

WHERE COLOR MEETS COMPLIANCE

The New Standard for Medical-Grade
Polymer Design in the Healthcare Market



Kumar Parimal
Product Development Manager

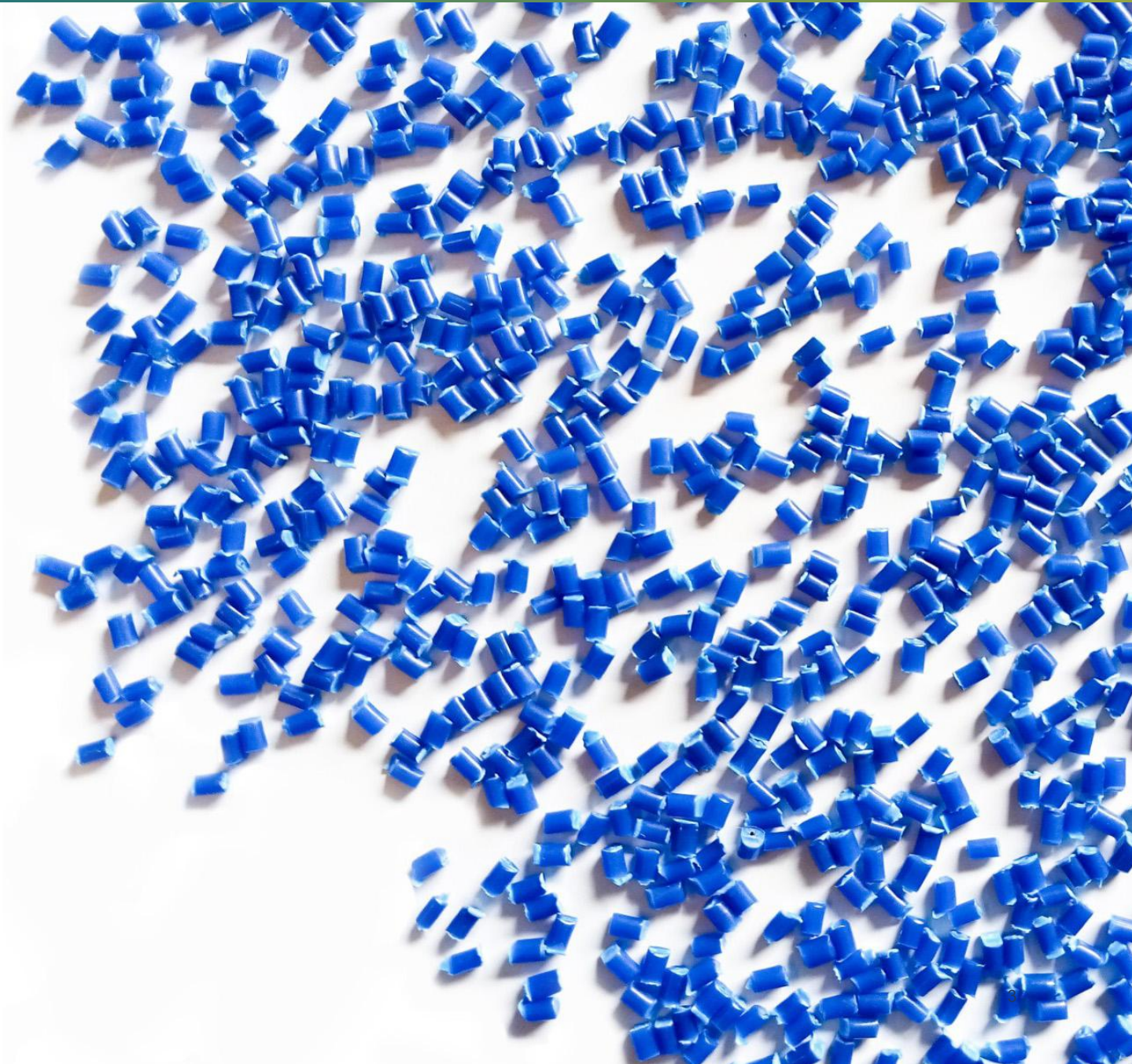
Dr. Kumar Parimal is a Product Development Manager on the Global Research and Innovation Team at Americhem

- Over 15 years serving the plastic industry in extensive research and development roles
- Undergraduate study at IIT Bombay in India and doctoral studies in chemistry from Indiana University in the U.S.
- Since 2019, he has been part of the Global Research and Innovation team
- His current role supports research of new material development for various industries, including healthcare

Critical to Quality

What are your main quality requirements when developing an application?

