

NOVASYS MEDICAL: USING CLINICAL TRIALS TO DRIVE ADOPTION FOR INCONTINENCE

Novasys Medical hopes that its rigorous and costly clinical trials strategy, which slowed FDA clearance of its incontinence device, will pay off by providing reimbursement that will drive adoption.

BY STEPHEN LEVIN

- Novasys Medical is among the group of companies started by serial entrepreneur Stuart Edwards to use radio frequency (RF) energy to treat a variety of conditions, in this case, stress urinary incontinence in women.
- The company chose to adopt a much more rigorous and expensive clinical trials strategy than was needed to gain FDA approval of its device.
- This approach flummoxed the FDA, slowing approval of the company's *Renessa* system.
- Novasys is betting that the enhanced data collected from its clinical study will result in the company gaining faster reimbursement that it hopes will drive adoption.

Nowhere has the current increased concern of regulators and industry about the long-term safety of medical devices been reflected more directly than in the expansion of clinical trial requirements. Drug-eluting stent safety concerns regarding thrombosis, for example, have given rise to the launch of several mega-trials, including

one that is expected to enroll upward of 30,000 patients. But safety and efficacy aren't the only reasons device companies are employing more rigorous clinical trials strategies.

Another reason why product companies are looking to collect more extensive clinical data is to support their efforts to obtain reimbursement from both public and pri-

vate payers for their technology. This is particularly important for the increasing number of so-called quality-of-life or lifestyle products for which companies are looking to expand the potential patient populations beyond just the private-pay market.

One company that has adopted such a strategy is Newark, CA-based **Novasys Medical Inc.**, which has developed the *Renessa* system, approved for treating stress urinary incontinence (SUI) in women. Stress incontinence falls into the category of a quality-of-life, rather than a life-threatening, condition that can currently be cured only through surgery. Although the surgical procedures for SUI are covered by reimbursement, the vast majority of patients choose to avoid the risk and extended recovery time of undergoing surgery; a small number attempt to manage their condition through a variety of nonsurgical treatment options, whereas most simply choose to live with it.

Novasys' strategy was to develop a one-

time, nonsurgical procedure—*Relessa*—to treat SUI that could be performed in a physician's office under local anesthesia. Although the *Relessa* procedure does not cure stress incontinence, it produces outcomes that are much better than current nonsurgical therapies; 76% of women report a reduction in incontinence episodes and more than one-third are completely dry at one-year. According to Debra Reisen­thel, president and CEO of Novasys, women are willing to accept the fact that the treatment improves but doesn't necessarily cure their condition, provided the trade-off is that they don't have to undergo surgery.

Critical to the company's success, however, is obtaining reimbursement for the *Relessa* procedure because physicians are much less likely to adopt a procedure for which they will have difficulty ensuring that they are paid. Novasys' goal is to obtain a unique CPT reimbursement code for *Relessa* to help drive adoption. To that end, the company decided early on to employ a more rigorous clinical trials strategy than it needed for FDA clearance to provide payers with extensive clinical data to support reimbursement. The strategy had the unintended effect of slowing down the FDA approval process, but the company believes the approach will pay off in the long run because any delay in the approval process has been more than offset by having reimbursement in place by the time approval came.

NO LONGER A FACT OF LIFE

Stress urinary incontinence has long been a condition that women have simply accepted as an uncomfortable fact of life, largely because for many years there were no effective treatments other than a traditional open surgical procedure. "Many women don't even mention the condition to their physicians because they don't know that treatments exist and they think they have to live with the condition, just like their mothers did," explains Harvey Winkler, MD, co-chief of urogynecology and pelvic reconstructive surgery at New York's North Shore Long Island Jewish Health System, and a consultant to Novasys.

