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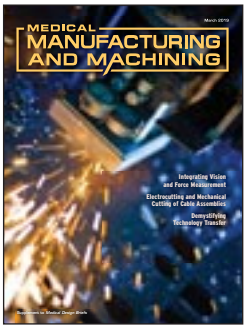

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Technology Leaders in Tubing/Extrusion

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SPECIAL SECTION

Technology Leaders in Tubing/Extrusion

ON THE COVER

Robotics design is hard work. These complicated surgical platforms are run by a highly trained team of five to seven clinicians, which includes the surgeon, scrubs, circulating nurses, and technicians. Typically, two to three multifunctional micro instruments and a 3D HD camera are controlled by the surgeon through a hand controller interface. To learn the five fundamental human factors that must be addressed in the design of any robotic surgical system, read the article on page 10.

(Credit: iStock)

MEDICAL MANUFACTURING & MACHINING (Selected editions only)

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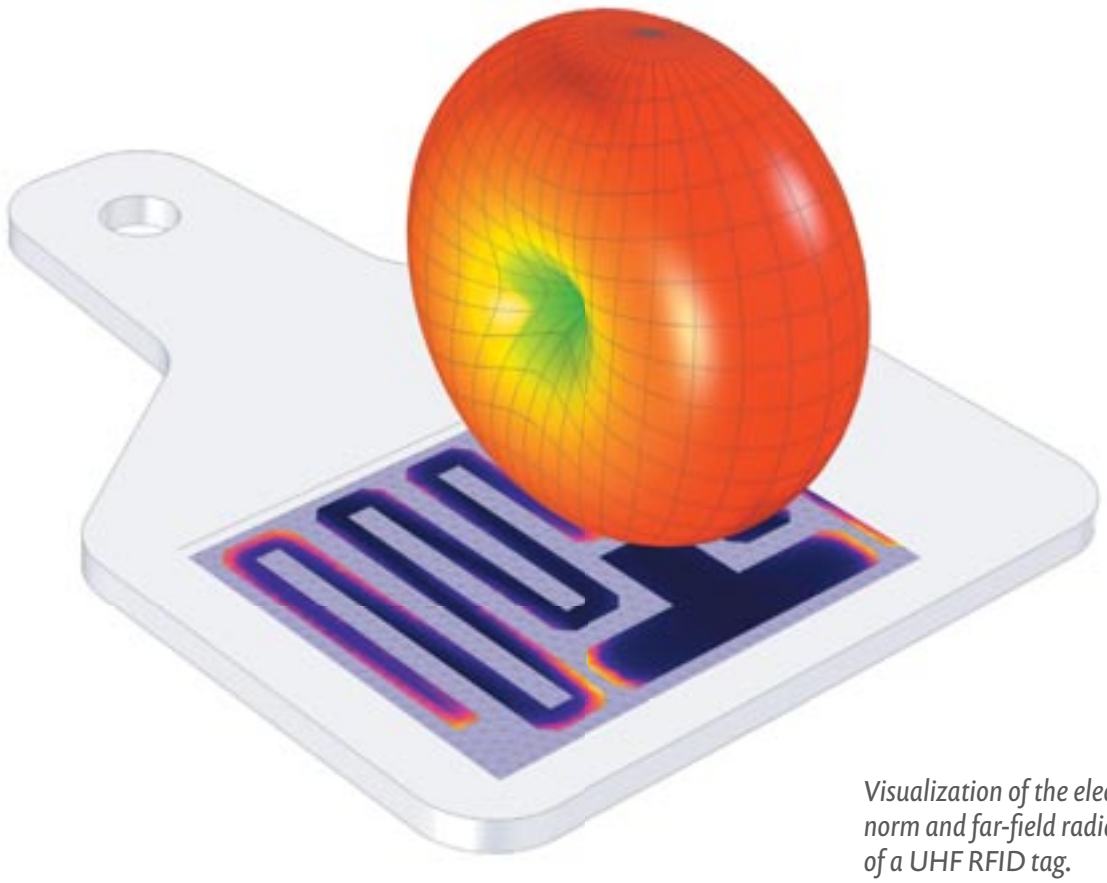

Visualization of the electric field norm and far-field radiation pattern of a UHF RFID tag.

RFID tags are used across many industries, but when it comes to healthcare, there is a major design challenge: size. If wearable RFID tags are too big and bulky, they could cause patient discomfort. Or, if the tag is for a biomedical implant, it has to be smaller than a grain of rice! Design engineers can optimize the size of an RFID tag for its intended purpose using RF simulation.

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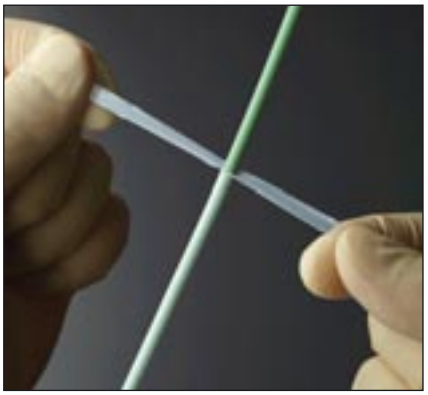
FROM THE EDITOR

And the Winners Are…

In December, we asked *Medical Design Briefs* readers to cast their ballot to choose from our 12 Products of the Month the technology they felt was the most significant new introduction to the design engineering community in 2018. This year, our two winners bring revolutionary new materials to the market. Here are the winners of the 2018 *Medical Design Briefs*' Readers' Choice Products of the Year.

Ultrasmall Heat Shrink Tubing

Junkosha, Tokyo, Japan, has released an ultra-small peelable heat-shrink tubing (PHST) and a high-shrink ratio PHST. The ultrasmall PHST is suitable for laminating a jacket coating to tiny guide wires (for example, 0.011 and 0.014 in.), leveraging the fact that PHST has a recovered ID down to 0.009 in. The miniature guide wires are ideal for applications such as the navigation of vessels to reach a lesion or vessel segment within, for example, the brain or heart. The high-shrink ratio PHST (2:1) is designed for processes where tapered



microcatheter shafts are used or where tolerance take-up is an issue.

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Additive Manufacturing Materials

Victrex, Lancashire, UK, has developed a high-strength material for laser sintering (LS) that attains lower refresh rates than ever, resulting in improved recycling for unsintered powder. Another material is a filament with better Z-strength than existing polyaryletherketone (PAEK) materials and better printability for filament fusion (FF). A first generation of PAEK material for LS can only be recycled in a very low extent and required nearly full refresh of the printing bed with new powder, and PEEK filaments available for FF have poor interlayer bonding, leading to a loss in Z-strength. The new polymer grades have shown encouragingly low refresh rates (improves recycle for unsintered powder) with similar mechanical properties in laser sintering, and good mechanical properties and printability in filament fusion.

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INSIDE STORY

Advances in manufacturing technologies are fostering unprecedented innovation in the development of reusable medical devices and instruments. As designers develop smaller, more-complex, and increasingly intricate devices, however, manufacturers must not overlook the importance of ensuring that such products can be effectively cleaned and disinfected before being reused. In fact, appropriate cleaning processes must be validated before a reusable product can be released. To find out more about the expertise required to establish safe processes for cleaning and disinfecting reusable medical devices, *MDB* spoke with Christopher Scott, Vice President of Eurofins Medical Device Testing (Lancaster, PA).

Christopher Scott
Vice President
Eurofins Medical
Device Testing

***MDB*: What characteristics define a 'reusable' medical device?**

Scott: Technically, the term encompasses any device that is intended to be used more than once. Most attention, however, is paid to the products that must be cleaned or sterilized between uses. The most common examples are surgical instruments, which include a range of products from stainless steel retractors and forceps to endoscopes and cutting jigs for orthopedic implants.

***MDB*: Are such instruments typically cleaned by hospital staff between surgeries?**

Scott: After use, instrument trays are typically sent to the hospital's central supply department, where they are cleaned and resterilized. In recent years, however, there has been a growing trend toward outsourcing this activity to third-party reprocessors.

***MDB*: Is it the responsibility of the hospital to validate these processes?**

Scott: No. It is the responsibility of the device manufacturer to provide a validated cleaning protocol to the hospital. Such protocols are typically included in the product's instructions for use or provided in a standalone instruction manual. It then becomes the hospital's responsibility to follow the instructions provided by the manufacturer.

***MDB*: Is that responsibility dictated by FDA regulations?**

Scott: Yes. FDA's guidance document on the topic explains the agency's logic for applying its quality system regulation (21 CFR 820) to the validation of reprocessing methods for reusable devices. The guidance links instructions for cleaning instruments to the quality systems requirements for ensuring that a device conforms to defined user needs and intended uses — which naturally include preventing cross-contamination among patients.

***MDB*: How does a company go about validating a method for reprocessing its instruments?**

Scott: Generally speaking, the process involves inoculating a device with an artificial contaminant, known as a 'soil,' and then testing the device for cleanliness after it has undergone a well-defined cleaning method. The choice of a particular soil is based on the application of the device, and is a synthetic formulation of proteins, acids, and lipids meant to simulate the environment where the device will be used, which may be blood-filled, mucosal, or gastric. Validation should be conducted under worst-case conditions, including inoculation of the device at a site identified as the most challenging location for cleaning.

***MDB*: Instruments used in orthopedic procedures can involve nearly a dozen different trays, each filled with a dozen or more instruments or trial implants. Does the manufacturer need to validate its reprocessing protocol for each part, or for the entire instrument set?**

Scott: Every manufacturer needs to assess how its instruments are going to be used — including obvious or typical uses as well as less-likely scenarios — and ensure that its reprocessing protocols address each such application. Regulators will accept the bundling of products if a sufficient justification can be provided for treating items as a single family of products. In such a case, data for a worst-case example, or perhaps for a bracketed set of devices, can then be applied to an entire set of devices. A typical example might be a set of trial implants, or a set of reamers that vary only in diameter or length.

***MDB*: In your view, why is it that the reprocessing of devices has lately become such a hot topic?**

Scott: Advances in design and manufacturing technologies have resulted in devices with much greater complexity than those available a generation ago. The age of miniaturization and 3D printing has enabled engineers to develop products with tremendous functionality that would have been considered science fiction just 30 years ago. As such instruments have become smaller and incorporated more moving parts, however, they have also become more difficult to clean and reprocess. In recent years, unfortunately, there have been some cases in which patients died as a result of cross-contamination due to inadequate cleaning between surgeries.

***MDB*: It seems like reusability is something of a two-edged sword.**

Scott: There is no doubt that the innovations we are seeing in surgical instrumentation offer tremendous benefits for patients. The rise of minimally invasive surgery, for instance, has revolutionized medical outcomes for millions of people, and that is a trend that needs to continue. However, as engineers are developing their next generation of innovative reusable products, it is important that they remain mindful that the cleanability of those instruments is a critical design requirement.

To find out more about Eurofins Medical Device Testing, visit the full-length version of this interview, available online at ***www.medicaldesignbriefs.com/InsideStory0319***.

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The Ergonomics of Robotics: Part 2

As technology evolves, augmented reality and virtual reality will play a more significant role in the human interface. (Credit: iStock)

In this two-part series on robotics and wearable devices, part 1 highlighted the wearable device product category. Part 2 moves the discussion from wearable devices to how robotic surgery is changing the future of surgery. This article discloses five fundamental human factors that must be addressed in the design of any robotic surgical system. And not unlike part 1 on wearable devices, the terms *ergonomics* and *human factors engineering* are used interchangeably.

Robotics design is hard work. These complicated surgical platforms are run by a highly trained team of five to seven clinicians, which includes the surgeon, scrubs, circulating nurses, and technicians. Typically, two to three multifunctional micro instruments and a 3D HD camera are controlled by the surgeon through a hand controller interface.

Robotics permit the user the ability to perform tasks with miniaturized electromechanical devices that could never be done with the user's hands. These micro instruments allow for smaller incisions, more finite control at the surgical site, and faster surgeries. These state-of-the-art robotic assistants collectively contribute to quicker recovery times. In robotic surgery, it's all about control. And control starts with the tip of the spear — the human hand, the gateway to good surgery.

The Big Hairy Problem: Mimicking the Human Hand

The surgeon controller interface is one of the toughest design challenges in robotic surgery. This is where the rubber meets the road. Precision and control are the primary objectives in robotic surgery. A robotic surgical tool must be optimized for the three smartest fingers on each hand — the thumb, index, and middle fingers. These three smart fingers are used the most, day in and day out, for fine dexterous precision-based tasks. Several times throughout the day, people routinely use their smartest grips, the "trilateral precision grip" (see Figure 1).

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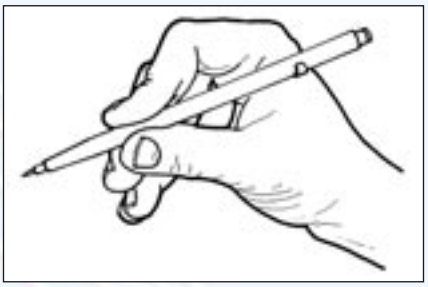

Fig. 1 – Trilateral precision grip (Credit: Kapandji, 1970)

The controller design must allow the surgeon to use their fingers in a natural unencumbered way, but with just enough resistance for the sense of touch without impedance by the design of the controller itself. And the design must accommodate for differences in hand size and strength, from 5th female to 95th male percentiles. This is the toughest part; millimeters matter in getting a synchronous motion that optimizes dexterity and precision while also fitting across the full range of hand sizes. Not only the physical fit of the controllers matter, but also how they behave.

Gain — How Far Do You Turn It Up?

Research on system gain dates back to at least the 1960s, when the focus was on human factors and human performance. Research shows that magnification and gain are interrelated. For example, it is reported in vitreoretinal systems that they require high precision and have used gain ratios as high as 40:1. Experiments to date show that for more traditional robotic surgical systems, gain ratios from 2:1 to 7:6 is an optimal range.

Learning Curves — How Long Does It Take to Learn Robotics?

There are numerous studies citing learning curves comparing expert surgeons to novice medical students or novice volunteers. Clinical studies typically report performance on a specific procedure or task in urology, cardiothoracic, gynecology, or general surgery. Here are the highlights of what is known today about learning curves related to robotics and laparoscopic techniques:

- Surgeons performing simple tasks demonstrated rapid learning, performing equally well on laparoscopic and robotic platforms.
- The surgeons demonstrated faster learning and peak performance times on the advanced task of tying a suture on the robotic platform.
- Surgical performance continued to improve as practice time continued, making the suture tying task faster using a robotic system.
- Skilled laparoscopic surgeons performed robotic tasks in less time, both initially and after practice.
- Learned laparoscopic tasks transferred to robotic surgeons, in both simple and complex tasks.

Interestingly, the greatest improvements are seen in participants with the least amount of laparoscopic experience. And, learning basic skills to carry out a surgical procedure in both laparoscopic and robotic platforms have steep learning curves, and skills plateau after as few as five to 10 surgeries. But learning is influenced by workload.

Workload — What Are They Thinking?

Workload is a key design factor to consider in robotic surgery. It is the amount of work that an individual must do, or the individual's perception of the amount of work. Humans have limits to the amount of workload they can effectively cope with before it impacts performance. When thinking about workload, it is convenient to dissect it into physical workload and cognitive workload.

Physical workload is measured by how the body interacts with tools or the environment, and the effects of those interactions on the body with regard to posture, repetitive motion, workplace layout, material handling, musculoskeletal stress, and any associated injuries or disorders.

Cognitive workload is about the mental resources a person has available to use and considers the mind, memory, sensory motor response, perception, and stress. Everyone has a fixed cognitive bandwidth that when exceeded reduces performance, judgment, and decision making. Any aspect of a design that requires the surgeon or the scrub for the circulator to think longer than they should consumes valuable mental resources that would be better focused on the surgical procedure itself. Designers must be careful that the design does not block the road of usability.

Here's how workload interacts with surgeon comfort, stress and cognitive loading, and processing:

- Laparoscopic surgery demands greater physical workload than general surgery.
- Physical workload demands are greater during laparoscopic surgery than robotic surgery.
- Lower muscular activation levels have been demonstrated in neck, arms, shoulders, and back while performing robotic surgery than laparoscopic surgery.
- Laparoscopic and robotic surgeons show lower physical workload when performing robotic tasks.
- First-year residents and expert surgeons alike display lower levels of nervousness while using a robotic surgical system.
- Stress and concentration are higher for laparoscopic surgical tasks than for robotic tasks as measured by skin conductance, eye blinks, and questionnaires.

Cognitive workload is often used interchangeably with biological stress, although stress and mental workload are different constructs. (Credit: iStock)

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- The incidence of occupational symptoms or injuries in laparoscopic surgeons was reported to be as high as 87 percent.

Stress — The Wild Card

Cognitive workload is often used interchangeably with biological stress, although stress and mental workload are different constructs. Assessments of biological stress are concerned with measuring an individual's response to stimulus events that disturbs their equilibrium and taxes or exceeds their ability to cope. A wide range of physiological measures are used to measure biological stress, including average heart rate, heart rate variability, blink rate, and skin conductance. While not widespread in use, these types of metrics are used by human factors engineers and designers to measure surgeon performance when testing new ideas, concepts, and prototypes.

The Looking Glass — Reflected vs. True Motion

In traditional laparoscopic surgery, moving the robotic instrument in one direction causes the tip inside the body to move in the opposite direction. This is known as the fulcrum effect. For example, moving the surgeon's hand down brings the instrument tip up and vice versa. Everything is backward and presents a challenging learning curve for novice surgeons.

Experienced laparoscopic surgeons have learned to operate in reflected motion by making continuous real-time computations in their heads to flip what they are doing with their hands with what they are seeing. The broken mental model is that their movement input results in the opposite movement output. Regardless of how easy experienced laparoscopic surgeons deal with reflected motion, the fact remains that making these automatic adjustments in real time comes at a cost of the surgeon's cognitive bandwidth. All cognitive resources used to make these real-time compensations for working in reflected motion rob the surgeon of vital cognitive assets that could be used on the surgical procedure, rather than compensation for traditional laparoscopic instrumentation designs. It is difficult to see a case where reflected motion makes any sense.

The Future

The medical robotics industry is on fire. While only a few companies play in this space, all are significant global giants. Intuitive Surgical, the pioneer in the industry, remains dominant. Other companies including Johnson & Johnson, Google, Stryker, and Medtronic have all cut deals to move forward in some fashion into the robotic surgery space. And everyone is trying to figure out who is focusing on what surgical procedures to define how specialized their own robotic system needs to be and how to differentiate their platform from competitors.

It's hard to deny how robotics are transforming surgery. The naysayers who challenge the efficacy of going robotic versus traditional laparoscopic are muted. Robotics improve surgeon performance, minimize procedure invasiveness, and offer faster recovery times. As more competition enters this field, there will be a suppression in the cost of the systems as this industry morphs from a monopoly to an open market.

As technology evolves, augmented reality (AR) and virtual reality (VR) will play a more significant role in the human interface. The physical size and complexity of these robotic platforms will shrink, transforming them from current day monolithic pieces of hardware to smaller flexible designs that better adapt to the wide range of hospital architectures they are currently being shoehorned into today. The future of robotic surgery will not be singular, but also a convergence of nano-like surgical tools, on-skin and in-vivo micro wearables, and tissue/organ visualization technologies that will allow surgeons to see things they've never seen before. This industry is on the cutting edge of the next wave of surgical procedures and techniques.

In part 2, five critical success factors in the design of robotic surgical systems have been disclosed. Regardless of how sophisticated these robotic surgical systems are, their success boils down to designing human interfaces that allow surgeons to work in ways that are natural, intuitive, and unencumbered. These are fundamental human factors engineering issues that must be taken into account to develop high-fidelity robotic solutions that work the way humans think, feel, and behave.

This article was written by Dr. Bryce Rutter, founder and CEO of Metaphase Design Group Inc., St. Louis, MO. For more information, visit ***http://info.hotims.com/72991-163.***

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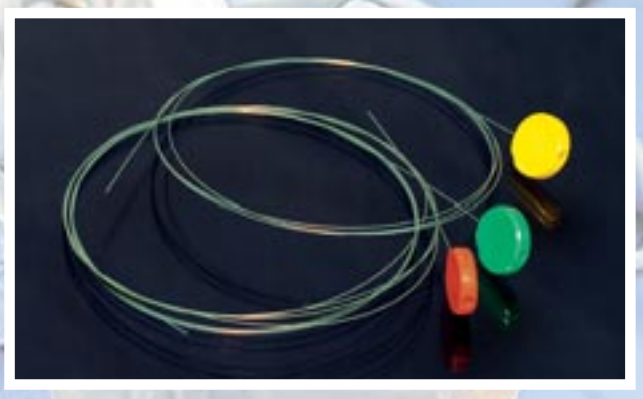

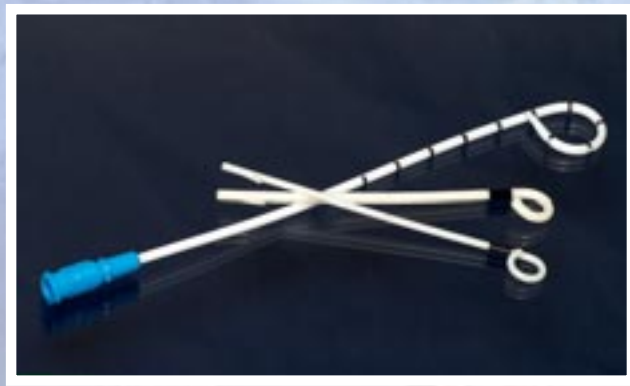

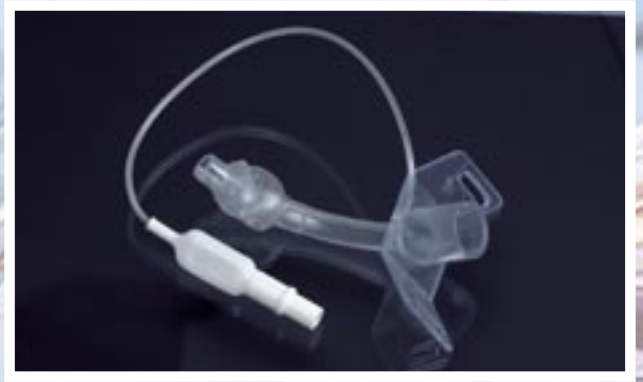

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Fig. 1 – A sample M12 connector head with a push/pull mechanism where a simple mate ensures a radial seal.

Electrical Connectors:

Design Considerations for Medical Devices

The myriad of devices used in surgical, interventional, imaging, diagnostic and therapeutic, sensors, and single-use medical applications use some form of transmission medium to transport electrical signals. While the construction of a cable seems relatively straightforward compared with the complexity of the apparatus it is connected to, the environmental considerations and regulations behind these constructions all bring with them additional design constraints. This article provides an overview of particular characteristics found in medical device cables and connectors along with some respective design considerations.

Ingress Protected

Medical settings are saturated with electrical equipment to supplement patient care. This equipment can vary from portable defibrillators to MRI machines. Connector heads used in these applications require a high resistance to dirt and moisture ingress as well as the ability to be easily mated and unmated. A precertified connector with an Ingress Protection (IP) rating of at least IP67 — a ranking that indicates a device is dustproof and can withstand immersion in water for an extended period of time (e.g., 30 minutes) — would be favored because they would function regardless of time in storage or in case of accidental liquid entry. As an additional note, an IP69K rating would indicate further protection against high temperature and high-pressured spray downs at a close range. Connector heads at this ranking would be able to withstand both washdowns and submerges.

