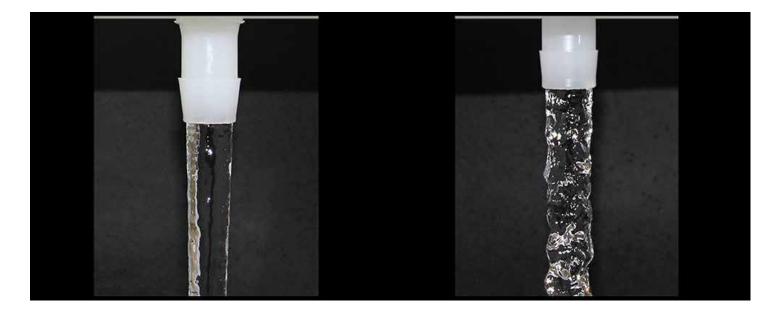


BAG PORT
Test Data

Speed to market is a key factor of success in the biopharmaceutical industry, yet it can be difficult to achieve without compromising product quality. In an attempt to avoid sacrificing either competitive advantage, companies continuously seek out products that are able to provide maximum efficiency while maintaining first-rate quality. These requirements were designed into our bag port line. Two aspects unique to our bag port series are flow alignment ribs and parabolic entrance geometry. These features, respectively, promote a uniform flow by guiding the media into a consistent, rotational path while reducing the flow separation from the wall. In order to validate this performance, extensive testing and analysis was carried out and then used in comparing the bag ports to other commercially available products.

BAG PORTS FLOW TEST RESULTS

To test volumetric flow rates, square-shoulder lead-in bag port models were measured against a Nordson MEDICAL design that included a parabolic-shaped lead-in. When evaluating the difference in performance, the curved entrance alone saw a volumetric flow rate of 8.37 gallons per minute (GPM), translating to a 26.6% increase over the model with a square entrance. This test was followed by comparing the same square model to Nordson MEDICAL's final product design – a bag port that includes both flow alignment ribs and a parabolic lead-in. Nordson MEDICAL's bag ports yielded a 33.85% GPM increase in volumetric flow rate over the square model.

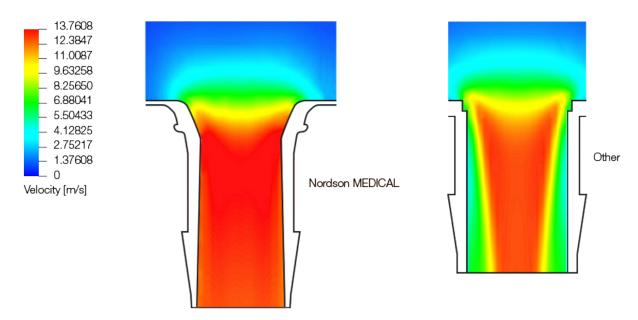


Test Data



COMPUTATIONAL FLUID DYNAMICS (CFD) ANALYSES

Computational fluid dynamics (CFD) analyses were also performed. In these studies, the Nordson MEDICAL bag ports saw a 30.86% increase in volumetric flow rate when compared to other commercially available products. This can be attributed to the bag port's curved entrance which promotes a consistent velocity profile being maintained throughout the flow path and a near elimination of flow separation. The result is a maximized use of space, allowing the largest amount of media to flow through the given inner diameter.



Flow characteristics were observed in additional testing. While the square-shouldered lead-in bag port generated an erratic turbulent flow, the parabolic lead-in produced a straight streamline flow. Incorporating the alignment ribs led to the eventual streamline rotating flow, providing the media with a more consistent and stable path.

Test Data



VALIDATION TEST RESULTS

Validation testing was performed on the two available bag port designs – barbed and ferrule. The features assessed included, but were not limited to:

- Aged Environmental Stress-Cracking Resistance (ESCR)
- Chemical Compatibility
- Post-Alcohol Stress During Extended Use
- Barb Fatigue

- Suction Relief
- Hydrostatic Pressure
- Side Load
- Impact

- Gamma Sterilization
- X-Ray Sterilization
- Leak
- Pressure

ESCR with Alcohol Testing in particular was a key milestone to overcome in proving these components. Many polyethylene bag port components may experience cracking when exposed to alcohols and stress. This experimental procedure helped validate that Nordson MEDICAL materials have appropriate ESCR, ensuring that cracking will not occur during the designed life of the bag ports.

Nordson MEDICAL's positive results in these tests are coupled with other critical features in biopharm applications such as an animal-free resin, USP Class VI verification, and guaranteed heat sealing and conformance with polyethylene bags. The Value Pharma™ resin used in these ports is unique in the market due to the combination of these qualifications.