MEDICAL DESIGN BRIEFS

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Critical Cooling in Medical Devices

Making Devices Easier to Use with Force-Sensitive Resistors

Highly Sensitive Optical Fiber Pressure Sensors

Pre-Engineered Fluid Control

Addressing Changes in ISO 13485

SPECIAL SECTION: Technology Leaders in Testing

TECH BRIEFS

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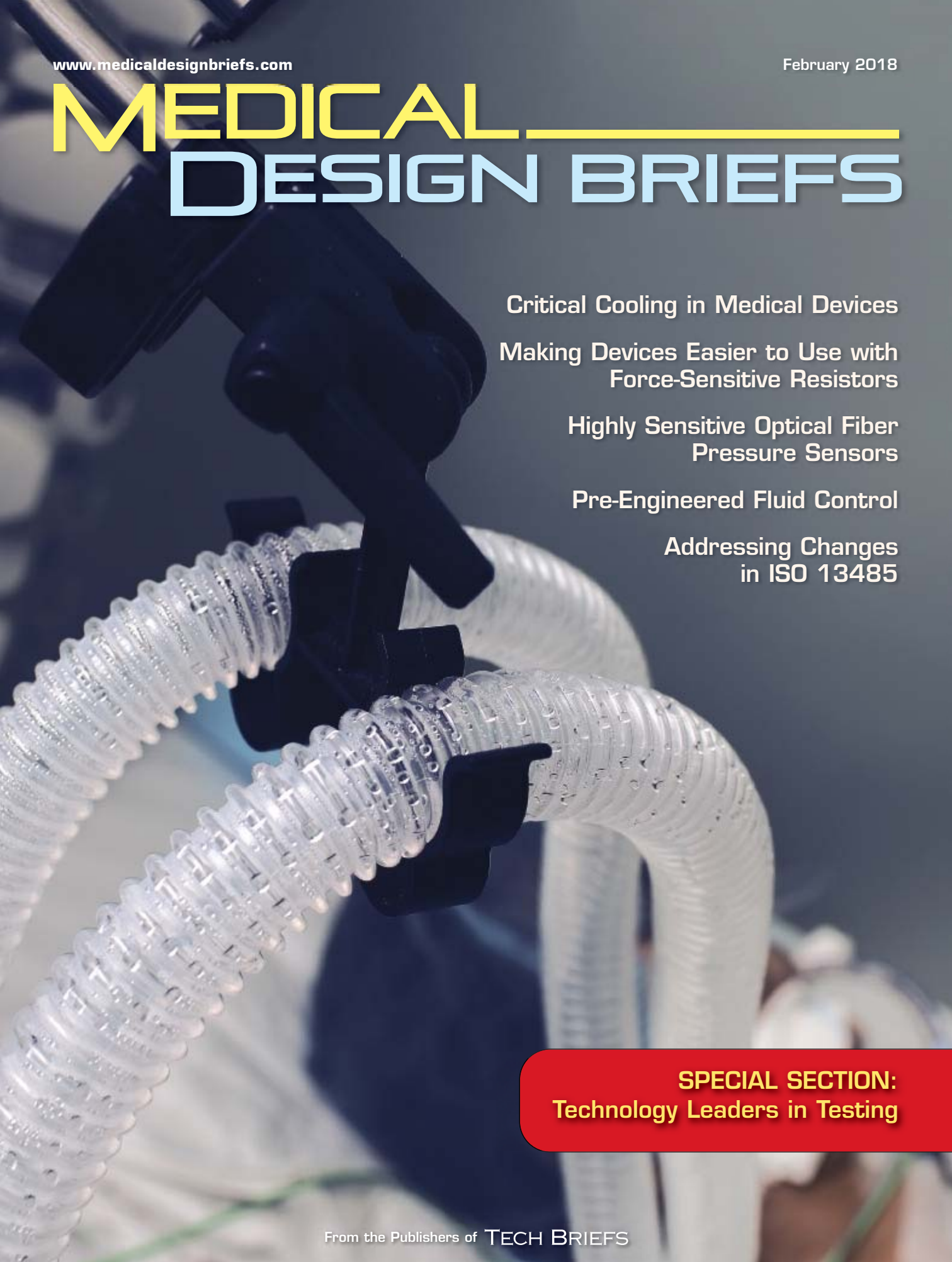

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February 2018

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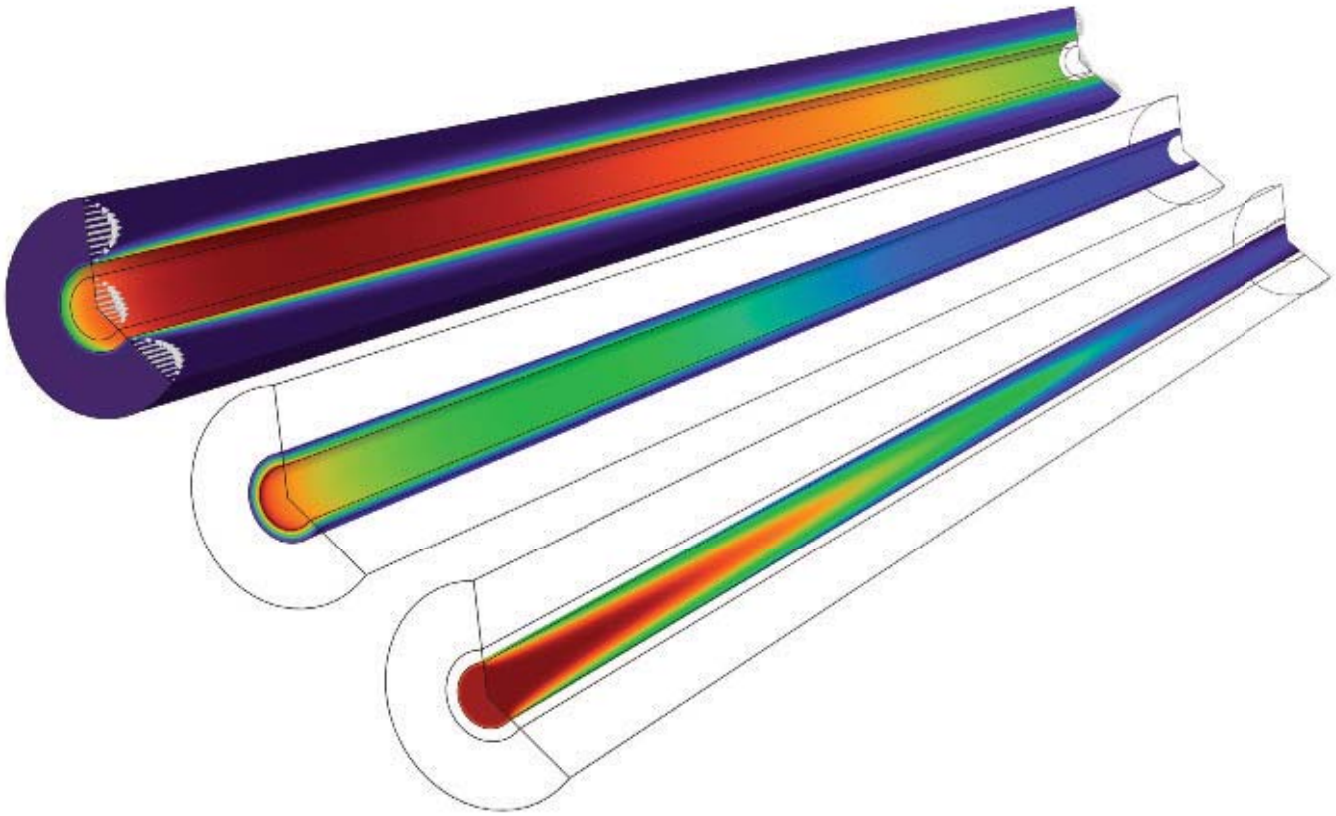
Technology Leaders in Testing

ON THE COVER

In March 2017, ISO published a four-part standard aimed at providing the general framework required to adequately determine the acceptability of medical devices that contain breathing gas pathways. Read the article on page 36 for and in-depth look at the testing requirements of ISO 18562 and the details necessary for medtech companies to satisfy this new standard.

(Credit: Eurofins Medical Device Testing)

An improved design process yields improved designs.



Visualization of contaminant concentration in the dialysate, membrane, and permeate (from left to right) based on inputs into an app.

Improving the hemodialysis process for renal patients involves designing high-performance equipment that more effectively removes contaminants. Numerical modeling is a useful tool for analyzing and optimizing designs, but it can also be time-consuming. What if there was a way to test and improve designs faster without sacrificing accuracy? By building simulation apps, you can.

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FDA Ushers in a New Era of 3D Printing and Additive Manufacturing

FDA is monitoring the emerging field of 3D printing and additive manufacturing, an area FDA once considered a "futuristic technology on the distant horizon."

As the agency prepares for its first big wave of 3D printed products, it has put in place a technical framework and released its new guidance document, "Technical Considerations for Additive Manufactured Devices," in December 2017.

In a statement released with the guidance, FDA Commissioner Scott Gottlieb, MD, notes, "Patients have already benefitted from 3D printed medical products through access to personalized devices and innovative drugs that have led to significant health improvements. But the FDA is now preparing for a significant wave of new technologies that are nearly certain to transform medical practice," he says. "We're working to provide a more comprehensive regulatory pathway that keeps pace with those advances, and helps facilitate efficient access to safe and effective innovations that are based on these technologies."

The new guidance was issued to help advise device manufacturers on technical aspects of 3D printing, which FDA refers to as *additive manufacturing*. It is intended to clarify what FDA recommends that manufacturers include in their submissions for 3D printed medical devices.

"It includes our thinking on various approaches to 3D printing, including device design, testing of products for function and durability, and quality system requirements," says Gottlieb. "Overall, it will help manufacturers bring their innovations to market more efficiently by providing a transparent process for future submissions and making sure our regulatory approach is properly tailored to the unique opportunities and challenges posed by this promising new technology."

Gottlieb points out that this guidance is what FDA calls a "leap-frog" guidance because it is designed to provide FDA's initial thoughts on an emerging technology, he says, "with the understanding that our recommendations are likely to evolve as the technology develops in unexpected ways."

He notes that the agency is already seeing the beginning of this evolution as hospitals and academic centers use their own 3D printers to create innovative dental implants, replacement knee joints, and experimental heart valves and bone implants for use in clinical studies. FDA has reviewed more than 100 devices currently on the market that were manufactured on 3D printers.

As innovations in 3D printing impact healthcare by lowering costs and personalizing treatments, it is great to see FDA create this pathway that can respond appropriately to the "unique attributes" created through 3D printing and additive manufacturing.

Sherrie Trigg
Editor and Director of Medical Content

Note: The guidance is available online at ***https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf****.*

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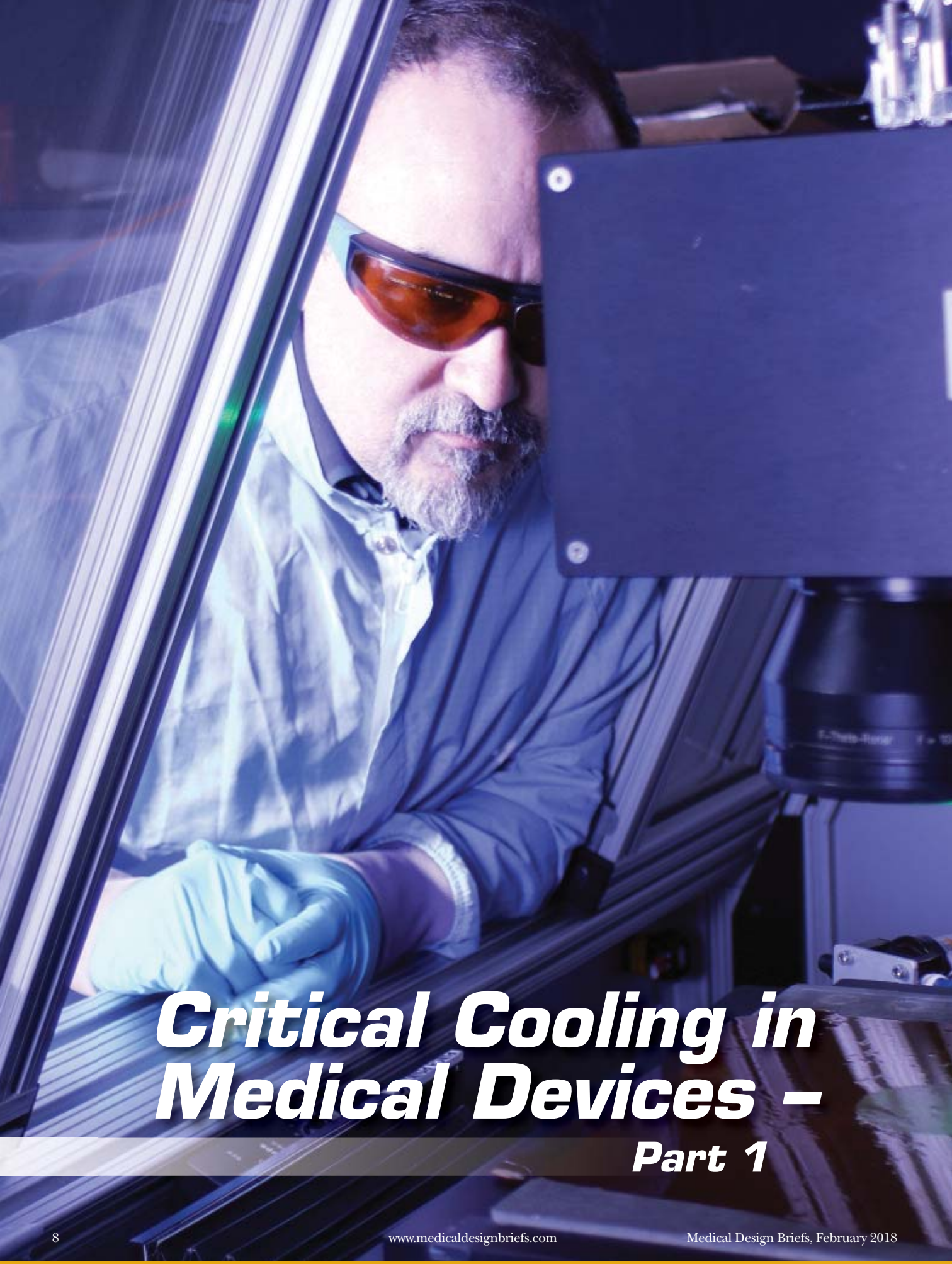


Critical Cooling in Medical Devices – Part 1

Active thermal management is vital in a number of medical device applications including patient core temperature management, skin cooling, medical device cooling, and laboratory equipment cooling. These applications include initial emergency medical services, in-hospital patient thermal management, a range of procedures that take place in doctor's offices, and in laboratory equipment. To meet this growing need, medical device designers need highly efficient and compact cooling systems that can be integrated into their systems, often with the option of battery power for mobility.

Cooling medical devices presents unique challenges to the engineers responsible for the thermal management designs in these systems. To gain acceptance in a medical setting, these devices must be compact, quiet, effective, and often must be placed inside the chassis of the medical system to keep tangled wires and hoses off the floor and out of the way of practitioners. These required features conspire to make thermal management in these applications challenging. A variety of solutions including simple fans, liquid cooling, or compact refrigeration systems are being used to meet these challenges.

This article provides a review of some of the most interesting thermal cooling applications. A variety of cooling methods will be reviewed including passive techniques such as direct, air, and liquid loop. Part 2, which will appear in a future issue, will examine active cooling methods that provide additional cooling for direct, air, and liquid cooling using vapor compression, as well as thermoelectric methods.

Patient Thermal Management

Patient thermal management applications include therapies where the patient core temperature is altered to achieve a more optimum outcome. To attain a change in patient core temperature, heat must be removed from the body in sufficient quantity to overcome the body's heat production with sufficient control to remain safe and effective while not interfering with other procedures that are taking place. There are many methods of removing heat at the patient interface that have been researched, but the least invasive of these involve pads that have embedded water channels of various designs that are placed in good contact with the patient's skin. All systems of this type require a cooling system. Most often, a chiller that provides a recirculating stream of cooled liquid is used.

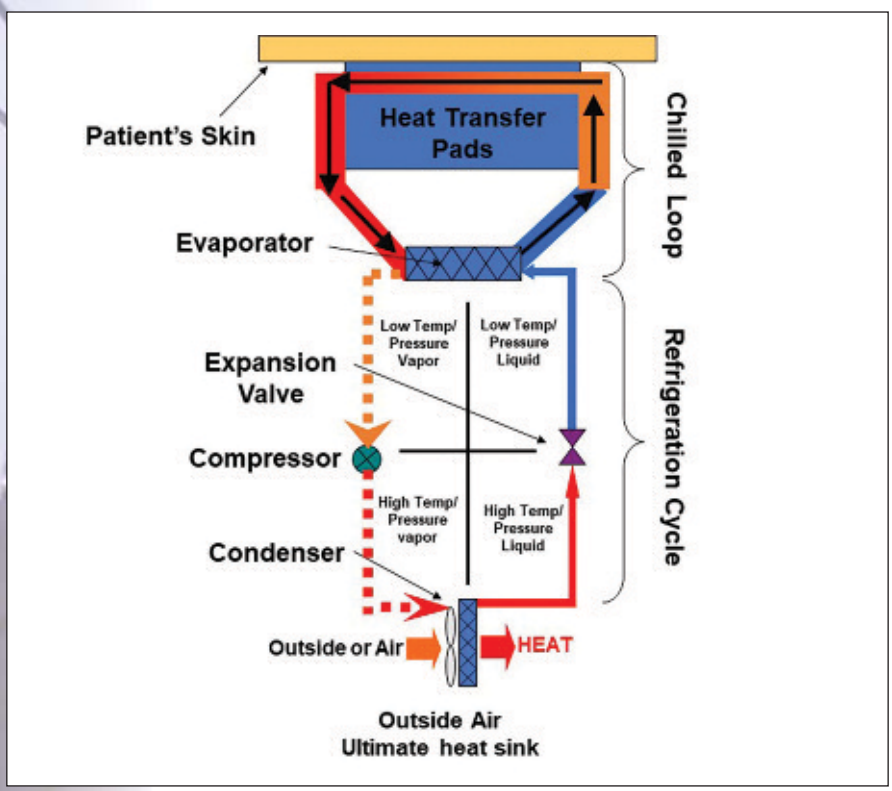


Fig. 1 – Schematic of a hypothermia and skin cooling system.

Research has shown that the inducement of mild brain hypothermia within the first three hours after injury to a temperature of between 34° and 35 °C will greatly mitigate the two major sources of secondary brain damage.[1] One is a neurohormonal dysfunction related to cardiopulmonary function, hemoglobin dysfunction, neuronal hypoxia, blood brain barrier dysfunction, and brain thermopooling. The other is related to brain edema, ischemia, and intracranial pressure elevation. The early induction of brain hypothermia, within three hours, is most effective because epinephrine, a trigger factor in these changes, is released in high concentrations immediately after injury.[2]

Enabling emergency medical services personnel to minimize the time lag between injury and hypothermia treatment to less than three hours after injury is critical to the efficacy of this approach. By inducing mild hypothermia soon after injury, the temperature at which hypothermia must be maintained can be set at 34–35° C. According to Hayashi and Dietrich, if time after injury prior to brain hypothermia treatment were to be delayed until three to six hours after injury, the hypothermia treatment must be carried out at 32 °C, which requires a level of care in the control of hyperglycemia not likely to be found in a medical emergency vehicle.[2] The effectiveness of hypothermia treatment is highly dependent upon the rapid induction of hypothermia after injury and should be initiated no longer than six hours after injury at the latest. Research indicates that even with early induction of brain hypothermia, the duration of treatment should be between three and seven days, depending upon the severity of brain damage. Once the hypothermia treatment is complete, careful and gradual rewarming is a necessity for safe treatment.[1,2]

Refrigerated centrifuge (–20° to 40 °C), for PCR, DNA, and RNA, and analysis.

