

IntelliStent®: Minimally Invasive Pulmonary Blood Flow Adjustment

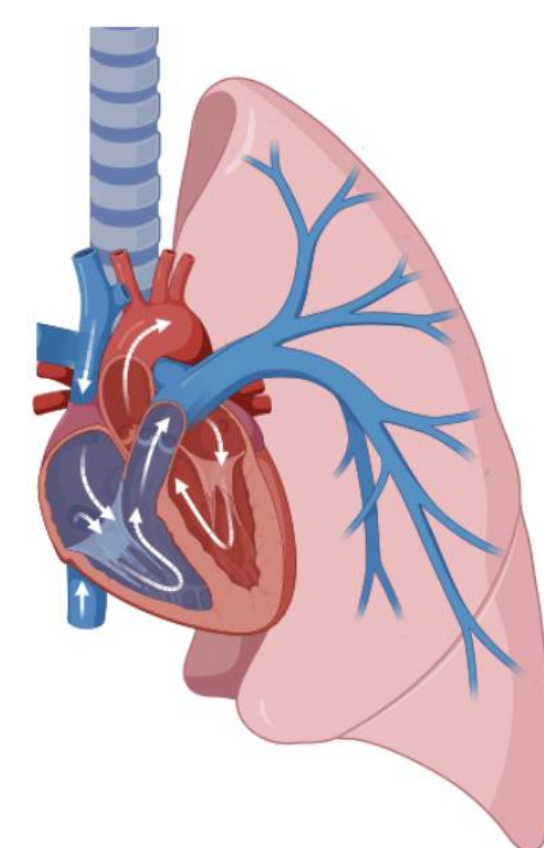
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Relevant Indications

1. Pulmonary Artery Hypertension associated with Congenital Heart Disease (PAH-CHD)

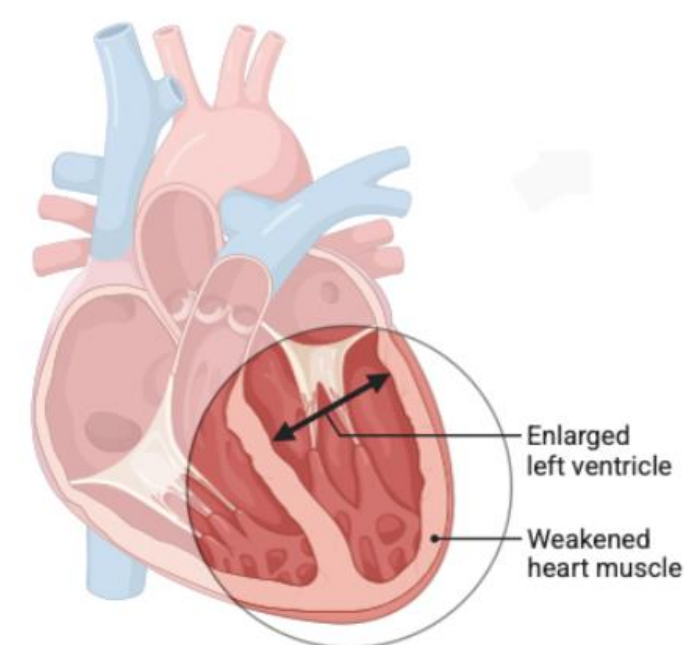
If a defect in the heart creates abnormal blood flow, then...

