
ICD-9-CM Coordination and Maintenance Committee Meeting

September 18, 2013

Agenda

- Introduction
- Description of P-15 (Peptide Enhanced Bone Graft)
- Cervical fusion and IDE clinical study
- Rationale for new ICD-10-PCS codes
- Q&A

Introduction

Cerapedics, Inc. is a medical device company developing & commercializing innovative bone graft substitute products based on a small peptide technology:

P-15 Peptide Enhanced Bone Graft

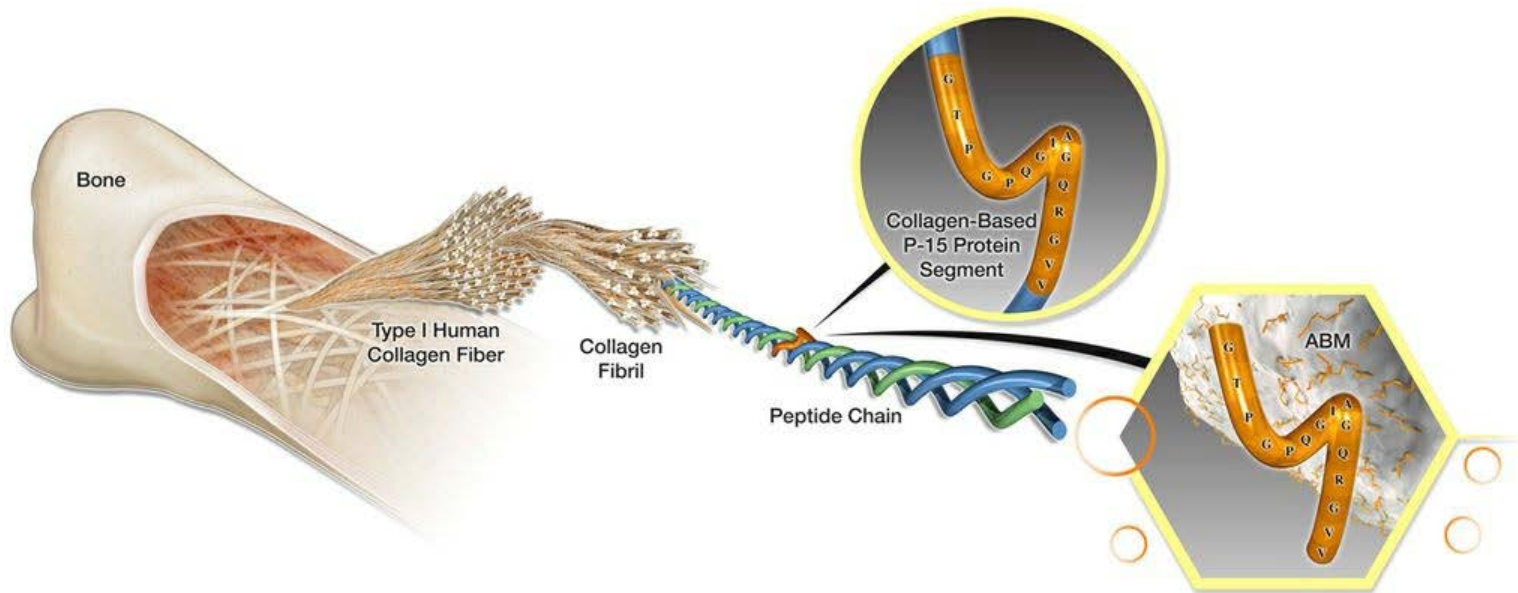
Cerapedics requests that CMS develop ICD-10 procedure codes for the percutaneous and open insertion of P-15 Peptide Enhanced Bone Graft



P-15 Peptide Enhanced Bone Graft

- Is a synthetic osteoconductive bone substitute that has proven to significantly improve bone repair in dental applications (in the US) and is currently awaiting FDA approval for use in cervical fusion.
- Advantages of P-15 Peptide Enhanced Bone Graft:
 - SAFETY
 - FDA approvals in dental in USA (1999-2002)
 - No ectopic bone formation
 - No antibody formation
 - No tumorigenicity
 - No human tissue
 - No need to harvest iliac crest bone graft (ICBG)
 - EFFICACY
 - Will have FDA IDE level 1 data documenting efficacy relative to autograft
 - Superiority claims versus other bone graft substitutes from prior FDA PMA approvals in dental
 - DATA
 - FDA PMA Approvals in dental (4)
 - FDA Approval for cervical fusion expected in 2014

P-15 Peptide



- P-15 Peptide is a segment of the type I human collagen protein which is a known cellular binding domain
- Peptides generally have more specific biologic activity than full proteins



