JANUARY 2026 | Vol. 13, No. 01

MedTech STRATEGIST

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IN BREAST CANCER, INNOVATORS ARE COMING UP THE CURVE

Breast cancer is highly manageable when caught early, yet clinicians still face challenges: patient stratification after screening isn't precise enough, and surgical outcomes could be improved. We spoke with Clairity, Cairn Surgical, and Resilient Medical—innovators working to raise the standard of care for this disease that predominantly affects women.

MARY STUART

Breast cancer is unique among cancers—even beyond the fact that men account for only 0.5–1% of cases. Many breast cancers grow slowly, so early-stage disease is often treatable with minimal surgery, targeted therapies, or radiation. It also uniquely has "its own color [pink] and its own month [October]," quips Andrew Weems, PhD, CEO, and co-founder of **Resilient Medical** (discussed below).

But the path for patients is far from simple. Choices around breast conservation versus mastectomy, reconstruction options, chemotherapy versus hormone therapy, and the potential impact on fertility and menopause create significant anxiety. Surgical decisions can also affect hormonal balance and body image, adding another layer of complexity.

The clinical community and innovators have made meaningful progress. In the US, breast cancer mortality has fallen sharply—40–44% fewer deaths since 1989—thanks largely to early detection through screening.

Yet challenges remain. "For most women, a breast cancer diagnosis still comes as a complete surprise," says Connie Lehman, MD, PhD, founder of **Clairity**. "Only a small fraction of cases are explained by inherited genetic mutations or strong family history, and breast density alone is a weak predictor of who will develop cancer."

Innovators are tackling these gaps, improving detection, risk prediction, surgical precision, and postoperative healing for better cosmetic outcomes (*see Figure 1*). Three companies stand out: Clairity had a banner year in 2025, earning FDA clearance for the first AI platform that predicts a woman's five-year risk of developing breast cancer from a screening mammogram. The platform bridges the gap between routine screening and the decision to pursue advanced imaging.

Cairn Surgical offers a simple device that guides surgical margin assessment *in situ*, potentially providing greater clinical and economic value than high-tech approaches that examine tissue after removal.

Resilient Medical aims to improve postsurgical recovery with an implant that encourages tissue regrowth, delivering less painful, more natural-looking healing.

Together, these innovators are helping to bring breast cancer care into a new era—more precise, patient-centered, and forward-looking.

Figure 1

Selected Start-Ups Improving Breast Cancer Interventions

Goal	Representative Start-Ups
Risk Assessment/Risk Stratification	Clairity (only company with FDA authorization), Color Health, DeepHealth, iCAD, Lunit INSIGHT Risk, Prognosia
AI-Enabled Detection (novel breast cancer screening modalities, AI, and/or multiomics-enabled analysis of conventional screening)	BiRed Imaging, BreastScreening-AI, NoCancer, MICA AI Medical, Niramai Health Analytix, PreciseDx, Prognica Labs, ScreenPoint Medical (Transpara), Vara.Ai
Surgical Margin Accuracy (intraoperative guidance, tumor bed assessment, or specimen analysis)	Cairn Surgical, Clarix Imaging, Dilon Technologies, Lumicell, NovaScan
Better Healing, Cosmetic Results Implants, biomaterials	BellaSeno, GeneSisTissue, Healshape, Lattice Medical, Resilient Medical, Tensive
Recurrence Prediction and Postsurgical Surveillance (liquid biopsy and minimal residual disease detection)	Natera, Guardant Health, Caris Life Sciences

Source: MedTech Strategist


Connie Lehman

Clairity Finds Five-Year Breast Cancer Risk

One truth about cancer is beyond dispute: the earlier it's found, the better the outcome. Few people understand that better than Connie Lehman, MD, PhD, a professor of radiology at Harvard Medical School and a breast-imaging specialist at Massachusetts General Hospital. Over decades of research spanning computer-aided diagnosis, deep learning, artificial intelligence, density assessment, and risk modeling, Lehman has authored or co-authored more than 300 peer-reviewed papers.

