



Eurosets Recognized for

2021

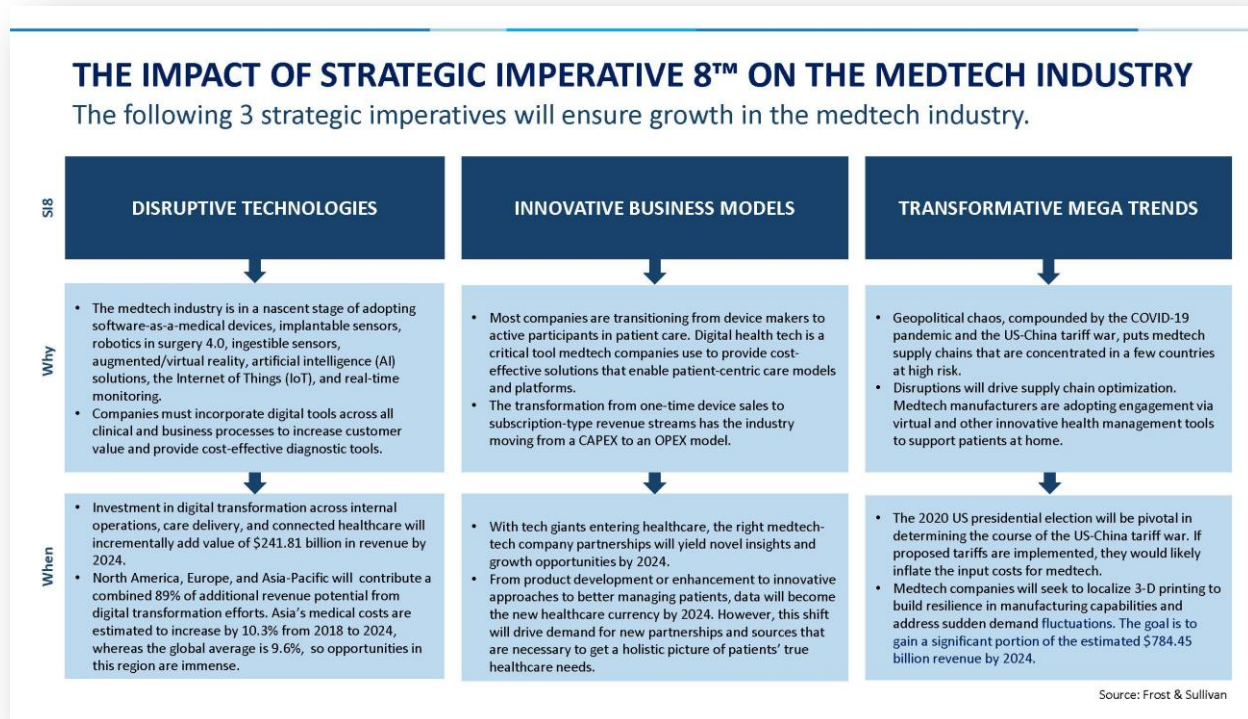
New Product Innovation

Global Extracorporeal Membrane
Oxygenation (ECMO) Industry

Excellence in Best Practices

Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the medtech industry: disruptive technologies, innovative business models, and transformative Mega Trends. Every company that is competing in the medtech space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan’s recognition of Eurosets is a reflection of how well it is performing against the backdrop of these imperatives.



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated companies. Eurosets excels in many of the criteria in the ECMO space.

AWARD CRITERIA	
<i>New Product Attributes</i>	<i>Customer Impact</i>
Match to Needs	Price/Performance Value
Reliability	Customer Purchase Experience
Quality	Customer Ownership Experience
Positioning	Customer Service Experience
Design	Brand Equity

Expertise and Technological Superiority

Eurosets, founded in 1991 and headquartered in Italy, is part of GVM Care & Research, a company with an annual turnover of €800 million that operates in an integrated system of high-quality hospitals across the European and Mediterranean regions and in general consultancy and surgery with private outpatients. Eurosets is a leading Italian manufacturer of medical devices for cardiopulmonary or

