THE POLYMER MINUTE

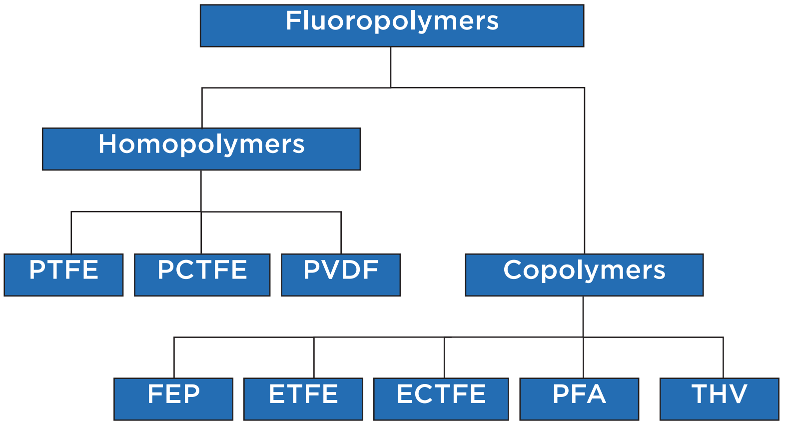
Emerging Polymer Designs in the Medical Device Industry

Introduction

Continuous innovation is not an option for the medical community. However, without simultaneous advancements in polymer science, many of the novel devices and therapies of today would cease to exist. As recent history demonstrates, the evolution of medical technology is inextricably linked to that of polymers.

From the advent of angioplasty in the 1960's to drug eluting stents now in use, the ability to manipulate polymer design to precisely fit applications has led to medical breakthroughs that have saved countless lives. The future of this symbiotic relationship is pointing toward bioabsorbable implants; but the diverse range of polymeric materials and their excellent properties mean possibilities are virtually limitless.

Below is a chart showing the fluoropolymer family, to which most of the materials discussed in this guide belong.



Overview of Fluoropolymers

History of polymers in medical devices

- 1960s – Angioplasty
- 1970s – Implantable vascular grafts
- 1970s – Introducers
- 1980s – Guiding catheter liners
- 1990s – Laparoscopic insulation sheaths and stent packaging
- 2000s – Drug-eluting stent packaging and manufacturing

Types of extrusion used in the medical device industry

Typically, polymers are extruded using two methods: paste extrusion and melt extrusion. Melt extrusion is similar to what occurs in a meat grinder where a rotating screw reduces the size of the meat, mixes it all up, and then extrudes the result out as a fine stream through the die at the face of the grinder.

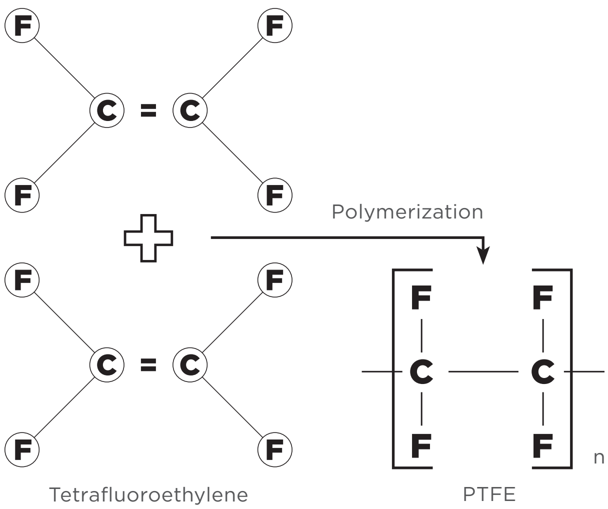
The other main type of extrusion, paste extrusion, is similar to a tube of toothpaste where pressure is applied to the tube, which forces the toothpaste out of the hole and onto the toothbrush. Most fluoropolymers are melt-extruded, except for PTFE, which is one of the most commonly found fluoropolymers in the medical device market.

Common polymers found in medical devices

The following is a breakdown of some of the more commonly-used polymers in the medical device industry, along with some of their respective advantages and disadvantages.

