Overview of Medical Polymers

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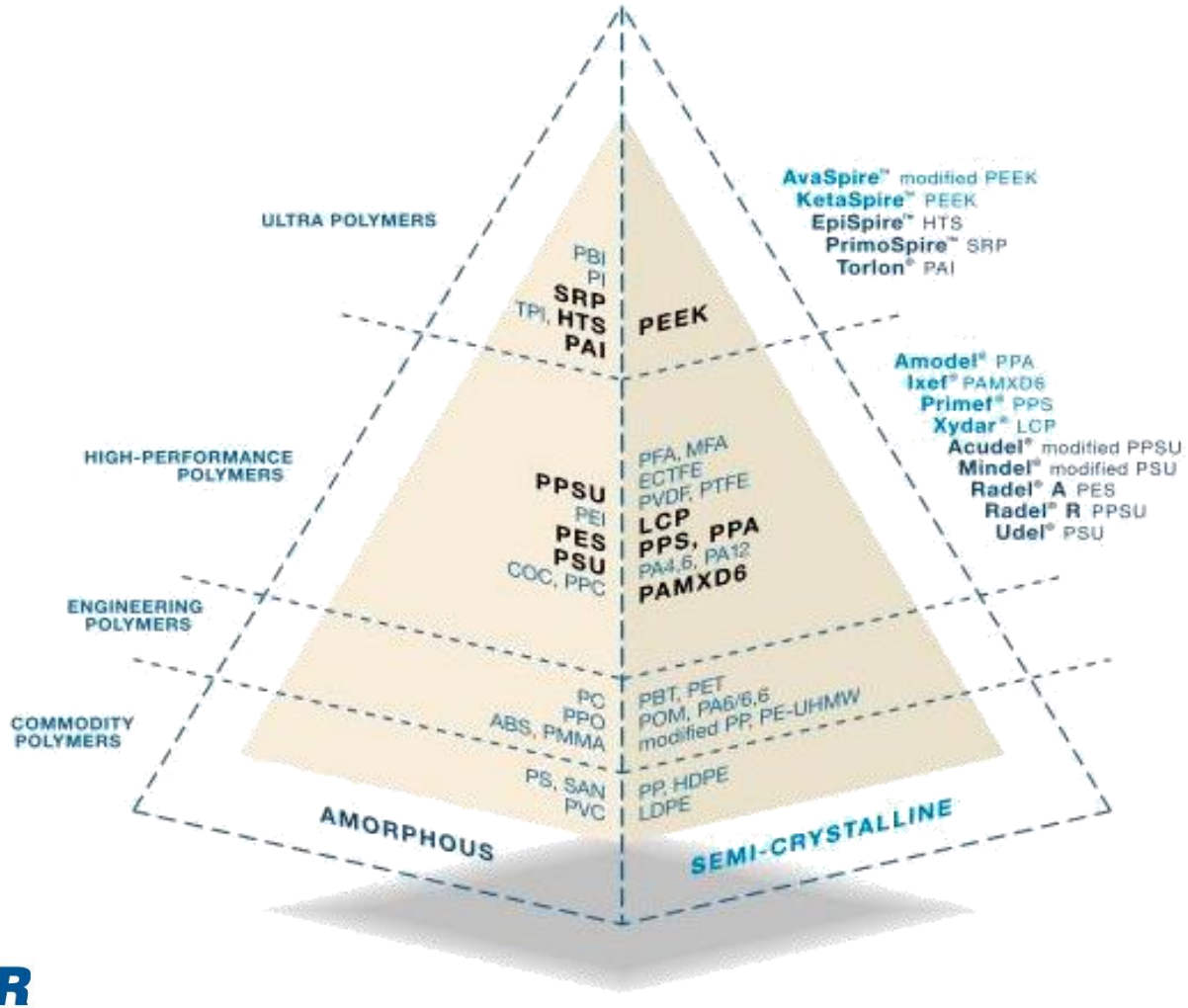
Polymer Pyramid



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Confidential

Crystalline & Amorphous Polymers

Crystalline polymers

- Chemical structure that allows the polymer chains to fold on themselves and pack together in an organized manner
- Regularly defined pattern

