

IPAC-RS Supplier QC Guideline Training Session

Management of Change

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Sharing our futures

SABIC – Our Parent Company



Standalone SBUs



Representative Healthcare Segments



Blood Care

blood collection & separation devices, blood filters, oxygenators, dialysis equip.



Fluid & Drug Delivery

stopcocks, luers, Y-sites, infusion pumps, insulin pens, needle-less injection devices



Labware & Clinical Diagnostics

vials, diagnostic trays, pipettors

Medical Lighting

reflectors, handles, housings, covers

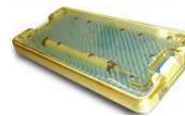


Surgical Instruments

handles, triggers, housings

Medical Trays

sterilisation: surgical, orthopedic, dental storage & transport



Animal Research & Care

cages, bottles, racks, health devices

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Application Requirements

Polymer Performance Options

Common General Considerations

- ✓ **Optical Clarity; colorability**
- ✓ **Impact Resistance**
Ductility for rigorous use
Cold & high temp performance
- ✓ **Dimensional Stability**
- ✓ **High Flow & Release**
complex designs, miniaturization
- ✓ **Specialization**
added strength, lubricity, shielding
- ✓ **Flame Resistance**

Common Healthcare Considerations

- ✓ **Sterilization Diversity**
gamma, autoclave, EtO
- ✓ **Biocompatibility⁺⁺**
ISO 10993 or USP Class VI
Advanced Biocompatibility
increased platelet retention,
low protein binding
- ✓ **Food Contact Compliance**
US FDA, EU FC
- ✓ **Chemical Resistance**
disinfectants, cleaners, lipids, IV solutions
- ✓ **Welding & Bonding**

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A Wide Variety of Resins For Healthcare Applications

■ = Manufactured by SABIC Innovative Plastics

High Performance Engineering Thermoplastics	PEI ■ PPSU ■	LCP ■
	PEI/PCE ■	PPS ■
	PPE/PA ■	PBT ■
Commodity	PC ■ PPE/PS ■	POM ■
	PC/ABS ■ PC/PBT ■	PA ■
	PC/ASA ■	
	ASA ■ PS ■	PP ■ PET ■
	ABS ■ PVC ■	PE ■
	Amorphous	Crystalline

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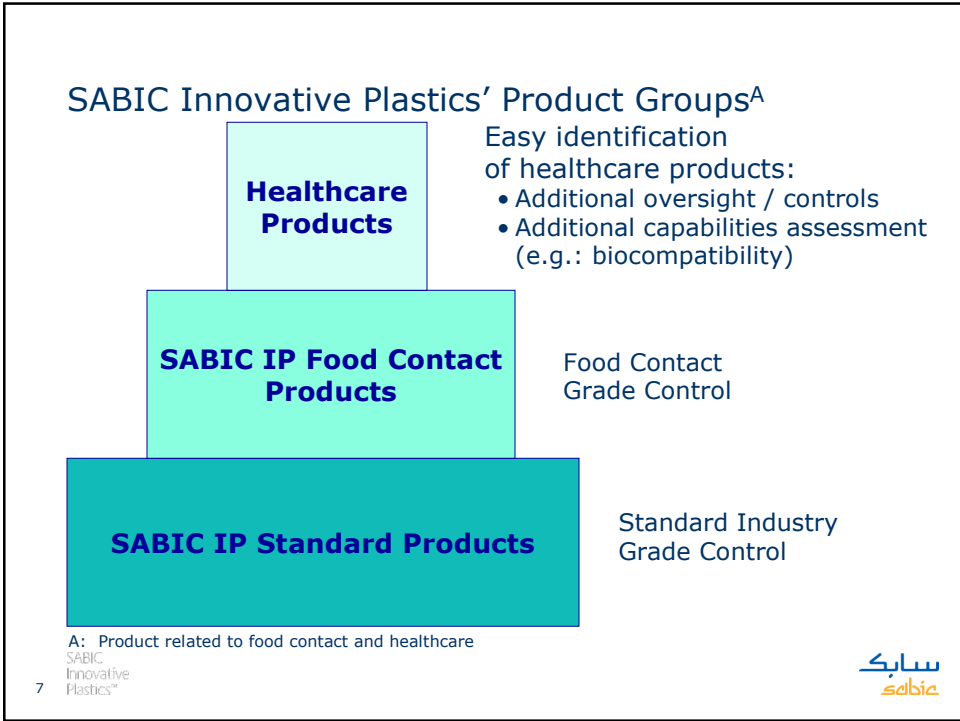


