



Bayer MaterialScience



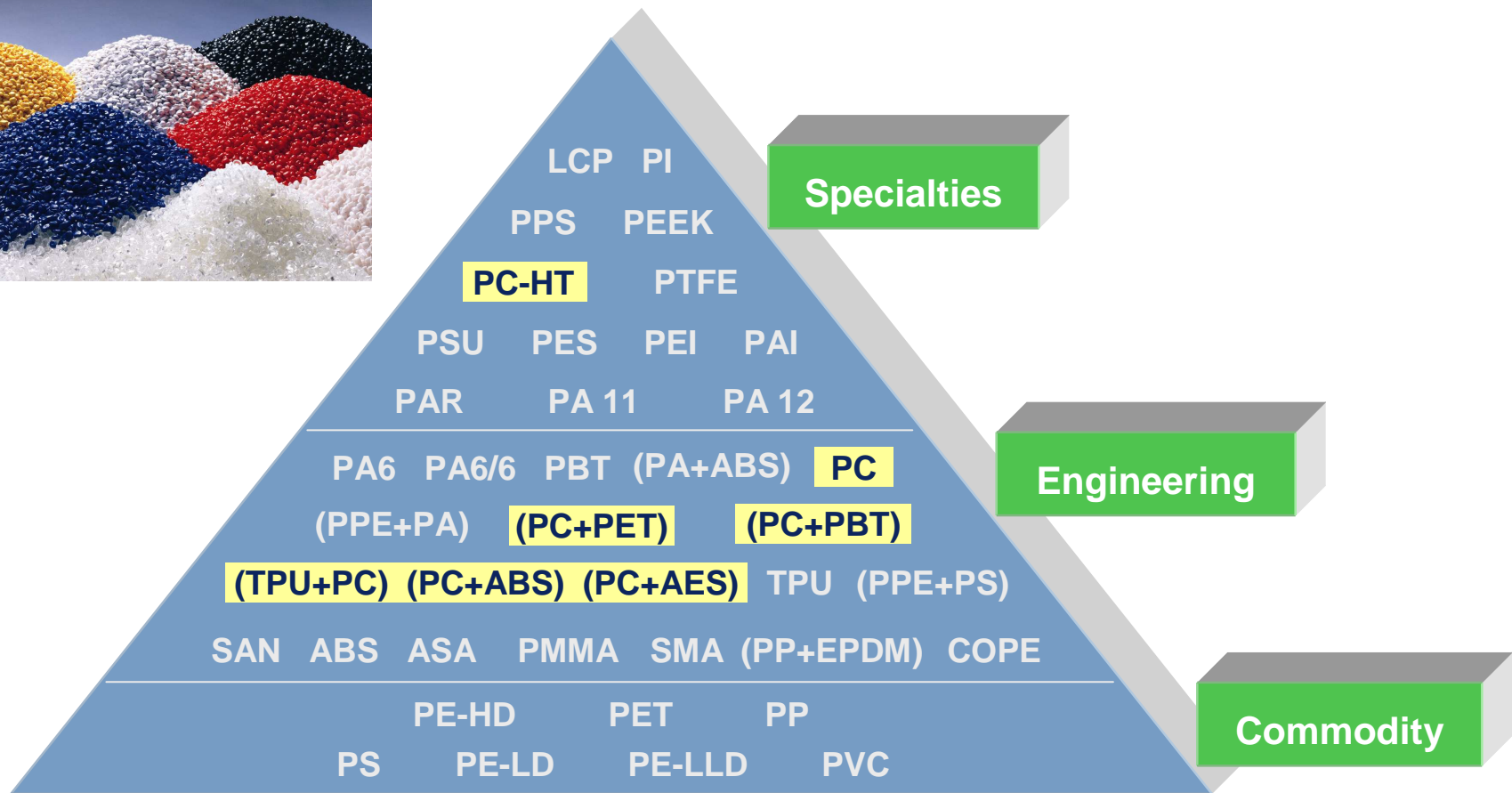
**Polycarbonate for
Medical Applications**

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Topics for Discussion

- Medical Plastics and Industry Trends
- Features and Benefits of Polycarbonate
- Regulatory and Sterilization Methods
- Makrolon[®] Polycarbonate
 - Applications and Reasons for Choice

