



## CARDIAC CLINICAL COMPENDIUM

For over 35 years, LifeNet Health has been a leader in allograft implants. Our CardioGraft® allografts deliver the high-quality and proven performance you expect for all of your procedures. The list of articles below demonstrates the efficacy of cardiac solutions.

### Published Literature for LifeNet Health Cardiac Grafts

#### Pulmonary Arterioplasty with Decellularized Allogeneic Patches – Hopkins, 2014

- Strong patient population
  - This study used data from a consecutive series of the first 108 patients to receive Matracell patch repairs at a single institution
  - To further substantiate data the 91 patients that received a Matracell patch and had full follow up were compared with 100 patients that had received a synthetic (PTFE) or cryopreserved artery allograft
- Good results in patients receiving CardioGraft patch processed with Matracell®
  - No device related serious adverse events occurred
  - No pulmonary artery aneurysms or stenosis developed that were related to Matracell patch or required replacement of the patch
    - \* Vs 14% of patients that required reoperation in the PTFE/Cryopreserved group for patch related failure
  - No excessive inflammatory scarring or calcification has been identified with diagnostic tools or staged operative repairs

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#### Initial Pediatric Cardiac Experience With Decellularized Allograft Patches – Lofland, 2012

- High risk patient population
  - 44 patients with a mean age of 290 days
  - Tetralogy of Fallot and hypoplastic left heart syndrome accounted for 36.4% of diagnoses
- Good results for patients receiving CardioGraft patch processed with Matracell
  - Severe disease-related complication occurred in 4 patients, all unrelated to patch repair
    - \* 41 other patients have shown no device-related adverse events (no stenosis, thrombi, or need for revisions)
  - One patient elected to have her allograft replaced with a new conduit at 169 days. Histology revealed active autologous revascularization of the graft with no inflammatory markers.

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## **Clinical Utility of Preimplantation Homograft Cultures in Patients Undergoing Congenital Cardiac Surgery – Mehrotra, 2017**

- Large study population
  - 437 homografts (aortic valves, pulmonary valves, and pulmonary patches) were placed in 388 patients from 2010-2014 at Boston Children's Hospital
    - \* Total of 1376 cultures were performed preimplantation: 483 bacterial, 435 fungal, and 458 AFB cultures
- Low rates of positive cultures
  - 73/1376 (5%) of preimplantation cultures returned positive
    - \* 69/483 (14%) bacterial cultures were positive, 2/437 (.5%) fungal cultures were positive, and 2/458 (.4%) of AFB cultures were positive
    - \* No differences in rates of positive cultures based on manufacturer (CryoLife® vs LifeNet Health)
- Positive cultures were not predictive of clinical outcomes and led to no changes in clinical management

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## **Pathology of Valved Venous Homografts Used as Right Ventricle-to-Pulmonary Artery Conduits in Congenital Heart Disease Surgery – Carreon, 2019**

- Young, complex patient population
  - Median age was 5 days
    - \* 50% of patients had hypoplastic left heart syndrome, 15% had double-outlet RV, 15% has tetralogy of Fallot
    - \* Truncus arteriosus, transposition of great arteries, and critical aortic stenosis were also present
  - 13 patients received allograft for a Sano shunt for Norwood stage I procedure and 7 received one to establish RV-to-PA continuity
- Explanted allografts appeared to be working well
  - Grafts were excised from these 20 patients for upsizing or because of death
    - \* The authors found minimal inflammation or calcification, predominately recipient cells in the medial and intimal layers, and functional valves in a majority of conduits up to one year
      - Primary limitation to longevity appeared to be universal thickening of graft leading to stenosis

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## **Risk Factors for Development of Endocarditis and Reintervention in Patients Undergoing Right Ventricle to Pulmonary Artery Valved Conduit Placement – Mery, 2016**

- Large patient population
  - 586 patients received 792 valved conduits over 19 years
  - Median age was 4 years
  - 289 received pulmonary homografts, 121 received aortic homografts, 245 received bovine jugular grafts, and 137 received porcine heterografts
- Allograft had lower odds of recurrent endocarditis
  - Actuarial 10-year freedom from endocarditis was 83% for bovine jugular grafts, 95% for porcine heterografts, 98% for pulmonary homografts and 100% for aortic homografts

