FROST & SULLIVAN

NOVIAN HEALTH

2022 NEW PRODUCT INNOVATION

EUROPEAN BREAST TUMOR ABLATION INDUSTRY

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. Novian Health excels in many of the criteria in the Breast Tumor Ablation space.

According to the World Health Organization, 2.3 million women across the globe were diagnosed with breast cancer in 2020. Statistics also reveal that the disability-adjusted life years (DALYs) lost by women are highest for breast cancer.[1]

Breast-conserving surgery (BCS), along with radiation therapy, is currently the standard of care for early-stage breast cancer. BCS-- also called lumpectomy or partial mastectomy--, coupled with radiation and adjuvant therapies is the preferred procedure as it helps preserve the breast and lowers the recurrence rate. However, lumpectomy can cause significant scarring and deform the breast following removal of the tumor. In addition, lumpectomy may require repeated excision due to local recurrences. Retreatments add to the patient's psychological distress and affect breast cancer survivors' quality of life. Ablation technology is a favorable alternative to invasive surgical excision for a lumpectomy. However, most available ablation technologies have only been cleared for treating benign

> *"This quick, percutaneous, and ultrasound-guided laser procedure needs only local anesthesia, offers minimal scarring, and ensures lower pain and fatigue and quicker recovery for the patients. It facilitates a paradigmatic shift in the perception of breast tumor treatment, putting the patients' minds at ease. This helps the patients tackle the next set of treatments, be it radiotherapy or adjuvant chemotherapy, with a lot more positivity and energy."*
>
> ***- Debarati Sengupta, Senior Industry Analyst***

[1] World Health Organization, "Breast Cancer", https://www.who.int/news-room/fact-sheets/detail/breast-cancer.

breast tumors. The current technologies are in investigational stages for treating malignant breast tumors.

Minimally invasive focal destruction of benign and malignant breast tumors with minimal scarring and no general anesthesia

Based in Chicago, with a subsidiary in Evry, France, Novian Health has redefined the way early-stage breast cancer tumors are treated. Novilase® Breast Therapy, also known as the Novilase® Laser Therapy System, is a minimally invasive, non-surgical technology to focally destroy benign as well as malignant tumors. It is a thermal ablation device that uses laser heat to destroy tumor cells in situ without lumpectomy surgery. The device consists of two small probes, which are inserted under the guidance of ultrasound or x-ray imaging. One probe is inserted into the tumor to deliver laser energy via an optical fiber to kill the tumor cells, while the second is inserted at the edge of the ablation zone to monitor the ablation temperature. The tumor cells die as soon as the periphery ablation zone temperature reaches 60 degrees centigrade. The temperature-controlling feature at the periphery of the ablated tumor makes the procedure extremely safe, protecting the tissues outside the target zone. Unlike invasive lumpectomy surgical procedures, no tissues are removed, thereby ensuring that there is no dimpling or deformity of the breast. Post-surgery, the natural tissue rebuilds in the tumor region through the body's natural healing process. The probes leave behind two small skin nicks about 1/8th of an inch in size, whereas a lumpectomy requires a 2- to 3-inch incision. This reduces the risk of infection and speeds up the recovery process. This novel device is protected by over 90 patents, designs, and trademarks in the United States, Europe, and other parts of the world.

This entire procedure takes 15 to 30 minutes and does not require a hospital stay or general anesthesia. The simplicity of this outpatient procedure reduces the psychological distress and anxiety associated with invasive surgery. The procedure, being far less intimidating than other forms of cancer treatment, encourages women to opt for early detection, which improves the chances of complete recovery.

While there are some commercially available ablation devices for the treatment of benign breast tumors, Novilase® is the first thermal ablation device to have obtained a CE mark for the focal destruction of malignant tumors. The focal destruction of malignant breast tumors up to 20 mm in size has been evaluated in several clinical studies. The results from a multicenter trial in the United Kingdom and the United States were published in the *Annals of Surgical Oncology* and reported that percutaneous laser ablation (PLA) is a potential alternative to complex surgery in the treatment of invasive ductal breast carcinoma (IDC), as the procedure showed complete tumor ablation in 98% of patients with tumors up to 15 mm and 91% up to 20 mm. The trial also reported better health-related quality of life outcomes compared to lumpectomy surgery.[2]

Following the promising results, the Novilase® Interstitial Laser System was termed a Breakthrough Device in 2021 by the US Food and Drug Administration, accelerating the product's path to market. It has already received 510K clearance in the United States for treating benign breast tumors (e.g., fibroadenomas) and soft tissue ablation. The low risks associated with Novilase® Breast Therapy have also contributed to the

[2] Schwartzberg, B., Lewin, J., Abdelatif, O. et al., "Phase 2 Open-Label Trial Investigating Percutaneous Laser Ablation for Treatment of Early-Stage Breast Cancer: MRI, Pathology, and Outcome Correlations." *Annals of Surgical Oncology* 25, 2958–2964 (2018). https://doi.org/10.1245/s10434-018-6623-2.

