



# Recovery Update



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## UPCOMING EVENTS

- 1 **AATB Annual Meeting**  
September 10-14, 2010  
National Harbor, MD
- 2 **NAME 2010 Annual Meeting**  
October 1-6, 2010  
Cleveland, OH
- 3 **CARE**  
December 7-8, 2010  
Kennesaw, GA

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*Surgeons prefer using human tissue over porcine valves for training.*

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## Human tissue is preferred by surgeons for training

Natural anomalies, positive microbiology results, recovery and processing errors can render tissue unsuitable for transplantation. While every effort is made to minimize these instances, achieving a zero percent error rate is impossible. So what happens to the "Gift"? It is then utilized for research or training as long as the necessary consent has been provided.

At CryoLife, Dr. William F. Northrup III and his team in the Physician Relations and Education department utilize these gifts for physician training. Dr. Northrup, a Board Certified Cardiovascular & Thoracic Surgeon, conducts monthly training at our learning facility in Kennesaw, GA.

### Aortic Allograft Training Workshops

During these workshops, visiting surgeons learn how to perform the aortic root technique. Dr. Northrup describes this procedure as complex, and "the ability of the surgeon to use human tissue as they would in surgery has a definite advantage over animal tissue".

Consider a pilot who must choose between training in a generic cockpit simulator versus one customized to the aircraft of his/her specialty. "It allows the surgeon to practice and make mistakes, which is not allowed in the operating room. Ultimately, the surgeon will be able to perform the surgery quicker, better, and safer", says Dr. Northrup.

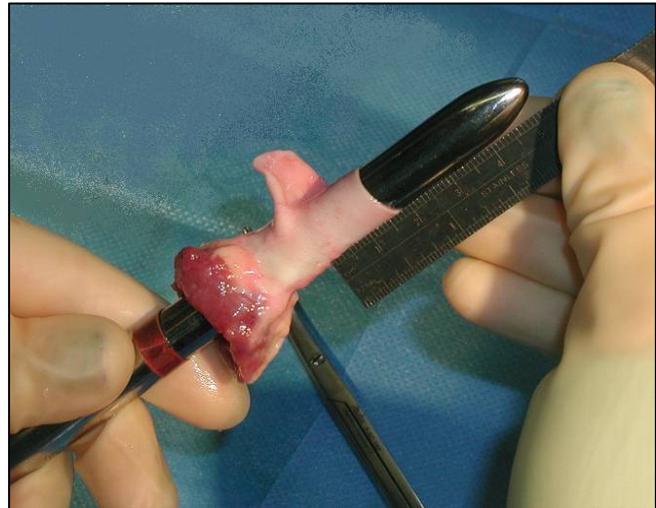
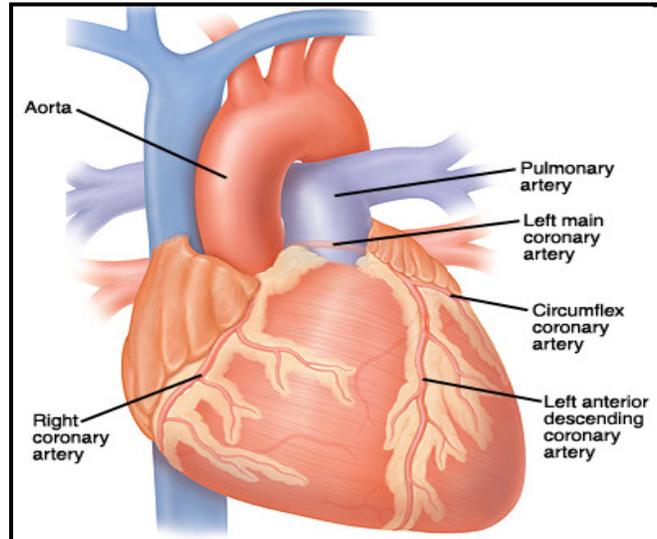
CryoLife's Physician Relations and Education department is very thankful to the Donors' families and the Recovery Partners who recover and provide us with the tissue.

## From the Technical Trainer: Pulmonary artery length is critical

Cardiac surgeons are regularly requesting pulmonary patch grafts which require longer lengths of the pulmonary artery (3+ centimeters) than are normally required.

CryoLife has always emphasized the importance of having at least 1-2 cm length of the left and right pulmonary arteries when recovering a heart. This artery length has been a minimum requirement for creating a usable graft with multiple applications.

