



Hg range]. Next you put the *TriggerFish* on and look at pressure changes. Our value is not in giving a specific pressure reading at any point in time, but in providing the full 24-hour pressure profile for a patient.”

That strategy might help Sensimed get to market more quickly than it would if it sought to replace a diagnostic standard because its product is based on a novel way of measuring IOP. Rather than deforming the cornea and measuring its reaction to pressure, Leonardi’s approach measures changes in the diameter of the eye in reaction to IOP. “Think of a balloon. If the pressure inside the balloon changes, the balloon inflates or deflates slightly. And we are talking about tiny changes—microns of variation in the diameter of the eye,” Wismer explains.

Many other research groups are attempting to develop continuous pressure sensors, but most are developing implants. To avoid invasive implantation, Sensimed developed a disposable contact lens that should provide visibility and feel as comfortable as a conventional contact lens. The sensor and microprocessor are embedded in the lens and only the hydrophilic surface and edges come into contact with the eye. Moreover, because the device measures changes in the eye’s diameter, the sensor is in a ring on the outside edge of the contact lens, outside the field of vision. “The patient wearing the lens doesn’t see the device inside the contact lens,” says Wismer.

Sensimed has conducted *ex vivo* studies in the eyes of pigs in which it induced and accurately detected pressure changes, and it has also performed studies in healthy human volunteers where it discovered that the device was sensitive enough to measure the tiny waves of pressure that result from intraocular pulsation (related to the beating of the heart). “The device is sensitive enough to capture intraocular pulsation, and in doing so, provides a validation of the quality of the IOP measurement,” says Wismer. That is, if the device picks up the intraocular pulsations, clinicians can be sure that it fits properly and is working as it should, providing a validation of the quality of the IOP trend data.

In late 2008, the company was anticipating a CE Mark by year’s end as well as the start of US clinical trials. A Series B financing round with US VC firms is planned for mid-2009 to finance commercialization in the US. Wismer believes the product can be cost-effectively manufactured, and although Sensimed has not finalized pricing, he says, “The initial feedback on the part of patients and clinicians to the proposed industry price is positive. In many cases, patients are willing to pay for their device, although we will seek reimbursement.”

If successful, *TriggerFish* will serve several roles in clinical practice; it will help ophthalmologists choose effective drug strategies for patients, monitor the success of treatment, and finally, achieve the early diagnosis of patients because today half of patients with glaucoma are not diagnosed. False negatives may occur in patients with fluctuating IOP levels, since their pressure may be in the normal range at the time of screening yet spike up at some other point in the day.

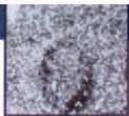
The company’s most immediate markets include the replacement of 24-hour curves gleaned from single-point measurements in sleep laboratories and treatment monitoring. There are two million patients eligible for those applications for a \$350 million market potential in the US alone, Wismer believes. Together with the early diagnosis application, the company faces a market potentially exceeding \$1 billion, he says. “There are several risk factors for glaucoma—a family history of the disease, race, and advanced age, for example. I believe there is a compilation of factors that should compel ophthalmologists to test patients with our device.”

Mary Stuart

### DiFUSION Technologies: Safer Spine Surgery

The need to address hospital-acquired infections has quickly become one of the most pressing issues among providers, who’ve been aware of the problem for some time, but are now operating under regulations that limit reimbursement for treating the incidents. New rules put in place by the Centers for Medicare and Medicaid Services

*The sensor and microprocessor are embedded in the lens and only the hydrophilic surface and edges come into contact with the eye.*



*Electronic pressure sensors, like those used by the defense industry in guided missiles, are employed to ensure compliance by sensing the body's activity level and adjusting as needed.*

have brought an embarrassing hospital occurrence into a broader light, and the industry is looking in earnest for solutions. The situation presents an ideal opportunity for any company that can produce a product that effectively deals with infections.

One company well-positioned to capitalize on the current opportunity is start-up **DiFUSION Technologies Inc.**, which is preparing to debut an orthopedic device that will target the costly area of surgical site infections (SSIs) in spinal surgeries, a problem that costs providers about \$2 million per year.

DiFUSION, officially launched in January 2009 has developed a proprietary compound called *CleanFUZE*, which uses the antimicrobial properties of silver in a mixture that can be used in manufacturing a medical device. The company is preparing to introduce a spinal cage made from *CleanFUZE*, and company founder Matthew Geck, MD, told *Medtech Insight* the product is capable of killing 650 types of bacteria in the surgical site for up to four weeks. Although silver is currently used with several types of devices as a coating designed to reduce infections, *CleanFUZE* allows antimicrobial properties to be embedded in the device and substantially increase its antimicrobial effectiveness.

All told, SSIs cost the US health care system \$5 billion in expenditures annually by some accounts, and as much as \$10 billion in other studies. In acute care facilities, 2% to 5% of patients undergoing inpatient surgeries develop SSIs, and approximately 500,000 cases are reported each year. These infections can add seven to ten days to a patient's hospital stay, at a cost of between \$3,000 and \$29,000, depending on the type of operation and infection.

Additionally, patients that develop SSIs have a two to eleven times higher risk of death, with 75% of deaths in these patients directly attributable to the SSI, according to a report published in September from The Society for Healthcare Epidemiology of America. (See Exhibit 1.)

DiFUSION is anticipating 510(k) approval this year and the company will open its first round of private financing at the end of the first quarter. Officials say they will be looking for \$2 million to \$3 million to help fund inventory and staffing, which will include two to five sales management positions. To date, angel investors have contributed about \$750,000 to fund product concept and preparation for the 510(k) submission.

The company already has agreements with 15 distributors in place, and its marketing strategy calls for working with hospital materials management departments, a move that many young companies fail to consider.

Robert Neil

### Carmat: Building a High-Tech Artificial Heart

Over the years, the technical constraints of weight, volume, and biocompatibility have dogged developers of implantable, permanent, total artificial human hearts, but one young company believes it has a high-tech solution to these problems.

Exhibit 1

#### Facts about Surgical Site Infections

Occurrence	Two percent to five percent of patients undergoing inpatient surgery in the US develop SSIs; approximately 500,000 cases each year
Costs	\$3,000 to \$29,000 per case; from \$5 billion to \$10 billion annually
Additional hospital days	Seven to ten
Patient mortality risk	Two to eleven times higher than operative patients without an SSI

SOURCE: The Society for Healthcare Epidemiology of America, Strategies to Prevent Surgical Site Infections in Acute Care Hospitals, September 2008