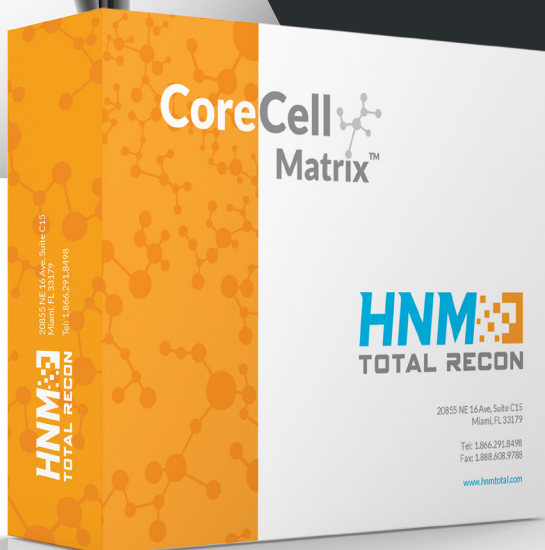




HNMTOTAL RECON

CoreCell Matrix

PRODUCT INFORMATION



- 100% ALLOGRAFT DBM

- OSTEOCONDUCTIVE

- OSTEOINDUCTIVE



1.866.291.8498
1.888.608.9788



20855 NE 16 Ave
Suite C15, Miami, FL 33179



www.hnmtotal.com
info@hnmtotal.com



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HNM Total Recon is committed in providing surgeons and health care professionals with advanced surgical solutions for effective and time-saving treatment of their patients. Our most important task is meeting surgeons' needs. We accomplish this by creating key partnerships and driving innovative product development.



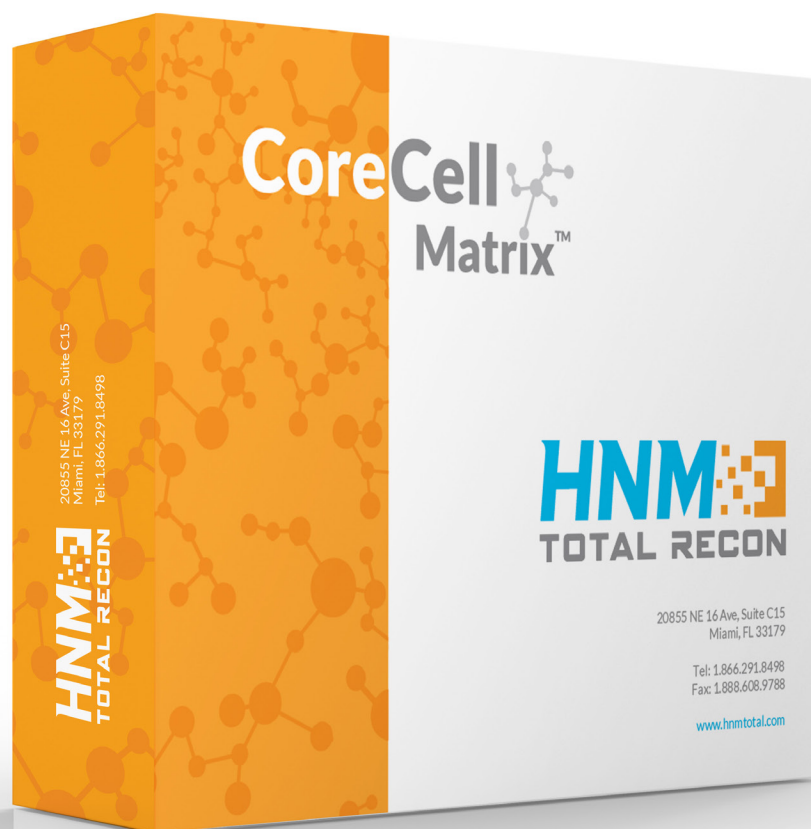


CoreCell Matrix

CoreCell Matrix is a compressible osteoinductive and osteoconductive stem cell containment matrix derived from 100% allograft bone.

CoreCell is processed using a next-generation proprietary processing method that maintains the interconnected structure of trabecular bone in a manner that preserves native bone morphogenic proteins (BMP). It allows the clinician to imbibe it with the patient's own stem cells, bone marrow aspirate (BMA), growth factors, platelet rich plasma (PRP), or with an antibiotic solution.

