An introduction to

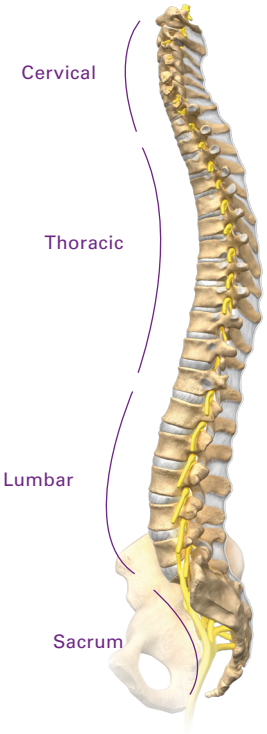
Osteocel®

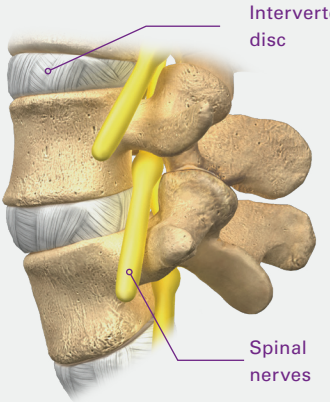
This booklet provides general information on Osteocel cellular allografts as a bone graft substitute in your spinal fusion surgery. It is not meant to replace any personal conversations that you might wish to have with your physician or other member of your healthcare team. Not all the information here will apply to your individual treatment or its outcome.

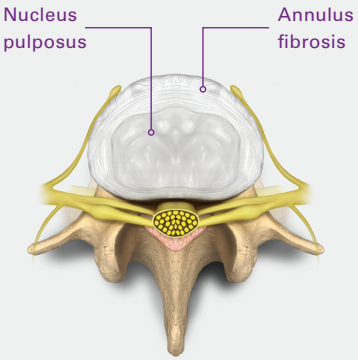
About the spine

The human spine is made up of 24 bones or vertebrae in the cervical (neck) spine, the thoracic (chest) spine, and the lumbar (lower back) spine, plus the sacral bones.

Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to move, and also provide shock absorption.





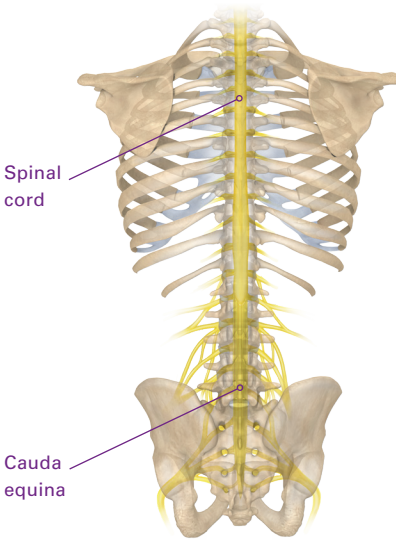


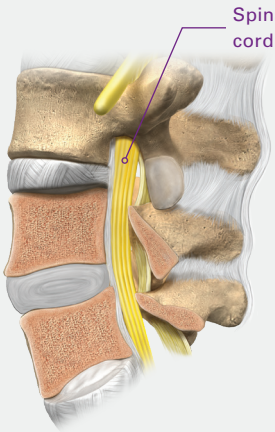
About the spinal cord and cauda equina

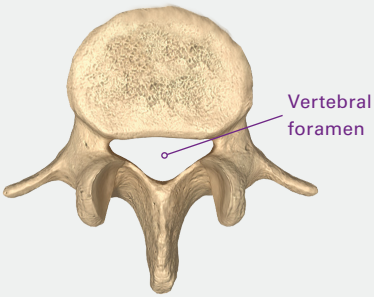
Each vertebra has an opening (vertebral foramen) through which a tubular nervous structure travels. Beginning at the base of the brain to the upper lumbar spine, this structure is called the spinal cord.

Below the spinal cord, in the lumbar spine, the nerves that exit the spinal cord continue to travel through the vertebral foramen as a bundle known as the cauda equina.

At each level of the spine, spinal nerves exit the bony spine then extend throughout the body.







What can cause pain?

There are several primary causes of spine problems. The majority of the symptoms are caused by either instability or by disc, bone, or ligaments pressing onto the nerve roots, spinal cord, and/or cauda equina.

What are the treatment options?

