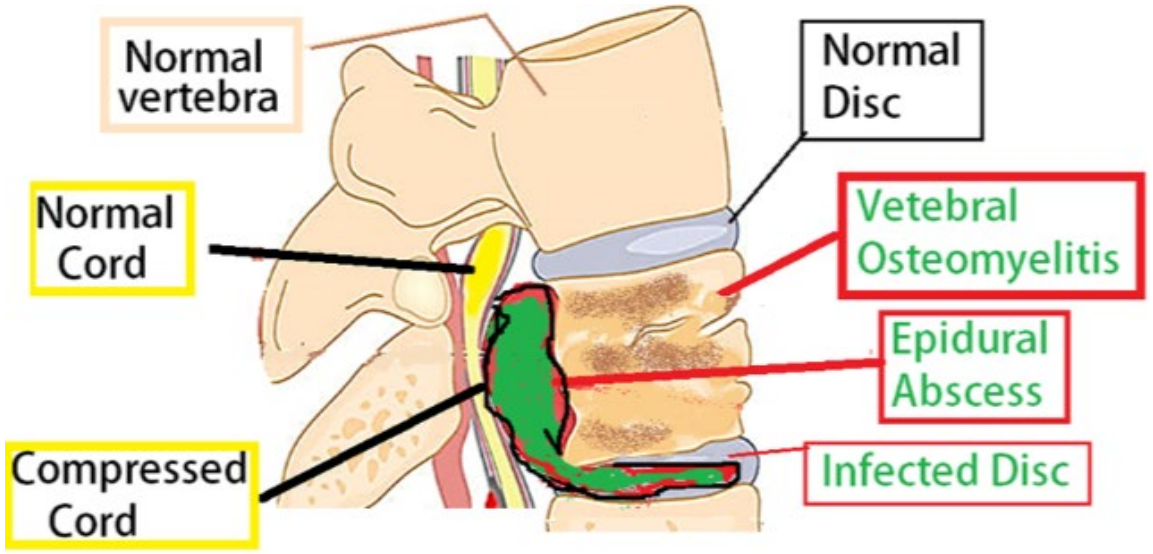
Posterior Fixation of the Thoracolumbar Spine

March 19, 2024 ICD-10 Coordination and Maintenance Committee Meeting

Spinal infection has an incidence of 1.5 – 6 / 100,000 in western countries with up to 20% mortality



Source: www.orthopaedia.com/spinal-infection

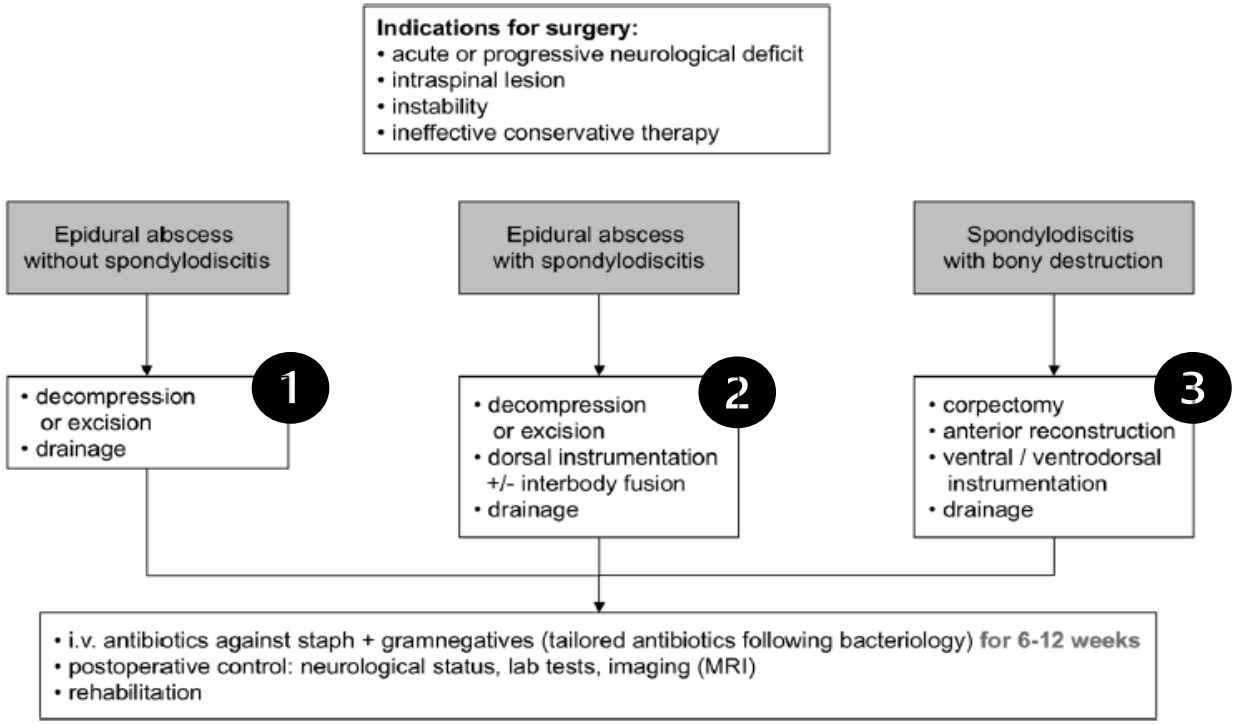
Depending on stage of infection, patients present …

