

Start-Up News

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Summary: Noteworthy news from medtech start-ups, including Epinex Diagnostics' new handheld diabetes monitoring device and OmniGuide's flexible CO2 laser.

Article begins on the next page . . .

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by Robert Neil

Epinex Diagnostics: Improving Diabetes Management

The diabetes market is one of the most attractive for manufacturers and investors because innovative products can become the staple of a very large and growing patient base that is always looking for new ways to manage a disease that affects an estimated 23.6 million people in the US and 300 million worldwide. The area of diagnostic testing is a particularly important field within diabetes care, because patient well-being is so heavily tied to understanding sugar levels within the body, and repeated testing is the only way to gauge a patient's condition. Researchers at **Epinex Diagnostics Inc.** of Irvine, CA, believe they've come up with a new product in this area that could significantly improve patient care with a test that measures a specific protein in the blood.

The Epinex *GIA* Rapid Diabetes Monitoring Index Test is a handheld system that measures the level of protein glycation—the process of sugar bonding with protein in the blood. More specifically, the test measures the amount of glycation to albumin, the most abundant protein in the body. Company president and CEO Asad Zaidi says glycation measurement provides a much better picture of the effect diabetes is having on type 2 diabetics than daily self-monitoring of blood glucose, which only offers points-in-time readings of sugar levels. Glycation is an indication of how much damage sugar is doing to proteins, and glycation is the main cause of diabetic complications. Zaidi also says a monthly over-the-counter glycated albumin test can offer more timely results and allow for earlier therapeutic intervention than HbA1c testing performed at the physician's office. (See *Exhibit 1*.)

Exhibit 1

Advantages to *GIA* Test Compared to Currently Available Glucose Monitoring Techniques

Type of Measurement	Period of Measurement	Testing Frequency	Function
Glucose	At a point in time	Once to several times daily	Tests fluctuations in blood glucose levels
HbA1c	4-6 month average	Twice a year	A measure of long-term glycation
Glycated Albumin (Epinex <i>GIA</i> Test)	1 month average	Once monthly	A specific index for monitoring glycation

SOURCE: Epinex Diagnostics

Although the value of measuring glycation is well known, the testing process has involved complex lab instruments that can take hours to days to deliver results. Epinex has developed a portable device that can not only provide readings at the point-of-care, but also can produce those readings within five minutes. Albumin is replaced in the body every three to four weeks, allowing a renewable test to be performed once a month, and the *GIA* device enables monthly assessment of protein glycation with built-in data storage capabilities that allow monthly trend analysis.

Similar to a glucose test, a patient places a drop of blood on a disposable test cassette that is inserted into the handheld reader, which then analyzes the sample and displays results. The device is being designed with the capability of transmitting data through a computer connection or wireless interface to a patient's physician or any other appropriate destination.

Founded in 2004, Epinex currently is in a second round of funding and is seeking \$15 million over 18 months to move the project forward. The company has already developed a prototype for the *GIA* test and instrument, and funding will be used to complete overall product development, commercialization, Food & Drug Administration (FDA) approval, and initial production and marketing.

OmniGuide: Bending the Beam

One of the chief benefits successful start-up companies bring to the medical device industry is the ability to view current technology as merely a starting point for newer and more progressive ideas. Sometimes this type of innovative process means taking existing technologies and bending them a bit to create wider opportunities that didn't exist before, and one young company is literally following that path with improvements in the use of CO2 lasers in surgery.

OmniGuide Inc. has taken CO2 lasers, so popular in certain surgeries because of their unique ability to perform precise cutting and coagulation, and expanded the type of cases in which these devices can be used. For more than 30 years, surgeons have only been able to rely on CO2 lasers for "line-of-sight" procedures, where there's straight, direct access to the area that needs to cut. However, OmniGuide's *BeamPath* flexible CO2 laser fiber scalpel is capable of bending the laser beam so it can be used in a variety of surgeries where direct access isn't possible. The process is possible due to the use of an innovative photonic band gap mirror lining that guides light through a hollow core, which allows the beam to be manipulated.

The concept for this technology was developed at the **Massachusetts Institute of Technology**, and results from an initial lab prototype were published in 2002, followed by an exclusive development agreement with OmniGuide the next year. Since then, the company has moved at a fairly rapid pace for a start-up firm, with FDA approval of the *BeamPath* coming in 2006, and about 5000 surgical procedures performed to date in the areas of neurosurgery and spine oncology, otology and neurotology, head and neck oncology, laryngology, gynecology, pulmonology, and gastroenterology. (See *Exhibit 2*.)

Exhibit 2

Clinical Applications for OmniGuide's *BeamPath* System

Neurosurgery: Neurosurgery and Spine Surgery

- Intracranial tumor resection
- Base-of-skull tumor resection
- Spine tumor resection
- Transnasal endoscopic/microscopic procedures

Otolaryngology: Otology and Neurotology

- Stapedectomy/revision stapedectomy
- Cochlear implant (soft cochleostomy)
- Cholesteatoma removal
- Tympanomastoidectomy

Otolaryngology: Head and Neck Surgery

- Base of tongue tumor resection
- Laryngeal tumor resection
- Tracheal tumor resection

Otolaryngology: Laryngology and Airway Surgery

- Papilloma ablation
- Tracheal stenosis radial cuts
- Laryngeal lesion resection

Gynecology

- Chondyloma removal
- Cervical dysplasia ablation

SOURCE: OmniGuide

Most recently, the company announced the launch of the *BeamPath* NEURO fiber, a microsurgical tool for various central nervous system procedures, including intracranial tumor surgeries, spine tumor surgeries, and transnasal pituitary surgeries. OmniGuide officials believe their product is ideal for these types of surgeries because the laser beam can be used in hard to reach areas with precise targeting that minimizes thermal injury to adjacent, healthy tissue in the brain or spine.

Earlier this year the company closed on a series E private equity round that brought in \$25 million and is being used to continue growth in the US and overseas, where *BeamPath* received the CE Mark in 2007. [W#200830269]

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