



Market Need in the US and Europe is Estimated at 200,000 Artificial Hearts per Year - Equivalent to SEK 200 Billion - And the Trend is Accelerating

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Industry players and Realheart estimate that the market potential for total artificial hearts (TAHs) is over 200,000 units per year in Europe and the US. Realheart believes it is well positioned to take significant market share with its four-chamber artificial heart.

"Sales will likely only be limited by the number of artificial hearts we have the capacity to produce," said the company's CEO Ina Laura Perkins. "We have great advantages with our TAH because we have started to automate parts of the production process at an early stage of development. Having said that, we have no long-term limitations for volume production," Ina Laura continues.

An important factor in the production is the awarded Eurostars 3 grant of 10 MSEK that Realheart has received together with Berlin Heart to automate the process of membrane production. The membranes are a critical component of the company's artificial heart and must be manufactured with high precision and unwavering repeatability. The best way to achieve this is to automate the manufacturing process. This is why Realheart collaborates with Berlin Heart, who are experts in the field of developing and manufacturing membrane technologies that are successfully used in their external heart pumps.

According to WHO and several other actors, cardiovascular diseases are today the most common cause of death globally in high-income countries, and the number of people affected is only increasing, as well as the number of years the patient can live with their disease. All of this means a significant increase in the burden and cost of healthcare. According to research^[1], the global bill will increase from USD 346 billion in 2012 to USD 400 billion in 2030. Heart failure is a type of cardiovascular disease where the heart is no longer able to pump the amount of blood the body needs. Around 300,000 Swedes^[2] have heart failure and around 64 million^[3] people are affected globally.

New treatment options are needed, and an artificial heart may be a near-term option for patients with severe heart failure. A sufficiently good TAH can help reduce the suffering of those affected and at the same time has the potential to reduce the cost of care for heart failure.

Realheart expects to initiate clinical trials in 2024 and a market launch in 2025/2026.

^[1] Lippi, Giuseppe; Sanchis-Gomar, Fabian. 2020. *Global epidemiology and future trends of heart failure*. AME Medical Journal.

^[2] <http://janusinfo.se/lakemedelskommitte/lok/artiklar/lakemedelsbehandlingvidkroniskhjartsvikt.5.6b0cec9617a2d3d28f8699b5.html>

^[3] (1): Savarese G, Lund LH. *Global Public Health Burden of Heart Failure – a comprehensive and updated review of epidemiology*, <http://pubmed.ncbi.nlm.nih.gov/28785469/>

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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 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.