Thermal management for neonatal encephalopathy is referred to as *brain hypothermia*. This process cools a baby to around 33 °C for three days after birth in cases where there has been a deprivation of oxygen to a newborn that lasted long enough during the birthing process to cause physical harm, usually to the brain. Brain hypothermia has shown to be the only medical intervention that reduces brain damage, improving the baby's chance of survival with reduced disability. In cases of targeted thermal management during the post-cardiac arrest period, it has been proven that hypothermia is helpful because it can "restrict the area of injury, improve epicardial reflow, decrease myocardial metabolic demand, and conserve intracellular high-energy phosphate stores" (see "Further Reading").

Localized Skin Cooling

In localized skin cooling, cooling the core temperature of the patient is undesirable; it is preferred that the skin be cooled locally to achieve a variety of desired effects. In a manner similar to that used in hypothermia treatments, a liquid chiller and cooling pads are often used to achieve the desired heat transfer.

Skin cooling has been applied with good effect in cancer patients (see Figure 1). It is widely known that hair loss is a side effect of chemotherapy treatments and can have a traumatic impact on patient emotional well-being. By cooling the scalp both during and after chemotherapy treatment, hair loss can be reduced. By placing cold scalp caps on the patient, the vessels in the scalp are cooled, and the capillaries that carry the chemotherapy vasoconstrict. This vasoconstriction reduces the blood flow to the area, and the low temperature reduces the reaction of the chemotherapy treatments with the hair follicles. The end result is that the damage to hair follicles is significantly reduced, mitigating or reducing hair loss.

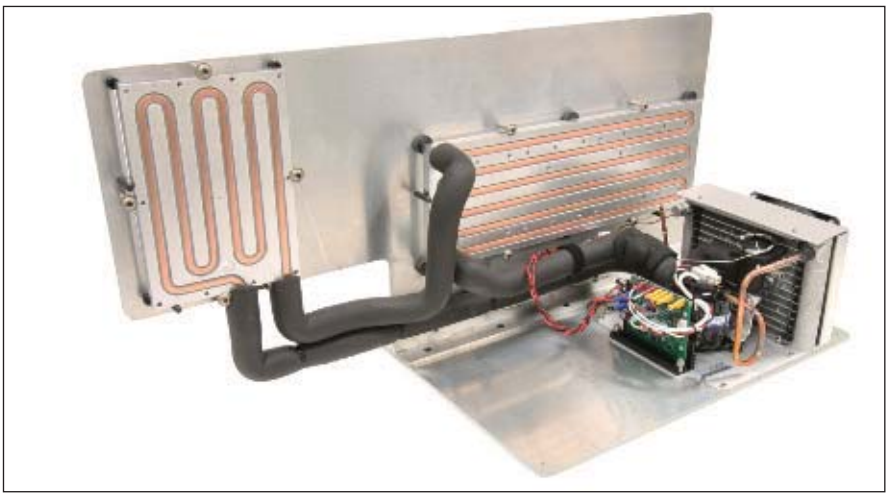
Some studies have shown that thermal therapy is effective for stroke patients (focused on upper limb functional recovery). Known as *thermal stimulation*, it has shown to enhance sensory and motor function recovery. The key seems to be the activation of motor and sensory function at the same time. Thermal stimulation consists of alternate cycles of heating and cooling.

Another class of treatments that benefit or require skin cooling are laser aesthetic applications. Laser procedures such as hair or tattoo removal involve the direct interaction of the laser with the skin. While the lasers are tuned to minimize the pain, the energy absorbed can be painful. Skin cooling is used to mitigate this pain and enable longer treatment sessions than would otherwise be possible.

Medical Device Cooling

This class of cooling applications includes medical devices that are used with patients where the system, not the patient, requires the cooling. These devices can include lasers, diodes, or electronics that are particularly sensitive to overheating.

Mobile, battery-operated (12 VDC) patient thermal management to reduce core body temperature.



Dual cold plate direct refrigerant system for blood processing.

Laboratory Equipment

PCR is the preferred scientific method for generating a sufficient amount of identical genetic material for study and analysis. The process uses repeated heating and cooling cycles. During the thermal cycles, DNA primers bind to the target DNA sequence, making it possible to produce millions of copies of a DNA sequence in a test tube in just a few hours (see "Further Reading").

Thermal management is a critical piece in the proper storage of blood products and other biomedical supplies. Lab cooling equipment is needed to keep reagents at a definite temperature to remain stable. Many lab products are extremely sensitive to certain high or low temperatures. Many types of lab cooling products are used, including blood bank refrigerators, close loop water chillers, hermetically sealed compressors, and lab refrigerators. Although developments made in lab equipment heating and cooling processes are not often highlighted, they remain a critical factor to the success of clinical laboratories.

New innovations in laboratory systems include wireless monitoring, remote sensors, dual convection technology and advanced microprocessor controls. Today, it is agreed that wireless monitoring systems are indispensable for cooling of laboratory equipment. Scientists and engineers agree that having reliable cold storage with the latest technology protects research and ensures more reliable results.

Conclusion

While cooling medical devices presents unique challenges for the design of thermal management into them, a variety of solutions are available to ensure that they meet requirements — whether the need is to minimize noise or to keep tangled wires and hoses contained. Everything from simple fans or liquid cooling to compact refrigeration systems can help address these challenges.

Part 1 of this article reviewed some interesting thermal cooling applications and their requirements. Part 2, which will appear in a future issue, will examine cooling system choices, including the factors that help determine the best cooling system design for the application.

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Force-Sensitive Resistors:

Making Medical Devices Easier to Use

For many of us, life is complicated enough without having to be constantly reminded about our medical situations. Living with a disease that requires frequent doctor visits and rigorous treatment processes does not just take a physical toll on the patient — making significant lifestyle changes can be a mental battle itself. This is why medical device design engineers are all faced with a challenging but noble task: to develop effective, minimally invasive treatment technologies that allow patients to live a normal life.

As recent trends in therapeutic and drug-delivery devices have shown, patients generally prefer treatment methods that give them more control and freedom. According to a 2017 "Markets and Markets" medical device report, home-use insulin delivery devices are expected to reach $17.85 billion (USD) by 2021 — exceeding the current market by around 9.1 percent. A major reason for this projected growth comes from technological advancements in insulin-delivery devices, many of which now put patient experience at the forefront of the design.

However, devices to treat diabetes only represent one category of the grander therapeutic and drug-delivery device market. More and more patients with medical conditions ranging from arthritis to multiple sclerosis are electing to use self-injectors, wearable auto-injectors, and other home-use therapies for their treatments. Device simplicity, convenience, and portability are key attributes that often factor into a patient's decision to choose one treatment method over another.

The Role of Force in Therapeutic and Drug-delivery Devices

Most therapeutic and drug-delivery devices, in some way, require a change in force to function. This change in force is either made manually by the patient, or made automatically by the device. For some devices, having the ability to capture and/or monitor these changes in force can streamline or automate certain processes and make the device smarter. Therefore, embedding force-sensing technology into therapeutic and drug-delivery devices can go a long way in addressing patient needs.

As with embedding any kind of new technology into an already compact device, embedding force-sensing technology into a medical device requires striking a balance between functionality and flexibility. The challenge then becomes selecting the right force-sensing technology to innovate the device without adding more burden to the end user.

A Comparison of Force-Sensing Technologies

Ease of integration, sensing component size, and power efficiency are always top of mind for medical device design engineers. However, depending on the type of force feedback the device is capturing, some embedded force-sensing technologies may be better choices than others.

Load cells, strain gauges, and piezoresistive sensors are the most common force-measuring technologies used in medical devices today. Load cells are the most well-known force sensor and offer the highest precision among the other force sensor types. Due to their large size, weight, and significant power requirements, load cells may not be as practical to embed as other options.

Strain gauges yield measurements that are the result of an indirect force measurement drawn by correlating the strain of a small wire to an assembly load. Although strain gauges are a small and thin force-sensing alternative, they are

Because most therapeutic and drug-delivery devices require a change in force to function, capturing this force feedback can help drive a wireless communication network between patients and physicians.

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often powered with complex, expensive electronics, which can add difficulty to the design-in process.

Piezoresistive sensors — or touch sensors — consist of semiconductive material sandwiched between two flexible polymer substrates. A touch sensor acts as a force-sensitive resistor in an electrical circuit. When a force is applied to the sensor, its resistance decreases. This resistance change can be customized to trigger another action by the device.

Touch sensors may not have the precision of a load cell or a strain gauge, but they are effective methods to measure force or contact between nearly any two surfaces. They are thin, flexible, and require less power to function than load cells or strain gauges. Also, touch sensors are quite customizable to conform to, or around, specific areas of a device to capture force changes wherever needed.

Examples of Touch Sensors Embedded in Therapeutic and Drug-Delivery Devices

Application Example 1: **Monitoring Performance of Automated Pumps.** Even the slightest change in force can be an indicator of a significant performance issue within a drug-delivery system. For automated drug-delivery pumps, it is extremely important to design for a way to detect potentially life-threatening blockages that can build up over time. When blockages occur, there is typically an increase in pressure within the delivery tube that causes the tubing to expand.

Embedding touch sensors into specific areas where the infusion pump's tubing meets the housing can be used to help detect expansions. If the sensor captures a change in pressure on the tubing, an alarm on the device would be triggered to alert the patient to a possible blockage, and to seek assistance. These same principles can also be applied to other infusion pumps or devices designed for operation by medical professionals in settings such as hospitals or hospices.

Application Example 2: **Aiding Administration of Micro-Needle Therapy.** Naturally, drug-delivery methods that cause less pain to the patient will certainly factor into their willingness to accept treatment. Transdermal micro-needle drug-delivery methods are beginning to emerge as a viable alternative to deliver complex biologics or vaccines for patients who may be uncomfortable giving themselves injections.

Embedding touch sensors into a high-pressure micro-needle drug-delivery device can enhance the device in a few different ways. In one application, sensors designed around the delivery areas of the micro-needle could help ensure complete and thorough administration of the micro-needle patch onto the patient. Sensors can also detect occlusion and measure the position of the device in relation to the subject. As this category of drug-delivery devices continues to grow, devising ways to make micro-needle administration devices smarter will be critically important.

Application Example 3: **Ensuring Safe and Accurate CPR Treatment.** Accuracy and consistency are vital to all types of therapeutic treatment — no matter whom or what is delivering the therapy. Touch sensors can be used to mediate human error and confirm a successful therapeutic administration process.

It is always a chaotic situation whenever a patient is struggling to breathe and needs CPR. When a life is on the line, there's little time for CPR administrators to consider whether they are applying too much or too little compression force to the patient. Because of this, a force-sensitive CPR assistive device was developed to help quantify that force is applied in a safe, consistent manner. Force sensors embedded into pads and connected to a small digital monitor could measure the amount of force made by the administrator, instantly alerting the administrator if adjustments need to be made. This type of application can also be used to train emergency personnel on proper CPR technique.

Application Example 4: **Providing Actionable Data for Connected Devices.** The term Internet of Things (IoT) is a hot topic within most engineering communities, and especially so in the medical device market. The term is broadly defined as a Web-based network of smart devices effectively communicating with one another with little or no direct human interaction. Sensors of all kinds function as the touchpoint to provide data that can be used to trigger communication among other smart devices.

From a medical device perspective, embedding capabilities for physicians to monitor their patient's health and treatment while they are on the go is an important IoT-style concept that touch sensors can help make a reality. Embedding sensors onto devices to count the amount of dosages made by a patient, or to monitor the amount of medicine available in the device, could be a driver for a powerful wireless communication system between the patient and their physician.

Smart, simple, and compact therapeutic and drug-delivery devices are becoming preferred choices for treatment over traditional methods.

With each force impact — either done automatically by the delivery device, or made manually by the patient — a digital, real-time signal could be sent to the physician to review exactly how the patient is using the device. Based on the data, the physician could then make suggestions to increase or decrease the patient's dosage frequency, or even automatically schedule a medicine refill with the patient's pharmacist, all without needing to schedule an office visit.

Questions to Consider When Embedding Force-Sensing Technology

Considering how challenging and time-consuming it is to advance a medical device through the regulatory approval process, it is important to be efficient while in the prototyping and design-in process. Making the right investment in a force-sensing technology, and using third-party resources to ensure a successful integration process, will keep your device design on a clear path to success. Here are a few questions for design engineers to ask themselves when considering embedding force-sensing technology:

- What patient usability challenges can we solve by capturing changes in force, or force impacts on the device?
- Will the chosen force-sensing technology require too much power or space to keep the device functional?
- Is there a specific force range, or is there some leeway in how precise the sensing technology needs to be?
- Is the force sensor supplier a qualified, ISO 13485-certified company with a history of working with medical device companies?

The ultra-thin, flexible nature of touch sensors offer design engineers new opportunities to address key user needs.

Today more than ever, patient preference should to be top of mind when developing therapeutic and drug-delivery devices. As this article has shown, touch sensors offer many different applications to answer patient demands for simple, smart methods that can be used by the broadest population of users. Now, how will your device deliver?

This article was written by Mark Lowe, Vice President of Sensors for Tekscan, South Boston, MA. For more information, visit ***http://info.hotims.com/69503-162.***

Highly Sensitive Optical Fiber Pressure Sensors with Potential for Cardiology and Other Medical Applications

Optical fibers. To the average person, the phrase might conjure up an image of glowing hairs twisted artistically into a beautiful shape or fountaining out of a lamp holder. But these light-transmitting silica strands are much more than decoration. Since the initial development of optical fibers in the 1950s, applications have evolved and now include power transmission, communication, imaging, and sensing.

Specifically, they are often used in situations where other sensing techniques can fail. Optical fibers are dielectric, versatile, and with minimum volume, they can be used in environments such as electricity transmission towers, explosive atmospheres, and on the ocean floor, as well as in medical applications.

From Fiber Optics to Pressure Sensors

Standard optical fibers are designed to act in telecommunications setups and, usually, are not useful for sensing purposes. In order to make optical fibers sensitive to a parameter of interest, processing procedures such as the imprinting of fiber gratings are necessary, or specialty microstructured optical fibers can be employed. Microstructured fibers show promise for obtaining highly sensitive pressure sensors used in activities such as medical applications, where technicians and engineers can use them to detect fluid pressure. Figure 1 presents some examples of optical fibers that can act as pressure sensors, as reported in the literature.

Typically, microstructured optical fibers for pressure sensors are configured so that the application of an external load causes an asymmetric stress distribution within the fiber cross section. This, in turn, causes variations in the fiber birefringence — a material property referring to an optically anisotropic refractive index — which can be used for sensing purposes.

"Advantages of optical fiber-based sensors include high sensitivity, electromagnetic immunity, and the possibility of functioning in harsh environments," says Jonas Osório from the Universidade Estadual de Campinas (UNICAMP). "They are usually very compact, lightweight, and provide great liberty when choosing a sensor's characteristics."

But the fiber pressure sensors reported to date have sophisticated microstructures and usually require several drawings and a delicate manual procedure for assembling the structure. At UNICAMP and at the Instituto de Estudos Avançados (IEAv) in Brazil, work is being done to develop a different type of an optical fiber — an embedded-core capillary fiber — that can act as a highly sensitive pressure sensor. This type of fiber requires a simpler fabrication process that involves a preform preparation method and direct fiber drawing.

A Closer Look at Geometric Characteristics

The embedded-core capillary fiber is a silica capillary tube endowed with a germanium-doped region (the fiber core)

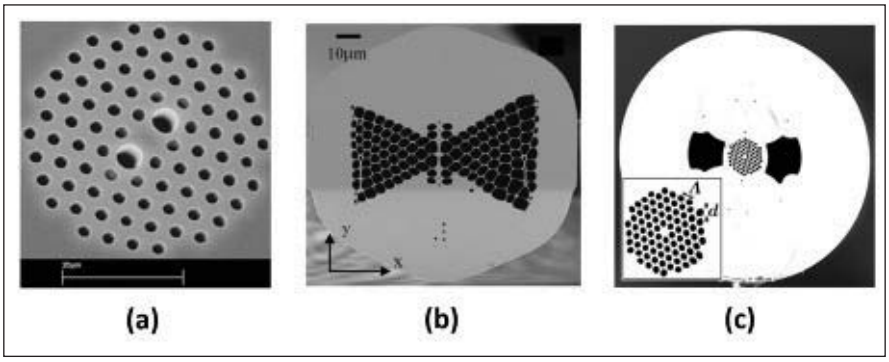

Fig. 1 – Microstructured optical fibers used in pressure sensing measurements. Photonic-crystal fiber (a)[1]; microstructured fiber with a triangular lattice of holes (b)[2]; side-hole photonic-crystal fiber (c)[3].

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placed inside the capillary wall (Figure 2 shows representations of the fiber structure and cross section). The newly developed embedded-core fiber is much simpler than the typical microstructured fibers employed in pressure sensing applications.[4]

The research investigated pressure-induced birefringence in microstructured fibers in order to develop and validate a new design concept. It focused on fibers designed to sense hydrostatic pressure — pressure induced by a fluid at rest, such as a body of still water surrounding the sensor. However, the research diverged from existing designs by using capillary fibers (very thin, hollow tubes) instead of solid conventional fibers or structures with a complex air hole pattern.

The goal was to maximize the birefringence dependence on pressure variations, since this would improve the sensing capabilities of the fiber. Beginning from an analytical model, the researchers studied pressure-induced displacements and mechanical stresses in the capillary walls (see Figure 3).

The analytical model showed that applied pressure generates an asymmetrical stress distribution inside the capillary wall due to the capillary structure. Via the photoelastic effect, these stresses cause variations in the material refractive index that are different along the horizontal and vertical axes, generating the desired birefringence.

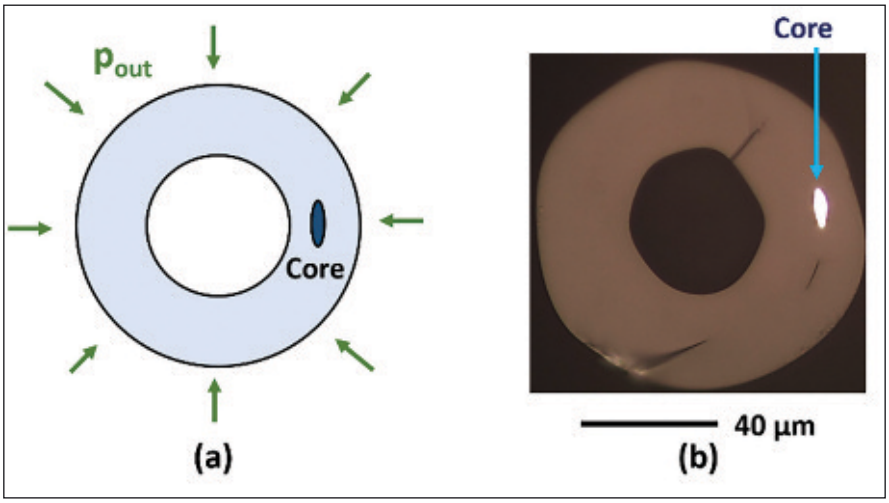

Fig. 2 – Concept of embedded-core capillary fiber, showing a cross-section of the tube with an embedded core, under hydrostatic pressure (a). Embedded-core fiber cross-section (b).

