**Manufactured by:**
Altis Biologics (Pty) Ltd.,
1 Allan Cormack Street,
Biopark Building BA4,
Innovation Hub, Persequor, 0087
Tel: +27 82 853 0644
+2712 844 0098

Email: nic@altisbiologics.com

**Distributed by:**
Southern Medical (PTY) LTD.,
Building 10, Southern Implants Office Park, 1 Albert Road, Irene, 0062, South Africa
Tel: +27 12 667 6243/4

Email: info@southmed.co.za

## IMPORTANT: PLEASE READ

**Description:**
Southern Medical DBMX is a convenient, injectable bone void filler indicated for clinical specialties including orthopaedic and craniomaxillofacial uses where bone volume needs to be preserved/augmented. The product is manufactured using the company's patented tissue matrix reassembly technology, and is a tissue derivative of porcine demineralised bone matrix (DBM). Southern Medical DBMX contains two endogenous DBM derivatives: OsteaPLEX™ and AltiCOLL™. OsteaPLEX™ is the endogenous bone morphogenetic protein complex (BMP complex) that has demonstrated the ability to stimulate, induce and regenerate bone voids in human subjects. The third component is a viscoelastic carrier that gives the product its convenient ready-to-inject properties. The result is a unique biomaterial that resorbs and is rapidly replaced by *de novo* host bone.

**Radioactivity warning:**
No radioactive substance or radioactivity.

**Composition:**
Southern Medical DBMX is an engineered collagenous bone matrix (AltiCOLL™) containing endogenous bone morphogenetic protein complex (OsteaPLEX™), in a convenient prefilled syringe that allows instant injection into the bone void as an osteoinductive bone graft substitute during orthopaedic and maxillofacial procedures. The components are:

- Telopeptide depleted type I porcine collagen as scaffold.
- pBMP Endogenous Bone Morphogenetic Protein complex (OsteaPLEX™).
- A medical grade viscoelastic modifier.

**Intended purpose:**
The intended purpose of the Southern Medical DBMX is to act as a bone void filler for clinical specialties including orthopaedic and craniomaxillofacial uses where bone regeneration is required:

- As an osteoinductive bone graft substitute during lumbar spinal fusion procedures.
- In oral and maxillofacial procedures where bone grafting is needed such as in sinus lifts, alveolar ridge augmentation and socket preservation.

**Undesirable 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.

**Indications:**
Implantology

- Restoration and regeneration of peri-implant bone lost due to periodontitis and dehiscence-two wall defects, lateral and crestal access sinus lift. Southern Medical DBMX may be protected and segregated from surrounding soft tissue using collagen membrane.

Instrumented intervertebral fusion of lumbar, thoracic and cervical spine

- Southern Medical DBMX is routinely used in conjunction with anterior interbody cages and posterior lumbar cages.

Oral Surgery

- Orthognathic surgery
- Alveolus splitting
- Bone granulomas
- Dentigerous cysts

Orthopaedic surgery

- General bone void filler

Periodontology

- Regeneration of furcation and of deep intrabony defects.

**Contraindications:**

- Bacterial infected wound site.
- Patients with known allergy to collagen or oxirane co-polymer.

**Directions for Use:**
Each syringe contains 1, 2, 3 or 5 cc of osteoinductive bone graft substitute in a sealed peel-pouch.

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 Southern Medical DBMX putty into the osseous defect.
5. Where required, Southern Medical DBMX can be mixed with the autogenous bone, coagulum or the patient's own blood.
6. To maximize *de novo* bone formation Southern Medical DBMX should be placed in direct contact with well vascularized bone with a sterile instrument.
7. Southern Medical DBMX should be segregated from the oral environment to prevent soft tissue infiltration by a bioresorbable collagen membrane.

**USAGE WARNING:**

- Southern Medical DBMX should only be used by trained surgeons and dentists.
- Southern Medical DBMX should be used with special caution in patients with acute or chronic infection, uncontrolled metabolic diseases, prolonged corticosteroid therapy, autoimmune diseases, radiotherapy and heavy smoking.
- For single use only.

**Sterility:**
Southern Medical DBMX is supplied as a sterile prefilled ready-to-inject syringe containing 1, 2, 3 or 5cc of injectable putty sealed with a luer lock cap inside a peel-pouch. The device is intended for single-use and single-patient-use only. Use before the labeled expiration date. Do not re-use device. Do not use device if the packaging has been damaged or previously opened, or if the expiration date has passed. If uncertain be sure to contact a Southern Medical Representative.

**STERILIZATION WARNING:**
Do not re-sterilize, device produced sterile. Devices are sterilized by gamma irradiation. Re-sterilization could cause material degradation and could result in rejection and/or infection. The device is designed for single patient use only and must never be reused.

**Post-Operative:**
An appropriate antibiotic, analgesic and postoperative care regimen should be prescribed by a trained specialist.

**Storage instructions:**
Store in a cool, dry place. Store between 15°C and 25°C.

**Descriptions of Symbols Used in Packaging:**

| | |
|---|---|
| ***USE BY*** |  |
| ***LOT NUMBER*** |  |
| **DATE OF MANUFACTURE** |  |
| **DO NOT REUSE** |  |
| **STERILIZED USING IRRADIATION** |  |
| **CAUTION** |  |
| **CONSULT THE INSTRUCTIONS FOR USE** |  |
| **DO NOT RESTERILIZE** |  |
| **DO NOT USE IF PACKAGING IS DAMAGED** |  |
| **LEGAL MANUFACTURER** |  |
| **STORAGE CONDITIONS** |  |