Tissue regenerative procedures are now an integral part of Reconstructive Periodontics, Implantology and Oral & Maxillofacial Surgery.

Guided Tissue and Bone regenerative procedures have become more predictable with the evolution of osteoconductive materials and bioresorbable barriers.

Equinox Medical technologies is pleased to present the Regenium™ product line comprising a continuum of three state of the art regenerative products.

The Regenium™ product line has been developed using the expertise of leading biomaterial scientists, working closely with a team of worldwide renowned clinicians in the field of guided tissue and bone regeneration.

The products are manufactured at world class production facilities in the US and the Netherlands. These facilities are certified to EN - ISO 9001:79 and EN 46001:1093 standards and the products are also registered in extensive US-FDA master files.

Ossiifi™

A unique biphasic hydroxyapatite-β-tricalcium phosphate molecule, with the highest documented degree of interconnecting porosity. The molecule is synthesized using a highly specialized and patented technology.

ProGide™

A Bi-textured resorbable collagen barrier membrane, produced using the latest triple collagen technique. This technology ensures the highest degree of strength & stability combined with the most predictable resorptive process.

INAKT™

A titanium tack-barrier fixation system. Intakt™ ultrasharp hacks feature a locking groove that firmly anchor them into bone thereby, securing and stabilizing barrier membranes.
Intakt™ titanium tacks are packaged in a unique self dispensing-lift off double sterile package. Tacks can be directly lifted off by the applicator straight from the blister, without transferring to the dispenser. Unused tacks can be stored in the stainless steel dispenser and autoclaved for future use.

The Intakt™ titanium tacks have an ultrasharp penetration point combined with a locking groove to prevent micromotion and offer stability to the membrane and graft material mass.

Intakt™ tacks are available in a pink/magenta colour so that they merge with underlying soft tissue without the graying of the tack showing through. Therefore in most cases removal of the tacks would not be necessary.

Ossifi™ is a porous biphasic bone graft material with exclusive features. This innovative product is supported by 20 years of clinical research and offers an evidence based solution for optimum bone ingrowth.

It is the result of an extensively researched and evaluated combination of Hydroxyapatite and ß-tricalcium phosphate in a 70/30 ratio. Biphasic calcium phosphates are the most tested and clinically proven biomaterials to date.

Ossifi™ is a synthesized combination of hydroxyapatite and ß-tricalcium phosphate creating a new molecule with new characteristics. This molecule remains constant throughout the whole process of resorption and bone formation, reducing the risk of cavities of fibrous ingrowth.

Moreover, Ossifi™ has a bioceramic matrix that is extremely biocompatible and highly osteoconductive.

The exceptional purity of the raw materials used in the production of Ossifi™ and its highly interconnected pores with 90% porosity, make it one of the worlds finest osteoconductive biomaterials.

Ossifi™ has been developed in such a way that it mirrors the chemical composition and structure of human bone. The biologic similarity to natural bone results in optimum biocompatibility and ensures that Ossifi™ is well tolerated by the body.

Ossifi™ at 3 months

The fully interconnected porosity of the Ossifi™ granule assures full interaction with host bone. The calcium phosphate composition of Ossifi™ enhances the biological resorption of the granule and ensures optimum bone ingrowth and formation.

Ossifi™ at 6 months

Ossifi™ offers the highest degree of 90% interconnected porosity. When Ossifi™ is placed in a bone defect, it only occupies 10% of the defect space leaving 90% of the space for regeneration of new bone. No other currently available biomaterial offers this degree of interconnected porosity. Unlike other xenogenic porous biomaterials where the pore size cannot be controlled and varies from batch to batch, the pore size of Ossifi™ is highly reproducible and constant. This reproducible interconnected porosity combined with a large granule innersurface area, provide the highest degree of osteoconductivity through clot stabilization, vascularisation, cell adhesion and penetration of host bone repair into the inner part of the graft material.

Applications

Implantology

- Alveolar ridge augmentation
- Alveolar socket preservation
- Sinus Grafts
- Defects around implants

Periodontology

- Periodontal infrabony defects
- Space filler in Guided tissue regeneration procedures

Oral Surgery

- Root resection defects
- Cysts and pathological defects
- Additive to autogenous grafts

Interconnected Porosity

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Ideally bone graft substitutes should be made of hydroxyapatite in its purest form, as this prevents trace elements from having a negative effect on bone ingrowth. Ossifi™ is produced from calcium phosphate in its purest possible form.