- Mechanical
- Regulations
- Temperature
- Aesthetics
- Supply Chain



About Americhem

Americhem is your global partner in manufacturing polymer solutions



Over 80 years of growth and innovation in a privately held company



Worldwide sales and technical support



12 locations across NAFTA, Europe, and Asia



Cutting edge organization of diverse people



Over 900 global employees



Recognized global technology leader in the plastics industry

WE HAVE THE POWER TO TRANSFORM THE WAY YOUR PRODUCT:



LOOKS



FEELS



PROCESSES



PERFORMS

Survey Results

Disposable vs. Durable

Mechanical Performance

Impact, strength, working temp

Physical Attributes

FR, lubricity, antistatic

Aesthetics

Brand color, high gloss, color coordination with mating parts

Secondary Processes

Sterilizations, exposure to chemicals, branding, assembly, marking

Manufacturing

Resin vs. masterbatch

Americhem's

Manufacturing Capabilities

Optimized assets for customization, clean compounding

Supply

Global support in U.S., EU, China, and India

Regulatory Requirements

UL listing, REACH compliance, EPEAT, ROHS

Compliance

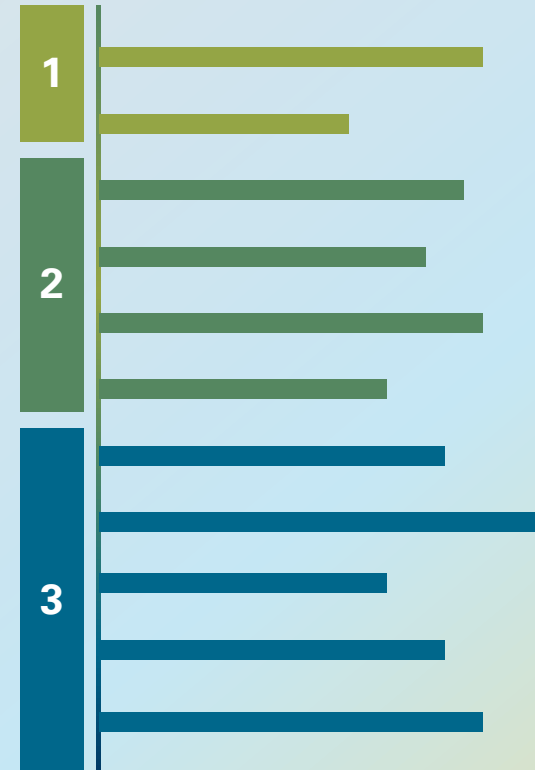
FDA, USP class, biocompatible

Americhem's

Manufacturing Controls

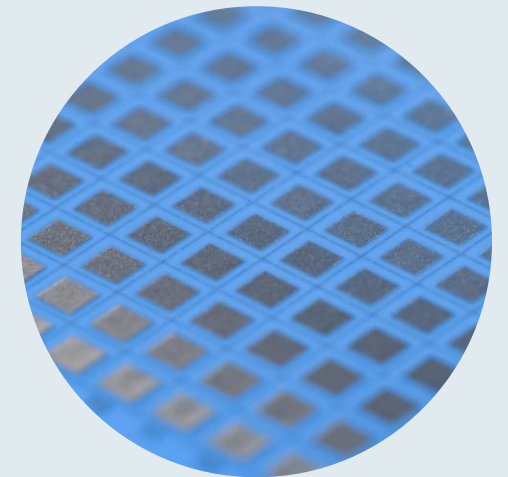
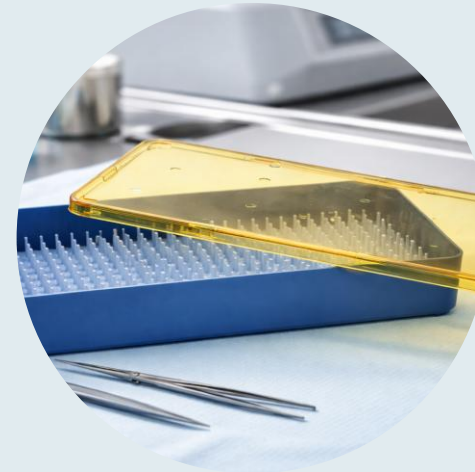
ISO 13485 facility, change management process

Voice of Customer



What Is ColorRx®?

Americhem's premier medical custom compound, masterbatch, and alloy product portfolio



What Is ColorRx®?

