



Realheart reports the fall's development plan

Realheart continues according to the development plan that was laid out in the beginning of the year and keeps a good pace in its work. After the animal trials during spring and summer and refinement of the implantation technique, the fall and winter will include, among other things, further animal trials and additional development activities to fulfill the requirements of the American authority FDA, which is a prerequisite to be allowed to go through with studies on humans.

The development plan that was communicated in the beginning of the year consists of three parts: product development, laboratory tests and longtime tests on animals. The focus areas of the fall for each part are described below

Product development

CONTROL

Realheart TAH is the only pump concept in the world that is equipped with atria. Because of this the system can detect the amount of blood flowing back to the atria. This provides information that makes it possible to control the pump through the software of the control system. This development step, that was reached during spring of 2019, has increased the intelligence of Realheart TAH and leads to minimizing complications and increased usability for the patient. The first software prototype for the control system is developed and has shown good results. During fall and spring the control system will be developed and tested further.

RELIABILITY AND CAPACITY

Realheart TAH now works well medically. There are, however, still significant work to attain a stable, durable product that is ready for production and clinical trials in humans. The next step is some adjustments to increase the pump capacity and extensive evaluations in test rigs to ensure the long term reliability according to one of the FDA's requirements. That work has been initiated and several test rigs have been developed.

Laboratory tests

BLOOD TESTS

Realheart has during this year performed blood tests in a laboratory in Germany. The company is now building its own laboratory in cooperation with Karolinska Institutet, and performs necessary tests in the study that shall establish the exact effect that the heart has on the blood.

Ling time tests on animals

ANIMAL TESTS

A new series of animal tests on sheep is started in the middle of October and continues until the end of January. The plan is to successively improve the surgical technique to finally wake the animals up completely. One important step is to develop an optimal post-operative intensive care, which is now being established.

"It feels very satisfying that our team together with the network of experts has succeeded to achieve the mile stones we have set up in the ambitious development plan. We have also succeeded in developing the first prototype for an automatic control and increase Realheart TAH's unique characteristics. Now I am looking forward to the work during fall and winter when we continue to prepare the product for the initial trials on humans in 2022", says Azad Najar, the CEO of Realheart"

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Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atriums and two chambers) which provides the opportunity to generate a physiologically adapted blood flow that mimics the body's natural circulation. A unique concept in the medical technology world.