

HEARTWARE LIMITED

ABN 34 111 970 257



HeartWare
Level 57

**19-29 Martin Place
Sydney NSW 2000**

Ph: (+61 2) 9238 2064

Fax: (+61 2) 9238 2063

www.heartware.com.au

Manager of Company Announcements
ASX Limited
Level 6
20 Bridge Street
SYDNEY NSW 2000

2 November 2007

BY E-LODGEMENT

Dear Sir / Madam

**Presentation on Miniaturization of Blood Pumps
International Society of Rotary Blood Pumps Conference in Sydney**

Attached is a presentation being given today at a conference being held in Sydney by the International Society of Rotary Blood Pumps.

The presentation provides information regarding the Company's next generation pump, the MVAD.

Yours faithfully

David McIntyre
**Chief Financial Officer &
Company Secretary**

HeartWare Limited



Miniaturization of Wearless Blood Pump Technology

Jeffrey LaRose,
Charles Shambaugh
Michael Ashenuga

*International Society of
Rotary Blood Pumps
Sydney, Australia
2 November 2007*



Blood pump design constraints

- Therapeutic Support => capacity for patient population
- Hemodynamic Compatibility => high & low blood shear limits
- Reliability => resistance to wear out
- Implantation Method => device size & cannulation
- Efficiency => heating & battery change interval
- Economics => manufacturability



What does “significant” miniaturization mean?

- Selected full output, wearless HeartWare® LVAD as size reference – 50 cc
- Arbitrarily define “significant” miniaturization as a minimum of 2/3 volume reduction – device volume < 17 cc’s
- Maintaining requirement of full output and mechanically wearless design



Is “significant” miniaturization possible?

Where to start?

Types of full output, wearless rotary LVADs:

- Centrifugal pumps – requires a sufficiently sized volute to convert kinetic energy into “pressure”
- Axial flow pumps – requires upstream and downstream support structures for axial and/or radial support
- Mixed flow pumps – none known

Focused on axial flow pump and removing supports as opposed to developing a very compact and efficient volute



Miniaturizable, wearless axial flow blood pump with hybrid suspension

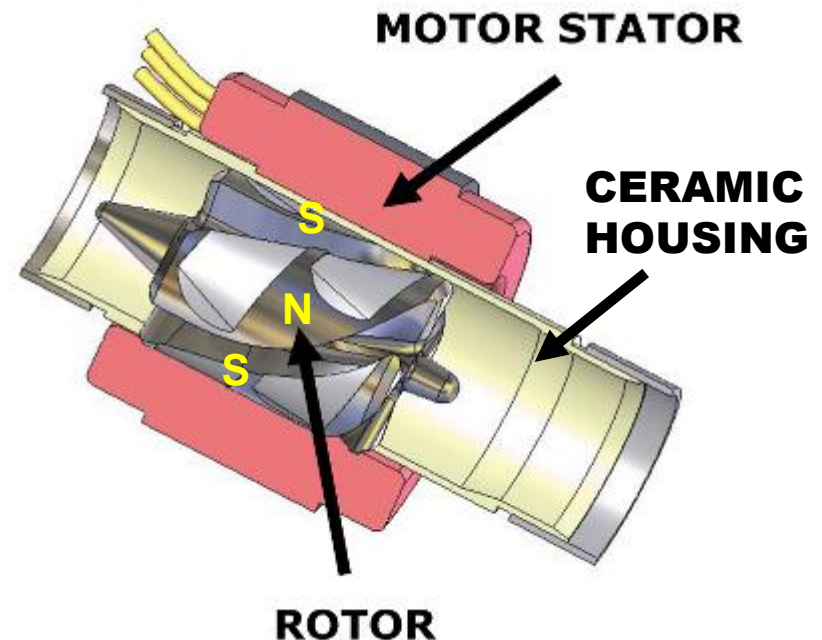
- **Axial constraint with strong magnetic coupling** between stator and motor magnets – small motor air gaps (minimize distance between magnetic poles and stator) and large motor embrace (maximize magnetic flux area)
- **Radial constraint with hydrodynamic forces** – new blade design (sufficient surface area for bearings) with tight control of diametrical clearance (minimize radial loading but allow sufficient surface washing)