PTFE – Used in catheter liners, artificial tendons and ligaments, blood vessel prosthetics and vascular grafts

- Excellent high temperature performance for all mechanical properties
- Excellent low temperature performance for all mechanical properties
- Excellent electrical performance at high temperatures
- Excellent chemical resistance over a wide range of temperatures
- Excellent weathering and UV resistance
- Extremely low coefficient of friction



The Chemical Makeup of PTFE

FEP – Used in electrocautery devices and fusing sleeves

- Melt-processable fluoropolymer
- Very good high and low temperature performance for all mechanical properties
- Excellent electrical performance at high temperatures
- Excellent chemical resistance over a wide range of temperatures
- High transparency with good transmittance of both UV and visible wavelengths and a very low refractive index *(1.34)*
- Gamma-sterilizable

PFA – Used for critical fluid handling

- Melt-processable fluoropolymer
- Improved mechanical properties at high temperatures in comparison to FEP
- Very good high and low temperature performance for all mechanical properties
- Excellent electrical performance at high temperatures
- Excellent chemical resistance over a wide range of temperatures
- High transparency with good transmittance of both UV and visible wavelengths and a very low refractive index *(1.34)*
- Gamma-sterilizable

Polyamides – Used primarily in catheter outer jackets

- Abrasion resistant
- Low density
- Gamma-sterilizable
- Bondable
- High elasticity
- Thermal stability
- Low hysteresis
- Good coextrusion and over-molding compatibility

PEEK – Used in surgical instruments, analytical equipment, orthopedic and dental devices, Class VI and implantables

- For temperatures up to 500ºF
- Extremely high burst pressure, chemical resistance and tensile strength
- Exceptional stiffness
- Excellent impact and wear resistance
- Ideal replacement for stainless steel
- Walls as thin as 0.001" – 0.0015"
- Convoluted and heat shrink available
- Thermoformable

ETFE – Used in oxygen respirator components, blood analyzer valves, evaporating dishes, and centrifuge tubes

- Excellent impact resistance
- Good resistance to stress cracking
- Thermoformable
- Excellent dielectric strength
- Typical applications include mechanical parts
- Good radiation resistance
- Common trade name: Tefzel®

ePTFE – Used in sutures, artificial blood vessels, hip socket replacement, soft tissue replacement

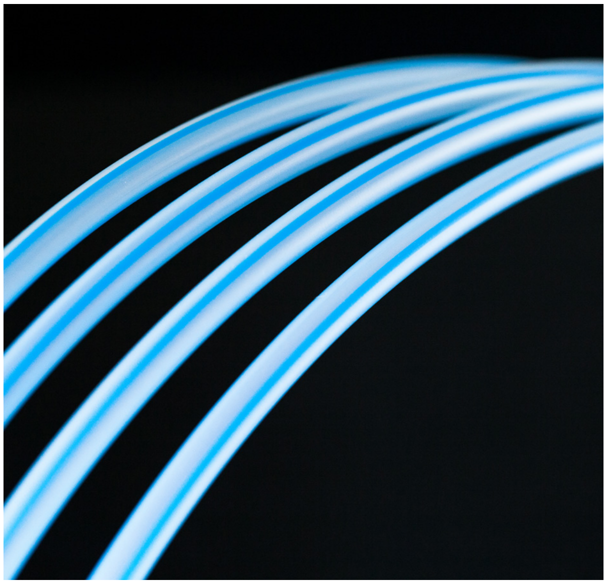
- Available in ribbon, tape, multi-lumen, monofilament and customized forms
- Similar chemical resistance and biocompatibility to that of PTFE
- Soft and flexible
- Implantable
- Microporous
- Air permeable
- Fluid impermeable
- Low dielectric constant

Biocompatibility in medical devices

PTFE, ePTFE, FEP, PFA, ETFE, PEEK and Pebax® are all USP Class VI-approved. One of the issues raised by the industry has been long-term biocompatibility. In this case, that means longer than 30 days. Going forward, one of the possibilities for the use of polymers would be as implants. While this remains a possibility, the success of any particular implant is dependent upon the resin grade and usage requirements that are determined by the manufacturer. Of course, where the implant is going to be placed in the body has an enormous impact on how successful it will be. Examples of suitable polymers for implants include PEEK-OPTIMA®, PTFE, ETFE, ePTFE, PU and even some polyamides.

Suitable sterilization methods for medical devices

The majority of polymers are highly suitable for all of the common major sterilization methods, which is especially important when one is considering using them in medical devices. The primary exception is PTFE, which is suitable for autoclaving and EtO treatment, but has a low resistance to gamma and e-beam radiation sterilization. It can suffer substantial radiation damage at exposures less than those required for adequate sterilization. PE is also not suitable for repeated autoclave cycles. On the other hand, PEEK maintains its mechanical and chemical properties past 3,000 hours in high-pressure steam.



It has excellent stability upon exposure to radiation and provides almost complete chemical resistance with the exception of extremely strong oxidizing acids.

