Compounding Solutions®

J&J Medical Grade Materials Overview

August 23rd , 2023

About Us

Compounding Solutions is a leading manufacturer specializing in the highest quality custom medical compounds, color concentrates and additive masterbatches for healthcare applications.

Founded in 1999 by Scott Neal, privately owned

State-of-the-art 120,000+ square foot facility located in the Northeast United States with the largest clean production area of its kind

International locations in Ireland and China

Global customer base

Strategic supplier and distribution partnerships

ISO 13485 Certified

Our Services

From concept to commercialization, our extensive range of polymer services are designed to quickly and efficiently support any project need with excellent customer service throughout the entire process.

Materials

- Custom compounds, additive masterbatches and color concentrates
- Toll compounds
- Dry blends
- Distribution
- MOQ as low as 1kg for all materials

Research & Development

- Complimentary technical support
- Material testing and identification
- Access to plastic and additive tech
- Full customer control over material specification

Other Services

- Lab scale cast film and extrusion
- Biodegradable material development
- Repackaging
- Sustainable thermoplastics

Regulatory & Analytical

- Full range of ASTM testing services
- Specification management
- TDS development
- Regulatory support for all materials and additive components

Our Process – Built for Speed

We strive to minimize your product development times by optimizing our process to deliver the highest quality compounds in the shortest time possible, keeping your development on-schedule and on-budget.

Quotes typically in 24 hours or less

Sample chips sent within 5-7 business days

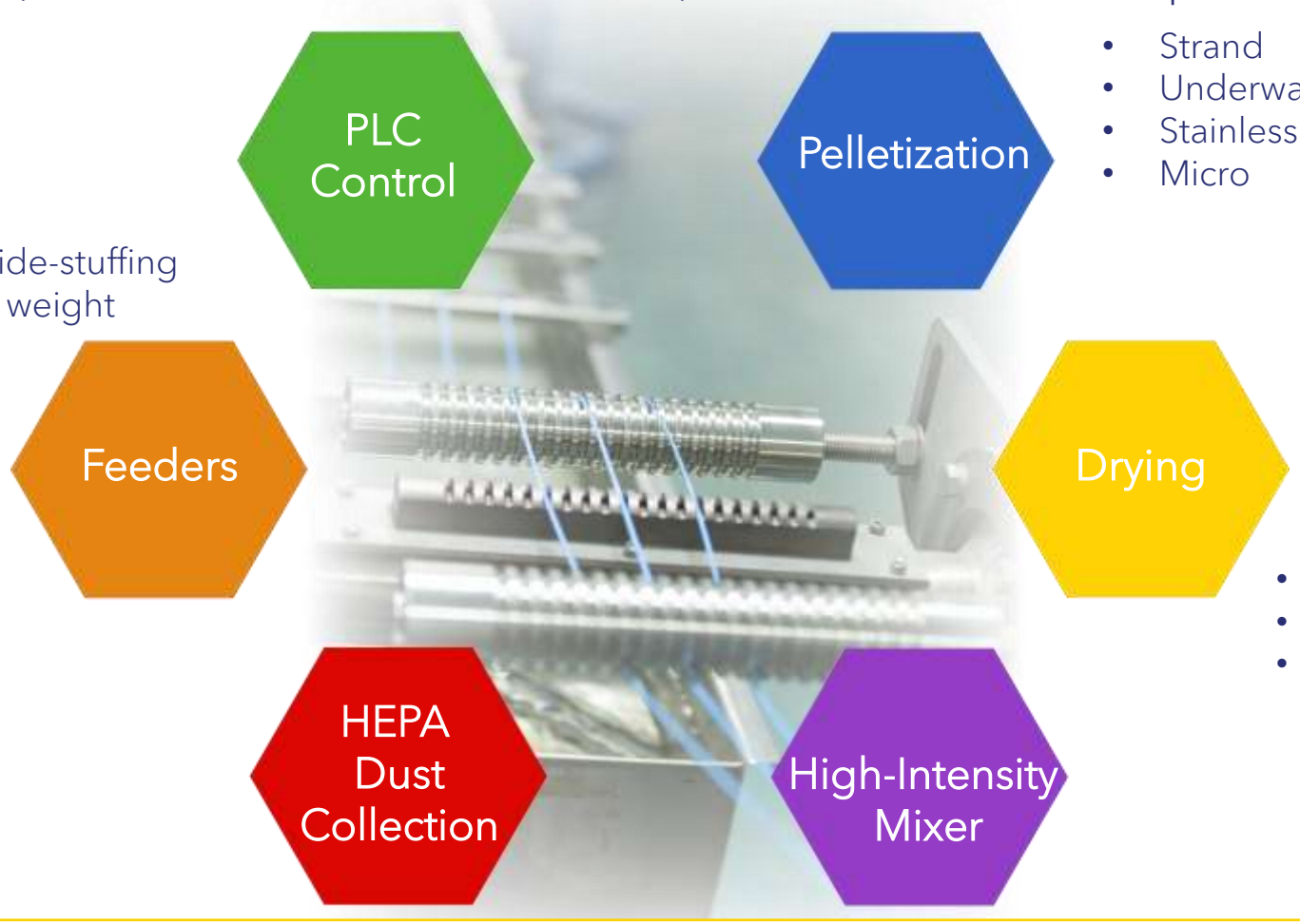
Custom compounds shipped within 3-4 weeks* in quantities as low as 1kg

* A fee-based expedited delivery option for up to 1500 lbs. of material within 5 business days is available; Certain restrictions and limited availability apply

Compounding and Development Capabilities

With **17 co-rotating twin screw lines** ranging from 18-50mm, we have substantial capability and capacity to handle any development or production need. For those applications requiring the most stringent production standards, we offer a state-of-the-art clean, controlled white room production environment.

- Nitrogen charged
- Loss in weight with side-stuffing
- Heated liquid loss in weight
- Micro



- Strand
- Underwater (27mm, 40mm, 50mm)
- Stainless Steel, Polymer Belts
- Micro

- Oven
- Vacuum Oven
- Forced Hot Air Desiccant

Highly Accurate Auxiliary Equipment For The Ultimate In Repeatable Precision

White Room Production

Our medical compounding is performed in a controlled white room environment which ensures our compounds are made with the highest purity by minimizing exposure to airborne particulates, contaminants and moisture.

