‘Just Make It Smaller’

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In the effort to make electronic medical devices smaller, there are a number of obstacles that must be overcome to achieve success. While “just making it smaller” may be the request from the OEM, the component suppliers have a much tougher road to provide the required part. This article looks at a number of factors that need to be examined and offers tips for success.

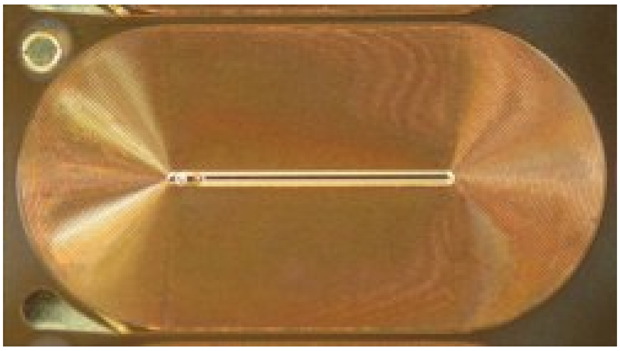

Figure 1: Four Layer Induction Coil with 12.5-µm lines and spaces

If you’ve heard it once, you’ve heard it a thousand times—devices are getting smaller and smaller. Not only is this true of commercial products, but also in the medical device marketplace. In that arena, designers have to deal with very tight process control, FDA-driven ISO 13485, and biocompatibility. In addition, there are numerous applications where miniaturization is a challenge—multilayer flex circuits, nozzles and nebulizers, molds, and structural devices. While cost, producibility, and functionality all play critical roles in the design of a component and in its manufacturability, the most significant issue remains as getting everything the designer needs into the smallest space possible.

Simple—Just Make It Smaller

While the semiconductor world is certainly one way to handle “making it smaller,” unless the project calls for making millions upon millions of the device, it’s not likely an economically viable approach. Packaging alone cannot provide the solution, as the parts and circuits themselves need to be small enough to fit inside the limited space. The device must also be able to be assembled to handle the stresses and environment that it will likely encounter in the medical applications for which it is intended.

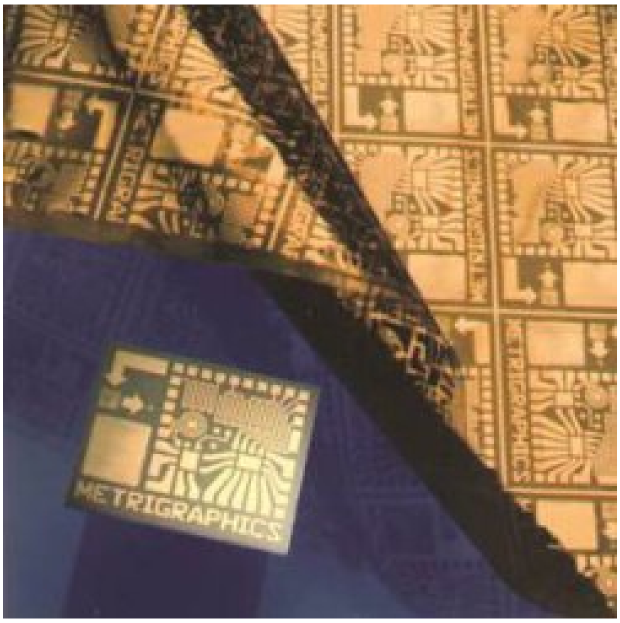

Figure 2: Single layer micro flex circuits (ERMF) in three sizes

Many factors, including mechanical insertion, temperature extremes, bodily fluids, cleaning processes, and stresses from body motion, can place large stresses on the components. Regardless, the medical device OEMs need smaller and smaller, and the component industry has to find ways to resolve these problems.

Technology

When it comes to circuit technology for small medical devices, there are essentially two: subtractive (etching) and additive (sputtering or electroforming). They share many common tools and techniques, but the latter is more likely to achieve the finer pitch circuits required for medical devices. Typical trace and line widths are from five to ten microns with special features as small as two to three microns. Having up to six metal layers and dielectrics of sheet or spun Polyimide make these circuits functional and durable. With features this small, it is common for hundreds of devices to be fabricated from one base plate of 6.0 × 6.0 in. (typical size for prototyping and even production volumes). For larger quantities of production parts, the process can be scaled to substrates of up to 12 × 12 in., achieving a lower cost per part. Like moving to semiconductor solutions, there needs to be a volume and price payback to make the investment in capital feasible and worthwhile.

