MEDICAL DESIGN BRIEFS

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ON THE COVER

The in vitro diagnostic home point-of-care (POC) product landscape will look very different over the coming years as new products to detect the COVID-19 virus are launched. These new IVD products will use the latest in sensor technologies, ultra low power analog, precision mixed-signal, and digital processing, and they will be highly portable, including using biocompatible enclosures for wearable applications. They will also harness the enormous computing power of smartphones and the cloud. To learn



more about how to integrate electrochemical measurements into POC devices, read the article on page 14.

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New Innovative Technologies Continue to Emerge in the Fight Against COVID-19

Even as the world inches foward to achieving a fully vaccinated population against COVID-19, innovators are working hard to develop new technologies that diagnose and treat this awful virus. The disease continues to thrive in many parts of the world, and new variants are still a concern. One such innovative company, for example, is Medivolve, which seeks out disruptive technologies and exclusive partnerships to develop technologies to help combat COVID-19. The company teamed with Marvel Diagnostics, the developer of the noninvasive exhaled breath diagnostic technology called BlowFISH. Medivolve announced its investment in Marvel Diagnostics in January 2021, providing up to \$1 million



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in funding. BlowFISH has now successfully cleared the first milestone in a series of clinical tests targeting application of an Emergency Use Authorization (EUA) from FDA to test for the COVID-19 virus.

During the clinical trial, BlowFISH's proprietary technology, designed to efficiently collect a substantial liquid sampling directly from deep within the lungs, successfully detected the COVID-19 virus in three test samples. Developed by Marvel Diagnostics and funded by Medivolve, the technology offers the potential for a simple, inexpensive, noninvasive, massively deployable, rapid diagnostic system for detecting respiratory illness and airborne viral threats in approximately 10 minutes.

"This is an exciting and important milestone in advancing BlowFISH toward achieving EUA status in testing for COVID-19, and providing a noninvasive, cost-effective, and scalable testing alternative to nasal swab solutions currently in market," says David Preiner, CEO of Medivolve. "Making testing more accessible to populations such as children and the elderly, where it may be difficult to administer a nasopharyngeal swab test, will become important in our transition to resuming daily life in the new normal. Data obtained from BlowFISH-powered testing will also further Medivolve's mission to use innovation and artificial intelligence to close the loop in health management for every American."

Marvel Diagnostics is partnering with a research team from Louisiana State University Health Shreveport (LSUSH) to conduct clinical trials. With the second phase of testing now in progress, BlowFISH is currently on the right track to seek EUA approval from FDA.

"BlowFISH's detection of the COVID-19 virus brings us one significant step closer to changing the future of diagnostics for not only COVID-19, but for a wide range of respiratory illnesses," says Dr. Pirouz Kavehpour, UCLA professor and Marvel Diagnostics co-founder. "We are moving forward with urgency through proof-ofconcept clinical trials, as these studies are a critical next step in making respiratory testing more comfortable, convenient and accessible for all ... one breath at a time."

Technologies like this are changing the future of the healthcare landscape, providing diagnosis faster and with more accuracy than ever before.

Sherrie Trigg Editor and Director of Medical Content

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CYROLITE[®] with balanced optical transmission and mechanical robustness offers chemical resistance to IPA, lipids, blood, disinfectants, and oncology drugs, necessary for safe BPA-free, infusion therapy applications such as filter housings.

Evaluating Chemical Resistance

previous article discussed acrylic-based medical copolymers that are designed through extensive R&D to carefully balance properties and perform-

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ance for healthcare applications.¹ More importantly, it emphasized the key role of polymer mechanical behavior in governing the chemical resistance of CYROLITE[®] and delivered an understanding of the chemical attack, specifically environmental stress cracking. Here in Part 2, the key parameters for evaluating chemical resistance, understanding industry-wide testing discrepancies, and identifying opportunities for a unified and regulated approach for material evaluation are presented. A case study on chemical resistance testing of CYROLITE acrylic-based medical copolymers is presented following these key considerations against various chemical agents.²

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Evaluating Environmental Stress Crack Resistance (ESCR) in Medical-Grade Polymers

Leading resin manufacturers offer products designed for ESCR applications in medical devices. They support performance metrics to quantify chemical resistance and cross reference material endurance with chemical agents.^{2–6} These compatibility matrices are insightful in understanding their material specific performance but could be highly

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subjective when screening through industry-wide choices. Foremost, the test methods to quantify compatibility against a chemical agent show disconnect and widespread practices across suppliers. Therefore, the medical device industry should combine input from resin producers, medical device manufacturers, and the application environment to define a regulated approach for measuring ESCR and corroborating material comparisons. As a result, the different resin solutions available for a given application would be assessed through the same metrics and ranked for performance/resistance against these chemicals. Key aspects to consider for universal harmonization and evaluating ESCR are discussed below.

Preconditioning. Foremost, polymer mechanical response to applied mechanical stress or strain depends on its chemical structure and morphology during polymer processing. Test specimens should be annealed to minimize the effect of molded-in stress (i.e., part design/geometry and external factors that are application dependent). Annealing and preconditioning are practices to establish comparable testing conditions and to eliminate specimen history (storage, processing). It is also critical to bring the material into equilibrium by establishing controlled temperature and humidity conditions before testing. Depending on the polymer, crystalline or amorphous, controlled conditioning ensures reproducibility and repeatability of analysis. Polymer-specific standards should be followed for conditioning before testing. For example, ASTM D-4066 stipulates the need for testing to be carried out on dry as-molded specimens for hygroscopic materials such as nylon. ASTM-D 618-13 specifies preconditioning the test bars for >40h, at 23 ± 2 °C, 50 \pm 5% relative humidity before strain exposure.7

Measuring Mechanical Properties. Mechanical strength of medical plastics can be expressed using tensile, compressive, flexural, impact, fatigue, weathering, and other similar metrics, depending on the targeted application. For ESCR evaluation of medical plastics, the mechanical test type studied is varied, e.g., tensile or impact or flexural, etc.^{3–6} However, the property retention upon chemical agent exposure to establish compatibility is an industry-wide practice. The stress-strain curves as part of tensile testing provide the ductile or brittle response of the

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Fig. 1 – Typical tensile stress-strain curve of plastic material showing ductile and brittle failure behaviors. ASTM-D543-14, Section 12 and ASTM D638-14 recommend ESCR testing using tensile testing.

material along with modulus and elongation at break properties (see Figure 2). For tensile testing, ASTM-D618 lists tensile bar dimensions and tolerances for standard tensile specimens with regard to size and geometry. Moreover, the test parameters such as extensometer capacity and crosshead speed for testing require rigorous attention specific to a material tested.⁸ ASTM D543-14 provides guidelines for chemical exposure under



Fig. 2. – ASTM tensile type 1 exposed to three different strains at 0.5 percent, 1.0 percent, and 1.5 percent. The strain is determined primarily by the thickness of the tensile bar type, T, and the radius of curvature of the strain jig, R, as shown in the expression.

strained environments and evaluating tensile property retention.⁹

Percent Strain Loading and Chemical Agents for Exposure Parameters. ESCR testing measures the tensile property retention of material upon simultaneous exposure to a controlled strain and a chemical agent. The test assembly is designed to mimic the mechanical loads in use and simulate the internal stresses the material undergoes in the healthcare environment. Figure 3 shows control strain jigs at 0.5 percent, 1 percent, or 1.5 percent strain, with tensile bar held in place and exposed to chemical agent. Notice the increase in curvature as the strain is increased from 0.5 to 1.5 percent. Depending on the application, chemical exposure to numerous chemical agents is tested for the duration of exposure (typically ranging from 5 to 24 hours), to evaluate material response in a controlled environment.

Evidently, a material is likely to show different response against variable strain, chemical agents tested, and to the extent of exposure. More importantly these are critical variables in context to the application, whether it is short-term use as in the case of disposables, or longterm medical devices as in equipment housings. The current data reports don't shed much insight on the selection of strain percent or the chemicals in context of the application and do not address the medical device manufacturer's unmet needs.

Chemical Exposure Method and Duration of Exposure. ASTM D543-14 lists the wet patch method for ESCR testing against various chemical agents. The wet patch method allows for exposing the strained tensile bar to the chemical agent periodically - for example, every 30 minutes for a maximum duration of the test exposure. Resin manufacturers are discussing three approaches for exposure: periodic wipe method, wet patch exposure by periodic saturation, and continuous immersion by creating an isolated environment. Method comparisons are enlightening, revealing the potential variability in mechanical responses and property retention.

A periodic wiping test is reported to be more aggressive than continuous immersion for polycarbonate (PC) and PC blends and linked to the added stressors from the concentration build of highboiling chemicals in the formulations.⁴ However, this does not guarantee the same mechanical behavior for all materi-

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Fig. 3 – Scenario to evaluate mechanical response of material upon strained exposure to a chemical agent. Compatibility assessment showing the stress-strain curves at variable strains (0.5 percent, 1.0 percent, and 1.5 percent) for duration and environment of exposure. The curves in different colors denote stress strain behavior for five test specimens tested from the same sample/product.

| Strain (%) | Modulus | Strength | Elongation at Yield | Elongation at Break | Crazing |
|------------|---------|----------|---------------------|---------------------|---------|
| 0.5% | | | | | No |
| 1.0% | | | | | No |
| 1.5% | | | | | No |

Table 1a. Tensile property retention for CYROLITE[®] Med 2 after exposure to IPA/water (70 percent) for 5 hours at strain rates of 0.5, 1.0, and 1.5 percent. Property retention: >90% (green), 80–90% (yellow), <80% (red).

| Strain (%) | Modulus | Strength | Elongation at Yield | Elongation at Break | Crazing |
|------------|---------|----------|---------------------|---------------------|---------|
| 0.5% | | | | | No |
| 1.0% | | | | | No |
| 1.5% | | | | | No |





Fig. 4 - Compatibility assessment to include visual evaluation across the test specimens and proposed ranking system.

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als. Relevance needs to be established on the chemical exposure method with guidelines laid out for the dimensions of the patch, frequency of chemical agent reapplication, the setup in a controlled environment, and duration of exposure — all with respect to the chemical agent tested. Lack of a standardized methodology leads to inconsistency in data comparisons between resin manufacturers.

Evaluation of Test Results and Tensile Property Retention. The goal is to gauge representative behavior of the polymer under investigation. Property retention can be expressed in terms of one or a combination of tensile modulus, strength, elongation at yield, and break elongation characteristics. Undoubtedly, all of these present a unique piece of information about the mechanical characteristics of the material to the medical device manufacturer.

A unanimous parameter(s) (modulus, strength, elongation at yield, and break elongation) should be published for ranking the compatibility matrix against chemicals tested in line with the geared application. Tensile strength and elongation at vield present closer relevance to materials deformation behavior under mechanical loads in use.7 Elongation at break measures the materials failure stress but often is misleading and shows the most scatter across the tested pool of tensile bars as shown in Figure 4. In addition, visual observations linked to onset and development of crazing or stress whitening of material during exposure should be recorded (see Tables 1a and 1b). Figure 4 and Tables 1a and 1b present the twofold scenario expressing ESCR output.

Case Study: Environmental Stress Crack Resistance (ESCR) Performance Testing

For CYROLITE Med 2, ASTM type 1 tensile bars molded from the material were annealed for 4 hours at 64 °C. The test bars were preconditioned for at least >40h, at 23 ± 2 °C, $50 \pm 5\%$ relative humidity prior to strain exposure (ASTM-D 618). Note: ESCR Upon Exposure to (70 percent) IPA/Water (ASTM D543-14) and Mechanical Property Changes (ASTM D638, Section 12).

The tensile bars were mounted on control strain jigs at 0.5, 1.0, and 1.5 percent respectively (see Figure3). A wet patch saturated in 70 percent IPA was applied every 30 minutes for 5 hours. Tensile testing per ASTM D638 was performed on all specimens (5 replicates)

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| Disinfectants | Modulus | Strength | Elongation at Yield | Elongation at Break | Crazing |
|---|---------|----------|----------------------------|---------------------|---------|
| Control (unexposed at 1.5% strain) | | | | | |
| Formaldehyde | | | | | |
| Peracetic acid (PA) | | | | | |
| Hydrogen peroxide (HP) | | | | | |
| HP/PA/Acetic acid | | | | | |
| Bleach | | | | | |
| Glutaraldehyde | | | | | |
| Ortho-phthaldehyde | | | | | |
| Diethylene glycol butyl (DEGB) ether | | | | | |

Table 2. ESCR for CYROLITE[®] Med 2 after 1.5 percent strain and exposure to 10 different disinfectants for 24 h showing the tensile property retention (percent). Note: For formaldehyde and peracetic acid, CYROLITE[®] Med 2 retained \geq 90 percent property retention at 1 percent strain. Property retention: >90% (green), 80–90% (yellow), <80% (red).

| Oncology Drugs | Modulus | Strength | Crazing |
|--|---------|----------|---------|
| Cisplatin (1.0 mg/ml), Water | | | No |
| Carboplatin (10.0 mg/ml), 10 mg Mannitol, Water | | | No |
| Mitomycin (0.5 mg/ml), 1 mg Mannitol, Water | | | No |
| Gemcitabine (Gemzar) (38.0 mg/ml), Mannitol, Water | | | No |
| Oxaliplatin (2.0 mg/ml), 5% Dextrose, Water | | | No |
| 5-Fluorouracyl (50.0 mg/ml), Water, pH 9.2 | | | No |
| Epirubicin (Ellence) (2.0 mg/ml), Water, pH 3.0 | | | No |
| Propofol (10.0 mg/ml), Soybean Oil, Glycerin, Egg Phospholipids | | | No |
| Cyclosphosphamide (20.00 mg/ml), 0.9% Benzyl Alcohol, Water | | | No |
| lfosfamide (50.0 mg/ml), Additives, Water | | | No |
| Doxorubicin Hydrochloride (2.0 mg/ml), Water, pH 3.0 | | | No |
| Paclitaxel (Taxol) (6.0 mg/ml), Castor Oil, Alcohol | | | No |

Table 3. Tensile property retention for CYROLITE[®] Med 2 after 1.0 percent strain and exposure to 10 oncology drugs for 24 hours. Property retention: >90% (green), 80–90% (yellow), <80% (red).

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and the percent change in tensile properties of each material reported for each reagent reported. Tensile property retention was measured using an extensometer at 10 percent based on 50 mm gage length at a cross head speed of 2 in./min. Tensile strength and modulus were reported to three significant figures with standard deviation reported to two significant figures. Elongation at yield (percent) and elongation at break (percent) were reported to two significant figures (ASTM D6436).

Interestingly, the material shows tensile property retention ≥95 percent, specifically tensile strength, modulus, and elongation at yield, after exposure to IPA for 5 hours at all strain levels (see Table 2). Certainly, the high performance is a direct function of the composition and the careful formulation of components that present a compatibilized blend. It is essential to understand that the preconditioning enables sufficient segmental motion during annealing to potentially eliminate any residual molding stresses and offer a homogenous part with representative properties, hence yielding a ductile, toughened, and IPA-resistant material.

Exposure to Disinfectants

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This test was conducted using Wet Patch Method (ASTM D543 - 14). Standard type 1 ASTM tensile testing specimens were mounted to strain jigs

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designed to apply a predetermined amount of strain onto the specimens. A saturated cotton patch (such as sterile gauze) was draped over them such that test specimen is in direct contact with the disinfectant reagent being tested. The length of exposure was 24 hours at room temperature. Three sets of measurement data were taken; a set of specimens (five replicates) under no strain and no reagent applied, strain and no reagent, and strain and each disinfectant reagent.

Table 3 shows the impact of disinfectant exposure on CYROLITE Med 2 at 1.5 percent strain for 24 hours. The data shows excellent chemical resistance to 6 of 10 disinfectants tested, with tensile property retention \geq 95 percent, and no visual signs of crazing or stress cracking. For the remaining four agents, the bars show \geq 75 percent tensile property retention. The elongation at yield and break had \geq 90 percent retention for all 10 disinfectants tested, indicating that the ductility of the polymer is maintained after chemical exposure and induced stress.

Exposure to Chemotherapy Drugs in Carrier Solvents

ASTM type 1 tensile bars were annealed at material-specific VICAT softening temperature for ~4 hours. These were mounted on jigs designed to induce a 1 percent strain and held for 24 hours. Five test bars were tested per chemotherapy drug in their carrier solvent for 13 different drugs by wet patch method.

Figure 8 shows the impact of chemotherapy drugs in their carrier solvents for CYROLITE Med 2. CYROLITE Med 2 shows excellent tensile property retention, \geq 95 percent after exposure to chemotherapy drugs while strained at 1 percent for 24 hours. It is imperative to understand the impact of the carrier solvents these drugs are administered in; they can potentially pose a more aggressive interaction with the polymer material than the therapeutic drug component and lead to brittle catastrophic failures.

Conclusion

Ideally, the industry would benefit from both objective and standardized metrics to provide an overview of different product offerings with their respective pros and cons and performance thresholds. However, the feasible implication of these standardized metrics would require industry-wide harmoniza-

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tion, collaborative partnership, and a defined framework for assessing the material offerings industry-wide.

This article has presented the key considerations for evaluating ESCR, thereby mitigating the aforementioned inconsistencies in testing and highlighting the need to meet customer needs. Unifying the testing methods in line with the proposed key considerations would present the medical device manufacturer with an objective selection process. Moreover, the standardized approach would synergize the therapeutic measures in healthcare with the protection offered through advanced material solutions from evolving harmful disease-causing pathogens.

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NEXT->GEN POC Diagnostics: Dectronic Measurement Technology Driven by Global Demand for COVID-19 Testing

he in-vitro diagnostic (IVD) home point-of-care (POC) product landscape will look very different over the coming years as new products to detect the COVID-19 virus are launched. It is driven in part by FDA's Emergency Use Authorization (EUA), which fast-tracks the traditional 510(k) process so that COVID testing can be as ubiquitous as measuring your temperature.

And \$157 million has already been distributed by the Biomedical Advanced Research Development Agency (BARDA) to support the development of more than 40 COVID-19 diagnostic products. Some of those products are targeted for POC use cases versus laboratory testing. Many new companies entering the market are planning a diagnostic roadmap of capabilities beyond their entry point of COVID-19 testing.

IVD and POC Defined

"In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of speci-

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mens taken from the human body" compared with in-vivo products, which perform the same but within the human body as defined by the FDA. According to FDA, "POC testing means that results are delivered to patients in the patient care settings, like hospitals, urgent care centers, and emergency rooms, instead of samples being sent to a laboratory."

Optical vs. Electrochemical Test Techniques

IVD POC products available today like glucose meters or pregnancy test kits will soon share "shelf space" with start-ups offering novel sensors and meters using nasal swabs, saliva, urine, sweat, and blood. These new IVD products will use the latest in sensor technologies, ultra low power analog, precision mixedsignal, and digital processing, and they will be highly portable, including using biocompatible enclosures for wearable applications. They will also harness the enormous computing power of smartphones and the cloud.

The two basic measurement techniques for IVD POC home testing are optical and electrochemical (EC). Pregnancy test kits, for example, detect human chorionic gonadotropin (hCG) in urine. Urine is placed on the end of the nitrocellulose strip and flows; hCG binds with dyed mobile antibodies and is captured using fixed antibodies to produce a color line that LEDs and photodiodes will detect. Glucose test strips require a very small drop of blood at the tip of the strip where the chemical enzymes are stored.

An electrical connection is made from the meter to the test zone on the strip to allow a voltage stimulus and measurement, whereas a system using nitrocellulose strips only requires a simple mechanical interface like a light pipe to focus the LED signal on the strip and capture the reflected signal on the photodiode. This article focuses on the more widely used POC electrochemical measurement technique. Future articles will address optical techniques.

EC Measurement Background

In every household, two-terminal batteries are the most common example of a dc power supply. They are used for flashlights, mobile phones, clocks, etc. A well-known EC application is the electrolysis of compounds. A common industrial example is the chlor-alkali process where the salt (NaCl) and water (H₂O) in saltwater are split into chlorine (Cl₂), hydrogen (H₂), and sodium hydroxide (NaOH).

The disadvantage of two-terminal EC applications is that it is not possible to

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investigate a single electrode and thus a single event (see Figure 1). The current flows through the anode (electrode where oxidation happens) and the cathode (electrode where reduction takes place). So, both these electrodes influence the measured current and the current-limiting process cannot be determined. This is especially an issue in analytical chemistry. Another issue is concentration polarization. This is the effect of an electrode changing its environment and thus its potential during an electrochemical reaction. For most electroanalytical methods, a poten-



Fig 1 – Current and potential in a two-electrode system (a) and in a three-electrode system (b), and the schematic of a potentiostat control circuit (c).