MEDICAL TUBE ENGINEERING

Factors to consider when designing for the medical device industry

$$P=\frac{T(x^2-y^2)}{y^2\left(1+\frac{x^2}{y^2}\right)}$$

P=Burst Pressure

$x=\frac{OD}{2}$

$y=\frac{ID}{2}$

T=Tensile Strength

Burst pressure, a theoretical calculation using tensile strength, OD, and ID values to determine an approximate guideline for the conditions under which a tube might break open due to pressure from within, is clearly an important factor to consider when designing a medical device. Using the formula shown above, tensile strength values for some of the more common polymers are as follows:

- PTFE: 2,500 psi
- FEP: 3,000 psi
- PFA: 4,000 psi
- ETFE: 6,500 psi
- PEEK: 13,000 psi

Bend radius

Bend radius is determined by three factors: diameter, wall thickness and resin properties. For some applications, bend radius may be not be as pivotal as tensile strength, whereas other applications may call for the opposite. As a general rule, the bend radius is ½ the diameter at room temperature.

Torque

Torque is a force that produces or tends to produce rotation. To determine torque ratio up to 360°, the degree of distal rotation is divided by the degree of proximal rotation. The material must be able to provide sufficient rotation to the distal end of a catheter, while a lower torque ratio may provide better steerability.

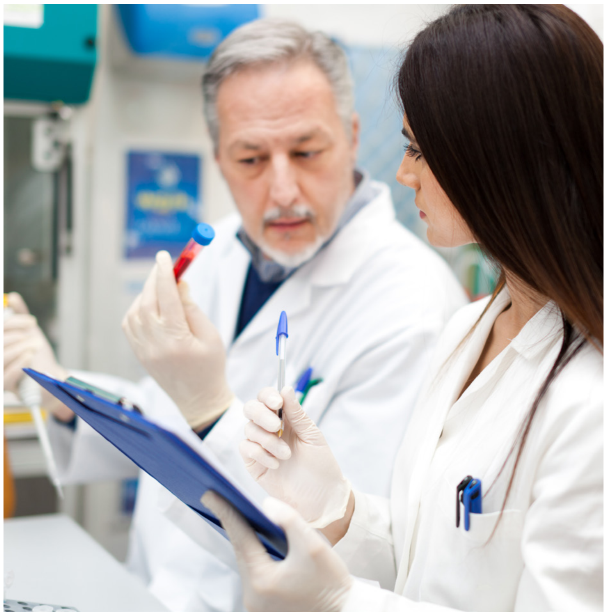
Columnar stiffness

Columnar stiffness is the ability to transmit force or movement from the proximal end to the distal end of a catheter. Polymer selection and material enhancing options are available in certain applications for targeting desired columnar stiffness properties

Six Sigma manufacturing as used in the medical device industry

Six Sigma is a business improvement methodology that was originally developed by Motorola to systematically improve processes by eliminating defects. In this case, defects are defined as units that are not members of the intended population. The objective of Six Sigma is to deliver high performance, reliability, and value to the end customer. When developing designs for medical devices, Six Sigma is a worthy standard to which to adhere.

While it works, and works well, for existing processes, the question remains: what about new projects? Design for Six Sigma (DFSS) is incorporated into new projects for significant improvements and competitive advantages; however, each company tends to adopt their own methodology to suit their particular business.



Several existing methodologies include:

1. DMADV or DMADOV:

Define	Measure	Analyze	Design	Verify	
Define	Measure	Analyze	Design	Optimize	Verify

2. DCCDI:

Define	Customer	Concept	Design	Implement

3. IDOV:

Identify	Design	Optimize	Validate

4. DMEDI:

Define	Measure	Explore	Develop	Implement

Keys to Six Sigma:

- To bring a new project to market using Six Sigma, a strong customer partnership must first be established.
- Cross-functional teams that consist of R&D, QA, QC, manufacturing, engineering and sales.
- A project must be designed with both supplier and customer benefit – a signed project charter is recommended.
- Determining how to combine with Lean principles.

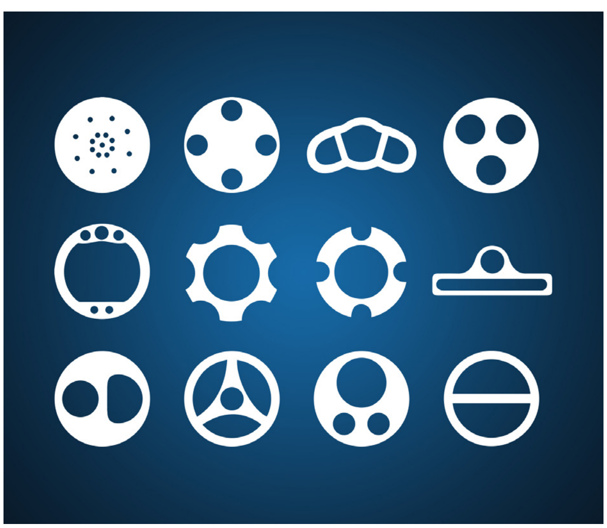
FORMS OF EXTRUSIONS AND TUBING IN THE MEDICAL DEVICE INDUSTRY

Single lumen tubing – Inside diameters ranging from .0015" to 3", and wall thicknesses ranging from .0015" up to .200". These types of tubes are typically available in straight, cut lengths, coiled or spooled.

