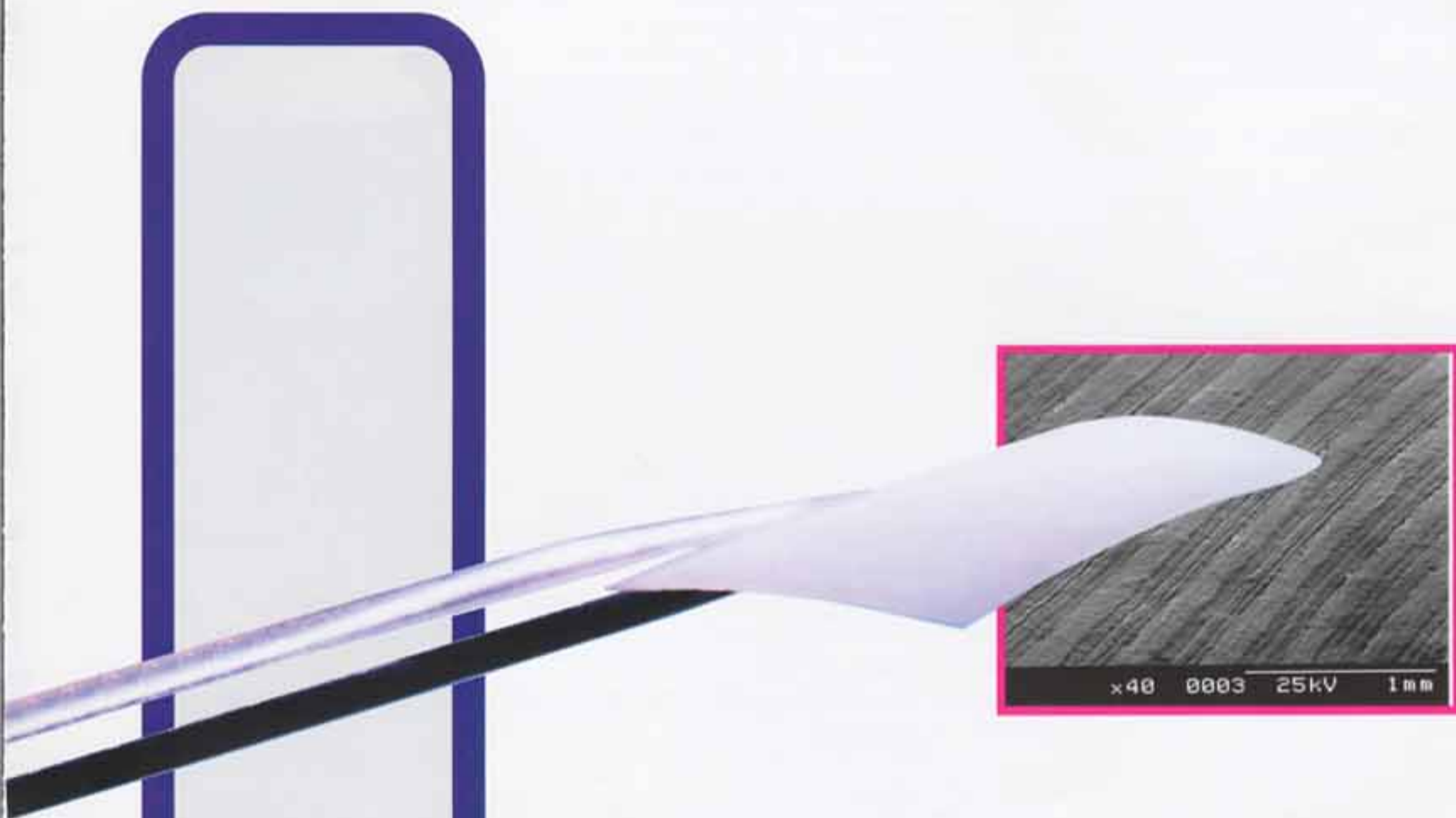




# New Bone<sup>®</sup>

BIOMEMBRANE



## ORIGINS OF THE BIOMATERIAL

Studies on equine cartilage revealed that this material possesses many properties typical of human cartilage.