As a result, there are many misconcep-

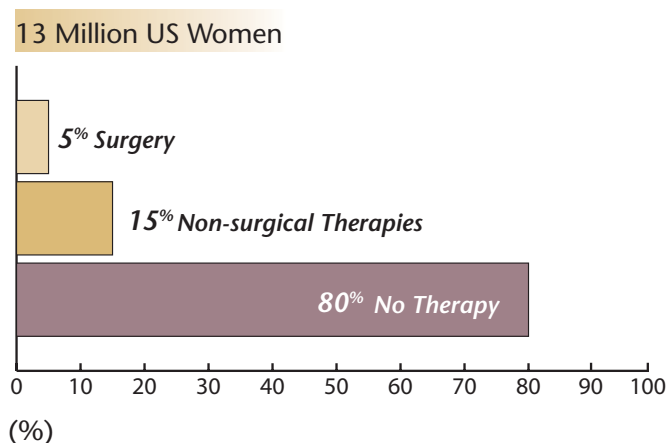
tions about the condition. Perhaps most notably, SUI is often confused with urge incontinence, a different condition that produces frequent urination generally in elderly patients and results from an anatomic deformity or neurological condition. Stress incontinence is the involuntary loss of urine due to an increase in intra-abdominal pressure, typically from physical stress on the abdomen. The condition occurs almost exclusively in women and is not limited to the elderly—

points out that estimating the size of the SUI patient population and the severity of the condition (currently assessed as either mild, moderate, or severe) is a very inexact science, though studies have found that as many as 50% of all women suffer from at least occasional stress incontinence and 10% from severe incontinence.

As baby boomers age and want to maintain their active lifestyles, more younger women are seeking treatment for this condition, instead of simply being resigned to it. This growth in patient interest has also been driven by recent therapeutic advances that now make it possible to treat many patients through a much less invasive surgical approach, but the prospect of surgery remains the primary factor discouraging most women from seeking treatment. "As women get more information about the condition and possible treatment options, more patients are seeking treatment at younger ages. In our office, we're now seeing more women in their 30s and 40s coming in, where we used to see mostly patients in their 50s and 60s," Harvey Winkler says.

Exhibit 1

Novasys' Potential Patient Market



SOURCE: Novasys Medical

the mean age of SUI patients is 50. The condition can result in a number of health issues, including depression, sleep disturbances, lack of physical activity, obesity, and diabetes.

Indeed, Debra Reisen­thel points out that about 23% of female athletes suffer from stress incontinence, and Olympic speedskater Bonnie Blair was the spokeswoman for the first national public service advertising campaign launched recently on SUI awareness (having nothing to do with Novasys). "Athletic women are prone to this condition because of the stress their activity places on their pelvic floors," Reisen­thel explains.

Child-bearing (particularly through vaginal delivery) and excess weight are also contributing factors to SUI. It doesn't require stressful exercise such as running or sit-ups to trigger SUI. "Routine activities such as laughing, coughing, and lifting a bag of groceries can cause incontinence episodes," she says.

The patient population is huge; in the US alone, an estimated 15 million women suffer from stress incontinence. Reisen­thel

SURGERY STILL BEST HOPE FOR CURE

While there have been advances in the surgical treatment of stress incontinence, the fact remains that the best hope for a cure for the condition still requires surgery, and that continues to be a major impediment to most women seeking treatment, Harvey Winkler points out. Indeed, in the US, it is estimated that only 5% of SUI patients undergo surgery, whereas 15% pursue nonsurgical therapies, and 80% are so-called watchful waiters, who don't pursue any therapeutic options. (See Exhibit 1.) Incontinence patients manage their conditions with the use of pads and diapers; SUI contributes significantly to the fact that sales of adult diapers have now surpassed those of infant products, creating a \$2 billion market in the US alone.

Winkler explains that stress incontinence results when the bladder neck and proximal urethra open when abdominal pressure occurs, a process called funneling, which is generally caused by weakened urethral sphincter muscles. There are a couple of possible fac-

tors that lead to the weakening of those muscles, most commonly urethral hypermobility (the movement of the urethra), which is what Novasys received FDA clearance to treat with its *Renessa* device, and other urethral sphincter deficiencies (which can be treated with other approaches, such as the injection of collagen or other bulking agents). No matter the cause, there are a variety of surgical procedures that can be used to successfully cure stress incontinence in most cases, with the most common being the so-called sling procedure.