Standard	Title	Description
ANSI/AAMI EC53/Ed.2	**ECG Trunk Cables and Patient Leadwires**	Provides minimum safety and performance requirements for electrocardiographic (ECG) systems.
21 CFR 820.30	**Code of Federal Regulations Title 21 Subpart 820.30**	Details design control requirements for product development of medical devices.
ISO 13485:2003	**Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes**	Specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation, and servicing of medical devices.
ISO 14971:2007	**Medical Devices — Application of Risk Management to Medical Devices**	Specifies a process for a manufacturer to identify the hazards associated with medical devices.
MDD 93/42/EEC	**Medical Device Directive**	Harmonizes laws relating to medical devices within the EU.
ISO 14698-1: 2003	**Cleanrooms and Associated Controlled Environments — Biocontamination Control**	Describes principles and basic methodology to control biocontamination.
ISO 18250-3:2018	**Medical Devices — Connectors for Reservoir Delivery Systems for Healthcare Applications — Part 3: Enteral Applications**	Specifies dimensions and requirements for the design and functional performance of connectors intended to be used on enteral reservoirs.

Table 1. Standards and regulations applicable to the design and integration of connectors and cables in medical instrumentation.

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Push-Pull Connectors

A push-pull connector can be used for a number of cable configurations including coaxial, fiber, and multi-conductor cables. The type of connector utilized depends on whether the wire or cable must carry data, a high-frequency signal, power, or a combination. The latching is generally accomplished through a straight, axial motion where a spring-loaded contact becomes engaged. Disconnections are done similarly where the outer sleeve is pulled back to rapidly disengage, or in other words, pop off. The push-pull mechanism can be broken down into two main interfacing types: male or female. The female-based push-pull type connectors involve a female cavity that includes threads extending radially outward to be engaged by a male connector head. The male-based push-pull type connector typically has threads that project radially inward that can be engaged by the female cavity. These types of connector heads can have pin counts ranging from 1 to 400 depending on the number of data lines and amperage per line.

Certain materials used in the push-pull mechanism must be compressible materials in order to enable thousands of mating cycles without performance degradation. The image shown in Figure 1 provides an example of a keyed IP69K push-pull M12 connector with five pins that attach to a cable containing five unshielded wires. This type of a cable assembly would typically be used for data and communication, the type of signal transmission that is most often used for medical devices. Push-pull connectors are often leveraged in medical applications for a relatively simply connection and disconnection as compared to a threaded or screw-down connector head.

Push-Pull Considerations

The main benefit of a push-pull connector is the ability to generate a rapid connection. This, however, does come with some drawbacks depending upon the application. Certain segments of the connector require specific dimensions of compressible material that may not fit industry standards. Moreover, these connector heads are often keyed to enable a very specific mate. While this simplifies mating, it limits the interoperability of push-pull connector heads. As an additional note, there is often an unshielded gap left at the mating surface, which leaves that connection open to electromagnetic interference (EMI).

Fig. 2 – I/O data connectors come in a large range of configurations but there is almost always an IP-rated variant that would be beneficial in medical applications.

Screw-In Connectors

As made evident by the name, screw-in connectors involve thumbscrews, or a threading mechanism to accomplish a screwed mate. This could range from d-subminiature connector heads to custom high-voltage connectors. More often than not, connectors such as d-sub or USB would be used for instrument control within portable and non-portable equipment such as ultrasound or patient monitoring machines for data transfer. High-voltage connections would be necessary for high-powered equipment such as imaging and laser equipment as well as defibrillators. These connectors are contrary to the push-pull connector types that would be leveraged by a physician or technician on a daily or weekly basis.

Parameters of high flexibility or high mating cycles are not paramount but rather supplementary for these types of connectors. These types of connectors are necessary for almost any equipment utilizing a computer regardless of application. For medical applications in particular, however, the IP rating is relevant. As shown in Figure 2, a rating of IP67 and above can be accomplished on d-sub connectors with kits where the backshell can conform to a variety of cable diameters with an adjustment to the sealing nut. Custom connectors for particular equipment would have specific latching mechanisms and materials that are often proprietary.

Screw-In Connector Considerations

Connectors with thumbscrews are generally not meant for frequent mating/unmating due to the time it takes to screw and unscrew. They are also generally not an ideal connection for situations where the cable is flexed frequently because the lateral strain can bend the pins that are exposed in the shell. There are alternatives that take the strain off the port such as socket savers for d-sub connectors or additional strain relief boots could add flexure to any cabling. High-voltage rated connectors can range from 1 to 100k VDC, when leveraging powers as high as this, it is best to avoid a simple friction fit. In this case, screw-in is ideal.

A Myriad of Connector Topologies

While these are some commonly used connector architectures, the medical industry is not limited to them. High-frequency signals will use a coaxial interface with one conductor, a dielectric, and shielding surround it.

These types of signals would require a coaxial connector that introduces another realm — signal dynamics. The burgeoning field of Medical Body Area Networks (MBAN), for instance, would have to consider high-frequency electronics and their respective interconnections. There are also single-use connector heads that would have to be constructed of materials such as PVC that can be disposed of inexpensively.

Ultimately, the many different medical instruments demand a fairly large range of connections and wires. The general rule is that these cable assemblies must be safe for technician and patient use. Overmolded cables are popular because, similar to strain relief boots, they add flexibility. Overmolding also adds a watertight, or even a chemical tight, seal to an assembly as the mold extends over to the connector head. This, however, may not be necessary for a connector that has already been IP rated.

Medical Cables and Connectors Standards

The medical industry has no global cable standard that can be specified for any medical application. This does not mean that there are no regulations applicable to medical cable assemblies. For example, the ANSI/AAMI 53 standard from the Association for the Advancement of Medical Instrumentation includes minimum safety and performance specifications for ECG cable and lead wires. The standard is designed to prevent inadvertent connection of the patient leads to a power source. The standard specifies that all controls, switches, and connectors be clearly labeled for their function. Warnings and current rating labels must also be placed in areas where maintenance personnel could get shocked. The maximum output display noise is also specified where cables are a direct contributor to this and are therefore a significant consideration.

There are no other cable-specific standards. However, Table 1 identifies additional relevant medical device standards. The practices for ensuring that any of these standards are met could extend to the interconnect. For instance, FDA 21 CFR 820.30 subpart for medical devices defines requirements for sterility to prevent the growth of microorganisms. ISO 14971, which is a risk management standard, encourages manufacturers to use specific connectors that cannot be connected to the wrong component, thereby mitigating any human error. All of these are considerations that have a direct impact on connector and cable design.

Conclusion

The medical industry has very stringent regulations compared with commercial and even military standards. This, in turn, affects the design and selection of the cables and connectors attached to medical devices globally. With the wide variety of connector and cable configurations available, it is important to consider the end use and function to determine which is right for the application. These considerations should be valued according to the specific instrument and application.

This article was written by Dustin Guttadauro, Product Manager for L-com, North Andover, MA. For more information, visit ***http://info.hotims.com/72991-160****.*

High-Consistency Rubber Provides Versatility for Medical Device Manufacturing

With more insight about the characteristics of this versatile silicone material, medical device manufacturers can better understand potential applications and considerations for selecting and using high-consistency rubbers in medical devices.

High-consistency rubber silicone (HCR) is a versatile material with a long history of use in medical devices and other industries. Commonly found in a wide variety of end-use applications, such as tubing, balloons, sheeting, and some molded parts, HCRs consist of a high molecular weight polymer combined with silica to produce a silicone that has a clay-like consistency in its uncured form.

Silicone and HCRs in Medical Devices

Medical device manufacturers often choose silicone for use in components and devices because of its established biocompatibility pedigree, broad processing parameter ranges, and excellent physical properties. One of the earliest uses of HCRs was to create an im-plantable hydrocephalus shunt. Since that time, HCR use has expanded into a vast number of medical applications: both implanted and not.

One of the key appealing characteristics of HCR is its versatility. HCRs can be processed using different types of fabrication methods, including extrusion, calendering, and compression or transfer molding. Compared to other silicone products such as liquid silicone rubber (LSR), HCRs are generally stronger materials with more robust physical properties.

Another key aspect that's appealing about HCRs is their proven history of use in countless approved implant and non-implant applications. This heritage makes it easier for medical device manufacturers to consider using HCRs for new devices or new generations of existing devices.

High-consistency rubber (HCR) consists of a high molecular weight polymer combined with silica to produce a material that can be molded, extruded, or calendered into a useful component. (Credit: NuSil)

Versatility in HCRs

The physical properties and process considerations of HCRs are important to understand along with the advantages that both peroxide- and platinum-catalyzed solutions provide.

A key advantage of peroxide-catalyzed systems is that their curing mechanism — the cross-linking of polymers to cure the HCR — is not initiated until the HCR is exposed to heat. This means that the HCR has a very long work time which is beneficial for molding or extrusion. Larger, more intricate parts may benefit from delayed cure initiations as more time is required to fill the mold. Conversely, operations involving smaller, simpler parts may benefit from faster cure for greater throughput. Silicone HCRs can be tailored to adjust the cure rate to a given temperature for optimal performance. One consideration to be aware of is that the peroxide-catalyzed

systems call for a post-curing process to remove residual byproducts.

The "random" cross-linking of peroxide-cure HCRs provides unique elastomeric properties that can be useful in balloons, or similar applications where "tension set" is an important property. If a balloon needs the ability to be inflated and then, when deflated, to return to its original shape, a peroxide-cure HCR may provide the best solution. Similarly, in peristaltic pump applications, the silicone tubing may be faced with cycles of repeated compression and relief.

Platinum-catalyzed systems typically consist of a Part A component, which contains the platinum catalyst, and a Part B portion that contains hydride-functional cross-linkers and cure inhibitors. Once the two parts are combined, the HCR retains its pre-cure consistency for one to two hours. A key advantage of using platinum-catalyzed HCRs is the ability to heat-accelerate

Two-roll mill processing. (Credit: NuSil)

Medical device manufacturers often choose silicone for use in components and devices because of its established biocompatibility pedigree, broad processing parameter ranges, and excellent physical properties. (Credit: NuSil)

the cure, allowing for faster cure times and increased throughput with the added benefit of no corrosive byproducts. Platinum-catalyzed HCRs typically yield much higher physical properties than traditional peroxide-catalyzed HCRs, which may be valuable for specific medical device applications that use molded or extruded components.

HCR Processing for Medical Device Fabrication

It is helpful to know that when using HCRs, certain steps must be taken depending on the fabrication methods. For example, prior to molding or extruding, HCRs need to be processed with a two-roll mill. The mill softens and mixes the material on cylinders spinning in opposite directions at slightly different speeds to impart shear to the material. This modifies the consistency of the HCR, making it softer and able to flow more easily through the die or into the intricate area of the mold.

If the HCR is a two-part material, Parts A and B need to be separately softened on a cooled mill before being combined. This ensures that the heat of milling does not prematurely trigger curing once the two parts are combined. If the HCR is a one-part material, it will also need to be softened on the mill prior to use.

Different end-use applications call for different fabrication methods. For example, if a device manufacturer is producing a Foley catheter, or another medical device that incorporates silicone tubing, the most efficient method of production would be extrusion. Once the processing method is established, there are further, more specific requirements associated with the tubing that need to be determined: What properties should the tube have? Does it need to be soft and flexible, or stiff and rigid? Is there a tensile strength or modulus requirement? These and other factors can help decide whether a device is produced using a peroxide-cure or platinum-cure system.

The broad processing parameters of silicone elastomers make them ideal for molding. For molded products, like hydrocephalic shunts, consideration needs to be given to the performance of the valve mechanism in the shunt. With this type of molded product, the device manufacturer will seek to select an HCR that can reliably provide the proper modulus, tension set and other elastomeric properties to ensure the valve functions properly.

HCRs are often calendered into flat sheets that may be die cut. A major application for this type of processing method is a gasket used as a seal in the overall medical device. By using a peroxide-cure HCR, it's possible to create gaskets that have self-adhering properties. If stored properly, an uncured peroxide HCR sheet has

Device designers should be sure to consider high-purity, medical-grade HCR products manufactured using robust quality systems and supported by Master Files with U.S. FDA and international authorities. (Credit: NuSil)

almost infinite shelf life. A supplier could fabricate the sheet, package it and ship it to another manufacturer who die-cuts the gaskets which are pressed in place and then cured to provide the complete seal.

Key Factors for Using HCRs

The versatile material properties, processing features, and cure options that HCRs offer make them well-suited for a broad range of medical device applications. There are several factors that device designers and fabricators should consider when choosing HCRs for their next project.

Integration/interaction with other materials: One of the advantages that HCRs offer is the ability to incorporate additives into the formulation prior to curing for special medical device purposes. For example, some device manufacturers may seek to use additives, such as colorants, radiopaque fillers, antimicrobial agents, or even active pharmaceutical ingredients (APIs) into the device.

It's also important to consider how these additives or other materials within the medical device interact with the silicone material and the molding process, in terms of chemical and mechanical behavior. If any of the additives are temperature-sensitive (i.e., degrade after exposure to high temperatures) or adversely interact with formulary components resulting in an incomplete cure, the silicone supplier may be able to provide custom solutions to address the issue.

It is essential to avoid cross contamination. Platinum-cured HCRs, like other platinum-cured silicones, can be negatively impacted by chemicals that may come into contact with the silicone prior to curing. These contaminants can partially or completely inhibit the platinum-catalyzed cure system. Most inhibitors typically have a sulfur-containing material (e.g., natural rubber, latex and neoprene), a nitrogen-containing material (e.g., amines) or an organotin-containing material (e.g., condensation-cured silicones). In order to prevent contamination, clean manufacturing practices should be followed. This includes having dedicated instruments like spatulas for subdividing HCR and cleaning all surfaces between uses.

Flexibility in HCRs is equally important. Since no two medical devices or fabrication processes are exactly the same, leading-edge silicone providers will have solutions that provide greater flexibility for the manufacturing process. NuSil, for example, offers a three-part optimization system that device manufacturers can use to modify the material on the production floor. Device engineers can optimize process requirements, such as work time and cure profile, by varying the ratios of three components, rather than modifying their production systems and equipment to match the HCR's properties.

Final Considerations for HCR Selection

There is a great advantage gained when working with a silicone supplier with extensive experience providing HCRs to the medical device community. Material suppliers that can demonstrate expertise in working with regulatory authorities, along with a focus on supplying materials specifically for medical device applications, can help clear regulatory hurdles efficiently.

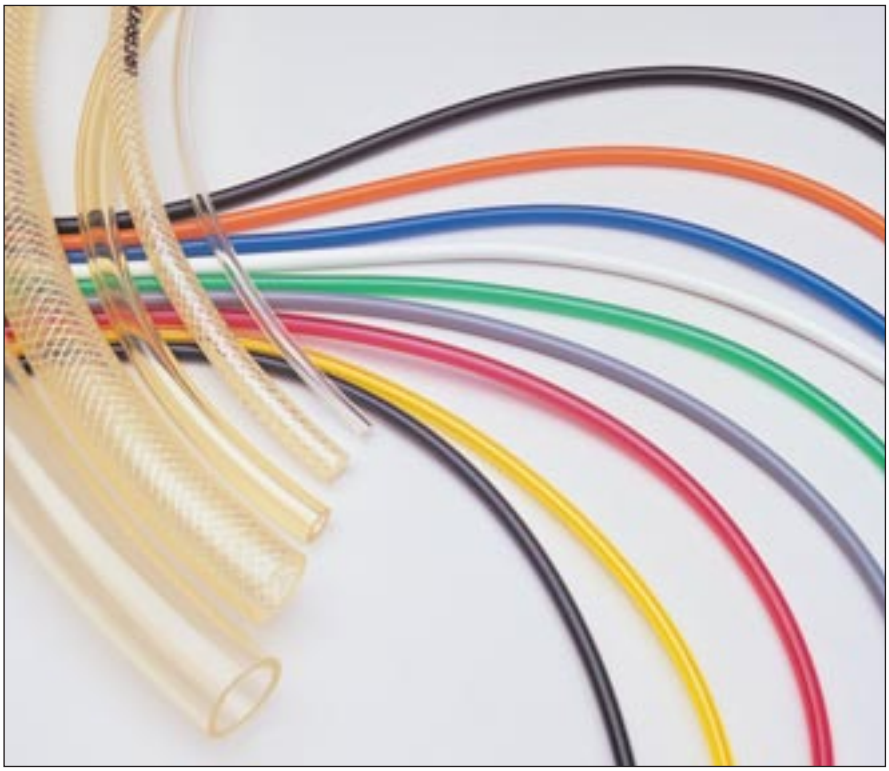
Important credentials to consider when evaluating suppliers include whether they have a robust quality system with ISO 9001 certification, deep knowledge of ISO 13485 quality management requirements for medical systems, and experience with the U.S. Food and Drug Administration (FDA) Master File submissions (MAFs).

And, while FDA's 21 CFR Part 820 Quality System Regulations for Medical Device Current Good Manufacturing Practices (cGMP) only recommend that a material supplier or parts manufacturer meets its outlined requirements, a medical device manufacturer should work with a partner that can provide support throughout the entire design and regulatory submission process. A materials partner that has established relationships with regulatory bodies can prove invaluable and save a device manufacturer time and money, while navigating the path of getting a device to market.

This article was written by Brian Reilly, Business Development Director, Biomaterials for NuSil™ – part of Avantor®, Carpinteria, CA. For more information, visit ***http://info.hotims.com/72991-165****.*

Tubing and Hose Buying: Top 20 Tips

It can be challenging to make sure you've covered all the bases during the tubing and hose selection process for medical instrumentation. For each application, there are many elements to consider, including chemicals, temperatures, pressures, and flexibility needs. The tips in this article are designed to help avoid situations in which the wrong tubing or hose is integrated. The article also presents critical details that can often be overlooked.



Some materials will absorb water and other liquids, and that may be unacceptable. (Credit: NewAge Industries)

1. Check for Approved Ingredients

Know whether the tubing or hose must be constructed with the Food and Drug Administration (FDA) or other association-approved ingredients. If so, check the supplier's catalog or specification sheets for these approvals. Before proceeding, it is also important to determine whether the application calls for specifically approved ingredients.

2. Be Aware of Pressure or Vacuum Requirements

Some products must travel through the tubing or hose under pressure or by vacuum. Certain tubing materials cannot handle these situations, but reinforced hose often can. In fact, depending on the type of reinforcement (polyester braid, fabric, stainless steel wire, corrugation, convolution), certain types of hose are well suited for pressure applications, while others are better for vacuum.

3. Know the Temperatures Involved

It is important to know whether the tubing or hose being investigated can withstand the temperature of the product traveling through it, as well as the temperature of the environment it's in. Be aware of the temperatures operating within the tubing or hose as well as the temperatures surrounding it. And keep in mind that the higher the temperature, the less pressure the tubing or hose can handle.

4. Consider Flexibility and Resistance to Kinking

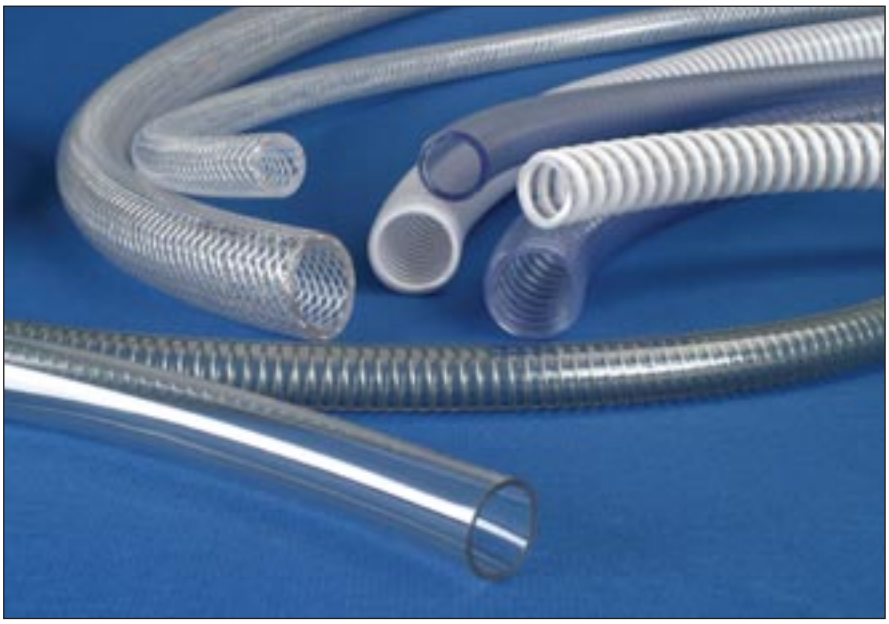
In some applications, the tubing or hose needs to bend around machinery. If so, products manufactured with characteristics to prevent kinking should be used. Similarly, for applications that involve repetitious movement, such as those dealing with robotics, the tubing or hose must be able to withstand this repeated flexing.

5. Look for Incompatible Ingredients or Substances

Product flowing through the tubing or hose may contain ingredients that could react with the tubing or hose material. In addition, the material of the tubing or hose may contain substances that could react with the product being conveyed. If an application involves transferring harsh chemicals, it is important to conduct any necessary research and to consult chemical compatibility charts to determine what tubing and hose materials can handle those chemicals. It is also important to note any other fluids and gases with which the tubing or hose may come in contact. Consider, for instance, cleaning products that may be used on the exterior or gases that may exist in the same room as the tubing or hose. The chemicals may seem harmless enough, but their effects on particular tubing and hose materials should be investigated.

6. Know Whether the Tubing or Hose Will Impart a Taste or Odor

Certain tubing and hose materials will, simply by their nature, not transfer a taste or odor. If an application involves items such as foods, beverages, laboratory fluids, or medicines, any taste or odor transferred to those items could be of concern. Also, some tubing and hose materials contain plasticizers to help them stay flexible. These plasticizers can occasionally leach out from the tubing or hose, thereby contaminating the product within. Other materials (silicone and polyurethane, for instance) are naturally flexible, so no plasticizer is needed. When selecting tubing or hose, be aware of these characteristics and how they can affect the product.



The overall weight of the tubing, hose, and/or assembly components used in an application needs to be considered. (Credit: NewAge Industries)

7. Determine Whether the Products Must Be Seen

In some applications, the user needs to see the flow of the product to check for consistency, progression, or to note measurements. Understanding the eventual application of the tubing or hose and whether products must be viewed as they run through it will affect hose choice. Depending on its material and construction, tubing and hose can be transparent, translucent, or opaque.

8. Learn Whether the Tubing or Hose Can Be Sterilized and Reused

Some applications require sterilization for reuse, so the tubing or hose must withstand sterilization with a chemical cleaning agent. These questions should be addressed: Can it be autoclaved? Does it simply flush clean? Can it withstand low-pressure steam sterilization or gamma irradiation? Knowing the answers to these questions could save money, so be sure to ask. And, depending on the labor and equipment involved to clean the tubing or hose, it may be less costly to simply replace it.

9. Consider Indoor or Outdoor Use

Note whether the application will require that the tubing or hose be used inside or outside. Conditions can vary greatly in either environment, but outdoor usage often has particular requirements. Tubing and hose that is used outside may need to resist a wider range of temperatures. It may need to handle the effects of rain, wind, and gases such as ozone. Sun exposure is another important consideration. Certain tubing materials and/or colors handle the effects of sunlight and UV better than others.

