DBX. Bone Graft Substitute.
The osteoinductive power.

Osteoinductivity for challenging bony fusion

Excellent handling properties

Certified safety

The answer to bone voids
The osteoinductive power.

Introduction

DBX is composed of demineralized bone matrix (DBM) from human donors in a biocompatible carrier. DBX is completely replaced by new host bone after 4 to 6 months.

The demineralized bone matrix (DBM) is produced by removal of minerals from cortical bone. It consists of collagen and bone growth factors such as bone morphogenic proteins (BMPs).

The bone growth factors present and active inside of DBX, are responsible for its osteoinductive properties. They actively stimulate bone formation and regeneration.


BMPs inside cortical bone

BMPs present and active in DBM

Carrier

- High quality medical grade sodium hyaluronate in phosphate dibasic buffer
- GMP manufacturing, ISO 13485 certified
- Produced through fermentation processes

BMPs present and active in DBX
Indications

DBX is used to fill bone voids or gaps that are not intrinsic to the stability of the bony structure.

Long bone fracture

Treatment of a gunshot in left proximal radius: the fracture was fixed by LCP T-Plate and filled with DBX, mixed with bone chips. At three weeks, X-rays showed no displacement and some sign of healing. At eleven weeks, patient advanced to "activities as tolerated" including a return to the practice of martial arts.

**Surgeon:** Dr. David Hubbard, Department of Orthopedics, West Virginia University Morgantown, West Virginia.

Lumbar fusion

140 patients affected by degenerative disc disease, on one or two levels, between L2 and S1, have undergone instrumented posterolateral fusion in a multicenter, randomized, controlled clinical study. In sixty patients only autograft was applied along the fixation system. Eighty patients received autograft mixed with DBX Putty 1:1. Fusion rates at 24 months was 100% for the DBX group and 96% for the autograft group indicating that DBX was as effective as autograft when used as a bone graft extender. 4

**Surgeon:** Dr. Emilio Nardone, St. Joseph’s Hospital, Bloomington, Illinois.

Periodontal intraosseous defects

Intraosseous periodontal defects in systemically healthy patients have been treated with either DBX Putty or with demineralized freeze-dried bone allograft (DFDBA). Only sites with a defect ≥3 mm in depth have been considered. A statistical analysis was conducted 6 months postoperative. Both groups of patients yielded significant improvements in percent bone fill, with 37%±18.7% bone fill achieved in patients treated with DFDBA and 50%±25% in case of patients treated with DBX. 5

**Surgeon:** Dr. J. T. Mellonig, The University of Texas Health Science Center at San Antonio, TX

4 AANS 2005, Article ID: 24971

Proven osteoinductivity

DBX is aseptically produced and not treated by irradiation or heat to preserve osteoinductivity.

Proven osteoinductivity in vivo

Ectopic bone formation in an athymic mouse muscle proves the osteoinductive properties of DBX.

10 mg DBX were placed in the biceps femoris muscle of nude athymic mice. Radiographs taken 28 days postoperatively showed dense material indicating mineralization at the implant site. Histological findings confirm the presence of bone at the intramuscular site.


7 Gerzmann A.A., Sunwoo M.H. a pilot study evaluating sodium hyaluronate as a carrier for freeze-dried demineralized bone powder. Cell and Tissue Banking 2: S87-S9, 2001

Quantification of growth factors

The content of specific growth factors, playing a central role in bone regeneration, was investigated in DBX and two other commercially available DBM-based products (DBM1, DBM2).

DBX showed higher quantities of TGF-β1, FGFα and VEGF compared to the other analysed DBMs.

Study: PD Dr. med. G. Schmidmeier, Centrum für Musculoskelettale Chirurgie, Berlin, 2004
Excellent handling properties

**A carrier with ideal characteristics**

Sodium hyaluronate is a polysaccharide formed by plasma membrane proteins in the human body. The largest amounts are found in the extracellular matrix of skin and musculoskeletal tissue. Sodium hyaluronate plays an essential role in cell proliferation, migration and adhesion and has been correlated to angiogenesis.\(^8\)\(^,\)\(^9\)

Sodium hyaluronate is proven to be extremely safe. It confers positional stability to the product.\(^10\)

MTF uses high quality medical grade sodium hyaluronate, ISO 13485 certified, produced through fermentation processes under GMP guidelines.

The DBX formulation has been specifically designed to model the osmotic pressure of human blood and physiological pH for optimal bone growth.

**Benefits of DBX**

- Remains contained at surgical site
- Does not stick to gloves
- Moldable to any size and shape
- Storage at room temperature
- Mixes with autograft, blood or bone marrow
- Physiological pH
- Biocompatible

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Safety

DBX is sourced by Musculoskeletal Transplant Foundation (MTF) in the United States and marketed through Synthes.

Founded in 1987, MTF is the largest non-profit musculoskeletal tissue recovery organization in the United States.
– Accredited by the AATB (American Association of Tissue Banks).
– Complies with all FDA regulations regarding the recovery, processing and distribution of allograft tissues.
– Certified according to ISO 9001 and 13485.

Stringent donor selection
Every donor is screened thoroughly. Exclusion criteria for tissue donation include infectious diseases, malignant diseases, neurological degenerative diseases, diseases of unknown aetiology and exposure to toxic substances.

Comprehensive testing
All tissue donors undergo stringent serological testing, including tests for HIV-1, HIV-2, hepatitis B, hepatitis C, syphilis and HTLV-1. The tissue is microbiologically tested before and after processing. HIV and hepatitis C are tested through NAT.

Donor release
Donors are only released to processing after extensive review of all charts and records by MTF’s Medical Directors, who are all physicians with infections disease or pathology backgrounds.
Production
Tissues are processed in ISO class 5 static certified clean rooms. Donors are not pooled: each donor represents a single batch. MTF has provided over 2.9 million grafts for transplantation to date.

Viral inactivation
The manufacturing process of DBX has been validated* to inactivate and clear viruses such as HIV-1, hepatitis A, hepatitis C, cytomegalovirus/herpes, polio and parvovirus B19.

* Study performed in accordance with the “International Conference on Harmonization for Viral Clearance Studies of Biotechnology Products”.

Biocompatibility
DBX has undergone and passed a series of standard tests according to ISO 10993-1. The tests showed the product to be non-toxic and non-immunogenic. Sodium hyaluronate is present in its natural form in the ocular and joint fluids of the human body. The carrier is quickly cleared from the body via the normal renal route in less than one week and confers physiological pH.
Ordering information

**DBX Putty**
93% DBM by volume in sodium hyaluronate. Packaged in a glass syringe, not to be used as an applicator directly in the patient.

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**DBX Mix**
DBM in sodium hyaluronate, ready mixed with cortical bone chips, in glass jars.

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**DBX Strip**
Flexible Strip with no need for re-hydration. DBM in sodium hyaluronate and porcine gelatin.

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