



# Osteocel<sup>®</sup>

## *The Cellular ADVANTAGE.*

### **A Cellular Bone Matrix Retaining MSCs and Osteoprogenitors**

#### **Mimics the Biological Profile of Autograft**

The proprietary processing technology that produces Osteocel<sup>®</sup> results in a viable bone matrix product that preserves the native MSCs and osteoprogenitors found in marrow-rich bone. It was the first product available to have the desired beneficial properties of autograft - osteoconduction, osteoinduction and osteogenesis - and that allows surgeons to provide their patients with a complete solution without the added risk and cost of a secondary procedure.



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# Osteocel® *The Cellular ADVANTAGE.*

## A Cellular Bone Matrix Product Retaining Mesenchymal and Osteoprogenitor Cells.

### Osteocel®

Osteocel is an allograft cellular bone matrix retaining native mesenchymal stem cells (MSCs) and osteoprogenitor cells

- **Complete:** provides all 3 components for bone formation:
  - > **osteoconductivity:** cancellous scaffold
  - > **osteoinductivity:** MSC growth factor production and demineralized cortical bone
  - > **osteogenicity:** MSCs and osteoprogenitor cells
- **Physiological:** mimics biologic profile of autograft
- **Consistent:** each lot tested for cell concentration, cell viability, and cell activity (osteogenic potential)

Osteocel grafts have been used since 2005 in over 30,000 procedures, with no reported adverse events<sup>1</sup>

### Low Immunogenicity

Mesenchymal stem cells are immune privileged cells that do not stimulate a cellular immune response. Osteocel does not activate T cell proliferation, as shown *in vitro* from Mixed Lymphocyte Reaction (MLR) testing.<sup>2</sup>

### Histologic Evidence

Histology from a human sinus augmentation study using Osteocel shows high vital bone content at 16 weeks, with very low residual graft material.<sup>4</sup>

### Bone Formation

MSCs contained in Osteocel are capable of differentiating into bone-forming cells (osteoblasts).<sup>3</sup> Every lot of Osteocel is tested for bone-forming potential.

### Viable Cell Content

The osteogenic potential arises from the mesenchymal and osteoprogenitor cells in Osteocel. Following processing of marrow-rich bone, release testing demonstrates osteogenic potential according to the following criteria:

- Rich supply of osteopotent cells: Greater than 50,000 cells/cc
- Viability: Greater than 70% cell viability
- Positive osteogenicity: *In vitro* cell culture assay

Safety Profile	Donor Testing	Donor Screening	Quality Assurance
Aseptic tissue processing	Hepatitis B Surface Antigen	Medical and social history evaluation	GTP compliant according to FDA regulations
Antimicrobial treatment of tissue	Hepatitis B Core Antibody	Physical examination	State of FL, MD, NY, CA, and OR licensure / registrations
Sterility cultures performed on every lot	Hepatitis C Virus Antibody	Medical record evaluation, including autopsy report (if performed)	AATB Accreditation
Selective immunodepletion process	Hepatitis C Nucleic Acid Test	Licensed physician review and release of every donor record	
No evidence of ectopic tissue formation or inflammatory cellular response with experimental high doses of MSCs. <sup>5</sup>	HIV-1 and 2 Antibody		
	HIV-1 Nucleic Acid Test		
	Human T-Lymphotropic Virus Antibody I/II		
	Syphilis (Treponema Pallidum)		

### Ridge Augmentation clinical case



### Ordering Osteocel

509-0103	Osteocel®, Cellular Bone Matrix	1 cc vial
509-0081	Osteocel®, Cellular Bone Matrix	5 cc vial

### Important Ordering Details

Due to the nature of the product, the order and delivery of Osteocel needs to be carefully coordinated. Please call for ordering details.

### References

<sup>1</sup> As of December 2009. Data on file with NuVasive®, Inc. <sup>2</sup> Mesenchymal Stem Cells Avoid Allogeneic Rejection. — Ryan, Barry, Murphy, Mahon. — Journal of Inflammation, July 2005  
<sup>3</sup> Data on file with NuVasive, Inc. <sup>4</sup> Histologic Evaluation of a Stem Cell Based Sinus Augmentation Procedure: A Case Series. — McAllister, Haghighat, Gonshor. — Journal of Perio., April 2009  
<sup>5</sup> Data on file with Osiris Therapeutics  
 Osteocel is a federally registered trademark of NuVasive®, Inc. used by ACE Surgical under licence. Protected by U.S. Patent 5,811,094 and 6,355,239. Other patents pending.