PearlMatrix™

P-15 Peptide Enhanced Bone Graft

Value Analysis Committee Packet

Class III Drug-Device Combination Product Approved for Use
in the Lumbar Spine (Single-Level TLIF) with Level 1 Human PMA IDE Study Data[1]

Created for Value Analysis Committee

Cerapedics®
Repairing bones. Healing lives.

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Product Overview

PearlMatrix™ P-15 Peptide Enhanced Bone Graft is the first and only bone growth accelerator shown to accelerate lumbar fusion in both overall and higher-risk patient populations, achieving over 2x more patients fused at 6 months vs. the local autograft control.*^[1,2]

PearlMatrix is the only Class III P-15 Peptide combination product FDA approved for use in single-level TLIF procedures based on a robust Level 1, Investigational Device Exemption (IDE) study inclusive of ~ 60% high-risk patients.^[1,2]

PearlMatrix is a composite Class III drug-device combination bone graft material consisting of P-15 Peptide which is stably bound onto porous calcium phosphate particles and incorporated into a collagen matrix carrier.[1] PearlMatrix is a standalone bone graft replacement that does not require bulking agents or extenders.

The natural interconnected porosity of the calcium phosphate particles creates a large surface area for P-15 coating and potential cell binding sites, providing an abundance of attachment sites for osteogenic cells.[1,2,3-5]

P-15 Peptide, the active component in PearlMatrix responsible for osteogenic cellular attachment activity[3-5], is a synthesized 15-amino acid sequence that mimics a cell binding domain of Type 1 collagen, thus providing an environment that facilitates attachment and activation of osteogenic cells to accelerate new bone formation.[1]

The P-15 coated calcium phosphate particles are incorporated into a fibrous collagen matrix as a carrier to facilitate handling and containment of the P-15 coated particles at the fusion site.[1]

^High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
*Demonstrated substantially faster time-to-fusion in a single-level TLIF PMA IDE study vs. local autograft.

Evidence

The safety and effectiveness of PearlMatrix was proven through a pivotal, Level 1 IDE study that was required by the FDA for Pre-Market Approval (PMA). The PMA IDE study was a statistically powered, prospective, randomized, controlled, multi-center, human clinical study.[1]

The PearlMatrix PMA IDE study reflected a real-world patient population with 293 patients across 33 US clinical sites and included a majority (~60%) of patients with high-risk comorbidities which have been shown to impact the risk of non-union in spinal fusion procedures.[^1,6]

PearlMatrix is one of only three Class III spinal drug-device combination bone grafts that are FDA approved with a PMA based on Level 1 human clinical trials.[1,2]

Safety

PearlMatrix has met robust FDA Class III PMA IDE study requirements to demonstrate safety and efficacy in humans.[1]

- PearlMatrix was shown to be **as safe as human local autograft**.[†7]
- There were no meaningful differences in device related adverse events compared to the local autograft control.[†1]
- There was no observation of ectopic bone formation or osteolysis.[†1]
- There were no meaningful differences in reported seroma formation or radiculopathy compared to the control.[†1]

PearlMatrix does not contain human cells or tissues.[1,7]

- Mitigates the potential of disease transmission related to donor bone.[8]

PearlMatrix is provided sterile.[1,7]

- PearlMatrix is terminally sterilized in the final packaging.[1,7]

Potential adverse events specific to PearlMatrix include allergic reaction to components of PearlMatrix Bone Graft.[1] Please refer to the PearlMatrix Instructions for Use for complete safety and risk information.

Efficacy

The Level 1 PMA IDE Study was statistically powered and PearlMatrix demonstrated the following when compared to human local autograft in single-level TLIF procedures[1]:

In the overall study population, PearlMatrix demonstrated:

- Statistically superior overall clinical success[§] at 24 months.
- Substantially higher fusion rates at 6, 12 and 24 months.
- Statistically superior fusion speed between 0 and 24 months.

In the high-risk[^] subgroup (~60% of the study population[1]), PearlMatrix demonstrated:

- Substantially higher overall clinical success[§] among high-risk patients at 24 months.
- Substantially higher fusion rates among high-risk patients at 6, 12 and 24 months.
- Substantially faster fusion among high-risk patients.

PearlMatrix is the only bone graft shown to accelerate lumbar fusion achieving statistically superior fusion speed in a Level 1, PMA, IDE study with ~60% high-risk patients.[^†1,2]

^High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.

§Overall clinical success is defined by a composite score including fusion, function (ODI), neurological, no serious device related adverse events and no index level secondary surgical interventions.

