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AHA Scientific Sessions

PFO/stroke connection remains perplexing medical conundrum

By DIANA TUCKER
***Medical Device Daily* Contributing Writer**

CHICAGO — Sometimes logic and anecdotal information just can't connect the dots. Such was the case with the long-awaited CLOSURE 1 randomized controlled clinical trial results to evaluate the safety and efficacy of **NMT Medical's** (Boston) STARFlex septal closure system that were reported this week at the **American Heart Association** (AHA; Dallas) 2010 Scientific Sessions. The AHA annual meeting is well known for its late breaking clinical trials presentations that are showcased daily both in press conferences and during plenary sessions,

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Medtronic unveils mobile health app for diabetes management

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Sometime in the not-too-distant future diabetes patients will be able to manage their condition on mobile devices such as smartphones or **Apple**'s (Cupertino, California) iPad. William Hawkins, CEO/chairman of **Medtronic** (Minneapolis) demonstrated just such an application two weeks ago as the **Cleveland Clinic** was wrapping up its eighth annual Medical Innovation Summit.

During a lunchtime presentation at the tail end of the meeting Hawkins demonstrated a new application his company is developing that would allow diabetes patients to track their glucose level, physical activity, food intake, and other key factors they need to pay attention to in order to manage their condition.

The development represents a trend in the industry

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Research shines spotlight on regenerative medicine

By OMAR FORD
***Medical Device Daily* Staff Writer**

In the wake of **McMaster University** (Hamilton, Ontario) researchers discovering a method to turn human skin into blood cells a huge spotlight is shining on regenerative medicine and med-tech firms that have applications in the market.

The team created blood progenitor cells, which are the mother cells that multiply to produce other blood cells, as well as mature blood cells.

Their research was published in the journal *Nature* on Nov. 7. Researchers found that a patch of skin the size of a fingernail could one day create enough blood for a total blood transfusion.

"The extraordinary advance made at McMaster

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Washington roundup

Company replacing Colleague pumps faces its own FDA recall

By MARK McCARTY
***Medical Device Daily* Washington Editor**

FDA let **Baxter Healthcare** (Deerfield, Illinois) know in no uncertain terms earlier this year that its Colleague line of infusion pumps were not up to par, and the firm contracted with **Sigma** (Medina, New York) to fill the product gap with its Spectrum line of infusion pumps while Baxter redesigns its own infusion pumps, an agreement the two firms forged earlier this year (*Medical Device Daily*, May 5, 2010). Unfortunately for Sigma, its Spectrum pumps have also been the subject of a class I recall, which FDA updated last week.

According to the Nov. 12 announcement at the FDA website, the affected pumps, Sigma's Spectrum model

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Hamilton Thorne

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University promises to open the entire regenerative medical research market to thousands of additional researchers and therapeutic companies," Meg Spencer, CEO of **Hamilton Thorne** (Beverly, Massachusetts) told *Medical Device Daily*.

Spencer went on to say that the findings from the researchers open up many possibilities for the company and research into regenerative medicine.

"Not only is the McMaster advance immune to political issues surrounding embryos, but the new process shows greater productivity, reduced costs and much shorter development time than other methods used to produce regenerative cells and tissues," she said. "This promise of far greater productivity is the carrot that will draw many new researchers and corporations into the field. Regenerative medicine involves replacement and repair of diseased tissue or cells by introducing new cells or tissue to repair the damage, rather than using drugs. In this case, there is the additional benefit that the new cells derived from your own skin, will not be rejected by your body."

She added that "Hamilton Thorne's Stiletto and Staccato lasers will play an important part in speeding the research and improving productivity. Naturally, the increased number of researchers will create a much larger market for Hamilton Thorne."

The company said that its family of lasers operates as robotic micro-surgeons and speed key processes in regenerative cell production and development. It said that the devices, which are used for research processes and don't require FDA approval, shorten times from months to days and from hours of work to seconds of automation. A recent published result revealed that the firm's Staccato laser increased lab productivity by more than 10 fold.

Formed in 2002, Hamilton Thorne is a venture-backed company, and employs an engineering, research, production and professional staff of thirty. In May 2008, the company spun off its molecular diagnostics unit to **Thorne Diagnostics**.

The firm was formed to meet key needs and problems in cell research. It said that its devices are the first lasers ever mounted directly inside a microscope objective; an innovation which gives the products real advantages in speed, accuracy, ease of use and safety for the cells. Each member of the laser family serves a different research application. Merely turning the microscope turret gives the researcher a new world of capabilities. These capabilities might include cellular identification and manipulation, eradication of unwanted cells, removal of cell nuclei without harm to the cell, etc.

"Advances that our lasers provide are central to work toward solutions for Alzheimer's, Parkinson's disease, Lou Gehrig's and all the age-related diseases such as macular degeneration," Spencer told *MDD*.

Since inception the company has raised roughly $22 million and was listed on the Toronto TSXv Exchange in October 2009. The market for lasers in regenerative medical research is estimated to be more than $2 billion — a market that the company hopes to get involved in quite a bit more.

Spencer said she believes this recent news also will stir up additional investor attention.

"Absolutely," she said when asked about increased investor activity in the space in the future. "The world publicity will bring the potential benefits of regenerative medicine home to millions of people, and highlight the field for investors."

As for the research itself, the McMaster team said they are now planning on testing whether these blood cells can be safely transferred into humans: similar to a normal blood transfusion. The checks will be carried out by 2012, raising the prospect that the process could be available in hospitals within the next few years.

The new process is said to be more reliable than trying to turn embryonic stem cells into blood. That technique has disappointed so far because of difficulties in converting the stem cells into mature cell types for transplantation. In addition, that method produces embryonic blood cells that can't be transplanted into adults. ■

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People in the News

• **Neoprobe** (Dublin, Ohio) has named Mark Pykett, PhD, executive VP and chief development officer. Previously, Pykett held senior leadership positions at a number of biotechnology and diagnostics companies where he was charged with product and corporate development efforts. Neoprobe makes oncology surgical and diagnostic products.

• **Scientia Advisors** (Boston) has named Patrick Terry to the position of principal in the company's pricing and reimbursement/market access practice. Most recently, Terry was founder and CEO of Technic Solutions. Scientia Advisors is a management consulting firm specializing in growth strategies for major and emerging companies in healthcare, life sciences, biotechnology and nutrition.