Upstream and downstream support structures may be eliminated with passive magnetic and hydrodynamic support



Wide-blade, axial flow blood pump

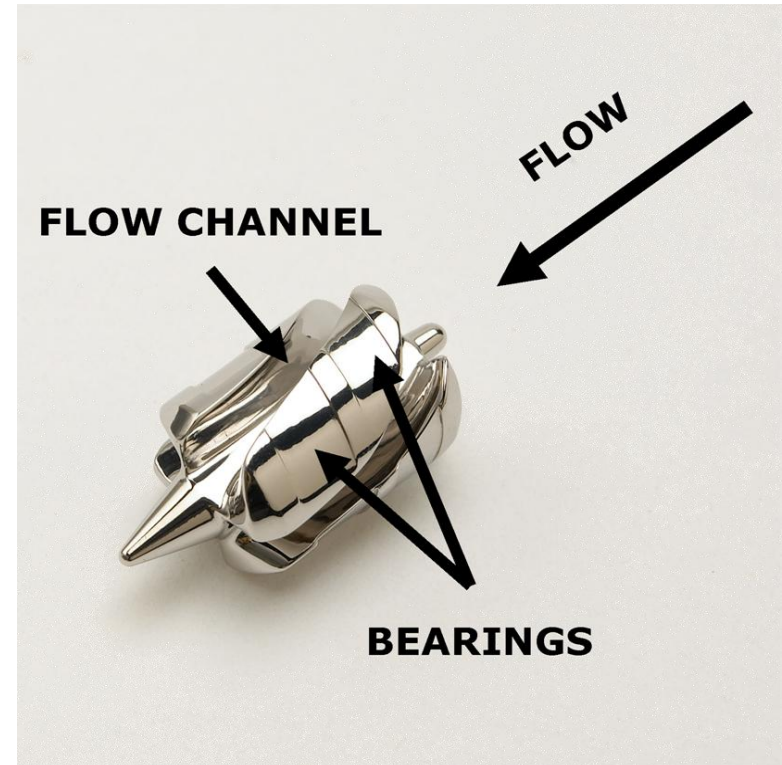
- **Wide-blade, axial flow rotor** to (1) move magnetic poles close as possible to motor stator, (2) provide large motor embrace, and (3) contain sufficient blade tip surface area for hydrodynamic thrust bearings
- **Ceramic rotor housing** to (1) reduce eddy current losses, (2) provide a thin, durable structural wall, and (3) allows high precision on ID for good thrust bearing performance
- **Conventional stator design**



A "wide-blade rotor in a tube"

Wide-blade, axial flow rotor

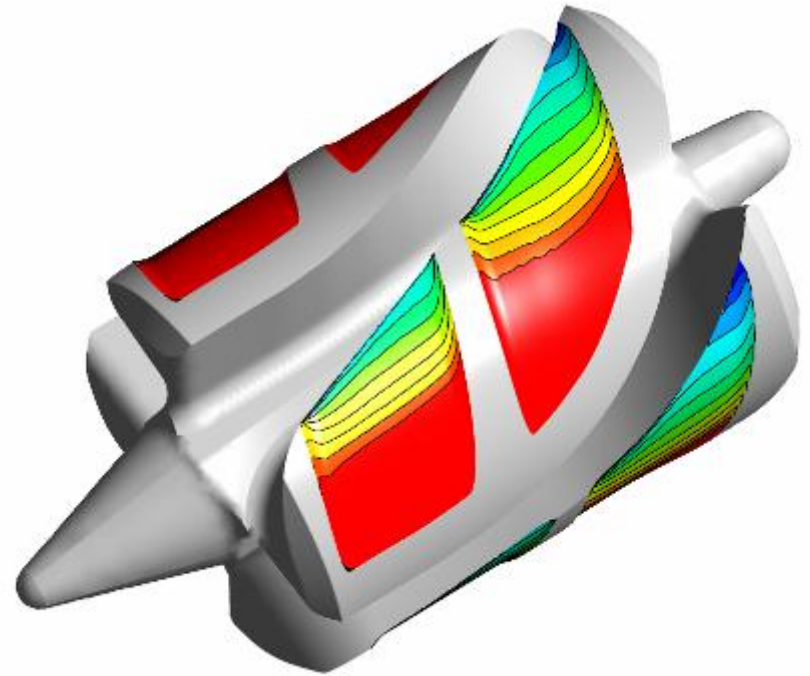
- **A magnetizable, biocompatible, abrasion-resistant, platinum alloy is a significant enabling technology**
 - » *Magnetic strength comparable to rare earth magnets encased in thin titanium shell*
 - » *Machineability – rod stock for auto-feed*
 - » *Polishing – automated polishing*
 - » *Abrasion resistant - no need for protective coatings such as TiNi or DLC*
 - » *Cost – small quantity of platinum required and scrap is recycled*