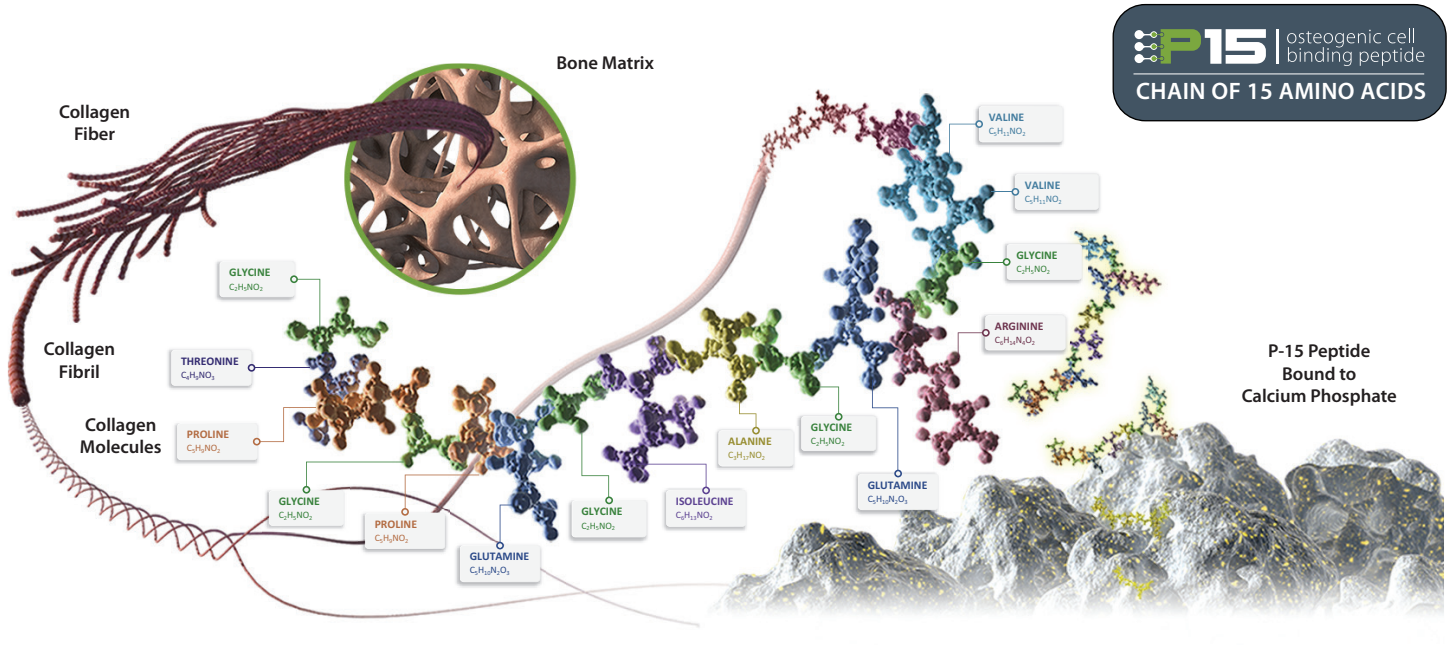
†As demonstrated in a single-level TLIF PMA IDE study vs. local autograft.

Mechanism of Action

Cerapedics' P-15 Osteogenic Cell Binding Peptide provides a distinct and proven mechanism of action, to **Attach and Activate osteogenic cells and Accelerate** new bone formation.[3-5,9,10]

In the human body, P-15 is a naturally occurring peptide, a unique 15 amino-acid sequence found in type-1 collagen, the predominant protein in bone. It serves a crucial role in the bone regeneration process as a powerful cell attachment and activation factor.[3-5,11]

At Cerapedics, pharmaceutically manufactured P-15 Peptide is bound onto calcium phosphate particles, creating a P-15 enhanced scaffold that provides an abundance of attachment sites for osteogenic cells.[3-5,7]

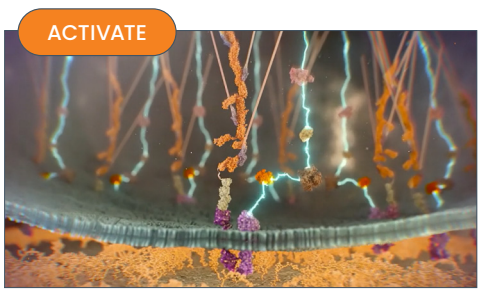


Attachment to a substrate is essential to maintain cell viability. P-15 naturally exhibits a high-affinity for binding these cells through specific surface receptors, enhancing cell attachment, spreading and survival.[3-5,11]

When cells attach to P-15, multiple cellular signaling pathways are activated. These signaling pathways not only induce osteoblast proliferation and differentiation, but they also enhance osteogenic activity by releasing osteoinductive growth factors and other important signaling molecules. These growth factors then signal to recruit mesenchymal stem cells and promote differentiation along the osteoblast lineage.[3-5,13-20]

Furthermore, **this signaling stimulates the release of bone forming enzymes** and upregulates growth factors that promote new blood vessel ingrowth.[3-5,14,17-20]

