Inspira Technologies Recognized for

2021

Technology Innovation Leadership

European
Artificial Respiratory Industry
Excellence in Best Practices

FROST & SULLIVAN

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 company. Inspira Technologies excels in many of the criteria in the artificial respiratory space.

Innovative Oxygenation and Respiratory Support

Incorporated in 2018 and headquartered in Ra'anana, Israel, Inspira Technologies (Inspira) provides innovative medical technology in the respiratory care industry. The company maintains a clear mission: to develop a cost-effective, less-invasive respiratory support system to minimize the need for invasive mechanical ventilation (MV) to save the lives of patients with acute respiratory failure. The COVID-19 pandemic exposed limitations in various medical technologies, specifically MV. But even before 2020, the medical industry reported millions of people worldwide brought to intensive care units (ICU) required MV due to respiratory failure or other conditions. To this end, the coronavirus contagion exacerbated an already unsteady treatment regimen. Additional challenges include delivering lung-protective ventilation to prevent the ventilator from inducing lung injuries which add further complications and extends the mechanical ventilation and rehabilitation period. In addition, during COVID the use of extracorporeal membrane oxygenation (ECMO) increased. Many physicians and medical facilities turned to ECMO as a last resort treatment, a technique that bypasses the lungs by injecting oxygen directly into the blood. This methodology also poses high risks to patients as it oxygenates all the cardiac output of the patient (between five to seven liters per minute). This procedure also carries high risks of blood clotting, seizures, and strokes. Thus, physicians only administer ECMO to patients with an 80% mortality chance because it is more expensive and complicated, requiring a high level of thought and abilities.

Inspira's ART™ system, a proprietary early extracorporeal respiratory support system that elevates oxygen saturation levels, designed to be the new Standard of Care as a second line treatment, minimizing the need for MV. The system acts as an external artificial lung, leveraging Inspira's hemo-protective flow technology, which balances oxygen saturation levels while the patient is awake and spontaneously breathing. The ART™ differs significantly from ECMO in many areas, including size.

> *"Frost & Sullivan finds Inspira's ART™ demonstrates the company's excellence in innovation. The device overcomes the limitations of its predecessors to deliver a less-invasive respiratory support system, aligning with the company's mission."*
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> ***- Samantha Fisher,***
> ***Best Practices Research Analyst***

ART is designed to allow for early intervention. In the case patient deteriorates while receiving ART treatment , alternative treatments can be applied (Mechanical ventilation). For ECMO treatment, typically, two large (21-25 fr) single lumen cannulas are used to withdraw and return 5-7 liters of blood per minute, while for ART treatment the company plans to use one (16-21 FR) dual lumen cannula, that will be used to withdraw and return1 -1.5 liters of blood per minute. In addition, ECMO which is a high flow device is not designed to support low flow treatment. ART is designed to optimize the effectiveness profile of low flow extracorporeal treatment. During ECMO treatment patients are sedated and paralyzed while ART is designed to treat patients while they are awake and spontaneously breathing.

As a result of its unique features, ART™ minimizes the need for invasive mechanical ventilation and associated damages to the patient's lung and overall survival. In addition, due to the single insertion point, it has the potential to reduce bleeding and infection significantly in comparison to ECMO treatment. . Moreover, Inspira's novel design minimizes the need for a perfusionist intervention due to its "plug-and-play" disposable cartridge and auto-priming system, which also prevents human errors. ART™ also features a permanent module and disposable respiratory support unit, and it works in five steps: insert, withdraw, enrich, circulate, and rebalance.

- **Insert** dual lumen cannula into the jugular vein
- **Withdraw** blood with a minimum drop in blood pressure leveraging hemo-protective flow technology
- **Enrich** the blood with high concentrations of oxygen while removing carbon dioxide
- **Circulate** the enriched blood to the body via the dual lumen cannula
- **Rebalance** the patient's saturation levels and ease the burden on the sick lungs

ART™ might be applied in (1) patient prior invasive mechanical ventilation, to avoid MV, and (2) in addition to MV to decrease MV duration and subsequent ventilator associated lung injury.