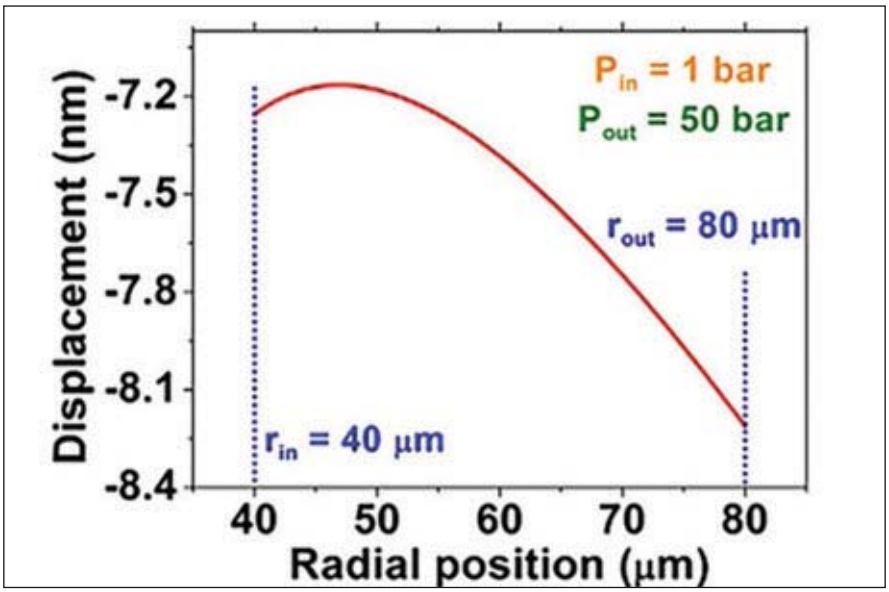

Fig. 3 – Study of a pressurized capillary fiber without the embedded core, under pressure. The displacement profile was initially studied for an inner radius of r_{in} = 40 µm, an outer radius of r_{out} = 80 µm, an inner pressure p_{in} of 1 bar, and an outer pressure p_{out} of 50 bar.

Maximizing Pressure-Dependent Properties

Using COMSOL Multiphysics® software, the elliptical core — a germanium-doped region inside the silica capillary wall — was added to the mathematical model. Through simulation, the change in modal birefringence as a function of the applied pressure and the location of the core in the capillary wall was obtained (see Figure 4). Modal birefringence describes birefringence of the optical modes that can travel through the fiber core.

The model calculated the effective refractive indices of the fundamental mode for different pressure conditions. This mode occurs when incoming electromagnetic waves are guided through the fiber core. To make the birefringence as dependent on pressure as possible and therefore maximize the sensitivity of the sensor, it was necessary to embed the core area completely within the capillary structure, close to the inner wall. Analyzing the changes in stress distribution for different geometries showed that the birefringence variation derivative with respect to pressure values was higher for fibers with thinner walls and for positions closer to the inner radius of the capillary.

Microstructured Optical Fiber Sensors for Medical

The new sensor's resolution limit is estimated to be 0.3 bar for a nonoptimized fiber structure. Even with this nonoptimized resolution figure, this configuration may allow the realization of pressure measurements for cancer treatment since the pressure level in this application field may vary within the interval between 0 and 2 bar.[5]

Additionally, the simulation results showed that it is feasible to increase the sensor sensitivity by a factor of six (via optimization of the geometric parameters of the fiber; e.g., the capillary wall thickness and the core position within the capillary wall. Therefore, the resolution limit could be reduced to 0.05 bar, which would make the sensor suitable for cardiology and urology applications. Furthermore, the optical fibers are minimally invasive, and they potentially could be made of biocompatible materials.[6]

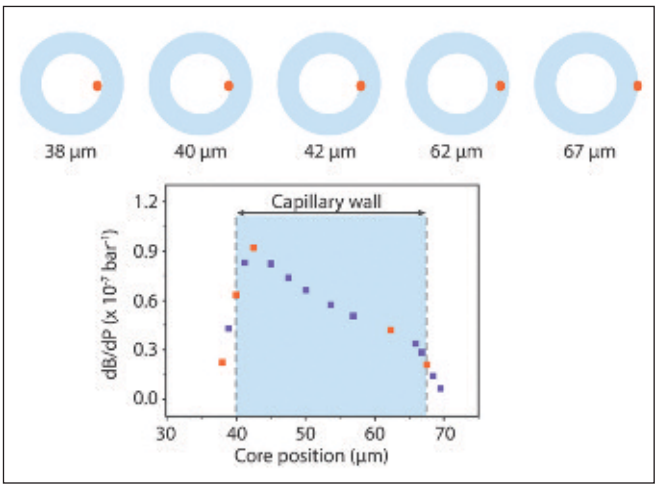

Fig. 4 – Changes in modal birefringence as a function of the position of the germanium core within the capillary wall. The case with the highest changes in birefringence due to pressure variations occurs when the core is very close to the inner radius of the fiber (top center case).

Conclusion

Understanding birefringence pressure dependence enabled simplified production of microstructured optical fibers and confirmed that the design would perform properly as a pressure sensor. Comparing the sensitivity of the new concept to existing, more complicated fiber structures showed that the new design produced similar results but required less assembly work.

The embedded-core fiber provides a new route for obtaining highly sensitive optical fiber pressure sensors, which will make it easier for medical practitioners to evaluate the fluids they extract in real time. The embedded-core fiber presents a new route toward the simplification of optical fiber-based pressure sensors. It is much simpler than typical microstructured fibers, and the highly sensitive sensors are potentially suitable for a number of medical applications, including cardiology, urology, and cancer treatment.

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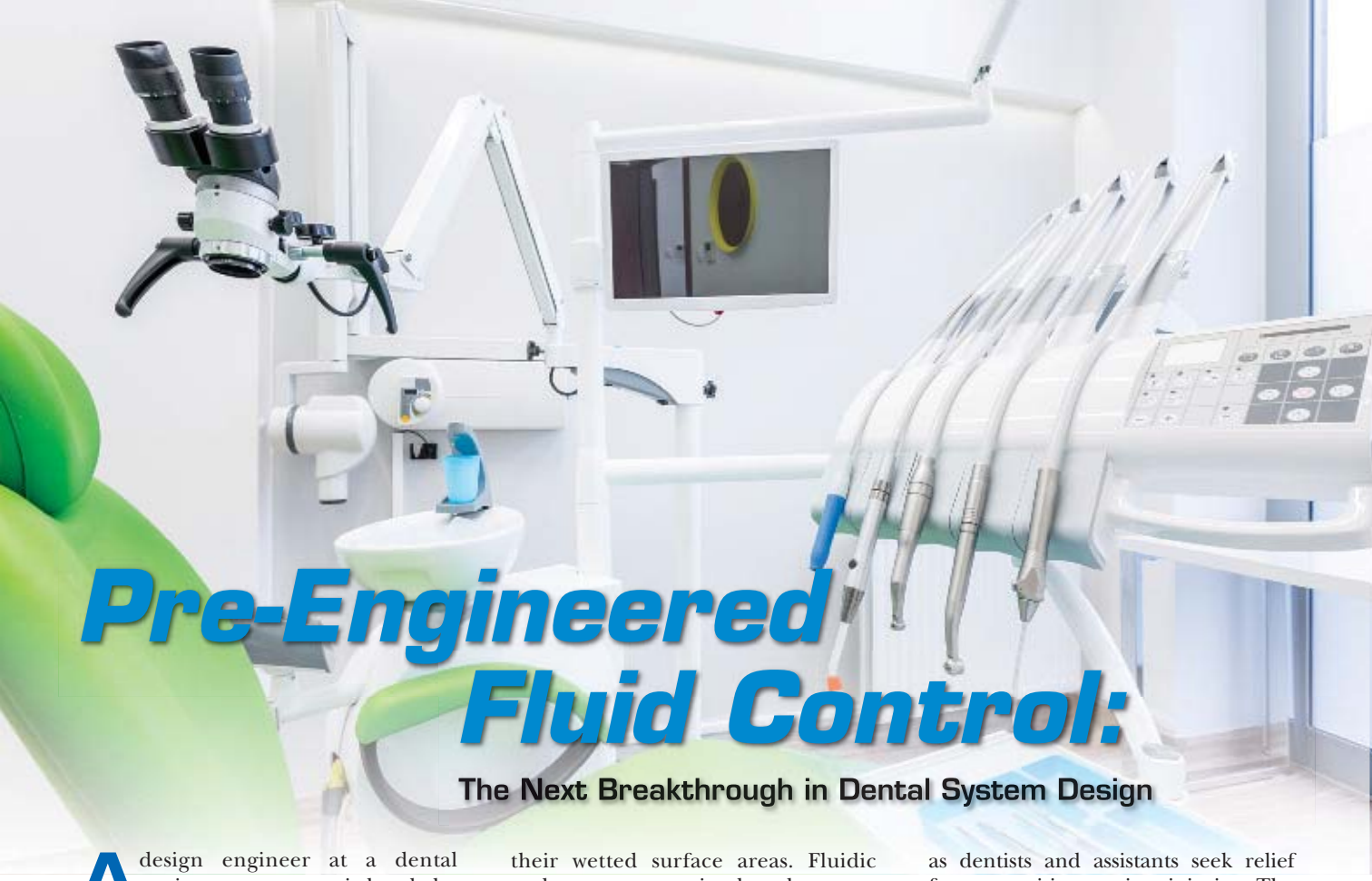
This article was written with the help of the Brazilian researchers Marcos A. R. Franco from the Instituto de Estudos Avançados (IEAv) and Jonas Osório and Cristiano M. B. Cordeiro from the Institute of Physics at Universidade Estadual de Campinas (UNICAMP). The research team also included Valdir Serrão from IEAv and Giancarlo Chesini from UNICAMP. For more information, visit ***http://info.hotims.com/69503-161****.*



Pre-Engineered Fluid Control:

The Next Breakthrough in Dental System Design

A design engineer at a dental equipment company is handed a challenging assignment. The firm's development team must devise a suite of products that includes a new dental delivery system. The system's improved ergonomics and compact nature will require the engineer to redesign its fluidic path. And the new suite of products must be ready for market introduction in nine months.

That's a challenge that haunts many medical and dental equipment design engineers. The dental delivery system is a key element in the practice suite — supplying air and water to the dentist's hand tools. It must have efficient and reliable fluid control to permit effective operator performance and patient comfort.

In the past, the engineer could have adapted a legacy fluidic path design to meet the needs of the new delivery system's specifications. However, a host of demands are driving significant changes in fluid control design.

- A U.S. Safe Drinking Water Act (SDWA) amendment went into effect January 4, 2014, that lowered the lead content of plumbing fittings and fixtures used with potable water to not more than a weighted average of 0.25 percent of their wetted surface areas. Fluidic path components in dental systems must comply with these regulations.
- Dental suites are getting smaller, driving equipment and delivery systems to more compact sizes that require miniaturized fluid control components.
- Dental practices are embracing more stylish and pleasing environments that address the psychological needs and comfort of patients. These include sleeker, more elegant, and refined delivery system armatures, controls, and tools.
- Improved equipment ergonomics has emerged as an important design issue as dentists and assistants seek relief from repetitive motion injuries. The result has been the development of new over-the-patient and rear dental delivery configurations.
- Product development cycles are getting shorter. Times to market are shrinking from years to months, leaving less time for engineering and qualification work.

Designing an all-new fluidic path — plus qualifying and sourcing its components — has been a complex undertaking that requires considerable engineering time.

In response, engineers are beginning to embrace a promising new design

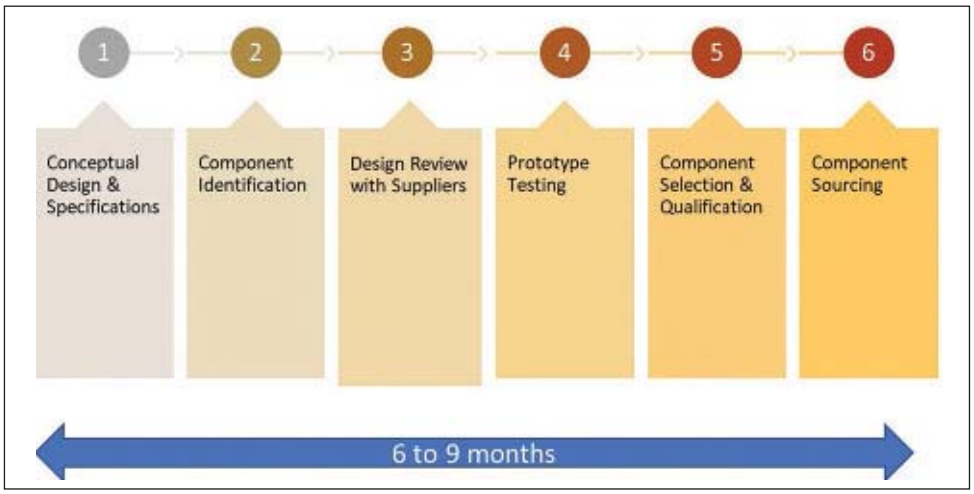


Fig. 1 – Traditional fluidic path design workflow.

strategy — pre-engineered fluid control. These plug-and-play modules simply drop into the delivery system and incorporate integrated fluidics that fulfill the needs of virtually any design. They reduce system complexity and dramatically speed up the development process.

Delivery System Fluid Control — What's Inside?

It's beneficial to understand the components that make up a dental delivery system's fluidic path. These devices regulate the volume and pressure of the hand tool's air, suction, and irrigation media. They also control the pneumatic air that drives the system's rotary tools.

The key components of the typical fluid control system include the following types of miniature devices:

- Liquid isolation valves control dental irrigation and flushing. Hermetic separation of the control mechanism and the fluid ensures maximum water purity and minimizes the formation of limestone on internal parts. This drastically reduces the need for cleaning and maintenance.
- General service valves control the air and suction functions. They turn the air or vacuum on or off.
- Proportional valves regulate the speed of the rotary tools. Controlled by a foot-pad, the valves proportionally adjust the pneumatic air that drives the tools' turbines.
- Manifolds hold the valves that control the system's air and water. They also incorporate the fittings for tube attachment.

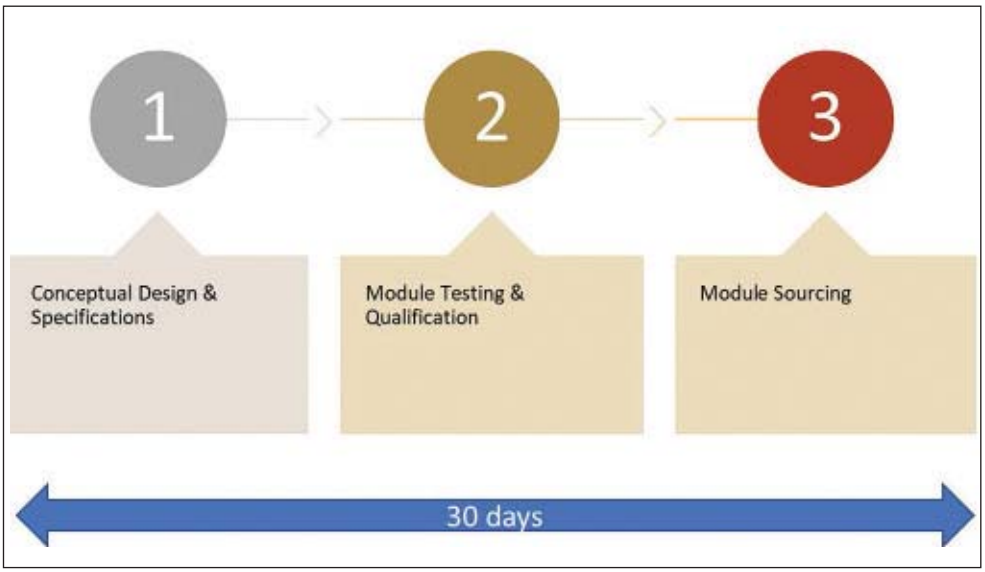


Fig. 2 – Fluidic path design with pre-engineered assemblies.

- Flow controllers allow the user to adjust the flow of the media.

Traditional Fluid Control Design Requires a Custom Approach

Traditionally, when a dental delivery system demanded a new fluidic path, the engineer developed a custom design. This approach calls for a highly iterative product development process with considerable interaction between the original equipment manufacturer (OEM) and its suppliers. However, valve suppliers' lack of dental application knowledge left OEM engineers with limited technical support. As a result, designing an all-new fluidic path required substantial amounts of time and money.

The typical workflow to design and develop a new dental delivery system's custom fluidics involves the following steps (see Figure 1):

- Conceptual design: this step begins with the development of a fluidic path that integrates with the new dental suite. The delivery system's functional capabilities and specifications must be determined.
- Component identification: the types of components are identified that fulfill the functions required by the fluidic path. This work includes selecting material types approved for dental application, determining valve sizes and fluidic channel lengths that optimize efficiencies and flow rates, mating valves with manifolds, and developing component specifications.
- Design review with suppliers: fluidic path design and specifics are shared with component suppliers. Product samples are procured for flow rate testing.
- Prototype testing: fluid control system prototypes are assembled and tested to determine proper fit, channel efficiencies, and life cycle expectations for individual components.
- Component selection and qualification: final components (valves, manifolds, flow controllers, fittings, and tubing) are chosen and qualified. Proper regulatory approvals are confirmed.
- Component sourcing: manufacturers are selected, prices are negotiated, quality is validated, and products are shipped.

While the customized approach results in a solution designed for a specific dental delivery system, it is a time-consuming process that can require from 9 to 12 months to complete. Different manufacturers build the valves, manifolds, and flow controllers — adding supply chain complexity. Plus, the components require configuration and integration work that adds considerable time to the process.

The Breakthrough: Pre-engineered Fluid Control

An alternative to custom design is now available to dental system designers. Pre-engineered fluid control eliminates the OEM design work that adds time and cost to dental equipment development. This approach follows a trend in the broader medical device market where fluid control manufacturers are offering pre-engineered assemblies that contain customizable packages of valves, manifolds, and fittings.

The pre-engineered modules are sized and configured by the fluid control

manufacturer to the typical specifications and materials required for dental delivery systems. For example, pressure ratings range from 0 to 6 bars for general service valves and 0 to 3 bars for water isolation valves. The modules' solenoids can accept 12-V, or 24-V DC power. Seals are made of ethylene propylene diene monomer (EPDM) rubber that resists contamination.

Pre-engineered fluid control modules are flexible and have valves that can control all types of fluidic channels — air for drying or suction, liquid for irrigation, and pneumatic air for drills and rotary tools. (Credit: Emerson)

Dental equipment OEMs can easily integrate these off-the-shelf, plug-and-play fluid control modules into their designs. The assemblies are pre-qualified for dental applications and are manufactured in a ISO class 8 equivalent clean room.

In the past, a manifold module could control only one type of fluidic channel. This resulted in a complex design scheme that required multiple space-consuming devices. In contrast, a pre-engineered module is flexible and can control all types of fluidic channels — air for drying or suction, liquid for irrigation, and pneumatic air for drills and rotary tools. Each module can support three fluidic channels, and up to four modules can be mated in a system to support a total of 12 channels. For example, one manufacturer is offering three types of pre-engineered modules.

