Orthocell *CelGro™ Dental Collagen Scaffold*

Product Information

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Orthocell CelGro™
Bioabsorbable Implantable Collagen Scaffold
CelGro™ is a type I collagen scaffold which is sterile and suitable for use in guided tissue repair and bone regeneration in dental applications.

CelGro™ is ideal for use in surgical implantations as it is highly biocompatible with little antigenicity. The scaffold enables the ingrowth and proliferation of cells and actively functions in normal physiological repair mechanisms. The scaffold structure retains its strength as a tissue support when wet. The collagen scaffold is a hydrophilic tissue support which conforms to the contours of the tissue surface. As the product is naturally derived, slight variations in the surface texture of the scaffold are to be expected and these do not alter the functionality of the product. Each scaffold is subject to careful inspection to assure high quality.

COMPOSITION

CelGro™ is a type I collagen scaffold manufactured by a quality controlled process. The raw material used for manufacture is approved by veterinarians to assure quality. The collagen scaffold has been manufactured and purified to remove reactive materials and to minimise the potential for immunologic reaction. The product is completely natural without the addition of additives or cross-linking to facilitate normal physiological processes of integration, resorption and remodelling.

CelGro™ has a bilayer structure with a porous and a smooth layer. The porous (or rough) layer is to be applied contiguous to the tissue surface and promotes the ingrowth of cells. The smooth side facilitates smooth articulation within joints and cavities, preventing ingrowth of fibrous tissues.

CelGro™ is sterilised by γ-irradiation in sealed double-layer trays.

As a biologically derived product being predominantly comprised of collagen, CelGro™ is not anticipated to result in reciprocal interference during specific investigations or treatment.

INDICATIONS FOR USE

CelGro™ is intended as a tissue support and barrier membrane in guided bone and tissue regeneration procedures. CelGro™ is recommended for:

- Simultaneous use of GBR-membrane (CelGro™) and implants
- 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

⚠ CONTRAINDICATIONS

CelGro™ must not be used if there is evidence of active infection at the treatment site. CelGro™ is contraindicated for use in:

- Pregnant or lactating women
- Immunocompromised or immune suppressed patients
- Patients with existing, untreated infections, including sinus or periapical pathology
- Patients with prior malignancies of the head and neck treated with radiotherapy or antineoplastic / chemotherapy drugs
- Patients being treated with medications affecting tissue metabolism (calcium channel blockers, epilepsy medications, cyclosporin)
- Patients with diseases affecting tissue metabolism (gingival fibromatosis or other fibrous dysplasias)
- Patients with diseases which may contribute to a poor healing response (gingival recession and other mucocutaneous disease, hypertension, uncontrolled diabetes, renal disease, collagen disorders [e.g. Ehlers-Danos Syndrome])
- Patients receiving treatment with high doses of NSAID medications or other medications which affect connective tissue metabolism (bisphosphonates). Maintained usage at therapeutic plasma levels should be avoided for 3 months post-implant
- Patients who have conditions causing bone or tissue loss (osteomalacia, osteoporosis, renal osteodystrophy)
- Patients with blood clotting disorders or anti-coagulant / blood-thinning medication unless managed appropriately
- Patients with clinically significant response to porcine materials or collagen

DIRECTIONS FOR USE

General principles of surgical practice and aseptic technique must be adhered to when using CelGro™. All reasonable precautions to minimise the potential for contamination, including the control of saliva, must be taken.
The directions for use of CelGro™ are as follows:

1. Following the completion of surgical procedure(s), bone defects are filled as required with bone graft or other void-filling material (allograft, HA, natural bone substitute, e.g. Bio-Oss®).
2. CelGro™ is trimmed to the required size with sterile technique
   a. The scaffold should significantly overlap the walls of the defect to assure adequate enclosure and prevent soft-tissue invasion
   b. The rough side of the scaffold is placed facing the bone defect
3. CelGro™ is applied over the defect and pressure applied until bleeding is adequately controlled and the scaffold is uniformly wet with fluids (thus conforming to the defect void)
4. Complete wound closure is recommended but not essential as excess tension may increase the risk of dehiscence

POST-OPERATIVE CARE

Patients should be monitored in the initial post-operative period (4-6 weeks). Orthocell recommends the use of prophylactic antibiotics, oral antiseptics and/or education in post-operative oral hygiene in the weeks following surgery. Post-operative symptoms may include swelling, pain or mild inflammation. Surgeons are encouraged to instruct patients in appropriate symptom management and to make contact if concerned.

1. Surgical re-entry is not recommended for a period of at least 4 months to allow sufficient time for bone regeneration.
2. The scaffold can be removed in the case of severe infection or adverse reaction. Inflamed or infected tissues should be excised with the residual membrane.
3. Prophylactic treatment with antiseptic rinses is highly recommended if the scaffold becomes exposed due to wound dehiscence.

⚠ PRECAUTIONS

CelGro™ is intended for use only in dental and oral surgery by qualified dentists/oral surgeons.

Safety and efficacy in applications other than those indicated cannot be assured.

The long-term safety and effectiveness of the membrane in conjunction with bone-filling materials has not yet been established.

Use of the scaffold in the presence of infection or inadequate oral hygiene may predispose the patient to an adverse reaction. Bone fillers or implants must be adequately localised or fixed in place (as appropriate) prior to use of CelGro™.

Safety and efficacy of repeat doses cannot be assured.