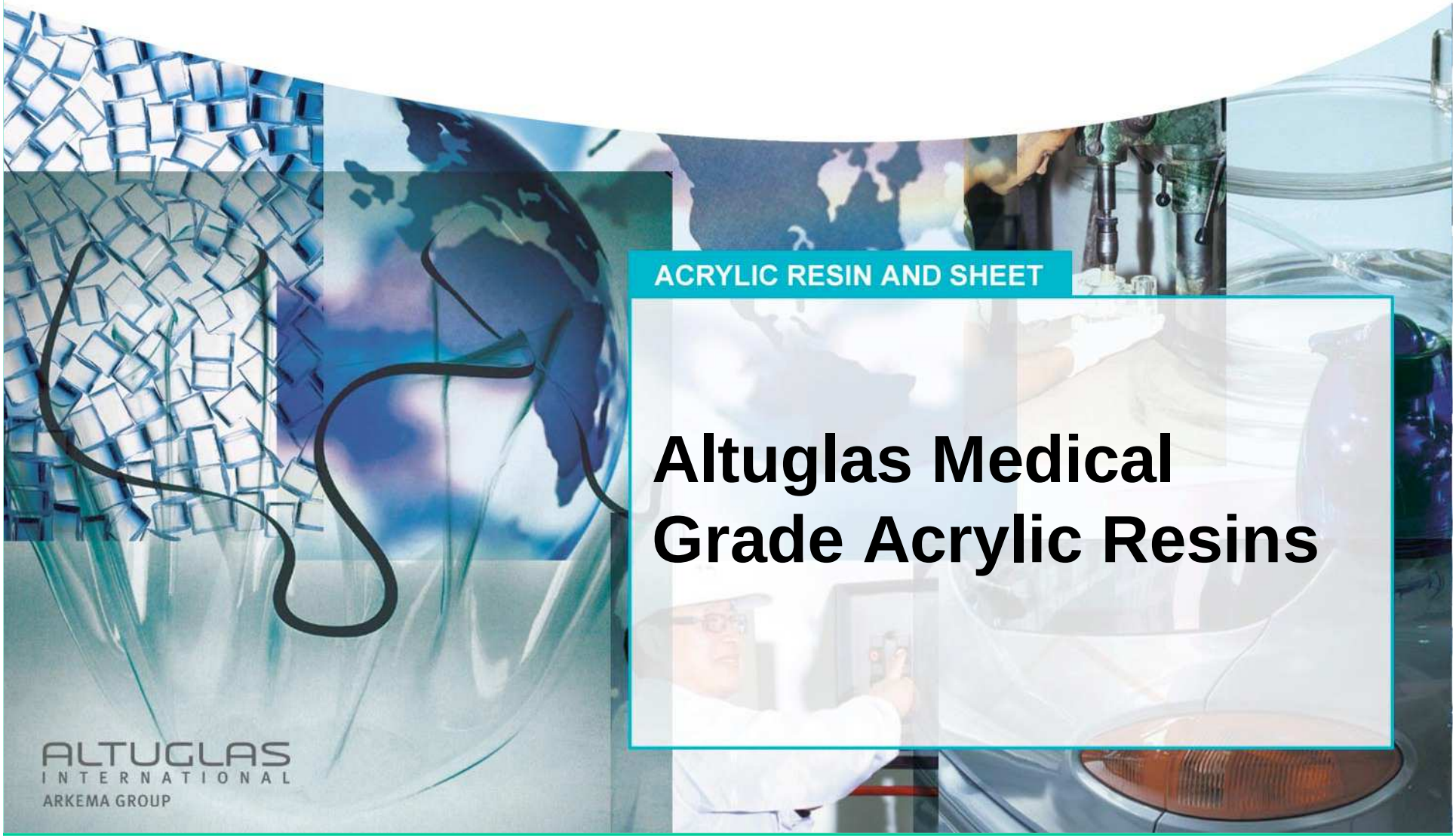
Altuglas®



ACRYLIC RESIN AND SHEET

Altuglas Medical Grade Acrylic Resins

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Agenda

- **Relevant Trends in the Market**
  - Environmental Stress Crack (ESC) Resistance
  - Concerns over BPA
- **Overview of *Altuglas*® Medical Resins**
  - ***Altuglas***® CR30
  - ***Altuglas***® SG Grades
  - ***Altuglas***® VS-UVT
- **Product Selection Guide**
  - Which Altuglas® grade is right for the application

Environmental Stress Cracking

Definition

Environmental Stress Cracking (ESC) is a phenomenon where a particular polymer cracks when in contact with a specific chemical agent while under stress[1]

Polystyrene eyes for soft toys

Polycarbonate crash helmet

Styrene acrylonitrile piano keys

Polyethylene static oil tank

~ 25% plastic part failures are due to ESC

Polycarbonate pacifiers

Polymethyl methacrylate small appliances

1. *Jeffery A. Jansen, Environmental Stress Cracking, The Plastic Killer, Advance Materials and Processes, June 2004.*

Why the Need to Improve ESC Resistance in Altuglas®?

- Drugs and disinfectants that contact devices are more aggressive than ever

- Devices in service for longer times
  - → Increased potential for environmental stress cracking
  - → More frequent replacement of device components
  - → Increased risk for patients to acquire infections

- Regulatory “concerns” may limit the use of specific polymers
  - Altuglas® can fill this void

Why BPA Free?

Definition of BPA

Bisphenol-A is a monomer used to make certain plastics. It is produced by reacting phenol with acetone.

Regulatory bodies have expressed "Some Concern" with BPA

- *In 2010 the Canadian & European competent authorities imposed restrictions on BPA-based polycarbonate baby bottles*[1]
- In April 2008, National Toxicology Program (NTP) concluded that **"***exposure to BPA could be linked to developmental problems of the endocrine system in infants and young children"*[2]
- *The "some concern" about potential effects of BPA based on studies using novel approaches to test for subtle effects, which had been stated by FDA/NHIES in 2008, will be addressed by a specific FDA research program which is already ongoing.*[3]

The outcome of this assessment could lead to regulation of BPA-containing medical devices

1. *European Information Centre of BisPhenol A*
2. Federal Register/Vol. 73. No. 200/Wednesday, October 15, 2008/Notices
3. *www.fda.gov/downloads/AdvisoryCommittees/.../UCM176835.pdf*

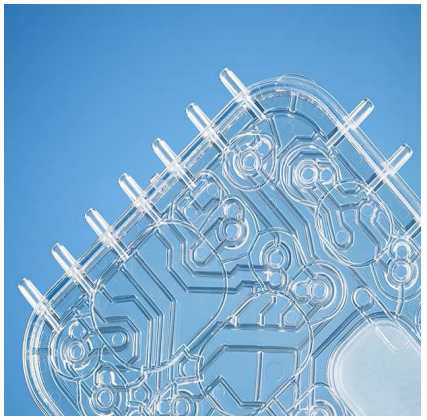
Altuglas® Medical Resins

Altuglas® Medical Resins Provide a Balance of Properties

- Chemical resistance
- Optical clarity
- Resistance to gamma sterilization
- Welding options (ultrasonic welding, adhesives, & solvents)
- Ease of melt processing

And Regulatory Compliance

- USP Class VI approved
- ISO 10993 Parts 4 & 5 (cytotoxicity, hemolysis)
- Device Master Files
- Zero BPA or plasticizers
- No solvent concerns



Altuglas® Medical Product Range

Chemical Resistance	*Altuglas® CR30*
High Flow	*Altuglas® SG7, Altuglas® SG10*
UV Transmitting	*Altuglas® VS-UVT*
Altuglas® Product Selection	*Comparative Advantages*

Chemical Resistance	*Altuglas® CR30*
High Flow	*Altuglas® SG7, Altuglas® SG10*
UV Transmitting	*Altuglas® VS-UVT*
Altuglas® Product Selection	*Comparative Advantages*

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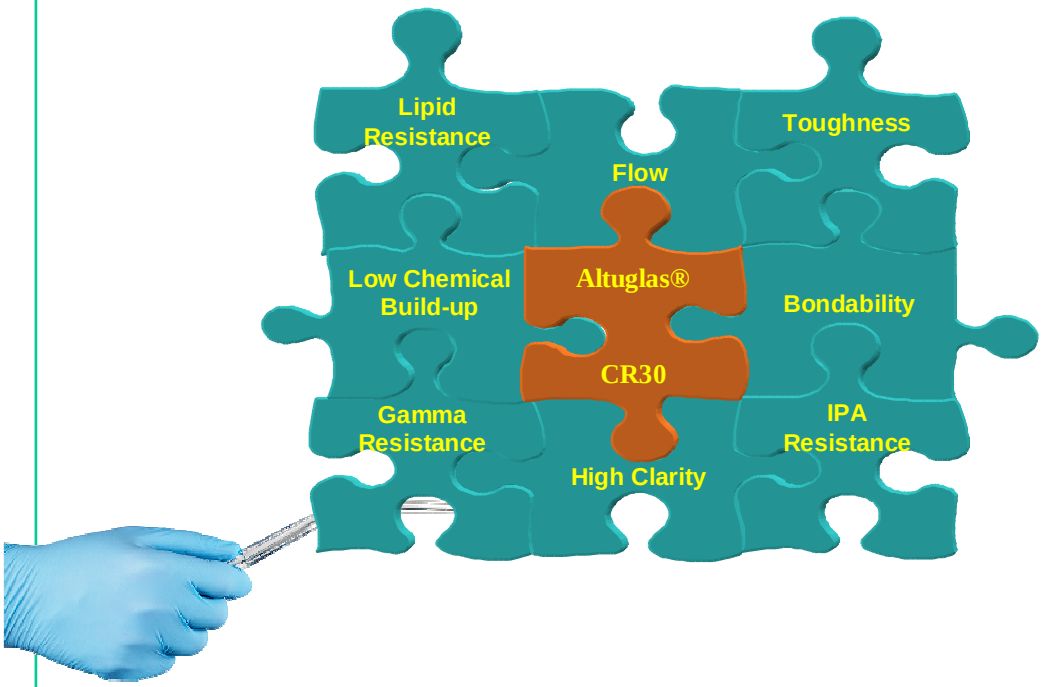
New Acrylic Polymers for Transparent Medical Devices

Altuglas® CR30

- The next generation impact acrylic medical polymer offers an optimized balance of properties required for transparent disposable medical devices



Altuglas® CR30 provides performance and durability

Desired Properties for Transparent Medical Polymers

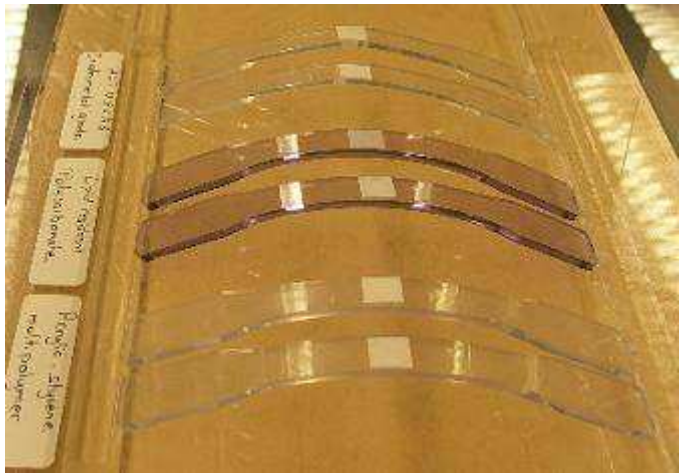
Properties

- Resistance to environmental stress cracking (ESC)
- Good optics
- Resistance to sterilization
  - Gamma
  - e-beam
  - Ethylene oxide
- Good melt processing characteristics

How Is ESC Resistance Measured?