10. Be Aware of Moisture-Related Factors

Applications that involve water, condensation, or humidity have special considerations Tubing and hose materials react in different ways to moisture. Some materials will absorb water and other liquids, and that may be unacceptable. Absorption can cause the tubing to swell and can affect its physical properties. Certain materials like ether-based polyurethane resist attack from moisture and help inhibit mold growth.

11. Investigate Hardness and Softness Needs

Tubing hardness is measured as its durometer. Different scales, namely Shore A, Shore D, and Rockwell R, are commonly used for plastic and rubber materials. The lower the scale number, the softer and more flexible the material will be. For instance, a typical silicone tubing rating is Shore A50. Polyurethane tubing is not as soft as silicone and can measure between Shore A70 and A95. Harder materials like nylon and polyethylene are normally measured on the Shore D scale, and others (polypropylene, for example) use the Rockwell R scale. Flexibility and softness/hardness requirements differ greatly between applications, so the needs for a particular job must be carefully considered.

12. Check for Flammability

Depending on the type of material, tubing or hose can react differently if it catches on fire. Some might emit fumes, while others self-extinguish. Still others are nonflammable. Some tubing and hose, such as that made from particular polypropylene formulas, meets burn ratings established by Underwriters Laboratories (UL). Silicone tubing can self-extinguish. Fluoropolymer is nonflammable. But when tubing manufactured from the high-performance synthetic rubber Viton™ burns, hazardous chemicals can be released, and extreme caution should be taken.

13. Consider Quality

Some applications require that the tubing or hose transfer critical fluids. In some cases, there is reason to be concerned with the environmental conditions in which the tubing or hose is manufactured. In others, the application simply needs a drainage tube to transfer condensation from point A to point B. Applications vary greatly and the highest quality product available is not always a necessity. When the application is critical, it is important to research the tubing or hose under consideration to ensure it meets the required standards. When that's not the case, it may be possible to save money by using tubing or hose that doesn't meet such standards. Products discontinued by the manufacturer may be acceptable and available at a reduced cost.

14. Evaluate Surface Characteristics

Surface characteristics can also play a role in tubing selection. Questions to consider include: Does the tubing or hose need to have a mirror-smooth interior surface for efficient transfer with little to no friction? Will it transport gran-

ular materials, dry powder, or another substance where the surface condition is not a crucial matter? What about the outside? Should it be smooth, or does it need a surface texture like ribbing to make it easy to grip and hold on to? Surface properties can also affect electrical conductivity and static dissipation.

15. Consider Weight

Some single-layer tubing is very lightweight and a perfect match for applications where overall weight is a concern. Some hoses are multilayered and heavy. Add metal fittings and clamps to form an assembly, and that increases the weight. The overall weight of the tubing, hose, and/or assembly components used in an application needs to be considered. It is essential that the hose assembly's weight does not pull on other equipment.

16. Check for Abrasion Resistance

If the application involves rubbing of the tubing or hose against other equipment, it is critical that both the tubing or hose and, of course, the other equipment can withstand that abrasion. Certain tubing materials like polyurethane are better suited to abrasion resistance than others (silicone, for example). Corrosion resistance is another concern that is sometimes overlooked. Perhaps the liquid in the application is acidic. If so, it needs to flow through tubing or hose that can withstand it. Consider, too, the environment the tubing or hose will be in and whether corrosive fluids will come into contact with the tubing or hose.

17. Research Alternative Materials

Research each need individually to make sure the application is not being overengineered or that the tubing or hose is more than what is needed. Also consider coextrusions, which can save costs. Sometimes demanding performance characteristics required for the inside of a hose can differ from those needed on the outside. Hytrel®-lined PVC is one example — oil-resistant Hytrel makes up the interior while durable PVC protects the outside.

18. Know Packaging Requirements

Packaging should also be considered. It can dictate whether a 100-ft coil of tubing or hose acceptable or whether 20 straight pieces, each five feet long, is more appropriate. Consider whether it must it be bagged, double bagged for extra cleanliness, or boxed, or whether stacked coils on a wooden pallet are acceptable. Knowing how the tubing or hose will be used can help determine your packaging needs, allow for easier handling, and result in less waste. The product can be packed so that it's ready to use upon delivery.

It is important to understand the conditions, such as temperature, in which the tubing or hose will be used. Tubing and hose materials react in different ways to moisture. (Credit: NewAge Industries)

19. Explore Custom Options

This can relate closely to packaging requirements. For instance, if the end use of the tubing or hose requires that it be cut into 6-in. pieces, why not have it delivered that way? Other customization can include special colors, heat-formed shapes, thermally bonded tubing, printing, coiling, molded components, or hose assemblies. Don't consider only stocked products — know the ultimate use of the tubing or hose to determine whether a custom product will save time and cost.

20. Don't Forget about Fittings and Clamps

In most cases, the tubing or hose must be attached to other equipment. Fittings and clamps come in many different materials — from nylon to PVDF, fluoropolymer to brass — so it is important to select the best match for the application. For some applications, a system can be built from one material (polypropylene, nylon, polyethylene, or fluoropolymer). Remember that the fitting's material must also be compatible with your application.

Conclusion

For any given medical application, it is important to consider everything from chemicals to flexibility when selecting the tubing. Applying the tips described above should help designers select the right tubing, avoiding situations that can lead to downtime add unnecessary cost.

This article was written by Alex Kakad, Product Manager for NewAge Industries, Southampton, PA. For more information, visit ***http://info.hotims.com/72991-164****.*

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Company Description

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Primary materials include Polyimide, PTFE, Nylon, Pebax®, Tecoflex® (polyurethane), and various polymers specifically designed to provide exceptional mechanical, thermal, and chemical properties. Our proprietary process delivers significantly tighter tolerances than conventionally extruded products.

MicroLumen offers innovative solutions and aids engineers in the design of very specialized medical devices. Our diversified product line and secondary operations include: custom laser machining, etching, composite constructions, assembly, and braid/coil reinforced shafts that solve specific tasks. Contact our engineering team for possibilities.

Target Markets

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Products/Services Offered

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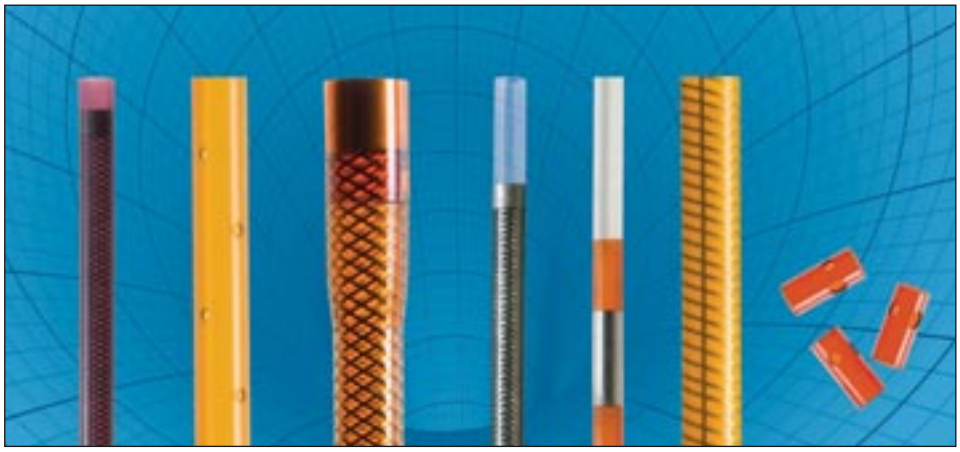

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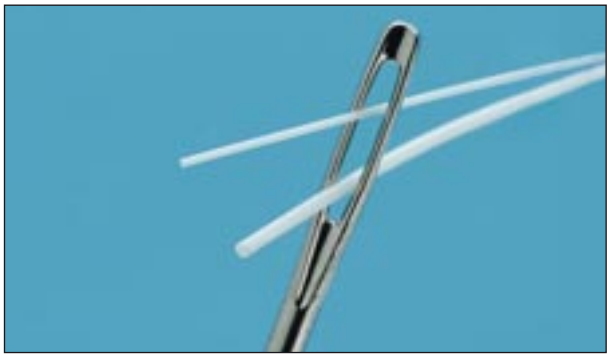
Teleflex Medical OEM offers leading-edge capabilities such as bonding or welding stem sections, softs tips, and atraumatic tips to tubing sections. Step grinding and centerless grinding are available in-house, along with comprehensive finishing operations.

There are plenty of extrusion suppliers in the world. But only Teleflex Medical OEM offers you a winning combination of vertically-integrated capabilities, deep expertise, decades of experience, and a history of industry-changing innovations.



Target Markets

Teleflex Medical OEM partners with companies across the globe, both large and small. Our world-class facilities are located in the United States and Ireland.

Product/Services Offered

If innovation in medical devices is on your agenda, TELEFLEX MEDICAL OEM should be on your team. We are a well-qualified team of engineers, material experts, and skilled technicians that will seem like a natural extension of your own R&D department. Together, we will develop tailor-made solutions for existing challenges and emerging medical innovations. Our vast, in-house capabilities include:

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Company Description

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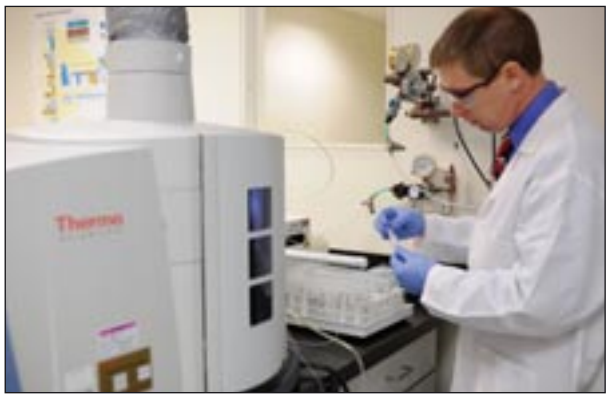
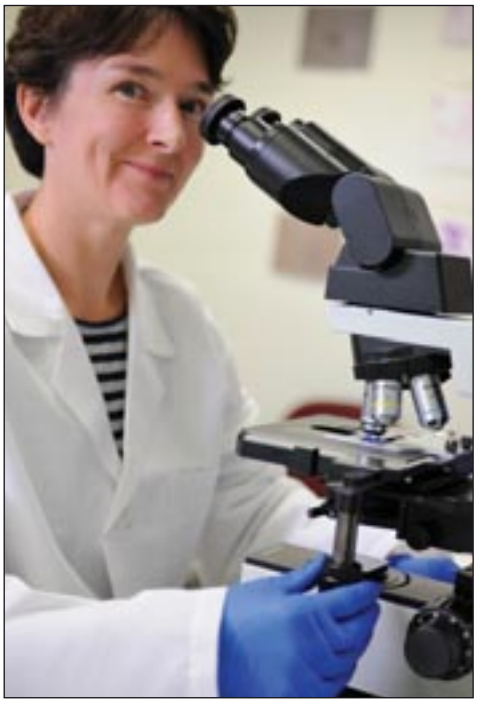
Target Markets

Medical devices, pharmaceuticals, combination products, biologics



Products/Services Offered

- Accelerated Aging
- Analytical Chemistry
- Biocompatibility
- Chemical Characterization
- Compendial Testing
- Disease Models
- Drug Development & Research
- Drug Safety Studies
- Extractables & Leachables
- Medical Device Cleaning Validation
- Medical Device Risk Assessment
- Microbiology
- Ocular Studies
- Pathology
- Risk Assessment
- Stability Testing
- Surgical Research



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E-mail: support@zeusinc.com
www.zeusinc.com

Company Description

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Branchburg, NJ facility

Target Markets

Peripheral vascular, cardiovascular, neurovascular, structural heart, cardiac rhythm management / electrophysiology, gastrointestinal endoscopy, and fiber optics.

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Products/Services Offered

At Zeus, we are dedicated to providing custom designed solutions for medical applications. Our product lines include extruded tubing, heat shrinks, PEEKshrink™, FluoroPEELZ® peelable fusing sleeves, thin-walled Sub-Lite-Wall® tubing, Aeos™ ePTFE porous products, Absorv™ bioabsorbable tubing, Bioweb™ electrospun composites, drawn fiber, and multi-lumen tubing. Zeus also offers a full array of secondary and value-add services including flaring, flanging, pad printing, etching, and more.

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Zeus FEP 2:1 Heat Shrink for Fusing Sleeves

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Fax: 951-698-4346
E-mail: info@medicalextrusion.com
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Company Description

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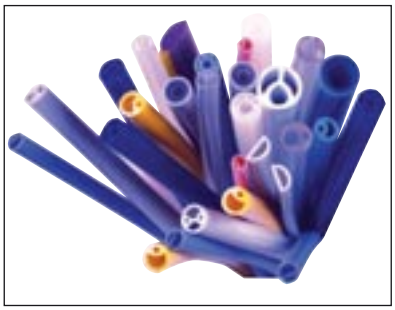

Target Markets

Medical Device

Products/Services Offered

Medical Extrusion Technologies, Inc. offers a full range of consultation services from material selection to tooling development.

- Consultation
- Design
- Development

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Target Markets

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Products/Services Offered

Full-service contract manufacturer of medical devices and subassemblies – including injection/insert molding, MIMs, and fabricated tube assemblies. We offer product development and design assistance – from prototyping and validation to full-scale production.

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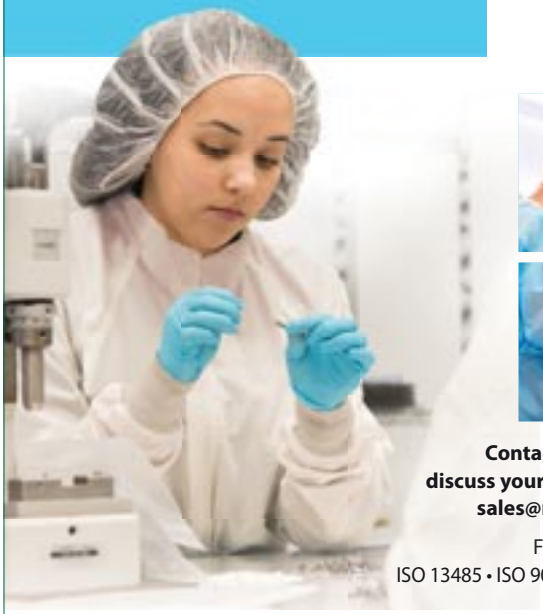

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Proactive Cybersecurity Saves Healthcare Organizations from Data Breaches

Continuous real-time monitoring of the network connections in the system is of paramount importance. (Credit: iStock)

Over the past few years, healthcare organizations have increasingly become one of the leading targets for cyber criminals with data breaches exposing personal patient data, medical records, and financial information, resulting in millions of dollars of added cost to these institutions. As the healthcare organizations become savvier with their cybersecurity, the criminals just get more creative.

The list of targets and the methods by which cyber threats are perpetrated are long and varied; however, one of the primary conduits for cyberattacks is the ecosystem of Internet-connected devices. To help minimize system pitfalls and to protect the confidentiality and availability of patient and network

data, healthcare organizations have been working on consolidating their systems to reduce gaps and vulnerabilities that ultimately serve as "hot spots" for malicious activity.

While an expanded use of network technology, Internet-enabled medical devices, and electronic databases for clinical, financial, and administrative operations can prove to be a significant benefit for patient care data delivery and organizational efficiency, it also increases the exposure to potential cyberattacks. In addition, required industry laws and regulations are ever-changing, and while tedious security measures provide a good platform to ensure the basic protection of the infrastructure, it is no longer enough to prevent breaches. See the sidebar, "Cyberattacks by the Numbers" for statistics that illustrate the scale and impact of data breaches.

The First Step: Assess the System

For any IT environment, the total state of the network, including individual connected devices as well as the effective topology of the network itself, must be evaluated to determine potential risks and vulnerabilities. These include the following areas:

- Network segmentation connections.
- Identified rogue connections.
- Data leak detection.
- Bad actor site connections.
- High-risk open ports.

In addition to the vulnerability identification, cyber real-time situational awareness monitoring of the network is needed to detect any changes over time. All connected known and unknown IP addresses need to be identified and validated, and the system should provide real-time awareness of their behavior. Meta data, which can identify the operating system, properties, and connections, should also be collected on all IPs on the network to determine where the organization needs to update vulnerabilities before a cyber breach occurs.

Cyberattacks are becoming more sophisticated and damaging, and these potentially crippling assaults are premeditated, deliberate, and coordinated. When a device such as a network switch, firewall, or router is identified as end of life, it either has a technological market disadvantage or a technical flaw that renders the device vulnerable in certain situations. Software patches are similar in respect but are much more frequent and are typically called security updates or security bulletins. Many of the updates are categorized as critical, important, or moderate, and they identify the issue as either part of the native vendor products or vulnerabilities in third-party applications used by the native applications that can compromise the OEM publisher's products. Once a flaw is known, the hacker communities also then know and start targeting their attacks to enter an organization through the identified vulnerabilities.

The issue of deployment of patches or updates by companies is the biggest concern given the public awareness of these broad-based cyber/malware attacks. Recently, some attacks have been based upon gaps in the patching software. These attackers develop their software hacks to automatically detect and exploit these unpatched software and systems that are not updated with the current software as the bases for the attack and entrance into the healthcare facility.

Cyberattacks by the Numbers

1,579: Number of reported data breaches in 2017
1,093: Number of reported data breaches in 2016
781: Number of reported data breaches in 2015
$400 billion: Estimated global cost of cyber-attacks annually
$2.1 trillion: Projected global cost of cyberattacks in 2019

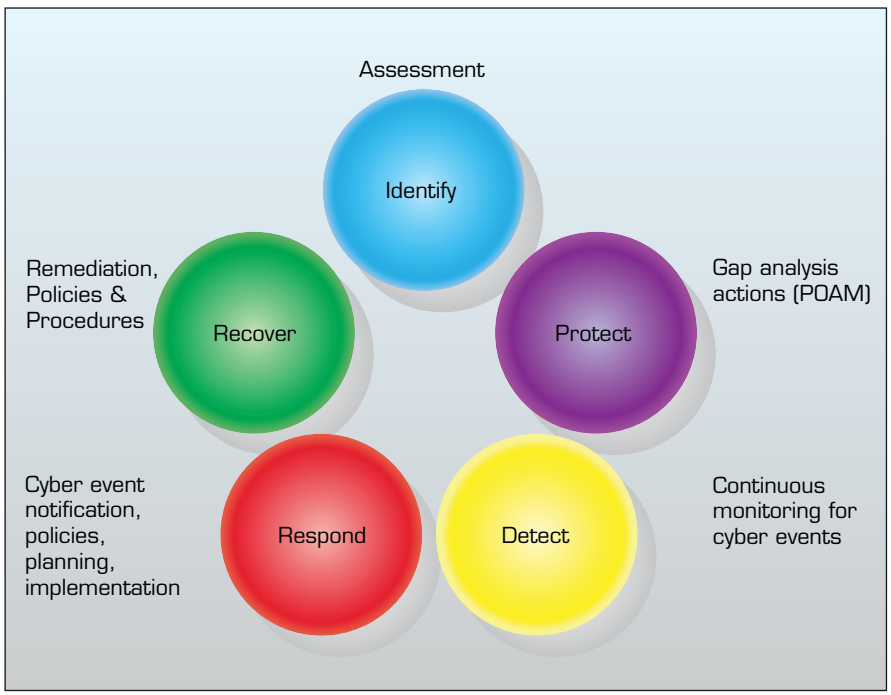


Fig. 1 – A cybersecurity plan includes activities that identify, protect, detect, respond, and recover when an attack occurs.

The Foundation of Network Security: Visibility

Comprehensive network behavioral analytics and proactive cybersecurity situational awareness are key to maintaining system security. A structure needs to be developed and implemented that has the ability to assess, identify, and detect, in real-time, known and unknown threats in the enterprise environment, while providing complete network visibility. Data traffic should be analyzed as well as the behavior of all IP addresses in the organization's infrastructure. Frequent threats identified include the following:

- Segmentation.
- Rogue connections.
- Data leaks.
- Bad actor site connections.
- High-risk open ports.

The First Line of Defense: Real-Time Monitoring

Continuous real-time monitoring of the network connections in the system is of paramount importance to develop and align an organization's security posture, network, endpoints, cloud devices, and applications. This serves as the first line of defense in identifying and addressing potential threats, while ensuring continuity through any changes. Proactive cybersecurity situational awareness is needed with complete visibility of complex networks to protect the healthcare organizations, and their vast web of connected devices, with real-time continuous monitoring, while maintaining compliance with a range of regulatory requirements such as HIPAA, HITECH, and NHS Directive, among others.

These elements are a necessity to ensure that the gap between known and unknown threats does not grow. In many cases a 20 percent gap in network situational awareness can develop. Utilizing gap analysis technology, the healthcare organization can assess network changes to narrow this gap with the ultimate goal of identifying and monitoring 100 percent of network connections and devices.

Best Practices

To effectively create network situational awareness with complete visibility of an organization's IT assets, there is a need for integrative capacity, scalability, and real-time assessment capabilities. Understanding best practices in developing effective cybersecurity measures is a strategic approach to delivery on this agenda (see Figure 1). The following four factors must be taken into account:

- Comprehend the threats facing an organization.
- Identify the company's critical assets and proprietary knowledge.
- Understand the strengths and weaknesses of current cybersecurity arrangements.
- Develop a cybersecurity roadmap.

On the last point relative to developing a cybersecurity plan, executives in coordination with their IT departments and vendor partners should focus on several important actions, including:

- Ensuring that all company technology has the latest security software, web browser, and operation system.
- Creating a mobile device action plan.
- Protecting company Internet connections by using a firewall and encrypting information.
- Controlling physical access to computer and network components.
- Ensuring that service and SaaS providers are using the most trusted and certified or validated tools that include protection for antifraud/antimalware on their systems.

With the range of cyber threats constantly changing, healthcare organizations need to be even more vigilant in their approach to mitigating cyber risks and strengthening their security profile. Executives can benefit from the insight and expertise of a trusted IT solutions team to assist them in navigating the complexities of the cyber security world.

This article was written by Brian Berger, Executive Vice President of Cytellix, Commercial Division, Aliso Viejo, CA. For more information, visit ***http://info.hotims.com/72991-161****.*

R&D ROUNDUP

Ultrasensitive Sensor with Gold Nanoparticle Array

In the sensor, gold nanodisks are arranged in squares. The arrangement causes the sensor to emit UV light (in blue). (Credit: V.K Valev and D.C Hooper)

Physicists have developed a new type of sensor platform using a gold nanoparticle array that is 100 times more sensitive than current similar sensors. The sensor is made up of a series of gold disk-shaped nanoparticles on a glass slide. The team discovered that when they shone an infrared laser at a precise arrangement of the particles, they started to emit unusual amounts of ultraviolet (UV) light.

This mechanism for generating UV light is affected by molecules binding to the surface of the nanoparticles, providing a means of sensing a very small amount of material. The researchers hope that in the future they can use the technology to develop new ultrasensitive sensors for air pollution or for medical diagnostics.

This new mechanism has great potential for detecting small molecules. It is 100 times more sensitive than current methods. This technique could enable ultra-sensitive detection of molecules in tiny volumes. It could in the future be used for detecting very low concentrations of biological markers for the early diagnostic screening for diseases, such as cancer.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0319/sensor.***

Positive Results for Artificial Pancreas and Smartphone App

Overview of the iAPS system components: smartphone running the client app, Dexcom G5/G6 CGM, and Tandem or Insulet insulin pumps. (Credit: Diabetes Technol-ogy & Therapeutics)

The results of a new clinical trial have shown the safety and efficacy of the interoperable Artificial Pancreas System smartphone app (iAPS), which can interface wirelessly with leading continuous glucose monitors (CGM), insulin pump devices, and decision-making algorithms. The app runs on an unlocked smartphone.

