

Altis® AlticOLL™ lyophilized bone putty

AlticOLL™ lyophilised bone putty, is a tissue-engineered collagenous bone matrix graft substitute that is designed for ease of use for the surgeon. The bone void filler can be mixed with water for injection or patient blood (thrombus) and rehydrates to form a putty in under 5 minutes ensuring there are no delays in theatre.

The material allows for quick and precise placement into the void or defect. The tissue-engineered bone matrix in AlticOLL™ possesses a high affinity for locally produced bone morphogenetic proteins and transforming growth factor- β 1, absorbed from degranulating platelets at the impanation site, during the injury response process. This novel design activated the AlticOLL *in vivo*, leading to improved bone formation when compared to demineralized bone matrix implants. The device contains coarse bone matrix granules with a particle size of 150-1000 μ to allow for optimal cell infiltration and neovascularization as well as a reverse-phase viscoelastic modifier that produces a gel at body temperature for easy handling. AlticOLL™ is resorbable and is replaced by *de novo* host bone.

AlticOLL™ can be used alone as a bone-void filler or in combination with auto- or allograft as a bone graft extender.

Physical properties

AlticOLL™ lyophilised granules is comprised of 90% humanized bone matrix of porcine origin and 10% reverse-phase viscoelastic modifier. The addition of two volumes of WFI results in a mouldable putty.

Indications

Orthopaedic Surgery: Indicated as a bone void filler of long bones of the appendicular skeleton (ulna, radius, humerus, tibia and femur), axial skeleton and craniomaxillofacial skeletal structures.

- Spinal Surgery: As an autogenous bone graft extender and allograft substitute during instrumented fusion procedures of the spine
- Oral surgery: osteoconductive scaffold for orthognathic surgery, alveolus splitting, bone granulomas, dentigerous cysts.
- Periodontology: as a scaffold and graft extender for the regeneration of furcation and of deep intrabony defects.
- Implantology: as a graft extender in the restoration and regeneration of peri-implant bone lost due to periodontitis and dehiscence- two wall defects, lateral and crestal access sinus lift. AltiCOLL™ may be protected and segregated from surrounding soft tissue using an AltiMEM-gtr™ collagen membrane.

Benefits

AltiCOLL™ in combination with bone marrow aspirate or autologous thrombus offers the potential to reduce:

- Requirement for harvesting of iliac crest autologous bone
- Costs associated with hospital stay and autologous bone harvesting
- Recovery time
- Length of hospital stay

AltiCOLL™V.15082023 Rev 05



- Costs - immediately following surgery and over time
- Complications that would require follow-up visits
- Pain and infection at harvest site in autograft procedures
- Late onset complications from autogenous bone harvesting procedure

Advantages of AltiCOLL™

- Clinically superior to natural healing in a randomized, controlled study (*Shruthi et al., 2015*)
- Extensive clinical experience as a BMP carrier material
- High biocompatibility in animal studies (*Sibiya et al., 2013*)
- Bone formation superior to regular demineralized bone matrix in bioassay studies
- High batch to batch consistency as opposed to commercial DBM (*Bae et al., 2006*)
- Space maintaining bone matrix architecture supporting new bone formation
- Excellent safety profile
- 100% naturally derived tissue engineered bone matrix (*Rothman et al, 2007*)
- Histological evidence of new bone formation and biocompatibility shown in humans
- Extensive preclinical research supporting performance and safety
- Cost Effective versus Standard of Care

Catalogue no.	NAPPI code ZA	Description
ALTICOLL2	251239-001	Alticoll Bone Matrix for Bone Voids, 1.2g
ALTICOLL4	251240-001	Alticoll Bone Matrix for Bone Voids, 3g
ALTICOLL8	251241-001	Alticoll Bone Matrix for Bone Voids, 6g
ALTICOLL16	251242-001	Alticoll Bone Matrix for Bone Voids, 9g

References

- Shruthi MS. Hard and soft tissue alterations following tooth extraction with socket preservation employing tissue engineered DBM versus extraction alone: a randomized, controlled clinical study. 2013 Dissertation. *Rajiv Gandhi Hospital of Health Sciences, Karnataka, India.* http://www.rguhs.ac.in/cdc/onlinecdc/uploads/02_D003_18112.doc
- Bae HW, Zhao L, Kanim LE, Wong P, Delamarter RB, Dawson EG. Intervariability and intravariability of bone morphogenetic proteins in commercially available demineralized bone matrix products. *Spine.* 2006;31(12):1299-306.
- Rothman B, Olivier E, Duneas N. Acid swelling overcomes osteogenesis inhibition of xenogeneic collagenous matrix delivery system used for naturally-derived bone morphogenetic protein complex. *J Bone Miner Res.* 2007;22:S165-S165.
- Sibiya SJ, Olivier EI, Duneas N. High yield isolation of BMP-2 from bone and in vivo activity of a combination of BMP-2/TGF- β 1. *J Biomed Mater Res Part A.* 2013;101A:641-6.
- Takaoka K, Koezuka M, Nakamura H. Telopeptide-depleted bovine skin collagen as a carrier for bone morphogenetic protein. *J Orthop Res.* 1991;9:902-7.
- Badylak SF. The extracellular matrix as a biologic scaffold material. *Biomaterials.* 2007;28(25):3587-93.

Address: Altis Biologics (Pty) Ltd ,1606 Allan Cormack Street .The Innovation Hub, 0087
Pretoria, South Africa

SAHPRA reg. no. 000002464MD

Contact: Tel. +27 (0)12 844 0098/99

email. nic@altisbiologics.com sales@altisbiologics.com

AltiCOLL™V.15082023 Rev 05

