



First Animal Trial with Clinical Version Completed

Press release, 2 June 2022

Yesterday, the first in a series of sheep implantations to test the newly developed clinical version of the Realheart artificial heart was performed. Surgically, the trial was very successful, and the pump performance optimal. Nevertheless, the decision was made to end the trial today to make some adjustments for the next surgery which will take place later this month.

This was the first implantation of the clinical version of the Realheart® TAH – the version that will eventually be used in humans.

The operation was performed in an animal laboratory in Belgium by three very experienced heart surgeons: Dr Dilek Gürsoy, Dr Joeri van Puyvelde and Professor Bart Meyns.

"Dr Gürsoy and Professor Meyns are familiar with Realheart TAH since before, but Dr van Puyvelde, who worked on our heart for the first time, was impressed by how stable everything was running. Other international experts present during the operation had never seen a such a smooth implantation of a total artificial heart. These are aspects that could have a major impact on the future uptake of the Realheart® TAH in healthcare" said Ina Laura Perkins, CEO of Realheart.

It took the surgical team 2 hours and 10 minutes to implant the pump. To reach a total time from starting the heart-lung machine until the pump is fully connected to the body of less than 3 hours is key for the animal to have a good chance of survival. This was achieved by good margins. It was also found that energy consumption was lower and pump performance higher compared to previous versions of the Realheart® TAH.

"I like that the device is controlled by the inflow pressure. It is operating in a very controlled, physiological manner, similar to the human heart, which is important for the exercise capacity and preventing suction" said Professor Bart Meyns.

The data collected is now being evaluated as part of preparations for future operations.

"What our team has achieved is amazing and we are very close to achieving our goals. Heart surgery is one of the biggest procedures you can do and there is a lot going on, but we have seen that our pump always does what it is supposed to do. I'm looking forward to the next operation and coming back to let you know how it went," says 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 atria and two ventricles) designed to generate a physiological blood flow pattern that mimics the body's natural circulation. A unique concept in the medical technology world.