CelGro™ Dental

Instructions for use

DESCRIPTION

CelGro™ Dental is a sterile, resorbable collagen barrier membrane intended for use in guided bone and guided tissue regeneration.

CelGro™ Dental is a highly purified collagen membrane of porcine origin produced using quality-controlled manufacturing processes. Raw materials are sourced exclusively from within Australia and collected at certified facilities under strict quality controls. The collagen is purified to remove materials that may elicit antigenic reactions. CelGro™ Dental is manufactured with no crosslinking to ensure a highly biocompatible product.

Slight variations in the appearance of CelGro™ Dental due to the biological origin of the membrane do not influence its clinical performance.

PROPERTIES

CelGro™ Dental is designed to protect the bone defect space from ingrowth of gingival tissue to provide a favourable environment for osteogenesis and allow sufficient time for bone regeneration to occur. CelGro™ Dental collagen membranes have a bilayer structure with a rough and a smooth side. The rough side is composed of a random, loose distribution of collagen bundles that provides a scaffold for cellular ingrowth and the smooth side is composed of parallel arrangements of densely packed collagen bundles that permits passage of fluids but acts as a barrier to cellular ingrowth.

CelGro™ Dental is hydrophilic, conforming to the contours of the defect, and may be sutured or pinned in place if required. A second surgical procedure to remove the membrane is not needed. Animal studies have shown that CelGro™ Dental is still visible 5-13 weeks after implantation but is fully resorbed through normal physiological processes within 26 weeks.

INDICATIONS FOR USE

CelGro™ Dental is indicated for use in:

- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Filling of bone defects after root resection, cystectomy, removal of retained teeth;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in periodontal defects.

DIRECTIONS FOR USE

General principles of surgical practice and sterile technique should be adhered to.

Procedures

1. Prior to guided bone and tissue regeneration procedures, anti-infective therapy to eradicate any bacterial infection and counselling of the patient in good oral hygiene is highly recommended.
2. Surgically expose the bone defect and create a mucoperiosteal flap suitable for wound closure. Debride and plane the root surface carefully. Adequate debridement and implant surface disinfection should be achieved before bone augmentation around implants in peri-implantitis bone defects.
3. Fill the bone defect with bone graft or other void-filling material, taking care not to over-fill the defect. Bone fillers or implants must be adequately localised or fixed in place prior to application of the CelGro™ Dental membrane.
4. Trim CelGro™ Dental to the required size using sterile technique. The membrane should significantly overlap the walls of the defect to assure adequate enclosure and prevent soft-tissue invasion.
5. Apply CelGro™ Dental over the defect and apply gentle pressure until the membrane is uniformly wet and conforming and adhering to the defect. The rough side of the membrane is placed facing the bone defect and the smooth side faces the oral cavity.
6. To avoid the formation of excessive junctional epithelium when treating periodontal defects, it is important to adapt CelGro™ Dental closely to the treated tooth.
7. To prevent membrane displacement, CelGro™ Dental may be fixed in place with sutures, if required.
8. Use the previously created mucoperiosteal flap to close the wound over the membrane. Complete wound closure is recommended but not essential. Excess tension to achieve wound closure may increase the risk of dehiscence and should be avoided.

Post-operative care

1. Patients should be monitored closely in the initial post-operative period. The use of prophylactic antibiotics and oral antiseptics following surgery is recommended. Good oral hygiene is essential in the period following implantation and dental

practitioners should provide additional guidance to patients on maintenance of oral hygiene post-treatment.

2. Post-operative symptoms may include swelling, pain or mild inflammation and dental practitioners should provide guidance to patients in appropriate symptom management.
3. Exposure of the CelGro™ Dental membrane through wound dehiscence may occur and generally resolves spontaneously and membrane removal is usually not required. In the event of membrane exposure, prophylactic treatment with antiseptic rinses to minimise the risk of bacterial contamination is recommended.
4. Surgical re-entry is not recommended for a period of at least 4 months to allow sufficient time for bone regeneration.
5. In the unlikely event of severe infection or an adverse reaction, inflamed or infected tissues should be excised together with residual membrane under local anaesthesia.
6. Destructive parafunctional habits (bruxism, clenching), attrition or existing orthotic appliances may impede repair if in contact with the site of repair. In that case, dental practitioners should provide guidance to the patient in how to minimise damage to the treatment site.

LIMITATIONS OF USE

Contraindications

CelGro™ Dental should not be used if there is evidence of active infection at the treatment site.

The use of CelGro™ Dental in patients with known sensitivity to porcine-derived materials or collagen is contraindicated.

Adverse reactions

Complications which may be associated with the surgical procedure such as infection, swelling, bleeding, dehiscence or pain should be discussed with the patient prior to the procedure.

Adverse reactions to porcine-derived collagen membranes in dental procedures are extremely rare however immune reactions are possible.

Patients should be monitored closely in the initial post-operative period to identify and address any adverse reactions which may occur.

Precautions

CelGro™ Dental should only be used by qualified dentists and oral surgeons.

Caution and close patient monitoring during the post-operative period may be required when using CelGro™ Dental in patients with compromised healing capacity including due to:

- Uncontrolled metabolic disease (e.g. diabetes, thyroid disorders)
- Anti-coagulant / blood- thinning therapy
- Treatment with high doses of anti-inflammatory medications or bisphosphonates
- Connective tissue diseases
- Autoimmune diseases
- Radiotherapy
- Heavy smoking

STORAGE AND HANDLING

Store CelGro™ Dental in its original packaging at room temperature (15-25°C) in a dry place.

SYMBOLS


Use-by date


Distributor


Batch code


Catalogue number


Sterilized using irradiation


Do not resterilise


Do not use if package is damaged


Double sterile barrier system


Keep away from sunlight


Keep dry


Temperature limit


Do not re-use


Consult instructions for use

HOW SUPPLIED

CelGro™ Dental is supplied in a double PETG/Tyvek blister pack contained in a labelled cardboard box.

REF	Size (mm)
OCG-152	15 x 20
OCG-203	20 x 30
OCG-304	30 x 40
OCG-405	40 x 50
OCG-050	50 (diameter)
OCG-070	70 (diameter)
OCG-310	30 x 100
OCG-710	70 x 100

Manufacturer: Orthocell Ltd
Building 191, Murdoch University
South Street, Murdoch WA 6150
Australia

If you have any concerns or questions about this product please contact Orthocell.

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