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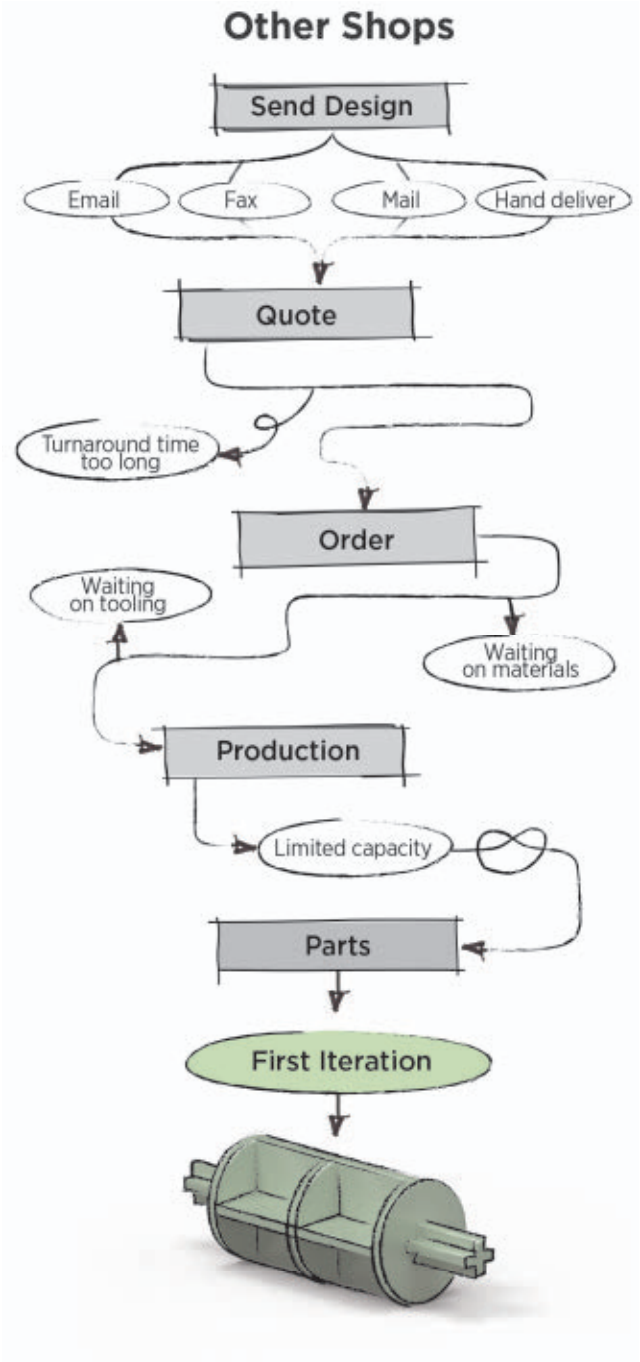

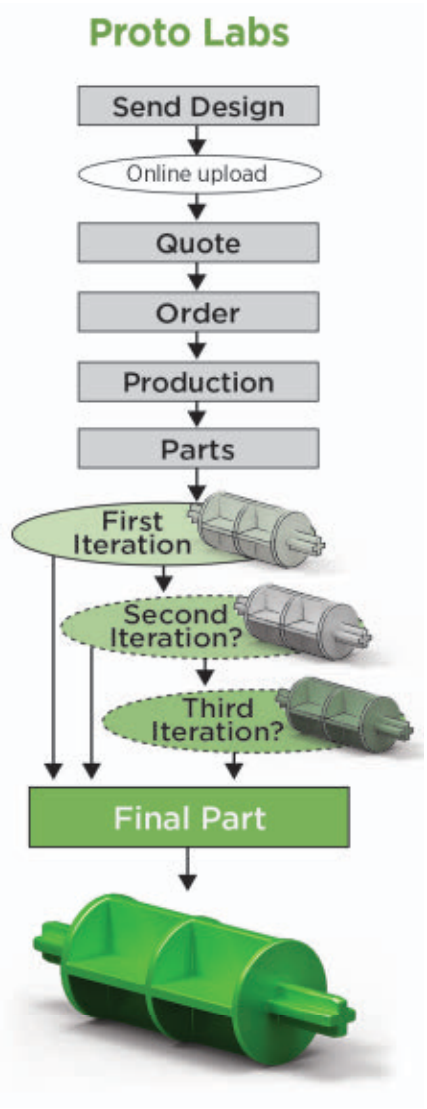

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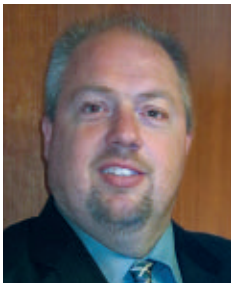

From the
Editor's Desk

BY SEAN FENSKE | EDITOR-IN-CHIEF
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App-t Development for Next Generation Healthcare

I am a recent addition to the "smartphone revolution." While I never doubted the usefulness of these devices, I was simply steadfast in holding out for a reduction in data rates. I figured that with more users adopting smartphones, eventually, providers would reduce rates to get the rest of us who were waiting for a more affordable plan to hop aboard the bandwagon.

Finally realizing that this was unlikely to happen anytime soon, I folded (like a cheap suit…) and signed a new contract for a brand new, shiny Samsung Galaxy. The many advantages simply outweigh the cost concerns I had, and every couple of days, it seems I find a new benefit to having the device that I hadn't even realized might be useful.

One of the offerings that many smartphone users have explored are the medical/healthcare apps. Whether using them for monitoring of vital signs during an exercise routine or tracking calories for a weight-loss program, these apps are becoming a daily touch point for users and their health. If nothing else, it keeps them conscious of their well-being, and that alone has to be considered a benefit.

What I've also come to realize is that any company developing such an app (whether it be healthcare related or not) has many more concerns to address beyond the general usefulness of their offering.

One of the first things I was shocked to find with my smartphone was how quickly the battery drained. Granted, much of that is due to the large screen, but since I was able to specifically delve into the battery "report" and see what was using up my power the most, I suddenly became very selective in which apps I allowed to run on the device (as much as I could anyway). Anything that I wasn't using at all was immediately shut down completely or uninstalled. Any app I download that shows up on this power "report" page better be truly worthwhile or it's likely to get the boot.

Just as power is a concern for mobile medical device developers, power consumption has to be on the minds of any designers of healthcare apps. If using the app results in having to charge the phone more often, users are going to get frustrated and stop using it. If they feel the need to plug the phone in while the app is in use, they've completely eliminated the purpose of having an app on a *mobile* phone to accomplish the task.

Any app I download that shows up on this power "report" page better be truly worthwhile or it's likely to get the boot.

Additionally, since my plan provides me with a fixed amount of data, that report also went on my "watch list." I set up alerts to let me know when I get too close to my limit and have a hard stop set up to prevent charges should that limit be reached.

Again, developers need to address how often data is sent and the size of the data packet so as to not seem like a burden for the user. And I found that apps that used significant data while not being put into active use by me were more "offensive" than those that only broadcast data when I had the program open. If data needs to be transmitted at fixed times – regardless of whether the user has the app open or not – perhaps allowing the user control over that would alleviate any concerns of data being sent when the person is not using the app actively.

These issues are nothing new to medical device manufacturers who are developing standalone, mobile healthcare technologies. Addressing data transmission and power consumption is something they have been dealing with long before smartphones and apps were offered. However, given that those devices are typically serving one purpose (i.e., the medical application), designers need not be concerned with the user's impression of these factors (power consumption and data transmission) since the user is likely not monitoring them as closely as they are with apps on a smartphone. Sure, developers certainly need to optimize these elements, but it's unlikely the user is going to form an opinion based around them.

When it comes to app development in the healthcare space, there are an array of other considerations designers need to keep in mind. FDA oversight, the use of accessories and connectivity with them, aesthetics, and usability are all additional and very relevant factors that need to be addressed. This likely would ensure continued usage of an app. Any one of these design elements can derail user adoption and kill an app. But these are true of most other medical devices being used in home healthcare today. The user's perception of a medical app based on data transmission and/or power consumption is fairly unique to medical device apps and something developers certainly need to keep at the forefront of their minds. MDT

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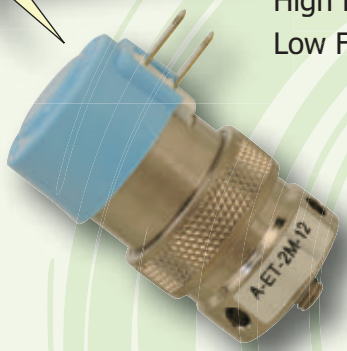

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VIDEO

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In this episode, we're making heart models for fewer recalls, taking vital signs with an iPhone, tracking activities with Moov, and finding a new way to grow stem cells.
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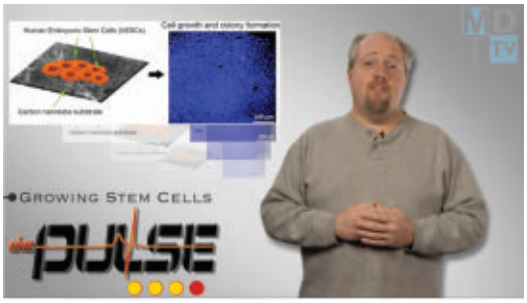

1,600

Number of deaths this app, called The Phone Oximeter, could help to prevent in developing countries.
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NEWS

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NEWS

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NEWS

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New findings show that much of the mineral from which bone is made consists of 'goo' trapped between tiny crystals, lubricating and allowing movement. It is this flexibility that stops bones from shattering.
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ARTICLE

Tiny Camera Sees for the Blind

Three years into development, OrCam has developed an eyeglass-mounted device that helps the visually impaired better understand the world around them, and its primary use is to help users process text.
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NEWS

3D Printed Heart Model Saves Life

A software solution played a pivotal role in helping surgeons save a baby boy's life through the use of a 3D printed heart model.
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2006

Year that then junior U.S. Senator Barack Obama introduced a bill that proposed to increase funding for research on genomics, expand the genomics workforce, provide a tax credit for the development of IVD tests that can improve the safety or effectiveness of drugs, and reaffirm the need to protect genetic privacy.
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ARTICLE

