

Risks associated with the use of PVC-based plastics in Orthotics

William A. DeToro, CPO, LPO



1399 E. Western Reserve Road, Poland, OH 44514-3250 • (800) 837-3888
www.anatomicalconceptsinc.com

The application of thermoplastics in the orthotics industry has proliferated over the last 30 years making it the predominant material used today in both custom and off the shelf orthotic systems. The physical properties afforded by thermoplastics make it the natural choice when designing support systems that require structural integrity, light weight, dynamic responses and most of all adjustability. Many of the polymer based plastics possess these desirable traits and selection is predicated on the ultimate goals of the orthotic design. These advancements have clearly contributed to the growth and success of the orthotic industry as well as the functional rehabilitation of the patients we manage.

However, research shows that there exists a class of thermoplastics that has been initiated into the orthotic landscape with, what we believe to be, little regard for the imminent danger it presents to both the health care professional and the patients themselves. Kydex® plastic is used for many prefabricated lower extremity and spinal orthotic systems due to its relative low cost, availability and workability, but at what risk? Kydex® is principally composed of polyvinyl chloride (known as PVC)¹ which is the main structural material in many orthotic systems on the market today. This has occurred despite volumes of compelling evidence classifying PVC as a carcinogen and, at nonspecific levels of exposure, a severe irritant to the viscera of the eyes, nasal passages and lungs. The compound Dioxin,² a well-known harmful carcinogen, is formed during the manufacturing of PVC and also when PVC items are re-exposed to heat or flame. This Dioxin is then released into the environment exposing those in contact to substantial health risks.³ Herein lies the leap from hypothetical danger to a real health risk! Studies have demonstrated that heating PVC based products will indeed expose the health care professional, their patient and environment to those aforementioned carcinogens and its most hazardous gaseous state.

Secondarily, a review of the research shows that DEHP di (2-ethylhexyl), a phthalate used to soften PVC plastics can leach from PVC medical devices and has been linked to many illnesses, according to animal studies (which is the customary biocompatibility/toxicity testing procedure for medical devices).⁴ Studies have shown that exposure to vinyl chloride presents a risk for many diseases including anigosarcoma, liver cancer, liver disease, brain cancer, Raynaud's syndrome and acro-osteolysis that can be directly linked to PVC. While those distributing devices composed of PVC may argue that in its cooled state the risks are minimal or nonexistent, the fact remains that even in its inert state, these items are being applied to our children, parents and into our environment.⁵ Most noteworthy however is the fact that existing marketing strategies promote Kydex® (PVC) based products and its ease of "adjustability" with the application of heat so the orthotic system can be customized for optimum fit. Medical institutions are becoming much more judicious in what they allow within their walls relative to health risks, patient care and equally important, likability to risk. As such, PVC based products are being banned from use in more and more and more hospitals and clinics.⁶

There is no question that Kydex® is a reputable product with a proven track record in many applications worldwide. Kydex® and other PVC-based plastics can be used safely in many products, however, it is Anatomical Concept's position, based on publicly-available, sound evidence, that when used in certain medical devices and adjusted with the use of heat, this material can be harmful.

The compelling question is this: why expose yourself, your patients, your environment and your litigation team to the very real risks that could be linked to your support of PVC (Kydex®) products? There are other viable, alternative orthotic systems available that are designed responsibly, using only safe, structural sound superstructures that are easily adjustable without the need for heat. Let your referral sources know that you are cognizant of the potential risks that exist with synthetic materials used in the health care industry. Tell them that you care enough to make sure that you will only support products that will help insure total safety.



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5. <http://machinedesign.com/article/materials-controversy-brewing-over-pvc-in-toys-0424> and http://healthychild.org/blog/comments/big_news_apha_calls_for_a_phase_out_of_pvc/
6. http://chej.org/wp-content/uploads/Documents/PVC/healthcare_institutions_reducing_pvc.pdf

Additional Resources

- http://en.wikipedia.org/wiki/Polyvinyl_chloride
- <http://www.who.int/mediacentre/factsheets/fs281/en/>
- http://www.noharm.org/global/issues/toxins/pvc_phthalates/alternatives.php
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- http://www.ronsimonlaw.com/vinyl.html?gclid=COSSpM_11pACFQ9THgodO31oPQ
- <http://www.wisegeek.com/what-is-polyvinyl-chloride.htm>
- <http://www.ejnet.org/plastics/pvc/>
- <http://www.chron.com/default/article/EPA-sets-new-rules-for-emissions-from-PVC-3324417.php>

- <http://www.mindfully.org/Plastic/BPTF-PVC-Resolution.htm>
- <http://www.epa.gov/ttn/atw/hlthef/vinylchl.html>
- http://chej.org/wp-content/uploads/Documents/PVC/bad_news_comes_in_threes.pdf
- http://www.sustainablehospitals.org/HTMLSrc/IP_PVC.html
- <http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.7617107>

About William A. DeToro, CPO, LPO

With over 20 years experience in orthotics and prosthetics industry, Bill DeToro serves as the President of Anatomical Concepts, Inc. He is ABC certified in Prosthetics and Orthotics, and he is a licensed Prosthetist/Orthotist in the state of Ohio. Bill received his BA in Human Performance & Exercise Science at Youngstown State University and later studied Orthotics & Prosthetics at Northwestern University Feinberg School of Medicine in Chicago. He completed his Prosthetic and Orthotic residencies at ABi O&P Labs. Bill previously served as on-call orthotic/prosthetic practitioner for Hanger Orthopedic Group in Boardman, OH before joining Anatomical Concepts, Inc. E-mail him at wadetoro@anatomicalconceptsinc.com.

About Anatomical Concepts Inc. USA

Since 1990, Anatomical Concepts has developed industry-leading medical devices, custom-fit and custom-fabricated orthoses for both upper and lower extremities. Anatomical Concepts Inc. is the manufacturer and distributor of the V-Vas™ Knee Orthosis (KO) and Knee Ankle Foot Orthosis (KAFO). It is a team of practitioners, designers, and manufacturers utilizing advanced technology to develop superior products that not only deliver effective outcomes, but present ease-of-use for the medical professional. The company is the original concept developer of the PRAFO® Orthosis, its patented design for the orthotic management of the ankle foot that minimizes undesired contact with the bony prominences of the ankle or foot.

Anatomical Concepts is headquartered in Poland, OH, and provides medical devices, services, and consulting both nationally and internationally. The company's innovative product line has inspired the procurement of over seventeen US product patents and or trademarks. Providing solutions for medical professionals and helping to improve patient outcomes is still the driving force behind the corporation. Anatomical Concepts, Inc. products are FDA registered and also carry the CE marking. All products, including the ELLIOTT™, are designed, manufactured, and trademarked by Anatomical Concepts, Inc.

To learn more about Anatomical Concepts' range of products, learning resources, and events, please visit <http://www.anatomicalconceptsinc.com> or call (800) 837-3888.

This article can be found online at <http://www.anatomicalconceptsinc.com/use-of-pvc-based-plastics>.