

Specimen Vial Sealing

No. TSD 5405B1-USA

TechSeal precision cut face seals and FDA/USP Class VI approved materials provide critical sealing for medical specimen vials.

Application: Cap seals for specimen vials that are used to transfer fluids from the patient to the laboratory for testing and analysis.

Potential Customers: Plastic injection molders who produce specialty "labware" for the healthcare industry. Labware is usually considered to be bottles, jars, vials, and containers to store or transfer body fluids and blood.

Design Requirements: Precision tolerance, engineered static face or radial seals made from FDA "White Listed" or USP Class VI silicone or EPDM materials. These seals are designed to prevent leakage and contamination during the transfer or storage of fluids. TechSeal offers application engineering assistance, rapid prototypes and fast production ramp-up.

The TechSeal Solution: By utilizing a precision extrusion and cutting process, TechSeal produces seals that are free of flash, parting lines, non-fills, and voids, which are common concerns with molded parts. To ensure cleanliness, finished parts can be washed in deionized water and double bagged under environmentally controlled conditions.



The Preferred Source...

- FDA "White Listed"
- USP Class VI

SUMMARY: TechSeal's precision extrusion and cutting process offers the designer and manufacturer of medical specimen vials the best static seal product with no tooling cost, a broad range of materials to choose from, design flexibility, and speed to market. TechSeal's extruded and precision cut product line is a natural fit for high volume healthcare industry applications.



Key Features:

- Static face seals custom engineered specifically for specimen vial applications.
- TechSeal precision extrusion and cutting technology provides maximum sealing surface contact.
- No molds required.
- Cost effective solution.
- No flash, parting lines, or non-fills.
- Translucent, white, or special colored compounds are available.
- Lot traceability with every shipment.
- Excellent quality products supplied "on time" at a competitive price.
- "Sealing Grade" materials used exclusively.
- Accelerated sample lead times
- TechSeal design and manufacturing process provides flexibility and speed to market.
- Design engineering assistance available.

TechSeal Materials for the Healthcare Industry

FDA “White Listed” Materials

TechSeal’s FDA “White Listed” materials are formulated exclusively from ingredients listed in Federal Regulation Title 21 “Food and Drugs,” CFR 177.2600, “Rubber Articles Intended for Repeated Use.” It is important to note that the FDA does not “approve” rubber compounds. TechSeal formulates food-grade materials from the FDA list of ingredients.

USP Class VI Materials

Class VI materials have been tested to (USP) XXII Class VI requirements, which include system toxicity and intracutaneous toxicity. TechSeal products are sold for use in non-implant devices. It is the customer’s responsibility to determine the suitability of TechSeal products for each specific application, and to comply with all applicable statutory, regulatory and healthcare industry requirements and/or standards for efficacy, labeling, safety and testing. TechSeal’s USP Class VI materials and products have Controlled Batch Identification (CBI) traceability for each product lot.

Flat Surface Sealing Advantage

The physics of a face seal is not terribly complicated. In most sealing systems, the objective is to prevent fluid from leaking from a high pressure location to a lower pressure location through a sealing gap. Static seals are typically subject to a preload to help attain this. This occurs when the seal height is designed to be greater than the sealing gap. The seal is elastically deformed, producing internal stresses and generating a reaction force on the top and bottom of the sealing gap. When fluid pressure is applied it causes additional internal stress, which supplements the preload and prevents leakage.



When the sealing surfaces are assembled, the seal element is contained on three sides. Contact against the seal actually takes place prior to complete compression. Maximum sealing surface contact occurs immediately and compression forces are spread uniformly, due to the flat part geometry.