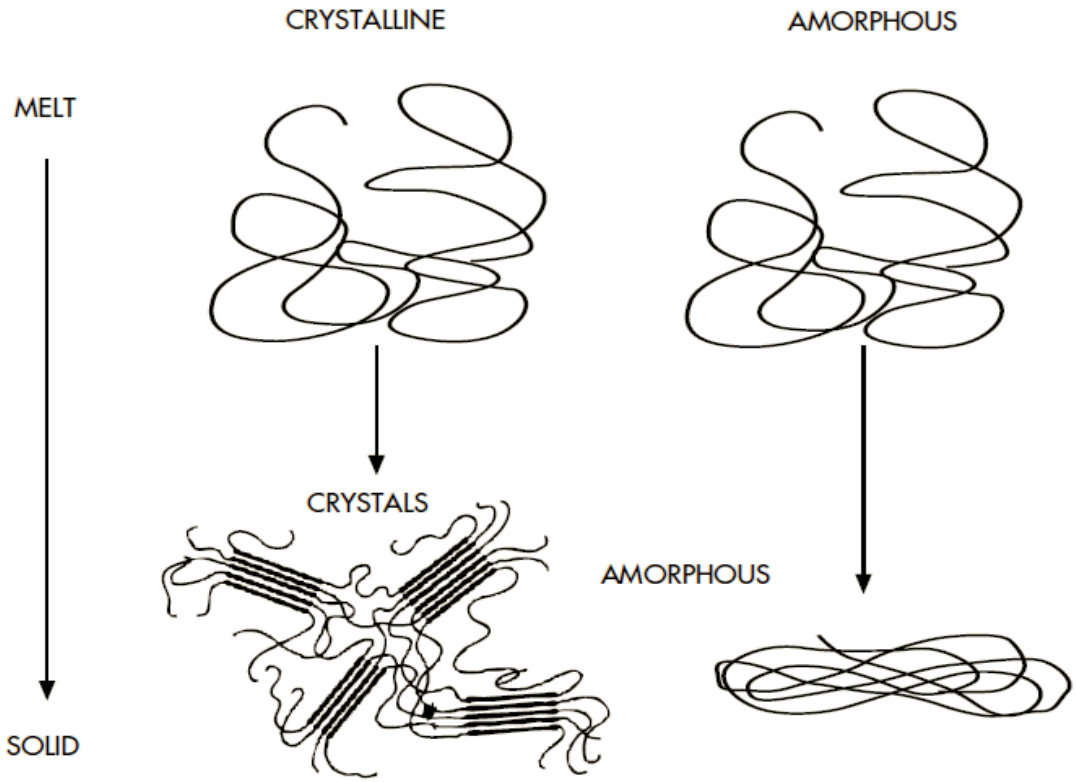
Amorphous polymers

- Plastics without the above crystalline regions
- Having no defined shape

Semi-crystalline polymers

- All of the crystalline plastics have amorphous regions between and connecting the crystalline regions
- Almost all "crystalline" polymers are actually "semi-crystalline"

Molecular Structures



Characteristics

Amorphous

- Soften over a broad temperature range
- Easy to thermoform
- Tend to be transparent
- Bond well using adhesives and solvents
- Prone to stress cracking
- Poor fatigue resistance
- Structural applications only (not for bearing and wear)

Crystalline

- Sharp melting point
- Difficult to thermoform
- Tend toward opacity
- More difficult to bond using adhesives and solvents
- Good resistance to stress cracking
- Good fatigue resistance
- Good for bearing and wear
- Good for structural applications
- Good for higher heat applications

Property Comparison

Property	Crystalline	Amorphous
Specific Gravity	Higher	Lower
Stiffness	More Stiff	Less Stiff
Tensile Strength	Higher	Lower
Tensile Modulus	Higher	Lower
Ductility Elongation	Lower	Higher
Resistance to creep	Higher	Lower
Impact	Less Impact	Better Impact
Max Usage Temp	Higher	Lower
Shrink and Warp	More	Less
Flow	Higher	Lower
Chemical Resistance	Higher	Lower

Examples by Class

Type	High Performance	Engineering	Commodity
Amorphous	Polysulfone, Polyetherimide, Polyethersulfone, Polyarylsulfone	Polycarbonate, Modified PPO, Modified PPE, TPU	Acrylic, Polystyrene, ABS, PVC, PETG, CAB
Crystalline	PVDF, PTFE, ECTFE, FEP, PFA, PPS, PEEK	Nylon, Acetal, PET, PBT, UHMW-PE	Polyethylene, Polypropylene

