BIORIPAR

Bovine pericardium membrane

Technical Data Sheet

Manufacturer: Assut Europe S.p.A.
Registered Office: Via Giuseppe Gregoraci, 12 – 00173 Rome - Italy
Manufacturing plant: Zona Industriale – 67062 Magliano dei Marsi (AQ) - Italy

CE: 0373 – Class III, according to EU Directive 93/42, as amended by EU Directive 2007/47

Description
This medical device is a bovine pericardium-derived collagen membrane; bovine pericardium is treated with an accurate multiphasic processing system, designed and developed in ASSUT EUROPE S.p.A.. The manufacturing process ensures, in addition to pathogens inactivation, the complete destruction or removal of cells, fats and non-collagen proteins, not altering collagen's three-dimensional structure and biomechanical properties.
The membrane is available in various shapes and sizes: damp or dry, with or without perforations. Damp membrane is kept in a Propylene Glycol and Ethanol solution, while dry membrane is subjected to soaking with pure acetone. The membrane is opaque white, but it may have light yellow (dry membrane) or rosy (damp membrane) streaks.

Product characteristics
The most important characteristic of Bioripar is its collagen structure, which guarantees its stability while remaining soft and flexible. The membrane is easily sutured.
After its application, the collagen matrix repairs damaged surfaces. The body reacts to collagen beginning a process of repair of the damaged tissues: it starts releasing a large number of cytokines, factors of growth, and gradually replaces the material implanted with healthy tissues.

Origin: the raw material for Bioripar comes from bovine animals born, bred and slaughtered in Italy.

Thickness: 0,150 mm - 0600 mm

The device is "latex-free" and "phthalate-free"

Indications
Non-perforated membrane is not intended for soft tissue repair, for muscle flaps reinforcement, for tendon structures reinforcement, augmentation and covering, for reinforcement and / or replacement of connective tissues, to prevent the formation of adhesions and accelerate the tissue recovery times in: abdominal, cardiac and thoracic surgery, urology, gynecology, vascular surgery, orthopedics, plastic surgery, andrology, oral surgery, traumatology, implantology and periodontology. This medical device is not intended to come into contact with central nervous system and with eyes.
Perforated membrane is used for soft tissue, abdominal and thoracic wall surgical repair, providing greater liquid permeability.

Instructions for use
Before use, immerse BioRipar, at room temperature, in 500 ml of sterile saline solution (0.9% NaCl).
Fix the membrane by suturing it.

Contraindications
- Known allergic hypersensitivity to bovine collagen
- Closure of tissue where liquid impermeability is required
- Any autoimmune disorder or disease resulting from, or affecting, the tissues

Precautions
BioRipar must only be used by medical-surgical staff, in operating rooms, outpatient clinics or in any hospital environment. The surgeon must evaluate the benefits versus the risks of use for each single patient. The surgeon must assess if it is appropriate to use BioRipar in pregnant and/or breastfeeding patients and in patients with infections in the surgical site.

Sterilization: Gamma Rays (R)

Shelf life: 3 years from the date of manufacture

Packaging: double sterile packaging – 1 unit box

Warnings
Single-use device
Use only if the package is unopened and undamaged
Do not use after the expiry date
Keep in a cool, dry place, at a temperature between 5°C and 25°C
Dispose of as hospital waste
The medical device must not be used in patients with acute or chronic infection at the surgical site.

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