

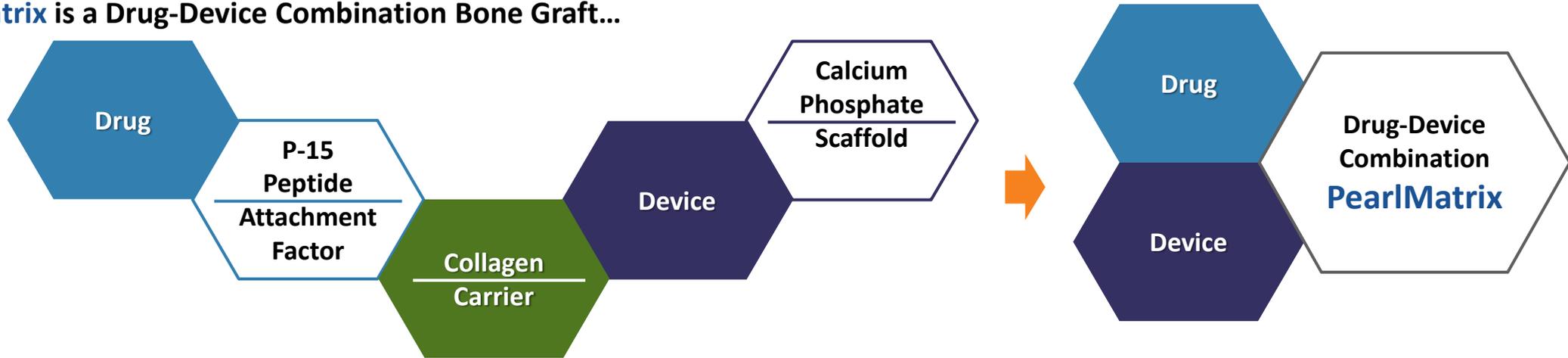


ICD-10-PCS Code Request for the Introduction of Peptide Enhanced Bone Graft in Transforaminal Lumbar Interbody Fusion Procedures

Spring 2025

PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite drug-device combination bone graft material consisting of synthetic P-15 peptide bound onto calcium phosphate particles, which are incorporated into a collagen matrix carrier.

PearlMatrix is a Drug-Device Combination Bone Graft...



...equipped by P-15 peptide that provides a proven mechanism of action to attach and activate osteogenic cells to accelerate new bone formation.¹⁻⁵

ATTACH

Osteogenic cells **attach** to P-15 peptide via specific surface receptors enhancing cell retention, spreading and survival.^{1-3,6}



ACTIVATE

Once attached, cellular pathways are **activated** that enhance osteogenic activity by releasing growth factors and other important signaling molecules.^{1-3,8}

