

**SURGICAL  
DEVICES**

# CleveX Inc.

*Disposable skin-lesion biopsy and wound closure device*

Patients undergoing a biopsy of a skin lesion will soon have the option to be treated in-office with a novel device that is quicker and more cosmetically acceptable than traditional methods. So says **CleveX Inc.**, which is developing an inexpensive, compact, single-use product for biopsy, skin lesion removal, and wound closure. The company's *ExiClip* was 510(k) cleared for those uses in May 2007.

Co-founder Jill Banbury is a plastic surgeon, who is married to Michael Banbury, MD, a cardiothoracic surgeon. Both husband and wife were formerly affiliated with the **Cleveland Clinic Foundation**, during which time Jill identified the need for a simple skin biopsy and closure device. Jill and Michael's joint interests spurred the innovations exhibited by the *ExiClip*.

CleveX's other co-founder, Warren Williamson, is also founder and president of IDx Medical, Ltd., a small medical technology incubator/R&D company started in 1995 and located in Cincinnati, Ohio. Williamson is a prolific inventor with over 70 patents, the majority in medical devices.

"Following the disclosure of Jill Banbury's idea in 2004, the Cleveland Clinic Foundation sought out IDx Medical to be the co-inventor," says Gary L. Smith, president and CEO of CleveX. "Warren Williamson turned the idea into

a three-dimensional product."

CleveX has royalty-free, worldwide, exclusive perpetual rights to the Williamson-Banbury pending patent for the *ExiClip*. CleveX also owns all subsequent intellectual property. Furthermore, although the Cleveland Clinic Foundation has founder's shares in CleveX, it will receive no royalties and there are no on-going licensing agreements with the clinic.

"With this technology, we now have an opportunity to accelerate the diagnosis and treatment of skin cancers, melanoma in particular," says Smith, who has nearly 25 years of sales, marketing, and management experience in the medical device and diagnostics industry. Most recently, in 2005, he served as interim CEO for PrognostiX Inc., a developer of a cardiovascular biomarker. Prior to that, Smith was vice president at Battelle Memorial Institute's Commercial Health and Life Sciences group from 1996 to 2005.

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When a biopsy is performed surgically, it usually takes 15 to 20 minutes and involves making an elliptical cut with a standard surgical blade, then pinching the lesion back together and suturing. "The technique is very manual and extremely manipulated," Smith explains. "It also requires a degree of surgical skill." In contrast, the *ExiClip* procedure can be performed in less than five minutes from the time of injecting a local anesthetic. Tissue is pulled through the lesion aperture, then finger holds on the device are squeezed together that cause a proprietary skin clip to secure the skin tissue. Immediately afterward, a blade moves across the aperture and excises the tissue. Hence, biopsy and closure occurs almost simultaneously.

Following the procedure, a steri-strip

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**Contact:** Gary L. Smith, President & CEO  
**Business:** Instruments for skin biopsy, closure and repair  
**Founded:** April 2004  
**Founders:** Jillian Banbury, MD; Warren Williamson (IDx Medical Ltd.)  
**Employees:** 6  
**Financing to Date:** \$3 million  
**Investors:** Ohio TechAngels Fund; IDx Medical; Cleveland Clinic Foundation; Individual angel investors  
**Board of Directors:** Walter Doyle (Forest Capital; Industrial Data Technologies Corp.); William Post (Minimally Invasive Devices LLC); George Trutza (PrognostiX Inc.); Warren Williamson; Gary L. Smith  
**Scientific Advisory Board:** Jillian Banbury; Robert Rau, MD (Riverside Methodist Hospital; Columbus, Ohio); John Wakelin, MD (Columbus Aesthetics and Plastic Surgery Inc.); Drore Eisen, MD (Dermatology Research Associates of Cincinnati)

is placed over the site and the patient is released. "Because the clip is positioned before excision, bleeding is prevented at the site," Smith says. "Skin is squeezed snugly. Two very fresh edges of tissue are brought together before cutting. In addition to the absence of bleeding, scabs do not start prematurely." The skin clip stays in place 10 to 14 days, then is easily removed with a suture-removal tool. The *ExiClip* is ergonomically friendly in size and the finger grips themselves are incorporated with a release mechanism that provides subtle tactile feedback to the clinician.

The learning curve to properly use the *ExiClip* is minimal, Smith asserts. Users first train on a piece of mock tissue of simulated skin. After three or four times, most physicians or other health care professionals "feel they are ready for the first patient," Smith notes.

To date, about 200 *ExiClips* have been evaluated by four practitioners at four different sites. All “are very pleased with the performance overall and clearly see the time savings,” Smith reports.