US FDA's decision to grant an IDE (investigational device exemption) to conduct a confirmatory pivotal trial which may expedite the device's path to market approval in the USA

Approved by Regulatory Bodies, Novel Novilase® is Cost Effective and Less Traumatic than Lumpectomy, Accelerating Customer Adoption

Novian Health closed its convertible round financing in August 2021, raising $11 million, with National Securities Corporation, a B. Riley Financial company, as the lead investor. The Company has begun manufacturing the device, which will be available commercially in Europe by 2023. In the United States, it is conducting a confirmatory trial to get US FDA clearance for the focal destruction of malignant breast tumors. Moreover, to support a reimbursement code in the United States, Novian launched a post-marketing surveillance study, ABLATE (American Breast Laser Ablation Therapy Evaluation), that collected data for treating benign breast tumors. The clinical data has been showcased at the American Society of Breast Surgeons Conferences and the Paris Breast Rendez-Vous Congress. Novian will launch LASE, a post-marketing surveillance study, upon initiating European commercialization. Novilase® has also been validated by breast surgeons and radiologists across the globe. This response from the medical community will help Novilase revolutionize the approach to breast cancer tumor treatment.

> *"Besides the improved quality of life for the patients, this interstitial laser therapy is significantly more cost-effective than standard breast cancer surgery, as it eliminates the need for hospital stays. The high efficacy and significantly lower chances of repeated excision also drive adoption. Novian's ablation system is housed in a mobile cart, helping in easy movement of the device across the hospital facility and freeing up space in the operating room."*
>
> *- **Debarati Sengupta, Senior Industry Analyst***

One of the primary reasons patients and doctors prefer this mode of treatment as opposed to more complex surgery is that the process is much simpler and less traumatic. The Novilase® procedure can be performed by any surgeon or radiologist with experience in image-guided breast procedures such as biopsies. This quick, percutaneous, and ultrasound-guided laser procedure needs only local anesthesia, offers minimal scarring, and ensures lower pain and fatigue and quicker recovery for the patients. It facilitates a paradigmatic shift in the perception of breast tumor treatment, putting the patients' minds at ease. This helps the patients tackle the next set of treatments, be it radiotherapy or adjuvant chemotherapy, with a lot more positivity and energy.

Besides the improved quality of life for the patients, this interstitial laser therapy is significantly more cost-effective than standard breast cancer surgery, as it eliminates the need for hospital stays. The high efficacy and significantly lower chances of repeated excision should also drive adoption. Novian's ablation system is on a mobile cart, helping in easy movement of the device across the hospital or breast center facility and freeing up space in the operating room. The system includes disposable laser and thermal probes, making sanitization easier, and adding efficiency to the hospital workflow.

Novian was founded by a pioneer in breast cancer diagnosis and treatment, the late Dr. Kambiz Dowlat. Dr. Dowlat, the developer of the Novilase® image-guided laser therapy system, introduced stereotactic

core needle biopsy in the United States. The stereotactic core needle biopsy was the standard of care for many years and the inspiration behind the Novilase® Breast Therapy prototype as he envisioned a therapeutic benefit from the technique. Novian Health continues to take forward the legacy of Dr Dowlat's ground-breaking work in this field and move towards the vision of treating breast tumors in a less invasive fashion with minimum side effects.

Frost & Sullivan believes that Novian Health has tremendous potential to disrupt the lumpectomy industry, making the treatment of breast cancer much simpler and more effective, with significantly lower side effects.

Conclusion

The proprietary Novilase® Breast Therapy by Novian Health enables minimally invasive focal destruction of benign and malignant breast tumors with minimal scarring and no general anesthesia in a 15-to 30-minute outpatient procedure. This breakthrough CE-marked and patented device is much safer and less traumatic than a lumpectomy and ensures greater comfort and peace of mind as well as lower hospital expenses for the patients. With its strong overall performance, Novian Health earns Frost & Sullivan's 2022 European New Product Innovation Award in the breast tumor ablation industry.

© Frost & Sullivan 2022

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 New Product Innovation 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

© Frost & Sullivan 2022

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

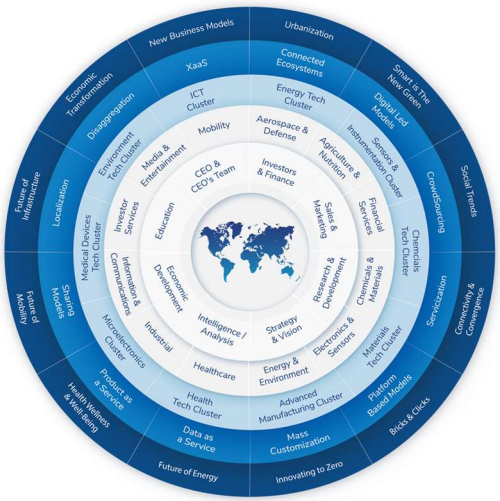
Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
Learn more.

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)