- One configuration incorporates two channels for general service valves controlling the air and suction channels, and one channel for an isolation valve that regulates irrigation water.

- Configuration two includes one channel for each of the three valve types: liquid isolation, general service, and proportional.
- Configuration three has a channel for one liquid isolation valve plus two open ports that allow the OEM to add additional fluidic path functionality to the dental delivery system.

As a result, there is an almost unlimited amount of functionality available to the designer. In addition, the modules can be modified to meet specific OEM requirements.

The compact pre-engineered modules enable OEMs to provide a significant range of options that accommodate the diversity of tools required by dentists. These include pneumatic rotating tools with interchangeable tool heads for brushing, polishing, and cutting; water spray tools for wetting and cleaning teeth; air-spray tools for drying the teeth and blowing away debris; and vacuum suction tools to remove debris and liquid waste. Each module's channels have their own manual flow controllers that allow fine tuning for maximum performance. In addition, barbed brass ports used for hydraulic and pneumatic connections reduce assembly time.

Pre-engineered fluid control enables OEMs to easily provide options that accommodate the diversity of tools required by dentists. (Credit: Emerson)

The new pre-engineered approach brings multiple benefits to dental equipment designers. Since the fluidic path comes as a single unit, engineering time is eliminated (see Figure 2). Modules can be selected, qualified, and installed in 30 days. This enables OEMs to get dental delivery systems to market faster, and reduces design cost and the nonrecurring engineering expense associated with tooling.

Conclusion

Dental industry trends, patient demands, and government regulations are changing the size, functionality, and materials of dental delivery systems. OEM engineers can no longer rely on legacy fluid control designs for the systems of the future. New fluidic paths must be developed to meet the pressures and trends of the market.

Using a traditional custom design approach for fluid control development is a time-consuming and expensive process. OEM engineers are turning to a promising alternative — pre-engineered fluid control. These highly flexible, plug-and-play modules enhance functionality, eliminate design time and engineering, dramatically reduce cost, and accelerate times to market.

This article was written by Tony Gaglio, Emerson Product Marketing Manager for ASCO, Novi, MI. He has 20 years of experience in the analytical and diagnostic instrumentation industry. For more information, visit ***http://info.hotims.com/69503-160****.*

Considerations for Specifying Ultra-Engineering Polymers for Extruded Medical Applications – Part 2

With the shift in the medical industry to more minimally invasive, quicker, and more effective procedures, the goal is to minimize patient recovery times, reduce access incision sizes, and provide better patient outcomes through advanced medical procedures. This necessitates new medical devices that tend to be more demanding of their components than in devices past. This requires medical devices and their components to use advanced polymers. Many of these advanced materials fall under the general description of high heat polymers.

As noted in Part 1 of this article (January 2018), ultra-engineering polymers fall under the general classification of engineered polymers, yet they are at the pinnacle of performance for all thermoplastics. Ultra-engineering polymers bridge the performance gap between standard engineering polymers, such as nylon and polycarbonate; and metals, composite materials, and thermoset plastics like polyimide (see Figure 1). Their description of "high heat polymer" indicates not only that these materials are processed at higher temperatures, typically between 600° and 750° F+, but that they subsequently, also have high continuous operating temperatures, most well over 300° F.

Ultra-engineering polymers have very good chemical resistance, which makes them ideal for the hospital environment and the many harsh chemicals and drugs to which plastics can be exposed. The physical properties of ultra-engineering polymers also outperform all other standard engineered polymers in the areas of tensile strength, flexural strength, and impact resistance. Additionally, these materials have good dielectric properties and have some level of inherent flame resistance without additives. All the materials to be discussed in this article have USP Class VI and ISO 10993 approvals, and some have permanent implant-approved grades as well as MAF support.

All the materials listed here are suitable for the extrusion of profile shapes, multilumens, microbore tubing, large diameter tubing, thin wall tubing, rods, and filament. All can be compounded with additives, radiopacifiers, colors, and reinforcements but will have some limitations due to their high processing heats. Additionally, due to their high processing temperatures, tooling and processing equipment need to be specialized to withstand these high heats. Part 1 of this article focused on PEEK, PAEK, PEKK, FEP, and LCP. Part 2 focuses on amorphous polymers: polyphenylsulfone (PPSU), polysulfone (PSU), polyether sulfone (PESU), and polyetherimide (PEI), as well as some additional ultra-engineering polymers.

Amorphous Polymers

The remainder of the ultra-engineering polymers — PPSU, PSU, PESU and PEI — to be discussed are all amorphous and range from transparent to clear in appearance (Solvay Specialty Polymers 2016). An amorphous polymer does not have a distinct melting point and has no crystalline structure (see Figure 2).

PPSU

PPSU has the highest heat resistance of all the sulfones and PEI. PPSU has a continuous operating temperature of about 400° F, which allows it to handle some of the same high heat applications as PEEK. PPSU is very hydrolytically stable, which enables it to excel in high heat and humidity environments. PPSU is highly chemical resistant to all hospital solvents and wipe down chemicals (Solvay Specialty Polymers 2015) and also can withstand 100 or more cycles of all sterilization methods as well as 1000+ cycles of steam sterilization (Solvay Specialty Polymers 2015).

These properties, along with its transparency, allow this material to also bridge the gap between one-time use and durable devices where the ability to see the placement or position of catheters or endoscopy tools, or the flow of fluids is critical to the functionality of the device and procedure. PPSU has very high ductility, which is quantified by the lowest

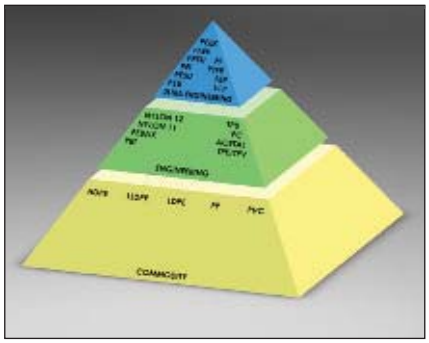


Fig. 1 – This pyramid illustrates the classification of various polymers. Ultra-engineering polymers fall under the general classification of engineered polymers, yet they are at the pinnacle of performance for all thermoplastics.

tensile and flexural strengths of all the materials discussed in this article. This high ductility positions this material as a candidate for steerable catheters and catheters that need to follow torturous paths through the body while still having need of high heat and chemical resistance. Permanent implant grades of PPSU are available for applications such as wire lead coatings, fluid transfer, and orthopedics (Solvay Specialty Polymers 2015).

PPSU is transparent, which means it can be colored with transparent tints to cover its natural transparent amber color. PPSU can be thermally formed for catheter applications as well as RF welded and reflowed, providing for easier assembly and connection methods for device and catheter assemblies. PPSU has the highest raw material costs of these amorphous materials, but it is still less expensive than PEEK. PPSU has a transparent amber appearance, which may not be aesthetically pleasing for some users. However, the amber color appears less pronounced in thin-wall and micro-bore configurations. This transparent amber color can limit how well it can be colored, especially with light colors, and may affect how vibrant bright colors may appear. The high processing temperatures of PPSU can also limit which colors and additives can be used because not all are thermally stable at those high heats.

PSU

The strength and toughness of the amorphous materials start to increase from this point forward. PSU is a high-strength sulfone material with greatly improved clarity over PPSU. PSU has the lowest continuous operating temperature of all these high heat polymers at about 340° F, but it is still considerably higher than other common engineered polymers. PSU has good chemical resistance to many hospital chemicals (Solvay Specialty Polymers 2015) and is hydrolytically stable for hot and humid environments (Solvay Specialty Polymers 2015). It can withstand 40 kGy of gamma sterilization and up to 100 cycles of all other sterilization methods (Solvay Specialty Polymers 2015).

PSU can be a choice for a durable component but it doesn't have as long of a life span in some environments as

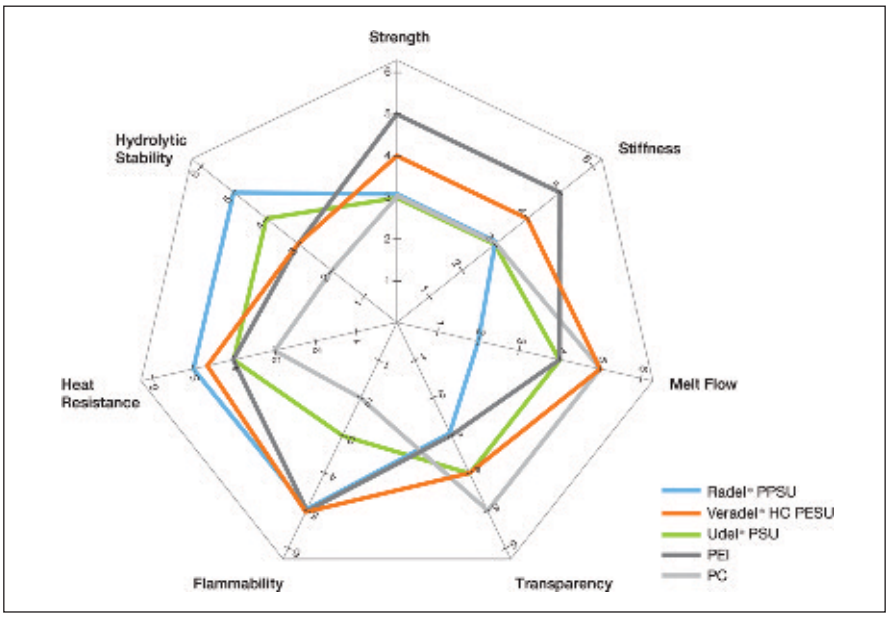


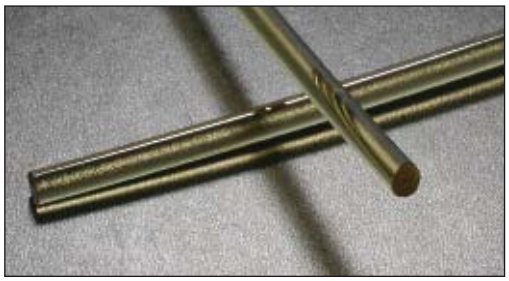
Fig. 2 – Amorphous ultra-engineering polymers such as PPSU, PSU, PESU, and PEI have no distinct melting point and no crystalline structure.

the other materials covered in this article. PSU's properties position it as a great, higher-end replacement for polycarbonate. PSU has better chemical resistance, higher hydrolytic stability, and much higher temperature resistance than polycarbonate (Solvay Specialty Polymers 2015).

Even though PSU can have a slight yellowish tint to it, PSU still has good clarity, which allows for a wider variety of colors and tints, while most grades of medical polycarbonate need to have a noticeable purplish tint to them to compensate for color shifts during gamma sterilization.

PSU has good ductility and better toughness. PSU is a good option for dental tools and components because of its toughness and hydrolytic stability. PSU comes in permanent implant grades that are not suitable for structural components but can be used in applications where ductility, strength, toughness, and clarity are necessary.

PSU can be thermally formed for catheter applications and can also be RF welded and reflowed, providing for easier assembly and connection methods for device and catheter assemblies. Raw material prices for PSU are moderate, about 50–75 percent higher than polycarbonate and similar to prices for PEI and PESU.



PEI, commonly known by the brand name Ultem, is the highest strength polymer of the amorphous materials.

Some of the limitations of PSU include the following: it has decreased sterilization and chemical resistance compared with the other ultra-engineering polymers that are discussed here. And, because of its higher processing temperatures, some colors and additives can be limited because not all of those components are thermally stable at such high heats. PSU also has lower tensile and flexural properties than PESU and PEI but are higher than PPSU.

PESU

Another member of the sulfone family that has high potential for use in medical applications is PESU. PESU has the highest tensile and flexural strength of the sulfones discussed in this article. It also has excellent clarity. PESU has better chemical resistance to hospital solvents and disinfectants and has good hydrolytic stability (Solvay Specialty Polymers 2014). In combination with PESU's continuous operating temperature of about 390° F, these properties make it a good candidate for harsh applications where high strength and clarity are needed for applications such as sight windows and patient access components where being able to see fluid movement, and device location and position are necessary.

Because of the stiffness and hardness of PESU, it has good pushability and torque properties that can potentially eliminate braiding and other reinforcement methods in some applications. PESU has just a slightly decreased phys-

ical and thermal properties compared with PEI, which makes it a good option for replacement of PEI while adding greatly improved clarity. PESU is also an option as a much higher performing alternative to polycarbonate with greater physical, thermal, and chemical properties and with only the slightest yellowish tint. But as stated earlier, polycarbonate needs to be tinted noticeably purplish to compensate for color shifts during gamma sterilization while PESU does not retain its clarity during all sterilization methods.

PESU can be thermally formed for catheter applications as well as RF welded and reflowed providing for easier assembly and connection methods for device and catheter assemblies. Raw material prices for PESU are moderate, and similar to prices for PEI and PSU.

PESU can withstand 4 megarads of gamma, greater than 1000 steam sterilization cycles, and 100 or more cycles of the other major sterilization methods (Solvay Specialty Polymers 2016). PESU is susceptible to environmental stress cracking due to exposure to certain families of solvents that can be present in the hospital environment (Solvay Specialty Polymers 2016). PESU has slightly lower tensile and flexural properties than PEI.

PEI

PEI is the final ultra-engineering material discussed in this article. PEI is commonly known by the brand name Ultem. PEI is the highest strength of the amorphous materials covered here, with higher tensile strength, flexural strength, and hardness than all of the sulfones. PEI's continuous operating temperature is about 390° F (Saudi Basic Industries Corporation [SABIC] 2016) and is hydrolytically stable, as well as having better chemical resistance to many hospital solvents and disinfectants (Saudi Basic Industries Corporation [SABIC] 2014).

These properties allow PEI to be used in durable products such as device sheaths, access devices, and sterilization tray dividers and supports. Because of PEI's strength and durability, it is also suitable for dental tool parts and fixtures. PEI can withstand greater than 1000 steam sterilization cycles, and it is suitable for gamma, ethylene oxide, and vaporized hydrogen peroxide sterilization processes (Saudi Basic Industries Corporation [SABIC] 2014). PEI also has excellent color stability through hundreds of sterilization cycles (Saudi Basic Industries Corporation [SABIC] 2014).

PEI can be thermally formed for catheter applications as well as RF welded and reflowed, providing for easier assembly and connection methods for device and catheter assemblies. Raw material prices for PEI are moderate, and similar to prices for PSU and PESU.

PEI has a transparent amber appearance, which may not be aesthetically pleasing for some users. This transparent amber color can limit how well it can be colored, especially with light colors, and may affect how vibrant bright colors may appear. PEI is attacked by some solvents that may be present in the hospital environment, and this attack can be exhibited by environmental stress cracking.

Other Ultra-Engineering Polymers

There are a variety of families of ultra-engineering polymers beyond those discussed in this article. These other high heat polymers tend to fall in similar property ranges as those defined by the materials discussed here. Most of these other polymer families have extrusion grades or grades suitable for extrusion.

These other materials are sometimes formulated for very specific application types or targeted for certain physical, chemical, or thermal properties and can subsequently have notable processing limitations that can dictate what types of parts and configurations are possible and the types of equipment that are necessary to process them. That is not to say that ultra-engineering polymers other than those listed here should be avoided by any means, because they can fill in and extend the performance gaps of the materials discussed here. Utilizing a processor with experience and knowledge of these other families of materials is key to the success of devices specifying other ultra-engineering polymers.

Metal Replacement

Despite all the high strength physical properties of the materials covered here, they still fall short of the performance of metals such as stainless steel. An ongoing goal for medical device designers and engineers is to find polymer solutions in applications that might typically use metals. Some of the benefits of polymer solutions to metals are lower product lifetime costs, more design and manufacturing flexibility, and a decrease of sterilization risks of multiuse devices.

Some of the challenges related to polymer substitutions for metals is still a relatively large performance gap between ultra-engineering polymers and metals. It is difficult to quantify actual physical needs of a project because of possible overengineering with stainless steel, and stainless is still such a legacy material that it can be difficult to present a polymer as a consideration.

One way that polymers can come very close to stainless steel performance is by adding fiber reinforcements into the polymer. Fiber reinforcement of ultra-engineering polymers increases all physical properties of the base polymer and can even improve thermal and chemical performance. Adding fiber reinforcement to a polymer drastically affects the polymer in multiple ways that need to be considered. The fibers can add unwanted properties to an extrusion because of the properties of the fiber, such as weight and conductivity. The extrusions can have increased stiffness but can seem fragile, especially in thin-wall and small diameter configurations. The fibers can affect surface finishes, but low fiber loadings of 10 percent or less can improve finishes while increasing properties and retaining ductility of the base polymer. Fiber loadings affect the processing and tooling design and require specially designed tooling to manage and compensate for fiber-reinforced ultra-engineering polymers.

Conclusion

Ultra-engineering polymers have added a level of performance that wasn't possible until somewhat recently in the medical device industry. Navigating the properties and differences between ultra-engineering polymers requires those in development and specification roles to gain a new knowledge set.

This article has examined the amorphous polymers: PPSU, PSU, PESU, and PEI. Together with Part 1, which reviewed PEEK, PAEK, PEKK, FEP, and LCP, this article provides a high-level overview of these materials to help designers and engineers gain awareness of the many ultra-engineering polymers that are available for their extruded medical applications.

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Making the Gas Assist Plastic Molding Process Work for Medical Applications

Gas assist molding offers a variety of process and design advantages for medical equipment applications. It produces parts that are smooth and extremely cleanable, while offering increased strength and rigidity, weight reduction, design flexibility, and improved surface finish. Gas assist may also lower production costs by reducing cycle time compared with producing solid sections.

To take advantage of these process and design advantages, it is important to pay careful attention to gas entry and exit locations, select the geometries that will work best with the design, and avoid sharp corners that may lead to weaknesses. Collaborate with a gas assist injection molding specialist who can help design for manufacturability. This article presents useful tips for making tubular structures that are strong, smooth, and cleanable.

Gas Assist Injection Molding Basics

Gas assist injection molding is a process in which a pressurized gas (usually nitrogen) is injected into the molten plastic melt stream (see Figure 1). The gas produces a bubble that pushes the plastic into the extremities of the mold, coring out the part and leaving a hollow tube-like cross section.

Two kinds of parts can be produced by gas assist injection molding. Closed channel parts include tubes, armrests, handles, and frames. Examples of open-channel parts are access covers, panels, shelves, and chassis.[1]

Almost any thermoplastic material can be used in a gas assist application, including polycarbonate, polyphenylene oxide (PPO/Noryl®), polybutylene terephthalate (PBT/Valox), acrylonitrile butadiene styrene (ABS), PC+ABS, polyamide (nylon), and high-impact polystyrene (HIPS), as well as polypropylene, and high-density polyethylene (HDPE).

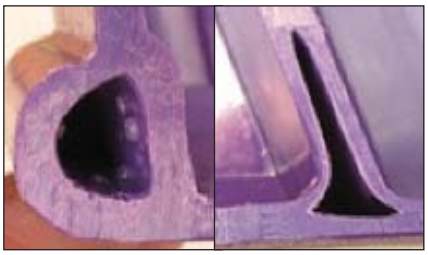
High-end medical housing applications often use materials such as PC+ABS, Noryl, or polycarbonate. These materials are more rigid and look attractive when painted. They have a great finish and solid feel, but of course are much lighter. Nylon is frequently used for canoe paddles due to its overall ruggedness, while handles for many applications are made out of polycarbonate or PBT.

