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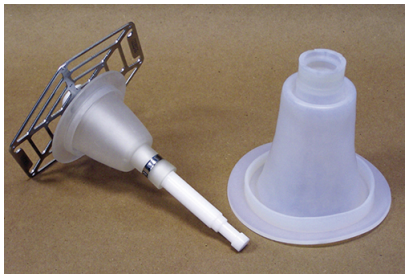
From speech therapy devices to diaphragms and tubing

Medalist TPEs open up new applications in the medical field



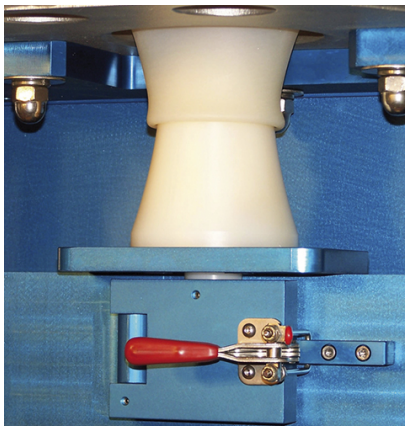
Bell-shaped diaphragm made with Medalist MD-140 standing alone (r.) and as part of assembly (l.) including shaft and slotted metal mixing disk. The polyethylene mixing bag (not shown) is welded to flange at the base of the diaphragm.

Rugged TPE diaphragm maintains seal on fast-cycling disposable system

An injection-moulded elastomeric diaphragm that constantly rolls and unrolls over the drive shaft of a mixer is a critical component in a patented single-use mixing system that enables pharmaceutical manufacturers to prevent cross-contamination while eliminating the need for cleaning and sterilising traditional stainless steel equipment between batches. HyNetics Corporation introduced its first system of this type in 2002, but for the diaphragm it recently switched from a conventional thermoplastic elastomer to Medalist MD140 medical elastomer from Teknor Apex Companie.

The bell-shaped diaphragm is welded to a polyethylene bag that serves as a mixing chamber. It provides a seal between the bag and a shaft affixed to a mechanical drive that is part of the permanent hardware for the HyNetics system (fig. 1). Inside the bag, the shaft connects to a slotted disk which moves up and down to provide mixing action. To maintain a seal during each up-and-down cycle, the diaphragm rolls and unrolls over a mandrel located below the diaphragm (fig. 2). HyNetics supplies the bag, disk, diaphragm, and other components as a disposable assembly used for a single pharmaceutical batch.

"We switched to the Medalist medical elastomer for the diaphragm after conducting an extensive search for a compound that would weld readily to polyethylene, be free of animal-derived materials such as stearate lubricants, and provide superior mechanical properties," said Kenneth L. Bibbo, Vice President of Operations for HyNetics. "In view of the dynamic function of the component, we were particularly concerned about eliminating stress cracks that had occurred with the earlier material." The Medalist compound proved highly resistant to stress cracking. "We subjected diaphragms made of each material to rolling/unrolling cycles of two per second," Bibbo said. "The standard TPE failed after 50,000 cycles, while the Medalist part continued working through a million cycles."



Rolling diaphragm shown as installed in the HyNetics hardware. The elastomeric diaphragm (large white component at top) rolls and unrolls over a nylon mandrel (large white component beneath the diaphragm). Just visible below these components is part of a third white component, the drive shaft.

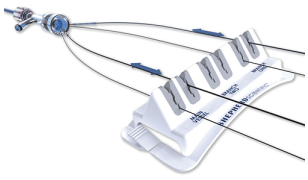
Another issue cited by Bibbo for the previous TPE was that of leachables and extractables. The Medalist elastomer provided greater assurance of purity, since Teknor Apex warrants all Medalist compounds to be free of animal-derived materials, phthalates, latex, and additives not directly required for medical applications.

HyNetics reports that its system is used to mix powder/liquid or liquid/liquid ingredient combinations, hydrating powders in five minutes or less and efficiently mixing materials that are difficult to process or are shear-sensitive. The system includes permanent stand-alone hardware in six sizes from 30 to 5,000 liters, with corresponding disposable assemblies. The mixing disk operates by moving up and down, not rotating. Mixing speeds are variable from mild to aggressive agitation, and mixing action is consistent from full to empty.

"The diaphragm in the HyNetics disposable mixing system is an excellent example of how Medalist medical elastomers can help material specifiers design, develop and bring their products to market," said Nick Sandland, Senior Medical Market Manager for the Thermoplastic Elastomer Division of Teknor Apex. "The Medalist range of medical elastomers has been well received in the marketplace because it is supported by a comprehensive set of data and regulatory compliance certificates, enabling people to have greater confidence in the materials they are selecting at an early stage in product development."

