LSI Alumni Innovator Spotlight: Innoblative's Rick Stark

Rick Stark (Source: Rick Stark)

What if one of the biggest opportunities to improve breast cancer care isn't changing the surgery itself, but rethinking what happens immediately afterward? Here, CEO Rick Stark shares Innoblative's vision for advancing breast-conserving therapy and reducing the physical and emotional burden that can follow a lumpectomy. He also reflects on the clinical need driving the company's work, the importance of building strong evidence, and the long journey of bringing a new medtech innovation from concept to the operating room.

When a 64-year-old woman with Stage II luminal A breast cancer entered an operating room in Istanbul, Turkey, in July 2024, she became the first patient treated with **Innoblative Designs**' investigational *SIRA RFA Electrosurgical Device* following a lumpectomy. For CEO **Rick Stark** and his team, this milestone marked the culmination of years of research, engineering, clinical collaboration, and regulatory preparation.

"It was an emotional and humbling moment," Stark recalls in a recent interview with *The Lens*. "When you work on a technology for years, you spend so much time discussing design, regulatory strategy, clinical plans, financing, and execution. But the first time it is used in a patient, everything becomes very real. What went through my mind was the patient. This is ultimately why we do the work."

That moment had been years in the making.

Innoblative is developing a technology designed for use immediately following a lumpectomy, when surgeons have removed the visible tumor but cannot yet know whether microscopic cancer cells remain at the surgical margin. If pathology later shows positive margins, many patients must return for another operation before continuing treatment.

"Positive margins remain persistent because the problem is not simply surgical skill," Stark explains. "It's biology, anatomy, and the limitations of real-time intraoperative assessment."

Breast cancer remains a major global health concern. Many patients undergo breast-conserving therapy, which typically involves lumpectomy followed by several weeks of radiation. Roughly one in five patients requires a second procedure to address residual cancer, and radiation therapy can involve side effects that affect quality of life, according to Innoblative.

For patients, a second surgery often means another round of anesthesia, more recovery time, additional time away from work and family, and a longer wait before moving on to the next phase of treatment. For many women, radiation therapy may also follow, bringing weeks of frequent appointments and, for some, long drives to treatment centers.

"A second surgery is a major burden," Stark says. "It extends the emotional journey for a patient who has already been told she has breast cancer and is trying to move forward with treatment."

Those challenges are part of why Stark believes breast-conserving therapy deserves continued innovation.

"Breast cancer treatment is not one decision; it's a sequence of decisions," he says. "If we can reduce uncertainty, reduce repeat procedures, and potentially reduce treatment burden, that can have a meaningful impact."

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For Innoblative, the goal isn't to replace lumpectomy. It's to explore whether surgeons can do more during that initial procedure to help reduce what patients may face afterward.

That idea didn't begin with a company. It began with a surgeon who wanted to do more.

A Surgeon's Focus on Improving the Patient Journey

Long before Innoblative was founded, Dr. **Suzanne Klimberg** was seeing the same challenge play out in her breast surgery practice.

A nationally recognized breast surgeon and former president of both the **American Society of Breast Surgeons** and the **Society of Surgical Oncology**, Dr. Klimberg had spent years treating women undergoing breast-conserving surgery. While advances in imaging, pathology, and surgical technique had improved outcomes, one stubborn problem remained. Too many patients still learned days after surgery that cancer cells were present at the margin, requiring them to return for another operation.

For many of the women she cared for in Arkansas, the burden didn't end there. Radiation therapy often meant weeks of daily treatments, requiring repeated trips to specialized centers that could be hours from home. For patients balancing work, family responsibilities, and the emotional weight of a breast cancer diagnosis, those extra weeks of treatment, plus potential radiation side effects, could become overwhelming.

Rather than accepting those challenges as inevitable, Dr. Klimberg began asking whether surgeons could do more during the initial operation to reduce what might come afterward.

That question eventually led to a collaboration at **Northwestern University**, where surgeons and engineering students worked together to explore a different approach. Instead of adapting existing radiofrequency technologies, the team started with the clinical problem itself and designed a solution specifically for the unique anatomy of the post-lumpectomy cavity.

"Northwestern created a unique environment where clinical insight and engineering creativity came together," Stark says. "Surgeons understood the problem firsthand, and the engineering team was able to think differently about how to solve it. The best medical technologies often come from close collaboration between the people who understand the clinical need and the people who can design a practical solution."

When Stark joined Innoblative, that work was already well underway. What attracted him wasn't simply the technology, but the opportunity to help bring it through the next stage of development.

"The goal is not just to improve a procedure," he says. "It is to improve the patient journey."

Turning that vision into a therapy that surgeons can confidently adopt, however, requires far more than a promising idea. It takes clinical evidence, physician champions, regulatory progress, and years of careful execution, one milestone at a time.

Designing for the Way Surgeons Operate

As Stark tells it, Innoblative wasn't founded to reinvent radiofrequency ablation. The challenge was figuring out how to apply an established technology to a very different clinical situation.

By the time a surgeon has completed a lumpectomy, the tumor has already been removed. What remains is the surgical cavity, where microscopic cancer cells may still be present around the margins. Existing radiofrequency devices weren't designed for that setting.