Many symptoms can be treated without surgery including rest, heat, ice, medication, injections, and physical therapy. It is important to speak with a physician about the best option.

If symptoms do not improve with conservative treatment, physicians may recommend spinal surgery. Surgery is reserved for those who do not gain relief from non-operative forms of treatment, patients whose symptoms are increasing or worsening, and/or patients that present with a spinal condition which indicates the need for surgery.

What is spinal fusion?

Fusion is a surgical procedure performed to stop motion between two or more vertebrae by encouraging bone to form across the problem area. In order for fusion to occur, bone graft must be applied to the surgical site as it provides a nutrient-rich environment that promotes new bone growth. The body heals the grafts over time, joining the vertebrae together to form a rigid immovable column. This type of procedure attempts to reduce back pain and other symptoms.

Traditional bone grafting

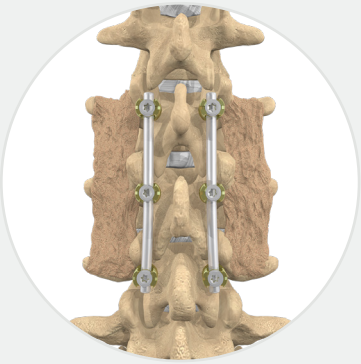
The standard against which all bone grafts are measured is autograft or a graft of tissue from the same patient's body. Autograft is an effective bone graft material because it contains all of the components necessary for natural bone healing: living cells, signals to direct bone formation, and structural 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

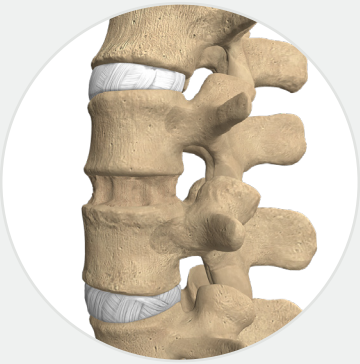
Additionally, not all patients are good candidates for autograft harvesting due to inadequate bone quantity and/or quality.

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.

Posterolateral Fusion



Interbody Fusion



How Osteocel technology works

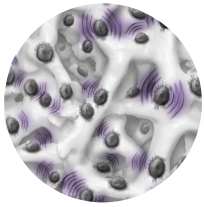
Osteocel Cellular Allograft

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

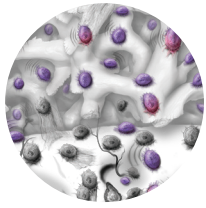
Osteocel retains the natural scaffold, or support structure, for new bone to grow on and through.

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.

Since Osteocel contains the three necessary components for bone growth: the cells, the signals, and the scaffold, patients now have an alternative to traditional bone graft material.

Next Generation Bone Grafting Solution

Osteocel preserves native bone cells, making it a next generation 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 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.[1,2] 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 is supplied to NuVasive®, a leader in spine technology innovation, by AlloSource®, an experienced, non-profit tissue bank located in the United States. NuVasive and all establishments that process Osteocel are registered with the FDA and are accredited by AATB. 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.

Osteocel grafts have been used since 2005 as a next generation solution for restoring quality of life.

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.

References

1. McAllister DR, Joyce MJ, Mann BJ, et al. Allograft update: The current status of tissue regulation, procurement, processing, and sterilization. *Am J Sports Med* 2007;35:2148-58.
2. Edwards JR, Peterson KD, Andrus ML, et al. National Healthcare Safety Network (NHSN) Report, data summary for 2006 through 2007, issued November 2008. *AJIC* 2008;36(9):609-26.

Notes

Resources

For more information about Osteocel, please visit:
nuvasive.com

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

If you have any questions about Osteocel or spine surgery, please call or visit 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.

About The Better Way Back®

The Better Way Back is a nationwide patient support program created by NuVasive, a leader in developing minimally invasive, procedurally-integrated spine solutions. The Better Way Back is a free community built on the power of empathy, and is dedicated to providing hope, support, and information to individuals suffering from chronic back, leg, or neck pain.

Through its Patient Ambassador Program, The Better Way Back pairs patients considering spine surgery with patients who have previously undergone a spine procedure. Ambassadors volunteer their time to discuss their experiences in order to provide additional, first-hand perspectives.

To learn more about The Better Way Back, please

call **1-800-745-7099**

visit **thebetterwayback.org**

text "TBWB" to **858-360-8292**

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