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- Srinath Venkatasubramanian, Industry Analyst, Transformational Health

extracorporeal life support (ECLS) and wound and blood management. The company develops, produces, and commercializes a range of products for ECLS function. Eurosets has gained expertise in advanced medical devices by supplying products to healthcare facilities worldwide and, as original equipment manufacturer (OEM), key components to leading companies, such as Fresenius and B. Braun . In the ECLS market, the company specializes in oxygenators, tubing packs, and integrated

extracorporeal membrane oxygenation (ECMO) systems. The company has various patents for its specialized ECLS components and sensor-based digital monitoring,¹ and its products have been extensively tested for effectiveness in several clinical studies. In addition, Eurosets has partnered with leading companies, such as Abbott, to distribute its specialized components, such as the AMG PMP adult oxygenator.²

¹ Justia; [“Patents Assigned to Eurosets S.R.L.”](#)
² Abbott; [“AMG PMP Adult Oxygenator”](#)

Commitment to Creativity and Technology Incubation

Eurosets constantly develops new products in the ECLS segment and is emerging as a strong challenger to established competitors. In September 2020, the company launched its ECMOLife device, which is a compact integrated system for ECMO/ECLS therapy and equipped with non-invasive sensors, ensuring the continuous monitoring of 10 parameters. In addition, the company is in the process of launching new devices in the ECMO space and in the extracorporeal carbon dioxide removal (ECCO2R) space. Through these new launches, Eurosets is expanding its product line, despite its already strong presence in the European oxygenators market for several years. The company's CO2 reset device treats chronic obstructive pulmonary disease (COPD) and acute respiratory distress syndrome (ARDS) patients who are hypercapnic, and the device is more sophisticated and advanced than competing solutions, in terms of integrating into the ICU workflow.

Eurosets has the in-house capability to manufacture the ECMO system and related disposables. In addition, the company is one of the frontrunners in the ECLS/ECMO market for building components in a biocompatible design, such as using phosphorylcholine-coated circuits and high-contact surface, hollow-fiber oxygenators with a biocompatible surface coating to enhance the gas transfer and minimize the risk of hemolysis and coagulation.^{3,4}

Commitment to a User-friendly Design that Enables an Efficient Workflow

Eurosets's ECMOLife is a versatile platform for applications in ECMO and ECLS therapy and enables mobility or inter-facility transfer through its compact design and proprietary Leonardo trolley. The device is a multi-functional, integrated system that decreases the total cost of ownership and is easy to operate by clinical professionals with less training. Eurosets's console provides professionals with versatility in therapy administration by combining a full range of functionalities (e.g., Mechanical Circulatory Support and oxygenation) in a single platform, with advanced monitoring capabilities for decision support. The system involves various safety functions, such as non-invasive, real-time monitoring through integrated sensors of key metabolic and hemodynamic parameters, auxiliary external battery for extra procedural time in cases of emergencies, and integrated backup system in case of failures, thus ensuring superior comfort for clinicians.

"The ECMOLife system offers enhanced biocompatibility, providing patients with the ideal and close to native physiological perfusion, and is one of only two systems in the market that is validated for intra- and inter-hospital transportability."

- Srinath Venkatasubramanian, Industry Analyst, Transformational Health

Competitive Positioning

Unlike competitors that offer integrated systems with conventional technology and with dated versions of components, Eurosets designed the ECMOLife with the best contemporary technology in the market, in terms of pumping, monitoring, and transporting, thereby improving the standard of

³ National Library of Medicine: National Center for Biotechnology Information; M Pieri, et al.; March 2013, "[A new phosphorylcholine -coated polymethylpentene oxygenator for extracorporeal membrane oxygenation: a preliminary experience](#)"

⁴ ResearchGate; Denis A Berdajs et al.; August 2011; "[The new advanced membrane gas exchanger](#)"

care. The system includes the benefits from the advanced blood pump technology (magnetic levitating pump), which minimizes both hemolysis and friction to prevent coagulation.⁵ The ECMOLife system offers enhanced biocompatibility, providing patients with an ideal and close to native physiological perfusion, and is one of only two ECMO systems in the market that is validated for intra and inter-hospital transportability. ECMOLife is designed to ease operations in the ICU for professionals by offering a backup console integrated into the system, which automatically runs within 30 seconds (first in the industry) during the primary device failure. This feature avoids pumping manually until the primary device is fixed and prevents the risk of complications. Eurosets is well positioned to stave off the threat from emerging startups that do not have the right product-market fit because their technologies are not aligned with current market needs. In contrast, Eurosets designs its products, such as ECMOLife, based on the real needs of clinicians, with proven benefits in terms of improving outcomes and creating workflow efficiencies.