The Artificial Pancreas phase, compared to the Sensor-Augmented Pump phase, trended toward improved time in the target glucose range (70–180 mg/dL) and yielded a statistically significant reduction in time below 70 mg/dL.

The iAPS provides wireless integration with Dexcom G5 and G6 CGM and two different insulin pumps: a modified Tandem t:slim™ insulin pump (the Tandem t:AP pump) and an OmniPod® insulin pump with a modified Personal Diabetes Manager. The modifications made to each pump system by the different vendors allow for Bluetooth Low Energy (BLE) communication with a smartphone.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0319/pancreas.***

Representation of the movement of the flower-like particle as it makes its way through a cellular trap to deliver therapeutic genes. (Credit: Washington State University)

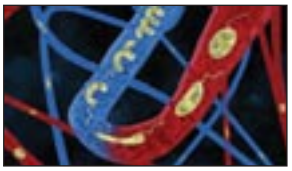
Bioinspired Drug Delivery

Researchers have developed a novel way to deliver drugs and therapies into cells at the nanoscale without causing toxic effects that have stymied other such efforts. The work could someday lead to more effective therapies and diagnostics for cancer and other illnesses.

The flower-like particle is about 150 nm in size. It is made of sheets of peptoids, which make for a good drug-delivery particle because they're fairly easy to synthesize and because they're similar to natural biological materials, work well in biological systems.

The researchers added fluorescent probes in their peptoid nanoflowers so they could trace them as they made their way through cells, and they added the element fluorine, which helped the nanoflowers more easily escape from tricky cellular traps that often impede drug delivery. The flower-like particles loaded with therapeutic genes were able to make their way smoothly out of the predicted cellular trap, enter the heart of the cell, and release their drug there.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0319/drug-delivery.***



The robots are modeled after bacteria and are fully biocompatible. (Credit: EPFL/ ETHZ)

Smart Microrobots Adapt to Surroundings

Scientists have developed tiny elastic robots that can change shape depending on their surroundings. Modeled after bacteria and fully biocompatible, these robots optimize their movements so as to get to hard-to-reach areas of the human body. They stand to revolutionize targeted drug delivery, leading to ingestible robots that deliver drugs directly to diseased tissue.

The smart, biocompatible microrobots are highly flexible. Because these devices are able to swim through fluids and modify their shape when needed, they can pass through narrow blood vessels and intricate systems without compromising on speed or maneuverability. They are made of hydrogel nanocomposites that contain magnetic nanoparticles allowing them to be controlled via an electromagnetic field.

The scientists are able to "program" the robot's shape so that it can easily travel through fluids that are dense, viscous, or moving at rapid speeds.

The robots can be either controlled using an electromagnetic field or left to navigate on their own through cavities by utilizing fluid flow. Either way, they will automatically morph into the most efficient shape.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0319/microrobots.***

Finger Support Could Help Regain Motor Function

Support could help correct deformities.

Kennesaw State University
Kennesaw, GA

A Kennesaw State University engineering professor and her team of students have developed a new finger support that could ultimately help those suffering from finger deformities regain motor function.

Simin Nasseri, who teaches mechanical engineering in the Southern Polytechnic College of Engineering and Engineering Technology, says finger deformation is very common among people who struggle with arthritis, Dupuytren's contracture, and mallet finger, among other ailments. While there are supports available to help slow the onset of finger deformation, the devices had limited capabilities that rendered them unwieldy and uncomfortable, according to Nasseri. Additionally, many supports cannot be adjusted to fit different finger sizes and positions.

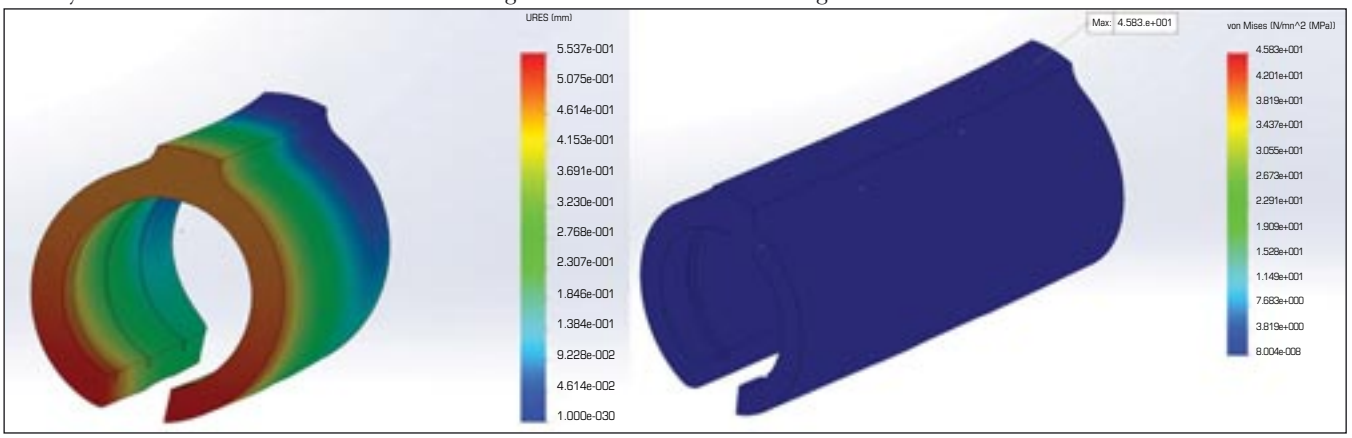
Finger deformation is very common among people who struggle with arthritis, Dupuytren's contracture, and mallet finger, among other ailments. (Credit: David Caselli)

Armed with extensive experience in biomedical and manufacturing engineering, and with several family members and friends who have finger deformities, Nasseri says she was inspired to develop an improved finger support that would allow others to tackle daily tasks more freely. With the help of students, and after several months of research and mechanical testing, she has created a composite support with a soft polymer shell and a thin aluminum, steel, or carbon fiber sheet running the length of the apparatus to provide rigidity. The shell was printed entirely in KSU's 3D Center and the sheet was cut in the machine shop just across the hall in the University's Engineering Technology Center.

"Our support was designed to be used in 'functional positions,' meaning that you are able to slip it over your finger and perform normal tasks with your hands without difficulty," says Nasseri, who will be completing the project this semester alongside student Shanice White. "Our final design is very durable and allows for a wide range of finger positions in order to maximize function."

Nasseri started by conceptualizing designs of her own and soon began to recruit some of her undergraduate students in order to introduce them to the intricacies of engineering research. Since spring 2017, five students have played roles in writing literature reviews, perfecting the design, running simulations, fabricating and conducting mechanical testing on the finger support.

As a team, they have co-authored two journal papers and presented their findings at a regional conference. White, who is conducting a directed study with Nasseri this semester, will complete further testing and hopes to present her discoveries at the National Conference on



The device is a composite support with a soft polymer shell and a thin aluminum, steel, or carbon fiber sheet running the length of the apparatus to provide rigidity. (Credit: Kennesaw State University)

Undergraduate Research to be held at KSU in April.

In a similar project, Nasseri and two additional students have conducted research on a foot support for bunion deformity using the same concepts. Though the finger and foot supports are still under development, the team hopes to obtain patents for their designs and bring it to market.

"This has been an excellent way for me to introduce our students to research and offer them a glimpse into the complete design and manufacturing processes," Nasseri says. "This is an opportunity outside of the classroom where they can apply what they've learned on something tangible and ensure that it works as designed."

Kyle Castellano, who served as student lead prior to graduating with a degree in mechanical engineering technology, says his experience working on the project is what ultimately guided him toward graduate school. Under Nasseri's purview, he conducted computer simulations to test the feasibility of the design before it was printed.

This article was written by Travis Highfield for KSU. For more information, visit, ***https://news.kennesaw.edu.***

Artificial Skin Could Give Superhuman Perception

Sensors may help burn victims feel.

University of Maryland
College Park, MD

A new type of sensor could lead to artificial skin that someday helps burn victims 'feel' and safeguards the rest of us, University of Connecticut researchers suggest in a paper in *Advanced Materials*.

The skin's ability to perceive pressure, heat, cold, and vibration is a critical safety function that most people take for granted. But burn victims, those with prosthetic limbs, and others who have lost skin sensitivity for one reason or another, can't take it for granted and often injure themselves unintentionally.

Chemists Islam Mosa from UConn, and James Rusling from UConn and UConn Health, along with University of Toronto engineer Abdelsalam Ahmed, wanted to create a sensor that can mimic the sensing properties of skin. Such a sensor would need to be able to detect pressure, temperature, and vibration. But perhaps it could do other things too, the researchers thought.

"It would be very cool if it had abilities human skin does not; for example, the ability to detect magnetic fields, sound waves, and abnormal behaviors," says Mosa.

Mosa and his colleagues created such a sensor with a silicone tube wrapped in a copper wire and filled with a special fluid made of tiny particles of iron oxide just one billionth of a meter long, called nanoparticles. The nanoparticles rub around the inside of the silicone tube and create an electric current. The copper wire surrounding the silicone tube picks up the current as a signal. When this tube is bumped by something experiencing pressure, the nanoparticles move and the electric signal changes.

A new type of sensor could lead to artificial skin that someday helps burn victims "feel." (Credit: Getty Images)

Sound waves also create waves in the nanoparticle fluid, and the electric signal changes in a different way than when the tube is bumped.

The researchers found that magnetic fields alter the signal too, in a way distinct from pressure or sound waves. Even a person moving around while carrying the sensor changes the electrical current, and the team found they could distinguish between the electrical signals caused by walking, running, jumping, and swimming.

Metal skin might sound like a superhero power, but this skin wouldn't make the wearer Colossus from the X-men. Rather, Mosa and his colleagues hope it could help burn victims "feel" again, and perhaps act as an early warning for workers exposed to dangerously high magnetic fields. Because the rubber exterior is completely sealed and waterproof, it could also serve as a wearable monitor to alert parents if their child fell into deep water in a pool, for example.

"The inspiration was to make something durable that would last for a very long time, and could detect multiple hazards," Mosa says. The team has yet to test the sensor for its response to heat and cold, but they suspect it will work for those as well. The next step is to make the sensor in a flat configuration, more like skin, and see if it still works.

Among the authors of the paper are Esraa Elsanadidy and Mohamed Sharafeldin from UConn, and Islam Hassan from McMaster University, and Professor Shenqiang Ren from State University of New York at Buffalo. This work is supported by the National Institutes of Health (NIH), National Science Foundation (NSF), and U.S. Department of Energy.

This article was written by Kim Krieger, UConn Communications. For more information, visit ***https://today.uconn.edu.***

Wireless Sensor Monitors Blood Flow after Surgery

Sensor can warn a patient's doctor if there is a blockage.

Stanford University
Stanford, CA

A new device developed by Stanford University researchers could make it easier for doctors to monitor the success of blood vessel surgery. The sensor, detailed in a paper published in *Nature Biomedical Engineering*, monitors the flow of blood through an artery. It is biodegradable, battery-free, and wireless, so it is compact and doesn't need to be removed, and it can warn a patient's doctor if there is a blockage.

"Measurement of blood flow is critical in many medical specialties, so a wireless biodegradable sensor could impact multiple fields including vascular, transplant, reconstructive, and cardiac surgery," says Paige Fox, assistant professor of surgery and co-senior author of the paper. "As we attempt to care for patients throughout the Bay Area, Central Valley, California, and beyond, this is a technology that will allow us to extend our care without requiring face-to-face visits or tests."

Monitoring the success of surgery on blood vessels is challenging as the first sign of trouble often comes too late. By that time, the patient often needs additional surgery that carries risks similar to the original procedure. This new sensor could let doctors keep tabs on a healing vessel from afar, creating opportunities for earlier interventions.

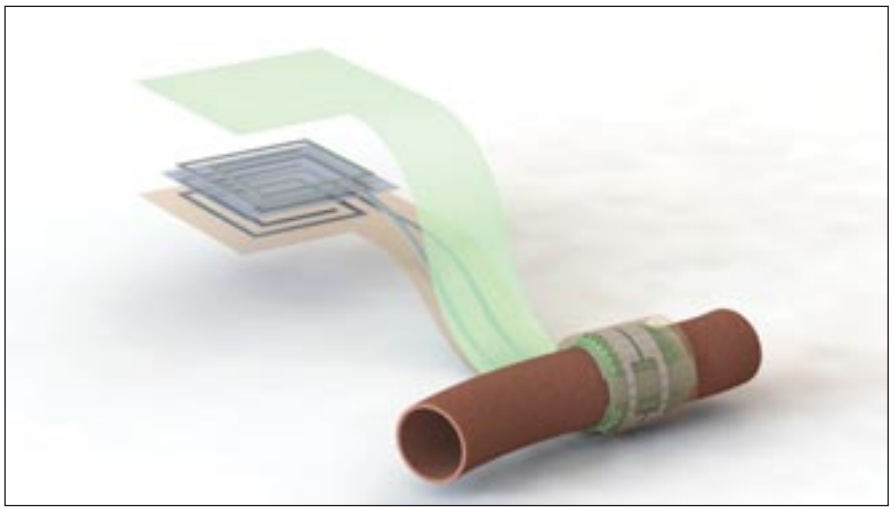
Flow or No

The sensor wraps snugly around the healing vessel, where blood pulsing past pushes on its inner surface. As the shape of that surface changes, it alters the sensor's capacity to store electric charge, which doctors can detect remotely from a device located near the skin but outside the body. That device solicits a reading by pinging the antenna of the sensor, similar to an ID card scanner. In the future, this device could come in the form of a stick-on patch or be integrated into other technology, like a wearable device or smartphone.

The researchers first tested the sensor in an artificial setting where they pumped air through an artery-sized tube to mimic pulsing blood flow. Surgeon Yukitoshi Kaizawa, a former postdoctoral scholar at Stanford and co-author of the paper, also implanted the sensor around an artery in a rat. Even at such a small scale, the sensor successfully reported blood flow to the wireless reader. At this point, they were only interested in detecting complete blockages, but they did see indications that future versions of this sensor could identify finer fluctuations of blood flow.

The sensor is a wireless version of technology that chemical engineer Zhenan Bao has been developing in order to give prostheses a delicate sense of touch.

"This one has a history," says Bao, the K. K. Lee Professor in the School of Engineering and co-senior author of the



Artist's depiction of the biodegradable pressure sensor wrapped around a blood vessel with the antenna off to the side (layers separated to show details of the antenna's structure). (Credit: Levent Beker)

paper. "We were always interested in how we can utilize these kinds of sensors in medical applications but it took a while to find the right fit."

The researchers had to modify their existing sensor's materials to make it sensitive to pulsing blood but rigid enough to hold its shape. They also had to move the antenna to a location where it would be secure, not affected by the pulsation, and redesign the capacitor so it could be placed around an artery.

"It was a very exacting project and required many rounds of experiments and redesign," says Levent Beker, co-lead author of the paper and a postdoctoral scholar in the Bao lab. "I've always been interested in medical and implant applications and this could open up a lot of opportunities for monitoring or telemedicine for many surgical operations."

Making Connections

The idea of an artery sensor began to take shape when former postdoctoral fellow Clementine Boutry of the Bao lab reached out to Anaïs Legrand, who was a postdoctoral fellow in the Fox lab, and connected those groups — along with the lab of James Chang, the Johnson and Johnson Professor of Surgery.

Once they set their sights on the biodegradable blood flow monitor, the collaboration won a 2017 Postdocs at the Interface seed grant from Stanford ChEM-H, which supports postdoctoral research collaborations exploring potentially transformative new ideas.

"The researchers are now finding the best way to affix the sensors to the vessels and refining their sensitivity. They are also looking forward to what other ideas will come as interest grows in this interdisciplinary area.

"Using sensors to allow a patient to discover problems early on is becoming a trend for precision health," Bao says. "It will require people from engineering, from medical school and data people to really work together, and the problems they can address are very exciting."

Additional Stanford co-authors include Clementine Boutry (co-lead), Christopher Vassos, Helen Tran, Allison C. Hinckley, Raphael Pfattner, Simiao Niu, Junheng Li, Jean Claverie, Zhen Wang and Yukitoshi Kaizawa. Bao is also a member of Stanford Bio-X, a senior fellow at the Precourt Institute for Energy, a fellow at Stanford ChEM-H, an affiliate of the Stanford Woods Institute for the Environment and a member of the Wu Tsai Neurosciences Institute. Chang is also a member of Stanford Bio-X. Fox is also a fellow at Stanford ChEM-H. This work was funded by the Swiss National Science Foundation, the European Commission, Stanford ChEM-H and the National Science Foundation.

This article was written by Taylor Kubota, Standford. For more information, visit ***https://news.stanford.edu.***

Smart Knee Implants Could Reduce Number of Knee Replacement Surgeries

The self-powered implants can provide doctors with regular activity updates and are powered by the patient's movement.

Binghamton University
Binghamton, NY

Smart knee implants may soon be a reality thanks to research done by Binghamton University, Stony Brook University, and the University of Western Ontario.

Knee replacement surgery is the most common joint replacement procedure, with the number of surgeries increasing every year. Many of those surgeries are done to replace an older implant or one that has worn out.

Increasingly, this surgery is being performed for younger, more active patients who are faced with a dilemma. When they undergo the surgery, they are expected to remain physically active for their overall health, but that activity can also wear down the new implant. Often, doctors don't know if patients are overexerting themselves until they begin to develop symptoms. By that point, the damage to the implant has already been done. For a young patient, going through knee replacement surgery every five or 10 years is a daunting task, but finding the perfect balance of activity levels to maintain the integrity of the implant has been equally daunting.

Researchers decided it was time to create smarter knee implants that could monitor changes in activity as they happened. Assistant Professor Sherry Towfighian from Binghamton University served as the lead principal investigator on the study, which has been supported by the National Institutes of Health (NIH).

"We are working on a knee implant that has built-in sensors that can moni-

tor how much pressure is being put on the implant so doctors can have a clearer understanding of how much activity is negatively affecting the implant," explains Towfighian.

The sensors allow doctors to tell patients when a certain movement has become too much for the implant so patients can quickly adjust and avoid further damage to the implant. It helps them find the sweet spot of activity for each particular patient.

While the sensors solved one problem, they brought in another. The researchers did not want to power the sensors with a battery that might need to be replaced periodically and therefore, defeat the purpose of a smart implant. Instead, they worked on an energy harvesting mechanism that can power the knee implant from motion. A postdoc in Towfighian's group, Wathiq Ibrahim developed a prototype of the energy harvester and tested that under a mechanical testing machine to examine its output under equivalent body loads.

They used triboelectric energy, a type of energy that is collected from friction. Once someone walks, the friction of the micro-surfaces coming into contact with each other can be used to power the load sensors.

Associate professor Emre Salman from Stony Brook University designed the circuit and determined that it would need 4.6 μW. The preliminary testing showed the average person's walk will produce 6 μW of power, more than enough to power the sensors. This part of the research was complemented by Ryan Willing, an assistant professor from the University of Western Ontario, who worked on the implant design and the package of the sensor.

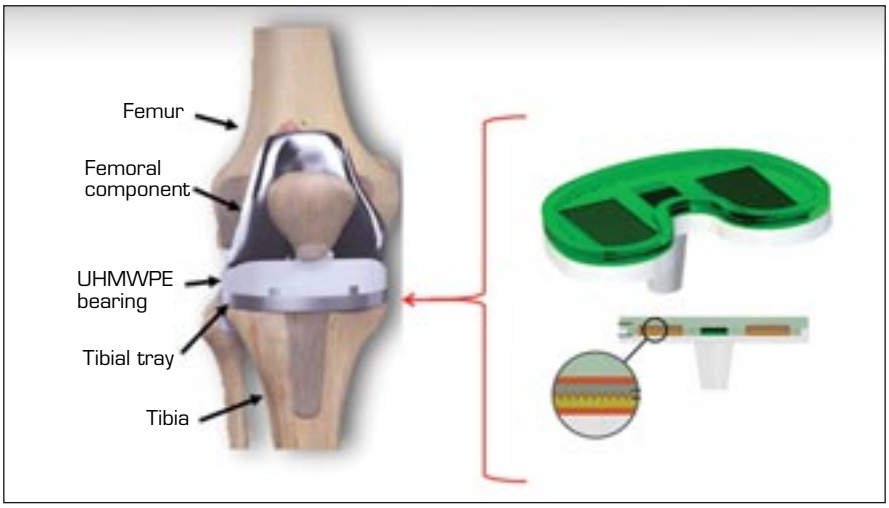


Diagram of the smart knee implant. (Credit: University of Binghamton)

These smart implants will not only give feedback to doctors but will help researchers in the development of future implants. "The sensors will tell us more about the demands that are placed on implants, and with that knowledge, researchers can start to improve the implants even more," says Towfighian.

Towfighian is hopeful that the combination of a self-powered system and activity sensors and will increase the life span of knee implants and reduce the need for follow-up surgeries. For young patients looking at the possibility of knee replacement surgery, this development has the potential to be life-changing.

This research has been supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institute of Health under award number R21AR068572. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The research was published in *Smart Materials and Structures*.

For more information, ***visit https://www.binghamton.edu.***

3D Nanoprinting Strategy Opens Door to Revolution in Medicine, Robotics

Engineers have printed the smallest-known 3D microfluidic circuit element.

University of Maryland
College Park, MD

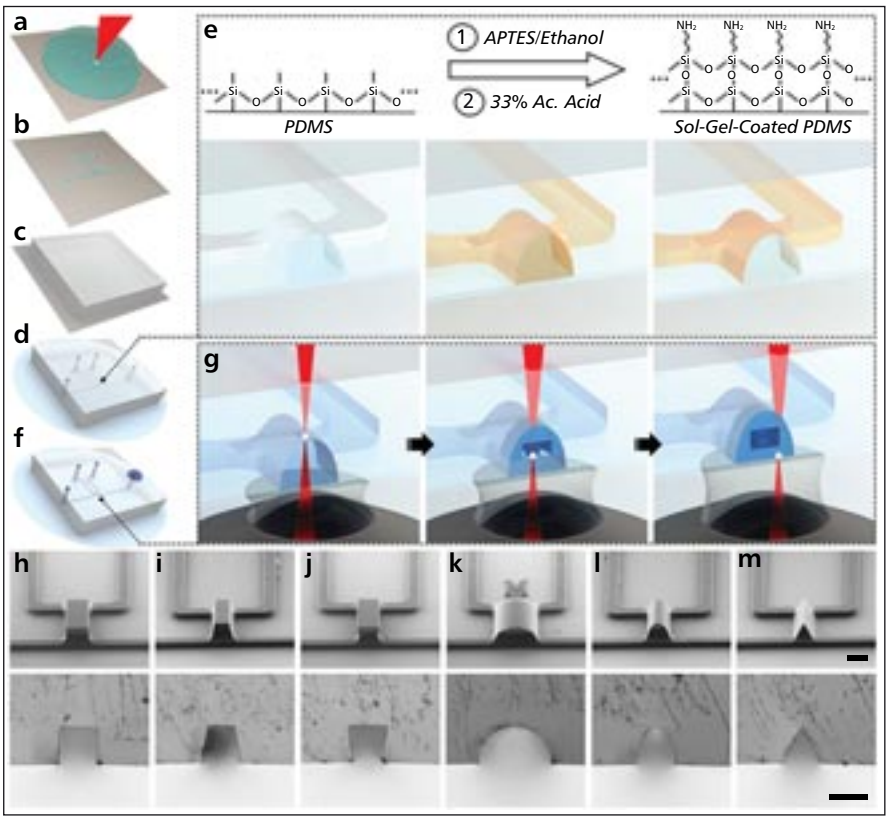
Engineers at the University of Maryland (UMD) have created the first 3D printed fluid circuit element so tiny that 10 could rest on the width of a human hair. The diode ensures fluids move in only a single direction — a critical feature for products like implantable devices that release therapies directly into the body.

