

## AN INTRODUCTION TO

# OSTEOCEL®

## ALLOGRAFT CELLULAR BONE GRAFT

*This booklet is designed to inform you about Osteocel cellular allografts as a bone graft substitute in your spinal fusion surgery. It is not meant to replace any personal conversations that you might wish to have with your physician or other member of your healthcare team.*

*Not all the information here will apply to your individual treatment or its outcome. The information is intended to answer some of your questions and serve as a stimulus for you to ask appropriate questions about the procedure.*



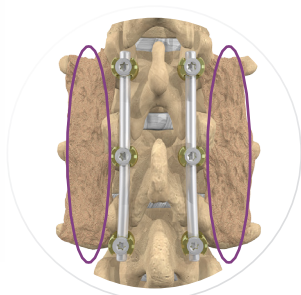
## Your Surgeon Has Recommended Osteocel

In preparation for your upcoming procedure, your surgeon is planning for your individual case. Surgical treatment of spine and orthopedic conditions often requires a bone graft, which is a material used to replace missing bone and promote new bone growth.

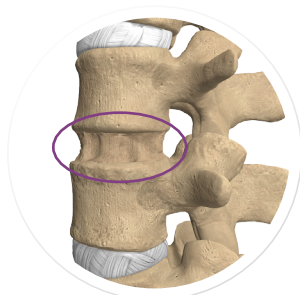
For many years, use of the patients' own bone (autograft) has been considered the industry "gold standard" for bone grafting. Osteocel is designed to mimic the same physiologic properties of autograft without the effects and limitations that can be associated with using your own bone as a graft. Because of the unique properties of Osteocel, your surgeon has identified this material as the best option for you.

## What is Spinal Fusion?

Fusion is a surgical technique in which one or more of the vertebrae of the spine are joined together ("fused") so that motion no longer occurs between them. Bone grafts are placed in or around the spine during surgery. The body then heals the grafts over time—which joins the vertebrae together.



**Posterolateral Fusion**



**Interbody Fusion**

## **WHEN IS FUSION RECOMMENDED?**

There are many potential reasons for a surgeon to consider fusing the vertebrae. Fusion is primarily performed to eliminate the pain caused by abnormal motion of the vertebrae. Some other examples include: treatment of a fractured (broken) vertebra; correction of a deformity (spinal curve or slippage); treatment of instability; and treatment of some cervical disc herniations.

## **DISADVANTAGES OF TRADITIONAL BONE GRAFTING**

The standard against which all bone grafts are measured is autograft. Autograft is an effective bone graft material because it contains all of the components necessary for natural bone healing, including living cells, signals to direct bone formation, and structural support. However, to harvest enough bone for a fusion procedure, a second incision is typically necessary which can lead to:

- Longer surgical procedure
- Harvest-site infection
- Prolonged recovery time
- Long-term pain and other side effects

Additionally, not all patients are good candidates for autograft harvesting due to inadequate bone quantity and/or quality.

For these reasons, a number of autograft alternatives are often used. One common option is allograft, which is bone graft taken from a tissue donor. However, traditional allograft materials lack living cells and thus do not contain all of the components necessary to encourage new bone growth.

# How Osteocel® Technology Works

## OSTEOCEL ALLOGRAFT CELLULAR BONE GRAFT

Osteocel is a comprehensive bone graft developed to mimic your own bone autograft. To facilitate your return to daily activities, Osteocel provides the following bone-growing components:

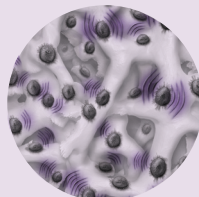
### SCAFFOLD

Osteocel retains the natural scaffold, or support structure, for new bone to grow on and through.



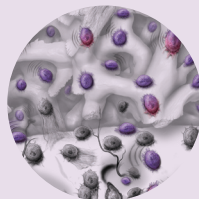
### SIGNALS

For bone formation to occur, specific signals are necessary to direct the process. These signals act on the cells within Osteocel, and help direct your body's own cells to stimulate bone formation.



### CELLS

Osteocel contains viable mesenchymal stem cells. These bone-forming cells are naturally present in our bodies and are essential for bone tissue formation and healing.



Osteocel technology preserves the live bone-forming cells in donor tissue. These cells are not manipulated or artificially added to the product and are specifically tested for cell viability and ability to form bone before clinical use is approved.

Osteocel provides a complete and physiologic bone graft, since it contains all of the necessary components for bone growth: the cells, the signals, and the scaffold. As a patient, you can now be treated with Osteocel and avoid the limitations of traditional bone graft alternatives.