- the blood pressure in the heart and lungs raises
- blood vessel walls thicken and resist flow
- heart will work harder to overcompensate
- **heart failure**



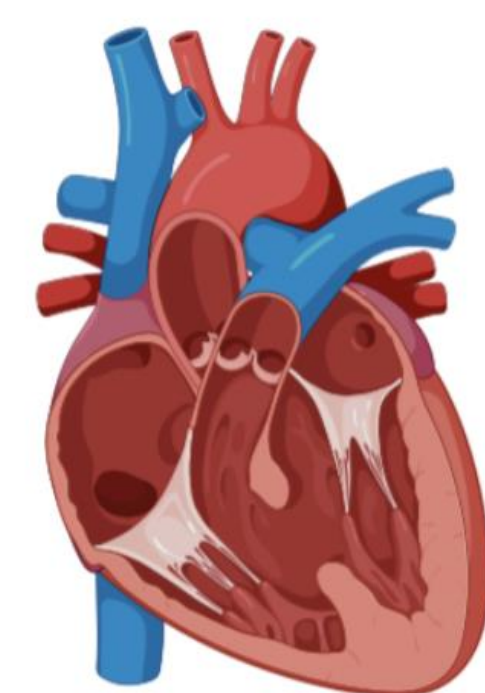
*"Complex CHD" = high risk for developing PAH-CHD.

2. Left Ventricle Dilated Cardiomyopathy (LV-DCM)



If the LV is weak, then...

- it pumps less blood out to the body
- blood backs up in the lungs
- LV dilates more, gets weaker
- **heart failure**



3. Single Ventricle Defects (SV)

If the heart only has one ventricle, then...

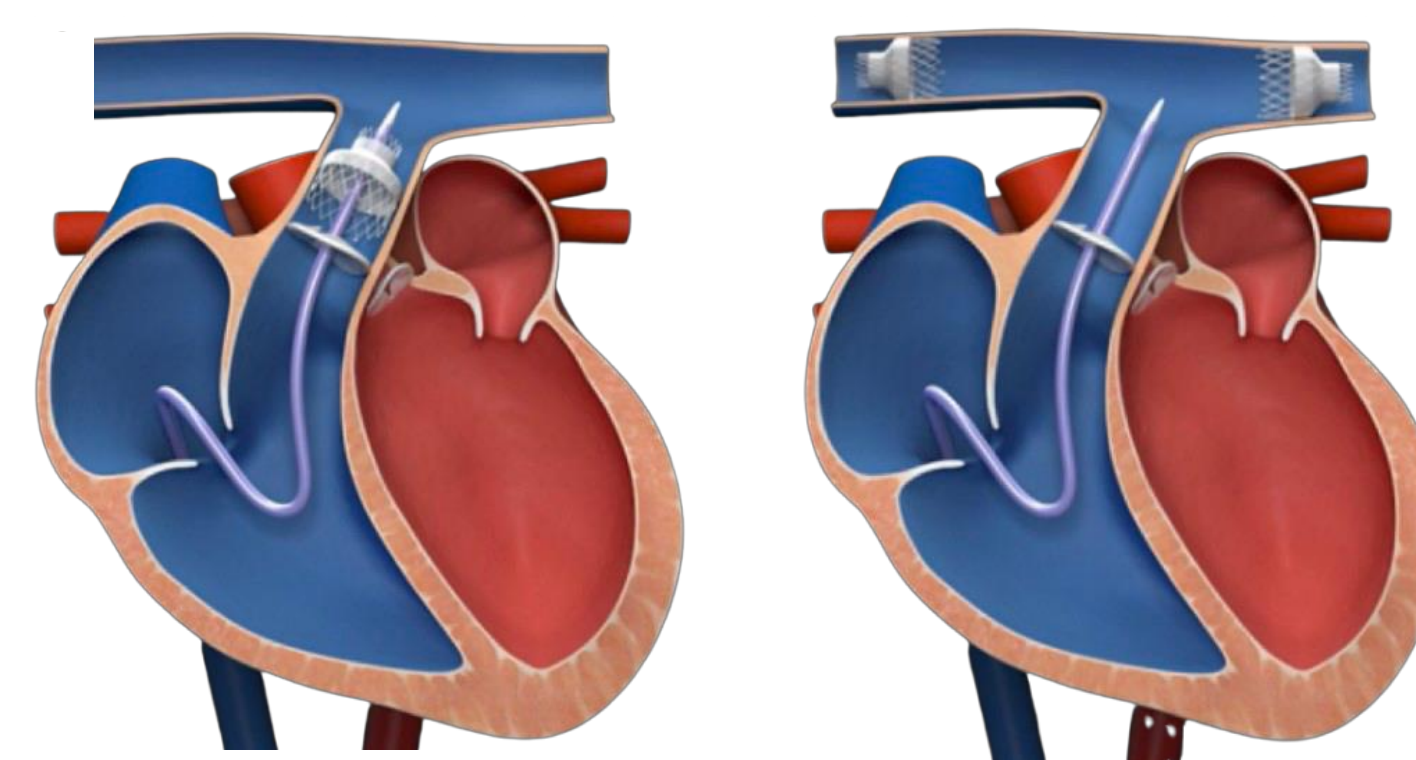
- the one ventricle must pump blood to the heart and the lungs
- the ventricle becomes overworked and weakens
- **heart failure**

