



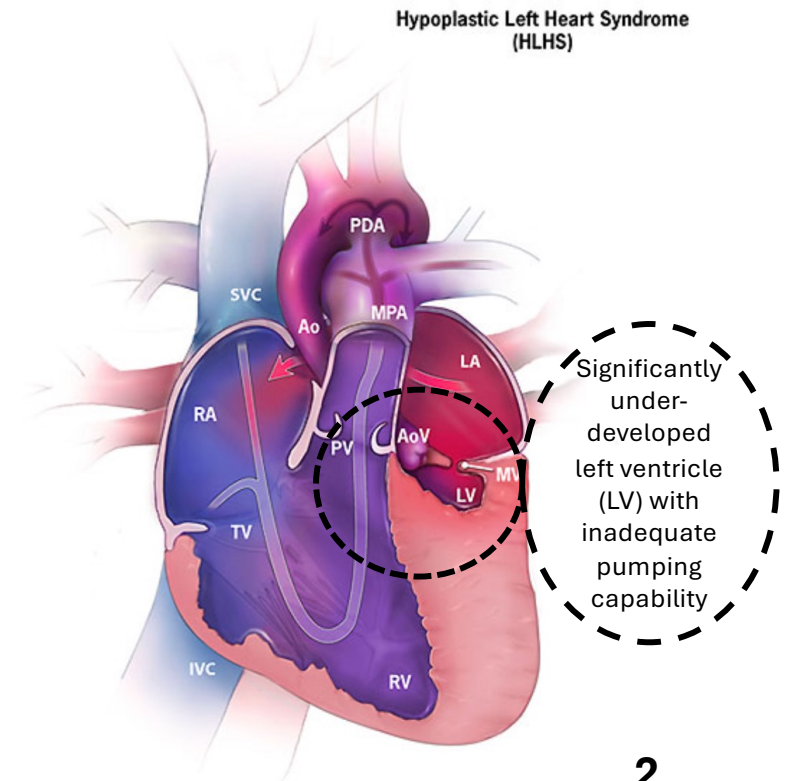
## **Cardiovascular Bypass with Autologous Cell Seeded Tissue Engineered Resorbable Scaffold**

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Nationwide Children's Hospital  
Columbus, Ohio

ICD-10 Coordination and Maintenance Committee Fall Update

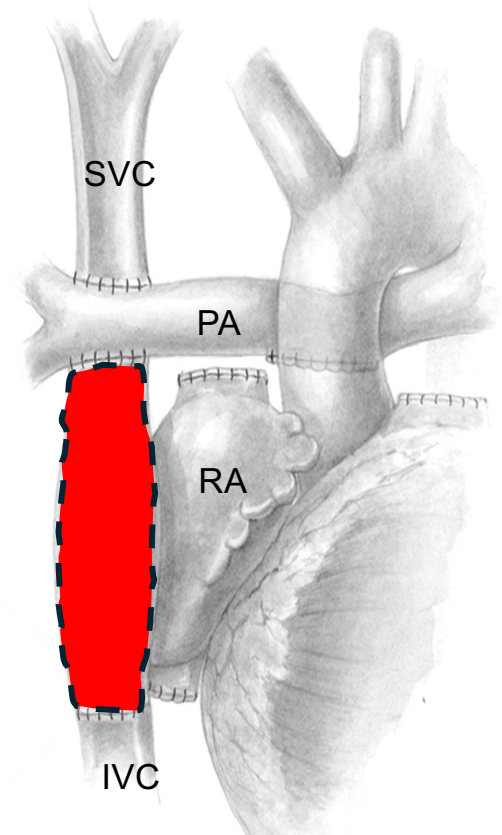
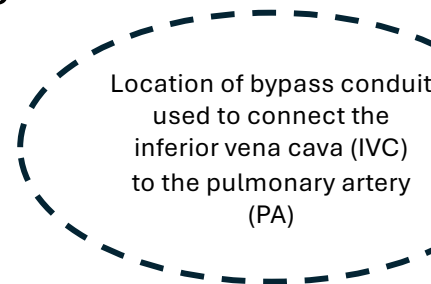
# Single Ventricle Disease Overview

- Can arise from any pediatric congenital cardiac anomaly causing the formation of a single functional ventricle.
- Critical cardiac defect, life-threatening without intervention.
- Incidence: Approximately 1000 cases per year in United States for children ages 0-4 years.



