



Implantable Medical-Grade UHMW Polyethylene (UPC15)

Material Data Sheet
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Overview

UPC15 is an ultra-high molecular weight (UHMW) polyethylene-based material. It is manufactured through an extrusion process in a clean room environment for purity, and it is suitable for use in implantable medical, as well as pharmaceutical and food contact sealing applications.

UPC15 has excellent wear resistance in water and other aqueous media. It is recommended for use in temperatures ranging from -450 °F to +180 °F (-268 °C to +82 °C).

Chemical Compatibility

UPC15 exhibits excellent compatibility with most fluids and gases, including ketones, alcohols, amines, and esters. It has limited applications with oxidizing acids and chlorinated solvents. For more details, reference Technical Report 60A, "Chemical Compatibility Guide," in the technical library section of our website at www.balseal.com.

UPC15 can be repeatedly sterilized with standard ethylene oxide (EtO) methods without loss of biocompatibility or degradation of mechanical properties.

Statement of Compliance

- UPC15 meets ASTM F648 Type II (Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants)
- UPC15 meets FDA Regulation 21 CFR 177.1520, and is an FDA compliant* material suitable for use in food contact
- UPC15 has been certified by an independent testing authority to meet ISO 10993-5 standards (Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity)
 - Tested for biological and cytotoxicity responses, UPC15 produced no reaction, confirming its suitability and safety for both direct and indirect contact with the human body

* Bal Seal Engineering defines "FDA Compliant" as materials listed by the FDA as "safe for use in food contact," or "acceptable for use in food contact."

Color

White (color variations may occur during processing).

Heat Treatment

Certain seal sizes are supplied as UPC15 HT where HT stands for a heat treatment to limit dimensional changes. Material properties and composition remain the same.

Mechanical Properties of UPC15

Tensile Strength (typical)	Elongation (typical)	Hardness
5000 PSI (352 kg/cm ²)	300%	62 ShoreD (46 Rc)

Typical Applications

- Implantable devices for joint arthroplasty, reconstruction, and replacement
- Powered surgical tool motors
- Cardiac and arthroscopic catheter drive units
- Blood collection and processing equipment

For more information, contact a technical sales representative, or e-mail us at solutions@balseal.com.

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