Introducing IntelliStent®

Multi-lumen stent system for transcatheter adjustment of pulmonary blood flow.

Major Advantages:

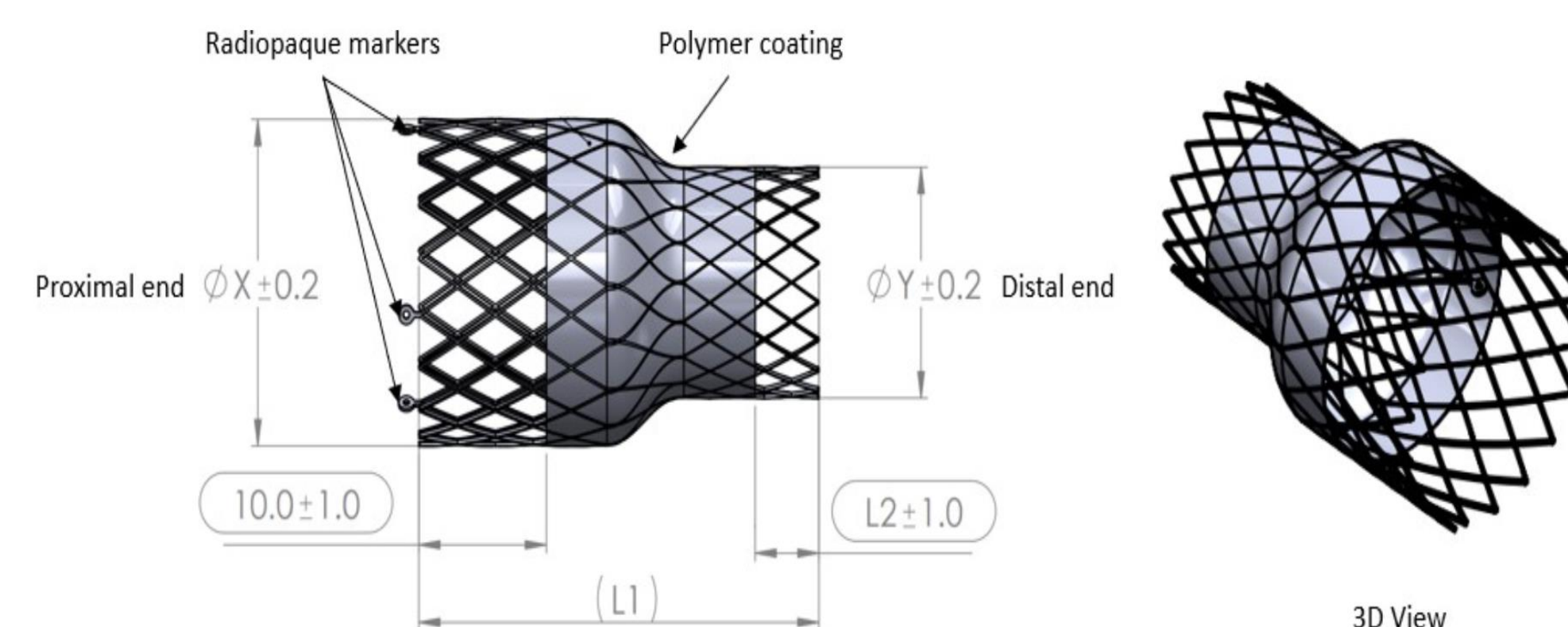
1. Adjustable and Reversible
2. Minimally Invasive
3. Rapid Transcatheter Placement
4. Infant and Pediatric Use
5. Cost Effective



IntelliStent can be placed in the main pulmonary artery or any of its branches.

