410 Medical Recognized as the

2021

Entrepreneurial Company of the Year

Global Fluid
Resuscitation Devices Industry
Excellence in Best Practices

410 | MEDICAL

FROST & SULLIVAN

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 410 Medical 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. 410 Medical excels in many of the criteria in the fluid resuscitation devices space.

AWARD CRITERIA	
Entrepreneurial Innovation	*Customer Impact*
Market Disruption	Price/Performance Value
Competitive Differentiation	Customer Purchase Experience
Market Gaps	Customer Ownership Experience
Leadership Focus	Customer Service Experience
Passionate Persistence	Brand Equity

Founded in 2013 by a critical-care physician and headquartered in North Carolina, United States (US), 410 Medical is a medical device company engaged in developing innovative products that help clinicians improve care quality for severely ill patients. 410 Medical's first product, LifeFlow® Fluid Infuser, features a unique design for enhanced fluid resuscitation efficiency and speed. In 2016, LifeFlow Fluid Infuser received US Food and Drug Administration (FDA) clearance for human use with the product launched in 2017. The company currently markets two products to hospitals and emergency medical services groups in the US; the LifeFlow Fluid Infuser is approved for delivery of crystalloids and LifeFlow PLUS approved for delivery of blood and blood products as well as crystalloids.

Advancing Care Outcome and Patient Safety through Rapid, Easy, and Efficient Fluid Resuscitation

For patients presenting with hypotension or shock (e.g., septic shock, anaphylaxis shock, or hemorrhagic shock), early goal-directed fluid resuscitation restores intravascular volume, preventing organ failure and subsequent mortality risks. Hence, it is a critical element of care and the first step of shock treatment. Fluid resuscitation enhances microcirculation, optimizes organ perfusion, and improves outcomes in sepsis patients. However, the tools at healthcare providers' (doctors, nurses, and paramedics) disposal for immediate fluid resuscitation are limited, i.e., slow, cumbersome, and complicated. IV pumps and gravity infusion are inadequate for hypotension and shock patients requiring rapid fluid delivery. Particularly, in pediatric patients, infusion pumps limit delivering a maximum rate of 1,000 milliliter/hour (ml/hr) and achieve 60 ml/kilogram (kg) over 15 minutes in patients weighing less than 4 kg. The manual "push-pull" syringe technique (PPT) applied for pediatric emergency care is labor-intensive and complicated.

The Pediatric Advanced Life Support sepsis guidelines direct using the PPT technique to deliver 60 ml/kg of intravenous fluids in pediatric patients, ideally in 15 minutes and minimally within 60 minutes. While the ideal scenario happens only about 10% of the time, the minimally acceptable scenario occurs in about 30% to 35% of cases. The PPT technique also faces patient safety issues as the syringe design is not suitable for more than one push and risks syringe contamination.

Another method, pressure bags, requires constant tracking, re-inflation, and determining the fluid delivery volume, a laborious and time-intensive task[1]Therefore, providers often fail to meet the industry guidelines for delivering fluids to stabilize patients.

410 Medical designed the LifeFlow® Rapid Infuser to enable critical care healthcare providers to address challenges related to providing volume resuscitation more effectively and quickly.

Design Innovation

The LifeFlow Fluid Infuser is a unique commercial solution that improves the resuscitation workflow significantly. The device enables early, rapid, intuitive, and controlled fluid bolus delivery in acute care patients through any vascular access type.

Twice as fast as PPT and up to four times faster than a pressure bag, LifeFlow is a closed system with a unique design that effectively addresses the speed, control and contamination issues. Also, LifeFlow's simple set-up takes providers less than two minutes, in contrasts to other expensive, complex rapid infusers which require users to conduct four to five steps during an emergency, a time-consuming undertaking that may lead to stress and improper fluid delivery. Moreover, the device's one-hand operation frees the provider to address other patient care issues concurrently.

> *"LifeFlow fully protects the sterile syringe plunger at the time of usage, eradicating the risk of nosocomial infection related to standard syringes' repetitive use. By eliminating the risk of contamination (source of healthcare-associated infections) accompanying the PPT technique for pediatric patients, the device reinforces patient safety and reduces provider stress."*
> ***- Supriya Lala, Best Practices Research Analyst***

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Frost & Sullivan's analysis points that within the numerous solutions and devices available for fluid infusion, LifeFlow is preferable compared to PPT. As the only alternative technique for fluid resuscitation, it delivers a higher infusion rate coupled with decreased microbial contamination risks.

LifeFlow adapts to large-bore and high resistance access (e.g., catheters as small as a 24 gauge). The manually operated device supplies measured fluid boluses efficiently using a repetitive and automatic filling 10-ml syringe enclosed within a single-use handle. The device allows clinicians to manage and observe fluid delivery, monitor patient response, and limit the risk of over-infusion by stopping fluid administration immediately. LifeFlow successfully delivers 500ml of fluid in less than two minutes. The rapid delivery allows providers to quickly analyze the need for additional fluids and make additional treatment decisions based on bedside markers of perfusion.