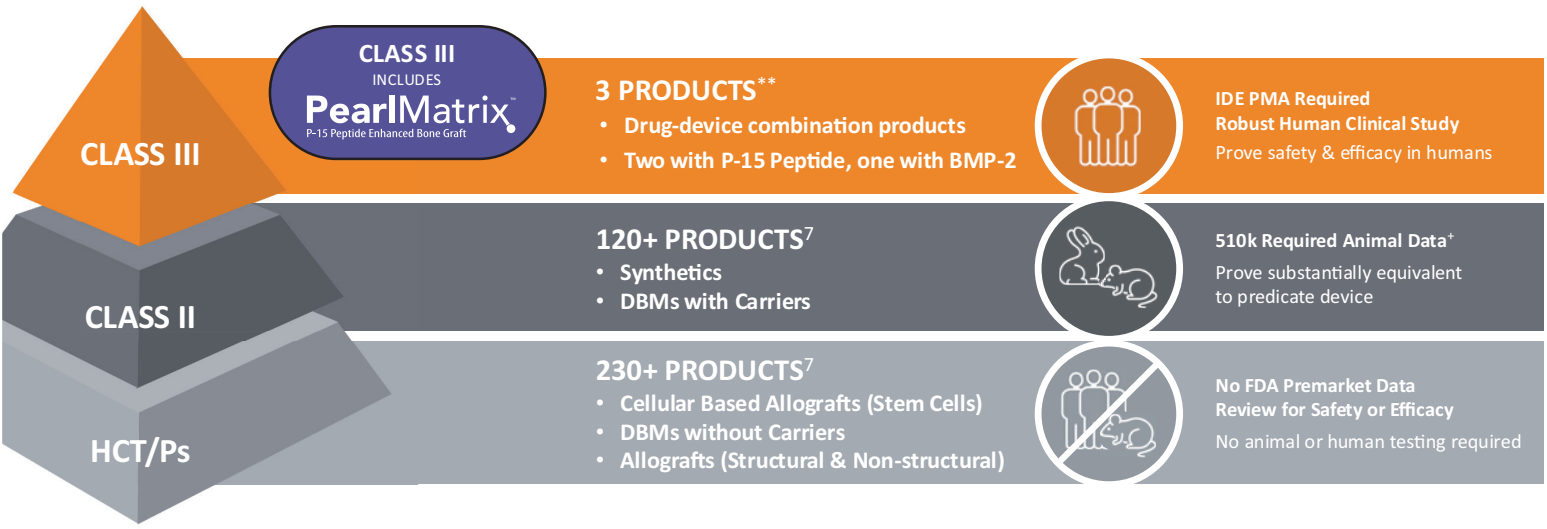
Osteogenic activity is amplified as more cells are recruited and attach to the P-15 enhanced surface. This creates a cyclical attachment and activation process that leads to an acceleration of new bone formation.[3-5,9,10,14-16]



Rigor of Evidence

Only Three of 350+ Spinal Bone Grafts Have Met Robust Class III FDA Evidence Requirements**[7,21]

Only one (PearlMatrix) has achieved statistically superior fusion speed in a Level 1, PMA, IDE study with ~60% high-risk patients. *[1,2]



FDA Regulatory Pathways & Evidence Requirements for Bone Grafts

Class III

Class III devices have the most rigorous pathway to market requiring human clinical evidence demonstrating safety and efficacy. For the current Class III spinal bone graft **Premarket Approvals (PMAs)**, the FDA has required a prospective randomized clinical trial under an Investigational Device Exemption (IDE). Of 350+ products, PearlMatrix is one of three Class III FDA approved spinal bone grafts, and the only Class III bone graft approved for single-level TLIF.

Class II

Class II products require a **510k** for market clearance, demonstrating substantial equivalence to predicate devices and typically with animal studies. Human testing for safety and efficacy has not been required to bring existing 510k spinal bone grafts to market, however human testing may be required for future products.