Elongation Retention After Exposure to Select Chemicals

- Annealed tensile bars exposed to chemical @ constant strain for given time
- Measure elongation at break
- Reported as % retention

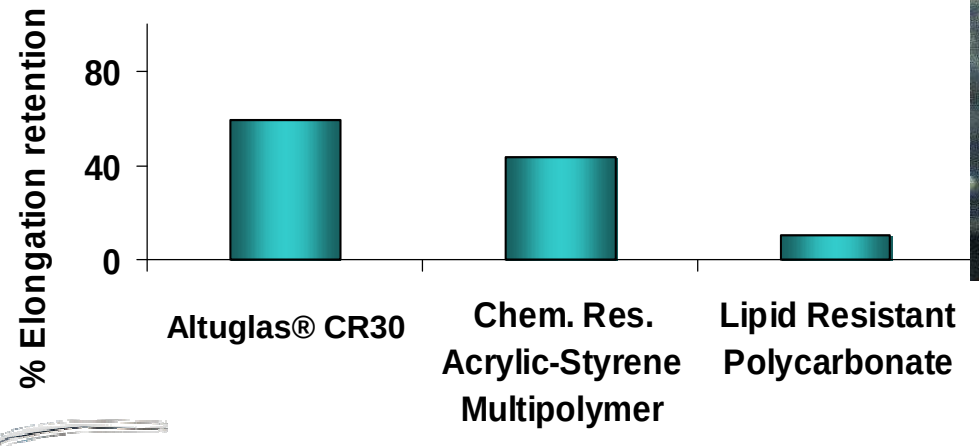


Lipid Resistance of Altuglas® CR30

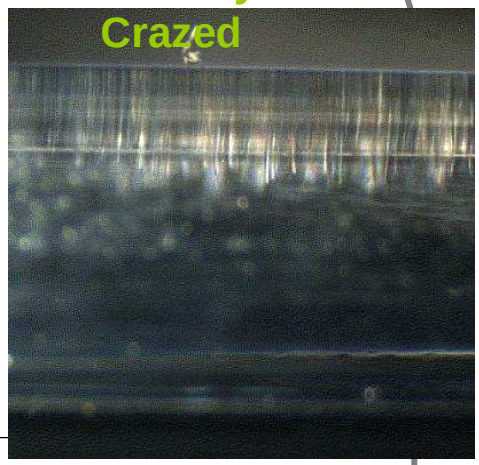
Exposure to Liposyn® III 20% for 24 Hours

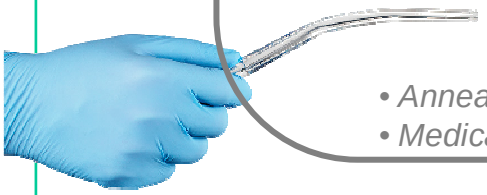
- 1% constant strain

Resistance to Lipid (Liposyn® III)



Severely Crazed

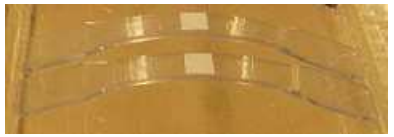




- *Annealed tensile bars exposed to chemical for 24 hrs at 1% constant strain*
- *Medical Grade Copolyesters severely crazed upon exposure-Test discontinued*

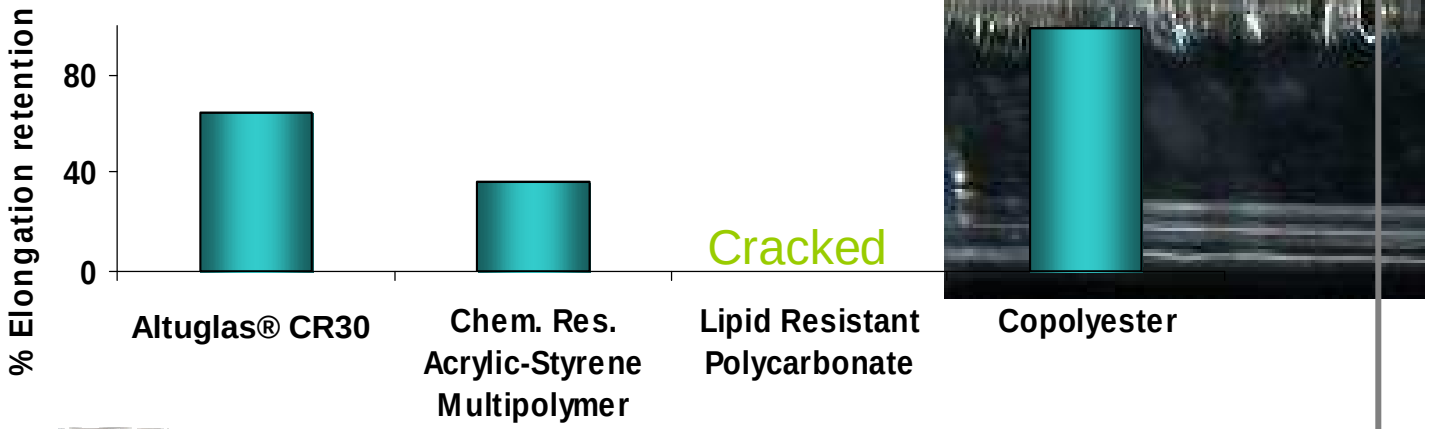
Lipid Resistance of Altuglas® CR30

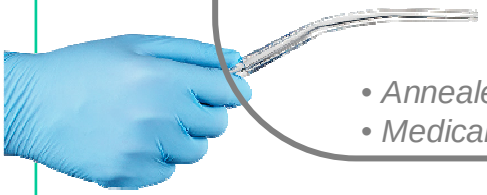
Exposure to Cremophor® RH40 for 24 Hours



- 1% constant strain

Resistance to Lipid (Cremophor® RH40)





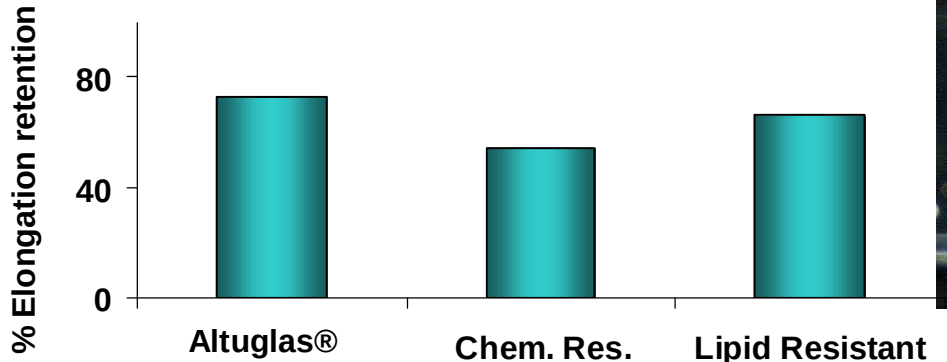
- *Annealed tensile bars exposed to chemical for 24 hrs at 1% constant strain*
- *Medical Grade Copolyesters severely crazed upon exposure-Test discontinued*

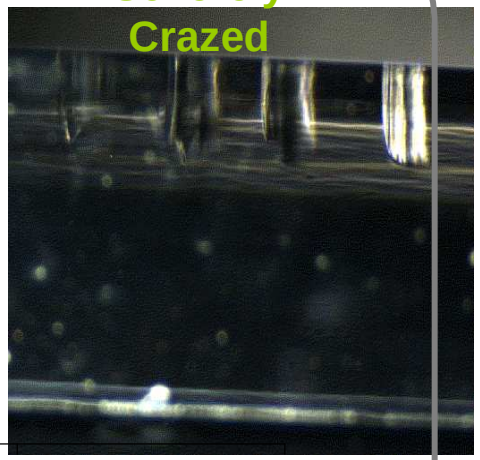
IPA Resistant of Altuglas® CR Series

Exposure to 70% IPA/H_2O for 6 Hours

- 0.75 % constant strain

Resistance to 70% IPA





- *Annealed tensile bars exposed to chemical for 6 hrs at 0.75% constant strain*
- *Medical Grade Copolyesters severely crazed upon exposure - Test discontinued*

IPA = Isopropyl Alcohol

Acid/base & Antiseptic Resistance of Altuglas® CR30

Constant Strain Test – Time to Failure

- 2% constant strain
- Exposure to chemical mixture
- 👍 ESC resistance if no crazing within 1 hour

	Strong Base (NaOH pH=11)	Strong Acid (HCl pH=3)	Betadine®	Hibiclens®
Altuglas® CR30	👍	👍	👍	👍
Chem. Res. Acrylic Styrene Multipolymer	👍	👍	👍	👍
Lipid Resistant Polycarbonate	👎	👍	👍	👍
CoPolyesters	👍	👎	NA	NA