No rotor subassembly required!

Radial support from eight hydrodynamic bearings

- **Dual hydrodynamic thrust bearings for enhanced rotor dynamic stability** provides support fore and aft of the center of mass
- Bearings are “flow aligned” to maximize performance
- Bearings are cut into material to provide “shrouds” to minimize end leakage

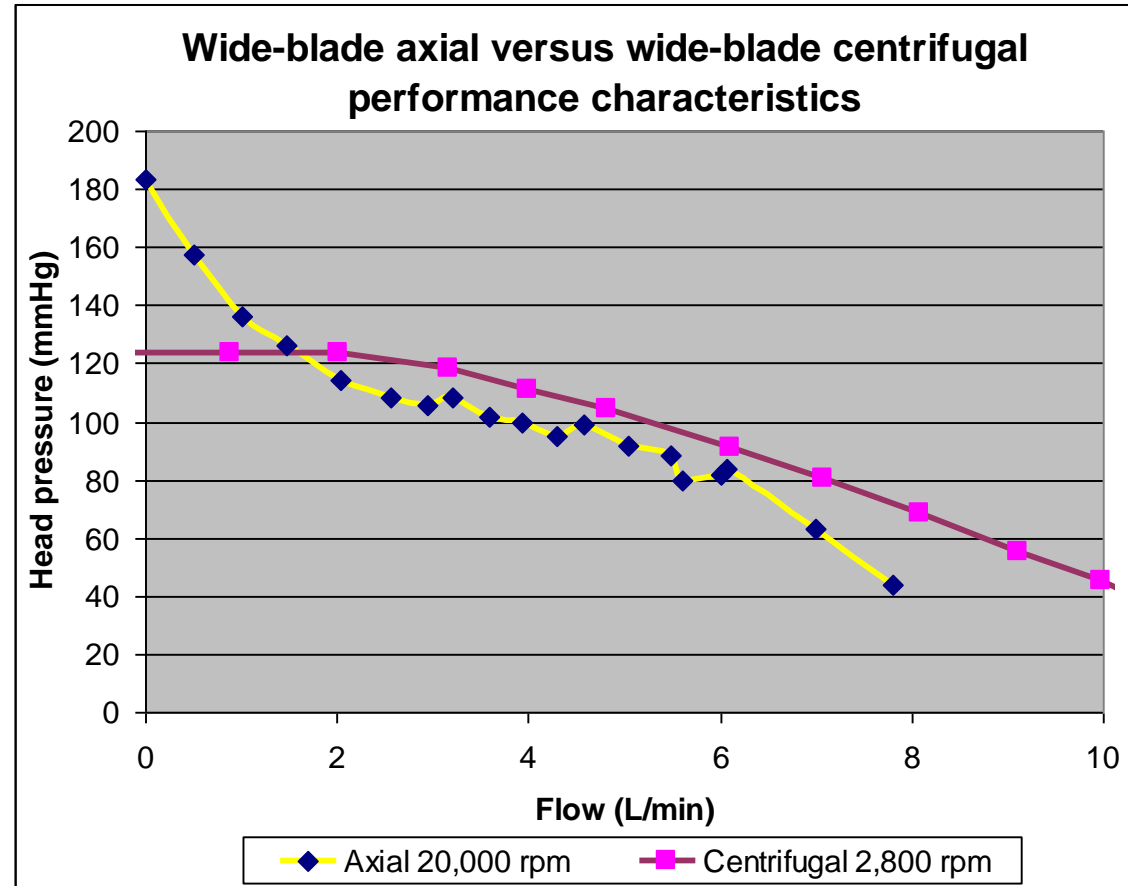


Self restoring, passive suspension system



Performance

- Wide-blade axial flow pump without upstream and downstream flow structures has similar performance characteristics as a centrifugal device
- Frank Starling mechanism will be similar to centrifugal devices
- Better resistance to retrograde flow than centrifugal devices



Behaves like a centrifugal pump!



Implantation method

- Current LVAD implantation methods:
 - » *intra-ventricular*
 - » *pericardial (HeartWare® LVAD)*
 - » *Abdominal*
- New methods are being developed:
 - » *intra-aortic*
 - » *mini-thoracotomy*
 - » *subcutaneous*

