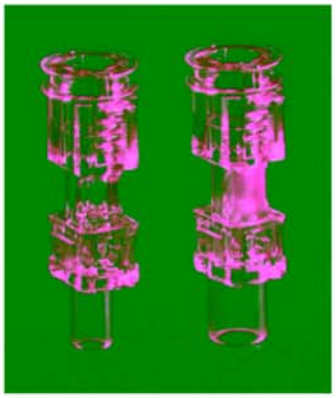


Silicone saddle molded on a polycarbonate connector used as a component in a drainage catheter (photo courtesy of Rogan Corp.)

Molders Address Leading Medical Device Issues

By Sean Fenske, Editor-in-Chief, MDT

There are many "hot button" issues that are of concern to medical device manufacturers. Bring up infection control, the upcoming UDI rule, or the movement of healthcare from the hospital to the home and an engineer should have something to say about at least one of those areas. It is likely that any one of those issues is a current challenge with a project or will be for the next product in development.

Since plastics are such a huge part of the design and manufacture of medical devices, the molders who work with the medical device OEM are doing everything they can to address these same issues to help alleviate the challenges faced by engineers. Fortunately, getting the molder involved early in the design process enables them to help "attack" these areas of concern.

Battling HAIs

Due to the change in the rules for reimbursement from healthcare associated (or hospital acquired) infections, hospitals and healthcare providers are seeking solutions that will reduce the likelihood that germs can be spread. As such, molders are offering several solutions to help device makers answer this call.

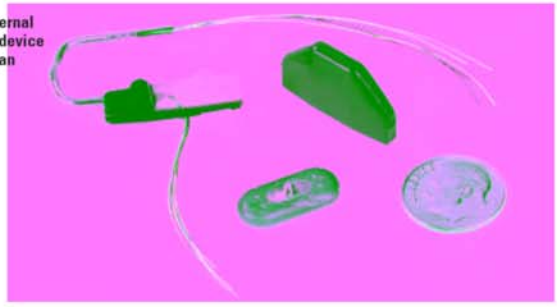
For materials used in the surgical suite, it is critical that they be able withstand harsh cleaning agents, gamma radiation, and the autoclaving process. The focus on patient safety and infection avoidance is tightened each day; materials must be able to meet the challenge," explains Randy Pell, senior staff design engineer at MackMedical/Mack Molding (www.mack.com).

It goes beyond the surgical suite, however, as all areas of a healthcare facility need to be maintained such that the chance of infection is significantly reduced. "It is essential that molded medical device parts be biocompatible, including being hypoallergenic and hygienic, giving bacteria and fungi little chance to grow and spread, and bioabsorbable where applicable," states Jim Ritzema, director of operations and technology at Rogan Corporation (www.rogancorp.com).

Home Healthcare

As more medical devices are used in the home by the patients themselves, device manufacturers realize new factors that are necessary for their products that can differ from those used in the hospital. The appearance of a device becomes a much greater issue for the designer than perhaps previously. Everyone wants a device to be designed well, but whereas the aesthetics may have been much lower of a concern in the past, with home-based or mobile products used on the go by the patient, appearance and discreetness is of great importance. Fortunately, molders can aid with this as well.

Stephen Lee, business development manager at Pelham Plastics Corp. (www.pelhamplastics.com) is aware of this trend and the needs of the company's customers as well as the patients. "As a custom molder and component assembly company, we are focused on providing capabilities



Components for an external hearing enhancement device (photo courtesy of Rogan Corp.)

that meet the shifting needs of our customers. We expect the move toward home healthcare and patient-based devices will result in new aesthetic and functionality requirements of devices, and the molded components from which they are comprised."

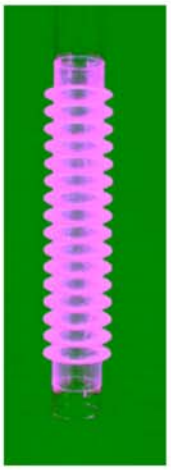
David Johnson, engineering manager at Advanced Molding Technologies (www.advancedmt.com), along with his team, points to a number of areas where his company is addressing the needs of device OEMs working on products for the home environment. He lists solutions that include soft-touch overmolding, human factors prototyping, higher-volume cleanroom molding, pad printing and other decorating at the molding machine, more mechanization and automation at the molding machine, molders more involved in material selection, and chemical stress testing.