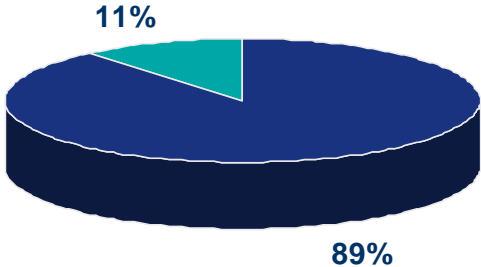
Thermoplastic Portfolio Classification



PC = Polycarbonate

Medical Thermoplastics Demand - US

4.4 billion pounds in 2007

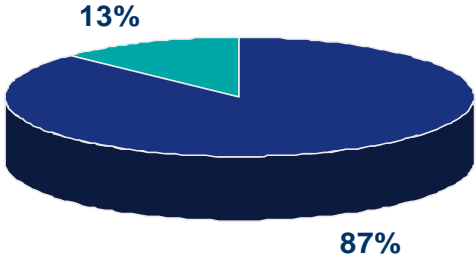


■ Commodity ■ Engineering



5% growth for engineering

5.0 billion pounds in 2012



■ Commodity ■ Engineering

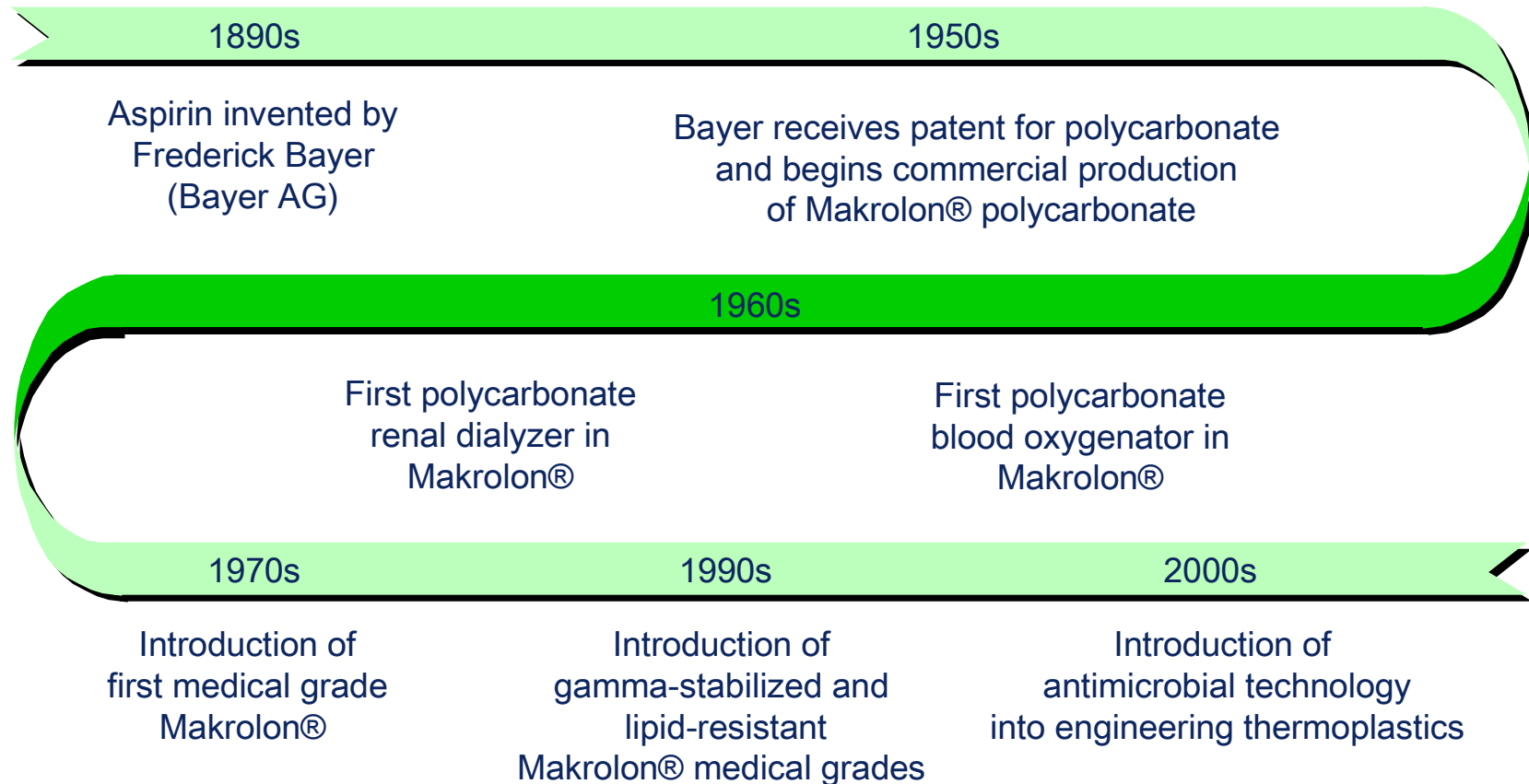
Source: Freedonia

Industry Trends

- Aging population
 - Increased demand for selected devices
- Minimally invasive devices
 - Reduce patient trauma, operating & recovery time
 - Improved robustness needed for smaller devices
- Managed care / cost containment
 - Outsourcing and shift in production from NAFTA
 - Shift from hospitals to outpatient clinics and home
 - New products that are user-friendly
- Reimbursement restrictions for hospital-acquired infections
 - Improved chemical resistance for equipment housings
- Integration of IT, telecommunications, biotechnology, and materials
 - Electro-medical use increase
 - New technologies (combination products)



Bayer Milestones



Product Features - Benefits

Makrolon® Polycarbonate

- Dimensional Stability – Predictable part size and shape retention over a wide temperature range
- Durability – Injection molded components that are tough and shatter-resistant to provide maximum safety
- Joining – Wide selection of techniques including snap fits, bonding (adhesives and solvent), and welding (vibration, ultrasonic and thermal)
- Processability – High flow grades with a balance of properties to allow for thin-wall injection molding
- Reliability – Almost 50 years of proven performance in medical devices
- Sterilizability – Ethylene oxide (EtO), high energy radiation (gamma and e-beam), and heat (autoclave and dry)
- Transparency – Allows easy visual and automated inspection

Transparent Polymer Comparisons

Product Family	Property			
	Impact Strength	Flexural Modulus	Heat Resistance	Bondability
Polycarbonate	Excellent	Excellent	Excellent	Excellent
Amorphous Polyester	Excellent	Fair	Fair	Fair
Acrylic	Poor	Fair	Fair	Excellent
Clear ABS	Fair	Fair	Fair	Fair
Polystyrene	Poor	Excellent	Fair	Excellent