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Next-Gen POC Diagnostics



Fig. 2 – Desktop potentiostat (left) from the 1990s and handheld potentiostat (right) from 2020. (Left photo courtesy of University of Rostock – Institute for Electronic Appliances and Circuits)

tiostat is required (see Figure 2). A potentiostat uses three electrodes and a feedback loop to control the potential and measure the current flowing at just one of these electrodes, the working electrode. The potential will be measured to a fixed reference point and thus a lot of information about the event happening at the working electrode can be gathered.

Why not just two electrodes? One reason is that the potential of the working electrode cannot be measures against a fixed point when there are only two electrodes. Imagine a two-electrode system that consists of the already mentioned working electrode, and the electrode, whose potential should be the fixed reference point, is the reference electrode.

In this case, a certain potential is applied between these electrodes and an electrochemical reaction happens at the working electrode, but since the circuit needs to be closed and current needs to flow, a reaction that is inverse to the reaction at the working electrode must occur; that is, if an oxidation occurs at the working electrode, a reduction must take place at the reference electrode. If a current flows at a constant potential, an electrochemical reaction must happen according to Faraday's law.

The change of the solution surrounding the reference electrode, due to a flowing current, leads to a change of the potential that is supposed to be the fixed reference point. But the current flow cannot be limited through the reference electrode (RE), because all limitations should be caused by the desired process to investigate; that is, the process at the working electrode (WE).

The solution for this problem is a third electrode. At this counter elec-

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| Technique | Working principle | Advantages | Application areas |
|--|--|--|--|
| Cyclic Voltammetry | Linear potential ramps, current recorded | Shape often characteristic, fast, quantitative signal | Fundamental research, characterization |
| Square Wave Voltammetry | Potential pulses superimposed on a linear ramp, current difference between right before the pulse and the end of the pulse | Sensitive, overcomes diffusion limitation, quantitative signal | Quantitative measurements |
| Open Circuit Potentiometry | Zero current, potential is measured | Noninvasive, quantitative signal | Corrosion research, ion-selective electrodes |
| Electrochemical Impedance Spectroscopy | AC potential applied, impedance and phase shift from AC current calculated | Very interface- sensitive, label-free detection | Coatings, corrosion, battery research, label-free biosensors |

Table 1. Different electrochemical techniques enable precise potential control and current measurement for the detection of many substances.

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trode (CE), also known as auxiliary electrode, the counter-reaction to the working electrode's reactions takes place. The current is flowing between the working and the counter electrode. The potential is controlled between the working electrode and reference electrode. The potential between the counter electrode and reference electrode is adjusted in such a way that the current flowing through the working electrode at a certain potential between working and reference electrode is satisfied.

This technology allows the use of many different electrochemical techniques like cyclic voltammetry, square wave voltammetry, open circuit potential measurements, etc. (see Table 1). The precise potential control and current measurement allow the detection of many substances. This has led to many lab-based quantitative measurements. It is not always possible to wait for a laboratory or to ship samples. On-site POC measurements, especially during the pandemic, have become very important.

Electroanalysis, the detection of substances by electrochemistry, offers many options to quantitatively determine different substances and species, but for many years potentiostats were lab bound (see Figure 3). Now the newest generation of compact potentiostats offered by PalmSens, for example, with expertise in instrument design, including hardware, firmware, and software offer potentiostat systems with high precision, portability, programmability, and low cost.

The compact and ready-to-use potentiostats like the Sensit Smart, are capable



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Next-Gen POC Diagnostics



Fig. 3 – The electrochemistry chip ADuCM355 by Analog Devices is part of the EmStat Pico potentiostat module, which was used to build the handheld, Bluetooth-operated potentiostat Sensit BT.



Fig. 4 – Potentiostat module on a development board (left), modular potentiostat (middle, right). Another reason for long development times is software development. Potentiostat modules often have specialized firmware and software development kits (SDK) which allow writing simple user interfaces in a short amount of time, because the communication with potentiostat itself is simplified. The software developer is in full control without learning the details on a circuitry level.



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Fig. 5 - Block diagram of an IVD system.

of common electrochemical techniques and advanced techniques like electrochemical impedance spectroscopy (EIS). While having the size of a common glucose meter, these devices offer more functionalities and are more versatile.

EIS is a very interface-sensitive technique, which allows among other applications label-free detection of biomolecules for example DNA.¹ It is no surprise that in 2021 these compact potentiostats were also used for different SARS-CoV-2 detection systems.^{2–5} While the academic world reacted swiftly and developed many new detection methods for SARS-CoV-2, the translation of the proof of principles into a commercial product is a challenging task. Developing a dedicated device including electronics design, firmware, and software requires a team of specialized staff and time.

Commercial solutions that support this translation are available as well. The development can be accelerated by using potentiostat modules. Instead of designing your own potentiostats and firmware, potentiostat modules provide the electrochemical methods of the measurement system. Another option is to use modular potentiostats, which can be changed into an individual product with just a few customizations. The simplest version of such a solution is just exchanging the logo on the device. More advanced solutions allow modification of the electrode connection, as well as offering battery and Bluetooth options and customized keypads. Such turnkey electronic design services allow having prototypes of a reader within a few months (see Figure 4).

IVD System Architecture

Let's take a closer look at what's in the box of a typical EC system and the tradeoffs needed when creating a requirements document for a new meter design. System power management is typically a good starting point in any new design (see Figure 5). The number of tests a meter will need to perform, along with the timing, voltages, and currents of those tests and communication (wired/wireless/display/sound) will define the capacity requirements for the battery.

Many home glucose meters on the market today use 3 V CR2032 batteries, as they are small and provide sufficient power of 250 mAHr to support up to a year of daily testing with each test lasting less than 5 seconds. For example, if the

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system electronics consume 10 mA over 5 seconds (0.00138Hr), then each test draws 0.0138 mAHr, which supports 250 mAHr/0.0138 mAHr = 18,000 tests before replacing the battery. However, if the electrochemical test takes tens of seconds or even minutes and the electrochemical reaction requires higher currents, then much higher capacity batteries must be employed, which increases the enclosure volume, weight, and cost. Rechargeable batteries are an option, but time-sensitive testing to address immediate treatment decisions for home use typically avoids rechargeable batteries.

In such cases, stand-alone potentiostat modules like the EmStat Pico are ideal for the analog front-end function. Onchip sequencers and deep ADC FIFOs allow the analog front end to operate while the processor is shut down, thus saving power. High-speed analog-todigital conversion enables duty cycling of the front-end measurement system to reduce power consumption. In addition to the battery capacity, it is important to consider the voltage requirements for each block. High-precision, wide dynamic range analog circuits may require boost circuits and LDOs to ensure clean stable supply voltages to the measurement front end.

Conclusion

POC devices to diagnose viruses, joint infections, or nutrient deficiencies, for example, are here to stay. They will become smaller, cheaper, produced in high volume, and more versatile. As competition increases, proven measurement technologies and system design expertise will be a competitive advantage and speed time to market. PalmSens, for example, delivers tested market-ready potentiostats or calibrated potentiostat modules to integrate into hardware, while Tri-Star Design offers turnkey certified product design and development services with expertise in high precision, low-power wireless systems. Both companies are official partners of Analog Devices.

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Algorithms and wearable sensors help clinicians to monitor the progression of Parkinson's disease. (Credit: EPFL)

Algorithms, Wearables Help Monitor Parkinson's

Scientists have developed algorithms that, combined with wearable sensors, could help clinicians to monitor the progression of Parkinson's disease and assess the effects of medications commonly used by people with this neurodegenerative disorder.

Doctors caring for people with Parkinson's disease need to be able to assess the severity of the symptoms and alter the doses of medications that reduce such symptoms. To do so, clinicians rely on a handful of tests, such as those that measure gait speed — or how fast people walk.

Researchers recruited 27 people with Parkinson's disease and provided each of them with a foot-worn sensor that recorded how fast they walked. During the clinical assessment, the researchers asked patients to do two types of walking tests: in one, people had to walk for 20 meters in a straight line; in another test, they were asked to walk in circles for five times. The walking tests were done when patients were on a medication that reduces motor problems, and then they repeated when individuals were off the medication. Based on data collected from the sensors, the team calculated the average and the fastest gait speed for each individual.

The findings suggest that monitoring gait speed during daily activities with wearable technology could help doctors optimize medication dosages depending on motor symptoms of individual patients. The sensors and the dedicated algorithms allow clinicians to monitor patients remotely, which could help to protect vulnerable people in situations such as the coronavirus pandemic.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/wearables.



Strategically placed cuts to structural films can create 3D nanostructures when force is applied to the films. (Credit: Jennifer M. McCann/ Penn State MRI)

Kirigami-Style Fabrication Enables 3D Nanostructures

A new technique that mimics the ancient Japanese art of kirigami may offer an easier way to fabricate complex 3D nanostructures for use in applications, including healthcare.

The researchers used kirigami at the nanoscale to create complex 3D nanostructures. These 3D structures

are difficult to fabricate because current nanofabrication processes are based on the technology used to fabricate microelectronics which only use planar, or flat, films. Without kirigami techniques, complex three-dimensional structures would be much more complicated to fabricate or simply impossible to make.

By introducing minimum changes to the dimensions of the cuts in the film, the researchers drastically changed the 3D shape of the pop-up architectures and demonstrated nanoscale devices that can tilt or change their curvature just by changing the width of the cuts a few nanometers.

Future research will focus on applying these kirigami techniques to materials that are one atom thick, and thin actuators made of piezoelectrics.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/kirigami.

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The optomechanical ultrasound sensor on a silicon photonic chip provides unprecedented sensitivity. [Credit: imec]

Ultra-Sensitive, Small Optomechanical Ultrasound Sensor

An optomechanical ultrasound sensor on a silicon photonic chip provides unprecedented sensitivity due to an innovative optomechanical waveguide. Because of this high-sensitivity waveguide, the 20-µm sensor has a detection limit two orders of magnitudes better than piezoelectric elements of identical size. The low detection limit of the sensor enables new clinical and biomedical applications of ultrasonic and photoa-

coustic imaging such as deep-tissue mammography and the study of vascularization or innervation of potential tumorous tissue.

The sensor is based on a highly sensitive split-rib optomechanical waveguide fabricated using new CMOS-compatible processing. A low detection limit can improve the trade-off between imaging resolution and depth for ultrasound applications and is crucial for photoacoustic imaging, where pressures are up to three orders of magnitude lower than in conventional ultrasound imaging techniques. Furthermore, it may enable low-pressure applications like through-skull functional brain imaging, which suffers from the strong ultrasound attenuation of bone.

A fine-pitched (30 μ m) matrix of these tiny sensors can be easily integrated on-chip with photonic multiplexers. This opens the possibility of new applications such as miniaturized catheters because the sensor matrices require only few optical fibers to be connected instead of one electrical connection per element in the case of piezoelectric sensors.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/sensor.



A flexible heat harvesting

device shows better effi-

ciency at retaining heat

to power the device.

(Credit: Mehmet Ozturk)

Reduced Heat Leakage Improves Wearable Heat Harvester

Researchers report significant enhancements in preventing heat leakage in the flexible body heat harvester. The harvesters use heat energy from the human body to power wearable technologies such as smart watches that measure heart rate, blood oxygen, glucose, and other health parameters and

never need to have their batteries recharged. The technology relies on the same principles governing rigid thermoelectric harvesters that convert heat to electrical energy.

Improvements to the device in 2020 included a high thermal conductivity silicone elastomer — essentially a type of rubber that encapsulated the EGaIn interconnects. The newest iteration of the device adds aerogel flakes to the silicone elastomer to reduce the elastomer's thermal conductivity. Experimental results showed that this innovation reduced the heat leakage through the elastomer by half.

One the patented technology's strengths is that it employs the same semiconductor elements that are used in rigid devices perfected after decades of research. The approach also provides a low-cost opportunity for existing rigid thermoelectric module manufacturers to enter the flexible thermoelectric market.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/harvester.

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Covering the antibiotics with lamellar inorganic protectors protects the antibacterial agents. (Credit: KeAi)

3D Printed Implants with Antibiotics

Researchers have fabricated antibiotic-containing 3D scaffold implants at high temperatures. These scaffolds not only support bone regeneration but manage the bone infections that can

arise as a result of injury or surgery. Incorporating antibiotics into these scaffolds is not straightforward because the 3D printing process consists of melting the material at high temperatures and antibiotics are heat sensitive.

Scientists found that covering the antibiotics with lamellar inorganic protectors, prior to mixing them with the polymer and placing them in the 3D scaffolds, not only protected the antibacterial agents but also enabled a more controlled release. This extended the period the antimicrobials were active and helped keep local antibiotic concentrations under potentially toxic levels. At the same time, the cells in contact with these scaffolds maintained their viability and could perform normal cell functions, including bone formation — the goal of the implant.

Until now, the direct incorporation of antibiotics and other bioactive molecules within 3D printed scaffolds has been limited to the few polymers that can be processed at low temperatures. This novel approach shows that the library of polymers can be expanded to include many more.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/implants.



Multilayer antibacterial coatings offer a prolonged effect and a universal spectrum of action. (Credit: MISIS)

Bioactive Implant Coatings Resistant to Most Bacterial Strains

Multilayer antibacterial coatings offer a prolonged effect and a universal spectrum of action. The coating is based on modified titanium oxide and several antiseptic components. The coatings can be used in modern implantology as a protective layer for the prevention of concomitant com-

plications — inflammation or implant rejection.

The multilayer coating synthesizes the protective properties of nanoparticles, biopolymers, anticoagulants, and antibiotics. The antibiotic and silver nanoparticles provide an antibacterial effect, while heparin prevents bacterial cells from sticking to the tissue surface, which reduces the amount of antibacterial agent required.

The chemical composition of the resulting coating layers was carefully studied by the developers using infrared and x-ray photoelectron spectroscopy. Scientists have found out that the incorporation of therapeutic components occurs throughout the whole plasma-applied polymer layer.

According to the developers, the coatings can be used as an antibacterial implant modifier, allowing it to accelerate implantation by reducing the risks of associated inflammation and stimulating the growth of osteoblastic cells. Researchers are currently planning to move to the preclinical development stage.

For more information, visit www.medicaldesignbriefs.com/ roundup/0621/coatings.



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Cohesive Circuit Protection for Wearable Electronics

The cellulose nanofiber coating counters bending damage and retains electrode function under water.

Osaka University Osaka, Japan

Most electronic devices aren't waterproof, much to your irritation if a sprinkler suddenly sprays you while you're talking outside on your cellphone. Some electronics can be made at least water-resistant by, for example, using special glues to fuse outer components together. Flexible electronics are another story. Their sealant materials must be able to bend, yet with current technology it's inevitable that eventually such a sealant will crack or separate from the device — and there goes your water-resistant coating.

Researchers are determined to come up with a solution. Cellulose nanofibers are a proposed polymer coating for flexible electronics. These fibers are made from renewable resources and are environmentally friendly. However, they usually absorb water — commonly thought to be a fatal limitation for imparting water resistance.

In a study recently published in ACS Applied Nanomaterials, researchers from Osaka University developed self-healing cellulose nanofibers that slightly disperse in water and act to protect a copper electrode, enabling the electrode to function for an extended period. The researchers' flexible circuit protection mechanism retains electrode function underwater and can undergo hundreds of bending cycles.

"In our initial work, an unprotected copper electrode failed after 5 minutes of dripping water onto it," says Takaaki Kasuga, lead author. "Remarkably, a cellulose nanofiber coating prevented failure over at least a day of the same water challenge."

Why is this? Remember that cellulose fibers don't repel water. Instead, this polymer coating migrates in the electrode in such a way to prevent formation of conductive metal filaments that cause short-circuits. The electrodes even maintained their function after the cellulose coating was scratched to simulate bending damage.

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Fig. 1 – Water is detrimental to electronic devices because it easily causes short circuits and accidents, such as overheating/ignition. By coating electronic circuits with cellulose nanofibers (CNFs), it is possible to prevent water-induced short circuits in a completely different approach compared with conventional waterproofing coatings.



Fig. 2 – Water inevitably penetrates waterproof coatings if they are damaged, and water can easily cause malfunctions due to dendrite growth. Cellulose nanofibers (CNFs) migrate toward the anode and gel, thus inhibiting short circuits even if the CNF coating film is damaged.

"Our results aren't attributable to simple ion-exchange or nanofiber length," explains Masaya Nogi, senior author. "The nanofibers aggregate in water into a protective layer made cohesive by locally acidic conditions and polymer cross-linking."

A more rigorous test of the polymer coating was its performance after 300 cycles of bending underwater over the course of an hour. A conventional polymer coating usually failed, but the cellulose nanofibers continued to power LEDs.

"You'll be able to stretch, bend, and fold electronics with our coating, and they'll still retain their water resistance," says Kasuga. "This is critical for use in applications under extreme conditions where device failure is unacceptable — for example, medical devices used in emergency disaster response."

In preliminary work, even an ultrathin polymer coating thickness of only 1.5 µm, and some other polymers, performed similarly to the originally tested setup. They'll become a staple of wearable electronics, and perhaps even medical devices, in the coming years.

The article, "Cellulose nanofiber coatings on Cu electrodes for cohesive protection against water-induced short-circuit failures," was published in *ACS Applied Nanomaterials* at DOI: https://doi.org/10.1021/acsanm.1c00267.

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<u>TECH BRIEFS</u>

Tiny Wireless Implant Detects Oxygen Deep Within the Body

The implant provides realtime measurements of tissue oxygen levels.

UC Berkeley Berkeley, CA

Engineers at the University of California, Berkeley, have created a tiny wireless implant that can provide real-time measurements of tissue oxygen levels deep underneath the skin. The device, which is smaller than the average ladybug and powered by ultrasound waves, could help doctors monitor the health of transplanted organs or tissue and provide an early warning of potential transplant failure.

The technology, created in collaboration with physicians at the University of California, San Francisco, also paves the way for the creation of a variety of miniaturized sensors that could track other key biochemical markers in the body, such as pH or carbon dioxide. These sensors could one day provide doctors with minimally invasive methods for monitoring the biochemistry inside functioning organs and tissues.

"It's very difficult to measure things deep inside the body," says Michel Maharbiz, a professor of electrical engineering and computer sciences at UC Berkeley and a Chan Zuckerberg Biohub Investigator. "The device demonstrates how, using ultrasound technology coupled with very clever integrated circuit design, you can create sophisticated implants that go very deep into tissue to take data from organs."

Maharbiz is the senior author of a new paper describing the device, which appears in the journal *Nature Biotechnology*.

Oxygen is a key component to cells' ability to harness energy from the food that we eat, and nearly all tissues in the body require a steady supply in order to survive. Most methods for measuring tissue oxygenation can only provide information about what is happening near the surface of the body. That is because these methods rely on electromagnetic waves, such as infrared light, which can only penetrate a few centimeters into skin or organ tissue. While there are types of magnetic resonance imaging that can provide information about

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This wireless implant, developed by engineers at the University of California, Berkeley, can measure the oxygenation of living tissue deep below the surface of the skin. (Credit: UC Berkeley/Soner Sonmezoglu)



A schematic of the oxygen-detecting implant, which measures 4.5 mm long by 3 mm wide. The μ LED, O₂-sensing film, and optical filter make up the oxygen sensor, and are controlled by an integrated circuit (IC). The piezo-crystal converts an electronic signal from the IC into ultrasonic waves that can be transmitted safely through living tissue. (Credit: UC Berkeley/Soner Sonmezoglu)

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deep tissue oxygenation, they require long scanning times, and so are unable to provide data in real-time.

Since 2013, Maharbiz has been designing miniaturized implants that use ultrasonic waves to wirelessly communicate with the outside world. Ultrasonic waves, which are a form of sound too high in frequency to be detected by the human ear, can travel harmlessly through the body at much longer distances than electromagnetic waves and are already the basis of ultrasound imaging technology in medicine.

One example of such a device is Stimdust, designed in collaboration with UC Berkeley electrical engineering and computer sciences assistant professor Rikky Muller. Stimdust can detect and stimulate electrical nerve firings in the body. Soner Sonmezoglu, a postdoctoral researcher in engineering at UC Berkeley, led the effort to expand the implant's capabilities to include oxygen sensing.

Incorporating the oxygen sensor involved integrating both an LED light source and an optical detector into the tiny device, as well as designing a more complicated set of electronic controls to operate and read out the sensor. The team tested the device by monitoring the

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A Manufacturing Work Horse

WorkSeries 300 Large Format 3D Printer

Traditional desktop 3D printers are fine for prototyping parts, but can be costly in terms of volume production and time-to-market. With the 1000 x 1000 x 700 mm build area, industrial manufacturers can produce near-net shape parts and have greater ability to customize. The result is decreased costs and reduced time-to-market.

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oxygen levels inside the muscles of live sheep. Sonmezoglu points out that this type of oxygen sensor differs from the pulse oximeters that are used to measure oxygen saturation in the blood. While pulse oximeters measure the proportion of hemoglobin in the blood that is oxygenated, the new device is able to directly measure the amount of oxygen in tissue.