In 1985, New Bone Laboratories began a series of trials with bovine, swine and equine cartilage with a view to be able to use it as a substitute for human cartilage. Up to date, this product has been used in thousands of cases for the reconstruction of the floor of the orbit, of the external and middle ear, of the nasal septum, of the cranial wall and, more recently, in dental implantology.

In all fields this product has been widely acknowledged for the total absence of irritative phenomena.

## GUIDED TISSUE REGENERATION

Guided tissue regeneration is achieved by isolating a space in bone structures from surrounding soft tissues. Connective tissues regrow more rapidly than bony tissues, and by invading empty spaces it prevents bone regeneration. An essential condition for bone regrowth is the construction of a layer under which the connective tissue is kept away for a period long enough to consent regeneration. NEW BONE BIOMEMBRANE creates these conditions, it is stiff enough to create a "tent effect" and can even be used without filling biomaterials.



New Bone Biomembrane  
thickness of 500 microns  
It is stiff enough  
to create a  
"tent effect".

## INSTRUCTIONS

NEW BONE BIOMEMBRANE can be fixed where needed either by applying pressure or with a few stitches.

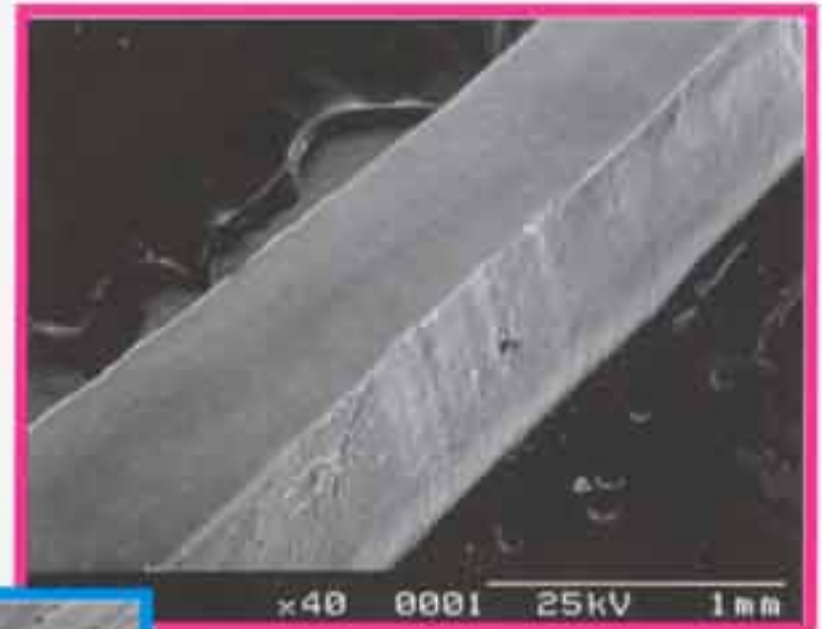
NEW BONE BIOMEMBRANE can be easily cut and modelled using any surgical tool. The product is preserved in alcohol solution; before use rinse briefly in physiological solution.

Once open, any remaining NEW BONE BIOMEMBRANE should be thrown away and not re-used.

## FIXING

The finely furrowed surface of NEW BONE BIOMEMBRANE increases the surface-volume ratio and favours a solid adherence to surrounding tissues thus stabilizing the implant. It can be fixed either by applying stitches with nylon or polypropylene or by using reabsorbable materials. After roughly 6 weeks NEW BONE BIOMEMBRANE will be naturally encapsuled by a thin layer of fibrous tissue which adheres to surrounding tissues and not to cartilage. Within 6 months the total or subtotal reabsorption of the biomembrane will have taken place.