Our white room production environment is the largest facility of its kind.

The design incorporates an Air Lock with a positive pressure environment, sealed and polished concrete floors and epoxy coated wall surfaces to repel dust.

Temperature and humidity is precisely controlled, and air is exchanged through an advanced HEPA filtration system.

Our scientific and precise approach to compounding yields compounds of the highest quality and consistency.

Regulatory Support

Our Regulatory Affairs Department manages the supporting documentation and reporting standards to ensure regulatory compliance and safety requirements for all our products and services. Our systems are designed to quickly provide all requested regulatory information including but not limited to:

- Safety Data Sheets
- Regulatory Data Sheets
- Materials & Processes
  - Animal derived materials (BSE/TSE)
  - Prop. 65
  - Reach
  - RoHS
  - Conflict Materials
- Pigments
- Carcinogenic and Toxic Chemicals
- Latex
- Bisphenol A (BPA)

- Plasticizers (Phthalates)
- Food Contact – Direct and Indirect
- UL Yellow Card Certifications
- UV Certification
- Various Immersion Certifications
- Offgassing and Leaching

<u>Medical Specific:</u>

- ISO 10993 and USP Class VI*
- Regulatory Body Updates
  - FDA
  - European MDR
  - cFDA

* Testing process managed by CS and performed by accredited 3rd party lab

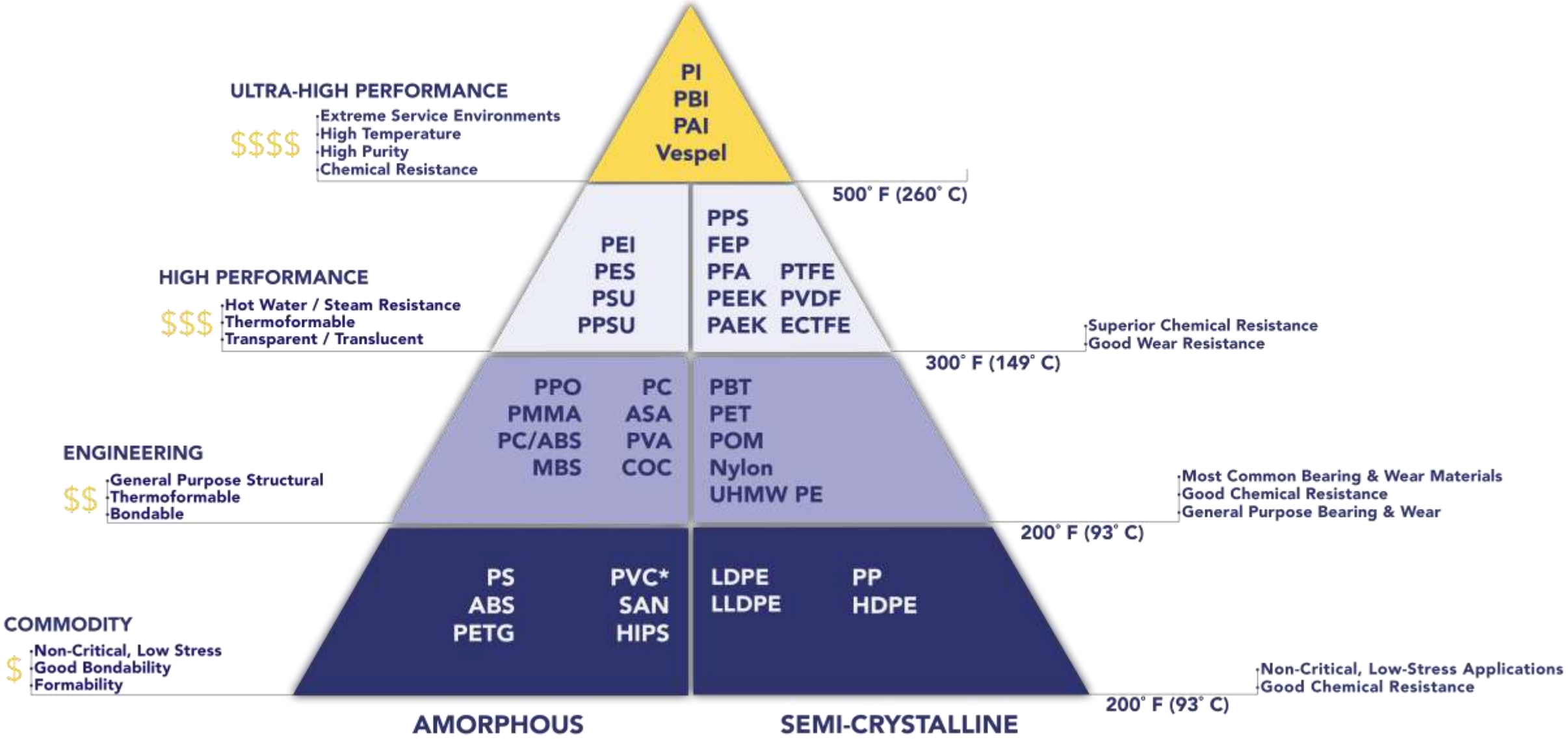
nqa. ISO 13485 Registered

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Our comprehensive ISO 13485:2016 certification standard is designed to meet strict quality and regulatory requirements for quality management, risk management, process validation, and traceability systems.

Available Thermoplastics

We work with all polymer types for either new developments or existing specifications.



*Flexible PVC less than Shore 55D only; no rigid PVC

Available Elastomers

By combining TPU, PEBA, or COPE with plasticizers or softer polymers lower hardness levels can be achieved for custom applications.

	Extra Soft	Soft	Medium Soft	Medium Hard	Hard	Extra Hard
Shore A		0	10 20 30	40 50 60	70 80 90	100
Shore D			0	10 20 30	40 50 60 70	80 90 100

TPE

ReZilient™ Rx TPE

TPU

TPV

PEBA

COPE

Examples of Common Durometers:

20A 40A 70A 80A 95A 50D 80D 90D

Enabling Filler and Additive Technologies

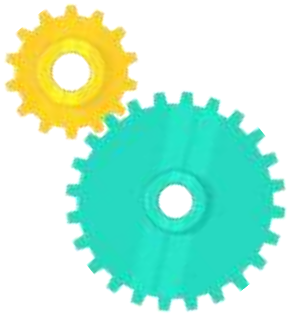
We work extensively with a full range of standard and innovative additive technologies to bring specific mechanical, process and/or aesthetic properties to your compounds and concentrates.