"One potential application of this device is to monitor organ transplants, because in the months after organ transplantation, vascular complications can occur, and these complications may lead to graft dysfunction," Sonmezoglu says. "It could be used to measure tumor hypoxia, as well, which can help doctors guide cancer radiation therapy."

Study co-authors Jeffrey Fineman and Emin Maltepe, who both are pediatricians at UCSF and members of the Initiative for Pediatric Drug and Device Development, became involved in the work because of its potential for monitoring fetal development and caring for premature babies.

"In premature infants, for example, we frequently need to give supplemental oxygen but don't have a reliable tissue readout of oxygen concentration," Maltepe says. "Further miniaturized versions of this device could help us better manage oxygen exposure in our preterm infants in the intensive care nursery setting and help minimize some of the negative consequences of excessive oxygen exposure, such as retinopathy of prematurity or chronic lung disease."

The technology could be further improved, Sonmezoglu says, by housing the sensor so that it could survive long term in the body. Further miniaturizing the device would also simplify the implantation process, which currently requires surgery. In addition, he says, the optical platform in the sensor could be readily adapted to measure other biochemistry in the body.

"By just changing this platform that we built for the oxygen sensor, you can modify the device to measure, for example, pH, reactive oxygen species, glucose, or carbon dioxide," Sonmezoglu says. "Also, if we could modify the packaging to make it smaller, you could imagine being able to inject into the body with a needle, or through laparoscopic surgery, making the implantation even easier."

This work was supported by the Chan Zuckerberg Biohub and by the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development through grants R44HD094414 and R01HD07245.

This article was written by Kara Manke, UC Berkeley. For more information, visit https://news.berkeley.edu.

Tiny Implantable Tool for Light-Sheet Imaging of Brain Activity

The tool shows promise for imaging brain activity in 3D with high speed and contrast.

SPIE Bellingham, WA

Tools that allow neuroscientists to record and quantify functional activity within the living brain are in great demand. Traditionally, researchers have used techniques such as functional magnetic resonance imaging, but this method cannot record neural activity with high spatial resolution or in moving subjects. In recent years, a technology called *optogenetics* has shown considerable success in recording neural activity from animals in real time with single neuron resolution.

Optogenetic tools use light to control neurons and record signals in tissues that are genetically modified to express light-sensitive and fluorescent proteins. However, existing technologies for imaging light signals from the brain have drawbacks in their size, imaging speed, or contrast that limit their applications in experimental neuroscience.

A technology called *light-sheet fluorescence imaging* shows promise for imaging brain

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Optical microscope image of the implantable shanks (141 μ m pitch) of a light sheet neural probe. Light is emitted by nanophotonic gratings on the shanks to form light sheets. (Credit: Sacher et al., doi 10.1117/1.NPh.8.2.025003)

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activity in 3D with high speed and contrast (overcoming multiple limitations of other imaging technologies). In this technique, a thin sheet of laser light (light-sheet) is directed through a brain tissue region of interest, and fluorescent activity reporters within the brain tissues respond by emitting fluorescence signals that microscopes can detect.

Scanning a light sheet in the tissue enables high-speed, high-contrast, volumetric imaging of the brain activity. Currently, using light-sheet fluorescence brain imaging with nontransparent organisms (like a mouse) is difficult because of the size of the necessary apparatus. To make experiments with nontransparent animals and, in the future, freely moving animals feasible, researchers will first need to miniaturize many of the components.

A key component for the miniaturization is the light-sheet generator itself, which needs to be inserted into the brain and thus must be as small as possible to avoid displacing too much brain tissue. In

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Optical addressing method and proposal for deep-brain photonic-probe-enabled light-sheet fluorescence microscopy (LSFM). Schematic of the optical addressing method (not to scale) (a). The scanning system addresses on-chip edge couplers via spatial addressing of the cores of an image fiber bundle. Bottom inset: micrographs of the distal facet of a fiber bundle connected to the scanning system with different cores addressed. Top inset: annotated photograph of a packaged light-sheet neural probe inserted into an agarose block. Illustration of the proposed use of the light-sheet neural probe with a GRIN lens endoscope for deep brain LSFM (not to scale) (b). (Credit: Sacher et al., doi 10.1117/1.NPh.8.2.025003)

a new study reported in *Neurophotonics*, an international team of researchers from the California Institute of Technology (USA), University of Toronto (Canada), University Health Network (Canada), the Max Planck Institute of Microstructure Physics (Germany), and Advanced Micro Foundry (Singapore) developed a miniature lightsheet generator, or a photonic neural probe, that can be implanted into a living animal's brain.

The researchers used nanophotonic technology to create ultrathin siliconbased photonic neural probes that emit multiple addressable thin sheets of light with thicknesses <16 micrometers over propagation distances of 300 micrometers in free space. When tested in brain tissues from mice that were genetically engineered to express fluorescent proteins in their brains, the probes permitted the researchers to image areas as large as 240 \times 490 µm. Moreover, the level of image contrast was superior to that with an alternative imaging method called epifluorescence microscopy.

Describing the significance of his team's work, the study's lead author, Wesley Sacher, says, "This new implantable photonic neural probe technology for generating light sheets within the brain circumvents many of the constraints that have limited the use of light-sheet fluorescence imaging in experimental neuroscience. We predict that this technology will lead to new variants of light-sheet microscopy for deep brain imaging and behavior experiments with freely moving animals."

Such variants would be a boon to neuroscientists seeking to understand the workings of the brain.

The open access research article, W.D. Sacher et al., "Implantable photonic neural probes for light-sheet fluorescence brain imaging," was published in *Neurophotonics* 8(2), 025003, doi 10. 1117/1.NPh.8.2.025003.

For more information, visit https://spie.org.

E-health Patches Monitor Pulse and Blood Pressure

The wireless patches power themselves with harvested energy.

Osaka University Osaka, Japan

Scientists at Osaka University, in cooperation with Joanneum Research (Weiz, Austria), have introduced wireless health monitoring patches that use embedded piezoelectric nanogenerators to power themselves with harvested biomechanical energy. This work may lead to new autonomous health sensors as well as battery-less wearable electronic devices.

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Fig. 1 - Sheet-type piezoelectric system with self-generation and storage functions.

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The sheet-type piezoelectric system. Accurate biomonitoring is possible without being noticed; the ultrathin and soft sheet system realizes attachment of the device to the skin. (Credit: Osaka University)

As wearable technology and smart sensors become increasingly popular, the problem of providing power to all of these devices become more relevant. While the energy requirements of each component may be modest, the need for wires or even batteries become burdensome and inconvenient. That is why new energy harvesting methods are needed. Also, the ability for integrated health monitors to use ambient motion to both power and activate sensors will help accelerate their adoption in doctor's offices.

Now, an international team of researchers from Japan and Austria has invented new ultraflexible patches with a ferroelectric polymer that can not only sense a patient's pulse and blood pressure, but also power themselves from normal movements. The key was starting with a substrate just 1 µm thick. Using a strong electric field, ferroelectric crystalline domains in a copolymer were aligned so that the sample had a large electric dipole moment. Based on the piezoelectric effect, which is very efficient in converting natural motion into small electric voltages, the device responds rapidly to strain or pressure changes. These voltages can be transduced either into signals for the medical sensors or to directly harvest the energy (see Figure 1).

"Our e-health patches may be employed as part of screening for lifestyle-related diseases such as heart disorders, signs of stress, and sleep apnea," says Andreas Petritz, first author on the paper.

The authors estimate that multilayer patches can harvest up to 200 mJ per day from biomechanical motions if placed on joints, like knees or elbows. This is enough to monitor cardiovascular parameters several times a day. And the patches are so thin that they are barely perceptible thus making a necessary evil for many patients — daily health monitoring — less unpleasant.

"We expect that our findings will assist in the development of other sheet-type sensor systems that can perform precise biomonitoring when affixed to the skin surface," says Tsuyoshi Sekitani, senior author. Additional modules allow other features, such as wireless communication with a smartphone or computer.

The article, "Imperceptible energy harvesting device and biomedical sensor based on ultraflexible ferroelectric transducers and organic diodes," was published in *Nature Communications* at DOI: https://doi.org/10.1038/s41467-021-22663-6.

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<u>TECH BRIEFS</u>

Surgical Sutures Inspired by Human Tendons

Next-generation sutures can deliver drugs, prevent infections, and monitor wounds.

McGill University Montreal, QC, Canada

Sutures are used to close wounds and speed up the natural healing process, but they can also complicate matters by causing damage to soft tissues with their stiff fibers. To remedy the problem, researchers from Montreal have developed innovative tough gel sheathed (TGS) sutures inspired by the human tendon. These next-generation sutures contain a slippery, yet tough gel envelope, imitating the structure of soft connective tissues. In putting the TGS sutures to the test, the researchers found that the nearly frictionless gel surface mitigated the damage typically caused by traditional sutures.

Conventional sutures have been around for centuries and are used to hold wounds together until the healing process is complete. But they are far from ideal for tissue repair. The rough fibers can slice and damage already fragile tissues, leading to discomfort and post-surgery complications.

Part of the problem lies in the mismatch between our soft tissues and the rigid sutures that rub against contacting tissue, say the researchers from McGill University



Tough gel sheathed (TGS) sutures. (Credit: Zhenwei Ma, McGill University)

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and the INRS Énergie Matériaux Télécommunications Research Centre.

Inspired by the Tendon

To tackle the problem, the team developed a new technology that mimics the mechanics of tendons. "Our design is inspired by the human body, the endotenon sheath, which is both tough and strong due to its double-network structure. It binds collagen fibers together while its elastin network strengthens it," says lead author Zhenwei Ma, a PhD student under the supervision of Assistant Professor Jianyu Li at McGill University.

The endotenon sheath not only forms a slippery surface to reduce friction with surrounding tissues in joints, but it also delivers necessary materials for tissue repair in a tendon injury. In the same way, TGS sutures can be engineered to provide personalized medicine based on a patient's needs, say the researchers.

Personalized Wound Treatment

"This technology provides a versatile tool for advanced wound management. We believe it could be used to deliver drugs, prevent infections, or even monitor wounds with near-infrared imaging," says Li of the Department of Mechanical Engineering.

"The ability to monitor wounds locally and adjust the treatment strategy for better healing is an exciting direction to explore," says Li, who is also a Canada Research Chair in Biomaterials and Musculoskeletal Health.

For more information, visit www.mcgill.ca.

Exosome-Coated Stent Heals Vascular Injury, Repairs Damaged Tissue

The stent delivers regenerative stem cellderived therapy to bloodstarved tissue.

North Carolina State University Raleigh, NC

Researchers from North Carolina State University have developed an exosomecoated stent with a "smart-release" trigger that could both prevent reopened blood vessels from narrowing and deliver regenerative stem cell-derived therapy to blood-starved, or ischemic, tissue.

Angioplasty — a procedure that opens blocked arteries — often involves placing a metal stent to reinforce arterial walls and prevent them from collapsing once the blockage is removed. However, the stent's placement usually causes some injury to the blood vessel wall, which stimulates smooth muscle cells to proliferate and migrate to the site in an attempt to repair the injury.

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The result is restenosis: a re-narrowing of the blood vessel previously opened by angioplasty.

"The inflammatory response that stents cause can decrease their benefit," says Ke Cheng, corresponding author of the research. "Ideally, if we could stop smooth muscle cells from over-reacting and proliferating, but recruit endothelial cells to cover the stent, it would mitigate the inflammatory response and prevent restenosis." Cheng is the Randall B. Terry Jr. Distinguished Professor in Regenerative

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Exosomes (magenta) released from a stent in the blood vessel. (Credit: Cheng Lab)

Medicine at NC State and a professor in the NC State/UNC-Chapel Hill Joint Department of Biomedical Engineering.

There are drug-eluting stents currently in use coated with drugs that discourage cell proliferation, but these anti-proliferative drugs also delay stent coverage by endothelial cells — which are the cells healthcare providers want to coat the stent.

To solve this problem, Cheng and his team developed a stent coating composed of exosomes derived from mesenchymal stem cells. Exosomes are tiny nano-sized sacs secreted by most cell types. The idea behind the coating was two-fold: first, since the exosomes are composed of materials not much different from cell membranes, they camouflage the stent to trick smooth muscle cells and the body's immune system. Second, the exosomes promote coverage of the stent by endothelial cells and, in the case of injury, travel downstream to the site to promote tissue repair.

To prevent premature depletion of the therapy, the stent releases exosomes when it encounters reactive oxygen species (ROS) — which are more prevalent during an inflammatory response.

"Think of it as a smart release function for the exosomes," Cheng says. "Ischemic reperfusion injuries, which occur when blood flow is diminished and then reestablished, create a lot of ROS. Let's say the heart is damaged by ischemia. The enhanced ROS will trigger the release of the exosomes on the stent, and regenerative therapy will travel through the blood vessel to the site of the injury."

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The research team performed in vitro testing to ensure biocompatibility and test the release mechanism. They found that in the presence of ROS, the exosomes released up to 60 percent of their secretions within 48 hours post-injury.

In a rat model of ischemic injury, the researchers compared their exosomeeluting stent (EES) to both a bare metal stent (BMS) and a drug-eluting stent (DES). They found that in comparison to the BMS, their stent performed better in both decreasing stenosis and promoting endothelial coverage. While the DES performed similarly to the EES in preventing restenosis, the EES was less injurious to the vessel wall and had better endothelial coverage overall. In addition, the exosomes released from EES promoted muscle regeneration in rats with hind limb ischemia. The researchers plan to test the stent in a large animal model with an eye toward eventual clinical trials.

"This bioactive stent promotes vascular healing and ischemic repair, and a patient wouldn't need additional procedures for regenerative therapy after the stent is in place," Cheng says. "The stent is the perfect carrier for exosomes, and the exosomes make the stent safer and more potent in tissue repair."

The research appears in *Nature Biomedical Engineering* and was supported by the National Institutes of Health and the American Heart Association. NC State postdoctoral research scholars Shiqi Hu and Zhenhua Li are co-first authors.

This article was written by Tracey Peake, NC State. For more information, visit https:// news.ncsu.edu.

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APPLICATIONS

AM: Quickly Adapting in Tandem with Medical Innovation

Recently, we've seen a lot of talk around the topic of the healthcare industry still being in the midst of stabilizing inventory and recovering from the post-pandemic peak. When resources were being drained rapidly due to the increased demand onset by the COVID-19 pandemic — hospitals, doctor's offices, and other healthcare providers were forced to develop solutions quickly to maintain adequate safety measures for their staff and patients alike.

This last year is just one proof point of how additive manufacturing (AM) is shaping the narrative around health. While AM brings speed and efficiency along with the option of an alternative supply chain, it also brings the ability to create a bespoke approach to patient care.

Why Adaptability Is Crucial

Additive manufacturing, otherwise frequently referred to as *3D printing*, was instrumental in assisting businesses to quickly pivot their manufacturing services to personal protective equipment (PPE) at scale during the peak of this unprecedented period of time. The ability to respond quickly and adapt to the current landscape makes AM an ideal solution to produce parts that are in short supply, either due to a surge in demand or as a result of supply chain disruption. When patient morphologies or supply deviate from the understood norm, the adaptability of 3D printing is crucial.

The manufacturing time for a 3D printed product can be as soon as a couple of hours, and depending on the application, this method could be quite faster than other methods of production. When it comes to developing prototypes for new medical devices, 3D printing can not only be much faster, it can also be cost-effective to manufacture products.

With AM, supply can be determined based on the day's current demand or by printing "as needed" — leading to increased efficiency, by reducing the amount of wasted product. There are also greater technical capabilities with 3D printing being able to produce lightweight, lattice-type structures, compared to injection molding manufacturing.¹

Materials Usage In AM

AM's unique ability to utilize various polymer and metal materials is significant in medical device manufacturing. With the varying properties of each filament, engineers can develop customized options for their end users. For example, materials like nylon and titanium are ideal for use in healthcare production due to their biocompatibility.²



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Anatomically accurate jaw created by Forecast 3D.



Custom orthotics created with additive manufacturing by Forecast 3D for FitMyFoot.

Throughout the past couple of decades, engineers and scientists have also been researching the possibility of using organ cells and tissues in additive manufacturing. With this research, the industry is working towards the ability to 3D print new organs for transplants.

The applications of this technology would lead to the availability of custom-made organs, derived from patient's own cells and tissues. These manufacturing breakthroughs would in turn lead to a significant decrease in the rejection rate of organ transplants.³ This research shows the potential future possibilities of 3D printing in the healthcare field.

Custom Applications of AM

The AM process has immense value when it comes to creating patient-specific solutions. Each 3D printed item can be developed to precise specifications for patients who require a custom-fitted device. These medical devices range anywhere in complexity from anatomically correct models for complex surgeries to custom-made arch-supporting shoe inserts.

One type of custom solution that has been developed using 3D printing are life-sized anatomical prototypes — not to be confused with 3D printing of actual organs. These 3D models are used as tools for complicated surgeries and educational opportunities for medical students.

Utilizing these resources as diagrams, doctors can gain a better visual understanding while preparing for patient treatments. This can be especially useful in surgeries that are not routinely performed — or even when comparing the physiology of an adult to a child for determining surgical procedures.²

An example of a custom AM hybrid-solution product would be FitMyFoot's arch support insoles. Doctors and engineers identified the arch as being the most valuable component of shoe support inserts; so they set forth in identifying a way to custom build a product specific to the recipient.

Their solution was a combination of a stock injection-molded piece for the bottom layer, with the 3D printed arch support being manufactured for the top layer. This unique approach digitally maps each foot, using over 200 points to create a 3D printable file unique to each individual foot.⁴

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Nasopharyngeal swabs created by Forecast 3D.

Other Capabilities of AM

Alternatively, sometimes the need for mass production outweighs customization. During a disruption brought on by natural disasters, pandemics, or even foreign conflicts, AM has the ability to quickly produce products for consumer use without supply chain disruption. Rapid prototyping processes were initially created to enable a component to be produced in a matter of hours, which would be much faster than other manufacturing processes that took multiple days.² A great example of this type of manufacturing being put into action was when AM specialists all over the world were able to help quickly meet the urgent needs of healthcare professionals and medical device providers during the COVID-19 pandemic.

Early last year, Forecast 3D participated in a consortium with healthcare partners to leverage rapid prototyping to develop and distribute nasopharyngeal swabs on a large scale in as few as eight weeks. At this moment, the company is able to massproduce up to 100,000 swabs per day with Multi Jet Fusion, using a fleet of industrial-grade HP Jet Fusion 3D printing systems.⁵ This mass production of swabs helped better prepare healthcare workers in their ability to test for respiratory viruses.

AM has a broad spectrum of applications. Not only do the technological advancements over the last couple of decades provide the ability to adapt quickly in high-pressure situations, but 3D printing also empowers the healthcare field to continue pushing the envelope of innovation when it comes to patientcentered care.

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This article was written by Ted Rowan, Strategic Business Development at Forecast 3D, Carlsbad, CA. For more information, visit http://info.hotims.com/79414-344.

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GLOBAL INNOVATIONS

Gold Nanoparticles Enable Long-Term Implantable Sensor 'Tattoo'

Johannes Gutenberg University, Mainz, Germany

he idea of implantable sensors that continuously transmit information on vital values and concentrations of substances or drugs in the body has fascinated physicians and scientists for a long time. Such sensors enable the constant monitoring of disease progression and therapeutic success. However, until now, implantable sensors have not been suitable to remain in the body permanently but had to be replaced after a few days or weeks. On the one hand, there is the problem of implant rejection because the body recognizes the sensor as a foreign object. On the other hand, the sensor's color, which indicates concentration changes, has been unstable so far and would fade over time. Scientists at Johannes Gutenberg University Mainz (JGU) have developed a novel type of implantable sensor that can be operated in the body for several months. The sensor is based on color-stable gold nanoparticles that are modified with receptors for specific molecules. Embedded into an artificial polymeric tissue, the nanogold is implanted under the skin where it reports changes in drug concentrations by changing its color.

Implant Reports Information as an 'Invisible Tattoo'

Prof. Carsten Sönnichsen's research group at JGU has been using gold nanoparticles as sensors to detect tiny amounts of proteins in microscopic flow cells for many years. Gold nanoparticles act as small antennas for light: They strongly absorb and scatter it and, therefore, appear colorful. They react to alterations in their surroundings by changing color. Sönnichsen's team has exploited this concept for implanted medical sensing.

To prevent the tiny particles from swimming away or being degraded by immune cells, they are embedded in a porous hydrogel with a tissue-like consistency. Once implanted under the skin, small blood vessels and cells grow into the pores. The sensor is integrated in the tissue and is not rejected as a foreign body. "Our sensor is like an invisi-

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Gold nanoparticles embedded in a porous hydrogel can be implanted under the skin and used as medical sensors. The sensor is like an invisible tattoo, revealing concentration changes of substances in the blood by color change. (Credit: Nanobiotechnology Group, JGU Department of Chemistry)

ble tattoo, not much bigger than a penny and thinner than one millimeter," says Sönnichsen, head of the Nanobiotechnology Group at JGU. Since the gold nanoparticles are infrared, they are not visible to the eye. However, a special kind of measurement device can detect their color noninvasively through the skin.