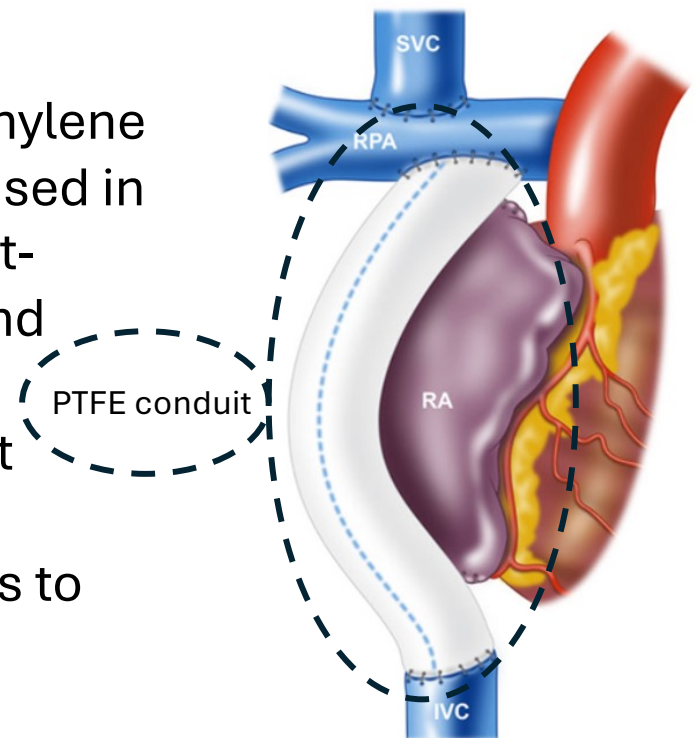
# Fontan Circulation

- Historically, the standard of care for patients with single ventricle disease has been a series of procedures designed to create Fontan circulation.
- While life-saving, it is only palliative, because abnormal Fontan hemodynamics cause liver disease, including cirrhosis.



# Fontan Operation

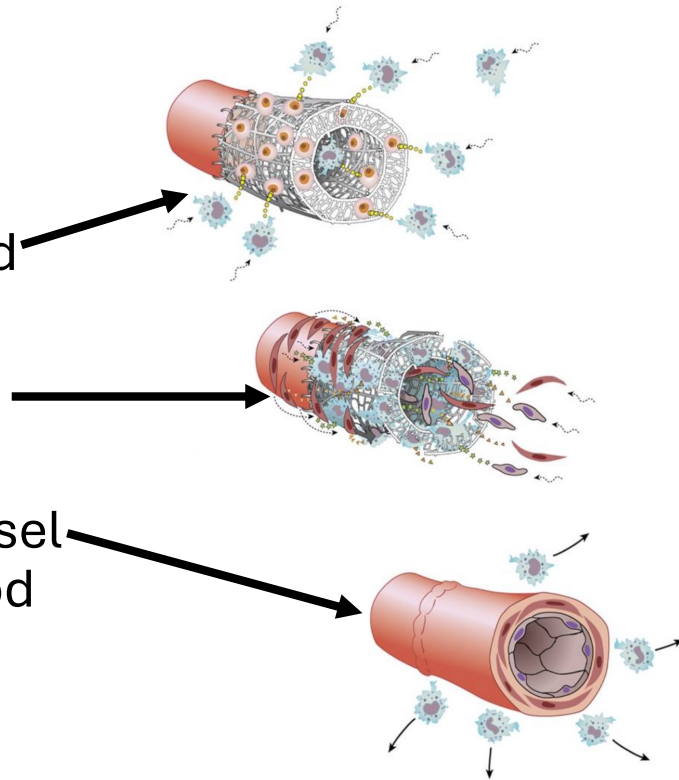
- Conventional synthetic [Polytetrafluoroethylene (PTFE)] and biological vascular conduits used in Fontan procedure result in significant graft-related complications such as stenosis and calcification.
- Further problem: vascular conduits do not expand as the child grows.
- May require additional corrective surgeries to accommodate the child's growth.



<https://www.ahajournals.org/doi/10.1161/CIR.0000000000000696>

## Autologous Cell Seeded Tissue Engineered Resorbable Scaffold Technology

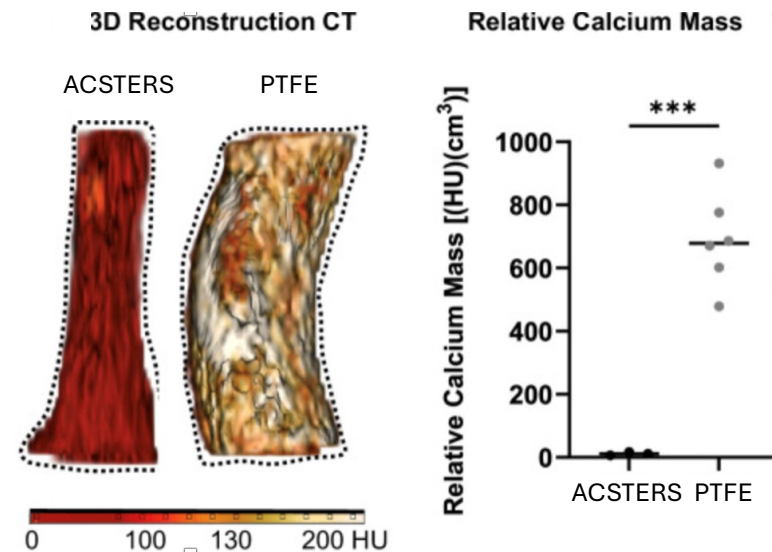
- Innovative tissue engineering from autologous mononuclear cells seeded onto a scaffold.
- Scaffold resorbs into the vasculature.
- Within 6 months of implant, induced vascular regeneration forms a neovessel functioning clinically like a native blood vessel.

