



# **Insertion of Posterior Cervicothoracic Spinal Stabilization System**

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ICD-10 Coordination and Maintenance Committee Update

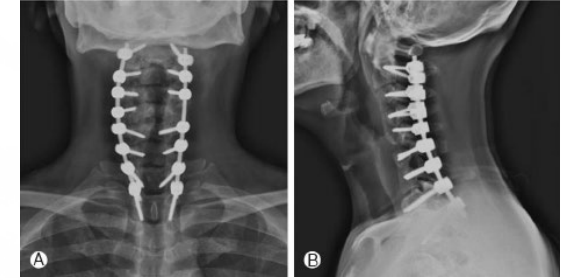
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# Posterior Cervical Fusion (PCF) – US market



- Number of PCF procedures<sup>1</sup>: ~29K (2020) to ~35K (2040)
- Largest impact in elderly population
  - Aging population: >115% increase of >85 y.o. and >84% of 75-84 y.o.
- Evidence of increased rate of degenerative cervical spine indications
  - Produces pain
  - Spondylotic or myelopathic developments
  - Altering biomechanics of cervical spine
  - Predisposed to upper cervical spine fractures
- Leads to severely compromised patient function and quality of life
- PCF – high morbidity profile, complicated by co-morbidities in elderly





# Background

- **The biomechanical stability of a patient's cervical spine can be compromised due to numerous causes:**
  - Traumatic spinal fractures
  - Traumatic dislocations
  - Instability or deformity
  - Failed previous fusions (pseudoarthrosis)
  - Tumors
  - Degenerative diseases
- **Patients affected by any of the listed causes, among others, may experience a range of symptoms:**
  - Neck pain and shoulder pain
  - Numbness and/or weakness in the neck, arms, or hands
  - Difficulty walking
  - Headaches
  - Minimal neck lordosis
  - Straightening of cervical spine



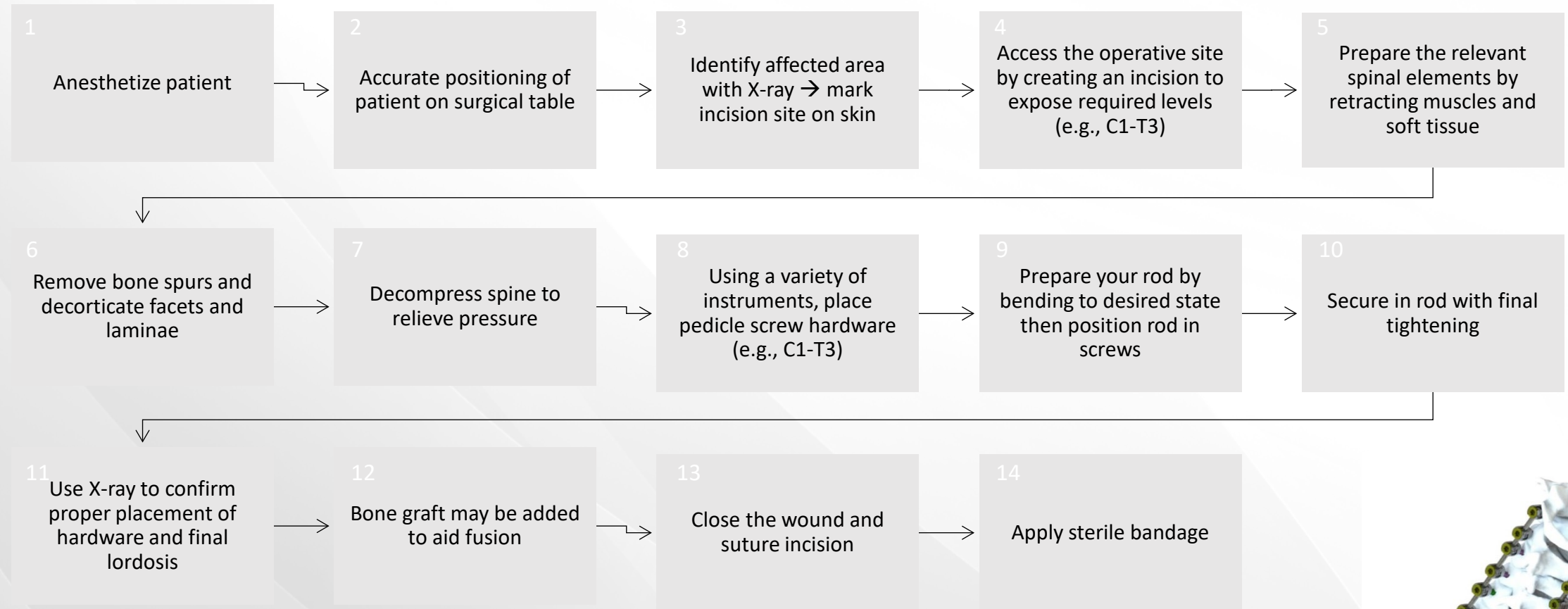


# Treatment & Common Complications

- Treatment would involve posterior cervical fusion (PCF) surgery to restore stabilization.
  - PCF is the act of joining two or more damaged vertebrae in the cervical spine to restore stabilization.
- PCF complication incidence is between 15%-25%. Common complications with current PCF procedures include, but not limited to:
  - Surgical site infection (SSI)
  - Neurologic deficit
  - C5 palsy
  - Dural tear
  - Adjacent segment pathology
  - Proximal junctional kyphosis (PJK)
  - Distal junctional kyphosis (DJK)
  - Pseudarthrosis
- Please note that the EUROPA™ Posterior Cervical Fusion System is not yet commercially available and there have been no reported adverse events or complications.