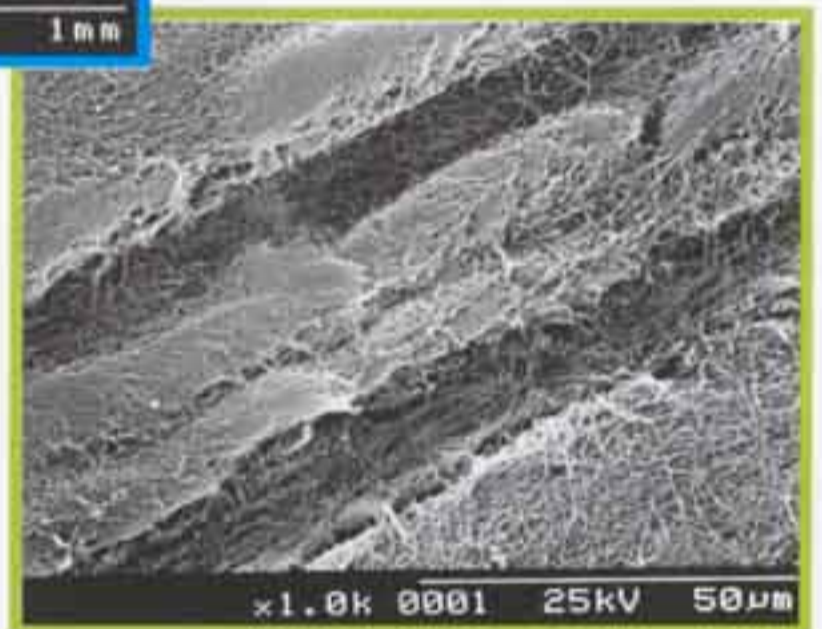
SEM image of the edge of the New Bone Biomembrane 500 microns thick. Edge of amorphous section, surface of the membrane delicately grooved.



SEM image of the surface of the New Bone Biomembrane. The furrowed appearance increases adhesion to coating tissues, thus favouring its early stabilization.



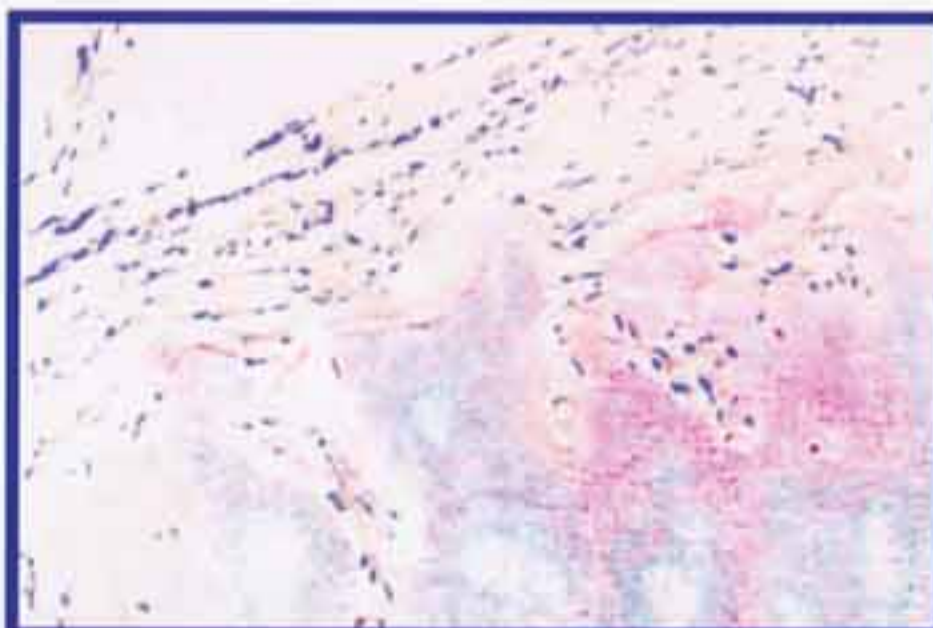
SEM image of the surface of the New Bone Biomembrane. Two microgrooves are visible. The apparently amorphous mass of the cartilage is made up of interlacing collagen fibres.