Unlike most other biphasic calcium phosphates, Ossifi™ is not just a mixture of hydroxyapatite and β-tricalcium phosphate. Ordinary mixtures do not guarantee the exact distribution of elements. Ossifi™ is synthesized through a combination of hydroxyapatite and β-tricalcium phosphate creating a new molecule. This composition has the advantage that the two elements are equally distributed over Ossifi™ without clustering, thereby reducing the risk of cavitation or fibrous ingrowth to almost zero.

Ossifi™ is available in two particle sizes for a perfect volumetric fill depending on defect topography.

The 1 - 2mm particle size would be indicated for filling of large defect spaces and sinus augmentations. The 0.25 – 1mm Ossifi™ particle size is indicated for smaller peri-implant/bone defects as well as periodontal defects.

Ossifi™ can be used on its own or in combination with an autograft. When wet with saline or blood the material instantly gels to a cohesive mass that can be carried and manipulated/adapted with ease. The granules should always be lightly packed without overfilling of the defect space.

Ossifi™ consists of calcium phosphate in its purest form and is free of human or animal material. The purity and synthetic nature of Ossifi ensure safe grafting without the risk of transmitting viral infections. The manufacturing facilities in the Netherlands adhere to the strictest guidelines for good manufacturing practice. The facilities are certified by TUV product services to EN-ISO 9001:79 and EN 46001:1093 standards and the product is also registered in an extensive FDA masterfile.
**Ossifi™ + ProGide™**

**Periodontal regeneration**

- Infrabony angular defect - pre-operative radiograph
- (Infrabony angular defect pre-operative radiograph)
- Mucoperiosteal flap raised and defect debrided
- (Flap raised showing thin ridge and root piece for extraction)
- Defect grafted with Ossifi™ granules 0.25 - 1mm
- (Defect grafted with Ossifi™ granules 0.25 - 1mm)
- Grafted site protected with ProGide™ stabilized by sutures
- (Grafted site protected with ProGide™ stabilized by sutures)
- Clinical picture 7 months post-op
- (Clinical picture 7 months post-op)

**Osseous regeneration**

- (Pre-operative clinical picture)
- Flap raised showing thin ridge and root piece for extraction
- (Flap raised showing thin ridge and root piece for extraction)
- Two Implants placed after bone splitting and immediate implantation
- (Two Implants placed after bone splitting and immediate implantation)
- (All peri-implant defect spaces grafted with Ossifi™ granules 0.25 - 1mm)
- (All peri-implant defect spaces grafted with Ossifi™ granules 0.25 - 1mm)
- Graft site protected with ProGide™ stabilized by Intakt™ titanium tacks
- (Graft site protected with ProGide™ stabilized by Intakt™ titanium tacks)
- (7 month post-operative radiograph)
- (7 month post-operative radiograph)

**Sinus augmentation**

- (Pre-operative X-ray of posterior maxilla requiring sinus graft)
- (Pre-operative X-ray of posterior maxilla requiring sinus graft)
- Autogenous cortico-cancellous bone harvested from symphysis & mixed with Ossifi™ granules 1-2 mm
- (Autogenous cortico-cancellous bone harvested from symphysis & mixed with Ossifi™ granules 1-2 mm)
- Buccal window with elevation of sinus lining
- (Buccal window with elevation of sinus lining)
- Simultaneous implantation & sinus grafted with autogenous bone - Ossifi™ mixture
- (Simultaneous implantation & sinus grafted with autogenous bone - Ossifi™ mixture)
- (Post-operative X-ray at 6 months after implant placement)
- (Post-operative X-ray at 6 months after implant placement)
- (Clinical picture 7 months post-op)
- (Clinical picture 7 months post-op)
- Post-operative X-ray at 6 months after implant placement
- (Post-operative X-ray at 6 months after implant placement)

**Root resection repair**

- (Pre-operative X-ray showing periapical lesion)
- (Pre-operative X-ray showing periapical lesion)
- Periapical lesion debrided and root resected
- (Periapical lesion debrided and root resected)
- ProGide™ membrane fixated with Intakt™ titanium tacks
- (ProGide™ membrane fixated with Intakt™ titanium tacks)
- Bone defect filled with Ossifi™ Granules 1 - 2mm
- (Bone defect filled with Ossifi™ Granules 1 - 2mm)
- ProGide™ free surface fixated with Intakt™ tack
- (ProGide™ free surface fixated with Intakt™ tack)
- 6 month Post op xray shows homogenous bone fill
- (6 month Post op xray shows homogenous bone fill)
Resorbable barrier membranes are today considered the standard of care in guided tissue and bone regeneration procedures.

