A HEART VALVE

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An innovative percutaneous aortic heart valve with unique advantages over the competitors has been designed. The device may be implanted through a minimal invasive procedure and provides a solution to old and fragile patients who are often denied traditional valve replacement.

Brief Description

The innovation comprises of a new prosthetic aortic valve that may be placed in a patient who is suffering from aortic valve malfunction through minimal invasive surgery. This type of surgery significantly reduces the overall cost of care and length of hospital stay and presents a lucrative alternative to traditional procedures. Additionally, the use of a cardiopulmonary bypass machine is not required.

Target Market

Approximately 1 400 aortic valve replacements are performed annually in South African alone. Internationally it is estimated that almost 140 400 patients require percutaneous aortic valve replacements. There is thus a significant market for this technology.

Medical device manufacturers and suppliers interested in this technology are offered the further incentive in that these valves require minimally invasive surgeries, thereby adding to their demand and value.

Value proposition/ Benefits

- There exists a huge cost advantage as compared to traditional valve replacements (cost of procedure and cost of device)
- The device may be implanted with minimal invasive procedures, which is much less expensive and places less physical stress on the body.
- It provides a solution to old and fragile patients who otherwise have a very limited life expectancy.

Unique characteristics

Valve Lining

- ultra-thin velour sleeve ensures easy implantation and minimal leakage
- highly biocompatible allowing for easy ingrowth of the native tissue
- minimises risk of initial migration after implantation through increased frictional area

Valve Frame

- special cobalt-chrome alloy has increased strength, bio-compatibility and potential MRI - compatibility.
- diamond shaped structure specifically designed to be self-positioning

Valve Leaflets

- tissue material pre-processed with newly developed technique (ADAPTTM)
- has a life expectancy of at least double that of current tissue valves

Cost Advantage

- a heart valve of lower costs, plus an associated simple surgical procedure for implantation means an additional financial saving

Technical Description

The material currently used to manufacture the valve leaflets of tissue valves is based on a porcine (from pigs) fibre material. This material does not have a very high resistance to wear and an expected life span of approximately 8-10 years when subjected to loading condition. Patients who receive this product will not be able to survive for a long time without receiving additional cardiac intervention.The valve leaflets of thisinnovation will be manufactured from a tissue material which is pre-processed with the ADAPTTM processing technique (recently developed by Australia associates Celxcel Ltd Pty). This process ensures valve leaflets which are highly resistant to wear and have a life expectancy of at least 20 - 25 years – double the current values!

Specialised cobalt-chrome alloys have recently gained popularity over stainless steel for use in stent design due to its increased strength, bio-compatibility and potential MRI-compatibility.The heart valve of this innovation employs a unique stent design which is manufactured from a special cobalt-Chrome alloy (MP35N). The unique diamond-shaped stent is specifically designed to be self-positioning – it exhibits enhanced “dog-boning” during implantation which results in an easy self-aligning implantation procedure.

The ultra-thin polyester velour sleeve along the full outer length of the stentensures easy implantation and minimal leakage between the device and arterial wall. The sleeve is highly bio-compatible and allows for easy in-growth of the native tissue to anchor the device. The sleeve also increases the fictional area between the device and native arterial tissue which minimises the risk of initial migration, which often occurs shortly after implantation.

During insertion the valve is mounted onto a balloon-fitted catheter and inserted through the femoral artery to the heart, where the balloon is inflated and the valve opens up like a parachute. The procedure will place much less physical stress on the patient.

A conservative approach to the design has been followed compared to US based competitors to develop the heart valve at a much lower cost. It will therefore be possible to gain a competitive pricing advantage. This will be especially advantageous in the South African and African markets, where, due to a lower standard of hygiene and health, cardiac disease is more common as compared to first world countries.

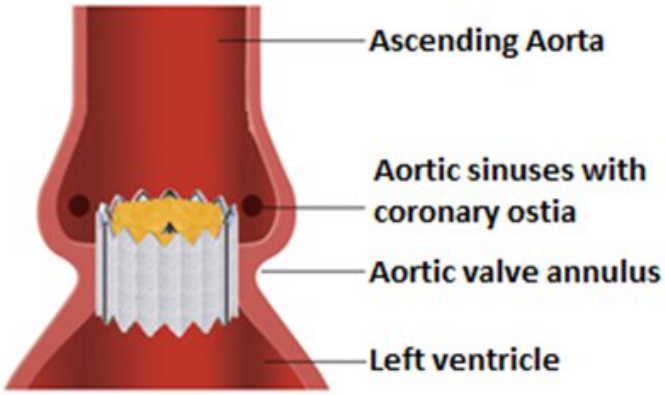
Innovation Status

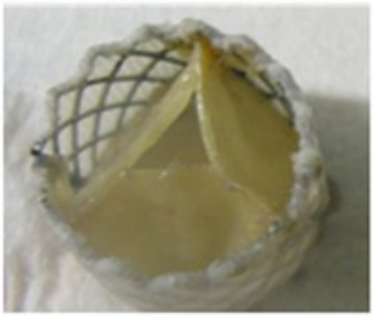
The first prototype development phase is complete. In-vitro testing in a pulse duplicator will commence shortly and the animal trial phase will also be initiated.
A national phase application was filed for this invention.

Principle Researchers

- Hellmuth Weich, Cardiologist at the Division of Cardiology in the Department of Medicine and Lecturer at the Faculty of Health Sciencesat Stellenbosch University
- Cornelius Scheffer, Associate Professor, Design and Mechatronics Division in the Department of Mechanical Engineering at Stellenbosch University
- Anton Doubell, Head of the Division of Cardiology in the Department of Medicine at Stellenbosch University

Photograph:





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