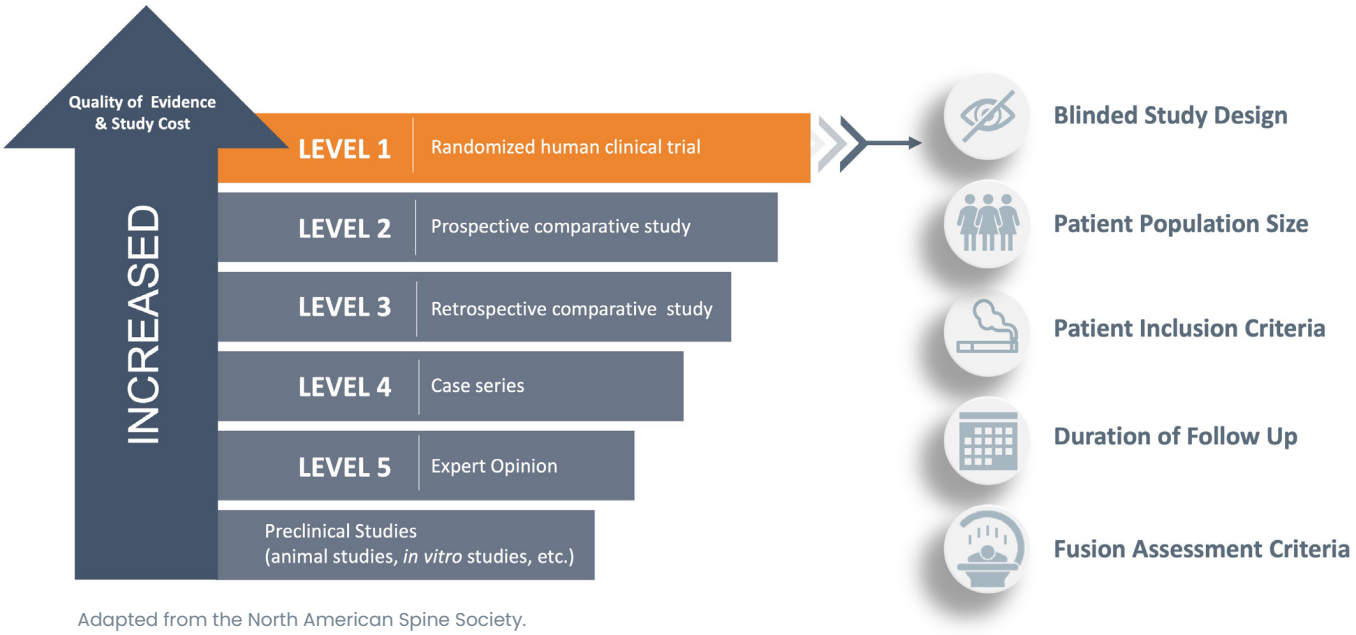
HCT/Ps

HCT/Ps **do not require FDA premarket data review** for safety or efficacy, no human or animal testing is required. HCT/Ps must demonstrate that they are minimally manipulated, are for homologous use only, do not have a systemic effect, and are not dependent on the metabolic activity of living cells for their primary function, in addition to other qualifications.

^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
† As demonstrated in a single-level TLIF PMA IDE study vs. local autograft.
** Three drug-device combination products with spinal indications, i-FACTOR, Infuse™ and PearlMatrix as of June 2025.
+ 510(k) FDA clearance may require human data.

Levels of Evidence

Levels of evidence range from Level 1 randomized control human clinical trials to level 5 expert opinion.[22]
Level 1 evidence is considered the highest quality of evidence and involves randomized human clinical trials.
Not all Level 1 studies are considered equal. The quality of data can vary depending on study design protocols.



Adapted from the North American Spine Society.

The PearlMatrix PMA IDE was a Level 1, prospective, randomized, multi-center, blinded, controlled, statistically powered human clinical study.[1]

Bone Osteobiologics and Evidence (BOnE) Classification[23]

AOSpine developed a universal evidence classification system for osteobiologics based on level of evidence.
The BOnE classification, a universal evidence classification system for osteobiologics, evaluates each osteobiologic based on the highest level of evidence available and if the evidence is based on human, animal or in vitro studies.

Type A (Human Studies)

Type B (Animal Studies)

Type C (In Vitro Studies)

Level	Description for Type A levels
1	Prospective, randomized, controlled trial with statistical significance or narrow confidence intervals, performed for the indication
2	Prospective cohort study or lesser-quality randomized study++
3	Retrospective cohort studies or lesser-quality prospective cohort studies++
4	Uncontrolled case series or lesser-quality retrospective cohort studies++

PearlMatrix meets the criteria to be considered A1, the highest level, according to the AO Spine BoNE Classification system.[1,23]

++ Lesser-quality studies: Low numbers, poor follow up, different indication, poor analysis, bias.

Clinical Evidence Overview

The safety and effectiveness of PearlMatrix was demonstrated through a pivotal, Level 1 IDE study that was required by the FDA for Pre-Market Approval (PMA). The IDE study was a statistically powered, prospective, randomized, controlled, multi-center, human clinical study evaluating PearlMatrix compared to human local autograft in single-level TLIF procedures.[1] PearlMatrix was used as a standalone bone graft with no bulking agents or supplemental graft material. Local autograft was optionally mixed with allograft (cancellous chips) to supplement autograft volume if required.

Prospective, randomized, controlled, statistically-powered, PMA, IDE Study

- PearlMatrix vs. local autograft in single-level TLIF (L2-S1).
- Graft was placed both in and around a static PEEK TLIF cage.
- There was no grafting permitted in the facets or posterolateral gutters.

Study inclusion reflected a real-world patient population

- 293 patients, 33 US clinical sites, ~60% high-risk patients.
- High risk = nicotine use, BMI ≥ 30 and/or Type 2 diabetes.