Colorants
Pigments, Dyes

Conductive Spectrum
Thermal, Electrical,
EMI/RFI Shielding

Reinforcement
Glass, Carbon, Aramid,
Cellulose, Wood Flour

Antimicrobial
Silver, Copper, Zinc,
Quats, Surfactant



Friction Modifiers
PTFE, Silicone,
Tackifiers

- Radiation Shielding:
  Bismuth, Barium, Tungsten, Tantalum
- Specialized colorants and Effects
  Phosphorescent, Streaking agents
- UV, Heat and Antioxidant Stabilizers
- Minerals
  Talc, Calcium Carbonate, Wollastonite, Barium, Mica
- Nanoparticles
  Clay, Carbon (SWCNT, MWCNT, CNS, Graphene)
- Flame retardants
  Brominated, non-brominated

- Metal Powders
- Antifouling
- Hydrophobic
- Hydrophilic
- Nucleating agents
- Clarifiers
- Wear reduction
- Maleic Anhydride
- Glass beads
- Hollow glass microspheres
- Silica
- Matte agents

- Laser marking
- Laser Welding
- Impact modifiers
- Viscosity modifiers
- Density Modifiers
- Compatibilizers
- Dispersion aids
- Adhesion aids
- Plasticizers
- Chain extenders
- Crosslinking agents
- Lubricants

Distribution

Evonik's Care line of high-performance medical-grade polymers deliver outstanding performance for a wide range of medical applications from housings to coronary catheters.

HIGH STRENGTH
Vestamid® Care ML Polyamide 12 Series

EVONIK
Leading Beyond Chemistry

TRANSPARENT
Trogamid® Care Polyamide Series

Biocompatible
Highest quality
Filled and unfilled
Proven performance
Custom options

HIGH TEMPERATURE
Vestakeep® PEEK Series

FLEXIBLE
Vestamid® Care ME PEBA Series

Distribution

TEIJIN
Human Chemistry, Human Solutions

- Panlite PolyCarbonate
  - MD-1200 YA
  - MD-1220 YA
  - MD-2200 YA
  - MD-2220 YA
- Multilon PC/ABS & PC/PET
  - TN 7500M
  - AM 9835Z

eni
versalis

- Pharmalene
  - HDPE
  - LDPE
  - LLDPE
  - EVA
- Chemically Recycled Grades
  - PE

Compounding Customization and Optimization

COPERO
made with Arnitel® Care
Radiopaque

MOBILIZE
Friction Reduction

STABILIZE Rx
UV & Heat

Master Mark
UDI, Markings

DefendRx
Antimicrobial

Arnitel® Care
Polyester-based thermoplastic elastomer (TPC)
Tubing, Hubs

REZILOK Rx™
Tie-Layer

PurTone Rx
Medical Color

Color Concentrates for Medical Applications

PurTone Rx color concentrates set the standard for high quality color dispersion for medical devices with every formulation fully optimized for the target resin.

- In-stock or fast custom match
- Guaranteed accuracy with dE < 1.0
- FDA batch exempt and ISO 10993-5 biocompatible pigments
- Color stable high temperature options for PEEK, Fluoropolymers, Nylon 6, Nylon 6/6, PPA, PEI, PSU, PC, LCP, and PPS
- Low MOQ of 1kg for both in-stock and custom options

FDA 21 CFR Part 73 Subpart D Compliant Colors

Blues	
Pantone	Shade
290C	
2925C	
301C	
295C*	

Greens	
Pantone	Shade
3248C	
3268C	
3298C	

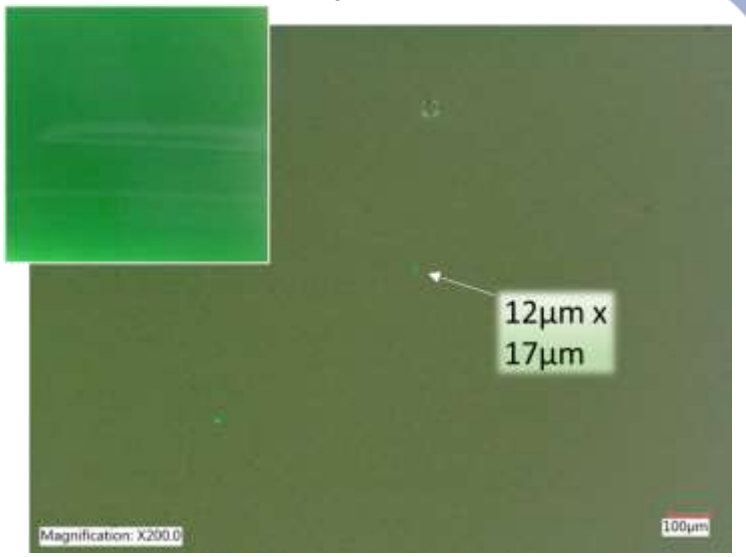
Purples	
Pantone	Shade
2655C*	
Violet C*	
White*	

Greys	
Pantone	Shade
Cool Grey 4C	
Cool Grey 7C	
Black**	

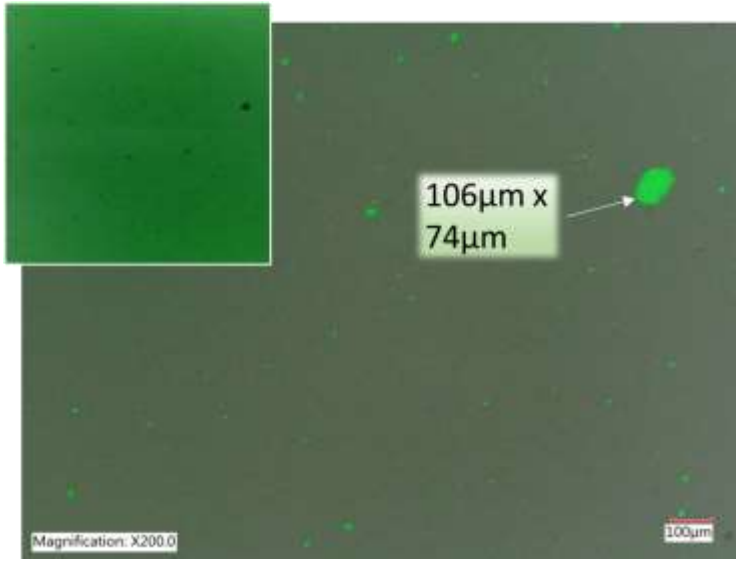
IN-STOCK
PurTone Concentrates Offered For:

PolyAmides - PA6, PA6/6, PA11, PA12, PEBA
PolyOlefins - PP, LDPE, LLDPE, HDP
Thermoplastic Polyurethanes

Excellent Dispersion

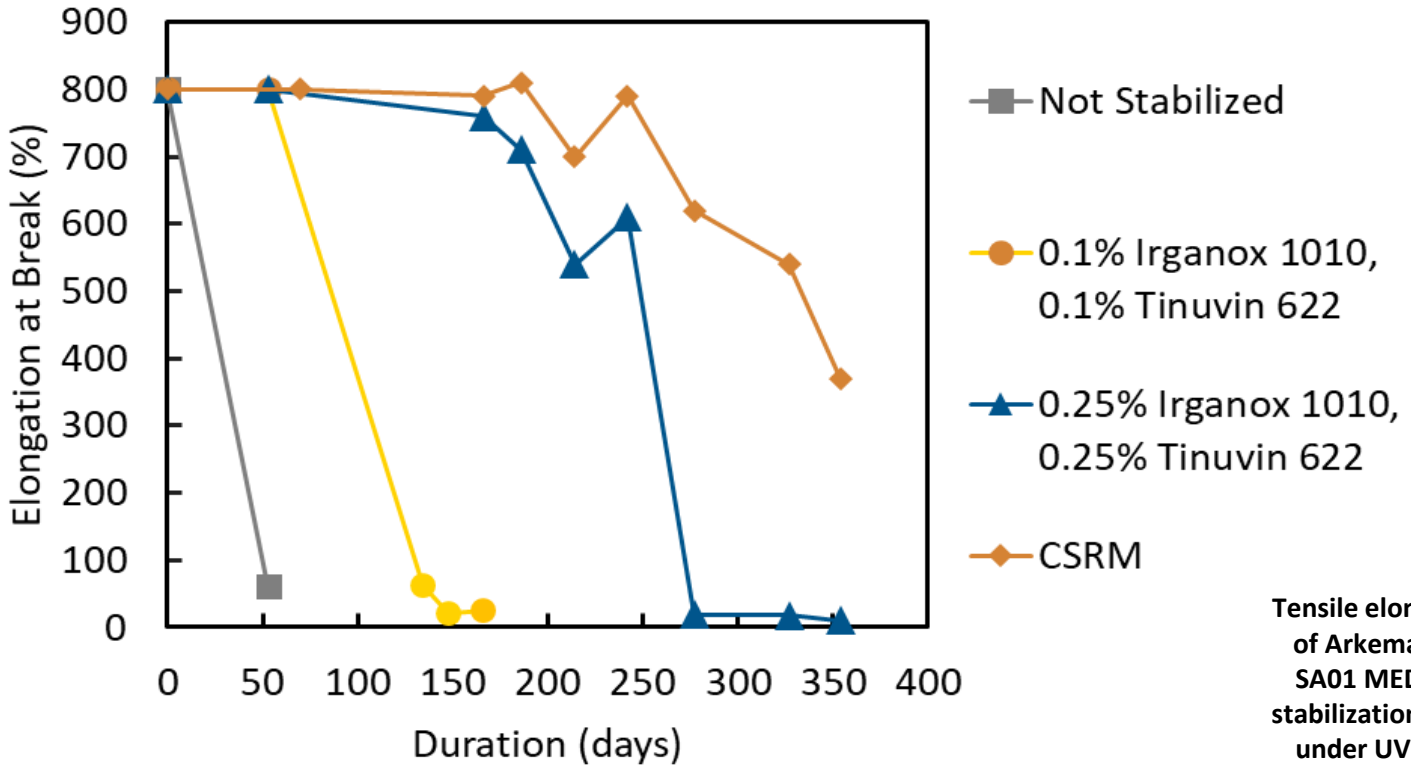


Poor Dispersion

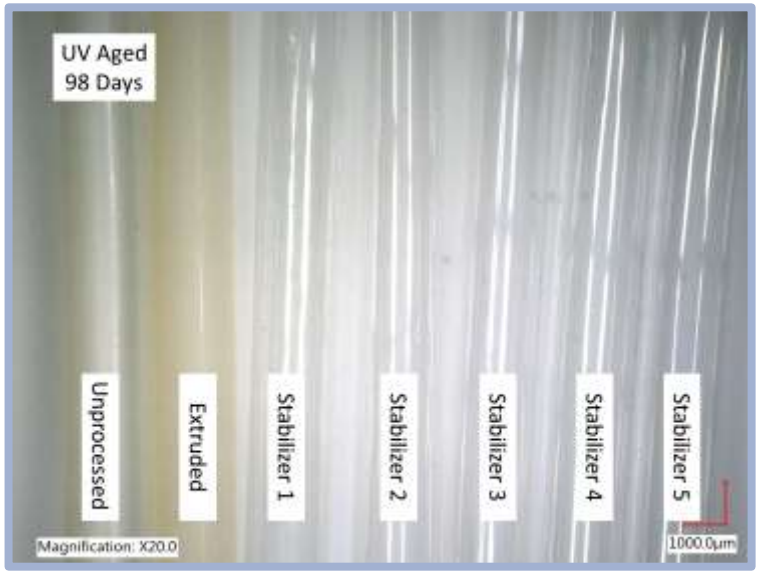


Medical-grade stabilization packages to reduce degradation and extend shelf life
Optimized for PEBA and Polyamide-12

- Protects polymers during extrusion, injection molding, reflow, annealing, sterilization, and storage.
- Minimizes discoloration and embrittlement caused by UV exposure.
- Reduces potential product failure.
- Certified biocompatible per ISO 10993-5



Tensile elongation at break of Arkema Pebax® 5533 SA01 MED with various stabilization packages aged under UV lamp at 23°C.



