



TEN THINGS YOU NEED TO CONSIDER WHEN USING POLYMERS FOR MEDICAL DEVICES

A Regulatory Expert's Guide by Michael Wallick

In partnership with Invibio Biomaterial Solutions

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WHY THIS GUIDE MATTERS?

Implantable medical devices must perform reliably and safely in one of the most demanding environments: the human body. For professionals involved in the design, development, or regulation of these devices, understanding **biocompatible polymers** is essential.

Invivo have been providing PEEK-OPTIMA™ biomaterials for decades and can be your trusted guide when considering your options for materials of construction.



SUMMARY

Selecting the right polymer for a medical device involves far more than choosing something strong or flexible. It's about:

- ▶ Understanding how the body will react
- ▶ Anticipating how the material will behave over time
- ▶ Meeting global testing and regulatory requirements

By mastering these **10 things** to know, you'll:

- ▶ Avoid costly testing mistakes
- ▶ Reduce regulatory delays
- ▶ Reduce risk
- ▶ Improve patient safety and clinical performance



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Polymers bring versatility, lightweight design, and radiolucency to implants- features not achievable with traditional materials.

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It's about appropriate host response in a specific context- not just being non-toxic.

3. BIOCOMPATIBILITY DEPENDS ON THE WHOLE MATERIAL PROFILE

Beyond base chemistry, factors like fillers, shape, processing residues, and surface finish matter.

4. NOT ALL POLYMERS ARE SUITABLE FOR MEDICAL USE

Only certain medical-grade polymers meet the standards for long-term implantation and consistent bioperformance. Potential challenges in adoption without sufficient education on benefits.

5. MEDICAL-GRADE POLYMERS MINIMIZE RISK AND ACCELERATE DEVELOPMENT

Using medical-grade materials supported by FDA Masterfiles can reduce development time and strengthen regulatory confidence.

6. INDUSTRIAL PLASTICS POSE LEGAL AND PERFORMANCE RISKS

Industrial versions of polymers may contain unknown impurities and are often disallowed by suppliers due to liability history and lack of controls.

7. MANUFACTURING PROCESSES CAN AFFECT BIOCOMPATIBILITY

Polymerization conditions and processing steps (extrusion, molding) can introduce cytotoxic contaminants or change material properties.

8. STERILIZATION METHODS CAN ALTER POLYMERS

Steam, gamma, and EtO sterilization each affect polymers differently- some may degrade or retain harmful residues.

9. BIOSTABILITY AND DEGRADATION ARE APPLICATION-SPECIFIC

Hydrolysis, oxidation, or stress cracking can compromise implant longevity. Consider environment and use case.

10. THE INTENDED USE DEFINES THE TESTING REQUIREMENTS

Device classification (implant, surface, external-communicating) and contact duration determine the extent of testing.

1.

POLYMERS OFFER UNIQUE BENEFITS OVER METALS AND CERAMICS

In the realm of implantable medical devices, material choice can be the difference between success and complication. While metals and ceramics have historically been favored for their mechanical strength and durability, polymers have redefined what is possible in design, function, and manufacturing.

Why Polymers?

Polymers offer a suite of advantages tailored to the complex demands of the human body:

Property	Benefit
High strength-to-weight ratio	Lighter implants reduce patient discomfort and ease surgical handling
Radiolucency	Imaging modalities (X-ray, CT) can pass through without scattering artifacts
Tunable properties	Fillers and additives can adjust wear resistance, opacity, or flexibility
Lower elastic modulus	Reduces stress shielding compared to metals- especially beneficial in bone
Versatile processing	Enables mass production through injection molding, extrusion, 3D printing

These capabilities make polymers particularly suitable for orthopedic, cardiovascular, and neurological implants.



2.

BIOCOMPATIBILITY MEANS MORE THAN INERTNESS

The Biological Lens on Materials

Biocompatibility refers to the ability of a material to function in a specific biological setting without causing harm or eliciting an unacceptable response.

Historically, biocompatibility meant **inertness**- the idea that the material should do nothing to interfere with biological function. But that definition has evolved. As device designs grow more complex (e.g., drug-eluting stents, bioresorbable scaffolds), so too does the need for materials to **interact appropriately** with the body.

Foundational Definitions

The most widely accepted definition comes from Professor D.F. Williams, a pioneer in biomaterials:

“Biocompatibility refers to the ability of a material to perform with an appropriate host response in a specific situation.”

— Williams (1987, updated 2008)

Today, this means that a material must:

- ▶ Perform its intended function
- ▶ Integrate with the host tissue
- ▶ Avoid triggering undesirable local or systemic effects

3.