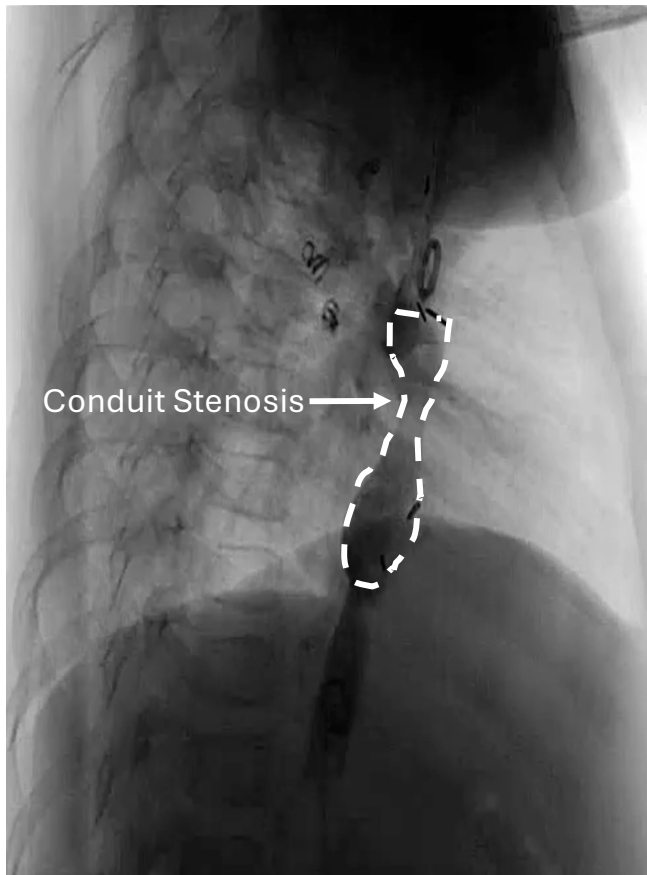


Roh et al, PNAS 2010

## Autologous Cell Seeded Tissue Engineered Resorbable Scaffold (ACSTERS)– Clinical Implications

- Solving the problems of conventional care
  - Highly resistant to calcification
  - Improved compliance match - improves blood flow consistent with the child's clinical needs
  - Biological growth as the patient grows
- May reduce the number of follow-on corrective surgeries





## Adverse Events

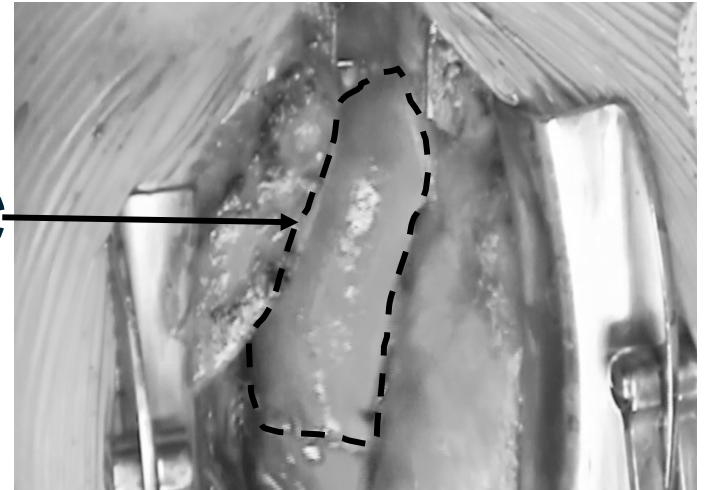
|                      | ACSTERS         | PTFE            |
|----------------------|-----------------|-----------------|
| <b>Infection</b>     | None or limited | None or limited |
| <b>Aneurism</b>      | None or limited | None or limited |
| <b>Thrombosis</b>    | None or limited | None or limited |
| <b>Embolism</b>      | None or limited | None or limited |
| <b>Calcification</b> | None or limited | Universal       |
| <b>Stenosis</b>      | Present         | Universal       |

