INSTRUCTIONS FOR USE FOR :

PeriBeam

TamaBio

Pericardial Membrane

INSTRUCTIONS FOR USE FOR

TamaBio PeriBeam Pericardial

Membrane

INDICATIONS

Reconstruction or repair of the pericardium

CONTRAINDICATIONS

Not for reconstruction of:

CARDIOVASCULAR DEFECTS such as cardiac, great vessel, and peripheral vascular

- DURA MATER
- HERNIAS

Use of this product in applications other than those indicated has the potential for serious complications, such as suture pullout or failure of the repair (aneurysm formation).

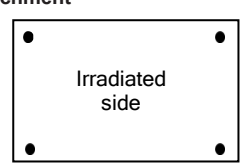
STERILITY

PeriBeam Pericardial Membrane is supplied STERILE. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the “use-by” (expiration) date printed on the box.

ORIENTATION

Ion beam irradiated side should be placed facing the pericardium only.
Correct surface orientation is extremely important for PeriBeam Pericardial Membrane to function as intended.
Ion irradiated surface has been stamped at the 4 corners for identification. This ion irradiated surface should be placed facing those tissues where tissue ingrowth is desired (i.e., pericardium). The other, smooth surface should be placed facing those tissues where minimal tissue attachment is desired (i.e., myocardium).

Smooth Surface for Minimal Tissue Attachment



Irradiated Surface (marked with stamping on 4 corners) for Tissue Ingrowth

RECOMMENDED TECHNIQUES

HANDLING

Store in a cool, dry place. This product has an expiration date and should be used before the labeled "use-by" (expiration) date marked on the box. Use clean, sterile gloves and/or atraumatic instruments when handling PeriBeam Pericardial Membrane.

SIZING

Size the material appropriately to completely cover and overlap the defect. The PeriBeam Pericardial Membrane should not be stretched to fit the pericardial defect. Inadequate overlap may expose the defect to possible adhesion formation and may result in pericardial effusion. If the PeriBeam Pericardial Membrane is cut too small, excessive stress may be placed on the tissue or material and suture line leakage or suture pull out could occur. If the material is cut too large, excessive wrinkling may occur, possibly resulting in undesired tissue attachment.

SUTURING

Use **nonabsorbable** sutures (with a radii ratio close to 1:1 with needle) and a noncutting needle (such as taper or piercing point) to anchor the material. Final suture selection should be determined by surgeon preference and the nature of the pericardium repair.

After properly sizing PeriBeam Pericardial Membrane to completely cover and overlap the defect, suture the material in place using the appropriate number of sutures and uniform spacing.

PRECAUTIONS

Use appropriately sized material for the repair. If the PeriBeam Pericardial Membrane is cut too small for the repair, excessive tension may be placed at the fixation points, which may lead to pull-out. Inadequate overlap will expose the defect to possible adhesion formation. Inadequate fixation may allow the material to migrate and expose the defect.

If the PeriBeam Pericardial Membrane is fabricated into a sleeve to protect the internal mammary artery, the pedicle should fit loosely in the sleeve. A tight fit could result in graft occlusion.

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WARNINGS

The PeriBeam Medical Device is designed for single use only; do not reuse device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.

Strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the material.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions, suture line adhesions, fibrous reaction, tissue encapsulation, and cardiac tamponade. Additionally, contraindicated uses may result in material failure.

DEFINITIONS

STERILE Sterilized using Steam or Dry Heat

Do not resterilize

Do not use if package is damaged

Do Not Reuse

MR MR Safe

Store in Cool Place

Keep Dry

Manufacturer

LOT Lot number

Use-by-date

Caution

Consult Instructions for Use

℞Only Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufacturer
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