

NEW PRODUCTS, MATERIALS & COMPONENTS FOR MEDICAL DEVICE DESIGNERS

## Companies Team to Create New Dialysis Products

*New Development Promises Reduction in Cost and Infection Rate*

**P**olyzen, Inc., a developer and manufacturer of specialty disposable components and devices for medical industry OEMs and custom dip molding firm, has teamed with Med-Conduit, Inc. to develop a revolutionary new percutaneous access device. By merging a model of human biology and high-performance dip molding techniques, Polyzen has made it possible for Med-Conduit to cost-effectively produce limited production runs of their innovative products without developing costly molds, while adhering to extremely precise manufacturing standards.

Dr. Gerald Bousquet, MD, President of Med-Conduit, is the inventor of a percutaneous access device for peritoneal dialysis. The conduit he developed is appropriate for patients who need the device for longer than four weeks. In developing his product, Dr. Bousquet needed to find a way to make a conduit that displayed the properties of flexible, thin-walled medical tubing, contained several component details within the part, and could be produced at a reasonable price. He chose to work with Tilak M. Shah, President of Polyzen, Inc. be-

cause he could get the quality needed at an economical price.

When Dr. Bousquet began his search for a manufacturer for this product, his chief engineer at Med-Conduit, Joe Antocci, recommended the North Carolina firm, Polyzen. After a meeting with Tilak Shah, Dr. Bousquet was convinced that the firm had the medical device expertise and experience to create the features his product needed. "At each phase of the project, Polyzen was a key partner in development. They were willing to work with us in the design phase of the project to make the product a success, and their enthusiasm was infectious," said Dr. Bousquet. "The value-added was tremendous—without their design know-how, materials expertise, and dip-molding skills, we might still be looking at the drawing board," says Dr. Bousquet.

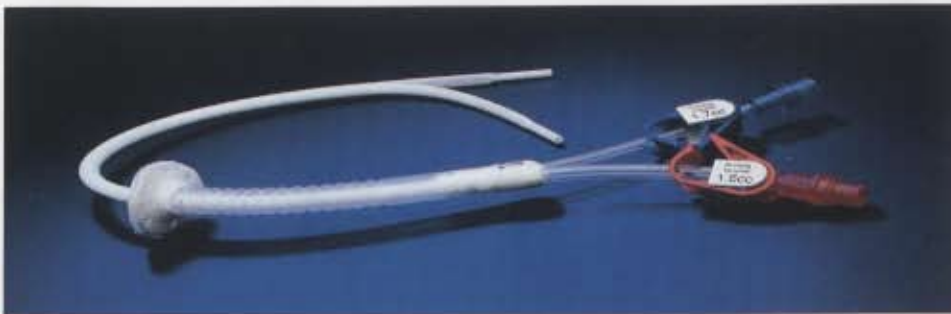
### **Dip Molding Provides Solution**

Dip molding offered the solution that Med-Conduit needed to get off the ground. The dip molding process is unique in the medical polymer design business because it uses low cost molds

and specially designed equipment. In this instance, Polyzen began working on this project by asking many questions about how the part would be used. After an extensive R&D program, where the firm streamlined the part design, Polyzen crafted a mandrel that would become the pattern for the part. Some of the challenges that needed to be met in the design included the inclusion of an accordion section, a cuff, and a component to anchor the conduit in the body. Although small and detailed, Polyzen's machinists were able to create a stainless steel mandrel that incorporated these features.

The next step in the dip-molding process is the actual "dipping." The mandrel is dipped up to four times into the polymer solution to form the desired thickness, after which the shape is baked until it hardens. At this point, the part can be peeled from the mandrel. "This process is more an art than it is conventional manufacturing," said Tilak Shah. "We control the thickness of a part through the number of times we dip it, and we constantly control the quality by monitoring the product in each phase of development," Shah added.

What keeps the part strong is the proprietary formulations of the polymers. The staff at Polyzen is specially trained in this process, and the firm is one of fewer than 4 in the United States that offers this specialized manufacturing service. Shah developed the technique in 1987, when he was developing ways to fabricate gloves and condoms from polyurethane. At the time, latex was the only material used in this application. Latex allergy issues con-







vinced Shah to develop dip molding techniques using polyurethane solutions. These were made possible with chemical modifications to the polyurethane that bolster the many advantages of the material over latex. With the Med-Conduit product, the combination of medically approved materials and the cost-effective dip molding technique proved essential in its development.

