

Orthocell *CelGro™ Dental Collagen Scaffold*



Product Information

Safety and efficacy in patients exceeding the recommended age range of 18-65 years cannot be assured

Destructive parafunctional habits (bruxism, clenching), attrition or existing orthotic appliances may impede repair if in contact with the site of repair. Dental practitioners should provide additional guidance to prevent damage to the repair.

Impeccable dental hygiene is a necessity in the period following implantation, smokers may need to modify their intake. It is recommended that practitioners assure the likelihood of patient compliance to oral hygiene requirements.

CelGro™ has a smooth and a rough surface and it is imperative that the rough side be implanted in contact with the bony defect (smooth side facing outwards) (Figure 1)

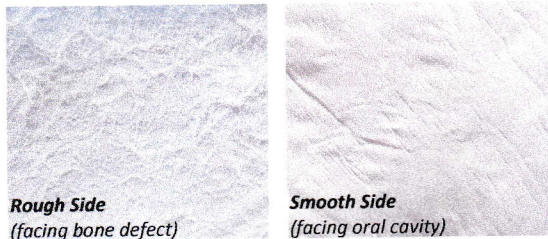


Figure 1: CelGro™ Scaffold Appearance



ADVERSE REACTIONS

CelGro™ is a porcine-derived collagen product. Although improbable due to decellularisation and removal of genetic material, persons highly sensitive to porcine material may react to the scaffold. Humoral immunity against collagen is rare but can be detected with a serologic test if concerns exist. General complications such as swelling, bleeding, dehiscence, pain etc. may be associated with the surgical procedure itself rather than the scaffold and should be discussed with the patient prior to the procedure.

STORAGE AND HANDLING



CelGro™ is supplied sterile, γ -irradiated at $\geq 25\text{kGy}$



Do not use the product if damaged or opened. The blister pack is tamper evident and cannot be opened without being visible



The scaffold must not be re-sterilised.



Scaffold is a single-use product. Re-use may result in severe adverse reaction, illness or infection. Any unused scaffold must be discarded.



Use the product within expiry period stated on labels



CelGro™ poses no known risks in all MR environments.



The product must be stored in its box (away from sources of light) at room temperature (15-25°C) in a dry place. CelGro™ is shipped with temperature indicators - red colour at arrow (Fig. 2) indicates that the product may be unsuitable for use ("Activated"). Please contact Orthocell or your distributor for stock replacement.

UNACTIVATED (CORRECT STORAGE)



ACTIVATED (INCORRECT STORAGE)

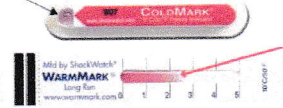



Figure 2: Transit Temperature Indicators

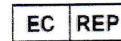
The scaffold must be handled using sterile surgical technique.

APPEARANCE

CelGro™ is presented in a sterile double blister pack. Each package contains one (1) collagen scaffold. The product codes for re-ordering are as follows.

Product No.	Size (mm)
OCG-304A	30x40
OCG-405A	40x50
OCG-050A	50 (ϕ /diameter)
OCG-070A	70 (ϕ /diameter)
 Thickness	A = 200-399 μm

SUPPLY AND DISTRIBUTION INFORMATION



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Manufacturer:

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Concerns / Questions

Contact Orthocell: medicalaffairs@orthocell.com.au

GMDN Code

58709