Resorbable barriers primarily are available as derivatives from synthetic polymers (lactide & polylactic acid) or from natural sources such as collagen.

Collagen is one of the most biocompatible, documented and researched biomaterials. Collagen is a fibre protein that has the structure of a triple helix consisting of fibrils intertwined together resulting in high strength. The resulting product mirrors the functional periostem to act as a physiological barrier.

ProGide™ is a bi-textured, resorbable, non friable barrier membrane engineered from highly purified type 1 collagen derived from bovine Achilles tendon.

ProGide™ is produced using the latest triple collagen technique to provide an optimized degree of flexibility & rigidity combined with a very predictable resorptive process.

The product has a defined geometry, in vivo stability, permeability and mechanical strength for use as a barrier material and to aid in wound healing of periodontal defects, bone repair, ridge augmentation and dental implant procedures.

Bi-Textured surface & Cell occlusivity

ProGide™ is specially engineered to provide two distinctive surface textures. A dense outer surface and a roughened porous inner surface. The dense outer surface in contact with the soft tissue is cell occlusive and designed to retard and or prevent epithelial downgrowth. It therefore prevents contact of gingival connective tissues with the implant or healing bone surface. At the same time its macromolecular pore size allows for nutrient transfer.

The roughened porous surface favours bone ingrowth at a cellular level. This surface is in contact with the bone and encourages cellular osteoblastic integration surface at the same time stabilizing the blood clot.

Resorption time

Resorbable membranes promote wound healing and remain unaffected by even small dehiscences or exposures. They provide an excellent barrier and negate the need for a second stage surgery to remove them. To achieve true guided bone regeneration the membrane should not begin resorbing before at least the fourth month and completely resolve at the end of 6–7 months. The healing graft material mass needs this minimum period for true ossification being protected by the membrane from any connective tissue ingrowth.

ProGide™ has the longest in vivo stability or resorption time of 26–38 weeks, this accounts for sustained function during bone repair process.

The natural resorption process of ProGide™ is the result of the enzyme collagenase that splits the collagen molecule into fragments that are further denatured at 37 °C to gelatine, which is taken care of and broken down by gelatinases and proteinases to oligopeptides and natural amino acids.

High tensile strength

The unique arrangement of the collagen fibres in ProGide™ make it a tear proof non friable barrier. The high tensile strength allows it to be sutured or fixed with pins or tacks to prevent micromotion of the graft material mass.

Product size & delivery

ProGide™ is available in a size of 20mm x 25mm or 25mm x 30mm and is cut and adapted to the defect size. Templates can be used to facilitate cutting of the membrane to the right dimensions.

The product is delivered in a double sterile blister pack.

The smooth surface faces the soft tissue while the easily identifiable rough surface faces the bone. Once moistened the collagen fibre gel formation allows the membrane to be perfectly adapted to any bone defect surface or topography.

In case of wound dehiscences the area should be kept clean with antibacterial rinsing and the properties of collagen allow for predictable healing over these dehiscences.

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Scan electron micrographs of the ProGide™ membrane at various magnifications

(a) Smooth surface at 1600x
(b) Rough surface at 200x
Stabilisation of a barrier membrane is a key factor to predictable results and success in GTR for periodontal defects as well as in GBR procedures around dental implants.

The Intakt™ system is a state of the art titanium tack barrier fixation system that ensures a safe and rapidly effective method to easily secure membranes to underlying bone.

The system comprises a well designed application set offering straight and angled applicators as well as a tack dispenser.

Intakt™ titanium tacks are packaged in a unique self dispensing-lift off double sterile package. Tacks can be directly lifted off by the applicator straight from the blister, without transferring to the dispenser. Unused tacks can be stored in the stainless steel dispenser and autoclaved for future use.

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It is the result of an extensively researched and evaluated combination of Hydroxyapatite and ß-tricalcium phosphate in a 70/30 ratio. Biphasic calcium phosphates are the most tested and clinically proven biomaterials to date.

Moreover, Ossifi™ has a bioceramic matrix that is extremely biocompatible and highly osteoconductive. The exceptional purity of the raw materials used in the production of Ossifi™ and its highly interconnected pores with 90% porosity, make it one of the world's finest osteoconductive biomaterials.

Applications

- Implantology
- Periodontology
- Oral Surgery

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