However, cardiac surgeons are now regularly requesting pulmonary patch grafts which require even longer lengths of the pulmonary artery (3+ centimeters). Of course, the possible maximum pulmonary artery length is dependent on the age/size of the donor, but we are requesting that in recovering all future hearts that you **transect the pulmonary artery at the point where it branches into the lung tissue**. Providing this extra artery length will help meet needs of surgeons everywhere, so please keep this in mind during the next cardiectomy.



**Do not include any lung tissue with the recovered artery**

This can be a source of contamination. Instead, follow the artery through the pericardial sac to where the branching begins, and then make your cut.

## CryoLife receives FDA 510(k) clearance for CryoPatch<sup>®</sup> SG Pulmonary Human Cardiac Patch Shelf-life Extension

CryoLife, Inc. has received 510(k) clearance from the Food and Drug Administration (FDA) for a five-year shelf-life on its CryoPatch<sup>®</sup> SG pulmonary human cardiac patch processed with the Company's proprietary SynerGraft<sup>®</sup> technology. CryoLife's SynerGraft technology is designed to remove allogeneic donor cells and cellular remnants from tissue without compromising the integrity of the underlying collagen matrix.

"This shelf-life extension allows us to make this advanced technology available to more patients," said Steven G. Anderson, CryoLife's president and chief executive officer.

CryoPatch SG is indicated for the repair or reconstruction of the right ventricular outflow tract (RVOT), which is a surgery commonly performed in children with congenital heart defects, such as Tetralogy of Fallot, Truncus Arteriosus, and Pulmonary Atresia. CryoPatch SG is distributed in three anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch.

Implantation of the CryoPatch SG reduces



the risk for induction of HLA class I and class II alloantibodies, based on Panel Reactive Antibody (PRA) measured at up to one year, compared to standard processed pulmonary cardiac tissues. Data have not been provided to evaluate the effect of reduced alloantibodies on the long-term durability, or long-term resistance to rejection by the patient, of the CryoPatch SG.

Avoiding elevated PRA is important for patients receiving CryoPatch SG as some may ultimately require a heart transplant. While the link between immune response and allograft tissue performance is still being debated, there is evidence that an elevated PRA can pose a significant risk to future organ transplant patients.

## New AATB Requirement

AATB revised the **Standard D5.400 Time Limits for Tissue Recovery**. The new requirement states:

*Warm Ischemic Time (C)* shall not exceed 24 hours from *Asystole* if the body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *Asystole*. The time limit shall not exceed 15 hours if the body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 **cumulative** hours.

*Warm Ischemic Time (V)* shall not exceed 24 hours from *Asystole* if the body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *Asystole*. The time limit shall not exceed 15 hours if the body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 **cumulative** hours.

**Effective September 2, 2010**, Donor Quality Assurance (DQA) will require this information as it appears on the revised Recovery Information Form (Donor Demographic Form DS00029A). DQA will calculate the total unrefrigerated time to determine if the new AATB time limits have been met.

Was the body refrigerated?  Yes  No

Document the Date/Time Donor is moved into and out of cooling.	Date/Time	Reason
Cooling Started		
Out		
In		
Out		
In		
Out		
In		
Out		

**Table from Donor Demographic Form DS00029A**

Please ensure the above information is provided and thank you, in advance, for your continued effort in providing donor information in a timely manner.

## From the Account Managers:

### PEDS Program (Pediatric Emphasis by Donor Services)

Your Donor Services Account Manager is involved in a program with major pediatric centers around the nation. This program is designed to promote donation and encourage the use of human tissue for transplant by working with the surgeon and hospital staff to understand the important gift they use in these pediatric cardiac procedures. The PEDS Program focuses on bridging the gap between donation and implant by educating and sharing information on the donation process. It is also a great opportunity to discuss the caringtoshare website for recipients and their families and to ensure these recipients have this information from their surgeons.

The focus is on 16 pediatric hospitals in the PEDS program. They are:

- Children's Hospital Atlanta
- Children's Hospital of Boston
- Children's Hospital of NY
- Mt. Sinai Hospital
- Primary Children's Salt Lake City
- Medical City Dallas
- Children's Memorial Herman
- Phoenix Children's
- Children's Mercy Kansas City
- Children's Memorial Chicago
- Children's Hospital of Wisconsin
- Children's Hospital and Clinics of Minnesota
- UCSF
- UC Davis
- Lucile Packard Children's Hospital
- Emanuel Hospital

Your Donor Services Account Manager will periodically have the opportunity to present to the OR Staff during their continuing education meetings. When this opportunity arises, we will involve the OPO/Tissue Bank involved with that hospital to co-present on their organizations and service to the communities. It is a great way to educate the hospitals in each service area about donation in your area and donor families that give the gift.

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