Safer Drug Delivery to the Brain

The blood-brain barrier and systemic side effects are issues of concern when it comes to delivering drugs to the brain. This article highlights technology that offers an alternative to current methods.
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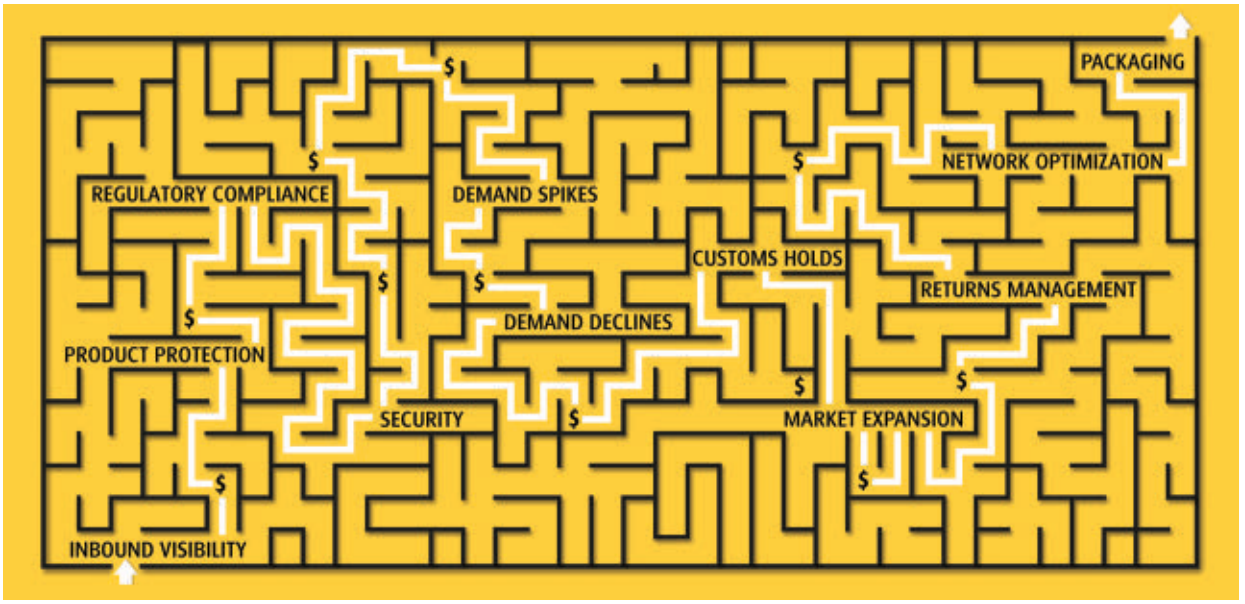

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Perspectives On Crowdsourcing

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Q: Is crowdsourcing for funding medical device development a viable alternative to the traditional venture capital model?

Jonathon Kemnitzer
Principal, KEM STUDIO

At KEM STUDIO, we've successfully funded an industrial design project, called "Skate Bench No. 1," through Kickstarter in 2011. This skateboard-inspired bench was noticed by professional skateboarders Mike V (Vallely) and Tony Hawk, who used it to raise funds and awareness for skateboarding through the Tony Hawk Foundation. We've also recently crowdfunded a playground revitalization project through Neighbor.ly.

Since then, we've helped educate the community and share KEM STUDIO's experiences with crowdfunding through presentations at the Industrial Designers Society of America (IDSA) and the International Housewares Association (IHA).

Although we haven't yet used crowdfunding for a medical device product, we have developed products in this space, such as the Cool Stretch night splint developed for BrownMed for the treatment of plantar fasciitis. I think that the crowdsourcing model would work exceptionally well for this type of product because consumers are always looking for a better way to take care of their medical issues. Products such as the night splint consider both the user and the context of use, which makes the design more approachable and useable. Given the opportunity, I think consumers would vote with their dollars through crowdfunding for better-designed medical devices that lead to better living.

I think that the crowdsourcing model would work exceptionally well for this type of product because consumers are always looking for a better way to take care of their medical issues.

–Kemnitzer

David Bratvold
Founder, Daily Crowdsource

I believe crowdfunding for medical device development is not only viable, but it's an absolute necessity. However, the biggest benefit of crowdfunding is not the money you receive to develop your device, but rather a concrete understanding of the market demand for your solution. In any other testing scenario, the input gathered from "prospects" is almost always slanted in your favor. Asking potential buyers to back-up their positive remarks with a dollar amount really shakes out if your product is wanted or not.

MDT EDITORIAL ADVISORY BOARD MEMBER

Marc Dubreuil
Vice President of Business Development, Farm Design

In some ways, venture capitalists and high net worth individuals are already doing this by funding syndicates that number anywhere from six to 20 investors. However, these are seasoned investors who possess a vast knowledge of the competitive landscape, an awareness of potential exit strategies, a familiarity with the FDA minefields, and recent memories of a VC industry that has seen considerable downsizing due to poor investment decisions.

If crowdsourcing or crowdfunding attracts a high number of individual investors who are enamored with medical devices but have no experience in the space, it's only a matter of time before they realize that picking winners is both much more difficult and much riskier than picking stocks of companies that they may have known as consumers. With both a higher level of risk and a much longer investment window (because of the longer time involved in launching medical products), crowdfunding within the medical device arena will struggle to get positive press and momentum in the near future.

Alex Fair
Chief Crowdologist, MedStartr.com

I run the leading crowdfunding site for medical innovations and about a third of our clients have some sort of medical device. So far, we have helped about a dozen medical device companies get found and funded just with rewards- and donations-based crowdfunding. While they have not generally raised large sums of money through the site, they have crowdsourced what they needed to go to market, namely manufacturing and distribution partners, investors, and press. We find that when you get 70,000 people to watch your two-minute-long video, great stuff happens. While not a replacement for traditional VC, it certainly can make a company far more attractive to investors and acquirers, and get the word out.

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–Fair

Dynaflo Pumps

Vacuum Suspension

Dynaflo's 2102X series vacuum pump was originally developed as part of an integrated system for maintaining vacuum as a means of retention between an amputee's residual limb and his or her prosthetic socket. For lower-limb amputees, this method of retention is commonly referred to as vacuum suspension, and vacuum levels as high as 25"Hg can be utilized.

Early systems for vacuum retention relied on purely mechanical means for vacuum generation. These systems required the amputee to provide the "power" to generate vacuum via ambulation. According to Ray McKinney, certified prosthetic orthotist (CPO) of McKinney Prosthetics, the "old mechanicals had to be stood on, compressed, and moved up and down to create a pumping action to draw vacuum" and were large, relatively heavy, and difficult to package, "it felt like you were dragging around a ball and chain." Bill Fleming, president of Dynaflo, worked directly with Ray McKinney to develop a compact, lightweight, battery-powered system to overcome these shortcomings using a small, DC motor driven vacuum pump.

In operation, the pump is cycled on to draw a vacuum within the lined interface between limb and socket, and shut off once a preset level of vacuum is achieved. Dynaflo's fully sealed diaphragm design and low-leakage valves result in near zero loss of vacuum through the pump itself, but while each amputee will have a unique, custom fitted prosthetic, the seal between liner and socket is never perfect, and over time the vacuum level will be diminished. The pump must then restart against a significant level of vacuum - up to 20"Hg. Dynaflo's 2102X achieves this capability by utilizes the highest quality components available and ball-bearing construction throughout to deliver the maximum force possible to the pumping diaphragm.

Physical size is another challenging aspect of this application, as esthetic concerns require the system to be as small as possible - the entire vacuum system must be easily concealed beneath a foam rubber covering that surrounds the prosthetic's structural elements. Smaller than the average adult's thumb, Dynaflo's 2102X is uniquely capable of meeting the challenges of high vacuum and restart demands in applications where size constraints leave other diaphragm-type pumps unsuitable. Fleming "designed a pump that weighs 2 3/4 oz. He was able to put together a system that we could fit into almost any prosthetic. I can't tell you how many amputees lives are better because of what Bill has done," says McKinney.

4 Key Features to Look for in a Miniature Coil Supplier

With the increasing popularity of miniature coils made with ultra-fine wire winding, finding a supplier that can suit all of a medical device manufacturer's needs can be significant to reduce time to market and save costs. This article reviews four key areas of focus OEMs need to review with a potential supplier to ensure the company is the right choice for their specific project.

By David J. Anderson, President, Precision Inc.

Miniature coils made with ultra-fine wire winding are quickly growing in popularity in the medical device industry. With gauges ranging from AWG 45 (0.0018 in.) to AWG 60 (0.000309 in.), these wires can be as small as 1/10th the diameter of a human hair, allowing for noteworthy miniaturization in charging and receiving devices.

Miniaturization provides significant benefits to design engineers. In addition to real estate savings and enhanced design flexibility, the use of ultra-fine wire makes it possible to create smaller and more accurate computer-assisted surgery and medical device navigation technologies for intervention or tracking. These smaller technologies are:

- Less invasive or implantable
- Safer
- More precise
- Capable of enhanced sensing

As one might anticipate, the precise winding, handling, and manufacturing of wire so small and delicate that it is invisible to the human eye requires significant technical expertise. Even the smallest of technical missteps can create significant performance issues.

To identify a miniature coil supplier who offers the very latest in ultra-fine wire capabilities for maximum design flexibility (while also meeting the strict performance parameters required to ensure success with these extremely delicate components), be sure to identify companies who provide each of the following four key features:

To handle extremely delicate ultra-fine wire, cleanroom facilities should have state-of-the-art technologies for microscopic soldering and performance testing. It is also important that the cleanroom be flexible and scalable to meet evolving needs.

1. 58 AWG Wire Expertise

While there are many providers worldwide who work with ultra-fine wire in the 45 AWG to 55 AWG range, there are only a select few who have the technical expertise and specialized machinery required to work with 58 AWG ultra-fine wire. Every aspect of handling and assembling technology of this size requires very specialized technology and training.

The ability to use ultra-fine 58 AWG wire provides important benefits for design engineers. Specifically, 58 AWG ultra-fine wire generates up to 50% space savings when compared to the use of 52 AWG wire and up to 30% space savings when compared to the use of 55 AWG wire. These real estate savings allow for the creation of smaller medical technologies and also provide engineers with significantly enhanced options in the design of new navigation technologies.

2. Quality Focus

It is essential to identify a partner with a top-to-bottom commitment to state-of-the-art quality. A good way to do this is to take a close look at a prospective supplier's experience, facilities, and processes.

Expertise

A supplier with deep expertise in the medical device industry offers the peace of mind of knowing they have an understanding of the strict performance standards required. Ask a prospective miniature coil supplier how many medical device companies they have worked with? Have they worked on global projects? Do they have material selection to integrated component expertise on a wide number of projects? The more extensive their expertise, the better.

Facilities

When dealing with sensitive ultra-fine wire that is as small as 1/10th the diameter of a human hair, state-of-the-art cleanroom facilities are a must. It is best to identify suppliers with cleanrooms that are not only top-of-the-line, but also highly flexible to meet evolving needs. Be sure to ask about ISO certifications, cleanroom classification, as well as flexibility (can the room be

divided in two, for example, with each part working at different classification). It is also helpful to ensure the cleanroom is flexible and scalable with significant equipment redundancy to ensure capacity for quick turnarounds.

Processes

It is also key to ensure that a prospective miniature coil supplier has an established project management method designed to ensure optimal outcome. Inquire into their process to ensure it allows for proper quality checks as well as for flexibility when required for a unique project.