Molding Advantages

The ability to create hollow thick parts, or thick sections within parts, enables production of large ribs and results in a higher stiffness-to-weight ratio in structural parts. It facilitates the molding of large cross sections, which may lead to parts consolidation. The gas assist process pushes plastic against the cavity of the mold, producing an attractive flat finish, eliminating such irregularities as ripples or waves — offering a very smooth surface appearance compared with structural foam.

Dimensional stability is also increased with gas assist injection molding. The uniform packing from within the cavity reduces stress within the part, while also reducing warping and sink marks — indentations or dimples that are caused by thick areas on the front of a part.

Fig. 1 – The gas assist molding process. (Credit: *Injection Molding Gas Assist Technology Guide*, GE Plastics)



These two images show cross sections of parts created with gas assist molding.

Making parts using gas assist injection molding can provide incredible strength to plastic parts. Tubular sections produced are stronger than a flat or even a solid plastic piece. At the same time, the process reduces weight. For example, PSI Molded Plastics, which specializes in injection molded component requirements from large parts to small and from low to high volumes, uses gas assist injection molding to produce a variety of handle designs that reduce the weight by as much as 50 percent compared with traditional injection molding. For parts where maintaining strength is a high priority, gas assist designs can reduce weight by 30 percent and increase strength at the same time.

The process offers a great deal of design flexibility. Instead of a solid tube with a 1-in. diameter, gas assist produces a thin wall that is a tube, with all the material removed from the middle. This gives designers the ability to add thick sections as required and core them using gas assist technology.

Producing Tubular Structures

Gas assist has been around for decades, but its use in medical equipment is growing, since plastic works so well where cleanliness and cleanability are crucial. Manufacturers have to produce tubular structures for medical equipment that are smooth, with no kinks, nooks, or crannies that would make them difficult to clean.

Plastic tends to be easier to clean than sheet metal, especially for tubular structures in which internal areas can be hollowed out. Exercise, rehabilitation, and physical therapy equipment is another good candidate, since it is essential to be able to clean the surfaces of such equipment easily.

The latest entries into the gas assist arena are based on new exotic carbon-filled materials. Customers are taking

Cross sections of gas assist parts.

engineered plastic resin — which is already lightweight — and then using gas assist to make it even lighter. They are also combining the use of gas assist with structural foam (using a blowing agent inside of plastic, which also reduces weight and increases strength) to obtain the advantages of both technologies.

Design Considerations. Here are a few key design considerations to keep un mind during this process. First and foremost, follow these two general rules:

- Do not try to use gas to solve fundamental design problems. Some designs are not going to work.
- Do not split the flow of gas into several different directions because it will be too hard to control. Use one continuous stream.

Gas Entry and Exit Locations. The ideal situation is one in which the gas enters at one end of the part and exits at the other end. Think of the tube as a straw — you want to basically blow the "water" out of the straw to make the tube hollow.

There are other options that also work. The gas can be inserted into the same point as it is vented, akin to blowing a bubble, holding the bubble, and then letting the gas come out from the same location. Another option is to insert a number of gas pins in specific spots to inject the gas.

These spots should be located where there is some kind of thickness problem; inserting the gas there would eliminate the sink mark or blemish that would otherwise appear. Or, one can insert a number of small holes as vents in the back part of the mold, and blow gas in the core side of part, which forces the material against the cavity. These are ways to achieve a clean definition and a nice first surface finish without having necessarily the ideal geometry on the back side.

Typical Geometries. Ideally, design gas channels should be round, or as close to round as possible. The bubble is always going to be round, so it is best to surround it with a round part. They need not be perfectly round — ovals or half-round geometries work well, particularly for reinforcing ribs on the back side of structures. Most handles are designed to be oval for cosmetic or aesthetic reasons. Sometimes, trapezoidal geometries may work; however, these may result in thicker material in the corners, which is usually not desirable.

Sharp Corners and Wall Thickness. Sharp corners should be avoided in gas areas, because the plastic tends to get too thin. Ensure that there is a large enough radius to create a better thickness distribution. Wall thickness can be ¼, or ½ in. thick. Thickness can be changed by varying the gas pressure, or by changing the temperature of the mold or resin.

Gas Assist Molding Success Stories

Gas assist injection molding works very well for medical equipment parts where the outer side is visible to the user and the backside is not visible. The process makes the structure far stiffer than could be done with typical injection molding. Manufacturers can simulate a higher end

Gas Assist Plastic Molding

Gas assist molded handle and cross section.

material by putting the structure on the back side and leaving the visible surface with the desired finish.

PSI Molded Plastics, for example, has experience helping customers successfully use gas assist to solve challenges with medical equipment applications, as well as numerous other industries. In one case, a manufacturer had a long handle with a two-piece clamshell design that was screwed together. The 4-ft tubular handles were expensive and were not aesthetically pleasing, because the two-piece design didn't fit together properly. The gas assist process was used to combine the pieces into one long tubular part, eliminating all the screws and the seam between the two halves. Consolidating it into one piece eliminated the customer's appearance and fit problems.

Gas assist can be a great tool for many medical equipment applications and many designs. Every application is different, and it is important to collaborate with a gas assist injection molding specialist to develop a design that is manufacturable — so the mold and the part do not cost a fortune, and the process will run at a reasonable cycle time. The goal is to design a good part that can be made efficiently and have it look good too.

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Design Controls:

Addressing Changes in ISO 13485

When ISO 9001 was produced by the International Standards Organization, it put forth the general quality standard that organizations could adopt to ensure that the organization is focused on quality, the basic structure is in place, and the product it is offering will be at acceptable levels. That was readily accepted and embraced. For the medical device industry, ISO 13485 specifies requirements for a quality management system where a medical device organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

FDA has always been a leader in the world when it comes to ensuring the safety of medical devices. It has been pioneering regulations to ensure that the medical devices being brought to market are safe. This is a consistent trend; it was the first to offer a Quality System Regulation (QSR), which set the stage for the basic structure for quality that a lot of medical device companies now routinely have in place. FDA demanded that medical device organizations prove that the medical device will do what it is intended to do.

During the research and development (R&D) process, the company would need to break it down by specifications — such as electrical, mechanical, and software and tie them to functional requirements. The company would go through the design process, meeting laid out requirements and specifications, identifying risks, and so on to specify exactly the functional requirements. They would go through the design processes and then address the specific requirements, identify the associated risks and hazards, and apply appropriate risk mitigations.

The end result is to ensure that the patient uses a safe product. The way FDA does this is to have medical device companies think through their processes of developing a medical device. ISO 13485 is in line with this approach, particularly as it relates to the design control cycle.

Design controls are essentially defined as a set of management practices used to control the process of design and development of medical devices. By focusing on the process first, companies gain a better understanding of the design control inputs and outputs. Both FDA and ISO 13485 design control requirements can then be applied to a process that best enables the company to develop a quality product.

Looking at other industries that handle product development, there is generally a thought process of first identifying the customer problem that needs to be solved and then working from there to develop a product. Similarly, for medical devices, developers must first identify the patient's problem as a foundation to the design and development of the device — and then, the company must document the design all along the way. The intent is not to make companies jump through hoops, but to have companies design and build products with intent and ensure that they address the problem they want to solve.

Verification and validation is the last step. At the end of the design control cycle, the company will have a design master file that is home to documentation showing all the steps taken during the design control process.

Changes to ISO 13485

In 2003, ISO released the first version of the 13485 standard, which focused on harmonizing and organizing the requirements for a quality management system (QMS). There were still gaps that were not covered so within the last year, ISO updated the standard and incorporated more than a decade of experience, learning, and understanding. More structure and guidance for medical device companies was added.[1]

The ISO 13485 standard has been adopted by medical device manufacturers and distributors as well as many regulatory agencies around the world. The original intent of ISO 13485 was to help companies establish a QMS where they can prove that they are designing a product according to plan and that they have controls over the R&D and manufacturing processes. In the end, they will produce a product that does good, not harm.

The New ISO 13485:2016

The new standard provides direction on design controls. The following are changes that relate to design controls and the impact the changes will have on medical device companies (see Table 1). It is important to remember that the medical device company is responsible for the quality regardless of whether a deviation or product flaw came from the supplier or within the company's own walls. At the end of the day, the medical device is theirs and the responsibility belongs fully to the device manufacturer.

Does this make a hard road? A common question that arises when people learn about additional changes is whether adding more structure adds more burden to a company.

The truth is, if a company is designing and putting out a good product, these standards will make life easier. This can be particularly true for smaller organizations. For instance, a small medical device company can find it increasingly difficult to compete head-to-head against a large company with more resources. The place they can compete one-to-one is on standards and regulations.

Standards such as ISO 13485 level the playing field between global powerhouses and small companies because everyone is forced to make a good product. Those companies that leverage lean and agile models can focus on bringing a product to market that is equal in quality to massive companies that have more resources.

When embraced, standards and regulations are not a hindrance but rather a help. In fact, they are an enabling factor that can help companies compete on a level playing field and succeed.

Reference

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CLAUSE	CHANGE	WHAT IT MEANS
7.3.1 – Design and Development Planning	"The Organization shall document procedures for design development"	Previous version required planning — now the emphasis is not only on planning but for the organizations to document planning and results as well. Traceability staring from design inputs through design outputs required. It was a soft requirement before (as far as ISO is concerned), but now mandated per the new standard.
7.3.6 – Design and Development Verification, 7.3.7 – Design and Development Validation	"Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements" "The organization shall document verification plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size" "Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use." "The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size"	More emphasis on planning design and development activities. Establish the thought process and scientific background for why a particular sample size was chosen or why a particular spec was chosen (e.g., if you determine the motor needs to run at 200 rpm, provide background on how you came up with 200 rpm, why not 250 rpm or 175 rpm). Validation on representative product (production units or documented equivalents). This matches up to FDA requirement 21 CFR 820(g).
7.3.8 – Design and Development Transfer	New Clause	Requires a documented plan for transferring design to manufacturing (or a contract manufacturer). Ensures that your design and development outputs can actually be produced. Shifts the focus to production of medical devices to the company that designs them. Makes medical device company to manage their suppliers better — focus on quality and patient safety overall.

Table 1. The changes in ISO 13485:2016 and the impact the changes will have on medical device companies.

If the gas pathway of a medical device can reach 100 percent saturation with water causing condensation to form, and that condensate can then reach the patient, there could be a considerable risk to patient safety. This is typically associated with medical devices which deliver humidified gas to patients. In this case, ISO 18562-4 testing should be considered.

Biocompatibility Evaluation of Breathing Medical Devices: Understanding ISO 18652

Traditionally, toxicologists and biocompatibility experts considered the materials in breathing gas pathways as external communicating devices and evaluated these materials according to the ISO 10993 series of international standards.[1] In the past, testing laboratories would refer to the ISO 10993-1 matrix of biocompatibility endpoints and simply check off the tests recommended for external communicating devices. Unfortunately, this approach leads to testing that provides questionable benefit and potential hazards being missed. In order to bridge these gaps in ISO 10993, ISO Technical Committee 121 released a new set of standards specifically geared toward the biocompatibility evaluation of breathing gas pathways in healthcare applications.[2] In March 2017, the committee published ISO 18562, a four-part standard aimed at providing the general framework required to adequately determine the acceptability of medical devices that contain breathing gas pathways.2 This article takes a dive into the testing requirements of ISO 18562 and discusses the details necessary for medtech companies to satisfy this new standard.

ISO 18562 is comprised of four parts:

1. Evaluation and testing within a risk management process,[2]
2. Tests for emissions of particulate matter,[3]
3. Tests for emissions of volatile organic compounds (VOCs),[4] and
4. Tests for leachables in condensate.[5]

The scope of ISO 18562 covers the gas pathways of every medical device, device parts, or device accessories that are intended to provide respiratory care or supply substances via the respiratory tract to patients. Therefore, not only does the facemask of a breathing device need to be tested, but also any connectors, filters, and tubing that may come into contact with the gas being delivered to the patient.

Each of these sections is designed to address a potential hazard that is specifically associated with the breathing gas pathway of a medical device. The scope of devices covered by ISO 18562 can range from simple breathing tubes to complex gas mixing stations and ventilators.[2] Further, it includes any and all accessories of these devices that may come in contact with the gas stream before it reaches the patient. This does not only include devices that deliver air or oxygen to patients, but also those that deliver inert gases to patients, including nitric oxide and anesthesia.[2] The immense range of devices that may contain these potential hazards highlights the necessity for a specific set of standards dedicated to the evaluation of these breathing gas pathways.

In recent years, FDA has developed a renewed focus on limiting unnecessary testing with the biological evaluation of medical devices. Therefore, Part 1 of ISO 18562 follows very closely the general guidance for ISO 10993 in which testing and evaluation of these breathing gas pathways should fall under a larger risk management approach.[6] The first step in the evaluation and testing of breathing gas pathways of medical devices is identification of all the potential hazards to patients that are specifically associated with the gas stream coming from your device. These are the hazards that will be evaluated according to ISO 18562. However, this standard is not prescriptive

when it comes to evaluating these hazards. It does include some specific details that need to be considered when designing a test plan. For example, ISO 18562 provides guidelines for parameters such as using the correct clinically relevant flow rates depending on the target patient population, sampling at adequate intervals throughout the testing depending on the duration of use of the device, and maintaining the correct temperature of the device during testing.[4] However, when it comes to the methods used to sample and measure the potential hazards associated with the gas stream, ISO 18562 only provides general strategies.

Hazards and Test Methods

There are three main hazards that can be associated with the breathing gas pathways of medical devices. The first of these hazards are evaluated under Part 2 of ISO 18562, Tests for emissions of particulate matter.[3] There are two size ranges of particulates that needs to be measured, $PM_{2.5}$ and PM_{10}. $PM_{2.5}$ includes all particles between 0.2 and 2.5 µm in size, while PM_{10} includes all particles between 2.5 and 10 µm.[3] $PM_{2.5}$ particles pose a more dangerous hazard to patients because they can bypass the human body's natural defense mechanisms. This allows them to penetrate deeper into the patient's lungs, causing significant health risks. ISO 18562-2 requires that the total mass of $PM_{2.5}$ particles emitted not exceed 12 $\mu g/m^3$ of gas.[3] PM_{10} particles pose fewer hazards but can still be dangerous to patients. These particles cannot penetrate as deep into the lungs. However, they still pose significant health risks to patients. ISO 18562-2 requires that the total mass of PM10 particles emitted not exceed 150 $\mu g/m^3$ of gas.[3]

Particulate Matter. ISO 18562-2 details two methods for measuring particulate matter emitted from medical devices. The first is a filter collection method that has been used for environmental testing for decades.[3] Conceptually, this is the simplest method that involves measuring the difference in mass of a filter before and after collection of particulate matter. Unfortunately, measuring particulate

Volatile organic compounds and particulate matter picked up the gas stream of breathing medical devices can be inhaled by patients causing significant health complications. The risks associated with inhalation of VOCs and particulate matter can include direct lung irritation and inflammation, and even lead to systemic issues including blood clots, heart problems, cancer, and liver, kidney, and central nervous system damage.

matter emitted from medical devices is not that simple. In most cases, the amount of particulate matter emitted from a medical device is minuscule. Therefore, one must pass sufficient gas through the filter to measure the change in mass. This can sometimes require an extremely sensitive balance and can be disrupted by the slightest artifact. Some recommend maintaining the filters in an environmentally controlled chamber for up to three weeks before and after testing to ensure that moisture accumulation does not impact the measurements.[7] In short, this method is not good for short duration tests where the amount of particulate matter will be diminutive.

The second method detailed in ISO 18562-2 for measurement of particulate matter emissions is a particle counter method.[3] This method uses an analytical particle counter or particle sizer to measure and count each particle emitted from the medical device. Particle analyzers employ a light scattering technique in which the gas stream from the medical device enters an isokinetic sampling probe and is directed past a laser that illuminates the particles. The light from the laser is redirected or absorbed and detected by the analyzer, allowing for accurate measurements of particulates.[7]

As mentioned above, ISO 18562-2 specifies limits for particulate matter in total mass of particulates in the gas stream. Many particle counters and sizers will output a total mass of the measured particulates. However, for those that only provide a count of the number of particles, ISO 18562-2 includes a guide for converting this count to a total mass based on the density of the materials used in the gas pathways of the device.[3]

VOCs. The second major hazard associated with breathing gas pathways of medical devices is VOCs that can be emitted in the gas stream. VOCs are evaluated under Part 3 of ISO 18562.[4] Since ISO 18562-3 does not recommend specific methods for collecting and sampling VOCs, many laboratories have decided to use thermal desorption tubes/canisters for the collection of VOCs emitted from the medical device and thermal desorption GS/MS for the analysis of the VOCs collected.8 Thermal desorption tubes/canisters are packed with mixtures of different carbon-based absorbent materials that are designed to attract and trap VOCs. These tubes/canisters are then transferred to a GC/MS with a thermal desorption unit that heats the tubes/canisters. VOCs by nature become more volatile at higher temperatures, allowing them to desorb from the absorbent material and enter the equipment for analysis.[8] Since higher temperatures increase the volatility of VOCs, during testing the medical device must be maintained at its highest rated ambient temperature as this allows for the most VOCs to be emitted.[4]

Leachables. The final hazard specific to the gas pathway of medical devices is addressed in Part 4 of ISO 18562. This section of the standard outlines the testing requirements for leachables in condensate.[5] This becomes important for

devices that deliver humidified gas; where the gas pathway can reach 100 percent saturation with water, condensation can form in the gas pathway of the device, and that condensate can reach the patient. ISO 18562-4 requires that leachables in the condensate be evaluated for all of devices that meet these conditions.[5] This part of the standard suggests three methods for collecting these leachable substances:

1. Use clinical conditions to cause the formation of condensation in the gas pathway,
2. Circulate water through the gas pathway in conditions similar to clinical use, or
3. Perform an aqueous extraction[5] according the principles established in ISO 10993-129.

All three of these methods are sufficient to collect any hazardous leachables that may be present in condensation that develops during clinical use.

Once the condensation has been generated and collected or the aqueous extract collected, ISO 18562-4 requires analysis and identification of any leachable compounds that are found. ISO 18562-4 specifies that the metal ion concentrations in these samples should be determined using pharmacopeia methods and also any organic impurities quantified and identified using GS/MS5.

Although it is not specifically mentioned in ISO 18562-4, many laboratories also recommend quantifying and identifying less volatile compounds using LC/MS. Importantly, if the materials within the gas pathway of the device have previously been evaluated according to ISO 10993-12, testing according to ISO 18562-4 is not necessary.[5]

Toxicological Evaluation

Following the emission testing outlined in ISO 18562, the chemical compounds identified in Parts 3 and 4 of ISO 18562 must undergo a full toxicological evaluation according to ISO 10993-17.[10] The first step in this evaluation is to calculate the actual dose of the identified compounds to the patients. This includes considering parameters such as dilution from the amount of gas and the breathing volume of the target patient population.[2] Once a dose to the patient is established for each compound, an extensive literature search of all available toxicological data and derivation of allowable daily limits for each compound can be performed. It is important that toxicologists pay extra attention to available inhalation toxicity data as this data will be the most relevant to breathing gas pathways. If there are any compounds that are found to pose a toxicological concern to patients, ISO 18562 recommends performing cytotoxicity and sensitization testing according to ISO 10993-5 and -10, respectively.[11,12]

Once all of this information and data is collected, the acceptability of the breathing gas pathway device can be sufficiently determined.2 With that being said, the medical device must be evaluated in total. No single test or evaluation is adequate to

evaluate a medical device. Instead, it is the consideration of all the test data and toxicological information that allows regulatory bodies to adequately determine the safety of a breathing device.