Surgery to treat SUI has undergone the same progression toward increasingly less invasive approaches as have other surgical therapies. A decade ago, Debra Reisen­thel points out, most of these operations were done using a traditional open approach. More recently, the procedure evolved to where it could be performed laparoscopically, and now market estimates indicate that more than 80% of sling procedures are performed percutaneously, using only small needle punctures. This evolution in treatment has been driven by the development of new smaller devices and tools in what has become an extremely competitive and increasingly commoditized product segment of the women's health market. **Johnson & Johnson** is the leader in this closely divided area, which also includes **Boston Scientific Corp.**, **Coloplast AS** (through its acquisition of Mentor's urology business in March 2006), **Caldera Medical Inc.**, and **American Medical Systems Holdings Inc.**

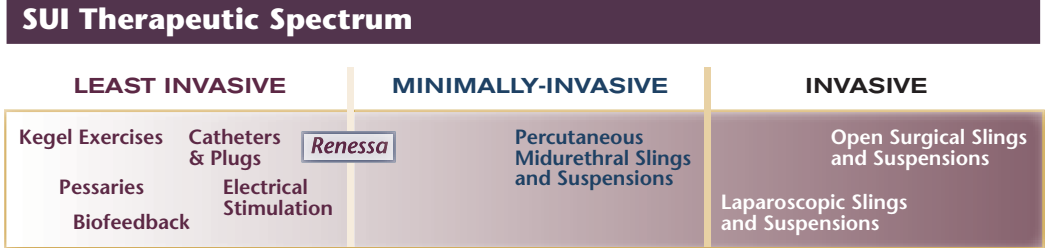
The sling procedure typically involves implanting a polypropylene mesh device under the urethra to lift it up and provide support that prevents inappropriate opening when abdominal pressure is applied. The surgery takes between 30 minutes and one hour, and it can be performed in a hospital or out-patient operating room (OR), using a general, regional, or local anesthetic, depending on the patient. The result is an 85% cure rate that, according to Harvey Winkler, means that the patient remains "completely dry after the procedure."

Nevertheless, despite the extremely high success rate of this surgery, when patients are told that treatment requires a surgical procedure, even one performed percutaneously, the overwhelming majority decline, choosing instead to pursue much less successful nonsurgical therapies or no therapy

at all. Reisen­thel says that patients' reluctance to undergo surgery is the result not only of an unwillingness to expose themselves to the risks of the procedure (typical surgical risks such as those resulting from excess bleeding, anesthesia, and damage to adjacent organs), but also of a concern that they may temporarily need to have a catheter implanted following the procedure (2% risk), as well as the embarrassment of having to disclose their condition when recovery

when asked if they would undergo a procedure in the clinic (as opposed to surgery) that produced a 60% improvement but did not cure their condition, without any long-term risk, 57% of patients said they would undergo such a procedure and only 24% said no. "When this study came out, it validated what we had found to be true from our focus groups," says Debra Reisen­thel. "Women select their initial treatment for stress incontinence based on invasiveness and ad-

Exhibit 2



SOURCE: Novasys Medical

prevents them from performing normal activities. Recovery times average four to six weeks, during which a woman has to avoid moderate-to-heavy lifting. In addition, women who have not completed childbearing are not candidates for surgery, and 15% to 40% of women who have had surgery continue to leak after the procedure.

Despite such concerns, the number of surgical procedures in the US has doubled over the past five years, reaching around 350,000 in 2006, driven primarily by the availability of the percutaneous procedure, suggesting a more widespread desire to treat SUI. Thus, Novasys' opportunity: SUI patients want to find a treatment, but it has to be the right treatment and they're willing to make some trade-offs to find that right treatment.

The question of what type of procedure and outcome SUI patients found acceptable was the subject of a study conducted in 2002. Novasys had no connection with the study; indeed, the company was in stealth mode with its product development still in its earliest stages, thus the study authors didn't know of the Novasys option. The survey found that only 23% of patients said they would undergo a major operation with an 85% cure rate and 2% risk of temporary catheterization; 57% said they would not undergo such a procedure. Asked whether they would choose a minor surgical procedure with the same cure rate and risk, only 38% said yes and 43% said no. But

verse events, not on curing the condition."

The idea of developing a nonsurgical approach that would treat, but not necessarily cure, SUI is not unique to Novasys. Several such approaches currently exist ranging from nondevice therapies (Kegel exercises, which involve flexing muscles to strengthen the muscles surrounding the urethra, and which can be conducted with and without biofeedback assistance) to the placing of devices such as plugs and pessaries to stop the flow of urine or provide additional support to the urethra. "The theory behind why stress incontinence occurs in most patients is that the urethra is mobile and because some of the ligaments, muscles, and other support structures are weakened, the urethra moves out of position, resulting in more pressure being put on the bladder than on the urethra, which results in leakage," Harvey Winkler explains. "The thinking is that if you insert a device to hold up the urethra and keep it in place, that may help." Although these products address patients' interest in a less invasive treatment option, compliance levels with these exercises and devices are very low and outcomes are only marginally improved, according to Reisen­thel. (See Exhibit 2.)

