

Optecure[®]
Optecure[®] +ccc

Our science.
Your choice.

Surgeon focused. Patient driven.™

Exactech[®]



The cure for your concerns about bone graft performance.

Optecure® is an engineered bone graft for reconstruction of the spine, pelvis and extremities. Its room temperature convenience facilitates rapid mixing with buffer solution or blood. Optecure and Optecure+CCC can be used with autologous bone graft and bone marrow.

An optimal concentration of demineralized bone matrix (DBM) and a resorbable hydrogel carrier provide for osteoinductivity.^{1,2*} And with cortical cancellous bone chips, Optecure+CCC also provides an impressive 3-D matrix for osteoconductivity. The convenience, constituents and robust handling properties make Optecure the optimal “cure” for your concerns about bone graft performance.

Optecure®+CCC
Optecure®

Confidence

Optecure is an aseptically-processed human DBM-based product that is 100 percent lot tested for sterility per United States Pharmacopeia guidelines. Every lot of DBM is verified for osteoinductive potential in an *in-vivo* animal model. Only DBM material demonstrated by histology to be osteoinductive is used in the production of final products.

The hydrogel carrier is designed to provide versatile handling characteristics. Hydrogel technology has been used clinically for other medical applications demonstrating excellent biocompatibility and passes rigorous ISO 10993 biocompatibility evaluation.¹

Donor tissue is obtained from tissue banks accredited by the American Association of Tissue Banks (AATB), and donor suitability is determined in accordance with AATB standards and Food and Drug Administration (FDA) regulations. Each donor undergoes stringent testing to ensure patients receive tissue appropriate for donation.

Systematic, scientific testing ensures an optimum DBM concentration in Optecure for new bone formation.²

DBM concentration may be the single, critically overlooked engineering variable in bone graft material design. No matter how intuitive, more DBM may not be better.^{1,2}



Convenience

Optecure is engineered to accommodate application-specific solutions. Surgeons now have the opportunity to craft the handling characteristics they desire.¹ Hydrate the dry granular material with patient's whole blood or the fluid provided to achieve the desired consistency. Optecure and Optecure+CCC may be combined with autogenous bone and bone marrow. Products are provided in a single package that is stored at room temperature.

When continuing to be predictable is a good thing.

Constituents

Demineralized Bone Matrix

Optecure is a human DBM-based product that is 100 percent lot tested for osteoinductivity. DBM contains Type I collagen and naturally occurring growth factors including bone morphogenetic protein (BMP). BMP is a glycoprotein that is secreted locally in skeletal structures during the development phase of bone remodeling and is recognized by experts to be osteoinductive.³

Cortical Cancellous Bone Chips

Optecure+CCC contains a high volume percentage of cortical cancellous bone chips to provide for osteoconductivity. The chips are sized to provide a porous conductive lattice for early vascularization and an effective scaffold for bone cell migration.⁵

Resorbable Hydrogel Carrier

Hydrogel biomaterials are an effective matrix for tissue engineering applications in bone restoration.⁶ Optecure features a resorbable hydrogel carrier that provides robust cohesion to resist irrigation.¹ The hydrogel carrier ensures the bone forming constituents remain at the intended site for host regeneration.¹



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INDUCTIVE/CONDUCTIVE

Cortical Cancellous Chips (CCC)

- Gamma irradiated
- Chips are sized approximately 1-3mm
- 100 percent lot tested for endotoxins
- 100 percent lot tested for sterility

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INDUCTIVE

Demineralized Bone Matrix (DBM)

- Optimal 81 percent concentration of DBM by dry weight for Optecure^{1,2}
- 100 percent lot tested for sterility
- 100 percent lot tested *in-vivo* for osteoinductivity
- 100 percent lot tested for endotoxins

Carrier

- 100 percent lot tested for sterility
- Resistant to diluent migration¹
- Intra-operative flexibility to craft the desired handling characteristics¹
- 100 percent lot tested for endotoxins



1. DBM:

- Optimal 81 percent concentration of DBM by dry weight for Optecure^{1,2}
- Each lot tested for sterility
- Each lot tested *in-vivo* for proven osteoinductive potential

2. Cortical Cancellous Bone Chips:

- Chips are sized approximately 1-3mm
- High volume percentage of chips
- Gamma Irradiated

3. Resorbable Hydrogel Carrier:

- Intra-operative flexibility to craft the desired handling characteristics
- Resistant to migration¹
- Ethylene Oxide sterilized

