Materials Report 2008

With device designers constantly seeking the next unique material that will help make their latest device a reality, it is important to stay abreast of what the material suppliers are developing. This article reviews a number of material technologies that are generating interest and will soon be making waves in medical device design.

By Joyce Laird

Joyce Laird has written a number of articles for a variety of industries, including the medical device manufacturing market.

Today, material innovation comes from both new materials and also unique material combinations. This is truly a time where materials are seeing changes coming from all directions.

Reinventing the Basics

Invibio LTD, developer of PEEK-OPTIMA polymer, widely used for nearly a decade by the implantable medical device industry worldwide has recently introduced two new PEEK-OPTIMA-based compounds, carbon fiber-reinforced (CFR) and image contrast. Both of these are certified for human implantation and blood, bone, or tissue contact of more than 30 days.

Michael Callahan, president, Invibio Biomaterial Solutions says, “We’ve observed that orthopedic device manufacturers are increasingly interested in improved wear performance in applications involving articulating joints, such as the hip. Recent data indicate that CFR PEEK-OPTIMA compounds demonstrate excellent wear performance when coupled with ceramic, metal and polymeric materials.

“The flexural stiffness of CFR PEEK-OPTIMA is more similar to human bone than other biomaterials, making these new compounds an excellent choice for orthopedic applications,” he says. “Implants developed from CFR PEEK-OPTIMA exhibit better load sharing, reducing the impact of stress shielding and related complications that could shorten the life of an implant.”

Additionally, PEEK-OPTIMA image contrast compounds contain a radiopaque additive that allows tailored visibility of the implant for placement verification post-surgery while still permitting the surgeon to see the healing site.

Silicone is another material that has been in use for decades. Steve Bruner, Nusil Technology, says, “With silicones, medical device companies want proven materials that have bio compatibility. Introducing, radical new materials is quite difficult, so our innovation comes in small changes, making it easier to process or making a slight modification that results in an improvement in a physical property, but we’re not moving outside of the basic chemistry that defines silicone.”

The latest area Nusil is working on is in the area of silicones used as the basis for drug delivery applications. “This is where the end user is loading active pharmaceutical compounds into materials where they will allude out in a controlled release rate over time,” Bruner says.

While much of the science behind the drug alluding properties is highly complicated, it is based on the physical properties of the silicone material and the specific drug and how they interact. “There are some additives and chemistries that can speed up or slow down that allution rate,” Bruner says.

Although only in the beginning development stage, Nusil is also taking a look into chemistries that can make silicones more hydrophilic. Bruner states that will open new possibilities for drug delivery applications and might provide some interesting possibilities for medical device companies.

Smart Biomaterials

“We are beginning to recognize that material bulk properties can be one thing and we can have different surface properties that do something else,” Len Czuba, president of Czuba Enterprises and past president of the Society of Plastics Engineers, says. “We can have very soft, flexible material that is membrane-like, then we can tailor the surfaces to interact with a drug delivery system or with flowing blood, or to promote tissue adhesion.”

One of the leading companies in this area is the Polymer Technology Group Inc. (PTG). Robert S. Ward, president/CEO says, “Our approach is to synthesize polymers to create surface modification and then to fabricate them under a controlled process that enhances the ability of the built-in surface modification to take effect.”

SAME (self assembling monolayer end groups) is the hot topic around PTG. SAMEs are composed of three parts: a chemically reactive group to bond them to the polymer raw material as it is being made, spacer chains (e.g., alkanes that act as hydrophobic chains that promote self assembly on the surface of devices made from the polymer), and a head group presenting a specific surface chemistry.

End groups could include drug functionality, biological groups such as peptides, or surface functionality for post device fabrication surface reactions. They can be engineered into biomedical polymers during synthesis to provide a robust, built-in surface chemistry that self-assembles after device fabrication.

One very unique application for this technology is seen in a project done in conjunction with ExThera AB, a technology transfer partner of Karolinska Institute, Stockholm, where PTG SAME technology is used to render polymer surfaces capable of removing pathogens from blood.

“In this particular project, we are using this self assembly technology to modify the surface of a polymer so it will bind heparin. Then we use that heparin modified surface to selectively remove microbes from the blood,” Ward says. “It does this as blood flows through a column of surface modified polymers containing the binding sites of heparin molecules. It's a unique therapeutic use of a biomedical polymer."

Innovation in Composites & Special Materials

Combining known materials to create new and better geometries that give materials a whole new set of applications is an ongoing area. Secant Medical LLC, for example, takes known and qualified polymers and metals and creates fabric that is used in a wide variety of medical applications.

Jeff Koslosky, director of research and development, says, "Textiles have unique structure and geometry in that it is delivered very small and then expands, becoming what we see in many new catheter based therapies and the orthopedic structures."

One of the big benefits of these surgical textiles is that they can be controlled so well. Some applications need an impermeable barrier, while others need to be designed so that they will have a bit of porosity.

"Envision if you will, a bone cement that is being injected into a containment system that is somewhat porous so it has the ability to flush out from that surface and actually connect to the underlying bone as well," Koslosky says. "We can design the density of the structures to be selectively permeable."