BIOCOMPATIBILITY DEPENDS ON THE WHOLE MATERIAL PROFILE

Polymers are more than their base molecules. Unlike metals or ceramics, they are synthesized from monomers and catalysts, and often modified with additives, fillers, or processing aids- each of which can influence the biological response.

Key Influencing Factors:

- ▶ Residual monomers or catalysts from incomplete polymerization
- ▶ Fillers that can alter leachability
- ▶ Colorants or stabilizers, sometimes proprietary and not always biocompatible
- ▶ Processing additives like lubricants or spin finishes that remain as surface residues

The chemical complexity of polymers means every formulation- and every processing step- should be scrutinized. Two samples of the “same” polymer can perform differently based on how they were processed or cleaned.

Bottom Line:

Biocompatibility is never just about the polymer name. It’s about the entire material system and how it was handled.

Biocompatibility in polymers is influenced by more than just the base polymer. The following aspects are critically important:

Factor	Why It Matters
Polymer type	Each polymer family reacts differently in vivo
Shape and surface	Surface roughness, energy, and topography affect tissue and protein interactions
Filler materials	Used to enhance wear, opacity, or color- but can impact biocompatibility
Polymerization process	Incomplete reactions may leave behind residual monomers or catalysts
Processing conditions	Temperature, shear, or contamination can introduce leachables

4.

NOT ALL POLYMERS ARE SUITABLE FOR MEDICAL USE

While thousands of polymers are available in industrial markets, only a limited set meet the requirements for long-term implantable medical devices. These requirements span mechanical performance, chemical stability, and most importantly, biocompatibility.

What Makes a Polymer Suitable?

A medical-grade polymer must:

- ▶ Biocompatibility test data
- ▶ Manufacturing controls
- ▶ Raw material traceability

Just because a polymer performs well in an industrial or consumer application does not mean it is safe for medical implantation.

Selecting a Suitable Polymer

While many polymers exist commercially, **only a select few are appropriate for use in implantable medical devices.**

A **biomaterial** must be:

- ▶ **Fit for purpose** (mechanically, chemically)
- ▶ **Biocompatible** with the intended site of use
- ▶ **Processable** without degrading or altering key properties

Even small changes in **processing parameters, sterilization, or raw material sources** can drastically impact performance and safety.

Best Practice:

Start testing with **medical-grade** polymers from the outset. These are typically sourced with controlled purity, processing, and supplier declarations for medical use.

5. MEDICAL-GRADE POLYMERS MINIMIZE RISK AND ACCELERATE DEVELOPMENT

Working with medical-grade polymers offers a strategic advantage for device developers: built-in confidence.

Benefits of Using Medical-Grade Polymers:

- ▶ Backed by material masterfiles that can be cross-referenced in regulatory submissions
- ▶ Produced under controlled conditions with repeatable purity and processing
- ▶ Supported by suppliers who understand regulatory requirements
- ▶ Manufacturing control and strict notification of change policy

Using a pre-qualified medical-grade polymer allows development teams to:

- ▶ Focus on device-specific validation (not base material characterization)
- ▶ Accelerate time-to-market by reducing redundant testing
- ▶ Minimize the risk of regulatory rejection or delays

FDA does not “approve” materials, but it accepts data from tested and compliant polymers- especially those with well-documented usage histories, like PEEK-OPTIMA™.



6.

INDUSTRIAL PLASTICS POSE LEGAL AND PERFORMANCE RISKS

Not all polymers are created for healthcare- and some aren't even legally allowed to be used in medical devices. Industrial-grade plastics, while chemically similar to medical-grade counterparts, can present serious risks when repurposed for implants.

Key Differences

Medical-Grade Polymers

- ✓ **Produced under GMP-like controls**
- ✓ **Batch-tested for purity and consistency**
- ✓ **Backed by regulatory masterfiles**

Industrial-Grade Polymers

- ✗ Often lack traceability or documentation
- ✗ May contain unknown additives or contaminants
- ✗ Not supported for medical use—often with explicit disclaimers



Legal Precedent

In the 1990s, companies like Dow Corning and DuPont were sued after polymers originally intended for industrial use were found in faulty medical devices. Though the device manufacturers were responsible for the final products, lawsuits reached back to material suppliers- prompting many to stop offering industrial polymers for any medical use.

Regulatory Protection

In response, the U.S. Congress passed the Biomaterials Access Assurance Act (1998), offering limited liability protection to raw material suppliers- provided their polymers are sold for approved medical use with documented limitations.

Reminder:

If a supplier refuses to certify a polymer for medical use, using it in an implant not only carries performance risk, but also legal exposure.