Commitment to Innovation for Solving Market Needs

The annual number of ARDS incidences in the United States alone is estimated at 190,600,⁶ with close to a 40% case fatality rate and attributable to 10% of ICU admissions.⁷ Most ARDS cases (80%) require mechanical ventilation; however, the survival rate is low because prolonged mechanical ventilation can lead to lung injury. Various trials show that ECCO2R and low tidal volume ventilation (LTVV) or venovenous ECMO can protect the lungs and improve survival rates. The World Health Organization (WHO) guidance document, released during the COVID-19 pandemic, recommends ECMO for COVID-19 cases because of failures in the conventional therapy. Currently, only 10% of US hospitals have an ECMO facility, creating a huge unmet need, where only about 4% of eligible patients receive the recommended therapy.

Eurosets addresses market needs and existing gaps in clinical adoption by creating advanced and new-generation products to improve the therapy's clinical efficiency and outcome. The company's ECMOLife and CO2 Reset device provide safe therapies for ARDS patients by minimizing the risk of mechanical ventilation and preventing acidosis by effectively removing carbon dioxide.

“Innovative companies, such as Eurosets, are trying to establish a new standard of care by designing products to tackle a range of challenges, such as the lack of training and standardized protocols for patient selection, evidence gap on outcomes, and the resource-intensive nature of ECMO therapy.”

- Srinath Venkatasubramanian, Industry Analyst, Transformational Health

Growth Potential and Future Vision

Eurosets's ECMOLife device, even though new in the market, has already gained fast adoption, with about 60 centers actively using the device on-site. In addition, the product has gained good response from several ECMO specialty centers in Italy, Belgium, France, and Germany. This growing market is witnessing stiff competition, with the entry of new

⁵ Sage journals; Denis Berdajs et al.; June 20, 2020; [“Performance characteristics of the new Eurosets magnetically suspended centrifugal pump”](#)

⁶ The New England Journal of Medicine; Gordon D. Rubenfeld, et al.; October 20, 2005; [“Incidence and Outcomes of Acute Lung Injury”](#)

⁷ National Library of Medicine: National Center for Biotechnology Information; Giacomo Bellani, et al.; February 23, 2016; [“Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries”](#)

participants, and most established participants have legacy technologies. Eurosets, with the right product and the right presence in the field, is well positioned to scale up rapidly by riding on the growth wave because the clinical indications for the use of ECMO are widening, and the therapeutic adoption of ECMO as a bridge to recovery and a bridge to other interventional decisions is growing.

Eurosets is establishing a new standard of care by designing products to tackle a range of challenges, such as the lack of training and standardized protocols for patient selection, evidence gap on outcomes, and the resource-intensive nature of ECMO therapy. While the company has a strong presence in Europe, China, and the Middle East, it is ready for geographical expansion and has recently partnered with a leading US distributor to sell its disposables initially and then later expand to the ECMOLife product. The company's products have a presence in over 60 countries, with a direct operational presence in Italy, France, Belgium, the Netherlands, UK, Germany and China. Through its recent distribution partnership with a leading company for its ECMO products and with plans to open subsidiaries in Asia Pacific, Latin America and the Middle East, Eurosets is targeting accelerated market expansion to shore up revenues in the high-demand ECMO segment, which has been catapulted by the COVID-19 pandemic.

Conclusion

With the expansion of clinical indications and increasing evidence on the benefits of extracorporeal oxygenation therapy, compared to conventional therapies, providers are more inclined to adopt devices that are safe, proven, and easy to use. The COVID-19 pandemic has accelerated the adoption of ECMO therapy, in addition to the higher number of incidences of COPD and ARDS progressing to critical stages, where ECMO is the only solution for survival.

Eurosets, with its long-standing expertise in component innovation for sustainable value creation in the competitive market, is well positioned to leverage the growth opportunity arising from recent trends, such as the increasing prevalence of ARDS cases and the COVID-19-induced accelerated demand for ECMO products. With its commitment to address the market's evolving needs and focus on future growth strategies, such as building compact ECMO systems, Eurosets has partnered with leading companies to develop a specialized device for ECCO2R that brings new advancements in the market, which is a testament to the company's sustainability in this specialized segment.

For its strong overall performance, Eurosets has earned Frost & Sullivan's 2021 New Product innovation Award in the global ECMO industry.

What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Award recognizes the company that offers a new product or solution that uniquely addresses key customer challenges.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire product design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