The microfluidic diode also represents the first use of a 3D nanoprinting strategy that breaks through previous cost and complexity barriers hindering advancements in areas from personalized medicine to drug delivery.

"Just as shrinking electric circuits revolutionized the field of electronics, the ability to dramatically reduce the size of 3D printed microfluidic circuitry sets the stage for a new era in fields like pharmaceutical screening, medical diagnostics, and microrobotics," says Ryan Sochol, an assistant professor in mechanical engineering and bioengineering at UMD's A. James Clark School of Engineering.

Sochol, along with graduate students Andrew Lamont and Abdullah Alsharhan, outlined their new strategy in a paper published in the open-access journal *Nature: Scientific Reports*.

Scientists have in recent years tapped into the emerging technology of 3D nanoprinting to build medical devices and create "organ-on-a-chip" systems. But the complexity of pushing pharmaceuticals, nutrients, and other fluids into such small environments without leakage — and the costs of overcoming those complexities — made the technology impractical for most applications requiring precise fluid control.



Sol-gel-based in-situ direct laser writing concept. (Credit: University of Maryland)

Instead, researchers were limited to additive manufacturing technologies that print features significantly larger than the new UMD fluid diode.

"This really put a limit on how small your device could be," says Lamont, a bioengineering student who developed the approach and led the tests as part of his doctoral research. "After all, the microfluidic circuitry in your microrobot can't be larger than the robot itself."

What sets the Clark School team's strategy apart is its use of a process known as sol-gel, which allowed them to anchor their diode to the walls of a microscale channel printed with a common polymer. The diode's minute architecture was then printed directly inside of the channel — layer-by-layer, from the top of the channel down.

The result is a fully sealed, 3D microfluidic diode created at a fraction of the cost and in less time than previous approaches.

The strong seal they achieved, which will protect the circuit from contamination and ensure any fluid pushed through the diode isn't released at the wrong time or place, was further strengthened by a reshaping of the microchannel walls.

"Where previous methods required researchers to sacrifice time and cost to build similar components, our approach allows us to essentially have our cake and eat it too," Sochol says. "Now, researchers can 3D nanoprint complex fluidic systems faster, cheaper, and with less labor than ever before."

For more information, ***visit https://eng.umd.edu.***

3D Printed Implant Promotes Nerve Cell Growth to Treat Spinal Cord Injury

Novel scaffolding mimicked natural anatomy and boosted stem cell-based treatment.

UC San Diego Health
San Diego, CA

Researchers at University of California San Diego School of Medicine and Institute of Engineering in Medicine have used rapid 3D printing technologies to create a spinal cord, then successfully implanted that scaffolding, loaded with neural stem cells, into sites of severe spinal cord injury in rats.

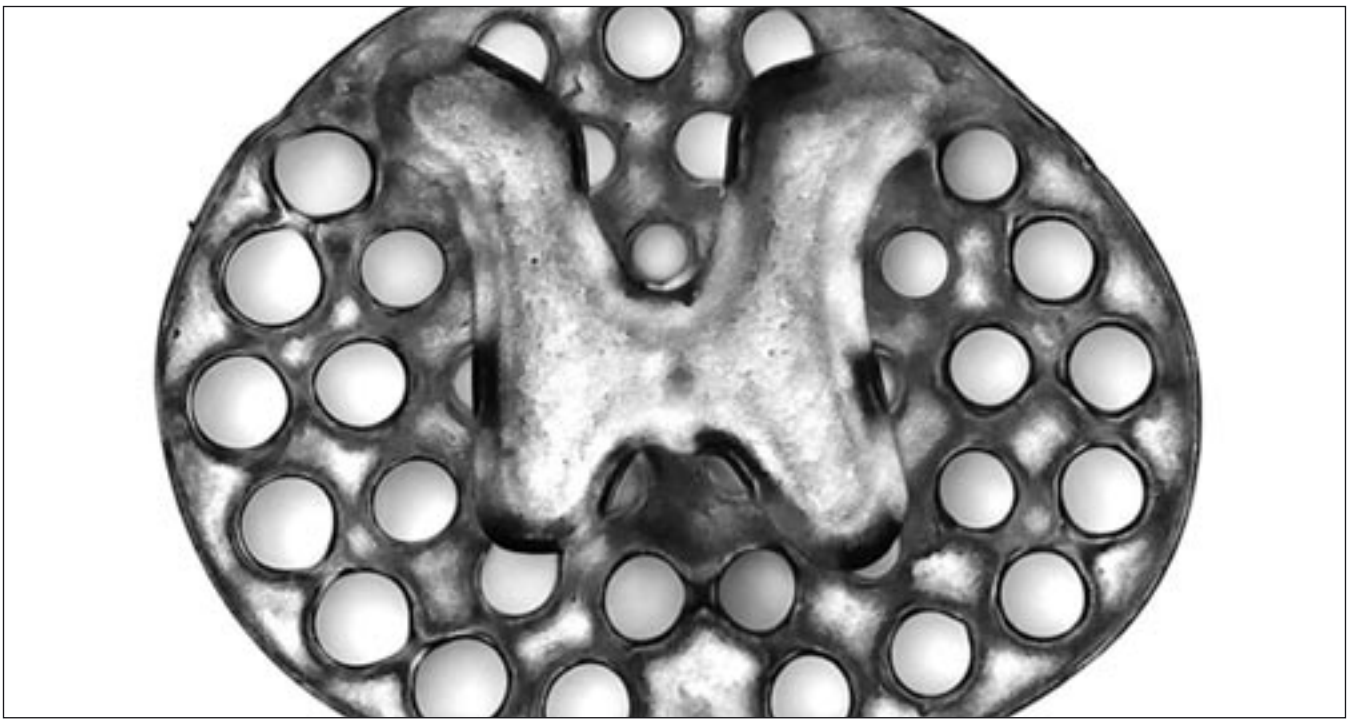
The implants, described in a study published in *Nature Medicine*, are intended to promote nerve growth across spinal cord injuries, restoring connections and lost function. In rat models, the scaffolds supported tissue regrowth, stem cell survival, and expansion of neural stem cell axons out of the scaffolding and into the host spinal cord.

"In recent years and papers, we've progressively moved closer to the goal of abundant, long-distance regeneration of injured axons in spinal cord injury, which is fundamental to any true restoration of physical function," says co-senior author Mark Tuszynski, MD, PhD, professor of neuroscience and director of the Translational Neuroscience Institute at UC San Diego School of Medicine. Axons are the long, threadlike extensions on nerve cells that reach out to connect to other cells.

"The new work puts us even closer to real thing," adds co-first author Kobi Koffler, PhD, assistant project scientist in Tuszynski's lab, "because the 3D scaffolding recapitulates the slender, bundled arrays of axons in the spinal cord. It helps organize regenerating axons to replicate the anatomy of the pre-injured spinal cord."

Co-senior author Shaochen Chen, PhD, professor of nanoengineering and a faculty member in the Institute of Engineering in Medicine at UC San Diego, and colleagues used rapid 3D printing technology to create a scaffold that mimics central nervous system structures.

"Like a bridge, it aligns regenerating axons from one end of the spinal cord injury to the other. Axons by themselves can diffuse and regrow in any direction,



A 3D printed, 2-mm implant (slightly larger than the thickness of a penny) used as scaffolding to repair spinal cord injuries in rats. The dots surrounding the H-shaped core are hollow portals through which implanted neural stem cells can extend axons into host tissues. (Credit: Jacob Koffler and Wei Zhu, UC San Diego)

but the scaffold keeps axons in order, guiding them to grow in the right direction to complete the spinal cord connection," Chen says.

Faster, More Precise Printing

The implants contain dozens of tiny, 200-µm-wide channels (twice the width of a human hair) that guide neural stem cell and axon growth along the length of the spinal cord injury. The printing technology used by Chen's team produces 2-mm-sized implants in 1.6 seconds. Traditional nozzle printers take several hours to produce much simpler structures.

The process is scalable to human spinal cord sizes. As proof of concept, researchers printed 4-cm-sized implants modeled from MRI scans of actual human spinal cord injuries. These were printed within 10 minutes.

"This shows the flexibility of our 3D printing technology," says co-first author Wei Zhu, PhD, nanoengineering postdoctoral fellow in Chen's group. "We can quickly print out an implant that's just right to match the injured site of the host spinal cord regardless of the size and shape."

Restoring Lost Connections

Researchers grafted the 2-mm implants, loaded with neural stem cells, into sites of severe spinal cord injury in rats. After a few months, new spinal cord tissue had regrown completely across the injury and connected the severed ends of the host spinal cord. Treated rats regained significant functional motor improvement in their hind legs.

"This marks another key step toward conducting clinical trials to repair spinal cord injuries in people," Koffler says. "The scaffolding provides a stable, physical structure that supports consistent engraftment and survival of neural stem cells. It seems to shield grafted stem cells from the often toxic, inflammatory environment of a spinal cord injury and helps guide axons through the lesion site completely."

Additionally, the circulatory systems of the treated rats had penetrated inside the implants to form functioning networks of blood vessels, which helped the neural stem cells survive.

"Vascularization is one of the main obstacles in engineering tissue implants that can last in the body for a long time," Zhu says. "3D printed tissues need vasculature to get enough nutrition and discharge waste. Our group has done work on 3D printed blood vessel networks before, but we didn't include it in this work. Biology just naturally takes care of it for us due to the excellent biocompatibility of our 3D scaffolds."

The advance marks the intersection of two longstanding lines of work at the UC San Diego School of Medicine and Jacobs School of Engineering, with steady, incremental progress. The scientists are currently scaling up the technology and testing on larger animal models in preparation for potential human testing. Next steps also include incorporation of proteins within the spinal cord scaffolds that further stimulate stem cell survival and axon outgrowth.

Co-authors include: Xin Qu, Oleksandr Platoshyn, Jennifer Dulin, John Brock, Lori Graham, Paul Lu and Martin Marsala, all at UC San Diego; and Jeff Sakamoto, University of Michigan.

Funding for this research came, in part, from the National Institutes of Health (R01EB021857, R21HD090662), the National Science Foundation (1644967, 1547005), the California Institute for Regenerative Medicine (RT3-07899) and the Dr. Miriam and Sheldon G. Adelson Medical Research Foundation. Disclosure: Chen and Zhu have co-founded the startup, Allegro 3D, to commercialize their rapid bioprinting technology.

This article was written by Scott LaFee and Liezel Labios, UCSD. For more information, visit ***https://health.ucsd.edu.***

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

Health Sensor Platform

Mouser Electronics, Inc., Mansfield, TX, offers a health sensor platform from Maxim Integrated. The MAXREFDES101 Health Sensor Platform 2.0 incorporates a comprehensive range of Maxim products to provide a rapid prototyping, evaluation, and development platform for medical applications, providing accurate monitoring of body temperature, heart rate, and electrocardiogram (ECG). The platform is comprised of a watch enclosure that houses a display, battery, micro board, and sensor board. The micro board integrates a microcontroller, power-management IC, dual-mode Bluetooth® technology, and a six-axis accelerometer and gyroscope. The board includes an optical sensor, integrated biopotential and bioimpedance analog front-end (AFE), temperature sensor, and biometric sensor hub.

For Free Info Visit http://info.hotims.com/72991-166

Product Focus: Materials

Alloys

RTP Company, Winona, MN, has released a group of proprietary alloys that are formulated for the design and manufacture of hospital equipment and plastic housings that require frequent disinfection. The RTP 2000 HC series materials offer superior resistance to the damage, cracking, and premature failure caused by harsh cleaners and disinfectants. Ideal applications include equipment such as x-ray machines, enteral feeding devices, drug pumps, blood filtration, and other frequently cleaned apparatus.

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Soft-Skin Adhesive

DowDuPont Specialty Products Division, Wilimington, DE, has released a soft skin adhesive. The Dow Corning MG 7-1010 soft skin adhesive for medical device applications can be used for wearable monitoring devices, wound care products, medical tape applications, and medical device attachments. This adhesive allows designers to tune the coat weight and adhesion level for greater flexibility in manufacturing. The adhesive has high anchorage properties that can be direct or transfer coated. It is a two-part, low-viscosity silicone adhesive that provides excellent adhesion to stainless steel and polycarbonate substrates.

For Free Info Visit http://info.hotims.com/72991-170

Halogen-Free Parylene

Specialty Coating Systems, Indianapolis, IN, has developed a halogen-free variant of Parylene. The company developed ParyFree in support of the global initiatives that continue to drive toward the elimination of halogens in electronics. ParyFree is applied through a vapor deposition process that results in an ultra-thin, uniform, pinhole-free conformal coating. The thin film forms at a molecular level to fully encapsulate components and devices, offering complete protection and increased reliability of intricate, complex electronic devices. The coatings were tested in accordance with BS EN 14582:2007 at an independent testing facility. The results show that there are no detectable levels of chlorine, bromine, fluorine, or iodine.

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Translucent Compounds

A new compound from Foster Corp., Putnam, CT, offers lower lubricity and translucency in medical device components when added to lower durometer TPU and Pebax polyamide elastomer compounds. Similar to the existing ProPell product line, ProPell T offers reduced coefficient of friction (CoF) while maintaining critical mechanical properties and improved manufacturing and handling of medical catheter tubing. It also offers a proprietary surface-enhancing additive that also provides translucency. It reduces tackiness and friction in medical device components, especially soft, flexible polymers such as low durometer TPU, commonly used in central venous catheters (CVC), and Pebax polyamide polymers that are used in interventional vascular catheters.

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Silicones

Shin-Etsu Silicones of America, Akron, OH, offers a line of optically clear silicones. The KEG-2000 LIMS products have consistent properties from batch to batch and offer dynamic viscosity. The silicones have high clarity and range in Shore A hardness from 10 to 80. Additionally, the products have been tested for compliance with FDA, USP Class VI, and ISO 10993 regulations. The products can be used as is or colored easily.

For Free Info Visit http://info.hotims.com/72991-168

3D Printing Ceramics

Morgan Advanced Materials, Windsor, UK, has released a line of materials suitable for 3D printing for use in radiological applications such as x-ray power tubes. The AL-300™ grade alumina ceramic, known for its dielectric strength, strong metallization capability, and high strength, is now available for 3D printing. Using 3D printing, cooling channels can be integrated for high-temperature applications.

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Flush-Head Studs

Self-clinching flush-head studs from Penn-Engineering, Danboro, PA, feature a thread profile that enables quick mating with push-on plastic nuts, wire tie products, or other plastic fasteners in thin metal assemblies. The PEM® FHX™ coarse thread design — larger threads relative to the stud's diameter — reduces assembly time by allowing for easy mating of plastic parts and promotes especially high retention force. The thread design additionally accommodates paints and coatings without compromising fastener performance in service. The studs install permanently in metal sheets as thin as 1 mm.

For Free Info Visit http://info.hotims.com/72991-175

Motorized Digital Test Frames

The L.S. Starrett Company, Athol, MA, has introduced a series of motorized digital test frames for performing a wide range of basic, high-volume in-situ lean manufacturing force testing applications including tension, compression, flexural cyclic, shear, and friction. The FMM digital force testers are part of the new Starrett L1 Line of entry-level computer-based force measurement solutions. Optimized for production and quality control testing, the architecture of the L1 system is designed for fast, easy-to-use, reliable and repeatable operation. The to be used with either Starrett L1 software for computer-controlled testing or with a Starrett DFC digital force gage.

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Cloud-Based DHR

42Q, San Jose, CA, has released a cloud-based solution for its MES platform that enables medical device manufacturers to quickly implement and start using eDHR capabilities. Rapid eDHR automatically collects, records, and reports all required regulatory data, and it provides manufacturing executives with secure and instant access to the status of eDHR activity, from any location and on any mobile device. It digitally records quality records in accordance with GAMP5 guidelines and can be used to produce Class 2 and Class 3 medical devices with UDI (universal device identifier) labeling.

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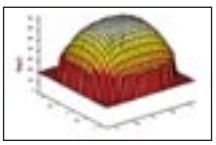

High-Temperature Coatings

Electro Optical Components, Santa Rosa, CA, has released a low internal stress coating that is biocompatible and has high temperature stability. The coating has high temperature stability up to 750 °C. These nanoamorphous carbon coatings can also be made electrically conducting, with conductivity varying from dielectric to metallic. A current was sent through the coating with rapid heating to cauterize surgical tools. Sample coatings on suitable substrates such as titanium are available for testing.

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Resistors

KOA Speer Electronics, Bradford, PA, has introduced a new 0.2 mΩ resistance value to its PSJ2 series of power shunt current sense resistors. This resistor features a 12 W power rating and is available in a 3920 package. The resistors offer ultralow resistance suitable for large current sensing, as well as a broad operating temperature range of –65° to +175 °C. The resistors offer T.C.R. of ±75 ~ ±200 ppm/°C with resistance tolerance of ±1 percent. The power shunts are offered in resistance values of 0.2, 0.5, and 1 mΩ and are AEC-Q200 qualified.

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Displacement Connectors

Low-profile insulation displacement connectors (IDCs) are available from AVX Corp., Fountain Inn, SC. The 9176-800 series reduce the z-axis height of the next-lowest-profile insulated IDC connector, the 9176-400 series, by 1 mm, reduce the total overall volume of the standard 00-9176 Series IDCs by more than 50 percent. Designed to connect discrete 22–26 AWG solid and stranded wires and leaded components to PCBs, or to connect PCBs together in a daisy chain configuration, the low-profile IDCs feature redundant, fatigue-resistant phosphor bronze contacts that provide gas-tight, cold-welded wire connections compatible with potting and overmolding encapsulation processes for environmental protection.

For Free Info Visit http://info.hotims.com/72991-178

DC Current Transducers

NK Technologies, San Jose, CA, has introduced a series of DC current transducers. The DT-FD series provides a large sensing window and the ability to safely monitor circuits with voltages up to 1500 VDC, and up to 400 A. The sensor can be mounted on a DIN rail or attached to a back panel with screws. The easily accessible power supply, output-signal, and finger-safe terminals are located on the top of the sensor to allow for a clean and trouble-free installation. The one-piece design combines the current sensing elements and the signal conditioning to provide an output compatible with most control systems. Features include industry standard analog output and externally powered 24 VAC or DC.

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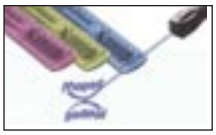
Miniature Coded Structures



Mimotec SA, Sion, Switzerland, has developed a process to manufacture miniature coded structures as mold inserts using proprietary CLR-Liga technology. The inserts can be placed at the tip of ejector pins or in other noncritical areas, forming a coded logo or text, invisible to the naked eye, each time an injection molded part is made. The patterns are created using diffractive nanostructures, tuned to laser light frequencies. A simple laser pointer reveals the text or image, so inspections can easily be performed in the field. For clear material, the light will shine through and project the message onto a surface behind the part. In the case of opaque material, the message will be reflected to a surface held at an angle.

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High-Temperature Adhesive

EpoxySet Inc., Woonsocket, RI, offers advanced polymers used extensively for medical device manufacturing. Included are high-performance biocompatible adhesives, sealants, and potting materials approved and certified to USP Class VI and ISO-10993-5, including EB-177, a very high-temperature adhesive used extensively in medical devices. This epoxy can withstand continuous operation at 250 °C and intermittent temperatures to 300 °C. Approved to USP Class VI for biocompatibility, it is used in any applications where high strength at elevated temperatures is required. It also provides excellent optical transmission of over 95 percent at 1500 nm with a refractive index of 1.52.

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Medical Extrusions

Spectrum Plastic Group, Alpharetta, GA, recently launched an upgraded e-commerce store on behalf of Apollo Medical Extrusion. The online store showcases the company's quick turn, off-the-shelf extrusion program. Products, which are available as both stock and custom, feature the most common medical-grade materials and additives related to catheter delivery system development and innovation. Examples include single-lumen tubing with ultra-thin walls down to 0.003 in. (0.08 mm), dual-, triple- and quad-lumen medical tubing, and 5-lumen steerable catheter liners. Tubing and catheters are available in Nylon 12, Pebax® (35D-72D), PEEK, and FEP with radiopaque and low-friction additives.

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Wall Mounting Kit

OKW Enclosures, Bridgeville, PA, has launched a new suspension element for its EVOTEC designer tabletop enclosures, enabling them to be wall mounted. The wall kit makes the enclosures ideal for access control. Although designed for EVOTEC, the new suspension element will suit any small plastic enclosure with a flat base. Each kit comprises two parts: an adapter attached to the enclosure and a holder fitted to the wall. The adapter (and enclosure) can then be clipped to the wall holder. The adapter is attached to the base of the enclosure using four tamperproof Torx stainless steel screws (supplied). Both the adapter (4.17 × 2.95 in.) and the holder are molded from UV-stable ASA+PC-FR (UL 94 V-0).

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The Arthur G. Russell Company designs automatic assembly equipment for the medical device industry. We specialize in high-speed, mechanical systems designed for products like syringes, blood collection tubes, catheters, and dosage dispensers. AGR's manufacturing process adheres to stringent FDA requirements. http://www.arthurgrussell.com/

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Master Bond LED405Med is a one component, LED curing adhesive that meets USP Class VI and ISO 10993-5 cytotoxicity requirements for use in medical device assembly. It features a high viscosity of 2,000–8,000 cps and can be used for bonding, sealing, coating, and encapsulating. This biocompatible compound withstands sterilization methods such as gamma radiation, EtO, and radiation. http://www.masterbond.com/tds/led405med

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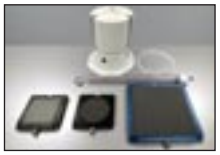

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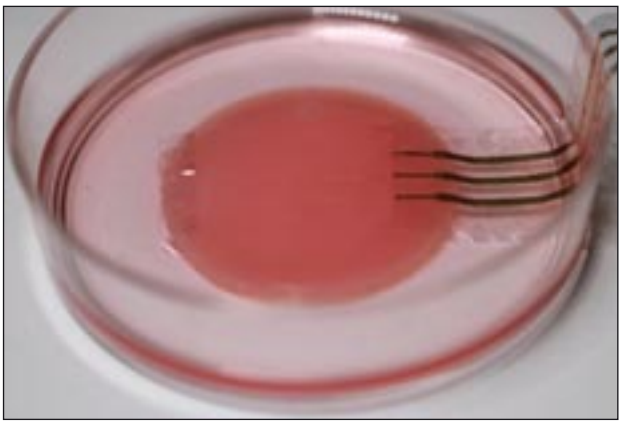
MEDICAL DESIGN BRIEFS

Ultrasoft Sensor Monitors Heart Cells with Minimal Disruption

University of Tokyo
Tokyo, Japan
www.u-tokyo.ac.jp

For the first time, engineers have demonstrated an electronic device that can closely monitor beating heart cells without affecting their behavior. A collaboration between the University of Tokyo, Tokyo Women's Medical University, and RIKEN in Japan produced a functional sample of heart cells with a soft nanomesh sensor in direct contact with the tissue. This device could aid study of other cells, organs, and medicines. It also paves the way for future embedded medical devices.



