



MAGGI Biotechnology
LTD
BIOINNOVATION

Exaflex

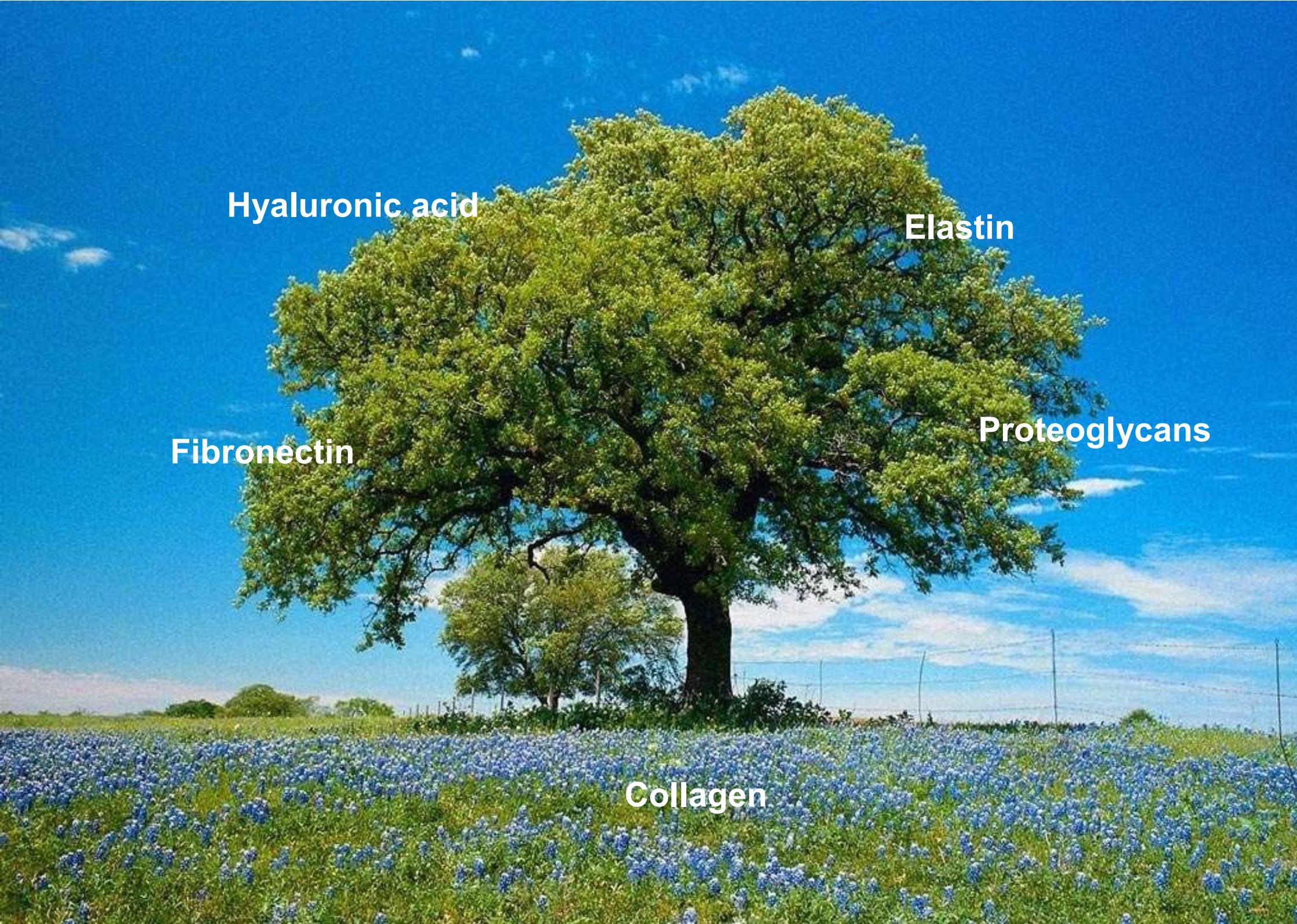
Bilayer bovine pericardium

Exaflex

The bovine pericardium appears as a membrane with elevated tensile strength and good elasticity.

This product category is widespread in all countries and in many medical disciplines. The products present so far were made up essentially from multi-directional and braided collagen fiber they had a single layer.

An innovative is used for the preparation of the **Exaflex** membrane deantigenization process that allows to maintain the functional elements of the ECM and thanks to a controlled freeze-drying process the fibrillar layer is preserved.



Hyaluronic acid

Elastin

Fibronectin

Proteoglycans

Collagen

Exaflex

Cellular matrices are designed by various chemical and mechanical processes. The ultimate goal is to remove all components cell phones using a harmless procedure that is capable of maintain the structure and function of the original tissue. The more compatible the final product is with the host tissue, the less likely it is to trigger an adverse reaction. The different production phases of each product, however, can degrade the structure of the original tissue or eliminate the growth factors linked to the components of the ECM. This can cause rapid degradation and rapid resorption of the matrix and the formation of scar tissue.

