Singjoint®

NMPA

Bone Repairing Materials

- Moldable
- Absorbable
- Easy Operation
- Osteoinductive

China's First Type Ⅰ Collagen Composite β-TCP Tissue Regenerative Bone Repair Material

NMPA REG. NO: 20263130091

Hangzhou Singclean Medical Products Co.,Ltd.

SingJoint Bovine Type I Collagen & β-Tricalcium Phosphate Composite Ceramic Bone Repairing Materials

PRODUCT FUNCTIONS

Structural Adaptability:

Collagen fibers and bioceramics form the product's unique three-dimensional porous structure.

Customizable Molding:

After hydration, it conforms closely to the bone surface and can be shaped as needed.

Dual Efficacy:

Collagen induces bone regeneration, while β-tricalcium phosphate provides a creeping substitution scaffold, enabling osteoconduction.

Safe & Efficient:

Biodegradable and absorbable, with a degradation rate that matches new bone regeneration.

TECHNICAL ADVANTAGES

Patent:

A Collagen/Bioceramic Porous Bone Implant and Method for Its Preparation

Safety:

(1) Biological evaluation: Biological evaluation indicates that the product exhibits no potential cytotoxicity, no sensitization, no irritation reactions, no acute systemic toxicity, and no significant subchronic systemic toxicity. In addition, the results of tests such as the Salmonella typhimurium reverse mutation assay, intradermal reaction test, in vitro mammalian cell gene mutation assay, and in vitro mammalian cell chromosome aberration assay all meet the required standards.

(2) Degradation study: The product is degradable in vitro. After 26 weeks of implantation in vivo, the ceramic component is largely degraded, and new bone ingrowth is observed in the implantation area. The product is safe and effective.

EFFECTIVENESS

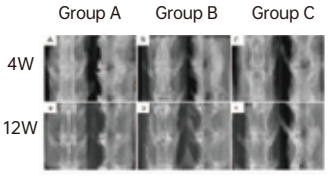
Animal study:

New Zealand white rabbits were used as experimental subjects to undergo posterior two-level spinal fusion. The animals were randomly divided into three groups and implanted with either a moldable artificial bone repair material(SingJoint), β-TCP ceramic granules, or autogenous iliac bone, respectively. At 4 and 12 weeks post-surgery, the animals were sacrificed and sampled for evaluation, including X-ray examination, micro-CT, biomechanical testing, calculation of bone deposition rate, and histological assessment.

Conclusion:

The product demonstrated superior efficacy over β-TCP in posterior two-level spinal fusion and shows promise as a substitute for autogenous bone in the treatment of spinal disorders.

X-ray examination

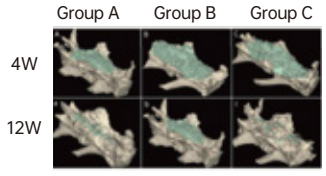


At 4 weeks post-surgery, no fusion was observed in any group; fusion was observed at 12 weeks post-surgery. Continuous bone bridges appeared between the two vertebrae. The fusion rate of the moldable artificial bone repair material was higher than that of β-TCP ceramic and comparable to that of autogenous bone.

Biomechanical testing

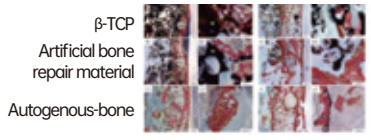
The stiffness and yield strength of the moldable artificial bone repair material at the bone graft fusion site showed no significant difference from those of autogenous bone.

Three-dimensional CT reconstruction



The degradation of the moldable artificial bone repair material was greater than that of β-TCP ceramic, but showed no difference compared with autogenous bone.

