



Posterior Vertebral Body Tethering

March 8, 2022
ICD-10 Coordination and
Maintenance Committee Meeting



Clinical Background: Adult Spinal Deformities

Adult spinal deformities (ASD) are a well-recognized contributor to pain, disability, and depression¹.

- ASD can include scoliosis, kyphosis, positive sagittal balance, and spinal and neuroforaminal stenosis².
- ASD patients often suffer significant disability³ and report functional limitations, increased pain, and increased use of analgesic medications⁴.
- ASD patients are often limited to light work and household chores and may not be able to participate in sports or perform heavier work like unaffected adults⁴.
- ASD patients are more likely than non-ASD individuals to suffer from anxiety and depression⁵.
- ASD pose a significant impact on patients' health-related quality of life (HRQL)³. The mean SF-36 PCS values for ASD patients were lower than the average for the U.S. total population and were similar to values reported by patients with other high-profile and significant chronic conditions such as diabetes, heart disease, and rheumatoid arthritis².

As the prevalence of adult spinal deformity rises, secondary to the increase in the aging population, the need is greater than ever for a more effective surgical treatment option that addresses the debilitating symptoms and minimizes postoperative complications.



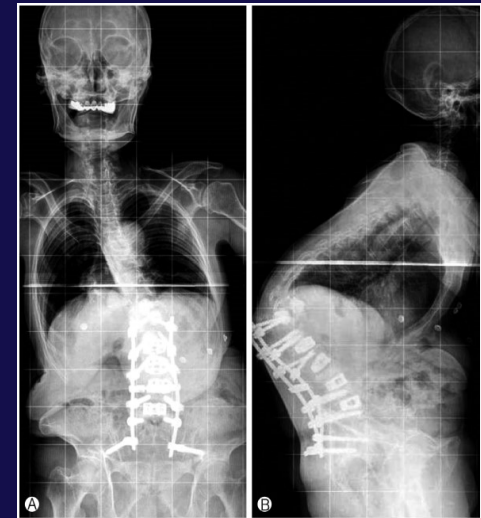
Source of illustration: <http://spinal-deformity-surgeon.com/case-studies/severe-thoracic-hyperkyphosis-deformity/>

Proximal Junction Failure (PJF) and Proximal Junction Kyphosis (PJK): Clinical and Economic Burden

Adult spinal deformities are an irreversibly debilitating disease state that are a well-recognized contributor to pain, disability, and depression in adult populations. As nonsurgical treatment options fail to produce successful outcomes long-term, surgery has become the preferred treatment method despite its associated complications.

There is an unmet need for a surgical option that reverses ASDs' debilitating sequela while mitigating the risks of surgery. **Proximal junction failure (PJF) is recognized as one of the most frequent reasons for reoperation after ASD surgery and requires large, time consuming, and expensive revision surgeries estimated to cost \$119,217⁶.** Preventing PJF/proximal junctional kyphosis (PJK) poses significant clinical and economic impact.

Post-operative rates of PJK vary by the tested definition, but most range from **17% to 39%**. Reports show that PJK onset occurs early after the operation, with 66% of cases observed in the first 3 months and 80% within the first 18 months.



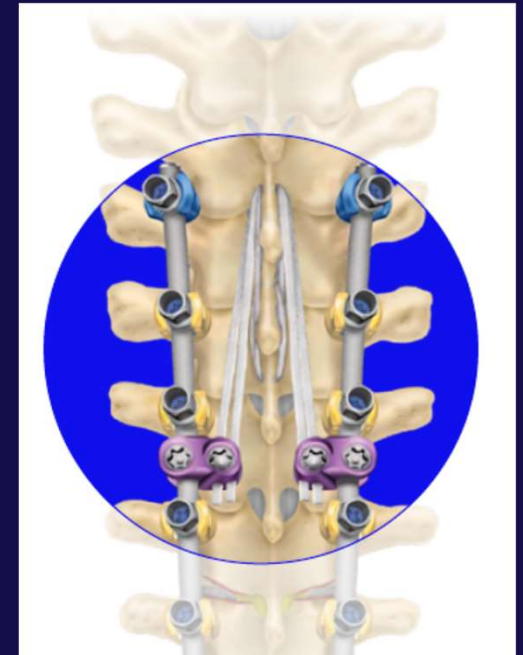
Source of illustration:

Kim, Yongjung J., et al. Proximal junctional kyphosis in adolescent idiopathic scoliosis following segmental posterior spinal instrumentation and fusion: minimum 5 year follow up. Spine 30.18 (2005): 2045-2050.

