An Interspinous Implant to Improve Dynamic Motion in the Lumbar Spine Region

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Problem and Clinical Need

- Lumbar spinal stenosis affects 8-11 percent of the population in the United States, with an estimated 24 million affected by 2021[1]
- While minor back pain can be eliminated using physical therapy and pain medication, more severe forms of back pain require surgery
- Current procedures are able to relieve the pain through a decompression and fixation procedure, but fail to maintain dynamic motion of the spine

Market

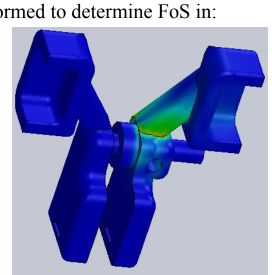
- Potential consumer base is 6 million people, but realistically target market is 500-800 thousand people[2]
- Customers are hospitals and the end users are patients with lumbar spinal stenosis

What is Novel?

- The device takes the best features of interspinous fusion, interspinous spacers, and facet replacement systems
- The device is a semi-interspinous device that provides the stabilization of a facet replacement system and the minimally invasive surgical procedures of an interspinous device

Simulation

- A static simulation was performed to determine factor of safety and evaluate modes of failures
- Model was loaded with 6.5 Nm
- Simulations were performed to determine FoS in:
  - Flexion: 13.5
  - Extension: 13.6
  - Torsion: 7.0



Output for Torsional Loading

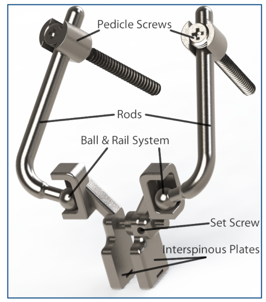


Figure 1
Isometric View of Design
Rendered in Solidworks

Figure 2
Anterior View of Design
Rendered in Solidworks

Figure 3
Exploded View of Polyaxial Pedicle Screw
Rendered in Solidworks

Design Features

- Attached using pedicle screws above functional spinal unit (FSU) and interspinous plates below FSU
- Interspinous plates mated with corresponding shafts with set screw and 6mm flat ligature
- Ball and rail system provide stabilization in flexion, extension, lateral bending, and torsion similar to facet replacement systems
- Polyaxial screws utilized to make easy adjustments in the operating room

Production Costs

- Material selection:
  - Titanium alloy Ti6Al7Nb primary structure
  - Cobalt-Chrome alloy CoCrMo articulating surfaces
- Costs include raw materials, machining, plating, and pedicle screws
- Estimates for machining and plating estimated with approximate quotes for production given a batch size of 500-1000
- Price comparison: average spinal implant cost - $13,000[3]

ITEM	COST
Titanium Alloy	$50/kilogram(kg) * 0.0518kg = $2.59
Titanium Machining	$2,200/unit
Cobalt-Chrome Plating	$150/unit
Pedicle Screws	2 * $600 = $1,200/unit
TOTAL COST PER UNIT	**~ $3,550/unit**

Anticipated Regulatory Pathway

- Regulatory pathway is 510(k) for class II devices
- VertaMotion is similar in magnitude to the ACADIA Facet Replacement System
  - Both devices target patients suffering from spinal stenosis and maintain dynamic motion

Acknowledgements

- We would like to thank Professor Conrad Zapanta and Mentor Boyle Cheng, PhD, for their constant support and helpful guidance.

References

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