In their study published in Nano Letters, the JGU researchers implanted their gold nanoparticle sensors under the skin of hairless rats. Color changes in these sensors were monitored following the administration of various doses of an antibiotic. The drug molecules are transported to the sensor via the bloodstream. By binding to specific receptors on the surface of the gold nanoparticles, they induce color change that is dependent on drug concentration. Thanks to the color-stable gold nanoparticles and the tissue-integrating hydrogel, the sensor was found to remain mechanically and optically stable over several months.

Long-Lasting Implantable Sensors

"We are used to colored objects bleaching over time. Gold nanoparticles, however, do not bleach but keep their color per-

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manently. As they can be easily coated with various different receptors, they are an ideal platform for implantable sensors," explains Dr. Katharina Kaefer, first author of the study.

The novel concept is generalizable and has the potential to extend the lifetime of implantable sensors. In the future, gold nanoparticle-based implantable sensors could be used to observe concentrations of different biomarkers or drugs in the body simultaneously. Such sensors could find application in drug development, medical research, or personalized medicine to aid in the management of chronic diseases.

Interdisciplinary Teamwork Brought Success

Sönnichsen had the idea of using gold nanoparticles as implanted sensors in 2004 when he started his research in biophysical chemistry as a junior professor in Mainz. However, the project was not realized until 10 years later in cooperation with Dr. Thies Schroeder and Dr. Katharina Kaefer, both scientists at IGU. Schroeder was experienced in biological research and laboratory animal science and had already completed several years of research work in the United States. Kaefer was looking for an exciting topic for her doctorate and was particularly interested in the complex and interdisciplinary nature of the project. Initial results led to a stipend awarded to Kaefer by the Max Planck Graduate Center (MPGC) as well as financial support from Stiftung Rheinland-Pfalz für Innovation.

"Such a project requires many people with different scientific backgrounds. Step by step we were able to convince more and more people of our idea," says Sönnichsen. "Ultimately, it was interdisciplinary teamwork that resulted in the successful development of the first functional implanted sensor with gold nanoparticles."

For more information, visit https://www. uni-mainz.de.



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Cover image supplied by Web Industries

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Coping with the **Pandemic:**

Transitioning from Aerospace to Medical

hen the COVID-19 pandemic grounded much of the U.S. aerospace business in 2020, Web Industries, a Massachusetts-based contract manufacturer, was forced to improvise. The business shifted its attention and resources from aerospace, the company's largest profit center, to its medical sector, which had experienced a surge of demand.

The transition proved a daunting challenge. It meant transforming virtually every aspect of the company's operations, from infrastructure to technology, logistics to staffing — all while establishing strict guidelines to prevent infection and keep employees safe. Web reinvented itself and scaled up to produce vast quantities of lateral flow immunoassay (LFI) antigen tests and personal protective equipment (PPE) in a matter of months. Its story offers pointers for other companies considering a similar transition.

Adapting to Changing Market Forces

The story begins with the pandemic's bringing air travel to a halt and devastating the aircraft manufacturing industry. As a result, the company suffered a slump in its aerospace unit, which fashions materials for parts in aircraft interiors, engines, wings, fuselages, and other structural elements. The slump triggered

Once completed, the kits are fed horizontally into a flow wrapper and securely packaged in foil pouches, with each pouch identified by product information labels. A camera system [not pictured] scans each printed label and verifies that the information is correct and meets FDA requirements. (Credit: Web Industries)

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Web's turn to the medical sector. Despite the challenges, the company had a solid foundation on which to build. It was one of the few U.S.-based contract manufacturers with a network of domestic factories capable of processing the type of flexible materials used in diagnostic tests. Plus, its medical business featured an LFI competency, established in 2014.

Web consulted first with potential supply partners and identified a new opportunity in the medical field: producing rapid LFI antigen test devices. Antigen tests are one of the two main diagnostic tools used to detect COVID-19 infections, along with molecular RT-PCR tests. Speed and ease of use are LFI antigen test hallmarks. The antigens recognize proteins on the virus's surface by sampling a nasal or throat swab. They can be administered and read close to the point of care. Results appear within 15-30 minutes. In contrast, RT-PCR tests require specialized laboratory processing and can take a few hours up to an entire week for results.

As with vaccines, diagnostic tests usually take years to design, develop, and earn approval. But under Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA), Web and its partners were able to move forward much quicker. The company faced a tight deadline — 12 weeks — to complete the first stage of test development.

"It is not the strongest of the species that survives, nor the most intelligent. It is the one that is most adaptable to change."

- Charles Darwin

Phase One: Proof of Concept Web invested millions in its Holliston, MA, LFI facility to accommodate rapid antigen test device production and reassigned engineers and technical staff from the aerospace division to Holliston. The relocated employees brought with them experience in converting flexible materials and working in a regulated industry to manufacture the critical components for antigen test devices. At the same time, the company began a massive recruiting effort to hire hundreds of new employees to fill manufacturing positions.

The ramp-up in test production occurred in two phases. Phase one entailed building capacity, mostly manual, to scale to 1 million devices per week. Phase two involved full automation of all processes and high-volume production to exceed 2 million test devices per week. Web, with its supply partners and strong support from its OEM partner, built a solid supply chain and procured the necessary automation to support this volume's production of antigen test devices. The production process also adhered to exceptional quality standards and took place in an FDAregulated environment.

The COVID-19 antigen test kit contains a plastic cartridge housing an LFI test



Web Industries converted from manual operations to completely automated production. The equipment is now integrated seamlessly on the factory floor. Automated production steps include reagent deposition, lamination, test strip cutting and placement, and packaging. (Credit: Web Industries)



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Coping with the Pandemic



Automated reel-to-reel machines precisely align and laminate treated materials. (Credit: Web Industries)

strip; a collection swab; positive and negative control swabs; and a tube filled with reagent fluid that also works as dropper. During use, the sample swab is inserted into the tube and mixed with the reagent solution. Fluid from the tube is then dispensed into a designated well on the test device. The fluid flows across the device's treated sample pad, prompting a chemical response to the specimen. Trained clinicians then insert the test into a portable test-reading device to obtain the results.

The initial development phase was mainly a batch process involving separate manual operations. During this phase, the lateral flow strips were cut using offline cutting machines. Multiple layers of material were aligned and laminated together. Assembly technicians then manually inserted the laminated strips into the test cassettes. It was a labor-intensive process, but over the next few weeks Web steadily increased its test kit output, and within just 12 weeks, Web produced 12,000 devices, meeting its OEM's time to market. This was confirmation to Web and its OEM partner that the project was viable and could be successfully scaled to high-volume production.

Taking Precautions

A challenge to scaling from an initial volume of 12,000 to a million per week

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was ensuring the safety of all employees. Preventing COVID-19 infections among on site-based employees was critical. Workers' health was paramount. From the pandemic's start, a team of 14 Web Industries' employees met every day, seven days a week, via Zoom to develop an infection-prevention strategy. Relying on guidance from the Centers for Disease Control and Prevention, the team identified and implemented best practices at all company locations.

Social distancing and masking were mandated, and temperature checks were required whenever an employee or visitor entered a Web facility. The team also developed procedures for necessary actions in case of an infection, including rules on quarantining workers and cleaning affected areas. The group continues to meet regularly to review prevention practices.

Phase Two: Full Automation

After the initial market push, Web scaled to full production. This entailed not just incremental changes, but a total transformation of operations and processes. It meant producing millions of antigen tests per week, rather than thousands.

To accommodate full automation, Web repurposed and added thousands of square feet at its Holliston facility. This included more space for dry rooms needed to maintain the right test production humidity. The company also obtained additional offsite warehousing to store test materials and components and installed a new enterprise resource planning (ERP) software suite, which consolidated many business functions including production, distribution, finance, and supply chain. The ERP system keeps close track of data needed to meet FDA record-keeping requirements.

Web acquired capabilities that facilitated conversion from manual operations to completely automated production. These included pick-and-place machines, machine vision cameras, and checkweigher systems. The equipment is now linked together and integrated seamlessly on the factory floor. The company automated each production step, including reagent deposition, lamination, test strip cutting and placement, and packaging.

In simplified form, the production process works as follows: After large batches of reagent and conjugate are made according to the test recipe, they are deposited onto test strip materials via precision spraying or coating. Automated reel-to-reel machines precisely align and laminate the treated materials. Cutting machines, formerly offline, were brought online and integrated with pickand-place machines. These lightly grasp

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and accurately insert the lateral flow strips into the test cassettes. Accurate placement is necessary for the test to function properly. Camera systems automatically verify the correct positioning of the strip.

Once completed, the kits are fed horizontally into a flow wrapper and securely packaged in foil pouches, with each pouch identified by product information labels. Another camera system scans each printed label and verifies that the information is correct and meets FDA requirements. The automation made possible high-volume production. By early 2021, the company reached a key milestone: several million antigen tests per week produced, packaged, and shipped to its OEM partner.

In addition to technology issues, the production ramp-up also resulted in personnel-related challenges. Web's HR department assisted employees in transferring to Holliston from other Web facilities. HR also scoured the country for new employees with specialized skills. It was difficult, for example, to find workers with experience operating automated pick-and-place machines. Often, new or current employees had to be trained in the requisite skills. Holliston's workforce grew at an exponential rate. In less than a year it increased tenfold, from about 50 to over 500 employees.

More Changes

Making Medical Gowns. Elsewhere, Web facilities geared up to supply PPE. The Ft. Wayne, IN, plant was configured to meet the demand for nonwoven materials for protective gear for healthcare professionals. When gown-demand eventually outstripped available capacity, the company employed its machinery and expertise for aircraft engine and satellite components at facilities in Vermont, Georgia, and Texas to craft medical gowns.

New Testing Era. To date, Web's OEM has shipped rapid LFI antigen tests for COVID-19 to dozens of U.S. nursing homes, schools, government agencies, and other settings for administration to thousands of people. The tests inform individuals of their infection status within 15 minutes. The success of rapid tests and other innovations spurred by the pandemic will likely usher in new generations of tests for various diseases, tests

that can be purchased over the counter and administered at home.

The future might bring more challenges for the company. After the COVID-19 virus runs its course, new applications for diagnostic testing are sure to arise. Some experts have stated that the pandemic moved forward the acceptance of diagnostic testing by 10 years. The acceptance of LFI antigen test has opened doors for more infectious and non-infectious disease tests. Additionally, demand for PPE will likely recede, and PPE manufacturing and engineering resources will be adapted to yet unknown applications.

Likewise, when the aerospace industry rebounds from the downturn, the company is prepared to support the uptick in demand from the commercial aerospace market. Maintaining its core competency during this downturn is critical to ensure that Web meets its customers' needs.

This article was written by Kevin Young, Vice President of Corporate Development & Medical, Web Industries, Marlborough, MA. He can be reached at kyoung@webindustries.com. For more information, visit http://info.hotims.com/ 79414-342.



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Axis Prototypes Inc. www.axisproto.com

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AccuCoat, Inc. www.accucoatinc.com

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Porex Corporation www.porex.com

Röchling Group www.roechling.com/us

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AW-Lake Company www.aw-lake.com

Backer Hotwatt Inc. www.hotwatt.com

Bimba Manufacturing www.bimba.com



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Cole-Parmer www.cole-parmer.com

Diener Precision Pumps www.dienerprecisionpumps.com



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EMERSON

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Fairchild www.fairchildproducts.com

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NanoComposix www.nanocomposix.com

TUV Rheinland of North America, Inc. www.tuv.com/usa/en/ Laser Cutting/ Marking



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MECCO www.mecco.com

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ProMed https://promedmolding.com

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RenyMed www.renymed.com

Seaway Plastics Engineering seawayplastics.com

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Senior Metal Bellows www.metalbellows.com

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maxon www.maxongroup.us

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Nexen Group, Inc. www.nexengroup.com

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Wind River www.windriver.com

Zontec Inc. www.zontec-spc.com

Sterilization

Anderson Sterilizers www.anpro.com



B.Braun Medical Inc. OEM Division 484-240-8301 info@bbraun.com us.bbraunoem.com medicaldesignbriefs.com/rd121/ bbraunoem

E-BEAM Services, Inc. www.ebeamservices.com

MicroCare www.microcare.com

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Sterilization continued

Nordion, a Sotera Health Co. www.nordion.com

Noxilizer, Inc. www.noxilizer.com

Sterigenics https://sterigenics.com

Sterilucent, Inc. www.sterilucent.com



Applied Sterilization Technologies STERIS Applied Sterilization Technologies 877-783-7479 ast_info@steris.com https://www.steris-ast.com/ medicaldesignbriefs.com/rd121/ steris-ast

Steri-Tek www.steri-tek.com

Tovatech Ultrasonic www.tovatech.com

Test Services

Advanced Inspection Services www.advancedinspect.com

Akron Rubber Development Laboratory, Inc. www.ardl.com

Anderson Materials Evaluation, Inc. www.andersonmaterials.com

Avomeen www.avomeen.com

Boston Analytical www.bostonanalytical.com

CertifiGroup https://certifigroup.com

Compliance West USA www.compwest.com

Consumer Product Testing Co. www.cptclabs.com

CSZ, a Weiss Technik company www.cszindustrial.com



DDL, Inc. 952-941-9226 ddlinforequests@ddltesting.com www.ddltesting.com medicaldesignbriefs.com/rd121/ ddl Dynatec Laboratories www.dynatec-labs.com

EAG Laboratories www.eag.com

Element www.element.com



Eurofins Medical Device Testing 717-656-2300 Medical-Device@Eurofins.com https://www.eurofins.com/ medical-device

Exact Metrology www.exactmetrology.com

Gilero www.gilero.com

Hexagon Manufacturing Intelligence www.hexagonmi.com

Highpower Validation Testing & Lab Services www.highpowervtls.com

Laboratory Testing Inc. www.labtesting.com

MDT - Medical Device Testing Services www.devicetesting.com

Microtest Laboratories, Inc. https://microtestlabsinc.com

NAMSA www.namsa.com

Nelson Labs. A Sotera Health company

Nelson Laboratories, LLC 801-290-7524 sales@nelsonlabs.com www.nelsonlabs.com medicaldesignbriefs.com/rd121/ nelsonlabs

Q-Plus Labs www.qpluslabs.com

Stress Engineering Services www.stress.com

Toxicon www.toxikon.com

UL LLC www.ul.com/healthcare-andlife-sciences

ViVitro Labs Inc. www.vivitrolabs.com

Intro

WestPak www.westpak.com

WuXi AppTec https://medicaldevice.wuxiapptec.com

X2 Metrology www.x2metrology.com

Zaxis www.zaxisinc.com

Test/Inspection/ Metrology



3DT LLC 262-253-6700 sales@3DTLLC.com www.3DTLLC.com medicaldesignbriefs.com/rd121/ 3dt

4D Technology Corporation www.4dtechnology.com

Actco Metrology Services www.actcometrology.com

Bristol Instruments, Inc. www.bristol-inst.com

Chroma Systems Solutions, Inc. www.chromausa.com

Cincinnati Test Systems www.cincinnati-test.com

Creaform www.creaform3D.com

ED&D www.productsafet.com

Excel Technologies www.exceltechnologies.com



physical. chemical. biological.

A

Innovative Sensor Technology - IST AG 702-894-9891 ivelina.peneva@ist-ag.com www.ist-ag.com/en-us medicaldesignbriefs.com/rd121/ ist-ag

in-phase technologies www.in-phasetech.com

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Instron www.instron.com

Lenox Instrument Company, Inc. www.lenoxinst.com

Mahr Inc. www.mahr.com



Marposs 248-370-0404 marposs@us.marposs.com www.marposs.com medicaldesignbriefs.com/rd121/ marposs

MB Dynamics, Inc. www.mbdynamics.com

MSI-Viking Gage www.msi-viking.com

NI www.ni.com/en-us.html

Nikon Metrology www.nikonmetrology.com

Pfeiffer Vacuum www.pfeiffer-vacuum.com

RENISHAW.

apply innovation[™]

Renishaw 847-286-9953 usa@renishaw.com www.renishaw.com medicaldesignbriefs.com/rd121/ renishaw

Servo Innovations LLC www.servoinnovations.com

The L.S. Starrett Co. www.starrett.com

Werth, Inc. www.werthinc.com

Tubing & Extrusion



Asahi Intecc USA, Inc. 760-473-4265 davidz@asahi-intecc-us.com https://components.asahi-intecc. com/us/home medicaldesignbriefs.com/rd121/ asahiintecc

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Tubing & Extrusion continued

Axis Medical Extrusion www.axismedicalextrusion.com

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Duke Extrusion www.dukeextrusion.com

Exalt Custom Tubing www.exaltcustomtubing.com

GenX Medical www.genxmeds.com

Guill Tool & Engineering Co., Inc. www.guill.com



ENGINEERING International Polymer Engineering (IPE) 877-410-3265

customerservice@ipeweb.com www.ipeweb.com

Junkosha www.junkosha.com/en



Kahle Automation 973-993-1850 Kahle@KahleAutomation.com www.KahleAutomation.com medicaldesignbriefs.com/rd121/ kahleautomation



Medical Extrusion Technologies, Inc. 800-618-4346 info@medicalextrusion.com www.medicalextrusion.com medicaldesignbriefs.com/rd121/ medicalextrusion



Microlumen, Inc. 813-886-1200 sales@microlumen.com www.microlumen.com medicaldesignbriefs.com/rd121/ microlumen

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Microspec Corporation 603-924-4300 info@microspecorporation.com www.microspecorporation.com

MRPC www.mrpcorp.com

New England Tubing Technologies www.newenglandtubing.com



NewAge Industries, Inc. 215-526-2300 info@newageindustries.com www.newageindustries.com

Polygon Company www.polygoncomposites.com

Putnam Plastics www.putnamplastics.com

SPECTRUM

Spectrum Plastics Group 404-564-8560 marketing@spectrumplastics. com www.spectrumplastics.com

Superior Tube www.superiortube.com

Teel Plastics www.teel.com



Teleflex Medical OEM 800-295-8505 oeminfo@teleflex.com www.teleflexmedicaloem.com medicaldesignbriefs.com/rd121/ teleflexmedicaloem



Trelleborg Healthcare & Medical 224-223-2129 amy.swab@trelleborg.com www.trelleborg.com/healthcare

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Xponent Global www.xponentglobal.com

Zeus www.zeusinc.com

Intro



NSK NH-NS Series Linear Guides with K1 Lubrication Units

High positioning accuracy and high load capacities for medical equipment

Combining maximum precision with extremely high load ratings, the NH-NS series linear guides are the ideal solution for high-speed, long-life linear positioning for medical imaging equipment. Available with K1 lubrication units for smooth, reliable performance and longer maintenance-free service life.

Enabling Automation in Motion & Control.

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NSK

WWW.NSKAUTOMATION.COM

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BBRAUN SHARING EXPERTISE

B. Braun Medical Inc.

861 Marcon Blvd. Allentown, PA 18109 Phone: 484-240-8301 Fax: 610-691-1785 E-mail: info@bbraun.com us.bbraunoem.com

Company Description



Whether you are looking for a solution, medical device, fluid administration set, custom kit or individual components, we can provide the products and capabilities to meet your needs.

A division of one of the world's leading healthcare companies, our dedicated project management teams have the expertise to turn your ideas into reality. With in-house capabilities that include everything from design and assembly through packaging and sterilization, we are an OEM partner in the most complete sense of the word.



Intro

Cov

Target Markets

B. Braun's OEM Division services all areas of the medical device and pharmaceutical space.

Products/Services Offered

B. Braun's OEM Division delivers complete contract manufacturing capabilities focusing on fluid administration and admix-

ture products, kits, valves, catheters and interventional accessories. In-house services include product development, laboratory, design, prototyping, tooling, molding, validation, manufacturing, packaging, sterilization, quality



control, private labeling, regulatory guidance, and supply chain management services.



us.bbraunoem.com

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Carl Stahl Sava Industries

4 North Corporate Drive Riverdale, NJ 07457 Phone: 973-750-9911 Fax: 973-835-0877 E-mail: bruce.staubitz@savacable.com savacable.com

Company Description

Using tungsten, stainless steel, and other materials, Carl Stahl Sava Industries has prioritized three things for 50 years now: producing the mechanical cable assemblies that move the surgical robotics and medical devices world — and do so as small and as fast as our customers' markets demand.

Sava knows its customers operate within fiercely competitive markets. That's why Sava delivers on the world's surgical robotics, endoscopic, laparoscopic, and exoskeleton innovations, without compromises to speed or quality. From the first piece, to the millionth, Sava's world-class engineers, quality and production experts ensure there's never too great a production, manufacturing or deadline challenge to overcome.

