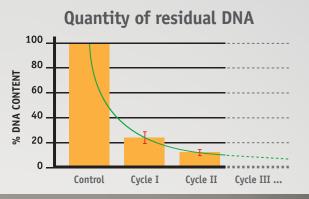
Biochemical characterisation

Biochemical Laboratory/Quality Control - Bioteck S.p.A.

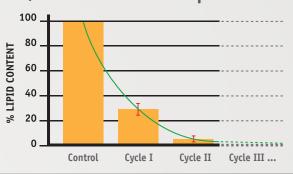


The DNA content is directly proportional to the cell population pre-

sent in the tissue.

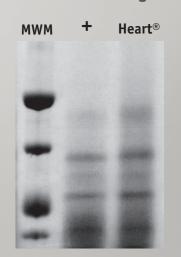
The "control" is untreated pericardium. The other columns show the constant reduction of residual DNA following the first treatment cycle according to the Zymo-Teck® process. Further cycles help guarantee complete deantigenation.

Quantification of the lipid content



The "control" is untreated pericardium. The other columns show the drastic reduction of the lipid content after the first treatment cycle according to the Zymo-Teck® process.

Preserved collagen



Electrophoretic separation on denaturing gel (SDS-PAGE). The first column (MWM) shows the molecular weight markers, the second (+), a type I collagen sample treated with pepsin, an enzyme able to cut the proteins at specific points. The third column shows a sample Heart® membrane subjected to the same treatment. The bands visible in the column (+) are entirely comparable with those seen in the Heart® membrane, confirming the presence of collagen in its native conformation.

BIOTECK*

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Bioteck® is an Italian company producing bone substitutes and protective membranes that are successfully used in orthopaedics, neurosurgery, oral and maxillofacial surgery.

Founded in 1995, the company continues to grow constantly and now operates in more than 50 countries around the world. A firm commitment to scientific research forms the basis for



Production and R&D Center

the innovative solutions offered by **Bioteck**® products. The company collaborates on numerous national and international research projects, which have driven the basic research and helped in writing important chapters in bone biology.

The in-depth knowledge acquired by **Bioteck**® through its research ensures the absolute quality of its products, which are subjected to strict environmental and quality controls, thereby guaranteeing a product meeting the highest quality and safety standards. Bioteck® applies a policy of total transparency, opening up the doors of its Production and R&D Center for the monitoring of its innovative manufacturing process and the intense scientific research carried out by its staff.



Quality and safety guarantee



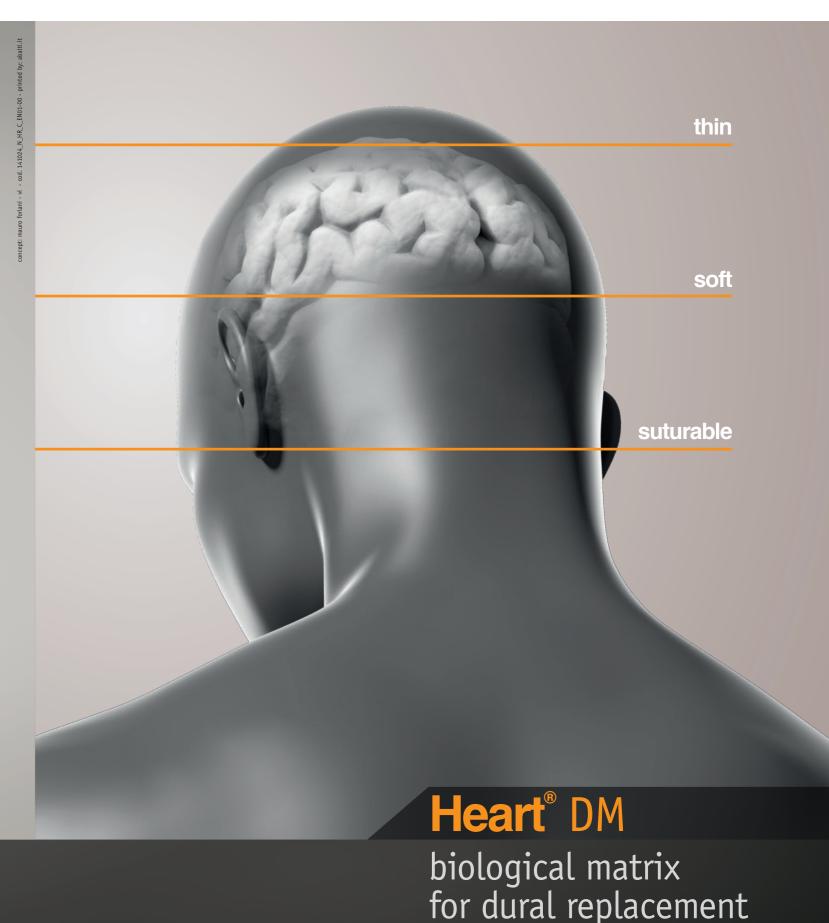
Biochemical Laboratory/Quality Control

Heart® - an equine pericardium membrane range for neurosurgery, orthopaedics, general surgery, oral and maxillofacial surgery.