# Is Osteocel® Technology Safe?

## AN ADVANCED BONE-GRAFTING SOLUTION

Osteocel preserves native bone cells, making it an advanced solution compared to traditional allograft bone-grafting materials. Traditional allograft bone grafts do not contain viable cells and are able to provide only the support structure for bone growth.

Clinical safety is very important as you and your physician consider bone-grafting options. Due to stringent standards required by the U.S. Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB), reported allograft related infection rates are much lower than those associated with the surgical procedures themselves.<sup>1,2</sup> To ensure the safety of Osteocel grafts, specific processing guidelines are strictly enforced:

- Tissue donors are thoroughly screened and tested to meet or exceed safety standards mandated by the FDA and AATB.
- Tissue is cleaned and specifically processed to deplete components that could be rejected by your body and to retain only the elements to support bone growth.
- Each and every lot of Osteocel is meticulously tested, not only for safety, but also to confirm the presence of active cells for forming new bone.

Osteocel grafts have been used safely since 2005 as an advanced solution for restoring quality of life to more than 140,000 patients.

<sup>1</sup>The American Journal of Sports Medicine, December 2007, 35:2148-2158 (allograft-related infection rate: 0.0004%).

<sup>2</sup>NHSN Report, 2008 (spine surgery-related infection rate: 1.57%).

# Frequently Asked Questions

## **HOW LONG WILL IT TAKE FOR BONE TO FORM WITH OSTEOCEL®?**

The length of time it takes to grow bone and achieve fusion is a complicated process that depends on multiple factors. This process can take up to a year or longer. You should consult your physician for proper guidance specific to your procedure.

## **IS THERE EVIDENCE THAT SUPPORTS THE CLINICAL BENEFITS OF OSTEOCEL?**

Since 2005, more than 225,000 patients have been treated with Osteocel with no attributable adverse events. There are more than 20 peer-reviewed publications with Osteocel being used for bone repair procedures in spine, foot and ankle, and dental procedures.

## **WHERE IS OSTEOCEL PROCESSED?**

Osteocel is supplied to NuVasive® by AlloSource®, a non-profit tissue bank that is one of the largest and most experienced in the United States. NuVasive and all establishments that process Osteocel are registered with the FDA and are accredited by the AATB. Moreover, these establishments do not receive donated tissue from outside the U.S. Only tissue recovered by organ procurement organizations, certified by AATB, are used in Osteocel processing.

# Glossary

**Allograft** - Tissue taken from one individual (the donor) and implanted in another individual of the same species (the recipient). Allograft tissue is regulated by the AATB and by the FDA under allograft-specific regulations in the U.S.

**Autograft** - Tissue graft from the patient's own body. Examples of bone autograft in spine surgery include iliac crest and local bone from the surgical site. May also be referred to as autogenous bone.

**Differentiation (of cells)** - The process by which a less specialized cell, which has the potential to become many cell types, becomes a more specialized cell, with very specific functions.

**Immune response** - This is how your body recognizes and defends against substances that appear foreign and harmful. Standard laboratory tests confirm that Osteocel does not cause an immune response. Osteocel was shown not to provoke an immune response in a standard laboratory test.

**Immunodepletion** - The process used to remove all of the components in Osteocel that have the potential to provoke an immune response.

**Mesenchymal stem cells (MSCs)** - Cells that have the ability to differentiate into bone, cartilage, and fat. When signaled to form bone, MSCs differentiate into osteoprogenitor cells and then osteoblasts, the bone-forming cells.

**Osteoblasts** - Cells that build bone. MSCs can differentiate into osteoblasts.

**Osteoconductive** - Used to describe a graft material's ability to provide scaffolding for bone to grow onto.

**Osteoinductive** - Used to describe materials or signals that have the potential to induce bone formation.

**Osteoprogenitor cells** - Cells that are in between mesenchymal stem cells and osteoblasts in the cell differentiation process. Osteocel® retains MSCs and osteoprogenitor cells.

**Scaffold** - A supporting structure that reinforces new bone formation through cell and protein attachment. In Osteocel, the cancellous bone matrix acts as a scaffold.







# Notes

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## RESOURCES

For more information about Osteocel® please visit:

**[www.nuvasive.com](http://www.nuvasive.com)**

If you would like to learn more about patient support and education for chronic back and leg pain sufferers and their loved ones, please visit:

**[www.thebetterwayback.org](http://www.thebetterwayback.org)**

*If you have any questions about Osteocel or spine surgery in general, please call or see your physician, who is the only one qualified to diagnose and treat your spinal condition. This patient information brochure is not a replacement for professional medical advice.*

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# **OSTEOCEL<sup>®</sup>** | **ALLOGRAFT CELLULAR BONE GRAFT**



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