MEDICAL DEVICE DAILY™

ADVANCES IN BIOMATERIALS: STATE OF THE INDUSTRY AND EMERGING MARKETS 2009

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Developments in biomaterials portend changes in med-tech

One of the featured presentations at the annual **Cleveland Clinic**-sponsored Medical Device Innovation Summit last year was a look at a "Top Ten" list of medical innovations and their implications for the medical technology industry and healthcare in general in 2008 and beyond.

As reported by *Medical Device Daily* Managing Editor Holland Johnson, who covers that interesting conference each fall, biomaterials had a prominent position on the list – not only as one of the 10 areas of interest, but also with something of a role in several of the others.

Occupying the No. 9 position on the David Letterman-like list was "Engineered cartilage products for joint repair." As presenter Joseph Iannotti, MD, PhD, chairman of orthopedic surgery at the clinic, noted, natural biomaterials are used to replace joint cartilage tissue damaged from injury or arthritis. The engineered cartilage is surgically implanted into the joint with the intent to avoid artificial joint replacement.

"This is clearly going to be a large, expanding area in 2008 and 2009," Iannotti said.

Roy Greenberg, MD, assistant professor of surgery and director of endovascular research at the clinic, noted that a panel of 20 physicians then ranked the roughly 40 finalists for the Top Ten list.

He said that ranking the innovations was a bit of a challenge, "because we're somehow trying to compare apples with oranges. How do you compare a genomics project with a percutaneous valve, or something like that, which is a bit of a challenge?"

Surprisingly, Greenberg said, there was frequent convergence among the experts making the selections.

"When you look at medicine and the effect of these new inventions on the medical community at large, there's a lot of agreement between them. This year there were not actually any arguments about what should be on the Top Ten list and what shouldn't."

By way of reference, here is the clinic's complete Top Ten list of medical innovations for 2008, last to first, in Letterman style. Biomaterials, representing a key advance unto themselves, play a role in several of the other innovation items, including drug delivery, imaging and implants:

10. **Dual energy source computed tomography**: CT scanners use two radiation sources and detectors, speeding medical imaging and exposing patients to less radiation. Presenter Thomas Masaryk, MD, head of the clinic's neuroradiology section, said such scanners will enable the imaging of patients with high or irregular heart rates, previously a limitation for imaging. "Dual energy CT improves speed, both spatial resolution and temporal resolution and it allows for [excellent] tissue characterization," said Masaryk.

9. **Engineered cartilage products for joint repair**.

8. **Neuromodulation implants/Brain stimulation**: Neural control devices that could restore movement of arms and legs to patients with spinal chord injuries, stroke ALS and other central nervous system injuries. Ali Razi, MD, director of the clinic's **Center for Neurological Restoration**, said that researchers are only now glimpsing the tip of the iceberg with this technology. "Basically, the era of the brain chips is here," Razi said. "This is not science fiction anymore; it's here being translated into human beings and the applications for the future are enormous." He likened the level of sophistication for these systems to cardiovascular implant technology 20 or 30 years ago.

7. **Image fusion for diagnostic and therapeutic use**: Merging of different medical technologies to better diagnose both anatomic and physiologic problems and guide minimally invasive procedures. Why is this being considered an innovation now?

According to Greenberg, who presented this technology for the panel, "the image resolution . . . has increased to the point where it's becoming very useful."

6. **Nasal drops that deliver flu vaccine to infants**: Nasal drops containing live attenuated flu can be used to deliver a vaccine instead of needles and provide protection from influenza for this high-risk population as young as 6 months of age.

5. **New drugs to prevent blood clots or bleeding**: Newer anticoagulant treatments, which include low molecular weight heparins, are being introduced to reduce complications such as bleeding or thrombosis. Presenter John Bartholomew, MD, section head of vascular medicine said that based on the successful development of anticoagulants made from leeches, researchers are looking into developing other compounds from blood-sucking creatures like fleas, ticks and bats.