Primary Endpoint: 24 Month Composite Clinical Success (CCS)

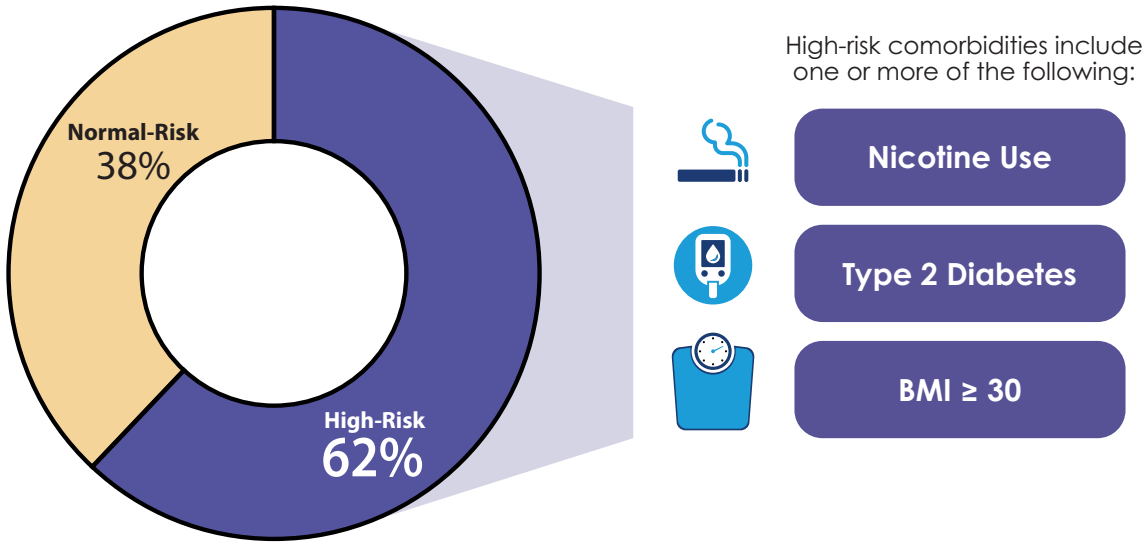
- Five components: fusion, function (ODI), neurological, no serious device related adverse events and no index-level secondary surgical interventions.
- CT follow-up: 6, 12 and 24 months.

Rigorous fusion assessment criteria

- High resolution, thin-cut CT.
- Multiple independent reviewers.

High-Risk Inclusion^

The majority (~60%) of the enrolled PMA IDE study population were considered high-risk.^
High-risk comorbidities have been shown to complicate bone healing and can impact the risk of non-union in spinal fusion procedures.[6]



^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.

Clinical Evidence Overview

Primary Clinical Endpoint: Composite Clinical Success (overall clinical success) at 24-months.

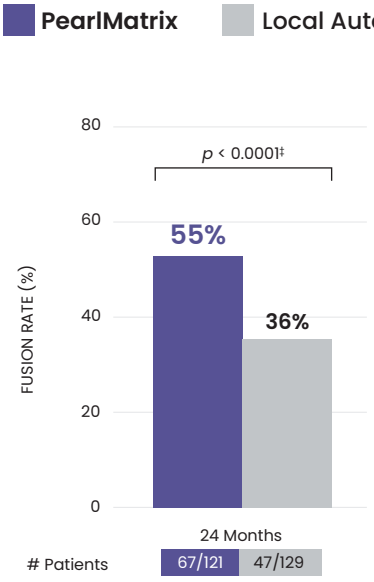
PearlMatrix achieved **statistically superior overall clinical success** at 24-months vs. the control.§†1

Overall clinical success is determined by a composite of five components:

- **Fusion:** Achievement of fusion.
- **Function:** At least 15-point improvement in ODI.
- **Neurological:** No new or worsening persistent neurological deficit.
- **No** serious device-related adverse events.
- **No** secondary surgical interventions at the index level.

To be considered an overall clinical success, a patient must achieve success in all 5 out of 5 components.

Composite Clinical Success



Fusion Rates

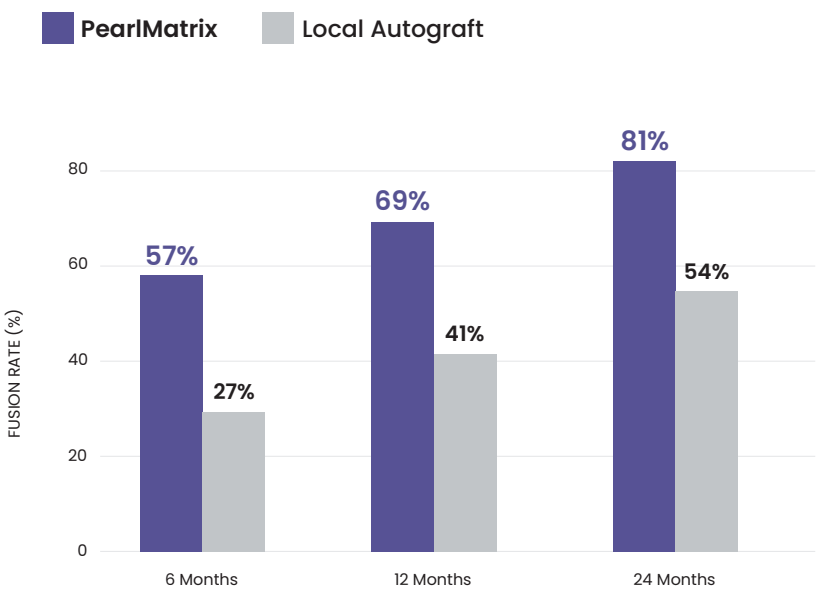
PearlMatrix demonstrated **substantially higher fusion rates** at 6 months, 12 months and 24 months vs. the control.†1