Medical-Grade vs Industrial Polymers

Why not use industrial-grade plastics? Because:

- ▶ **Polymerization pathways** may vary significantly
- ▶ **Impurities, processing aids, or residual solvents** can leach out
- ▶ **Material suppliers often prohibit** use in medical devices due to liability



7.

MANUFACTURING PROCESSES CAN AFFECT BIOCOMPATIBILITY

Polymerization Matters

Unlike metals and ceramics, polymers are **synthesized via chemical reactions** that can vary based on:

- ▶ Monomer purity
- ▶ Catalyst type
- ▶ Reaction time and temperature
- ▶ Environmental contaminants

If the reaction is incomplete or conducted under suboptimal conditions, the resulting polymer may contain **residual monomers, unreacted catalysts, or degradation products**- all of which may leach out and cause adverse tissue responses.

With polymers, how a material is processed can be just as important as what it is made from. Many developers mistakenly assume that if a raw polymer passes initial biocompatibility tests, the finished product will too- but processing steps can change everything.

Processing Risks

- ▶ Shear forces during extrusion or molding can create chemical by-products
- ▶ Residual solvents, plasticizers, or lubricants may remain on the surface
- ▶ Cross-contamination from metal tools, rollers, or hoppers can leave behind trace metals
- ▶ Inconsistent temperatures or residence times may produce degraded fractions

These changes can influence:

- ▶ Material strength and color
- ▶ Surface reactivity
- ▶ Toxicity of leachable compounds and biocompatibility

Best Practice:

Always test the fully processed and sterilized form of the final finished device, not just the base resin.

FDA guidance makes clear that manufacturing changes, even those considered minor, should be assessed for potential impact- often necessitating requalification- to ensure device performance and safety are maintained.

Manufacturing & Processing Considerations

Polymers can be **chemically sensitive materials**, and their biocompatibility can be greatly influenced by how they are **manufactured and processed**. From polymerization to final device shaping, every stage introduces potential risks that must be carefully controlled.

Pro Tip:

Always test the **final processed form** of the material- not just the raw polymer- for biocompatibility.



8. STERILIZATION METHODS CAN ALTER POLYMERS

Sterilization is essential for any implantable device- but for polymers, it's a critical variable that can affect biocompatibility, appearance, and long-term stability.

Common Sterilization Methods & Their Impacts

Method	Pros	Risks for Polymers
Steam (Autoclave)	Effective and common	High heat and moisture can degrade hydrolytically sensitive polymers like PE or PLA
Gamma Radiation	Deep penetration, good for bulk items	Can cause chain scission, embrittlement, or discoloration- especially in PTFE, PLLA
Electron Beam	Fast, no heat	Limited penetration- less suitable for thick devices
Ethylene Oxide (EtO)	Effective at low temperature	Can leave behind toxic residues; requires degassing and validation
UV Sterilization	Surface disinfection	Degrades many polymers, causes brittleness or yellowing



Design Tip:

Always verify that your polymer is compatible with your intended sterilization method- and test after sterilization for:

- ▶ Mechanical integrity
- ▶ Cytotoxicity
- ▶ Chemical residuals or leachables

Because some sterilisation-related changes may not be immediately visible, both mechanical performance and biocompatibility should be evaluated following sterilisation to confirm that material properties and safety remain acceptable.

Don't assume your sterilization process is benign- what works for metal or ceramic may be destructive for polymers.

Cleaning & Sterilization

Sterilization and cleaning are **mandatory** for any medical device- but polymers must be treated with care. Some polymers are **incompatible with traditional sterilization methods**, which can degrade their structure or create harmful by-products.

Key Point:

Sterilization should be tested **alongside biocompatibility** because degradation products may be cytotoxic or inflammatory.

9.

BIOSTABILITY AND DEGRADATION ARE APPLICATION-SPECIFIC

Once implanted, a polymer doesn't just sit passively in the body- it is exposed to a dynamic and complex biological environment. Understanding how and where a polymer is used is crucial to predicting its long-term behaviour.

What Affects Biostability?

Factors influencing polymer degradation include:

- ▶ **Anatomical site** (e.g. blood vs. bone)
- ▶ **Mechanical stress** (e.g. load-bearing joints)
- ▶ **Chemical exposure** (e.g. oxygen, enzymes, or metal ions)
- ▶ **Residual internal stress** from processing

Biostability testing should simulate **actual implant conditions** - including sterilization, mechanical loading, and body temperature.