# Procedural Steps for PCF





# EUROPA™ Posterior Cervical Fusion System

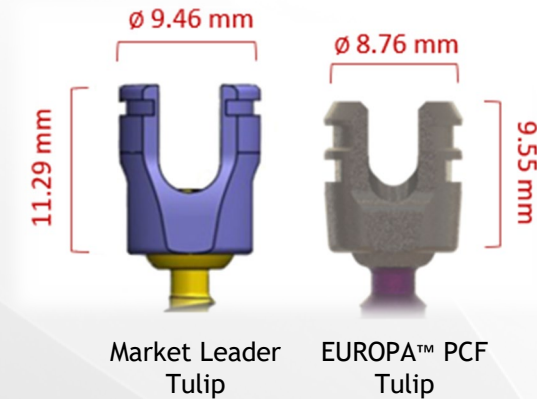


- The EUROPA™ Posterior Cervical Fusion (PCF) System, based on its proprietary Molybdenum Rhenium (**more**®) alloy, provides a better alternative for stabilization of the cervical and upper thoracic spine.
- EUROPA PCF granted Breakthrough Device Designation on July 30, 2024
- Received 510(k) clearance on November 19, 2024
- An NTAP application for FY2026 was submitted
- Features of the EUROPA PCF System:
  - Lowest profile in market (tulip & **more**® rods)
  - Superior strength, rigidity, and fatigue resistance than commonly used alternative alloys (Titanium or Cobalt Chromium).
  - Can connect to thoracic-lumbar via EUROPA™ Lumbar System, also based on the **more**® alloy.



2.7 & 2.9 mm Rod  
2.9 – 4.5 mm Transition Rod

**more**®  
Superalloy



**~40%**

Smaller Tulip  
Volume than  
Current  
Market Leader





# EUROPA™ Posterior Cervical Fusion System Indications

- The EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the **cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3):**
  - Traumatic spinal fractures and/or traumatic dislocations
  - Instability or deformity
  - Failed previous fusions (e.g., pseudarthrosis)
  - Tumors involving the cervical/thoracic spine
  - Degenerative disease, including intractable radiculopathy and/or myelopathy
  - Neck and/or arm pain of discogenic origin as confirmed by radiographic studies
  - Degenerative disease of the facets with instability
- The EUROPA™ Posterior Cervical Fusion System is **also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. **In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod to rod connectors.**



# EUROPA™ PCF Mitigates Current PCF Challenges



## Challenges

Failures – pull out of hardware

Pseudoarthrosis

Implant volume

Space in surgical area for more biologics

Skipping C6 or C7 vertebrae

Addition of more hardware (e.g., quad rod constructs, connectors, etc.)

Need to use CoCr rods – high wear debris – in sensitive part of neck

## Solutions

MoRe® alloy holds construct for longer time even with pseudo to aid time to fusion.

More robust construct with 2.9 mm MoRe® alloy rod

EUROPA™ PCF is the lowest profile PCF system in the market.

Lower profile system allows for 20% more biologics.

Low tulip profile and fatigue resistant rods allow for screw placement at all levels.

Superior MoRe® alloy rod eliminates need for additional hardware.

