Training Manual Altis OBM for surgeons and tissue engineers

IS THERE A DIFFERENCE BETWEEN INFUSE AND ALTIS?

Yes- Altis OBM is an engineered or 'manipulated' DBM- it is 100% naturally derived from DBM starting material that has been engineered to remove unwanted proteins, increase biocompatibility (humanization process) and simultaneously boost the BMP content (BMP-complex mixture of proteins) to levels 80 times higher than regular DBM, increasing its clinical efficacy over regular DBM, and comparing in efficacy to synthesized recombinant BMP -7 (Stryker Biotech/Olympus) and BMP-2 (Infuse). Medtronic Infuse product is a recombinant synthesized BMP-2 protein (made in bioreactors versus

Table 1: Mechanisms of action for Altis OBM

1	**Implantation into site**	Surgical implantation of AOBM into site of injury
2	**Recruitment of osteoblast-forming mesenchymal stem cells.**	Mesenchymal stem cells, the precursor cells for osteoblasts, migrate to the site of injury
3	**Differentiation**	Cell differentiation into osteoblasts is encouraged by BMP provided by AOBM
4	**Osteoinduction and Osteoconduction**	Osteoblasts produce mineralized tissue, replacing AOBM with newly synthesized host tissue. Blood vessel formation also occurs.
5	**Remodeling**	Bone formation continues to replace and shape existing tissues according to local chemical and mechanical factors – forming normal bone

Altis extracted BMP-2/BMP-complex) is a single protein, versus Altis BMP-complex which is an important feature of Altis OBM- the BMP-complex exists naturally in DBM and functions by inducing new bone formation through the synergistic co-operation of multiple BMP proteins (BMP-2, BMP-7, TGF-beta).

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DBMXtra-rti™

COMPOSITION

DBMXtra-rti™ is a tissue-engineered demineralized bone matrix with a verified content of endogenous bone morphogenetic protein complex, in a convenient prefilled syringe that allows instant injection into a bone void as an osteoinductive bone graft substitute during periodontal and maxillofacial
procedures. The components are:

- Tissue-engineered

demineralized bone matrix of porcine origin

- A medical grade hydrogel viscoelastic modifier Pluronic F127 that gels at body

temperature.

CLASSIFICATION

DBMXtra-rti™ is classified
as follows:

EU	Brazil	SA	US/FDA
III	IV	D	III

PROPERTIES/ACTIONS

DBMXtra-rti™ is a convenient, injectable bone
void filler indicated for clinical specialties including orthopaedic and craniomaxillofacial uses where bone volume needs to be preserved/augmented. DBMXtra-rti™ is a human-compatible tissue derivative of porcine demineralised bone matrix (DBM). DBMXtra-rti™ with verified endogenous bone
morphogenetic protein complex (BMP complex) has demonstrated the ability to
stimulate, induce and regenerate bone voids in animals and human subjects. The
viscoelastic modifier gives the product its convenient ready-to-inject properties. The result is a unique bone graft substitute that resorbs and is rapidly
replaced by de novo host bone.

SIDE EFFECTS

In very rare cases an allergic reaction to collagen, gelatin or oxirane polymer products may occur. An inflammatory response may be observed following implantation of the product which subsides over time.

STORAGE CONDITIONS

Store below 25°C in a dry place out of direct sunlight.

INDICATIONS

1. Oral surgery: orthognathic surgery, alveolus splitting, bone granulomas, dentigerous cysts
2. Periodontology: regeneration of furcation and of deep intrabony defects.

I3. implantology: restoration and regeneration of peri-implant bone lost due to periodontitis and
dehiscence- two wall defects, lateral and crestal access sinus lift. DBMXtra-rti™ may be protected and segregated from surrounding soft tissue using AltiMEM-GTR™ collagen membrane.

4. Orthopaedic surgery: general bone void filler

CONTRAINDICATIONS

DBMXtra-rti™ should not be
used in the following instances:

1. Presence of bacterial infection.

I2. in patients with a known allergy to collagen or
oxirane co-polymer.

3. In patients with known hypersensitivity or allergic reactions to porcine products.

WARNINGS AND SPECIAL PRECAUTIONS

1. DBMXtra-rti™ should only be used by trained surgeons and dentists
2. DBMXtra-rti™ should be used with special caution in patients with uncontrolled metabolic
diseases, prolonged corticosteroid therapy, autoimmune diseases, radiotherapy
and heavy smoking
3. Do not use DBMXtra-rti™ if the sterilization dot on the containing package is not red.

PREGNANCY AND LACTATION

DBMXtra-rti™ should not be administered to pregnant women. The effect of DBMXtra-rti™ in pregnant women or on the human fetus has not been evaluated.

DOSAGE AND DIRECTION FOR USE

Each syringe contains 1, 2 or 5 cc of osteoinductive bone graft substitute in a sealed peel-pouch.

IDENTIFICATION AND PRESENTATION

DBMXtra-rti™ is supplied as a sterile prefilled ready-to-inject syringe present inside a peel-pouch. The syringe contains 1, 2 or 5 cc of injectable an ivory off-white putty sealed with a white luer lock cap.

PATIENT RECORD

Patient records must be maintained by the consignee and hospital for the purpose of traceability post-implantation. This will allow Altis Biologics to facilitate the investigation of any adverse events. A patient label peel off sticker has been included with each package of tissue. Copies of this information should be retained by the hospital for future reference. Please report any serious incident/adverse event to Altis Biologics.

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Instructions for use

1. Open peel-pouch and place syringe on a sterile cloth or surface under theatre conditions.
2. Unscrew the luer-lock cap from the syringe. The implant is now ready for use.
3. Following exposure of the intrabony defect, remove all necrotic and granulomatous tissue.
4. Depress the syringe plunger to start the outflow of the DBMXtra-rti™ putty into the osseous defect.
5. Where required, DBMXtra-rti™ can be mixed with autogenous bone, or the patients' own blood coagulum.
6. To maximize de novo bone formation DBMXtra-rti™ should be placed in direct contact with well vascularized bone with a sterile instrument.
7. DBMXtra-rti™ should be segregated from the overlying soft tissues to prevent soft tissue infiltration, by careful placement of a bioresorbable collagen membrane such as AltiMEM-GTRTM.
8. DBMXtra-rti™ can be combined with AltiCERAM™ sintered spongiosa hydroxyapatite to provide a long lasting scaffold in applications such as sinus lift procedures.
9. An appropriate antibiotic, analgesic and postoperative care regimen should be prescribed by a trained specialist.

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