"Traditional radiofrequency systems were generally designed to ablate discrete tumors or tissue targets," Stark explains. "SIRA was designed specifically for the ablation of post-lumpectomy cavities. The goal is not to ablate a tumor mass; the goal is to treat the margins of the lumpectomy cavity immediately after excision."

Rather than modifying an existing device, the team designed one specifically for the shape of the post-lumpectomy cavity. The spherical electrode delivers radiofrequency energy around the cavity in a controlled, consistent way, with the goal of treating tissue that can't be seen during surgery.

"The spherical design came from the clinical problem itself," Stark says. "A lumpectomy cavity is not a flat surface or a single-point target. It is a three-dimensional space. To treat that space effectively, the device needed to deliver energy around the cavity in a way that was controlled, consistent, and intuitive for the surgeon."

Innoblative's SIRA RFA Electrosurgical Device components, including the spherical SIRA electrode on the right (Source: Innoblative Designs)

The technology also had to fit naturally into a procedure surgeons already know well.

"A technology can have strong science behind it, but if it disrupts workflow, takes too long, or feels cumbersome, adoption becomes difficult," Stark says. "The goal is not to change lumpectomy. The goal is to make breast-conserving surgery better by adding a step that is intuitive, efficient, and clinically meaningful."

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That emphasis on workflow carried into the company's first-in-human procedure in Istanbul. Breast surgeon Dr. **Cem Yilmaz** described the device as straightforward to use and easy to incorporate into the operation, allowing him to treat the lumpectomy cavity immediately after removing the tumor.

"The first clinical experience helped confirm that the device could be integrated into a surgical procedure in a practical way," says Stark. "It also gave us valuable feedback as we continued to refine training, workflow, and our clinical strategy."

That measured approach has become a theme throughout Innoblative's development. Each milestone has answered one question while raising the next, as the company continues building toward larger clinical studies and broader physician adoption.

Building Evidence, *and Keeping it Real*

Ask Stark about the biggest milestones in Innoblative's history, and he doesn't immediately point to a financing round or regulatory achievement. Instead, he talks about the steady process of answering one question after another.

"The questions that matter most are: Can SIRA be used safely and efficiently? Can it integrate into the standard lumpectomy workflow? And can it generate the type of clinical evidence needed to support a larger pivotal study?" Stark says.

Those questions have guided Innoblative from the beginning, and each milestone has brought the company one step closer to answering them.

"There have been several important milestones, with the first clinical use certainly being a defining moment," he says. "Another major milestone was receiving FDA Breakthrough Device designation, which validated the importance of the problem we are trying to solve."

The FDA granted Breakthrough Device designation in 2023 for the investigational use of SIRA in breast-conserving surgery. For Stark, the designation was encouraging not only because of what it meant for the technology, but because it reinforced that the underlying clinical need was being recognized.

Today, that work continues through the company's ongoing prospective, open-label, single-center feasibility study at the **University of Texas Medical Branch** (UTMB). The study is evaluating the safety and usability of SIRA while helping answer the questions that will shape the next stage of clinical development.

Innoblative has also established a global registry to collect additional clinical experience as surgeons begin using the technology in different settings. Together with the feasibility study, those efforts will help inform the company's planned pivotal trial.

In March, the company received Category III Current Procedural Terminology (CPT) approval from the **American Medical Association** for its SIRA device. The new code, approved for intraoperative radiofrequency ablation in patients with breast cancer, is expected to take effect in 2027 and will provide a formal mechanism to track real-world data on utilization, outcomes, and health economics.

Innoblative is also preparing financially for its next phase of growth. Stark says the company is actively raising additional capital to support continued clinical development and the larger studies needed to bring the technology closer to patients.

He is also realistic and practical about what comes next.

"The biggest barriers are clinical evidence, reimbursement, training, and workflow adoption," he says. "Surgeons and hospitals need to see strong data. Payors need to understand the value. The procedure needs to fit into the operating room efficiently. And the technology has to be easy to teach and reproduce. Those are the areas we are focused on now."

Looking *Ahead*

Today, the focus for the Innoblative team has shifted from proving the concept to building the evidence. Just as important, Stark is continuing to build the types of relationships that help young medtech companies grow.

Over the years, LSI has been one place where those relationships have developed. For Stark, the events offer the ability to sit down with investors, strategic partners, physicians, and fellow entrepreneurs who understand the long timeline required to bring a new technology to patients.

"LSI has been valuable because it brings together people who understand the medtech journey, such as investors, strategics, operators, and entrepreneurs," he says. "The value is in the quality of the conversations. You get direct feedback, develop relationships, and often leave with a clearer view of how to move the company forward."

Those conversations will continue as Innoblative continues along its journey. For Stark, every milestone answers one question while raising the next, a process he believes is essential to building the clinical evidence that will ultimately determine where the technology fits in breast-conserving therapy.

When asked what motivates him after years of development, however, his answer isn't about engineering or regulatory milestones. It's about the impact on patients.

"My hope is that SIRA gives surgeons and patients more confidence," he says. "Ultimately, we want patients to have more options, better information, greater confidence in choosing breast conservation when it is clinically appropriate. But beyond this, quality of life is central to the mission." LSI

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