3. Associated Expertise

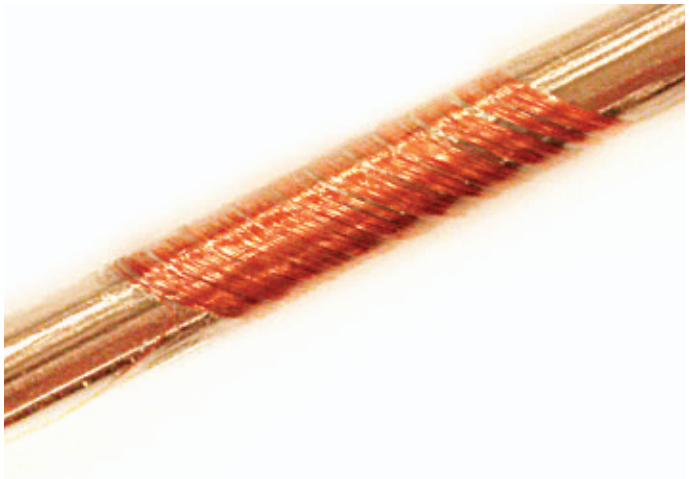
To ensure optimal performance, a quality supplier must provide more than ultra-fine wire winding capability. They must also provide the associated skills necessary to handle, solder, test and process such immensely delicate coils. In particular, look for a supplier who offers the following.

Specialized Machinery

Inquire as to whether a potential supplier has created ultra-precise winding and dereeling equipment specially designed to handle ultra-fine wire. It will also be important that they have cutting-edge microscopic soldering technology and CCD camera equipped microscopes to provide top quality inspection, training, and dimensional conformity verification at 40x to 50x magnification.

Certification

In addition to ISO 9001:2008 and ISO 13485:2000 certifications for medical device manufacturing, it is very helpful to make sure personnel at a prospective supplier have undergone extensive training in ultra-fine wire handling. Look to see that employees have J Standard Solder/NASA Soldering: ISO 14644 certifications. The best suppliers will not only have personnel qualified in handling ultra-fine wire, they will also have certified instructors in expert handling on their staffs.



Precision´s miniature coil assemblies feature ultra-fine wire (58 AEG) winding for significant real estate savings as well as a wide variety of configurations that allow for enhanced signal intensity (including unique-in-the-industry angular winding configurations).

Extensive Capabilities and Value Added Services

Due to the highly specialized nature of handling ultra-fine wire, a quality supplier of miniature coils will offer not only coil production but also extensive related capabilities and value-added services including:

- Testing – Full range of electrical tests for optimal quality and performance including resistance, dielectric, phase, and inductance testing.
- Range of Product Options
  - A wide range of termination and connection options including surface mount/PCB, wire to wire, and wire to cable.
  - Multiple primary wire and jacket filar materials, including ETFE, PFA, FEP, PEEK, Polyethylene, and Polyurethane
  - Helically wound micro-gauge coils for superior flexibility, allowing multiple paths for cameras, ablations, fluids, air, etc.
  - These diverse options should be accompanied by significant stock on hand for rapid prototyping in order to speed time to market.
  - Value Added Services – The ability to reduce costs and streamline supply chains by incorporating miniature coil design, assembly, and packaging into a single supplier. This requires in-depth expertise of the entire production process from material selection to completed component integration for optimized supply chains and manufacturing performance.

4. Cutting Edge Winding Capabilities – Angular Winding

Finally, it is key to ensure that a prospective supplier is up to date on the very latest in ultra-fine wire winding. Today's top suppliers not only provide 58 AWG ultra-fine wire, but they also offer advanced angular wire winding configuration.

Angular winding configuration features wire at up to a 55° angle to the coil axis, which has been proven to improve signal intensity for optimal sensing performance.

This unique configuration greatly simplifies design processes. Previously, miniature coils required the addition of some element that would position the coil at up to a 55° angle to the coil axis. Now, the real-estate and cost associated with this extra element are no longer required as the wire itself is already wound at up to a 55° angle to the coil axis. Removing the need for an additional angling element ensures superior performance as less components provide fewer areas for error. It also makes multi-dimensional sensing possible with a single axis coil.

Conclusion

Miniature coils provide design engineers with a large number of design and performance benefits. The highly delicate nature of the wire requires finding a provider with the highest level of specialized technical knowledge. Be sure to investigate whether potential suppliers offer 58 AWG wire, have state-of-the-art cleanroom facilities, possess demonstrated expertise in all related technologies and processes, and are up to date with the very latest developments (like angular wire winding). Diligent research into these four key areas will uncover a miniature coil supplier who can provide optimal performance and design flexibility. **MDT**

For more information, visit www.precision-inc.com.

13 Contract Manufacturer's Testing Guidelines

As more tasks are being pushed to manufacturing partners by OEMs, testing to industry Standards is becoming the responsibility of outsourcing providers. While this article is written as a guide for service partners, it also serves as a list of considerations for OEMs to keep in mind when creating the procedures for the contract manufacturer.

By Jeff Lind, President, Compliance West

As the industry evolves and budgets shrink, quality requirements remain constant and contract manufacturers (CMs) feel the pinch. Now, OEMs are requiring CMs to conduct electrical test sequences to ensure product quality before shipment. Many times, these sequences have a basis in published Medical Standards from the IEC, AAMI, or other Standards bodies. In some cases, the test procedure received from the OEM may be modified for the production environment. The procedure presented from the OEMs has been greatly simplified from the presentation in the IEC or other Standard.

Some OEM procedures are straightforward hipot or ground continuity/ground bond testing, but there are others that are more complex. These could include functional tests to determine proper function on a sample of production, or safety tests on components. These more complex procedures might require a CM to obtain specialized equipment needed to fulfill the OEM's testing requirement.

Hipot, surge, and other hazardous tests should be separated from the normal workflow to protect other personnel.

The following steps offer a common-sense checklist for review of the OEM's test plan. By following these basic steps, a CM can quickly verify that the procedure is complete.

OEM Procedure Completeness Checklist

A. Test Specification and Evaluation

If the OEM has not referenced an IEC or other published Standard as the basis for the test, items 1 and 2 of this checklist can be skipped.

1. *Is the Standard the correct one for the type of equipment being tested?*
2. *Does the specification received for the type of test agree with the version of the test in the latest copy of the Standard?*

The adoption of IEC 60601-1:2005 and reisssuance of many IEC 60601-2-XX Standards have caused test protocols for many types of medical equipment to change. However, it's not always correct to assume that testing to the the newest Standard version is required. In some cases, notified bodies are accepting construction based on older versions of the Standards, and at least at this point, the newer versions have not been universally adopted worldwide. If the Standard referenced in the procedure is not current, consult with the OEM to see if this is deliberate or if an update to the plan is required.

3. *Is the test specification complete regarding pass/fail criteria and disposition of failing material?*

What exactly comprises a failure? Can the failing part be reworked and tested again, or is it to be disposed of?

4. *Does it test the parameter in question?*

The test point should reasonably test the part. If the test seems too stringent or if the test does not seem to apply, check with the OEM to make sure the requirement is being applied correctly. Does the procedure need to be rewritten or the parameters changed to properly test and exercise the product to make sure it's built to specification?

5. *How will the test impact production?*

Consider multiplexing or duplication of test stations if throughput suffers.

6. *Is test station infrastructure in place?*

Does this area of the plant have infrastructure to support the test (personnel, power, network connections, etc.)?

B. Production Setup and Testing

1. *Does the test have a reasonable procedure and a realistic pass/fail point?*

The pass/fail point has to be reasonable for the part, the equipment, and the infrastructure of the manufacturing location. A cleanroom-style test won't be practical in most manufacturing areas, and one with complex results may have a very long training curve for the second shift. Is there a way to make it simpler and still have a valid result for the OEM? If mechanical fixtures are involved, are they supplied or do they have to be fabricated? Is the fixture designed to withstand test voltages and currents anticipated? Test with known good parts to know the limits of the fixture.

2. *Is the test performed while the equipment is energized?*

Most times, the production tests would be conducted without power applied, but type tests can specify this condition. Consult with the OEM if the answer isn't obvious.

3. *What is the sample size?*

While some tests like hipot and ground continuity or ground bond tests are run on 100% of production, there are other tests that are conducted periodically. For periodic tests, procedures are needed to define steps to take when a non-compliant test result is recorded.

4. *Is specialized test equipment required?*

If the procedure requires equipment that generates a signal or waveform that is going to be used to make the part produce a response, purchase the exact equipment the OEM is using for its in-house testing. If there is ever a problem with the test procedure, it will be much easier to determine the problem if both sites are using identical test setups.

5. *Is the test accurate enough to find a sample that is prone to failure in the field?*

CMs use surge testers based on IEC 60601 for verification testing.

This point is difficult to determine. Take time to empirically determine that the test parameters give anticipated results, and allow time to perform evaluation testing to make sure the parameters are correct to cull the bad parts and pass the good ones. A small change in the application could make a big change in the accuracy of the test results. Check testing is essential to optimize the results.

6. *Is the test being done early enough in the manufacturing process?*

This point gets enough thought, but this list would be incomplete without it. If the OEM will allow testing on an unfinished part, that procedure should be implemented.

7. *Is the testing being done safely?*

Most importantly, it is crucial to ensure that the equipment, test fixture and process is designed to keep operators and uninvolved plant personnel safe. Make sure the test is interlocked and guarded, and in a sequestered area if hazardous conditions exist during the test.

Conclusion

In order to stay competitive, OEMs have been placing new demands on CMs. In some cases, tests are being conducted by the CMs to maximize efficiencies. For CMs, a simple evaluation of the test plan can help formulate an effective implementation. Of primary importance is to determine if the test plan is properly applied to the product and if the procedure makes sense. Also consider what tools will aide in working with the OEM so that both parties quickly agree on the problem and implement a solution when things go wrong. As with every facet of a relationship with the customer – the OEM – the ability to discuss the test plan, its results, and possible solutions to deviations will be the most important part of the quality equation. MDT

For more information, visit www.compwest.com.

Crowdfunding and 3D Printing for Vital Signs Monitoring

Scanadu emerges with the largest step in home healthcare innovation since the thermometer, championing an elite field of medical device companies utilizing crowdfunding and early 3D printing. This article features an interview with Walter De Brouwer, CEO of the company, who offers his comments on the topics impacting medical device development.

The casings were 3D printed using a high resolution fused deposition modeling (FDM) process. The higher resolution aids in the surface finish for extrusion 3D printing. Button and attachment features were all 3D printed into the casings for each individual component and then assembled by Scanadu.

By Alyssa Parkinson, Marketing Communications Specialist, Solid Concepts Inc.

