

Polymer Melt Filtration for Catheter Shafts & Balloons

Polyether Block Amide (Arkema trade name Pebax®) is commonly used for catheter shafts and balloons for interventional cardiology and other minimally invasive devices. In such devices, contamination and foreign matter in the polymer are undesirable. These may include fibers, black specks, poorly dispersed fillers/pigments, and gels, which can propagate to the surface of the device causing a tactile imperfection or a stress concentrator for premature failure under load. Many original equipment manufacturers perform 100% inspection to remove devices containing these artifacts. Cleaner materials improve yields during manufacturing.

Foster has developed a filtration process to improve cleanliness of polymers supplied by resin manufacturers. Findings from three recent designs of experiments indicate that Foster's process can remove up to 70% of gels from a PEBAX® 7233 SA01 MED material.

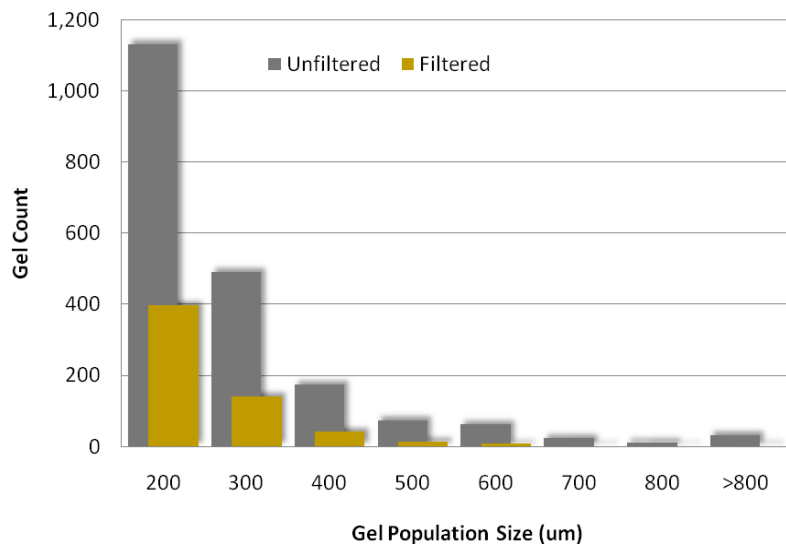
Material Tested PEBAX® 7233 SA01 MED

Test Equipment FSA100 Film Surface Analyzer (OCS analysis software)
Datacolor International Dataflash® 100 Spectrophotometer
Dynisco LCR 7000 Capillary Rheometer

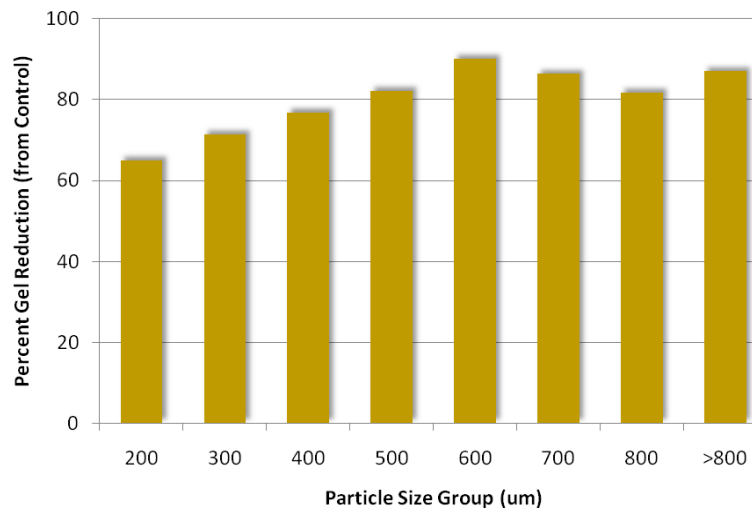
Test Results

A control sample was evaluated from the same lot of PEBAX® directly from the bag delivered from Arkema. Viscosity, yellowness index, and gel content were compared between filtered and control (unfiltered) samples.

Gels were measured by creating film and measuring using an OCS film surface analyzer and recording by gel count per size class before and after melt filtering. In general, gels were removed through the melt filtering process. Some gels remained in some of the size populations, indicating opportunity for additional process development.



Findings show a 70% reduction of gels on average can be achieved through the melt filtering process. Figure 2 illustrates the percent reduction of gels from the control at each of the size classifications.



Viscosity, measured using a capillary rheometer, was reduced by only 9% in the filtered samples due to the additional heat history during filtration.

Yellowness index was measured with a spectrophotometer in accordance with ASTM E313 using an empty cell as the standard, then comparing the change (*i.e.* delta) between the standard and the sample. The filtered lot was slightly more yellow than the unfiltered one due to the additional heat history, however the difference is negligible relative to the current specifications for catheter devices.

	Viscosity (Poise) 235°C, 100s ⁻¹	Yellowness Index (ASTM E313)
Control	8729	0.13
Melt Filtered	7941	0.30

Conclusions

Foster has developed a melt filtration process that on average removes 70% of gels from a PEBAX® 7233 SA01 MED material. Although the process adds an additional heat history, there is minimal reduction in viscosity and negligible yellowing.

About Foster

Foster Corporation supplies custom biomedical polymers for the medical device industry, including custom compounds for minimally invasive devices, polymers blends for implants, and drug/polymer blends for combination products. For more information, please call or visit us at:

Foster Corporation

45 Ridge Road
Putnam, CT 06260
(860) 928-4102
www.fostercomp.com

Foster Corporation (Foster) believes that the information contained in this document is an accurate description of the typical characteristics and/or uses of the product or products, but it is the customer's responsibility to thoroughly test the product in each specific application to determine its performance, efficacy and safety for each end-use product, device or other application. Suggestions of uses should not be taken as inducements to infringe any particular patent. The information and data contained herein are based on information we believe reliable. Mention of a product in this documentation is not a guarantee of availability. Foster reserves the right to modify products, specifications and/or packaging as part of a continuous program of product development.

FOSTER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF INTELLECTUAL PROPERTY NON-INFRINGEMENT, INCLUDING, BUT NOT LIMITED TO PATENT NON-INFRINGEMENT, WHICH ARE EXPRESSLY DISCLAIMED, WHETHER EXPRESS OR IMPLIED, IN FACT OR BY LAW. FURTHER, FOSTER MAKES NO WARRANTY TO YOUR CUSTOMERS OR AGENTS, AND HAS NOT AUTHORIZED ANYONE TO MAKE ANY REPRESENTATION OR WARRANTY OTHER THAN AS PROVIDED ABOVE. FOSTER SHALL IN NO EVENT BE LIABLE FOR ANY GENERAL, INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR SIMILAR DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES FOR HARM TO BUSINESS, LOST PROFITS OR LOST SAVINGS, EVEN IF FOSTER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, REGARDLESS OF THE FORM OF ACTION.