MOBILIZE

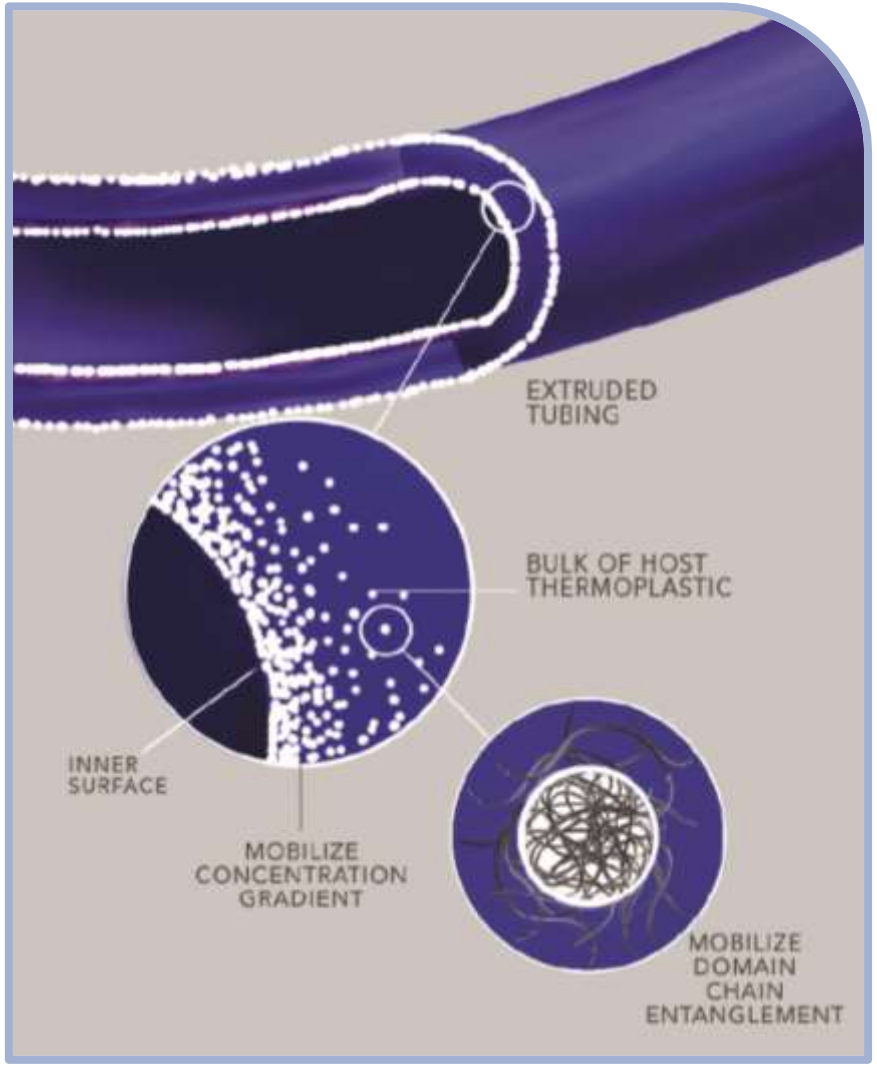
Medically Approved Surface Friction Reduction Technology

Mobilize is a proprietary high molecular weight polymeric additive with a high degree of chain mobility to reduce friction in various thermoplastics without significantly altering bulk properties.

Mobilize provides Lubricious Solutions For:

- 20 - 40%+ reduction in Coefficient of Friction (CoF)
- Allows potential elimination of FEP, PTFE, HDPE liners
- Does not migrate, bloom, leach or rub off from parts under normal operating conditions
- Ease of entry into the body and devices through the catheter
- Lowers CoF for gears and other sliding components
- Biocompatible per ISO 10993-5
- No impact on bonding
- Suitable for Polyolefins, Styrenics, Polyesters, Polycarbonates, PolyAmides, PEBAs, TPU, TPE

Sample Description	Max Insertion Force (N)	Force (N)	Force (N)	Force (N)
Pebax 6333 SA01 MED, Mobilize	0.382	0.093	-0.194	-0.142
Pebax 6333 SA01 MED, Natural	0.495	0.163	-0.319	-0.172
HDPE	0.740	0.325	-0.515	-0.253



Antimicrobial Masterbatches with BioCote® Technology

Defend Rx masterbatches combat a broad spectrum of microbes to offer hygienic protection to products used in healthcare environments and typical consumer applications.

BioCote® is a market leading antimicrobial additives provider for plastics, paints, coatings and textiles.

Advantages of Defend Rx

- Uses a medical grade universal EMA carrier compatible with a wide range of resins. Customized carrier and let down ratios available.
- Low loading of BioCote® antimicrobial needed for designed performance
- Protects for the expected lifetime of the product
- High efficacy rates across a variety of microbes
- Can be used in clear polymers with minimal impact on transparency
- Does not impact color, sterilization process, bonding, printing, welding or any other post process

Copptech Broad Spectrum Antimicrobial

TECHNOLOGY

COPPER SALTS

Biocidal properties – Can eliminate virus, fungi and bacteria.
Skin healing properties.

SYNERGETIC BIOCIDAL EFFECT

Technology patented by Copptech

ZINC SALTS

Biocidal properties – Can eliminate bacteria and fungi
Skin healing properties.