"Liberating" is the term Walter De Brouwer, CEO of Scanadu, uses to define the moment the medical equipment in his son's hospital room became comprehensible. The health of his son was in the hands of mysterious medical electronics and doctors. Until his son's accident, De Brouwer's experience was limited on both accounts. In a monumental effort to liberate average non-medical consumers from the dreary world of whizzing and beeping hospital machines, De Brouwer formed Scanadu. The goal of this venture was to invent a palm-sized electronic at-home health monitor. Called Scanadu Scout, this miniature "nurse" can read blood pressure, heart rate, oxygen level, and general vital signs. It can then share the information with a smartphone, leaving the patient's healthcare up to him or her.

Vital Signs Monitoring at Home

Scanadu Scout reads temperature, heart rate, breathing rate, systolic and diastolic blood pressure, and even emotional stress and blood oxygenation. The patient simply holds the device to his or her temple for a moment and the electronic "nurse" takes care of the rest. The data Scanadu Scout records is sent to a smartphone over a Bluetooth connection, allowing patients to store information about their body and track their vitals over time. It's essentially recording the same information the nurse does when a patient first enters a clinic.

"The Scanadu Scout utilizes a unique blend of software and algorithms that allow the handheld device to read a variety of vital signs quickly from only one spot on the body," explains De Brouwer. "The fusion of data from various sensors works thanks to finely tuned algorithms that interpret interference from the body and calculate readings to ensure accuracy."

Consumers, De Brouwer stresses, should have accurate readings of their bodies' vital signs; accurate readings they can individually interpret. "You'll better understand your vital signs and personal ranges; see how diet, exercise, and medicine affect your body," says De Brouwer. "For those with chronic disease or kids who are always sick, this kind of information is valuable to both patient and physician."

Perhaps De Brouwer's strongest argument for better at-home healthcare is that there has been "no innovation in home medicine since the thermometer; we don't have the tools we need to monitor and make decisions about our own health at home."

While bold, his assessment feels rather poignant in that Scanadu Scout affords something beyond a specialized device adapted from the hospital environment; rather, Scout is purposefully changing at-home health regulation and examination over time through one compact, multi-functional, and intuitive device.

Scanadu Scout has already undergone a few design changes. The original 3D printed functioning prototypes were rounder in shape, but have taken on a narrow approach as the design evolves. Such an evolution would have been highly expensive via traditional prototype methods, but 3D printing gives a freedom of design for one-off parts while remaining durable and functional for performing units.

Crowdfunding

Scanadu Scout had a phenomenally successful Indiegogo campaign run. With a goal of $100k, the company finished at over $1.6 million. It's partnered with some big names, conducting research at the NASA Ames research lab and collecting engineers and scientists alike.

So why crowdfunding? They aren't the first medical company to turn to crowdfunding, but the choice was a highly appropriate one. The field of medical devices (it really goes without saying) is secretive, proprietary, and involved. Since most of the general population is not made up of biomedical engineers, Scanadu saw its opportunity. Its end-user is the average consumer, and that's who they're targeting. So why not go straight to the source, the average consumer (and technology enthusiast), to begin the funding of this project.

3D Printing

To build the device, Scanadu began with prototyping via 3D printing. 3D printing lends itself well to crowdfunding projects where a working prototype model is vital to convince and prove the capability of the design before large amounts of overhead funding is available – especially with a project like the Scanadu Scout. Sure, the Tricorder from the 1960s Star Trek TV series looked snazzy, but translating that technology to a 21st century palm-sized instrument is another matter (De Brouwer will happily tell you the Tricorder was an inspiration).

For Scanadu, 3D printing came at a tetra-fold advantage. "Having 3D printed prototypes from Solid Concepts [www.solidconcepts.com] of Scanadu Scout along the way was very valuable. We were able to use them in our research labs to finely tune our algorithms, finalize product design, enhance user experience, and give demos," says De Brouwer. "Having a tangible product in hand helped show our future customers, advocates, and partners that Scanadu Scout was on its way to becoming a reality." With a public unveiling at CES 2014 and Series A funding of $10.5 million, it's very much on its way to becoming a reality.

Conclusion

It's daunting to fathom taking stronger, more conscientious agency over our own health, especially in a culture where at the first sign of a fever, many are wont to turn to the ER. What are our bodies really doing? How does our health fluctuate with the idiosyncratic changes of our diet, aging, and exercise (or lack of)? Can we really, as health-wary individuals, take better control of the most familiar and yet mysterious object in our lives – ourselves? Come the end of 2014, we just might be put to the test. **MDT**

Liquid Flow Sensor

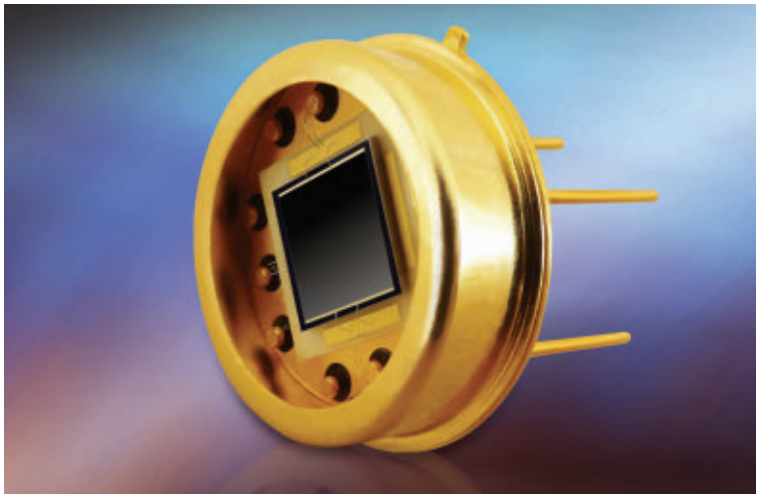
Sensirion AG, a manufacturer of digital microsensors, is expanding its range of liquid flow sensors for measuring low flow rates. The new LS32-1500 liquid flow sensor is designed for flow rates of 0 to 40ml/min, extending the range of potential application areas over the successful LG16-series. A completely redesigned housing enables a compact size of 18 x 18 x 59mm and ensures mechanical robustness. Its fast response time of 30ms, excellent repeatability and outstanding chemical resistance makes the sensor ideal for use in biomedical applications, such as diagnostic analyzers. The sensor is completely non-invasive; the MEMS chip is located on the outer wall of a capillary and measures through the wall of this channel.
Sensirion AG 41-44-306-4000 www.sensirion.com

Digital Pressure Sensor

Measurement Specialties, an expert in sensor design and manufacturing, now offers the 86BSD, a media-isolated digital output pressure sensor. Combining a low-profile, 16mm diaphragm diameter with a rugged 316L stainless steel housing, the new sensor is ideal for high performance, low pressure applications in hostile environments. The new piezoresistive silicon pressure sensor incorporates a custom ASIC for temperature compensation and offset correction. The 14-bit digital output supports both I2C and SPI interface protocols to meet specific application data requirements. The sensor provides both pressure and temperature readouts.
Measurement Specialties 760-466-7614 www.meas-spec.com

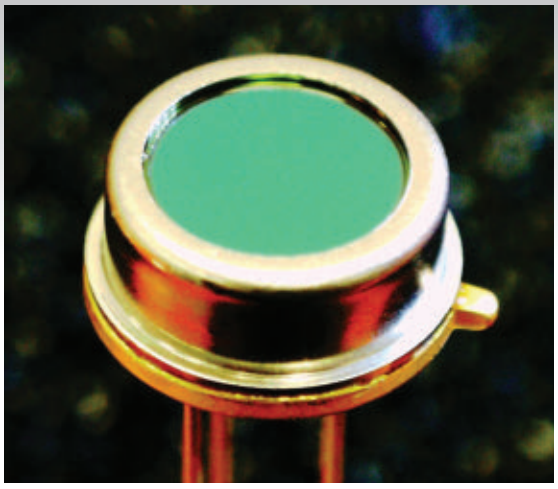
Enhanced Fiber Optic Position Sensor

The Micronor MR330 series fiber optic absolute position sensor system now features 14-bit single-turn resolution. The enhanced performance is accomplished via improved electronics and a new firmware-based algorithm update to the MR330-1 SSI controller module, which is backwards compatible with earlier units. Rotary sensors are offered in two models - Standard MR332 and MRI Safe MR338. The innovative, all-optical, passive sensor design outperforms resolvers and conventional electronics-based encoders by offering interference-free sensor transmission up to 300 meters. The controller is designed to be mounted in the same non-hazardous location as the user's control equipment and features multiple, built-in interfaces for maximum system compatibility and utility - SSI, USB, RS485 Serial, Modbus RTU, two analog outputs (4-20mA and ±10V), and two digital set points.
Micronor Inc. 805-499-0114 www.micronor.com



Submicron-Position Resolution Sensor

Opto Diode, a division of ITW and a member of the ITW Photonics Group, introduces the ODD-SXUV-DLPSD, a duo-lateral UV/EUV submicron-position resolution sensor. The new device provides a highly stable response after exposure to ultraviolet and/or extreme ultraviolet radiation. It is available in a TO-8 windowless package to minimize changes in the diode's responsivity after exposure to intense UV/EUV photons. With a 5.0 x5.0mm active area, the ODD-SXUV-DLPSD is ideal for applications in advanced lithography, and any other positioning application requiring the use of a sub-200nm wavelength. The continuous position sensing photodiode is designed for position detection of light from 1.0 to 400nm wavelengths.
Opto Diode 818-708-1704 www.optodiode.com



Line of Single Channel Detectors

Cal Sensors announces the launch of a new line of single channel detectors (SCD) that blocks unwanted radiation below 1.2 microns. Exploiting the innate transmission bandwidth of silicon, the new SCD-Si detectors are packaged with anti-reflection silicon windows to block undesirable energy in the UV and visible spectrums. Thus, these detectors focus on the infrared spectrum, minimizing the effects of unwanted radiation. Optimizing performance in the 1.2 to 5.5 microns infrared spectrum, the SCD-Si detectors combine the superior sensitivity and fast response times of lead salt detectors with the band-limiting attributes of silicon to provide excellent quality, long life, and high performance detection.