Material Selection

If the average MDT reader represents the medical device engineering community as a whole, materials are very high on the list of areas of interest. As such, material selection for the designer is a critical process as it is ideal to get as much benefit from the materials being used in a device as possible. Working with the right molding partner can certainly help in that regard, as they are much more intimately familiar with the available materials and what each offers for a given project.

When it comes to material selection, Jason Meslin, senior industry manager of healthcare – thermoplastics at PolyOne Distribution (www.polyone.com), speaks to the importance of taking the full value of the material into consideration rather than just the price point at the time of purchase. "Too often a designer goes from a strategic perspective to a tactical one by concentrating on price. We often talk with our customers about comparing the overall cost or impact of a using one polymer versus another. Price represents one point in time whereas cost takes into consideration the entire supply chain and manufacturing process. The medical device designer who is best able to look at an application from the polymer perspective and focus on cost versus price will be the designer who gets to market faster and stays there at a lower overall cost."

More specifically to the advantage materials can offer to the device designer, Mark McCourtney, director of sales and marketing at JunoPacific (www.junopacific.com), lists many of the most critical factors engineers are seeking from the material. "Impact resistance for hand-held devices that are likely to get dropped, biocompatibility, melt-flow for thin wall and micro-molded components, and flexibility for snap and press-fit assembly" are all important factors for engineers, McCourtney states. He goes on to say that "designers should also consider pre-colored vs. colorant as colorants can affect flow and biocompatibility." Still other factors of significance



This image shows 0.008 in. silicone ns over-molded onto a polycarbonate tube. It is used as a cervical seal during uterine ablation (photo courtesy of Rogan Corp.)

for medical device designers include llers, such as glass ber/ bead and carbon ber, etc. Fillers can add strength and conduct electromagnetic energy.

UDI Compliance

Soon, device makers will be required to identify every medical device being produced with its own unique device identi er. This will need to be on the device directly in the form of a traditional barcode, 2D DataMatrix barcode, embedded RFID tag, or some other format that is compliant with the regulation.

Molders offer a number of solutions to aid in this effort that can save the device maker additional investments in equipment or adding an extra step in the production process.

Molders have several ways to help device manufacturers meet UDI requirements. In-mold decorating capability can make the unique identifying code and any necessary part identi cation codes an integral part of the component, explains Ritzema. Permanent engraving of the code into the tool steel can achieve the same result more cost-effectively than in-mold decorating, as long as the component is to be used in one device and not in multiple devices. Another possible option is a removable engraved tool steel insert.

Johnson offers another solution, Medical molders can help facilitate the unique marking of individual devices by working with material suppliers to recommend base resins or additives that react favorably with speci c wavelengths of lasers to promote readability for devices that are being marked directly with a laser unit.

Looking Ahead

Molding and medical make for a couple that is not soon to separate. Plastics are a major part of just about every area of medicine and that's not going to change in the near future. Looking ahead, the roundtable participants see this trend continuing, offering a relationship between the molders and the device manufacturers that leads to a greater degree of innovation for healthcare technology.

We see no sign of medical molding slowing down. If fact, we see the increasing need and bene t for more comprehensive collaboration with our customers. Demand for greater product performance, such as burst pressure in a catheter device, with decreasing part sizes and wall thickness requires that we work with product designers earlier in the process to ensure parts are designed for manufacturing, says Lee.

McCourtney offers a similar view, We will continue to see a push for smaller components, faster development time and manufacturing cost-downs. Medical device companies are driving toward devices that are less invasive, disposable and lower net cost. I think we will see a major shift in manufacturing technology with the development of high resolution 3-D printing equipment for metals and plastics. The ability to produce 'one-off' custom components/ devices without tooling will drive the patient-based device market.