- Extremely high thermal stability to temperatures exceeding 1000°C
- Compatible with ALL thermoplastics
- Highly Effective antimicrobial protection for the lifetime of the product
- Cost effective with final article loadings as low as 0.3%; 0.6% typical
- Copper and Zinc are safe and essential elements to human health

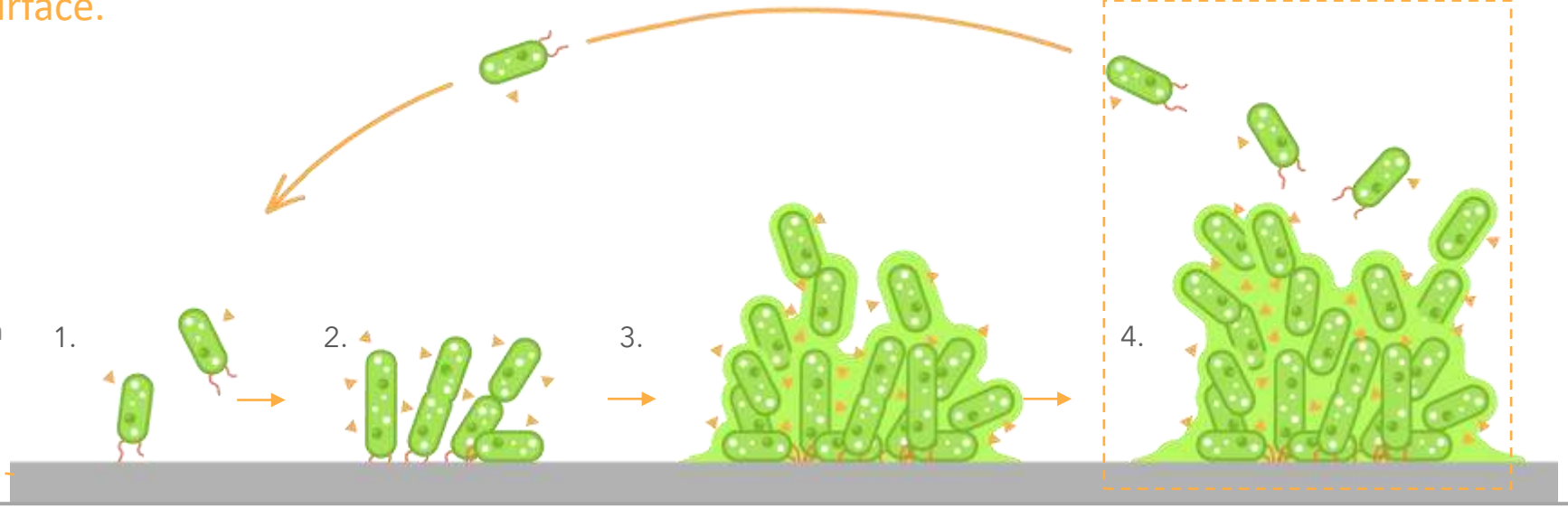
Passive Action Polymer (PAP) Technology

Formation of biofilm and complex bacteria communities on a surface.

1. Attachment – Surface attachment facilitates

2. Proliferation, cell-cell adhesion and colonization

Product/material surface



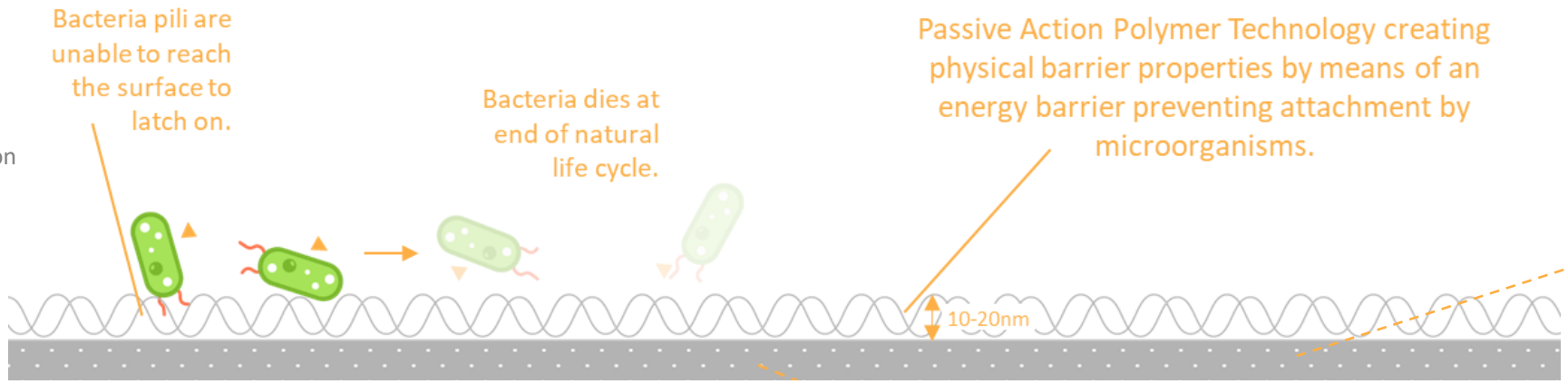
3. Quorum sensing (QS), EPS and matrix formation

4. Mature biofilm and detachment

Prevent microbial colonization due to an optimized anti-adhesive mechanism.

1. Preventing adhesion – normally surface attachment facilitates nutrient uptake by bacteria

2. No proliferation – no adhesion and limited uptake prevent proliferation and prevent Quorum Sensing actions and prevent biofilm formation



3. Death phase – bacteria follow their normal life cycle and without exponential stage reach death stage in reduced time frame

Technology has homogenously dispersed inside the product material – Not just a coating.

Preventing attachment means no proliferation, no colonization, no biofilm and no infection.

* According to the US National Institute of Health

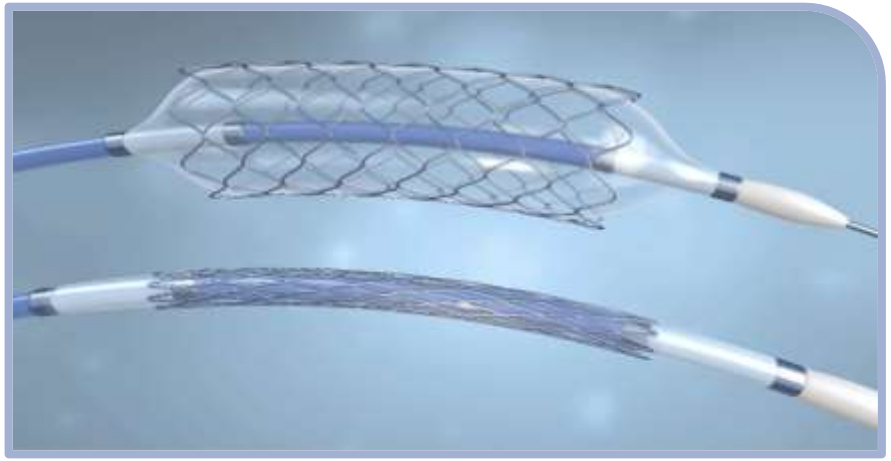
Medical Grade SEBS TPE

ReZilient TPEs offer material solutions for a variety of applications, ranging from low-cost general-purpose elastomers for industrial use to specialty compounds for high-performance applications. Our ReZilient TPEs can be formulated to achieve high or low extremes of critical material properties.