HyNetics Corporation, a subsidiary of Turnkey Modular Systems Inc., is located in Warminster, PA, USA.

TPE in new device for organising catheters and guide wires in minimally invasive medical procedures



The new Teirstein Edge device allows interventionalists to organise catheters and guide wires at a site just prior to insertion of the wires into the catheters. The ABS bondable medalist grade provides the required level of rubber-like performance.

Bondability to ABS and regulatory pre-compliance have enabled a Medalist TPE to play a key role in a device that simplifies the delicate and often complicated deployment of catheters and guide wires for interventionalist procedures, which are less invasive alternatives to surgery. Interventionalist methods, such as the placement of stents to open blocked arteries, typically require the insertion of catheters with guide wires into blood vessels and may involve more than one pair of these devices, as in the case of blockages in both main and branch arteries. The new Teirstein Edge device, developed by Paul S. Teirstein, M.D., lets interventionalists organise catheters and guide wires at a site just prior to insertion of the wires into the catheters, keeping them

neatly separated and readily identifiable while allowing precise control of their movement during procedures (fig. 3). The device incorporates clips for attachment to surgical towels and has a curved underside that enables it to lie on a flat surface or over a patient's leg.

Using two-component injection moulding, elastomer specialist Da/Pro Rubber, Inc. produces the Teirstein Edge device for Dr. Teirstein's company, Shepherd Scientific. Da/Pro moulds Medalist MD-305 elastomer onto six sites in a one-piece ABS base, forming slits for the placement of up to three catheter/guide wire pairs (fig. 3). The rubber-like traction of the Medalist compound and its elastomeric "give" combine to enable the slits to hold the catheters and wires securely while permitting them to be adjusted or removed without being bent. The intricate design of the inside edges of the slit accommodates devices of different diameters and permits forward and backward movement or, at the bottom of the slits, no movement at all.

"Because interventionist practitioners are hypersensitive to the 'feel' of the devices used in their procedures, we went through a number of prototypes, varying the slit geometry and durometer until we arrived at just the right combination," said William D. Morrison, plant manager at Da/Pro's facility in Newburyport, MA, USA. "We considered several other thermoplastic elastomers but chose the Medalist compound because it chemically bonds with the ABS substrate and was already compliant with the relevant regulations."

Shepher Scientific, founded by Paul S. Teirstein, M.D., is headquartered in La Jolla, CA.
Da/Pro Rubber, Inc., a custom moulder of rubber, TPE, and plastic products, has facilities in California, Massachusetts, Oklahoma, and Singapore.

High-purity elastomers speed regulatory compliance of speech therapy devices

The therapeutic chew tools can be supplied with various flavours. This makes them more attractive for children and facilitates the work of the therapist.

A supplier of tools to aid in speech therapy has switched from conventional thermoplastic elastomers to Medalist TPEs, citing advantages in compound selection, blending, moulding, and resistance to chewing and other rugged treatment.

Ark Therapeutic Services, Inc., owned by speech-language pathologist Debra C. Lowsky, MS, CCC-SLP, and her husband John Lowsky, a mechanical engineer, is a company that designs, manufactures, and distributes speech and occupational therapy tools and other healthcare products. Many of its devices are for use only by professional therapists or trained caregivers to help correct sensory oral motor problems by stimulating muscles that correlate with specific movements of the lips, tongue, jaw, etc. Ark Therapeutic Services now uses Medalist elastomers for the soft tips of oral probes, a complete line of chew tools (fig. 4, 5), and the Z-Vibe vibratory tool. Non-speech applications of Medalist elastomers include lids for the Sip-Tip liquid feeding cup and the E-Z Eye Med dispenser for eye medicine.

The Medalist programme for medical manufacturers now includes 28 standard high-purity elastomer compounds, along with test data and resources for designers and processors. Compounds are available with Shore A hardness from 5 to 87 and include clear, translucent, and opaque formulations.

The Tri-Chew is designed with ridges, bumps, and swirls on each end to simulate the various textures of food used for chewing.

The company's switch to Medalist compounds was prompted by its plan to obtain the CE mark, which requires subjecting each raw material to costly and stringent biocompatibility tests to meet European Union standards. "Every grade in the Medalist range of compounds has already been pre-tested for cytotoxicity, one of the three biocompatibility categories required," said Lowsky. "In addition, we found that we could use four different Medalist compounds to produce the same number of applications that previously required eight or nine grades of the other elastomers. The Medalist compounds blend very readily, enabling us to vary durometer without increasing the number of materials in our inventory." The Medalist compounds are also easier to process, noted Lowsky. Cycle times are shorter, and there is no need for processing aids, additive lubricants, or silicone releases.

