KYDEX THERMOPLASTIC SHEET

Restorative Care

Thermoforming Plays Critical Role in Enhancing Orthotic Devices

Leap in Orthotics Design

Restorative Care of America Inc.'s first stride into the design and manufacture of orthotics came decades ago when it launched its patented Multi Podus System®. The MPS is a high-performance version of the Ankle Foot Orthosis (AFO), the most widely used of orthotic devices. The forward leap in orthotics design, evident in the MPS, primarily springs from RCAI's innovative use of thermoformed plastics in several of its most critical components.

"Our combination of a proprietary drape-forming process and specially chosen thermoplastic sheet made the significant advances achieved in the MPS feasible," says Connie Wasserman, RCAI's product manager. The MPS, as with other orthotics, is designed to assist in the restoration of limbs — in this case it correctly positions the foot and ankle during a long rehabilitation process.

The upgraded (Phase II) version of the MPS provides controlled static stretch of foot and ankle muscles, by virtue of a drape-formed splint and adjustable metal turnbuckles.

Today, drape forming is still used in the latest version of the ever-evolving MPS for the splints (which support limbs) and separator bars (that spread the ankles apart by a set distance). To supplement drape forming, RCAI recently added capability for the vacuum forming of deeper-drawn components.

RCAI has subsequently continued to expand its use of drape and vacuum-formed components in splints, cuffs, stays, hinges, braces, joints and other parts for many of the roughly 70 different orthotic products making up its current full-service line. Some 12,000 custom components are drape formed monthly using the selected thermoplastic sheet at the company's 75-employee manufacturing site in St. Petersburg, FL, along with about an equal number of additional parts that are vacuum formed using the alternative thermoplastics.

Production

Thermoforming is increasingly being used to enhance RCAI's broad product slate, which now includes orthotics for the ankles, but also for arms, wrists, fingers, knees, elbows and hips. The company's products also utilize formed plastic parts to tackle specific ailments (e.g. carpal tunnel syndrome) and the broader age and size (e.g. geriatric and pediatric) requirements that orthotics are being designed to meet. A 30-member sales team markets RCAI's proprietary orthotics directly to buyers in hospitals, medical centers and rehabilitation centers across the nation.

According to Wasserman, orthotics' design traditionally depended heavily on aluminum and stainless-steel parts, one consequence being that the devices generally have been subject to several serious deficits. Conventional orthotics often exert pressure on sensitive body areas in a manner that can contribute to body sore development. Further, orthotics once placed in the field, tend to be extremely difficult or even impossible to adapt in line with any progressive changes required in courses of treatment prescribed for each individual patient.

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Strides in Thermoforming

RCAI recently extended its capability to also include vacuum forming of orthotic parts that require high levels of blow-up ratio, more variable wall thickness profiles or properties realized only when alternative thermoplastics are used. Examples are PE parts used on the Universal Wrist Thumb Spica, PE shoe insert components and nylon hinge, support plate, ball and socket joint and other parts. In a different twist, the toe support plates on the current MPS are injection molded out of a glass-reinforced nylon (by an outside molder) as a way to boost the strength of this breakage-prone part.

The Respond Range of Motion (ROM), Elbow Orthotic uses drape-formed humeral and lateral cuffs to secure the limb. The cuffs are easy to modify to conform to individual arm sizes.

"Virtually all of the many hundreds of different parts used in our orthotics are made and assembled under one roof in St. Petersburg," states Bud Hess, RCAI's chief operating officer. He says strong cost pressures in recent years have driven many U.S. orthotics suppliers to manufacture their parts off-shore. But Hess says the made-in-USA approach continues to work well for RCAI. He credits in part the low scrap and reject rates for drape and vacuum formed parts, plus ability of the technologies to meet demanding just-in-time inventory requirements vital in the customized orthotics business.

In addition to thermoforming, RCAI does most of its own metal component fabrication (e.g. high-load splints, hinges and braces) and flexible liner (e.g. foamed rubber, synthetic leather and textile) manufacturing at the plant. Sewing and assembly of rigid and flexible parts is also largely done in-house. RCAI achieves turnaround times for custom plastics parts of three to four weeks, versus typical 10-week times for competitors who depend on parts made off-shore.

Drape-Form Method Offers Design Freedom

"RCAI sought out a material that would permit splints to exert steady counter-pressure during rest periods or ambulation, while at the same time ensuring that the ankle consistently stayed in an upright position during extended use cycles," says Wasserman. That required a material providing an appropriate balance of tensile strength and toughness, and prompted RCAI to adopt 0.125- to 0.187-inch thick, virgin and recycled-content thermoplastic sheets in several colors supplied by KYDEX, LLC, in Bloomsburg, PA, and sold under the KYDEX® sheet trade name.

The Dorsal Resting orthotic employs a drape-formed shell that is easy to modify and conform to individual positioning needs.

In addition to imparting "dynamic memory" to MPS, drape-formed thermoplastic parts also open new potential in orthotic device design freedom. In particular, the approach makes it feasible to design orthotics that eliminate pressure points (e.g. by sculpting out empty space at the offset heel of the MPS), the outcome being the reduced risk of contact sore generation.

Drape molding also permits RCAI to exploit the ability of thermoplastic parts to be reheated and reshaped in the field, says Wasserman, in a reference to the ability of medical practioners to soften a part or region using a heat gun to reheat the plastic to around 150F. "Heat molding," in turn, permits parts to be manually bent or adjusted in their shape, diameter, angle of positioning or permitted range of motion. In this manner, splints on various orthotics can easily be repositioned at a new angle, or modified in terms of range of motion setting as prescribed by the progressive treatment regimen.

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The heat moldability of drape-formed thermoplastic parts also means that orthotics (supplied in basic pre-fabricated sizes) can be more accurately custom-fitted to individual limb size or conditions (e.g. degree of swelling). Further, the diameter of a holding cuff can be modified to ensure a precise fit around any affected limb. According to Wasserman, "KYDEX® sheet allows parts to be adjusted innumerable times without compromising tensile strength or other key properties."

Multi Podus System® (MPS) uses a drape-formed splint to impart spring-back properties for foot and ankle positioning over a long product life.

Steven Sensabaugh, RCAI's materials manager, says drape-molding brings other benefits to orthotics design. RCAI's process involves the feeding of a pre-cut 4 × 4-ft KYDEX® sheet into the oven for heating to around 295˚F, i.e. considerably below the thermoplastic's 320-390˚F melting point range. The semi-molten sheet is then machine-stamped into templates of various parts optimally arranged to keep sheet scrap rates at around 3%. Templates are CNC-routed to guarantee smooth, uniform edges, gently reheated to around 295˚F, then loaded in a cold male-female mold, cooled and extracted. Sensabaugh says drape forming yields parts that have minimal built-in thermal stresses, exceptionally low and predictable shrinkage rates and highly uniform wall thicknesses. Reject rates are extremely low.

RCAI currently uses KYDEX® sheet in splints for the MPS, but also the Dorsal Carpal Tunnel, Opponent Hand and Resting Hand Orthotics, plus the Range of Motion (ROM) Knee and Pediatric Dorsal Wrist Splints. The sheet is also used for the humeral and forearm cuffs of the Post-Operative Arm Brace and thigh and calf cuffs for the ROM Knee Splint. And KYDEX's material is used in adjustable, removable stays for the Elbow Stabilizer and adjustable wrist parts for the Pediatric Contour Hand, with components being designed to control or limit the range of movement.

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