Perspectives on Design Challenges

Would you please share one of the most challenging design obstacles you have faced in the development of a medical device?

Larry Carlberg
Services Manager, GKS Inspection Services, division of Laser Design

All manufactured parts, including medical devices, distort somewhat during the molding, casting, forging, or forming process due to various factors. Further processing steps can often result in even more distortion. When our medical device-maker customers are challenged by materials that distort in size and shape away from the original design, GKS helps to solve the problem with 3D laser scanning. Laser scanning quickly identifies the unplanned anomalies, giving the manufacturers accurate dimensional information about how much the mold needs to be adjusted in order for the parts to come out in spec with the design intent.

Larry Acquarulo
CEO, Foster Corporation

As interventional catheters target more distal vascular regions, devices are becoming smaller in diameter while inside diameters remain sufficiently large to allow for passage of instruments or fluids under pressure. This results in longer catheters with thinner walls. This is placing greater demands on materials to achieve device performance characteristics. Thin walls have exposed material property limitations of traditional polymers such as Pebax* polyether block amide and nylon 11. This includes flexural modulus, a key property linked to catheter pushability. As a specialty provider of custom polymer formulations for minimally invasive devices, Foster Corporation was challenged to provide polymer formulations that bridge the gap in flexural modulus properties between traditional polymers while retaining flexibility, processability, and appearance. To achieve this, Foster Corporation has incorporated nanoparticle reinforcements, with the dimensions less than a nanometer, in traditional catheter polymers. The result is a polymer formulation with appearance and processability similar to that of unmodified material. With nano technology, Foster Corporation has engineered compounds with 45% greater flexural modulus, while retaining flexibility of the base polymer.

Steve Sheehan
Director of Medical Industry Marketing, Hypertronics Corporation

A top-tier medical device customer approached Hypertronics in search of a “fail-proof” solution to address a serious and costly failed interconnect problem

emanating from a contact technology installed by a competitor. The customer was experiencing increasing intermittencies in a hand-held bone-drill due to increasing contact failure. A custom connector with a tulip-style contact system that was being used for the application served as the power and control interface to the drill console unit.

The failure mode was induced by cycling the drill on and off, and by vibration created by the internal motor. To address the customer's need for an alternative contact offering that would enhance the dependability of the drill, Hypertronics delivered a solution utilizing its high reliability Hypertac hyperboloid contact system.

Hypertronics engineered a custom contact that fit with the existing plastic housing in order to avoid additional tooling costs, while at the same time, dramatically increasing the reliability of the drill. In addition, the contact solution mated to existing male contacts in the field in order to support backwards compatibility.

Working in close concert with the customer, Hypertronics was able to provide a contact design that addressed the customer's need for a fail-proof solution while also showing true customer value in the design and capability of its interconnect offering.

Darrin Manke
Director and Program Manager, Farm

One key obstacle is successfully entering the healthcare market with a disruptive technology. A disruptive technology is a new technology that has the ability to create a new market and may eventually displace earlier technologies and/or methods of performing a task or procedure. This new method or technology must provide real improvements in performance, cost, time, features, clinical outcomes, and be easily adopted by existing users. User adoption is critical, which usually means the technology has to be designed in a way that it can be integrated into current workflow and methods, and not require extensive training. Easy integration means increased adoption and ultimately leads to market penetration.

Don Hannula
Principal Engineer, Specialty Silicone Fabricators

In the field of medical device development, there is a growing need for silicone balloons with specific compliance characteristics. Compliance is defined as a change in the balloon's physical properties as the balloon is inflated. Compliance is often measured as volume, pressure, and/or diameter while the balloon is filled past the nominal resting balloon geometry. Compliance is also an important component of medical device testing. A need exists for modeling arterial structures that mimic biological counterparts. Using these models, a medical device's function, effectiveness, and long term performance can be tested and predicted.

Designing a balloon to meet a given compliance specification was one of our most challenging obstacles. First, a mold was fabricated. Next, balloons of various durometers were molded. The balloons were attached to a pressure gage and fill syringe. Balloons were inflated from the nominal diameter to 126% fill while we documented fill volume, pressure, and balloon diameter. Balloon pressure and diameters were plotted as a function of fill volume for each durometer balloon. By interpolating the data, we determined the intermediate durometer. We then formulated a silicone of the calculated durometer by mixing two silicones of different durometers. Fabrication and testing of the balloons at the interpolated durometer silicone produced the expected results, successfully meeting the required balloon compliance characteristics.

Jacques E. Hoffmann
President, InterTech Development Company

A new standard of care for patients with renal failure has been achieved by home

dialysis machines, enabling shorter and more frequent treatments that virtually eliminate side effects.

The significant testing challenge InterTech faced with one such device was to ensure failsafe operation by confirming all valves and flow paths operate as designed: on a machine with 80 ports and multiple solenoid valves, conduct a total of 80 leak tests and 20 flow tests – in under ten minutes.

InterTech designed a multiple channel combination pressure decay leak test and mass flow test that enables asynchronous testing of up to four channels, important for cost effective test these home dialysis machines and other, complex multi-valve and multi-port medical products using our InterTech MED75-COMBO leak tester.

Asynchronous testing provides exceptional flexibility, as each test channel is able to run either leak tests or high flow tests. Testing proceeds along a flow path through the device. A solenoid valve is closed, a leak test is performed. The first valve is opened and the next valve in the flow path is closed and similarly leak tested – until the entire path is confirmed leak free.

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