



# 4BONE RCM

Next generation of dental membrane

Nature provides all needs for bone regeneration...

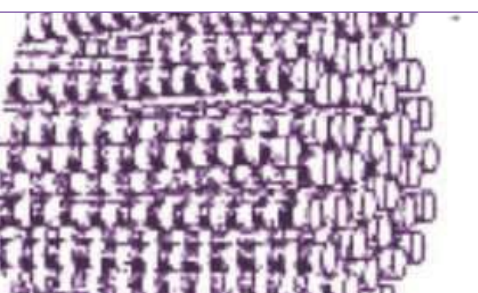
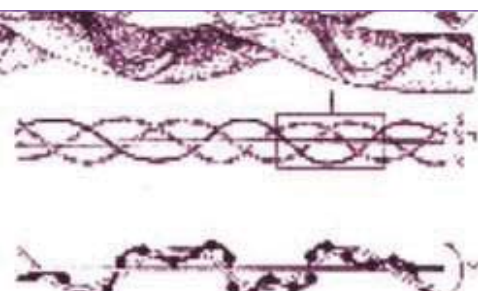
Our goal is to help and improve this process.

#### 4BONE RCM Advantages.

- Excellent Handling Characteristics
- Unique Manufacturing Process to optimize Cross linking
- Barrier Functionality Guarantee



## Concept / Biocompatibility.



4BONE RCM is a resorbable porcine skin-sourced collagen dental membrane for Guided Bone Regeneration (GBR) and Guided Tissue Regeneration (GTR), which is manufactured using unique cross linkage technology provides the membrane with its ability to maintain barrier functionality for 4-6 months.

4BONE RCM is derived from porcine collagen which has been successfully used in a variety of medical and dental applications for many years due to its high degree of biocompatibility. Porcine tissue is viewed as the material of choice in many medical xenograft procedures. In the literature it has been demonstrated that the immunogenicity of porcine collagen is very low, lower than seen with bovine collagen. Porcine collagen also avoids many of the issues related to Bovine Spongiform Encephalopathy (BSE).

### Purified collagen

- Purified collagen from skin
- Collagen type I and III
- Conservation of the fibrous structure (mechanical strength)

### Crosslinkage

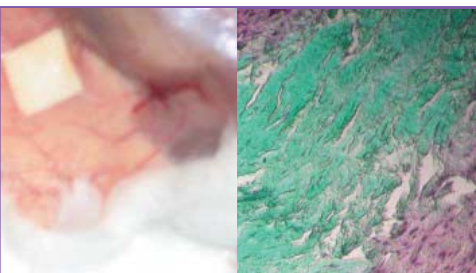
- A bath in the crosslinking reagent
- Chemical bounds between the molecules
- Enhancement of the resorption time
- Neutralisation : elimination of the residual crosslinker
- Chemical analysis of residual reagent



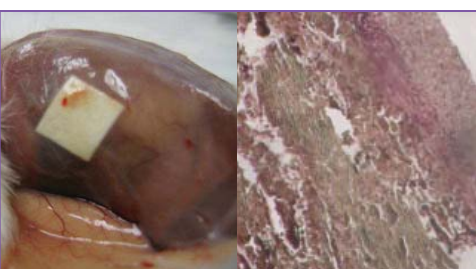
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## Resorption Control.



3 months explantation



6 months explantation

A control process of collagen cross-linking provides 4Bone Rcm Membrane its ability to function as a 4-6 month barrier that allows sufficient time for osseous defects to achieve optimum bone regeneration. We can directly control the level of collagen cross-links to affect the longevity and degradation profile of the material. Micro Porous; 4Bone Rcm permit the diffusion of fluids and nutrients related to soft tissue health. 4Bone Rcm degradation has been tested in animal model. At 3 and 6 months we observed that 4Bone Rcm assume its barrier function as desired. Cross-Linking technology differs from one membrane to another one, these differences influence considerably the degradation of the membrane in time. We performed accelerated enzymatic degradation in vivo comparing 4Bone Rcm to other membranes technology from several sources (Porcine/Bovine).



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## Soft and Elastic.



Mechanical strength tests :

- Tensile strength
- Suturability

elastic resistance  $> 1\text{N}$  (on a test tube of  $2 \times 0.5\text{cm}$ )

suturable with a resistance to the joining  $> 0.5\text{N}$  (test tube sutured of  $2 \times 0.5\text{cm}$ )

Indications and contraindications:

Indications: 4BONE RCM is a bioabsorbable membrane. The 4BONE RCM intended for use in periodontal/dental surgery procedures as a material for placement in the area of periodontal defect, dental implant, bone defect or ridge reconstruction to aid in wound healing post surgery. Considering 4BONE RCM indications and resorption time, it is recommended to combine the membrane with bone graft to new bone healing by osteoconduction and osteoinduction (ex 4BONE SBS).