Polarity of Polymers

Another key component of a polymers innate functionality is its "polarity"; which has a big effect on adhesion characteristics

Polar molecules

- Electrons are not equally shared
- One part of the molecule is more negative than another part of the molecule
- Molecules thus have negative and positive "poles" like a battery
- This makes them hydrophilic (water loving)

Nonpolar molecules

- Electrons are equally shared
- No one part of the molecule is distinctly negative or positive…no poles
- This makes them hydrophobic (water hating)

Examples & Characteristics

Polymer Type	Examples	Characteristics
Polar	Nylon, POM, PC, PMMA, PEI, Water soluble polymers, PVC, TPU, Polyesters, ABS	Generally higher surface energy; good wettability (hydrophilicity); easier to bond and adhere to
Nonpolar	PE, PP, SEBS, PS	Generally lower surface energy; poor surface wettability (hydrophobicity); more difficult to bond and adhere to

Amorphous Polymers

Poly Vinyl Chloride (PVC)

Long positive history in medical applications
Dispersion & Suspension resins
Rigid and flexible grades (phthalate and non-phthalate plasticizers)

Properties

- No drying
- Good UV resistance
- Good innate fire resistance
- Low melt
- High performance with low cost
- Excellent clarity
- Can degrade when processed too hot
- Excellent bondability to a wide variety of substrates by a wide variety of bonding methods
- Very good physical property matrix

Sterilization

- EtO – yes but must be out-gassed for 7 to 14 days
- Gamma – yes but must be specially formulated

Regulatory

- USP Class 6
- FDA

Acrylic (PMMA)

Properties

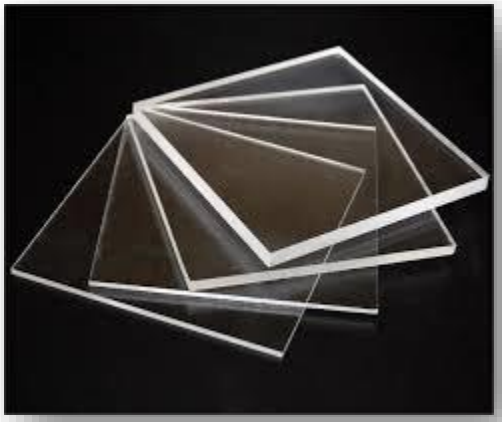
- Excellent transparency – up to 92% light transmittance
- Good mechanical strength and dimensional stability
- Good chemical resistance
  - Alcohol promotes crazing
  - Attacked by organic solvents
  - Resistant to inorganic acids and alkalis
- Inert
- Good UV resistance
- Excellent dimensional stability
- Good bondability and printability

Sterilization

- EtO – yes
- Gamma – yes but discolors if not modified

Regulatory

- USP Class 6
- FDA



Styrenics (ABS, SAN, PS)

Properties

- Lower melt point
- Easily fabricated
- Good dimensional stability
- Low to moderate price
- Adequate physical property matrix
- Transparency
  - PS and SAN – transparent
  - ABS – opaque or transparent
- Fair bondability

Sterilization

- EtO – yes, but avoid repeated cycles
- Gamma – yes, but may loose some impact

Regulatory

- ISO 10993 (ABS, SAN)
- USP Class 6
- FDA

PETG (Polyethylene Teraphthalate Copolymer)

Properties

- Excellent clarity and gloss
- Good impact resistance
- Excellent alcohol and lipid resistance
- Good barrier properties
- Excellent bondability & joinability
- Lower cost than PC
- Fair weatherability

Sterilization

- EtO – yes
- Gamma – yes

Regulatory

- USP Class 6
- ISO 10993
- FDA

Polycarbonate (PC)

Properties

- Moderately priced
- Good dimensional stability
- High temperature resistance polymers
  - Good in alcohols & acids
  - Poor in hydrocarbons, phenols, esters, ketones, and alkalis
- Excellent clarity
- High stiffness, impact, and toughness
- Excellent scratch resistance
- Poor weatherability
- Good bondability and joinability
- Contains BPA