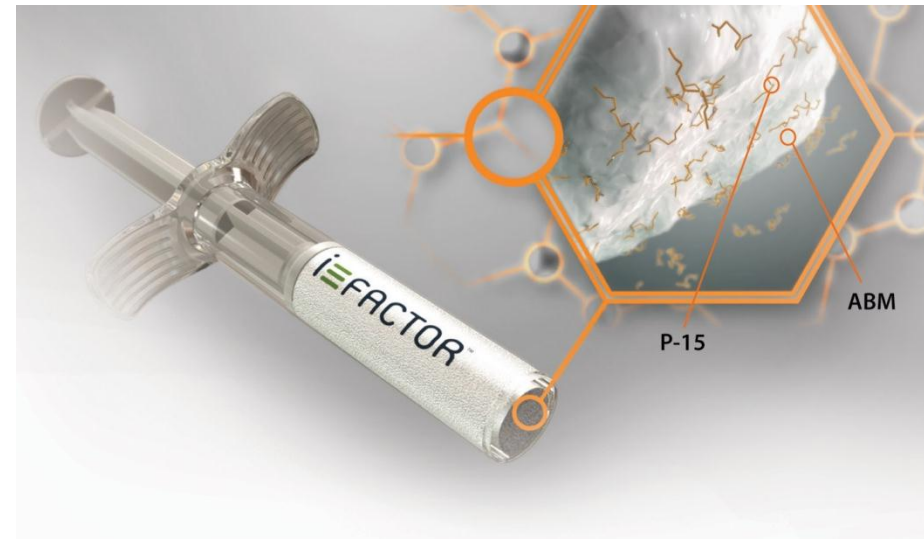
CERAPEDICS
Enhancing the Science of Bone Repair

P-15 Peptide Enhanced Bone Graft Technology

"P-15" peptide is a fifteen amino acid synthetic analog of a cell-binding domain of type I human collagen

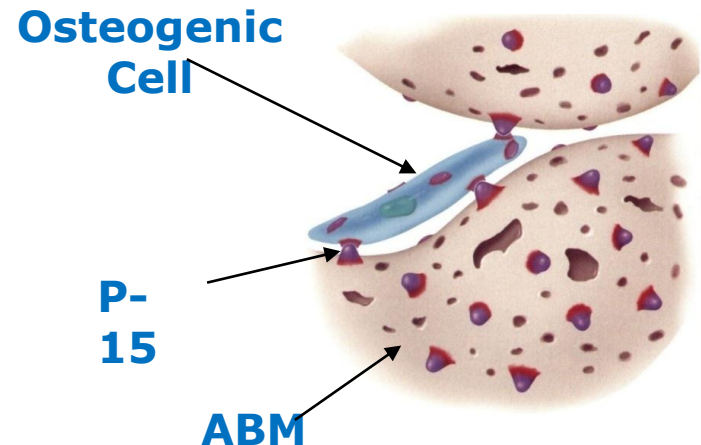
"ABM" is Anorganic Bone Mineral (natural hydroxyapatite)

"CMC" (carboxymethylcellulose) hydrogel carrier



Mechanism of Action

- ABM/P-15 acts as an attachment factor for osteogenic cells
- Cell binding to P-15 peptide
 - Stimulates osteogenesis
 - Facilitates natural production of BMPs and other cytokines
- Natural bone healing occurs leading to fusion

