BIOTECK®

# HEART®

## TECHNICAL SHEET

| **HEART®**<br>**Disposable sterile device** | CE 0477 |
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• **Description:** HEART Membrane
• **Device constituents:** Equine pericardium.
• **Properties/Intended use:** Resorbable, not cross-linked equine pericardium membrane, to be used as: protective barrier in bone regeneration operations in dental surgery, orthopedics and neurosurgery, to reinforce damaged tendons and ligaments (orthopedics application) and to repair the dura mater (neurosurgical application).
• **Indications of use and clinical performances:**
Specific indications of use for dental surgery, orthopedics and neurosurgery are listed below:

***Dental surgery:***

- **HEART PERICARDIUM MEMBRANE** may be used in surgical procedures alone or in combination with suitable augmentation materials for immediate or delayed guided tissue and bone regeneration: augmentation or reconstructive treatment of the alveolar ridge; filling of defects after root resection, apicoectomy, and cystectomy; filling of extraction sockets to enhance preservation of the alveolar ridge; Elevation of maxillary sinus floor (protection of the Schneider membrane and closure of the lateral antrostomy); filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR) ;in case of surgical bone defects and bone wall defects; in the context of maxillary ridge reconstruction for prosthetic treatment; in the context of Fenestration defects; in case of periodontal bone defects (3 wall defects) and furcation defects (class I and II);in case of dehiscence defects and in case of Immediate or delayed augmentation around implants in extraction sockets. It provides protection of the grafting site from invasion by soft tissues/epithelial cells. The barrier effect is exerted for 3-4 months, after which the product begins to be reabsorbed by the endogenous collagenases. It provides containment and stabilization of the grafting material and/or coagulum inside the grafting site and it favors the bone regeneration inside the grafting site.

***Orthopedics surgery:***

- **HEART PERICARDIUM MEMBRANE** may be used in surgical procedures for reinforcement, where weakness exists, of tendons and ligaments repaired by sutures or by suture anchors during tendon/ligament repair surgery including, but not limited to: reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. It acts as scaffold for soft tissue regeneration of damaged tendons/ligaments favoring their healing; it reinforces the structure of damaged tendons/ligaments favoring their healing; it improves the functional outcome.
As a barrier membrane: may be used in surgical procedures such as filling of voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. It can also be used in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. It provides protection of the grafting site from invasion by soft tissues/epithelial cells. The barrier effect is exerted for 3-4 months, after which the device begins to be reabsorbed by the endogenous collagenases.

***Neurosurgery:***

- **HEART PERICARDIUM MEMBRANE** may be used as a dura substitute for the repair of localized defects of the dura mater. It provides a barrier effect avoiding the leaking of cerebrospinal fluid; it acts as a matrix for fibroblast infiltration and as a substrate for the deposit of new collagen and it favors the formation of a new duramater membrane.

• **Restrictions on use /target population:**
- **HEART PERICARDIUM MEMBRANE** must only be used by experienced dentists and/or surgeons. The device has not been tested on pregnant patients. The device has not been tested on children who have not reached skeletal maturity. The device is single use and single patient; it cannot be reused or re-sterilized.
• **Contraindications:**
- **HEART PERICARDIUM MEMBRANE:** must not to be used in patients who present individual hypersensitivity to collagen of equine origin. Do not use in the presence of infected wounds. Do not use as a tendon replacement; in fact, the device does not have a mechanical strength suitable for this purpose.
• **Instructions for use:**
- **HEART PERICARDIUM MEMBRANE:** if necessary, shape the membrane before hydrating. Hydrate for 1-2 minutes in a sterile physiological solution. Apply to the surgical site. The membrane may be stabilized by means of sutures or fibrin glue; for the coverage of bone grafts, osteosynthesis means can be used. When used for dura mater repair: position the membrane by at least partially overlapping the existing dura mater portions at the edge of the defect. Suture the membrane at not

less than 2 mm from the edge of the membrane to prevent it from tearing. Proceed suturing along the whole edge of the membrane, using a running suture. Be careful not to apply excessive stresses that could tear the membrane.

