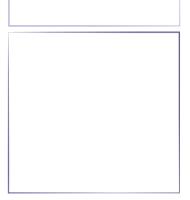


Resorbable Collagen Membrane

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MIS Warranty: MIS exercises great care and effort in maintaining the superior quality of its products. All MIS products are guaranteed to be free from delects in material and workmanship. However, should a customer find fault with any MIS product fatter using it according to the directions, the delective product will be replaced.



MIS Bone Grafting Solutions.

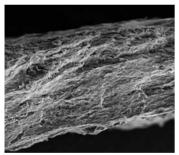
MIS offers a variety of advanced bone and tissue regeneration products aimed at a wide variety of clinical conditions and surgical requirements. All products in this category are packed in varying weights and volumes and in user-friendly containers and utensils, allowing practitioners to choose the precise quantity required for each procedure.

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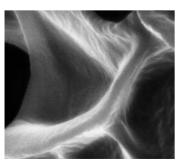


Product Description.

4BONE RCM is a resorbable dental membrane made from porcine skinsourced collagen, aimed for guided bone and tissue regeneration (GBR and GTR). Due to its substantially proven biocompatibility and low immunogenicity, porcine collagen has been successfully used in a variety of medical and dental procedures for many years. 4BONE RCM production involves a cross-linkage technique, enabling functionality as an efficient barrier for a 4-6 months period.



Microporosity 100µm



Microporosity<5µm

Purified collagen properties

Purified skin-sourced collagen = Collagen types I and III = Preservation of the fibrous structure (supporting mechanical strength)

Cross-linkage production technique

A bath in a cross-linking reagent - Prolonged resorption time

Neutralization: elimination of the residual cross-linker
Chemical
analysis of residual reagent

Resorption Control

Unique Cross-Linkage Technique.

The controlled process of collagen cross-linking allows sufficient time for bone regeneration and rehabilitation of osseous defects. The collagen cross-linking is directly controlled to assure the material's ideal longevity and degradation profile. Verified by animal testing, the degradation of 4BONE RCM membranes is perfectly consistent.

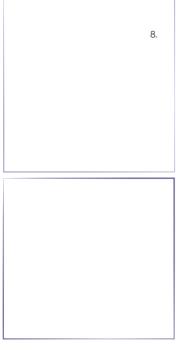




Cross-linkage



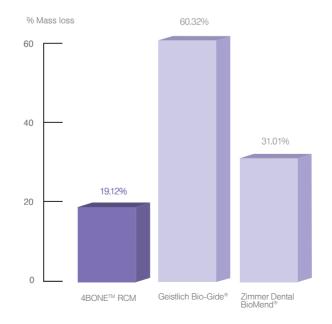
Collagen structure



In-Vitro Resorption Control.

The following comparison demonstrates the rate of mass loss after 48 hours of in-vitro degradation in different types of membranes.

Averages loss of mass



Advantages.

The 4BONE RCM membrane is the result of extensive research and development, aiming at a functional barrier that remains intact for a specific period of time.

Efficient

Allowing sufficient time for osseous defects to achieve optimal regeneration, 4BONE RCM barrier enables successful application for various indications.

Easy handling

Easy to handle, cut to size, shape and apply. Easy to place, with no need for sutures or pins. Flexible and adaptable to various bone topographies.

Safe

The porcine source ensures an improved sanitary safety and a complete and validated traceability.

Architectural bone remodeling

The 4BONE RCM microstructure and macrostructure represents a dynamic process, including physico-chemical processes, crystal/protein interactions, cell and tissue colonization and bone remodeling.

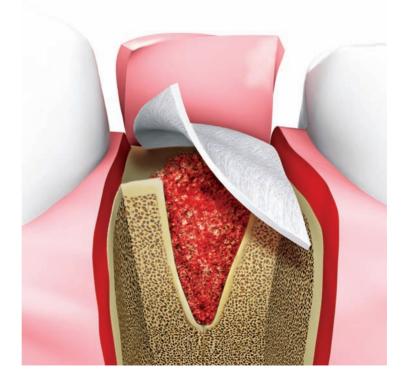








4BONE RCM is a bioabsorbable membrane. It is intended for use in periodontal/dental surgery procedures, for placement in areas of periodental defect, dental implant, bone defect or ridge reconstruction; to support wound healing post surgery. It is recommended for use with a bone graft material to promote new bone healing.

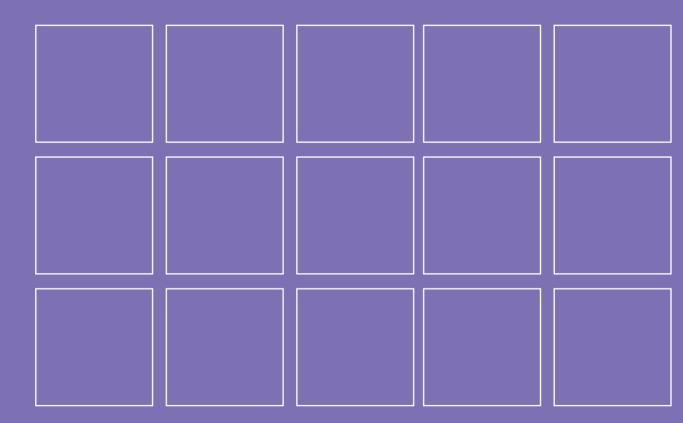


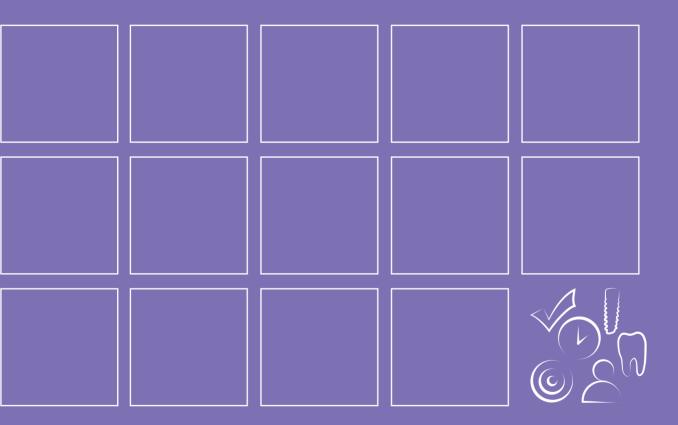
Tissue preservation is essential for efficient primary closure of the wound and for the correct positioning of the flaps.

Packaging.

4BONE RCM packaging is designed to ensure sterility. The external layer of the double pouch should be carefully opened and the inner pouch placed onto a sterile field. The membrane should be removed from the inner pouch using sterile gloves or instruments.







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MIS Quality System complies with international quality standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 - Quality Management System and CE Directive for Medical Devices 9342/EEC. MIS products are cleared for marketing in the USA and CE approved.