The LigaPASS™ 2.0 Prevention System

The LigaPASS™ 2.0 PJK Prevention System is intended for use when ligament augmentation is considered appropriate to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF).

- Consists of a polyethylene terephthalate (PET) band and titanium connector to make the rod-bone connection
- Allows surgeons to perform a tethering technique with specific band lacing options through spinous processes of UIV* and adjacent levels.
- Provides surgeons the ability to mimic anatomical muscle and ligament functionality and stabilization between vertebrae adjacent to fused levels in a spine surgery
- This technique is not a stand-alone procedure but complements a spinal deformity correction procedure.



*UIV: Upper Instrumented Vertebrae

LigaPASS™ 2.0 Indications for Use

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The LigaPASS™ 2.0 PJK Prevention System is indicated for “spinal trauma surgery, used in sublaminar or facet wiring techniques; spinal reconstructive surgery, incorporated into construct for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis and kyphosis; spinal degenerative surgery as an adjunct to spinal fusions; intended for use at the *non-fused level(s) adjacent to a posterior spinal instrumentation* construct when ligament augmentation is considered appropriate to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF). The LigaPASS system may also be used in conjunction with other medical implants made of titanium or cobalt-chrome alloy whenever ‘wiring’ may help secure the attachment of other implants.”

LigaPASS™ 2.0 Procedural Steps

1. Spinous process preparation:

Once posterior construct and spinal correction are performed, spinous process of the UIV and adjacent segments are drilled with Midas Rex™ MR8™ high speed drills and matchstick burrs.

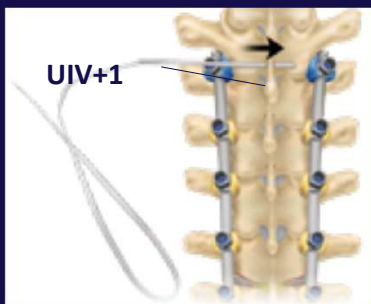


2. LigaPASS Lacing:

Two single bands are inserted through drilled holes:

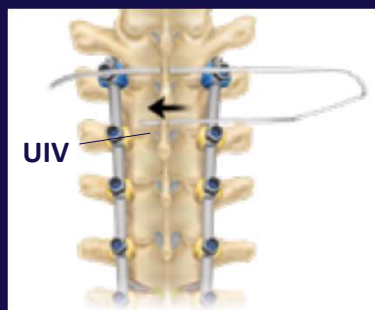
STEP 1

Pass the band through the ipsilateral process.



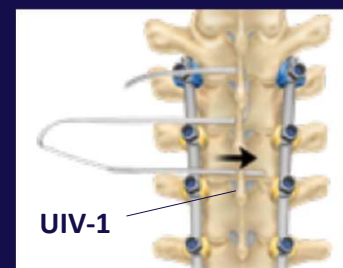
STEP 2

Pass the band through the contralateral side of the UIV spinous process hole.



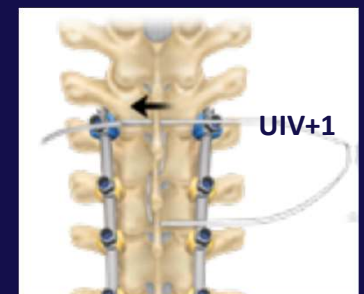
STEP 3

Insert the band through ipsilateral side of the distal hole of UIV 1.



STEP 4

Pass the band into the UIV+1 side of the UIV+1 spinous process so both ends of the band are exiting UIV+1 on the ipsilateral side.



LigaPASS™ 2.0 Procedural Steps

Using the same spinous process holes, the second band of the tether is performed in a mirror fashion.

3. Connector Engagement

- Band extremities into the LigaPASS™ 2.0 medial open connector.
- Once connected, connectors are slid along bands until seating onto the rods of the construct.

4. Tensioning

- The tension application is achieved through a free hand maneuver (according to surgeon feeling and intra operative observations).
- Allow surgeon to place the spine slightly in extension.
- Tension pulleys can be used if tension cannot be achieved through a free hand maneuver.



