ELUTIA
Medicine *Humanized*™

Tyke®

FOR
PATCH, PLEDGET AND INTRACARDIAC

INSTRUCTIONS FOR USE

Manufacturer:
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INDICATIONS FOR USE

Tyke® is intended for use in neonates and infants for repair of pericardial structures, as an epicardial covering for damaged or repaired cardiac structures, as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing, and cardiac repair.

CONTENTS: One (1) sterile, non-pyrogenic Tyke

PRODUCT DESCRIPTION

Tyke is a multilaminate sheet (2-ply) of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) derived from porcine small intestinal submucosa. Tyke is MR (Magnetic Resonance) Safe in that it poses no known hazards in MR environments.

HOW SUPPLIED

Tyke is supplied **STERILE**. Provided that the integrity of the sterile pouch is not compromised in any way, it serves as an effective sterile barrier until the "Use By" (expiration) date printed on the pouch.

Tyke is provided in one size, 4 x 7cm.

CONTRAINDICATIONS

Tyke is derived from a porcine source and should not be used in patients with a known sensitivity to porcine material.

WARNINGS AND PRECAUTIONS

- Tyke should only be used to reconstruct curved structures less than or equal to 12mm in diameter.
- Tyke should only be used to reconstruct structures where the post-operative pressure is not expected to exceed 50 mmHg.
- Tyke is not indicated for the construction or replacement of total valves or conduits.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- After opening, discard all unused Tyke product.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Refer to storage conditions on product label. Do not use if proper storage conditions have not been maintained.
- The device must be used prior to the expiration date.
- Discard device if mishandling has occurred that may have caused damage or contamination.
- Always handle the device using aseptic technique.
- Ensure that the device is hydrated according to the Instructions for Use prior to use. Insufficient or excessive hydration may result in tears, insufficient suture strength, or separation of layers. If these defects are observed, do not use Tyke.
- Once hydrated, Tyke should either be used or discarded. Tyke should not be rehydrated and reused. Do not allow hydrated Tyke to dry out.
- The device must not be sutured to homografts or synthetic or chemically cross-linked materials. The device should only be sutured to the patient's own viable tissue.
- Device is not recommended to be used with glue containing glutaraldehyde.
- Device is not recommended to be used with platelet gel.

CAUTION: FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

POTENTIAL COMPLICATIONS

The following device-related complications are possible:

- Allergic reaction
- Aneurysm
- Bleeding
- Calcification
- Dehiscence or rupture
- Death
- Embolism
- Fever
- Hematoma
- Hemothorax
- Infection
- Inflammation
- Pseudoaneurysm
- Reformation of intracardiac defect
- Stenosis
- Thromboembolism
- Thrombus formation
- Undesired remodeling (e.g., poor tissue integration, excessive scar tissue formation, adhesions, or rapid degradation of Tyke)

STORAGE
This device must be stored in a clean, dry location at 10° C - 30° C.

STERILIZATION
This device has been sterilized with ethylene oxide gas.

REQUIRED MATERIALS FOR IMPLANT
- Sterile dish (kidney dish or other bowl)
- Sterile forceps
- Hydration fluid: a sufficient quantity of room temperature sterile water, sterile saline, sterile lactated Ringer's solution, or other sterile, isotonic solution to completely immerse Tyke.
- Suture

SUGGESTED INSTRUCTIONS FOR SURGICAL USE OF TYKE
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1. Inspect Tyke packaging/pouch for signs of damage. Do not use if package is opened or damaged.
2. Using aseptic technique, remove the inner pouch from the outer pouch, and place the inner pouch containing Tyke into the sterile field.
3. Open the inner pouch carefully and remove Tyke.
4. Tyke may be trimmed to size before or after hydration. To hydrate Tyke, completely immerse it in a bowl of hydration fluid (see "Required Materials for Implant" above) for up to 1 minute prior to use.
5. Device will be translucent and flexible when fully hydrated. Hydration longer than 1 minute may result in difficult handling characteristics.
6. After hydration, inspect Tyke for tears or separation. Do not use if defects are observed. Implant immediately. Avoid excessive handling of hydrated material.
7. When implanting Tyke into the patient, suture Tyke to viable tissue.

NOTE: Suture bites should be placed at least 2 mm from the edge of Tyke during implantation. Suture spacing should be less than 3mm for most effective blood barrier.

IINTENDED EFFECTS OR ACTIONS
Tyke is intended to provide a permanent (>30 days) repair of pericardial structures, as an epicardial covering for damaged or repaired cardiac structures, as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing, and cardiac repair.

ADVERSE EVENT REPORTING
Any potential adverse incident involving Elutia Products should be reported immediately by calling +1 470-514-4080.

RETURN GOODS POLICY
For information on product returns and return authorization, contact Elutia by calling +1 470-514-4080. All products returned to Elutia must be accompanied by a Return Goods Authorization Number.

SYMBOLS AND THEIR EXPLANATIONS

	Use by
	Store at 10° C - 30° C
	Consult Instructions for Use
	Catalog Number
	Lot Number
	Sterilized using Ethylene Oxide
	Do Not Reuse
	Do Not Resterilize
	Do Not Use if the Package is Damaged or Open
	Non-pyrogenic
	MR Safe
	Manufacturer
	Contents
	Contains Biological Material of Animal Origin
	Double Sterile Barrier System