

ORD Problem Solved!

Medical-Grade EPDM Seal Material



As those within the various life science industries become better aware of the critical role rubber seals play in system performance and patient health, material requirements grow increasingly more strict. "FDA grade materials" are no longer sufficient in applications where the seal or fluids that contact the seal come in contact with the patient.

There are several medical-industry requirements for elastomers in common use today:

USP Class VI testing is typically required for medical device applications that directly contact the patient. The extraction portion of the test is typically done at 50° C (121° F) since this exceeds the normal exposure temperature of most medical devices.

In "small molecule" pharmaceutical manufacturing and some medical devices, the USP Class VI extraction test is done at 121° C (250° F) to simulate a higher temperature application.

For biopharmaceutical manufacturing, the seals must also comply with USP <87> cytotoxicity requirements to ensure that the seals themselves will not kill a cell culture.

Parker's ethylene propylene material E3609-70 meets all of these requirements. Contact an O-Ring applications engineer today at 859-335-5101 to see if this material is right for your application needs.



Success Story

Application:

Pharmaceutical manufacturing facility

Problem:

The customer was using competitive USP Class VI EPDM O-rings and sanitary gaskets. After only a few steam sterilization cycles, the EPDM seals were breaking down, adhering to the stainless steel gland components, and shedding rubber particles into the process stream.

Parker Solution:

Parker recommended compound E3609-70 for this application. In addition to meeting the USP Class VI biocompatibility requirements at multiple extraction test temperatures, E3609-70 also meets the cytotoxicity requirements of USP <87> and has outstanding resistance to steam, cleaning sterilization agents, and process fluids.

Outcome:

Parker's E3609-70 material was successfully tested to 500 steam sterilization cycles with no leakage, no significant degradation of the material, and no sticking of the rubber material to the mating stainless steel components. O-rings and sanitary gaskets could be easily removed by hand with no damage. Improved design of the O-ring glands and sanitary gaskets (available from Parker ISS Division) eliminated the shedding of particles into the process stream.