Cal Sensors 707-545-5113 www.calsensors.com

Smart Meter Delivers Accurate Analytical Measurements

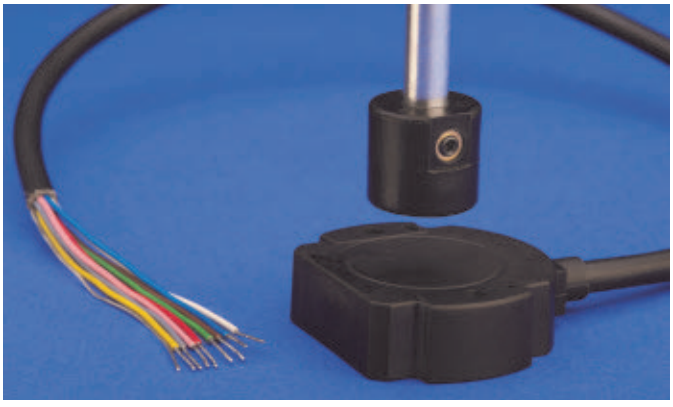
The SAM-1 Smart Aqua Meter from Sensorex harnesses the convenience of handheld smart devices to measure and record pH, ORP, conductivity, and temperature values. Compatible with both Apple and Android smartphones and tablets, SAM-1 delivers accurate analytical measurements in the lab or field for use in environmental, education, and industrial applications. The SAM-1 plugs into the headphone jack of a smartphone or tablet and connects to Sensorex smart analytical sensors for measurement. The SAM-1 App, available as a free download, instantly recognizes the smart sensor type and calibration data. The interface makes taking measurements and managing data simple and error-free, eliminating handwritten logs and potential for transcription errors.

Sensorex 714-895-4344 www.sensorex.com

Low Energy Wireless Sensor

Parker Hannifin Corporation, a leader in motion and control technologies, introduces a low energy wireless sensor platform for monitoring pressure, temperature, and humidity in liquid and gas applications. Parker's SensoNODE low energy wireless monitoring sensors and SensoNODE mobile iOS application are the first in a family of products the company is launching in 2014. The SensoNODE family puts data in the palms of users' hands, helping to predict problems and prevent downtime in a variety of equipment and facility applications, thus saving time and money on costly labor or repairs.

Parker Hannifin 763-544-7781 www.parker.com



Touchless Rotary Angle Sensors

Novotechnik, U.S. introduces the RFC4800 Series of touchless rotary angle sensors that provide absolute, rotary position. Output options for analog, digital, redundant, and switch outputs are standard. The RFC4800 Series utilizes a magnetic pickup to provide a touchless measurement range of 0 to 360°. Key specifications include ingress protection from liquids and dust to the IP 69K standard, resolution to 12 bits, repeatability of 0.1°, and independent linearity of ±0.5%. Outputs include SSI, Incremental, SPI, 0.1 to 10V, 4 to 20mA, 0.25 to 4.75V - ratiometric to supply, 0.5 to 4.5V - ratiometric, 2 PNP switches, and redundant analog.

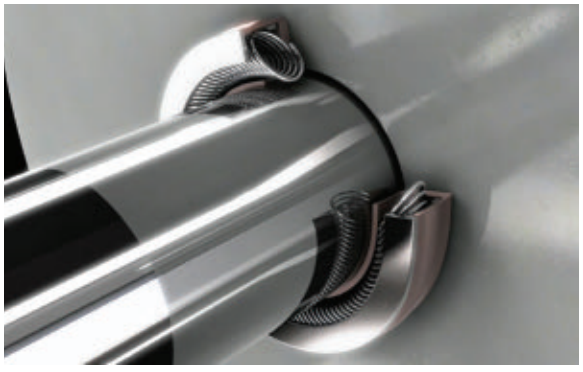
Novotechnik 508-485-2244 www.novotechnik.com

Implantable Pump Seal Improves Service Life and Cuts Power Use

Implantable devices can significantly impact the quality of care offered to a patient. Since they function within the human body, they must be able to exist in that hostile environment without fail. As such, ensuring the proper sealing of a device – maintaining a barrier between critical components and potentially hazardous fluids – is essential for success.

By Steve Twork, Global Market Manager, Medical Devices, Bal Seal Engineering Inc.

With a goal of improving the quality of life for patients with ascites, engineers at a Swiss medical device company designed an implantable low-flow pump that dramatically changed the standard of treatment (Sidebar: Understanding Ascites). Doing so, however, required protecting their pump's inner workings from exposure to bodily fluids, and that proved to be a major challenge prior to testing and launch.



The addition of the spring-energized seal to the alfapump design reduces device power consumption by 40% and increased battery life by 20%.

Device designers at Sequana Medical reasoned that if they could move fluid from the peritoneal cavity into the bladder by employing a battery-powered, low-flow pump and a set of two catheters, they could eliminate the need for paracentesis, reduce much of the discomfort associated with ascites, and help patients reclaim their mobility. With the implanted pump, fluid transferred to the bladder could be expelled during normal urination, so the patient's quality of life would be greatly improved as well.

The task seemed simple enough – build on a pump prototype (originally conceived by a physician with years of experience in the treatment of ascites) and make a few improvements to ensure that performance and battery life expectations could be consistently met. However, it soon became apparent that the device motor would require an added level of protection against malfunction caused by the potential ingress of moisture, fibrins, large proteins, blood clots, and other organic materials.

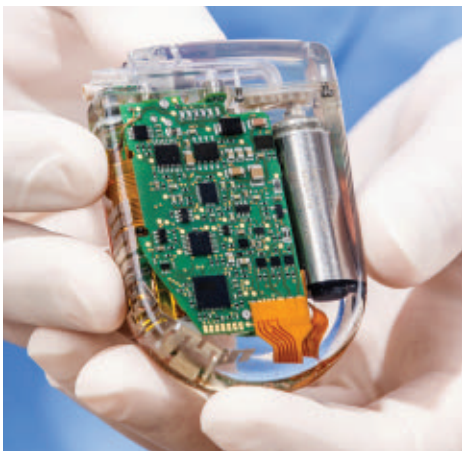
With clinical trials for the newly developed Automated Low-Flow Ascites Pump (or alfapump system) in its sights, Sequana Medical began looking for a solution that combined the required FDA USP Class VI compatibility with low friction and good sealing performance to help maximize device performance inside the body. The company's search led to several important design changes and, ultimately, to the use of a Bal Seal spring-energized rotary seal in the motor housing.

Starting at the Heart

Before they even considered a final sealing solution, engineers at Sequana Medical took a step back and examined their pump's most crucial component – its motor.

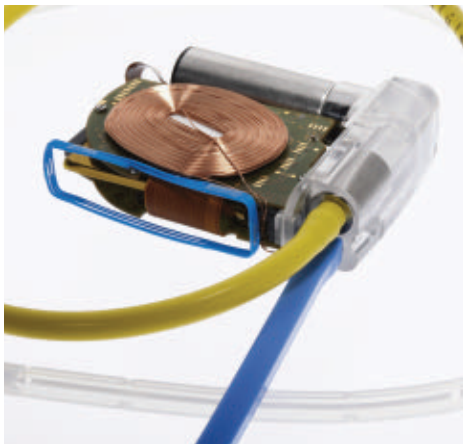
Earlier designs employed a brushed DC motor, but tests had proven this was too susceptible to humidity, which could significantly impede or even prohibit pump performance. In addition, abrasions from the brushes could lead to particulate generation over time.

In order to address these issues, designers incorporated a brushless DC motor, which proved to be far more humidity-tolerant.



The alphapump, which eliminates the need for paracentesis, reduces much of the discomfort associated with ascites and helps patients reclaim their mobility.

Even with this fundamental change, however, Sequana Medical knew it needed to be absolutely sure the motor could perform for extended periods in a critical implantable environment. That meant



The alphapump employs a battery-powered, low-flow pump and a set of two catheters to transfer fluid to the bladder.

finding the right seal. Together with its seal supplier, Bal Seal Engineering, Inc. (www.balseal.com), the company began looking at sealing options and considering how a number of different factors (including hardware, operating conditions, performance requirements, and seal geometry) would affect seal performance.

"We knew from the start that we couldn't overlook sealing," said Thomas Degen, Sequana Medical's Chief Technology Officer. "The risk of clogging the motor would be too great, and any fluid in the motor would result in a need for excessive charging or other negative consequences for the patient. So instead of trying to shoehorn an off-the-shelf solution into our application, we decided to team up with Bal Seal and take a very holistic approach to meeting the challenge."

A Hard Look at Hardware

Initial designs for the alfapump featured a relatively large shaft and a self-centering seal used to reduce the influence of misalignment between the gearbox and motor. However, this combination didn't meet performance requirements, as it resulted in very high motor friction and power consumption (low battery life).

In the ensuing redesign, stainless steel shaft hardware material was selected. Although the material's hardness (30 RC) could be considered low for dynamic sealing, it posed relatively low risk to wear.

The selected shaft allowed for the design of necessary lip contact stresses to seal and minimize the breakout, or "stiction," to running friction ratio. This addressed previous concerns about high torque values and their potential drain on the device battery. Although very small, the diameter still allowed for the fabrication of a sealing component.

The housing size was set to a dimension that allowed the seal cross section to remain within an aspect ratio greater than 1:1. This size enabled engineers to optimize radial sealing lip deflection forces as they relate to material "hoop strength."

The selected shaft surface was non-coated, with a plasma-polished finish of 0.2 µm Ra. All edges and lead angles were set to

minimize the possibility of seal damage during installation, as any nicks or burrs could have created a leak path to the motor.

Understanding Expectations

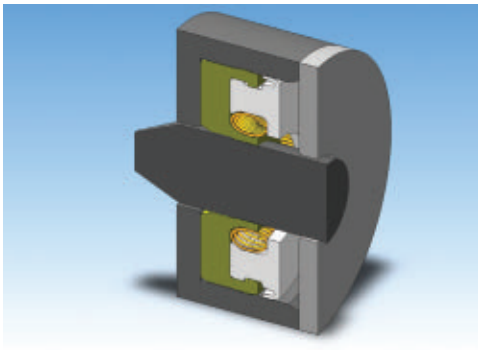
Engineers from Sequana Medical and Bal Seal also carefully assessed the environmental conditions in which the seal would be operating, as well as its intended performance parameters. These factors included rotary speed, pressures from <10psi to slight vacuum, a pressure/velocity value of ~500, and temperature ranges of 25 to 50°C.

Since the application had specific biocompatibility requirements, seal material choices were limited. Ultimately, a specially processed, pure medical grade, ultra-high molecular weight polyethylene (UHMWPE) was chosen for its superior wear factor (a 4:1 ratio over PTFE in water) and resistance to degradation under gamma radiation. The inherently low friction properties and high wear resistance of the UHMWPE allowed engineers to design-in more contact stress on the sealing lip for better performance under slight vacuum or low pressures.

As stiction was identified as an important influence on pump power consumption, Sequana Medical looked to Bal Seal engineers for a seal geometry that could provide sealing in low pressures. The seal manufacturer created a custom solution that employed a Bal Seal Canted Coil Spring energizing element and a metal locking ring to maximize the seal lip contact area. The press-fit locking ring, made from the same stainless steel material as the pump motor housing, minimized the thermal expansion rate of the material by encapsulating the outside diameter (OD) of the seal. It also prevented the seal from spinning, and allowed for minimal material on the inside lip diameter (ID).

The seal's OD configuration consisted of a "dual bump" contact area (in the design, both the metal locking ring and UHMWPE ring contacted the housing), which provided excellent protection against leakage.