When she diagnoses cancer in women who were screened, Lehman says, it often feels like good news. "Yes, we diagnosed cancer, but because you were being screened, we found it early. It's not only something we can cure; we can cure it with minimal impact on your quality of life."

Yet over time, she grew disenchanted. While imaging technology had advanced dramatically, the science of determining which women were actually at high enough risk to warrant more intensive screening had not kept pace. "Many women are well served by mammography alone," she says. "But many aren't."

The problem with today's risk models

Current risk-stratification tools are poorly suited to clinical decision-making after a screening mammogram. The most commonly used risk criteria—family history and genetic mutations—identify only a small minority of women who develop breast cancer. "We have inadvertently created the false impression that if you don't have a family history or a mutation, you're not at increased risk," Lehman says.

Another commonly used risk criterion is breast density. Dense tissue makes cancers harder to see on mammograms and is itself associated with higher risk. But the measure is crude. "In our studies, dense breast tissue increases risk by less than 10%," Lehman notes. Since roughly half of all women have dense breasts, it is neither clinically nor economically feasible to send them all for MRI.

Federal law now requires that women be informed if they have dense breast tissue, a mandate that, though well-intentioned, has produced widespread confusion. "Most women with dense breasts do not need MRI," she says. "Yet I meet patients all the time who believe they need ultrasounds, MRIs, and twice-yearly visits simply because of density. That's not based on science—it's misinformation."

What clinicians were missing, Lehman realized, was a way to extract far more predictive information from the mammogram itself. "With AI and computer vision," she says, "we can actually derive a woman's future risk of breast cancer directly from the image."

The clinical infrastructure to act on that information already exists. High-risk women can be placed into specialized screening and prevention programs that reduce their risk of late-stage diagnosis. "The technology was there," Lehman says. "The pathways were there. What was missing was identifying the right women."

The missing piece

In 2020, Lehman founded **Clairity** with a simple but ambitious goal: "to change the standard of care in breast cancer from reactive diagnosis to proactive prevention."

Rather than building a model around predefined human inputs, Lehman chose deep learning. "I can see many things on a mammogram—prior biopsies, surgical clips, skin thickening from radiation, weight change," she says. "But I wanted a model that could learn patterns on its own and go beyond what the human eye or brain might recognize."

Clairity trained its algorithm on over 1.6 million mammogram images from a uniquely diverse international consortium spanning Germany, the UK, South America, and multiple US regions. Each exam was labeled based on whether the woman did—or did not—develop breast cancer within five years. The algorithm learned to detect subtle, previously invisible patterns in breast tissue and to convert them into calibrated five-year risk probabilities.

The result was a model that performed accurately across age, race, and breast density. "That's what excited us most," Lehman says. "It worked across the diversity of women at risk for breast cancer."

A healthcare first

In June 2025, the FDA granted De Novo authorization to *Clairity Breast*, making it the first AI platform cleared to predict a woman's five-year risk of developing breast cancer from a screening mammogram.

"This is the only FDA-regulated model for future breast cancer risk assessment," Lehman says. Traditional tools—including breast density, Tyrer-Cuzick, Gail, and the NCI model—are not regulated.

That fall, at the Radiological Society of North America meeting, Clairity presented findings from five peer-reviewed studies evaluating its image-based risk model across multiple screening populations. Together, the studies demonstrated that women classified as high risk by the AI model had substantially higher rates of subsequent breast cancer than those categorized as

average risk, while maintaining consistent performance across age, race, and breast density.

In one multi-site analysis, women identified as high risk by the model had more than four times the cancer incidence of those in the average-risk group (5.9% vs. 1.3%). By contrast, breast density alone showed only modest separatin between groups, reinforcing the limitations of density as a stand-alone risk criterion.

Christiane Kuhl, MD, PhD, director of radiology at University Hospital RWTH Aachen, summarized the findings: "AI risk models provide far stronger and more precise five-year cancer prediction than breast density alone."

