Engineering Plastics (Polycarbonate) for Medical Device Application

Raymond Wong

18th March, 2016
Seminar Agenda

1. Overviews of Medical Device and Medical Plastics Market
2. The Regulatory of Medical Plastics
3. The Properties of Medical Plastics and Polycarbonates
4. Processing of Medical Plastics and Polycarbonates
5. Q & A
Medical Device Manufacturing is a Large and Growing Global Market

- U.S. medical manufacturers: 46%
- Global growth rate: 4.5%
- China – double digit growth

Source: Medtech
1. The population is aging

2. Healthcare access in emerging markets
   - Increasing healthcare expenditures
   - Growing middle class
Renal Care

Dialysis system

Dialyzer housing

Adsorber system
Electromedical Equipment

Defibrillators

Patient monitor
Drug Delivery

Injection pump

Needle-free injector and ampoules

Auto-injector

Dry powder inhaler
Cardiovascular Equipment

Cardiotomy reservoir

Cardiac monitoring system

Oxygenator

Artificial heart driver
Surgical Instruments

- Ophthalmic micro forceps and scissors
- Bone stapler
- Arthroscopic access cannula
- Trocars
- Orthopedic – knee balancer
The Global Market for Medical Devices of $331B in 2012
CAGR 4.5% (2012-2018)
Source: Kalorama, Medtech
Global Medical Plastics Distribution

PC Share of Total Medical Polymers Revenue 2012, $3.8B
Source: Frost & Sullivan, BCC

PC: 31%
PVC: 29%
PP: 14%
PE: 11%
Styrenics: 6%
PMMA: 6%
TPE: 2%
Regulatory Compliance Tests

Target: Biocompatibility

Method: Toxicity Tests on Material Extractables according to FDA-modified ISO-10993-1 and USP XXV, Class VI

1. Acute System Tox. 敏锐系统毒性试验
2. Intracutaneous Tox. 皮内毒性试验
3. Muscle Implantation 肌肉培植试验
4. Cytotoxicity 细胞毒性试验
5. Hemolysis Direct and Extraction 溶血和萃取试验
6. Pyrogen Study 热原质研究
7. Sensitization 至敏性
8. Mutagenicity 诱变性
9. Heavy Metal Analysis 重金属分析
10. Physicochemical Tests 物理化学试验
Regulatory Support to Medical Device Manufacturer is Important

- Biocompatibility: ISO 10993-1 and USP Class VI for contact of 30 days or less
- Maintenance of FDA Device (MAF) and Drug Master File (DMF) and Letters of Authorization
- Manufactured at certified GMP sites
- Supplier notification of change
Medical Device Sterilization

- Most medical devices must be sterilized
- Sterilization aims to eliminate microbes
- Thermoplastics may be sterilizable by:
  - Heat (steam autoclave or dry heat)
  - Radiation (gamma or electron beam)
  - Chemical (mostly EtO)

Makrolon 2858 : ≤ 121°C  Time : 15 - 30 min
Polycarbonates After Gamma Sterilization

Tensile Strength @ Break (psi)

- Makrotron 2458
- Makrotron Rx2530

Notched Izod Impact (ft-lb/in)

- Makrotron 2458
- Makrotron Rx2530

Sterilization method is gamma radiation
### Various Plastic Gamma Sterilization Tolerance

<table>
<thead>
<tr>
<th>Material</th>
<th>Gamma Sterilization Tolerance (KGY)</th>
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<tbody>
<tr>
<td>PP</td>
<td>20-50</td>
</tr>
<tr>
<td>PVC</td>
<td>100</td>
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<tr>
<td>PMMA</td>
<td>100</td>
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<td>PC</td>
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<td>PETG</td>
<td>1000</td>
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<td>HDPE</td>
<td>1000</td>
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<tr>
<td>ABS</td>
<td>1000</td>
</tr>
<tr>
<td>PSU</td>
<td>10000</td>
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</table>

Source: Nodion Ltd
Gamma compatibility material comparison
Copolymer For High Heat Sterilization

Steam-sterilization at 134°C and up to 143°C possible (advantage: very short cycle times)