# Clinical Results



Intraoperative Photo

ACSTERS

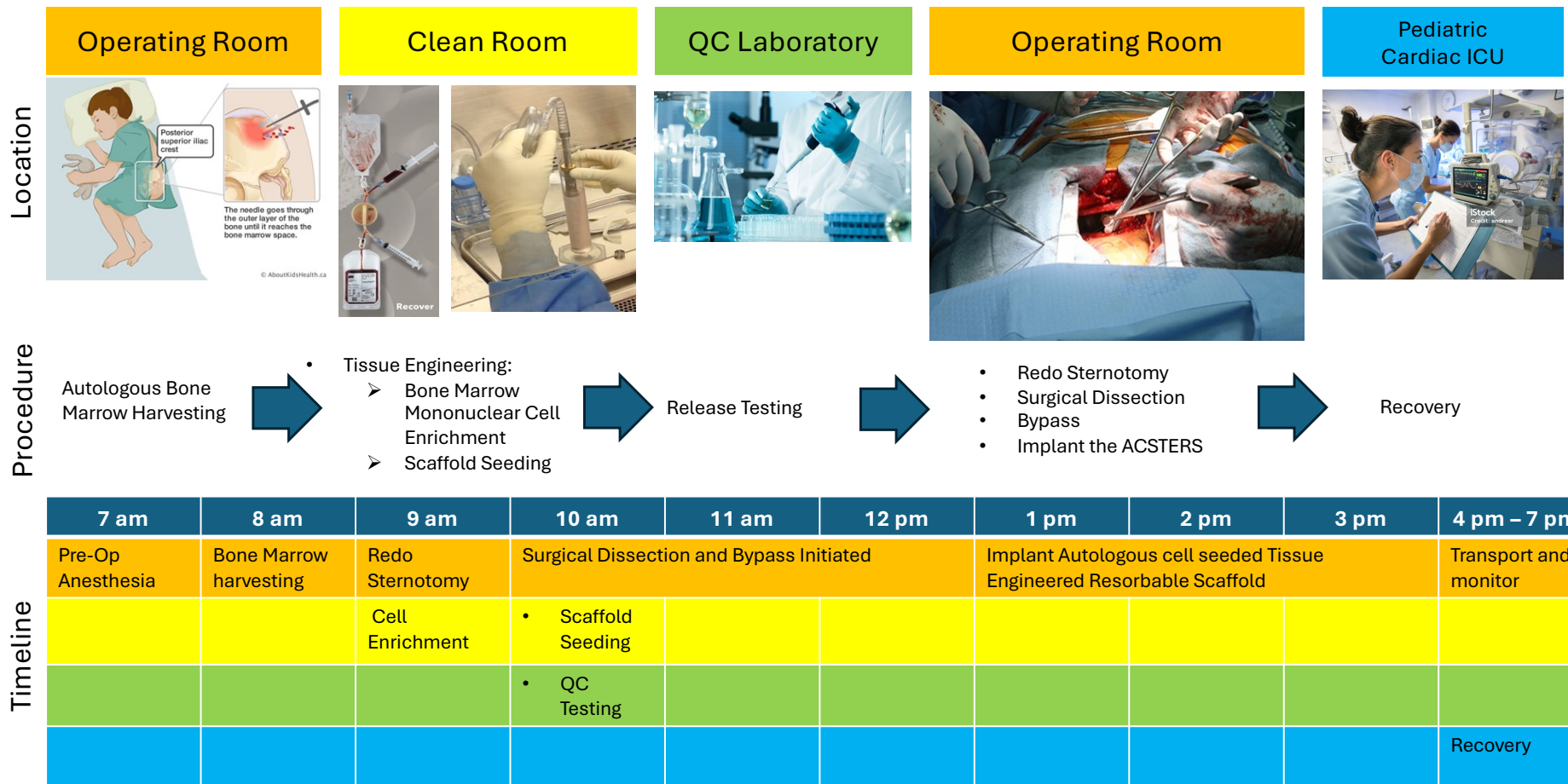


Photos used with authorization of patient's parents/legal guardians



# FDA Status

- Investigational Device Exemption with CMS Category B  
(Approved August 22, 2019)
- Humanitarian Use Device (HUD Designation 2008)
- Breakthrough Designation (December 2024)
  - Unique Autologous Mononuclear Cell Enrichment and Seeding onto Resorbable Scaffold
  - Resistance to Calcification
  - Compliance Match
  - Vascular regeneration
  - Biologic growth capacity
- Humanitarian Device Exemption (HDE - Planned submission December 2025)
- Plan to submit Premarket Approval Application based on HDE



# Key Technology Device Descriptor Terms

**ACSTERS:** Autologous **c**ell **s**eeded **t**issue **e**ngineered **r**esorbable **s**caffold

**ACSTERS-VRBG:** Autologous **c**ell **s**eeded **t**issue **e**ngineered **r**esorbable **s**caffold for **v**ascular **r**egeneration and **b**iological **g**rowth

Documentation of the procedure using the scaffold may be found in the operative report.

# Thank you!

