

# PIPE MEDICAL ENGINEERING

## CARDIOLOGY – HEARTVALVE SURGERY

### **Work platform for PAVA (ZEE20001002a)**

This invention describes a work scaffold, suitable for the minimally-invasive replacement of aortic heart valves. Simultaneously, it increases safety and work comfort, while simplifying and shortening surgeries. It consists of elastic and deformable surface material that on the spot automatically unfolds into a cylinder, which can be firmly anchored to the adjacent cell wall. By means of a catheter, the folded scaffold is inserted into a tube and can be transported intracorporeally to the desired site. After anchoring in the vessel wall, the great advantage of this scaffold is that by means of a bayonet joint, subsequently inserted catheter tools can be fixed, decoupled or pulled backwards via a fixed connection device. A surgeon's advantage lies in the fact this device provides a fixed site for performing fast and efficient surgical maneuvers using several individual instruments within a range of a few millimeters.

**IP-Inhaber:** Albert-Ludwigs-University Freiburg

**Status:** German and US patent granted

DE 100 49 814 (PRD: 09.10.2000),

US 7115141 (Priority date: 09.10.2001)

### **Device for the safe removal of an aortic valve (ZEE20001002b)**

This invention describes an instrument and strategy, with which a calcified aortic heart valve can be replaced in a simpler, safer and more compact manner, while also being minimally invasive and at the same time allowing maintenance of natural heart function. With the preferred form of surgery provision is provided for a working scaffold, on to which a can be attached by a bayonet coupling (see ZEE20001002a above).

The device consists of an intracorporeal-insertable cylinder, which can be attached to the pre-positioned scaffold within the aorta. A cutting tool is attached to the head of the cylinder, below which a suction device and a surrounding artificial heart valve is positioned, that can be externally controlled to give a fluid-tight closure of the aorta.

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The aortic valve is exfoliated by the cutting tool from within. During this processing cycle, which can continue of several cardiac cycles, the temporary heart valve closes the aorta and the blood along with the removed tissue are pumped through an opening outside the body. The temporary heart valve opens during pauses in the operation, thereby preventing ablated material from passing directly into the bloodstream. After an appropriate recovery phase, this machining cycle is repeated until the entire natural aortic valve as been removed. Thereafter, the cylinder is unbolted and disposed. The permanent artificial valve can be positioned immediately afterwards using additional surgical instruments.

**IP-Holder:** Albert-Ludwigs-University Freiburg

**Status:** German and US patents granted.  
DE 100 49 865 B4 (Priority date: 09.10.2000), US 6764494 (Priority Date: 09.10.2001)

***Patient specific aortic valve stent (ZEE20010330)***

This invention involves a vascular support fashioned with a heart valve replacement component. The device has a low volume in its initial folded form, and as such can be delivered and attached to the correct position within the body by means of a catheter.

Due to its shape memory properties, the vascular support material expands to take on its final form once placed in the correct position. This cylinder-like form features an enlargement on the rear of the original aortic valve to ensure adjustment to the bulbi, which is the slightly bulbous beginning of the aorta.

Furthermore, the vascular support becomes curved over the course of time to conform to the curved form of the aorta. In this manner, the possibility of the vascular support to displace or rotate is eliminated. In addition, small thorn-like protuberances lie on the surface of the device in order to ensure a secure fit with the vascular wall.

After proper deployment into the working position, the wire structure with the new valve is expanded to give a form-locking attachment to the aorta.

**IP-Holder:** Albert-Ludwigs-University Freiburg

**Status:** German and US patent granted  
DE 101 21 210 B4, US 6790230 (Priority date: Apr 30, 2001)

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**Minimally invasive,  
intravascular aortic  
valve extraction  
(ZEE20020225)**

The invention describes a surgical method for the minimally invasive removal of a heart valve. The method is an improvement on existing technologies in that it eliminates the possibility of an embolism, which can be caused by tissue or deposits, freed during the operation, finding their way into the blood stream. In addition, this technology provides for the first time a method for the creation of a blood free working environment, and with that a clear view of the cardiac valve. As a consequence, both comfort for the surgeon, as well as improved safety throughout the surgery are improved.

Two inflatable dilation-units are arranged along the length of a perfusion catheter. During an operation, these balloon elements are positioned 2 cm opposite each other, above and below the aortic valve. In the inflated state these elements create a fluid-tight seal with the vascular wall, so that a natural volume of blood is trapped within the aorta enclosing the aortic valve. Both dilation-units are perforated with perfusion canals. In this way, natural blood flow is principally maintained, because a sufficient volume of blood can flow through channels in the perfusion catheter.

The dilation-unit on the proximal side of the aorta is fabricated with a transfer channel, enabling the introduction of appropriate catheter instruments for the removal of the cardiac valve. Additional transfer channels allow for the connection of suction and cleansing tubes, so that the volume within the work region can be pumped free of blood. With this, the operator obtains free view over the cardiac valve through an optical observations catheter. In contrast to other technical solutions, the fluid-tight connection within the working volume guarantees:

- That all pieces of detached tissue can be safely removed outside the body.
- That following the valve extraction the work volume can be cleaned in order to safely remove all detached tissue.
- An operations method under direct visual observation and without time pressure on the surgeon to maintain normal hemodynamic conditions due to the help of a perfusions catheter.