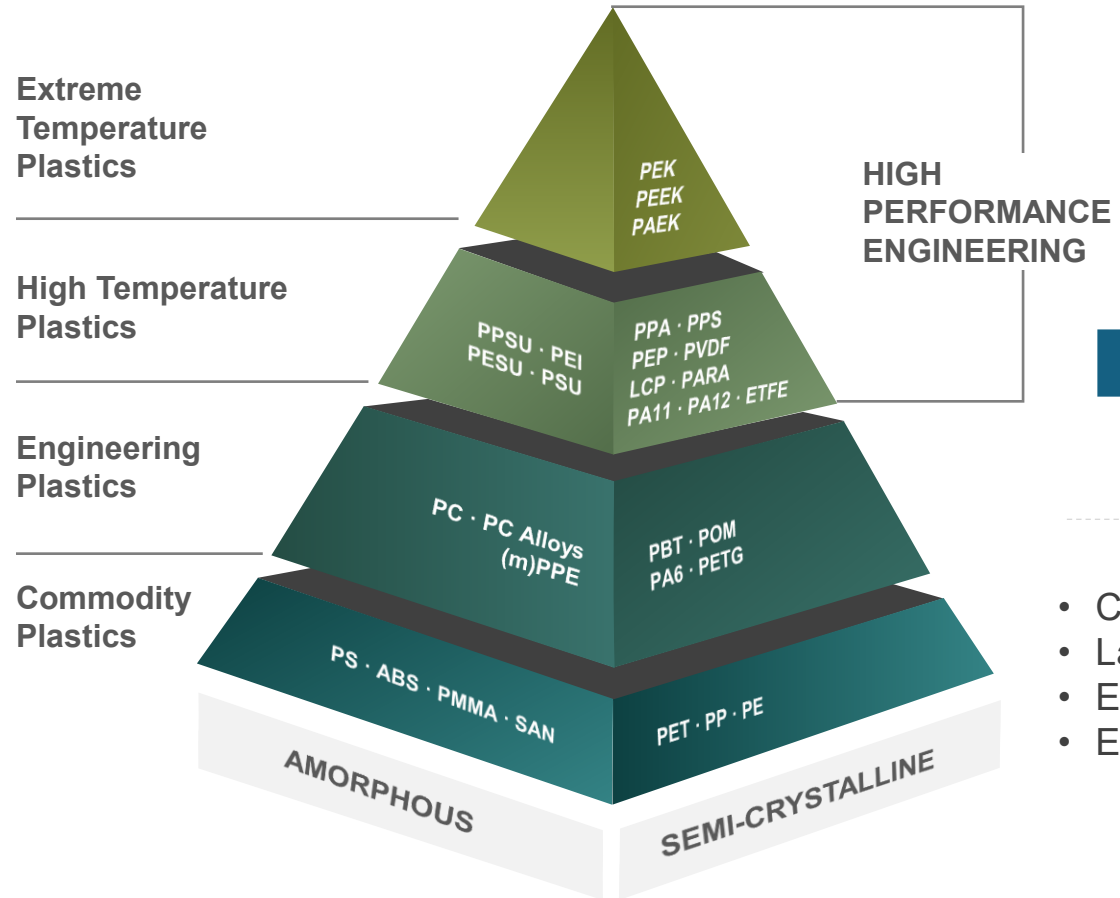
More Than Color

- **Medically compliant locked formulations**
 - ISO 10993-5 biocompatibility and global compliance
 - Process change management with notice of change
 - Sustainable eco-friendly formulations
 - Transparent global formulation and equivalency
- **Three state-of-the-art global facilities**
 - ISO 13485 and cGMP compliant facilities in the U.S., Denmark, and China
 - State-of-the-art clean compounding manufacturing areas
 - Global QMS and procedures
 - On-site development and quality labs
- **Global supply and compliance**