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## **Homograft Use in Reoperative Aortic Root and Proximal Aortic Surgery for Endocarditis: A 12-year Experience in High-risk Patients – Preventza, 2014**

- High risk patient population
  - 39 consecutive patients underwent reoperation of proximal aorta due to infection of their prosthetic aortic root, ascending or arch graft, or both
    - \* All patients received a cryopreserved homograft conduit from LifeNet Health
    - \* Previous procedures/preoperative conditions include:
      - ◊ Aortic root and ascending aortic replacement – 53.8%
      - ◊ Ascending aortic replacement – 17.9%
      - ◊ Aortic valve replacement – 15.4%
      - ◊ Supracoronary ascending graft with aortic valve replacement – 12.8%
      - ◊ >1 previous sternotomy - 30.8%
      - ◊ Hypertension – 82%
      - ◊ Smoker – 60.5%
      - ◊ CHF on admission – 56.4%
      - ◊ Thoracic aortic disease – 41%
      - ◊ Prior stroke/TIA – 20.5%
      - ◊ COPD – 17.9%
- Good performance of LifeNet Health tissue
  - 10.3% operative mortality
    - \* All four patients that died had complex history of CV surgery
  - 2.6% permanent stroke rate
  - 100% freedom from reinfection during median follow-up 2.4 years
  - 2.9% required reoperation due to severe aortic stenosis developed at 10 years

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## **Reoperative Right Ventricular Outflow Tract Conduit Reconstruction: Risk Analyses at Follow Up – Rodefeld, 2008**

- Large study population
  - Out of 372 grafts used in RVOT reconstruction, 127 were cryopreserved allografts, 86 were Contegra® jugular vein conduits, 29 were non-valved PTFE grafts, 35 were transannular with/without PTFE monocusp, 17 were Medtronic® freestyle porcine stentless, 31 were porcine stented bioprostheses, 15 were Hancock porcine stentless, 15 were decellularized SynerGraft® homografts, 10 angioplasties, 4 stent implantation and 3 St. Jude® mechanical valves
- Multivariate analysis found significant risk factors for replacement of the conduit to be small conduit diameter and diagnosis of truncus arteriosus. Multivariate analysis found significant risk factors for survival to be diagnosis of truncus arteriosus and surgery before 1992
  - Allografts were significant risk factors on a univariate analysis

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## **Reconstruction of Right Ventricular Outflow Tract in Neonates and Infants Using Valved Cryopreserved Femoral Vein Homograft – Schiller, 2014**

- Well matched patient cohorts
  - 20 patients underwent RVOT with cFVH (cryopreserved femoral vein homograft) from 2008-2012 and 16 patients received A/PH (aortic/pulmonary homograft) for same surgery before 2008
    - \* All patient information was comparable except for shorter mean aortic crossclamp time for cFVH group
- Strong performance of cFVHs
  - Catheter reintervention was lower for cFVH than A/PH (35% vs 81%)
  - Surgical conduit reoperation was lower for cFVH than A/PH (12% vs 56%)
  - Time to conduit replacement was comparable
- Favorable qualities of cFVH for CV surgery on neonates
  - cFVH from LifeNet Health are available in 25 to 30-cm lengths with diameter tapering from 15mm to 9mm
  - cFVH has 2-4 competent valves that the surgeon can choose from intraoperatively
  - cFVH has thin walls that match width of neonates pulmonary artery

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## **Tolerance to Incompatible ABO Blood Group Antigens in Not Observed Following Homograft Implantation – Feingold, 2011**

- Implantation of homograft does not change isohemagglutinin profiles
  - This study found that infants and children that receive ABO incompatible homografts have statistically equivalent scores for anti-A and anti-B antibodies as those that receive ABO compatible homografts
    - \* Therefore, tolerance to incompatible A and B blood group antigens does not appear to result
  - No statistically significant difference in HLA allosensitization between ABO incompatible and ABO compatible groups was found

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## **Additional Published Literature for Cardiac Allografts**

### **Pulmonary Valve Replacement Function in Adolescents: A Comparison of Bioprosthetic Valves and Homograft Conduits – Batlivala, 2012**

- Strong study population
  - Retrospective review 254 adolescents (84 homografts; 170 bioprosthetic valves)
- Strong performance of homograft compared to bioprosthetic valve
  - No differences in outcome were related to graft type
    - \* Freedom from RVOT reintervention: 90% at 5 yr; 67% at 10 yr, 47% at 15 year