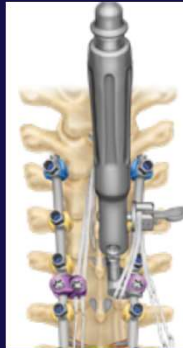
LigaPASS™ 2.0 Procedural Steps

5. Tension Pulley Assembly and Positioning

To connect the tension pulley to the band, the procedure described below must be followed:

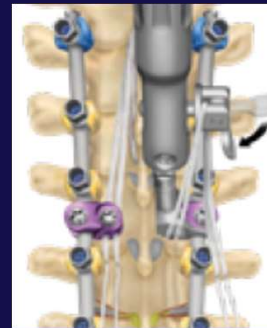
Step 1:

Place the tension pulley shaft on the LigaPASS medial open connectors



Step 2:

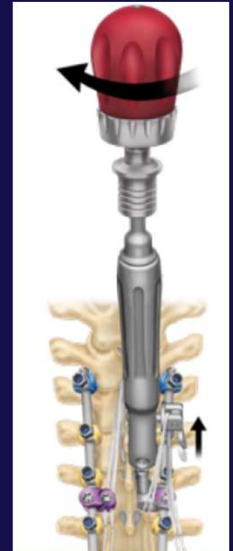
Slide the two band extremities into the buckle and press the buckle lock down to tighten the pretensioned bands.



Step 3:

Tension the band by turning the palm Ratchet Handle

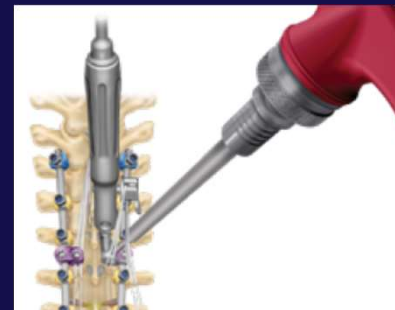
(the buckle will begin to move upward as tension is applied)



6. Final Tightening

Once the full posterior osteosynthesis construct is frozen and desired tension has been achieved, the bands are locked within the connector by tightening the band locking set screw.

(with a torque limiting handle to avoid damaging the band)



LigaPASS™ 2.0 Procedural Naming Conventions

Existing naming conventions do not uniquely identify the use of the LigaPASS system and do not allow for accurate reporting and outcomes-tracking when utilizing this device.

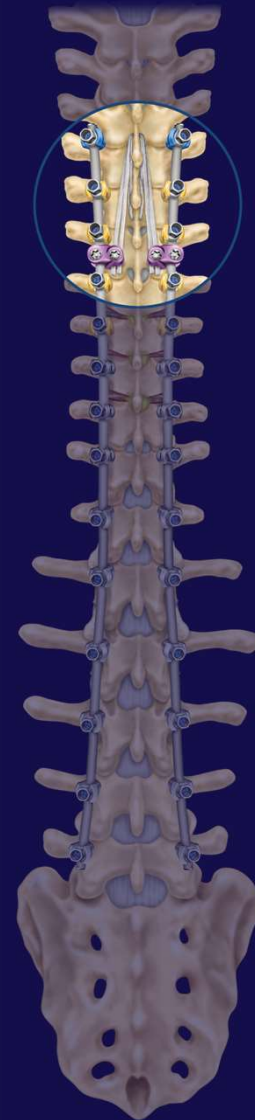
Relevant Root Operations

- Reposition: for treatment or correction of current postoperative kyphosis
- Insertion: for prevention of postoperative kyphosis
- Removal: remove of spinal tethering

Relevant Body Parts

- Thoracic vertebra
- Lumbar vertebra

The use of LigaPASS will be dictated into the procedure section of the provider/operative notes in the medical record.



Summary

LigaPASS™ 2.0 PJK Prevention System is expected to be cleared by the FDA in Q2 2022

LigaPASS™ 2.0 PJK Prevention System is intended for use when ligament augmentation is considered appropriate to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF)

LigaPASS™ 2.0 system used in a ligament augmentation technique help surgeons to mitigate risk of PJK and PJF in adult spinal deformity cases and reduce need for revision procedure

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