

Carter Lonsberry, CEO
icotec Medical, Inc.

Laurence D. Rhines, MD
Professor/Director
Spine Tumor Program
Dept. of Neurosurgery
MD Anderson

Radiolucent Carbon/PEEK Pedicle Based Screw System

ICD-10-PCS Code Request
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Traditional Metal Pedicle Screws

- Metal Pedicle Screws have long been the standard for:
 - Degenerative, deformity, trauma and tumor stabilization permanent implants
 - ***Spinal Tumor patient treatment*** is more complex and extends beyond just treatment for pain and instability
- Treatment issue in spinal tumors when receiving radiation before or after surgery
 - Metal implants block and scatter radiation
 - Metal implants create artifacts making post-surgical visualization of recurrence difficult

Radiolucent Carbon/PEEK Pedicle Screw System

Advanced Technology for Spinal Tumor Stabilization Treatment

Insertion of a posterior pedicle based system at one or more levels of the thoracic or lumbar spine, via an open or percutaneous approach using a ***radiolucent/carbon PEEK pedicle screw system*** for spine stabilization procedures with or without the intention to fuse the posterior column in patients with early or advanced stage spinal tumors to restore the integrity of the spinal column.

Coding Request

We are requesting the creation of new codes within ICD-10-PCS because currently there are not unique codes to accurately describe the insertion of a posterior pedicle based system at one or more levels of the thoracic or lumbar spine, via an open or percutaneous approach using a proprietary ***Radiolucent Carbon/PEEK pedicle based system*** for spine stabilization procedures with or without the intention to fuse the posterior column in patients with early or advanced stage spinal tumors to restore the integrity of the spinal column.



Radiolucent Carbon/PEEK Pedicle Screw System

- Carbon fiber-reinforced polyetheretherketone (CF/PEEK) rod and screw shaft are thermoplastic composite biomaterial suitable for load-bearing implants¹
- CF/PEEK does not cause artifacts or shadows with all imaging modalities including X-ray, CT, or MRI²
- Radiopaque markers or fibers made from titanium or tantalum are embedded

Indications for Use

FDA 510(K)

The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with ***advanced stage tumors involving the thoracic and lumbar spine*** in whom life expectancy prior to oncological treatment is of insufficient duration to permit achievement of fusion. The VADER®one Pedicle System MIS is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery. The LightMore® Pedicle System 6.0 is indicated to provide the surgeon with an open approach for posterior spinal surgery.

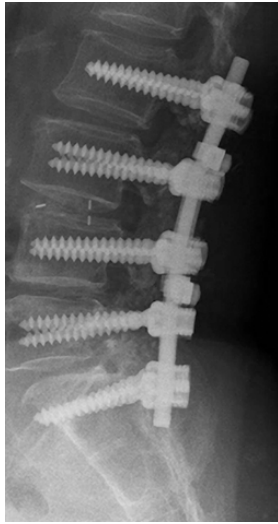
- 10,000 people a year in the US develop spinal tumors³
- Between 15-20% of central nervous system tumors occur in the spine⁴
- The number of new cancer cases is expected to increase to 1.9 million and survival rates are increasing along with the incidence of spinal metastases⁵
- Spinal metastases occur in 60-70% of all systemic cancer patients⁶

Spinal Tumors: Prevalence

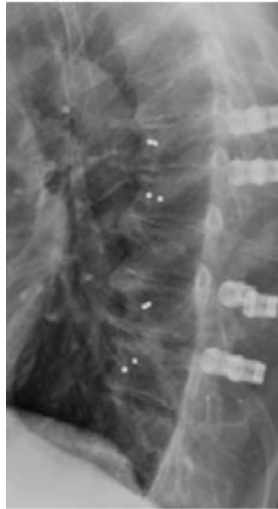
- Implants are critical for stabilization and/or decompression of the spine which is often required in tumor cases
- Radiation therapy is a key element of spine tumor treatment but often best in combination with surgery
- Current surgical treatment to stabilize spinal tumors includes pedicle screw instrumentation made of titanium or stainless steel
- A significant clinical disadvantage is that metal devices cause shadows and artifacts in digital imaging hampering postoperative exploration of spinal disease
- A second significant clinical disadvantage of metal implants is that they absorb radiation and hinder percutaneous radiation therapy

