

# PearlMatrix™

P-15 Peptide Enhanced Bone Graft

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## Patient Information Brochure

## PATIENT INFORMATION BROCHURE

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This brochure is designed to help you make an informed decision about your surgery. Please read this entire document carefully. Keep this document because you may want to read it again. If you have additional questions, talk to your doctor. Only your doctor can determine the types of treatment that may be appropriate for you. Please speak to your doctor about having this procedure, and about individualized recommendations for you.

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## GLOSSARY

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### **Allograft Bone**

Bone that is taken from another person. Also called 'banked bone'.

### **Anorganic Bone Mineral (ABM)**

Structural component of PearlMatrix™ P-15 Peptide Enhanced Bone Graft. ABM is a mineral component manufactured to leave only the non-living (inorganic) material, eliminating the potential for disease transmission.

### **Autologous Bone Graft (Autograft)**

Bone that is taken from one part of your body and placed into a different part of your body to promote bone healing.

### **Degenerative Disc Disease (DDD)**

A term used to describe degenerative changes in the intervertebral disc(s) due to aging and wear-and-tear, which may result in chronic pain and restricted movement.

### **Fusion**

When two bones grow together to stop movement.

### **Incision**

A cut in the skin made during surgery.

### **Interbody Fusion Device**

A type of spinal fusion device often made from a biocompatible polymer or titanium that is implanted between two vertebrae to help restore and maintain height, provide stability and aid in bone fusion.

Also called a "spinal fusion cage" or "spacer"

### **Lumbar (Spine)**

Includes the last five vertebrae of the spinal column (lower back).

### **Nerves**

Fibers that move messages to and from the brain. Nerves control feeling and movement. Nerves connect the skin, organs, and muscles through the spinal cord to the brain.

### **Nerve Roots**

Bundles of nerve fibers extending out from the spinal cord.

### **PEEK**

Acronym for Poly-Ether-Ether-Ketone, a common inert surgical grade plastic material used in multiple surgical implants.

### **Physical Therapy**

Using exercise and massage to help regain movement.

### **Spinal Cord**

Bundles of spinal nerves. The spinal cord starts at the bottom of the brain and runs to the lower back. The spinal cord moves messages between the brain and the body.

### **Spinal Disc**

Soft pad of cartilage between each vertebra of the spine. The discs hold the vertebrae apart, act as a cushion, and allow the vertebrae to move.

### **Spine**

The 33 vertebrae start under the skull and end in the small of the back. Grouped into three sections: upper (cervical), middle (thoracic), and lower (lumbar). Protects the spinal cord and provides body support.

## **PATIENT DIAGNOSIS**

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You have been given this brochure because you have been diagnosed with lumbar degenerative disc disease (DDD) and have not responded to at least six months of non-surgical treatment. Your doctor has determined that you should have a region of your low back (called the lumbar region) fused and that you may benefit from the use of PearlMatrix™ Bone Graft as part of this surgery.

## **WHAT IS LUMBAR DEGENERATIVE DISC DISEASE?**

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The bone segments in your spine are separated and cushioned by ‘spinal discs’. These discs are what make your spine flexible, allowing it to bend. The term degenerative disc disease (DDD) refers to changes in spinal discs that occur in most people as they age. DDD can occur at different locations in your spine, and sometimes results in pain or difficulty with daily activities that may be treated with surgery.

## **WHY DOES LUMBAR DDD NEED TO BE TREATED?**

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Lumbar DDD can cause nerve roots in your lower back to become irritated or pinched, causing pain, weakness, or tingling down the legs or feet. DDD also can irritate the spinal cord causing a loss of feeling or movement. DDD may have an impact on your ability to conduct daily functions.

## **HOW CAN LUMBAR DDD BE TREATED?**

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There are several options for treating lumbar DDD. Physical therapy is a non-surgical option. Several surgical options also exist. The first type of surgery involves removing the damaged spinal disc and filling its space with bone graft. The goal of this surgery is to fuse the two bones that surround the disc to prevent them from moving and pressing against your nerve roots or spinal cord. Another surgical option is to remove the damaged spinal disc and replace it with a disc replacement implant. The goal of this surgery is to try and maintain motion in that region of your lower back.

You have not responded to at least six months of physical therapy and your doctor has determined that the most appropriate treatment for you is fusion surgery.