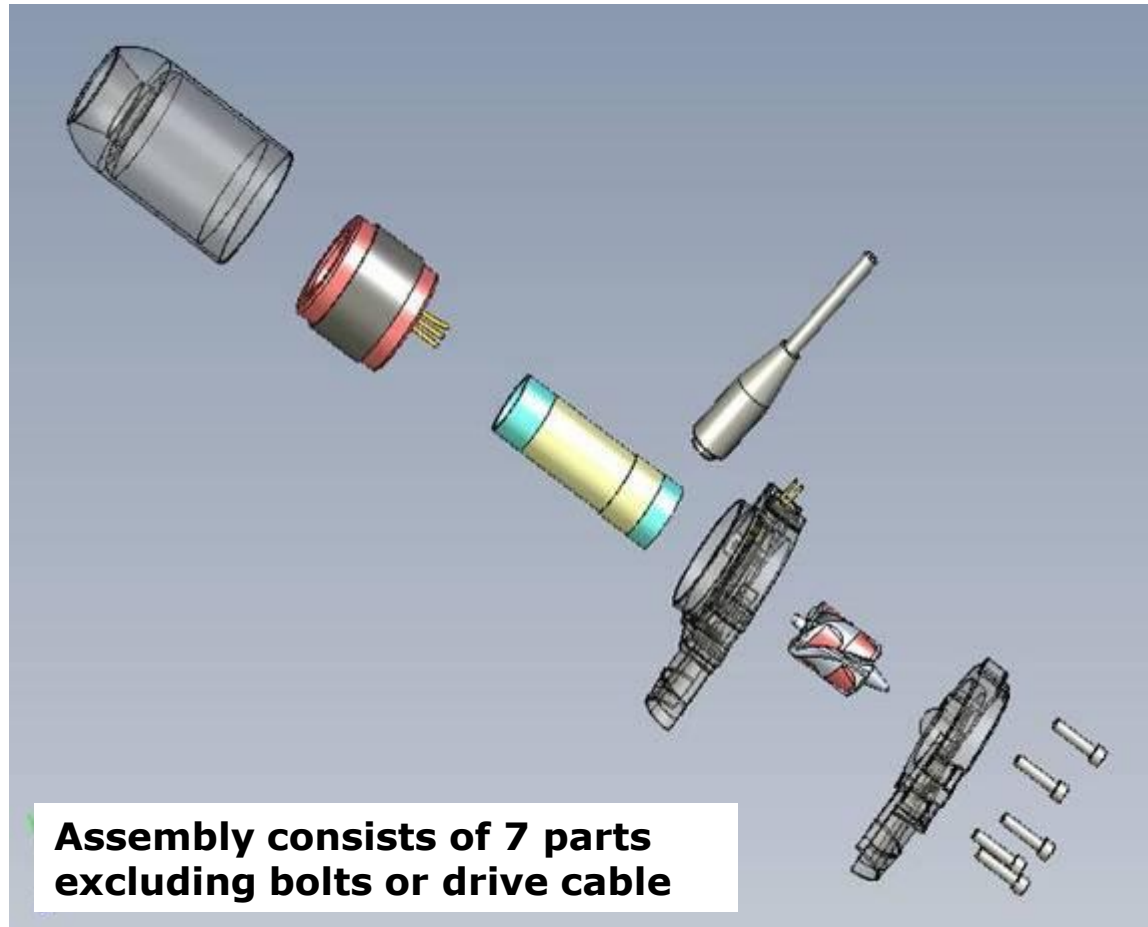


New technology platform is flexible for a variety of cannulation methods



Manufacturing simplicity

- No new manufacturing technology development required
- Tight tolerance between ceramic rotor housing ID and rotor OD is easy to control on circular parts
- No alignment or pre-load force adjustment required

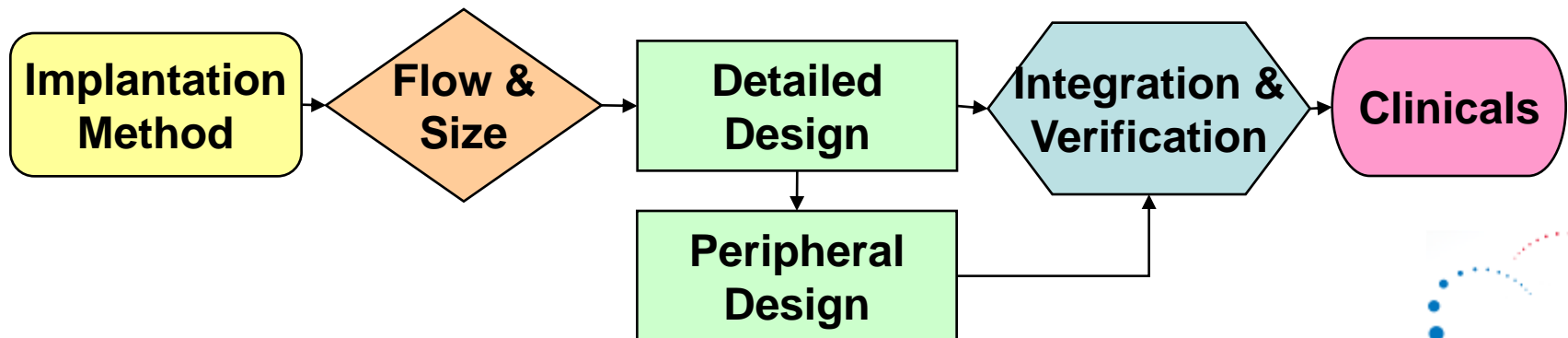


Rotor "drops" into tube

Development status

- **Working on implantation methodology** to take advantage of miniaturized pump technology
- Once implantation method and associated patient population selected, focused design effort will commence
- Intention is to modify existing HeartWare® LVAD peripherals for use with new platform

DESIGN PROCESS:



Is “significant” miniaturization possible?

The HeartWare® wide-blade axial flow pump:

- **Therapeutic Support** => **Yes**, performs similar to centrifugal
- **Hemodynamic Compatibility** => **Yes**, lightly loaded bearings and straight through design result in good hemodynamics
- **Reliability** => **Yes**, mechanically wearless and simple construction results in good reliability
- **Implantation Method** => **Yes**, small size enables less invasive cannulation
- **Efficiency** => **Yes**, strong motor and good hydraulic efficiency results in high system efficiency
- **Economics** => **Yes**, simple construction with new rotor material



Significant miniaturization is possible!

- ***New pump technology allows significant miniaturization*** by removing upstream and downstream flow structures without capacity loss
- ***New rotor material*** enables strong electromagnetic coupling and greatly simplifies manufacturing
- ***Minimally invasive implantation methods are being developed***