Sterilization

- EtO – yes
- Gamma – yes but some discoloring can occur
- Autoclave – limited

Regulatory

- USP Class 6
- ISO 10993
- FDA

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Modified PPO/PPE (polyphenylene oxide/ether w/HIPS)

Properties

- High temperature resistance
- Good chemical resistance
  - good to acids & bases
  - attacked by some hydrocarbons
- Excellent dimensional stability and stiffness
- Good toughness
- Low moisture absorbance

Sterilization

- Gamma – yes
- EtO – yes
- Autoclave – yes w/limitations

Cellulosics (Acetate, Butyrate, Propionate)

Properties

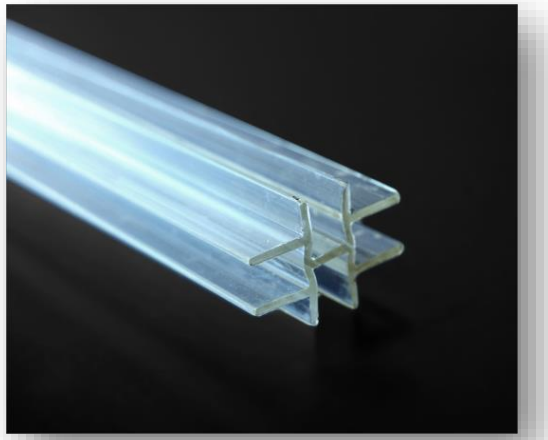
- Good impact
- Transparent glossy surface
- Good resistance to UV
- Fair bondable and joining
- Chemical resistance
  - Good in aromatic hydrocarbons, greases, oils, lipids
  - Fair in alcohols
  - Poor in acids, alkalis, ketones

Sterilization

- EtO - yes
- Gamma – yes

Regulatory

- USP Class 6
- ISO 10993



Sulfones (Polysulfone, Polyethersulfone, Polyarylsulfone)

General Properties

- Good clarity (brownish tint)
- High stiffness & dimensional stability
- High heat resistance
- Low shrink
- Chemical inertness and resistance
- Good fire resistance
- Higher cost
- Good bondability & joinability
- Universally sterilized

Sterilization

- EtO – yes
- Gamma – yes
- Autoclave – yes

Regulatory

- USP Class VI
- ISO 10993
- FDA

Crystalline Polymers

Polyethylene (Low & High Density)

Properties

- Moderate melt point
- Low COF
- Good physical property matrix
- Difficult to bond to anything
- Low moisture absorption
- High thermal expansion
- Excellent chemical resistance
- Good ductility
- Very low cost
- No drying
- Non-toxic
- Minimal clarity

Sterilization

- EtO – yes
- Gamma – yes

Regulatory

- USP Class 6
- FDA

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Polypropylene

Properties

- Moderate melt point
- Low COF
- More rigid than PE
- Good physical property matrix
- Difficult to bond to anything
- Low moisture absorption
- High thermal expansion
- Excellent chemical resistance
- Very low cost
- No drying
- Non-toxic
- Some clarity

Sterilization

- EtO – yes
- Gamma – yes but must be stabilized version

Regulatory

- USP Class 6
- FDA

Polyesters (PBT, PET)

Properties

- Materials are ester based so hydrolization could be an issue
- Moderately priced
- Very good chemical resistance
- Must be dried
- Good creep and fatigue resistance
- Fairly high melt
- Good dimensional stability
- Transparency
  - PET, PBT – opaque unless crystallized quickly
- High stiffness

Sterilization

- EtO – yes
- Gamma – yes

Regulatory

- USP Class 6
- ISO 10993

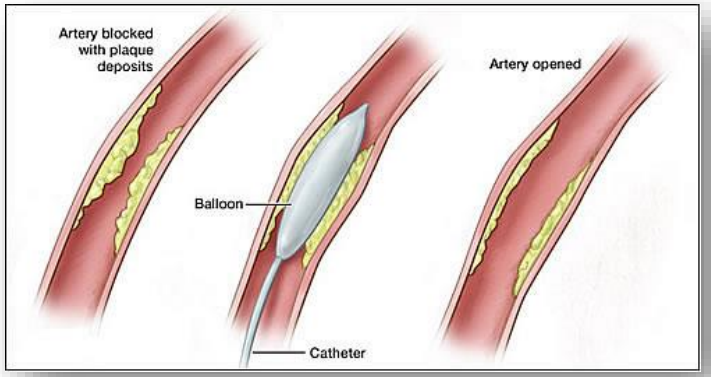
Polyamides (Nylons)