Our 100,000 sq. ft. headquarters, located in Riverdale, New Jersey, is where Sava constructs medical cables and cable assemblies using tungsten, 304 and 316 stainless steel, nitinol and other materials. Sava offers on-site mechanical and design engineering, manufacturing, stranding, extruding, machining, stamping and tooling — a true turnkey experience for your surgical devices. Additionally, Sava offers annealing, vapor degreasing, ultrasonic cleaning, proof loading, prestressing, prototyping and many other production services.



Intro

Target Markets

Surgical Robotics, Endoscopy, Laparoscopy, Exoskeletons, and other medical device markets.

Products/Services Offered

Carl Stahl Sava Industries has built mechanical, medical cable assemblies used in surgical robots, heart surgery, as well as a variety of implantable, endoscopic and laparoscopic applications. Sava's medical cable is used in robotic surgery appliances, devices and instruments, along with exoskeletons, and a host of other smart, ergonomic wearable devices. Other products Sava produces are used in feeding tubes, gastronomy feeding systems, breast lesion localization systems, sterilization products, and even in veterinarian and medical equipment products, such as x-ray machines and dental equipment.





savacable.com/medical

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The Chemours Company

1007 Market Street Wilmington, DE 19899 Contact: www.chemours.com/en/contact www.chemours.com

Company Description

Chemours is a different kind of chemistry company, driven by our purpose to create a more colorful, capable, and cleaner world through the power of chemistry. Built upon a 200-yearold legacy and a world-class product portfolio, we bring everyday convenience to virtually everything people touch – in industries ranging from automotive, paints, and plastics to electronics, construction, medical, energy, and telecommunications. We bring solutions that are better, safer, more reliable, and more sustainable, through the power of chemistry.





Products/Services Offered

Chemours features a broad portfolio of advanced high-performance materials that solve the world's most challenging problems and make possible products that make life better every day at home, at work, and at play.

Our deep technology competency is driving innovation that meets our customers' and the markets' needs. Our commitment to responsible manufacturing means that our products are safe, reliable, and create a net positive impact on the world. And, our desire to partner with our customers, to understand their challenges, and to bring their ideas to life, makes us a preferred partner.

When an application requires precision, the highest degree of quality, a very low coefficient of friction, and the ability to withstand varied sterilization processes, designers and design engineers use Chemours advanced performance materials. Their chemical inertness, low reactivity, high and low-temperature resilience, and low electrical conductivity make them the right choice for medical and any high-stakes applications.



www.chemours.com

Target Markets

- 5G
- Automotive
- Electronics

Hydrogen Economy

• Energy

- IndustrialMedical
- Packaging

Intro

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- Caralagand
- Semiconductor

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Cretex Medical

311 Lowell Ave Elk River, MN 55330 Phone: 763-441-2121 E-mail: info@cretexmedical.com www.cretexmedical.com

Company Description

Cretex Medical is a family of companies that provides contract manufacturing and engineering services to medical device OEMs. We offer a complete range of end-to-end manufacturing capabilities, the latest technologies, and the talent to match any engineering or manufacturing challenge. You have a partner in us who can grow with your business, backed by a strong financial portfolio, and long-term perspective.





Target Markets

Intro

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- Orthopaedic
- Spine
- Sports Medicine
- Cardiology
- Vascular
- Neuromodulation
- Robotics
- Ablation Therapies
- Laparoscopy/Endoscopy
- Diagnostic Devices
- Diagnostic Devices

Products/Services Offered

Our companies, rms Company, rms Surgical, Meier Tool & Engineering, JunoPacific, Spectralytics and QTS provide a broad range of contract services including, but not limited to:

- Design for Manufacturability Molding (DFM) • Insert &
- Prototyping
- Machining
- Direct Metal Printing (DMP)
- Subassembly & Assembly
- Cleaning & Passivation
- Sterilization Case & Tray
 Design
- Press Brake Forming
- Silk Screening & Laser Marking
- Electropolishing & Anodization
- Micro- & Multishot Injection

Insert & Implantable Molding

- Supply Chain Management
- Engineering Validation
- Silicone Molding
- Laser Welding, Drilling &
- Ablation

 Laser Cutting
- In-house Tool Design
- Progressive Metal Stamping
- Buffing & Deburring
- Cleanroom Assembly, Packaging & Labeling
- Sterilization & Lab Testing Coordination





www.cretexmedical.com

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Eurofins Medical Device Testing

2425 New Holland Pike Lancaster, PA 17601 Phone: 717-656-2300 Fax: 717-656-3772 E-mail: medical-device@eurofins.com www.eurofins.com/medical-device

Company Description

With extensive knowledge of commercialization processes, regulatory requirements and scientific trends in the Industry, Eurofins Medical Device Testing offers regulatory compliance expertise and experienced GMP/GLP/ISO 17025 testing to ensure rapid turnaround times with the highest level of service and advanced technologies for your analytical chemical, microbiological, biocompatibility, electrical, mechanical, and package testing needs.

Our team has been assisting companies with developmental testing for over 40 years; and our global network of 720 laboratories in North America, Europe and Asia Pacific the highest level of instrument technology with a full scope of testing services.

Eurofins Medical Device Testing can develop and execute your test plans and navigate the regulatory pathway to market anywhere in the world. Our laboratories maintain quality systems compliant with cGMP, GLP, and ISO 17025, and conduct testing in accordance with ISO, ASTM, ANSI, AAMI standards, and custom test methodologies to meet the unique needs of our customers.





Intro

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Medical Device Testing

Target Markets

From implants and instruments, to single-use and combination products, as well as active electronic devices, Eurofins Medical Device Testing works with medical device companies to provide the optimal testing strategy for all types of class I, II, and III medical devices.

Products/Services Offered



- Analytical Chemistry Our chemistry laboratories are equipped with nearly 400 HPLCs and 100 GCs with more than 600 detectors.
- Microbiology We offer validations for terminal sterilization, reprocessing of reusable devices, and environmental monitoring to support your clean manufacturing facilities.
- Biocompatibility Testing

 Our global biocompatibility team includes a vast group of certified veterinarians, pathologists and toxicologists.



- Electrical & Mechanical Testing We perform testing of active medical devices for compliance to electrical requirements of ISO 60601.
- Package Testing We provide the full range of testing required to assess every aspect of product packaging, from sterile seal integrity through pallet-level transit testing, to label durability and UDI compliance.
- Stability Testing & Storage Our laboratories contain over 187,000 cubic feet of environmental chamber space for accelerated and real-time stability and aging studies.

www.eurofins.com/medical-device

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FUTEK Advanced Sensor Technology, Inc.

10 Thomas Irvine, CA 92618 Phone: 949-465-0900 E-mail: futek@futek.com www.futek.com

Company Description

We Make Innovation Possible

FUTEK specializes in creating inventive custom solutions for today's leading tech innovators. Our sensing and test-measurement instruments have been to Mars and below the sea, they save people's lives and even help read their minds.

We have a fearless approach to new projects because we have the expertise to back it up. Our unique combination of innovation, honesty, quality, hard work, and great people make it possible.



Target Markets

Intro

Cov

- Medical
- Robotics & Automation
- Aerospace

Products/Services Offered

FUTEK is helping progress the emerging technologies by providing advanced standard and custom load, force, torque, and pressure measurement solution along with the signal conditioning electronics. The application environment of these solutions can be standard to extremely demanding in terms of very low to very high temperature and pressure, as well as non-magnetic, corrosive, and autoclavability requirement.

We aim to provide the most precise sensor solution for your specific project. Part of the FUTEK experience is having a thorough support team available to our customers, including preapplication R&D consultations, as well as post-sales technical support.

If you have a test-measurement application or control feedback need, please don't hesitate to contact us for support. Again, we are in the business of creating solution.



www.futek.com

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Interpower®

P.O. Box 115, Oskaloosa, IA 52577-0115 Phone: 800-662-2290 Fax: 800-645-5360 E-mail: sales@interpower.com www.interpower.com

Company Description

Design...Easy...Fast. At Interpower we want to make it easy for you to design, build, and maintain products for North American and global markets — that's our mission. We strive to provide our customers with quality products that delight — FAST.

As the premier supplier of AC power system components, Interpower offers hospital-grade products that are designed for use in medical settings throughout the world. This includes plugs and sockets, IEC 60320 connectors, power cords and cord sets, power entry modules, and more.

Interpower offers just a 1-week U.S. manufacturing lead-time on non-stock Interpower products. We have same day shipments on in-stock products and no minimum order or dollar requirements. Interpower manufactured products are made in lowa, U.S.A. and are 100% tested.

Free technical support is available. Contact Customer Service about pricing and technical aspects, such as application and/or approvals, for help in obtaining required documentation, and to assist you in designing specialty products.

Order a specific quantity of an Interpower product (e.g. 1,000 cord sets), lock in your price, and have a 1-year time frame for



Target Markets

Medical

Products/Services Offered

Interpower offers North American and international hospitalgrade power system components, including plugs and sockets, power cords and cord sets, and power entry modules with the appropriate approvals. And if you need hospital-grade replacement cords, Interpower has the solution. Since we have no minimum order or dollar requirements, you can order just want you need — whether it's 1, 5, 100, or more.

Specialized labeling is available — mark your cords with labels that contain your specific information, such as identifying a certain location (e.g., Operating Room 1, ER 2, etc.). With your cords specially labeled, hopefully they will stay in the correct location. But if you need to replace one, you only have to order one! Order the exact number you need.

Value-added services, in addition to specialized labeling, include special packaging, barcode labeling, and made-to-order assemblies. Contact Customer Service for more information or for assistance with designing, building, and/or maintaining your hospital-grade products for worldwide markets.



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Keystone Electronics Corp.

55 South Denton Avenue New Hyde Park, NY 11040 Phone: 800-221-5510 Fax: 516-328-1080 E-mail: sales@keyelco.com www.keyelco.com

Company Description

For more than 75 years, Keystone Electronics Corp. has been manufacturing precision electronic interconnect components and hardware, supplying quality products worldwide. Whether you are developing Ultrasound Devices; Defibrillators; Implantable Pacemakers:



Portable Medical Monitors or Electro-surgical Instruments, Keystone products are engineered specifically for use by OEM Designers and Engineers who create and develop state-of-the-art electronic products such as medical devices, instruments and systems.

All Keystone facilities are fully integrated with 3D/CAD modeling and CAD/CAM to produce precision tools and production parts. Keystone is an ISO 9001:2015 certified company and complies with



RoHS and REACH directives. It is our policy to continuously improve our products to better satisfy the needs of our customers and to deliver quality products, every time and on time. All products are available through our global distribution network.

Target Markets

Medical, Automotive, Electronics, Aerospace, Defense, Solar, Appliance and Consumer Products..

Products/Services Offered

Keystone has a diverse manufacturing base of equipment including progressive dies, four-slide, wire forming, in-die tapping and high-speed blanking along with automated and semi-automatic assembly procedures including eyeleting, riveting, staking, swaging, crimping, and screw insertion. Services to support the thousands of standard products you will find in Product Design Guide M70 and Keystone's Dynamic Catalog on-line.

Intro





Product Categories include:

- Battery Clips, Contacts & Holders
- Fuse Clips & Holders
- Terminals & Test Points
- Spacers & Standoffs
- Panel & Computer Hardware
- Pins, Plugs, Jacks & Sockets
- PC Board Hardware
- Multi-Purpose Hardware

While our Dynamic Catalog of products meets most standard requirements, modifications as well as custom fabrications can be manufactured to meet your special needs. Keystone's Design and Engineering specialists and our responsive customer service team are all vital in-house resources which constitute our Custom Manufacturing Division's capabilities that are available to support standard and customer specific requirements. Request our new Product Design Guide M70.

www.keyelco.com

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MicroLumen, Inc.

One MicroLumen Way Oldsmar, FL 34677 USA Phone: 813-886-1200 Fax: 813-886-3262 E-mail: sales@microlumen.com www.microlumen.com

Company Description

MicroLumen has been a leading manufacturer of high performance medical products since 1987. Our shaft and tubing systems are used in a wide range of minimally invasive, critical OEM applications such as cardiovascular catheters, stent delivery systems, urological retrieval devices, and drug delivery.

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.

Products/Services Offered

High Performance Medical Tubing. MicroLumen manufactures custom tubing for critical applications & minimally invasive medical devices. Polyimide is a thermoset plastic and has excellent mechanical, thermal, and chemical properties. Typical applications include cardiovascular and urological catheters, stent deployment, and drug-delivery systems.

ID ranges = 0.10 mm to 2.11 mm with various wall profiles. Ultra-thin PTFE liners are available for reduced surface friction and can be delivered on a mandrel. Braid and coil reinforced designs are available for added flexibility, torque, and column strength. Pebax & Tecoflex jackets are available, as well as flexible tips, marker bands, value added sub-assembly, and custom laser machining. ISO 13485:2016 certified & USP Class VI.

www.microlumen.com

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Target Markets

Cardiovascular, Neurovascular, Urology, Peripheral Vascular, Electrophysiology

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NEW ENGLAND WIRE

NEW ENGLAND TUBING

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New England Wire Technologies

130 North Main Street Lisbon, NH 03585 Phone: 603-838-6624 Fax: 603-838-7090 E-mail: sales@newenglandwire.com www.newenglandwire.com







Intro

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New England Wire Technologies has manufactured technologically advanced wire and cable for 120 years. Our 400,000 square foot, state-of-the-art facility, houses manufacturing, R&D, quality/ testing, tooling/machine fabrication and office space. As an ISO9001 registered company, we specialize in technical cable solutions, short lead times, and unparalleled customer service.

Founded in 1898, New England Wire is advancing innovation in several industries including medical device and electronics, aerospace, defense, robotics/automation, power generation,

and alternative energy. Our capabilities include custom Litz wire, miniature, micro-miniature, single and multiconductor cables, lownoise, high temperature, coaxial and hybrid cables.

Through our creative design and development expertise, our engineering staff specializes in product development, concurrent engineering, design for manufacturability. Our on-site manufacturing processes include



wire drawing, plating, braiding, cabling, insulating, and extrusion services.

New England Tubing Technologies, incorporated in 2001, occupies a 14,000 square foot state-of-the-art controlled environment manufacturing facility. Partnering directly with the world's leading medical electronics and device manufacturers, we design custom braid or spiral reinforced tubing, lined catheter shafts, and hybrid tubing built to exacting specifications.

Working directly with clients in the medical electronics and device industries, as well as with other custom industrial and commercial projects, we design and manufacture custom braid or spiral reinforced tubing, lined catheter shafts, multi-durometer and multi-lumen tubing, hybrid tubing configurations, as well as medical braid. New England Tubing is advancing innovation in thin-wall, tight tolerance tubing, reinforcing, bonding layers of thermoplastic to fluoropolymer, and braiding.

Our team of design engineers work personally with each customer to develop innovative, one-of-a-kind tubing solutions and custom OEM components from their specifications or to meet unique performance characteristic requirements.

We help our customers dream beyond today's technology and achieve the impossible!

www.newenglandwire.com

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ORCHID

Orchid Orthopedic Solutions

1365 N. Cedar Street Mason, MI 48842 Phone: 517-694-2300 Fax: 517-694-2340 E-mail: sales@orchid-ortho.com www.orchid-ortho.com

Company Description

Orchid is a worldwide leader of orthopedic medical device outsourcing, providing contract design and manufacturing services. We are a strategic sourcing partner that can handle an entire project or provide services at a single point in the process. We have the broadest portfolio in the industry, ranging from design and development through finished goods manufacturing and packaging, and we improve our customers' supply chains through our supply chain solutions. By providing reliable results, developing new technologies and being the best total supply chain value in the industry, Orchid is your strategic sourcing partner for **orthopedic device** solutions worldwide.

Target Markets

Hip reconstruction

Spine

- Knee reconstruction
- Extremities

Trauma

Sports Medicine



Intro

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Services/Products Offered

Orchid is a global company offering a broad array of services and capabilities for orthopedic and medical device development and manufacturing:

- · Product design, development and prototyping
- Forging and investment casting
- Advanced machining technologies (metal and plastic)
- Complex instrument assemblies
- · Bone in-growth coatings and surface treatments
- Sterile packaging
- Quality & Regulatory services





www.orchid-ortho.com

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PBC Linear

PBC Linear

6402 E. Rockton Road Roscoe, IL 61073 Phone: 800-962-8979 E-mail: sales@pbclinear.com www.pbclinear.com

Company Description

The story of PBC Linear begins with an innovative and patented solution in bearing design, the Frelon[®]-lined plain bearing. That successful bearing design, which remains integral to their signature Simplicity[®] bearing, is part of an expanding family of linear motion products manufactured at their headquarters in Roscoe, Illinois USA. In addition to their extensive product line, PBC Linear employs dedicated engineers that work together with industry professionals to produce prototypes, pilots, and small production runs, helping to bring customer ideas to market.



Target Markets

PBC Linear supplies components and linear motion systems to a variety of applications in the medical industry, including devices, diagnostics, and lab automation.

Products/Services Offered

PBC Linear is a leader in the engineering, manufacturing, and assembly of a wide range of linear motion products, along with custom engineering services. Their signature Simplicity® line of plain bearings includes pillow blocks, flange mounts, precision sleeve, and die set bushings. In addition to their Simplicity plain bearings, they offer a core line of linear components that includes ball-type bearings, heavy duty cam roller sliders, roller pillow blocks, linear shafting, support rails and assemblies. Building off that strong foundation, they have further pushed their sophisticated family of products to include lead screws and motor lead screw assemblies, actuators, and cartesian robotics.

www.pbclinear.com

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Advertisement **Nepical OEM**

Teleflex Medical OEM

3750 Annapolis Lane North Plymouth, MN 55447 Phone: 800-474-0178 or 508-964-6021 Email: oeminfo@teleflex.com www.teleflexmedicaloem.com

Company Description

Vertically integrated capabilities. Deep expertise. Decades of experience. "Work With The ExpertsTM" at **Teleflex Medical OEM**. We are the product development and manufacturing partner that can hear what you are saying, understand your needs, and deliver innovative solutions. Partner with us for custom-engineered:

- Extrusion/Micro-diameter tubing
- Diagnostic and interventional catheters
- Balloons and balloon catheters
- Medical wires and conductors
- Sheath/dilator sets
- Sutures and performance fibers
- · Bioabsorbable sutures, yarns, and resins

Let's get to work on your next project.

Target Markets

Teleflex Medical OEM is a leader in medical device development and manufacturing. We partner with companies across the world, both large and small, to get their projects off the drawing board and into the market.





Products/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 and polymer experts, and skilled technicians that will seem like a natural extension of your own R&D department and operations staff. Our extensive capabilities include:

- Product concept development
- Engineering
- Design for manufacturability
- Material selection and formulation
- Prototyping, testing, and validation
- Custom tooling
- Production process development
- Manufacturing
- Finishing operations
- Assembly
- Packaging and labeling

EPIC Medtec® Centers: Device Development Reimagined Virtual, device development service available. This is device development accomplished in DAYS...not weeks, months or years.

- Get your device to market faster
- Develop a market-ready device
- Reduce technical risks
- Work with us on site or remotely

You have a great idea for a medical device. You know what this device needs to do. But your R&D resources are involved with other projects; or you may need insight or unbiased opinion of a device's design for manufacturability. Working together at one of our three EPIC Medtec[®] Centers, we can identify challenges and find innovative solutions.



www.teleflexmedicaloem.com

Free Info at http://info.hotims.com/79414-818

www.medicaldesignbriefs.com

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2021 Resource Guide

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The Lee Company

2 Pettipaug Road, P.O. Box 424 Westbrook, CT 06498 Phone: 860-399-6281 Fax: 860-399-2270 E-mail: inquiry@theleeco.com www.theleeco.com

Company Description

Since its founding in 1948, The Lee Company has pioneered the development of miniature fluid control components for automated fluid handling in medical and scientific instrumentation, analytical/clinical chemistry, and medical disposable applications. In response to the ever increasing demands of the medical and scientific industries, The Lee Company continues to redefine miniature fluidics by integrating new and more advanced technology into smaller packages.

The Lee Company employs more than 1000 people at its Technical Centers in Westbrook and Essex, Connecticut, where all engineering and manufacturing is performed. Lee Company sales offices, staffed by degreed sales engineers, are located throughout the United States and Europe, and the company's distribution network spans the entire globe.



Target Markets

In vitro diagnostics, scientific instrumentation, drug discovery, and medical equipment such as oxygen delivery, patient monitoring, dialysis, and compression therapy

Intro

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Products/Services Offered

Lee's unique capabilities in miniaturization and engineering expertise keep the company at the forefront of fluid flow technology, and enable it to work effectively with customers to solve difficult fluid control problems.