Provides technical solutions via additive and/or modifier technologies	Provides application solutions via healthcare resin portfolio and application development support	Provides Mfr solutions and material & application support	Provides value through application design and innovative new solutions	Provides distribution related services to deliver application to end-user	End-user: require functional easy-to-use applications for use in multiple settings
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Competencies Along Value Chain Drive and Support Optimised, Efficient Material Selection / Application Development

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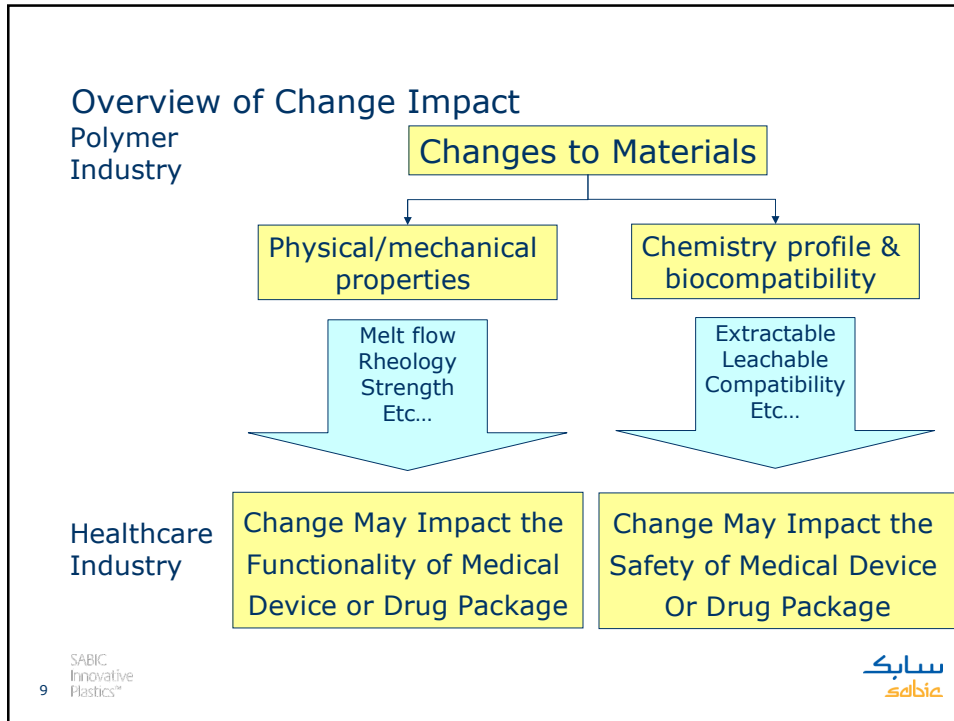


What is a thermoplastic resin?

Potential ingredients

• Base Resin(s)	provides basic characteristics
• Impact Modifier	impact resistance
• Flame Retardant	level of flame retardance
• Fiber Reinforcement	modulus, strength, special performance
• Stabilizers	processing and oxidative stability
• Processing Aids	processing performance
• Colorants & Pigments	aesthetics and visual effects

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SABIC Innovative Plastics: "Healthcare Product" Policy