One unlooked-for advantage of the Medalist compounds was their superiority in the special type of toughness required for oral tools to endure during repetitive biting and chewing exercises required to improve feeding skills. "We built our own machine to test what we call 'chewing cycle durability' by simulating the biting of one of our oral therapy tools at different frequencies–for example, one chew per second," said Lowsky. "While a tool made from a well-known standard brand of elastomer began to break down after 80,000 cycles, the same product moulded from a Medalist compound withstood 120,000."

The Medalist MD-500 series compounds exhibit crystal clarity and mechanical properties comparable to those of PVC.

Recently Ark Therapeutic Services began redesigning its Z-Vibe tool to make it a one-piece product of all-elastomer construction. Until now this has been a two-part product, with an elastomeric tip and a polypropylene handle. Inside the handle is a tiny battery-powered motor that provides the vibration. Ark Therapeutic Services began switching to Medalist compounds six months ago. Lowsky credits Teknor Apex for its technical support and responsiveness, including speed in providing samples for product development. The company uses three different grades from the Medalist Versatile series, with Shore A ranging from 43 to 87. As with all materials that Ark Therapeutic Services uses for oral tools, Medalist compounds are compliant with regulations of the Food & Drug Administration and are latex- and phthalate-free.

Ark Therapeutical Services, Inc., headquartered in Lugoff, SC, USA, produces a wide range of speech therapy tools and healthcare products.

TPEs for medical tubing perform like PVC and provide superior gamma stability

Medalist TPEs can provide a fully practical alternative to PVC for many tubing applications. The new Medalist MD-500 series compounds exhibit crystal clarity and mechanical properties comparable to those of PVC (fig. 6). They provide similar clamp resilience and resistance to kinking and necking, they have a PVC-like "feel", and are substantially more flexible and significantly less dense. At the same time they undergo minimal colour shift upon heat ageing after exposure to gamma irradiation. A typical compound in the series, Medalist MD-575, actually exhibits 70 % less heat-aged colour shift than a gamma-stabilised PVC compound of comparable hardness (tab. 1).

Property	Test method	Medical grade compounds for tubing		
		Standard PVC	Gamma-stable PVC	Medalist MD-575
Specific gravity	ASTM D792	1.20	1.20	0.88
Shore A hardness (15 s delay)	ASTM D2240	75	75	72
Tensile strength, psi (mPa)	ASTM D412	2,150 (14.8)	2,150 (14.8)	1,961 (13.5)
Tensile stress, psi (mPa)	ASTM D412	900 (6.2)	900 (6.2)	623 (4.30)
Tensile elongation, %	ASTM D412	420	420	722
Colour shift, post-gamma[1], ΔE	CIELab	2.55	1.42	1.91
Colour shift, post-gamma, heat aged[2], ΔE	CIELab	10.52	7.01	2.02
[1]Dosage at 30 kGy - [2]Accelerated ageing at 50 °C for 48 h to simulate field performance				

Comparison of some key properties of PVCs and Medalist MD-575

"Medalist MD-500 series products outperform traditional PVC-alternative technologies by mirroring many of the performance and handling characteristics of flexible PVC tubing compounds, while providing distinct advantages in some key capabilities," said new business development specialist Elliott Pritikin. "These new crystal clear elastomers add to Teknor Apex's 30-year track record in tubing compounds, one that also includes such flexible-PVC innovations as gamma-stable, non-DEHP plasticised, and even non-plasticised compounds."

Medalist MD-500 series elastomers have been tested for compliance with ISO 109935 cytotoxicity standards and are free of animal-derived materials, phthalates, latex, silicones, and additives not directly required for medical applications. Standard formulations include five grades, with Shore A hardness (15 s) ranging from 53 to 86.

At K show Teknor Apex UK Ltd. will highlight two of its product ranges: thermoplastic elastomers and engineering thermoplastics. The company has manufacturing facilities for both types of compound in the UK. Three developments will be in the spotlight in Düsseldorf:

- *Teknor Apex has agreed to purchase the Sarlink TPV business from DSM. While the Sarlink team will be exhibiting with their distributor Ter Hell at K (hall 8a, stand K08), at the Teknor Apex stand (hall 8b, stand E83) there will be much discussion of how the acquisition will benefit TPE customers of both Teknor Apex and Sarlink (see also p. 193 of this issue).*
- *Medalist medical elastomers, introduced only two years ago, are now being used successfully in diverse applications (see above).*
- *The ETP Division of Teknor Apex UK will feature new formulations and applications for its reinforced and specially modified compounds of polyamide 6, 6/6, 6/10, and 6/12 under the Chemlon and Beetle brands.*

Adresse:
http://www.gupta-verlag.com/general/news/k-2010/8762/from-speech-therapy-devices-to-diaphragms-and-tubing