PAROGUIDE®

Membrane for guided tissue regeneration

PRESENTATION
Kit containing: 5 sterile double-packaging blisters (sterilization by gamma radiation).
Each blister contains:
• 1 single-use membrane, size 3 x 3cm, thickness about 0.5mm, weight about 110mg.
• 2 Tyveck models which must not be implanted; they are used to determine the exact shape of the membrane before implantation.

COMPOSITION
Type I horse collagen: 96 - 98%; Glycosaminoglycanes (chondroitin sulphate): 2 - 4%.

COMPOSITION - ORIGIN - MANUFACTURE
Paroguide is an opaque, cream-coloured membrane of medium rigidity, made of native lyophilized collagen from animal origin (equine): Type I collagen. Manufacture consists in a lyophilization of collagen gel. Collagen is exclusively obtained from equine tendons (horses certified by the Ministry of Health as usable in opotherapy), from agreed abattoirs (EEC stamp). The compresses obtained are then packaged under unit blisters and sterilised by gamma radiation at a dose of 25 KGray. A sterility test according to the European Pharmacopoeia is performed on each batch. Paroguide, membrane, shows a good guarantee of viral, bacterial and fungic security according to the scientific knowledge.

CHARACTERISTICS
Paroguide is a collagen and chondroitin sulphate-based membrane, resorbable in about 8 to 12 weeks, for guided tissue regeneration. Paroguide's components are link-crossed according to the AZIDE method (diphenylphosphorylazide). The reticulation allows to adapt the resorption of the product according to the requirements of the guided tissue regeneration. Paroguide has a barrier effect allowing a cellular selection. The membrane limits the access of osseous defects to the only bone cells, so that it allows the regeneration of osseous tissue and a normal ligament attachment.

INDICATION
• Reconstruction of osseous defects.
• Root furcations repair.
• Augmentation of crests' volume.
• Covering of peri-implantal spaces.
• Covering of alveoli after tooth extraction.
• Pre and peri-implantal guided tissue regeneration.

INSTRUCTIONS FOR USE
• Use Paroguide to obtain a barrier effect when the reconstruction of a defect is necessary.
• First perform an incision (carefully determined) to show up the defect.
• Cut the membrane into the most suitable shape to cover perfectly the defect to be filled.
• Use the two sterile models supplied as models. They must not be implanted.
• Once modelled, place Paroguide over the defect, taking care to leave 2 to 3mm more to superpose the borders of the membrane to those of the defect.
• Eventually, keep Paroguide in position with resorbable sutures.
• Suture the flap with care without excessive tension.
• As Paroguide is a resorbable membrane, it is unnecessary to take it off.

PRECAUTIONS FOR USE
• Single use.
• Do not re-sterilize nor autoclave.
• Do not use if the package is damaged.
• This medical device must only be used by medical personnel.
• Keep out of the reach of children.

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CONTRA-INDICATION
Known allergy to any of the components.

SIDE EFFECTS
Up to the present, no side effect following the treatment with Paroguide has been registered. As Paroguide is a collagen-based product, it is impossible to rule out the possibility of allergic reactions.

VIRAL SECURITY
These membranes have been approved by the Work Group « Viral Security » of the French Agency of Sanitary Security of Health Products on March 5th 2001.

STORAGE
- 5 years from the manufacturing date, when correctly stored and if the original package is undamaged.
- Do not use past the expiry date indicated on the outer package.
- Store between + 10°C and + 25°C.

DISPOSAL
Recycle or dispose of according to current legislations, rather by a waste collector or an approved company. Do not dispose of in the environment.

CE
0373

Professional dental product.
Classification according to European Directive 93/42/EEC
Medical device class III

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