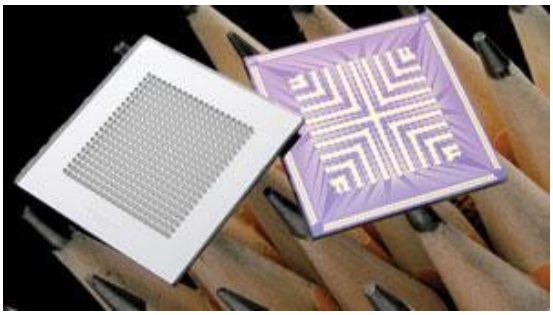
SMALLTIMES

A slow road to big impact: small tech in medicine

Strict regulations and costly ramp-up are delaying efforts to bring nano- and MEMS-based medical applications to commercial reality.

By Sarah Fister Gale

From biosensors to diagnostic tools, MEMS and nanotechnology have been touted as the Holy Grail for medical applications. But the dreams for custom cancer cures and self-regulating drug management have been slow to make their way to market. While small tech has made a big splash in the semiconductor and micro-electronics industries, it is only just taking hold in medical fields, where strict regulations and cautious investors make progress slow going.

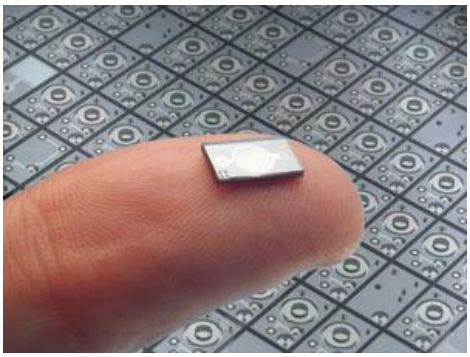


"People see that the opportunities are there, and MEMS is leading the foray into the commercialization of medical applications," says Karen Lightman, managing director of the MEMS industry group, a member-driven industry association based in Pittsburgh, PA. "However, FDA approval takes a long time."

Adriana Vela, founder and chair of NanoBioNexus, a non-profit industry organization for nanotechnology in San Diego, CA, agrees. "There is a much longer lead time from product development to commercialization," she says of medical applications, noting that some drugs can take 15 years to complete the process.

Still, Vela sees great progress and potential in this burgeoning field for nano. "It is the most lucrative and the most potentially disruptive area of research," she says, noting expectations that the next generation of nano-based medical applications have the potential to obsolete existing technology. In particular, implantable materials and devices such as hip joints or pacemakers could benefit significantly from nano-based coatings that can dramatically reduce infection and rejection rates. She's also optimistic about the progress being made in the use of nanotechnology for diagnostics, and the identification of biomarkers that will enable a more efficient diagnosis of diseases, such as Parkinson's disease or diabetes. "Institutes and researchers worldwide are receiving millions in funds to bring these ideas to market," she says. "It's just a matter of time."

For MEMS-based applications, Lightman believes that in the near term, much of the potential is in devices that were originally designed for other industries, such as automotive and consumer electronics. In particular, she sees the application of sensors that monitor and transmit the information as having great near-term promise for real-time health management. "MEMS components are rugged and reliable," she says. That ruggedness, and the fact that silicon-based components don't trigger rejection the way other materials do make them ideal for applications in the human body.



MicroChips, a Bedford, MA-based developer of implantable devices, is pursuing this path. The key component of MicroChips technology is its proprietary reservoir arrays, which are embedded in silicon wafers and filled with biosensors or drugs for timed-release delivery, according to John Santini, company president and CEO. "We use MEMS because we want the device to be small and we need to design precise, accurate features in a very tight space," he says. "MEMS material is also well-characterized to be tolerated by the body, and it is amenable to hermetic sealing."

MicroChips are using these tools effectively to deliver real-time information about health status and for drug delivery customized to the immediate needs of users. "MEMS is allowing us to build devices that go beyond a one-size-fits-all idea," adds Santini. "You can't achieve this level of precision with other materials."

The slow progress, while partly due to strict FDA evaluation procedures, cannot be blamed entirely on plodding regulatory requirements. There are also obstacles around costs and ramp-up. The price of any component goes down as high-volume manufacturing is implemented, but until a reasonable price is achieved, cautious physicians

and penny-pinching insurance companies won't embrace new medical technologies. "If a catheter requires an $800 MEMS component, you won't have a lot of buyers," Lightman points out.

This is why industry partnerships and investment can be critically helpful. "You have to have investors and partners to bring products to market," she adds, noting that MicroChips has actively pursued funding and partners, which contributes significantly to its success.

Another such partnership is currently underway between semiconductor giant STMicroelectronics and Debiotech, a Swiss developer of medical devices. The two companies announced a strategic cooperation agreement in April 2007 to manufacture a miniaturized insulin-delivery system, called the Nanopump. The device relies on microfluidic MEMS technology and allows a tiny pump to be mounted on a disposable skin patch to provide continuous insulin infusion for diabetics. The new ST-enabled Debiotech miniaturized MEMS device is about one-quarter of the size of existing pumps and can be worn as a low-profile patch on the skin. It also provides better control of the administered insulin doses. The original technology was given the Swiss Technology Award in 2006, and the agreement with ST makes its marketability inevitable.

It's a well-suited partnership: Debiotech developed the original concept, while ST has the expertise and capacity to develop silicon-based MEMS applications on a large scale. The first prototype has already been developed, and samples are in production. The two partners expect that a fully industrialized product, in the form of a disposable cartridge, will be available in selected markets in 2008. "The collaboration with ST represents a major step in the manufacturing of the Nanopump to make it available to a broad market at a cost compatible with a unique disposable use," says Frederic Neftel, MD, president and CEO of Debiotech SA.

While such partnerships deliver benefits to both researchers interested in ramping up production, and manufacturers looking to expand their product lines, establishing them isn't necessarily easy. "There are so many opportunities right now to pursue MEMS-based applications for medical devices, it's hard work determining which products correspond to areas of your expertise," says Stefano LoPriore, head of business development for microfluidics at ST. "There is a broad application of silicon for medical applications, and we bring that expertise from manufacturing semiconductors."

Small Times March, 2008
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