Polydioxanone (PDO): Medical relevance and material background

Polydioxanone (PDO) is best known as the base material for **absorbable surgical sutures**, where it has been used in routine clinical practice for several decades. Its long-standing adoption in surgery reflects a well-characterized balance of mechanical performance, biocompatibility, predictable bioresorption, and regulatory acceptance.

Medical relevance and clinical history

PDO was introduced into clinical use primarily through **monofilament absorbable sutures**, selected for their combination of strength retention, flexibility, and controlled degradation. In vivo, PDO undergoes **hydrolytic degradation of ester bonds**, producing low-molecular-weight byproducts that are subsequently metabolized and eliminated by the body. This degradation mechanism is **non-enzymatic**, resulting in a predictable and reproducible resorption profile across patients and anatomical sites. Importantly, PDO degradation does **not result in a pronounced local acidic environment**, which is considered a contributing factor to its favorable tissue response and relatively low biotoxicity compared with some other bioresorbable polymers.

Regulatory status and FDA precedent (510(k))

Medical devices manufactured from PDO—including absorbable sutures and other temporary implants—have been **cleared by the U.S. Food and Drug Administration through the 510(k) pathway** for multiple indications. These clearances establish PDO as a **well-characterized, predicate-supported biomaterial** with an extensive regulatory history in resorbable medical devices.

While 510(k) clearance is device- and indication-specific, the repeated clearance of PDO-based products demonstrates regulatory recognition of its **biocompatibility, degradation behavior, and clinical safety profile**. This precedent supports the use of PDO in new resorbable device designs where substantial equivalence to existing cleared devices can be demonstrated through material characterization, mechanical testing, and biocompatibility evaluation.

Key properties for medical use

- **Bioresorbability**
  Gradual resorption over several months, typically preserving mechanical integrity during the critical early healing phase before safely disappearing as native tissue regenerates.

- **Biocompatibility**
  Extensive clinical history demonstrating low inflammatory response, good tissue

tolerance, and minimal adverse foreign-body reaction, partly attributed to the absence of significant acidity during degradation.

- **Mechanical performance**
  Sustained tensile strength retention compared to faster-resorbing polymers (e.g., PGA), making PDO suitable for applications requiring **prolonged temporary structural support**.

- **Monofilament behavior**
  Smooth surface morphology associated with low tissue drag and reduced bacterial adhesion relative to braided materials, contributing to favorable healing outcomes.

Use in surgical implants and regenerative medicine

Beyond sutures, PDO has been explored and adopted in a range of **temporary surgical implants**, including fixation elements, meshes, and scaffold-like structures intended to provide short- to mid-term mechanical support. Its degradation timeline aligns well with **soft-tissue and bone healing processes**, enabling gradual load transfer from the implant to regenerating tissue as healing progresses.

As a scaffold material, PDO can be engineered to provide a temporary three-dimensional framework that supports **cell attachment, tissue ingrowth, and vascularization**, while progressively resorbing without leaving permanent foreign material.

Relevance for bone grafting scaffolds

For custom bone grafting applications, PDO offers a **clinically familiar and regulatory-established resorbable platform** that can be engineered into patient-specific geometries with controlled porosity and mechanical properties. PDO scaffolds provide early mechanical stability during osteointegration and gradually resorb as new bone forms, eliminating the need for secondary implant removal procedures.