V1274-75

USP Class VI Biocompatibility

Meets requirements of USP Class VI systemic toxicity, intracutaneous injection and muscle implantation studies:

Today's constant advancements in medical technology present a plethora of sealing challenges in the life sciences industry. The most critical concern normally faced in medical technology is the purity of a seal.

While some medical applications may never touch human tissue or fluids, deeming standard material selection as appropriate, more critical applications require elastomers to be manufactured and packaged with the utmost "clean" care.

In some instances, seals can react with tissue or fluid causing impurities to leach out of the seal. For this reason, engineers require materials like V1274-75 with few if any impurities.

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Benefits:

- Good steam resistance for sterilization cycles
- USP Class VI biocompatibility
- FDA compliant
- Low extractables
- Temperature range of -15 to 400°F
- Low compression set

Recommended For:

- Pharmaceutical processing
- Steam sterilizers
- Disposable and repeat medical device sterilization

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V1274-75

Elastomers selected for critical applications must consist of "clean" ingredients. These ingredients are outlined by the United States Pharmacopeia (USP), the official standard setting authority on health care products manufactured and distributed in the U.S.A. USP Class VI states that compounds must consist of ingredients with clear histories of biocompatibility and meet tighter requirements for leachables.

Parker's V1274-75 , primarily developed for pharmaceutical processing, meets the requirements of USP Class VI systemic toxicity, intracutaneous injection and muscle implantation studies. This fluorocarbon material provides good steam resistance for sterilization cycles, USP Class VI biocompatibility, FDA status, low extractables (all of which reduce the risk of contaminating a customer's product) and good compression set (long life in application / reduced maintenance costs). While V1274-75's primary application is in pharmaceutical processing, it can also be used in both steam sterilizers and disposable/repeat medical device sterilization.

USP and ISO Systemic Toxicity Study

Extract	Test Group # Deaths/ # Tested	Control Group # Deaths / # Tested
Saline	0/5	0/5
Alcohol in Saline	0/5	0/5
Polyethylene glycol 400	0/5	0/5
Sesame Oil	0/5	0/5

USP Intracutaneous Study

Extract	Avg. Test Score	Control Test Score	Difference
Saline	0.0	0.0	0.0
Alcohol in Saline	0.0	0.0	0.0
Polyethylene glycol 400	0.0	0.0	0.0
Sesame Oil	1.0	1.0	0.0

USP Muscle Implantation Study

Sample Size	Avg. Test Score	Control Test Score	Difference
1 x 10 mm	0.0	0.0	0.0

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