Degradation Mechanisms

Polymers can degrade through:

- ▶ Hydrolysis (especially in hydrophilic domains)
- ▶ Oxidation (by immune system oxidants or sterilization by products)
- ▶ Environmental Stress Cracking (ESC) when stress and oxidation are combined
- ▶ Interactions with metal ions or corrosion products





Consequences of Degradation

Degradation can:

- ▶ Lead to **loss of mechanical properties**
- ▶ Generate **toxic by-products**
- ▶ Trigger **chronic inflammation or immune response**

Testing for **accelerated aging** and **real-time degradation** is essential, especially for **long-term implants**.

Polymers may be tested via:

- ▶ **Accelerated aging**
- ▶ **Enzymatic or oxidative challenge tests**
- ▶ **Explanted sample analysis**

Degradation is not always visible. It may start microscopically but lead to serious long-term effects.

10.

THE INTENDED USE DEFINES THE TESTING REQUIREMENTS

Biocompatibility isn't one-size-fits-all. Regulatory bodies require testing strategies that reflect the intended use of a device- including its contact type, duration, and site of contact.

Device Categorisation and Contact Conditions (per ISO 10993-1)

Category	Examples	Contact Site
Skin-contact device	Electrodes, skin patches, wound dressings	Skin or mucosal surfaces
External communicating	Catheters, infusion sets, endoscopes	Blood or mucosal membranes
Implantable devices	Joint replacements, stents, pacemakers	Tissue, bone, or blood

Contact Duration Classification

Type	Duration
Limited	< 24 hours 24
Prolonged	hours – 30 days >
Permanent	30 days

Each combination of device category and contact duration corresponds to a different set of biological evaluation tests under ISO 10993. The more intimate and long-lasting the contact, the more extensive the testing required.

A permanent blood-contacting device, for example, must undergo full systemic toxicity, hemocompatibility, implantation, degradation, and chronic toxicity testing.

Why Biocompatibility Testing Is Necessary

Because direct evaluation of material safety in humans is neither appropriate nor feasible, ISO 10993-1 defines a structured **preclinical** approach using in vitro and, where necessary, in vivo evaluations to assess biological safety for:

- ▶ Cytotoxicity (toxicity to cells)
- ▶ Sensitization (allergic response)
- ▶ Irritation and reactivity
- ▶ Systemic toxicity (whole-body effects)
- ▶ Hemocompatibility (blood interactions)
- ▶ Implantation effects

The level of testing required is proportional to the risk posed by the device.

Example:

A skin patch worn for 12 hours requires far less testing than a hip implant intended to last 20 years.



BONUS TIP: PRIOR USE OF A POLYMER CAN SUPPORT REGULATORY CLEARANCE

In medical device development, **historical use matters**. If a polymer has previously been used in a similar device with a proven safety record, that history can serve as a **predicate**, easing regulatory burden.

What Is Predicate Use?

Under the **FDA's 510(k) pathway**, you may submit a new device for approval by demonstrating it is **substantially equivalent** to a previously cleared one- known as the **predicate device**.

If the **same polymer** (including grade and processing method) has been:

- ▶ Used in an approved device
- ▶ For the **same application**
- ▶ With a similar **contact site** and **duration**

...then the biocompatibility of that material may already be accepted by the FDA or other regulatory authorities.

Material Masterfiles

Some material suppliers, like Invibio, maintain an extensive FDA Masterfile built up of many years knowledge, testing and experience.

- ▶ Detailed biocompatibility data
- ▶ Manufacturing process controls
- ▶ Regulatory declarations

Device manufacturers referencing these files can:

- ▶ **Save time and cost** by reducing redundant material testing
- ▶ Increase confidence during submission reviews

Even with predicate support, changes in processing or new sterilization methods may still require supplemental testing.

SUMMARY: MAKING SMARTER DECISIONS ABOUT POLYMERS FOR MEDICAL DEVICES

The journey to selecting the right polymer for a medical device is about **much more than mechanical strength or manufacturability**. As we've seen, it's about:

- ▶ Ensuring **biocompatibility** at the cellular and systemic level
- ▶ Understanding the impact of **processing, sterilization, and chemical additives**
- ▶ Anticipating **degradation behavior** and its biological consequences
- ▶ Navigating a landscape shaped by **regulatory science, material history, and clinical context**

By mastering these 10 essential insights, you'll be better equipped to:

- ▶ Choose the right material from the start
- ▶ Streamline development and testing
- ▶ Minimize regulatory risk
- ▶ Improve patient safety and device performance

Invivo have decades of providing medical device companies with high performance PEEK-OPTIMA biomaterials along with extensive service and support.

Contact us now to sample our materials and speak with our experts about your next device.



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S-MS-PHA-E-0166-B (9/2017)