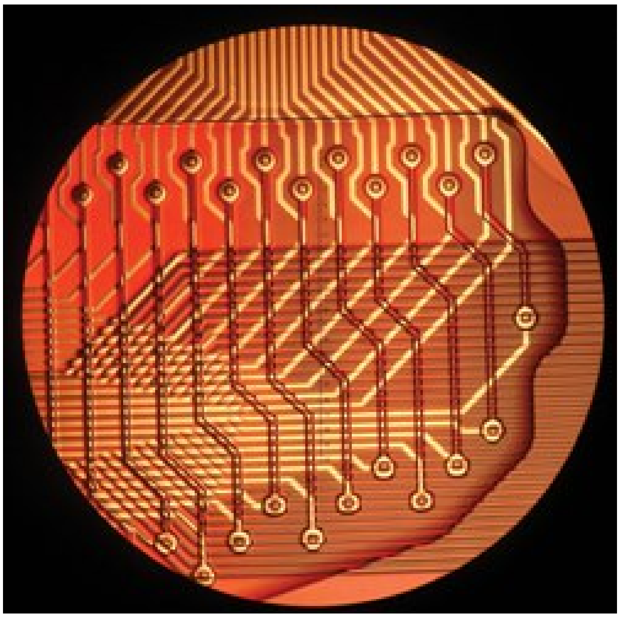

Figure 3: Multi layer medical circuit with formed vias

Material selection depends on a variety of factors—trace resisitivity, flexibility, layer count, dielectric needs, environmental factors, and cost. Often, the objectives to be achieved with the metal selection are not always compatible with the dielectric selection.

Device Purpose
For justifiable reasons, device manufacturers don’t want to divulge too much of what their device is doing in order to protect their intellectual property. However, failure to provide sufficient information early enough can lead to problems downstream as prototypes are tested. Issues such as flexibility, need for compressive or tension properties, environmental issues such as bodily fluids, whether the device will be conformally coated or not, and water permeability all affect the selection of, not only materials, but process steps in the fabrication cycle. The more the OEM can discuss its overall needs, the better the chance of success in the miniaturization process and achieving the OEM’s objectives. Many times, component manufacturers have gone down one path only to later uncover a design consideration that causes radical changes, impacting not only the cost and schedule of the development project, but potentially of the production targets as well. Especially with medical devices, the very small circuits need to be extremely flexible, often to be rolled and inserted into a catheter to attach a test device to the connecting cables. Bend radius structural loads and environment play an important role here as well.

Collaborative Process

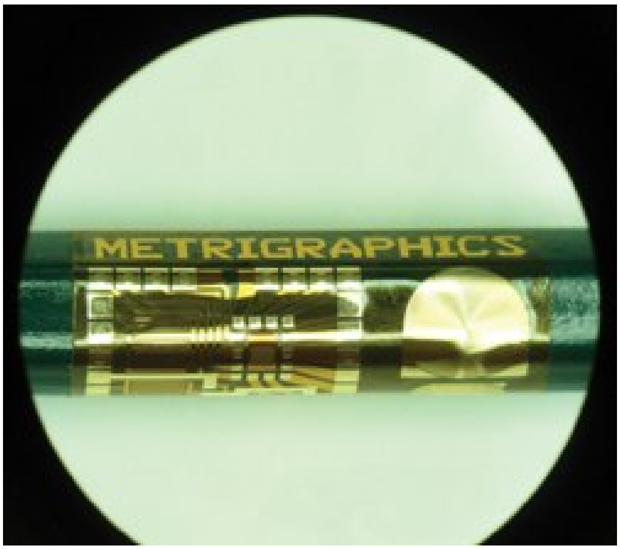

Figure 4: Metrigraphics sample wrapped around pencil to demonstrate ability to achieve small radius of curvature

The real secret to the successful miniaturization of medical circuits and components is how well the OEM and component manufacturer collaborate during the design and prototyping process. As indicated earlier, having a clear understanding of what the designer’s real objectives are offers a clearer insight into which processes are more likely to be successful. For example, with the circuit in Figure 4, knowing that the objective was for the assembly to be rolled (such as for a catheter application) helped in the selection of the materials and material thicknesses, as well as processes, that would provide the greatest flexibility while still maintaining dimensional and structure integrity.

In the final analysis, “making it smaller” is the easiest part. It is all the other issues that make it tougher. There is a great deal that can be accomplished in the area of miniaturization, but like everything, there are limits. Being able to identify and address them sooner rather than later is an advantage to both parties.

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Links:
[1] http://www.metrigraphicsllc.com/