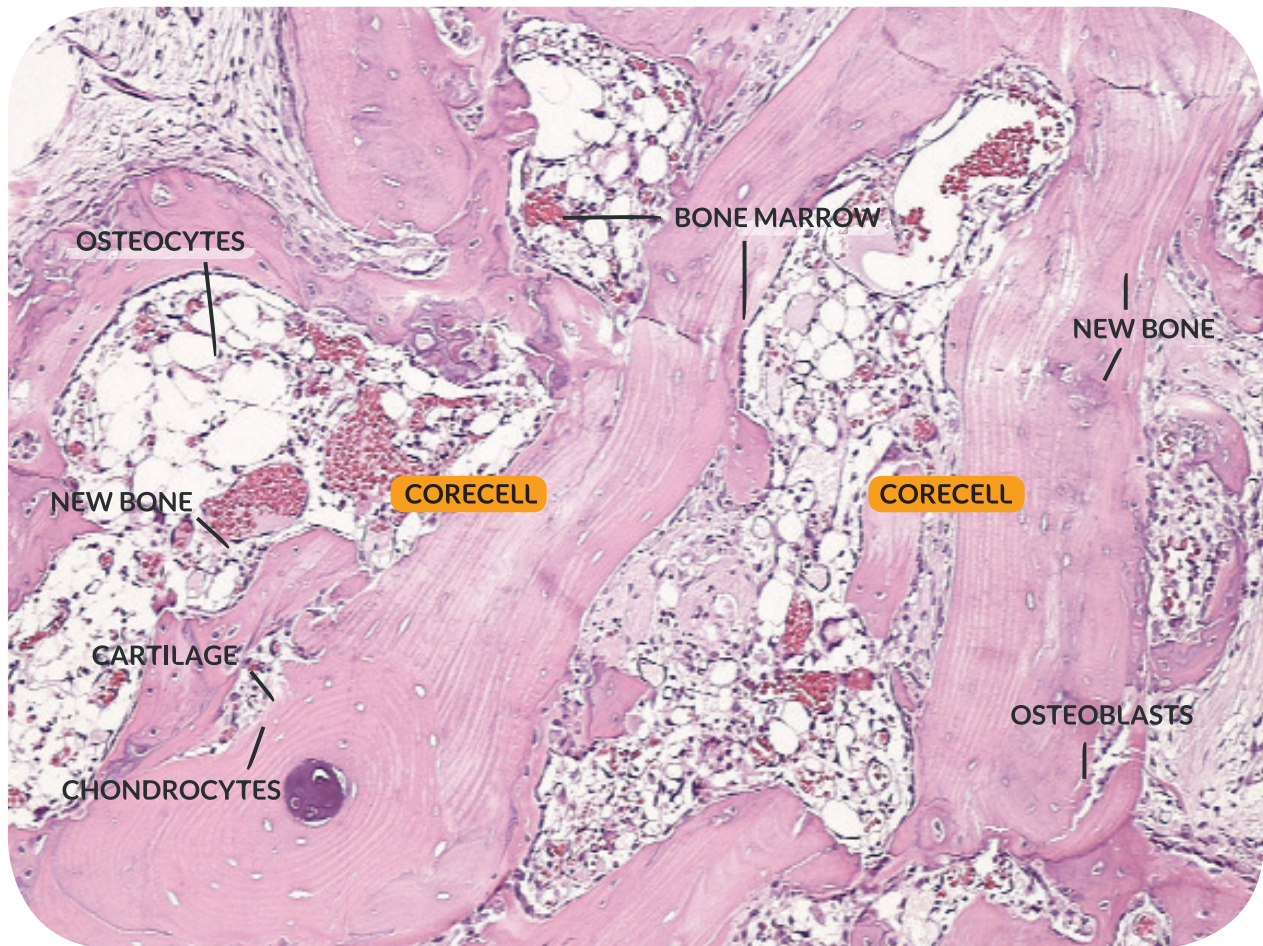
Each lot of CoreCell is verified for osteoinductivity post sterilization to ensure the presence of bone morphogenic proteins (BMPs) and growth factors. BMPs promote mesenchymal stem cells (MSC) to differentiate into chondrocytes and osteoblasts that lead to bone formation. Preserved native BMPs provide for an unparalleled osteoactive grafting material.