Mechanism of Action

The narrowed diameter increases resistance, reducing the volume of blood that can enter the pulmonary circulation, thereby lowering pressure downstream in the lungs.



Congenital Heart Disease

→ decreases the shear stress that drives vascular thickening
→ Unloads the right ventricle

Left Ventricle Dilated Cardiomyopathy

→ decreases the blood backing up into the lungs
→ reduces afterload on the ventricle

Single Ventricle

→ balances pulmonary and systemic circulations
→ decreases chronic ventricular overwork

Market

Total Addressable Market

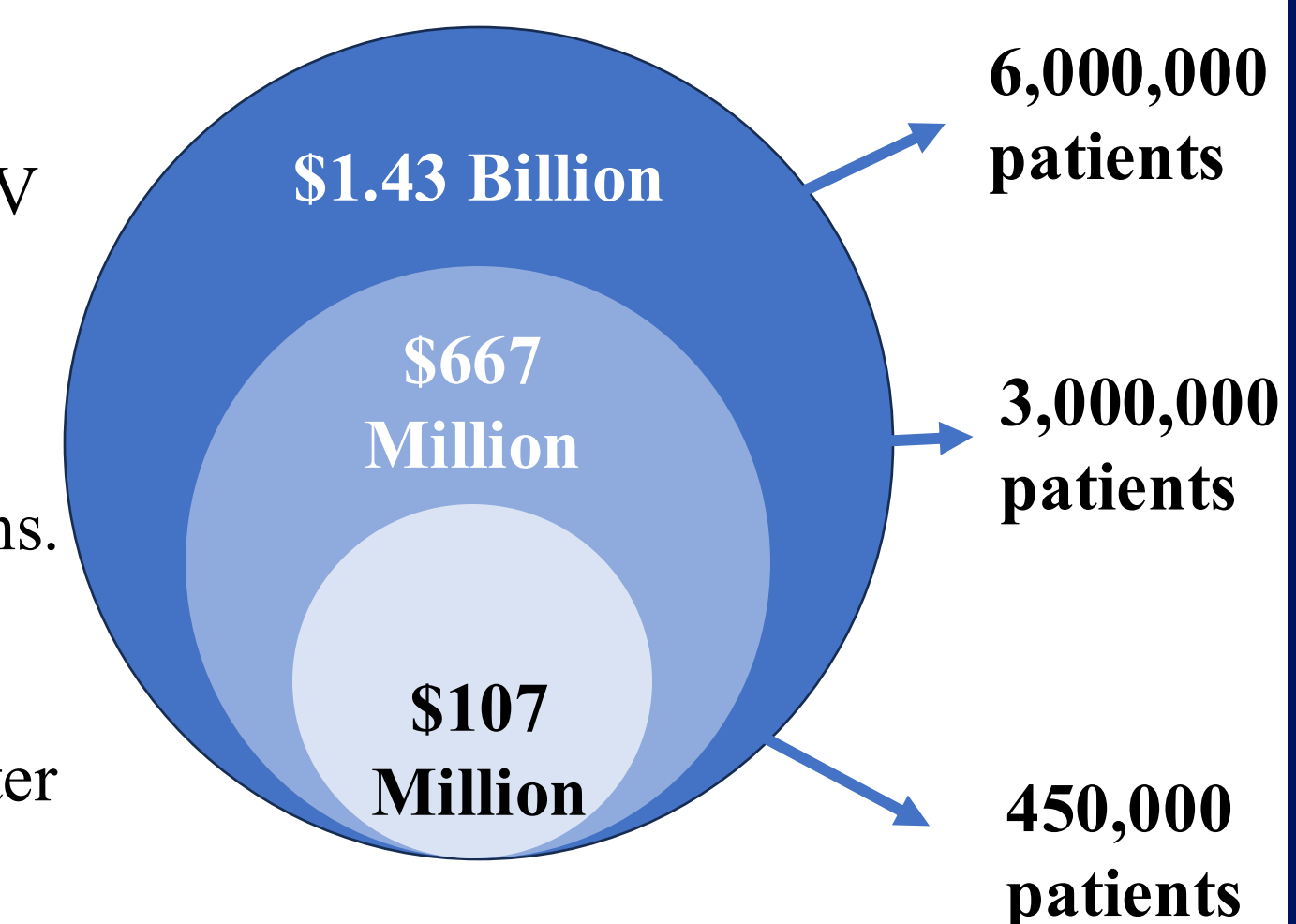
Global cases of PAH-CHD, complex CHD, LV-DCM, and SV eligible for flow restriction.