Early intervention avoids ventilator-associated lung injury (VALI) and circumvents the intubation and induced coma required for MV. It also prevents ventilator-associated pneumonia (VAP) and ventilator-induced diaphragmatic dysfunction (VIDD). Conversely, Inspira designed its adjunctive therapy for ventilated patients under an induced coma. This modality reduces the risk of ventilator-related injuries, including VALI, VIDD, and VAP; it also expedites ventilation and the weaning period. Frost & Sullivan finds Inspira's ART™ demonstrates the company's excellence in innovation. The device overcomes the

limitations of its predecessors to deliver a less-invasive respiratory support system, aligning with the company's mission.

Game-changing Outcomes with Early Extracorporeal Respiratory Support

Inspira designed its system to support patients with acute respiratory failure who continue to deteriorate following non-invasive treatment, while they are awake and spontaneously breathing. The company also offers small dual lumen cannula, 16-21Fr in diameter. The cannula designed to be inserted by any ICU practitioner reduces the need for surgical team.

The ART includes proprietary disposable cartridge (the disposable respiratory support unit) includes the disposable components – oxygenator, tubes, and pump head. In addition, it includes reusable components such as sensors. It's fully assembled, ready to use designed to allow for a faster response time by reducing assembly complexity. The cartridge is fully sterilized ,close system including Innovative automatic auto-priming system that eliminates the need for perfusionists and prevents air embolism.

- Additionally, the "brain" of Inspira's ART™ is an algorithm-enhanced control platform, controls and orchestrates multiple hemodynamic measurements documented via sensors HCT, SO2, CO2, PaO2 hemoglobin, blood temp and blood flow. The control unit is multi state blood flow regulator – an algorithm based "hemo-protective" patient's flow rate to determine the flow rate automatically based upon the patient's anatomic characteristics. It designed to allow both auto control and manual control) unlike commercially ECMO systems which are only controlled manually.

The company designed ART™ to minimize the possibility to hemolysis and thrombosis, managing blood at a low flow without damaging the red blood cells and reducing hemolysis and blood clotting risks.

ART potential advantages:

The Patient perspective: Immediate oxygen saturation elevation and stabilization decreased breathing efforts, patients can eat and drink, patients can communicate their symptoms and needs to the medical staff, patients can communicate with family and friends, no need for sedation - delirium can be prevented and muscle mass loss can be prevented.

The Clinician perspective: Clinicians would be able to offer an alternative to invasive mechanical ventilation, self-priming system results in less human errors, no prior extracorporeal respiratory systems experience is needed, and cannula size will allow ICU physicians to insert it without a surgeon involvement.

The Hospital perspective: Minimize the need for a medical team with prior experience with extracorporeal respiratory systems, reduced length of stay >>Increased patient throughput, reduced staffing, smaller Cannula (compared to ECMO's cannulas) may prevent the need for surgical access team, reduced costs associated with mechanical ventilation complications and reduction of patient load in ICU.

Inspira also sees potential penetration into emergency medical services, such as ambulances, as its ease-of-use and portability translates well into situations requiring quick response. Frost & Sullivan applauds Inspira for the ART™ system's plug-and-play simplicity, which eliminates the need for specialists to administer the system, and it also potentially circumvents the Cath room requirements. Thus, Inspira will potentially overcome the complicated set-up associated with ECMO and other systems, resulting in an efficient and effective procedure that safeguards a patient's health.