## HOW IS PEARLMATRIX™ P-15 PEPTIDE ENHANCED BONE GRAFT USED IN THE TREATMENT OF DDD?

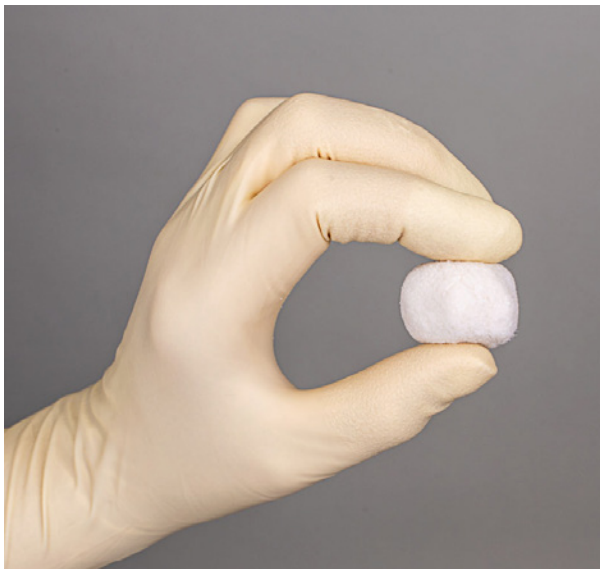
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In the surgical procedure, your physician will remove the degenerated disc that is causing pain. After removing the disc, your physician will place a device containing PearlMatrix™ Bone Graft in the disc space to help promote fusion of the lumbar spine. The device that contains PearlMatrix™ Bone Graft is made of a common surgical grade material, PEEK and/or Titanium. Since it is placed between the two bones to fuse them, it is called an interbody fusion device. Once these devices are in place, your doctor will use metal screws and rods to connect the two bones that surround your damaged disc. This will hold them in place while the bones are fusing.

## WHAT IS PEARLMATRIX™ P-15 PEPTIDE ENHANCED BONE GRAFT MADE OF?

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The main ingredients in PearlMatrix™ Bone Graft include a medical-grade version of a naturally occurring protein found in everyone's body called P-15. Another ingredient is a medical-grade mineral, calcium phosphate particles called 'anorganic bone mineral' or ABM. This ingredient provides a structure for new bone growth. PearlMatrix™ Bone Graft encourages new growth that attaches to the structure as the bones in the damaged part of your low back. These materials are suspended on another ingredient, a naturally occurring protein called collagen, that aids in the placement and containment of PearlMatrix™ Bone Graft at the treatment site. Below are images of PearlMatrix™ Bone Graft and how it is placed inside a fusion device.



PearlMatrix™ Bone Graft



PearlMatrix™ Bone Graft in an Interbody Fusion Device

## WHO SHOULD NOT RECEIVE PEARLMATRIX™ BONE GRAFT (CONTRAINDICATIONS)?

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PearlMatrix™ Bone Graft should not be used in situations where:

- The graft site is not mechanically rigid. This is called “an absence of load bearing structural support.”
- Your body is sensitive to ingredients in PearlMatrix™ Bone Graft
- You have an active infection at the surgical site
- The surgery site receives excessive impact or stress in your doctor’s judgment

## WHAT ARE SOME WARNINGS FOR USING PEARLMATRIX™ BONE GRAFT?

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PearlMatrix™ Bone Graft has not been tested in pregnant women or nursing mothers.

As with any surgical procedure, care should be taken if you have prior conditions that may affect the success of the surgery. Examples of such conditions include problems with bleeding or blood clotting, use of long-term steroid drugs or so called ‘immunosuppressive’ drugs prescribed by a doctor, or high dosage radiation given by a doctor to treat you.

PearlMatrix™ Bone Graft in lower back surgery is associated with a higher rate of needing another surgery compared to surgery that uses only your own bone with cadaver bone. It is not known what specific types of patients who receive PearlMatrix™ Bone Graft are more likely to need another surgery. These secondary surgeries can be related to the PearlMatrix™ Bone Graft or related to the surgery itself.

## WHAT ARE SOME PRECAUTIONS FOR USING PEARLMATRIX™ BONE GRAFT?

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PearlMatrix™ Bone Graft should only be used by doctors who are trained in using it and have experience performing low back fusion surgery.

PearlMatrix™ Bone Graft has been compared to using a patient’s local bone and cadaver bone alone in a clinical study. PearlMatrix™ Bone Graft has not been compared to using bone from the patient’s hip. Your doctor can explain these alternatives for you.

PearlMatrix™ Bone Graft is not intended to be used when the graft site is not mechanically rigid. This is called “an absence of load bearing structural support.” It must be used with other medical devices including a spacer between the bones and screws and rods. This is discussed in more detail in this brochure.

PearlMatrix™ Bone Graft should only be used where it can be adequately contained.

## WHAT ARE POTENTIAL COMPLICATIONS OR SIDE EFFECTS I SHOULD BE AWARE OF?

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As with any surgery, spine surgery of the lower back is not without some risks. Various complications arising out of the surgery or the use of PearlMatrix™ Bone Graft may occur. Some complications may be severe, affecting the overall outcome of surgery. It is possible that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. Sometimes you may need additional surgery to correct complications or in order to help you feel better. Your surgeon can explain this more.