- Durometer ranges from 35 ShA - 90 ShA
- Thermally bonds to polypropylene
- Transparent and easily colorable
- Sterilization by Gamma, E-beam and EtO
- Biocompatible and latex, phthalate, PVC and animal-derived component free

Medical TPU Alloys

ReZalloy Rx™ grades provides maximum flexibility for superior navigation in the tight spaces of the human body. ReZalloy Rx (TM) has exceptional bonding performance to polar substrates such as PEBA, TPU, COPE, SBC, PC, ABS, PET, etc.



Key Benefits:

- Available hardness range from 35 shA – 60 shA
- Superior flexibility
- Low tackiness
- Superior processing – Extrusion and Injection Molding
- UV stability and good moisture and oxygen barrier
- ISO 10993-05 Compliant
- Colorable
- Compatible with BaSO4, Bismuth Oxychloride and Tungsten
- Excellent bonding to PEBA, PA12, TPU, PET, PC

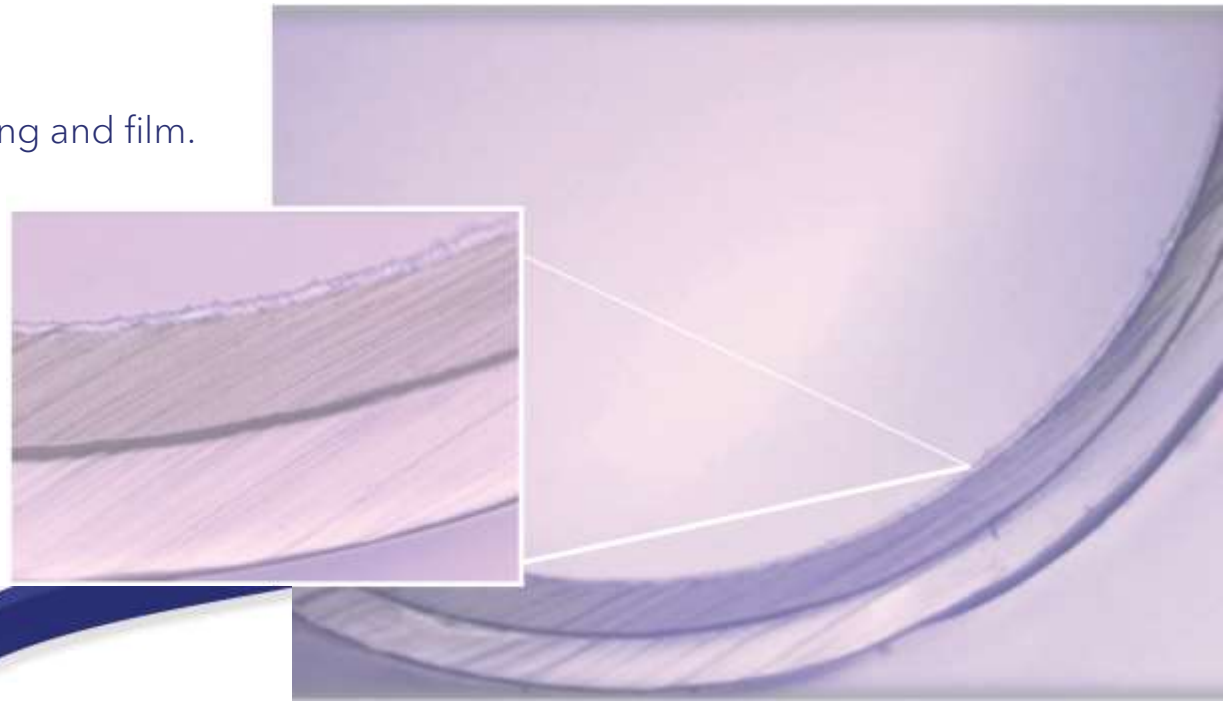
ReZalloy Grade	Compound Description
RX1135	ReZalloy 35A MED
RX1140	ReZalloy 40A MED
RX1140LV	ReZalloy 40A Low Viscosity MED
RX1150	ReZalloy 50A MED
RX1160	ReZalloy 60A MED

Tie Layer Resin for Medical Applications

Designed to bond dissimilar materials for multi-layer co-extruded tubing and film.

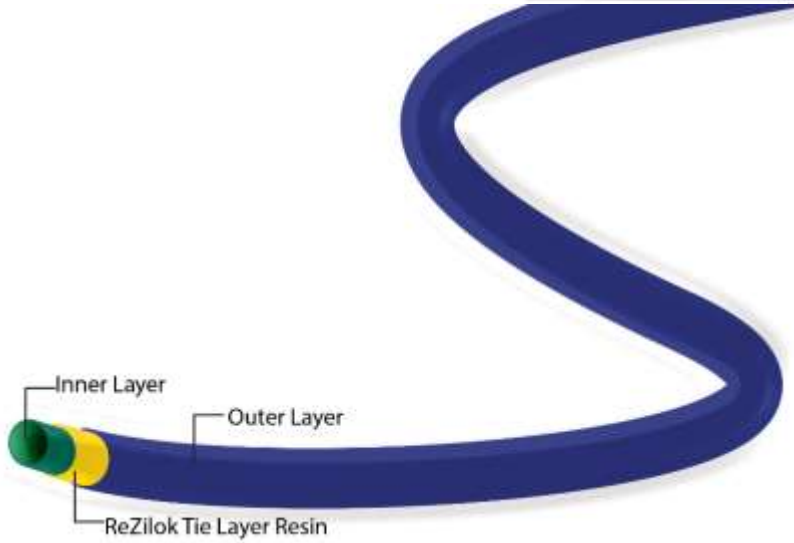
Benefits

- ISO 10993-5 cytotoxicity test results ensure safety
- No change agreements
- Direct offset to LBI Plexar and discontinued product offerings from SK Chemicals
- Perfect for tri-layer tubing and multi-layer film packaging for the medical and pharmaceutical industries



