Making a better implant

Implants are getting more sophisticated, thanks to regenerative materials, personalized instruments, and biocompatible electrical connectors.

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Senior Editor

Demand for medical implants should increase 9.3% annually to $43.6 billion in 2011, according to a report by industry researchers **The Freedonia Group**, Cleveland, (*www.freedoniagroup.com*). The company says cardiac implants are expected to remain the top-selling group, led by stents and defibrillators, with demand expanding 9% annually to almost $20 billion in 2011. Demand for orthopedic implants is forecast to exceed $19 billion in 2011, up about 9% annually from 2006. Other fast-growing segments include neurological stimulators, cochlear devices, and gastric bands, and are expected to be worth $5 billion in 2011, up more than 13% annually from 2006.

One reason for the rise in implant use is the performance and outcome advantages over alternative treatments, such as drugs. Another reason is the constant improvement and innovation of devices that keep getting smaller. A look at some recent developments shows why implants are increasingly the therapy of choice.

The data from a CT scan is turned into a 3D model of the knee. ConforMIS maps surface contours of the joint in the areas affected by disease.

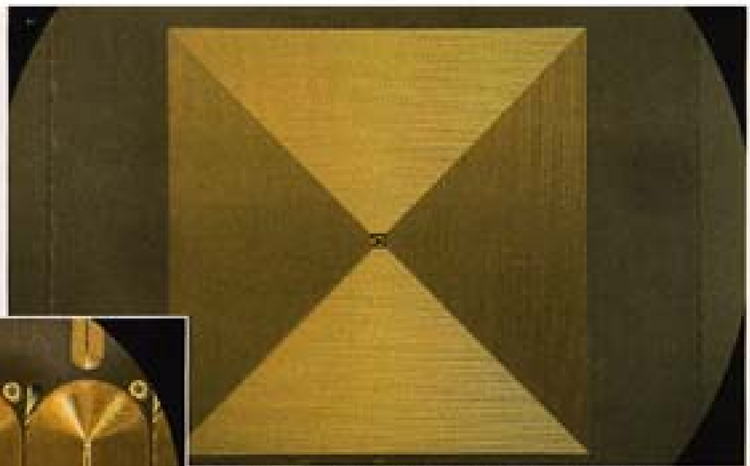
ConforMIS creates custom knee implants and associated fixtures so that surgeons can determine the exact placement of the implants.

A knee for only you

Minimally invasive surgeries and personalized medicine are two hot trends in the implant market. One device company has combined the two into an implant for orthopedic patients suffering from osteoarthritis which affects nearly 21 million people in the U.S. **ConforMIS Inc.**, Burlington, Mass., (*www.conformis.com*) uses proprietary software to build custom knee implants and instruments from CT scans. "iFit technology lets us scan the diseased joint, extract the surfaces, and convert them into an implant that essentially represents the pre-diseased knee," says John Slamin, vice president of implant engineering for the knee at ConforMIS. "We then manufacture a knee replacement specifically for that patient, and also the associated iJigs, or patient-specific cutting and placement guides needed to install the implant."

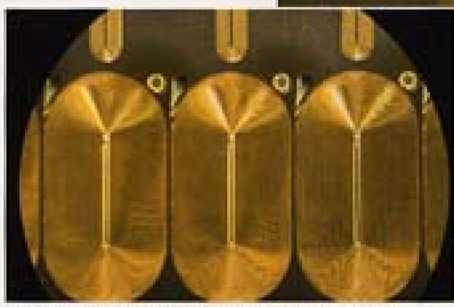
This 'image-to-implant' technology allows for precisely sized and shaped implants that reduce or eliminate the need for cartilage or bone resection and simplify the surgical procedure. This translates to less blood loss and less time in the operating room and recovery. The company makes implants from a cobalt-chrome alloy and an ultrahigh molecular weight polyethylene. The jigs are made from a specialized plastic composite using direct-digital manufacturing.

Because the company has the geometry of the patient's knee, it also makes simplified jigs that help surgeons reestablish alignment of the limb and place the implant where it needs to be. "Standard knee-implant instruments are relatively cumbersome stainless-steel tools that are designed to fit 'most' knees," says Slamin. "By making patient-specific jigs, we reduce the number of needed instrument trays from five to one disposable tray." This saves hospitals time and money. (Sterilizing a tray costs about $50 to 100.)



Induction coils from Metrigraphics are equipped with radio-frequency signal transmitters and signal and power induction capabilities, eliminating potentially harmful effects to the human body posed by battery-operated implants.

Slamin says the company is currently focusing only on knee implants, but the approach easily translates to other joints. "We plan to expand into hip, spine, and shoulder replacement," he says. "The technical kinks have been worked out, such as taking technology from the R&D and prototyping worlds and applying them to large-scale manufacturing. Developing a manufacturing method for quick turn arounds and nearly zero inventory was also a challenge," he adds. ConforMIS takes an average of five to six weeks to turn around parts from the time the CT scan is received.



Micro-induction coils can be used in a variety of medical applications including miniature loop antennas for both active and passive implanted devices, sensors, and neurostimulators.

Contacts make connecting easier

A lot of medical devices are contained in a housing then implanted into the body. Electrical leads are connected to the implant during surgery. The devices monitor sensory inputs and the leads, in turn, apply generated electrical signals to the body. "Some engineers design their own contacts," says Tom Kannally, medical industry manager at **Hypertronics Corp.**, Hudson, Mass. (*www.hypertronics.com*). "Others use set screws, which require surgeons to tighten down the captivated screw during surgery. Unfortunately set screws are easily damaged, either by misalignment or too much torque."