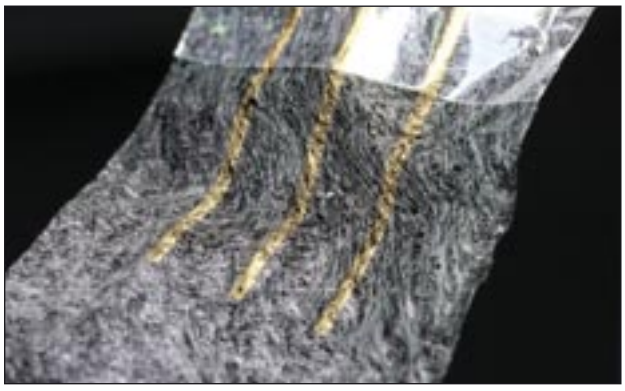
The layer of cardiomyocytes is only a few tens of microns thick and contracts with a force of just a few millinewtons. (Credit: Someya Group)

Inside each of us beats a life-sustaining heart. Unfortunately, the organ is not always perfect and sometimes goes wrong. One way or another, research on the heart is fundamentally important to us all. So, when Sunghoon Lee, a researcher in Professor Takao Someya's group at the University of Tokyo, came up with the idea for an ultrasoft electronic sensor that could monitor functioning cells, his team jumped at the chance to use this sensor to study heart cells, or cardiomyocytes, as they beat.

"When researchers study cardiomyocytes in action, they culture them on hard petri dishes and attach rigid sensor probes. These impede the cells' natural tendency to move as the sample beats, so observations do not reflect reality well," says Lee. "Our nanomesh sensor frees researchers to study cardiomyocytes and other cell cultures in a way more faithful to how they are in nature. The key is to use the sensor in conjunction with a flexible substrate, or base, for the cells to grow on."

For this research, collaborators from Tokyo Women's Medical University supplied a healthy culture of cardiomyocytes derived from human stem cells. The base for the culture was a very soft material called *fibrin gel*. Lee placed the nanomesh sensor on top of the cell culture in a complex process, which involved removing and adding liquid medium at the proper times. This was important to correctly orient the nanomesh sensor.

"The fine mesh sensor is difficult to place perfectly. This reflects the delicate touch necessary to fabricate it in the first place," says Lee. "The polyurethane strands, which underlie the entire mesh sensor, are 10 times thinner than a human hair. It took a lot of practice and pushed my patience to its limit, but eventually I made some working prototypes."



The sensor probes are formed by a 100-nm thick layer of gold because it is resilient and does not interfere with cell chemistry. (Credit: Someya Group)

To make the sensors, first a process called *electrospinning* extrudes ultrafine polyurethane strands into a flat sheet, similar to how some common 3D printers work. This spiderweb-like sheet is then coated in parylene, a type of plastic, to strengthen it. The parylene on certain sections of the mesh is removed by a dry etching process with a stencil. Gold is then applied to these areas to make the sensor probes and communication wires. Additional parylene isolates the probes so that their signals do not interfere with one another.

With three probes, the sensor reads voltage present at three locations. The readout appears familiar to anyone who's watched a hospital drama as it's essentially a cardiogram. Thanks to the multiple probes, researchers can see propagation of signals, which result from and trigger the cells to beat. These signals are known as an action or field potential and are extremely important when assessing the effect of drugs on the heart.

"Drug samples need to get to the cell sample and a solid sensor would either poorly distribute the drug or prevent it reaching the sample altogether. So, the porous nature of the nanomesh sensor was intentional and a driving force behind the whole idea," says Lee. "Whether it's for drug research, heart monitors, or to reduce animal testing, I can't wait to see this device produced and used in the field. I still get a powerful feeling when I see the close-up images of those golden threads."

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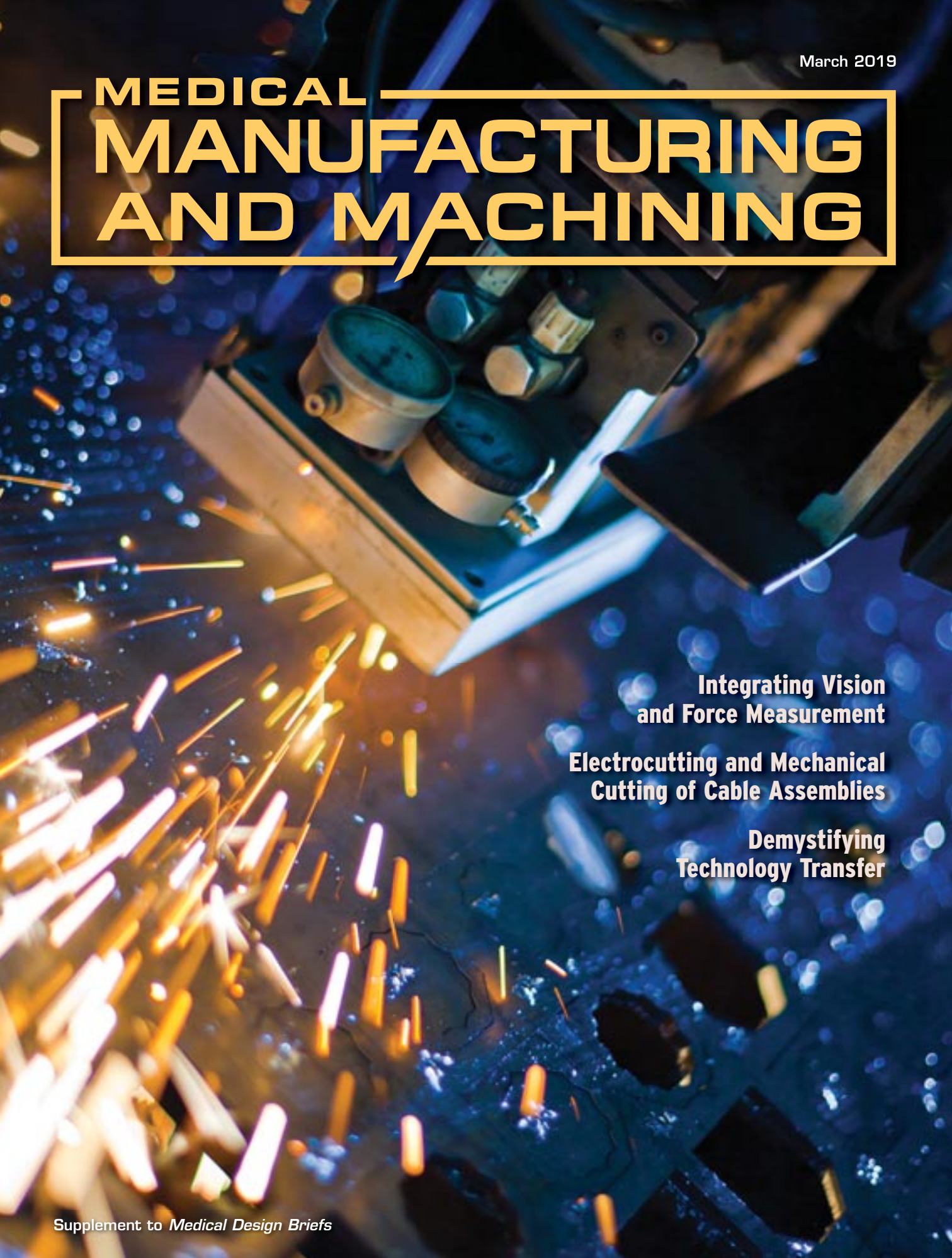


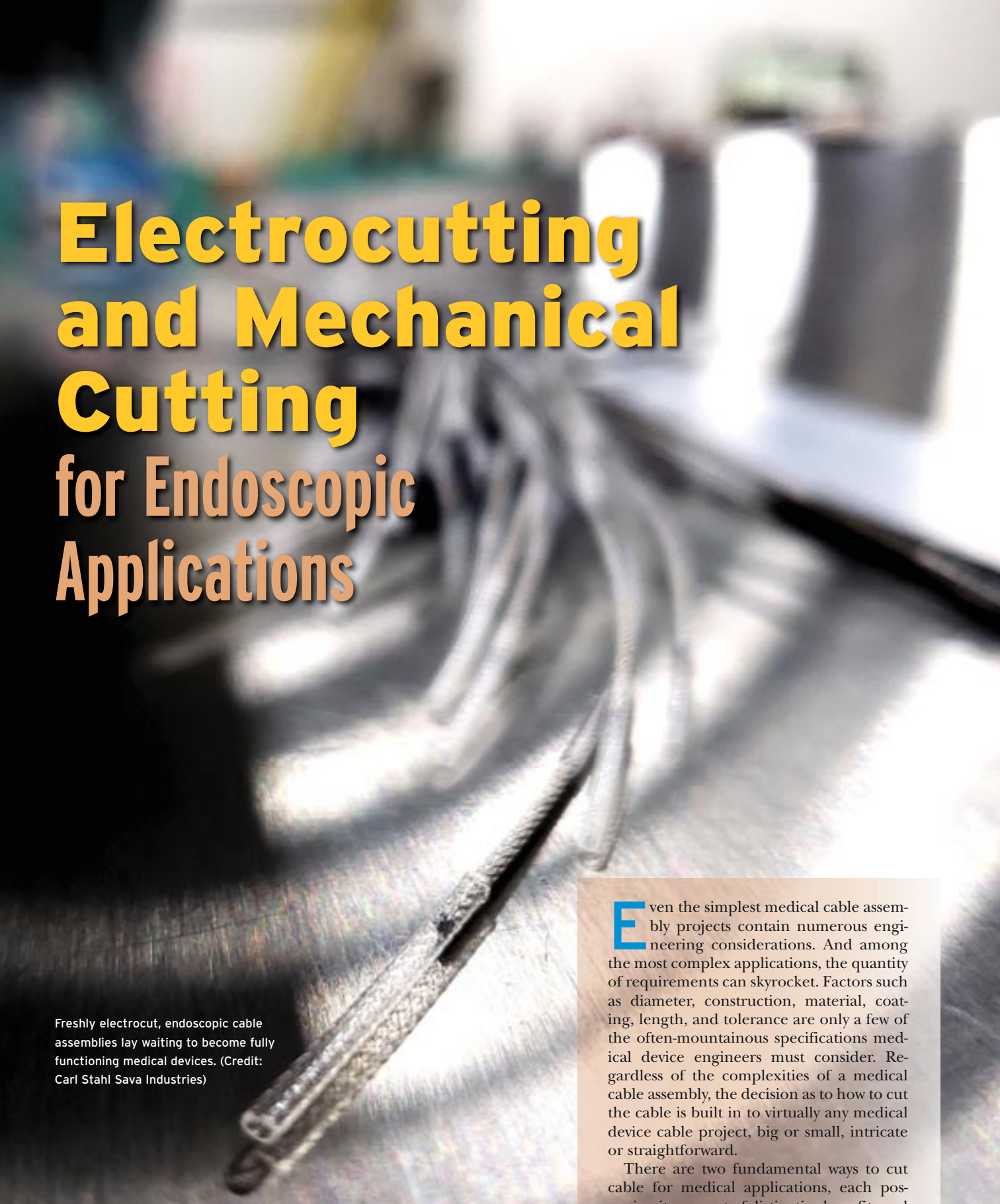
Integrating Vision and Force Measurement

Electrocutting and Mechanical Cutting of Cable Assemblies

Demystifying Technology Transfer

Supplement to *Medical Design Briefs*

Electrocutting and Mechanical Cutting for Endoscopic Applications



Freshly electrocut, endoscopic cable assemblies lay waiting to become fully functioning medical devices. (Credit: Carl Stahl Sava Industries)

Even the simplest medical cable assembly projects contain numerous engineering considerations. And among the most complex applications, the quantity of requirements can skyrocket. Factors such as diameter, construction, material, coating, length, and tolerance are only a few of the often-mountainous specifications medical device engineers must consider. Regardless of the complexities of a medical cable assembly, the decision as to how to cut the cable is built in to virtually any medical device cable project, big or small, intricate or straightforward.

There are two fundamental ways to cut cable for medical applications, each possessing its own set of distinctive benefits and appropriate applications — mechanical cutting and electrocuting. It is precisely

because each approach serves several specialized purposes, however, that it is vital to be well acquainted with the method that will meet the unique cutting needs of the application.

If a speedy, economical turnaround is required, for example, then mechanical cutting likely provides the quickest production run. And although electrocutting also can be utilized for high-volume production, in many instances, electrocutting may be slower and less economical than its mechanical counterpart. If, however, there is concern about fraying of the cable, especially when the cable is flexed, then electrocutting the cable may be the best solution, because a fused end prevents wires from separating under flexing conditions.

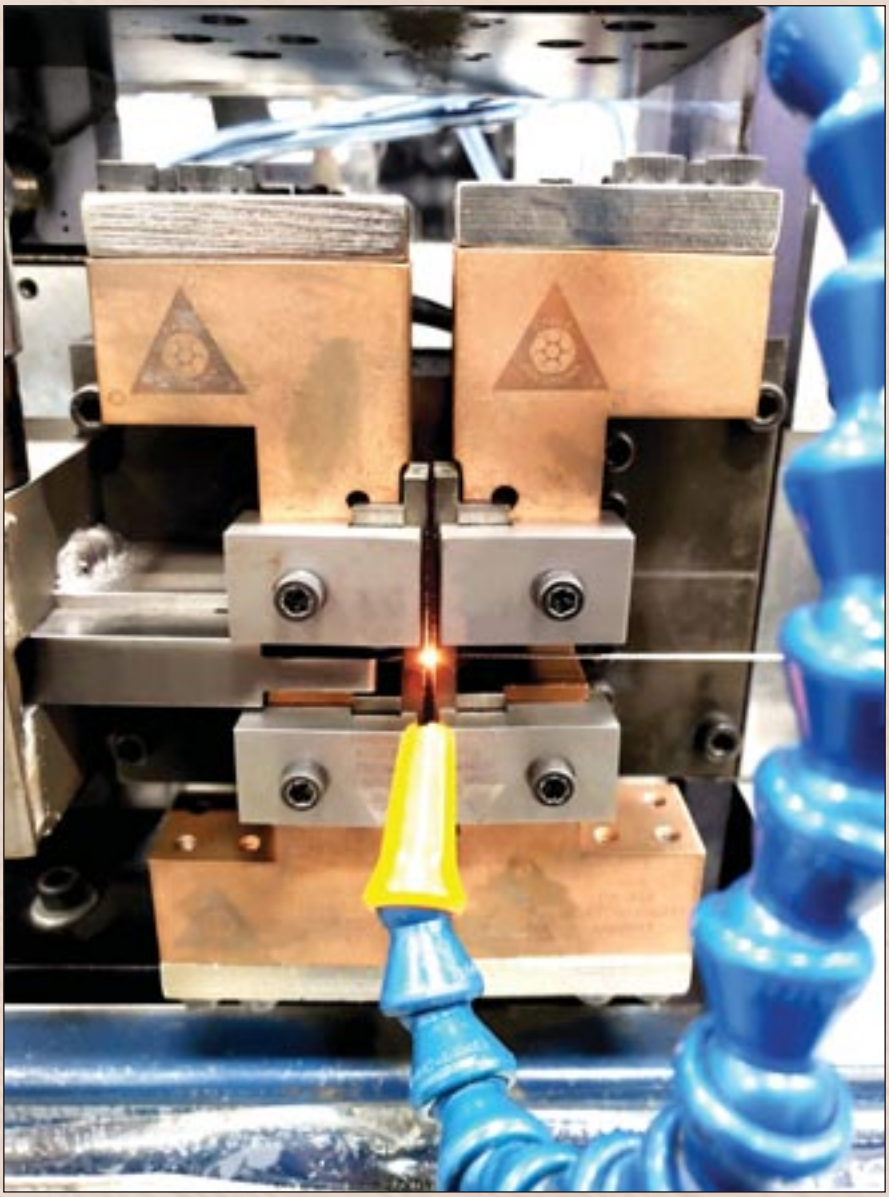
While these are merely two of the many variables that determine the right cutting decision, the bottom line is that the list of cutting considerations goes on and on. Getting the advice of a qualified endoscopic cable manufacturer will ensure that the intricate science of cutting medical cable, particularly for endoscopic purposes, is done right the first time.

Mechanical Cut Endoscopic Cable

Mechanically cutting cable is a process of mechanically shearing cable to length. With mechanically cut endoscopic cable, the cutting process does not bond the cable ends together, leaving the wires loose at the cut end. If an application does not require that the cable ends be bonded or swaged together, as in the case of an electrocut cable, then mechanical cutting may be well suited to the application. Among the most common applications for mechanically cut cable are those involving solid core wires regularly used in push-pull assemblies.

Lastly, one of the greatest advantages to mechanically cut cable is that it is often inherently faster, because the equipment required is not tasked with welding the wires together. This saves valuable production time, making mechanical cutting less expensive. The absence of the fusing process to form a single bonded surface edge allows for a speedier and more efficient production run, making mechanical cutting both easier to execute and control.

As mentioned, when cable is cut mechanically the wires are not bonded together. If preforming, or in the case of small cables, stress relieving is done properly, mechanical cutting should produce an acceptable cut. The cable can subsequently be used in further process steps, including swaging fittings to the cut end of the medical cable.



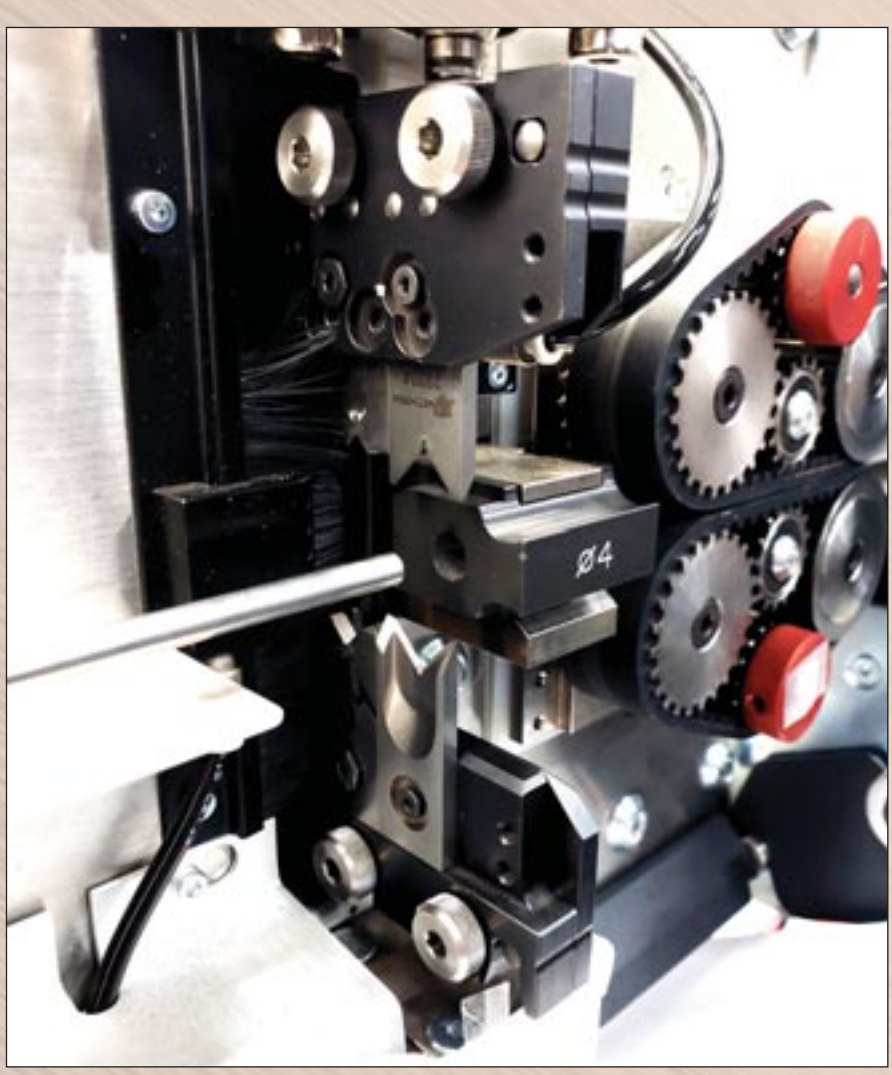
The bright flashing light is the endoscopic cable end being cut and fused into one, continuously bonded material. The newly electrocut end makes it easy to insert into a lumen or tube for medical applications. (Credit: Carl Stahl Sava Industries)

Mechanical Cutting Challenges

With mechanically cut endoscopic cable, the cutting blades are prone to wear over time and therefore must be carefully maintained and monitored to assure sharpness. If the blades get dull, the clean sheer required of the production run begins to suffer, and it is likely that burrs will appear over the end of the medical cable. Additionally, the cable spooling must be perfect to prevent the cable from wrapping on top of itself. When the cable is improperly spooled, the spool itself will periodically jerk ever so slightly; this disruption oftentimes is enough to create a bend in the finished product.

Electrocutting Endoscopic Cable

As the endoscopic cable assembly industry evolves, and medical devices become increasingly miniaturized, the assembly requirements become more difficult, challenging, and complex. As the industry "shrinks," the quality of the cable ends used for these sophisticated devices are, now more than ever before, of critical importance in perfecting an



Endoscopic cable being mechanically cut to length by razor sharp blades. These fixed lengths of endoscopic cable will ultimately be inserted into fittings to complete the medical assembly process. (Credit: Carl Stahl Sava Industries)

endoscopic assembly. Today, there is little clearance between cable diameters and fitting internal diameters, so a perfectly fused cable end is ideally suited to the endoscopic, and more broadly, medical devices manufacturing industry.

Before cable is even being prepared for cutting, the cable is run through a set of rollers, ensuring that the wires do not come apart over time. This process is known as preforming. Because endoscopic cable is typically miniature in size, it can be difficult to preform. Thus, when the cable is cut, the ends have a tendency to fray or unravel. While there are methods to prevent fraying from occurring, electrocutting the medical cable ends eliminates the potential for fraying because it fuses the wires together. Once the ends are fused together perfectly, the decision to electrocut the endoscopic cable ends makes all subsequent manufacturing steps easier and more efficient throughout the balance of the manufacturing process.

The chief rule of a sound electrocut cable is that the cutting process should not allow any loose wires or hangers in the finished cable assembly. Each individual wire will, therefore, be retained within the welded end itself. So, when the application calls for the cable to achieve its maximum strength, lifespan, and durability, an electrocut, or fused end, is recommended.

Before electrocutting existed, the wires were typically soldered together to achieve the bonded cut end seen in an electrocut alternative. However, this now obsolete approach introduced the unwanted side effect of solder, and its lead contaminants, being directly applied to the product. Additionally, the soldering process proved too labor intensive, time-consuming, and expensive. Soldering medical cable ends ultimately increased material and manufacturing costs, and produced, by comparison to today's electrocutting approach, an inferior product.

Today, electrocutting means that the cable is fuse-cut by way of machine, which welds the cable ends together to form a continuously bonded material at the cable's cut end. This cutting process essentially makes the cut end a single point, where all the wires merge into one, ensuring the cable's integrity is uncompromised by the cutting process. Once the cut is fused to perfection, enough material is deposited at the cut end of the cable, so it subsequently may be formed into various profiles, such as a taper, ball, sphere, and so on. With an electrocut, the cable ends can be fashioned into the ideal geometry for the application.