Despite the small envelope, the spring inside the seal jacket provided a 40% deflection, ensuring consistent wear and more reliable sealing performance.



Cutaway of the Bal Seal spring-energized seal used in alphapump.

Mission Accomplished, Market-Bound

As a result of this collaborative effort, Sequana Medical was able to achieve its desired performance. According to Degen, the addition of the spring-energized seal to the alfapump design enabled his company to reduce device power consumption by 40% and increase battery life by 20%.

The alfapump system was granted the CE Mark in July 2011, and is currently being intro-

Understanding Ascites

Refractory ascites, which describes an accumulation of pale yellow or clear "serous" fluid in the peritoneal cavity below the chest and diaphragm that does not respond to medical treatment, affects an estimated 100,000 people in the U.S. and Europe. The condition can be caused by liver disease, congestive heart failure, kidney failure, and certain types of cancers, and is often accompanied by a significant increase in abdominal girth. In the past, ascites treatment consisted of frequent paracentesis, a process in which a sterile needle is inserted into the abdomen to remove large amounts of fluid – up to 15 liters at a time in some severe cases.

duced into leading hepatology centers across Europe. In 2012, 2013, and 2014, the company obtained Germany's *Neue Untersuchungs und Behandlungsmethode* (NUB) approval. The yearly program enables new innovations to receive reimbursement prior to being included in the DRG reimbursement system.

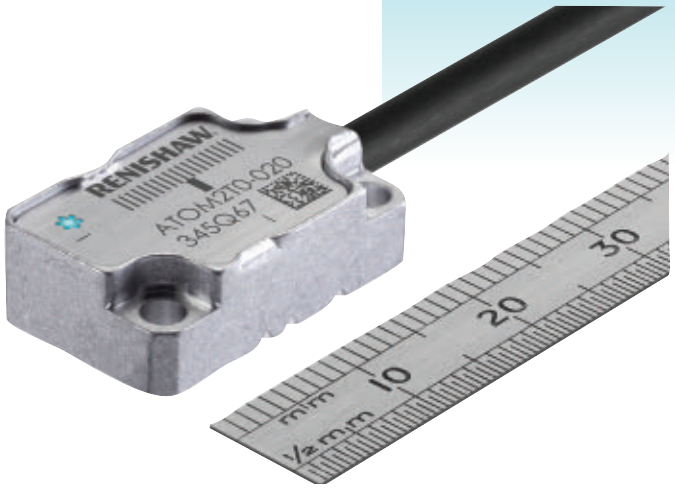
In January 2013, the *Journal of Hepatology* published the results of the pivotal Pioneer safety and efficacy clinical study. The study reports that, "the pump system removed 90% of the ascites and significantly reduced the median number of large volume paracentesis per month [3.4 (range 1–6) vs. 0.2 (range 0–4); p <0.01]. Cirrhosis-related adverse events decreased along follow-up." It concluded that the pump seems to be an efficacious tool for moving ascites from the peritoneal cavity to the bladder, and noted that "a broad use in different countries will improve the surgical technique, as well as the medical surveillance."

While originally evaluated for ascites in liver cirrhosis, the alfapump system has also been granted CE Mark for use in patients with malignant ascites (ascites caused by cancer).

In May 2013, an abstract based on a patient with malignant ascites was presented to the American Society of Clinical Oncology. The paper concluded that the alfapump system "represents a tolerable and effective means of diverting peritoneal ascites into the urinary bladder and thus preventing its re-accumulation in [platinum-resistant ovarian cancer]." According to the paper, "this innovative approach not only addresses an area of unmet need for the control of malignant ascites but also provides a method of collecting tumor tissue and evaluating longitudinal change in molecular tumor characterization." In October 2013, a second abstract on two patients with malignant ascites was presented to the European Society of Gynaecological Oncology with similar findings.

The alfapump system is now commercially available in the United Kingdom, Italy, Germany, Austria, Switzerland, Denmark, Sweden, and Norway. **MDT**

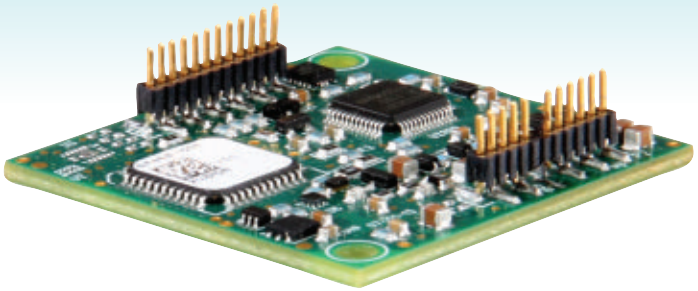
Motion Control



Incremental Optical Encoder

Renishaw's new ATOM non-contact optical linear and rotary incremental encoder system combines miniaturization with leading-edge dirt immunity, signal stability, and reliability. With a readhead as small as 6.7x12.7x20.5mm, ATOM is the world's first miniature encoder to use filtering optics with auto gain control and auto offset control for exceptional signal stability and dirt immunity. Applications include laser scanning, precision micro stages, semiconductor, medical, DDR motors, microscopy, and scientific research, as well as space-critical motion control, inspection, and metrology.

Renishaw 847-286-9953 www.renishaw.com



Micro-Sized Servo Drives

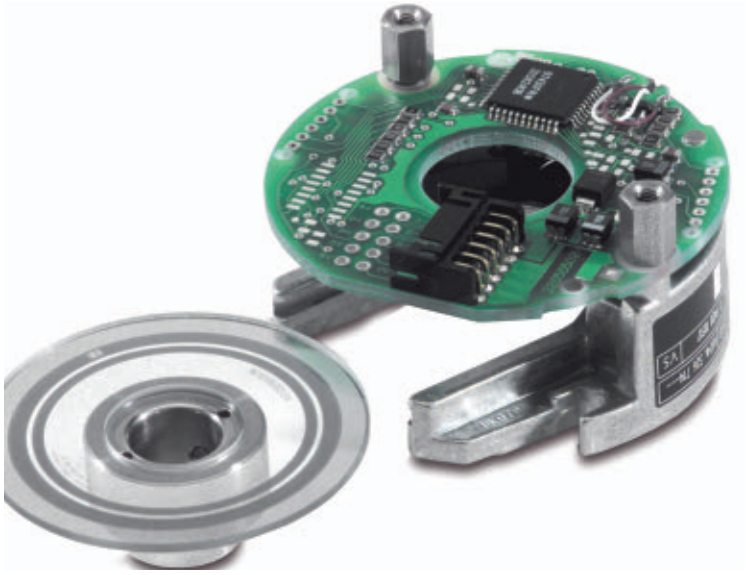
Available immediately are the AZB10A4 and AZBDC10A4 ultra-small analog plug-in brushless servo drives. The new µZs are the smallest off-the-shelf servo drives from Advanced Motion Controls. Pronounced "micro-Z," these plug-in drives are designed for embedded applications in a wide range of industries including lab automation, electric mobility, and medical. µZ servo drives are designed to drive brushless and brushed DC motors at a high switching frequency. To increase system reliability and to reduce cabling costs, the drives are designed for direct integration into the PCB.

Advanced Motion Controls 805-389-1935 www.a-m-c.com

Parallel Shaft Gearmotors

Bodine Electric Company announced that it has expanded its popular FX line of parallel shaft gearmotors to include AC models. The all-new 42R6-FX combines Bodine's new, three-wire, reversible 42R frame AC induction motor with their completely redesigned and updated FX gearhead. The new gearmotor provides up to 40% more torque than previous E/F models. New synthetic lubricant allows the FX gearhead to operate at a wider temperature range while, at the same time, improve overall gearhead performance. Stronger, hardened helical steel gears and new needle bearings provide more torque and 25% longer product life. The 42R-FX achieves these gains in power, performance, and flexibility without any change in the gearhead dimensions or mounting configurations.

Bodine Electric Company 800-7BODINE www.bodine-electric.com



Modular Optical Rotary Encoders

Heidenhain is offering the ERO 1200/1400 series of modular optical rotary encoders without integral bearing. Being a non-contact solution, the ERO 1200/1400 encoders are well suited for motion control use on dynamic stages and machines in the general automation or semiconductor industries, such as pick and place machines. They are also used on air bearing spindles, blood pumps, and servo motors in robotic applications. With on-board interpolation, the ERO 1400 can achieve resolutions of 37,500 signal periods per revolution, facilitating use on high-resolution viscosimeters or portable mass spectrometers.

Heidenhain 877-887-6431 www.heidenhain.us

Microstepping Drive

The STAC5 from Applied Motion Products provides up to five amps per phase from a high bus voltage with sophisticated current control, delivering high torque over a board range of speeds. An advanced anti-resonance algorithm with electronic damping allows for maximum torque utilization and fast settling times. The STAC5 is available in 120 and 220VAC versions, both housed in a compact package. All STAC5 models include 100Mbit Ethernet communication. The Ethernet interface is used to configure the STAC5 and motor, and also supports the SCL and Q languages over standard Ethernet cabling, addressing, and protocols. There are three control options available with the STAC5 stepper drives: S, Q, and IP.

Servo2Go 877-378-0240 www.servo2go.com

Brush DC Miniature Motor

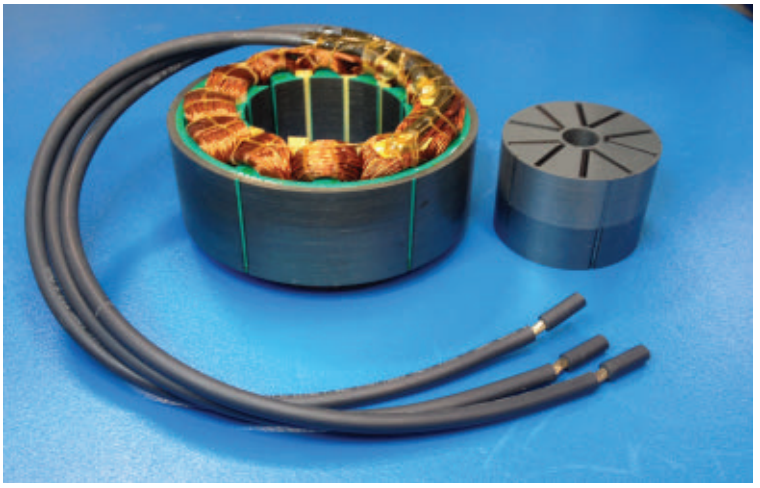
Portescap introduces the 22NT Athlonix brush DC miniature motor. The new motors offer excellent power-to-weight ratio, ensuring high battery life while providing high power up to 12.7W. This enables OEMs to build smaller, lighter, and higher performing machines and devices. This robust motor eliminates the need to choose between compact size and weight or battery life and equipment lifecycle. The 22NT miniature motors provide maximum continuous torque up to 16.6mNm to deliver higher endurance and performance while maintaining operational efficiency. The 22NT is an ultra-compact motor, weighing just 54g or 1.9oz.

