



OsteoInspire

100% DBM Putty

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





OsteoInspire

100% DBM PUTTY



OsteoInspire is a verified osteoinductive DBM putty derived from 100% allograft bone.

OsteoInspire is processed using a proprietary demineralization process and has been histologically proven post sterilization to exhibit five elements of bone formation. OsteoInspire does not contain any extrinsic and inert materials and its carrier is entirely derived from 100% allograft bone. OsteoInspire is provided in a ready to use syringe or jar.

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

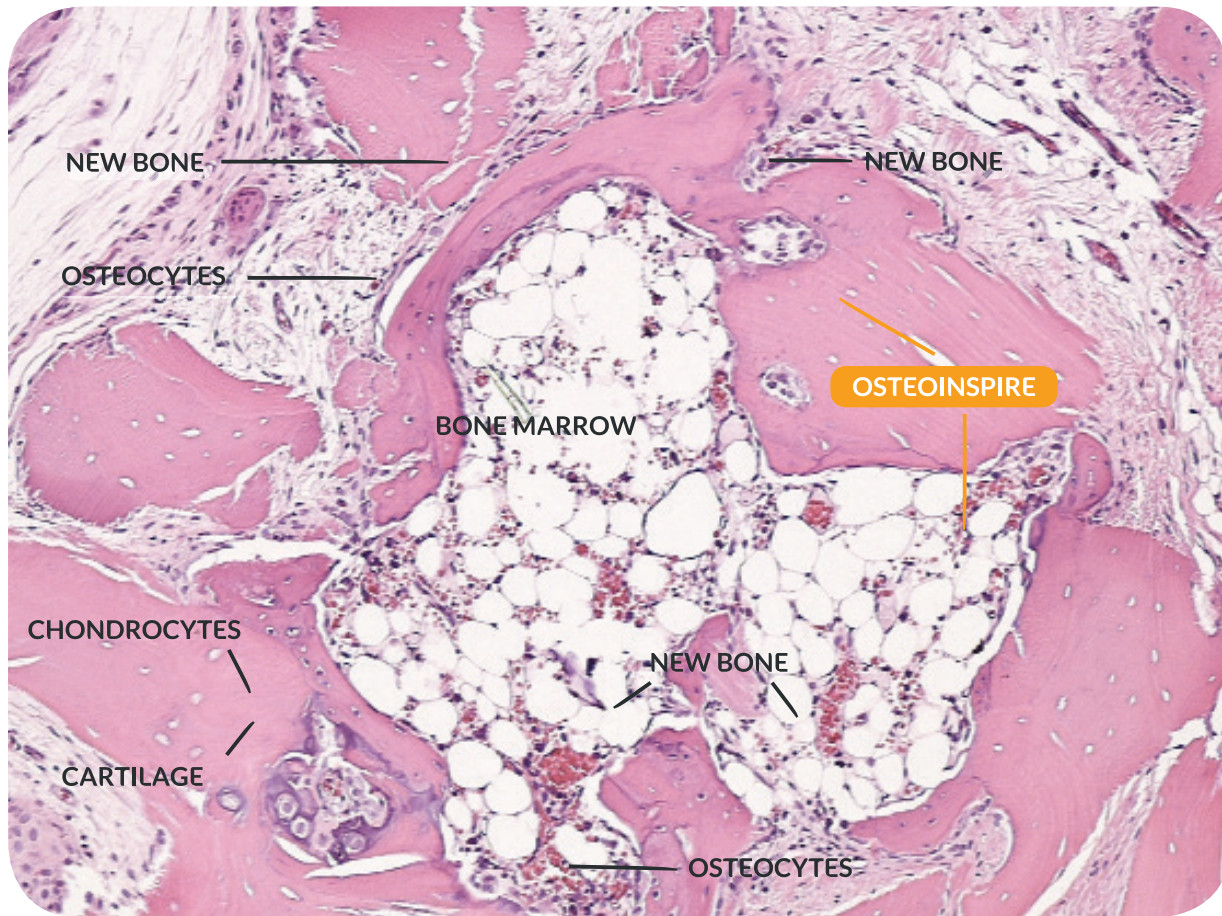
OsteoInspire's AATB accredited manufacturing partner employs strict quality assurance and quality control procedures to ensure patient safety. Our partner has a licensed physician acting as medical director that performs an extensive medical review of the donor's medical/social history to determine eligibility. Only donors whose screening, serologic, and microbiologic tests meet or exceed the current standards established by the US Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB) are accepted for transplantation.