Commercial readiness

In 2025, Clairity raised a $43 million Series B led by ACE Global Equity and Santé Ventures. Medtech entrepreneur Joe Kiani, founder of Masimo, joined the board.

With FDA authorization in place for *Clairity Breast*, clinical deployment is underway at Beth Israel Deaconess Medical Center, with additional health systems preparing to follow in the coming months. The initial deployments are focused on integrating AI-based risk prediction into existing screening workflows, enabling providers to identify women who may benefit from more personalized screening and prevention pathways.

To support broader adoption, Clairity has also announced a partnership with **MagView**, a leading provider of breast imaging workflow and analytics software. The integration allows image-based risk scores to be incorporated directly into MagView's *Luminary Risk* radiology and breast imaging workflows, reducing friction for clinicians and supporting consistent use at scale.

The next phase centers on clinical adoption and reimbursement alignment. Payors have long expressed concern about unnecessary advanced imaging driven by imprecise risk markers such as breast density alone. "The goal is not to send more women to MRI," Lehman says. "It's to be more precise about which women are most likely to benefit from additional screening."

Clairity is initially offering the service through a self-pay model, priced at under $200 per test, while working with CMS and private insurers to establish coverage pathways. Women can currently join a waiting list through the company's website.

What comes next

The need is clear. In the US, roughly two-thirds of breast cancers are diagnosed at an early, localized stage, meaning one-third are found later. Five to six percent of women with Stage IV disease are diagnosed only after metastases appear.

Clairity's aim is to change that dynamic by using information already embedded in routine care. Rather than asking women to provide more data, complete additional questionnaires, or undergo more testing, the company focuses on extracting more insight from the screening mammogram itself. Over time, Lehman envisions risk prediction becoming a standard complement to screening, helping providers guide women toward care that reflects their individual risk, rather than population averages.

The implications extend beyond breast cancer. Clairity is also exploring whether mammograms can be used to assess cardiovascular risk, another leading cause of death among women. "Women are more likely to die from heart disease than from breast cancer," Lehman points out, and the mammogram has always held more information than has been used. "If we can identify risk earlier using tools already in widespread use, the opportunity for prevention is enormous."


Dave Danielsen

Cairn Surgical Guides Breast Cancer Surgeons to Cleaner Margins

A long-standing rule of engineering holds that the simplest solution that works is usually the best one. Cairn Surgical has taken that idea literally in developing its *Breast Cancer Locator* (*BCL*) system—an intuitive device that gives breast surgeons something they have never had before: a precise, three-dimensional map of a woman's tumor in the same position it will occupy on the operating table.

MedTech Strategist first covered Cairn Surgical back in 2021, six years after its founding. (*See, "Cairn Surgical: Patient-Specific, Real-Time Guidance for Breast Cancer Surgery,"* MedTech Strategist, *May 14, 2021.*) At the time, the promise was straightforward but ambitious: translate what radiologists see on preoperative MRI into something surgeons can actually use in the operating room. The *BCL* and its companion software, the *Visualizer*, were built to close that gap.

That gap is not trivial. Roughly 20% of women undergoing breast-conserving surgery require a second operation because cancer cells are found at the edge of the removed tissue. The problem is challenging because tumors are irregular, three-dimensional structures, while traditional localization methods give surgeons only a single point for guiding their excision.

Since we last checked in, Cairn Surgical has moved well beyond proof of concept. In January 2026, the company completed enrollment in its US pivotal trial, a prospective, multicenter study of more than 400 patients randomized 1:1 to either the *BCL* or standard wire localization. The trial measured positive-margin rates, specimen volumes, additional shave biopsies, re-excisions, operative times, cancer localization success, and costs of care—exactly the variables hospitals and surgeons care about.

Earlier clinical data already suggests the approach works. In a multicenter European study published in *Annals of Surgical Oncology* in June 2025, 94% of women whose tumors were localized with the *BCL* had negative margins, compared with about 80% for conventional wire-guided surgery.