Portescap 610-235-5499 www.portescap.com

Lifting Columns

Thomson Industries Inc., a leading manufacturer of linear motion products, introduces a new series of lifting columns, offering compact, telescopic motion pre-aligned motion solutions. The LC Series requires no maintenance throughout its lifetime. These innovative products can save costs on overall machine design and are ideal for providing telescopic motion in medical and ergonomic applications. The lifting columns are self-supporting and designed for rapid installation and maintenance-free operation. They are highly reliable devices that provide outstanding performance, giving smooth, quiet, and fast operation with an excellent extension to retraction ratio.

Thomson Industries Inc. 540-633-3549 www.thomsonlinear.com



Frameless Motor Kits

Applimotion's ULT, UTH, UTS, and UTO frameless motor kits cover a wide range of applications in direct drive motion control with their large through-hole surface permanent magnet rotor configurations. Applimotion is now offering interior permanent magnet (IPM) versions of these motor kits, extending capabilities to new applications. These IPM frameless motor kits cover sizes from 44 to 533mm diameter and torque outputs that exceed 1,000NM. The IPM designs provide a combination of higher continuous torque output, smooth operation, higher inductance, and minimized magnet content for cost-effective performance to suit the application. The motors can be optimized for 12 to 600 volt applications by modifying the winding.

Applimotion Inc. 916-652-3118 www.applimotion.com

Choosing a Production Prototype Source

As prototype technology becomes more advanced, it can often be difficult to decide whether it is best to go right to a production ready supply partner or first work with a prototype-only component provider. This article represents the first in a series where a variety of factors will be examined and their importance to market success highlighted. Future installments will be featured at MDTmag.com.

By Rebecca Murphy, Inside Sales & Marketing Coordinator, GW Plastics Inc.

Choosing between a low cost prototype-only source and a full-service commercialization partner can often be a daunting decision for an OEM when outsourcing production prototypes. Design for manufacturability (DFM) expertise, process specialization, quick issue resolution, and high-volume capabilities are a few of the reasons industry and market leaders ultimately select commercialization partners for their production prototypes. These companies understand the many technical and commercial benefits that result from a more extensive knowledge and experience base.

Product engineers at GW Plastics work closely with OEMs to create high-quality prototypes.

Many major OEMs already have some internal prototype manufacturing capabilities. The first level of prototype, often referred to as proof-of-concept prototype, is used to validate the idea and prove feasibility. Proof-of-concept prototypes generally bear little resemblance to the final product and are often accomplished with stereolithography (SLA), 3D printing, and other rapid-prototyping processes.

The next prototype level, design prototype, is used to finalize design details and get samples into the hands of dealers, distributers, and even users like surgeons and medical practitioners. For plastic injection molded products, design prototypes are frequently manufactured using hand-loaded, single-cavity molds and may not meet material or performance requirements.

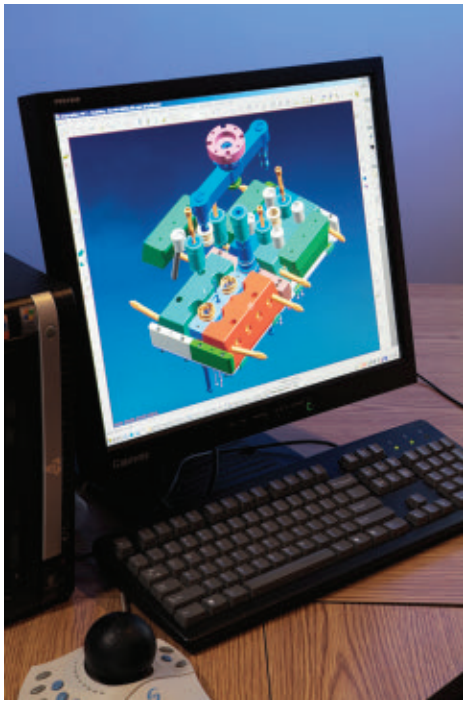
The third level of prototype, called production prototype, takes this concept to the next level by using the final production design and manufacturing processes. In addition to validating the product design for fit and function, tooling and processes are also validated during this phase of pre-production. It is at this level that the selection of a full-service commercialization partner contributes real value to the OEM. Unlike the sometimes narrow focus of the prototype-only source that strives to make several high-quality parts, the commercialization partner leverages technical know-how to assume a broader perspective and consider all of the factors that are required to efficiently and reliably produce parts in a high-volume market. The use and application of robust DFM methodologies during this prototype phase cannot be underestimated when evaluating the impact on overall program cost and timing.

Both the OEM and the commercialization partner benefit from early engineering involvement and capturing "lessons learned" during the production prototype phase. As has been shown repeatedly and across various industries and applications, new product launches are significantly more successful when the entire design and production engineering team is involved from the initial concept phase through prototype and all the way to production.

"Many of our product engineers have over 25 years of experience making complex injection molded parts with extremely tight tolerances," said Tim Holmes, Vice President of Engineering at GW Plastics Inc. (www.gwplastics.com). "By sitting alongside our customers as early as possible in a program, we're able to provide them with design guidance that reduces risks and helps make a long-lasting, high-quality product."

...the cost of not applying DFM principles is significant and results in a drawn-out iterative design process that lengthens overall time-to-market.

Since most of the product lifecycle costs are committed during the design and prototype phases, it behooves all parties to select the correct materials and processes prior to large scale production. For injection molded products, the use of mold simulation software and the application of sound scientific molding techniques helps to validate product design concepts well before



Using the best technology, commercialization partners are able to create prototypes designed for a high-volume market.

significant investment in production tooling is made. Moreover, the cost of not applying DFM principles is significant and results in a drawn-out iterative design process that lengthens overall time-to-market.

In addition to ensuring a good product design, a comprehensive DFM process can also help create robust tooling that will last throughout the life of the program. For injection molded parts, early cross-functional review of part drawings and CAD models may reveal mold geometry conditions that could lead to high wear in the production mold. Eliminating undercuts in the part geometry, reducing the number of mold actions, fitting wall sections wherever possible to reduce part weight and lower cycle time, and optimizing gate locations are several recommendations that a knowledgeable, full-service partner might make to extend tool life. In this manner, the commercialization partner helps the OEM to reduce tooling cost as well as the overall production cost.

According to Holmes, "Our company's roots are in mold-making, and we still build a majority of our molds in-house. Because of our extensive tooling knowledge, we spot issues before they become problems."

It is clear that proactive application of DFM tools throughout the design process assists both the OEM and the full-service commercialization partner in optimizing all manufacturing processes while assuring the best cost, quality, reliability, and time-to-market. So, how important are process specialization, quick issue resolution, and high-volume capabilities in the overall selection of a production prototype source? **MDT**

[Editor's Note: Look for the next article, which will offer a deeper dive into the benefits of using a full-service commercialization partner, online at www.mdtmag.com.]

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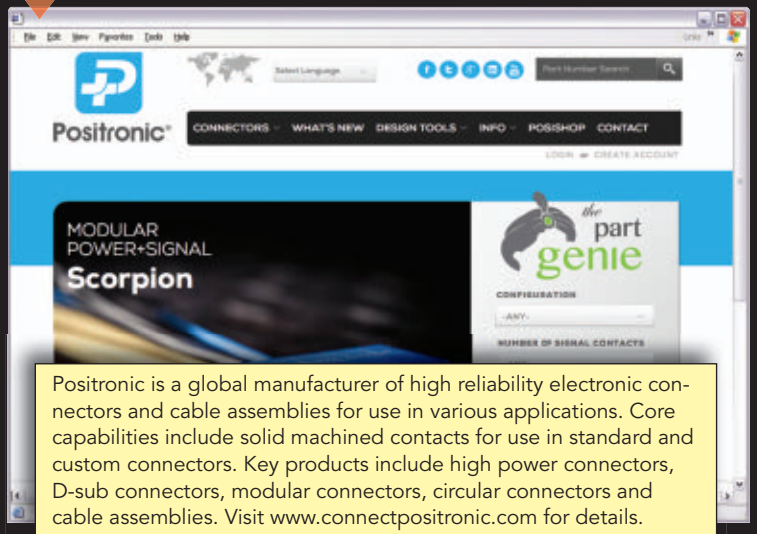

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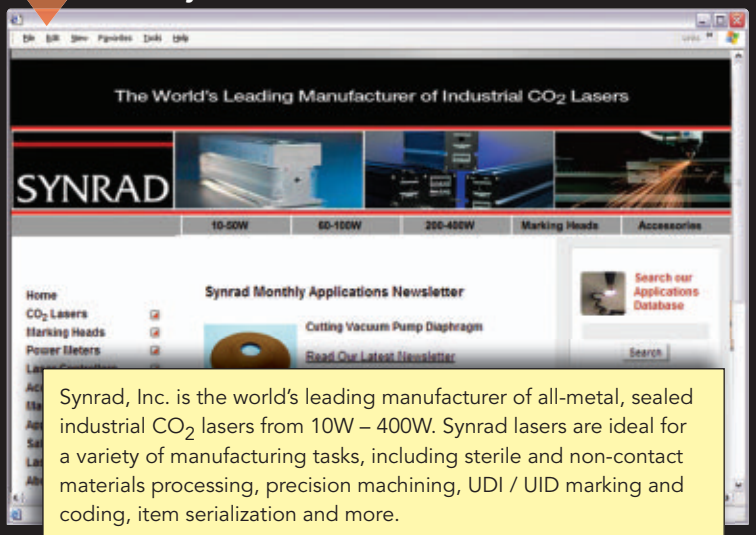

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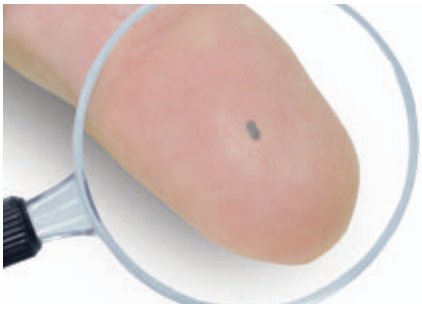
New Products

Mini Compression Springs



Lee Spring has expanded their popular Bantam mini compression springs. Originally introduced in 2010, Bantam mini springs respond to customers' requirements for off-the-shelf stock springs that fit increasingly reduced spatial parameters. The new metric Bantam series starts at wire diameter 0.1mm, just slightly thicker than a human hair, with outside diameters from 0.81 to 1.65mm and free lengths from 1.0 to 14mm.