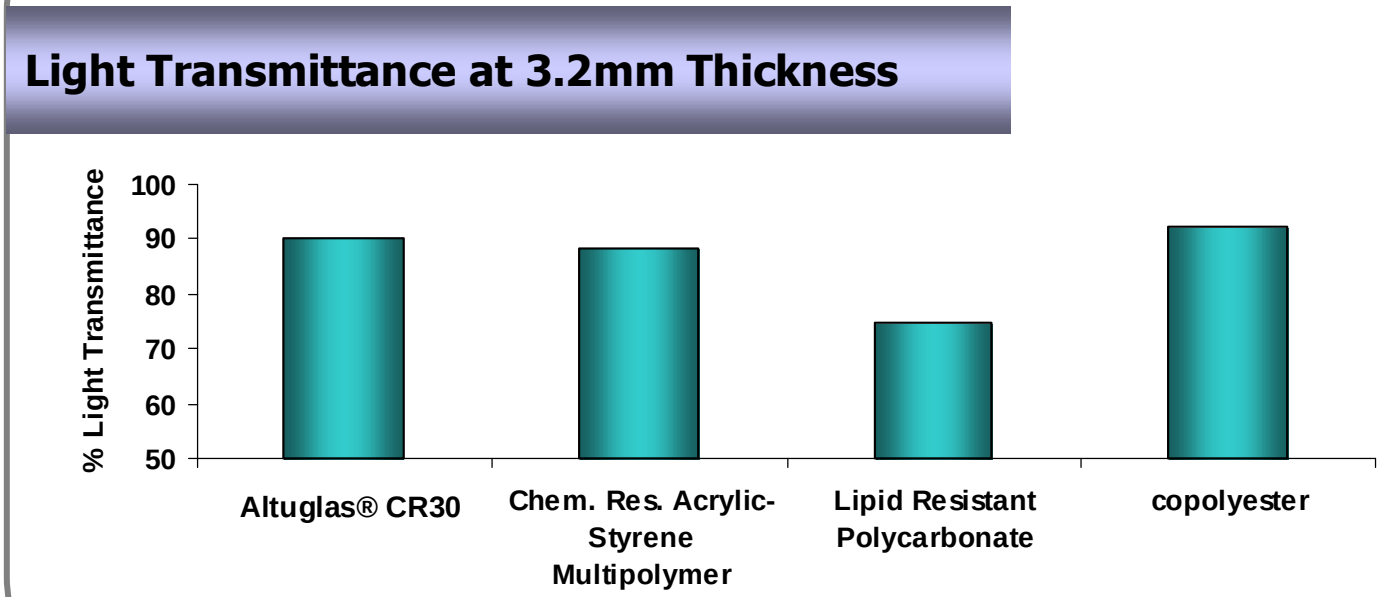
Desired Properties for Transparent Medical Polymers

Properties

- Resistance to environmental stress cracking (ESC)
- Good optics
- Resistance to sterilization
  - Gamma
  - e-beam
  - Ethylene oxide
- Good melt processability

Optical Transparency of Altuglas® CR30

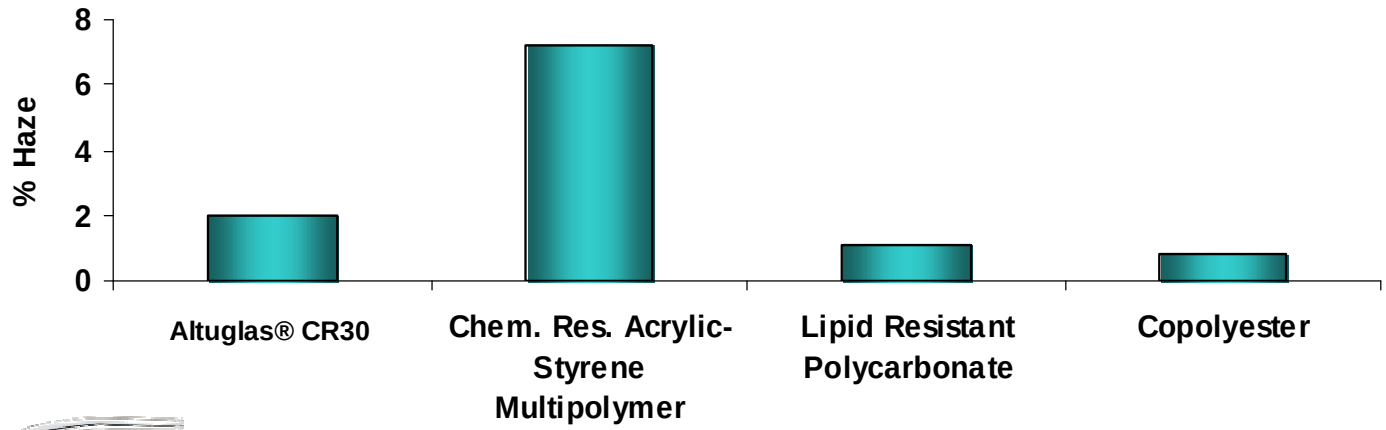
Light Transmittance



Optical Transparency of Altuglas® CR30

Haze

Haze at 3.2mm Thickness



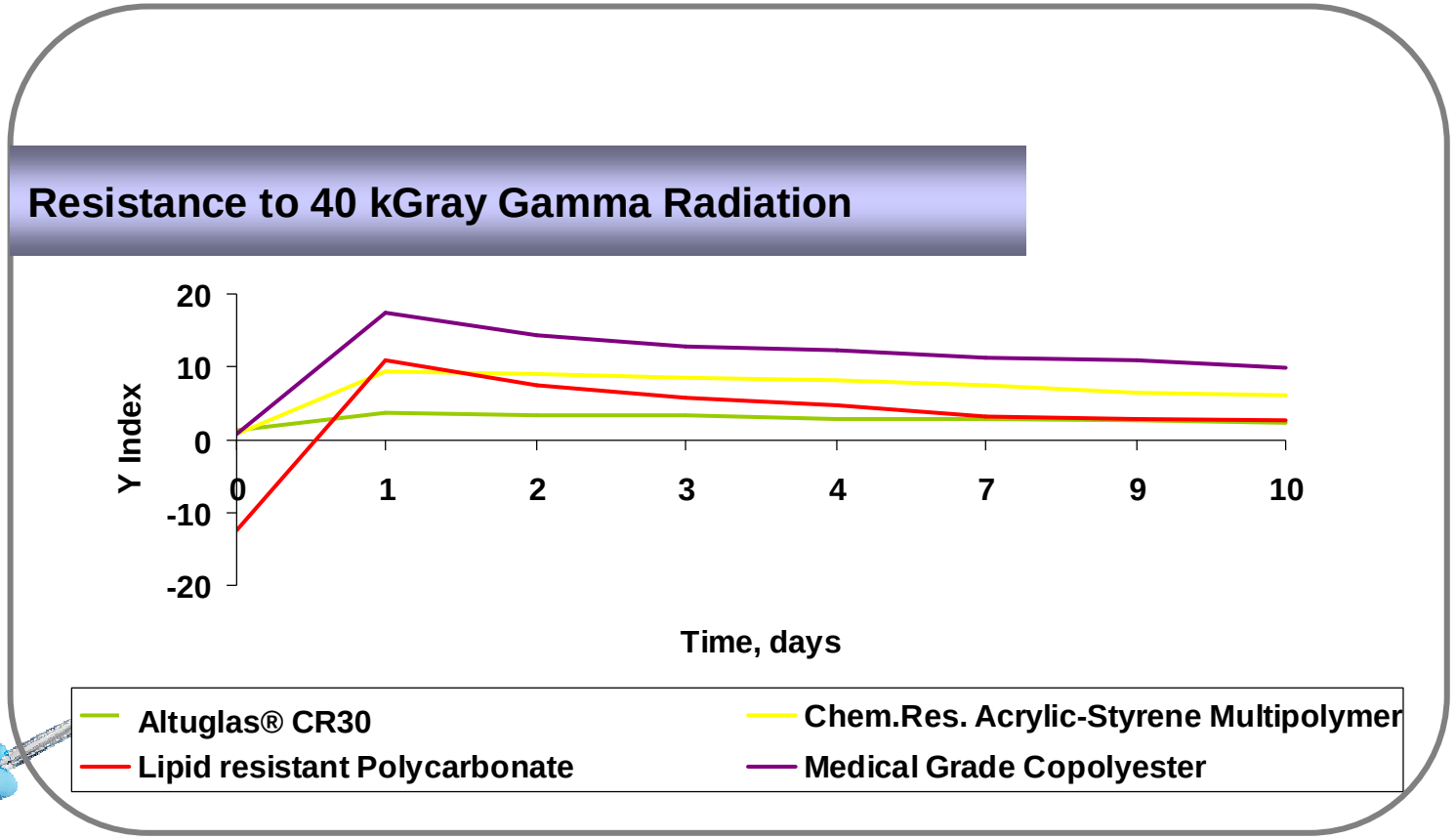
Desired Properties for Transparent Medical Polymers

Properties

- Resistance to environmental stress cracking (ESC)
- Good optics
- Resistance to sterilization
  - Gamma
  - e-beam
  - Ethylene oxide
- Good melt processability