## REABSORPTION

Reabsorption takes place starting around the 6th/8th week - according to subjective variability - as a foreign body reaction which manifests in fibroplastic phagocytosis. From the second month onwards the membrane is encapsulated in fibrous tissue, it presents serrated edges and splits into which fibroblastic extensions are seen to penetrate. Reabsorption continues until all the cartilage has been transformed into fibrous tissue, around which a moderate infiltration of lymphocytes, eosinophils and histiocytes can be seen, as well as small areas of calcification.

Histological preparation X 400 hematoxylin eosin. Biomembrane during reabsorption: encapsulating in fibrous tissue, fragmentation of the cartilage and fibroblastic compenetration.



## MECHANICAL RESISTANCE

New Bone Biomembrane resists to pressures of 50 kg./cm.<sup>2</sup> and to traction of 2.5 kg. on a linear tract of 1 cm. It can be folded at right angles without splitting, so long as too much compression is not placed on the fold.

NEW BONE BIOMEMBRANE presents resistance to pressure and to traction greater than that required for surgical procedures. It is so flexible that the membrane can be folded at right angles so long as not too much compression is placed on the actual fold. Stitches can be applied delicately; excessive pressure exerted by the suture thread can cut through the membrane.

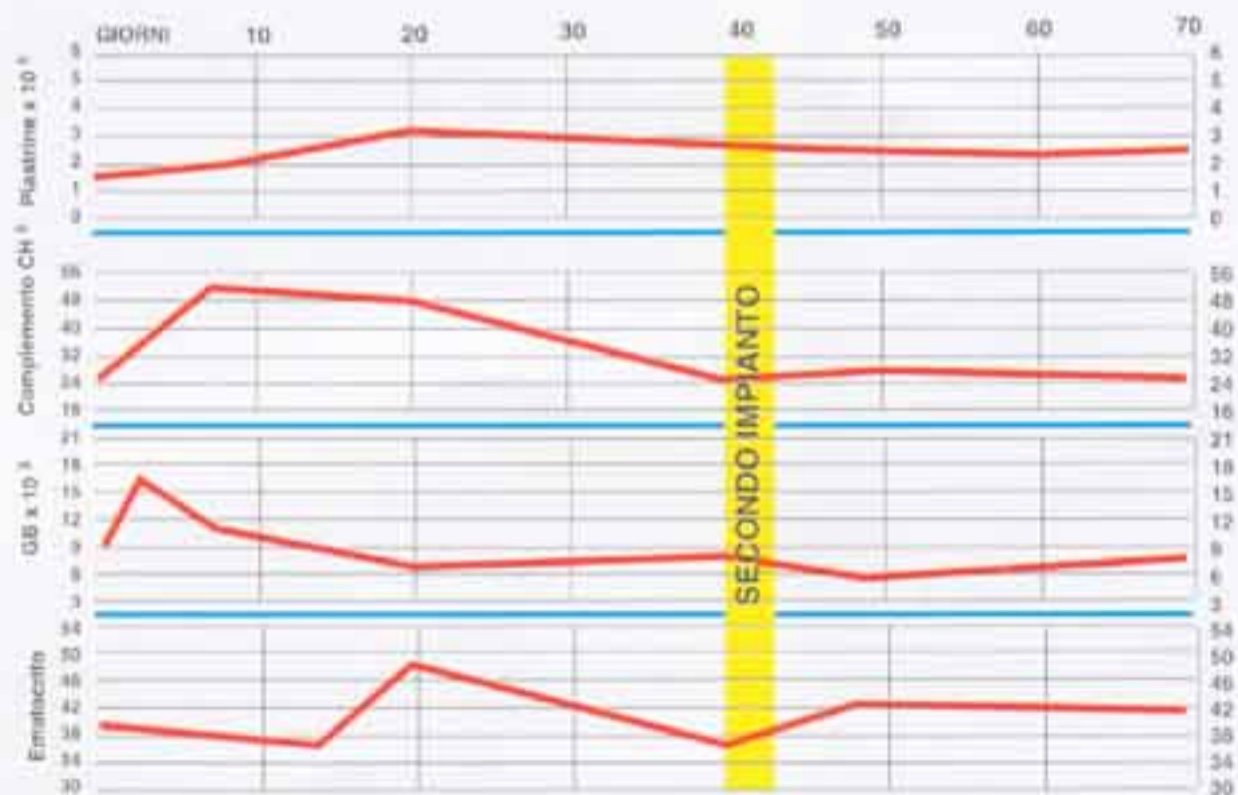


## CLINICAL CHARACTERISTICS OF THE BIOMATERIAL

The treated equine cartilage of which NEW BONE BIOMEMBRANE is made has been used in neurosurgery, plastic surgery, ear nose and throat surgery and eye surgery prior to its application in dental implantation technology. Treated equine cartilage has been used in close contact with nerve, bone, cartilage, muscle and subcutaneous tissues with excellent results. Experiments carried out on animals have shown that encapsulation takes place in the same way as for that of all inert foreign bodies. Research has shown that problems linked to antigenicity do not exist; clinical studies have shown that the use of treated equine cartilage in man is harmless.

Tests for pyrogenicity and direct contact cytotoxicity, carried out on commercially packaged NEW BONE BIOMEMBRANE proved that the product was not pyrogenic and not cytotoxic: direct contact cytotoxicity grade zero.

Results of a study which demonstrates that there are no significant changes in blood parameters after first implant with treated bovine cartilage and after second implant (study of sensitivity). Neither the first nor the second implants induce an antigen-antibody response that can be systematically observed.