Lee Spring 888-777-4647 www.leespring.com

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Schurter is pleased to announce the new series SHF 6.3 x 32 compact fuse. The series provides overcurrent protection up to 500VAC. The high breaking capacity of 1,500A at rated voltage safeguards electronic systems and operators in the event of a catastrophic short circuit incident. This 6.3 x 32mm series is offered in 10 current ratings ranging from 1 to 8A. The fuse has a quick-acting characteristic according to UL 248-14. The SHF is especially suited for primary protection of three-phase systems, as well as a wide range of industrial applications such as HVAC systems, photovoltaic, frequency converters, and power electronics. The operating temperature range is -40 to +85°C.

Schurter Inc. 707-636-3000 www.schurter.com

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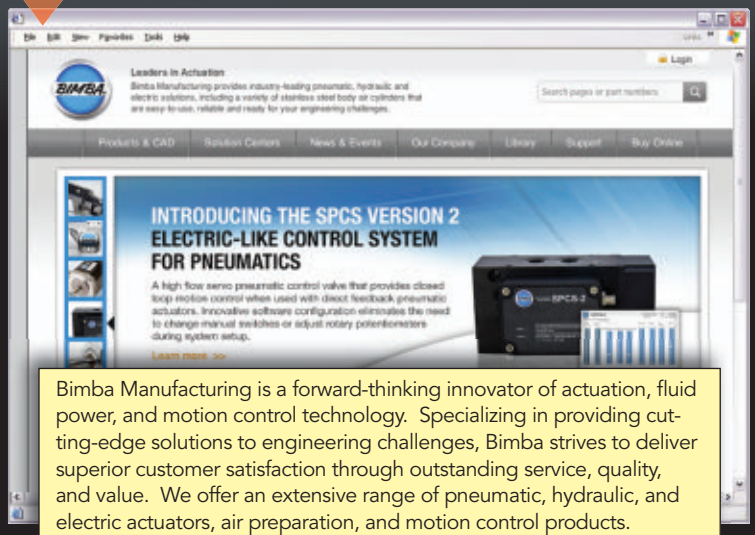

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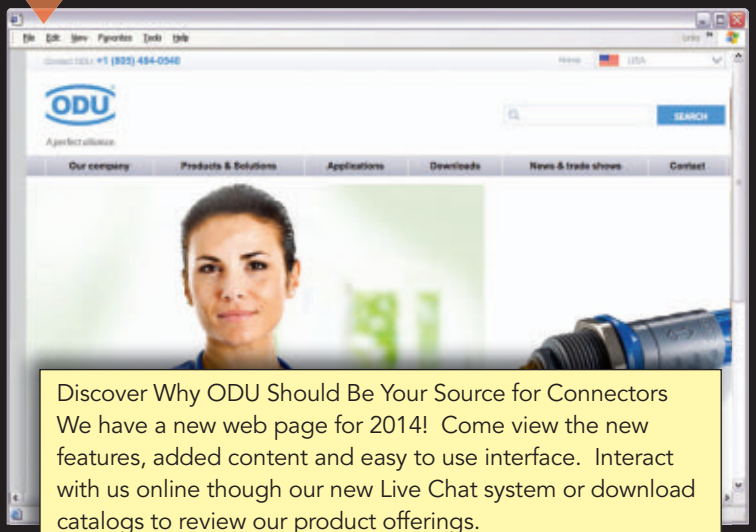

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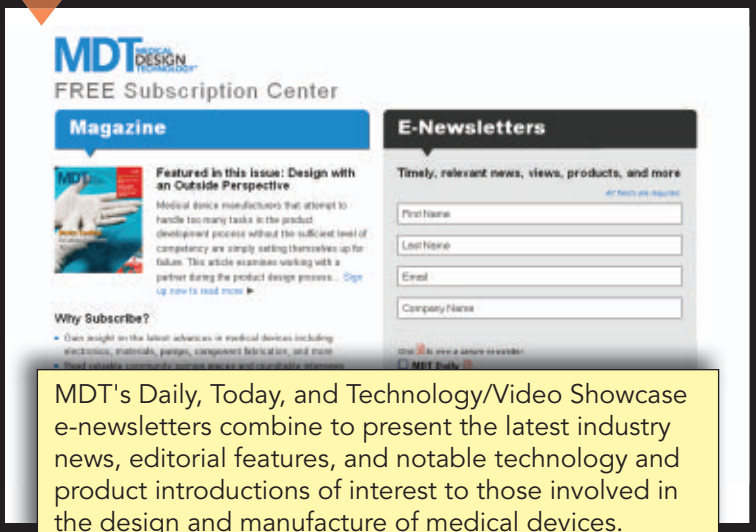

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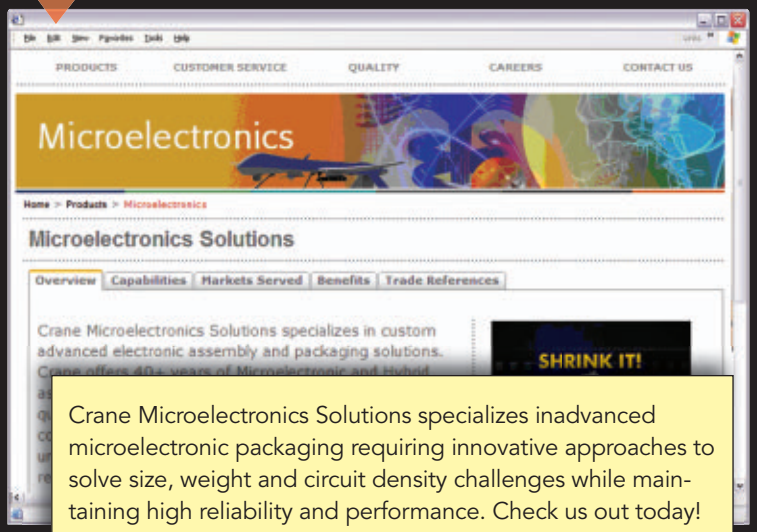

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Board's Back Page

Two members of MDT's Editorial Advisory Board respond to questions regarding the medical device space and offer their unique viewpoint on the industry. Look to this space in future issues to see what the other members of the board have to say.

Jinny Lee, Vice President of Strategic Marketing, Advanced Technology, Edwards Lifesciences

Tom O'Dwyer, Director of Healthcare Technology, Analog Devices

Q: In the medical device industry, where are you seeing the most exciting innovations?

Lee: What is remarkable about medical technology today – that wasn't the case 10 or 15 years ago – is that we are performing surgical procedures with minimal incisions or with catheter-based approaches, which promise a number of potential benefits to patients. For example, at Edwards Lifesciences, we are replacing diseased heart valves with artificial tissue valves using transcatheter technology, through small incisions made in the groin, in between the ribs and through the front of the chest, among other access points, while the heart continues to beat. It has been fascinating to witness the miniaturization of today's technologies, as well. Sensors that capture important biological information will continue to lead the future. We are seeing it now with ingestible pills that monitor medication adherence and others capable of taking images inside the body.

O'Dwyer: Traditionally, people think of healthcare as taking place at the hospital or in a clinical setting where a physician is measuring the body – and vital signs in particular. But healthcare in the last couple of years has evolved out of the hospital context to where people are taking more of a preventative approach by monitoring their own health, at home or at work. I think this new dynamic is changing our whole approach to healthcare. It's exciting, and I suppose is typified by the fact that the wristbands, Fitbits, and phones that people are buying today are really consumer devices with medical monitoring applications built in.

Q: What significant factors are influencing the development of medical devices?

Lee: Medical devices must ultimately work well for not only physicians, but also for patients who use the devices every day. If devices work from a technical standpoint, but prove cumbersome for patients, it's difficult to claim success in developing a solution. Medical technologies should accommodate patients in their everyday lives. Recently, I have noticed patients take a more proactive role in their diagnoses and treatments. They want to learn more about their specific disease or health condition, and also ask questions and hear from others who have had similar experiences. I think this explains the tremendous growth of online patient communities dedicated to disease management across the spectrum.

Medical device companies have a number of stakeholders that we are responsive to, including our customers, employees, investors, policymakers, and patients. As a result, we are significantly influenced by changes brought about by these constituencies. One area of change at this time is on the policy front, with respect to the medical device excise tax implemented beginning in 2013. A recent AdvaMed survey shows the medical device excise tax placing undue burdens on manufacturers. According to the report, the tax has led to employment reductions of approximately 14,000 industry workers and foregone hiring of 19,000 workers last year alone. The total job impact of the tax on industry employment just last year was approximately 33,000. We need policies that encourage strong investments in medical devices to ensure continued innovation for patients. Europe continues to introduce medical technologies before they are approved in the United States, but we are noticing improvements that have allowed medical innovations to reach patients in a much quicker manner, while maintaining a focus on safety and efficacy.

O'Dwyer: I see at least four technology enablers having a more or less profound effect on healthcare. The first is the smartphone itself and the second is the development of Bluetooth Smart, which is the low power version of Bluetooth that was released a few years ago and lets you wear your electronic gear 24/7 while beaming out data. This technology has allowed device makers to pack all kinds of sensors into their phones, and people are discovering that these sensors can have real practical health applications. Another important development was the opening of mobile phones to third-party developers who are able to write their own apps. There's a whole plethora of applications out there, and I just have to stand back in amazement at the imagination of the guys who developed them. For example, one app lets you detect your pulse just by holding a phone camera against your finger and using the reflection from the camera flash. The guys who developed the camera had no idea that these kinds of diagnostics were possible. The fourth enabler would be the standardization of the port at the bottom of the phone. This now enables you to attach a dongle and turn the phone into a medical instrument for measuring things like blood oxygen levels.

Q: Where is the medical device industry headed?

Lee: The future of medical technology will rely on robust datasets that provide a better look at population health worldwide, and the genetic underpinnings of disease. In our field, benchmarking tools such as the TVT Registry have provided useful data on real-world outcomes of the transcatheter aortic valve replacement procedure, or TAVR. Through the capture and reporting of patient demographics, procedure details, and facility and physician information, we can learn much more about clinical practice patterns and patient outcomes.

I also see an aging population determined to remain active as long as possible. Just as the baby boomer generation had an impact on the educational system and the labor market, this group will also drive changes in health care including ever-evolving medical technology solutions. It is also encouraging to witness the move toward preventive care, so that more patients avoid illness and its devastating symptoms.

O'Dwyer: In the next couple of years we're going to see an explosion of these body-worn sensors, which are only going to get more sophisticated. We're going to be able to monitor a lot more things, but I think the real breakthrough will be in the area of big data, where useful information will surface that nobody ever dreamed of. For example, the way companies develop drugs today is to come up with a pill and then put it in a clinical trial with a number of patients. With body-worn sensors, people who are on a medication will be continually uploading their data, and it will become perfectly obvious – and pretty quickly – if there are any unwanted side effects. Because of these sensors, the world's knowledge will have been increased, and I think this will create a lot of of opportunity for startups to mine this big data and discover correlations that nobody else had thought of.

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