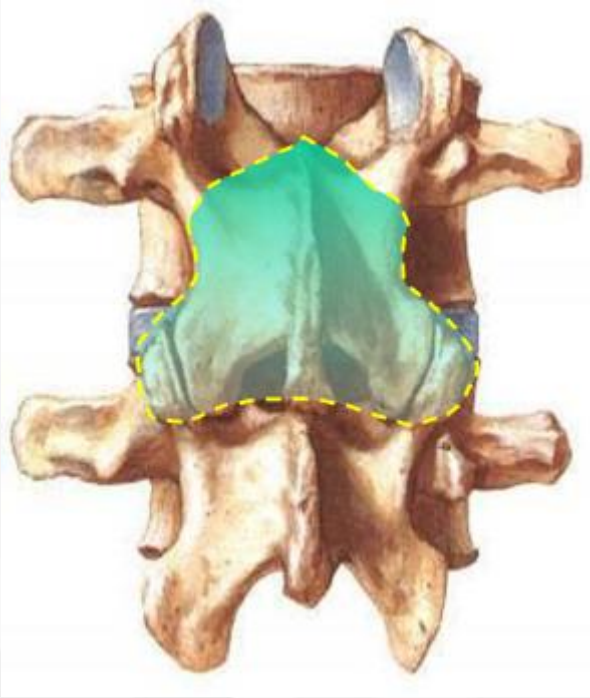
Incision/Approach

- Open, midline approach
- Incision: 6 – 11 cm
- Spinal muscle dissection up to spinous process
- Bilateral facet - visualization recommended

Surgical Technique

Decompression

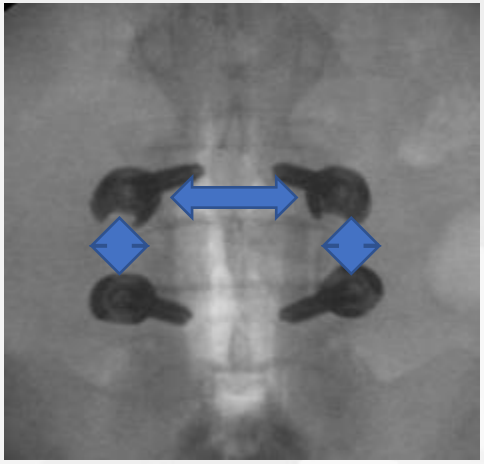
- Minimum Decompression
  - Resection of spinous process
  - Complete laminectomy (incl. Pars)
  - Resection of ligamentum flavum
  - Bilateral facetectomy of inferior articulating process & superior articulating process

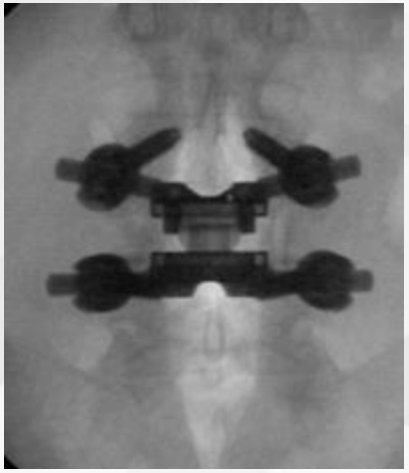


Surgical Technique

Screw Position and Orientation

- Screws are oriented such that there is symmetry between:
  - Right/Left side pedicle screws
  - Superior/Inferior positioning of the pedicle screws
- Positioning facilitates placement of the TOPS™ Motion Implant





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Surgical Technique

Operative Report

* Preliminary Report *

Operative Note (Unverified)

Pt Name: [redacted] MRN: [redacted] Date of Birth: [redacted]

DATE OF SERVICE: 06/11/2020

PREOPERATIVE DIAGNOSES:
1. L4-5 stenosis and spondylolisthesis.

POSTOPERATIVE DIAGNOSES:
1. L4-5 stenosis and spondylolisthesis.

PROCEDURE: Decompressive laminectomy, facetectomy and foraminotomy at L4-5 with placement of TOPS artificial facet device, nonsegmental fixation with TOPS artificial facet device.

SURGEON: Dom Coric, MD

ASSISTANT: Justin Brooks, PA and Stephen Mounk. Please note this case was in excess of what could be expected from a PGY1 assistant and required a midlevel assistance.

ANESTHESIA: General endotracheal.

ESTIMATED BLOOD LOSS: 250 mL.

Regulatory Status

- 1st implanted 16 years ago. Over 1,200 patients worldwide
- CE Mark
- Received FDA Breakthrough Device Designation in 2020
- US IDE study initiated in 2017
  - Minimum 300 patients (2:1 randomized)
  - 5-year follow-up
  - 2-year TOPS versus Fusion data analysis shows:
    - High double-digit primary end-point advantage
    - Similar risk profile but fewer revisions
- Premarket approval (PMA) application filed in 2022
- Commercial launch anticipated Q3, 2022

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Thank you