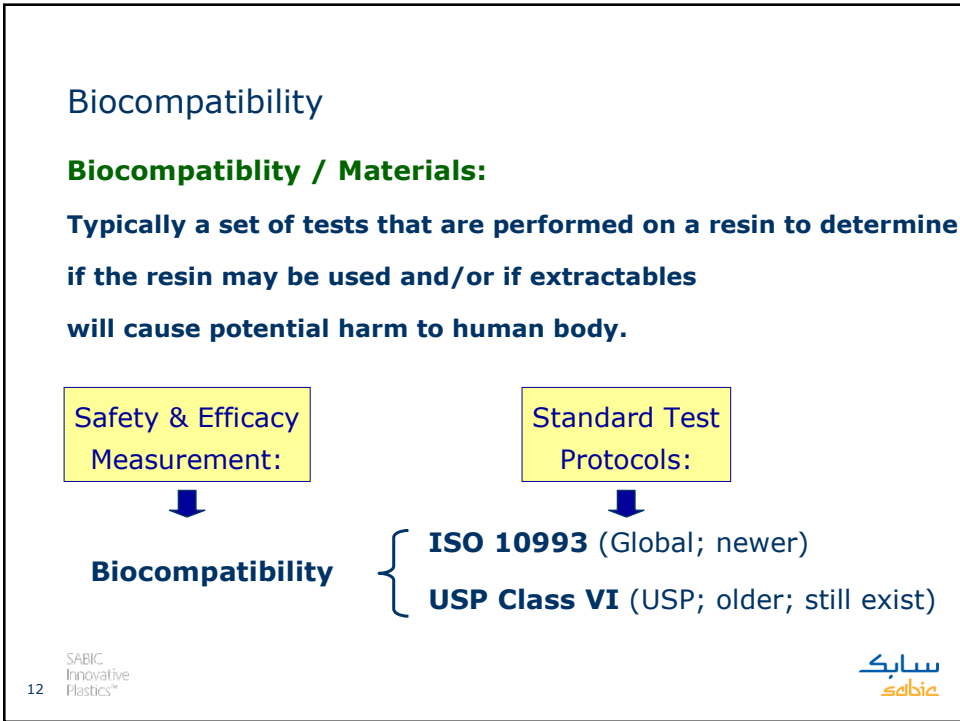
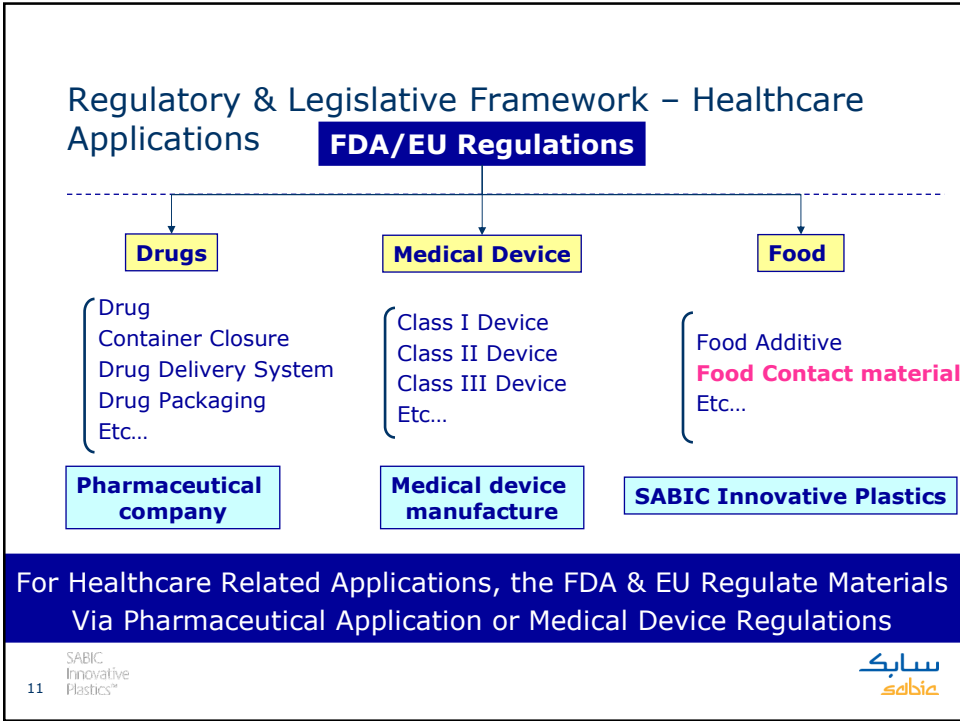
- ✓ **Easily identifiable "healthcare product" nomenclature**
 - Cylolac* HM resins
 - Cyloloy* HC resins
 - Lexan* HP resins
 - Noryl* HN resins
 - Ultem* HU and HA resins
 - Valox* HX resins
 - Xenoy* HX resins
 - Xylex* HX resins
- ✓ **Biocompatibility assessed (according to ISO 10993 or USP Class VI)**
- ✓ **Food contact compliance for most "healthcare products"**
- ✓ **FDA Drug Master File and/or Device Master File listing (letter of authorization provided as needed)**
- ✓ **SABIC Innovative Plastics "healthcare products" are subject to formula lock and stringent management of change process (ask your SABIC Innovative Plastics representative for more details)**