Specialty Thermoplastic Compounds and Masterbatch For The Medical Industry

WE ARE RESIN AGNOSTIC



Functionalized Solutions

- Total products on UL Prospector- 1005
- Products with UL yellow cards – 114

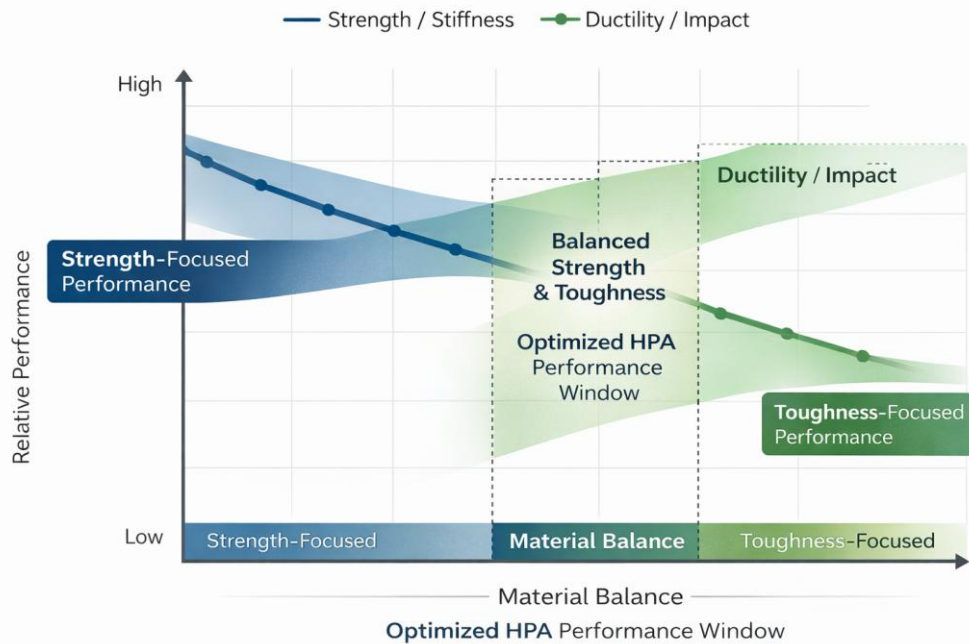
PLATFORM DRIVEN APPROACH

- Current R&D team has over 500 years of product development experience
- Labs that can generate most, if not all, of the datasheet properties
- Equipment and experience with all polymers
- Equipment not only to develop, but translate to production

High Performance Alloys

Engineered for high performance and customized for your application

Single polymeric solution can come with some constraints that leads to compromise. Americhem's knowledge can help to bridge the gap by bringing complementary polymers together.



- High Performance Alloy (HPA) is not a single formulation, but a material platform designed to align performance with application priorities.



LESS DEFORMATION WITH HIGH-PERFORMANCE ALLOY

MORE DEFORMATION WITH TRADITIONAL SINGLE POLYMER



- Balance between complementary material behaviors – high heat, chemical resistance, and sterilization performance while enabling targeted improvements in strength and toughness.

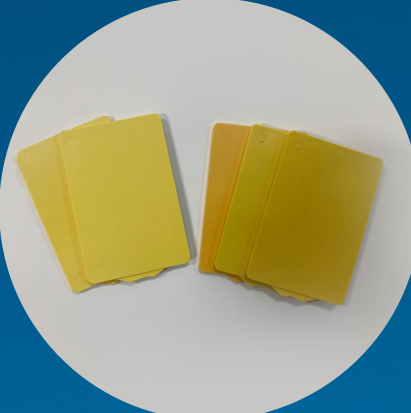
Driving Innovation in a World of Color



Color development for high-performance alloys



Brighter and consistent colors for polyamides



Biocompatible masterbatch solution

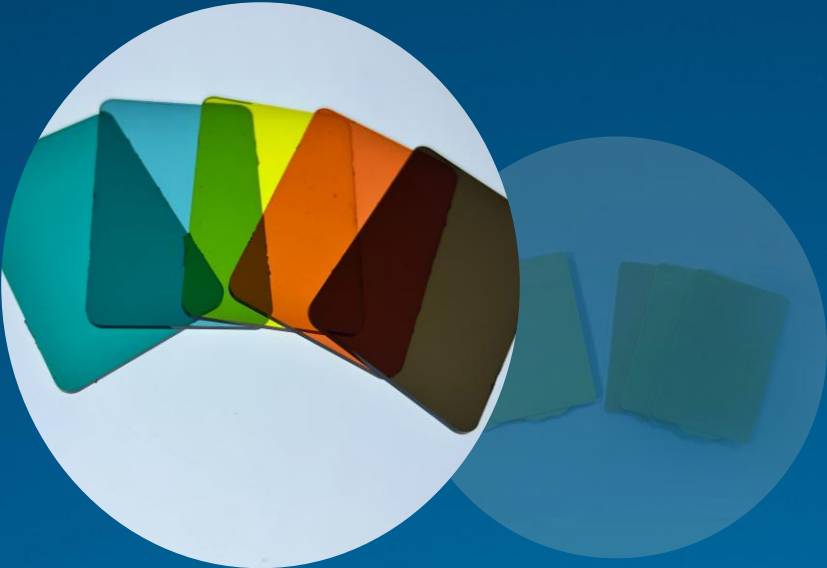


Laser marking beyond gray scale

Driving Innovation in a World of Color



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Biocompatible masterbatch solution

