Organ transplantation is often the only treatment for end-state organ failure, such as liver, kidney and heart failure. Tragically, most people on the waiting list die before they ever get an organ. Hence the dream of developing artificial organs made of electronic and mechanical parts has been around for decades. The first total artificial heart transplant was in the 1980s, yet since then few improvements have made these devices more efficient. Newcomers such as Carmat and Bivacor are aiming to change the paradigm from a single mechanical heart towards a smarter solution, with embedded sensors and intelligence. The next wave of development came from the diabetes epidemic that affects every country, hitting more than 8% of the global population today. The artificial pancreas market will therefore experience a huge 49% compound annual growth rate (CAGR) over the next five years, to reach $1.3B in 2022. The next breakthrough to happen will come in 5-10 years, bringing artificial lungs and kidneys. The first commercially approved devices will be wearable systems such as the Wearable Artificial Kidney Foundation, Inc. (WAKFI) system. Soon after the first wearable kidney we should be able see a leap to an implantable device like that developed by the kidney project at University of California, San Francisco and Vanderbilt University. Artificial organs combine many advantages besides availability, including fewer compatibility issues, eliminating ethical concerns around organ trafficking, and decreasing cost. The artificial organ market will be worth $1.3B in 2017 and its 20% CAGR over the next five years will see it grow to $3.5B in 2022.

This report describes artificial organ market dynamics, players and technological challenges.

**FIVE OUT OF THE TEN LEADING CAUSES OF DEATH IN THE WORLD WILL BENEFIT FROM ARTIFICIAL ORGANS**

Organ transplantation is often the only treatment for end-state organ failure, such as liver, kidney and heart failure. Tragically, most people on the waiting list die before they ever get an organ. Hence the dream of developing artificial organs made of electronic and mechanical parts has been around for decades. The first total artificial heart transplant was in the 1980s, yet since then few improvements have made these devices more efficient. Newcomers such as Carmat and Bivacor are aiming to change the paradigm from a single mechanical heart towards a smarter solution, with embedded sensors and intelligence. The next wave of development came from the diabetes epidemic that affects every country, hitting more than 8% of the global population today. The artificial pancreas market will therefore experience a huge 49% compound annual growth rate (CAGR) over the next five years, to reach $1.3B in 2022. The next breakthrough to happen will come in 5-10 years, bringing artificial lungs and kidneys. The first commercially approved devices will be wearable systems such as the Wearable Artificial Kidney Foundation, Inc. (WAKFI) system. Soon after the first wearable kidney we should be able see a leap to an implantable device like that developed by the kidney project at University of California, San Francisco and Vanderbilt University. Artificial organs combine many advantages besides availability, including fewer compatibility issues, eliminating ethical concerns around organ trafficking, and decreasing cost. The artificial organ market will be worth $1.3B in 2017 and its 20% CAGR over the next five years will see it grow to $3.5B in 2022.

This report describes artificial organ market dynamics, players and technological challenges.

**ARTIFICIAL HEART AND ARTIFICIAL PANCREAS: READY TO BLOW UP THE ARTIFICIAL ORGAN MARKET!**

Bringing a new artificial organ to market is a very long and costly project. The average time of development for such a complex technology is about 15-25 years in addition to the five to ten years of testing and regulatory approval. These gigantic delays explain why few companies have ever invested in artificial organs, even if the total available market is humungous. Investors have to be patient and developers determined to bring such a technology to market. Ventricular assist devices form an established market, with big players such as Abbott and Medtronic, who...
REPORT OBJECTIVES

- Explain the challenges linked to organ transplantation and the limits of the current processes.
- Introduce the technologies behind the different types of artificial organs, including kidneys, livers, lungs, hearts and pancreas.
- Give an overview of artificial organ history from first developments to today, along with a presentation of the main players and their respective technologies. Who’s providing what? Who’s working with who?
- Provide market data and forecasts
- Detail the current technology’s limits and how it might evolve in the future.
- Discuss the main challenges and how artificial organ companies can overcome them.
- Focus on artificial organs’ technical aspects: including batteries, biocompatibility, sensors, and pumping systems.

respectively bought the two leaders of the field Thoratec and HeartWare. However the total artificial heart is still an emerging market, since the only player has been Syncardia for years. With the arrival of newcomers, the total artificial heart market will experience substantial growth with a 15% CAGR, 2017-2022. We expect penetration of the artificial pancreas to be also very high and fast in the type I diabetic population, since the community has wanted this solution for years. Only Medtronic had an artificial pancreas system approved by the US Food and Drug Administration (FDA) in 2017 and none has a European CE mark. However, many companies are ready for approval and commercialization, especially two collaborations: one between Diabeloop, Dexcom and Cellnovo; and one involving TypeZero, Dexcom and Tandem.

After decades of development, artificial organ products are now ready to enter the medical device market. Yole Développement is uniquely positioned to provide your company with an understanding of the revolution that will happen in the next few years.

YESTERDAY ARTIFICIAL ORGANS WERE MADE OF MECHANICAL PARTS: TODAY THEY ARE BASED ON ELECTRONICS: TOMORROW THEY WILL BE SMART

Maybe you have watched a ‘transhumanist’ movie. Perhaps you’ve had a conversation about whether or not you would opt for bionic upgrades like superhuman lung capacity, or an immortal self-contained heart. You and your friends probably had different opinions, but concluded that it’s irrelevant because we are far away from making these choices. Well, it turns out that the option is only a few years away. Artificial organs today only have a few sensors. But in the near future, the next generation of artificial organs will have a myriad of embedded sensors to monitor the status of the patient, and more intelligence to take changes in physiology into account. The software that pilots these artificial organs must parallel engineering developments. For now, particularly in artificial pancreas, a multitude of different algorithms exist, each of those with advantages and disadvantages, but all with an internal control law. These span very simple binary answers and much more complicated combinations of multiple data from sensors, physical laws, and precise output calculations all embedded in a complex, fast algorithm. Next generation algorithms are in development today and we are expecting large improvements. New fashionable methods like machine learning, and deep learning when the data is available, are entering research through fuzzy logic algorithms. These methods seem promising and will allow full automated control of the artificial organ.

This report unravels the different algorithms used in artificial pancreas and total artificial heart. It also describes the technical aspects boosting artificial organ development progress, such as biocompatibility, batteries and sensors.
COMPANIES CITED IN THE REPORT (non exhaustive list)

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The “More than Moore” company Yole and its partners System Plus Consulting, Blumorpho, KnowMade and PISEO support industrial companies, investors and R&D organizations worldwide to help them understand markets and follow technology trends to develop their business.

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