The occurrence of an adverse reaction can be evidenced by the presence of inflammation with accumulation of cells around the edges of the matrix, which prevents cell or vascular infiltration (encapsulation).

The ideal response is minimal inflammation and gradual degradation of the matrix over time, with full integration into the host tissue. The way a product is manufactured is as important as its origin.



Substances normally used in production or conservation such as: acetone, alcoholic solutions or inadequate freeze-drying processes cause the destruction of the fibrillar layer

Exaflex

Acellular matrix products can be used in a wide range of applications, including burns and reconstructive surgery, soft tissue and abdominal wall repair, and as internal implants for orthopedic use in joint surface reconstruction and joint repair tendons.

The extracellular matrix (ECM) plays an important role in the regenerative process of the tissue. The composition of the ECM includes proteoglycans, hyaluronic acid, collagen, fibronectin and elastin. In addition to providing structural support to cells, some components of the ECM bind to growth factors, creating a reservoir of active molecules that can be rapidly mobilized after damage to stimulate proliferation and migration.

Once placed in the wound bed, the three-dimensional matrix provides a temporary scaffold or support on which cells can migrate and proliferate in an organized manner, leading to tissue regeneration.

The Exaflex membrane provides the substrate ideal for the establishment and proliferation of cells

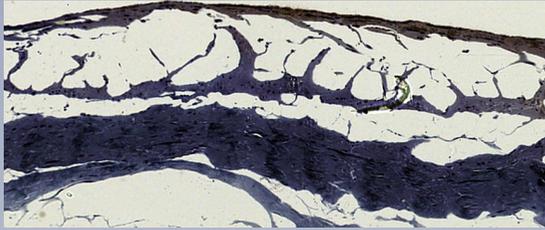


Exaflex

BILAYER

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The innovative system for the deantigenization of the bovine pericardium introduced in 2015 by the MAGGI Biotechnology allows to preserve the fibrillar layer constituting a bilayer cell matrix.

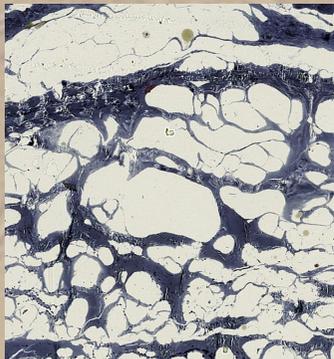


Compact non-stick layer and resistant to bacterial invasion



Bilayer bovine pericardium structure

Exaflex



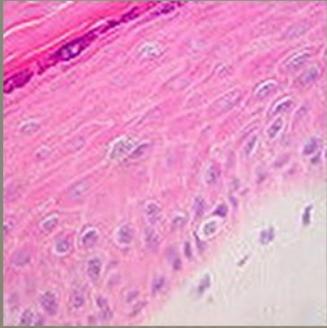
Fibrillar layer that allows revascularization and cell adhesion



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Collagen is the main constituent of resorbable membranes. The source of collagen collection is varied, usually of animal, bovine, porcine, equine origin. Collagen can be extracted from connective tissues, hence tendon, skin, bones.

Although it is the same protein, the source of withdrawal and the processing process can determine somewhat different biological behaviors.



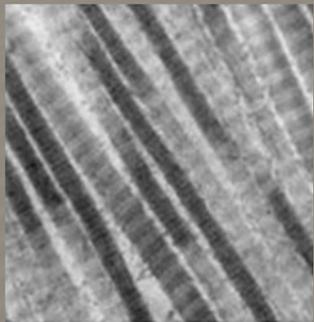
Derma

Il derma sia di natura bovina che porcina non viene rivitalizzato dopo il suo innesto.
A seguito dell' innesto inizia l' immediata demolizione della struttura da parte delle collagenasi.
La rapida demolizione è compensata da un prodotto a grande spessore, oltre 1 mm. che risulta poco maneggevole e richiede un costante drenaggio per lo scarico degli essudati.



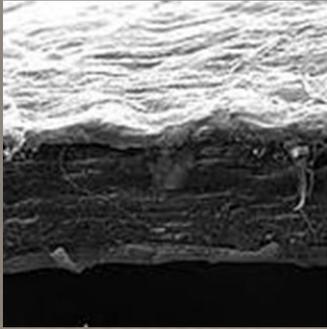
Reconstructed collagen

This collagen fiber is obtained by lyophilization of broken collagens from the skin or tendons. This type of membrane has weak mechanical characteristics as it arises as a cover for abrasion wounds. The collagen fiber is not revitalized and after contact with Injured epithelia begins the demolition phase by collagenases. The membrane has no anti-adhesion characteristics and its reabsorption time is approximately two weeks. In the event of inflammation of the graft area, the resorption time is significantly shortened.