Regulatory Compliance

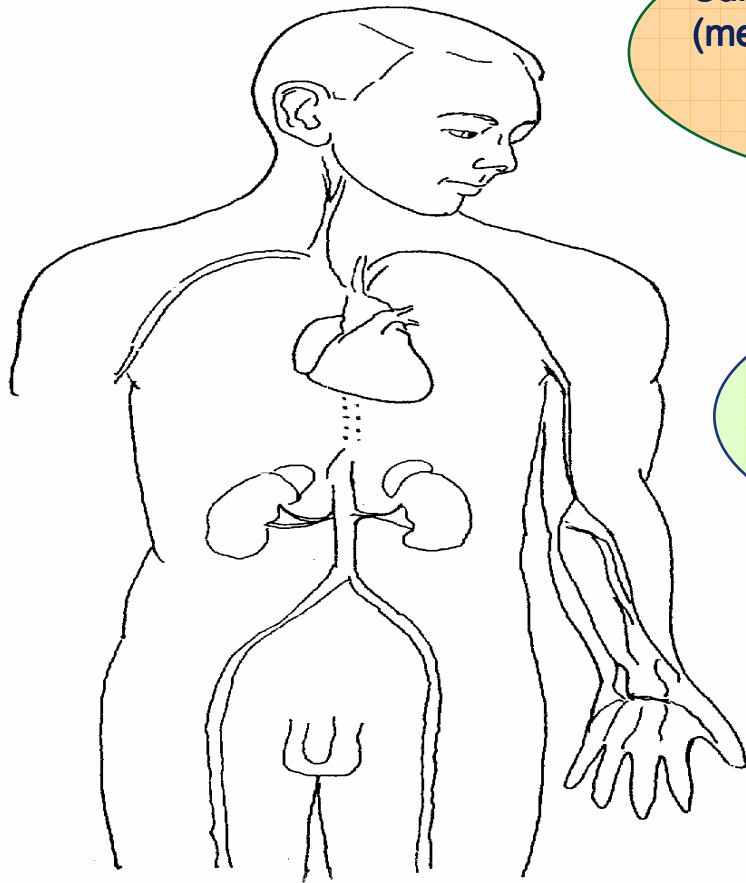
Classification of Medical Devices

Contact Duration

Limited \leq 24 Hours

Prolonged = 24 Hours to 30 Days

Permanent > 30 Days



Body Contact

Surface Devices (medical devices with skin contact)

- skin
- mucous membranes
- compromised surface



Needle free Injector

Externally Communicating Devices (medical devices in the fluid path)

- arteries and veins
- tissue, bone, dentin
- blood



IV Manifolds, Luers,
and Stopcocks

Implant Devices

- tissue, bone
- blood

Bayer Medical Grades and Regulatory Compliance

- Biocompatibility

- U.S. Food & Drug Administration (FDA)

- FDA-modified ISO 10993, Part 1 test matrix

- U.S. Pharmacopeia (USP)

- Biocompatibility: Procedure # 25 Class VI (subset of ISO10993, Part 1)

- Bayer medical grade products are tested for human tissue and bodily fluids storage or contact of 30 days or less

- Safe Medical Devices Act managed and enforced by CDRH (Center for Devices and Radiological Health)

- Maintenance of FDA Device (MAF) and Drug Master Files (DMF)

- Product Stewardship



Medical Device Sterilization

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



Blood Cardioplegia System

Sterilization Methods

Autoclave

- Rapid
- No residues
- Economical
- For reusable devices



Microsurgical Instrument

Radiation

- No residues
- Color shift of some products
- Gamma is best for complex shapes



Cardiotomy Reservoir

Ethylene Oxide

- Best compatibility with thermoplastics
- Lengthy cycle time to eliminate toxic residues
- Most common method



Aqueous Oxygen System

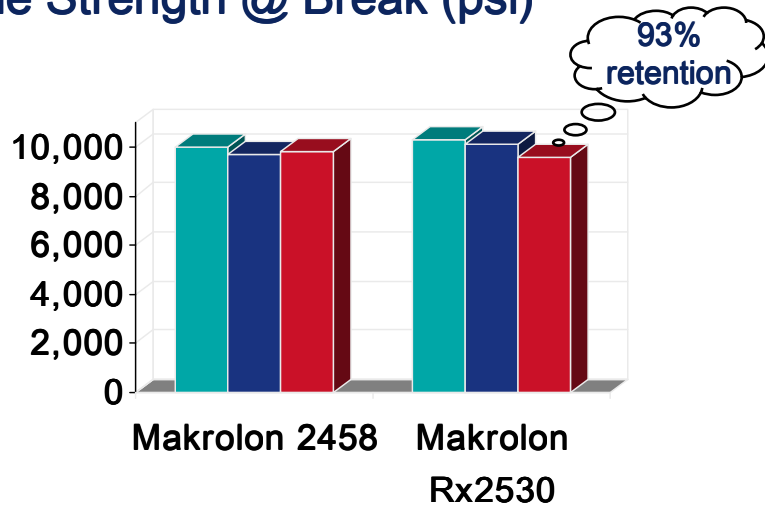
Effect of Sterilization on Transparent Thermoplastics

Thermoplastic	Steam Sterilizing Response	Radiation Sterilizing Response	Ethylene Oxide Sterilizing Response
Acrylic	Poor	Good	Good
Acrylonitrile Butadiene Styrene	Varies	Good	Varies
Nylon	Varies	Good	Good
Polycarbonate	Good	Good	Good
Polyester	Poor	Good	Good
Polystyrene	Poor	Good	Good
Polysulfone	Good	Good	Good

