



ENvizion Medical Ltd Recognized for

2021

Technology Innovation Leadership

North American Enteral Feeding

Tube Navigation Industry

Excellence in Best Practices

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. ENvizion Medical excels in many of the criteria in the enteral feeding tube navigation space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Technology Incubation	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

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Senior Research Analyst**

Introducing a Breakthrough Personalized Enteral Feeding Tube Navigation Platform to Address Healthcare’s Pressing Needs

Enteral nutritional support is a feeding method involving the use of a tube placed through the gastrointestinal tract. The method provides for caloric requirements and plays a significant role in helping avoid malnutrition in patients with poor voluntary oral intake, intestinal failure, or critical illness.

Tube placement for enteral feeding can be carried out through nasal insertion by techniques including unguided bedside insertion. Unguided bedside insertion or blind insertion is among the most common method of nasoenteral intubation; however, 0.5% to 16%¹ of cases result in misplacements in the tracheal, pulmonary, or pleural region leading to pulmonary abscess or pneumothorax in patients. Adjuvant technique using radiography is currently deployed to confirm the feeding tube placement through blind insertion. However, since the technique is carried out

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4093701/>

post blind insertion, it fails to overcome the issue with regards to tube misplacements and the associated complications in the patients. Moreover, this method involves the need for repeated X-ray confirmation resulting in increased financial burden and radiation exposure to the patients, leading to serious health risks (e.g., the chance of developing malignancies later in life) for sensitive patients such as children. Furthermore, the time required for tube placement is high, delaying the initiation of feeding

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To address the limitations of blind insertions and radiography-based adjuvant method, Tel Aviv, Israel-based ENvizion Medical has developed a revolutionary feeding tube navigation system for accurate enteral tube placement in adult patients. The FDA 510(k)-cleared ENvue system consists of an electro-mechanical device with embedded

software and enteral feeding tubes. Leveraging the power of electromagnetic technology, the device creates a personalized body map of patients, which along with the specially designed enteral feeding tube with built-in passive sensor and intuitive screen allows the medical staff to precisely place the tube in the stomach or small intestine through the oral/nasoenteric route. Unlike competing products, the ENvue system creatively displays a frontal, lateral, and axial view of the patients’ actual body contours simultaneously, while also highlighting the enteral feeding tube’s direction in real time. Hospital staff is thus alerted through visual indicators about any potential entrance in the airway. Such real-time and multi-faceted visualization and directional guidance provide greater confidence to healthcare support staff while inserting the feeding tube, eliminating the risk of placement in the patients’ lungs and, thus, associated complications.

The ENvue system’s novel electromagnetic tracking technology reduces the tube placement procedure time to half of that taken by commercially available products. Frost & Sullivan notes that shortening the time required to initiate feeding is extremely important for critically ill and malnourished intensive care unit (ICU) patients. Moreover, it eliminates the need for repeated X-ray confirmations, minimizing radiation exposure, and the associated health complications which subsequently reduce the healthcare costs for patients.

Building on the experience gained during the ENvue system development, ENvizion Medical is also developing a feeding tube navigation system for preterm infants. The platform is expected to feature localization technology and first-of-its-kind feeding tubes with a small-bore size of 5 to 6 French units. The development of the product assumes immense significance on preterm infants due to their high nutritional needs (the neonatal period requires higher caloric inputs than at any other time of life). The nutritional support offered through the system will help enable weight gain at appropriate rates in premature babies, reducing the risk of postnatal growth failure.

Robust Clinical Validation to Spur Growth

Clinical studies that have evaluated the accuracy and safety of the ENvue system demonstrate favorable outcomes in patients. The ENvue system was validated in partnership with the Cleveland Clinic

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Foundation and St. Vincent Indianapolis Hospital and Health Care Center, two prominent healthcare institutions in the United States. The results (published in the Trauma Surgery & Acute Care Open journal in November 2019) demonstrated the ability of the system to successfully place the feeding tube in the stomach, pylorus region, and small intestine in 100% of the subjects (All 57 patients witnessed successful tube placement procedure)². No lung placements, pneumothoraces, or any other guidance-related adverse

events were observed in the participants.

The promising results achieved in the clinical studies have helped ENvizion Medical receive regulatory approval in the United States within 2 years of the company’s inception. The system’s utility has generated strong interest from multiple US-based hospitals, including Ascension St. Vincent Hospital, Mercy Health-St. Elizabeth Youngstown Hospital, and one of the largest private health systems in the country, with more than 100 facilities under its network.

A key strategy driving ENvizion Medical’s growth is the use of a dynamic research loop wherein regular client feedback is actively incorporated to refine the ENvue system’s software and hardware. The use of a process that seeks input from customers to improve system functionality has helped decrease the learning curve and improved the product’s acceptance by hospital staff. Such an approach provides a key point of differentiation from competing products and is expected to play a pivotal role in driving adoption of the company’s solution among healthcare providers. Frost & Sullivan believes the development is a testament to the forward-looking approach adopted by ENvizion Medical to deliver a technology platform closely aligned to market needs. The company’s visionary thinking is greatly supported by prominent investors, including the Technion Venture Capital fund and private medtech backers. The company is also in the process of filing an initial public offering on the Tel Aviv Stock Exchange, with the aim to raise approximately New Israeli Shekel 35 million (\$ 10.6 million USD) to support its future growth plans.

² <https://tsaco.bmi.com/content/4/1/e000330>

Conclusion

Enteral feeding plays an important role in providing critical nutrition to hospitalized patients who cannot tolerate the standard method of food intake. However, the technique's success is compromised due to the limitations of blind insertion and radiography-based adjuvant method. ENvizion Medical's groundbreaking personalized enteral feeding tube placement system harnesses the power of electromagnetic technology with a sensor-integrated feeding tube. As a result, clinicians can quickly and accurately place the tube in the stomach or small intestine, decreasing the time required to initiate feeding and reducing radiation exposure. The pioneering ENvue system provides uniquely safe and rapid feeding tube positioning, assuming a vital role in improving outcomes for critically ill patients.

For its strong overall performance, ENvizion Medical earns Frost & Sullivan's 2021 Technology Innovation Leadership Award in the North American enteral feeding tube navigation industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation 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

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- **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 six 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)**

