

(en) ENGLISH

Instructions for Use

ARTIVION™ | **PhotoFix®**

Decellularized Bovine Pericardium



www.artivion.com/eIFU

A printed version of the Instructions for Use will be provided within seven days upon request to PhotoFix customer service through any of the contact means listed below.

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ARTIVION™

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



Phone: +1 (888) 427-9654










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www.artivion.com

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EXPLANATION OF SYMBOLS

	Manufacturer
	Date of manufacture
	Medical Device
	Do not use if package is damaged
	Single sterile barrier system/sterile packaging
	Single sterile barrier system with protective packaging outside
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Do not re-sterilize
	Do not re-use
	Temperature limit
	Consult instructions for use / Consult electronic instructions for use
	Caution
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

	Non-pyrogenic
	Contains biological material of animal origin
	MR safe
	Batch code
	Catalogue number
	Unique Device Identification
	Use-by date
	Country of manufacture
	Quantity

Device Description

PhotoFix® Decellularized Bovine Pericardium (PhotoFix) is prepared from bovine pericardium, which is stabilized using a dye-mediated photooxidation process, processed using ethylene oxide and sterilized using aseptic processing techniques. No aldehyde chemistry is used during any phase of pericardium manufacturing including tissue fixation or sterilization processes.

PhotoFix is available in the following sizes:

Product Code	Size
PFP6X8	6cm x 8cm
PFP1X6	1cm x 6 cm
PFP0.8X8	0.8cm x 8cm
PFP1X10	1cm x 10cm
PFP1X14	1cm x 14cm
PFP2X9	2cm x 9cm
PFP4X4	4cm x 4cm
PFP8X14	8cm x 14cm

PhotoFix is supplied in a packaging solution comprised of 22% buffered ethanol solution (Phosphate Buffered Saline Ethanol). PhotoFix is supplied in a storage container made with Polypropylene. The PhotoFix patch is sourced from bovine pericardial tissue. Bovine tissue is sourced to minimize risk of Bovine Spongiform Encephalopathy (BSE).

Glycerin was the only compound identified via extractable testing. Exposure to glycerin at levels observed have been determined to be safe.

Indications / Intended Purpose

PhotoFix is indicated for the following uses: intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels and arteriovenous access revisions).

Intended Use

PhotoFix is intended to be used as a permanently implanted device in direct contact with the patient's soft tissues and blood during cardiac and/or vascular surgery.

Target Patient Population

PhotoFix is intended to be used in patients requiring cardiac or vascular repair and reconstruction.

Intended Users

PhotoFix is intended to be used by experienced surgeons, as successful application is heavily dependent on the skills of the surgeon.

Performance Characteristics

Published literature demonstrates the following performance characteristics of PhotoFix:

- Increased pliability as compared to glutaraldehyde-fixed patches.¹⁻⁸
- Reduced preparation steps in the operating room as compared to glutaraldehyde-fixed patches, which require rinsing or rehydrating prior to use.¹⁻⁸
- Similar mechanical properties and therefore similar surgical handling characteristics (e.g., trimming and suturing) to autologous pericardium.¹⁻⁹

Clinical Benefits

Published literature demonstrates the following clinical benefits of PhotoFix when used as a surgical patch for cardiac congenital defect repair:

- Survival rates greater than 90% out to 5 years.⁶
- Freedom from all-cause reoperation rates of 92.6%, 90.3%, 85.6%, 75.6%, and 63.2% at 1, 2, 3, 4, and 5 years, respectively.⁶
- Reduced calcification when compared to glutaraldehyde-fixed patches.⁷

Contraindications

PhotoFix is contraindicated for:

- Use in patients that exhibit sensitivity to materials of bovine origin;
- Reconstruction of hernias and valve leaflet repair.

Warnings and Precautions

- **FOR SINGLE USE ONLY.** Do not re-use or re-sterilize. Re-use or re-sterilization of the device could cause infection, premature re-operation, critical or life-threatening patient injury.
- Do not use the pericardium if either temperature indicator is activated (see **TEMPERATURE INDICATORS** section). Immediately contact your Sales Representative to arrange for return or replacement of the tissue.
- **DO NOT USE THE PERICARDIUM** if the device container is damaged, the expiration date has lapsed, or the tamper-evident seal is broken or missing.
- PhotoFix should not be allowed to contact any solutions that contain aldehydes.
- Rinsing the pericardium with antibiotic solution is not recommended. The interactions of tissue with antibiotics have not been tested.
- The use of PhotoFix in pregnant/breastfeeding women has not been studied.

