



Realheart set to begin animal studies with clinical version

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Production of the clinical version of Realheart's artificial heart – the one that will eventually be used by human patients – is almost completed and will now be tested in a series of animal trials. Six surgeries are scheduled, with the first taking place mid-May.

The aim is the same as in previous trials, i.e. chronic animal studies with the aim of prolonging survival time, but with the difference that it is the clinical version being tested. It has an improved external design, smaller size, integrated pressure sensors and control algorithm compared to the prototype that has previously been used.

This is a major step forward in the development process and the company has therefore strengthened the operating team. There are now three highly experienced cardiac surgeons working together: Professor Bart Meyns, Dr Dilek Gürsoy and Dr Joeri van Puyvelde. The veterinary protocol has also been updated and an expanded animal care team, with ten years of experience in the care of animals with artificial hearts, is now present, responsible for the selection, preparation and aftercare, including medication.

"In all previous surgeries, we have confirmed that the pump is working properly. Issues that we have needed to address have rather been related to the adaptation to the animal's body. Its anatomy differs from that of a human and requires a completely different type of care approach. In 2021 and 2022, we have recruited more expertise in this field and updated our protocol to best care for the animal," said Ina Laura Perkins, CEO of Realheart.

She describes the animal studies as a team effort with many people involved where everything needs to flow smoothly between surgeons, the person operating the heart-lung machine, engineers, veterinarians, and animal caretakers all the way from preparation to aftercare.

"During the surgery, the pump is implanted and after that we monitor the animal closely. Should we encounter any problems, these will be addressed before future surgeries. The first day after surgery is always the most critical and we start by getting past that, to gradually build up from there. We will only keep the animal alive for as long as we can do so without causing suffering," said Ina Laura Perkins.

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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.