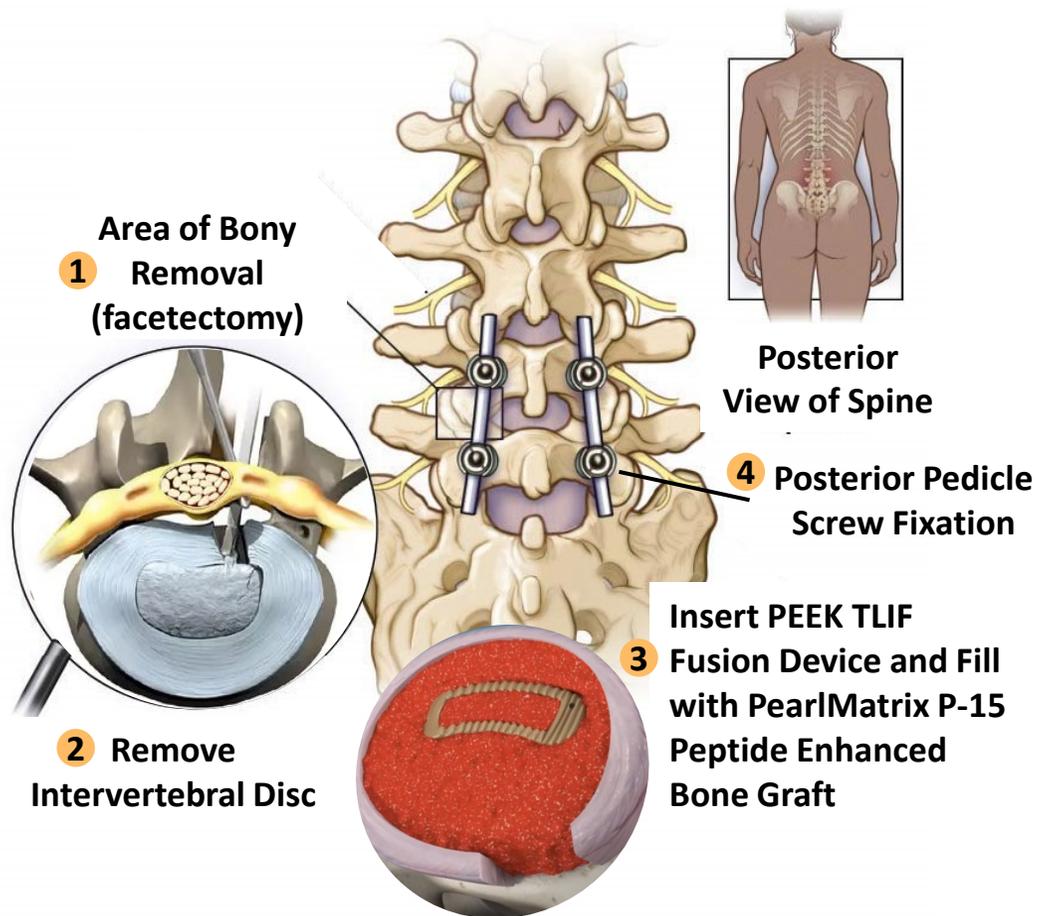


ACCELERATE

Upregulation of growth factors recruit additional osteogenic cells, creating a cyclical attachment and activation process that **accelerates** new bone formation.^{1-5,8-10}

PearlMatrix P-15 Peptide Enhanced Bone Graft is used as a bone graft material in conjunction with a PEEK TLIF fusion device and posterior pedicle screw fixation to assist with one-level TLIF surgery in the lumbosacral spine.

TLIF Surgery (Transforaminal Lumbar Interbody Fusion)



Available TLIF Surgical Options:

- ❑ **Open Procedure:** A vertical incision is made over the section to be fused in the lumbosacral region. During the open procedure, the skin, muscles and soft tissues are dissected back.
- ❑ **Percutaneous Procedure:** If the surgeon chooses to perform the TLIF percutaneously, only two small incisions are made to the skin to allow insertion of the surgical instruments and materials.
- ❑ **Percutaneous Endoscopic Procedure:** If the surgeon chooses to perform the TLIF percutaneously and guided by endoscopic techniques, small incisions are made to the skin to allow insertion of the surgical instruments and materials, which is assisted by visualization through an endoscope (a narrow tube) to access the spine to decompress and stabilize the spine.

Steps to Perform TLIF Surgery

- 1** The appropriate disc level is identified radiographically, and facetectomy is applied.
- 2** A discectomy is performed to achieve neural decompression and to allow further preparation of the disc space.
- 3** A PEEK TLIF fusion device is inserted, and then its central cavity is filled with PearlMatrix P-15 Peptide Enhanced Bone Graft.
- 4** Additional support is provided by the placement of posterior pedicle screw fixation bilaterally along the vertebral column. The screws are inserted through the pedicle bones of the vertebrae to be fused. Once the posterior pedicle screw fixation is implanted, the wound is closed.

Anticipated Utilization Settings and Associated ICD-10-CM Diagnosis Codes

PearlMatrix P-15 Peptide Enhanced Bone Graft is anticipated to be used in both inpatient and outpatient settings. Informed by the FY 2023 MedPAR datafile, we identified the following ICD-10-CM diagnosis codes that align with the proposed indications of degenerative disc disease in lumbosacral spine specified in the FDA Breakthrough Device Designation and PMA.