Simple, but surprisingly sophisticated

The *Breast Cancer Locator* doesn't look like sophisticated medtech. It's a 3D-printed personalized model of the operable breast, resembling a perforated plastic bowl (*see Figure 2*). Yet that simplicity is precisely its innovation: by stripping away electronics, radiation, and imaging hardware, Cairn Surgical has created a tool that is not only easier for surgeons to use, but in many cases more effective than far more elaborate localization technologies.

The contrast becomes clear when you look at how breast cancer surgery is done today.

With wire localization, a woman must go to radiology on the morning of surgery (or the day before) to have a wire inserted through her breast into the center of the tumor. In the operating room, the surgeon follows that wire down and removes tissue around its tip, hoping the cancer lies symmetrically around that single point. It rarely does.

Afterward, the specimen is often X-rayed to confirm the right region was removed, and additional tools such as *MarginProbe* (**Dilon Technologies**) or optical systems like the *LumiCell Direct Visualization System*—cleared in the US in 2025—may be used to check for residual disease. But these approaches are reactive: they tell the surgeon whether cancer might still be present after tissue has already been removed.

Localization seeds improve logistics because they can be implanted days or weeks before surgery, but they share the same fundamental limitation: they mark only the center of the tumor. Surgeons still have to guess how far the cancer extends in every direction.

The *BCL* takes a fundamentally different approach.

Recreating the breast as the surgeon will see it

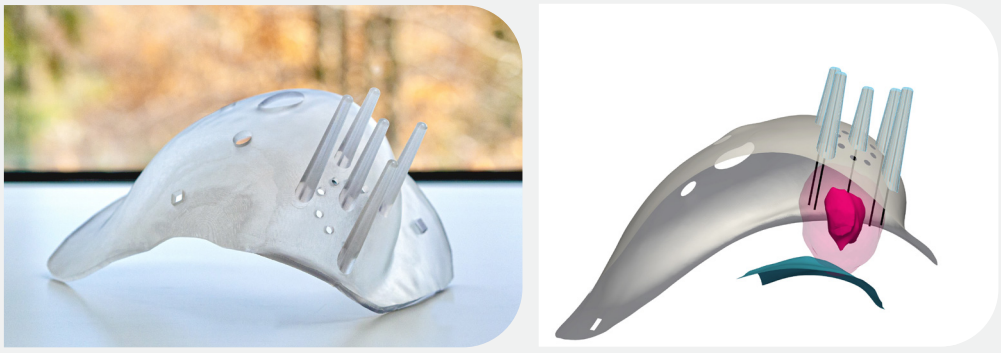
For the *BCL*, everything starts 10–14 days before surgery with a supine MRI—imaging the woman lying on her back, the same position she will be in during the operation. Conventional breast MRI is done face-down, with the breast hanging through an opening in the table. That improves image quality but produces a geometry that bears little resemblance to what the surgeon sees in the OR.

Cairn's chief technology officer and co-founder, Venkat Krishnaswamy, PhD, says the company spent years refining MRI protocols to make supine imaging effective without special coils or hardware. "We've done a lot of work to optimize image quality based on expected motion in the supine position due to natural breathing, all based on tools that exist for the MR suite, and without any special coils." He notes that the company has also developed a simple piece of foam to avoid compression of the breast in the supine position. The coil sits on top of the foam, about a centimeter above the breast. "During imaging, we want the breast to rest in a natural state so that we can recreate that position in the OR," he says.

Once the scan is complete, Cairn's software allows a radiologist to segment the tumor across all MRI slices. Cairn engineers then model the breast, chest wall, and tumor and design a personalized *BCL* for that specific patient. The guide is 3D-printed and delivered to the surgical site, typically within a few days.

Figure 2

The *Breast Cancer Locator* and *Visualizer*



Source: Cairn Surgical

Supine MRI lets surgeons see the breast in the position it will be in the operating room, which makes sense. However, since supine MRI isn't yet standard practice, Cairn Surgical has completed and will soon release an imaging study demonstrating its reliability, providing clear reassurance for clinicians, according to CEO Dave Danielsen. "Several hundred patients have been through that supine protocol, and we can show that it works very well for the radiologist to segment the tumor."