## BIOINERTIA

NEW BONE BIOMEMBRANE is a biomaterial treated and sterilized so that it can be tolerated by the human body in the same way as any inert implant. If infection takes place, it can be blocked with antibiotics; infection speeds up reabsorption times.

## TREATED EQUINE CHONDROPROSTHESIS

NEW Bone biomembrane is derived from equine cartilage, stripped of the perichondrium; the remaining structure is treated chemically and sterilized via radiation.

All animals were younger than 24 months and have valid veterinary certificates.

Immediately after being removed, the cartilage is transferred to laboratories where the best parts for construction of the biomembrane are selected.

The selected portions of cartilage are then treated chemically and examined under the operating microscope in order to select the areas which are more suitable for use on the grounds of consistency and elasticity; after which they are thinned down and cut into preformed shapes.

The surface of NEW BONE BIOMEMBRANE is modelled into microfurrows in order to increase the surface-volume ratio.

All above mentioned methods are in compliance with the ISO 9002 norms which require monitoring of each phase of preparation, of the origin of lots of the cartilage, of the control cards for machinery used, of flow charts for production and of quality controls carried out with purpose-built equipment for checks on the intermediate and final products.

NEW BONE BIOMEMBRANE, at the end of the work cycle, is tested for flexibility and resistance.

Processing and packing of NEW BONE BIOMEMBRANE is carried out in a white room with class 100 filtered atmosphere, on runout tables with laminar flow. A bacterial count is carried out on each lot of cartilage at the end of production, in order to establish whether it is suitable for sterilization.

Lots with concentrations greater than  $1,5 \times 10^4$ /gr. are eliminated. Test for cytotoxicity and pyrogenicity carried out on the final product ready for distribution, showed that NEW BONE BIOMEMBRANE does not cause inflammatory processes of the tissue.

NEW BONE BIOMEMBRANE is presented in double packets containing physiological solution for maintenance of the product. Each package exhibits production, sterilization and sell-by dates and lot number.

## CONTRINDICATIONS

NEW BONE BIOMEMBRANE should not be implanted in patients with allergies to equine meat.



# New Bone<sup>®</sup>

BIOMEMBRANE

distributed by



Produced by

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