Fully-Implantable Ventricular Assist Devices and Heart Replacement Devices

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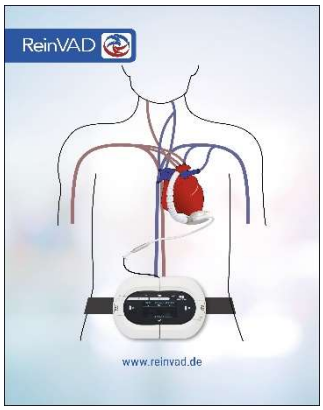
Initial situation

Cardiovascular diseases are the most common cause of death in the industrial world. In this context, a frequent diagnosis is ventricular insufficiency indicating a life-threatening illness of the left ventricle. From a particular stage onwards, only the transplant of a donor heart or, instead, massive support or replacement of the heart by implantable mechanical components can offer a sufficient and durable alternative.

Two new systems

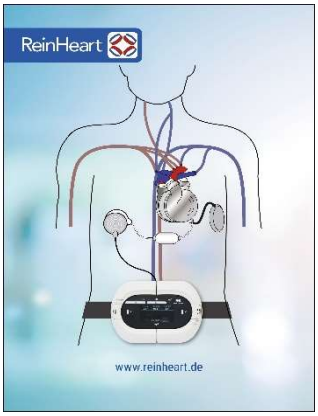
Originating in research activities at the Institute of Applied Medical Engineering (AME) at the RWTH Aachen University, two new enterprises committing themselves to this topic were founded in 2013 and 2015. Research and development activities of both companies are supported by public and private sponsors (see footer).

ReinVAD GmbH develops an implantable rotary blood pump incorporating a levitated rotor. Here, the circulation of the left ventricle is supported in a way that the patient will receive the physiologically needed amount of blood flow even during normal physical activity.



Principle of ReinVAD system (Source ReinVAD)

ReinHeart TAH GmbH develops a fully-implantable artificial heart. In its essential design it consists of a linearly and intermittently operating pump unit taking over the functions of the left and right pump of the heart.



Principle of ReinHeart system (Source ReinHeart)

Both devices are designed as low-maintenance and hemolysis minimizing systems, therefore being suitable as long-term implants.

Cooperating between development and production

Components for ReinVAD system (Source: Beutter)

Beutter Präzisions-Komponenten GmbH & Co. KG produces precision components, particularly comprising all areas of Medical Engineering. One special focus of the company lies on the participation in development and prototype production of active medical Risk Class III implants. In this field the company has the objective to offering its experience of production technology to a manufacturer and future distributing company, already doing so at a very early stage of development. The intent is here to ensure an optimal technical and economical solution from the viewpoint of production.

Components for ReinHeart system (Source: Beutter)

Production of precision components

Beutter's mechanical components are produced in machining procedures, primarily by turning and milling on machining centers. Beutter uses as material for components high-strength alloy titanium Grade 5. Besides, the thermally stable and low-warpage thermoplastic material PEEK is used. Both materials are preferably used for heavily strained implants. Besides their biocompatibility they show very good mechanical characteristics and thermal stability. Both production materials can be easily processed when using suitable machining parameters and tools. Permanently joined components can be laser-welded.

Given the present state of the art of CNC technology, dimensional tolerances of components are well controllable. However, concerning the thin-walled design of single components, tolerances for shape and position, in particular cylindricity, have to be paid special attention to and have to be secured by selecting suitable production strategies.

Cleanliness and surface quality

Although extensive absence of burr and a high surface quality is already sought during the processing on machining centers, reprocessing is necessary with respect to these parameters. The effort which is necessary here is often underestimated, particularly since, for implants constantly in contact with blood, they belong to the most important properties to avoid hemolytic damage to the blood.

Parts of component edges which are in contact with blood are either executed nearly sharp-edged or with low edge roundness. This can be done by vibratory finishing on centrifugal force finishing systems but, for individual cases, also by manual deburring. The objective is to produce a surface quality with roughness depth $Ra < 0.05$ µm for inside areas. This is, in particular, a challenge with the production material titanium. In this regard, tests are conducted at the time to optimize this by mechanical as well as electrochemical procedures.

Prototypes to batch production

Referring to the current stage of both projects, functioning and technical feasibility are paramount. However, special attention lies on the goal that implemented production procedures deliver reproducible results and batch production can already be possible. Ultimately, efficiency is an essential criterion with regard to the intended batches of production.

For medical products process reliability and documentation is of special significance. Beutter holds a DIN EN ISO 13485:2016 certificate and has experience with regard to comparable projects. With respect to current pre-batch production the focus still is on a careful documentation of all process steps which includes the development and optimization of process parameters. After the “Design Freeze” all production processes have to be formally locked, monitored and, equally, be fully documented. Although not acting as distributing company for the products, Beutter is obligated to use validated processes in case of critical processes, ensure a formal locking of processes and also, when necessary, carry out paper-based verification.

At that point in time a validated cleaning of the components including packaging inside the cleanroom is required. Beutter owns the corresponding equipment to do so.

Dr. Ing Wolf-Dieter Kiessling is a shareholder and advisory board member of Beutter Präzisions-Komponenten GmbH & Co. KG D-72348 Rosenfeld – www.beutter.de

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