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	Optecure+CCC	Optecure
Product Application	Optecure/Optecure+CCC is an engineered bone graft for the reconstruction of the spine, pelvis and extremities	Optecure/Optecure+CCC is an engineered bone graft for the reconstruction of the spine, pelvis and extremities
Constituents	<ul style="list-style-type: none"> Demineralized Bone Matrix, Cortical Cancellous Bone Chips, Hydrogel Carrier 	<ul style="list-style-type: none"> Demineralized Bone Matrix, Hydrogel Carrier
Resistant to Diluent Migration	<ul style="list-style-type: none"> Carrier keeps graft in place, facilitating bone growth during the remodeling process. Graft may be bulb lavaged and will not wash away.¹ 	
Mixing Options	<ul style="list-style-type: none"> Formable to desired shape 	<ul style="list-style-type: none"> May be dispensed into graft site using a syringe or molded to desired shape
Bioactivity		
Room Temperature Storage	<ul style="list-style-type: none"> Freeze dried (lyophilized) bone graft stored at room temperature maintains the osteoinductive potential of the proteins⁷ 	
Testing for Sterility	<ul style="list-style-type: none"> Optecure is tested for sterility per USP<71> and classified as Sterile A-Aseptic manufacture 	
Biocompatibility	<ul style="list-style-type: none"> The hydrogel carrier has been subjected to rigorous ISO 10993-biocompatibility evaluation 	
Viral Inactivation	<ul style="list-style-type: none"> The cortical cancellous chips are irradiated for viral inactivation 	<ul style="list-style-type: none"> Not applicable
Bone-Forming Potential		
Osteoinductive*	<ul style="list-style-type: none"> 100 percent DBM lot tested <i>in-vivo</i> for osteoinductive potential with strict adherence to minimum performance requirements. Systematic and scientific DBM concentration studies define the optimum concentration for new bone formation.^{1,2} 	
Osteoconductive	<ul style="list-style-type: none"> A specific ratio of cortical to cancellous chips aimed to provide the porous lattice for ingrowth of vessels and a 3-D matrix for bone cell migration^{4,5} 	<ul style="list-style-type: none"> Not applicable
Osteogenic	<ul style="list-style-type: none"> When Optecure is combined with whole blood, all three components required for bone formation are in your hands 	

*Finished product induced bone formation when implanted in an athymic nude mouse assay. Findings from an animal model are not necessarily predictive of human clinical results.

The Science of Bone Formation

Osteoinductivity, Osteoconductivity, Osteogenesis

The body's ability to regenerate bone is dependent on three key factors: osteoinductivity, osteoconductivity and osteogenesis.^{3,11,12}

DEMINERALIZED BONE MATRIX for OSTEOINDUCTIVITY³

Osteoinductivity is the stem cells' ability to differentiate into osteoblasts through stimulation by local growth factors. Demineralizing the bone exposes the organic cascade of growth factors. These growth factors, or bone morphogenetic proteins (BMPs), are the signaling molecules required for the recruitment, proliferation and conversion of new bone formation.

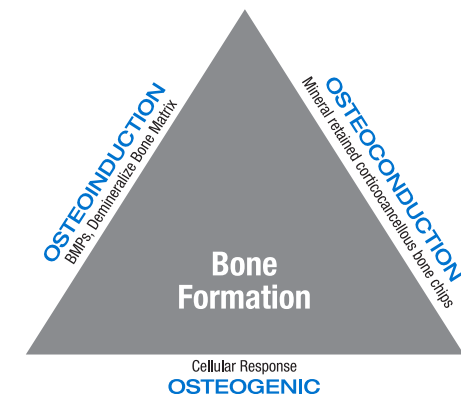
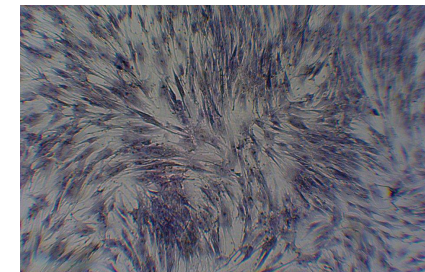
CORTICAL CANCELLOUS BONE CHIPS for OSTEOCONDUCTIVITY^{3,11}

Osteoconductive properties are determined by the presence of a scaffold that allows for vascular and cellular migration, attachment and distribution.

The optimal composite graft will provide stronger, quicker bone formation when an effective osteoconductive scaffold is present.³ This porous lattice is a crucial vehicle for housing osteogenic cells and osteoinductive growth factors at the formation site.

Mix with Cells for Osteogenesis³

Osteogenesis—the ability to produce new bone—is determined by the presence of osteoprogenitor cells and precursor cells in the area. Osteoprogenitor cells are found in bone marrow aspirate and autogenous bone graft.



References

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