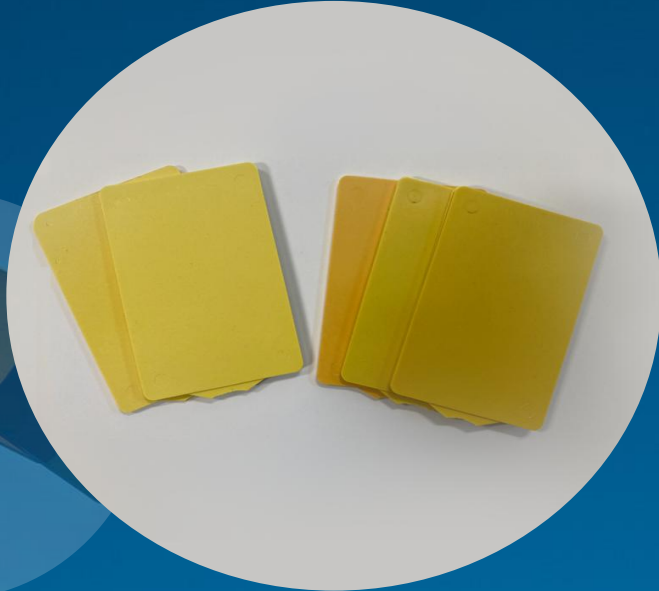


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ColorRx® Masterbatches and Compounds

ColorRx® Standard Color Palette

Americhem offers ColorRx® medical grade polymers in a standard color palette, with custom colors available upon request.

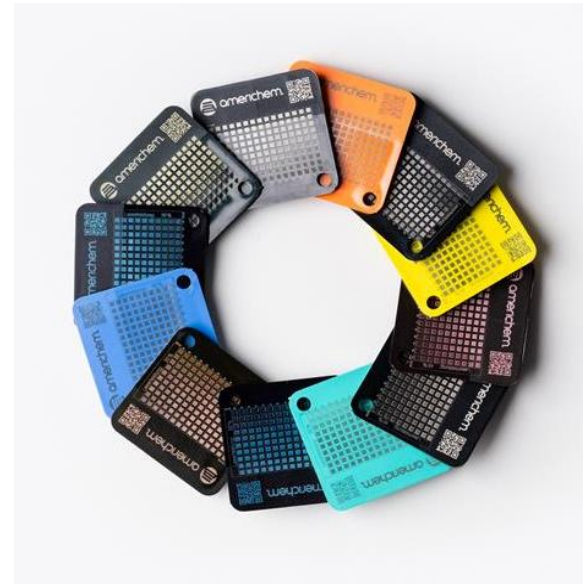


Specifications:

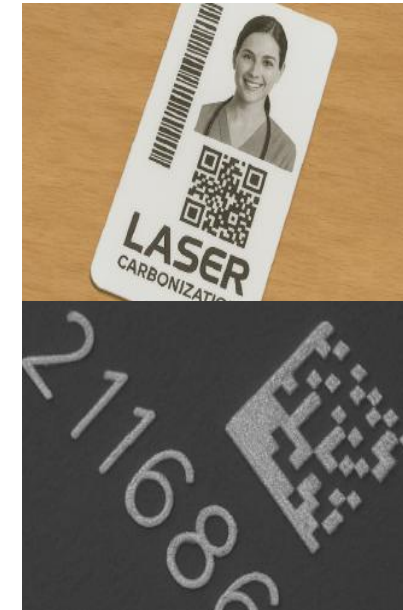
- Manufacturing according to GMP principles
- ISO 13485 manufacturing
- EU/FDA food contact statements
- ISO 10993-5
- Notification of change: 12 months
- Locked formulation
- Standard off the shelf and custom developments

Polymeric Laser Marking

Engineered for Permanent Traceability, Zero Consumables: Marking for the Modern Age



Color-toned markings on light or dark colored plaques



Gray scale

Applications

- Unique device identification
- Permanent part traceability
- Instrument marking
- Lot, batch, date coding
- Branding & product ID
- High resolution

Benefits

- Chemical resistance
- Sterilization resistance
- Tamper resistance
- Different polymers