The simple design and function are vital for critical care for pediatric and adult patients suffering from hypotension and shock and requiring rapid fluid delivery. The device gives providers, nurses, doctors,

[1] https://410medical.com/about/why-its-different/

and paramedics a secure and straightforward mechanism to quickly and effectively stabilize a crashing patient.

Next-generation Product Launch: LifeFlow® PLUS Blood & Fluid

In September 2020, 410 Medical received the US FDA 510(k) clearance for LifeFlow® PLUS, the new addition to the LifeFlow family. The latest product leverages the company's existing technology with the scheduled market release planned in early 2021. LifeFlow PLUS advances over the LifeFlow fluid infuser: it expands its utility from only fluid or crystalloid delivery to meet the growing demand of hospital customers and paramedics to deliver blood and blood products to patients suffering life-threatening hemorrhages and save lives. The customers recognize the device's operational simplicity and infusion speed as vital clinical parameters for blood and blood product infusion in patients with severe bleeding, potentially leading to fatal hemorrhage that obstructs treatment effectiveness due to blood infusion delay.

High Economic Value Proposition Meeting Return on Investment

As per the Sepsis Alliance, more than 1.7 million people receive a sepsis diagnosis every year in the US; the mortality rate is about 270,000 people (comparatively more than prostate cancer, breast cancer, and AIDS collectively). Sepsis is the leading cause of hospitalization and accounts for $27 billion in hospital expenses each year.[2]

By enabling early fluid resuscitation and sepsis care bundle compliance, the device potentially reduces patients' internal care unit (ICU) admissions, ICU stay days, and 30-day readmissions, significantly lowering care costs per patient. Simultaneously, the device-enabled early bolus of fluid infusion steadies collapsing patients and potentially saves their lives. LifeFlow's ability to realize healthcare economics and improve clinical outcomes at the same time warrants its high economic value proposition. Customers valued positive word-of-mouth, such as blogs and presentations, and engagements with the company validate clinical utility to spearhead market adoption.

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- Supriya Lala, Best Practices Research Analyst

LifeFlow provides an over tenfold return on investment by managing severe sepsis and shock in multiple health care environments such as small (100 patients) or mid-level (500 patients) hospitals, including emergency wards, ICU, urgent care, and military and community clinics.

410 Medical's marketing strategy targets hospitals with patients presenting septic shock, and its clinical goal is on limiting mortality through improved care outcomes. For the recently launched LifeFlow PLUS, the company partners with ambulance and paramedic service groups. It focuses on the urgency of getting blood into the field by emergency medical services (EMS) groups that administer stocked blood

[2] Analysing Sepsis Management Part I: Diagnosis,(*Frost & Sullivan, June 2020*)

in their trucks and helicopters and require a tool that infuses blood rapidly to save a collapsing patient.

Enabling Hospitals' Emergency Preparedness for COVID-19

Untreated sepsis potentially leads to septic shock, complicating respiratory ailments caused by COVID-19 and influenza viruses. Besides, vulnerable populations such as older people, and people with existing conditions, e.g., HIV/AIDS, liver cirrhosis, cancer, and autoimmune disease, are at increased risk of catching COVID-19.

Recent reports show that critically ill COVID-19 patients may develop hypotension and shock, requiring vasopressors. The Surviving Sepsis Campaign COVID-19 panel and the World Health Organization guidelines instruct precise and controlled fluid resuscitation for acute shock and hypotension. The recommendations advise using crystalloid fluid boluses of 250 to 500 ml for adults and 10 to 20 ml/kg for children, followed by reassessing and response monitoring after each bolus, and supported by a traditional fluid administration strategy.[3]

Several studies show that early and targeted fluid resuscitation after septic shock lowers endotracheal intubation risks, limits the span of mechanical ventilation, diminishes organ injury, and reduces hospital stay, vital for COVID-19 cases.[4] To that end, the portable LifeFlow device robustly delivers a 250ml fluid bolus in less than one minute, allowing rapid shock withdrawal and preventing fluid overload for patients with severe respiratory illness. The single-patient-use device is appropriate for the anticipated high patient numbers and isolation rooms with droplet precautions. Thus, the device enables hospitals to design intervention strategies to address fluid resuscitation for COVID-19 patients with septic shock.

Product's Clinical Impact and Research Focus Driving Market Adoption

LifeFlow PLUS strengthens 410 Medical's portfolio offering beyond the fluid infuser that effectively caters to the total addressable market for sepsis patients requiring fluid resuscitation. Today, the significant unmet need for fluid resuscitation for treating patients suffering from cardiac and respiratory failure, sepsis, drug overdose, hemorrhagic shock, excessive bleeding, anaphylaxis, and other forms of shock and hypotension drives company growth and LifeFlow's product family adoption. Currently, over 40 hospitals and EMS systems use the product. The 2020 third quarter (Q3) sales increased by 34% from Q3 in 2019, owing to increased LifeFlow product market adoption. Notably, Illinois-based OSF HealthCare, a 14 hospital group, purchased nearly 300 LifeFlow units.[5]

LifeFlow PLUS has high growth potential in the pre-hospital care and military markets due to the increased demand for blood resuscitation in the field. The company is expanding its resources and developing partnerships with distributors focused on the military and the pre-hospital care EMS market, with innovative strategies to drive adoption.

