Bolstering mobility

C-Pro Direct chooses Eastman Tritan™ copolyester for its next generation orthopedic brace.

To improve durability and eliminate stress fractures, C-Pro Direct and injection molder Omega Plastics collaborated with Eastman's Specialty Plastics team to improve a state-of-the-art foot brace: the Abduction Dorsiflexion Mechanism (ADM), which represents a major advancement in ankle–foot orthosis technology.

"The ADM can benefit the one in one thousand children throughout the world affected by clubfoot and is also helping children with neurological conditions, such as cerebral palsy, to walk better and improve their balance," said Philip Morris, Director of C-Pro Direct. "As an engineer and a father to a son with clubfoot, I created the ADM so children could live active lifestyles with a safe, reliable brace that allows them to be fully mobile."

The ADM is the only device of its kind that supports fully functional triplane foot motion, without any impact to the hips or knees. Unlike other foot abduction braces, it can be worn unilaterally and is more comfortable than alternative Ankle Foot Orthoses (AFOs).

To help prevent sudden unprovoked breakages in the device, C-Pro Direct chose BPA-free Eastman Tritan™ copolyester.

"Eastman offered a material that allows a rigid structure and thin components that don't degrade over time, so sudden fractures are less likely to occur and are not as harsh if they were to occur," said Morris. "Tritan allows us to improve the ADM without increasing the size and weight. Since the update, no fractures have occurred."

First made with polycarbonate, ADM launched in 2014. But there were reports of unpredicted stress fractures. To understand the cause of the breakages, C-Pro Direct and Omega Plastics turned to Eastman for help analyzing the ADM's parts. After testing existing molds, the Eastman technical team suggested Tritan and an adjustment to a metal insert that is manufactured with plastic molded over it.

"Through our test molds, we were able to formulate a solution to the unpredictable breaks that were limiting the full potential of the device," said Ferdi Faas, market development manager for Eastman Chemical Company. "The collaboration with Omega Plastics made incorporating the new Tritan part seamless so the product can continue its success."

The ADM is available worldwide and can be purchased online (www.c-proddirect.com) or through an orthopedic doctor. **For more information on how Tritan can improve medical devices, visit www.eastman.com/medical.**

EASTMAN

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Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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