**• Precautions:**

- Use of the device in direct combination with pharmaceutical products has not been tested. - It cannot be reused or resterilized. - Any color variation of the product is due to the natural origin of the membrane, and does not imply changes in its properties. - Position the membrane so as to cover the entire surface of the graft: any unprotected portions would be rapidly invaded by epithelial and connective cells, causing partial or total failure of bone regeneration.
- If deemed necessary, the membrane can be fixed by stitches. Pay particular attention not to suture less than 2 mm from the edge of the membrane, to avoid tearing it. Suture the soft tissues without tension by perfectly sealing the surgical site. - In the event of exposure and in the absence of infection, intervene to restore the integrity of the connective cover. The exposed membrane is in fact degraded by endogenous collagenases more quickly, with a consequent reduction in protection time. In the event of exposure and infection completely remove the grafted material, subject the patient to a proper antibiotic treatment and repeat the bone regeneration operation at least four weeks after the end of therapy.
- The use of components of autologous/homologous origin in combination with Bioteck devices is not contraindicated, but has to be performed at the discretion of the surgeon and should be decided from patient to patient, based on the individual's medical condition. The combination with autologous/homologous component is not a standardized procedure (each human derivative acts differently accordingly to its source and to the procedure used for its collection and its combination with Bioteck devices), therefore it introduces additional variables to the surgery outcomes.
- In the following cases HEART must be used with particular care: acute or chronic infections (e.g. osteomyelitis) of the surgical site; uncontrolled metabolic disorders, such as diabetes, osteomalacia, thyroid dysfunction, severe renal or hepatic diseases; long-lasting cortisone therapy; autoimmune diseases; radiotherapy; chemotherapy; use of bisphosphonates; chain smokers (> 10 cigarettes/day).

**• Adverse effects:** The device is biocompatible; no side effects attributable to the device have been clinically found. Latex free: the device does not contain latex.

**• Potential complications:**

Possible complications that may arise in any surgical procedure include: swelling of the operated site, bleeding, leakage of serum from the wound, formation of seroma, reopening of the wound, local inflammation, formation of adhesions, necrosis, infection or pain. In neurosurgical use, further possible complication are the release of cerebrospinal fluid and formation of Pseudomeningocele.

**• Sterilization and storage:** The device is sterilized by beta radiation at 25 kGy. Store out of direct sunlight in a cool, dry place, at a maximum temperature of 25°C + 2°C. The device can be stored/transported at temperatures up to 40°C for short periods (less than 6 continuative months). If stored correctly, the package seal and device sterility is guaranteed for 5 years as from date of manufacture (see expiry date on the external label).

**• Packaging:**

One membrane in double PETG blister pack. Informative leaflet. Alternatively, one membrane in a double OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

**• Patient labels:** For formats in blister/pouches: six copies are present on the outer blister/pouch, which can be removed in order to be affixed on the medical record. For all other packaging types, patient labels are provided inside of the package.

**• Breakage of casing and disposal of packaging:** Do not use the device if the packaging is damaged. The materials used to make the packaging do not require special disposal.

**• Manufacturer:** Bioteck S.p.A., Via E. Fermi 49 - 36057 Arcugnano (VI), Italy. Produced in the plant at no. 3 Via G. Agnelli - 10020 Riva presso Chieri (Turin), Italy.

**• Risk Class**

The risk class of this device, according to current EEC regulations is III (three).

**• Codes**

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| **HRT-001** | HEART Pericardium Membrane | Pericardium membrane - 1 pc. 25 x 30 x 0.2-0.4 mm. |
| **HRT-002** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 50 x 30 x 0.2-0.4 mm |
| **HRT-003** | HEART Pericardium Membrane | Pericardium membrane - 2 pc. 15 x 20 x 0.2-0.4 mm. |
| **HRT-003n** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 15 x 20 x 0.2-0.4 mm |
| **HRT-004** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 15 x 30 x 0.2-0.4 mm |
| **HRT-005** | HEART Pericardium Membrane | Pericardium membrane - 2 pc. 20 x 20 x 0.2-0.4 mm. |
| **HRT-005n** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 20 x 20 x 0.2-0.4 mm |

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| **HRT-019** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 50 x 30 x 0.2-0.4 mm |
| **HRT-020** | HEART Pericardium Membrane | Pericardium membrane - 1 pc. 50 x 50 x 0.2-0.4 mm. |
| **HRT-021** | HEART Pericardium Membrane | Pericardium membrane - 1 pc. 60 x 80 x 0.2-0.4 mm. |
| **HRT-024** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 40 x 50 x 0.2-0.4 mm |
| **HRT-025** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 40 x 100 x 0.2-0.4 mm |
| **HRT-050** | HEART Pericardium Membrane | Pericardium membrane - 1 pc 60 x 140 x 0.2-0.4 mm. |
| **HRT-40DM** | HEART Pericardium Membrane DM | Pericardium membrane - 1 pc. 30 x 25 x 0.2-0.4 mm. |
| **HRT-41DM** | HEART Pericardium Membrane DM | Pericardium membrane - 1 pc. 50 x 50 x 0.2-0.4 mm. |
| **HRT-42DM** | HEART Pericardium Membrane DM | Pericardium membrane - 1 pc. 60 x 80 x 0.2-0.4 mm. |
| **HRT-43DM** | HEART Pericardium Membrane DM | Pericardium membrane - 1 pc. 80 x 140 x 0.2-0.4 mm. |