When the cable is ultimately meant to be inserted into tight, narrow spaces, such as a lumen or tube, a fused end, with no risk of fraying, makes electrocutting the cable the logical cutting method as well. Lastly, if the cable's appearance is an important a design consideration, the electrocut process can be modified to cut under inert gases, so that when the cable ends are fused, inert gas floods the work area and yields a clean, color-free cable end.

These processes, coupled with the strand geometry, combine to form the rigidness and features needed for medical devices and endoscopic equipment, such as endoscopes, implants, orthodonture, and many others.

Electrocutting Challenges

For all its benefits, electrocutting endoscopic cable isn't without its nuisances, however. For instance, in endoscopic cable sizes <0.0020 in., occasionally the cut will produce weld splatter, which may introduce a burr to the cut end of the weld. Burring may also increase variability with cut lengths, where perfect lengths are critical to the application. While a secondary operation, such as sanding, swaging, or buffing may eliminate the burred end, it is recommended that the production team devote more time to the setup process. Making sure that electrocutter blades are machined properly, that gaps are setup correctly, and that heat and time delays are set to process routing requirements, all help to mitigate the

risks of burring. What's more, the potential for burring to occur on endoscopic cable ends can commonly equate to an inevitable increase in production time and, subsequently, costs to produce a burr-free electrocutting cable end could increase as well.

Another challenge inherent in electrocut cables is that at such small medical device cable sizes, the individual strands are often as thin as human hair. Endoscopic cables at sizes so miniature can make electrocutting especially difficult to ensure that all the wires are contained in the weld. Therefore, the cutting operation may result in small wires breaking free of the weld. If the cut end of the cable is to be inserted into a fitting, for example, fraying may be anticipated in the assembly's design. However, because the very nature of electrocutting promises a perfectly fused cut end, it is highly unlikely that an electrocut cable is meant to be obscured by a fitting or terminated in some other way that would render fraying unimportant.

Conclusion

There's no single solution for cutting cable that applies universally to all endoscopic projects. And because both mechanical cutting and electrocutting ensure full tensile strength, choosing either won't risk comprising the cable's mechanical properties or load-bearing qualifications. So, given that each cable cutting approach possess strong empirical arguments for their usefulness, discussing cable cutting requirements with a contract manufacturer's engineering team is vital.

If an application does not demand a fused end for instance, or if a fitting is not being applied to the cut end, mechanical cutting the endoscopic cable will produce a perfect product. If, however, the endoscopic cable application requires a fused end, where there can be no risk of the material fraying from the cut end, or strand breaking away from the product, an electrocut end is essential.

For endoscopic applications, it is important to note that the cable cutting technique applied influences the time spent making the device and its production complexities, as much as it does the medical device's ultimate function.

This article was written by Scott Dailey, Vice President of Sales and Marketing, and Greg Soja, Vice President of Engineering, Carl Stahl Sava Industries, Riverdale, NJ. For more information, visit ***http://info.hotims.com/72991-202****.*

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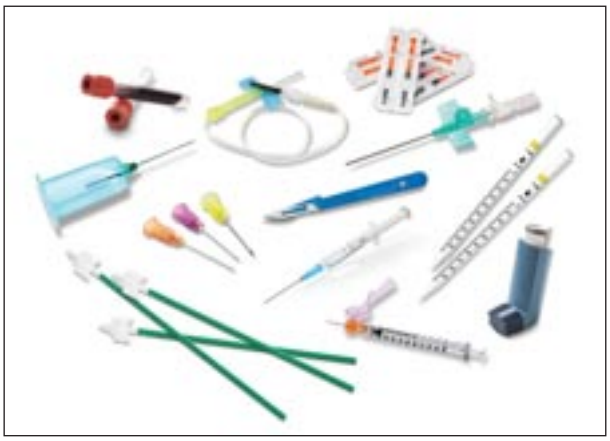

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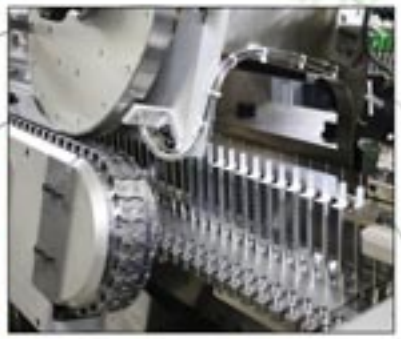

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Integrating Vision and Force Measurement *into Medical Quality Control*

Vital for ensuring compliance to federal regulations, dimensional metrology systems facilitate critical measurement of medical parts, and force testing systems are used to verify and validate material compliance of medical devices and materials used in the production of medical devices. It is important to understand the options when selecting the right metrology system and/or force testing solution to meet the requirements of increasingly tighter accuracies, traceability, and the need for 100 percent inspection (see the sidebar, "Metrology System Selection Tips").

Metrology Options Abound

A wide range of options exist for hardware and software, which can be combined to create different types of metrology systems, sometimes at broadly different costs and complexity ranging from easy-to-learn manual optical comparators to fully programmable multisensor CNC Systems.

Numerous higher-end products are electromechanical metrology systems, which may combine optics with precision mechanical motion, linear encoders, and digital image and data processing. These systems include optical comparators, vision (or video) metrology systems, and a new product category of digital video comparators. A *digital video comparator* is a vision metrology system that functions like an optical comparator but utilizes a DXF "digital overlay" instead of traditional mylar overlays. Many manufacturers have been accustomed to using go-no-go methods of gaging, which have limitations, such as the use of overlays in optical measuring or functional fit gages.

With overlays, operator subjectivity is a significant factor due to differences

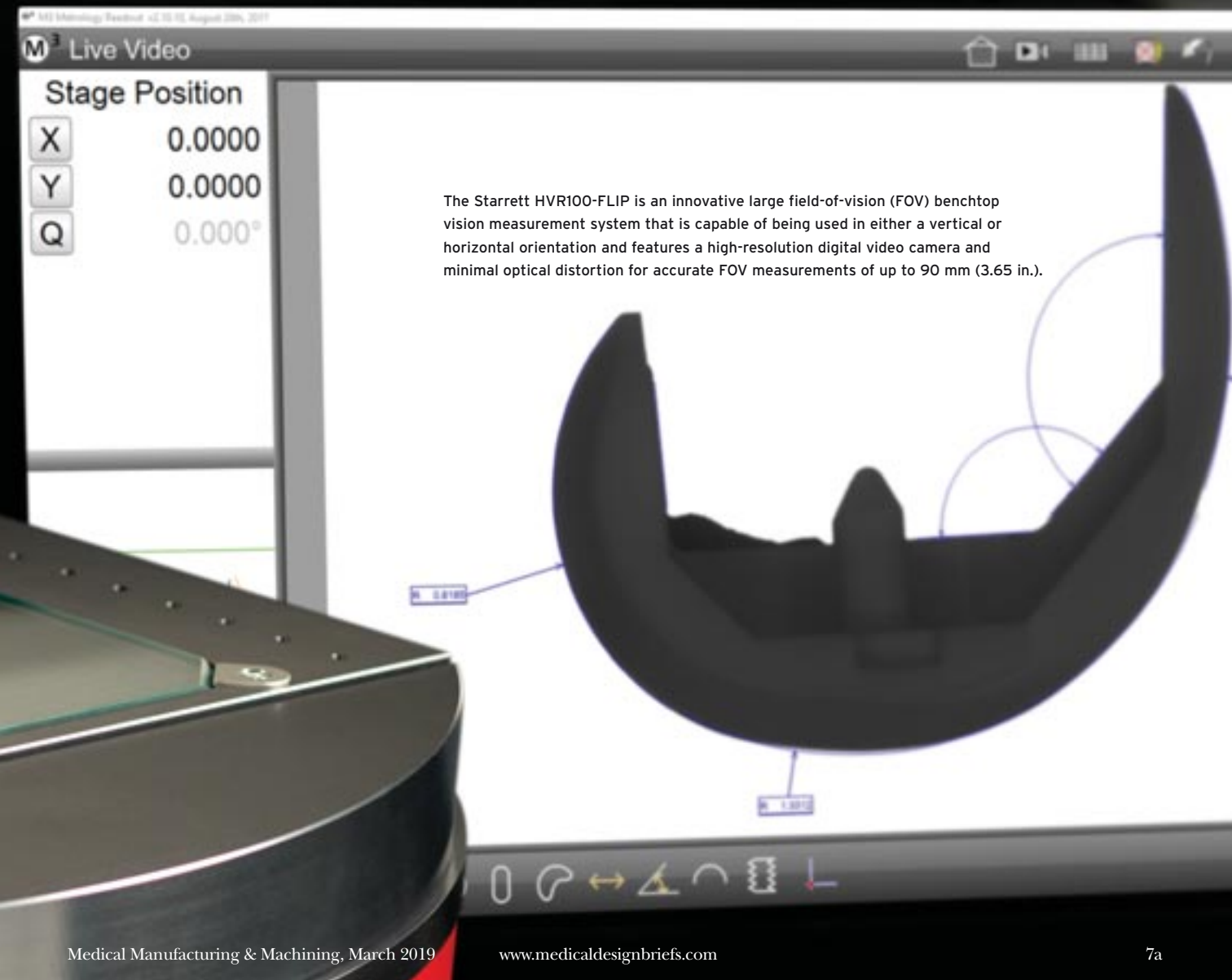
resulting from screen placement, imprecise or worn Mylars, magnification, complex part shapes, and especially the lack of detailed, variable data. Fatigue and data accuracy are also factors.

Functional fit gages also present a number of challenges. The gage development process is usually lengthy and expensive, with limited flexibility when parts change. And again, no variable data is attainable in the inspection process. Importantly, both overlays and functional fit gages provide no opportunity for a comprehensive audit trail and traceability process — paramount in medical manufacturing.

Ultimately, the goal in any good inspection program should be to attain maximum gage repeatability and reproducibility (GR&R) and in the process, provide comprehensive, data for statistical process control (SPC) and traceability.

Starrett's DFC Digital Force Controller, for example, features measurement accuracy within 0.1 percent full scale with internal data sampling at 25 kHz.

Reliable GR&R is possible with today's noncontact video and multisensor systems and their advanced software. Current display readout and software measuring technology such as the



The Starrett HVR100-FLIP is an innovative large field-of-vision (FOV) benchtop vision measurement system that is capable of being used in either a vertical or horizontal orientation and features a high-resolution digital video camera and minimal optical distortion for accurate FOV measurements of up to 90 mm (3.65 in.).

Metrology System Selection Tips

1. **Measurement complexity.** A 2D optical comparator may suffice for simple measurements and visual comparison, but more complex medical parts may require a multisensor metrology system with CMM style touch-probe capability.
2. **Measurement throughput.** A manual system may be an option for prototypes, occasional, and short run measurements by the QC department, but an automatic, CNC system is a more economical solution if complete production runs are to be verified.
3. **Tolerance requirements.** A vision metrology system with a granite base and higher magnification optics may be required for meeting tight tolerances.
4. **Harshness of environment.** Most optical comparators are designed for typical machining environments sometimes found in machine shops. Varying temperatures, vibration, dust, and oil particles can be present and need to be taken into consideration.
5. **Manmade interface.** Various interface options are now available for both optical comparators and video-based measurement systems, including digital readouts, touchscreen PC solutions, and rack-mounted computers with monitors and software.
6. **Software features.** Capabilities can range from a simple two-axis readout to 3D multisensor capability with a rich set of measurement software tools, CNC control, statistical packages, DXF CAD file import and export, touchscreen operation with Windows Operating Systems, and network connectivity.

The new Starrett AV450 Automatic Vision System is enhanced by either QC5000 or MetLogix™ M3 software that controls video edge detection and multiple-channel fiber optic or LED illumination.

MetLogix M3 provides full qualitative and quantitative profile analysis functions where an inspector can compare a part profile against a nominal CAD model and obtain an actual graphic representation of any deviation from the CAD file.

The system automatically finds and tracks the edge, continuously comparing it to a 2D profile, and superimposes the edge to a CAD model. In this scenario, an operator quickly, easily, and automatically collects tremendous amounts of data that is all archived and documented with date, time, lot number, job number, and so on, removing operator error from the equation. Not only can 100 percent inspection be realized, but inspection speed and throughput can also be dramatically increased due to automated system measurement routines and depending on the application, palletized multipart fixture inspection tables.

Latest Metrology Technology

New technology exists in the form of a large field-of-view benchtop vision measurement system that can be used in either a vertical or horizontal orientation, features a high-resolution digital video camera and precision optics for accurate, large FOV measurements. The latest system lends itself to an extremely wide array of applications from flat parts to turned, threaded and complex shaped parts such as orthopedic joint implants.

A main operator interface displays a live video image with touchscreen enabled software measurement tools and graphical digital display of measurements. A part image can be resized using pan and pinch zoom. Measurements can be taken by simply touching a feature on the monitor screen. A wireless keyboard and pointing device can be used to enter file names and target key functions. Software includes 2D geometric functions such as points, lines, circles, arcs, rectangles, distances, slots, angles, and skew, and utilizing the part design DXF/CAD file digital overlay makes part inspection simple.

In addition to examining dimensional metrology solutions, as part of the process to verify and validate material compliance of medical devices and materials it is helpful to start by investigating systems for tensile testing. Tensile testing is the most common test method used in both force measurement and material testing and is used primarily to

determine the mechanical behavior of a component, part, or material under static, axial loading.

The test method for both material testing and force measurement is similar; however, the measurement results are different. A tensile test is performed to determine the tensile properties of a material or component. The test sample's deformation is used to characterize its ductility or brittleness as well as important characteristics such as tensile strength, yield point, elastic limit, percent elongation, elastic modulus, and toughness (see Figures 1 and 2).

Material Testing

Material testing is the science that measures the mechanical properties of materials. It involves methods that quantify and qualify the physical characterization of materials — their strength, their reaction to deformation, and their ability and inability to withstand an applied force for a period of time.

Material testing involves measurements for stress and strain, which requires knowing the original cross-sectional area of the sample being tested. Common units of measure are N/mm2, MPa, PSI, and percent (%). Test samples are often prepared to a specified size according to an international testing standard from ASTM, ISO, DIN, or other organizations. During a tensile test, the sample's shape changes as load is applied. Understanding the change in the sample's dimension at various or specified forces helps determine the material's performance and suitability for a given application or product.

Force Measurement Testing

Force measurement testing is used to test components and products and generally uses units of measure of force: Newtons, pounds-force, and kilograms-force. The sample's cross-sectional area isn't involved in the measurement result. The most common force measurement is the "peak force" or maximum force value. These tests may also report the associated distance result at the peak force. Force measurement is conducted in the engineering laboratory, in quality control and inspection and on the production floor. Force testing in production has increased substantially in recent years, as more manufacturers recognize the importance of in-situ quality testing as a way to improve productivity, yields, and throughput.

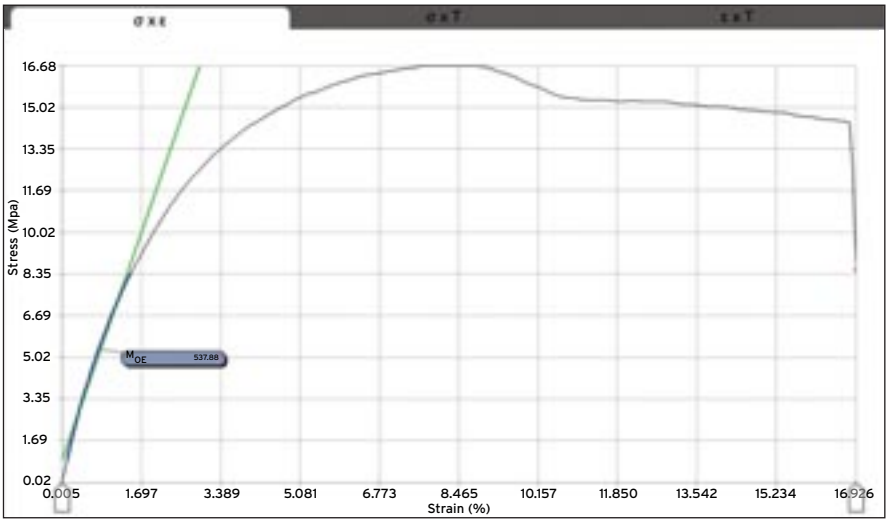


Fig. 1 – The modulus of elasticity represents the stiffness of the material under test. In tensile applications, this modulus is often called Young's Modulus and is the relationship between stress and strain within the proportional limit.

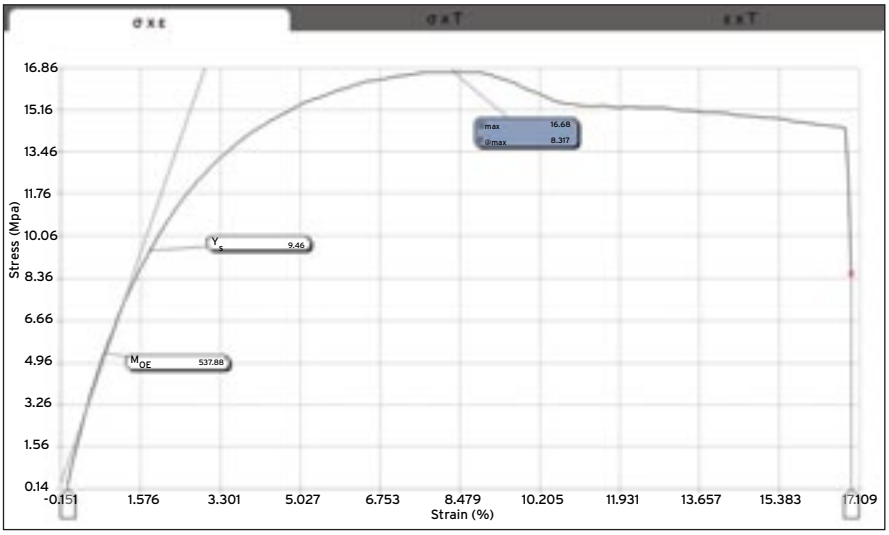


Fig. 2 – The maximum stress observed from the strain-strain curve.

Close-up of a DXF digital overlay shown via MetLogix™ M3 software and offered on Starrett Vision Metrology Systems.

Testing Instrumentation: The Case for Handheld Force

Tensile testing may be performed at a very basic level on the shop floor by simply using a handheld force gage where the gage measures the pull force applied on a sample, product or component in order to determine the maximum force. Quality control teams are often reluctant to conduct product inspections on the factory floor. Instead, part examination is usually redirected to the lab, where the inspection can be performed on a dedicated force measurement machine.

However, waiting until the end of the production process to conduct an inspection can cause problems. If any problems are identified with an aspect of the product, it may be more difficult to locate where in the manufacturing process the problem has occurred, especially if production comprises several different steps. As an alternative, quality assurance managers should be able to conduct inspections during the entire production process while on the shop floor, using portable force measurement devices.

Unlike traditional force measurement machines, portable force measurement devices are lightweight. Usually, the technology is handheld and can be operated by one inspector without the need for assistance. Where a stand is required, stands are smaller and a fraction of the weight of fixed-force measurement machines.

Using a portable device enables quality control managers across manufacturing, engineering and research and development sectors to perform accurate batch testing while on the move. For example, nonrepetitive applications, such as reverse engineering and rapid prototyping can also benefit from the technology.

There are common misconceptions that handheld force measurement devices provide less accuracy than traditional, static machines. However, that's not necessarily the case. Starrett's DFC Digital Force Controller, for example, features measurement accuracy within 0.1 percent full scale with internal data sampling at 25kHz. Quality control engineers can use the advanced device as a universal interface to set up tests and configure load and distance limits and break limits, as well as crosshead travel direction and speed.

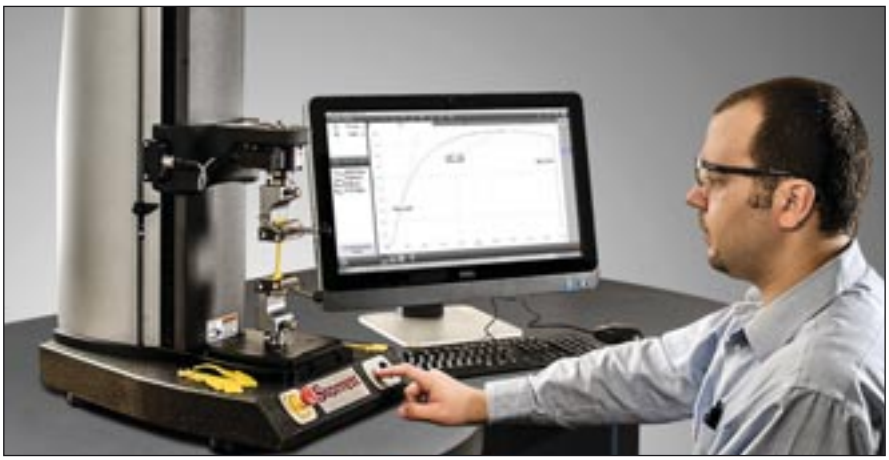
Using a handheld device gives production teams more flexibility, knowledge, and greater independence. Production will no longer rely on relatively involved quality inspection measures, nor will the

team have to wait for the quality control department to move and measure larger parts and products. With the possibility of measuring parts whenever they want, at any point in the production process, production teams can perform better quality control themselves and as a result, make fewer mistakes.

Advanced Testing Considerations

At the other end of the instrumentation spectrum are extremely sophisticated tensile testing systems equipped with advanced testing software and ancillary instruments, such as extensometers. These testing systems are able to pull the sample under test at a very precise velocity to a precise target. Large data sampling helps produce high-resolution data for both force and distance or stress and strain, so that very accurate measurements can be taken, analyzed, and reported.

The latest systems in this category meet the requirements of research scientists, design engineers, and quality managers, and employ a simple methodology for creating a test, performing a test, analyzing test results, and managing test data. Applications include measuring stress, strain, load, elongation, extension, and time using tension, compression, flexural, cyclic, shear, and friction tests. Tests can be set up using internationally accepted testing standards from ASTM, ISO, DIN, TAPPI, and more, or a custom test method can be created. A wide range of results can be measured and calculated graphically including points, modulus, slopes, and intercepts, offset yield, min/max/avg, peaks and valleys, and many more.



Starrett L3 Systems offer a new and easier solution for creating and performing a test, analyzing test results, and managing test data.

This article was written by Mark G. Arenal, General Manager, Starrett Kinemetric Engineering, Inc., Laguna Hills, CA, and James M. Clinton, Product Manager for Force and Material Test Products, The L.S. Starrett Company, Athol, MA. For more information, visit ***http://info.hotims.com/72991-201****.*

Scale-up studies and equivalency testing will be necessary to ensure consistent product performance as the CMO ramps up the manufacturing volume. (Credit: Web Industries Inc.)

DEMYSTIFYING TECHNOLOGY TRANSFER in Medical Device Contract Manufacturing

For medical device developers and original equipment manufacturers (OEMs), the transition from prototype to commercial-scale production with a contract manufacturing organization (CMO) shouldn't feel like a leap of faith across a giant chasm. The technology transfer phase, in particular, can mean different things to different people. By better understanding technology transfer's purpose and priorities, device designers and their CMO partners can embark on this important stage more unified in their shared goals. This article offers a roadmap for what to expect during the tech transfer phase of the medical device product life cycle.

Tech Transfer's Place in the Product Life Cycle

What is technology transfer and where does it fit within the product life cycle? It's the life cycle stage nestled between project planning and commercial production (see Figure 1). During tech transfer, the CMO determines how to best manufacture a product on the developer/OEM's behalf — economically and at high volumes. Not to be confused with product development, technology transfer is focused on manufacturing process development. Whereas product development prioritizes usability and performance, process development prioritizes manufacturability. Tech transfer's objective is to produce a quality product consistently and cost-effectively, while achieving all of the designer/OEM's physical and performance requirements for the device.