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## Results of Allograft Aortic Valve Replacement for Complex Endocarditis – Dearani, 1997

- High risk patient population
  - All 36 patients had complex endocarditis
    - \* Intraoperative finding revealed 25 valvular vegetations, 25 annular abscesses and 13 cusp destructions
    - \* Complex reconstruction of the aortic annulus was required in 25 patients as well as numerous other procedures
- Low rates of reinfection/reoperation
  - Reoperation risk at 5 yr = 8% and survival at 5 yr = 53.1%

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## Reconstruction of the RVOT with Valved Biological Conduits: 25 Years Experience with Allografts and Xenografts – Homann, 2000

- Large patient population
  - 505 patients (174 xenografts and 331 allografts) between 1974-1999
  - Large variety of congenital malformations treated in the patient population
- Better outcomes with allografts vs xenografts
  - Mean reoperation-free interval: allografts = 16.0 yr and xenografts = 10.3 years
    - \* Mean operation free time for patients with conduit diameter <18 mm: allografts = 13.1 years and xenografts = 8.6 years
    - \* Mean operation free time for patients with conduit diameter ≥ 18 mm: allografts = 14.1 years and xenografts = 12.5 years
  - Comparable survival probabilities

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## Intermediate-term Fate of Cryopreserved Allograft and Xenograft Valved Conduits – Kirklin, 1987

- Good size patient population with multiple treatment arms
  - 128 cryopreserved and 19 fresh allograft aortic valves and ascending aortas were placed in 147 patients between 1981-1986
  - 64 glutaraldehyde-preserved xenografts and 14 irradiated allograft aortic valves were placed in 78 patients from 1968-1981
- Strong performance of allografts
  - Freedom from reoperation at 3.5 years was 94% in patients receiving allograft
    - \* The two patients requiring reoperation were 6 and 36 months during initial operation and received 12 mm and 16 mm allografts respectively
  - 5-year survival rate in allograft cohort was 72% vs 60% in xenograft cohort

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## Results of Homograft Aortic Valve Replacement for Active Endocarditis – Tuna, 1990

- This article described the results at a single center of 10 cryopreserved homograft aortic valves due to endocarditis.
  - No patient has had recurrence of endocarditis. We conclude that cryopreserved homograft aortic valve/root replacement is an effective method for management of active endocarditis complicated by annular destruction.
  - Data suggest that risk of early endocarditis after aortic valve replacement with homograft prostheses is substantially lower than with mechanical valves or heterografts.
  - The absence of early or late reinfection encourages us to use cryopreserved homografts whenever possible for aortic valve replacement in active endocarditis.

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## **Surgical Treatment of Active Infective Aortic Valve Endocarditis with Associated Periannular Abscess – 11 Year Results – Knosalla, 2000**

- High risk patient population
  - All 65 patients had active aortic valve endocarditis and paravalvular abscess
    - \* Also all patients presented with CHF, systemic emboli or atrio-ventricular block III
- Better results with allografts vs prosthetic grafts
  - 30 day mortality was 23.5% in prosthetic group and 8.5% in allograft group
  - Recurrent valve infections over 11-years was 27.1% in prosthetic group and 3.2% in allograft group
  - 11-year survival rate was 82.1% in allograft group and 64.7% in prosthetic group

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## **Surgical Management of Acute Aortic Root Endocarditis with Viable Homograft: 13-year Experience – Yankah, 2002**

- High risk study population
  - 182 patients received aortic homograft
    - \* 110 patients were NYHA function class III and 72 class IV
    - \* 124 patients had periannular abscess
    - \* 107 patients has native valve endocarditis and 75 had prosthetic valve endocarditis
- Good outcomes with allograft
  - 1 year and 10 year survival rates were 97% and 91% respectively
  - Early and late reinfection rates were 2.7% and 3.6% respectively
  - Freedom from reoperation for 10-13 years in well-matched patients was 85%

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## **Mid-Term Results of Reconstruction of the Right Ventricular Outflow Tract Using Cryopreserved Homografts –Youn, 2007**

- Strong performance of allografts
  - No operative mortality and 3/20 patients had major complication
  - 8-year freedom from graft failure = 87.5%
  - 7-year freedom from graft dysfunction was 62.3%

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LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

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