Products include high quality miniature solenoid valves (conventional and chemically inert models), high speed microdispense valves, atomizing and dispense nozzles, fixed and variable volume pumps, integrated fluidic manifolds, inert tubing and fluid control components, and custom engineered designs.





www.theleeco.com

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Trelleborg Healthcare & Medical

WHO WE ARE

At Trelleborg Healthcare & Medical, we help medical device companies negotiate the development process from concept to commercialization. By forming lasting partnerships with customers, we help to design, develop, manufacture and bring to market innovative engineered solutions for demanding medical device, biotech and pharmaceutical applications.

Customers rely on Trelleborg to accelerate time to market through the use of advanced engineering processes, prototyping and validation, rapid scale-up, adherence to the strictest quality standards, and more. Once in market, our robust processes ensure a reliable, high-quality supply.

VITAL STATISTICS

Trelleborg Healthcare & Medical is a part of Trelleborg Sealing Solutions, which is a business area of Trelleborg Group.

- Employees: 6,899
- Facilities: 60 Customer Solution Centers, 32 Manufacturing Sites, 9 R&D Centers, 5 Logistics Centers

PRODUCTS & CAPABILITIES

Regardless of the project, our wealth of knowledge is at your disposal. Our capabilities include:

- Silicone & Thermoplastic Molding and Over-Molding
- Drug-Eluting Solutions
- Silicone Dipping & Coating
- Multicomponent & 2K LSR Molding
- Silicone Extrusion
- Micro-Molding
- Medical Device Assembly
- · Process Automation
- Silicone Sheeting & Film
- O-Rings and Seals
- Products are available in a wide range of materials, including EPDM, FKM, PTFE and Polyurethane

Intro

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WWW.TRELLEBORG.COM/HEALTHCARE



MAJOR MARKETS

Trelleborg Healthcare & Medical has a global footprint, servicing a range of medical device, biotech and pharmaceutical sectors, including:

- Cardiology/Cardiac Surgery
- Peripheral Vascular
- Endoscopy
- Laparoscopy
- Neurostimulation
- Cardiac Rhythm Management
- · Single-use processing solutions for pharma/biopharma
- Diabetes
- Drug Delivery
- Urology
- Neurology
- Neurovascular
- Orthopedics

CONTACT US

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Trelleborg Healthcare & Medical 1550 Utica Avenue South, Suite 555 St. Louis Park, MN 55416 Tel: +1 763-972-9206 E-mail: tssusa@trelleborg.com

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TRELLEBORG HEALTHCARE & MEDICAL



Your Partner for Life-Changing Technologies

Partner with Trelleborg Healthcare & Medical to develop, manufacture and bring to market innovative engineered solutions for demanding medical devices.

With 30 plus years of experience in medical device manufacturing, Trelleborg delivers:

- · Broad material and manufacturing capabilities
- Engineering expertise to solve complex challenges

Intro

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- Prototype to serial production
- Accelerated time to market
- High quality and reliable supply

CLICK HERE TO GET HELP WITH YOUR NEXT PROJECT, PRE-REGISTER FOR WHITEPAPERS, AND ACCESS WEBINAR RECORDINGS AND REGISTRATIONS.



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WORLD LEADERS IN MICRO-MOLD® MANUFACTURING SOLUTIONS

Accumold

1711 SE Oralabor Rd. Ankeny, IA 50021 Phone: 515-964-5741 E-mail: micromolding@accu-mold.com www.accu-mold.com

Company Description

Accumold[®] has been an expert in micro molding for more than three decades. Our 130,000 sq ft facility is home to our inhouse tooling and production teams. The company currently operates 155+ molding machines in several Class-7 and 8 clean room spaces. Accumold is ISO 13485, 9001 and 14001 certified.



Target Markets

- Medical Device
- Micro Optics
- Micro Electronics
- Other Emerging Technologies

Products/Services Offered

Accumold[®] is a high-tech manufacturer of precision micro, small and lead frame injection molded plastic components. Utilizing processes developed from Accumold's Micro-Mold[®] technology, the company designs, builds and produces unique molds and parts efficiently for a wide variety of applications.



Molded components range in size from 5 cm, with micro features, to parts that are less than 1 mm in size. These complex parts often include tight tolerances measuring only a few microns. Processes include: insert molding, clean room molding, 2-shot molding, and custom automated manufacturing cells. Common materials include: PEEK, Ultem, LCP, and most engineered thermoplastics.

www.accu-mold.com

Free Info at http://info.hotims.com/79414-822

YOUR MICRO-MOLD® TOOLING & PRODUCTION PARTNERS







MICRO ELECTRONICS MEDICAL DEVICE MICRO OPTICS EMERGING MARKETS MICRO-MOLD[®] SMALL MOLD LEAD FRAME & INSERT MOLDING

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TOGETHER WE CAN MAKE THE WORLD A **SMALLER** PLACE

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AMADA WELD TECH INC.

1820 South Myrtle Ave. Monrovia, CA 91016 Phone: 626-303-5676 E-mail: info@amadaweldtech.com www.amadaweldtech.com

Company Description

The challenges of today's medical device manufacturing applications are pushing the need for more sophisticated manufacturing technologies, and AMADA WELD TECH is leading the way with our compre-



hensive range of resistance and laser welding, laser marking, and laser cutting and micromachining equipment and systems. An ISO:9001-2015 certified company.

Target Markets

- Medical
- Automotive
- Aerospace
- Battery
- Electronic Components

Products/Services Offered

Based in Southern California, AMADA WELD TECH is a leading manufacturer of equipment and systems for resistance welding, laser welding, laser marking, laser cutting, laser micromachining, hermetic sealing, and hot bar bonding. Since 1948, AMADA WELD



TECH AMERICA has worked to achieve one goal: to solve our customer's manufacturing challenges. Knowing there is no one solution that fits all, we strive to provide our customers with innovative and reliable manufacturing technology solutions so that we may be their single source provider.

The company also offers free feasibility studies, training, and applications development support.

www.amadaweldtech.com

Free Info at http://info.hotims.com/79414-824

Laser Solutions for Medical Device Manufacturing Enhance Your Productivity

The challenges of today's medical device manufacturing applications – smaller and smaller devices with ever-increasing reliability and traceability requirements – are pushing the need for more sophisticated manufacturing technologies and AMADA WELD TECH, in consult with medical device industry expert customers like you, is leading the way with our comprehensive range of laser technologies.

- Equipment & systems for cutting, marking, micromachining and welding
- Fiber, UV, picosecond and femtosecond laser sources
- Cut fine features in tubes and stent no post-processing!

Intro

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· Black laser marking for UDI







www.amadaweldtech.com Speak directly with our advanced engineering experts (626) 303-5676

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Arthur G. Russell Company

750 Clark Avenue Bristol, CT 06010 Phone: 860-583-4109 Fax: 860-583-0686 E-mail: david.aquilino@arthurgrussell.com www.arthurgrussell.com

Company Description

The Arthur G. Russell Company, Inc. designs and develops innovative automatic assembly systems for the medical device industry that require the highest level of quality for products such as syringes, blood collection tubes, IV catheters, dosage dispensers, and other products that must satisfy stringent FDA requirements.

Target Markets

Medical Devices, Pharmaceutical, High-Volume Consumer Products, High-Volume Disposable Goods, Packaging

Intro

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Products/Services Offered



Knowing that quality and dependability are as important on the assembly line as in the final product — that's why we work with you from the start. In addition to custom designing a system that will exceed your expectations and be flexible enough to grow with you as your product demands change, we can provide "proof-of-principle," which helps develop key processes for automation.

AGR offers the best approach for the application. Complete systems include adhesive application and curing, ultrasonic and spin welding, high-speed inspection, labeling, and filling, all while providing the integration required for a turnkey system.

Providing more than just assembly equipment, we provide you with the edge you need to stay competitive in your market.

www.arthurgrussell.com

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Free Info at http://info.hotims.com/79414-827

ToC



Asahi Intecc USA, Inc.

22 Executive Park, Suite 110 Irvine, CA 92614 Phone: 949-756-8252 Fax: 949-756-8165 E-mail: davidz@asahi-intecc-us.com www.asahi-inteccusa.com

Company Description

Asahi Intecc Co., Ltd. ISO 9001/13485certified manufacturer of stainless, tungsten, nitinol components, ACTONE cable tube, TORQUE HYPO-TUBES, drivecables, torque coils, round or flat wire coils, single or multi lumen or

variable flexibility polymer extrusions in PU, PEBAX, PFA, PTFE or coatings inside/outside hollow stainless shafts or braids.

Intro

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Target Markets

Component, subassembly, or full assembly of catheters, delivery systems, access systems in cardiovascular, peripheral, neuro, abdominal, endoscopic, orthopedic, ENT specialties. Non-medical inquiries welcome.

Products/Services Offered

- Cable Tube OD 0.008 ~ 0.1539"
- Flat Wire Torque Coils and
- Flexible Shafts to 6mm • PTFE SPC MANDRELS from
- 0.45mm to 2.30mm. PTFE wall thickness (one side can range from 0.008mm to 0.012mm)



- OEM/ODM Guidewire: Guidewire, Diagnostic catheter, PTCA guiding catheter, PTCA balloon catheter, etc
- Stainless Steel Cables and Assemblies: 0.002" to 3mm ~ 4mm.
- Miniature Coil: round wire OD from .0039", flat wire OD from .0055"
- Torque Transmission Wire: 1x3, 1x7, 1x19 OD from .012" to 0.078"
- Torque Transmission Coil: OD from 0.012" to 0.1563", 2-3 layers rotational fidelity/motor, NURD
- Variable Durometer Tubes

www.asahi-inteccusa.com

Free Info at http://info.hotims.com/79414-828



Best in Class, High Performing Components for Your Medical Devices Drawing from our IN-DEPTH EXPERIENCE in the medical device field, our in-house wiredrawing, wire-forming, coating, torgue and assembly technologies provide a BROAD RANGE of OPTIONS for your device. Thinnest wall 0.0003" PTFE Liner TORQUE COIL Excellent lubricity and chemical resistance ONE Reinforced with SS304, Tungsten, 66PA, PEEK and more for torque and kink resistance Braid-reinforced Shaft Variable **Durometer Tube** Provides a linear smooth transition between a delicately soft tip to a hard proximal end

ASAHI INTECC USA, Inc. | 22 Executive Park, Suite 110 | Irvine, CA 92614 | phone: (949) 756-8252 ext. 302 | www.asahi-inteccusa.com

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Cadence, Inc.

9 Technology Drive Staunton, VA 24401 Phone: 540-248-2200 Fax: 540-248-4400 E-mail: sales@cadenceinc.com www.cadenceinc.com

Company Description

Cadence, Inc. is a full-service contract manufacturing partner for medical device and diagnostics companies worldwide. Our services range from initial design through manufacturing and full supply chain management of specialty metal components, complex sub-assemblies, and finished devices.



Target Markets

Medical and Life Science

Products/Services Offered

From concept through commercialization, Cadence can assist our customers every step of the way — product design, design for

manufacturing, rapid prototyping, complete supply chain management, and production of your finished medical device and life science products. We offer cleanroom manufacturing and assembly, as well as packag-



ing and sterilization services at our Product Realization Center™ located just outside of Pittsburgh, PA. We are vertically integrated with extensive in-house metals and plastics manufacturing expertise that includes machining, metal stamping, sharpening/grinding, tube fabrication, precision laser processing technologies, plastic injection molding, insert molding, and much more!

www.cadenceinc.com

Free Info at http://info.hotims.com/79414-830

CORRECT CADENCE

Intro

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A correct cadence for drug delivery devices.

Finished devices

Point-of-care testing

Sharps expertise - needles

Precision inserters for devices

Microstamping & multislide technologies



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Cotronics Corporation

131 47th St. Brooklyn, NY 11232 Phone: 718-788-5533 Fax: 718-788-5538 E-mail: sales@cotronics.com www.cotronics.com

Company Description

For almost 50 years, Cotronics' highly skilled staff of researchers, engineers, chemists, technicians and sales assistants have provided the aerospace, automotive, nuclear, semi-conductor, instrumentation, appliance, chemical processing industries a reliable source of superior quality, high temperature products specially formulated to meet the demanding specifications that today's technology requires.

Cotronics is ISO 9001:2015 certified and provides the utmost in excellence. Call 718-788-5533 or email: sales@cotronics. com for Cotronics' application engineers for specific technical information, adhesive suggestions and custom solutions; Cotronics' customer service department for price quotes and placing orders for high temperature stock materials.



Products/Services Offered

High temperature adhesives and materials for Electrical, Structural and Industrial applications for use to 4000°F.

We offer high temperature solutions to satisfy the most difficult electrical, structural, industrial and medical applications with our proven Cotronics brand name products:



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Duralco™ (High Temperature Epoxies), **Resbond™** (High Temperature Ceramic Adhesives), **Rescor™** (Machinable and Castable Ceramics), **Thermeez™** (Insulation Products), **Durabond™** (Maintenance and Repair Products) and **High Purity Materials**. You have challenging applications... we have solutions.

www.cotronics.com

Free Info at http://info.hotims.com/79414-832

HIGH TEMPERATURE MATERIALS FOR ELECTRICAL | STRUCTURAL | INDUSTRIAL APPLICATIONS TO 4000°F

Flexible Conductive Silver Based Epoxy

DuralcoTM 125 thermally conductive electrical epoxy bonds to most metals, ceramics and plastics to form a stress-free adhesive bond. Continuous service up to 450°F.

High Temperature Low Expansion Adhesive

Resbond[™] 905 Quartz is formulated for bonding low expansion and thermal shock resistant ceramics. Ideal for electronic and metallurgical applications to 2500°F.

Thermally Conductive Adhesives

Duralco[™] 132 thermally conductive adhesives combine Cotronics' unique, high temperature resins with highly conductive fillers to form thermally conductive, adhesive bonds with continuous service up to 500°F.

High Expansion Adhesive

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Thermeez[™] 7030 bonds and protects to 1800°F. Apply to ceramics, ceramic cloths, door and tadpole gaskets and metals. Excellent adhesion to steel, stainless, aluminum, lead and ceramics.

High Purity, Alumina Adhesive Protects Critical Electronic Components

ResbondTM 989 offers continuous protection to 3000°F. Apply directly to metals, glass, ceramics, graphite and silicon carbide. Provides high bond strength and excellent electrical, moisture, chemical and solvent resistance for bonding and sealing.



131 47th Street Brooklyn, NY 11232 www.cotronics.com sales@cotronics.com Tel: 718.788.5533 Fax: 718.788.5538

QUALITY PRODUCTS | CUSTOM FORMULATIONS | ISO 9001:2015 CERTIFIED

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Da/Pro Rubber, Inc. 601 N Poplar Ave. Broken Arrow, OK 74012 Phone: 918-258-9386 E-mail: sales@daprorubber.com www.daprorubber.com

Company Description

Since 1960, Da/Pro Rubber, Inc. has been a family-owned leading manufacturer of precision molded rubber, plastic, and TPE products. Our rubber and plastic manufactur-



ing facilities in Oklahoma, California, Massachusetts, Singapore, and Malaysia. Da/Pro offers liquid injection molding (LIM), compression molding, injection molding, transfer molding services, and is equipped with a class 10,000 clean room.

Intro

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Target Markets

- Medical
 Aerospace
- Computer/Industrial
- Oil & Gas

Products/Services Offered

Da/Pro offers rubber compression molding, liquid injection molding, transfer molding, overmolding/insert molding, custom compounding, sub-assembly, engineering design assistance, and conductive rub-



ber. For plastics, Da/Pro offers TPE molding, engineering plastic injection molding, commodity plastic injection molding, overmolding/insert molding, sub-assembly, hot stamping, and engineering design assistance.

www.daprorubber.com

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Free Info at http://info.hotims.com/79414-834



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DDL, Inc.

10200 Valley View Rd., Suite 101 Eden Prairie, MN 55344 Phone: 952-941-9226 Fax: 952-941-9318 E-mail: ddlinfo@ddltesting.com www.ddltesting.com

Company Description

DDL Inc. is an ISO/ IEC 17025 accredited testing lab that provides package, medical, drug device, and closed container integrity testing services. The company's team of engineers and technical and quality experts is devoted to



helping customers worldwide succeed by taking an independent, involved and informed approach to ensuring regulatory compliance.

Target Markets

Medical Device, Pharmaceutical and Consumer Goods

Products/Services Offered

Package Testing

DDL's package testing services evaluate the strength and integrity of packaging systems before and after simulating the anticipated distribution and storage conditions that the systems may undergo.



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Medical Device Testing

DDL specializes in testing medical devices such as luer fittings, syringes, needles, catheters, guidewires, surgical sutures, cannulae, and tracheal tubes.

Container Closure Integrity Testing

Package integrity verification requires careful examination of package leakage given the specific product and its life cycle. DDL's CCI services include both the most recent deterministic capabilities, as well as probabilistic methods, as outlined in USP <1207>.

www.ddltesting.com

Free Info at http://info.hotims.com/79414-836



DDL is an ISO 17025 accredited laboratory

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MEDICAL DEVICE + PHARMA

A Reputation for Extraordinary Packaging, Product and Materials Testing.

DDL has 30 years of experience navigating complex testing standards and regulations for medical device and pharma products. Our reliable quality, responsive attention, and onschedule completion for packaging, product and materials testing secure confidence in performance and safety while achieving regulatory compliance.

TESTING EXPERTISE

Packaging and Materials

Testing experts. Service specialists.

- Medical Devices
- Combination Products

NOW OFFERING CCIT TESTING

Partner with us and gain a reliable testing expert at your side! Visit us at **DDLtesting.com** or call us at **1-800-229-4235**

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Simplify Design • Trim Weight Improve Performance Reduce Costs

(909) 559-1300 DIVERSEOPTICS.COM



Diverse Optics Inc

10339 Dorset Street Rancho Cucamonga, CA 91730 Phone: 909-593-9330 E-mail: info@diverseoptics.com https://diverseoptics.com

Company Description



Diverse Optics is the leader in diamond turning and precision injection molding of custom polymer optics. For over 25 years, we've manufactured the most challenging components and assemblies for leading defense, medical, and commercial applications. Whether it's prototypes or production molded optics, we'll show you how polymer optics are perfected.

Target Markets

Medical, Defense, Commercial

Products/Services Offered

We know that your optics are as unique as you are. For over 25 years, Diverse Optics has manufactured the most challenging components and assemblies for leading defense, medical, and commercial applications. We use our knowledge of injection molding and diamond turning processes to help you reduce cost, simpli-

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fy design, and improve the performance of your optics. Whether its prototypes or thousands of molded optics, trust us with everything from spheres, aspheres, domes, plano/convex, bi-convex, free-forms, diffractives, Fresnels, prisms, cylinders, collimators, combiners, TIR's, micro-optics, mirrors, parabolics, off-axis, ellipses, cylinders, and more! Let us show you how polymer optics are perfected.

https://diverseoptics.com

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HALKEY | ROBERTS®

Halkey-Roberts Corporation

2700 Halkey-Roberts Place North St. Petersburg, FL 33716 Phone: 727-471-4200 Fax: 727-578-0450 E-mail: sales@halkeyroberts.com www.halkeyroberts.com

Company Description

Halkey-Roberts manufactures plastic components and subassemblies used in disposable medical devices, including flow devices, medical valves, needle-free valves, catheter and tracheal tube



valves, tubing clamps, closures, and hand pumps. Halkey-Roberts is ISO 9001 and ISO 13485 certified and manufactures to the standards of GMP.

Target Markets

Halkey-Roberts supplies medical OEMs and contract manufacturers worldwide. Our components are used in critical applications such as cardiovascular, urology, oncology, anesthesia, respiratory, IV/drug delivery, and surgical devices. Our products are also used in a number of biotech applications.

Products/Services Offered

Halkey-Roberts is a global leader in the design and manufacture of valves for medical device companies whose products require precise delivery of fluids and gases. We supply global medical device companies with off the shelf and custom solutions for their fluid and gas delivery applications. Since 1941, we have been offering innovative solutions like our new Male Luer Valves. Our vertically integrated facility in St. Petersburg, Florida, allows us to control the entire development and manufacturing process of our products: from design, tooling, molding, high speed automation, regulatory support, and product release. We offer extensive capabilities to customize our products to your specific application.

www.halkeyroberts.com

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INTERNATIONAL POLYMER ENGINEERING

International Polymer Engineering (IPE)

2445 West Medtronic Way Tempe, AZ 85281 Phone: 877-410-3265; 480-967-3265 Fax: 480-929-9799 E-mail: customerservice@ipeweb.com www.ipeweb.com

Company Description

International Polymer Engineering (IPE) is ISO one of the only companies worldwide engineering complete custom FluoroFlex[™] ePTFE solutions. We also provide advanced thermoplastic extrusions for your most demanding applica-



tions. On top of state-of-the-art extrusions, we offer design and development, material testing and analysis, bonding, bending, flaring, cleanroom processing, and more.