- with severe back pain
- with neurological deficits

Imaging (MRI) reveals intraspinal lesion(s)/ instability of the spine

➢ Indication for surgery

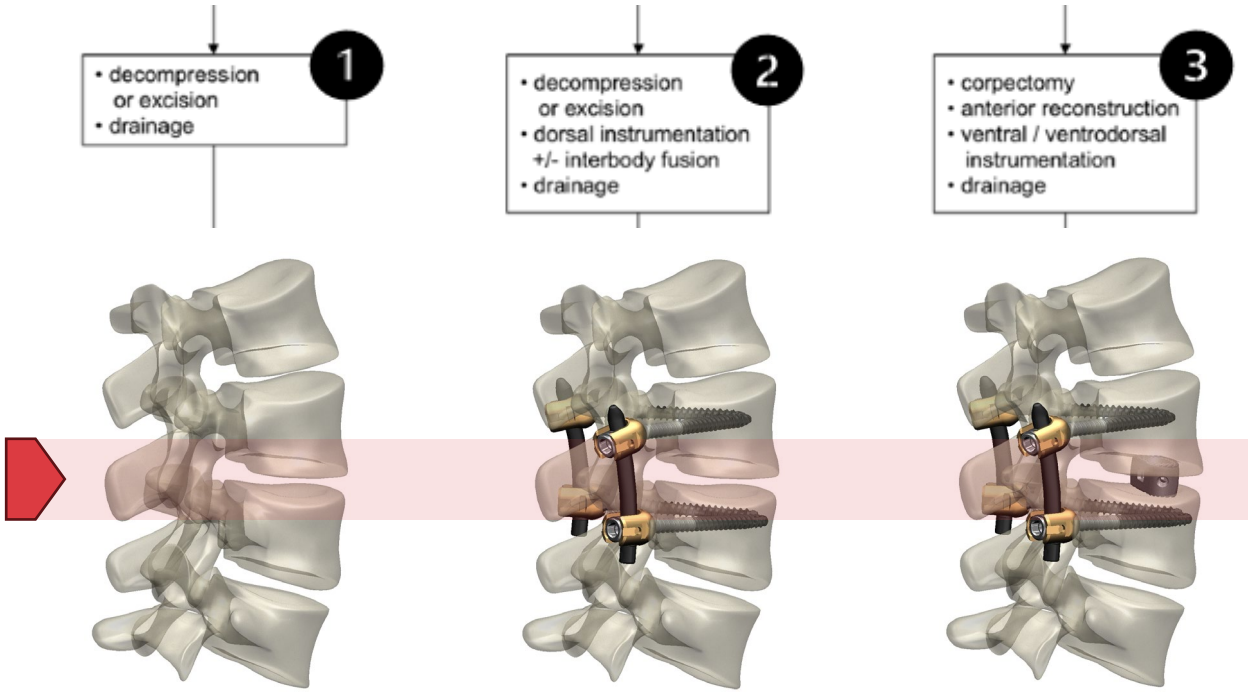
Surgical treatment is required



- Decompress and debride (clean and remove) the infected tissue
- Enable adequate blood flow to the infected tissue to help promote healing
- Immobilize the affected segment and restore spinal alignment with the use of instrumentation to fuse the spine
- Restore function or limit the degree of neurological impairment

Sources:
- Lener, S. et al (2018) Acta Neurochir (Wien) 160(3): 487-496.
- Rutges, J. P. et al (2016) Eur Spine J 25(4): 983-999.
- Taylor, D. G. et al (2018) Global Spine J 8(4 Suppl): 49S-58S.
- Pojskic, M. et al (2021) Brain Sci 11(8).
- www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Infections

Steps of surgical intervention in the thoracolumbar spine



- Open or minimally invasive surgical approach
- Decompression and debridement (❶)
- Placement of pedicle screws above and below the infected sites
- Posterior longitudinal connection of screws with rods (❷)
- Optional: Placement of anterior cage for alignment of the spinal column (❸)

