

TIPS & TECHNIQUES

FOR THE IMPLANTATION OF



FOR PATCH, PLEDGET, AND INTRACARDIAC
REPAIR IN NEONATES AND INFANTS

Refer to the Instructions for Use for indications, full implant instructions, warnings and precautions, and contraindications.

PRE-OP EVALUATION:

- **ASSESS REPAIR:** Tyke should be used in neonates or infants to reconstruct the pericardium or intra-cardiac repair structures *less than or equal to 12mm in diameter*. **If vessels exceed this size, use ProxiCor®.**
- **ESTIMATE POST-OP PRESSURE:** Tyke should only be used to reconstruct structures where the post-operative pressure is *not expected to exceed 50mmHg*. **If vessels exceed this pressure, use ProxiCor®.**

DO:

- **HYDRATE PROPERLY:** Hydrate (soak) Tyke in **room-temperature** sterile saline for **up to 1 minute**. Do not allow Tyke to dry out after soaking. Excessive hydration may result in delamination. **Do not use** if delamination is visible.
- **SIZE MATERIAL APPROPRIATELY:** To promote effective remodeling, use only what is needed of the material. Tyke should not be pulled too tight, and sutures should not be pulling. **Minimize material redundancy and tension.**
- **USE NON-ABSORBABLE SUTURES:** A non-absorbable, monofilament polypropylene suture is preferred.
- **IMPLANT PROPERLY:** Suture to healthy, viable tissue – Tyke ECM relies on angiogenesis and cellular infiltration from the sutured edge. Suture spacing should be **less than 3 mm**. Suture bites should be placed **at least 2 mm from the edge** of the ECM patch during implantation.
- **SUTURE CIRCUMFERENTIALLY:** Make sure all layers of Tyke are penetrated to ensure good tissue approximation and regeneration potential.

DON'T:

- **USE WITHOUT RECOMMENDED HYDRATION:** Without proper hydration, Tyke may tear and not retain sutures.
- **USE WITH GLUES, SEALANTS, OR PLATELET GELS:** Avoid using glutaraldehyde-based glue, platelet gels, and hemostatic agents as they may increase crosslinking and negatively impact remodeling.
- **SUTURE TO SYNTHETIC OR NON-VIABLE MATERIAL:** Do not sew to synthetic or non-viable material.
- **SAVE OR REUSE:** Discard all open or unused portions of Tyke.

NOTE:

- Tyke is not indicated for the construction or replacement of total valves or conduits.
- Users have reported that when repairing an ASD or VSD, disrupting the endothelial lining where Tyke contacts the tissue prior to implantation may facilitate remodeling.

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