

EXACTECH|BIOLOGICS



Shaping the Future of
Bone Repair

Our Vision for Exactech Biologics

Exactech recognizes the growing importance of biologic solutions for orthopaedics. We are developing a position of leadership in biologics by designing and acquiring the broadest range of innovative, relevant biomaterials, delivery systems and surgical techniques. We will provide these solutions through the most effective biologics distribution network in the industry.

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.¹⁻³

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.

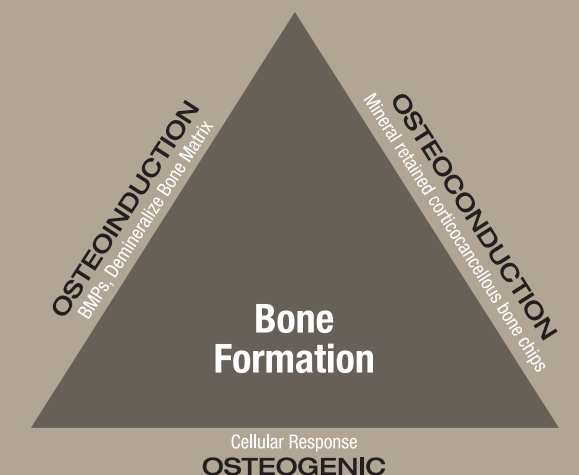
CORTICAL CANCELLOUS BONE CHIPS for OSTEOCONDUCTIVITY^{1,3}

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.



The Cure for Your Concerns about Bone Graft Performance



Optecure[®] Optecure[®]+ccc

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 autologus bone graft and bone marrow.

An optimal concentration of demineralized bone matrix (DBM) and a resorbable hydrogel carrier provide for osteoinductivity.^{4,5*} 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.

CONSTITUENTS

1) Demineralized Bone Matrix

- Optimal 81 percent concentration of DBM by dry weight⁴
- Each lot tested for sterility
- Each lot tested *in vivo* for proven OI potential

2) Cortical Cancellous Bone Chips

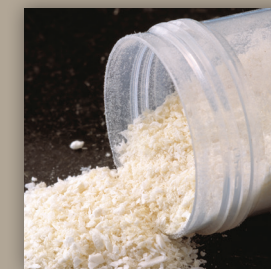
- Specific size range
- Densely packed for mechanical load sharing
- Gamma Irradiated

3) Resorbable Hydrogel Carrier

- Intra-operative flexibility to craft handling characteristics
- Site retention and resistance to lavage⁵
- Ethylene Oxide sterilized