SABIC Innovative Plastics Does Not Support Applications Which Remain Implanted Beyond 29 Days

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Application Examples

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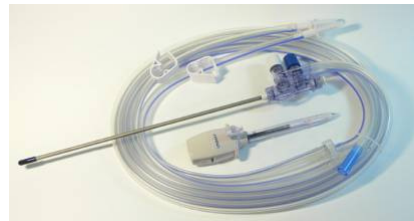
Case Study: Auto-Locking Trocar & Suction Irrigation Set

CHALLENGE

- Upgrade to impact resistant, gamma-stable Polycarbonate (PC)
- Optimize manufacturing system cost

SOLUTION

- Lexan* HPS resins for
 - Biocompatibility++
 - Clarity
 - Gamma sterilisation
 - Impact resistance
 - High flow and release for manufacturing complex part design



BENEFIT

- Gamma sterilisable instruments, faster production, reduced system costs

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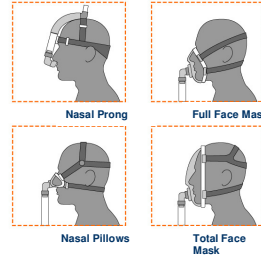
Case Study: Respiratory – Nasal & Face Masks

CHALLENGE

- Transparency and chemical resistance with biocompatibility, sterilisation capability and adhesion to soft polymers

SOLUTION

- Lexan* HPH & Lexan HPX polycarbonate (PC) resins for
 - > Clarity
 - > Good chemical resistance
 - > Biocompatibility++
 - > Good flow / processing
 - > Autoclave @ 134 °C and EtO sterilization



BENEFIT

- Durability
- Biocompatible for use in parts with direct airway contact and with humidified air contact
- Parts consolidation through good adhesion to silicones or Thermoplastic Polyurethanes

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Lexan* HPX Resin : Clarity, Toughness, Inherent Lubricity

CHALLENGE

- Metal replacement to eliminate concerns about infection and to improve accuracy of procedure

SOLUTION

- Transparent Lexan HPX resin providing optimal visibility during intubation procedure
- Inherent lubricity of Lexan HPX resin aiding speed and accuracy to procedure



BENEFIT

- Lexan HPX resin combines mechanical strength, toughness, smoothness and clarity facilitating insertion and providing excellent image performance
- Lexan HPX does meet stringent requirements for biocompatibility

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Closing Statement

- Healthcare Industry Trends and Drivers Do Raise Application Requirement Level
- Healthcare Industry Has An Increased Focus on Patient and Staff Safety
- Ownership Along the Supply Chain to Mitigate Potential Concerns
- Our Healthcare Product Policy Does Support Key Healthcare and Pharmaceutical Requirements
- Our Innovative Material Solutions Do Address Industry Trends in Terms of Design, Functionality, Property and Processing Performance Requirements.



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SABIC Innovative Plastics does not support applications which remain implanted in the human body beyond **29 Days**. Each user must identify and perform all tests and analyses necessary to assure that its finished parts incorporating GE's materials or products will be safe and suitable for use under end-use conditions.

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++ Biocompatibility: A representative lot of material tested either by ISO 10993 or USP VI protocol. Test data available via Type I or Type II letter. Type I Letter: Issued for products that have been specifically tested for biocompatibility. Type II Letter: Issued when specific product has not been tested but similar products have been tested for biocompatibility