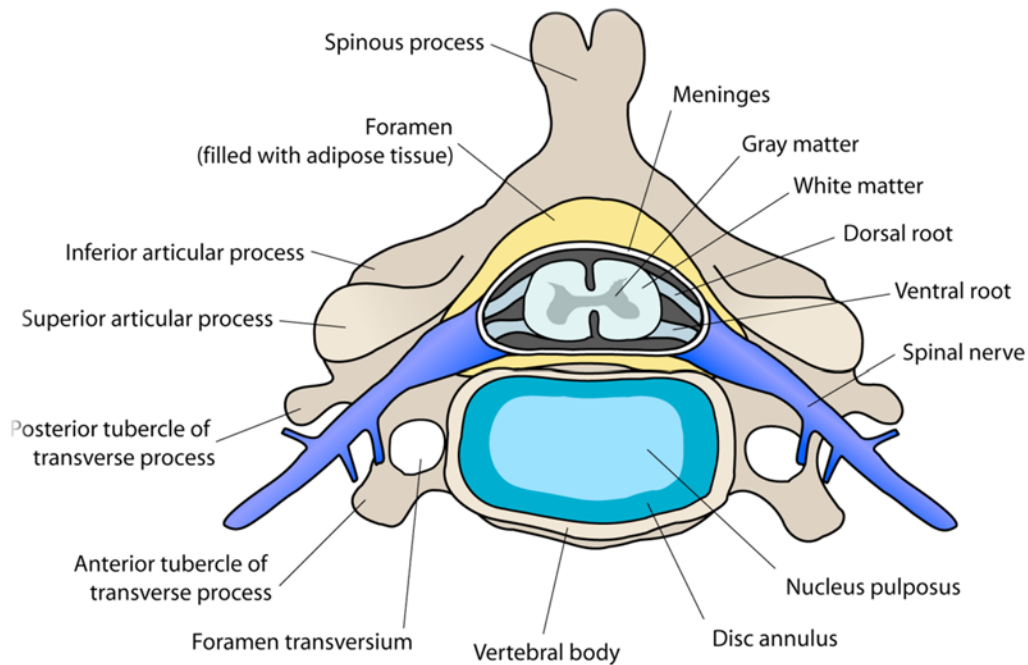


US IDE Clinical Study

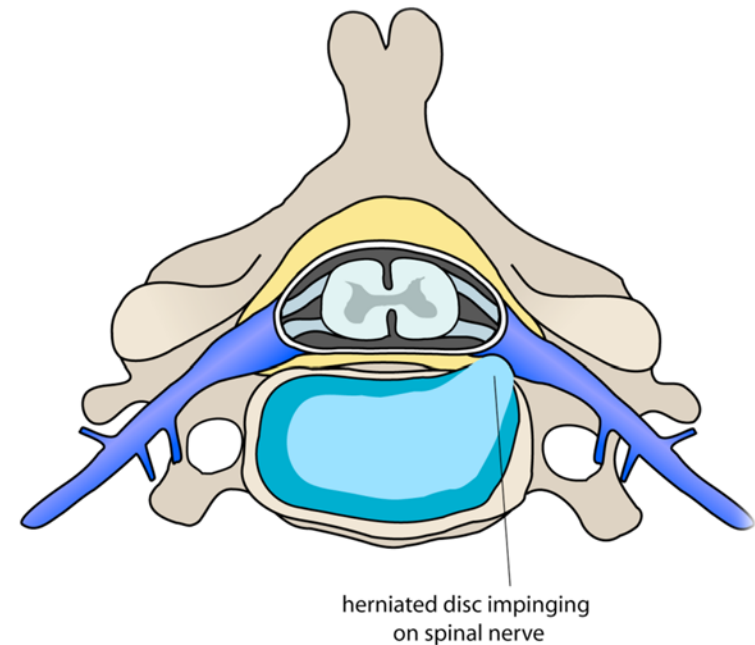
- P-15 Peptide Enhanced Bone Graft is being tested in single level Anterior Cervical Discectomy and Fusion (ACDF) procedures
- Enrollment included Medicare beneficiaries (up to age 70)
- [Enrollment completed in May 2013](#)
- FDA approval expected in 2014



Anterior Cervical Discectomy and Fusion (ACDF)



**Normal
Disc**



**Herniated
Disc**

IDE Trial

Objective:

The aim of this trial is to evaluate if P-15 Peptide Enhanced Bone Graft (investigational device) is not inferior in effectiveness and safety to local autologous bone (control device) when applied in instrumented anterior cervical discectomy and fusion (ACDF) with use of a structural allograft ring in patients with degenerative cervical disc disease.

Study Design:

- Prospective, randomized, controlled, multi-center
- 23 investigational sites in the US and Canada
- 250 patients (125 investigational, 125 control)

IDE Study Outcomes

I. Primary:

- Fusion
- Neck Disability Index (NDI)
- Neurological success
- Complications/Adverse Events

II. Secondary:

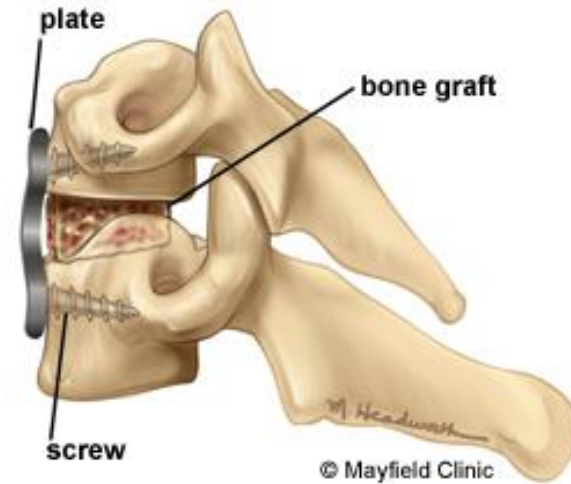
- Pain
- SF 36
- Kyphosis

ACDF Procedure with the Insertion of P-15 Peptide Enhanced Bone Graft



Insertion of P-15 Peptide Enhanced Bone Graft

1. Surgeon makes an incision and accesses the affected disc
2. Surgeon removes disc material causing herniation
3. Surgeon prepares disc space for implantation
4. P-15 is loaded into allograft ring
5. Allograft ring is implanted
6. Surgeon places cervical plate and closes incision



ACDF with P-15 Peptide Enhanced Bone Graft



Rationale for new ICD-10-PCS code

- P-15 Peptide Enhanced Bone Graft is an alternative to autograft and can be utilized in fusion procedures.
- Currently there are no ICD-9/ICD-10 procedure codes that describe the introduction of a peptide enhanced bone graft.
- There will be FDA IDE data demonstrating the safety and efficacy of P-15 Peptide Enhanced Bone Graft.
- Other autograft alternatives **with IDE data** (rhBMP) do have ICD-10 codes and therefore P-15 should have new codes developed to identify the introduction of this device.

Request:

CMS develop ICD-10 procedure codes for the percutaneous and open introduction of P-15 Peptide Enhanced Bone Graft.

Thank-you