Serviceable Accessible Market

Reduced by regulatory limitations.

Serviceable Obtainable Market

Reduced by sales capabilities after 5 years of commercialization.



Future Directions



Regulatory

Apply for Investigational Device Exemption. Apply for Breakthrough Designation.



Manufacturing

Optimize manufacturing process for clinical and commercial production.



Prototyping

Redesign IntelliStent for infants and neonates.



Reimbursement

Apply for New Technology Add-On Payment and eventually a Category III CPT code.

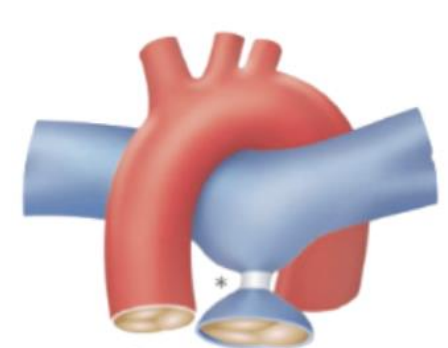


Funding

Continue applying for nondilutive grants.

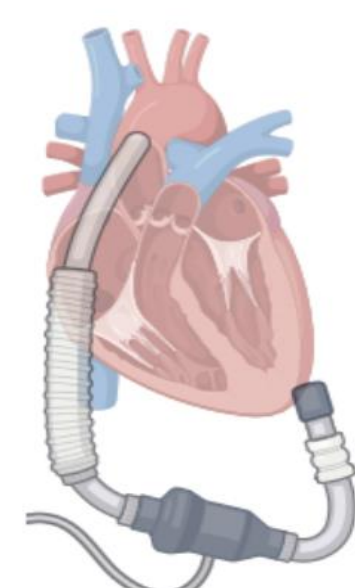
Current Treatments

Pulmonary Artery Banding



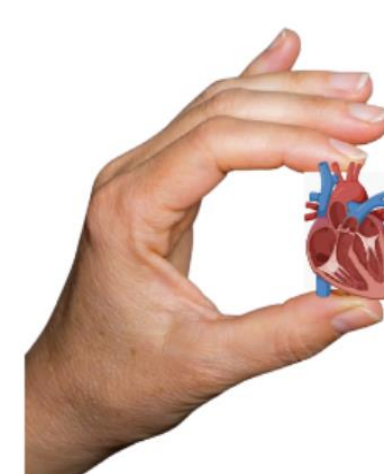
Invasive surgery
Often requires interventions
Not adjustable

LVAD



Invasive surgery
Limited pediatric use
Bridge to transplant

Heart Transplant



Invasive surgery
\$1,000,000+
Limited donors for pediatric cases

Modification of Vascular Plugs



Ineffective
Off-Label

Problem: Current treatments are invasive, expensive, and/or ineffective.

Acknowledgements and References

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