Histological evaluation



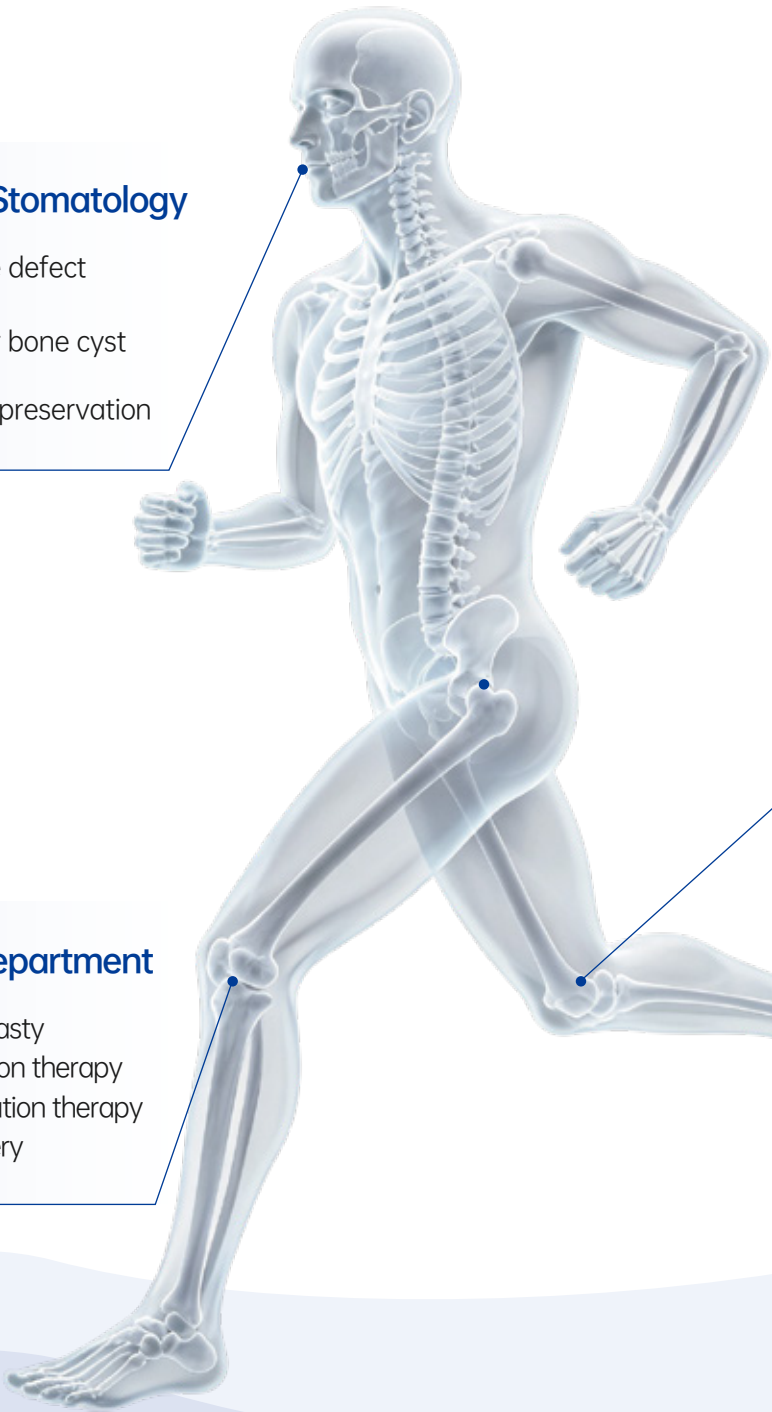
New bone formation with the moldable artificial bone repair material was significantly higher than that with β-TCP ceramic, and comparable to that with autogenous bone.

CLINICAL TEST

	Evaluation Indicators	Moldable Artificial Bone Repair Material	β-Tricalcium Phosphate Bioceramic
Primary Efficacy Endpoint	Fusion rate at 24 weeks post-surgery (FAS [Full Analysis Set])	98.57% (69/70)	97.14% (68/70)
	Fusion rate at 24 weeks post-surgery (PPS [Per Protocol Set])	100.00% (68/68)	97.14% (68/70)

The moldable artificial bone achieves the expected therapeutic effect. There is adequate evidence supporting both the safety and effectiveness of the device, and it is suitable for clinical application.

CLINICAL APPLICATIONS



Department of Stomatology

1. Maxillofacial bone defect reconstruction
2. Defect filling after bone cyst curettage
3. Extraction socket preservation

Department of Orthopedic Trauma

1. Old fracture
2. Osteoporotic fracture
3. Delayed bone union & bone defect
4. Fresh fracture requiring internal fixation
5. Bone lengthening /bone transport surgery
6. Orthopedic corrective surgery

Joint Surgery Department

1. Total knee arthroplasty
2. Hip joint preservation therapy
3. Knee joint preservation therapy
4. Joint revision surgery

Indication:

Indicated for filling limb bone defects caused by orthopedic trauma or surgery without compromising bone structural stability.

CONTRAINDICATIONS

Severe infection

Severe diabetes

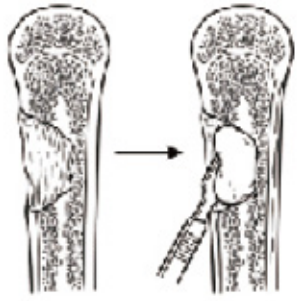
Impaired immune function

Allergy

Contraindicated for patients with systemic/local severe infection, uncontrolled severe diabetes, severe hepatic/renal insufficiency or immunodeficiency.

Not for patients with confirmed allergy to bovine-derived materials or collagen products.

OPERATION INSTRUCTIONS



(1) Cut or tear open the outer packaging, and remove the inner packaging under aseptic conditions;

(2) Open the inner packaging under sterile conditions;

(3) A physician with appropriate expertise, according to the shape requirements of the bone graft material for the patient's bone defect site, uses a sterile scalpel or rongeur to trim the product to the appropriate size and shape, moistens it with normal saline or the patient's own blood, fills it into the defect site, and covers it with the surrounding soft tissue. The specific implantation method for each site is the same as that of traditional autologous bone grafting. The amount used is determined according to the defect site, and the maximum amount shall not exceed 80 cm^2.

Source of literature:

Lu Y, Li M, Long Z, DiYang, Guo S, LiJ, Liu D, Gao P, Chen G, Lu X, Lu J, WangZ. Collagen/β-TCP composite as a bone-graft substitute for posterior spinal fusion in rabbit model: a comparison study. Biomed Mater. 2019 May 17;14(4):045009.

Model	Specifications (mm)
RGG-Ⅰ Strip	5x5x10, 5x5x20, 5x5x30
RGG-Ⅰ Block	10x10x10, 10x10x20, 10x20x30, 10x20x40, 10x20x50, 20x20x20, 25x25x10, 50x25x5, 50x25x8

Singjoint®

Bone Repairing Materials

Hangzhou Singclean Medical Products Co., Ltd.

Add: No.125(E),10th Street, Hangzhou Qiantang Area, Zhejiang, China P.C: 310018

Tel: +86-571-63431868 WhatsApp: +86 13362195396 Fax:+86-571-63431886

E-mail: marketing@singclean.net www.singclean.net