Adheres to many different materials:

- Polyamides
- PEBAs
- Etched Fluoropolymers
- Polyethylenes
- Polyesters
- TPUs
- Styrenics
- Acrylics
- PVC
- Metals



ReZilok Rx Grades	Compound Description
ReZilok Rx101	LLDPE grafted MAH
ReZilok Rx201	EVA grafted MAH

PEBA RO PU RO COPE RO

Made With DSM Arnitel® Care Products

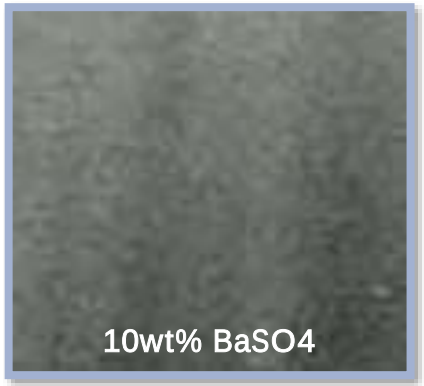
Radiopaque PEBA, TPU Compounds, and COPE Compounds

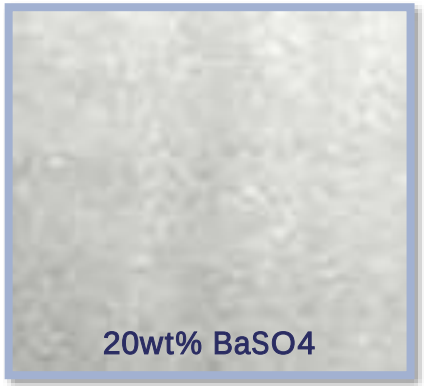
- USP biocompatible Pebax®, Vestamid®, Pellethane® and Arnitel® TPC with 20wt% Barium Sulfate ($BaSO_4$)
- Superior filler dispersion through advanced processing equipment and custom screw designs
- Ideal for demanding thin wall applications where dispersion is critical

PEBA RO Grade	Compound Description
PBX2520	Pebax® 2533 SA01 MED
PBX3520	Pebax® 3533 SA01 MED
PBX4020	Pebax® 4033 SA01 MED
PBX4520	Pebax® 4533 SA01 MED
PBX5520	Pebax® 5533 SA01 MED
PBX6320	Pebax® 6333 SA01 MED
PBX7020	Pebax® 7033 SA01 MED
PBX7220	Pebax® 7233 SA01 MED

PU RO Grade	Compound Description
PURO55D20	Pellethane 2363-55D MED
PURO55DE20	Pellethane 2363-55DE MED
PURO75D20	Pellethane 2363-75D MED
PURO90AE20	Pellethane 2363-90AE MED
PURO80A20	Pellethane 2363-80A MED
PURO90A20	Pellethane 2363-90A MED
PURO80AE20	Pellethane 2363-80AE MED
PURO64D20	Pellethane 2363-65D MED

COPE RO Grade	Compound Description
CPR2520	Arnitel® Care 2520 MED
CPR4020	Arnitel® Care 4020 MED
CPR4620	Arnitel® Care 4620 MED
CPR5520	Arnitel® Care 5520 MED
CPR6320	Arnitel® Care 6320 MED
CPR7420	Arnitel® Care 7420 MED





Thermoplastic Laser Marking for Most Common Laser Sources

MasterMark technology offers a high-quality, versatile and efficient solution for direct marking with most common laser sources, eliminating volatile inks and difficult pad printing processes.

Key Benefits:

- Effective in nearly all thermoplastics, INCLUDING TRANSPARENT
- Extremely low loading, retaining base polymer physical properties
- Does not affect appearance, whether transparent or custom colored
- Non-migratory
- Biologically tested ISO 10993-5
- Free of heavy metals and animal derivatives
- High thermal stability

Sustainability In Medical

Medical sustainability initiatives currently include:

- Using less dense and more recyclable materials to replace PET, PETG, PC, and PVC.
- Circular Economy - Evaluating the entire product lifecycle and designing with end-of-life recycling in mind.
  - Replacing flexible PVC with TPE or EVA alternatives eliminates non-recyclable PVC and phthalates, allowing for hospital-based incineration or recycling vs. landfill.
  - Designing plastic devices for limited reprocessing – "Resposable" with autoclave / chemical wipe down options.
- EU Packaging Directive 94/62/EC – Reduce wall thickness in rigid medical and pharmaceutical packaging, lower scrap, preserving barrier performance properties.
- Chemical Recycling / Filtration Technologies, i.e. depolymerization / repolymerization
- Bio-Mb Materials
- Prime Bio-based Materials and Additives
- Additive Manufacturing – Less / no material waste

*Until regulations change regarding lot traceability for 510k devices, medical sustainability does **not** include the use of mechanically recycled materials or virgin scrap / regrind.*

Sustainable Material and Additive Options

COMMERCIAL

Bio-based + Biodegradable

- PLA, PHA / PHB, PBS

Fossil-based + Biodegradable

- PCL, PBAT

Bio-based + Nonbiodegradable

- PE, PP, PET / PBT, POM, PC, TPU, TPE, PEBA, PA

Recycled Content

- PP, PE, PET, PETG, PA

Biodegradable Additives

- Compost /Degradation Catalysts
- Wood Flour, Cellulose, Other Natural Fibers
- Aragonite
- Starch
- Bio-based plasticizers
- Bio-based / non-toxic pigments

Working With Compounding Solutions

Materials Expertise

- Custom Formulations and in-stock products
- Complimentary world-class technical expertise
- Full customer control over specification

Superior Quality

- Clean and controlled production environment
- Highest quality and consistency with full lot traceability
- ISO 13485:2016 QMS

Exceptional Customer Service

- Your custom compound delivered in as soon as 5 days
- Minimum Order Quantities as little as one kilogram
- Highly detailed documentation for easy regulatory submissions

Innovative

- Access to the latest technological advancements
- Enabling additive and process technologies
- Unique proprietary products

Versatile

- Virtually any thermoplastic and additive
- You can own the formulation
- Flexible business model to meet critical development needs and timelines

Questions?

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