Dr. Bousquet began working with the idea of a biologically sealed conduit in the 1980s, with a product called the Dermport. Although excited by the potential of the product, the initial backers went away when the market shrank. Undaunted, Dr. Bousquet pressed on and formed his own company in 1997—Med-Conduit Inc. His goal was to produce a technology that would significantly reduce the probability of infection in dialysis patients, thereby enhancing patient comfort and quality of life.

The impact of the new technology pioneered by Med-Conduit is far-reaching. The major hurdle that a polyurethane percutaneous access device must clear is reducing the incidence of infection. With current technology, within twelve months, nearly 100% of patients with catheters have an infection in or around the catheter site. An infection on the surface of the skin is unsightly and oftentimes painful, but the real danger lies when an

infection gets inside the body. With the catheter serving as an ideal portal for infection, a patient has a 50% chance of developing bacteremia, a condition where bacteria infect the bloodstream. In those patients who develop bacteremia, 15% to 20% of cases are fatal, with the infection spreading into the body, causing abscesses in the brain and/or lungs. In addition to health risks, there is a heavy price tag for dialysis patients as well.

#### **Med-Conduit Device Trims Dialysis Expenses**

The financial cost of dialysis is high. On average, the per annum cost to treat a dialysis patient with a catheter is \$8,500, and roughly 200,000 Americans receive frequent dialysis treatments. As much as half of this cost is due to the high rate of infection, which must be treated with antibiotics in a continuous treatment plan. A fixed cost of treatment are the many man-hours spent by medical staff cleaning, irrigating, and improving the unsightly appearance of the percutaneous access port during routine dialysis sessions. With up to 75% of catheters removed due to infection, many dialysis patients are on a treadmill of medications to treat a problem that is the direct result of a design that promotes infection.

With plenty of evidence that the current technology is inadequate, Dr. Bousquet realized that a new paradigm was needed. Inspired by human biological models, Dr. Bousquet sought to replicate conditions in the body where a component projects through the skin. He found a working model in the tooth, where the bone projects through the gums, without infection. The tooth is a naturally occurring percutaneous organ, where a dense collagen barrier appears to inhibit epithelial migration to the tooth. Epithelial migration inward, towards the subcutaneous tissue creating a sinus between the surface of the skin and tubing, creates the potential for infection. Dr. Bousquet's approach was to replicate conditions found at the base of the tooth, noting that a successful outcome required a porous device at the surface of the skin that allowed for the

dermal cells to penetrate the interstices of the device and deposit collagen. The collagen anchors the device in situ, and serves to chemically inhibit epidermal mobility. In this way, a biologic seal is created. "An overshoe that fits any shoe," is how Dr. Bousquet describes the product. By sealing the conduit at the source of infection, the problem of the portal of entry is solved, and with it the complications of infection.

#### **Conduit Is Infection-Free for up to 51 Weeks**

The device is installed surgically in an outpatient facility. Clinical trials have shown that the conduit has lasted for up to 51 weeks, infection-free (the patient had it removed for non-medical reasons—the device was in excellent condition when removed). A notable advance with the Med-Conduit product is that the maintenance of the patient's conduit is a simple cleaning with soap and water. Protected by a patent, Med-Conduit is in the second phase of the design. New additions include bellows to allow the conduit to move with the patient, up to three inches outside the body. Also, a hydrophilic collar has been added, to absorb water and anchor the conduit securely in place.

Polyzen is a leading manufacturer of specialty and disposable components and devices for medical industry OEMs. Polyzen specializes in taking a project from conception all the way through to final production. The firm offers an array of services including extremely quick turnaround time, high quality products, technical expertise, and dependable service. Polyzen manufactures low pressure balloons, stent and scope tubing coatings, organ/tissue bags, protective barrier sleeves, clear probe covers, urethane bladders, thin wall films, and does various device assembly, among others.

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