Multi-lumen tubing – Can be manufactured with multiple tight tolerance passages.

Sub-Lite Wall® tubing – Walls as thin as .0005" and inside diameters as small as .0015".

Bump extrusions – Tubing with variable ID and OD, and short and long transitions from 2" to 100". These tubes offer exceptionally tight tolerances but are only available in melt-extrudable polymers.



Special shapes and profiles commonly seen in the medical device industry

Heat shrink tubing – Heat shrink tubing allows for the application of a tight, protective covering to items that will be subjected to the extremes of heat, corrosion, shock, moisture, and other critical environmental conditions. This type of tubing offers a unique combination of properties, including outstanding electrical characteristics, excellent chemical and solvent resistances, purity, lubricity, and outstanding performance reliability. Some of the more common heat shrinkable tubing choices include PTFE, FEP, PFA, PEEK, PET and PETG.

DEVICE FABRICATION TECHNIQUES USED FOR MEDICAL DEVICE APPLICATIONS

Catheter design goes beyond ID, OD and cut length. There are a number of variables that can alter the effectiveness of a fluoropolymer for a given application. One of the reasons fluoropolymers are so ideal for the medical device market is the amount of available customization. Some design issues to consider include:

- Torque translation
- Elongation
- Flexibility
- Wall thickness
- Etch contact angle
- Radiopacity
- Overall process consistency

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Guiding catheters are typically constructed with a PTFE liner, covered by an over-braid, which is covered by a Pebax outer jacket. The PTFE liner's superior lubricity allows for the smooth insertion of surgical components, while the over-braid increases torquability and kink resistance. The Pebax outer jacket provides a soft, smooth and flexible cover.

Adhesive bonding

Fluoropolymers are prized for their high performance properties including a high degree of lubricity (slipperiness), which allows them to excel in demanding applications such as endoscopes, guiding catheters, and other applications where friction is a concern.

However, the lubricity of these plastics also makes them difficult to bond to using conventional methods and adhesives. Chemical etching of the surface is required to create an acceptable bond.

- Etching is the necessary first step for highly lubricious fluoropolymer surfaces
- Involves the removal of fluorine atoms which are replaced with carbon groups present in the air
- Carbon groups are receptive to adhesion
- Uses solution of sodium naphthalene
- Etch depth is only a few angstroms
- Adhesives used include epoxies, cyanoacrylates, and silicone

Fillers

There are a number of reasons why fillers may enhance the performance of polymer tubing. Fillers are added for a variety of reasons, but most importantly they: modify and enhance the properties of the base polymer, reduce the cost of the final plastic material, and improve the processing of the base polymer. Listed below are some of the more common fillers used in medical devices.

Bismuth – Bismuth is used to allow PTFE tubing to be visualized on a fluoroscopic screen during invasive procedures. This allows the physicians to see the surgical implantable device both during and after the procedure has been completed. Visualizing the device allows the physician to guide and maneuver the device for proper placement or alignment. Bismuth will also allow the device to be visualized on routine diagnostic radiographs. Bismuth is well accepted in the medical profession to be in contact with the body.

Barium – Barium is used in FEP tubing as bismuth is used in PTFE tubing above. Surgical or implantable devices are able to be viewed on fluoroscopic screens during and after surgeries and on diagnostic radiographs. And, as bismuth, it is medically accepted for contact with the body.

Other fillers may include glass to change mechanical properties, carbon to change electrical and magnetic properties, and pigments to alter color, just to name a few.

Summary

Polymers are a group of plastics still being explored and examined. These materials and their unique properties make them natural candidates for the demanding applications found in the medical device industry. Given the wide range of materials and characteristics available, along with constantly-evolving Six Sigma standards, the future possibilities in the medical device market are truly limitless.

How Zeus Can Help

Zeus is the world's leading polymer extrusions and material science innovator. Almost 50 years of experience in medicine, aerospace, energy exploration, automotive, fiber optics and more allows us to leap past "can't" and into "how." Headquartered in Orangeburg, South Carolina, Zeus employs approximately 1,200 people worldwide and operates multiple facilities in North America and internationally.

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