In the operating room, the guide is aligned to the woman's breast using the nipple, breast fold, and additional reference points, which are marked on the skin through holes in the device. Through a series of ports on the device placed such that they bracket the boundaries of the tumor, the surgeon places needles, which become a physical roadmap for where to cut.

In effect, the *BCL* transfers the actual shape of the cancer from the MRI onto the patient's body. And it does so while the patient is already under anesthesia—eliminating the pain, anxiety, and cost of preoperative wire or seed placement.

The companion *Visualizer* software lets surgeons explore the 3D MRI model before and during surgery, showing the tumor shape, size, and how close it lies to the skin, chest wall, or other landmarks, and how wide their planned margins will need to be to remove the cancer completely.

Surgeon response has been striking. According to Danielsen, users in Italy, Germany, and Switzerland consistently describe the system as intuitive and long overdue. "They finally see the tumor in the same position they operate in—three-dimensionally, with its true shape and location," he says. "That simply didn't exist before."

A technology built for a high-volume procedure

Breast-conserving surgery is the dominant treatment for breast cancer. Roughly 180,000 lumpectomies are performed each year in the US, and 160,000–230,000 in Europe. Cairn Surgical is now preparing a Series B financing for early 2026 to achieve US regulatory clearance and move toward commercialization. Its Series A and A2 rounds, led by Morningside Ventures, raised about $25 million.

Danielsen believes that much of the traditional medtech risk has already been wrung out of the program. "We've largely de-risked the technology, the clinical performance, and even reimbursement," he says. What remains are regulatory approval and market adoption—both of which the pivotal trial is designed to address.

The economic argument is as important as the clinical one. Today, every wire or seed placed in radiology is a cost to the hospital. The *BCL* moves localization into the operating room and removes that step entirely. If it also reduces re-excisions, it could lower the total cost of care while improving outcomes—a rare combination in modern healthcare.

It may even open the door to more lumpectomies being done in lower-cost ambulatory surgery centers, since patients would no longer need to be shuttled between radiology and surgery with a wire in their breast.

After working with dozens of surgeons worldwide, Danielsen is confident about acceptance. "Across all of our studies, surgeons say it's easy to use, clear, and intuitive," he says. That's what happens when you finally give surgeons the information they've always needed—without making their lives more complicated.


Andrew Weems

Resilient Medical: A Lumpectomy Solution for Natural Healing

Resilient Medical was founded by biomedical engineer Andrew Weems, whose background spans polymer chemistry, 3D printing, and biomaterials. After co-founding 4D Biomaterials—a developer of tunable biodegradable and bioabsorbable medical devices for orthopedics, soft-tissue repair, and related applications—Weems began looking for another significant unmet clinical need where his expertise could make a meaningful difference. He found it in breast-conserving surgery.

Lumpectomy is the most frequently performed operation for breast cancer treatment. Annually, across the US and Europe, an estimated 500,000 lumpectomies are performed, including primary procedures and follow-on surgeries for positive margins or cancer recurrence following radiation therapy.

Despite its prevalence, lumpectomy leaves surgeons with few tools to manage what happens next. Once a large volume of tissue is removed, a void remains in the breast. Healing can be painful, and the defect often leads to contour irregularities, skin discoloration, or visible deformity. The resulting appearance can feel unnatural—an ongoing reminder of the disease and its treatment.

"Breast cancer is not just a physical disease," Weems says. "It's also psychological, because of how you feel about how you'll look at the end of this procedure."

Before founding Resilient Medical in Athens, Ohio, in 2023 with co-inventor Elizabeth Lawson, MD, an oncoplastic surgeon,

Weems surveyed existing solutions. He found no FDA-approved materials or devices specifically indicated for use in the breast following lumpectomy. With early support from the JumpStart Trailblazer HealthTech Accelerator in Cleveland, he set out to design an implant that could provide mechanical support while enabling more natural healing.