CleveX has conducted one clinical study of the *ExiClip* involving 40 patients. The late 2006 trial found that in all patients the suspect tissue on either the torso or limbs was sufficiently excised and that the biopsy sample was adequate for the pathologist. “Our tool allows the practitioner to be much more efficient in excising skin lesions and diagnosing those skin lesions.” Patients also report less anxiety and pain. Furthermore, “our cosmetic results are outstanding,” Smith claims.

The three largest competitors in this field are also key suppliers and potential partners with CleveX. Surgical blades, sutures, and staples are available through **Ethicon Inc. (Johnson & Johnson)** and **United States Surgical (Covidien Ltd.)**, whereas **3M Co.** offers a wide range of mechanical closure devices. “We have a novel technology that would certainly augment these product offerings at some point in time,” Smith says. In addition, punch biopsy equipment is available from the German firm **Miltex Inc.** (part of **In-tegra LifeSciences Holdings Corp.**).

Unlike autoclip wound closing systems, which consist of only a clip, the *ExiClip* both biopsies and closes the site, thus “saving surgeon time and producing a reliable, outstanding patient experience,” Smith says. “Less surgical skill is also required. This will allow primary care doctors to biopsy, improving the likelihood of early diagnosis.”

Other competing technologies include cryo-, thermal-, or laser ablation that destroys the lesion, but no biopsy sample is captured and there is poor healing and scarring. These devices are also expensive, “so these technologies tend not to be as rapidly adopted,” Smith says.

According to Smith, there are 24 million lesions evaluated annually in the US, ranging from moles treated cosmetically to growths that are cancer suspect. But only about six million of these lesions are actually excised and biopsied,

of which approximately 60% are candidates for the *ExiClip*, representing close to four million procedures yearly. “This consists of skin lesions smaller than 12 mm and located on the limbs and torso of the body,” Smith says.

Although the FDA has not regulated where, anatomically, the *ExiClip* may be applied, the company discourages use on thick tissue of the hands or feet; the face, head, or any surfaces above the base of the neck; genitalia; mucous membranes; or patients with stainless steel or nickel allergies. “We think from an ergonomic perspective, right now it would be difficult to use our device in these areas,” Smith says.

US product launch is slated for July 1, 2008, to coincide with two major dermatologic conferences: the summer conference of the American Academy of Dermatology in July, followed by the annual meeting of the American Society for Dermatologic Surgery in August.

The *ExiClip* will list for \$35. The company will also offer two accessory tools: a simple skin hook for capturing the lesion (\$10) and a clip removal instrument (\$2), both recyclable.

“Through the end of 2008, we anticipate \$500,000 in sales—all domestic,” Smith says. “The Sun Belt is clearly a key region for us because it has the greatest density of dermatology and plastic surgery practices. The Sun Belt also has the greatest incidence of skin cancer.” Worldwide, Smith estimates that the *ExiClip* is suitable for around eight to ten million procedures annually, with Australia and Pacific Rim countries leading the pack.

The company expects that 90% of 2008 sales will be in the core specialties of dermatology and plastic surgery, with the remaining 10% in primary care. “We want to establish our credibility first with the dermatology marketplace, then let it trickle down to the primary-care market,” Smith says. Sales projections

for 2009 range from \$4 million to \$5 million, with 75% domestic and 25% Australia/New Zealand and the Pacific Rim. Domestically, product will be sold through a combination of direct sales and dealer/distributor organizations.

The *ExiClip* will be sold in dispenser boxes of ten. “However, we know of some clinical dermatologic practices that perform 50 to 60 biopsies a week,” Smith points out.

Of the \$3 million CleveX has raised to date, \$1.4 million has been through a Series A equity round, including \$750,000 from local angels and an angel investment group, Ohio TechAngels Fund. The remainder represents founder shares, foremost the Cleveland Clinic Foundation and IDx Medical. “Some of that is intellectual property, in-kind services, and cash,” Smith says. The company hopes to raise a \$3 to 5 million Series B

round starting in October 2008. That money will go toward ramping up sales and marketing.

“We have a healthy and very robust pipeline of follow-on technologies that we hope to bring to market through CleveX,” Smith states. “Our focus is skin innovation. The follow-on products will all fit the channel very well in wound closure.” For instance, the company is investigating other closure devices for deeper biopsies in plastic surgery.

One of the challenges is the low reimbursement schedule for dermatologists. “But the *ExiClip* is a tool that can increase their throughput of patients,” Smith says, noting that a practice can expect a profitable \$150 reimbursement per patient.

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— BOB KRONENMYER

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