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The New Standard of Care

Inspira developed a flexible model to drive global deployment that distributes ART™ as an operating expense (OPEX) when bundled with disposable respiratory support units; thus, by providing medical facilities with these bundled kits, the company enables its customers to treat patients for a few months, overcoming difficulties associated with capital expenses. The company targets multiple customers, including healthcare centers, medical service providers, and medical device companies, with an estimated target price (based on high volume mass production) of at least to support the OPEX model. Inspira plans to use current procedural terminology codes with a "new approach" to an existing procedure. This strategy enables the company to reduce costs and OPEX while alleviating hospital staffing burdens and lowering the length of stay and re-admissions numbers.

Inspira plans to start in ICU beds with the goal of becoming the standard of care in every hospital around the world, as ART™'s affordability and ease-of-use provide an undeniable value proposition. From here, the company looks to move to other units and general wards before approaching small community hospitals that lack the highest level of ICU abilities, opening the market even further. Almost all ICUs reside in a major metropolitan, which poses logistical issues for patients 60 miles outside of the city, limiting access to life-saving technology. The goal is to build understanding in the market of the ART™ device's inherent ease-of-use and the dramatically reduced risks, translating to lower patient mortality, further supporting adoption and deployment further from the ICU.

Moreover, the company focuses on establishing multiple recurring revenue streams across medical sectors and markets. To achieve this, Inspira collaborates with strategic medical centers and professional associations. It also has purchasing collaborations with businesses such as global medical device companies, and it pursues worldwide regulatory approvals in various regions, including the United States, Europe, and Asia.

Strategic Planning for the Future

Moving forward, Inspira plans to target major milestones in 2022, 2023 and 2024, many of which involve filing with governing bodies, such as the Food and Drug Administration (FDA). The company aims to file its first product, an ECLS system and deploy in ICUs as soon as possible. Inspira Technologies'' regulatory pathway:

- H1-2022 - Listing the first Class I 510(k) (exempt) relating to component of the ART
- H1-2023 - Class II 510(k) submission of the ECLS
- H2-2023 - Regulatory filing for de-novo or PMA for the multi-function sources of ART in the US
- H2 – 2024 - Submission of an application for the CE Mark

Conclusion

Despite their widespread use during the COVID-19 pandemic, mechanical ventilation (MV) and extracorporeal membrane oxygenation (ECMO) pose high risks to patients and are extremely expensive. To solve these issues, Israel-headquartered Inspira Technologies (Inspira) developed ART™, a proprietary, early extracorporeal respiratory support device that elevates oxygen saturation to minimize the need for MV and ECMO. The device leverages the company's homegrown hemo-protective flow technology with a minimally invasive cannula to draw blood from the right jugular vein and enrich it with high concentrations of oxygen while also removing carbon dioxide. This early intervention method avoids ventilator-associated lung injuries, intubation, induced coma, weaning and MV. As Inspira moves forward with filing with governing bodies and clinical testing, it plans to improve the device to further assist intensive care units, general medical wards, and smaller rural hospitals.

For its minimally invasive and innovative technology, dedication to the improvement of patient care, and strong overall performance, Inspira earns Frost & Sullivan's 2021 European Technology Innovation Leadership Award in the artificial respiratory market.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

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

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

About Frost & Sullivan

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The Growth Pipeline Engine™

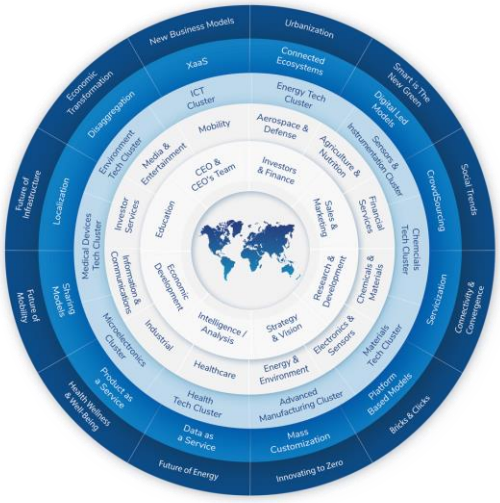
Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
Learn more.

Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)