Adverse Events/Reporting of Serious Incidents

Potential adverse events associated with the use of pericardium include: Abscess, adhesion, aneurysm/pseudo-aneurysm formation, calcification/mineralization, complete heart block, death, dehiscence, edema, embolism, inflammatory reaction, hemolysis, infection, rejection, stenosis/shrinkage, thrombosis, and possible transmission of infectious agents from material of animal origin.

Serious incidents that occur in relation to PhotoFix should be reported to Field Assurance at 1-800-438-8285 or 770-419-3355 or by email to fieldassurance@artivion.com.

Individualization of Treatment

Prophylactic antibiotic therapy is necessary for patients that receive an implantable device when undergoing any invasive procedure (including and especially dental procedures).

Patient Counseling

Patients undergoing any dental procedures should be considered for prophylactic antibiotic therapy.

Packaging

PhotoFix is supplied sterile and non-pyrogenic in a sealed container with 22% buffered ethanol solution.

Temperature Indicators


Each shipping carton contains low and high temperature indicators that signify if the tissue was exposed to unacceptable shipping temperatures. If the low temperature indicator is **RED**, the product was exposed to temperatures below the acceptable shipping temperature (**Figure 1**). If the high temperature indicator is **RED**, the product was exposed to temperatures above the acceptable shipping temperature (**Figure 2**).

Figure 1



Figure 2



 If either high or low temperature indicators have been activated, **DO NOT USE THE PERICARDIUM**. Immediately contact your Sales Representative to make arrangements for return or replacement.

Environmental Conditions

PhotoFix is MR safe (i.e., an item that poses no hazard in all MR environments).

Storage Conditions

PhotoFix should be stored between the temperature limit minimum of 5°C and maximum of 25°C (41°F and 77°F). Refrigeration is not required. Do not place PhotoFix in areas where significant temperature fluctuations may occur.

Directions for Use

Note: Before using PhotoFix, surgeons should be familiar with using cardiovascular patch materials via appropriate training with the surgical techniques and variations of their specific procedures.

1. Visually inspect the container and tamper-evident seal. If either is broken or damaged, **DO NOT USE THE PERICARDIUM.**
2. The exterior of the single-barrier container is non-sterile and should not be introduced into the sterile field.
3. Remove the tamper-evident seal by pulling tab adjacent to the seal perforation.
4. Grip the bottle lid and open the container by turning the lid counterclockwise.
5. Remove PhotoFix from the container by grasping the edge of the pericardium with atraumatic forceps. **ATRAUMATIC FORCEPS MUST BE USED WHEN HANDLING PHOTOFIX.** Alternatively, excluding 6x8cm and 8x14cm sizes, the tissue and bottle contents can be poured into a sterile basin.
6. PhotoFix does not require rinsing before implantation.
7. All subsequent handling must be with sterile gloved hands. Thoroughly wash surgical gloves to remove glove powder before touching the pericardium.
8. PhotoFix may be tailored during surgery as needed. Visually examine both sides of PhotoFix. If one side appears smoother, implant the smoother surface so that it faces the blood flow. Non-absorbable sutures, clips or staples may be used to implant the pericardium.
9. Flush the pericardium with sterile physiologic saline frequently during implantation to prevent tissue dehydration.

Disposal Instructions

Discard any unused material from open or damaged product by placing it in a biohazard bin. After implantation, the 22% buffered ethanol solution can be discarded according to hospital procedures for non-hazardous materials.

Lifetime of PhotoFix

PhotoFix is a permanently implanted device. Patient follow-up is determined by standard of care based on type of procedure, treatment plan and physician discretion.

References

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7. Majeed A, Baird C, Borisuk MJ, Sanders SP, Padera RF, Jr. Histology of Pericardial Tissue Substitutes Used in Congenital Heart Surgery. *Pediatr Dev Pathol.* 2016;19(5):383-388.
8. Pre-Clinical Data on File.

9. Hofferberth SC, Baird CW, Hoganson DM, Quiñones L, Emani SM, del Nido P Hammer PE. Mechanical properties of autologous pericardium changed with fixation time: implications for valve reconstruction. *Seminars in Thoracic and Cardiovascular Surgery* (2019), doi: <https://doi.org/10.1053/j.semtcvs.2019.03.00>.

Warranties

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