Spinal Stabilization & Tumor Treatment

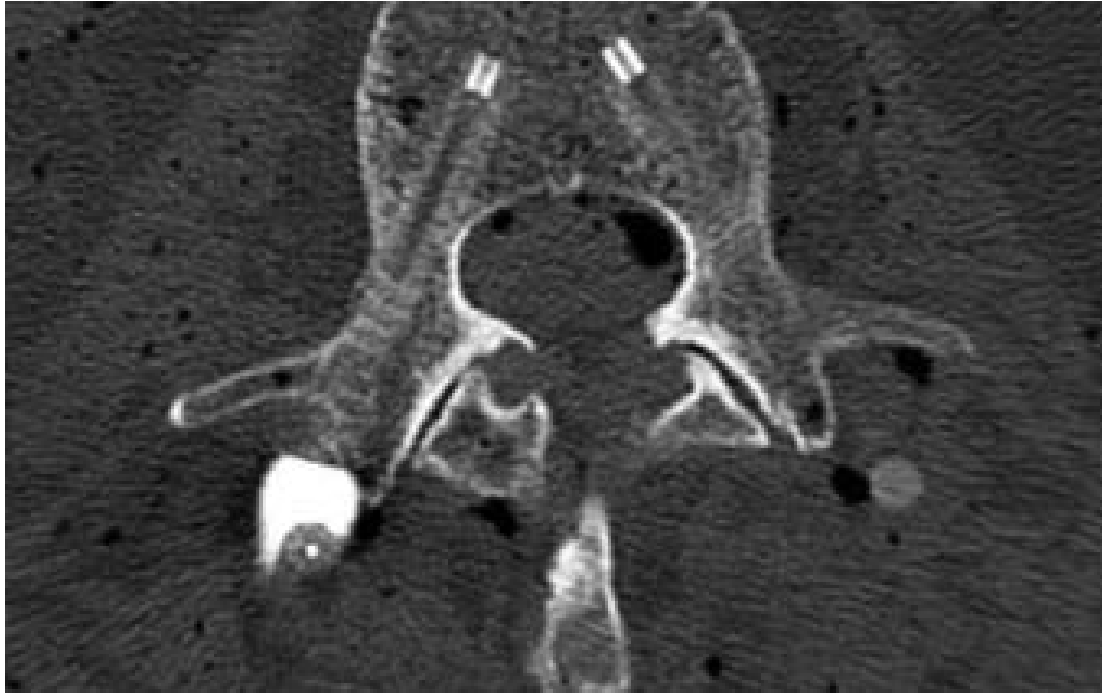
X-Ray Imaging of Pedicle Systems



Metal Screws



Radiolucent Carbon/PEEK Screws



Radiolucent Carbon/PEEK



Left Metal – Right Radiolucent Carbon/PEEK

CT Imaging Radiolucent Carbon/PEEK vs Metal



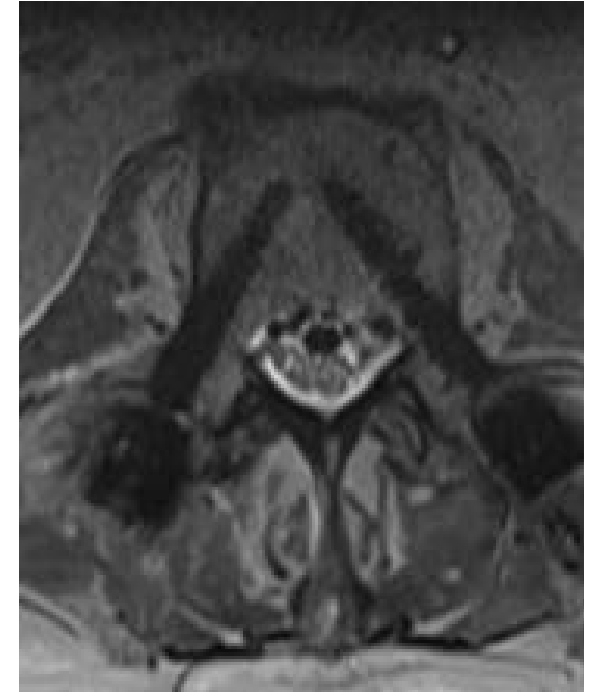
Left Metal – Right Radiolucent Carbon/PEEK



Metal



Radiolucent Carbon/PEEK



Radiolucent Carbon/PEEK

MR Imaging Radiolucent Carbon/PEEK vs Metal

Radiolucent Carbon/PEEK Pedicle Based System

Substantial Clinical Improvement

- Reduced planning time for radiation dosing
- Reduced artifacts yields clearer visibility for early recurrence detection
- Delivery of a more predictable dose in photon and proton treatments = higher radiation dose more safely delivered⁷
- Reduced toxicity to organs at risk
- Comparison of Radiolucent Carbon/PEEK to titanium implants found no statistical difference in post-operative clinical or hardware related complications¹

Summary

New codes need to be created to accurately describe procedures performed with this new technology to allow for:

- Differentiation from the existing procedures with titanium/metal instrumentation for spinal degeneration or instability treatment
- Differentiation from new technologies described by “nanotextured surface” and “radiolucent porous”
- Critical patient outcomes tracking and clinical differentiation based on patient tumor diagnosis and device FDA indications

References

- ¹ Cofano F et al. Carbon Fiber Reinforced vs Titanium Implants for Fixation in Spinal Metastases: A Comparative Clinical Study about Safety and Effectiveness of the “New Carbon-Strategy”. Journal of Clinical Neuroscience 75; (2020) 106-111.
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- ⁴ American Cancer Society. Brain and spinal cord tumors in adults. Available at <https://www.cancer.org/cancer/brain-spinal-cord-tumors-adults.html>. Accessed 8/12/2020.
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- ⁶ Tse V. Spinal metastases and metastatic disease to the spine and related structures. 2009. <https://emedicine.medscape.com/article/1157987-overview>. Accessed 8/12/2020.
- ⁷ Tedesco G et al. Composite PEEK/Carbon Fiber Implants Can Increase the Effectiveness of Radiotherapy in the Management of Spine Tumors. J Spine Surg 2017; 3 (3) 323-329.