



2018 APAC Fluorescence Surgical Imaging for Breast Cancer
New Product Innovation Award



2018
BEST PRACTICES
AWARDS

Background and Company Performance

Industry Challenges

Breast cancer is the most common cancer among women globally, with more than 2 million new cases diagnosed in 2016 alone. Although various screening programs have significantly reduced the mortality rate over the last 10 years, breast cancer remains the fifth leading cause of cancer-related death among women in the Asia-Pacific (APAC) region. During its early stages, breast cancer is often impalpable and does not exhibit any signs or symptoms. However, identifying and treating the disease as early as possible is critical for preventing it from metastasizing to the lymph nodes or other parts of the body; thus greatly improving a patient's chance of survival. When compared to all other cancer morbidity rates in women (e.g., cervical, uterine, ovarian), breast cancer has some of the highest morbidity levels.

When diagnosing the metastasis of cancer cells in breast cancer patients, identifying the position of the sentinel lymph nodes while excising them to diagnose the pathology remains a crucial part of the diagnosis protocol. If the cancer has not metastasized to the sentinel lymph node, then the axillary lymph node excision can be omitted to prevent lymphedema and help in maintaining the patient's quality of life after surgery. For this reason, surgeons need to accurately determine the position of lymph nodes and quickly proceed with surgery. As such, Frost & Sullivan points out that the industry is in dire need of a system designed to support breast cancer treatment through the visualization of lymph node, thereby allowing the surgeon to perform procedures while monitoring the position of lymph nodes being excised.

New Product Attributes and Customer Impact

Product Matched to Needs: The Imperative for Clinical Change

Over the last decade, Shimadzu has made considerable advances in optical control and biological tissue fluorescence imaging technologies; the company has played a key role in bringing fluorescence technology to the medical imaging industry. Driven by a commitment to research and development efforts, the company launched new near-infrared fluorescence (NIRF) imaging system, known as LIGHTVISION, in August 2016.

The NIRF LIGHTVISION system stands out as a combination of extensive R&D efforts coupled with key opinion leaders' input to deliver a breakthrough image-guided stereotactic solution with several unique value-adding capabilities. For example, it supports breast cancer treatment through the visualization of lymph vessels and blood vessels based on the detection of NIRF light emitted from an indocyanine green (ICG) dye.

Further, the unique additional clinical strengths of NIRF LIGHTVISION in breast cancer treatment lie in:

Sentinel lymph node mapping: Its ability to assist in sentinel lymph node mapping for a quick and easy trace of the flow of lymph which is extending far from the primary cancer lesion.

Perfusion assessment in breast reconstruction: In plastic and reconstructive surgical procedures, the NIRF LIGHTVISION system provides a 10x zoom usefulness to a wide target area of substantial abdominal flap. This 10x enlarger is utilized for top quality representation of blood vessels to evaluate patency after anastomosis and to perform flap perfusion, consequently giving a superior clinical investigation of breast reconstruction assessment of flap perfusion.

Lymphatic vessel mapping on lymphedema: The NIRF LIGHTVISION can bolster the affirmation of the progression of lymphedema by visualizing the movement through lymphatic vessels. Amidst the lymphovenous anastomosis (LVA) procedure, the near-infrared and visualization of lymphatic vessels can be of more noteworthy reference to easily decide the progression of lymphatic vessels.

The demand for precise surgical navigation continues to grow, since surgeons rely on it during cancer surgery. Physicians need detailed images of breast lymph nodes, tissues, and blood vessels in real-time to enable faster decisions and to ultimately reduce procedure times.

Though there are many competing systems available in the market today, Frost & Sullivan believes the NIRF LIGHTVISION system to be unrivaled, because it provides cutting-edge, real-time contrast images of lymph vessels. It achieves this by administering the ICG dye through the lymph vessels and thereby exposing the corresponding tissue to excitation light. With the NIRF LIGHTVISION system, surgeons gain a faster and deep visualization to assist in determining the ablation range using three different images at once (i.e., 'one' from the optical image, 'two' from the near-infrared fluorescence image, and 'three' a combined visible plus near-infrared fluorescence image). Furthermore, the NIRF LIGHTVISION system is superior in terms of resolution to visualize the position of sentinel lymph nodes for diagnosing the metastasis status of cancer cells. Another key advantage with the NIRF LIGHTVISION system is that it enables image acquisition in a bright field of view, without requiring the switching off of overhead lighting in the operating room.

Product Reliability and Quality

The NIRF LIGHTVISION system is currently approved for use in the APAC market. Upon introduction in the Japanese market, the company has installed about 10 systems. Currently, Shimadzu's focus is on new geographical penetration in the Southeast Asian countries.

With significant investment in R&D for diagnosis and treatment of breast cancer using intraoperative fluorescence imaging, Shimadzu is quite confident in its ability to expand globally to overtake its competitors in this space after regulatory clearance. The company

has a sterling reputation in optical imaging thanks to its superior fluoroscopic technology and valuable product attributes. Frost & Sullivan firmly believes that Shimadzu is setting a new industry benchmark in the near-infrared fluorescence imaging system space.