HISTOLOGY

OSTEOINDUCTIVE IN-VIVO LOT VERIFIED



INDICATIONS FOR USE

CoreCell Matrix is indicated for use in cervical and lumbar spine, scoliosis, lateral gutters, orthopedics, bone voids, recon, CMF, non-unions, foot and ankle, and dental procedures. When hydrated, CoreCell Matrix is a compressible scaffold that will contour with the defect.

FEATURES & BENEFITS

- Osteoinductive - each lot is verified for osteoinductivity (in-vivo and in-vitro testing; post sterilization)
- Osteoconductive
- Aseptically processed
- Terminally sterile - sterility assurance level of 10^{-6}
- Five-year shelf life
- Ambient storage, shipping and handling temperatures
- Resists migration
- Imbibes in minutes
- Available in multiple geometries and sizes



BMP TESTING

IN-VITRO ALKALINE PHOSPHATE INDUCTION ASSAY

ACCESSION NUMBER 13-003793 THROUGH 13-003798

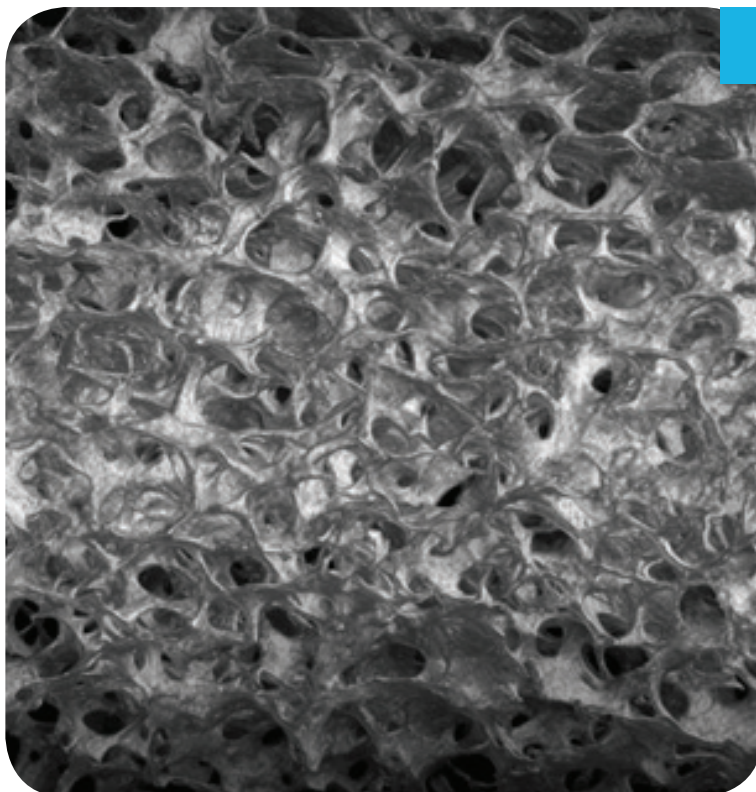
CORECELL MATRIX					
	Sample Number	Concentration Tested (mg/well)	Protein Dilution Factor	AP Dilution Factor	Specific Activity AP Units/mg Protein
N/A	BMP Control	N/A	N/A	N/A	15.433
	Cell Lysate Control	N/A	N/A	N/A	<LOQ
13-003794 CRT130023-DCM-OI-2	0001	20	10x	Neat	151.257
13-003796 CRT130032-DCM-OI-2	0001	20	10x	5	206.684
13-003797 CRT130035-DCM-OI-2	001	20	10x	5	219.062
13-003798 CRT130041-DCM-OI-2	0001	20	10x	5	283.482

CoreCell (Table Above) test articles 13-003794, 13-003796, 13-003797, and 13-003798 indicate the Specific Activity AP Units/mg Protein values exceed the BMP control by a factor 10-19 times greater.

