COUSIN SURGERY

Ronda MedTech

Synthetic Bone Substitute



CGEL

› Synthetic gel for bone ingrowth
› Osteo-conductive hydroxyapatite
› Syringes ready to use

CGEL



Description

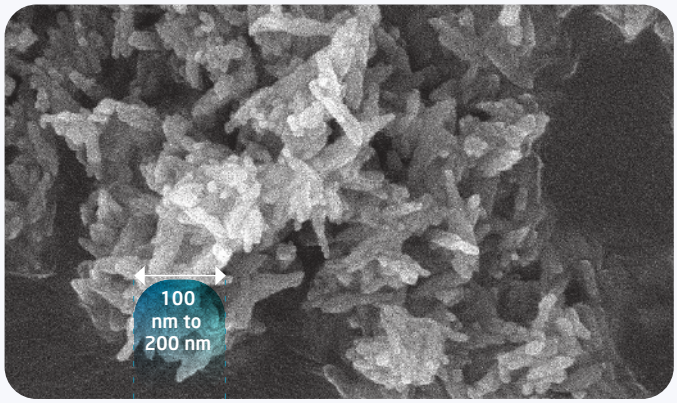
Cgel is an osteo-conductive hydroxyapatite synthetic gel for bone ingrowth, intended to be used for filling gaps or bone defect in orthopaedic or spine surgery.

Indications

Cgel is a indicated for the filling of bone defects due to bone injury (such as trauma, disease) or surgical procedure (such as arthrodesis, intervertebral cage filling).

Composition

The gel consists of hydroxyapatite nanoparticles ($Ca_5[PO_4]_3OH$) suspended in water, with particle sizes ranging from 100 to 200 nm.



(1) KP10125 - Internal report
(2) Lifetime report SG150719 - Internal report
(3) Biological Risk Assessment Report Cgel

Features

STRUCTURE
- Specific surface area higher than **80m²/g**[1]

INJECTABLE
- Syringe ready to use
- Luer Lock connection for trocars Gauge less than 13G

Advantages

ABSORBABLE
- HA nanoparticles resorb after a minimum of one year[2]

BIOCOMPATIBLE
- Compliant with ISO 10993-1[3]

Osteoconduction

Thanks to its hydroxyapatite nanoparticles, Cgel offers a high specific surface area (>80m²/g), offering contact with bone tissue and providing exchange surface for osteoblast activity and bone regeneration.

Clinical case

Clinical studies have shown a cellular invasion and high bone ingrowth within months after implantations[4].

Case

Osteoporotic women, 72-y old, presenting a Pouteau Colles wrist fracture [5]



Pre-Op



Post-Op at 1 month

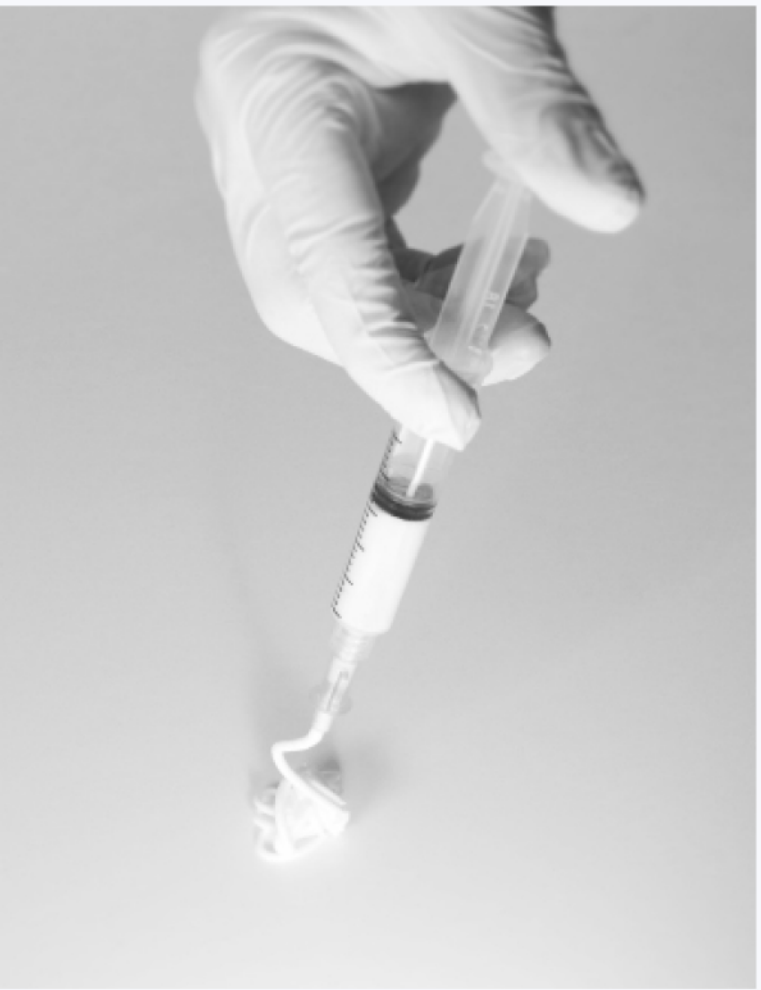


Post-Op at 3 month

(4) Rapport CIT Animal studies n°08-02 – Internal report
(5) Rapport PMCF NANOGEL - 15.02.2016

Storage conditions

Cgel must be stored in its unopened original packaging and at a temperature between + 2°C and + 25°C.
Freeze sensitive product, non compliance with the storage conditions may result in product demixing. In this case, do not use the product.
Cgel is delivered sterile under double packaging, ready to use in the operating room. Single use. Do not re-sterilize.



PRODUCT	REFERENCE
Cgel	
0.5ml Syringe	T860705
1ml Syringe	T860710
2.5ml Syringe	T860725
5ml Syringe	T860750

MANUFACTURER:
TEKNIMED S.A.S - 8, rue du Corps Franc Pommiès
65500 VIC-EN-BIGORRE - FRANCE - Tel: +33 (0)5 34 25 10 60

CE 2797

Cousin Surgery
Allée des roses
59117 Wervicq-Sud - FRANCE
www.cousin-surgery.com

Cgel is a class III medical device according to MDR 2017/745.
For any further information, please refer to the IFU.

Reference: BRRCGELGB01 - 09/01/26.

Non contractual pictures and texts. Specifications likely to be modified without notice.
Cousin Biotech S.A.S capital : 340 656 € - 398 460 261 RCS Lille - N°TVA FR 34 398 460 261
Cousin Biotech is the legal manufacturer of the medical devices proposed by Cousin Surgery

SC Ronda Medtech SRL
Distribuit în România și Republica Moldova
Str. Viilor nr. 20C, RO-400337 Cluj-Napoca
Office: +40 0264 237 212 Fax: +40 264 237 295 GSM: +40 727 221 112 e-mail: management@rondamedtech.ro