Segment treated for spinal infection

Options for surgical intervention are limited

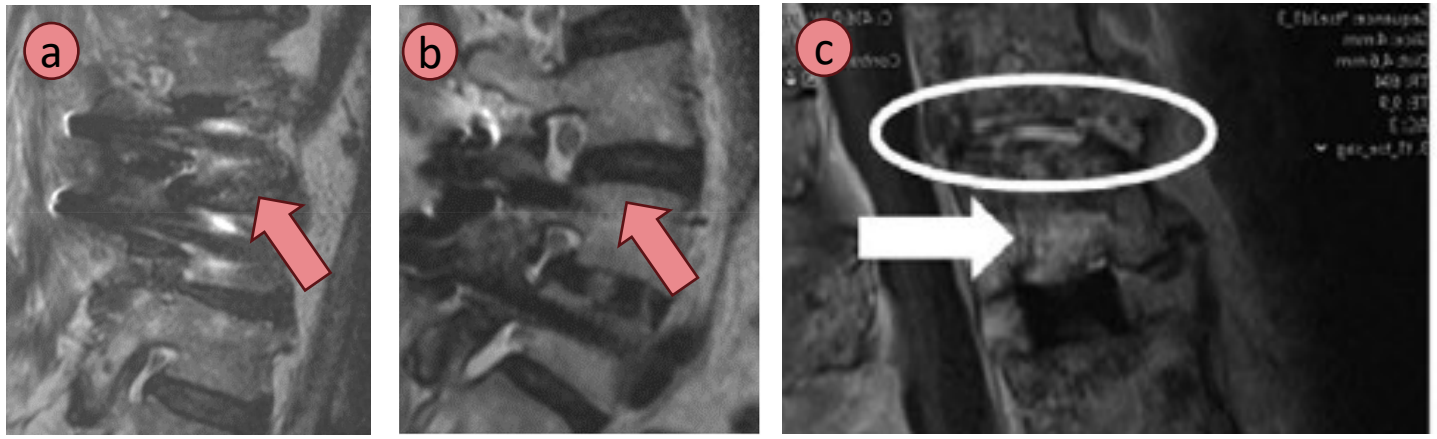
- Many patients with spinal infections require spinal stabilization with implants
- Currently available metal implants for surgical stabilization of spinal segments are not cleared for use in the case of spinal infection
- Icotec's VADER® Pedicle System is made out of BlackArmor® Carbon/PEEK material. It has received BDD (Q231299) for this indication noted below and an NTAP application for FY 2025 was submitted. The FDA granted 510k clearance on February 26, 2024.

Indication granted within BDD (Q231299):

"... the VADER Pedicle System is intended to stabilize the thoracic and/or lumbar spinal column as an adjunct to fusion in patients diagnosed with an active spinal infection (e.g., spondylodiscitis, osteomyelitis) who are at risk of spinal instability, progressive spinal deformity, or neurologic compromise, following surgical debridement."

Post-operative treatment and intensive follow-up is required

- Antibiotic therapy (intra-venous and/or oral) for 6-12 weeks
- Follow-up of systemic infection status with blood sampling/ lab tests
- Persistence or recurrence of pain, or other complications require MRI as gold-standard imaging modality
  - Assessment of local situation is compromised by image artifacts from metal implants (a)
  - Non-metallic Carbon/PEEK implants cause significantly lower artifacts in MR imaging (b), VADER® implants allow for accurate assessments of soft tissue structures, complications or follow-up in general (c)



a) conventional implants made of Ti-alloy cause massive image artifacts

b) implants of VADER® pedicle system made of radiolucent BlackArmor® Carbon/PEEK result in MR image, allowing for clear view and improved assessability of anatomical structures post-operatively

c) MRI scan 3 months after stabilization with implants made of BlackArmor® Carbon/PEEK allows to detect an adjacent segment spondylodiscitis (oval circle)

Sources: a) and b) Fleege, C. et al (2020) Sci Rep 10(1): 16094., c) Burkhardt, B. et al (2021) World Neurosurgery 151: E495-E506

Documentation in medical record

- Terminology that is relevant to this technology:
  - VADER® Pedicle System
  - Carbon/PEEK fixation system
  - Spinal Stabilization device
  - Posterior fixation
  - Approach: open, percutaneous

- Location in the medical record: operative note or intraoperative device record in EMR

Summary of Request

- The VADER® Pedicle System has received BDD for use in spinal infection patients with an FDA 510(k) decision granted on February 26, 2024.
- The proprietary Carbon/PEEK material used in the VADER® System reduces image artifacts allowing greater understanding of patient/ infection status
- An NTAP application was submitted for the VADER® Pedicle System for FY 2025
- There are currently no ICD-10-PCS codes that specifically describe the VADER® Pedicle System
- We are requesting the creation of an X code for the VADER® Pedicle System to identify the technology used in the treatment of patients with spinal infection