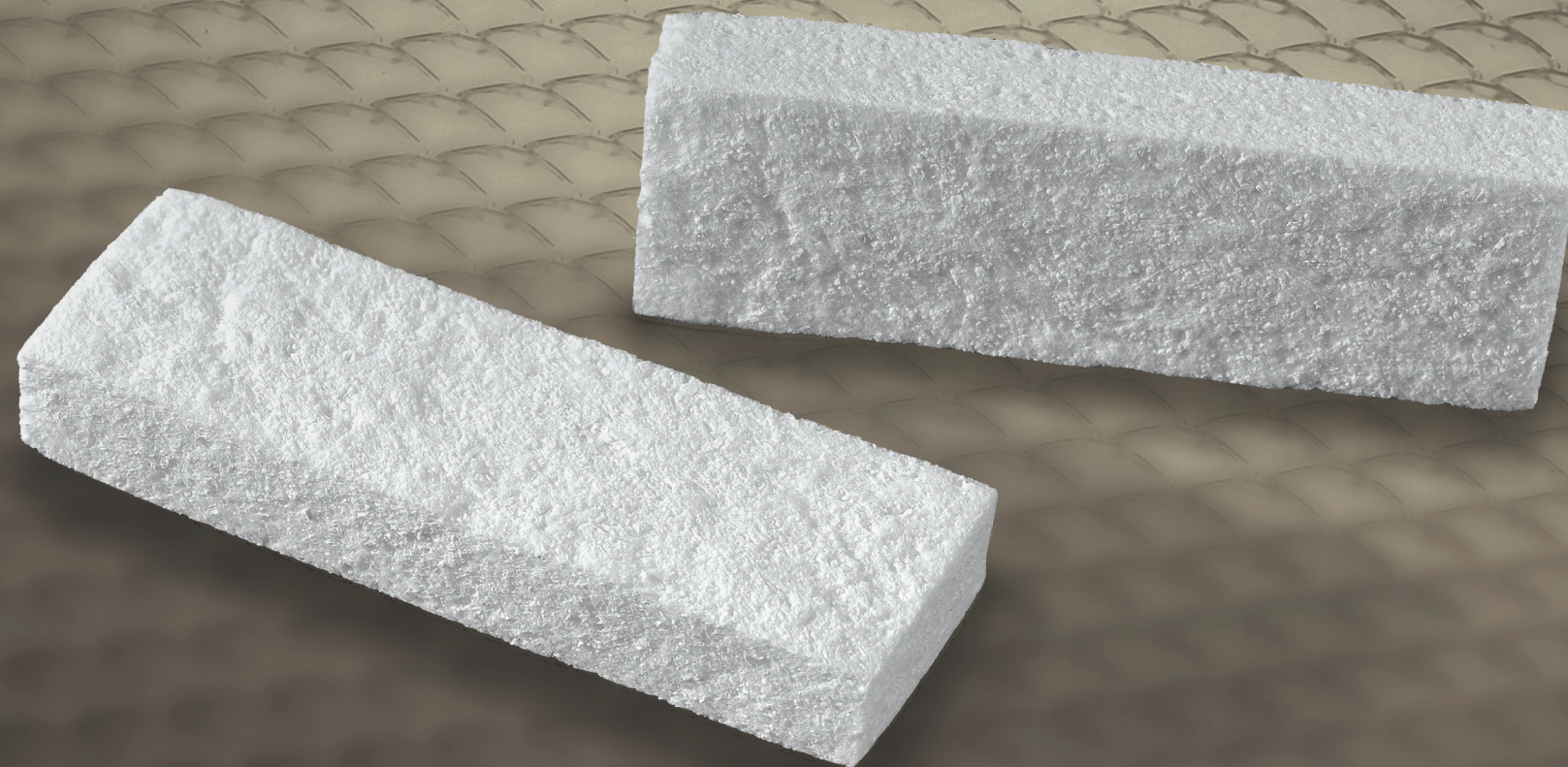


When combined, all three components required for bone formation – osteoinductive, osteoconductive and osteogenic factors – are in your hands.



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

All Natural Mineral-Collagen Composite



Ossigen®

Ossigen® is a mineral-collagen composite matrix processed into blocks for the repair of bony defects in the spine, extremities and pelvis. The mineral particles are dispersed within collagen fibers, forming a three-dimensional porous matrix consisting of 80 percent bone mineral and 20 percent collagen by dry weight.

Ossigen is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. Ossigen blocks may be cut into shapes, and they are designed to retain their shape and physical integrity following implantation into a bony site.

COMPOSITION

80 Percent Bone Mineral

- Similar structure as human bone
- Osteoconductive

20 Percent Type I Collagen

- Highly biocompatible and resorbable
- Intrinsically hemostatic to control minor bleeding^{6,7}

Highly Absorbent Delivery Matrix

- Absorbs fluid such as bone marrow aspirate (8-10cc) to deliver the stem cell rich composite matrix to the injury site
- 100-400 µm optimal pore size for tissue regeneration^{8,9}

Handling

- Flexible when hydrated
- Compression resistant



Flexible when hydrated



Compression resistant

The Optimal Matrix

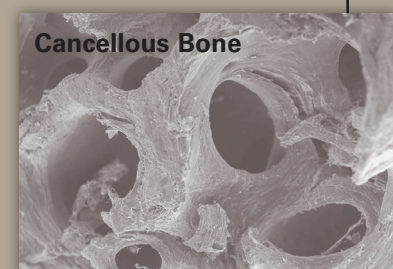
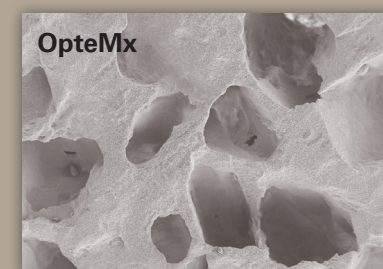
OpteMx®

OpteMx® is an engineered biomaterial that chemically and structurally mimics cancellous bone. More than 20 years of clinical use provides a foundation of confidence for your desired regenerative outcomes.¹⁰