Gamma Sterilization Resistance of Altuglas® CR30

Yellowness Index After 40 Kgray Gamma Radiation



Gamma Sterilization Resistance of Altuglas® CR30

Yellowness Index After 40 Kgray Gamma Radiation

Desired Properties for Transparent Medical Polymers

Altuglas®

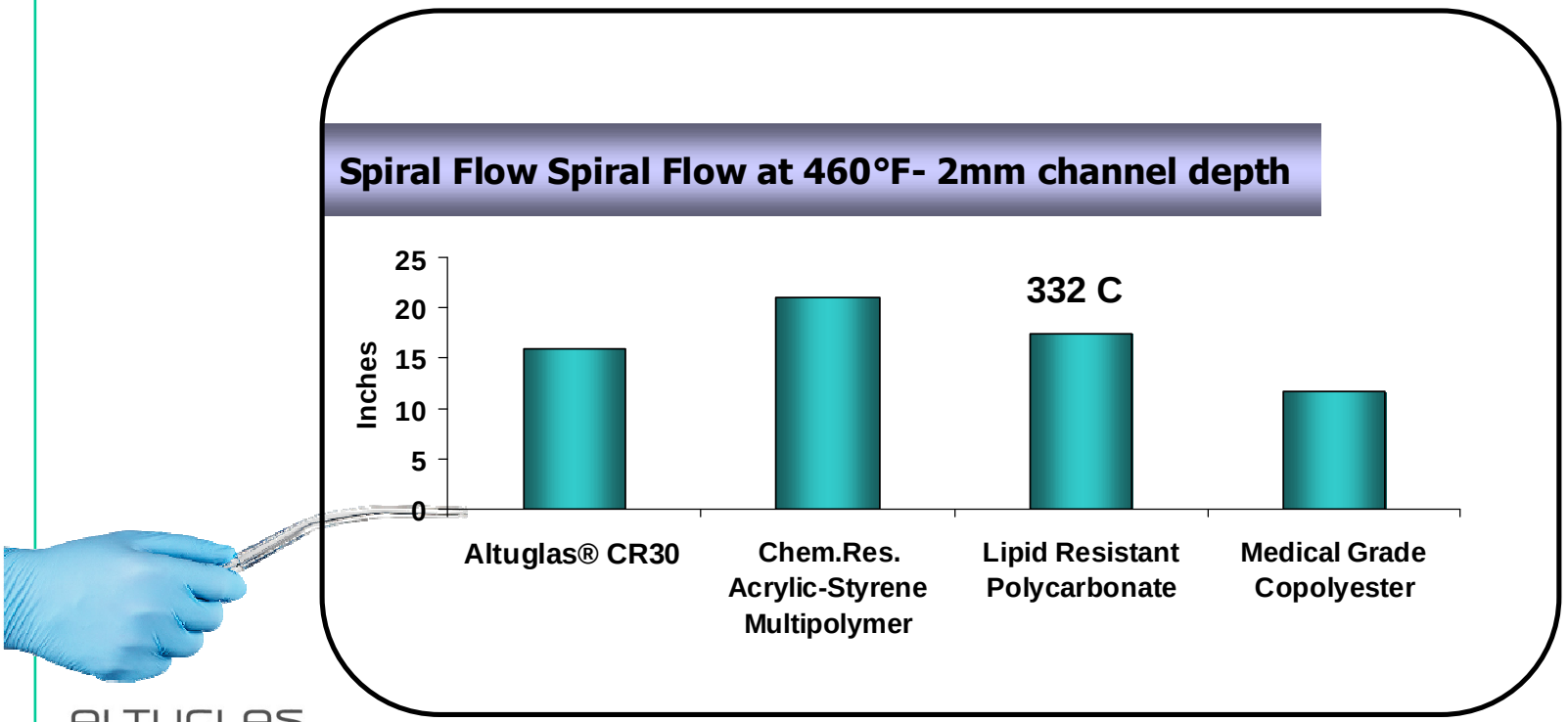
Properties

- Resistance to environmental stress cracking (ESC)
- Good optics
- Resistance to sterilization
  - Gamma
  - e-beam
  - Ethylene oxide
- Good melt for easy processing

Melt Processing of Altuglas® CR30

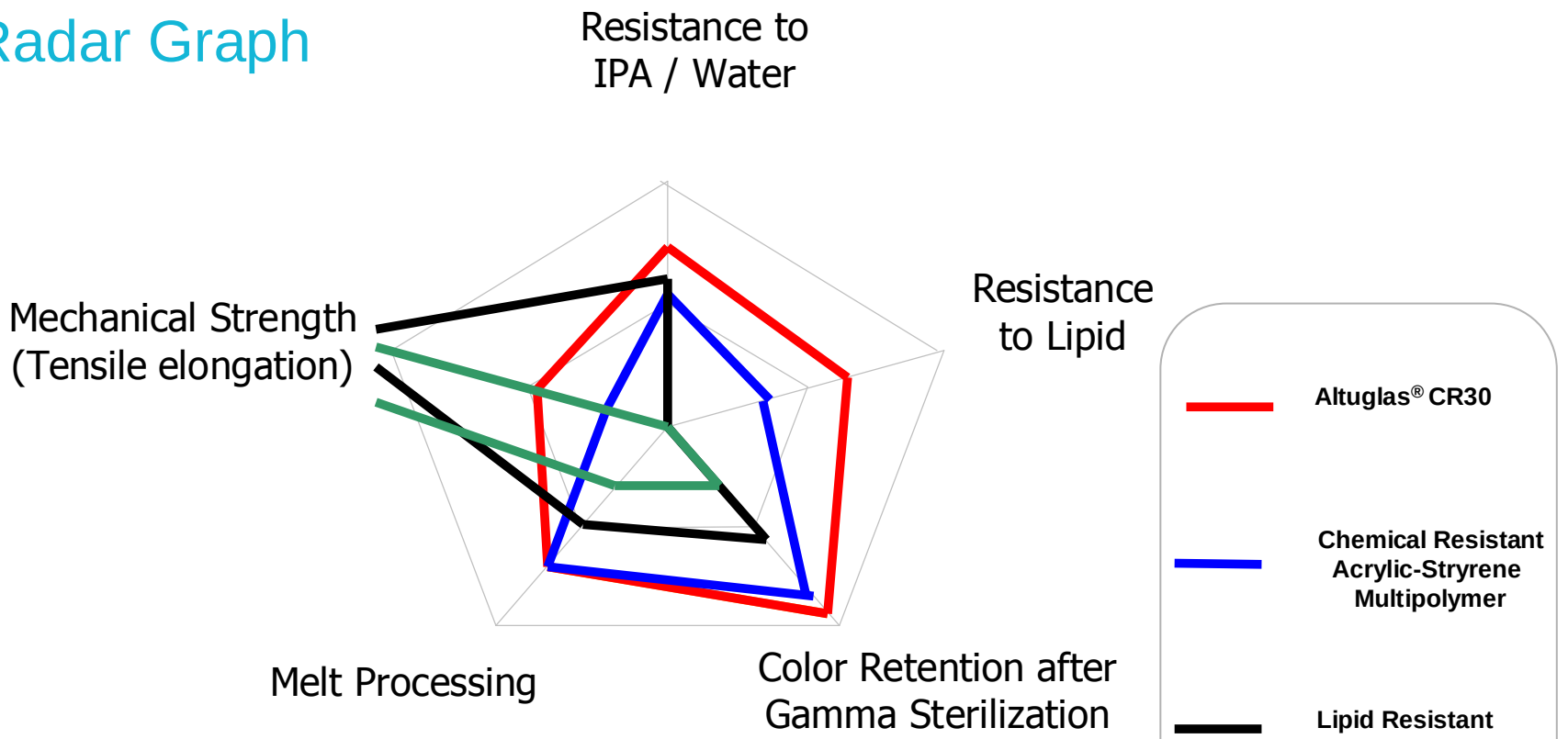
Spiral Flow @ 460F / 238C – 2 mm Channel Depth

- Well suited for injection molding processes
- Excellent shear-thinning properties
  - Ideal for thin-walled and multi-cavity molds



A Balance of Performance Properties

Radar Graph



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Product Comparison Summary

Property	Altuglas® CR30	Medical Grade Acrylic-Styrene Multipolymer	Lipid-Resistant Polycarbonate	Medical Grade Copolyester
Optical Transmittance	**E**	E	F	E
Optical Haze	**E**	F	E	E
Gamma Sterilization Resistance	**E**	G	G	G
Alcohol Resistance	**E**	G	F	P
Lipid Resistance	**E**	G	P	P
Melt Processing	**G**	G	F*	P

**Requires higher temperature*

E = Excellent
G = Good
F = Fair
P = Poor

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Summary

- BPA “Some Concern”
- ESC is caused by stress and chemical exposure
- Altuglas® CR30
  - Superior ESC resistance
  - Excellent optics
  - Excellent Gamma sterilization resistance
  - Good melt processability

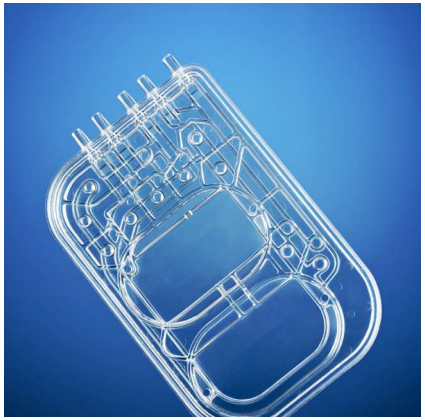
Position Products & Focus Targets

Chemical Resistance	*Altuglas® CR30*
High Flow	*Altuglas® SG7, Altuglas® SG10*
UV Transmitting	*Altuglas® VS-UVT*
Altuglas® Product Selection	*Comparative Advantages*

High Flow Grades

Achieving Balance of Properties with Altuglas® SG series Medical Resins

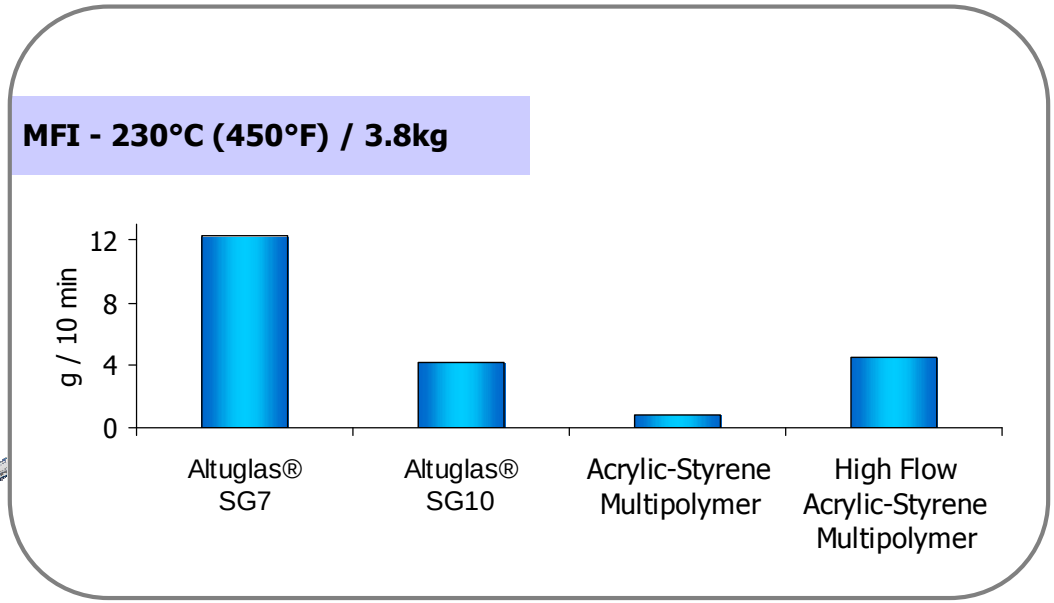
- Excellent Melt Processibility
- Excellent Optical Properties
- Outstanding Gamma Resistance
- Good Chemical Resistance
  - Lipid and IPA Resistance
  - Acids and Bases
  - Disinfectants
  - Antiseptics

