



December 7, 2010

Attention: Valued Flanders Customer

Subject: Fluid Seal Issues

To whom it may concern,

Fluid seal failures in Flanders Cleanroom filters have been seen in less than a fraction of a percent of the filters we have produced in our 60 year existence. These often happen for unforeseen reasons such as aerosol exposure, cleaning agent exposure, as well as ratio discrepancies and are extremely isolated cases with no connection between issues. Flanders is aware of the issues seen with Pfizer and we have diligently participated in root cause analysis alongside Pfizer personnel.

Although small in percentage, there have been circumstances in the last 5 years throughout the entire filtration market where degradation of fluid seal materials has occurred. Every filtration company servicing high purity markets has experienced this issue. These issues have led to many studies being conducted and technical papers being presented through organizations such as CETA (Controlled Environmental Testing Association) and ISPE (International Society of Pharmaceutical Engineers). During this timeframe, Flanders began extensive research into these issues and the root causes.

Results of this study concluded that the issue appeared in mainly pharmaceutical applications and began when the use of thermally generated Poly-Alpha Olefin became prevalent. All of these technical reports and papers studied the problem, but made no actual suggestions of resolution. Some filtration companies began switching to urethane based fluid seal materials to alleviate the issues only to find that urethane based materials were degraded quicker than the traditional silicone based materials, thus the companies that went this route continued to have issues. Some other competitors of Flanders switched back to the original Fluid Seal Slow Curing material that Flanders developed back in the 1980's.

The issue discovered through research is that the oil based aerosols used for testing and some harsh cleaning agents attack the link between molecules in the fluid substrate and weakens the bond that exists to form the spongy consistency that fluid seal material has. Basically, the aerosols have the ability of changing the solid gel back to it's liquid state.

The New Flanders Fluid Seal utilizes proprietary compounds that have properties developed exclusively by Flanders resulting in a more resilient fluid seal material that can handle long term exposure to oil based aerosols as well as various cleaning agents. The mechanical and chemical property changes in

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our new fluid seal material also results in a fluid seal material that out performs traditional urethane and silicone based materials. The penetration values for the new fluid seal are a fraction of competitive fluid seals, resulting in a longer life span and the ability of multiple insertions and removals while maintaining fluid seal integrity. The fluid seal was also subjected to submersion testing including, but not limited to Isopropyl Alcohol, PAO, DOP, PSL, bleach, and Spor-Klenz. This means that this material was combined with the agents above and allowed to sit for multiple months continuous without any degradation. Flanders installed this fluid seal in multiple filters, then installed these filters into ducted modules and operated them for a few months within our Research and Development Facility. During this time, the units were challenged uninterrupted with an excessive challenge of PSL, PAO, and DOP. Again the fluid seal material showed no signs of degradation. Lastly, Flanders has had this material tested and has gained approval from UL for UL900 and UL586, Factory Mutual, and lastly at Edgewood for compliance with ASME-AG-1 Section FC-5000 for HEPA filters. Final Testing is commencing and we expect a production release of this fluid seal material shortly. All of the data above is available in detailed test reports that are available upon request. Flanders maintains the right to deny access to these reports due to the sensitive nature of the proprietary information contained therein.

Thanks for all that you do for Flanders and feel free to contact me with any questions or concerns.

Regards,



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