Renessa, Reisen­thel maintains, offers the benefits of improved outcomes and a one-time procedure, compared with nonsurgical therapies. The procedure is performed in a doctor's office and takes 20 to 30 minutes under local anesthesia with or with-

out oral sedation. There are no incisions, bandages, or dressings, and no visualization component is required. The physician inserts a probe with a balloon and four needle electrodes through the natural opening of the urethra. The device is then used to administer nine short treatment cycles, lasting one minute each, in which the tissue is heated to 65 degrees Centigrade. Heating the tissue denatures the collagen within the bladder neck and upper urethra without narrowing the lumen.

As a result, Winkler explains, the treatment increases the tissue's ability to resist abdominal pressure, which limits the inappropriate opening of the bladder neck and urethra, thereby improving continence without affecting normal urination. Patients he has treated with the *Renessa* procedure experience few, if any, side effects. "They often resume normal activities the next day and any minor discomfort they feel is gone within a couple of days," he says. The learning curve is relatively short because it involves technology with which physicians are already familiar. Thus, says Winkler, adoption will be driven by compelling clinical data and getting reimbursement in place.

BORN FROM AN RF FAMILY

For serial entrepreneur Stuart Edwards, the reluctance of SUI patients to embrace both surgery as a potential cure and less invasive palliative treatment options created a huge opportunity, one that could, he reasoned, be addressed with a technology with which he was intimately familiar, radio frequency (RF) energy. Edwards has launched a number of device start-ups all centered around the use of RF energy to develop less invasive devices for treating a variety of conditions. These include *VidaMed* (which developed the *TUNA* device to treat benign prostatic hyperplasia and which was acquired by **Medtronic Inc.**), *Somnus Medical Technologies* (devices for snoring and obstructive sleep apnea, which was acquired by **Gyrus Group PLC**), *Oratec Interventions* (orthopedic devices, which was bought by **Smith & Nephew PLC**), *RITA Medical Systems* (oncology devices, which was acquired by **AngioDynamics Corp.**), **Curon Medical Inc.** (gastrointestinal disorders), and **Silhouette Medical Inc.** (obesity, which is Edwards' current company). (See "Stuart Edwards: Tale of a Serial Entrepreneur," *START-UP, October 1999*.)

Edwards' approach to company creation, which has attracted its share of industry criticism, is to find clinical applications that

lend themselves to less invasive treatment with RF energy-based devices, and then to start a company around each separate therapeutic area. Critics argue that this strategy fails to maximize the value that could result from creating a larger, RF-focused device company with the critical mass to develop multiple technologies. Critics charge that slicing the technology pie into multiple thin slices sacrifices long-term value for short-term gain, though Edwards' proponents argue that his track record of successful company exits speaks for itself.

Novasys Medical was launched in 1999 by Edwards and his chief medical officer, Peter Edelstein, MD, a colorectal surgeon who had left **Stanford University Medical Center** to work with Edwards. (Edelstein left the company in August 2006 to help launch another start-up, **Aragon Surgical Inc.**) Novasys benefited from the cross-pollination around the use of RF energy that occurred throughout Edwards' companies in those early years—for example, the company first used the RF generator developed by *Curon*. (In May 2006, Novasys also acquired rights to certain RF energy patents from *Curon*.)

Edwards' idea was that treating the tissue around the urethra with RF energy could essentially tighten and thereby strengthen that area, decreasing the severity of stress incontinence. Launched with seed money from Edwards, Novasys received its first venture funding in March 2000 when Onset Ventures provided the company's \$4 million Series A round.

Leslie Bottorff identified the opportunity at Novasys for Onset and has held a board seat since that initial investment. She recalls that in early 2000, which was the height of the Internet bubble, investing in medical devices specifically and life sciences generally had fallen out of favor. "Investing in women's health start-ups was seen by some at that time to carry even greater risk," Bottorff notes. That is because the sector proved initially disappointing to investors following a flurry of early start-up activity. The early- to mid-1990s saw a burst of interest in women's health in what was called the decade of women's health. President Clinton highlighted this area in his 1994 State of the Union address as a national priority and made September Women's Health Month. Along with this political interest came increased investor focus, and the launch of more than 20 women's health device start-ups during that time. But although some were successful, most were not, souring

investors on this space for several years.