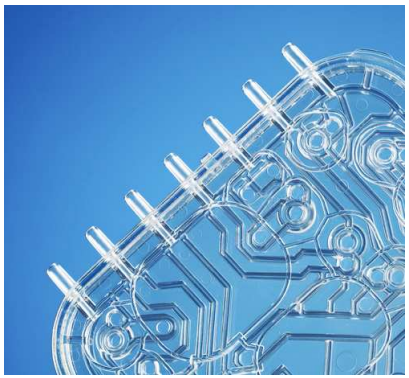


High Flow Grades

Melt Processing

- Altuglas® SG10 and Altuglas® SG7 Medical Resins are high flow resins
  - Perfect resin for for thin-walled and multi-cavity mold applications
  - Faster cycle times and/or lower processing temperatures possible
  - Provides good chemical resistance

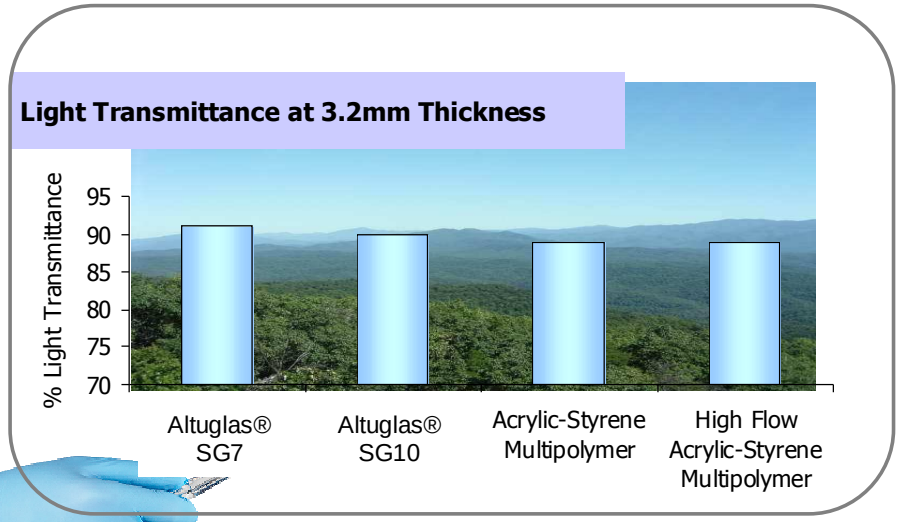


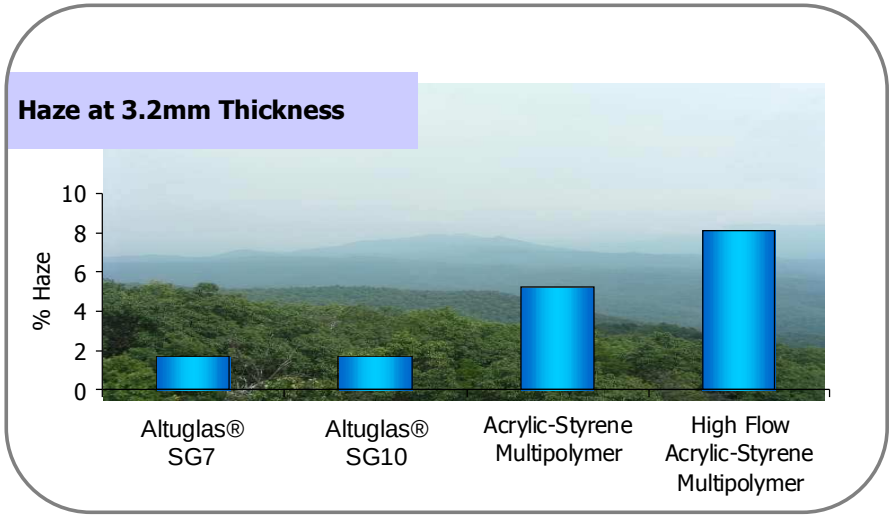


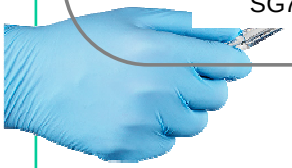
High Flow Grades

Optical Transparency

- Altuglas® SG Medical Resins provide exceptional optical transparency with a combination of high light transmission and low haze level.





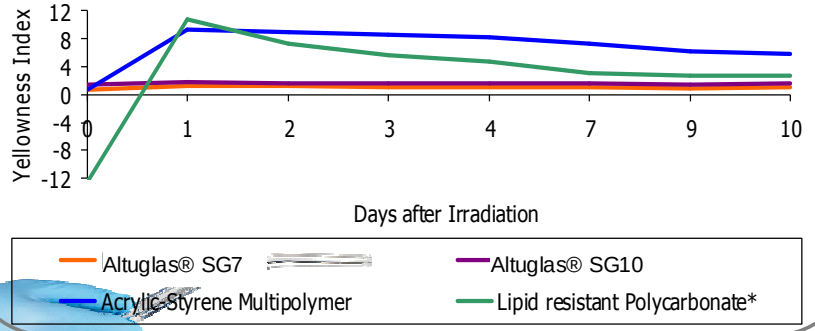


High Flow Grades

Resistance to Gamma Sterilization

- Devices exposed to gamma sterilization must retain excellent color, clarity, and transparency
- Altuglas® SG Medical Resins quickly recover all optical properties and retain 90 -100% of mechanical properties

Resistance to 40 kGray Gamma Radiation



Gamma sterilization
+ 2 week recovery

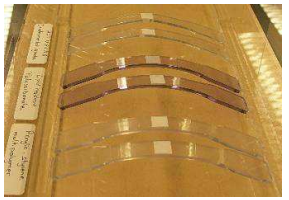
Before
Gamma sterilization

** Medical grade polycarbonate is masked to result in a gray tone after irradiation*

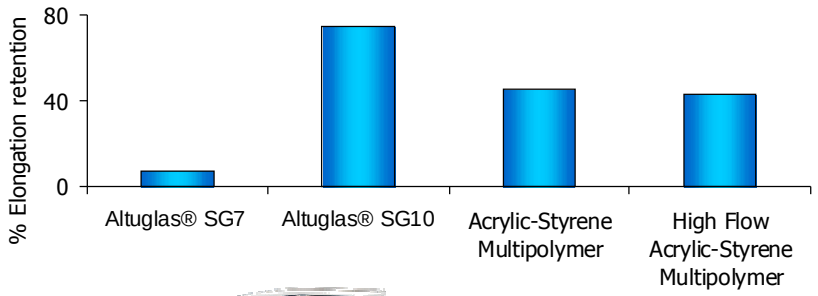
High Flow Grades

Resistance to Lipids and IPA *

- Altuglas® SG Medical Resins have good resistance to IPA
- Altuglas® SG10 has excellent lipid resistance in comparison to other high flow medical polymer

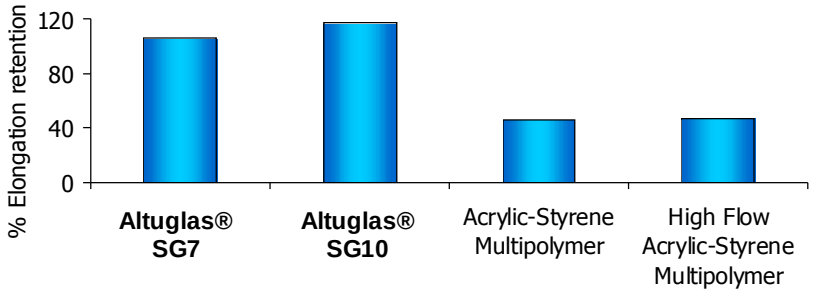


Resistance to Lipid (Cremophor® RH40)



Annealed tensile bars exposed to chemical for 24 hrs at 0.5% constant strain

Resistance to 70% IPA

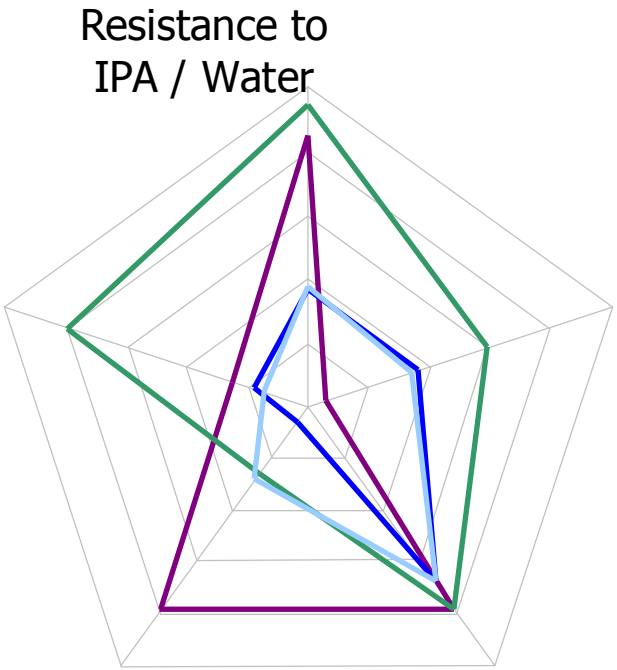


Annealed tensile bars exposed to chemical for 6 hrs at 0.5% constant strain

*** Altuglas® SG Medical Resins were tested under milder, lower strain conditions than Altuglas® CR Medical Resins**

High Flow Grades

Achieving a Balance of Properties with Altuglas® SG series Medical Resins



- Altuglas® SG7
- Altuglas® SG10
- Medical Grade Acrylic-Styrene Multipolymer
- High Flow Medical Grade Acrylic-Styrene Multipolymer

ACRYLIC RESIN

Altuglas® Competitive Comparison

	Altuglas® SG7	Altuglas® SG10	Medical Grade Acrylic-Styrene Multipolymer	High Flow Medical grade Acrylic-Styrene
Optical Transmittance	E	E	G	G
Clarity/Low Haze	E	E	F	F
Resistance to Gamma Sterilization	E	E	G	G
Resistance to Alcohol	P	G	F	F
Resistance to Lipids	G	G	F	F
Resistance to Surface Wetting	F	F	F	F
Melt Processing	E	F	P	F
Impact Resistance	G	G	G	G