410 Medical is exploring market opportunities in countries outside the US for next year. The private

[3] Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected: Interim Guidance. World Health Organization. 13 March 2020. Pg. 9. WHO/2019-nCoV/clinical/2020.4. who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected.

[4] Lee SJ, et al. (2014). Increased fluid administration in the first three hours of sepsis resuscitation is associated with reduced mortality: a retrospective cohort study. Chest. 2014 Oct;146(4): 908-915. DOI: 10.1378/chest.13-2702. https://www.ncbi.nlm.nih.gov/pubmed/24853382. Leisman D, et al. Association of Fluid Resuscitation Initiation Within 30 Minutes of Severe Sepsis and Septic Shock Recognition With Reduced Mortality and Length of Stay. Ann Emerg Med. 2016 Sep;68(3):298-311. DOI: 10.1016/j.annemergmed.2016.02.044. https://www.ncbi.nlm.nih.gov/pubmed/27085369.

[5] https://www.ncbiotech.org/news/410-medical-awarded-fda-510k-clearance-lifeflow-plus.

investor venture capital-backed company builds the product through a third-party manufacturing partner in the US and coordinates its sales, marketing, and distribution efforts internally. It is growing its research capabilities and presenting studies to validate its product's clinical utility.

The most recent presentation in the American College of Emergency Physicians (ACEP) highlighted the role of delayed fluid resuscitation, potentially causing sepsis and death.

A recent partnership with the Emergency Medicine Foundation, an organization created by ACEP's leaders to fund emergency medicine research, provided 410 Medical with a $250,000 grant to study LifeFlow devices' effectiveness and determine the exact timing, volume, and events impacting positive patient outcomes.

Conclusion

Critically ill patients with hypotension or shock require efficient, rapid, and intuitive fluid and blood administration methods to prevent a fatality.

410 Medical develops innovative devices to address volume resuscitation challenges through the rapid and accurate delivery of crystalloid and colloid fluid boluses, blood, and blood components, enabling clinicians to improve care for critically ill patients. The company's breakthrough LifeFlow® Rapid Infuser is a uniquely designed simple-to-operate product that allows a caregiver to inject resuscitating fluids early in an enhanced and controlled manner, lowering organ failure risks. The device's high infusion rate enables rapid and efficient fluid administration, while monitoring capabilities prevent over-infusion. LifeFlow eliminates inappropriate and stressful delivery and syringe contamination issues, providing better patient safety than the standard fluid resuscitation techniques. 410 Medical's next-generation product, LifeFlow PLUS, leverages the first product's technology to deliver blood and its components quickly to radically improve the care of patients suffering from life-threatening hemorrhages.

Frost & Sullivan recognizes that the company's LifeFlow products are market-disruptive alternatives to conventional fluid and blood components, resuscitation techniques. With its strong overall performance, 410 Medical earns Frost & Sullivan's 2021 Global Entrepreneurial Company of the Year Award in the fluid resuscitation device industry.

What You Need to Know about the Entrepreneurial Company of the Year Recognition

Frost & Sullivan's Entrepreneurial Company of the Year Award recognizes the best up-and-coming, potentially disruptive market participant.

Best Practices Award Analysis

For the Entrepreneurial Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Entrepreneurial Innovation

Market Disruption: Innovative new solutions have a genuine potential to disrupt the market, render current solutions obsolete, and shake up competition

Competitive Differentiation: Strong competitive market differentiators created through a deep understanding of current and emerging competition

Market Gaps: Solution satisfies the needs and opportunities that exist between customers' desired outcomes and their current market solutions

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

Passionate Persistence: Tenacity enables the pursuit and achievement of seemingly insurmountable industry obstacles

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

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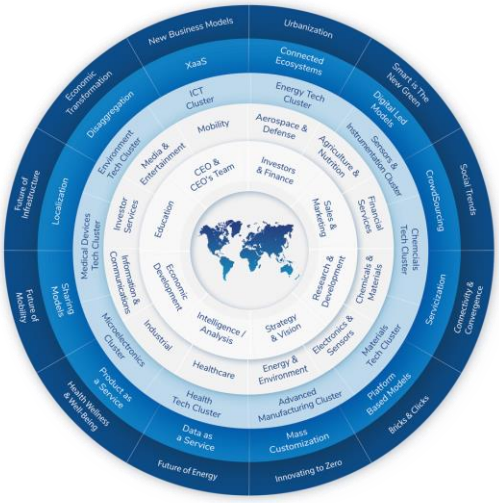
The Innovation Generator™

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



Analytical Perspectives:

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