**IP-Holder:** Albert-Ludwigs-University Freiburg

**Status:** German and US Patents granted.  
DE 102 17 559 B4, US 7338467 (Priority date: Apr 19, 2002)

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***A puncher for PAVA-  
For local removal of  
aortic valves  
(ZEE20000714a)***

The invention concerns a cutting device, designed for minimally invasive intracorporal application for safe removal of aortic valves by means of a concave catheter. A shearing device is located at the catheter end, by which cutting edges can be maneuvered against each other, resulting in similar removal to that of a punching device.

During this procedure, the distal end of the concave catheter with two open cutting edges is placed in such a way beyond the part to be removed, that the aortic valve is pushed into the hollow section behind the cutting edges.

Movement of the cutting edges against each other, result in aortic valve removal. At the same time, the hollow catheter component closes and traps removed tissue inside the cavity and can be removed by a suction device via the concave catheter.

This concave catheter is so flexible in the distal region, that it easily adjusts to the natural curvature of the aortic arch during intracorporal insertion. Exact positioning of the cutting device during the procedure is achieved by standard x-ray monitoring.

**IP-holder:** Albert-Ludwigs-University Freiburg

**Status:** German patent granted: DE 100 49 813 C1 (Priority date: 9.10.2000)

***Luper-mincer for local  
removal of aortic valves  
(ZEE20000714d)***

This invention also describes a cutting device, intended for minimally invasive intracorporal applications by means of a concave catheter, for safe and efficient removal of aortic valves.

The underlying mechanism of action of aortic valve removal is similar to a mincer or meat chopper. A sleeve-like structure with rotatable helix inside (wormshaft) is attached onto the distal end of the hollow catheter.

The diameter of the sleeve-like structure equals the outer diameter of the spiral, and is covered by a cap for vessel protection.

The catheter-head is positioned in a way that parts of aortic valve deposits protrude into the spiral, pulling aortic tissues inside the sleeve structure like a meat chopper during the procedure. The spiral edges possess sharp edges to improve the shear effects of the spiral. Aortic valve fragments are removed inside the catheter and transported outside the body. The hollow catheter is very flexible in the distal part, which allows intracorporal applications and alignment to the aortic arch shape.

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**IP-holder:** Albert-Ludwigs-Universität Freiburg

**Status:** German patent: DE 100 49 815 B4 (Priority date 10.09.2000)

**Filterscreen for PAVA  
(ZEE20000714c)**

This invention is used within the scope of minimal invasive surgical procedures for removal of aortic valves and deposits with the aim to lower thrombosis and embolism risks. This patented filter screen allows complete removal of arising tissue debris during aortic valve surgery.

Up to two filter screens can be assembled onto one axis and transported to desired sites via a hollow catheter. Ideally, the filter screens are positioned on both sites of the aortic valve to form a cage within which surgical procedures can be performed. While naturally occurring blood constituents can penetrate the filter screen, particles greater than 7,5  $\mu\text{M}$  become trapped. Upon completion of the surgical procedures the filter screens are folded in a way that all parts including the aortic valve are trapped and removed by means of a catheter.

**IP-holder:** Albert-Ludwigs-University Freiburg

**Status:** German patent granted: DE 100 49 812 B4

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## KARDIOLOGY - MONITORING

### ***EKG-system for large-scale measurements of EKG-signals (03017HPV/FUB)***

Through large-scale monitoring of EKG-signals (Body-Surface-Potential-Maps) using 30-256 electrodes, more clinically relevant and additional data (e.g. infarct localization) can be obtained compared to traditional 12-channel-EKG. However, the large number of electrodes, data recording / evaluation and high procedural expenditures have hindered the break-through of this procedure.

The present invention only requires a 12-channel-EKG instrument but achieves similar results when compared to the BSPM method, allowing everyday use of this method. This is possible by synchronizing a sequential EKG signal readout of a commercially available 2-channel system in a specific way, which makes it feasible to compile valid approximations to BSPMs.

The hereby described method is transferable to most 12 channel EKG-units by updating our proprietary software. This so called "Pseudo-BSPM" supplements a standard 12-channel-EKG unit with clinical information, without the need for mayor investments, and additionally allowing long-term EKG measurements.

**IP-holder:** Charité – Universitätsmedizin Berlin

**Status:** German patent: DE 103 36 809 B4

International Patent application underway:  
EP 1653851, US 2007/ 0060828

### ***In situ vital signs monitor (ZEE20051102)***

This implantable, autonomous sensor system serves to monitor in situ oxygen concentration, blood pressure and pulse rate in high-risk heart patients. An elastic, biocompatible silicon sleeve containing sensors is laid around an arterial blood vessel. Blood pressure is measured through a highly elastic stretch sensor, which senses the change in blood vessel diameter without restricting blood flow. A second elastic band carries an optical component – two light emitting diodes and a detector – to measure oxygen concentration.

**IP-Holder:** Albert-Ludwigs-University Freiburg

**Status:** German patent: DE 102006022854 B4

A laboratory prototype exists, demonstrating technical feasibility.

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