E = Excellent
G = Good
F = Fair
P = Poor
/ = Not available

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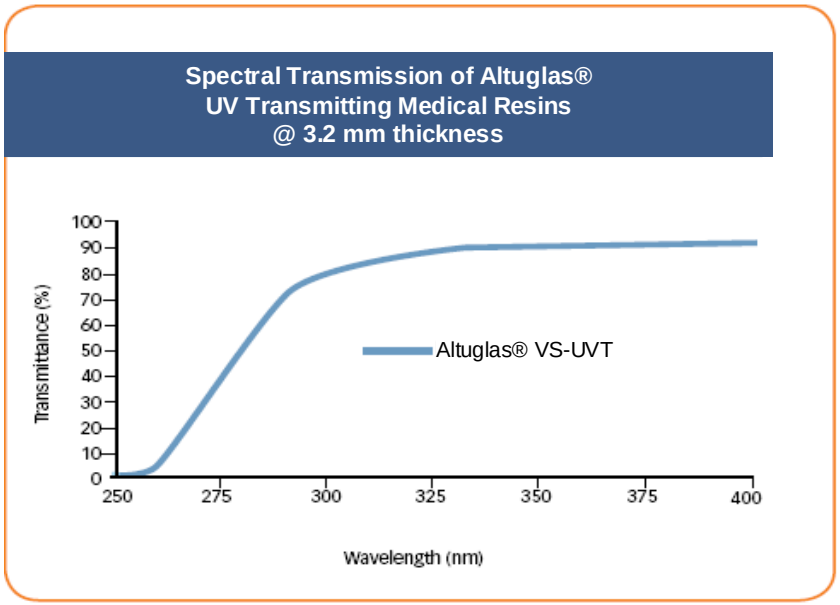
Chemical Resistance	*Altuglas® CR30*
High Flow	*Altuglas® SG7, Altuglas® SG10*
UV Transmitting	*Altuglas® VS-UVT*
Altuglas® Product Selection	*Comparative Advantages*

UV Transmitting Grades

UV Transmission Challenge

- Medical diagnostic applications require excellent transmission in the ultra-violet region
- Altuglas® VS-UVT has considerably higher UV transmission than non-acrylic materials
- Altuglas® VS-UVT has extremely low haze, good dimensional stability, good scratch resistance and high flow for multi-cavity or complex devices

- Examples of Testing:
  - DNA analysis
  - RNA analysis
  - Protein analysis
  - Blood/Body fluid analysis



Altuglas®

- Chemical Resistant Grades — *Altuglas® CR50, Altuglas® CR30*
- High Flow Grades — *Altuglas® SG7, Altuglas® SG10*
- UV Transmitting Grades — *Altuglas® VS-UVT*
- Altuglas® Product Selection — *Comparative Advantages*

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Altuglas® Medical Resins

- Altuglas® history of innovation, quality, and customer service
- Portfolio approach that focuses on specific market needs and ensures:
  - Robustness for wide range application
  - Balance of properties
  - Balance between price and performance
- Regulatory Compliance: USP Class VI and ISO 10993 Part 4&5
- Zero BPA, plasticizers, lubricants, solvents

Altuglas® Medical Resins

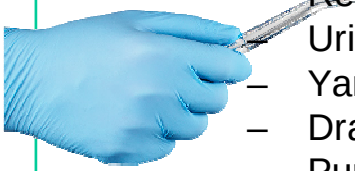
Altuglas® Medical Resins are designed for transparent disposable medical devices

Drug Delivery

- General Care Syringes
  - Oncology Delivery Syringes
  - High pressure Syringes
  - Drug Prefilled Cartridges
  - Drug Prefilled Syringes
- IV & Infusion
  - Fluid control valves
  - Luers
  - Connectors
  - Spikes
  - Filter Housings

Fluid Management

- Renal Cassettes
- Filter Housing
- Reservoirs
- Urine Meter
- Yankauers
- Drainage Tubes
- Pump Housings



Other Devices

- Respiratory Care
  - Aerosol Delivery/Nebulizers
  - Meters for therapy
  - Rigid Masks
  - Filter Housings
- Veterinary Care

Diagnostics

- Cuvettes
- Meters
- Kits
- Labware
- Petri Dishes
- T-Tubes
- Syringes

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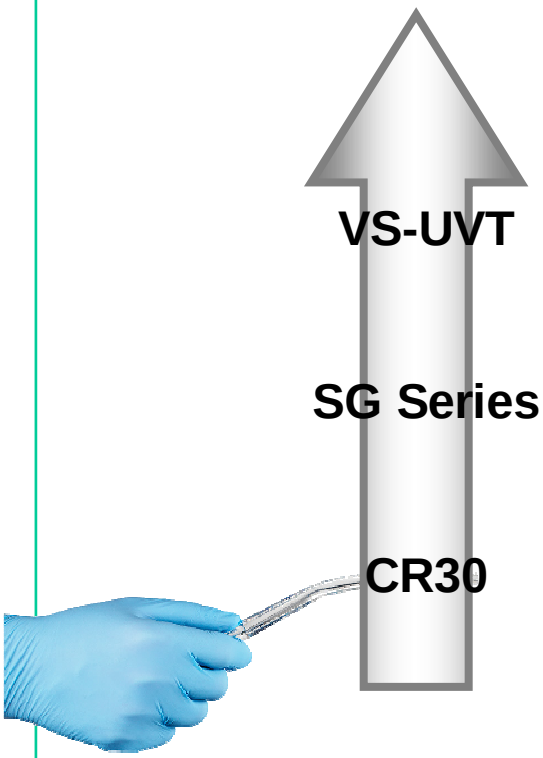
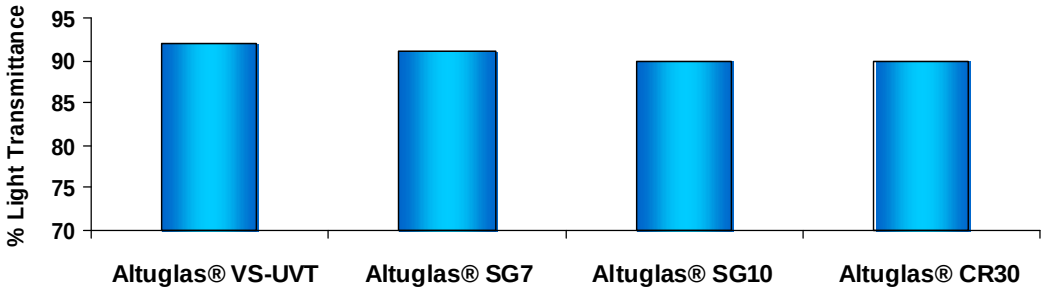
Altuglas® Product Selection

Optical Properties

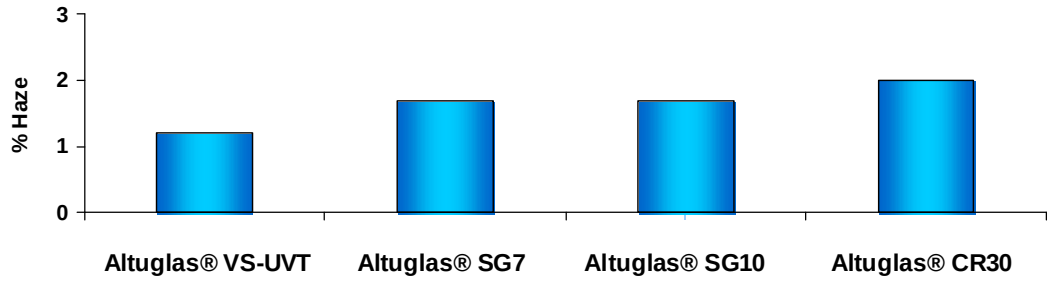
Highest Transmission
& Lowest Haze



Light Transmittance and Haze at 3.2mm Thickness



Light Transmittance and Haze at 3.2mm Thickness



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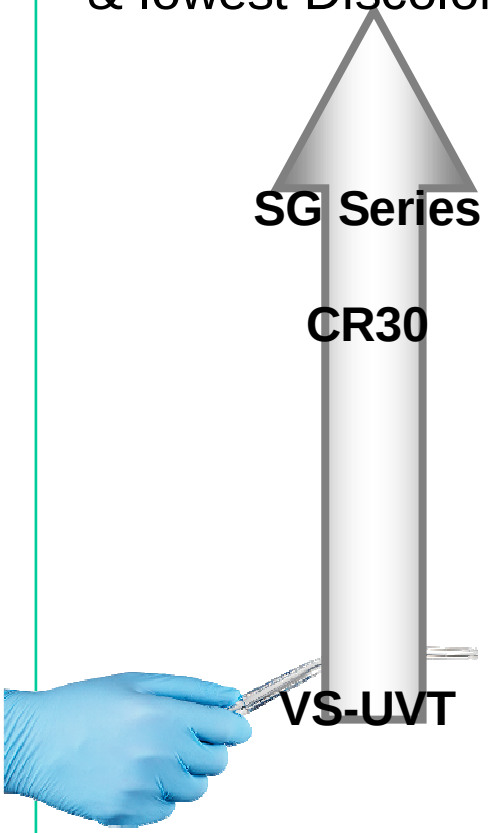
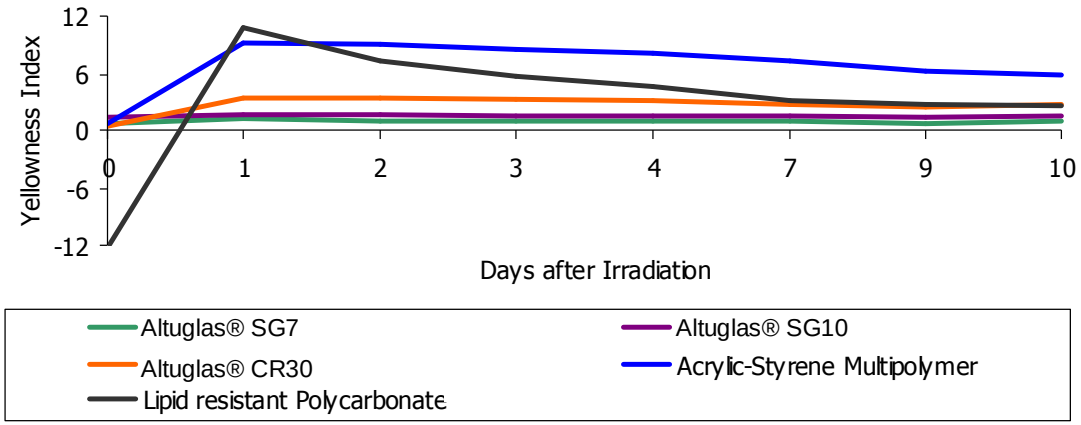
Altuglas® Product Selection