Fusion was evaluated by high-resolution, thin-cut CT with multiple independent reviewers.[1]

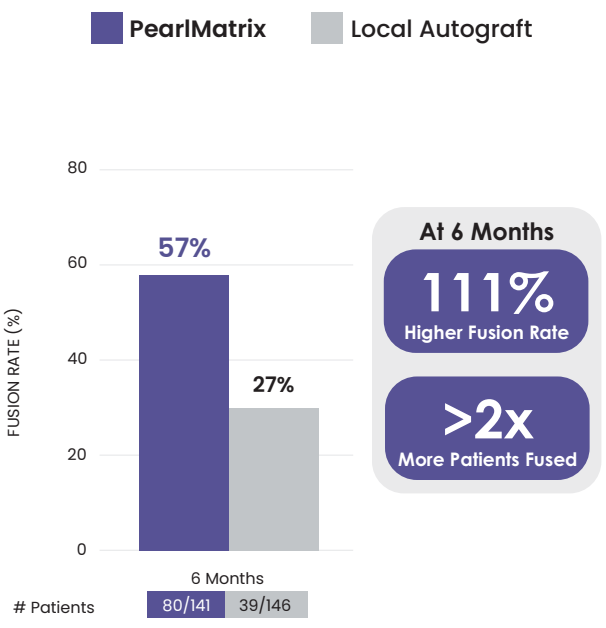
Fusion Speed (time-to-fusion)

PearlMatrix was proven to accelerate lumbar fusion achieving **statistically superior fusion speed** at 24 months with over 2x more patients fused at 6-months.†1

Fusion Rates



Fusion at 6-Months



† As demonstrated in a single-level TLIF PMA IDE study vs. local autograft.
‡ Statistical significance.

Clinical Evidence in High-Risk Patients

The majority (~60%) of the enrolled PMA IDE study population were considered high-risk.[^]

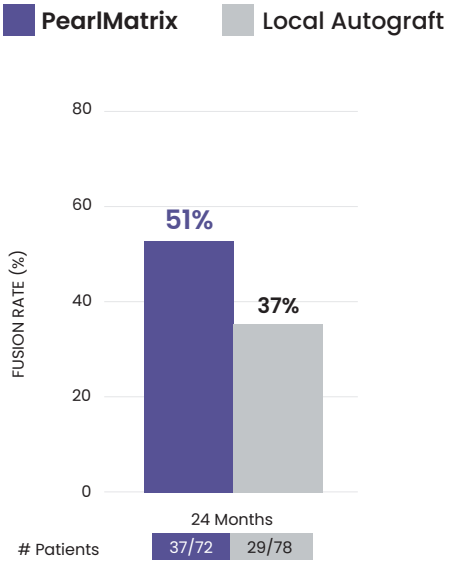
In high-risk patients, PearlMatrix achieved **substantially higher overall clinical success** at 24-months vs. the local autograft control.[^†§1]

Overall clinical success is determined by a composite of five components:

- **Fusion:** Achievement of fusion.
- **Function:** At least 15-point improvement in ODI.
- **Neurological:** No new or worsening persistent neurological deficit.
- **No** serious device-related adverse events.
- **No** secondary surgical interventions at the index level.

To be considered an overall clinical success, a patient must achieve success in all 5 out of 5 components.

High-risk Composite Clinical Success



Fusion Rates

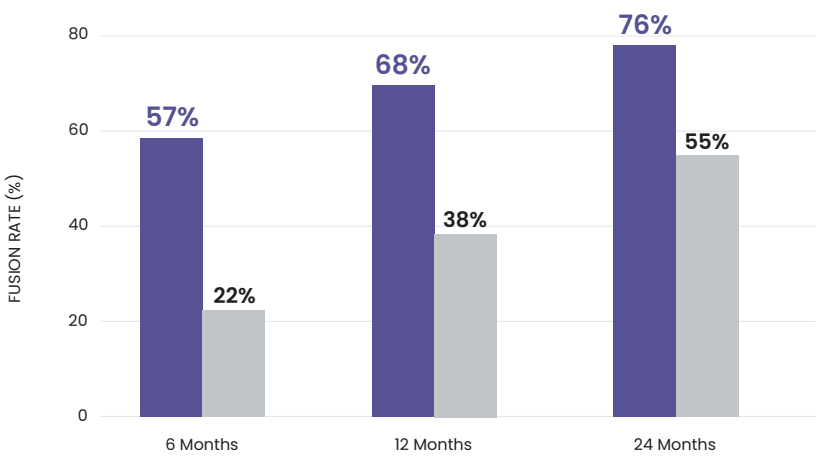
PearlMatrix demonstrated **substantially higher fusion rates** at 6 months, 12 months and 24 months vs. the control in high-risk patients.[^,1]