**Apec 1745** – High Heat Resistance Medical Grade

**High transparency** (comparable with Standard-PC)

**High toughness**

**United States Pharmacopeia USP Class VI,**

**Biocompatibility** (ISO 10993-1)

Luer Lock Adapter
Hospital Disinfectants are Aggressive to Medical Plastics
PC Blends For Hospital Disinfectant Resistance

Polycarbonate + Polyester

Polycarbonate (PC) Amorphous + Polyester Semi crystalline

PC

PBT or PET

+ Impact modifier

= makroblend®
Efficacy of Antimicrobial Polycarbonate

Efficacy of Makroolon Antimicrobial Polycarbonate

Note: formation of red color on sample plaque surface indicates bacterial growth

Untreated Control

Makroolon® Antimicrobial PC
1% Loading
2% Loading

98.4% Kill
99.998% Kill

Stain Test: Klebsiella pneumoniae (Gram -)

98.6% Kill
99.97% Kill

Stain Test: Staphylococcus aureus (Gram+)

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Defects Caused by Processing Moisture

Moisture streaks and small bubbles

Brittle fracture through hydrolytic degradation
Observing the Melt Strand

Appearance of the Melt Strand for dry and moist Material
Increase in the Moisture Content of PC Granules during Storage in Room Air
Factors related to Stress Cracking

Internal Stress

External Stress

Part Design

Material
Sensitivity against Stress Cracking and Mechanical Properties improve with increasing Molecular Weight
Material Consideration

- Material degradation due to chemical attack
- Material degradation due to inappropriate processing conditions
  - melt temperature too high
  - residence time in barrel too long
  - material not properly pre-dried
- Material degradation due to inappropriate runner system design
  - gate size too small may cause excessive shearing
External Stress

- Intended external loads during part testing
  
  e.g. impact load during drop test

- External loads during assembly or disassembly

- Long-term external loads due to tolerance problem

- Short-term external loads due to interaction with other assembled components

- Plastics like PA release stresses by creeping. Creep modulus of PC, PC-ABS is very high, it does hardly creep. Therefore, stresses may finally be released by cracking.
Recommend Load Limit for Polycarbonate

**Short term load, loaded once**

Recommended load limit = 55 MPa

**Long term load**

Recommended load limit = 8 MPa (10,000 h)
Part Design Consideration

Inappropriate part design
not stiff enough
Sharp corners (radii too small)
stress concentration
Gate Size
Etc…

Effects of a fillet radius on stress concentration.
Internal Stress

Inappropriate runner system design
- filling pressure too high
- holding pressure differences within the part
- over-packing

Inappropriate processing conditions
- holding pressure too high
- injection speed too slow
- mold temperature too low
- melt temperature too low
Checking for Internal Stress Level

Makrolon® stress test, TnP method for Polycarbonate

Toluene 1: n-propyl alcohol 3, immerse the part in the solution for 3 minutes. Immediately clean the part free of any solution. Carefully examine it visually for cracks.

<table>
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<th>For the following:</th>
<th>Use:</th>
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<tr>
<td>Polycarbonate parts which will not be subjected to</td>
<td>1:10 TnP solution</td>
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<tr>
<td>external loading</td>
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<tr>
<td>Assemblies containing polycarbonate components</td>
<td>1:10 TnP solution</td>
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<td>Polycarbonate parts which will be subjected to</td>
<td>1:3 TnP solution</td>
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<td>assembly</td>
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<td>Medical devices</td>
<td>1:3 TnP solution</td>
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![Graph showing PSi and MPa values for different solutions]
Annealing could release internal stress of PC

Annealing is generally performed by following methods:

- Hot air heating in suitable ovens
- Annealing temperature: 125-130°C
- Annealing time: 10 min per mm wall thickness
- Heating by means of infrared radiators
Annealing of Extrusion Blow Molded Returnable Bottles made from Makrolon

Fig. 1: Base of an unannealed bottle after cleaning

Fig. 2: Base of an annealed bottle after cleaning
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Thank You.

Raymond Wong
Product Technology Manager
Tel : 852-28947157
Email : raymond.wong2@Covestro.com