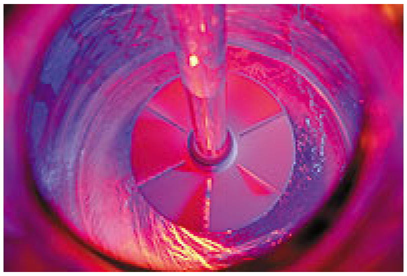
"We have expertise in a variety of different structures and forming techniques and the ability to handle very novel raw materials. Nitinol is probably one of the more interesting materials that we are dealing with right now," he explains.

A highly unique application uses an eight ten-thousandth of an inch Nitinol wire. Secant braids 96 of these nano-wires together. "The application is for distal embolic protection; a filter, if you will, that's deployed downstream during an angioplasty procedure to catch any of the emboli that could potentially flake off during that procedure and cause the patient to stroke on the table," Koslosky says. "The reason it works is that it is an incredibly fine material and Nitinol has shape memory properties and super elastic properties. In combination with the geometry itself, that is what makes the device functional."

"PEEK is also a material that is getting a lot of our attention," Karen West, General Manager adds. "We are beginning to explore turning it into a containment polymer, like a fiber. So again, it really marries some of the technologies we have, with a material that's well known in the industry, but hasn't been exploited in textile type of structures."

There is more than one way to create a composite and Polygon Company is on the leading edge in the development of new formulations used in their pultrusion technology.

Jim Shobert, chairman, says, "What's really unique in what is going on with materials right now is [the] ability composites have to embed things within their structure."



Polygon is embedding a range of materials into the base polymer materials—conductive fibers, very small wires, flexible circuit paths within the composite, fiber optics, and even RFID chips for location monitoring and device tracking.

A good example of this technology is embedded wire technology in prostrate cannula. The wire is embedded during the production of the tubing because it helps to avoid breakage and also alleviates the possibility of the cross connection of wires during the procedure when using the electrical current.

“The composite structure takes on a whole new meaning of functionality and instead of just being corrosive resistant or electrically insulative, suddenly you can make something that is electrically insulated on the inside and the outside, but have a conductivity path down the middle of it,” Shobert says. “These composites are only limited by your ability to be creative because you can add and subtract so many different things to make the end product do what you want it to.”

Strictly on the raw material composite side, New England Urethane Inc. (NEU) has introduced a new series of medical grade resins with features and benefits not found in currently used radio opaque polymers. These new grades include TPUs, nylons (polyamids), and olefins.

Curt Smith, PhD says, “We are a custom compounder which means we put together recipes that customers request. One of the most common things we do is put barium sulfate into polymers and that’s so it can be seen well under x-rays.”

Often customers will request a material with lower loading properties than barium sulfate. The most common material is tungsten. It has a high specific gravity, so a lot can be used weight wise, but doesn’t add much volume. It is often used in inter cranial where a lot of bone has to be seen. “Substantial filler is needed in there to light up and you can’t do it with barium. We use 70% tungsten by weight,” Smith says.

Antimicrobial materials are another area that is growing for NEU. They are working with many companies on a variety of very proprietary compounds. These can be anything from silver-based materials to a variety of antibiotic materials. “The key is to develop the right polymer blend so that the antimicrobial comes out when and where they want it to,” Smith says.

Other things NEU is involved with are in the area of polymer stabilization. As far as leading edge, there is a certain range where urethanes are used杪A up to a 70-75D in hardness.

“We are pushing both ends—the very hard and the very soft,” Smith says. “We have one material we call NEUSoft and we’ve applied for a trademark. We are trying to get that into the 50-55 range. Applications would be for a material with soft touch, better feel, better expansion for balloon applications, and to replace PVC.”

A Call for Niche Suppliers

Advanced Polymers recently signed a supply agreement with a company in the UK, Biomer Technologies LTD. Biomer makes special polyurethanes exclusively for medical applications. “Their whole business is geared to making custom polymers with very tight specifications. We can rely on them to deliver exactly what we need every time.” Mark Saab, president, says.

The melt index gives a good idea of the molecular weight of any polymer. It basically indicates the flow rate under standardized tests. Saab says that in many of the commercial polyurethanes, the specs are bulk index, so the minimum and the maximum for a particular grade of material can be as high as ten to one. “I could buy a lot tomorrow where it would come in at two, and buy a lot next month and it could come in at ten. Same supplier, same grade of raw material,” he says.

“There is a real need for materials to be made to tighter specifications for medical applications,” Saab says. “It is a niche market that has high growth potential for enterprising companies such as Biomer.”

On the Horizon

Czuba believes that the industry is definitely going to see a lot of new product development related to materials; things that will in turn, drive the development of still more new materials.

“It’s a very exciting field to be in because every year, I’m seeing things being done that couldn’t be done until some new material was developed that allowed it to happen,” he says.

This symbiosis ensures that material innovation is always a two way street.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com and the following websites:

• www.advpoly.com

• www.biomertechnology.co.uk

• www.invibio.com

• www.neuinc.com

• www.nusil.com

- www.polygoncompany.com
- www.polymertech.com
- www.secantmedical.com