Orders of magnitude less wear debris, nickel free alloy



# Clinical Image Examples of Current PCF Challenges



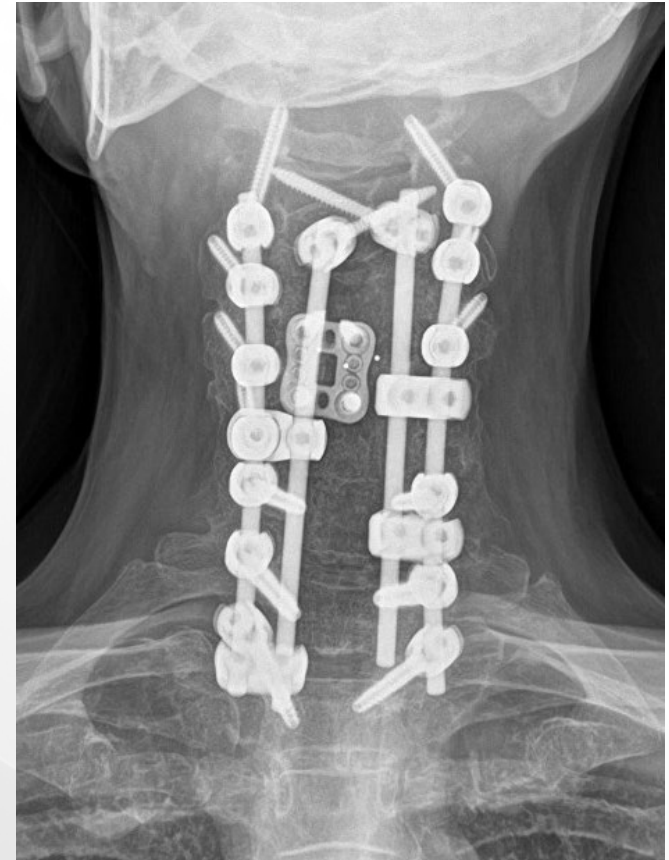
Pullout/Failures



Pseudoarthrosis



Quad Rod  
Constructs





# Patient Clinical Example



66-year-old male presents with a C1 and odontoid fracture. Treated at Occupational Safety and Health (OSH) in a collar for 6 months. Starts to develop severe pain and myelopathy symptoms after multiple falls.

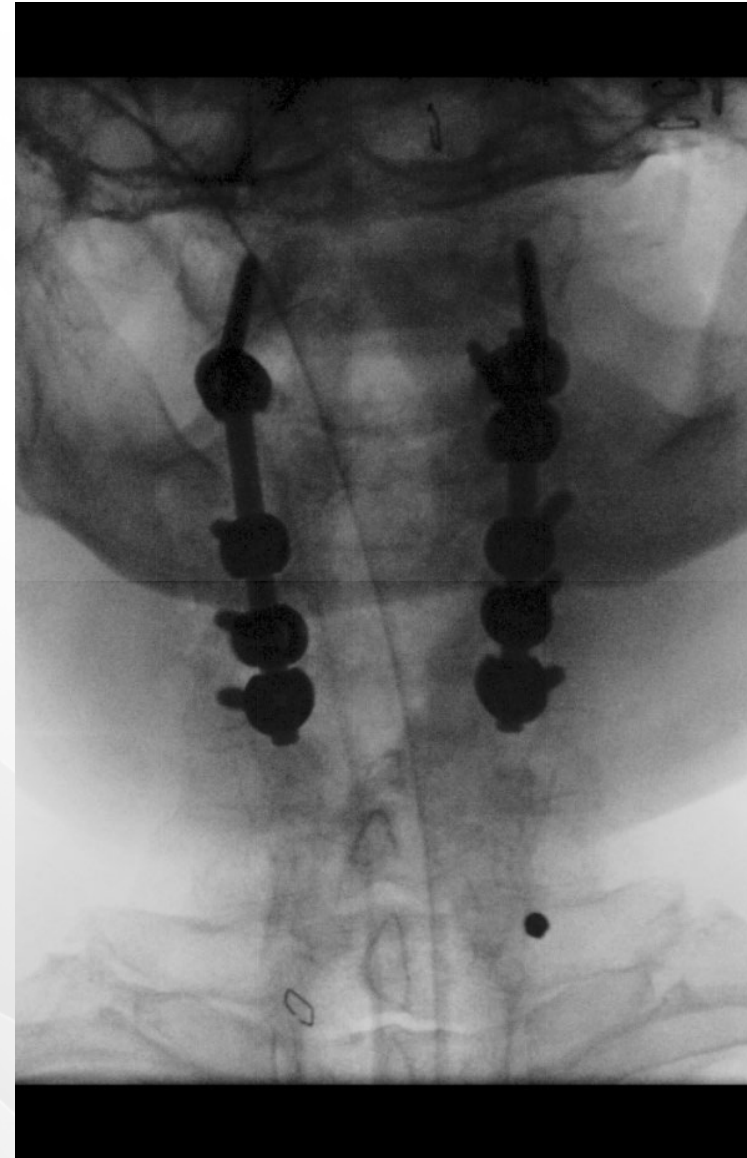


# Clinical Images





# Clinical Images continued





# Clinical Images with hardware







# Documentation in Medical Records

- Terminology to identify EUROPA™ PCF System:
  - MiRus's EUROPA™ Posterior Cervical Fusion System
  - EUROPA™ PCF
  - Molybdenum Rhenium
  - MoRe® Superalloy™
  - Spinal stabilization device
  - Posterior fixation
  - Screws, pedicle screws, set screws
  - Connectors
  - Rods
  - Cervical and cervical-thoracic instrumentation
- Location in medical record: The procedure will be documented in OR procedure or surgeon operative notes. The technology may also be reported in other EMR records, such as the nursing documentation or record of supplies/equipment used in OR cases in the patient record.





# Summary of Request

- The EUROPA™ PCF System was granted Breakthrough Device Designation on July 30, 2024, and received FDA clearance on November 19, 2024.
- An NTAP application for FY2026 was also submitted.
- The EUROPA™ PCF System is the lowest profile PCF system (~40% by volume) in the market as it is built around a 2.9 mm **more**® rod.