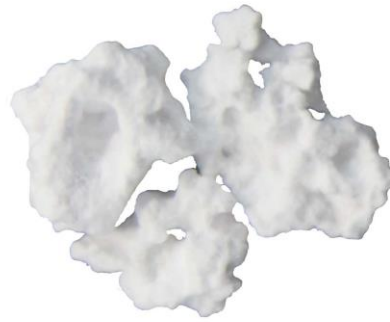


# TCM Associates Ltd

GelOS<sup>®</sup> GranOS<sup>®</sup> synthetic bone substitute  
Product Overview





### **Product Description and Materials:**

GranOS™ granules create a porous, resorbable osteoconductive scaffold when gently packed within the bony voids or defects of the skeletal system. The granules are constructed of highly pure  $\beta$ -tri-calcium phosphate, that when implanted in direct contact with viable host bone facilitates new bone growth by serving as a scaffold upon which new bone deposits and matures.

The broad size range of interconnected pores, within the granules, support re-vascularisation and cellular invasion as the regenerating bone is guided throughout the defect. Bone forming cells are infused, enhancing the processes of new bone development and the eventual resorption of the scaffold, as the healing process progresses.

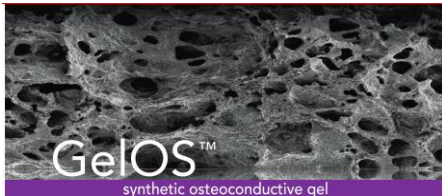
GranOS is presented in a vial that is double blister packed and supplied sterile for single patient use.

### **Intended Use and Indications:**

GranOS™ is intended to be used as a synthetic bone void filler. It is only indicated for filling and/or augmenting bony voids or gaps that are not intrinsic to the stability of the bone structure. GranOS should be packed gently into the irregular shaped bony voids or defects of the skeletal system (i.e. long bones, extremities, spine and pelvis mandible or maxilla). It is used in place of corticocancellous, or cancellous allograft or autograft bone.

Typical applications for bone substitutes include;

- Bone void filling following surgery, typical surgical techniques include;
- Small void filling e.g. after removal of a bone tumour or following bone fracture reduction or in osteotomies,
- Spinal fusion, where an interbody cage or mechanical fixation is used concurrently to relieve the graft site from load.
- Osseous defects created from traumatic injury to the bone
- Bone void filling following removal of a cyst or tumor



### **Product Description and Materials:**

GelOS consists of highly pure  $\beta$ - TCP granules within a defined particle size range suspended within an aqueous polymer gel carrier. When implanted the gel carrier dissolves leaving the granules as a porous resorbable osteoconductive scaffold for new bone growth. GelOS creates a three-dimensional matrix, which guides regenerating bone throughout the defect into which it has been implanted.

GelOS™ synthetic osteoconductive gel should be implanted directly into bony voids or defects of the skeletal system (i.e. long bones, extremities, spine and pelvis mandible or maxilla). The water soluble carrier gel then dissolves leaving behind the calcium phosphate matrix which is resorbed and replaced with bone during the healing process.

Gelos is presented in a polycarbonate syringe with a luer-lock connection. Each unit is double packed and supplied sterile for single patient use.

### **Intended Use and Indications:**

GelOS™ is intended to be used to fill bony voids occurring in the skeletal system which are not intrinsic to the stability of the bone structure, it is used in place of corticocancellous, or cancellous allograft or autograft bone.



GranOS Product Ref: No	Description
10.012.005	GranOS granular bone substitute Granule 1mm – 2mm Pack Volume 5cc FINE GRAIN
10.012.010	GranOS granular bone substitute Granule 1mm – 2mm Pack Volume 10cc FINE GRAIN
10.012.015	GranOS granular bone substitute Granule 1mm – 2mm Pack Volume 15cc FINE GRAIN
10.012.030	GranOS granular bone substitute Granule 1mm – 2mm Pack Volume 30cc FINE GRAIN
10.024.005	GranOS granular bone substitute Granule 2mm – 4mm Pack Volume 5cc STANDARD GRAIN
10.024.010	GranOS granular bone substitute Granule 2mm – 4mm Pack Volume 10cc STANDARD GRAIN
10.024.015	GranOS granular bone substitute Granule 2mm – 4mm Pack Volume 15cc STANDARD GRAIN
10.024.030	GranOS granular bone substitute Granule 2mm – 4mm Pack Volume 30cc STANDARD GRAIN



GelOS Product Ref No:	Description
20.00.001	GelOS Pack Volume 1cc
20.00.025	GelOS Pack Volume 2.5cc
20.00.005	GelOS Pack Volume 5cc
20.00.010	GelOS Pack Volume 10cc

# TCM Associates Ltd

For more than two decades TCM have been manufacturing and developing synthetic bone substitute materials for the restoration of the human skeleton.

The company is committed to improving patient outcomes with additional new products, and already has plans to extend its product range into the vertebral compression fracture market.

TCM has much to offer its worldwide partners, including wide-ranging experience of the orthopaedic, osteobiologics and vertebroplasty markets and extensive in-house technical expertise in these fields. The company can provide immediate access to proven, market-ready products to both local distributors and on an OEM own-label basis to international business partners.



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TCM/GelGran/ML/0214.00

