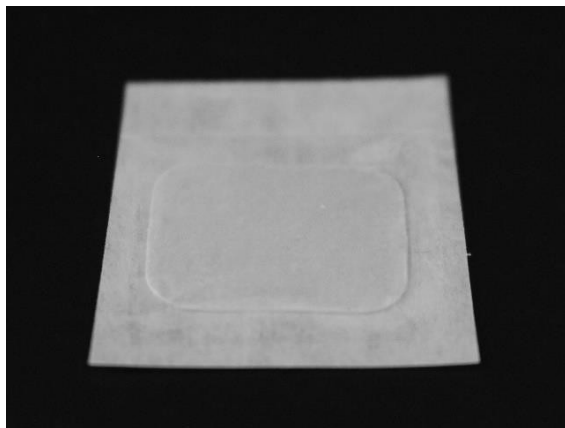


**AltiMEM-GTR™ generation II bioresorbable membrane for Guided Bone Regeneration**

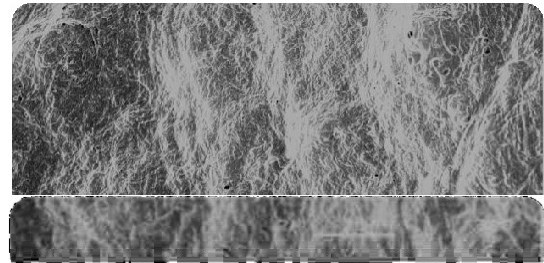
**Description of the device**

AltiMEM-GTR™ is a fibrillar collagen barrier membrane intended for the restoration of bone defects of the craniomaxillofacial skeleton.



AltiMEM-GTR™ is supplied as a 20 x 30 mm and 15 x 20 mm sterile, off-white collagen membrane inside a double-peel pouch pack. The membrane is a porcine type collagen that has been telopeptide reduced to ensure the highest biocompatibility. AltiMEM-GTR™ is partially crosslinked by gamma-irradiation to increase robustness. No chemical crosslinking agents are used. The packaging consists of a sealed peel pouch containing a single sterile collagen membrane within a smaller peel pouch. Removal of the peel cover allows for the

aseptic transfer of the membrane under theatre conditions

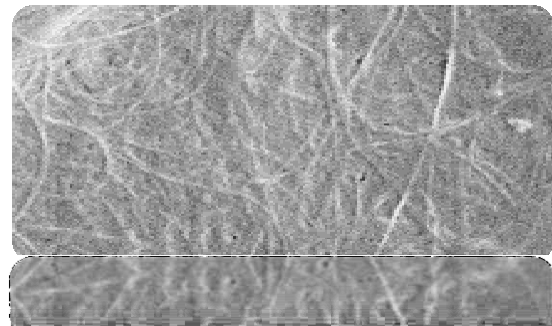


**Scanning Electron Microscopy Image demonstrating fibrillary architecture of AltiMEM-GTR™**

**Composition**

AltiMEM-GTR™ is a resorbable fibrillar collagen membrane of porcine origin. The collagen is extracted from tendons of specified pathogen-free herds and carefully purified to ensure the highest biocompatibility and lowest immunogenicity. The product is terminally gamma-irradiated to ensure sterility. The membrane components are:

- (1) type I porcine atelocollagen



of

## Indications

AltiMEM-GTR™ is intended as a barrier membrane in cases of maxillofacial trauma or periodontal disease where tissue segregation of a defect is required. The following are some of the applications for this device:

1. In periodontal and orthopaedic procedures as a barrier to prevent soft-tissue invasion into the defect.
2. In alveolar ridge preservation and augmentation procedures.
3. In peri-dental titanium implant bone augmentation procedures.
4. In sinus lift procedures as an adjunct to an osteoconductive/inductive bone graft to prevent migration of the graft.

AltiMEM-GTR™ may be combined with osteoinductive growth factor products such as Altis™ OBM and Altis™ DBMXtra, which provide bone morphogenetic protein stimulation of tissue regeneration. Bone voids requiring osteoconductive ceramics may be treated in conjunction with AltiCERAM™ ‘smart’ biomaterials.

## Instructions for use

Each membrane size provides 3 cm<sup>2</sup> and 6 cm<sup>2</sup> of material respectively. Prepare the membrane as follows before use;

1. Using aseptic techniques, open outer peel pouch and remove the inner peel pouch containing the membrane.
2. Aseptically open the peel pouch by removing the peel cover and remove the membrane and place it onto a sterile surface.
3. The membrane is now ready for use. The membrane may be pre-wetted with water for injection to soften it. The membrane will maintain its physical integrity during the procedure.
4. Place the membrane over the bone defect containing the bone graft/substitute
5. Secure the membrane with titanium pins or suture to prevent soft tissue infiltration into the void.

## Special Instructions

In order to avoid the ingress of long junctional epithelium, AltiMEM-GTR must be adapted closely to the tooth. It is a requirement of treatment to control any bacterial infection through the implementation of a suitable postoperative hygiene regimen.

### Contraindications

1. AltiMEM-GTR™ should not be used in the presence of bacterial infection.
2. AltiMEM-GTR™ should not be used in patients with a known allergy to collagen.

### Precautions

1. AltiMEM-GTR™ should only be used by trained surgeons and dentists.
2. AltiMEM-GTR™ should be used with special caution in patients with acute or chronic infection, uncontrolled metabolic diseases, prolonged corticosteroid therapy, autoimmune diseases, radiotherapy, heavy smoking.

### Side effects

1. In very rare cases an allergic reaction to collagen products may occur and an inflammatory response may be observed.

### Other information



The product is sterilized by gamma-irradiation.



The product is intended for single use.



Do not use product after expiry date.



The product must be stored in a dry place at room temperature and not exceed 25 °C.

### Catalogue and NAPPI Code

ALTIMEM15x20	251226-001
ALTIMEM20x30	251227-001
ALTIMEM25x25	251228-001
ALTIMEM40x60	251230-001
ALTIMEM10x10	251233-001

### Product description

Collagen membrane for guided bone regeneration 15x20
Collagen membrane for guided bone regeneration 20x30
Collagen membrane for guided bone regeneration 25x25
Collagen membrane for guided bone regeneration 40x60
Collagen membrane for guided bone regeneration 10x10

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