Resistance to Gamma Sterilization

Quickest Recovery
& lowest Discoloration



Resistance to 40 kGray Gamma Radiation



Altuglas® Product Selection

Resistance to Lipids and IPA

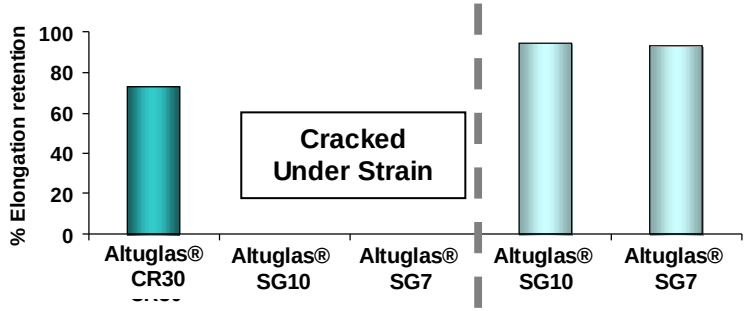
Chemical Resistance

CR30

SG10
SG7

VS-UVT

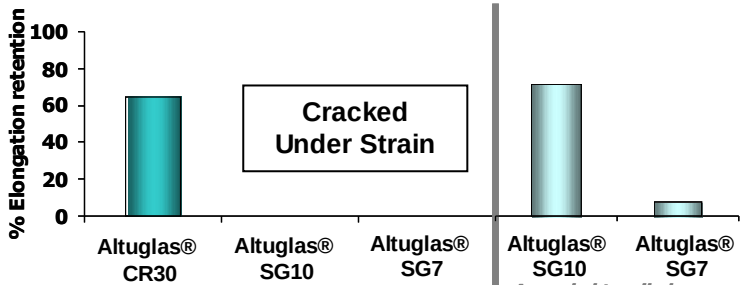
Resistance to 70% IPA



Annealed tensile bars exposed for 6 hrs at 0.75% constant strain

Annealed tensile bars exposed for 6 hrs at 0.5% constant strain

Resistance to Lipid (Cremophor® RH40)



Annealed tensile bars exposed to chemical for 24 hrs at 1 % constant strain

Annealed tensile bars exposed to chemical for 24 hrs at 0.5% constant strain

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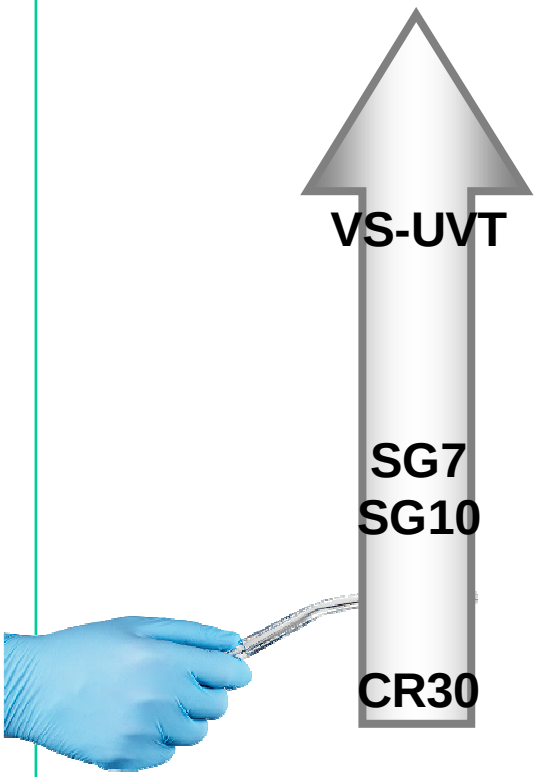
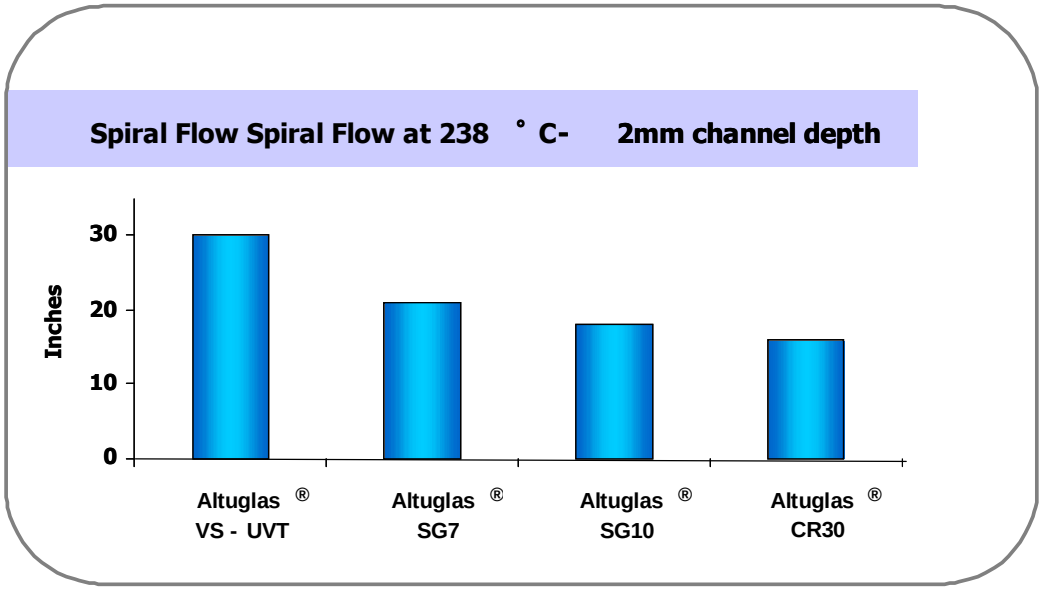
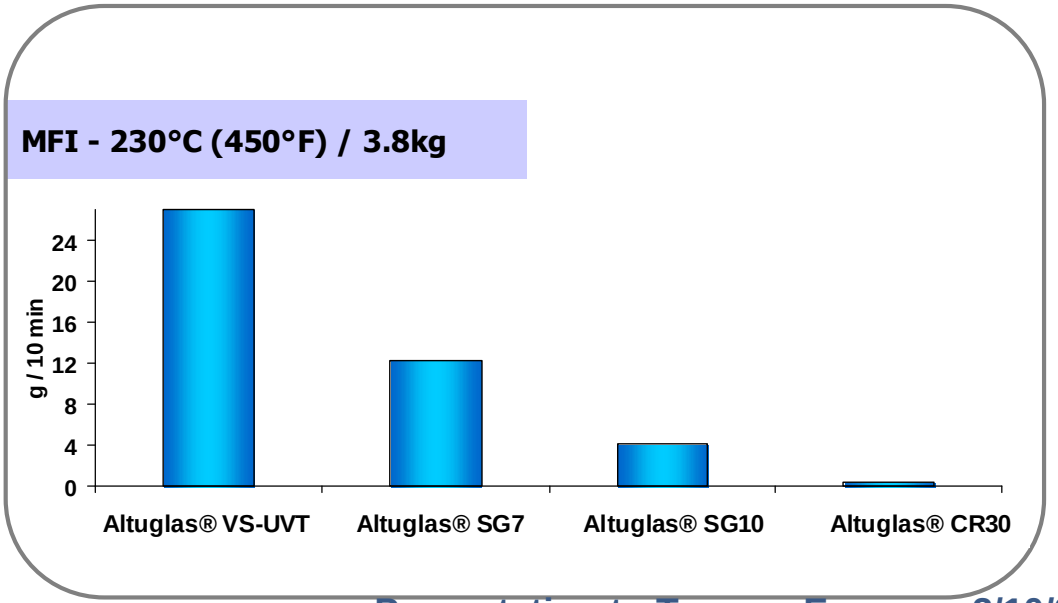
Altuglas® Product Selection

Melt Processing

Best Flow Characteristics







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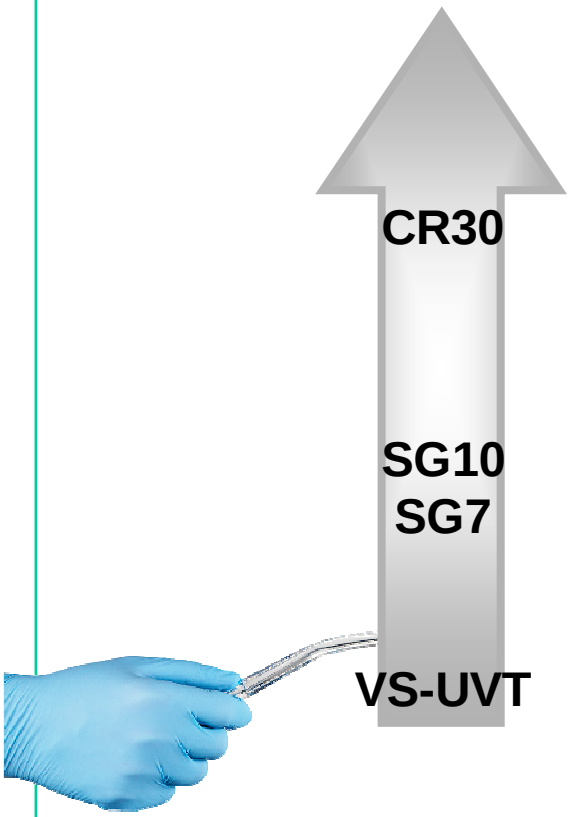
Injection Molding Startup Parameters

Altuglas® Grade	Cylinder Temperature				Other Parameters			
	Rear Zone (C°)	Center Zone (C°)	Front Zone (C°)	Nozzle (C°)	Injection Speed	Screw Speed rpm	Back Pressure Psi	Mold Temp (C°)
CR30	216	221	227	221	Medium	50-100	100	66
SG10	221	227	232	227	Medium	50-100	100	71
SG7	216	221	227	221	Medium	50-100	100	66
VS-UVT	182	188	193	188	Medium	50-100	100	54