OsteoInspire is provided with a medical device sterility assurance level (SAL) 10^{-6} . The product should be stored in ambient temperatures and has a shelf life of up to two years from the date of packaging.



HISTOLOGY

OSTEOINDUCTIVE IN-VIVO LOT VERIFIED



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}
- Two year shelf-life
- 100% allograft DBM - no extrinsic and inert carriers
- Ambient storage, shipping and handling temperatures
- Resists irrigation and migration
- Available in syringe or jar presentations

INDICATIONS FOR USE

OsteoInspire is indicated for use as a bone void filler for the treatment of surgically created or traumatic skeletal defects.

OsteoInspire may be used in surgical procedures including:

- Spine
- Neuro
- Orthopedics
- Trauma
- Reconstruction
- Foot & Ankle
- Dental





BMP TESTING

IN-VITRO ALKALINE PHOSPHATE INDUCTION ASSAY

ACCESSION NUMBER 14-001869 THRU 14001875

OSTEOINSPIRE - 100% DBM PUTTY

	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	15.693
	Cell Lysate Control	N/A	N/A	N/A	<LOQ
14-001869 CRT130033-DBM-OI-2	0001	50	10x	Neat	454.051
14-001870 CRT130002-DBM-OI-2	0001	50	10x	5	406.404
14-001871 CRT130062-DBM-OI-2	0001	50	10x	5	305.704
14-001872 CRT140008-DBM-OI-2	0001	50	10x	5	297.864
14-001873 CRT130001-DBM-OI-2	0001	50	10x	5	348.034
14-001874 CRT130059-DBM-OI-2	001	50	10x	Neat	516.592
14-001875 CRT130060-DBM-OI-2	001	50	10x	5	397.387

OsteoInspire 100% DBM Putty (above table) test articles 14-001869, 14-001870, 14-001871, 14-001872, 14-001873, 14-001874, and 14-001875 indicate the Specific Activity AP Units/mg Protein values exceed the BMP control by a factor 19 to 33 times greater.

TEST SYSTEM DESCRIPTION

OsteoInspire 100% DBM Putty 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 morphogenic 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 1-7 indicate up to 7 lots) is tested in athymic rats (# indicates rats: 7 thru 13) 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 1: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130033-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
7	L	X	X	X	X	X	X	2

TABLE 2: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130001-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
8	R	X	X	X	X	X	X	2

TABLE 3: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130002-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
9	L	X	X	X	X	X	X	2

TABLE 4: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130059-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
10	R	X	X	X	X	X	X	2

TABLE 5: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130062-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
11	L	X	X	X	X	X	X	1

TABLE 6: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 130060-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
12	R	X	X	X	X	X	X	3

TABLE 7: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT 140008-DBM-OI1

Animal Number	Site	OBSERVED ELEMENTS OF NEW BONE FORMATION						
		Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
13	L	X	X	X	X	X	X	2

KEY:

X: Presence of Elements - : Element not present L: Left Leg R: Right Leg



ORDERING INFORMATION

SYRINGE

Size	Item #
1 cc	HTR-06-522201
2.5 cc	HTR-06-522325
5.0 cc	HTR-06-522450
10 cc	HTR-06-522500



VIAL



Size	Item #
1 cc	HTR-06-512710
2.5 cc	HTR-06-512825
5.0 cc	HTR-06-512950
10 cc	HTR-06-512100



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