Heart® and Zymo-Teck® are registered Bioteck S.p.A. trademarks















Heart® DM

biological matrix for dural replacement

Zymo-Teck® Process: the secret of the quality of grafts

Heart® **DM** is a biological matrix for dural replacement and repair, obtained from carefully-selected equine pericardium, to ensure just the right quality and thickness, and which is thereafter treated using the exclusive **Zymo-Teck**® **process**.

This sophisticated Bioteck® patented biochemical processes enables the elimination of all potentially immunogenic elements: cells, lipids and non-collagenous proteins, combining oxidative phases with the use of enzymes, natural catalytic proteins. The low temperatures at which the Zymo-Teck®

process operates and a careful selection of the enzymes used, enables the **collagen fibres** to be preserved in their **natural conformation**.

Sterilisation with beta rays guarantees the complete elimination of any pathogens in respect of the three-dimensional structure of the fibres, keeping the excellent product **biomechanical characteristics** unaltered.

Heart® DM acts as an inert, biological scaffold, able to support the tissue repair process without causing undesired reactions in the surrounding tissues. Once applied, the Heart® DM membrane acts as a matrix for fibroblast infiltration and as a substrate for the deposit of new collagen.

Heart® DM is therefore **gradually degraded** and replaced by new, vital patient tissue

completely biocompatible

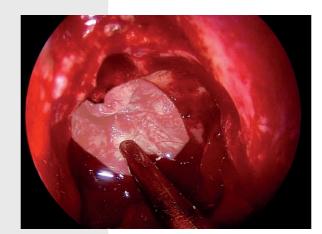
thin and traslucent

hard-wearing and easy to suture

impermeable to cerebrospinal fluid

scaffold for the formation of **new vital tissue**

A **natural membrane** with high biomechanical performance



Heart® DM membrane applied during pituitary adenoma removal by means of endoscopic transsphenoidal surgery The $\textbf{Heart}^{\circledR}$ DM membrane consists of a multi-directional layered weave of type I collagen fibres.

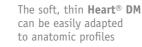
Its natural structure and the unique process to which it is subjected make it **slim and soft**, for a perfect **adaptability** to the anatomic profiles.

It is **impermeable to cerebrospinal fluid** and does not retract.

Thanks to its **excellent mechanical resistance**, it can be easily fixed using fibrin glue or stitches.

Differently to other materials available today on the market, which are far thicker and more rigid, the consistency and thickness of the equine pericardium make this membrane the ideal substitute for human dura mater.

Before use, Heart® DM must re rehydrated for a few minutes in physiological solution.



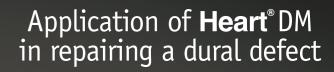


Surgical images thanks to Dr Letterio Morabito, Marche Nord Hospital. San Salvatore Hospital. Pesaro



Heart® DM natural, re-absorbable membrane

HRT-40DM	Pericardium membrane	25 x 30 x 0.2 mi
HRT-41DM	Pericardium membrane	50 x 50 x 0.2 mi
HRT-42DM	Pericardium membrane	60 x 80 x 0.2 mi
HRT-43DM	Pericardium membrane	80 x 140 x 0.2 mi
HRT-44DM	Pericardium membrane	120 x 160 x 0.2 mi

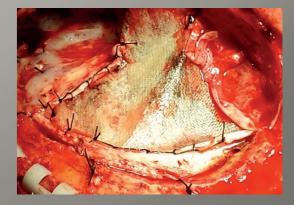




Once rehydrated, the Heart® DM is positioned on the site of the implant to evaluate the most appropriate positioning to correctly close the dural defect.



Once the surplus membrane exceeding the area of the defect has been cut, it is first fixed near the corners, using some single stitches, thereby fixing it properly laid out but not taut.



The membrane is then stitched along the whole edge, using a running suture.

Surgical images thanks to Dr Letterio Morabito, Marche Nord Hospital, San Salvatore Hospital, Pesaro