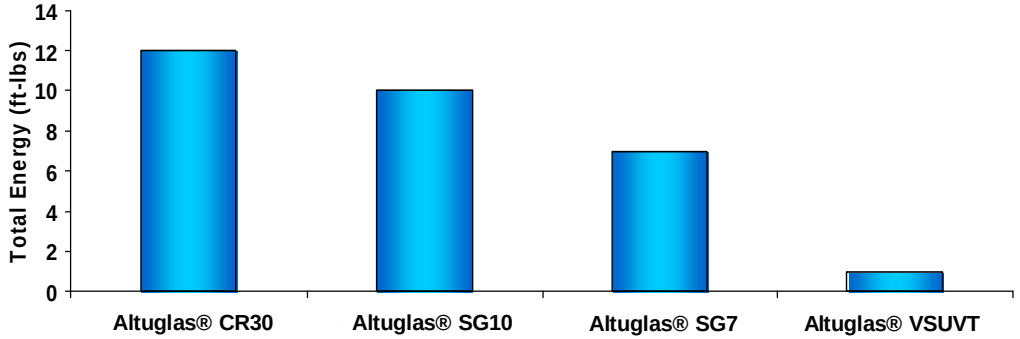
Altuglas® Product Selection

Impact Strength

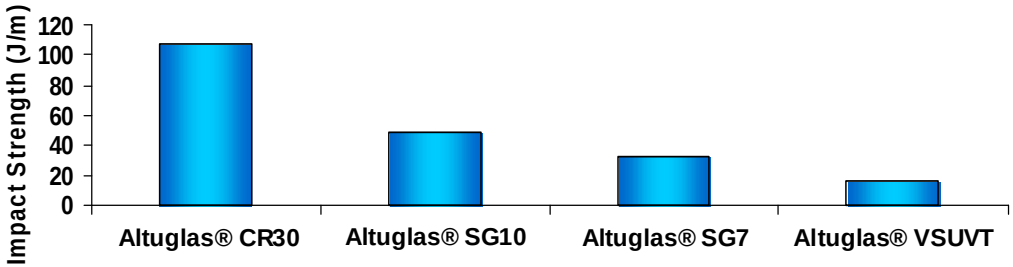
Toughness



Impact Strength (Falling Dart)
at 3.2mm Thickness, 3lb Dart, 14" Radius



Impact Strength (Notched Izod) at 3.2mm Thickness



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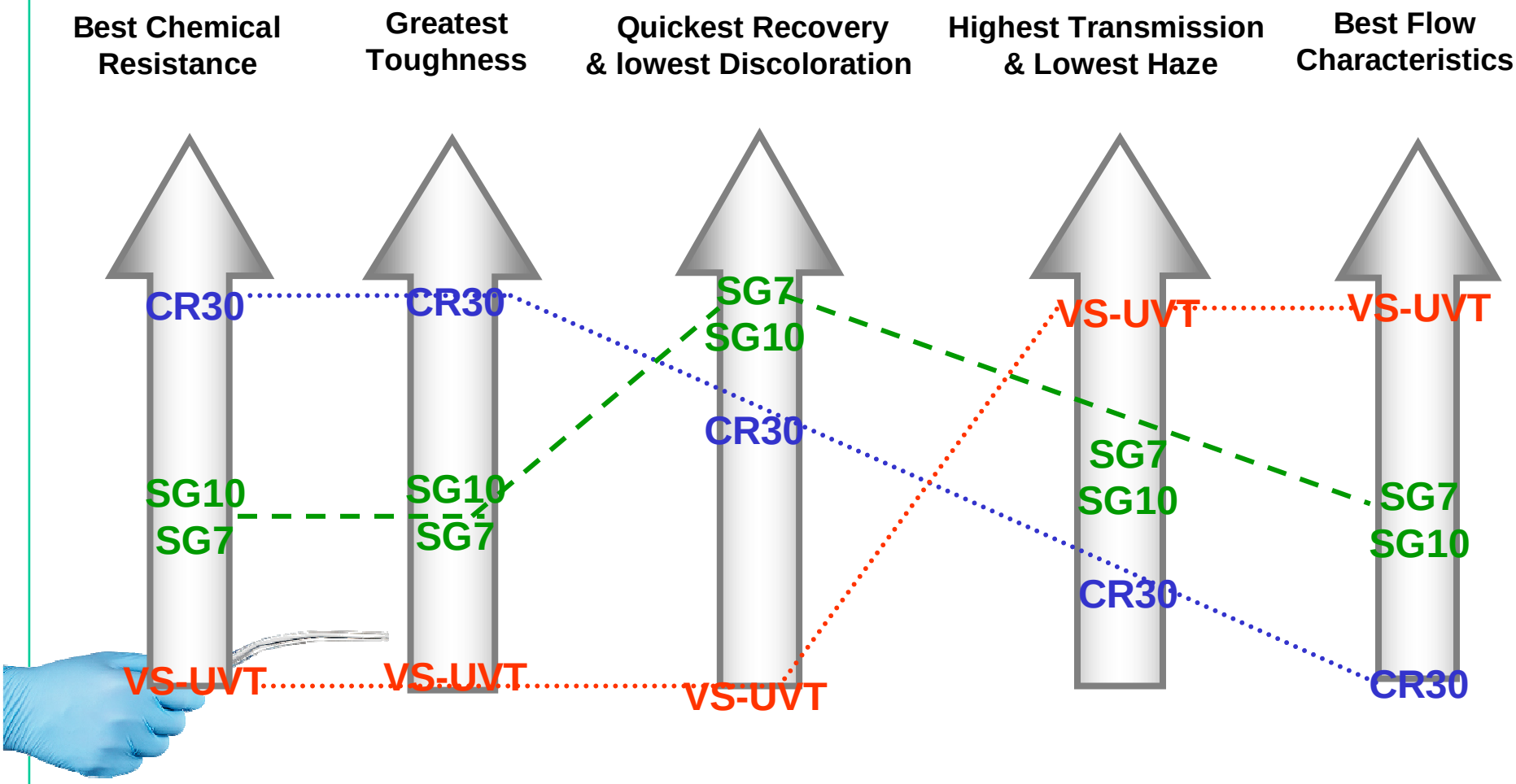
Altuglas® Product Selection

Relative Standing Amongst the Altuglas® Medical Resins



Summary

- **Relevant Trends in the Market**
  - Environmental Stress Crack (ESC) Resistance
  - BPA - Free
- **Overview of *Altuglas*® Medical Resins**
  - ***Altuglas***® CR30
    - **Outstanding chemical resistance**, excellent optics, gamma sterilization resistance and goo melt flow for harsh chemical exposure such as ***Fluid Management & IV and Drug Delivery applications***
  - ***Altuglas***® SG Grades
    - Good chemical resistance, excellent optics, gamma sterilization resistance and **exceptional melt flow** for ***Fluid Management and some diagnostic applications***
  - ***Altuglas***® VS-UVT
    - **UV transparent** for ***diagnostic applications***

Thank You!
Q & A

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Mobile: +33 (0)6 21 57 10 02

Altuglas®

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See MSDS for Heath & Safety Considerations

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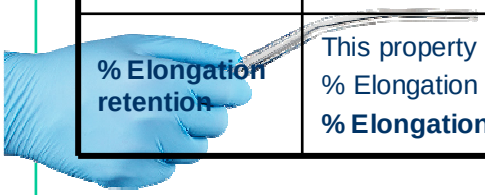
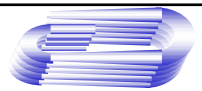
Appendix: Glossary

Term	Definition
Lipid	Natural oil-soluble compound. Include fats, oils, waxes, cholesterol, triglycerides, etc.
Cremophor®	Polyethoxylated lipid , widely used pharmaceutically for solubilization of water-insoluble drugs and vitamins. This class of lipids is known to be aggressive towards transparent plastics Cremophor® EL = Polyethoxylated castor oil. Cremophor® RH40 = Polyethoxylated hydrogenated castor oil.
Intralipid®	Lipid emulsion (also called fat emulsion) for IV administration, as a source of calories and essential fatty acids. Intralipid® 20% = 20% soybean, 1.2% egg yolk phospholipids, 2.25% glycerin, in water.
TPN solution	Total Parenteral Nutrition solution for IV administration, as a source of sugar, proteins, vitamins, and minerals.
IPA	Isopropyl alcohol = Disinfectant = Antimicrobial agent applied to non-living objects
Betadine®	Povidone iodine = Antiseptic = Antimicrobial agent applied to living objects
Hibiclens®	Chlorohexidine gluconate 4% = Antiseptic = Antimicrobial agent applied to living objects
Butylamine	Organic compound used to mimic a functional group of proteins
Chemical resistance	Ability of a plastic to maintain performance upon exposure to chemicals under stress. Loss of performance includes: crazes (or cracks), loss of mechanical strength
ESC resistance	Environmental Stress Cracking resistance = Other used term for “Chemical resistance”
% Elongation retention	This property is related to the retention of mechanical strength after chemical exposure under stress.  % Elongation (% Tensile elongation at break) = Amount that a plastic part can stretch before it breaks during a tensile test. **% Elongation retention** = % Elongation after chemical exposure compared to unexposed sample.



Glossary-continued

Term	Definition
Chemical Build-up	Accumulation of a chemical substance on the surface of a plastic material. Can potentially lead to clogging of IV lines, and to dosage issues with drug delivery
Spiral Flow	Length of spiral mold that can be filled with a resin in an injection molding process. Higher spiral flow means better melt processing. 
Gamma radiation sterilization	**Sterilization** = Process that effectively kills micro-organisms. **Gamma radiation** is 1 of the most used sterilization process for medical devices. Other common sterilization processes include: Electron beam, Ethylene oxide (EtO), steam.
kGrays or kilograys	Unit of gamma radiation - 1kGray = 0.1 Mrad (MegaRad) 25 kGrays (2.5 Mrad) of gamma radiation is typical for gamma sterilization
Bonding (or welding)	**Bonding (or welding)** = Creating a joint between 2 plastic parts Welding techniques include: ultrasonic, Radio frequency, hot plate, solvent
Rockwell Hardness	Measure of a plastic surface hardness by the depth of penetration of an indenter under a load. Different Rockwell scales exist based on different indenters and different loads