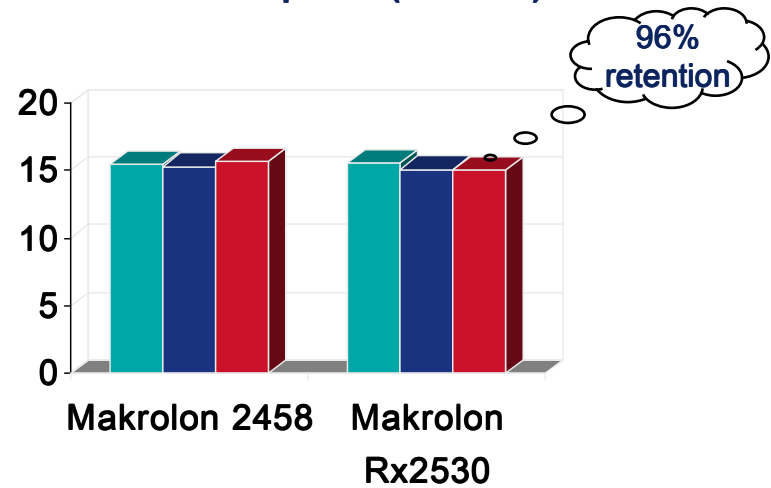
Source: MD&DI

Effect of Sterilization on Mechanical Properties

Tensile Strength @ Break (psi)



Notched Izod Impact (ft-lb/in)



Control After 2.9 Mrads After 5.7 Mrads

Control After 2.9 Mrads After 5.7 Mrads

Sterilization method is gamma radiation

Applications

Makrolon® Polycarbonate

- Exposure
 - Typically in components of single-use devices (SUD)
 - Medical Device Contact Duration
 - Limited contact (< 24 hours)
 - Some may be prolonged contact (24 hours up to 30 days)
 - IV Access components (can be up to 96 hours)

- Typical Segments
 - Blood Separation
 - Cardiovascular
 - Drug Delivery
 - IV Access
 - Renal Therapy
 - Surgical Instruments
 - Syringes and Catheters