Conclusion

It is important to remember that this is the initial release of a new international standard. As data is generated and experts continue to weigh in, ISO 18562 will continue to evolve until it is the preferred standard by regulatory bodies worldwide. While ISO 18562 is not currently on the FDA's list of Recognized Consensus Standards, many reviewers will still ask for the tests outlined in ISO 18562.[13]

These requests foreshadow the shift in perspective toward the eventual adaptation of this standard as it is revised and enhanced. Therefore, understanding the testing requirements of ISO 18562 will help to ensure a complete regulatory submission and save valuable resources when working to get a medical device to market.

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This article was written by James Lyons, PhD, Toxicologist for Eurofins Medical Device Testing, Lancaster, PA. For more information, visit ***http://info.hotims.com/69503-167****.*

Package Engineering for Sterilization

After years of research and development, surveys and polls, functional device testing, and countless other preparatory actions, your medical device is almost ready to go to market. You have determined your optimal sterilization method and the end is now in sight. But there is one more step that is usually downplayed or forgotten, and it is key to bringing your product to market. Your package must demonstrate that it is effective in facilitating sterilization, maintaining sterile barrier properties for the claimed shelf life, physically protecting and containing the product, and facilitating easy removal and use in the field.

Design and subsequent testing to meet and prove these criteria can be a time-consuming and involved process. While all of these necessary functions are critical to the success of the packaging, facilitating sterilization and maintaining sterile barrier properties is probably the least understood. This article looks at some of the most commonly used forms of sterilization and identifies which tests are appropriate for determining optimal packaging.

The first step in the packaging design journey generally starts with choosing which sterilization method is appropriate for each device. This relies on knowledge of the geometry of the device, how it will be used in the field, and its material composition. For example, items with long lengths of tubing may have trouble allowing ethylene oxide (EO) to reach the center of lumens, or items with sensitive electronics may not fare well with gamma radiation or electron beam sterilization. While there are many sterilization methods to choose from, there are four very common methods that tend to dominate the medical device industry: EO, ionizing radiation also known as gamma irradiation, or electron beam, steam sterilization, and vaporized hydrogen peroxide.

Ethylene Oxide

EO is the most common sterilization method used in the industry today, accounting for more than half of all medical device sterilization performed. EO is a colorless, flammable, and carcinogenic gas that is primarily used in industry as a precursor to polymers and products like antifreeze. The process for sterilization includes preconditioning the products, exposing the products, and then allowing them to off-gas or aerate. Preconditioning involves exposing the product to a warm, humid environment until a uniform internal temperature and humidity is reached (~52 °C and 55–65 RH). Products are then loaded into a sealed chamber where they are exposed to EO gas. After a validated exposure time, the devices are removed and allowed to off-gas to remove residual EO.

Common spunbond HDPE pouches.

This form of sterilization is known as a *gas-in, gas-out process*, because gas needs to be able to enter the packaging to come into contact with the device, and gas needs to be able to exit the packaging afterward to reduce toxicity levels. Because of this, one of the primary design considerations is the permeability or breathability of the packaging materials. The more breathable the materials are, the more easily EO enters and exits the package, reducing overall processing time and cost. One of the best standards for determining the breathability of packaging is ISO 5636-5, "Determination of Air Permeance." In this test, a device known as a densometer uses a cylinder pulled downward by gravity to pass a known volume of air through a porous material. The more porous a material is, the more quickly the cylinder falls. Due to the porous nature of spunbond HDPE and medical-grade papers, these materials are commonly used for this test. A good example of packaging that fairs well in EO sterilization is shown in the photo.

The same principles that apply to EO also apply to vaporized hydrogen peroxide (VHP). To properly sterilize a device using VHP, the gases involved must come into contact with the device surface and therefore need a porous material to allow penetration. Again, testing for maximum permeability while maintaining a microbial barrier is the critical path for optimization of the sterilization process.

Gamma Radiation

The next most prevalent form of sterilization is ionizing radiation, otherwise known as gamma radiation or electron beam. The process used for ionizing radiation sterilization is very much different from gas-based methods; however, it is also much simpler. In gamma radiation, packaged product is loaded onto totes that ride a conveyor system. The conveyor then transports the product around a radiation source of cobalt 60 until the appropriate dose of radiation has been applied. Electron beam is very similar to gamma, however, instead of energetic waves being projected at the test article, electrons are accelerated through an electric field and bombard the medical device.

One of the key characteristics of ionizing radiation is that it has a tendency to fundamentally change materials on a molecular level. One of the most common forms of change is known as scission (see Figure 1). Scission occurs when a long molecule chain is broken into smaller segments. If one imagines most polymers as a large knot of long

molecules, and then the molecules are cut short, the physical characteristics of the knot are going to change. Often this causes optical changes (color change, opacity, and gloss) as well as physical changes (becoming more brittle).

Because ionizing radiation can cause materials to become more brittle, the packaging designer should choose tests that challenge the materials for its strength characteristics. For example, imagine trying to open a medical device in an operating room environment. Rather than having the package open at the seal as it was designed, the packaging experiences material failure and opens by rupturing the film itself. This could cause the medical device to fall onto nonsterile surfaces like the ground and become unusable.

Preliminary testing should include ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems, or ISTA 3A. In these test regimes, the packaging is subjected to a series of mechanical stressors such as environmental conditioning, drop tests, vibration tests, etc., which simulate the distribution environment. Once these tests have been completed, designers should consider using several strength tests to gain a better understanding of how the sterilization and distribution simulation affected the material properties. The seal peel test, ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials, would be an appropriate first choice. This test essentially pulls a section of packaging apart at the seal. If the package has material breakage in a location other than at the seal, it would indicate poor material strength or an oversealed package.

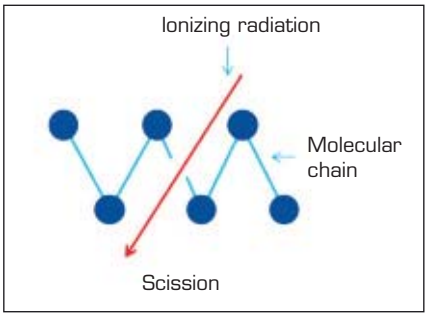

Fig. 1 – Ionizing radiation causing molecular chain scission.

Performing this test prior to and post sterilization allows the packaging designer to understand the effect that the sterilization has on the material, and helps determine whether it will meet performance needs. A similar approach could be the burst test method, ASTM F1140, "Standard Test Method for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications." Testing packaging prior to and post sterilization yields comparative results whereby the designer is able to determine any detrimental changes to the packaging.

Steam Sterilization

The next most prevalent form of sterilization is what is known as wet heat, or steam sterilization. In this process, the medical device and packaging are

placed within a chamber, and the chamber is filled under pressure with steam commonly at 121° or 132 °C. Because this is similar to the gas-based processes, packaging for steam sterilization must also be porous to allow free passage of the steam. Air permeance testing (ISO 5636-5) would once again be appropriate for this sterilization method.

Adhesives that are sometimes used to bond trays to their lid materials must also be taken into consideration. If the adhesive is not designed to withstand high temperature and moisture, the sterile barrier could be compromised. To test the integrity of adhesives, bubble emission testing (ASTM 2096) might be an appropriate choice. Premature bursting of the packaging or streams of bubbles emanating from the seals of the packaging may indicate a compromised adhesive layer. Seal peel testing may also be appropriate prior to and post sterilization to determine whether acceptance criteria is met and to determine whether detrimental changes to the seal strength have occurred.

Conclusion

This information, although not all encompassing, should provide a starting place when determining which testing should be performed to aid in design and engineering of packaging. Using the appropriate tests should illuminate possible modes of failure and should ensure that detection is made to assist with redesign if needed. Any process will affect materials and packaging to some degree. The goal is to understand how detrimental these changes are and how to successfully mitigate them.

More often than not, packaging design for the medical industry is a cross-disciplinary exercise involving engineering, material science, sterilization (microbiology), and regulatory understanding. Gaining insight into these areas will greatly assist in a timely packaging validation and approval. When navigating this process, it can be helpful to consult with outside experts to understand and determine the best test methods for the application.

This article was written by Andrew Manrique, Packaging Design Engineer and Sterilization Specialist at Nelson Laboratories, Salt Lake City, UT. For more information, visit ***http://info.hotims.com/69503-168****.*

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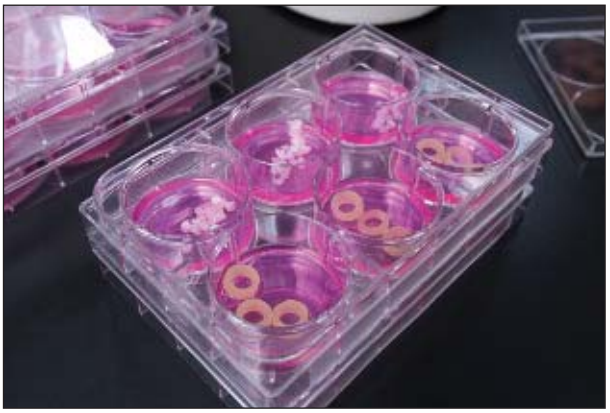

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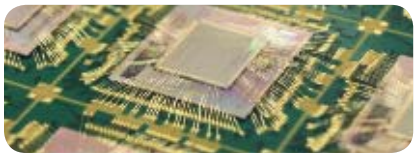

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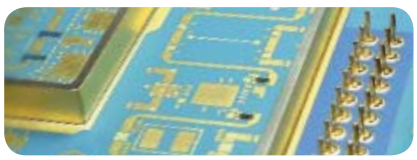

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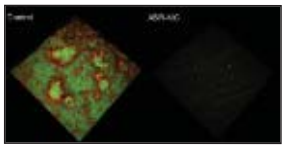
R&D ROUNDUP

Dental Material Resists Plaque, Kills Microbes



Biofilms were much easier to remove when grown on a newly developed dental material (right) compared to a control material. (Credit: University of Pennsylvania)

Researchers have evaluated a new dental material tethered with an antimicrobial compound that not only kills bacteria but also resists biofilm growth. In addition, unlike some drug-infused materials, it is effective with minimal toxicity to the surrounding tissue, as it contains a low dose of the antimicrobial agent that kills only the bacteria that come in contact with it.

The newly developed material is comprised of a resin embedded with the antibacterial agent imidazolium. Unlike some traditional biomaterials, which slowly release a drug, this material is nonleachable, thereby only killing microbes that touch it.

Test results showed it to be effective in killing bacterial cells on contact, severely disrupting the ability of biofilms to grow on its surface. Only negligible amounts of biofilm matrix, the glue that holds clusters of bacteria together, were able to accumulate on the experimental material.

While the smallest force removed almost all the biofilm from the experimental material, even a force four times as strong was incapable of removing the biofilm from the control composite material.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28199****.*

Low-Cost, Battery-Powered Reader Diagnoses Jaundice

A low-cost, battery-powered reader is designed to diagnose jaundice. (Photo by Jeff Fitlow/Rice University)

The first clinical study of a low-cost, handheld jaundice detector shows that saving newborn lives in sub-Saharan Africa is achievable. BiliSpec, a low-cost, battery-powered reader, is designed to diagnose jaundice by immediately quantifying serum bilirubin levels from a small drop of whole blood.

Babies in sub-Saharan Africa are about 100 times more likely to die of jaundice than are babies in the United States, partly because doctors diagnosing jaundice in sub-Saharan Africa have little to go on other than what their eyes tell them.

The clinical study showed that BiliSpec has comparable accuracy to the more expensive laboratory tests found in high-resource settings. Each BiliSpec test costs about five cents and can be performed in about two minutes right at the patient's bedside hospitals in sub-Saharan Africa.

BiliSpec is one component of a 17-piece neonatal package called NEST, short for Newborn Essential Solutions and Technologies, which is designed specifically for African hospitals.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28200****.*

Plasmonic Biosensors Enable Development of Easy-to-Use Health Tests

A plasmonic biosensor can detect diseased exosomes even by the naked eye. Exosomes, important indicators of health conditions, are cell-derived vesicles that are present in blood and urine. A rapid analysis by biosensors helps recognize inflammatory bowel diseases, cancer, and other diseases rapidly in order to start relevant treatments in time.

Visualizing the specular reflection color by a blackbody substrate. (Credit: Aalto University)

Researchers have created a new biosensor by depositing plasmonic metaparticles on a black, physical body that absorbs all incident electromagnetic radiation. Plasmonic materials have been used for making objects invisible in scientific tests. They efficiently reflect and absorb light. Plasmonic materials are based on the effective polarizabilities of metallic nanostructures.

Plasmonic dipoles are famous for their strong scattering and absorption. The research group has demonstrated the as-yet unknown specular reflection and the Brewster effect of ultrafine plasmonic dipoles on a black body host.

The novel approach enables a simple and cost-effective design of a perfect colored absorber and creation of vivid interference plasmonic colors.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28201****.*

Ultrasonic Sensor Allows Amputees to Control Prosthetic Fingers

Researchers have created an ultrasonic sensor that allows amputees to control each of their prosthetic fingers individually. It provides fine motor hand gestures that aren't possible with current commercially available devices.

The amputee's everyday prosthesis is similar to the majority of devices on the market. It's controlled by electromyogram (EMG) sensors attached to his muscles. He switches the arm into various modes by pressing buttons on the arm. Each mode has two programmed moves, which are controlled by him either flexing or contracting his forearm muscles. For example, flexing allows his index finger and thumb to clamp together; contracting closes his fist.

The arm has an ultrasound sensor, allowing it to watch the muscles as they move. (Credit: Georgia Tech University)

The team attached an ultrasound probe to the arm. When he tries to move his amputated ring finger, the muscle movements differ from those seen when he tries to move any other digit. The team fed each unique movement into an algorithm that can quickly determine which finger he wants to move. The ultrasound signals and machine learning can detect continuous and simultaneous movements of each finger, as well as how much force he intends to use.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28202****.*

Biochemical, Pain-Free Skin Patch Manages Type 2 Diabetes with Microneedles

The aginate-based microneedle array is applied to patients' skin, delivering a protein/peptide particle payload to treat Type 2 diabetes for as long as a week. (Credit: Chen lab, NIBIB)

Researchers have devised an innovative biochemical formula of mineralized compounds that interacts in the bloodstream to regulate blood sugar for days at a time. In a proof-of-concept study performed with mice, the researchers showed that the biochemically formulated patch of dissolvable microneedles can respond to blood chemistry to manage glucose automatically.

The base of the experimental patch is material called alginate, a gum-like natural substance extracted from brown algae. It is mixed with therapeutic agents and poured into a microneedle form to make the patch.

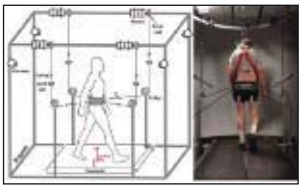
The team infused the alginate with a formula of biochemical particles that stimulates the body's own insulin production when needed and curtails that stimulation when normal blood sugar concentration is reached. The responsive delivery system of the patch can meet the body's need for days instead of being used up all at once.

The researchers demonstrated that a patch about a half inch square contained sufficient drug to control blood sugar levels in mice for a week. The patch would need to be altered for application on human skin, likely requiring longer needles.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28203***.

Combining Machine and Nanoparticles for Better Transplant Outcomes

A team of experts in rehabilitation robotics used a robotic system — the Tethered Pelvic Assist Device (TPAD) — to study whether or not Parkinson's disease affects patients' balance and diminishes their ability to react and adapt to walking with perturbations. The TPAD is a wearable, lightweight cable-driven robot that can be programmed to provide forces on the pelvis in a desired direction as a subject walks on a treadmill.



A subject uses the TPAD training method, designed to improve stability in Parkinson's disease patients as they walk. (Credit: Sunil Agrawal/Columbia Engineering)

The researchers evaluated the margin of stability and base of support while the study participants walked without cables on a treadmill. Then the participants were hooked up to the TPAD's cables and given waist-pull diagonal perturbations for brief periods to assess their reactions.

Parkinson's patients had a reduced stability in the forward direction before and after training compared to the healthy subjects and an inability to produce proactive anticipatory adjustments. Both groups were able not only to improve their response to the perturbations, but also to produce short-term aftereffects of increased gait stability.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28204***.

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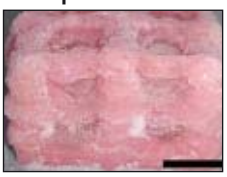
3D Printing Creates Super-Soft Structures that Replicate Brain and Lungs



A new 3D printing technique allows researchers to replicate biological structures. (Credit: Imperial College London)

Researchers have developed a new method for creating 3D structures using cryogenics (freezing) and 3D printing techniques. This builds on previous research but is the first to create structures that are soft enough to mimic the mechanical properties of organs such as the brain and lungs.

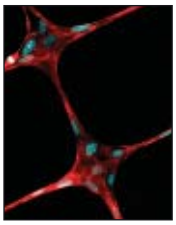
Being able to match the structure and softness of body tissues means that these structures could be used in medical procedures to form scaffolds that can act as a template for tissue regeneration, where damaged tissues are encouraged to regrow.

The use of scaffolds is becoming more common and varied in its applications, but this new technique is special in that it creates super-soft scaffolds that are like the softest tissues in the human body and could help to promote this regeneration. In particular, there might be future potential in seeding neuronal cells; those involved in the brain and spinal cord.

The technique uses solid carbon dioxide (dry ice) to rapidly cool a hydrogel ink as it is extruded from a 3D printer. After being thawed, the gel formed is as soft as body tissues, but doesn't collapse under its own weight.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28255.***

3D Printed Microfibers Could Provide Structure for Artificially Grown Body Parts



A figure displays the cells grown on polymeric fibers created by 3D near field electrospinning. (Credit: Penn State University)

Much as a frame provides structural support for a house and the chassis provides strength and shape for a car, a team of engineers believe they have a way to create the structural framework for growing living tissue using an off-the-shelf 3D printer.

The researchers report that their aim is to create a novel, low-cost and efficient method to fabricate high-resolution and repeatable 3D polymer fiber patterns on nonconductive materials for tissue engineering with available hobbyist-grade 3D printers. The method they use is a combination of 3D printing and electrospinning, a method that uses electric charge to spin nanometer threads from either a polymer melt or solution.

The researchers are looking for a way to grow replacement tissues reliably using inexpensive methods.

Their apparatus uses the electrospinner to replace the extruder nozzle on the 3D printer. The printer can deposit a precise pattern of fibers in three dimensions to form a scaffold in a hydrogel on which cells can grow. Once the tissue has grown sufficiently, the scaffolding can be dissolved, leaving only a structured tissue appropriate for use.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/28256.***

Nanotexturing Creates Bacteria-Killing Spikes on Stainless Steel Surfaces

The process may attack antimicrobials on implantables.

Georgia Institute of Technology, Atlanta, GA

By using an electrochemical etching process on a common stainless-steel alloy, researchers have created a nanotextured surface that kills bacteria while not harming mammalian cells. If additional research supports early test results, the process might be used to attack microbial contamination on implantable medical devices and on food processing equipment made with the metal.

