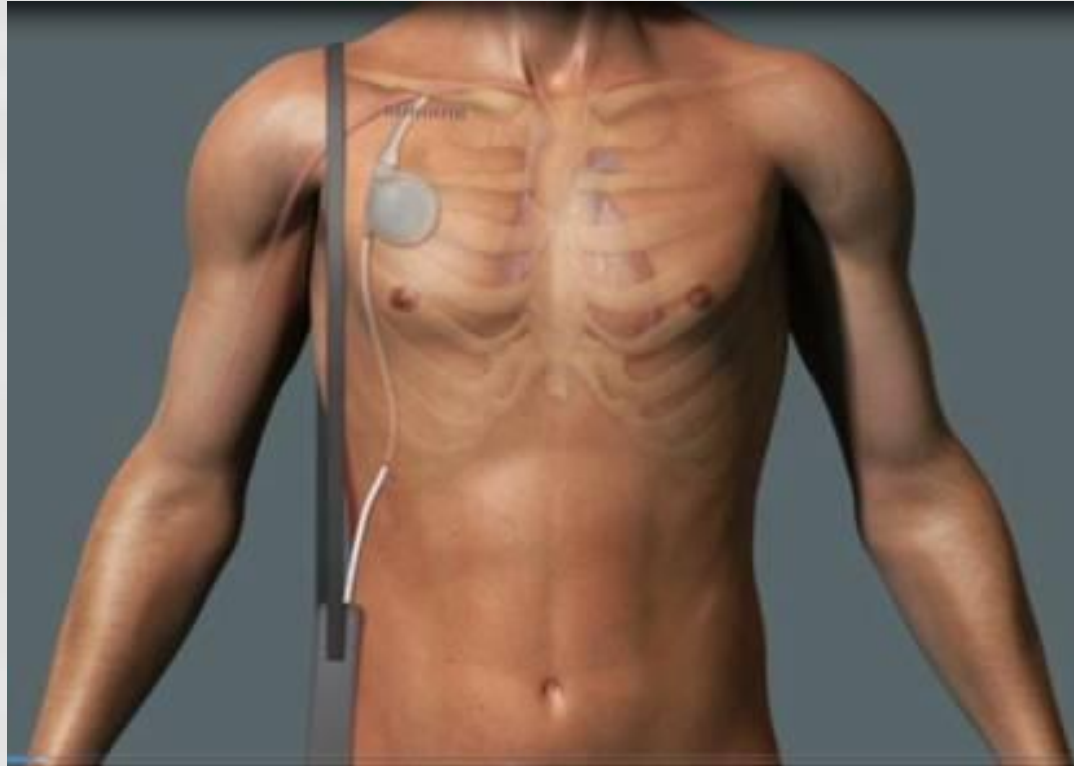


Development of Implantable Synchronized Cardiac Assist Device: Symphony™



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American Heart Association
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 **ABIOMED®**
Recovering hearts. Saving lives.™

Limitations of Heart Failure Therapy

- Progression of disease impacts patient's QOL
- Prognosis poor with advanced heart failure
- Limited heart transplant availability
- Implantable LVADs require major operation, long hospitalizations, readmissions and are costly
- No current implantable cardiac assist device has been designed for heart recovery/remodeling

Symphony™ Project Goals

Develop a synchronized, partial circulatory support device:

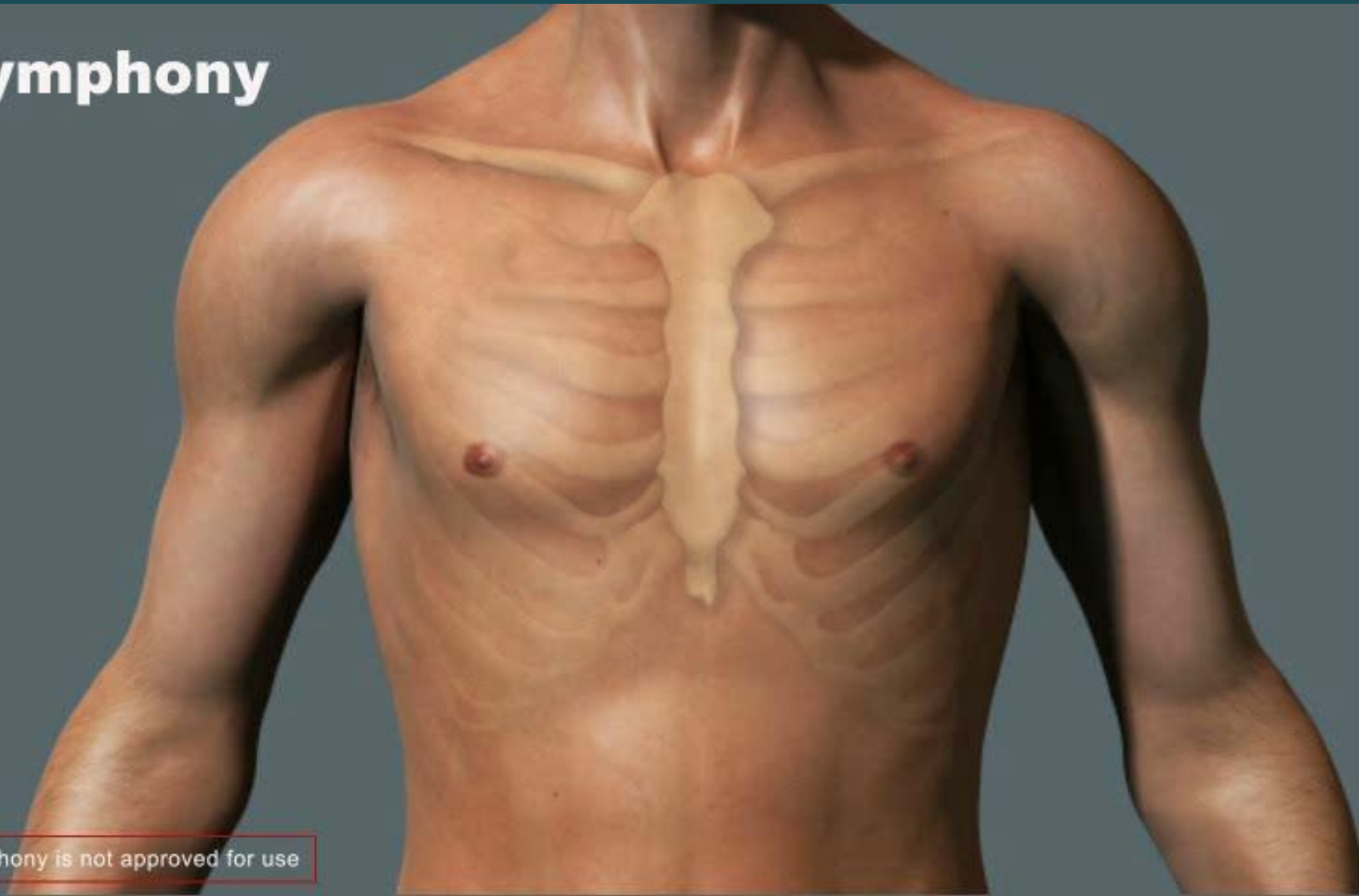
- Improves patient hemodynamics & QOL
- Simple implantation (No thoracotomy or sternotomy)
- Simple device design, low cost/cost effective
- Allows for short LOS and home discharge
- Promotes native heart recovery/remodeling with intent to explant

Symphony™ Device Design & Operation

- An implantable, synchronized assist device
- Placement in pacemaker pocket
- Single graft to subclavian artery
- Synchronized with subcutaneous EKG leads:
 - Afterload reduction-Decreased LV work
 - Increases Cardiac Output
 - Increases coronary and systemic blood flow
 - Decreases filling pressure
- Device output: 3.0 L/min
at 100 bpm