Product Design

Shimadzu has clearly demonstrated its technological supremacy in redefining the healthcare space in surgical oncology with its introduction of the NIRF LIGHTVISION system.

Below are the main NIRF LIGHTVISION system features that have greatly impressed Frost & Sullivan.

- A high definition image quality is emitted by the near-infrared fluorescent light from indocyanine green. This light clearly differentiates lymph ducts and blood vessels as well as the placement and position of surgical tools and tissues during surgery.
- User-friendly features are exhibited by the system's operability in terms of hands-free imaging, camera movement up to 180 centimeters, and camera positioning depending on the anatomical region of interest (breast, leg, and neck).
- NIRF LIGHTVISION is equipped with high-definition sensors that yield high-quality real-time images on a single monitor for surgeons to gain deep visualization and definitive ablation range during surgery.
- Additionally, features like automatic light exposure adjustment and automatic white balance adjustment aid in better visual resolution and obtaining images up to a magnification of 10 times.

Product Positioning

Shimadzu's remarkable performance in optical imaging is demonstrated by its high-definition image quality. The three colors (white, green, and blue) improve visualization of blood vessels and lymph ducts and provide clear differentiation from surrounding tissues. This feature helps surgeons reference and confirm a large amount of information at a quick glance, thereby reducing the procedure time.

Shimadzu strives to enhance the quality and safety of care by improving surgical workflows and generating efficiencies in the operating room. Frost & Sullivan believes that the unique selling points of NIRF LIGHTVISION lie in its overall system design and intuitive workflow coupled with it being a mobile surgical device system.

Brand Equity

Years of experience in optical control and biological tissue fluorescence imaging technologies have led to the scintillating success of the NIRF LIGHTVISION system, aligning Shimadzu's vision and transition towards transformational value-based healthcare. Frost & Sullivan concludes that this vibrant breakthrough will increase the

overall brand presence of Shimadzu when compared to other competitors in the market. With its new product launch, the company has achieved a comprehensive portfolio of products required for medical imaging solutions focusing on enhanced automation, efficiency, image quality, and cutting-edge applications that enrich clinical value and build solid partnerships with end users.

Conclusion

Frost & Sullivan's independent analysis identifies Shimadzu as a trendsetter in intraoperative near-infrared fluorescence imaging systems, specifically because it brings innovation in surgical treatment. Supported by the company's stellar reputation in medical imaging modalities, NIRF LIGHTVISION is expected to experience wide adoption as a surgical tool for breast cancer, while efforts are well underway for the technology to serve other anatomical regions (e.g. Liver – to assist in identifying tumors in liver before hepato-pancreato-biliary surgery, assessing vascular anastomosis during coronary artery bypass surgery and identifying sentinel lymph nodes for melanoma) in the future.

Shimadzu is acting on its promise to significantly influence real-world healthcare challenges with real-time medical imaging technologies that surgeons can rely on to locate lymph nodes, lymphatic vessels, and tissues precisely. This system shortens surgical procedure time frames, leading Frost & Sullivan to conclude that Shimadzu is on the right path for continuing its market expansion.

For its strong overall performance, Shimadzu is recognized with the 2018 Frost & Sullivan New Product Innovation Award in the Breast Cancer Fluorescence Surgical Imaging industry.

Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.

Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

New Product Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the product's design and positioning.

Criterion 2: Reliability

Requirement: The product consistently meets or exceeds customer expectations for consistent performance during its entire life cycle.

Criterion 3: Quality

Requirement: Product offers best-in-class quality, with a full complement of features and functionalities.

Criterion 4: Positioning

Requirement: The product serves a unique, unmet need that competitors cannot easily replicate.

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Customer Impact

Criterion 1: Price/Performance Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience

Requirement: Customers feel they are buying the most optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience

Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

Criterion 4: Customer Service Experience

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 Monitor, target, and screen	Identify Award recipient candidates from around the globe	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies 	Pipeline of candidates who potentially meet all best-practice criteria
2 Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates 	Matrix positioning of all candidates' performance relative to one another
3 Invite thought leadership in best practices	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps 	Detailed profiles of all ranked candidates
4 Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> • Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles 	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> • Share findings • Strengthen cases for candidate eligibility • Prioritize candidates 	Refined list of prioritized Award candidates
6 Conduct global industry review	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> • Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates 	Final list of eligible Award candidates, representing success stories worldwide
7 Perform quality check	Develop official Award consideration materials	<ul style="list-style-type: none"> • Perform final performance benchmarking activities • Write nominations • Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8 Reconnect with panel of industry experts	Finalize the selection of the best-practice Award recipient	<ul style="list-style-type: none"> • Review analysis with panel • Build consensus • Select recipient 	Decision on which company performs best against all best-practice criteria
9 Communicate recognition	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> • Present Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance 	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 Take strategic action	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> • Coordinate media outreach • Design a marketing plan • Assess Award's role in future strategic planning 	Widespread awareness of recipient's Award status among investors, media personnel, and employees