Human cancellous bone is comprised of more than 50 percent Hydroxyapatite (HA). OpteMx is a biocompatible, osteoconductive scaffold. Its chemical composition of 60 percent HA and 40 percent Beta-Tricalcium Phosphate (β -TCP) inhibits premature resorption, leading to effective host bone formation.¹⁰

OpteMx, like human cancellous bone, is 60-80 percent porous and is comprised of interconnected macropores and micropores. Micropores facilitate fluid absorption into the matrix by capillary action. Macropores allow deep invasion of bone cells into the matrix. When packed into a bony site, OpteMx gradually resorbs* and is replaced with bone during the conversion process.¹⁰

OpteMx mimics cancellous bone.¹⁰



**OpteMx is a bone filler without initial mechanical properties. Rigid fixation techniques are recommended to provide mechanical support until resorbed.*

Platelet-Rich Plasma

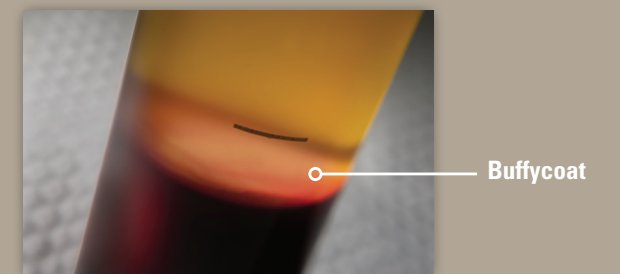


Accelerate[®] CONCENTRATING SYSTEM

Accelerate[®] is a platelet concentrating system that offers high yields through gentle centrifugal action, which preserves the fragile buffycoat layer.

The Accelerate Concentrating System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

- Increased platelet concentration (6x)¹¹
- Isolates/preserves buffycoat, extracting plasma above and below the buffycoat layer
- Closed system reduces transfer contamination
- Convenient: Offers volume flexibility and features a portable centrifuge



The Accelerate[®] Concentrating System is manufactured by Emcyte Corporation and distributed by Exactech, Inc. Accelerate Concentrating System has not been evaluated by the FDA for specific therapeutic indications or treatments.