Target Markets

- Plastics
- Medical
- Automotive Aftermarket
- Aerospace Manufacturing
- 3D Printing

Products/Services Offered

IPF manufactures custom profile extrusions made from Fluroflex[™] ePTFE and a variety of melt thermoplastic materials. We use the latest techniques to reduce costs and shorten manufacturing lead times. We manu-



facture a variety of components such as tubing, rods, sheets, 3D printer filament, biopsy channel components, light guide cover components, and CO₂ sensor cover components. We can also customize your products with laser markings and custom colorations. When looking for a flexible, lubricious, chemically inert, hydrophobic plastic for critical applications, few can meet or exceed the flexural properties needed in barrier, instrument delivery, and bending sections of instruments like Fluoroflex™.

www.ipeweb.com

Free Info at http://info.hotims.com/79414-842



Thermoplastic Extrusions & Complete Custom ePTFE Solutions For Your Most Demanding Medical Applications

Curved, formed, or extruded... we help solve your demanding medical application challenges & get your products to market faster.

- Design & engineering solutions to your specific requirements
- 100% virgin, medical-grade, materials Extreme temperature stability
- Custom formulas & colors

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ENGINEERING

INTERNATIONAL 877.410.3265

408.967.3265

IPEWEB.COM

- Sheets, tubes, rods, & profile extrusions
 Clean room manufacturing
- Extreme chemical & degenerative resistance

How can we help make your next project a success? **TOLL FREE**

ISO 13485:2016 = quality, guaranteed



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Kahle Automation

89 Headquarters Plaza N., 3rd floor Morristown, NJ 07960 Phone: 973-993-1850 E-mail: Kahle@KahleAutomation.com www.KahleAutomation.com

Company Description

Celebrating our 100th anniversary, Kahle is a worldwide supplier of automation and process equipment for the Medical Device and Pharmaceutical industries.



Target Markets

Medical Device and Life Science

Products/Services Offered

Kahle designs and builds machines for the assembly and inspection of all types of medical devices and drug delivery products. Kahle's services include custom equipment design, system integration, parts feeding, material and package



handling, and equipment validation, along with the documentation to meet the unique requirements of all types of manufacturing applications.

Kahle's staff is dedicated to designing solutions for only one industry, allowing us the opportunity to develop the expertise required to build turnkey production systems with a complete understanding of the challenges that face the Medical Manufacturing community.

www.KahleAutomation.com

Free Info at http://info.hotims.com/79414-844





Marposs

3300 Cross Creek Parkway Auburn Hills, MI 48326 Phone: 248-370-0404 Fax: 248-370-0991 E-mail: marposs@us.marposs.com www.marposs.com

Company Description

Marposs, founded in 1964, is a world leader in measurement, inspection and test technologies focused on improving



Marposs, a worldwide leading supplier of measurement solutions, offers tailormade leak and flow testing systems that can check everything from catheters, filters, needles, nebulizers and syringes to ventilation circuits.

Marposs offers an assortment of measuring equipment with cutting-edge technologies -- optical, laser or touch -- to aid in the production of your most vital medical devices and biomedical parts.

To see how you can improve your quality and productivity, while reducing manufacturing costs, contact us.



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quality and productivity while reducing manufacturing costs. It offers inprocess gauging and control to postprocess measurement and inspection on the shop floor for 100% inspection of medical components.

Target Markets

Materials & Manufacturing

Design & Testing

Products/Services Offered



Contact & non-Contact systems measure orthopedic joints, dental implants, fasteners, etc. Tecna leak and flow test systems verify pharma bottles, spray cans, blood bags, catheters, needles, nebulizers and syringes to ventilation circuits and dialysis equipment. It is also a patented solvent dispenser.

Aeroel laser systems measure outside diameters of tubes, rods and cables or dimensions of profiles featuring rectangular sections of transparent and opaque materials, such as medical tubing.

Stil optical instrumentation performs optical inspection for distance, dimension, thickness, multi-layers, flatness, shape, roughness and movement of transparent or opaque, polished or rough materials – be it metal, glass, ceramic, semiconductor, or plastic.

www.marposs.com

Free Info at http://info.hotims.com/79414-846

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Intro



mdi Consultants, Inc.

55 Northern Boulevard, Suite 200 Great Neck, NY 11021 Phone: 516-482-9001 Fax: 516-482-0186 E-Mail: info@mdiconsultants.com www.mdiconsultants.com

Company Description

mdi Consultants is a leader in providing consulting services to the healthcare industry worldwide. Our staff has over 200 years of industry, government, and consulting experience, which we use to assist medical device, pharmaceutical, biotechnology, and food companies achieve compliance with U.S., European, and Canadian regulations.





Dr. Anand Akerkar

Target Markets

Medical Device Companies, Pharmaceutical Companies, Biotechnology Companies, Food Companies, Tobacco Companies.

Products/Services Offered

mdi Consultants offers a full range of services focused on assisting companies across the globe achieve regulatory and standard compliance with U.S., European, and Canadian agencies and organizations. Our services include FDA Compliance services (Regulatory Strategy Development, Clinical Trial Development/Management, cGMP compliance, on-site audits, validation (process, software, and sterilization) and 510(k)/PMA/ANDA/NDA submission services), FDA troubleshooting services, 483 & Warning Letter Response services, MDSAP Assistance, Quality System Compliance services,

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CE Mark consulting, ISO Compliance (ISO 9000:2000, ISO 14000, ISO 13485:2016), Regulatory Consulting, U.S. Agent Services, Authorized Agent Services, Import Agent Services, Electronic Drug Listing and Registration, and Health Canada Compliance.

www.mdiconsultants.com

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mdi Consultants, Inc. Internationally Recognized Consulting Company to the MEDICAL DEVICE/IVD/PHARMACEUTICAL INDUSTRIES FDA Regulatory Specialists Servicing Companies Worldwide Visit our website: **Celebrating 40** www.mdiconsultants.com years in business! Services Include: 510(k)/PMA/ANDA/NDA/DMF Planning - Preparation and Submission Customized Quality Systems for DDA QSR/cGMP/ISO Compliance Design, Control, Review, and FMEA Assistance MDSAP Preparation and Inspection Assistance (NEW!) Strategic Planning and Responses to 483 and Warning Letters Mock Audits for GMP Compliance by Former FDA Officials FDA Troubleshooting for Current FDA Inspections E-drug, device listing, and registration with FDA "CE" Mark Planning and Assistance ٠ Clinical Trials – IDE Preparation, Monitoring, and IRB Review Customized In-House QSR/cGMP and ISO Training Programs UNIQUE DEVICE IDENTIFICATION (UDI) Assistance (NEW!!) US Agent and Official Correspondent (For Foreign Companies) Interactive Online FDA Training Courses in: Understanding QSR Intro to Design Control Understanding CAPA CMDCAS Compliance Assistance Providing Professional Service to the Industry Since 1978 Main Office: 55 Northern Blvd., Great Neck, NY 11021 Tel.: 516-482-9001 Fax: 516-482-0186 Email: info@mdiconsultants.com Website: www.mdiconsultants.com Other Office Locations: CA, NC, MA, China, Germany, Israel, Turkey, & India

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Medical



Medical & Biotechnology Manufacturing

Medbio, Inc.

5346 36th St., SE Grand Rapids, MI 49506 Phone: 616-245-0214 Fax: 616-245-0244 E-mail: Info@medbioinc.com www.medbioinc.com

Company Description

Located in Michigan, Medbio is an ISO 13485:2016-certified contract manufacturer offering innovative manufacturing solutions for the medical device and biotech industries. We specialize in precision injec-



tion molding, assembly, packaging, prototyping, and design support. Building strategic partnerships and conducting business with integrity, allows Medbio and our customers to achieve growth, success, and profitability.

Intro

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Target Markets

Products/Services Offered

The Medbio management team averages over 25 years of experience in the medical device industry. We have experience with most medical-grade thermoplastics, and implantable-grade resins. We currently mold products for the major OEMs in Orthopedics, Cardio-



vascular, Ophthalmology, Neurological Surgery, General Surgery, Wound Care, Biotech (Diagnostics & cell growth), and Dental. From components to full assemblies, Medbio will tailor our manufacturing services to meet your needs, taking your medical device from design to completion. We have the knowledge, passion, and experience to solve your most difficult manufacturing challenges.

www.medbioinc.com

Free Info at http://info.hotims.com/79414-850



www.medbioinc.com

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Medical Extrusion Technologies, Inc.

26608 Pierce Circle Murrieta, CA 92562 Phone: 800-618-4346 Fax: 951-698-4346 E-mail: info@medicalextrusion.com www.medicalextrusion.com

Company Description

Medical Extrusion Technologies, Inc. manufactures custom tubing extrusions from almost all thermoplastic resins. Our expertise is in smaller, multi-lumen configurations and single lumens to 1.0". We have process capa-



bilities for most thermoplastics including all polyethylenes, polypropylenes, EVA, metallocenes, PVC, thermoplastic elas-

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tomers, polyurethane, nylon, Pebax, ABS, butyrate, PET, polycarbonate, polysulfone, PEEK, PES, FEP, ETFE, PVD, FEP, and FEP heat shrink tubing, as well as multi-layer tubing. We produce close tolerance profiles in single and multi-lumen geometries, in either engineering study lot sizes or for production volumes.

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

- Desian
- Development



www.medicalextrusion.com

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MICRO

140 Belmont Drive Somerset, NJ 08873 Phone: 732-302-0800 E-mail: sales@micro-co.com www.micro-co.com

Company Description

Established in 1945, MICRO is a contract manufacturer that draws on 75 years of manufacturing expertise to deliver the





MEDICAL DEVICE MANUFACTURING FROM CONCEPT TO MARKET

We are vertically integrated to provide you with all the services and capabilities essential for complete medical device contract manufacturing.

HELPING OUR CUSTOMERS SAVE LIVES.



Contact us today to discuss your next project: sales@micro-co.com

FDA Registered • ISO 13485 • ISO 9001 • ISO 14001 MICRO 140 Belmont Drive, Somerset, NJ 08873 USA • Tel: 732 302 0800 • www.micro-co.com

Intro

highest quality products to customers in the medical device marketplace. A truly global company, with three locations, we manufacture and distribute our products to customers around the world.

Target Markets

- General
- Surgery • Orthopedics
- Cardiology
- Urology



- Women's Health
- Diabetes Management

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.

Our modern facility is cGMP-QSR compliant and ISO-9001, ISO-13485, and ISO-14001 certified. Staffed by highly trained individuals, we maintain an ISO Class 8 environmentally controlled cleanroom for surgical instrument assembly.

We also produce a wide variety of scissors, stapling and biopsy devices, as well as laparoscopic and arthroscopic minimally invasive surgical instruments. MICRO is the world's largest manufacturer of titanium and stainless steel ligation clips — class-critical implant devices shipped directly to inventory.



www.micro-co.com

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Microspec Corporation

327 Jaffrey Road Peterborough, NH 03458 Phone: 603-924-4300 Fax: 603-924-4310 E-mail: info@microspecorporation.com www.microspecorporation.com

Company Description

For 30 years, medical device companies the world over have turned to Microspec for medical tubing that challenges the limits of extrusion technology. From concept to commercializa-



tion, Microspec has built a global reputation for extruding some of the smallest, most complex, and tightest toleranced medical parts in the industry.

Microspec's mission is to supply innovative extrusion technology to the technologically advancing and changing medical device market and to deliver high quality parts on time.

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Products/Services Offered

Technical Services:

- Skillful proprietary processing
- In-house tool design and fabrication
- Exceptional customer service
- Product validation services
- Raw material and product testing
- Annealing services

Most Thermoplastic Elastomers Extruded:

- Polyurethanes
- NylonsHigh Heat Polymers: PEEK,
- Polysulfone and PEI

Extrusion Capabilities:

- New Concepts
- Single-lumen Extrusions
- Multi-lumen Tubing
- Bump Tubing
- Co- and Tri-Extrusions
- Multi-Durometer Extrusions
- Multi-layered Extrusions

- Fluoropolymers: FEP, EFEP, and PFA
- Bioabsorbable resins
- Custom formulations
- Micro-Extrusions
- Over-Extrusions
- Fully-Encapsulated Stripes
- Coated Wire
- Profile Extrusions
- Balloon Tubing
- Ribbon Extrusions

www.microspecorporation.com

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Nelson Laboratories, LLC

6280 South Redwood Rd. Salt Lake City, UT 84123 Phone: 801-290-7500 Fax: 801-290-7998 E-mail: sales@nelsonlabs.com www.nelsonlabs.com



Company Description

Nelson Labs is a leading provider of global lab testing and expert consulting services. We perform over 800 microbiological and analytical laboratory tests for the medical device, and pharmaceutical industries. Nelson Labs is regarded as a best-inclass partner with a strong track record of collaborating with customers to solve complex issues.

Target Markets

Cardiovascular, Orthopedics, Endoscopy, Wound Management, Hospital Consumables, Personal Protective Equipment, Pharmaceuticals.

Products/Services Offered

Research & Development: Process Validation, Material Assessment. Sterilization Validation: Radiation, Ethylene Oxide, Steam, VHP, STERRAD, Filtration. Packaging Validation ISO 11607: Stability, Distribution, Container Closure, Physical, Aging, Microbial. Biocompatibility ISO 10993: In Vitro and In Vivo, Chemical Characterization, Toxicological Assessments. Product Validation: Cleaning, Disinfection, Barrier Tests, Physical Tests, Environmental, Microbiologic. Lot Release (QC Tests): Bioburden, Sterility, Particulates, Bacterial Endotoxin, EO Residuals, BI Sterility.



www.nelsonlabs.com

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Safeguarding Global Health.

with every test we complete.

We are a leading global provider of laboratory testing and expert advisory services for MedTech and pharmaceutical companies.

Our major Pharmaceutical testing categories include:

Extractables & Leachables Biocompatibility Packaging Validation Lot Release Sterilization Validation Sterility Assurance Drug Device Combinations Analytical Chemistry

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Let us perform the necessary testing to get your pharmaceuticals to market. Contact our team of experts today.



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www.NelsonLabs.com

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ToC



OFS

2000 Northeast Expressway Norcross, GA 30071 Phone: 770-798-5555 E-mail: ofs_medical@ofsoptics.com www.ofsoptics.com

Company Description

OFS is a world-leading designer, manufacturer, and provider of optical fiber, fiber optic cable, connectivity, fiberto-the-subscriber (FTTx), and specialty fiber optic products. We provide reliable, cost-effective solutions for a broad range of applications including communications, medicine, industrial automation, sensing, aerospace, and defense.

urukawa Company



Target Markets

Communications, medicine, industrial automation, sensing, aerospace and defense

Products/Services Offered

Many of today's medical applications use high-quality silica optical fiber. Because a broad range of optical fibers is available to serve this market, users must carefully choose the right fiber to avoid delays in product design, time to market, along with increased development costs. Please contact OFS today for your optical fiber and or assembly needs.



www.ofsoptics.com/medical

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Qosina

2002 Orville Drive North Ronkonkoma, NY 11779 Phone: 631-242-3000 Email: info@qosina.com www.qosina.com

Company Description

Qosina is a leading global supplier of more than 5,000 single-use components to the medical and bioprocess indus-





tries. We provide practical solutions to meet the changing needs of today's engineer through innovation, technology and continuous improvement.

Target Markets

Medical device engineers, engineering management, product designers, manufacturing engineers, contract manufacturers/kitting personnel, and purchasing personnel in the medical device industry



Products/Services Offered

Qosina helps medical device engineers get their products to market faster and more efficiently by offering free samples of our products; downloadable 3D CAD models and technical product documentation; modification of existing molds; and new product design and development.

Purchase from Qosina to eliminate the cost of tooling your own components. If you need an item that is not a stock product in our inventory, we will work to develop the part to your exact specifications. We're committed to providing you with high quality products that meet your expectations and comply with industry standards.

www.gosina.com

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Intro

ELECTRONIC COMPONENTS

SCHURTER

447 Aviation Blvd Santa Rosa, CA 95403 Phone: 707-636-3000 E-mail: info.sinc@schurter.com www.schurter.com

Company Description

The SCHURTER Group is the world's leading Swiss technology company providing components and complex solutions that ensure safe power supply and simplified equipment operation. The safe&easy brand claim not only refers to

the products, but also the company's business philosophy, which strives for sustainable success through innovation, high-quality products and service.



Target Markets

SCHURTER products and solutions are developed especially for specific industry segments – medical, data and communication, automotive, avionics and space, energy, and the broader industrial market.

Products/Services Offered

SCHURTER is known globally as an innovator, manufacturer and distributor of fuses, connectors, circuit breakers, switches, EMC products, and input systems. Touch screens and touch panels, capacitive sensor keypads, membrane key-

pads, and housing systems are in close cooperation with its customers. Within its business unit Solutions, SCHURTER combines all competencies and puts them at the customer's disposal.



https://us.schurter.com/en/Landing-Page/ Industry/Medical-technology

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Intro



The most versatile Power Entry Module yet

Power, performance, protection and packing density have converged in SCHURTER's latest generation Power Entry Module.

DG11 and DG12

- IEC C14 Protection Class I or C18 II appliance inlet rated 10 A to IEC and 15 A to UL / CSA at 250 VAC
- Trip free resettable circuit protection current range 0.5 A 15 A
- Ingress protection rating against dust and liquids IP67
- Side or top and bottom flange mounting, or snap-in mounting for 1-3 mm panel
- Recessed circuit breaker protects against inadvertent actuation
- Compatible with V-Lock cord retention system to protect against unwanted disconnection

DG12 with line filter

- Filter ratings 1 A 10 A
- Standard or high inductance
- Standard X2 capacitors 220nF; optional X2 100nF or X1 47nF
- Standard leakage current rating < 0.5mA or low leakage medical < 5 μ A; optional <80 μ A

schurter.com

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Specialty Coating Systems 7645 Woodland Drive Indianapolis, IN 46278 Phone: 317-244-1200 E-mail: SCSsales@scscoatings.com www.scscoatings.com

Company Description

With 50 years of experience, SCS is a world leader in Parylene conformal coating technologies. SCS is a direct



SCS Parylenes: 50 Years of Protecting Advanced Technologies

Parylene coatings offer unmatched protection for medical devices, including implants, electrosurgical tools and other critical components.

- Ultra-thin, pinhole-free conformal coatings
- Superior moisture, chemical barrier and dielectric properties
- Low coefficient of friction
- Biocompatible, biostable and sterilizable

With 20 locations around the world and comprehensive FDA Device and Drug Master Files, SCS is the leader in Parylene coatings and technologies for the medical device industry. For more information on protecting your advanced medical technologies, contact SCS today.

US: +1.317.244.1200 scscoatings.com/medical SPECIALTY COATING SYSTEMS™ A KISCO Company

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descendant of the companies that originally developed Parylene and employs some of the world's foremost specialists, highly-experienced sales engineers and expert manufacturing personnel, working in 20 coating facilities around the world.

Target Markets

Electronics, consumer electronics, transportation, aerospace, defense and medical devices

Products/Services Offered

SCS combines the properties of Parylene with its worldwide resources to provide the industry with reliable coatings and services. Ultra-thin and pinholefree, SCS Parylene conformal coatings offer exceptional properties, including:

- Ultra-thin, lightweight conformal coating
- Micro-encapsulation capabilities
- Biocompatibility and biostability
- Thermal Stability up to 350°C (long-term)

SCS Parylenes play a critical role in protecting numerous components and applications, including circuit boards, MEMS, sensors, LEDs, semiconductors and more, for applications throughout the electronics, transportation, aerospace, defense and medical device industries. SCS's halogen-free variant of Parylene, ParyFree[®], optimizes barrier properties and complies with global halogen-free initiatives.



www.scscoatings.com

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Intro



Spectrum Plastics Group

2500 Northwinds Parkway, Suite 472 Alpharetta, GA 30009 Phone: 404-564-8560 Fax: 404-564-8579 E-mail: marketing@spectrumplastics.com Spectrumplastics.com

Company Description

Based in Alpharetta, Georgia with a global network of plants across the United States, Mexico, Canada, Costa Rica, Ireland and Malaysia; Spectrum Plastics Group is a leader in development through scaled manufacturing of critical polymer-based components and devices for medical and other demanding mar-

kets requiring guality, responsiveness, innovation and technical expertise.

ISO 13485:2016 and 9001:2015 Certified; FDA Registered

Target Markets

- Cardiovascular
- Structural Heart
- Electrophysiology
- Neurovascular
- Orthopedics / Sports
- Medicine • MIS / Robotic Surgery
- Fluid Management
- Urology • Trauma / Wound Care

Ophthalmology

• GI / Enteral Feeding

Pharmaceutical / BioPharma

- Diagnostics
- Industrial / Defense
- Food & Beverage

Products/Services Offered

With over 1.800+ teammates, 20+ locations, and one million square feet of manufacturing space including Class 7 and Class 8 clean rooms; Spectrum Plastics Group meets the requirements of ISO 9001 and ISO 13485 and has the resources to solve customers' most challenging problems.