Device designers, developers, and OEMs can enter into a relationship with a CMO at many different stages in the product life cycle. In an ideal case, the CMO is involved early in the product development process to help with material specification and to consult regarding manufacturability risks and opportunities.

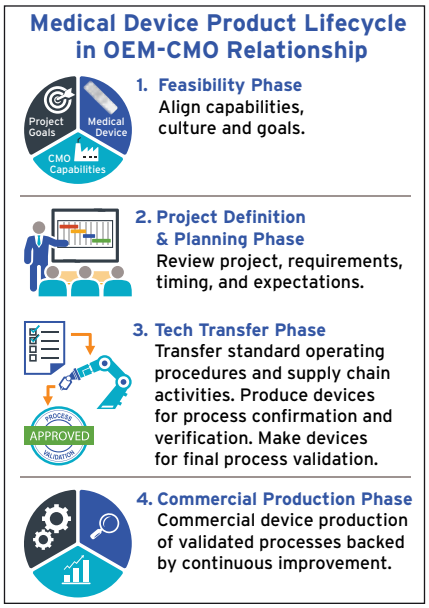


Fig. 1 – Medical device designers can enter into a relationship with a CMO at many different stages in the product life cycle.

To meet performance and economic objectives, tech transfer often requires the CMO to conceive an entirely different manufacturing process for a device — one that is highly scalable, fast, and efficient. Chances are, the way one device or hundreds of devices are made on the R&D bench or pilot line will need to be transformed, perhaps multiples times, to produce the thousands or millions of devices needed for commercial rollout. During this phase it is possible the CMO will make recommendations in device design for manufacturability.

In many cases, a device designer or startup has produced prototypes or small lots of devices and now needs to meet a much greater demand. The CMO works with the device developer to understand everything there is to know about how the device functions, how it is used, and how it has been manufactured to date, and then creates a plan for how to produce it at commercial-scale quantities.

At the end of the day, technology transfer is when a device's design, materials and performance all must be dissected, analyzed, and viewed afresh to make the transition to mass-scale manufacturing.

Steps in Technology Transfer

CMOs often lead technology transfer through a structured stage-gate process. With this process in place, all key players should have clear visibility and understanding of how the project is progressing. If at any point risks or issues arise, such as quality control hurdles or information gaps, they must be addressed before moving toward the next gate. Transparency, enabled by frequent communication and collaboration between partners, is crucial. This helps ensure continued focus on the project mission and its objectives. For example, a CMO like Web Industries might hold weekly internal meetings to discuss a project's progress and host biweekly updates with the device developer/OEM to debrief the customer. Here are some key steps in a tech transfer stage-gate process:

Documentation. During tech transfer, the device developer, designer, or OEM will share documentation about the product and how it has been produced to date. For example, a development house begins working with a CMO to scale up production of a lateral flow immunoassay (LFI) device. The documentation stage might include discussion and review of biochemistry, deposition, lamination, assembly, pouching, quality control test methods, packaging, raw materials, and supply chain management.

Raw Material Assessment. Raw materials are a huge factor throughout the entire device life cycle, but during tech transfer, they are truly put to the test. Ideally, most potential raw material issues will be discovered during the project definition and planning stage, when the CMO assesses material availability, quality, and specifications. As part of this initial design transfer review, the CMO might find that one of the specified materials is not readily available in large quantities or supplied in widths, lengths, or core sizes optimized for the CMO's high-speed production equipment. Such findings would raise a red flag, posing a risk to project success that needs to be addressed. For instance, the CMO may be able to identify another material that matches the specifications and is feasible to procure in the necessary quantities.

During technology transfer, a contract manufacturing organization performs a variety of studies to ensure devices meet OEM performance requirements. (Credit: Web Industries Inc.)

Often, device prototypes are made through manual processes with materials supplied on sample cards, sheets, or small sample rolls. The tension, pressure, friction, and temperatures of a manual, low-volume production process can be quite different from those needed to support a large continuous reel-to-reel web production line.

Process Verification and Validation

The technology transfer phase is a time for the CMO to prove precisely how it is going to produce a device. First, there will be feasibility studies to determine whether the CMO's existing equipment is capable of handling the materials and performing the processes to produce the customer's product. Then through process characterization and process development, the CMO will determine what methods, machinery, and tools to use to make the device to the customer's requirements, including initial equipment settings. Then there will be engineering studies to determine exactly how to calibrate equipment to get the desired results.

Scale-up studies and equivalency testing will be necessary to ensure consistent product performance as the CMO ramps up the manufacturing volume. To transition from 50 or 500 units to 50,000 units or eventually 5 million units, the CMO must test devices at frequent milestones along the way to ensure that the device's physical properties and performance meet design requirements. For example, in scaling up production of an LFI device, the CMO must evaluate whether the test solution still performs as it should when made in incrementally larger batches. The LFI device from a batch of 50,000 devices must perform in precisely the same way as a device from a batch of 50 devices, i.e., negative and positive readings must appear in the same way as they do on the reference device or per the OEM's specifications.

Conclusion

During OEM-CMO technology transfer, a prototype design does not enter one end of a "black box" and start coming out the other end at great quantities and speeds. Instead, tech transfer should entail a transparent, methodical, stage-gate process, with frequent communication between partners from day one until commercial-scale product delivery.

It is important to remember that tech transfer is not product development. Rather, during this important phase of the product life cycle, the CMO engages in process development to devise a way to make the device owner's product efficiently and in large volumes. When business partners are aligned on tech transfer's purpose, priorities and protocols, they can work together to successfully take medical device innovations from the bench to the big time.

This article was written by Claudio Hanna (channa@webindustries.com), Business Development Director, and Miranda Conary (mconary@webindustries.com), Product Specialist, Web Industries Inc., Marlborough, MA. For more information, visit ***http://info.hotims.com/72991-205****.*

Research Explores Internal Flow Behavior in Additive Manufacturing, Welding of Metals

Results show how to optimize this process to improve efficiency and cost.

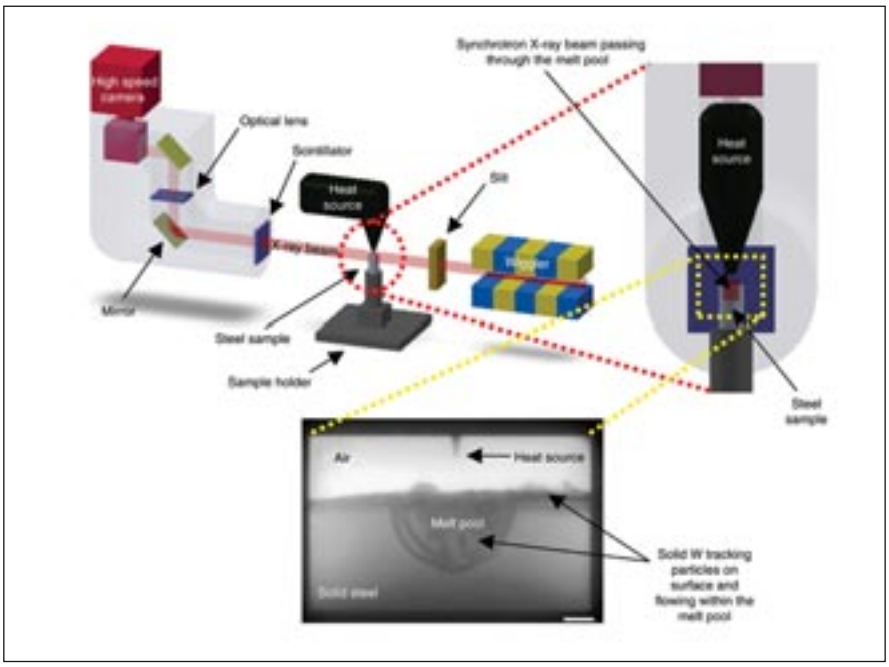
Delft University of Technology, Delft, Netherlands

Arc welding and additive manufacturing are hugely important for creating large metal components relatively inexpensively and quickly. New research by a team atf the University of Leicester, Delft University of Technology, Diamond Light Source, University College Dublin, and TATA Steel Research UK has shown how to optimize this process to improve efficiency and cost. A paper detailing the findings was recently published in *Nature Communications*. The research explores the internal flow behavior in additive manufacturing of metals and arc welding — the most widely used welding process in modern manufacturing. It focused on examining the melt pools that are created during the welding process.

To do so, the team inserted small tungsten and tantalum particles into the melt pool. Due to their high melting points, the particles remained solid in the melt pool long enough for them to be tracked using intense beams of x-rays. These x-rays were generated using the synchrotron particle accelerator at Diamond Light Source, which is the UK's national facility for synchrotron light. Beamline I12 was selected for this research due to its specialized high-energy, high-speed imaging capability at thousands of frames per second.

Using Beamline I12, the researchers were able to create high-speed movies showing how surface tension affects the shape of the welding melt pool and its associated speed and patterns of flow. The results showed, for the first time, that the melt flow behavior is similar to that previously only seen via computer simulations.

Anton Kidess, a PhD student at Delft University of Technology, developed new particle tracking algorithms that allowed for the visualization of the reported flow patterns in the weld pools. Together with Delft professors Ian Richardson and Chris Kleijn, he provided the theoretical explanations for and interpretations of the impact of trace chemical components on surface tension variations in the weld pool, which were shown to radically influence the flow patterns.



Schematic diagram of the experimental setup and an example radiograph annotated to show the key elements under observation during the experiment. A polychromatic (white) beam of ~50–150 keV was used to maximize the x-ray photon flux. The beam size was 12×50 mm2 (H×W) and was transmitted through the entire melt pool. The detector was a Vision Research Phantom v7.3 CMOS camera, lens-coupled to cadmium tungstate or cesium iodide scintillators. With an optical magnification of ×1.8, the linear resolution was 13 µm per pixel. Imaging was acquired at frame rates up to 2 kHz at 800×600 pixels per frame. Scale bar = 1 mm (Credit: *Nature Communications*)

The results reveal that arc welding can be optimized by controlling the flow of the melt pool and changing the associated active elements on the surface.

"Understanding what happens to the liquid in melt pools during welding and metal-based additive manufacturing remains a challenge," says Professor Hongbiao Dong from the University of Leicester. The findings will help us design and optimize the welding and additive manufacturing processes to make components with improved properties at a reduced cost. "Welding is the most economical and effective way to join metals permanently and is a vital component of our manufacturing economy."

It is estimated that more than 50 percent of global domestic and engineering products contain welded joints. In Europe, the welding industry has traditionally supported a diverse set of companies. Revenue from welding equipment and consumable markets reached €3.5 billion ($4 billion) in Europe in 2017.

The results will help with the future designing and optimization of the welding and additive manufacturing process.

For more information, visit ***www.tudelft.nl/en***.

Process Developed to 3D Print Piezoelectric Materials

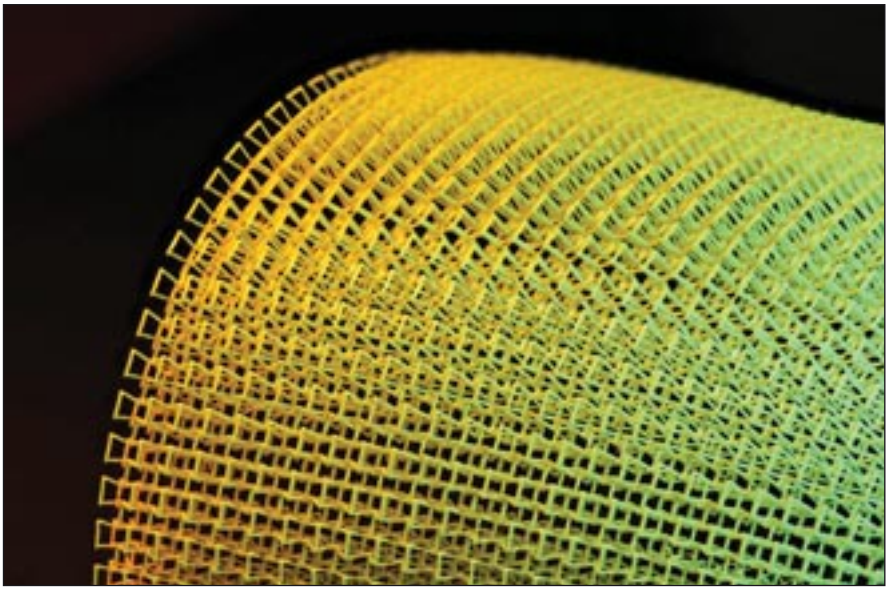
Materials can be custom designed to convert movement, impact, and stress to electrical energy.

Virginia Tech, Blacksburg, VA

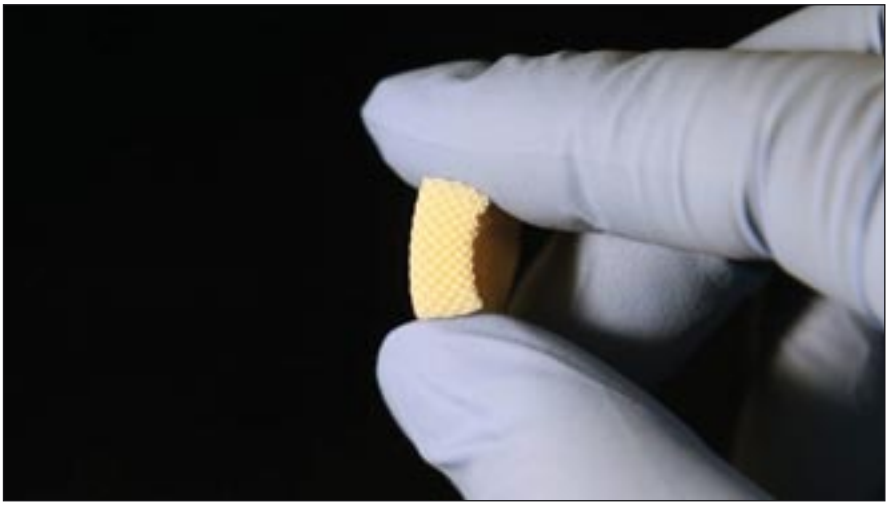
The piezoelectric materials that inhabit everything from our cell phones to musical greeting cards may be getting an upgrade thanks to work discussed in the journal *Nature Materials*. Xiaoyu "Rayne" Zheng, assistant professor of mechanical engineering in the College of Engineering and a member of the Macromolecules Innovation Institute, and his team have developed methods to 3D print piezoelectric materials that can be custom designed to convert movement, impact, and stress from any directions to electrical energy.

"Piezoelectric materials convert strain and stress into electric charges," Zheng explains.

The piezoelectric materials come in only a few defined shapes and are made of brittle crystal and ceramic — the kind that require a cleanroom to manufacture. Zheng's team has developed a technique to 3D print these materials, so they are not restricted by shape or size. The material can also be activated, providing the next generation of intelligent infrastructures and smart materials for tactile sensing, impact and vibration monitoring, energy harvesting, and other applications.



The printed flexible sheet of piezoelectric material. (Credit: Virginia Tech)



A 3D printed, flexible energy harvester. (Credit: H. Cui of the Zheng Lab)

Unleash the Freedom to Design Piezoelectrics

Piezoelectric materials were originally discovered in the 19th century. Since then, the advances in manufacturing technology have led to the requirement of cleanrooms and a complex procedure that produces films and blocks which are connected to electronics after machining. The expensive process and the inherent brittleness of the material have limited the ability to maximize the material's potential.

Zheng's team developed a model that allows them to manipulate and design arbitrary piezoelectric constants, resulting in the material generating electric charge movement in response to incoming forces and vibrations from any direction via a set of 3D printable topologies. Unlike conventional piezoelectrics where electric charge movements are prescribed by the intrinsic crystals, the new method allows users to prescribe and program voltage responses to be magnified, reversed, or suppressed in any direction.

"We have developed a design method and printing platform to freely design the sensitivity and operational modes of piezoelectric materials," Zheng says. "By programming the 3D active topology, you can achieve pretty much any combination of piezoelectric coefficients within a material and use them as transducers and sensors that are not only flexible and strong, but also respond to pressure, vibrations, and impacts via electric signals that tell the location, magnitude, and direction of the impacts within any location of these materials."

3D Printing of Piezoelectrics, Sensors, and Transducers

A factor in current piezoelectric fabrication is the natural crystal used. At the atomic level, the orientation of atoms is fixed. Zheng's team has produced a substitute that mimics the crystal but allows

for the lattice orientation to be altered by design.

"We have synthesized a class of highly sensitive piezoelectric inks that can be sculpted into complex three-dimensional features with ultraviolet light. The inks contain highly concentrated piezoelectric nanocrystals bonded with UV-sensitive gels, which form a solution — a milky mixture like melted crystal — that we print with a high-resolution digital light 3D printer," Zheng says.

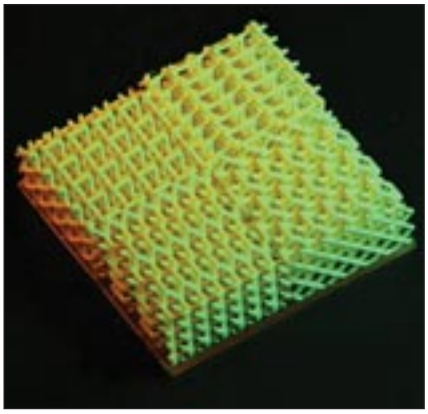
The team demonstrated the 3D printed materials at a scale measuring fractions of the diameter of a human hair. "We can tailor the architecture to make them more flexible and use them, for instance, as energy harvesting devices, wrapping them around any arbitrary curvature," Zheng says. "We can make them thick, and light, stiff, or energy-absorbing."

The material has sensitivities five-fold higher than flexible piezoelectric polymers. The stiffness and shape of the material can be tuned and produced as a thin sheet resembling a strip of gauze, or as a stiff block. "We have a team making them into wearable devices, like rings, insoles, and fitting them into a boxing glove, where we will be able to record impact forces and monitor the health of the user," says Zheng.

"The ability to achieve the desired mechanical, electrical, and thermal properties will significantly reduce the time and effort needed to develop practical materials," says Shashank Priya, associate vice president for research at Penn State and former professor of mechanical engineering at Virginia Tech.

New Applications

The team has printed and demonstrated smart materials wrapped around curved surfaces, worn on hands and fingers to convert motion and harvest the mechanical energy, but the applications go well beyond wearables and consumer electronics. Zheng sees the technology as a leap into robotics, energy harvesting, tactile sensing, and intelligent infrastructure, where a structure is made entirely with piezoelectric material, sensing impacts, vibrations, and motions, and allowing for those to be monitored and located. The team has printed a small smart bridge to demonstrate its applicability to sensing the locations of dropping impacts, as well as its



Internal topology of 3D printed piezoelectrics spanning the width of human hair. (Credit: Virginia Tech)

magnitude, while robust enough to absorb the impact energy. The team also demonstrated their application of a smart transducer that converts underwater vibration signals to electric voltages.

"Traditionally, if you wanted to monitor the internal strength of a structure, you would need to have a lot of individual sensors placed all over the structure, each with a number of leads and connectors," says Huachen Cui, a doctoral

student with Zheng and first author of the Nature Materials paper. "Here, the structure itself is the sensor — it can monitor itself."

The team's work is supported, in part, by the National Science Foundation, Air Force Office of Scientific Research, the Office of Naval Research, and the Virginia Tech Institute of Critical Technology Junior Faculty Award.

The paper in *Nature Materials* features the following authors: Huachen Cui (Mechanical Engineering), Ryan Hensleigh (Virginia Tech Macromolecules Innovation Institute), Desheng Yao (ME), Deepam Maurya (ME), Prashant Kumar (ME), Min Gyu Kang (ME), Shashank Priya, (ME & Penn State's Materials Research Institute), and Zheng. Zheng is also an affiliate faculty member of the department of materials science and engineering.

For more information, visit ***https://vtnews.vt.edu.***

Low-Cost Sensors Have High Impact on Productivity

Tooling insert embedded with smart sensors reduces machining stoppages.

AMRC/University of Sheffield, Sheffield, UK

An intelligent, low-cost tooling insert, embedded with smart sensors, has been developed to deliver in-process condition monitoring that reduces machining stoppages and improves productivity for manufacturers.

The prototype device, developed with Innovate UK funding, allows a machine tool operator to determine the condition of a cutting tool without manual inspection and is the first "plug and play" system of its kind with no process learning time required on installation.

"Currently, the task of monitoring the wear on the tool cutting edges is carried out by an operator who inspects the cutting tool using a laser or touch probe system; thus causing stoppages of machine tools which results in poor productivity and potentially higher costs," says AMRC Machining Group Technical Lead for Control Systems, Sensors, and Data Acquisition, Hatim Laalej, who has been working on the development of the device. "These are real concerns for manufacturers as stoppage costs in production can be high.

"Manual inspection also varies according to the skills and experience of the operator monitoring the tool wear. When tools are not changed at the right time, damage can be caused to a work piece, leading to increased costs due to scrappages and rework. Equally, if tools are changed before the end of their useful life this can increase consumable costs.

The prototype installed on the AMRC's DMG Mori NT5400 DCG five-axis turning machine. (Credit: AMRC)

"The cost of the system is relatively low as it involves using low-cost electronics. The device has been designed to be accessible to small and medium sized companies who are looking for ways to improve the efficiency, performance and quality of their operations, which is vital to improving the productivity of the wider UK economy."

Monitoring tool wear during machining processes is essential to achieve the desired accuracy and surface finish of a work piece. The tooling insert is embedded with sensors which produces data about the current condition of the cutting tool. This data is converted and sent wirelessly to the machine panel or a machine operator's control pad for them to make a decision about the condition of the cutting tool, whilst machining is in-process.

"The sensor monitors the resistance generated within the tool-embedded sensor, so if its resistance increases this indicates tool wear, chipping, or breakage."

The low-cost tooling insert embedded with smart sensors. (Credit: AMRC)

says Hatim. "This means errors can be recorded and operators can move to preventative maintenance planning to free up valuable time on the shop floor when operators could utilize extra capabilities increasing productivity."

The AMRC Machining Group successfully installed the prototype on its DMG Mori NT5400 DCG five-axis turning machine, to trial cutting operations and validate its capabilities.

The cutting operations were simulated before trialing the prototype on the DMG, where polycrystalline diamond and polycrystalline cubic boron nitride cutting inserts with embedded sensors were used to machine titanium Ti-6AI-4V and Inconel 718 bars respectively.

But Hatim is not resting on his laurels. His goal is to eliminate tool wear, machine downtime, and eventually tool breakage altogether: "Further development of the technology will look at extending the process for various milling processes as well as turning and adapt the system to send diagnosis and data to a portable device, such as a laptop, so an operator can be working remotely to the machine."

The Innovate UK project was a collaboration between fellow High Value Manufacturing Catapult partner CPI, alongside Element Six, Advanced Manufacturing (Sheffield) Limited, BAE Systems, Printed Electronics Ltd, National Physical Laboratory and DMG MORI UK and the resulting prototype device is now ready to be scaled up into an industry-ready solution.

AMRC is looking for partners, especially tool-holding manufacturers, who might be interested in developing the prototype as a commercially available product. The researchers believe the new system will have "massive benefits for machinists in all manufacturing sectors."

For more information, visit ***www.amrc.co.uk.***