Fusion was evaluated by high-resolution, thin-cut CT with multiple independent reviewers.[1]

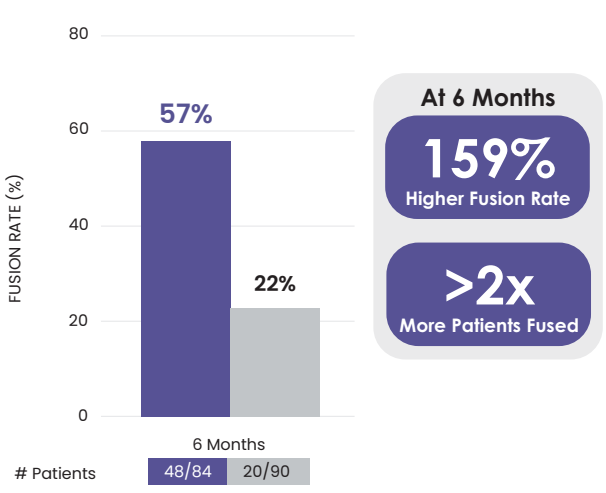
Fusion Speed (time-to-fusion)

PearlMatrix was shown to accelerate lumbar fusion in high-risk patients achieving **substantially faster fusion** with over 2x more patients fused at 6-months.[^†1]

High-risk Fusion Rates



High-risk Fusion at 6-Months

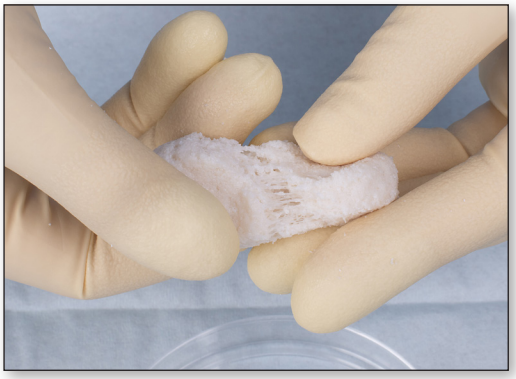


^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
† As demonstrated in a single-level TLIF PMA IDE study vs. local autograft.
§ Overall clinical success is defined by a composite score including fusion, function (ODI), neurological, no serious device-related adverse events and no index-level secondary surgical interventions.

Additional Supporting Information

PearlMatrix was formulated to optimize handling and efficiency in the operating room.

Handling



PearlMatrix contains a fibrous and moldable collagen matrix carrier, purpose-built for enhanced handling and surgical site retention.

- Fibrous, cohesive and moldable.
- Naturally resists migration and separation.
- Adaptable to open or MIS procedures.
- All-in-one bone graft replacement that doesn't require bulking agents or extenders.

Packaging & Storage

PearlMatrix is conveniently packaged as a freeze-dried material that does not require freezing or thawing.

- Stored at room temperature.
- Three-year shelf life.
- Offered in 1.0cc, 2.5cc, 5.0cc and 10.0cc sizes.
- Provided sterile and intended for single-use only.

Preparation

PearlMatrix is quickly hydrated with a simple preparation technique.

- Hydrated with sterile surgical solution (i.e., saline).
- Conveniently pre-packaged in a sterile hydration tray.
- No thawing, activation time or waiting for binding.
- Can be separated and molded into the desired shape(s).

PearlMatrix Ordering Information

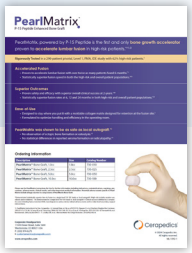
Description	Size	Catalog Number
PearlMatrix™ Bone Graft, 1.0cc	1.0cc	730-010
PearlMatrix™ Bone Graft, 2.5cc	2.5cc	730-025
PearlMatrix™ Bone Graft, 5.0cc	5.0cc	730-050
PearlMatrix™ Bone Graft, 10.0cc	10.0cc	730-100

Supporting Resources

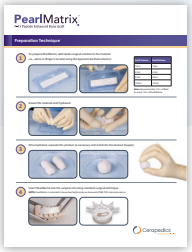
See below for additional information, or if you have product questions, please reach out to your Cerapedics representative to request additional information or product resources.