What attracted Onset to Novasys was the size of the market and the failure of patients to respond to the currently available treatments. "We saw a real need for a product that was nonsurgical and low risk, and that could do a better job with a one-time treatment," Bottorff says, noting that existing approaches that require frequent treatments tend to have lower compliance.

Although other venture firms were bailing out of medical devices in favor of IT investments, Onset remained committed to medtech and to the women's health space. "In our view, women's health did not become a high-risk area to invest in simply because some companies had not executed well and certain investors abandoned this segment," Bottorff explains. "We knew that the market need wasn't disappearing, and sometimes the best time to be investing is when certain sectors have fallen out of favor because the underlying market fundamentals are essentially the same."

Stuart Edwards didn't like to run his companies for very long, so one of Bottorff's first challenges as a Novasys board member was to help the company find a new president and CEO. One of the first candidates Bottorff thought of was Debra Reisenfel, with whom she had worked at *Nellcor Puritan Bennett* (now part of **Tyco Healthcare**, a division of **Tyco International Ltd.**). "She took on *Nellcor's* fetal oximetry business when it was a skunk works project, and she built that organization from the ground up into its own division within this large company. Even though she had never previously run a start-up, we thought that experience would be a good precursor for what we needed her to do at Novasys," Bottorff says.

Although lacking start-up background, Reisenfel had gone through several big-company experiences in her time at *Nellcor*, having stayed first through the company's acquisition by *Mallinckrodt*, and then when *Mallinckrodt* was bought by *Tyco*, which she thought prepared her to run Novasys. "Although I didn't know much about venture-backed companies, I was excited by the opportunity to run a start-up and thought that my experience at *Nellcor* prepared me to do that, knowing there was a lot I still did not know," she says.

FUNDRAISING DURING NUCLEAR WINTER

One area that Reisenfel knew well was how to manage large clinical trials, having done a 1,100-patient randomized controlled

trial at Nellcor for a PMA fetal oximetry device. One area she acknowledges knowing nothing about before joining Novasys was raising money. Soon after she accepted the job as the company's president and CEO in February 2001, those two areas became inextricably linked to form one of her earliest challenges.

At that point, Novasys' product development work had been limited to early pre-clinical research, and the company was running out of money. Reisen-thel knew that fundraising was an immediate priority. And there could not have been a worse time to try to raise venture money for any kind of start-up, particularly a women's health device company—some in the industry referred to this as a nuclear winter in terms of financing availability.

One of the potential investors that Debra Reisen-thel targeted was David Douglass of Delphi Ventures, largely because of the firm's reputation and experience in medical devices, including women's health companies. For Douglass, however, that women's health experience was a double-edged sword. "We had invested in UroMed and, as investors, we did extraordinarily well with that company, only to be disappointed when the technology failed in the marketplace," he explains. "That made us very skeptical of investing further in this sector."

Douglass credits Reisen-thel's persistence for getting him to take a closer look at Novasys, and by mid 2001, the company had done some early clinical work in Mexico that Douglass thought looked promising. "We knew that there was a large, clinically unmet need in this market, and we were impressed with the company's management team. When they produced early positive data, we decided to invest at a price that was in line with the market risk," he says, a diplomatic way of saying that the \$13 million Series B financing that closed in August 2001 was a flat round. Delphi led the round, putting in \$3.5 million, and it was joined by Onset and Alloy Ventures, which invested similar amounts, as well as Affinity Capital Management (\$1.5 million) and Rothschild BioScience (now GBS Venture Partners, \$1 million).

As she was raising money, Debra Reisen-thel was also aware of another challenge that Novasys would eventually face: getting reimbursement for its device would require a unique CPT code because no such code currently exists. Reisen-thel had been watching start-ups with innovative device

technology run into problems when trying to get payers to reimburse physicians for their technology. "I had attended meetings of groups like the Blue Shield Technology Assessment Committee where I'd seen them decline reimbursement for companies with terrific technology like Curon and Kyphon [spinal devices] because they didn't have enough clinical trials data or peer-reviewed publications," she explains.

Reisen-thel and Peter Edelstein met with both private payers and CMS to get an early understanding of what Novasys would need to do to facilitate reimbursement coverage, and she admits to being shocked at what they were told. "Both Blue Shield and CMS gave us the same answer," she recalls. "They said we were not going to get paid unless we did a randomized controlled clinical trial against a sham device." What was shocking was the requirement that the control group use a sham device. "Companies like ours did not conduct large, sham-controlled trials for 510(k)-cleared medical devices," Reisen-thel argues.