Sterilization Compatibility: Typical Sterilization Testing Methods

Category	Resin Abbreviation	Dry Heat	Autoclave (121C)	Autoclave (134C)	EtO	VHP	E-beam	Gamma	Plasma	X Ray	Chlorine Dioxide
Elastomer	SILICONES	●	●	●	●	▲	●	●	●	●	●
Elastomer	TPA	■	■	■	●	●	●	●	●	●	■
Elastomer	TPC	▲	■	■	●	●	●	●	●	●	▲
Elastomer	TPO	■	■	■	●	●	●	●	●	●	■
Elastomer	TPS	■	■	■	●	▲	●	●	●	●	■
Elastomer	TPU	■	■	■	●	●	●	●	●	●	■
Elastomer	TPV	■	●	▲	●	●	●	●	●	●	■
Fluoropolymer	ETFE	●	●	●	●	●	●	●	●	●	●
Fluoropolymer	PTFE	●	●	▲	●	●	■	■	●	■	●
Fluoropolymer	PVDF	●	●	●	●	●	●	●	●	●	●
High Temperature	LCP	●	●	●	●	●	●	●	●	●	●
High Temperature	PAEK	●	●	●	●	●	●	●	●	●	●
High Temperature	PEEK	●	●	●	●	●	●	●	●	●	●
High Temperature	PEI	●	●	●	●	●	●	●	●	●	●
High Temperature	PESU	●	●	●	●	●	●	●	●	●	●
High Temperature	PPS	●	●	●	●	●	●	●	●	●	●
High Temperature	PPSU	●	●	●	●	●	●	●	●	●	●
High Temperature	PSU	●	●	●	●	●	●	●	▲	●	●
Olefinic	COC	■	▲	▲	●	●	●	●	●	●	●
Olefinic	PE	■	■	■	●	●	●	●	●	●	●
Olefinic	PP	■	●	●	●	●	▲	▲	●	▲	●
Olefinic	PVC FLEXIBLE	▲	▲	▲	●	▲	●	●	▲	●	▲
Olefinic	PVC RIGID	■	■	■	●	▲	▲	▲	▲	▲	▲
Polyacetal	POM	●	●	▲	●	▲	■	■	▲	■	■
Polyamide	PA (ALIPHATIC)	▲	■	■	●	■	▲	▲	■	▲	■
Polyamide	PA (AROMATIC)	●	▲	▲	●	▲	●	●	▲	●	■
Polyamide	PARA	●	▲	▲	●	●	●	●	▲	●	■
Polyamide	PPA	●	●	●	●	●	●	●	▲	●	▲
Polyester	COPOLYESTER	■	▲	▲	●	●	●	●	●	●	▲
Polyester	PBT	▲	▲	▲	●	●	●	●	●	●	▲
Polyester	PET	■	■	■	●	●	●	●	●	●	▲
Styrenic/Polycarbonate	ABS	■	■	■	●	●	●	●	●	●	■
Styrenic/Polycarbonate	PC	■	▲	▲	●	●	●	▲	▲	▲	■
Styrenic/Polycarbonate	PS	■	■	■	●	▲	●	●	●	●	▲
Styrenic/Polycarbonate	ACRYLIC	■	■	■	●	▲	●	●	●	●	■

● = Recommended for use in most cases.

■ = Not recommended.

▲ = Recommended in some cases.
May not be good for high cycles, or certain applications.

Disclaimer 1: Some resins will require stabilization or color tint additives to mitigate degradation and color shift under certain processes. Americhem offers solutions.

Disclaimer 2: The above recommendations are based on natural resin. Fillers, colorants, UV stabilizers, flame retardants, and other additives may change the performance.

Chemical Resistance: Americhem Engineered Compounds Chemical Resistance

	Americhem Trade Name	Material Type	Applications	Clorox Healthcare® VersaSure®	All Purpose Virex® Disinfectant Cleaner	PDI Super Sani-Cloth®	PDI Sani-HyPerCide®	Clorox Healthcare® Hydrogen Peroxide	Metrex Cavi-Wipes™ HP	Diversey Oxivir® 1	Metrex Cavi-Wipes™ Bleach	PDI Sani-Cloth® Bleach	Clorox Healthcare® Bleach
High-Performance Engineering Thermoplastics	PPSU-2000RX	PPSU	Suitable for thin wall applications requiring high temperature stability and humidity resistance	●	●	●	●	●	●	●	●	●	●
	PEI-0900RX	PEI	High temperature stability with strength and stiffness suitable for metal replacement	●	●	●	●	●	●	●	●	●	●
	PSU-1000RX	PSU	Oxidation and hydrolysis resistant with high temperature stability	●	▲	●	●	●	✘	✘	●	●	●
	NY3-1030GFRX	Glass Filled PPA	Glass reinforced; high heat resistance, good chemical resistance & excellent dimensional stability	●	●	●	●	●	▲	●	●	●	●
Engineering Thermoplastics	POM2-0800RX	POM	Typically used for internal mechanical components requiring low friction & high wear resistance or short-term use where frequent disinfection is not required.	●	●	●	●	●	●	●	●	●	●
	PBT-3000RX	PBT	Good electrical insulation and a balance of chemical resistance, dimensional stability, and sterilizability.	●	●	●	●	●	●	●	●	●	●
	NY5-1000RX	PA12	Balanced impact resistance and flexibility, chemical resistance, and sterilizability	●	●	●	●	●	●	●	●	●	●
	PC-2000RX	PC	High impact resistance, optical clarity, and sterilizability where chemical resistance is less important	✘	✘	●	●	●	▲	✘	●	●	●
	ABS-0600RX	ABS	Ideal for housings, enclosures, and handles where aesthetics and colorability are important but chemical exposure is minimal	▲	✘	▲	●	✘	✘	✘	●	●	●
Polyolefins	PP1-2000LMRX	PP	Suitable for thin-walled parts and complex geometries requiring good chemical resistance and ease of processing	●	●	●	●	●	●	●	●	●	●
	PP1-1200RX	PP	Suitable for parts needing greater toughness and durability, where flowability is less critical	●	●	●	●	●	●	●	●	●	●
Flexible Elastomers	TPEV7500-65ARX	TPV based copolymer	Seals and Gaskets, soft-touch grips, and tubing where flexibility, good compression resistance and chemical resistance are important	●	●	●	●	●	●	●	●	●	●
	TPES5500-60ARX	TPE copolymer	Over-molded soft-touch grips on substrates like PC, ABS, PC/ABS, PC/PETG, and PC/PBT where ease of processing is more important than chemical resistance	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲

ASTM D543 72-hour wet patch exposure under 1% strain ● > 80% Tensile Retention ▲ 60-80% Tensile Retention ✘ < 60% Tensile Retention with acceptable visual aesthetics

Americhem: Your Full-Service Partner

Define Application Requirements

- Temps
- Chemicals
- Loading
- Impact
- Wear
- Conductive
- Flammability
- Color
- Regulatory

Base Resin Selection

- Amorphous
- Semicrystalline
- Alloys
- Elastomers

Reinforcement, Modifier, Additive, and Color Selection

- Glass Fiber
- Carbon Fiber
- PTFE
- Silicone
- Carbon Black
- Flame Retardants
- Minerals
- Pigments/Dyes

Compounding Process Development

- Blend/Feed
- Side Feeders
- Single Screw
- Twin Screw
- Screw Design
- Pelletization

QC, Testing and Packaging Requirements

- Required Testing
- Certification
- Release Criteria
- Specification Development
- Documentation

Final Product

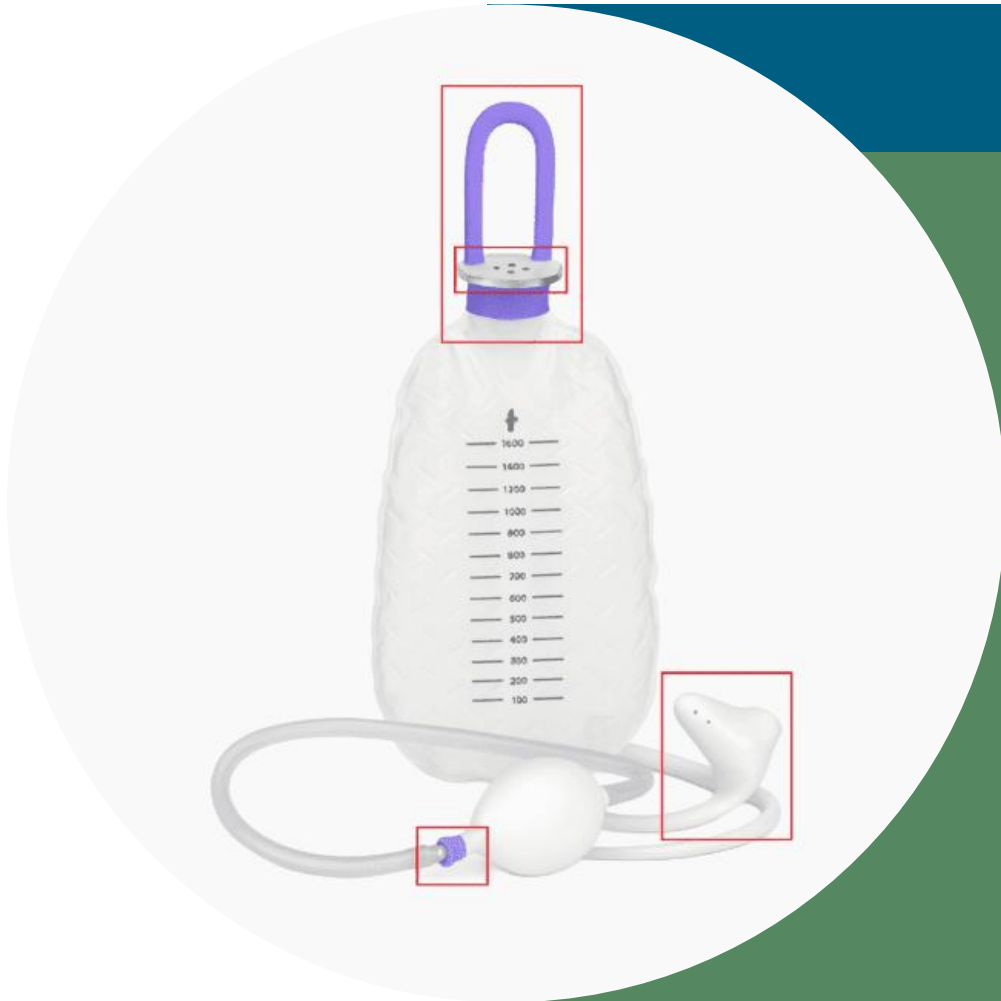


From early concept development to commercialization, Americhem has your needs covered.

Case Studies



At Home Bowel Device



Case Study

Customer Need

- Color harmony of visible parts made with different polymers that differs in translucency and color behavior

Americhem Solution

- Multiple customized masterbatch, taking into account the nuances of opacity, pigment dispersion, processing behavior, color consistency, and regulatory needs for biocompatibility

Value Proposition

- Harmonized color appearance across ABS and TPE substrates
- Materials supplied in volumes suited to development and production needs
- Color uniformity that supported production confidence

Laparoscopic Surgical Instrument



Case Study

Customer Need

- Multiple performance enhanced materials for lubricity, strength, and color
- Speed of delivering samples & color matching to support prototyping and first article

Americhem Solution

- Housing: ColorRx® PA-2000RX
- Internals: InLube® PPSi, PPACFTF, PA66CFTF
- Trigger: InStruc® PA66GF33
- Lever: InLube® PCGFTF
- Button: ColorRx® PC-2000RX Colors

Value Proposition

- Unbiased and diverse product offering
- Capability to supply materials for the complete assembly providing the total solution through early supplier Involvement

Orthopedic Sterilization Tray Latches



Case Study

Customer Need

- Repeat sterilization via steam autoclave
- Low temperature hydrogen peroxide
- Insert moldable to stainless steel
- Color stability and creep resistance

