



HEART[®]
TECHNICAL DATASHEET – INSTRUCTIONS FOR USE

Description

HEART[®] *equine pericardium membrane for covering, strengthening or replacing connective tissue, equine pericardium membrane for guided bone regeneration, equine pericardium membrane for tissue regeneration.*

Product constituents

Equine pericardium.

Indications and expected results

Protection of bone grafts:

HEART[®] acts as an anti-epithelial invasion membrane. The barrier effect works for 3-4 months, after which the product begins being reabsorbed by the endogenous collagenases.

Other uses:

The HEART[®] membrane acts to cover, strengthen or replace connective tissue. Specifically, it can be used as a dural replacement (codes HRT-XXDM), as tendon structure strengthener (codes HRT-XX), or to cover ulcers or injuries (codes HRT-XXWM).

Instructions for use

If necessary, shape the membrane before hydrating. Hydrate for 3-5 minutes in a sterile physiological solution. Apply to the surgical site. The membrane may be stabilized by means of sutures or fibrin glue and, in the case of coverage of bone grafts, by means of osteosynthesis.

Warnings and precautions

The device is disposable and for use on one patient only; it cannot be reused or resterilised.

Any non-homogeneous colouring of the product is due to the natural origin of the membrane and does not cause changes in the properties of the same.

The use of the product in direct combination with drugs has not been tested.

HEART[®] must be positioned without damaging the structure and in a stable manner, in order to encourage incorporation and avoid any early dislocation.

If covering bone grafts, the membrane must cover *the entire graft surface*: any unprotected portions will be quickly invaded by epithelial and connective cells, causing partial or total failure of bone regeneration. Again, if covering bone grafts, suture the soft tissues without pulling taut, and perfectly sealing the surgical site. In the event of exposure and where there is no infection, intervene to restore the epithelial-connective covering. The exposed membrane is in fact degraded by endogenous collagenase in a shorter time, resulting in less protection time. In the event of exposure and infection, remove all the grafted material, subject the patient to an antibiotic treatment if appropriate, and repeat the bone regeneration operation at least four weeks later.

Side effects

The product is biocompatible. It does not cause side effects.

Ensure that the patient shows no individual hypersensitivity to collagen of equine origin.

The product has not been tested on pregnant women.

Latex-free: the device contains no latex.

Sterilization and storage

The product is sterilized by beta radiation at 25 kGy. Store out of direct sunlight in a cool, dry place at a temperature of between 4°C and 40°C. If stored correctly, the package remains sealed and therefore product sterility is guaranteed for 5 years as from date of manufacture (see expiry date on external label).

Package

One membrane in double PETG blister pack. Informative leaflet.

Alternatively, a membrane in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.

Patient labels

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

Breakage of casing and disposal of packaging

Do not use the product if the packaging is damaged.

The materials used to make the packaging do not require any particular disposal conditions.

Manufacturer

Bioteck S.p.A., Via E. Fermi 49, 36057 Arcugnano (Vicenza), 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

IRT-001	HEART Pericardium Membrane	. pc. 25 x 30 x 0.2-0.4 mm.
IRT-002	HEART Pericardium Membrane	. pc. 50 x 30 x 0.2-0.4 mm.
IRT-003	HEART Pericardium Membrane	! pc. 15 x 20 x 0.2-0.4 mm.
IRT-005	HEART Pericardium Membrane	! pc. 20 x 20 x 0.2-0.4 mm.
IRT-020	HEART Pericardium Membrane	. pc. 50 x 50 x 0.2-0.4 mm.
IRT-021	HEART Pericardium Membrane	. pc. 60 x 80 x 0.2-0.4 mm.
IRT-022	HEART Pericardium Membrane	. pc. Ø 50 x 0.2-0.4 mm.
IRT-40DM	HEART Pericardium Membrane DM	. pc. 30 x 25 x 0.2-0.4 mm.
IRT-41DM	HEART Pericardium Membrane DM	. pc. 50 x 50 x 0.2-0.4 mm.
IRT-42DM	HEART Pericardium Membrane DM	. pc. 60 x 80 x 0.2-0.4 mm.
IRT-43	HEART Pericardium Membrane	. pc. 80 x 140 x 0.2-0.4 mm.
IRT-43DM	HEART Pericardium Membrane DM	pc. 80 x 140 x 0.2-0.4 mm.
IRT-44	HEART Pericardium Membrane	. pc. 120 x 160 x 0.2-0.4 mm.
IRT-44DM	HEART Pericardium Membrane DM	. pc. 120 x 160 x 0.2-0.4 mm.