Optics And Photonics Technology In Medical Devices: Go Small Or Go Home

By Josh Butia

The medical device industry is a rapidly growing area of opportunity for optics and photonics technology, with applications ranging from diagnostics to surgical tools to therapeutics. During the SPIE Optics + Photonics 2013 show last month, I had the opportunity to speak with executives at several optics and photonics companies that serve the medical market, discussing with them the challenges associated with the medical space, the future outlook for the sector, and more. One thing they all agreed upon is that smaller — from micro-sized components to handheld systems — is the wave of the future for medical devices. Read on for more of their insights on this exciting application area.

How has your organization established or increased its foothold in the medical space?

Aaron Johnson, marketing manager, Accumold: Well, Accumold is fortunate in the fact that our niche technology in micro molding and in providing very small, close tolerance plastic parts has actually been an advantage to us in the medical arena because there's a huge demand for devices to shrink, for devices to be less invasive, to do more in the same space, to take some of the expense out, etc. Our capabilities have been of high interest in the micro medical market as of late.

A couple of the other things that Accumold has done recently that also play into the medical market is that we've recently gone through the auditing process for ISO 13485. We already had 9001 for many years, and a very robust quality system, but the requests from our customers has increased over the last couple of years, and we finally pulled the trigger on going through the certification process to formalize our quality system and to help give our medical customers peace of mind that we have a quality system.

The third thing that has also been of value to our medical customers is the increased capacity and capabilities in our cleanroom molding. We recently added to our 100K-class cleanroom. We've almost tripled our cleanroom space in doing so. We also added 10K-class cleanroom space for some of those very high-end components that medical customers have specifically requested. So we have the ability to mold some of these parts in a very clean environment.

Michael Newell, director of sales and marketing, Deposition Sciences, Inc.: As a manufacturer of highly durable precision optical filters, our products can be found in applications across a wide variety of medical markets, from dental/surgical lighting mirrors to precision bandpasses. Heat rejection, precision bandpass filters, and laser coatings all have specific niches within the medical market. One specific area of focus that is growing for DSI is micro-optics. Our unique LPCVD coating platform allows us to uniformly coat small shapes and unusual geometries. We have coated parts down to 80 µm in size and routinely coat ball lenses, hyper hemispheres, and domes. This differentiated capability is finding application in medical laser systems and endoscopic lenses, among others.

Steve Smith, product manager, Pixelteq: A few ways.... First, by providing unique solutions — micro-patterned optical filters customized to fit OEM and device manufacturer applications. PIXELTEQ's technology can help simplify optical designs and reduce the cost and footprint almost anywhere a multispectral sensor or imager is used.

We are also collaborating with research teams at these companies and other academic and government institutions who are working on multispectral sensing and imaging applications. Through our MSInnovation grant program, we have helped provide multispectral imaging systems to support the work on several promising projects.

What do you see as the greatest potential opportunity in the medical market?

Michael Allen, director of product development and marketing, Ocean Optics: There is a strong push to integrate spectrometers into devices that are more transportable than ever. A decade ago, customers were excited about moving tests from a central lab to a hospital lab or an individual doctor's office. Today, the transportability is increasing even more. Smaller spectrometers with higher performance allow tests and analysis to be completed bedside or in the operating room.

Smith: There is a lot of great biophotonics R&D work being done, much in the multispectral space. We see great opportunities in translating the benefits of non-invasive multispectral sensing into devices that help improve preventive care, early diagnosis, and accurate treatment, from biometrics scanning and monitoring to improved imaging in diagnostic and clinical devices. All the great work pays off when it reaches the point of care — and extends better care wherever it's needed around the world.

Johnson: The greatest potential for us is that microelectronics continue to shrink. The desire for more technology to be on our person, for surgical tools to be more advanced, and for diagnostic tools to do more continues to grow — and really plays into our technology strength. We continue to advance what we can do with plastics with micro-features and micro-sizes and in exotic materials. That's very compatible with the trends in medical device design. We only see more growth opportunity as more and more manufacturers try to shrink their medical devices.

Newell: More emphasis is being placed on preventive care, which requires enhanced diagnostic tools. Many of these diagnostic tools are photonics based. If you want non-invasive tools, one of the most common and effective methods is to use different wavelengths of light to investigate different medical phenomena. The majority of these diagnostic tools use optical filters or coated optical components. Another very exciting trend is the desire for miniaturization and increased sensor fusion. Companies are now looking at performing full assays "on chip." In order to do this, they require the optical coatings to be deposited directly on top of the photodetectors and/or semiconductor wafers. The combination of DSI's photolithography and coating capabilities allows us to pattern coatings directly on the active-device wafers and photodetectors. We look forward to enabling these exciting new tools and systems as we move forward.

What are the biggest challenges associated with working in the medical market?

