

Plastics for Medical Devices

April 20, 2010

A Technical Conference sponsored by:
Medical Plastics Division of SPE
UMass Lowell Plastics Department
ENE Section of SPE

Challenges in Medical Device Product Development

Hot Topics / Insights & Considerations

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Overview

- **An introduction and why this topic?**
- **BPA in the news / Polycarbonate?**
- **The brief historical look at the use of polycarbonate in medical devices**
- **Properties that make it useful**
- **Alternative materials – benefits and drawbacks**

Introduction

1. Heavy metal residuals
 2. VCM residuals in PVC
 3. DEHP plasticized PVC leachables
 4. Silicone implantables
 5. Latex rubber sensitivity (NRL)
 6. Bis-Phenol A – Polycarbonates / Epoxies
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Introduction

When the industry learns of problems with materials, solutions are found or the materials are replaced with safer, better materials.

PVC additives

Heavy metal residuals

Lead

Tin

Copper

Cadmium

Chromium

Nickel

PVC additives

Heavy metal residuals

Lead

Tin

Copper

Cadmium

Chromium

Nickel

Eliminated

PVC additives*

VCM residuals in PVC

Found in the ppm levels

Reduced to below ppb levels

*VCM is not an additive but rather a process residual

PVC additives

VCM residuals in PVC

Found in the ppm levels

Reduced to below ppb levels

Eliminated

PVC additives

DEHP plasticized PVC leachables

- questioned since its first use in the '60s
- studies continue to show it safe
- removed from teething rings in Europe
- leading to restrictions on medical devices in EU
- more questions in US
- FDA review confirmed its safe use

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Safe for use

Natural Rubber Latex

Latex rubber sensitivity (NRL)

caused by the proteins from the plant

primarily on surface of parts but can also

come from exposed sections

eg needle sticks, balloons, gloves, etc.

Natural Rubber Latex

Latex rubber sensitivity (NRL)

virtually
Eliminated

Long-Term Silicone Implants

Silicone implantables

- **complaints by breast implant recipients**
- **suspected to cause autoimmune disease**
- **FDA withdrew approval for use**
- **comprehensive studies done all showing safety**
- **once again use allowed by FDA**

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Safe for use

BPA - Polycarbonate

Bis-Phenol A referred to as BPA

What will be the outcome of all the allegations of its toxicity?

Should anything containing BPA be banned?

**Safe for use?
tbd**

1. Historical review of PC use

- Filter housings
- Drainage bowls
- Molded rigid support structures
- Connectors and spikes

2. Properties of Polycarbonate

- Clear rigid moldable
- Solvent bondable to PVC and itself
- Ultrasonic weldable
- Sterilizable – steam, EO and radiation

3. Alternative Materials

- Polymethyl methacrylate
- Polyesters
- Acrylics

All are clear / transparent

All are ultrasonic weldable

Solvent bondable except P est

Only P est is steam sterilizable

Review

1. A long time reliable material now in question
2. Limited testing has been done
3. No regulatory action at present
4. Alternative materials available (if warranted)
5. Let's hear from the experts before deciding

Conclusions

1. Strive to use the best material for the job
 2. Conduct thorough testing
 3. Establish complete specifications
 4. Monitor the product and materials used
 5. Be ready to change if warranted
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