Types
- Diamine and diacid (66, 69, 610, 612)
- Amino acid (6, 11, 12)

Properties
- Low/moderate price
- Absorbs moisture
- Should be dried
- Excellent physical property matrix
- Very tough with some flexibility (PA 11, 12)
- Good chemical resistance except in strong acidic environments
- Most grades are opaque, some amorphous grades available
- Low COF

Sterilization
- EtO – yes
- Gamma – under 5 Mrad

Regulatory
- USP Class 6
- ISO 10993



Acetal

Properties

- Highly lubricious material
- Good physical properties
- Good chemical resistance
- Good solvent resistance
- Good dimensional stability & stiffness
- Low moisture absorption
- Good fatigue resistance
- Tricky Processing, formaldehyde generation
  - Can't process near PVC

Sterilization

- EtO – yes
- Gamma – no

Regulatory

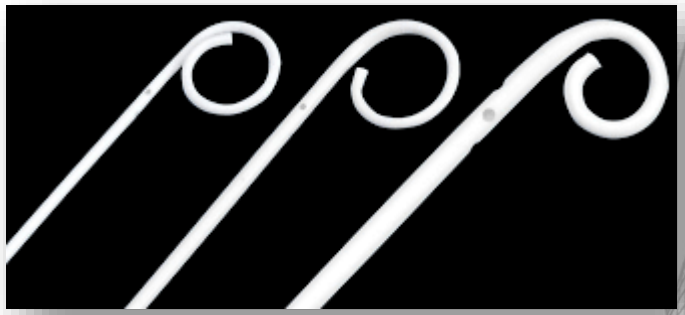
- USP Class VI
- ISO 10993

Fluoropoloymers (FEP, PFA, ECTFE, PVDF, MFA, THV)

DEFINED: paraffinic polymers where some or all hydrogen groups have been replaced by fluorine

Properties

- Chemically inert materials/excellent chemical resistance
- Very low COF
- High to very high priced
- High specific gravity
- Fire resistant
- UV resistant
- High temperature resins
- Expensive materials with high specific gravity
- Can get clarity
- Flexible to rigid material selection
- Highly inert material



Sterilization

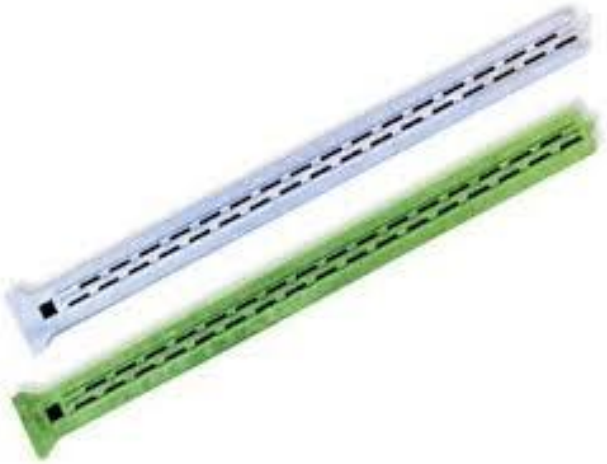
- EtO – yes
- Gamma – depends on material
- Autoclave – depends on material

Liquid Crystal Polymers (LCP)

Properties
- Very high modulus
- Low/no shrinkage
- Excellent dimensional stability
- Excellent chemical resistance
- High priced
- High temperature
- Outstanding mechanical properties
- Very difficult to extrude

Sterilization
- EtO – yes
- Gamma – yes
- Autoclave – yes

Regulatory
- USP Class VI



Polyetheretherketone (PEEK)

Properties

- Great for metal replacement
- Very high priced
- High specific gravity
- Very high heat resistance & processing temps
- Very high modulus
- Extraordinary mechanical properties
- Very low shrink
- Great chemical resistance except in some acids
- Can be implanted