In many cases, device trials don't use shams for ethical reasons so as not to deprive control group patients of necessary treatment, or to expose patients in the sham group to unnecessary and unacceptable risk with no accompanying benefit from the treatment. But even with companies such as Novasys, who aren't limited by such constraints, regulators have generally not required sham trials, in part because the added cost and complexity of running sham controlled trials places a significant burden on start-up companies. "We knew right away that this meant doing at least a million-dollar clinical trial," says Reisen-thel.

Having just raised \$13 million, Reisen-thel went back to her board and told them that she wanted to do a 200-patient randomized controlled trial with a sham device that would cost around \$1.3 million. "There was initial resistance because none of the investors had ever seen such a trial done before for a 510(k) device," she says. "But to their credit, the board approved the decision, and we did the trial and got great results."

Reisen-thel's strategy represented a shift in the typical approach that a device company took to clinical trials at that time. Most start-ups in 2001 viewed clinical trials, when performed at all, as a means of generating the minimal safety data necessary to achieve FDA clearance. Novasys' clinical

trials strategy was designed not only for obtaining general FDA marketing clearance, but also to generate sufficient data to obtain a specific indication for *Renessa*, and to secure a faster track to reimbursement. "From the outset, the clinical trial was designed to meet payers' needs," Reisen-thel explains. The irony is that the comprehensiveness of the clinical trial significantly slowed down the FDA review.

NO GOOD TRIAL GOES UNPUNISHED

Novasys never anticipated the problems that their clinical trial strategy would produce at the FDA; the path seemed pretty straightforward. Because Novasys was conducting what is called a non-significant risk trial, Reisen-thel explains, the company was not required to meet with the FDA; it could simply work through the institutional review boards (IRBs) for approval at each clinical trial site. And each IRB that Novasys worked with confirmed that the company was conducting a non-significant risk trial.

The result was that Novasys conducted its 173-patient randomized controlled trial comparing the *Renessa* system against a sham device, and it submitted that extensive data to the FDA in support of the product's 510(k) clearance application in January 2004. The problem, according to Reisen-thel, was that the office assigned to review the submission was not staffed appropriately to review the extensive data in the Novasys submission.

Agency action on the *Renessa* application was also delayed by an internal turf battle that developed over which office would review the submission. Initially, the application was referred to the office that handles surgical products because they typically review all RF devices. But more than 90 days after the application had been filed, the urology office claimed they should be the ones to review Novasys' submission. The result was a delay of one year, during which the company burned through \$7 million, that was only resolved by Reisen-thel making use of the FDA's formal appeals process, including utilizing the agency's ombudsman, and appealing to the agency's top officials to intercede and break the logjam. The *Renessa* device finally received 510(k) clearance in July 2005, and the first commercial patient was treated with the device in October 2005. Subsequently, Novasys has been working closely with the urology office, and recently it received approval for an IDE to

treat patients who have failed previous incontinence surgery.

PRACTICE EXPANSION, NOT COMPETITION

Three different physician specialties are potential customers for the Novasys device: urologists, urogynecologists (an emerging specialty of approximately 1,000 gynecologists in the US trained to treat the urinary tract), and gynecologists. Reisen­thel is not worried about *Renessa* creating competition among these specialists for SUI patients. Rather, she believes the Novasys device will provide an opportunity for each of these specialties to expand their practices, treating women who currently are not being treated for stress incontinence.

Novasys is beginning by targeting urologists because they are key opinion leaders in the treatment of SUI. "Of the 10,000 urologists in the US, only 30% focus their practice on treating women patients," Reisen­thel says. The remaining 70% focus on treating primarily male conditions, although she suggests that some may want to expand their practices to perform the *Renessa* procedure. "One thing we have going for us with urologists who currently only treat men is that they are familiar with VidaMed's *TUNA* procedure [now Medtronic's *Prostiva*] for BPH, which is also RF-based," she says. "We've had doctors refer to us as the *TUNA* procedure for women."

Harvey Winkler points out that, in addition to reimbursement concerns, physicians may be somewhat skeptical about *Renessa* because the procedure's success rates are not as high as surgery and because other nonsurgical approaches that have not had compelling outcomes haven't been popular with patients. Debra Reisen­thel believes that Novasys' aggressive early clinical trials strategy will provide the data to convince physicians that, although not necessarily a cure, *Renessa* offers improved outcomes and lower risk, which is a combination that patients will embrace.