"The state of the art in lumpectomy is to remove the tumor and close the wound," Weems says. In the absence of internal support, a seroma—a fluid-filled pocket—commonly forms within the breast. Seromas can stretch the skin, contribute to laxity or contour distortion, impede wound healing, or lead to wound dehiscence. The accumulated fluid also increases the risk of infection.

Resilient's solution, called *Bravo*, is an implantable mesh scaffold designed to address these challenges. The device provides immediate mechanical support to the surgical cavity, helping maintain breast shape while gradually integrating with surrounding tissue as it resorbs over time. Importantly, *Bravo* is engineered not to bind permanently during the early postsurgical period, when pathology results may reveal positive margins in which case a reoperation is required. In those cases, the implant can be removed easily and may also serve as a helpful radiocontrast marker.

"In short, the implant is removable when it needs to be," Weems explains, "but within 12 to 18 months, it's replaced by the patient's own healthy tissue."

Weems declines to disclose the exact composition of the biomaterial but notes that it is "FDA-friendly"—a biopolymer already used in other approved medical devices, albeit in different formats.

The *Bravo* workflow fits cleanly into existing lumpectomy procedures. Typically, the radiologist marks the tumor prior to surgery. Once the patient is under anesthesia, the surgeon creates an opening into the tumor bed, excises the tissue, and annotates margins for pathology. After tumor removal, *Bravo* is placed into the cavity and sutured in position, followed by standard wound closure using sutures or tissue flaps.

"It's straightforward," Weems says. "*Bravo* doesn't add significant time or complexity to the surgery, but the postsurgical benefits—for both patients and surgeons—are substantial."

Pathology results may take days or weeks. If margins are positive, Weems believes reoperation will be straightforward: the surgeon can remove both the residual cancerous tissue and the *Bravo* scaffold, then implant a new device during the same procedure. Over the following year to year and a half, the implant fully resorbs.

"At that point," he says, "there will be nothing but healthy tissue where the tumor once was."

Compatible with existing workflow

Resilient Medical plans to offer *Bravo* in two or three standard sizes, which surgeons can cut or shape intraoperatively. "We're not personalizing implants at this stage," Weems says. "That would add complexity that isn't compatible with how lumpectomy procedures often evolve once the surgeon is in the OR."

Pricing will need to align with the economics of ambulatory surgery centers, where many lumpectomies are performed and margins are tight. "Those centers might make about $2,500 on a surgery," Weems notes. "We need to be mindful of how the *Bravo* fits within the cost and reimbursement frameworks to meet the needs of the hospital as well as the patients and surgeons."

Still, the volume opportunity is significant. There are more lumpectomies performed each year than new breast cancer diagnoses, reflecting re-excisions, bilateral procedures, and repeat surgeries. "There's a huge need for what *Bravo* can do," he says.

The company is completing preclinical testing and plans to pursue an initial 510(k) clearance for a minimum viable surgical mesh. The breast-specific indication, Weems explains, will push the device into Class III territory, as mammary tissue is considered a high-risk organ and there are currently no approved healing scaffolds labeled for use in the breast.

Achieving a breast indication will require a clinical trial, which the company anticipates initiating in the third quarter of next year. Resilient is currently raising a seed round to support its regulatory and clinical milestones.

From an investor standpoint, Weems believes much of the technical and biological risk has already been addressed. "We've completed extensive preclinical testing, including full life-cycle studies in animal models," he says. "We've evaluated how long the device remains in the body and its local effects on tissue and healing. The data have been very encouraging."

Breast cancer, Weems notes, occupies a special place in medicine. "It uniquely creates deep relationships between patients, families, and physicians because of the psychological impact." Surgeons, too, face frustration. "There are very few tools that actually address these post-lumpectomy problems."

Resilient Medical aims to change that, by being first to offer a solution designed specifically for how patients heal, not just how tumors are removed. MTS