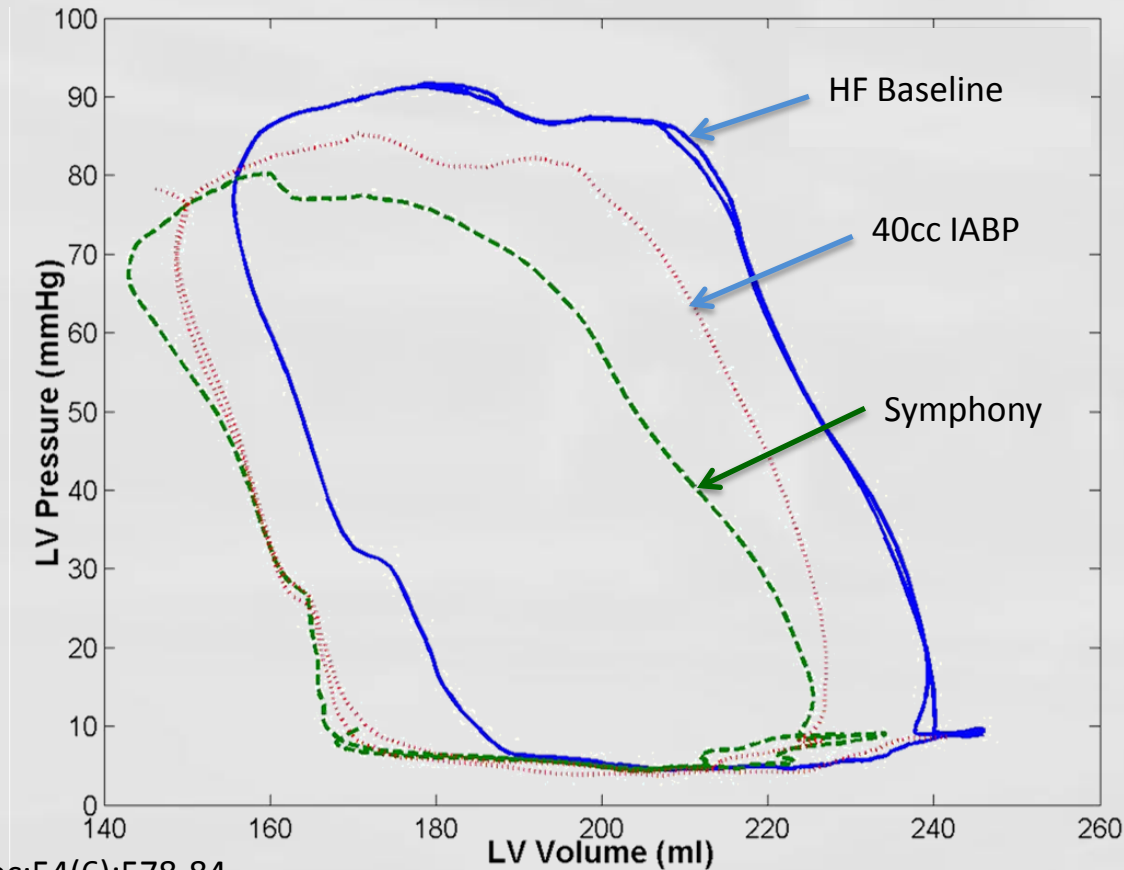
Symphony



Symphony is not approved for use

Symphony™ Device - Hemodynamics

Symphony demonstrated significant improvement in cardiac output, coronary flow, LV work and LV O_2 consumption versus Heart Failure baseline ($p < 0.05$).



ASAIO J. 2008 Nov-Dec;54(6):578-84

Symphony™ Synchronized Assist Device

• Why Partial Support?

- Increasing evidence of clinical benefit
- Promotes myocardial recovery/remodeling
- Avoids issues with continuous full flow devices: GI bleeding, aortic valve dysfunction

• Why Infraclavicular Fossa?

- Most common site for device placement
- Avoids thoracotomy / sternotomy
- Access to “central” circulation via subclavian artery
- Previous or future sternotomies not an issue

Symphony™ Pre-Clinical Implants

- Bovine model with anastomosis to carotid artery
 - Mimics position in human implants
 - Initial studies showed efficacy in bovine heart failure model
 - Final GLP studies prior to first-in-man implants (n=6)
 - ✓ 30 day implants, Warfarin (INR 2x baseline), anti-platelet therapy, full autopsies

Animal Model – Superficial Implant



Symphony™ Pre-Clinical GLP Results

- Operative time for device implant ~ 35 minutes
- No device malfunction
- No hemolysis
- No pocket or systemic infection
- No blood product transfusion
- No end organ dysfunction

Symphony™ Pre-Clinical Results

- No thromboembolism
- No vascular injury
- No renal injury



Symphony™ pumps at 30 day explant



GLP pumps: No deposits, Pumps clean

Symphony™ Project Status

- Early studies showed efficacy-NIH funding
- Over 90 bovine implants and 25 cadavers in development process
- Validated final device design
- Successful GLP pre-clinical study completed
- Ready for First in Man experience

Symphony™ Project - Summary

- Meets goals for a less invasive, cost-effective partial assist device designed for recovery:
 - ✓ Improves hemodynamics, may improve QOL
 - ✓ Simple implantation - Pacemaker pocket
 - ✓ Simple device design, less costly/cost effective
 - ✓ Potential to optimize heart failure medications or future therapies (stem cell, pharma)
 - ✓ Designed to promote recovery with future explant