

USP Class VI and FDA “White List” Silicone and Organic Elastomer Compounds for Healthcare Products

Darcoid and Parker offer a wide range of USP Class VI and FDA elastomeric materials for the Healthcare Industry. These materials can be supplied as precision extruded and cut seals used as static face or static radial seals, long length precision extruded profiles, or precision extruded and spliced rings or gaskets.

USP Class VI Materials

Parker’s offering of United States Pharmacopia (USP) XXII Class VI materials have been tested to (USP) XXII Class VI testing requirements which include: System Toxicity, and Intracutaneous Toxicity. Parker products are sold as industrial grade products only, for use in non-implant devices. It is the customer’s responsibility to determine the suitability of JBL products for each specific application and to comply with all applicable statutory, regulatory, and health care industry requirements and/or standards for efficacy, labeling, safety and testing. JBL’s USP Class VI materials and products have batch traceability (CBI) for each lot of product produced.

FDA “White List” Materials

Parker’s FDA “White List” materials are formulated exclusively from ingredients listed in Federal Regulation Title 21 “Food and Drugs,” CFR 177.2600, “Rubber Articles Intended for Repeated Use,” and have batch traceability. Please note that the FDA does not “approve” rubber compounds. It is the responsibility of the manufacturer to compound food-grade materials from the FDA list of ingredients and establish whether they pass the requisite requirements.