4. **Genome-based personalized medicine**: Genetic testing that can produce personalized health risk assessments to guide therapy that will head off disease before symptoms are seen.

3. **RNA anti-sense technology**: Gene-based therapies that reduce a protein that carries the "bad" cholesterol and triglycerides in the bloodstream. This could potentially help to reduce heart disease. The technology is already being studied for use in the treatment of age-related macular degeneration of the eye, and according to presenter Peter Kaiser, MD, a staff member at the clinic's **Cole Eye Institute** a compound is already in Phase II studies for that indication. He compared the mechanism of action of this RNA antisense technology to shutting off a faucet at its source, thus preventing a cascading effect further downstream.

2. **Percutaneous aortic heart valves**: Aortic heart valves can be delivered via catheter through a groin or small incision in the chest wall and then expanded inside the heart. X-ray screening lets doctors monitor the valve as it is positioned. Lars Svensson, MD, PhD, a staff member in the clinic's department of Thoracic and Cardiovascular Surgery, said that currently, about 48,000 aortic valve replacements are done annually in the U.S. He said that more than 125,000 patients in the U.S. with severe aortic stenosis could benefit from this type of procedure.

1. **Flexible intralumenal robotics**: A catheter-based technology to let surgeons manipulate tiny tools, in places where their hands don't fit, such as inside the heart. The flexible robotic system could be used for cardiology, neurology, urology and other specialty procedures. "This does represent a new paradigm of robotic surgery," said presenter Inderbir Gill, MD, section head at the clinic's transplantation center.

About this book

This market report focuses on the key areas of interest and importance for biomaterials researchers and companies as they look to the future. *Advances in Biomaterials* represents the first such collection of information – some 277 pages of it – put together by the staff of *Medical Device Daily*, the only daily newspaper serving the industry. Many of the items in this book originally appeared in our sister publication, *BioWorld Today*, the predominant publication covering the biotechnology industry.

On the pages that follow, you'll find overviews of those areas we have judged to be of the most interest moving forward. In the Overview section, we take a look at where we are as a sort of scene-setter for what's happening in the oncology diagnostics and device-centered therapy sector. In Legislative/Regulatory, we report on some of the efforts on both the legislative and regulatory sides of government that affect the sector. Finally, the Deals/Financings chapter covers some of the most significant mergers & acquisitions activity and financings that occurred between July 2007 and Oct. 1, 2008. That wraps up the Overview section of the book.

Following that section is what many might regard as the heart of our look at these

industries – some 208 pages devoted to 16 chapters ranging from Aesthetics to Wound Care. In each of these chapters, we take a look at some of the key developments – and companies – shaping that particular segment. Those overviews are followed by smaller stories, usually focused on single companies or developments, which add illumination to what is happening in those fields.

Let me note that this book is not intended to be a directory, so we have not sought to identify and include every company and technology involved in this burgeoning sector. What we have attempted to do is to make note of newsworthy activities in biomaterials, while weaving in promising areas of development that we'll hear more about in the future.

This book resulted from substantial efforts of the staff that brings you *Medical Device Daily*, along with *Diagnostics & Imaging Week* and our two monthlies, *Biomedical Business & Technology* and *Cardiovascular Devices & Drugs*. I especially want to cite the work of Managing Editor Holland Johnson; National Editor Don Long; Senior Production Editor Rob Kimball; Staff Writers Amanda Pedersen, Omar Ford, Lynn Yoffee and Karen Young; Washington Editor Mark McCarty; Sourcebook Editor Kathleen Kite-Powell; European Editor John Brosky; and Contributing Writers Jeffrey Berg, Michael Simonsen, Larry Haimovitch, Diana Tucker and Ron Trahan in producing the materials included in this book. A shout-out as well to our colleagues at *BioWorld Today* for their many contributions.

And, as always, my thanks to you for your interest in this book and our other publications.

— Jim Stommen, Executive Editor

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