Components & Technologies: Extruded Tubing • Plastic Components • Catheters • Laser Processing • Medical Balloons • Injection Molding • Finished Devices • Flexible Packaging & Film

Full-Service Capabilities: Design & Development • Component Webstore • Quick-Turn Prototyping • Materials Expertise • Components & Secondary Operations • Finished Device & Assemblies • Manufacturing Transfers • Quality & Regulatory Support • Scalability

> Spectrumplastics.com Shop.spectrumplastics.com

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Your needs. Our solutions. True partnership.

Intro

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From ideas to final products, our partnership spans the full spectrum of your project. With applications expertise and medical device experience that not only enables, but enhances, each step in the process.



Extruded Tubing | Catheter Technologies | Medical Balloons | Injection Molding | Flexible Packaging & Film Visit us at spectrumplastics.com

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Clippard

7390 Colerain Avenue Cincinnati, OH 45239 Phone: 877-245-6247 E-mail: sales@clippard.com www.clippard.com

Company Description

Clippard is third-generation family-owned and operated. For more than 75 years, we've been proudly supporting our local community and manufacturing right here in America. We are the pio-



neers of miniature pneumatics; our history and experience are unmatched in the industry. Our unique culture and strong values truly sets Clippard apart from our competitors.

Target Markets

Drug dispensing, laboratory equipment, medical devices, material handling, analytical, chemical analysis, sampling, life science/biotech, genetic research, gas chromatography, spectrometry, DNA synthesizing, blood analyzing, printing, diagnostic equipment, fermentation, packaging, water treatment and more.

Products/Services Offered

Clippard Precision Control products are used virtually everywhere for control, interface, sensing, logic, and actuation functions. Some of the many products include electronic valves, isolation valves, pinch valves, flow controls, control valves, manifolds, pro-



portional valves, 7/8/10/15 mm valves, cylinders, value-added assemblies and much more. With years of engineering and technical experience, Clippard continues to be a leader in manufacturing standard and custom products, as well as custom assemblies for a broad spectrum of industries.

www.clippard.com

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Branson

120 Park Ridge Road Brookfield, CT 06804 Phone: Americas 203-796-0400 Europe +49-6074-497-0 Asia +86-21-3781-0588 E-mail: Branson.Info@Emerson.com www.Emerson.com/Branson

Company Description

Emerson leads the medical global assembly technology market offering the Branson brand of advanced material joining and precision cleaning systems. Customers receive the most ro-



bust manufacturing solution to address product specifications, regulatory, budgetary needs, while providing competitive advantages in application development and product design for benchtop or automated processes.

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Target Markets

Medical Devices, OEM, Battery, Automotive, Business Electronics, Home Appliances, Robotics, Packaging, Nonwovens

Product/Services Offered

Emerson leads the welding and assemblytechnology market for medical device manufacturing by offering the advanced technology of Branson™ material joining and precision cleaning solutions for healthcare.



life sciences and chemical laboratory applications. The breadth of our expertise allows for a process-neutral approach to application development, resulting in advantages in product development and the delivery of robust manufacturing solutions. Our Branson portfolio offers an extensive array of assembly and joining technologies, including ultrasonic welding, laser welding, PulseStaking and precision cleaning equipment. Through the support of global application engineers and our applications lab, Emerson continues to introduce Branson plastics joining innovations.

www.Emerson.com/Branson

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Indo MIM Pvt Ltd

214 Carnegie Ctr. Ste 104. Princeton, NJ Zip: 08540 E-mail: infous@indo-mim.com www.indo-mim.com

Company Description

We are the world leaders in the Metal Injection Molding technology both in terms of installed capacity and global sales. Our production plants located in Bangalore, India and



San Antonio, TX USA offer you a fully integrated one stop solution for your requirements of small intricate steel and stainless components in the medical industry. USA based engineering after sales support. Option of producing components in India OR USA.

Target Markets

Surgical Instruments: Endoscopic graspers & scissors, disposable Trocar knives, Tri-staple / suturing device components, instrument bodies, scalpel handles, forceps, endoscopy ablation electrodes

Orthopedic: Trauma plates, screws, spine Implants & external fixation), orthopedic surgery tools (power & hand) Orthodontic & Dental: Orthodontic brackets, components for dental instruments

Hearing Devices: Housings, implants

Products/Services Offered

· Product design and material selection assistance • Small volume precision machined protosamples • MIM proto-typing and low volume development • Low and high volume MIM production • Micro-Molding (compo-



nents with wall thickness 0.010") • Automated manufacturing and inspection • Precision grinding, CNC machining • Laser cutting and welding • Heat treating • Micro-blasting and passivation • Pad printing • PVD coating • Dry lubricant coating (Teflon, PTFE etc) • Plastic insert over molding • Sub-assembly integration including sterilization • Integration and packaging in ISO Class 8 cleanroom • Complete ISO 13485 compliant quality documentation and traceability • Shipments through US warehouses for volumes above 100K per year or as needed • Full fledged engineering and after sales service through our US sales office

www.indo-mim.com

Free Info at http://info.hotims.com/79414-872

Orthogone

Orthogone

2250 Alfred-Nobel Boulevard, Suite 500 Saint-Laurent, Quebec, H4S 2C9 Phone: 514-316-1917 E-mail: lleblanc@orthogone.com www.orthogone.com

Company Description

Orthogone Technologies is a design house that provides revolutionary electronic medical devices and innovations to its alobal customers. We are embedded software and electronic experts who understand medical device product development, compliance challenges and FDA/CE certification requirements.

Our industry knowledge and IoT expertise reduce technical and security risks to bring connectivity to products.



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Target Markets

- Digital medical imaging
- Wireless IV pump
- controllers
- Robotic surgical systems
- Hearing aids
- Pacemakers
- Implanted defibrillators
- Glucose monitors
- MRI machines
- PET/CT scanners
- Ventilators
- Life support equipment

Products/Services Offered

Orthogone is a strategic outsourcing partner who can help you from the early stages of development, rapid prototyping, testing, compliance, and certification, to manufacturing readiness. We provide turnkey electronics product development and design services including software development, FPGA/ ASIC design and verification, and hardware design. The company also licenses intellectual property for FPGA, ASIC, or ASSP designs in latency-critical networking applications.

- System architecture
- Prototyping
- Design review & support
- Electronic engineering
- Embedded software development
- FPGA design and development
- Mechanical development
- Verification
- Environmental testing
- Certification support

www.orthogone.com

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Statek Corporation

512 N. Main Street Orange, CA 92868 Phone: 714-639-7810 Fax: 714-997-1256 E-mail: sales@statek.com www.statek.com



Company Description

In 1970, Statek Corporation was the first to use semiconductor technology such as photolithography, chemical etching, and micromachining to manufacture quartz resonators in wafer form. Today, Statek remains at the forefront of innovation in

the design, development and manufacturing of highly reliable, ultra-miniature quartzbased frequency control products.



Target Markets

- Medical Electronics
- Aerospace & Defense
- Industrial

Products/Services Offered

Product features:

- Ultra-miniature & low-profile
- Excellent long-term agingLow power consumption
- Helium impermeable
 High accuracy & stability
- Fast start-up
- Full medical high-reliability Full product traceability testing & screening
- \cdot CX16, SMT crystal, available form 32.0 kHz to 100 MHz, in 2.0mm \times 1.2 mm footprint.
- CX18, SMT crystal, available from 30 MHz to 100 MHz, in a 1.6 $\,$ mm \times 1.0 mm footprint.
- CXOU, SMT crystal oscillator, available from 32.768 kHz to 100 kHz, in a 2.0 mm \times 1.2 mm footprint

Statek's products are used in all classes of FDA approved medical devices in both implantable and non-implantable applications.

www.statek.com

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vebinars



Next-Generation Specialty Fluids for Industrial Critical Cleaning: What You Need to Know

Wednesday, June 9, 2021 at 11:00 am U.S. EDT

As the world transitions to environmentally preferred solutions to achieve net zero carbon emissions, regulatory pressure is starting to grow around the use of TCE (trichloroethylene) and nPB (n-propyl bromide) for vapor degreaser cleaning. In this 30-minute Webinar, experts discuss today's changing standards and provide suggestions for the most effective, affordable, and environmentally sustainable replacements. They outline the evolution of precision cleaning fluids and explain the safety, performance, and environmental benefits of switching to a modern HFO-based cleaning fluid.

The Webinar also provides information on vapor degreasing equipment requirements, including necessary upgrades and modifications to existing equipment, and how to determine the most suitable, cost-effective cleaning fluids and methods. **Speakers:**



David Ferguson Senior Technical Manager, Precision Cleaners, MicroCare

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Michael Fraser Technical Service Chemist, Chemours



Please visit www.techbriefs.com/webinar165



www.medicaldesignbriefs.com

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V PRODUCTS

PRODUCT OF THE MONTH



Proportional Isolation Valve

Clippard Instrument Laboratory, Cincinnati, OH, has released a flow controller that uses an extremely fastreacting mems technology sensor upstream from a proportional valve, with the option of a DR-2 regulator for accurate and precise pressure control in a small package. Unlike other mass flow controllers that require a 30minute warm-up time, large differential pressures, and limited flow ranges, the Cordis requires less than one minute warm-up, and its pressure drop is ≤ 14 in. H₂O. It features flow ranges as low as 0–30 sccm. Standard control options include 0.2– 10 VDC, 4.32-20 mA, and 3.3 VDC serial.

For Free Info Visit http://info.hotims.com/79414-345

Product Focus: Tubing

Silicone Elastomers

Silicone healthcare solutions from Dow Corning, Wilmington, DE, have been renamed to reflect the company's drive to develop innovative solutions for



patients. The Liveo[™] brand reinforces DuPont's commitment in healthcare and replaces Dow Corning and Silastic trade names for the product line that includes pharma tubing and overmolded assemblies for single-use systems in biopharma processing; transdermal and topical drug-delivery systems; medical adhesives for advanced wound care, ostomy care, and wearables; silicone elastomers for a wide range of specialty medical devices, and more.

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Reinforced Polyimide Tubing

Braid and coil-reinforced polyimide tubing from Zeus, Orangeburg, SC, helps medical device engineers optimize their catheter designs and finetune key performance characteristics, paving the way for improved procedural outcomes and increased patient safety. Reinforced polyimide tubing is available in full load and half load braid patterns, as well as in coil configurations. It is available

with total wall thicknesses (inner layer plus reinforcement plus outer layer) as low as 0.002 in./0.051 mm and inside diameters (ID) down to 0.010 in./0.254 mm. Polyimide tubing provides excellent strength and abrasion resistance and maintains its properties at very small dimensions. For applications where additional lubricity is needed, a PI/PTFE composite provides a lower coefficient of friction.

For Free Info Visit http://info.hotims.com/79414-349

Medical Connectors

A new series of connectors with plastic threaded rings is available from Binder, Camarillo, CA. The series 763 M12-A connectors have lightweight plastic threading rings that



offer a cost-effective alternative to steel threading rings, while remaining just as robust and meeting IP67 and IP68 seal requirements. Vibrationresistant crimp contacts ensure secure signal and data transfer. Male and female cable connectors are available with 3, 4, 5, 8, or 12 gold-plated contacts in a molded UV-resistant nylon (PA) housing. Series 763 ready-toconnect cable sets are available with 2- or 5-m cable lengths.

For Free Info Visit http://info.hotims.com/79414-351



Heat-Shrink Tubing

Junkosha, Gloucestershire, UK, has launched cut-to-length and slit peelable heat shrink tubing (PHST) for a wide range of catheterbased procedures where flexibility is the key requirement. Catheter delivery systems for



neurovascular treatments rely on increasingly complex shapes, constructs, and polymers to deliver their intended treatment. This intricacy in catheter bonding and welding applications can only be consistently achieved through advanced technology innovations such as cut-to-length and slit PHST, which enables catheter manufacturers to use different lengths to not only reflow a catheter's baseline materials, but also to attach complex shapes and constructions. Key application areas include balloon mounting, catheter lamination, forming, tacking, masking, bonding parallel tubes, and polymer jacket compression.

For Free Info Visit http://info.hotims.com/79414-348



Plastic and Rubber Tubing

NewAge Industries, Southampton, PA, has achieved B Corp[™] certification from B Lab[™], a nonprofit organization serving a global network of companies using business as a force to benefit others. NewAge manufactures plastic and rub-

ber tubing in reinforced and unreinforced styles. The AdvantaPure division of NewAge Industries is ISO 9001:2015 certified and specializes in high-purity tubing, hose, single-use process tubing manifolds, AdvantaFlex® TPE tubing, BioClosure® container closure systems, and other molded components.

For Free Info Visit http://info.hotims.com/79414-347

Micro Peltier Modules

CUI Devices, Lake Oswego, OR, has added micro-Peltier modules to its Peltier module product line. Carrying compact package sizes with dimensions from 3.4 to 9.5 mm and profiles as



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Motion Control Design Guide

Allied Motion Technologies, Amherst, NY, has released a new guide to its custom motion control solutions for advanced medical equipment applications. "Design Keys for Next Generation Medical Equipment" highlights several motors, drives, and control systems, as well as the advantages of each for specific applica-



tions. The company's industry experience, co-design and development process, ISO 13485 certified production facilities, and global supply chain are also covered. Specific application challenges and solutions featured include patient breathing equipment, cancer screening and oncology, medical hand tools and surgical robotics, medical microscopes and imaging cameras, and more.

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Servo Positioner

Destaco, Auburn Hills, MI, has added a servo positioner to its portfolio. The PGM40 servo positioner has been designed for use in small, medium, and relatively high-speed

positioning applications and can provide subpositioning on larger servo-positioning setups. The servo positioner features a precisionengineered parallel cam design, which enables it to combine high indexing accuracy with rigid performance. It has low input inertia, allowing it to operate more precisely while reducing the starting torque required and demanding less overall torque from the servomotor. The servo positioner has a high power-to-weight ratio and integrated motor-clamp system.

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Counterbalance Support Hinge

Southco, Concordville, PA, has released a counterbalance support hinge that reduces the total cost of lifting and positioning heavy panels and lids. The support hinge is designed to be used in tandem with the CB counterbalance hinge in applications where the counterbalance hinge can support the full torque requirements



of the panel or lid on its own. The support hinge enables ergonomic lifting and position control when combined with a counterbalance hinge by using stored energy to balance the weight distribution of a lid or panel. The hinges are fully adjustable, allowing the experience of opening and closing the panel to be tailored to the unique requirements of the application.

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UV-Cured Glob Top

EpoxySet, Woonsocket, RI, has introduced an epoxy chemistry designed as a glob top encapsulant that can be cured rapidly under 365 LED light. The Flashbond UV-3610 system was specifically developed for fully automated smart card assembly

lines but is also suitable for dam and fill and chip module encapsulations. It is very low shrinkage and produces a low ionic compound that is resistant to moisture, humidity, and other environmental conditions. With high-volume resistivity, it offers exceptional bond strength to metal, ceramic, and glass. It has superior temperature cycling performance from -55° to 150° C. The halogen-free system meets REACH and RoHS requirements.

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2D/3D Measurement System

Exact Metrology, Brookfield, WI, offers a high-speed integrated 2D and 3D measurement system. The InspecVision Planar is a 2D inspection machine that allows manufacturers to verify product quality simply and quickly by performing 2D inspection, CAD compar-



isons, and reverse engineering in seconds. Physical parts or even paper, acetate, or electronic image files can be reverse engineered to create CAD files. Reverse engineering processes can also be carried out in 3D using optional 3D modules. For full 3D capability, users simply add Opti-Scan 3D, while the SurfScan module extends Planar to 2.5D.

For Free Info Visit http://info.hotims.com/79414-359

SMT Jumpers



Keystone Electronics Corp., New Hyde Park, NY, has released a series of true-zero-ohm high-current SMT jumpers designed to replace zero-ohm resistors. Quick and easy to set up, the jump-

ers are suited as true-zero-ohm resistor replacements without the need to change board designs or layouts. Four resistor chip sizes are offered to simplify designs and footprint template compatibility: 0402 chip size (Cat. # 5112), 0603 chip size (Cat. #5110), 0805 chip size (Cat. #5106), and 1206 chip size (Cat. #5108). Manufactured from copper with silver plating, the jumpers provide a low impedance and circuit linkage with an identical footprint as a zero-ohm resistor.

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Power Entry Module

A power entry module from Schurter, Santa Rosa, CA, provides a high level of functional integration in minimal package dimensions. The series DD11 power entry module is ideally suited for equipment with low profile panels. Consisting of an IEC appliance inlet (C14),



which is compatible with cord retention, 1- or 2-pole fuse holder, and power ON/OFF switch, the module is available with side-mounting flanges in addition to the existing model with top and bottom flanges. Ideal for use in devices with limited space, it is suitable for applications in which high electrical and mechanical loads are present at the same time. Especially suited for medical applications, the series is designed to comply with IEC 60601-2.

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Vision System



its multi-sensor vision system with a 0.14 magnification lens. The AVR-FOV 0.14X offers a field of view of 2.36×1.90 in. $(60 \times 48 \text{ mm})$. For greater efficiency and accuracy, more of the part can be viewed a superimage technology, which allows

L.S. Starrett, Athol, MA, has enhanced

in every image on the system. Superimage technology, which allows multiple images to be stitched together to form one larger image, together with touch probe technology, enables the system to accurately inspect a wide range of features on large or complex parts, as well as on multiple small parts. It is equipped with the M3 software package from MetLogix, a traditional mouse, and a touchscreen monitor.

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PRODUCT SPOTLIGHT

Custom Motion Controllers

Nippon Pulse, Radford, VA, offers the creation of custom-designed motion controller boards that utilize the company's Pulse Commander core for multi-axis applications. The boards can be designed to meet



unique specifications, helping streamline the design process to bring a new product to market faster or reduce the manufacture/testing time on an existing product. A custom motion control board is ideal for application designs that need multiple axes of movement or that have many I/Os. The custom design contains all components necessary to operate such as drives, controllers, safety, and I/O. **For Free Info Visit http://info.hotims.com/79414-356**



Nanocrystalline Filters

Kemet, Fort Lauderdale, FL, has launched a series of plastic box singlephase filters. The GTX series filter uses a unique material and design designed to provide excellent EMI attenuation performance. The filter contains a nanocrystalline core, which offers higher permeability and lower loss-

es than ferrite material cores found in other EMI filters. This nanocrystalline core allows for a compact, lightweight, and high-density design, resulting in high attenuation and a small volumetric package compared to other EMI filters available.

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Servo-Drive System

Siemens, Plano, TX, has introduced a servo drive system in the safety extra-low-voltage range for 24–48 V EC motors. The Simatic Micro-Drive system with UL- and CE-marked components consists of the PDC (Profidrive Control) servo drive in conjunction with a range of motors and connecting



cables from product partners. The system offers units from 100 W to 1 kW and allows side-by-side rail mounting. It is available in a standard and a fail-safe version. STO, SS1, SLT, SLS, and SSM safety-integrated functions are included with the Micro-Drive F variant.

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Push-Pull Connector

LEMO, Rohnert Park, CA, offers a modular, ergonomic, rugged, and reliable circular multipole connector for applications needing quick and secure push-pull latching. The B-Series ranges from 00 to 5B size and features the LEMO chocolate design pattern. The keying system allows for a higher contact density while preventing mismating. Modular insert config-

urations include a wide range of high-density multi-pole or hybrid electrical contacts. Contact types can be solder, crimp, PCB straight or PCB elbow, fiber, coaxial, thermocouple, pneumatic, fluidic, or even high voltage. The connectors are UL listed.

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Motion Controller

A new series of motion controllers from Faulhaber, Clearwater, FL, are designed as slaves for control and positioning tasks of DC-micromotors, linear DC servomotors, or brushless DC-motors. The MC 3001 miniaturized controllers offer 1.4 A in continuous operation and up to 5 A peak current.



With an overall height from 2.6 mm and a format from 16×27 mm, the motion controllers feature very high control dynamics. The controllers include the same functionality and uses the same interfaces (RS-232 and CANopen) and encoder interfaces as the company's other MC V3.0 controllers. For Free Info Visit http://info.hotims.com/79414-361



Solenoid Valve

High-performance solenoid valves with a plastic body are now available from Solenoid Solutions, Erie, PA. The Wattimizer series valves are ideal for air, gas, and corrosive media. For many applications, plastic valve bodies offer significant value over metal-based bodies because they are lightweight and corrosion resistant, and they offer a lower profile

and use convenient push-to-connect fittings. These plastic bodies are CUL recognized. The plastic valve body is approximately 1-in. diameter, comes with integral ¼-in. OD tube push-to-connect port fittings and has a maximum pressure rating of 125 psig at room temperature.

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