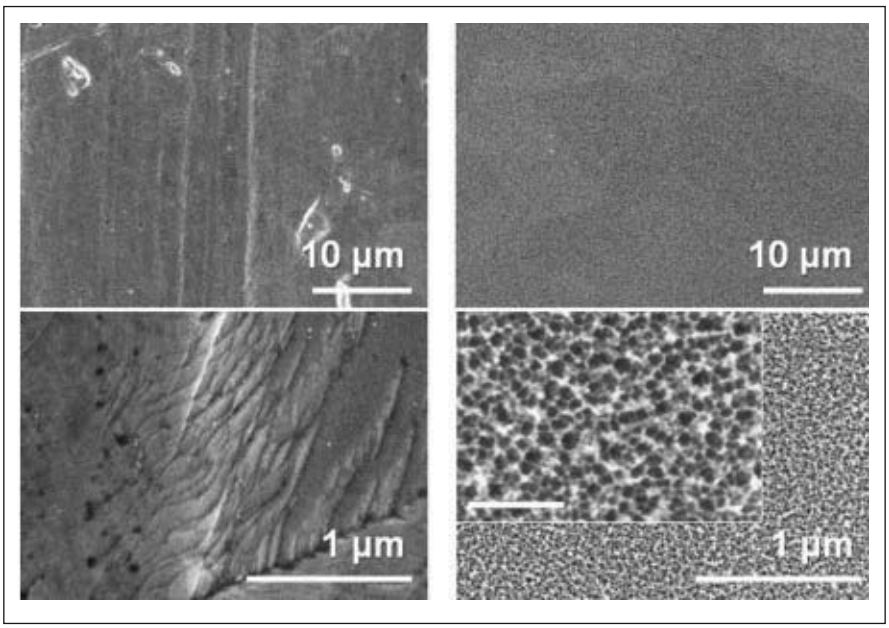
While the specific mechanism by which the nanotextured material kills bacteria requires further study, the researchers believe tiny spikes and other nanoprotrusions created on the surface puncture bacterial membranes to kill the bugs. The surface structures don't appear to have a similar effect on mammalian cells, which are an order of magnitude larger than the bacteria.

Beyond the antibacterial effects, the nanotexturing also appears to improve corrosion resistance. The research was reported in the journal *ACS Biomaterials Science & Engineering* by researchers at the Georgia Institute of Technology.

"This surface treatment has potentially broad-ranging implications because stainless steel is so widely used and so many of the applications could benefit," says Julie Champion, an associate professor in Georgia Tech's School of Chemical and Biomolecular Engineering.

"A lot of the antimicrobial approaches currently being used add some sort of surface film, which can wear off. Because we are actually modifying the steel itself, that should be a permanent change to the material."

Champion and her Georgia Tech collaborators found that the surface modification killed both Gram negative and Gram positive bacteria, testing it on Escherichia coli and Staphylococcus aureus. But the modification did not appear to be toxic to mouse cells — an important issue because cells must adhere to medical implants as part of their incorporation into the body.



Scanning electron microscope images show a standard-stainless steel surface (left) compared to a surface treated to create a nanotexture. (Credit: Won Tae Choi, Georgia Tech)

The research began with a goal of creating a super-hydrophobic surface on the stainless steel in an effort to repel liquids — and with them, bacteria. But it soon became clear that creating such a surface would require the use of a chemical coating, which the researchers didn't want to do. Postdoctoral Fellows Yeongseon Jang and Won Tae Choi then proposed an alternative idea of using a nanotextured surface on stainless steel to control bacterial adhesion, and they initiated a collaboration to demonstrate this effect.

The research team experimented with varying levels of voltage and current flow in a standard electrochemical process. Typically, electrochemical processes are used to polish stainless steel, but Champion and collaborator Dennis Hess — a professor and Thomas C. DeLoach, Jr. Chair in the School of Chemical and Biomolecular Engineering — used the technique to roughen the surface at the nanometer scale.

"Under the right conditions, you can create a nanotexture on the grain surface structure," Hess explains. "This texturing process increases the surface segregation of chromium and molybdenum and thus enhances corrosion resistance, which is what differentiates stainless steel from conventional steel."

Microscopic examination showed protrusions 20–25 nm above the surface. "It's like a mountain range with both sharp peaks and valleys," says Champion. "We think the bacteria-killing effect is related to the size scale of these features, allowing them to interact with the membranes of the bacterial cells."

The researchers were surprised that the treated surface killed bacteria. And because the process appears to rely on a biophysical rather than chemical process, the bugs shouldn't be able to develop resistance to it, she adds.

A second major potential application for the surface modification technique is food processing equipment. There, the surface treatment should prevent bacteria from adhering, enhancing existing sterilization techniques.

The researchers used samples of a common stainless alloy known as 316L, treating the surface with an electrochemical process in which current was applied to the metal surfaces while they were submerged in a nitric acid etching solution.

Application of the current moves electrons from the metal surface into the electrolyte, altering the surface texture and concentrating the chromium and molybdenum content. The specific voltages and current densities control the

type of surface features produced and their size scale, says Hess, who worked with Choi — then a PhD student — and Associate Professor Victor Breedveld in the School of Chemical and Biomolecular Engineering, and Professor Preet Singh in the School of Materials Science and Engineering, to design the nanotexturing process.

Postdoctoral Fellows Won Tae Choi and Yeongseon Jang demonstrate how the growth of bacterial colonies on agar plates was used to quantify the effect of the nanotextured surface on bacterial adhesion. (Credit: Rob Felt, Georgia Tech)

To more fully assess the antibacterial effects, Jang engaged the expertise of Andrés García, a Regents' Professor in Georgia Tech's Woodruff School of Mechanical Engineering, and Graduate Student Christopher Johnson. In their experiments, they allowed bacterial samples to grow on treated and untreated stainless-steel samples for periods of up to 48 hours.

At the end of that time, the treated metal had significantly fewer bacteria on it. That observation was confirmed by removing the bacteria into a solution, then placing the solution onto agar plates. The plates receiving solution from the untreated stainless steel showed much larger bacterial growth. Additional testing confirmed that many of the bacteria on the treated surfaces were dead.

Mouse fibroblast cells, however, did not seem to be bothered by the surface. "The mammalian cells seemed to be quite healthy," says Champion. "Their ability to proliferate and cover the entire surface of the sample suggested they were fine with the surface modification."

For the future, the researchers plan to conduct long-term studies to make sure the mammalian cells remain healthy. The researchers also want to determine how well their nanotexturing holds up when subjected to wear.

"In principle, this is very scalable," says Hess. "Electrochemistry is routinely applied commercially to process materials at a large scale."

For more Information, visit ***www.news.gatech.edu.***

Laser Direct Structuring for Sensor Manufacturing

Method reduces manufacturing and assembly steps.

SelectConnect Technologies, Palatine, IL

Every day the world's leading medical device companies rely upon laser direct structuring (LDS) to meet their most demanding design and performance requirements. Millions of electronic components with complex geometries are cost-effectively manufactured each year through the use of LDS to create circuit traces on three-dimensional molded interconnect devices (3D-MID).

A single 3D-MID employing LDS consists of multiple components that are incorporated onto a single part. When compared with traditional technologies, LDS enables significant reduction in both manufacturing and assembly steps. The result is an overall reduction in both cost and production time. A position sensor clearly demonstrates these benefits.

- This position sensor (see Figure 1) works by transmitting ultrasonic waves to bounce off an object and return to the sensor's antenna receivers for translation. The signal emitter is located in the center of the molded interconnect device (MID)

Fig. 1 – The signal emitter is located in the center of the molded interconnect device.

Fig. 2 – There are eight antennas surrounding the emitter on the front of the MID.

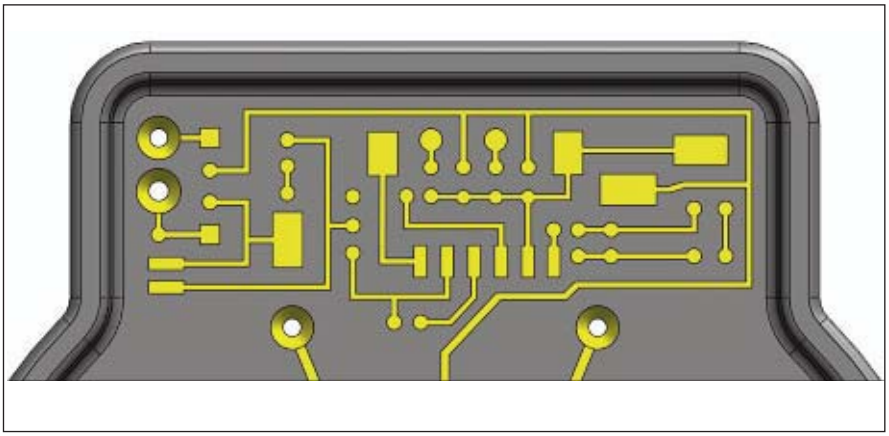


Fig. 3 – The circuitry can be designed directly onto the plastic housing.

Fig. 4 – The emitter, antennas, and circuit traces can be lasered onto the housing to increase their strength and durability.

and is connected to circuitry located on the back with the use of plated through-holes. There is no need for assembly or mounting of the emitter which is one of the many benefits of this design. The emitter is connected to the circuit traces, which reduces current or signal loss due to insufficient bonding of the emitter to the circuit.

- There are eight antennas on the front of the MID that surround the emitter (see Figure 2). The antennas receive a portion of the reflected signal, which is used to interpret information about the position and size of the object. The positions of the antennas are exact, consistent, and equidistant from the emitter, reducing error in the objects perceived position due to a variance in antenna placement.
- With LDS, there is no need to have a printed circuit board protected by a separate housing; the circuitry can be designed directly onto the plastic housing itself (see Figure 3). This reduces the amount of space needed within the housing and will save time

and money during assembly. Soldering or other mounting operations can then be done directly onto the plated circuitry.

- Lasering the emitter, the antennas, and the circuit traces onto of the housing also serves to increase their physical strength and durability (see Figure 4). An LDS MID's overall robustness is much greater than that of a similar part that has been assembled from separate components.

Engineering Plastic Versatility

The technical capabilities of LDS allow the creation of circuitry on a range of engineering plastics, including liquid crystal polymers, nylons or polyamides, polyethylene terephthalate/polybutylene terephthalate alloys, as well as a range of other plastic materials, which provide a mechanical base with outstanding chemical and environmental resistance. In addition to circuits, larger copper landing areas can be created for touch sensor capability. Furthermore, the combination of engineering polymers with noble circuit traces stand up to lifetime corrosion exposure and perform better over time.

Sensor Applications

In addition to position sensors, LDS is used to manufacture a variety sensors for use in medical devices, including:

- Temperature sensors.
- Motion sensors.
- Pressure sensors.
- Flow sensors.
- Optical sensors.

This article was written by Richard Macary, President, SelectConnect Technologies. He can be reached at rmacary@arlingtonplating.com. For more information, visit ***http://info.hotims.com/69503-163***

New Patch Aims to Turn Energy-Storing Fats into Energy-Burning Fats

The new type of skin patch contains hundreds of microneedles.

Nanyang Technological University, Singapore

A new system combines a new way to deliver drugs, via a micro-needle patch, with drugs that are known to turn energy-storing white fat into energy-burning brown fat. This innovative approach developed by scientists from Nanyang Technological University, Singapore (NTU Singapore), reduced weight gain in mice on a high fat diet and their fat mass by more than 30 percent over four weeks.

The new type of skin patch contains hundreds of microneedles, each thinner than a human hair, which are loaded with the drug Beta-3 adrenergic receptor agonist or another drug called thyroid hormone T3 triiodothyronine.

When the patch is pressed into the skin for about two minutes, these microneedles become embedded in the skin and detach from the patch, which can then be removed. As the needles degrade, the drug molecules then slowly diffuse to the energy-storing white fat underneath the skin layer, turning them into energy-burning brown fats.

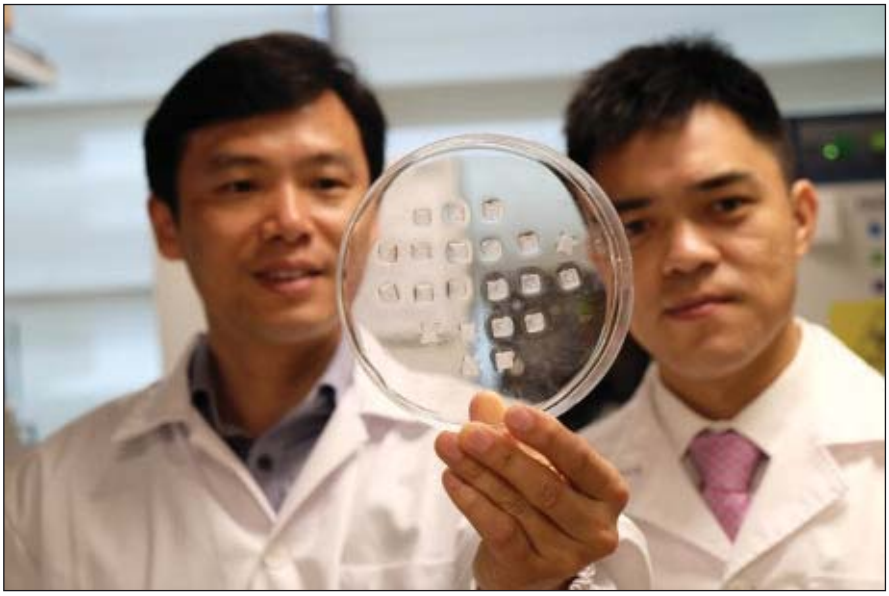
Brown fats are found in babies, and they help to keep the baby warm by burning energy. As humans grow older, the amount of brown fats lessens and is replaced with visceral white fats.

Published in the journal *Small Methods* by NTU professor Chen Peng and assistant professor Xu Chenjie, this approach could help to address the worldwide obesity problem without resorting to surgical operations or oral medication that could require large dosages and could have serious side effects.

"With the embedded microneedles in the skin of the mice, the surrounding fats started browning in five days, which helped to increase the energy expenditure of the mice, leading to a reduction in body fat gain," says Xu, who focuses on research in drug-delivery systems.

"The number of drugs we used in the patch is much less than those used in oral medication or an injected dose. This lowers the drug ingredient costs while our slow-release design minimizes its side effects," says Xu.

Obesity that results from an excessive accumulation of fat is a major health risk factor for various diseases, including heart disease, stroke, and Type 2 diabetes. The World Health Organization estimates that 1.9 billion adults in the world are overweight in 2016 with 650 million of them being obese.



A new approach to reducing bulging tummy fats has shown promise in laboratory trials. (Credit: Nanyang Technical University)

"What we aim to develop is a painless patch that everyone could use easily, is unobtrusive and yet affordable," says Chen, a biotechnology expert who researches obesity. "Most importantly,

our solution aims to use a person's own body fats to burn more energy, which is a natural process in babies."

Under the two scientists' guidance at NTU's School of Chemical and Biomedical Engineering, research fellow Dr. Aung Than conducted experiments that showed that the patch could suppress weight gain in mice that were fed a high fat diet and thus reduce their fat mass by over 30 percent over a period of four weeks.

The treated mice also had significantly lower blood cholesterol and fatty acids levels compared with the untreated mice. Being able to deliver the drug directly to the site of action is a major reason why it is less likely to have side effects than orally delivered medication.

The team estimates that their prototype patch had a material cost of about S$5 (US$3.50) to make. The patch contains beta-3 adrenergic receptor agonist combined with Hyaluronic acid, a substance naturally found in the human body and commonly used in products like skin moisturizers.

Approved by the US FDA, Beta-3 adrenergic receptor agonist is a drug used to treat overactive bladders, while T3 triiodothyronine is a thyroid hormone commonly used for medication for an underactive thyroid gland.

Both have been shown in other research studies to be able to turn white fats brown, but their use in reducing weight gain is hampered by potentially serious side effects and drug accumulation in nontargeted tissues if conventional drug-delivery routes were used, such as through oral intake.

NTU's Lee Kong Chian School of Medicine Melvin Leow, an associate professor who was not affiliated with this study, says it is exciting to be able to tackle obesity via the browning of white fat, and the results were promising.

"These data should encourage Phase I clinical studies in humans to translate these basic science findings to the bedside, with the hope that these microneedle patches may be developed into an established cost-effective modality for the prevention or treatment of obesity in the near future," adds Leow, an endocrinologist.

Since the publication of the paper, the team has received keen interest from biotechnology companies and are looking to partner with clinician scientists to further their research.

For more Information, visit ***http://media.ntu.edu.sg***

MEG Technology Improves Diagnosis of Epilepsy

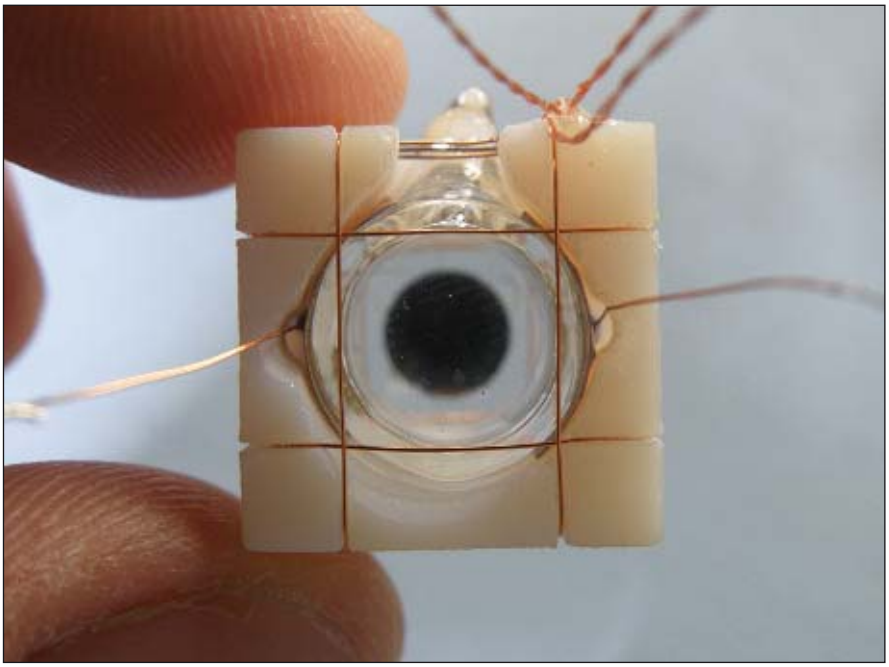
The system lowers costs and enhances scan accuracy.

Leti Research Institute, Grenoble, France

Leti, a research institute of CEA Tech, has taken a major step toward development of next-generation magnetoencephalography (MEG) that could significantly reduce the cost of

MEG systems and scans, improve diagnosis and treatment for epilepsy patients, and help guide surgeons performing brain surgery.

MEG is an imaging technique that measures brain functioning based on magnetic fields produced by the brain's electrical activity. It enables localization of electrical signals, coming from neural activity, with an increased spatial resolution. It is typically used to localize epileptiform brain activity, originating from the epileptic brain network, prior to surgical intervention.



The quantum sensor is an optical pumping magnetometer with improved sensitivity. (Credit: Leti)

Current MEG systems are cooled cryogenically, a process that requires periodic refilling of liquids. The maintenance-free Leti device operates at room temperature, eliminating the need for cryogenic cooling and reducing the size and weight of the device's magnetic shield from 5,000 to 150 kg.

For this advanced application, Leti refined its space quantum sensor, a device used in European Space Agency missions, to achieve performance superior to current MEG systems at a cost five times lower. In addition, Leti's sensors can provide more information on brain activity due to their vectorial nature, improving localization of epileptic foci.