Sterilization

- EtO – yes
- Gamma – yes
- Autoclave – yes

Regulatory

- ISO 10993
- Material used for implants

Advanced Biomaterials

Bioabsorbable and drug delivery polymers

- Implantable and bioabsorbable
- Can be engineered to degrade or release drug at a controlled rate
- Natural or synthetic
- Good processability
- Sterilizable – gamma or e-beam
- Extremely high priced (up to thousands of dollars per pound)
- Properties are "programmable": molecular weight variation via copolymerization or compounding
- Include polylactides, polyglycolides, polycaprolactones, etc

Thermoplastic Elastomers (TPE's)

Diverse family of "rubber-like" elastomeric materials that, unlike vulcanized rubbers (thermoset), can be processed and recycled like traditional thermoplastic processing equipment

Chemistry - Block copolymers and alloys

- Hard segments – provides thermoplastic properties
- Soft segments – provides elastomeric properties

Materials contain crystalline and amorphous segments

Thermoplastic Elastomers Categories

Engineering TPE's

PEBA--Polyether Block Amides

COPE--Copolyesters

TPU--Thermoplastic Polyurethanes

Specialty TPE's

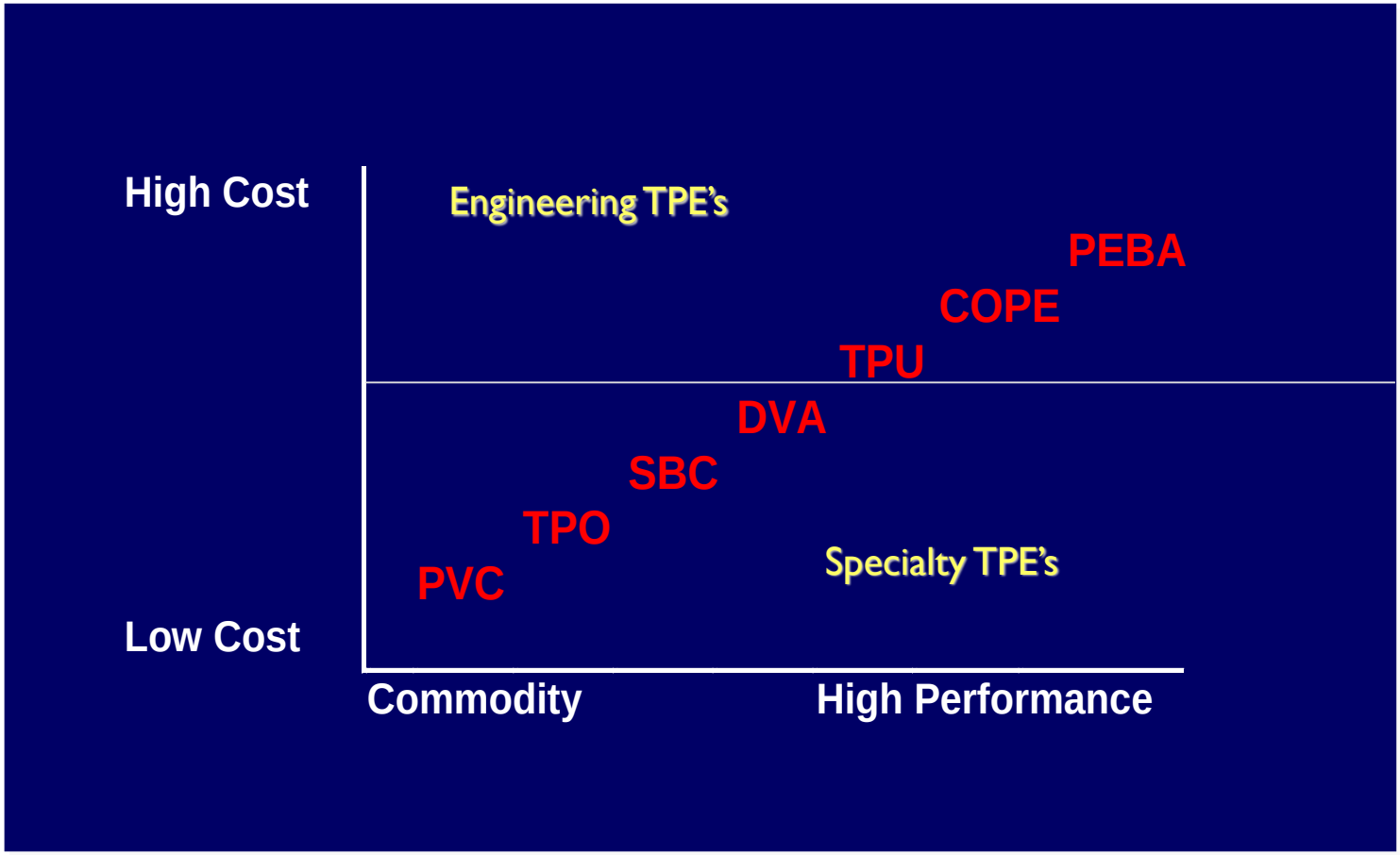
DVA--Dynamically Vulcanized blends

SBC--Styrenic Block Copolymers

TPO--Thermoplastic Olefins

PVC--PVC Blends (continuous & discontinuous) and Alloys (co-continuous)

Value vs. Performance



Polyether Block Amide (PEBA)

Properties

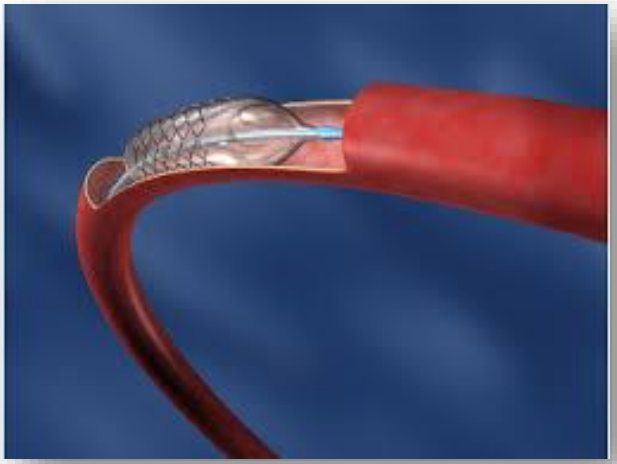
- Thermoplastic elastomer made up of soft polyether mid-block with hard polyamide (nylon 11, 12) end-blocks
- Premiere catheter shaft material for vascular therapy…enables outstanding operator control
- Excellent torqueability
- Easy to process
- Some clarity
- Maintains modulus in body temps
- Good chemical resistance
- Weak alcohol resistance
- Very good physical property matrix
- Durometer range