Some of the possible complications include:

- Side effects from being put to sleep for surgery or from the incisions for surgery, including difficulty swallowing or hoarseness
- Bleeding, which may require receiving donated blood
- Wound complications, including infection, drainage, collection of blood at the surgical site
- Scar formation or other problems with the surgical incision
- Movement of PearlMatrix™ Bone Graft from where it is placed, as is possible with any bone graft, which may result in pain, decrease or loss in physical functioning, and may require additional surgery
- Failure of the bones of the lumbar spine to fuse
- Temporary increase in calcium levels in your blood which may cause muscle weakness
- Degeneration of the bones of the lumbar spine next to the treated level
- Allergic reactions to the ingredients of PearlMatrix™ Bone Graft
- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- Damage to tissues or nerves near the surgical site
- Abnormal bone formation in an unintended location
- Excessive or incomplete bone formation
- Mild to severe swelling
- Arthritis, which is inflammation of joints which can cause pain, or other disorders in bone formation
- Breathing (respiratory) problems
- Kidney (renal) problems
- Nervous system problems
- In rare situations, heart attack, stroke, or death

Please speak to your doctor if you have any questions about possible complications or think you may be experiencing any of the above.

## WHAT WILL HAPPEN DURING SURGERY?

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Prior to the surgery, your doctor will instruct you of any special care or instructions to follow the day before the operation. This procedure is usually completed in one day. Your doctor will give you specific information about your individual procedure and recovery plan. When you get to the operating room, your doctor will explain the relevant surgery to you. During surgery, an incision is made in your lower back at the area of the damaged disc, and the damaged disc will be removed. Your physician will prepare the PearlMatrix™ Bone Graft with the other medical devices used, and these will be positioned into your spine.

## WHAT CAN I EXPECT AFTER SURGERY?

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Your doctor will provide you with specific recovery procedures that you should follow. Following these steps will help ensure your chances of a successful surgery. Be sure to ask your doctor if you have any questions regarding whether certain activities are permissible after surgery, as these directions will vary for each individual.

Contact your doctor immediately if:

- you get a fever
- you do not feel well after your surgery
- you experience pain
- you experience tenderness or swelling of the skin or surgery site
- you experience itching, redness, or drainage at surgery site
- you experience nausea and vomiting
- you have more tingling, numbness, pain, or weakness in the legs or feet than you had before surgery
- you experience anything else that is making you feel unwell even if it is not on this list

## IS THERE CLINICAL DATA FOR PEARLMATRIX™ BONE GRAFT?

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The safety and effectiveness of PearlMatrix™ Bone Graft has been tested in a total of 293 patients undergoing lumbar spine fusion surgery. A total of 33 different surgery centers participated in the study.

Patients were divided into two groups: a PearlMatrix™ Bone Graft group (143 patients), and a control group (patient's own bone and donor bone, 150 patients). The key study results were assessed at two (2) years after surgery.

The patients in the PearlMatrix™ Bone Graft group experienced similar decreases in pain and improvement in ability to function compared to the control group. Both groups experienced similar function of nerves and similar serious surgical complications. The majority of patients in the PearlMatrix™ Bone Graft group (84% vs. 57% for the control group) achieved fusion of the bones of the lumbar spine by two (2) years after surgery. The PearlMatrix™ Bone Graft group also fused faster than the control group. The PearlMatrix™ Bone Graft group had a higher rate of needing another surgery by two years after surgery (9.1% vs. 2.7% for the control group).

You should ask your doctor about the potential complications associated with your individual procedure.



## ARE THERE ALTERNATIVES TO USING PEARLMATRIX™ BONE GRAFT?

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Surgery will likely be recommended by your doctor if other non-operative methods have not been successful at reducing your pain. You may wish to ask your doctor about other exercises, physical therapy, or medications that might help improve pain as alternatives to surgery. Several other surgical options also exist.

The first type of surgery involves removing the damaged spinal disc and filling its space with bone graft.

The goal of this surgery is to fuse the two bones that surround the disc to prevent them from moving and pressing against your nerve roots or spinal cord. Another surgical option is to remove the damaged spinal disc and replace it with a disc replacement implant. The goal of this surgery is to try and maintain motion at that region of your spine.

Please ask your doctor for more information on possible alternatives to the use of PearlMatrix™ Bone Graft.



## TALK TO YOUR DOCTOR

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This pamphlet is meant to give you useful information and knowledge about PearlMatrix™ Bone Graft. However, it is not intended to replace medical advice or instruction from your healthcare professional.

Your doctor or physician is the only person responsible and qualified to appropriately diagnose and treat your health condition. Should you have any questions about PearlMatrix™ Bone Graft or its relevance to your course of treatment, please contact your healthcare professional.

# PearlMatrix™

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For additional information about PearlMatrix™ Bone Graft, visit our website at: [www.cerapedics.com](http://www.cerapedics.com)

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