The quantum sensor is an optical pumping magnetometer with improved sensitivity thanks to the use of low-noise laser source and the selection of magnetic resonance optimized for measure-

ment of very low magnetic fields. The laser can sense the movement of 100 billion atoms acting like small magnets whose behavior is directly linked to the magnetic field. It is an essential block of the high-performance sensor.

The system recently won the Best Early Stage Innovation Award from the European Commission in the gateone-project, one of the EC's Horizon 2020 programs to support development of smart technologies by European SMEs. The MEG project was coordinated by BLUMORPHO, a Paris-based innovation accelerator.

To develop this disruptive system, Leti's team developed sensors that can lower the cost of MEG scans by at least a factor of five," says Regis Hamelin, BLUMORPHO CTO, and Matthieu le Prado, group leader at Leti. "This new generation of MEG equipment will deliver dramatically improved visualization of brain activity to support neuromedicine's evolution to non-invasive surgery and regenerative medicine."

This new MEG system will be a flexible helmet that conforms to the heads of adults and children. In addition to improving diagnosis, it will increase patients' access to neurosurgery, beginning with those with epilepsy, which affects 6 million people in Europe.

For more Information, visit ***www.leti-cea.com****.*

Smartphone App Shows Promise Monitoring Chemotherapy Patients

Real-time estimates could provide early intervention.

UPMC Hillman Cancer Center, Pittsburgh, PA

Cancer patients receiving chemotherapy can be remotely monitored using their smartphone sensors and an algorithm that detects worsening symptoms based on objective changes in patient behavior, according to a new study from the University of Pittsburgh and UPMC Hillman Cancer Center.

The findings, published in the *Journal of Medical Internet Research*, indicate that worsening symptoms during cancer treatments can be detected using smartphones that patients likely already own and use. Real-time estimation of symptoms and side effects could provide an opportunity for doctors to intervene earlier between clinic visits, preventing unnecessary physician or hospital visits and improving patient quality of life.

The study enrolled 14 patients who were undergoing chemotherapy treatment for gastrointestinal cancer at UPMC Hillman Cancer Center. They were asked to carry a smartphone for four weeks as they went about their daily lives. Smartphone software developed by the researchers passively and continuously collected data on behavior patterns, such as the number of calls or texts sent and received, smartphone apps used, and the movement and location of the phone.

As part of the study, the patients were asked to rate the severity of 12 common symptoms, such as fatigue and nausea, at least once a day. They would classify each day as either a "higher-than-average burden," "average burden," or "low burden" day. Researchers then used the data collected from the

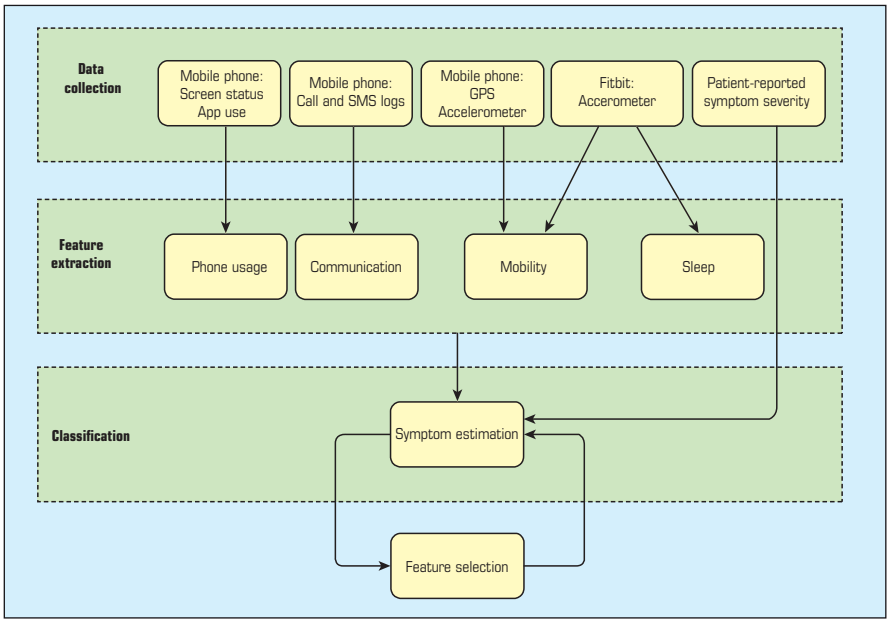
smartphone to develop an algorithm that could identify and correlate the patient's "high-symptom," "average-symptom" and "low-symptom" days with 88 percent accuracy.

"We found that on days when the patients reported worse-than-average symptoms, they tended to spend more time being sedentary, moved the phone more slowly, and spent more minutes using apps on the phone," says Carissa Low, PhD, assistant professor of medicine and psychology at the University of Pittsburgh, and lead author of the study. "Collecting these objective behavioral measures from smartphone sensors requires no additional effort from patients, and they could prove beneficial for long-term monitoring of those undergoing arduous cancer treatments or those with other chronic illnesses."

The researchers are conducting follow-up studies to determine whether the same passive sensing approach can be used to identify complications following cancer surgery. They also are working with health care providers to understand how to integrate this data into the workflow of clinical care.

This research was funded by research grants from the National Cancer Institute (K07CA204380) and by a Manners Faculty Development Award from the University of Pittsburgh Center for Social and Urban Research.

For more Information, visit ***www.upmc.com***.



Data collection and analyses methods; GPS: global positioning system. (Credit: *J Med Internet Res* 2017;19(12):e420)

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

DC Micro Welder

Amada Miyachi America, Monrovia, CA, offers a linear DC micro welder paired with an electronic resistance spot welding head. The UB29 also features the company's Advanced Data Analysis Monitor (ADAM). The linear DC welder features precision control for micro-miniature resistance welding. It is ideal for wire assemblies, sensors, connectors, squibs, catheters, orthodontic appliances, pacemakers, and implantable hearing devices.

The Series 320 electronic resistance spot welding head is a high-precision, low-force head designed specifically for applications requiring precise position and force control. This versatile series has numerous features to meet the process demands of micro-electronics manufacturing, yet is robust enough to endure industrial requirements and environments.

ADAM monitors what happens during the weld, as well as what happens before the weld is triggered, offering a 360° view of the process. Sophisticated SPC capabilities enable customers to analyze and collect data. Other key features include current, voltage, power, resistance, force, and cover gas flow monitoring; high resolution sensors; pre- and post-trigger viewing; envelope limits; and Ethernet communications capability.

For Free Info Visit http://info.hotims.com/69503-170

Product Focus: Power Supplies

DC Switching Regulators

CUI's Power Group, Tualatin, OR, has added four new series to its family of non-isolated dc switching regulators. The next-generation VX78 500, VXO78 500, VX78 1000, and VXO78 1000 series are extremely efficient, typically up to 96 percent, and balance maximizing economy with delivering a high level of performance as a direct alternative to using linear regulators. Utilizing switching technology, the models are footprint compatible with TO-220 package LM78XX and LM79XX model regulators and, unlike linear regulators, they do not require a heat sink. This makes them ideal for use in portable devices, battery-fed equipment, and embedded designs where board space is at a premium and energy efficiency is a concern.

For Free Info Visit http://info.hotims.com/69503-186

Battery Holders

Keystone, Astoria, NY, has released a broad selection of high-performance battery holders with solder lug contacts for cylindrical batteries. The solder lug contacts simplify the assembly of wires to the holders and easily connect solder lugs to solid or stranded wires with or without female quick fit terminals or crimp connectors. The new holders help streamline assembly of powered devices using AA, ½ AA, and 2/3A cylindrical cells. Equipped with heat-resistant nylon housings, these new entries are suited for traditional soldering processing. Contacts are nickel-plated stainless steel, ensuring low contact resistance and superior solder joints where lead-free soldering or reflow processes are employed. Retaining covers are also available for added battery security.

For Free Info Visit http://info.hotims.com/69503-187

ITE Power Supply

Power Partners, Hudson, MA, has released a 3 × 5 in. AC/DC open frame power supply with U-channel or enclosed (with fan) platforms available. The PFA300 series delivers 300 W of power with forced air convection cooling, 400 W of peak power capability, and 200 W of power with natural convection cooling. With universal input voltage range of 90–264 VAC and seven output voltage selections (12, 18, 24, 30, 36, 48, and 54 V), the series has built-in thermal protection, +12 V fan output, remote sense, and a power-on LED indicator. The series is EN 55032 Class B EMI approved and certified to UL/cUL/EN 60950-1. Additional features include <100 µA earth leakage current, short circuit, and overvoltage and overload protection.

For Free Info Visit http://info.hotims.com/69503-188

Dual Mode Chokes

Designed to suppress noise from switch mode power supplies and other sources, dual mode chokes from Triad Magnetics, Perris, CA, offer a dual function open-frame design that fits easily into a wide variety of devices and systems. The advanced CMF series dual mode chokes feature an economical dual-function design, which effectively combines the features of two separate components into one: they provide both exceptional common-mode noise suppression and their stray inductance is highly effective in suppressing differential mode noise. The two-in-one dual mode chokes compact in size and come in either a horizontal package (where height clearance is a concern) or a vertical package that requires minimal board space. With 21 different models to choose from, the chokes are available with a rated current ranging from 0.45 to 2.3 A, with a rated inductance ranging from 10 to 100 mH and a stray inductance ranging from 200 to 2100 mH.

For Free Info Visit http://info.hotims.com/69503-189

AC-DC Power Supplies

TDK Corporation, National City, CA, has introduced a series of AC-DC power supplies, rated at 30 and 60 W output power. The CUS30M and CUS60M series are certified to medical and ITE standards for Class I and II operation. The products meet both curve B radiated and conducted emissions without the need for additional filtering or shielding. The CUS30M and 60 M target applications include medical, home healthcare, test and measurement, broadcast, industrial controls, and household appliances. Initially available with 12, 24, and 48 V outputs, (5, 15, 18, and 36 V models to follow), the industry standard 2 × 3 in. footprint power supplies can accept an 85–265 VAC input and have operating efficiencies up to 90 percent. Off-load power consumption is <0.3 W for the CUS30M and <0.5 W for the CUS60M. The operating ambient temperature range is –20 to +70°C (–30 °C startup), derating to 50 percent load at 70 °C.

For Free Info Visit http://info.hotims.com/69503-190

Closed Loop Tube Inspection System

Hexagon Manufacturing Intelligence, North Kingstown, RI, offers an advanced tube inspection system. The closed loop work cell features the company's TubeShaper software and a portable ROMER Absolute Arm coordinate measuring machine (PCMM) integrated with a fully automatic Pines CNC Bender (Pines Engineering, Wickliffe, OH). The work cell demonstrates an automated bend-measure-correct approach to streamlining tube production. This scalable system can address various sizes of tube and pipes. The TubeShaper environment can interface directly with one or more CNC tube benders, and includes an advanced CAD engine for importing and exporting tube data in various formats.

For Free Info Visit http://info.hotims.com/69503-174

Structural Epoxy

A structural epoxy for bonding and sealing an extensive variety of substrates including metals, ceramic, glass, and many engineered plastics is available from epoxySet, Lincoln, RI. The room-temperature curing system, EB-316M, offers superior strength and can be used continuously at operating temperatures up to 150 °C. It is semirigid, making it excellent for thermal cycling, including passing 500 cycles from –55 to 150 °C. It has also been used in cryogenic applications. It has low toxicity and low outgassing while offering excellent electrical insulation.

For Free Info Visit http://info.hotims.com/69503-175

Oscilloscope

Pico Technology, Cambridgeshire, UK, has increased the bandwidth of its family of sampling oscilloscopes with two new 25 GHz models. The PicoScope is USB controlled 9300 offers low-cost, high-integrity options for viewing and measuring RF and microwave signals, paths, and networks. The new 2 and 4 channel 25 GHz oscilloscopes support fifth harmonic capture for data up to including 10 Gb/s and supports third harmonic capture up to 16 Gb/s. These rates, and others in between, are increasingly found in Ethernet, Thunderbolt, USB 3.1, PCIe 4, Rapid I/O, e-SATA, OC-192/STM-64, and OC-256. All have transmission lines, cables, components, transmitters, and receivers that need precompliance testing and characterization.

For Free Info Visit http://info.hotims.com/69503-176

Pull-Wire Switches

Wireless, pull-wire switches from Steute Industrial Controls, Ridgefield, CT, feature an internal electrodynamic energy generator. The switches require no battery, and displacement of the actuator generates power to send a unique, coded telegram to one or more compatible, easily programmed receivers. If pull-wire switch does not receive a signal that the telegram was received by the receiver within 15 ms, it transmits a second telegram.

For Free Info Visit http://info.hotims.com/69503-177

PRODUCT SPOTLIGHT

CLAD METAL MEDICAL WIRE

Anomet Products manufactures clad metal medical wire combining high-strength, highly conductive, biocompatible, and radiopaque alloys into one material "system" with a complete metallurgical bond between layers. Typical wire combinations include 316LVM, Gold, MP35N, Nitinol, Palladium, Platinum, Silver, Tantalum, Titanium, and others. Customized composite wire solutions to meet your unique wire challenges. www.anometproducts.com/content/medical-materials.

Anomet Products

Free Info at http://info.hotims.com/69503-749

PRECISION ORIFICES & FILTERS

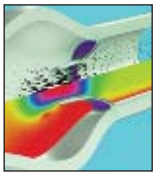
Bird Precision offers laser-drilled, wire-lapped ruby and sapphire orifices.

- Huge variety of Orifices, Inserts, Connectors, and Fittings
- Unique micron orifices series sizes from .0004" thru .081"
- Highly repeatable flow from < .5sccm at 5psi
- Extreme wear & chemical resistance
- Engineering resources & design guides.

Please visit our award-winning website for more information. Bird Precision, Waltham, MA; Tel: 800-454-7369; Fax: 800-370-6308; e-mail: sales@birdprecision.com; www.birdprecision.com.

Bird Precision

Free Info at http://info.hotims.com/69503-750



MULTIPHYSICS MODELING, SIMULATION, APP DESIGN AND DEPLOYMENT SOFTWARE

COMSOL Multiphysics® is an integrated software environment for creating physics-based models and simulation apps. Add-on products allow the simulation of electromagnetics, structural, acoustics, fluid flow, heat transfer, and chemical applications. Interfacing tools enable its integration with all major technical computing and CAD tools. Simulation experts rely on COMSOL Server product to deploy apps to their colleagues and customers worldwide. https://www.comsol.com/products

COMSOL, Inc.

Free Info at http://info.hotims.com/69503-751

SWABABLE STRAIGHT MALE THREADED VALVES

Halkey-Roberts needlefree swabable male threaded valves utilize a female luer lock connector and a male luer lock adaptor to mate securely with all standard luer syringes and connectors. The valves are available with a clear or red housing and a clear or blue septum in both polycarbonate and BPA-free copolyester. www.halkeyroberts.com

Halkey-Roberts

Free Info at http://info.hotims.com/69503-752

MEDISPEC PLASTIC CIRCULAR (MPC) CONNECTOR

Combining premium performance and ease-of-use, the MediSpec Medical Plastic Circular connector incorporates proven cost-effective technology to meet the stringent standards of medical-device users. Proven stamped and formed contact system with 10,000 mating cycles of reliable electrical performance. The simple, push-pull engagement mechanism provides ease-of-use — even with surgical gloves. In Stock at Heilind; 800-400-7041 or www.medicaldesignbriefs.com/heilind201802.

Heilind

Free Info at http://info.hotims.com/69503-753

BIOCOMPATIBLE EPOXY PASTE SYSTEM

Master Bond EP3HTND-2Med Black is a one-part system that combines easy processing with excellent physical strength and bonding properties. This epoxy fully meets USP Class VI specifications and is widely used in the manufacturing and production of both disposable and non-disposable medical devices. http://www.masterbond.com/tds/ep3htnd-2med-black

Master Bond

Free Info at http://info.hotims.com/69503-754

WHITE PAPER: A COMPARISON OF FITTINGS

Easy-to-read charts compare fittings commonly used with plastic and rubber tubing. Includes styles, materials, typical applications and how each fitting works. Clamps are also included. Download at http://www.newageindustries.com/whitepaper-request.asp.

NewAge® Industries, Inc.

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MEDICAL DESIGN BRIEFS

Metasurface-Based Technology Enables Safe MRIs for People with Implants

ITMO University
St. Petersburg, Russia

An international research team has developed a device capable of improving the performance of magnetic resonance imaging (MRI) units. The technology is based on local redistribution of a magnetic field with the help of a metasurface made of metal resonators. It was proven experimentally that the metasurface is capable of reducing the power required to produce high-quality images using an MRI unit. The use of MRI units of lower intensity makes it possible to make MRI diagnostics safe for people with medical implants. The results of this research were published in the *Journal of Magnetic Resonance*.[1]

MRI is currently used to diagnose a variety of diseases — from arthritis to cancer. The accuracy of such diagnostics depends directly on the quality of resulting images. To improve the image quality, scanning time must be longer and the field strength of the MRI unit must be great, both of which causes discomfort to patients. People with medical implants are unable to undergo examinations in MRI units of high field strength because tissue around the implant area may heat up and cause the implant to malfunction.

Scientists from ITMO University, in cooperation with colleagues from the Netherlands and the UK, were able to solve this problem using a metasurface-based device. The metasurface, in this case, is an ordered structure of metal resonators placed in a nonconducting medium. This structure is capable of redistributing the electromagnetic field inside the CT scanner and concentrating it around itself. If one places it under the part of the body that is being examined, reception and transmission of the local signal will improve, and the quality of the image will become higher.

"The patient's entire body is usually irradiated with an electromagnetic field of a certain power during MRI examination. During scanning, a significant portion of the field is present in the area of the patient's limbs, which are placed closely to the radiation source coil. This may cause undesirable heating of tissue. It's dangerous for the patient," says Alena Shchelokova, a PhD student at ITMO's department of nanophotonics and metamaterials and the lead author of the article. "Our experiments have shown that using the metasurface can increase the efficiency of the source coil by more than three times. This means that we can significantly reduce power consumption while ensuring high image quality. The lower strength of the MRI unit makes the procedure absolutely safe for people with medical implants."

The technology is based on local redistribution of a magnetic field with the help of a metasurface made of metal resonators. (Credit: ITMO)

MRI-unit prototype. (Credit: ITMO)

Researchers Alexey Slobozhanyuk and Alena Shchelokova with the MRI prototype. (Credit: ITMO)

The first MRI-boosting metasurface was presented by the researchers in early 2016. Its design was bulky, and the object being scanned had to be completely immersed in water. With this new design, the researchers have overcome these issues.

"We made the first prototype ourselves. We constructed it at an ITMO lab and then tested it at a local hospital using test samples imitating human body parts," says Shchelokova. "When we started working with medical device company Mediwise, we developed an improved prototype. We used it while working with volunteers at the medical center in Leiden, one of the best medical centers in the Netherlands. We are currently trying to introduce our invention to the Russian market. We are cooperating with doctors, optimizing the design, and actively seeking out investors."

"The process of bringing a scientific invention to the market is a critical transition from fundamental research to a product that can improve people's lives," says Alexei Slobozhanyuk, research associate at ITMO.

"Our team has already developed several devices based on new artificial materials capable of drastically improving MRI technology, and we continue this research work now. In two to three years, a series of such devices can improve the efficiency of a significant number of MRI scanners in Russian hospitals and increase the overall level of diagnostics in our country."

Reference

1. A. Shchelokova, A. Slobozhanyuk, et al., "Experimental Investigation of a Metasurface Resonator for In Vivo Imaging at 1.5 T," *Journal of Magnetic Resonance*, Nov. 22, 2017.

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