  - 75 A – 72 D

Sterilization

- Gamma – yes
- EtO - yes

Regulatory

- USP Class VI



Thermoplastic Polyurethane (TPU)

Properties

- Great history in medical applications
- Durometer range (55A – 75D)
- Many vendors
- Can be highly filled
- Good dynamic properties
- Excellent physical properties especially tensile and abrasion
- Changes modulus in body
- Excellent clarity
- Stable to most sterilization techniques
- Very good bondability and secondary processability

Sterilization

- Gamma – yes but may yellow
- EtO – yes

Regulatory

- USP Class VI
- ISO 10993

Copolyester Elastomers (COPE)

Properties

- Durometer range (85A – 75D)
- Excellent dynamic properties
- Excellent physical property matrix
- Clarity depends on processing technique
- Bondable but not as easy as PEBA and TPU
- Polyester backbone so it may hydrolyze over time

Sterilization

- Gamma – yes
- EtO - yes

Styrenic Block Copolymers (SBC)

Properties

- Very wide durometer range
- Bondability and bonding methods can be an issue
  - Functionalized bondable grades available
- Weak dynamic properties
- Good physical properties
- Lower cost
- Compounded product
  - Many formulation options
- Good for static parts on devices and grips
- Excellent elastomeric properties
- Easily processed

Sterilization

- Gamma – yes
- EtO – yes
- Autoclave – yes but limited

Regulatory

- USP Class VI and ISO 10993

Dynamically Vulcanized Allows (DVA)

Properties

- Physically cross-linked TPE's
  - Reaction extrusion of EPDM rubber with PP
- Durometer range 45A – 90A
  - Below 55A are alloys with SBC's
- Low compression set
- Physical properties are lower than most TPE's
- Opaque
- A little higher service temperature than SBC's
- Good chemical resistance to acids, bases
- Difficult to bond without additive bonding agents

Sterilization

- EtO - yes
- Gamma – yes

Regulatory

- USP Class VI and ISO 10993