Safety acceptance by thorough tests

In Europe, the safety assurance and health risk minimization of using medical devices made from PVC is strictly controlled under the European Union's Medical Device Directive 93/42/EEC. Biological test is performed under the Biological Evaluation of Medical Devices (EN/ISO 10993) to ensure no allergy with the patients.

Additives are well-screened for minimizing risk

Regarding concerns about safety, the additives used for PVC processing in medical devices has to be listed in the 'Food Contact Approval List" in the European country or approved safety in food and drugs by US FDA (US Food and Drug Administration) in the United States. The phthalate plasticizer diethylhexyl phthalate (DEHP) has been the subject of one of the biggest debates for safety issues till present. The main concern is the possible leaching out of DEHP from the devices into the body fluids that might pose risk to patients during medical treatments. However, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has published its opinion on the risk assessment of DEHP in 2008. The Opinion stated that "there is limited evidence suggesting a relation between DEHP exposure and some effects in humans" and "so far, there is no conclusive scientific evidence that DEHP exposure via medical treatments has harmful effects in humans".[2]

Proper waste managament

Dioxin can be unintentionally formed when chlorinated chemicals are improperly burned. Natural phenomena such as volcanic activities and forest fires or ordinary activities such as incineration of kitchen wastes, paper, wood and waste plastics alike can all produce dioxin. Based on studies in Japan, if proper incineration conditions and appropriate measures and controls/procedures are taken, dioxin formation can be well controlled and the influence of PVC and other chlorinated compounds become relatively smaller.[3] In Europe, most operators of municipal solid waste incinerators do not perceive PVC as a problem in incineration.[4] Wastes from medical devices wastes can be properly disposed in incinerators that can limit the emission of "Dioxin" under the standard regulations, i.e. based on European Union Directive 2000/76/EC in Europe.

The safety of PVC for medical devices has been proven for many years. When applied as single-use devices, it helps make critical health care products more dependable and affordable at all levels of society. There is thus no reason to withhold this application of PVC as long as no other alternative has been thoroughly tested, proven and accepted for their safety.

References:

1 "PVC Medical Applications" PVC Information, www.pvc.org.
2 Opinion on "The Safety of Medical Devices Containing DEHP-Plasticized PVC or Other Plasticizers on Neonates and Other Groups Possibly at Risk" Scientific Committee on Engineering and Newly-Identified Health Risks (SCENIHR) Report, European Commission, 2008.
3 PVC Fact Book, Vinyl Environmental Council (Japan) 2008 edition.
4 "PVC and Waste Incineration - Modern Technologies Solve Old Problems" by Alfons Buekens, Kefa Cen Zhejiang University, Hangzhou, China. (Prof. Emeritus Vrije Universiteit Brussel, Brussels, Belgium)

"PVC is the most Sustainable, Environment-Friendly and Safe-to-Use Commodity Plastic in The ASEAN Community."

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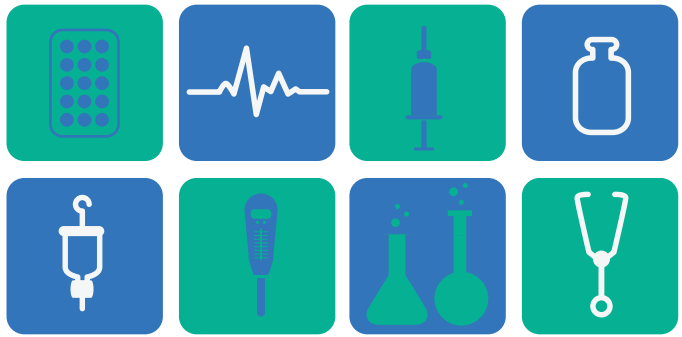


PVC Medical Devices

PVC has been marketed for over 50 years as a safe material for single use medical devices, replacing the use of traditional materials such as glass and natural rubber. Medical devices made of these materials usually demand cleaning and re-sterilization before reuse. This resulted in the big change in the sixties for the healthcare sector since PVC can minimize the risk of life-threatening infections caused by the multiple-use of traditional devices.[1]

Bloodbags, containers for intravenous solutions, and catheters are examples of single use medical devices made of PVC. The material can well-serve its purpose due to its clarity that facilitates medical activity monitoring. Due to its flexibility, toughness, less space requirement for storage and resistance to tear, it outperforms traditional materials for medical purposes.

Safe material for medical purposes

Toxicological test on PVC has been thoroughly undertaken and assessed before being accepted for medical applications. Its continuous use without any record of harm to human beings is indicative of the safety of the material. It is worth noting that PVC is currently the single material which successfully combines effectiveness of use, safety and reasonable price for single use medical devices.

PVC is stable and biocompatible

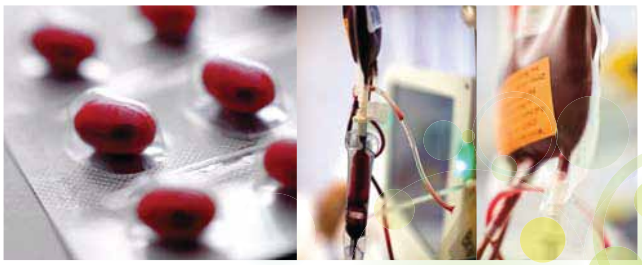
Chemical Stability and biocompatibility are the crucial properties for materials used for medical devices. PVC is the right choice for this purpose, given the properties it has exhibited in laboratory and clinical tests. Moreover, the additives used for facilitating the processing of PVC do not initiate any composition changes nor result to damages in the quality of fluids while stored.

Easy to monitor during medical treatments

Clarity and transparency are essential characteristics of medical devices to allow for obvious monitoring of fluid flow during medical treatments. PVC can be processed as colorized articles without losing its clarity and transparency attribute, expanding the use when differences of devices' colors are required for specific use.

Easy to process

The various ways by which PVC can be processed give rise to various PVC medical products. PVC can be easily extruded to make IV tubing, thermoformed to make blister packaging or blow moulded to produce hollow rigid containers such as blood bags and saline bags.



Affordable healthcare

Single use medical devices are designed to minimize concerns of hygiene and cross infection of the patients during medical treatments. This makes price crucial at a time when medical budgets are under increasing pressure. PVC is the only material that is able to guarantee all the in-service qualities demanded by healthcare professionals while remaining affordable. PVC accounts for over 25 percent of medical plastics currently in use. A switch to an alter-