Novasys has patient follow-up data for as long as four years that show both an outstanding safety profile and improved, sustainable clinical outcomes. Reisen­thel points out that at 12 months 76% of the women treated in the trial had reduced episodes of incontinence, 67% reported improvement based on a quality-of-life scale that physicians use for SUI patients, and 35% were cured (defined as continent, which means completely dry at one year). "The other big advantage of this procedure is that it does

not preclude any future therapeutic options, she adds. "If *Renessa* doesn't work for a particular patient, she can always go ahead and have surgery." The company has 40- to 48-month follow-up on roughly 25% of the treated trial patients, and 81% of those have not undergone any additional treatment for SUI; the remaining 19% underwent surgery without any adverse events.

With the launch of *Renessa* in the US in October 2005, more than 100 physicians have treated more than 800 patients using the system, with clinical results mirroring those achieved in the clinical study, Reisen­thel reports. Novasys' sales strategy employs 25 independent manufacturers' representatives in the US who specialize in selling to urologists, urogynecologists, and gynecologists, and they report to six regional managers who are among the company's 40 employees. The funding for this sales and marketing effort came from Novasys' Series C round, which closed in April 2004 and raised \$27 million in an oversubscribed offering, led by JPMorgan Partners (now Panorama Capital), Invesco Private Capital, and Ascension Health Ventures, along with existing investors.

"The *Renessa* system is sold based on a typical razor/razorblade model," Reisen­thel says, a model Nellcor used to sell pulse oximetry systems. Novasys' proprietary RF generator sells for around \$10,000 and the disposable probes are \$900 each.

REIMBURSEMENT: THE MISSING PIECE

Having developed the device, achieved positive clinical results, and obtained FDA clearance, Reisen­thel is convinced that the one piece missing from Novasys' successful launch is reimbursement, a recognition behind the company's aggressive clinical trial strategy. "There is no question that sales of this device would resemble a hockey stick if there was established, predictable reimbursement for this procedure," she says. "The physicians currently using our system have told us that they want to treat more patients but they need the assurance that they'll be paid a set amount on a regular basis."

The company is looking to get a specific CPT code dedicated to the *Renessa* procedure. Currently, physicians seek to get reimbursed from payers on a case-by-case basis. This requires significant work by a physician's office staff to pursue each claim individually without any assurance they'll receive payment.

And although there are a growing number of quality-of-life procedures that are succeeding without reimbursement because of patients' willingness to pay out of pocket, that is likely not going to be the case with *Renessa*. Harvey Winkler notes, "My experience is that patients are more willing to pay \$2,000 for a face-lift or other aesthetic procedure than to have this procedure done." Since virtually every other SUI treatment is reimbursed by payers, the expectation by patients is that *Renessa* should be too.

The real risk Novasys ran with its aggressive clinical trials strategy isn't that it would delay FDA clearance, but that payers ultimately won't bite. Reisen­thel hopes that the company's strategy of spending the additional time and resources to employ a more rigorous clinical trials strategy will pay off in achieving reimbursement more quickly than would otherwise have been possible had the company conducted a more limited typical 510(k)-type clinical study. The early findings are positive. It generally takes around three years of device adoption before the American Medical Association (AMA) starts to look at providing a specific new CPT code. But the *Renessa* system was considered in its first year following FDA approval, although it was decided that the device would be reconsidered in 2008, awaiting another year's worth of adoption and publication data before issuing a new code.

Despite having to wait a year, Reisen­thel remains convinced that the company's strategy is a winning one. "*Renessa* is the earliest-stage for a device to be considered for a new CPT code," Reisen­thel reports, and she is optimistic that the positive clinical results the company is generating will support obtaining a specific new code.

In the process, Reisen­thel points out, Novasys' clinical trials strategy has resulted in the company gaining credibility in the eyes of physicians through the positive data that the study generated. In addition, Novasys proved to be ahead of the curve, she says, with the FDA now requiring device companies to conduct more rigorous clinical trials in a variety of therapeutic areas.

Lack of reimbursement was among the key factors that proved the undoing of several of the women's health companies launched during the burst of interest in this area in the mid 1990s. Novasys is betting that it, for one, will not repeat that mistake a decade later.



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