Product Brochure

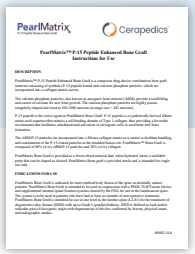
Sales Sheet



Preparation Guide



Instructions For Use



If you have questions about Contracting and need support in obtaining product approval in your health care system, please email Contractdetails@Cerapedics.com for assistance.

For questions regarding Market Access and Reimbursement for Cerapedics products, click the link below or scan the QR Code to get started and someone from our team will be in touch with you shortly.

https://info.cerapedics.com/reimbursement

June 18, 2025

Cerapedics, Inc.
Roger N. White
Clinical and Regulatory Affairs Consultant
11025 Dover Street, Suite 1600
Westminster, Colorado 80021

Re: P240001
Trade/Device Name: PearlMatrix™ Bone Graft
Product Code: NOX
Filed: January 2, 2024
Amended: February 1, 2024, August 21, 2024, and December 20, 2024

Dear Roger White:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for PearlMatrix™ Bone Graft. This device is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix™ Bone Graft is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix™ Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies.

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CERAPEDICS VENDOR INFORMATION SHEET

COMPANY NAME:

Cerapedics Inc.

Phone: 303–974–6275

CORPORATE ADDRESS:

11025 Dover Street
Suite 1600
Westminster, CO 80021

REMIT TO ADDRESS:

Cerapedics Inc.
Dept 1543
P.O. Box 30106
Salt Lake City, UT 84130-0106

CUSTOMER SERVICE :

Phone: 866-360-5612
Email: customerservice@cerapedics.com
Hours of operation: M–F 8:00 AM – 6:00 PM MST

Company Terms: Net 30
Tax ID #: 20–8302692
DUNS #: 800339702
Website: www.cerapedics.com

Contact Customer Service for Payment Options and ACH Payments

Cerapedics®

Cerapedics®
Repairing bones. Healing lives.

PearlMatrix™ Exclusions Certificate

Bisphenol free	Yes
PVC free	Yes
Mercury free	Yes
Free of intentionally added BPAs	Yes
Free of hazardous materials	Yes
DEHP free	Yes
Latex free	Yes
Free of halogenated organic compounds	Yes
Free of chemicals on CA Prop. 65	Yes
Bromine free	Yes
Free of chlorine-based compounds	Yes
Free of antimicrobial/antibacterial agents	Yes
PBTs free	Yes
PFCs free	Yes
Radiopacity	Yes
MRI compatibility	PearlMatrix does not contain any ferrous component that would be a risk under MRI.
Human tissue tracking	PearlMatrix does not contain human tissue or human cells and does not require tracking.
Storage	PearlMatrix does not require refrigeration and can be stored at room temperature.

Description	Product Code
PearlMatrix Bone Graft, 1.0cc	730-010
PearlMatrix Bone Graft, 2.5cc	730-025
PearlMatrix Bone Graft, 5.0cc	730-050
PearlMatrix Bone Graft, 10.0cc	730-100

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See ***Specific Instructions*** on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☐ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) . . . . .

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

5 Address (number, street, and apt. or suite no.). See instructions.

Requester's name and address (optional)

6 City, state, and ZIP code

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

___ – ___ – ____

or

Employer identification number

__ – _____

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** | **Date**

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

About Cerapedics Inc.

Cerapedics is committed to Repairing Bones and Healing Lives.

Cerapedics is a global, commercial-stage orthopedics company that is dedicated to redefining the path to bone repair by healing bones faster and at higher rates, so all patients can get back to living their fullest lives.

For Reimbursement assistance and support, contact us:


reimbursement@cerapedics.com


(303) 974-6275, press 7


info.cerapedics.com/reimbursement

Indications and Important Safety Information

PearlMatrix™ Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies.

PearlMatrix is contraindicated in situations where there is an absence of load-bearing structural support at the graft site, sensitivity to components or the product, active infection at the operative site, or operative site subject to excessive impact or stress.

The effect of PearlMatrix on pregnant or nursing patients has not been evaluated. Care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure such as individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy or high dosage radiation therapy. PearlMatrix in a TLIF procedure was associated with a higher rate of secondary surgical interventions compared to local autograft.

PearlMatrix should only be used by physicians who are experienced with TLIF procedure and in surgical procedures where it can be adequately contained at the bony void or defect.

To learn more about PearlMatrix, its indications, contraindications, warnings, precautions and potential adverse events, visit our website at www.Cerapedics.com or refer to the PearlMatrix Instructions for Use for complete safety and risk information.

Definitions

CCS, composite clinical success
DBM, demineralized bone matrix
FDA, Food and Drug Administration
HCT/P, human cell or tissue product
IDE, investigational device exemption
ODI, Oswestry disability index
PMA, premarket approval
CCS, composite clinical success
TLIF, transforaminal interbody fusion

References

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