ICD-10-CM Code	Description	ICD-10-CM Code	Description
M43.06	Spondylolysis, lumbar region	M48.062	Spinal Stenosis, lumbar region with neurogenic claudication
M43.07	Spondylolysis, lumbosacral region	M48.07	Spinal Stenosis, lumbosacral region
M43.16	Spondylolisthesis, lumbar region	M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M43.17	Spondylolisthesis, lumbosacral region	M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M47.26	Other spondylosis with radiculopathy, lumbar region	M51.26	Other intervertebral disc displacement, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region	M51.27	Other intervertebral disc displacement, lumbosacral region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region	M51.36	Intervertebral disc degeneration, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region	M51.37	Intervertebral disc degeneration, lumbosacral region
M47.896	Other spondylosis, lumbar region	M54.16	Radiculopathy, lumbar region
M47.897	Other spondylosis, lumbosacral region	M54.17	Radiculopathy, lumbosacral region
M48.061	Spinal Stenosis, lumbar region without neurogenic claudication		

Sources: Data on file; FY 2023 MedPAR Datafile.

Other Technology-Related Information

- **Technology Documentation in Medical Record:** PearlMatrix P-15 Peptide Enhanced Bone Graft will be documented in patient's operative record. The lot and/or serial number, manufacturer name, volume and anatomic site of the technology used in the TLIF procedure will be typically documented.
- **Naming Conventions:** PearlMatrix P-15 Peptide Enhanced Bone Graft is the technology's trade name while Peptide Enhanced Bone Void Filler, as its generic name, may also be used to describe the technology.
- PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite drug-device combination bone graft material in a "putty-like" form. Based on the clinical trial data (IDE#: G170300), the average number of units per procedure is 8.2cc.
- PearlMatrix P-15 Peptide Enhanced Bone Graft is considered permanent.
- PearlMatrix P-15 Peptide Enhanced Bone Graft is intended for use at one level in the lumbosacral spine (L2-S1).
- PearlMatrix P-15 Peptide Enhanced Bone Graft is intended to be used in conjunction with a PEEK TLIF fusion device and posterior pedicle screw fixation cleared by the FDA for use in the lumbosacral spine.

Device-Related Adverse Events Based on Clinical Study (IDE#: G170300)

The IDE study (IDE#: G170300; 141 and 149 patients using PearlMatrix P-15 Peptide Enhanced Bone Graft and autograft, respectively) showed that at 24 months, any device-related adverse event rate in the PearlMatrix group (15.6%) was non-inferior compared to the control autograft group(13.4%), which demonstrated the safety of PearlMatrix P-15 Peptide Enhanced Bone Graft to be used in the TLIF surgery.

Adverse Event Description	PearlMatrix (N=141) % of Patients	Autograft (N=149) % of Patients	Adverse Event Description	PearlMatrix (N=141) % of Patients	Autograft (N=149) % of Patients
Infections and Infestations	0.7%	0.0%	Nervous System Disorders	4.3%	4.0%
Wound infection	0.7%	0.0%	Hypoesthesia	0.7%	0.7%
Injury, Poisoning and Procedural Complications	2.1%	3.4%	Paraesthesia	1.4%	0.0%
Graft complication	0.7%	0.0%	Piriformis syndrome	0.0%	0.7%
Incomplete spinal fusion	0.7%	2.7%	Radiculopathy	2.1%	1.3%
Lumbar vertebral fracture	0.0%	0.7%	Sciatica	0.7%	0.7%
Seroma	0.7%	0.0%	Spinal claudication	0.0%	0.7%
Musculoskeletal and Connective Tissue Disorders	8.5%	7.4%	Renal and Urinary Disorders	0.7%	0.0%
Arthralgia	0.7%	0.0%	Micturition urgency	0.7%	0.0%
Back pain	3.5%	2.0%	Product Issues	2.1%	0.0%
Intervertebral disc space narrowing	0.0%	0.7%	Device dislocation	0.7%	0.0%
Lumbar spinal stenosis	0.7%	1.3%	Device fastener issue	0.7%	0.0%
Musculoskeletal pain	0.0%	0.7%	Implant subsidence	0.7%	0.0%
Pain in extremity	0.7%	0.0%			
Pseudarthrosis	1.4%	2.7%			
Spondylolisthesis	0.7%	0.0%			
Vertebral foraminal stenosis	0.7%	0.0%			

Source: Data on file.