Limitations for use:

Due to the adherence to the bone tissue and the elasticity of 4BONE RCM bone augmentation material is required to create and maintained space for bone formation (ex 4BONE SBS). 4BONE RCM is therefore not indicated for single use in guided bone regeneration (GBR) without any space-marking material. 4BONE RCM should not be placed where active infection exists. Before placement, the surgeon should be confident that any active or recent infection has been properly treated.

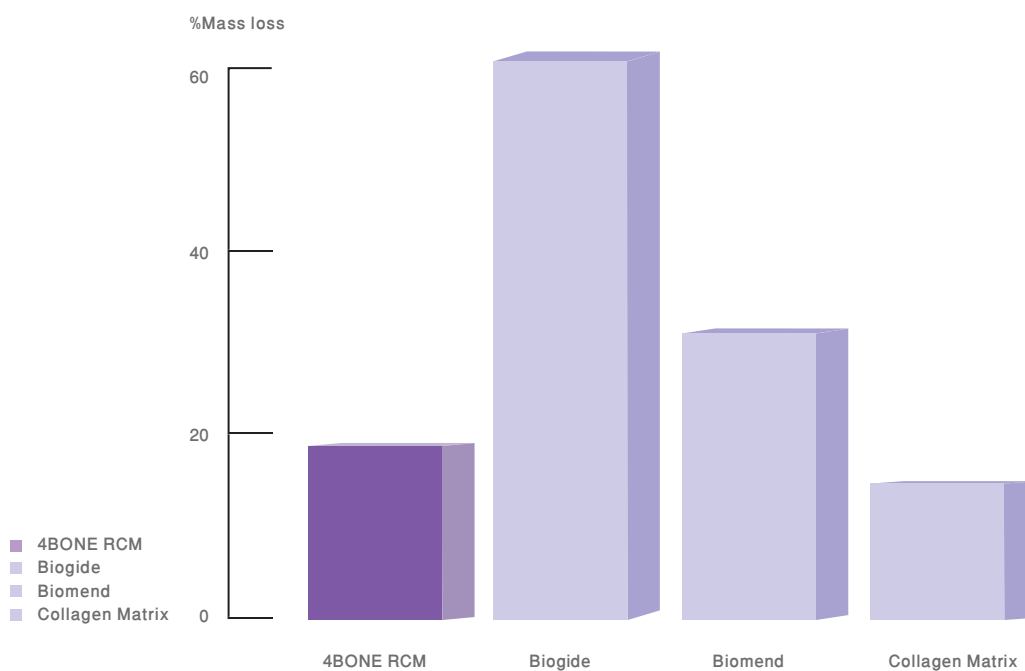


Adverse reactions:

4BONE RCM is high pure collagen membrane, adverse reactions after the use of 4BONE RCM have not been observed. Since it is a collagen product allergic reactions may not be totally excluded and adverse reactions like fever experienced with another microfibrillar collagen may be related. However, the following potential side effects may be noticed due to the surgical intervention; dehiscence, hematoma pain, increased sensitivity and pain, redness and inflammation.

## In Vitro Resorption Control.

Results demonstrate membranes percentage of loss of mass calculated during 48h of in vitro degradation.



Statistics averages loss of mass:

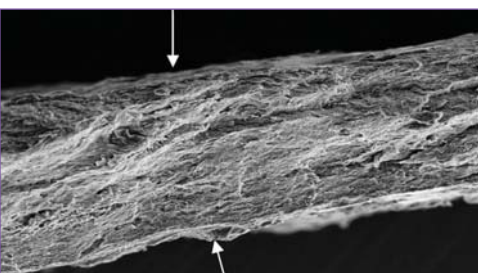
- BIOMEND: 31.01%
- COLLAGEN MATRIX: 15.83%
- BIOGIDE extend: 60.32%
- 4BONE RCM: 19.12%



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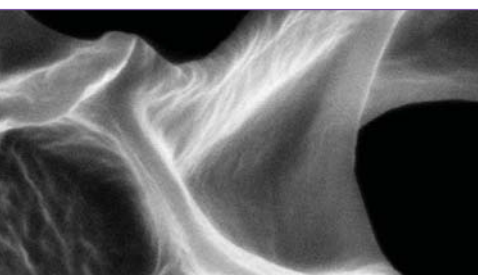
## Exceptional Handling.



Membranes are important to optimize clinical results of bone volume augmentation and therapeutic success.

4BONE RCM is the result of unique manufacturing process creates a longer resorption suitable to GBR procedures with exceptional handling properties.

- Easily cut to size, shaped and applied
- Easy to place with no need to tack or suture the material
- Exceptional tissue adherence during application
- Flexible and adaptable to varying bone topographies
- Available in different sizes



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