Americhem Solution

- ColorRx® PAEKGF colors

Value Proposition

- PAEK survived all autoclave cycle testing, post-drop test, and color stability testing
- Produced using GMP in an ISO13485 facility
- Versatility of going from lower temperature products to extremely high temperature products

Key Takeaways

In healthcare, color and compliance are **non-negotiable**.

Americhem **anticipates** evolving device requirements, by **partnering** in the earliest stages of development **to guide critical material decisions** across the **full product lifecycle**.

Americhem Technology Pillars

Masterbatch Technology

Custom formulations based on color specifications, end applications, and processing equipment that result in efficient manufacturing.

- Lot-to-lot consistency
- Color harmony across breadth of materials
- Formulate across multiple resin families

Functional Technology

Additive masterbatches and compounds that improve end-use applications and yield consistent results that further enhance product quality in the marketplace.

- UV resistance
- Softness
- Antimicrobial

Engineered Compounds

Custom colored and specialty compounds formulated for specific applications. Short lead times with no minimum order quantity to reduce manufacturing complexities.

- FDA and biocompatible
- Structurally reinforced
- Electrically active
- Specialty alloys

Performance Compounds

Thermoplastic compounds and polymeric alloys that provide processing ease, which result in less waste during the manufacturing process.

- Soft-touch elastomeric
- Outdoor weatherable

Branded Product Lines

Specialty thermoplastic compounds & masterbatches for the medical industry

ColorRx®
Biocompatible
Compounds & Alloy

ColorRx® Masterbatch
Color Masterbatch
Technology

EcoLube®
PFAS-Free Wear &
Friction Compounds

InStruc®
Structurally Reinforced
Compounds

InLube®
Wear & Friction
Compounds

ColorFast®
Custom Color
Compounds & Alloys

nShield® Masterbatch
Antimicrobial Masterbatch

nBalance®
Sustainable Masterbatch

nDryve™
PFAS-Free Functional
Fiber Solutions

Q & A

Ready to collaborate?

Now that you know us better, let's explore how we can help you achieve your product, process and business goals.



Kumar Parimal

Product Development Manager
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Contact us today to discover the right ColorRx[®] solution for your next application.

Thank You