Collagen Tendon Wrap



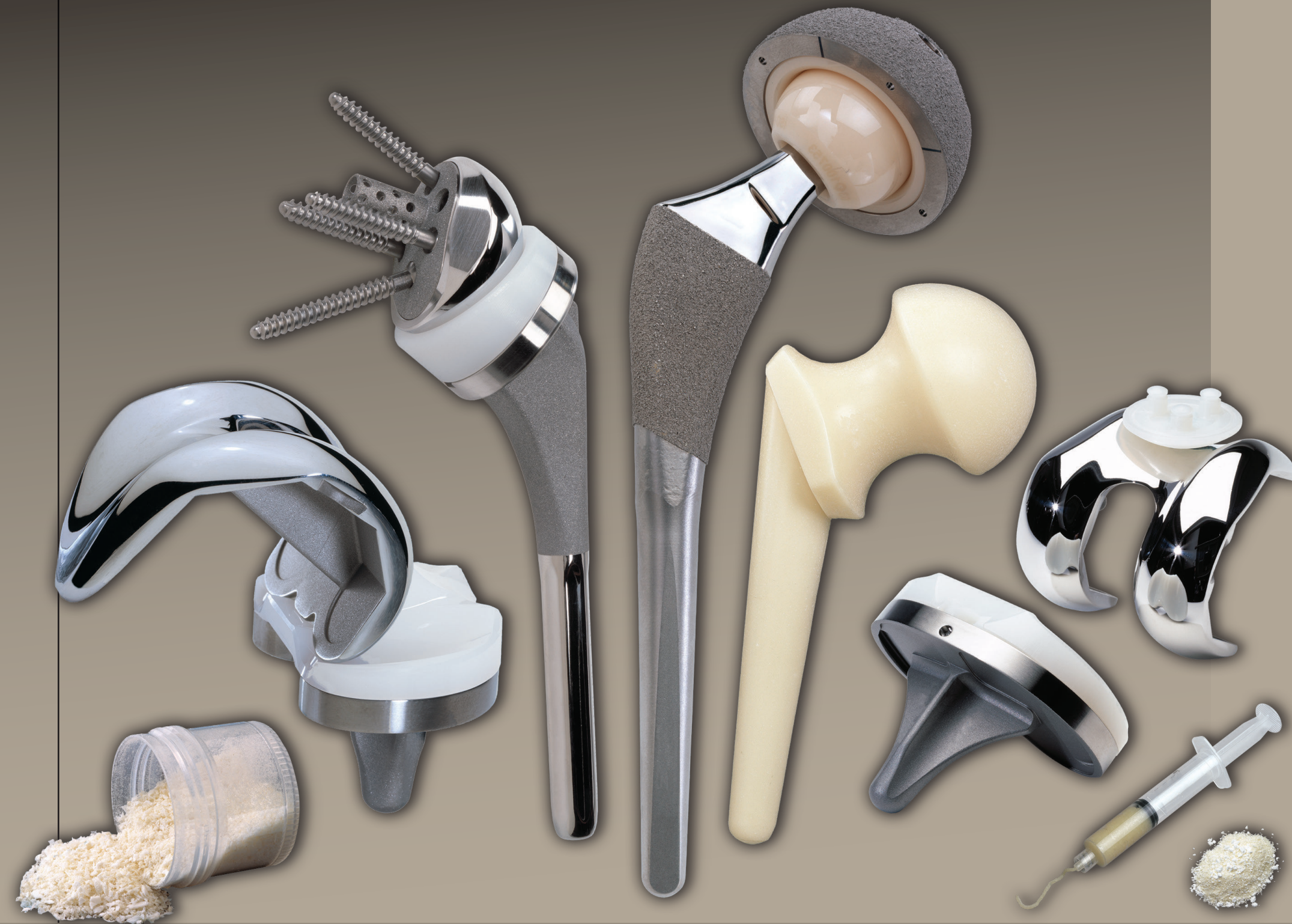
TenoMend™

TenoMend™ Collagen Tendon Wrap is a resorbable type I collagen matrix that provides a non-constricting encasement for injured tendons.

It is designed to be an interface between the tendon and the tendon sheath or the surrounding tissue. When hydrated, TenoMend is a conformable, nonfriable, self-curling collagen sheet designed for easy placement under, around or over the injured tendon. TenoMend provides a protected environment and gliding surface of the sheath for tendon healing.

- Patented self-curling design
- Proper alignment during surgery
- Convenient storage at room temperature
- Provides protective environment and gliding surface

Experience Exactech... A Great Day in the O.R.



Founded by an orthopaedic surgeon and a biomedical engineer, Exactech is committed to making every day a great day in the O.R. – for the surgeon, the O.R. staff and above all, for the patient.

Exactech's innovative biologics products can be used as bone void fillers with other implants and instrumentation in total joint replacement procedures where indicated. Exactech products are designed to meet surgeons' needs throughout the entire case.

- **Knee:** Exactech's Optetrak®/Opetrak Logic® knee system addresses concerns for contract stress, patellar tracking, polyethylene wear, joint stability and bone preservation with streamlined instrumentation that allows you to work quickly and efficiently.
- **Hip:** Exactech Hip systems provide stable reconstruction of a wide range of anatomical defects with state-of-the-art bearing surfaces and MIS-compatible implants and instrumentation.
- **Shoulder:** No matter what challenges a surgeon may face, the Equinox® shoulder system offers true "reversatility." The system enables surgeons to convert from a primary or fracture stem to a reverse shoulder without stem removal. The Equinox system includes a wide range of glenoid solutions for challenging bony defects.
- **Spacers/Cement:** InterSpace® hip, knee and shoulder are the first pre-formed temporary spacers with gentamicin for two-stage revision arthroplasty. Exactech also offers the Cemex® line of bone cement.
- **Patient education/practice marketing:** Exactech's patient education and practice marketing program includes ready-to-use tools, such as advertisements and brochures, designed to introduce new patients to surgeons' practices, educate the community on options for joint replacement and increase visibility within the community. Surgeons can choose to use prepared resources to supplement their existing patient education and practice enhancement activities, or Exactech can create a personalized proposal for individual surgeons.

References

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11. Data on File at Emcyte Corp.

Ossigen® is manufactured by Collagen Matrix, Inc. and is distributed by Exactech, Inc.

OpteMx® is manufactured by Biomatlante Surgical and distributed by Exactech, Inc.

The bone marrow aspirate needle is manufactured by Ranfrac and distributed by Exactech, Inc.

The Accelerate® Concentrating System is manufactured by Emcyte Corporation and distributed by Exactech, Inc. Accelerate Concentrating System has not been evaluated by the FDA for specific therapeutic indications or treatments.

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