Newell: The development and regulatory approval cycle can be very long, so the gap between prototypes and production can be significant. But on the flip side, once you are qualified you tend to be locked in, since the cost and time involved in requalifying a competitor can be prohibitive.

Allen: As more medical devices based on spectroscopy emerge, the challenge is to deliver devices that meet the demands of use. Because of their portability, spectrometers are being used in medical devices like never before. This is pushing the limits of customization, accuracy, and precision. Techniques like Raman and near-IR spectroscopy, once reserved for the bench top, are now making their way into new devices.

Smith: Time. Despite the fast pace of innovation, the cycle time from research to clinical trial to a production device frequently takes years. It's critical to be involved in the early design stage to evaluate alternatives and collaborate on the best design path — then stay engaged to gather real-world feedback that leads to improvements and a winning solution. Regulatory hurdles can also create unpredictable delays.

Johnson: The biggest challenge is the slow moving process. We've become accustomed to the fact that product development is slow. Sometimes, it starts with very slow ramp ups as they go through their 510(k) and clinical trials and their FDA or European approval process. It can take some time from when you build a mold for a plastic component to when they're actually seeing production. So, they can have challenges along the way that actually have nothing to do with the part, but could delay or even potentially derail a project. So for us, the biggest challenge in this market space is being able to work at our customers' pace and provide them the parts when they need them and make the changes that they need in the right time frame. A lot of times it's slow, slow, slow, then hurry up, hurry up, hurry up. We sometimes have to react quickly to what our customers need to get their medical device on the market.

The optics and photonics industry has had a major impact in the medical space over the last five years. What do you consider to be the most significant?

Johnson: There's been a huge increase in our experience in micro-optics, bio-optics specifically, for diagnostics involving catheter-based or endoscope-based surgical tools. Device makers want to get light or imaging into very small areas, and we've been able to make some parts to help achieve that. We did one particular project that involved a lens with a 125 µm diameter with a turning mirror and a gold-coated piece to it, all within what looked like a little speck. It was a very small part, because it had to go inside a catheter and be deployed inside veins and arteries. And bio-optics has really only scratched the surface of what it can do in diagnostics.

Newell: Non-invasive diagnostics continue to become more and more important. But the opportunities are huge. Researchers are working on non-invasive testing for blood sugar monitoring, so that diabetics no longer have to draw blood for each test. Early detection of cancer using photonic imaging techniques also has great potential.

Allen: Optics and photonics are the building blocks for medical devices. I believe miniaturization of components and the equivalency of performance from these smaller-sized devices is a significant advancement. Today's optics and photonics technologies are making the once-theoretical now possible. Also, the cost reduction of these devices will allow for better medical treatment accessible to more people.

Where do you see the medical market in five years?

Allen: Optical technologies will continue to drive medical diagnostics as imaging and spectroscopic techniques come together. Spectral data will serve as a "stain" to the images acquired today. This new layer of information will allow doctors to see more than ever before. Combining the power of spectroscopy to qualify and quantify compounds with real-time images will be a significant part of future instrumentation. No longer will doctors or patients be content with the analysis of a single sample or a static picture of a condition. They'll want to see the behavior of the body the same way we see other problems, in motion, and with multiple layers of information superimposed.

Newell: We see the medical market for optics and optical filters continuing to grow. We believe that photonics applications within the medical field have just scratched the surface. As we learn more about genetics, stem cell therapy, and new treatments, the need for optical imaging, monitoring, and testing techniques will continue to grow. DSI looks forward to participating in this exciting push to the future.

Johnson: Well, I hate to sound like a broken record, but smaller parts. My son had an appendectomy a number of years ago, and he had three centimeter-sized incisions in his abdomen. Today, you can't even see them. They didn't even stitch them. They glued them together, and he's virtually scarless. That's a result of the shrinking of technology. I only see that accelerating as more device companies look for better ways to heal people with as little intrusion into the body as possible. I see that only increasing in the next five years.

I also see huge growth in personal management — connecting your devices to your cell phone, your smart phone, or your computer — where you can monitor what's going on with your blood pressure, check your blood sugar, or perform any other kind of internal sensing. All of that requires micro-technology, and because of that, I see micro-technology as being at the forefront of medical device development over the next five years.

Smith: As a lifelong Star Trek fan, I see the tricorder concept becoming a reality. We're seeing handheld probes, biometric scanners, and specialized diagnostic and screening aids using multispectral sensors. There are all kinds of innovation in the personal healthcare market — integrated sensors, wireless activity trackers, and apps and accessories that provide continuous monitoring from all kinds of wearables, connected devices, and smartphones. There'll be more multispectral 3D imaging to support minimally invasive procedures — more capable endoscopes and robotic surgeries. Combining medical experience with intelligent sensor and imaging data is a huge worldwide trend. So expect to see more intelligent sensor and camera-based devices in more places — tools for better health — from better results in the OR to better lifestyle decisions. It's an incredibly exciting time!