Human skin

Human skin taken from donors is used on patients who have suffered severe burns. This fabric is used for external use only and has no mechanical resistance



Equine Pericardium

The equine pericardium is represented by a complex structure of single-layer collagen fiber. Although thin about 0.2 mm, it has excellent mechanical characteristics and good anti-adhesion qualities. It is usually incorporated into the tissue that welcomes it and thanks to its high density it has a rather long reabsorption time, about 12 months. It turns out to be a good substitute for the dura mater, the tympanic membrane and in all those cases where a very high tensile strength is not required.



Bovine pericardium

The bovine pericardium has the fundamental characteristic of being BILAYER. It has two sides, one completely smooth non-stick and with pores that do not allow the passage of liquids and bacteria, the other with three-dimensional crossed fibers that allow the revitalization of the fabric by the fibrocytes. It has mechanical characteristics such as to make it useful in all heavy-duty uses that require strong tensile strength, tear and sutures. It comes in thicknesses ranging from 0.2 to 0.8 mm. Its resorption time is about 35 months.

Exaflex

Exaflex pericardium consists of pure bilayer bovine pericardium collagen with multi-directional intertwined fibers. This collagen is type I, known for its low tendency to cause immunological reactions.

The preparation process tends to eliminate non-collagenic components such as lipids, proteins, enzymes, etc.

The freeze-drying process helps to maintain the natural structure of the collagen fibers, allowing optimal integration conditions to the tissues after implantation.

Material safety

Exaflex membranes are made from bovine pericardium. Bovine materials are considered to be at BSE risk e therefore they require a different CE certification procedure from other types of animal grafting.

The certification procedure requires the consent and validation of the processes by all the Higher Health Institutes of the European Community to allow the free circulation of material.

The checks require the following steps:

Analysis of the origin of the raw material and traceability of produced by the Notified Body. Annual control by the Notified Body of the pick up station.

Verification of the absence of cross-contamination in the production.

Verification and validation by the Higher Health Institutes of the deactivation and inactivation processes of prion charges.

Verification of Quality Systems.

Consent from all European Health Ministries al issue of CE certification.

The biological functioning

The **Exaflex** membrane consists of a double layer of fiber multi-directional braided collagen. It therefore has a side extremely compact non-stick and extremely resistant to the passage of bacteria and a fibrillar side which constitutes a ideal environment for cell revitalization.

Bilayer membranes undergo a revitalization by the endogenous connective tissue in 3 stages:

The contributing fibrocytes migrate into the fibrillar layer anchoring it to the surrounding structures through the formation of a neo membrane surrounding the implant.

Fibrocytes migrated into the three-dimensional structure of the membrane bilayer, initially they do not synthesize collagen but adapt their metabolism to contribute to the maintenance of existing collagen fibers.

After a few months the degradation of the structure begins three-dimensional collagenase induced. Collagen comes degraded and replaced by new fibrocytes. The neostructure is infiltrated and nourished by the capillaries that grow easily in the matrix three-dimensional.

Pericardial sampling comes carried out at the stations of slaughter by technicians Maggi srl specialists who ensure the absence of cross contamination and the correct tracing of the picked material that is isolated in double packaging ed labeled with the highest possible tracking system



Exaflex

The **Exaflex** membrane represents a new generation of ECM capable of combining the mechanical function thanks to a process of dedicated freeze drying that allows you to change the arrangement three-dimensional collagen by improving the characteristics of resistance to traction and tear and to the improved biological functioning that assists the regeneration processes.

The **Exaflex** membrane is therefore an advanced product for improve surgical therapies.

COLLAGEN

It forms the body of the membrane. Made up of two layers, one compact and impermeable to external agents and one fibrillar multi-directional that is placed in contact with the injured tissue. The three-dimensional fibrillar layer is the ideal environment for cell settlement and vessel proliferation

ELASTIN

It makes the membrane extremely manageable and easily adaptable to the conformation of the lesion

FIBRONECTIN

Cells need to attach themselves to the extracellular matrix to move, but they don't attach well to collagen. So another protein of the matrix acts as a bridge: fibronectin. Fibronectin dimers have two collagen binding sites and two membrane protein binding sites in cells: integrins.

PROTEOGLICANS

As collagen offers tensile strength, another component confers resistance to compression: proteoglycans, which serve to fill spaces. Due to their porous and hydrated organization, the chains of glycosaminoglycans allow the rapid diffusion of water-soluble molecules and the migration of cells and their extensions.

ACID HYALURONIC

In the amorphous matrix it is responsible for maintaining the degree of hydration, turgidity, plasticity and viscosity since it is arranged in the space in an aggregate conformation thus taking a considerable number of water molecules, preventing the dehydration of wound. It works as a filter against the diffusion into the tissue of particular substances, bacteria and infectious agents. Only substances with a molecular weight low enough to pass through the "mesh" of this network will be able to diffuse freely in the tissue; all substances with a higher molecular weight as well as bacteria will become entangled in the net.

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