The ImplanTac connector from Hypertronics is a low-force, low-resistance, contact made with biocompatible materials and designed to prevent faulty connections. The contacts let surgeons easily mate implanted leads into devices without misalignment, damage to the system, or risk to the patient. They eliminate the need for special mating tools and the life-threatening hazard of applying unnecessary pressure to the patient during the mating process.

The contacts feature a hyperboloid-shaped basket of individual spring wires strung at an angle to the socket's axis. When the pin is inserted into the sleeve, the wires stretch around it, creating a number of linear contact paths.

While the contacts are more reliable and consistent than other connectors, ImplanTacs are all custom designed. "For example, we take into consideration the material of the lead, whether it's stainless steel, titanium, platinum-iridium, or another biocompatible alloy," says Kannally. Another option comes when the contacts must be encapsulated onto the end of the device, forming a hermetic seal. "This means the outside of the contact must be encapsulated with implantable-grade epoxy without filling the center of the contact. For these cases, we add an O-ring at the back of the contact to keep encapsulant from touching the contact," he adds.

Induction coils eliminate batteries

As Hypertronics works to simplify power connections, another company has developed a way to eliminate batteries from devices altogether. **DRC's Metrigraphics Div**. recently introduced a family of micro-induction coils for implants and biomedical devices. "The coils are equipped with radio-frequency signal transmission and signal and power induction capabilities," says Randy Sablich, vice president and general manager at Metrigraphics, Wilmington, Mass. (*www.drc.com/metrigraphics*). This means implants can obtain power through induction, eliminating internal batteries and control and power wires passed through the body.

The coils are classified into two groups: single and multiple-layer forms. Single-layer electroformed coils are available in a variety of sizes, including round and square shapes for ease of fit into specific applications. Multi-layer coils offer greater field density for more high-end applications.

The induction coils are also available with different substrates. Coils are made using electroformed nickel cobalt over-plated with pure or hard gold, depending on the application. Coils can also be

ImplanTac socket contacts are made of biocompatible materials for use in implantable medical devices such as pacemakers, implantable cardioverter-defibrillators, neurostimulators, metabolic controls, and circulation pumps.

Biocompatible connectors from Hypertronics prevent electrical discontinuities in implants because their low-force, low-resistance contacts are easy to connect and resist damage during mating.

produced using copper. "The process starts with a photolithographic image of the desired shape in photo resist, and then either electroplated for a thicker coil material, or sputtered for extremely fine coils," says Sablich. Individual traces can be fabricated as small as three microns, but more typically in the five to ten-micron range, with metal thicknesses equal to the trace width. Aspect ratios of 2.5 to 1 and higher ratios are possible.

Two-shot molding does what metal can't

Another trend in implant manufacturing is using two-shot molding. For example, a company might mold an implantable grade of PEEK and overmold an implantable silicone onto it. "Part of what's driving the trend is new grades of implantable PEEK that can replace metals such as titanium," says Greg Riemer, vice president of sales and marketing, **MRPC**, Butler, Wisc., (*www.mrpcorp.com*). "We can now injection mold components with implantable PEEK at a lower cost than machined metal or machined PEEK." MRPC makes components for orthopedic applications such as hip replacements or in spine surgeries.

"There are two main advantages to the two-material components," Riemer adds. "One, you have design options not available with other assembly processes, where two components are manually assembled. For example, two-shot molding eliminates the costs of assembly and handling, and is less likely to get contaminated. The other advantage is a strong chemical bond between the two materials. This includes having the physical properties of two dissimilar materials."

Silicone, particularly liquid-silicone rubber, is a common material for implantable components because of its compatibility with the body. "Silicone is inert, has low toxicity, low extractables, and a low risk of biological reactions," says Riemer. "In addition, it can withstand all major forms of sterilization."

"One of the advantages of using an implantable-grade PEEK is it replaces higher-cost metals and the high cost of machining other thermoplastic materials," says Riemer. "And we can push design boundaries with molded components versus machined components," he adds.

Biofelt is a proprietary needle-punched non-woven felt scaffold material that lets human cells grow into its 3D interconnected pores so natural tissue can be formed to replace or repair damaged tissues.

Biofelt is shaped into tubes for growing blood vessels which are regenerated from cells and regrown as a natural tissue. They, in turn, can be attached to other shapes or organs as a conduit.

Disappearing tissue scaffolding

Resorbable and regenerative materials are increasingly getting more use as implants develop. "We get a lot of calls from customers looking for biodegradable polymers that are more tissue friendly," says Art Burghouwt, the executive vice president of medical at **Concordia Medical**, Warwick, R.I., (*www.concordiamedical.com*). For example, spinal implants might use metal rods to fix discs and prevent pain, but they reduce mobility. A more compliant material such as fiber and fabric based, high-strength implants might keep the fixation but add mobility.

Biofelt, from Concordia, is a non-woven felt scaffold used for cell seeding in tissue and organ regeneration. The tissue is grown in a bioreactor while the fiber or felt slowly degrades. The resulting tissue structure is then implanted.

"Some customers use the body as the bioreactor and implant Biofelt and seed cells *in-situ*," says Burghouwt. Other customers implant Biofelt as a barrier with no cell or biological treatment. For example, Biofelt is used in dental implants as a biodegradable barrier membrane that lets soft tissue heal without interfering with the bone in-growth.

There are also clinical trials in process for a urology implant in which Biofelt is the substrate that cells are grown onto to form a bladder structure. Burghouwt says future applications might include more complex shapes such as heart valves. The company is also working on custom polymers with properties that may be desirable for specific tissues. For example, making fibers swell better, they attract more moisture and increase in size to seal the space it occupies. ✝