Applications – Blood Separation



Blood Separation System



Centrifuge System

Applications – Cardiovascular



Cardiotomy Reservoir



Oxygenator



Cardioplegia System

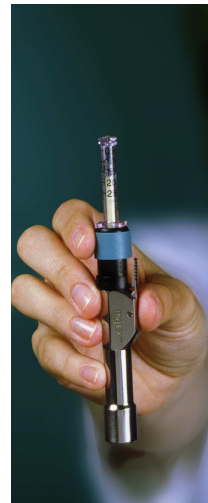


Cardiac Monitoring System

Applications – Drug Delivery Systems



Injection Pump



Needle-free Injector and Ampoules

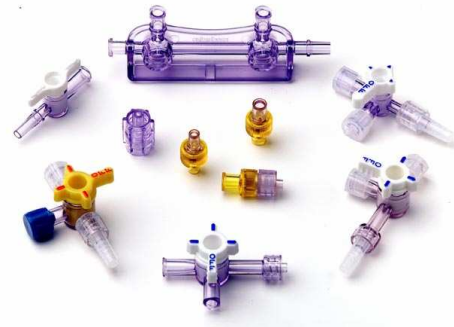


Needle-free Injector and Reservoir



Needle guard

Applications – IV Access



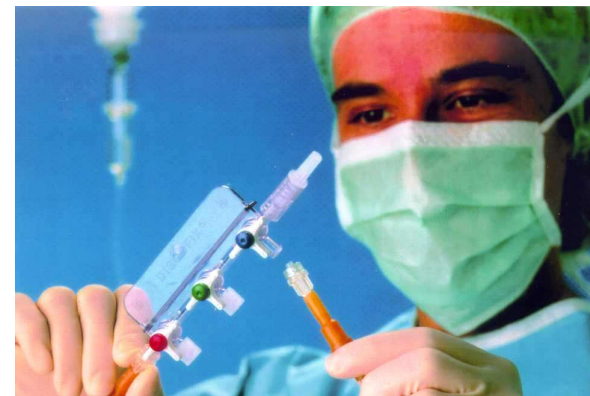
Luers and Stopcocks



Enteral Feeding Pump

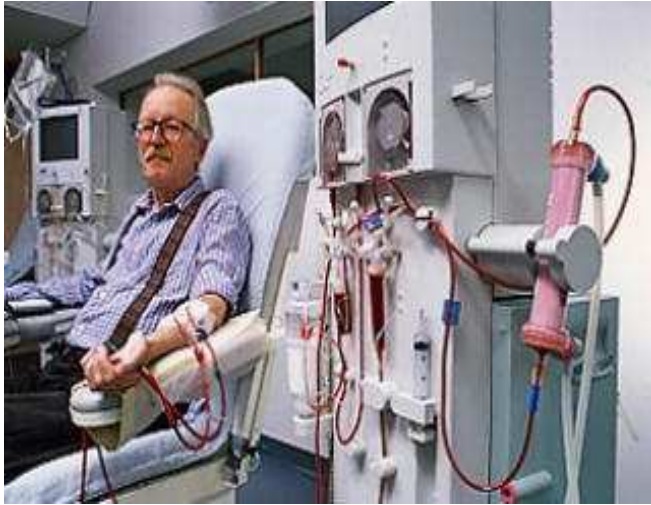


Needleless Access Connector



Manifolds

Applications – Renal Therapy



Dialysis System



Dialyzer Housing



Adsorber System

Applications – Surgical Instruments



Ophthalmic Micro Forceps and Scissors



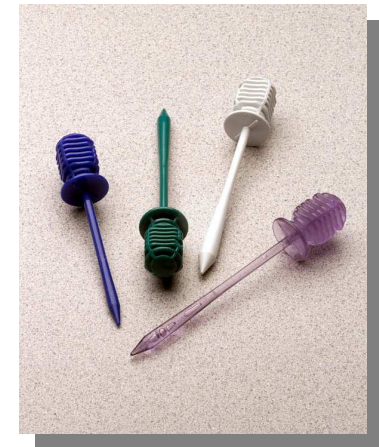
Inflator Pump



Surgical Stapler



Laparoscope



Trocars

Applications – Syringes and Catheters



Syringe
Components



Shielded IV Catheters



Catheter Connectors

Applications - Medical Equipment Housings

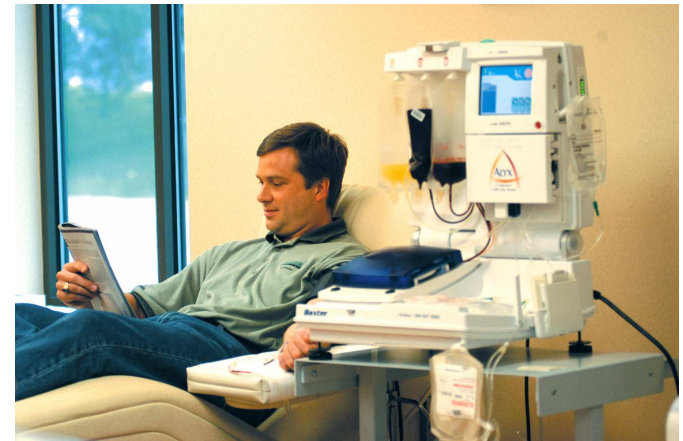
Flame-retardant polycarbonate blends for non-biocompatible applications



PC / ABS Blends



PC / Polyester Blends



Polycarbonate in Medical Applications

Key Reasons for Choice



makrolon[®]
the high-tech material

- Balance of properties ideal for critical end-use application requirements
 - Impact resistance, clarity, strength, processability, and joining techniques
- Sterilization by all common methods
- Makrolon[®] Medical Grades
 - For applications that require biocompatibility
 - Meets the requirements of the FDA-Modified ISO 10993 , Part 1 “Biological Evaluation of Medical Devices” tests with human tissue contact time of 30 days or less
 - Product stewardship (including notification of change)
 - Global availability to mitigate supply risk
- Proven performance in medical devices for almost 50 years
 - Used in devices to save lives and to improve the quality of people’s lives

Thank you for your attention !



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