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BIOMATERIAL SOLUTIONS

PEEK-OPTIMA™ Spinal Rods

A non-metal semi-rigid posterior spine stabilization technology

TECHNOLOGY OVERVIEW

Bridging the gap with PEEK OPTIMA™ Natural polymer

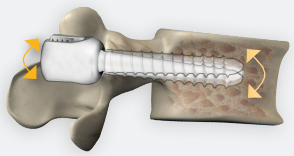
- Modulus similar to bone
- Radiolucency and artifact-free imaging
- Strong, durable and highly resistant to creep[1] and fatigue

Image provided courtesy of Innov'Spine

The Initial VEOS PEEK-Optima Osteosynthesis System (A) with PEEK-OPTIMA Rods and Pedicle Screws (B). PEEK rods provide elastic modulus similar to bone that offers both adequate rigidity for fusion and a flexibility that limits the stress created by rigid rods (C).

Potential benefits compared to metal

- Reduced stress at the bone-screw interface which may prevent screw loosening and device failure[2]
- Greater pull-out strength after dynamic loading[3]
- More physiologic loading at adjacent levels[4]
- Better fusion healing assessment
- Easier rod insertion due to lower stiffness[5]



Micro-motions at the bone-screw interface during dynamic loading of a stiff construct can toggle screws, allowing them to loosen.

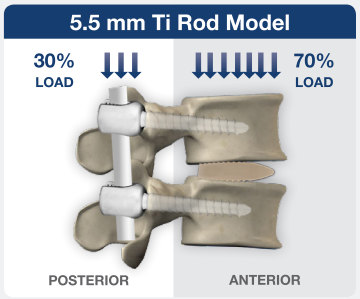
PRE-CLINICAL EVIDENCE

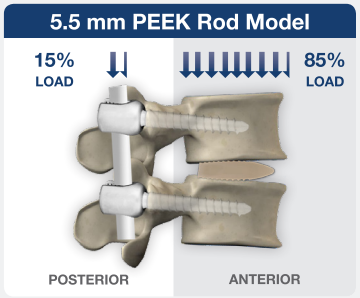
Potential to reduce hardware complications

- Complications related to screw loosening and pull-out, adjacent level disease, and implant failures continue to be a challenge[6,7]

Compared to metal PEEK-OPTIMA Spinal Rods provide:

- 20% greater anterior load[2]
  - May improve fusion according to Wolff's law
- 22% less anterior load on adjacent level[3,4]
  - May reduce adjacent level disease
- 22% greater screw pull-out force after fatigue testing[3]
  - May reduce screw loosening and pull-out, particularly in elderly patients with poor bone





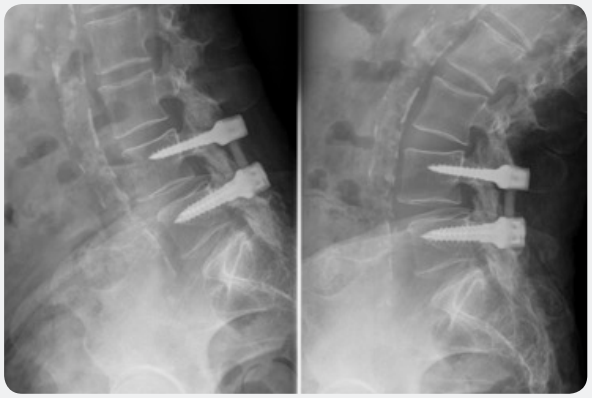
PEEK-OPTIMA Spinal Rod Components offer a 21% increase in anterior loading over Titaniaum Rods.[2]

CLINICAL EVIDENCE

Clinical history demonstrated with peer-reviewed publications:[8-14]

- 286 cases demonstrating:
  - 4.5% re-operation rate overall
  - 94.8% fusion rate overall

Beneficial clinical outcomes in patients with Grade 1 Degenerative Lumbar Spondylolisthesis



Post-operative flexion/extension dynamic X-rays at the L4-L5 level.[15]

Potential Advantages in Lumbar Spine Stabilization[15]

- Reliable and efficient surgical technique
- Safe and effective stabilization
- Substantial improvement in ODI
- Low rate of serious complications and reoperations
- No short-term incidence observed on adjacent levels

~9M PEEK-OPTIMA Devices Implanted Worldwide

20 Years of Clinical History

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PEEK-OPTIMA™ Spinal Rods: Promising clinical outcomes published

Title	No. of patients	Age	With cage	No. of levels	No. of reoperations	Reoperation rates	No. of fusions	Fusion rate	Average follow up (months)
Posterior lumbar fusion by PEEK rods in degenerative spine: preliminary report on 30 cases.[8]	30	61 (31 -80)	22	2.9 (2-5)	1	3.3%	29	96.7%	18
Polyetheretherketone (PEEK) Rods in Lumbar Spine Degenerative Disease: A Case Series.[9]	42	53.7 (31-83)			8	19.0%	37	89.3%	31.4
Comparative effectiveness of PEEK rods versus titanium alloy rods in lumbar fusion: a preliminary report.[10]	20	50.4 (32–74)	20	1	0	0%	20	100%	12
Posterior Spinal Fusion Using Pedicle screws.[11]	52	55.4 (35-71)	19	1-2	1	1.9%	50	96.2%	36 (1.5-5)
Retrospective Case Series Review of the Safety and Tolerability of Implanted Polyetheretherketone PEEK Rods.[12]	109	NC	NC	2-4	2	1.8%	NC	NC	60
Polyetheretherketone (PEEK) rods: Short-term results in lumbar spine degenerative disease.[13]	12	43 (25-62)	12	1-2	0	0%	12	100%	29 (22-36)
Flexible Stabilisation of the Degenerative Lumbar Spine Using PEEK Rods.[14]	21	70	0	1-2	1	4.8%	NC	NC	29.3
TOTAL	**286**	**NC**	**NC**	**N/A**	**13**	**4.5%**	**148**	**94.8%**	**NC**

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5. Testimonials presented have been provided by practicing orthopedic surgeons. Their view and experience are their own and do not necessarily reflect those of others. "Invibio" disclaims any liabilities or loss in connection with the information herein.
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