TEST SYSTEM DESCRIPTION

CoreCell Matrix has demonstrated the ability to induce ectopic new bone formation in the soft tissue of experimental animals. Some of this activity can be attributed to the presence of stimulatory proteins, including bone morphogenetic proteins (BMPs). BMPs irreversibly induce differentiation of perivascular mesenchymal-type cells into osteoprogenitor cells. BMPs can also act in-vitro to activate a differentiation pathway in the pluripotent myoblast C2C12 cell line.

C2C12 cells stimulated by these compounds produce increased levels of alkaline phosphatase. This assay was designed to quantitatively detect the presence of these stimulatory compounds in bone products by their ability to induce alkaline phosphatase activity in C2C12 cell culture.





INDEPENDENT LABORATORY TESTING

IN-VIVO OSTEOINDUCTION ASSAY IN ATHYMIC RAT

Every donor lot (Tables A1-A5 indicate up to 3 lots) is tested in 2 different rats (# indicates rats: 19, 20, and 21) which are euthanized on Day 28. Histological criteria for evidence of osteoinduction include the presence of: Chondrocytes, Osteoblasts, Cartilage, Bone Marrow, and New Bone (see last column). X verifies presence. Implants displaying a Grade score of #1 or greater are considered osteoinductive.

TABLE A1: PRELIMINARY ANIMAL DATA

Animal Number	Test Article Lot #		Initial Weight	Terminal Weight	Gained Weight
	Left Side	Right Side			
19	CRT 130009-DCM	CRT 130014-DCM	198.5	290.1	91.6
20	CRT 130009-DCM	CRT 130022-DCM	240.1	306.7	66.6
21	CRT 130014-DCM	CRT 130022-DCM	232.6	293.8	61.2

TABLE A2: MACROSCOPIC OBSERVATIONS

Animal Number	Left Side			Right Side		
	Location	Size	Shape	Location	Size	Shape
19	F	A	ND	F	A	ND
20	F	A	ND	F	A	ND
21	F	A	ND	F	A	ND

TABLE A3: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT130009-DCM

Animal Number	Size	Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
19	LL	X	X	X	X	X	X	1
20	LL	X	X	X	X	X	X	1

TABLE A4: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT130014-DCM

Animal Number	Size	Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
21	LL	X	X	X	X	X	X	2
19	RL	X	X	X	X	X	X	1

TABLE A5: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT130022-DCM

Animal Number	Size	Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
20	RL	X	X	X	X	X	X	1
21	RL	X	X	X	X	X	X	2

KEY:

F: Found in correct location

A: Average

ND: No defined shape

X: Presence of Elements - : Element not present

L : Left Leg

R: Right Leg



ORDERING INFORMATION

STRIP

Size	Item #
20 x 10 x 10 mm	HTR-06-422201
50 x 7 x 5 mm	HTR-06-422302
20 x 15 x 7 mm	HTR-06-422403
25 x 10 x 7 mm	HTR-06-422504
50 x 10 x 7 mm	HTR-06-422606
50 x 20 x 7 mm	HTR-06-422707
26 x 19 x 7 mm	HTR-06-422808

BLOCK

Size	Item #
10 mm ³	HTR-06-412810
12 mm ³	HTR-06-412912
14 mm ³	HTR-06-412114

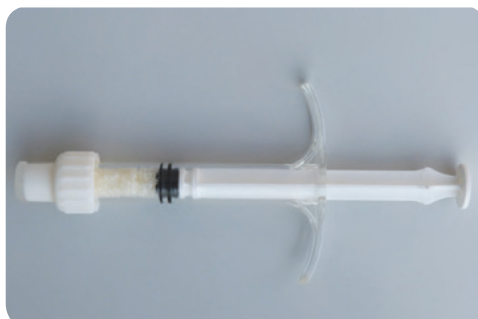


FILLER (SYRINGE)

Size	Item #
2.5 cc	HTR-06-442925
5.0 cc	HTR-06-442150
10 cc	HTR-06-442200
15 cc	HTR-06-442350

FILLER (VIAL)

Size	Item #
2.5 cc	HTR-06-442425
5 cc	HTR-06-442550
10 cc	HTR-06-442600
15 cc	HTR-06-442750





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📞 1.888.608.9788

✉ info@hnmtotal.com

🌐 www.hnmtotal.com