INEOS Styrolution and Teel Plastics partner on an innovative alternative material to common materials on the market, such as PVC, for tubing and infusion applications, where alternative or new materials are required.

Abstract:

- INEOS Styrolution developed a new grade of styrene butadiene block copolymer for the medical market.
- The new material, Styroflex® 4G80, is designed as an alternative material for tubing applications to traditional materials such as PVC.
- Teel Plastics processed Styroflex® 4G80 into a variety of different tubing sizes and dimensions.
- The material easily processed on standard extrusion equipment with only minor adaptations from flex-PVC processes.
- Styroflex® 4G80 is solvent bondable and bonds well with conventional IV system components with common solvent systems.
- Medical device OEMs looking for an alternative to their current resins should consider Styroflex® 4G80 for their next generation medical devices.

*INEOS Styrolution offers the world's largest styrenic specialties portfolio, including a broad range of transparent medical grade resins. With world-class production facilities and more than 85 years of experience, INEOS Styrolution helps its customers succeed by offering the best possible solution, designed to give them a competitive edge in their markets.

INEOS Styrolution employs over 3300 dedicated professionals and includes 20-production sites and 6 R&D centers for excellence worldwide.

Teel Plastics, is the premiere manufacturer of custom extruded plastic tubing and profiles, due to the expertise of their distinguished, skilled team – a group of problem solvers that pride themselves on being professional, progressive, and personable. For more than 60 years, Teel has demonstrated technical prowess paired with a can-do attitude and delivers with considerable knowledge of materials. Along with an ISO/IEC/17025:2005 accredited analytical laboratory on campus, Teel produces high quality custom tubing in a wide variety of materials and sizes with tight tolerances and specializes in complex projects.

Alternative to current tubing materials

Flex-PVC is one of the most common materials used in medical tubing. It has a wide variety of durometers available for different applications. The high degree of clarity and ability to quickly solvent bond to a variety of connector systems is important for economical assembly systems. It is also a very cost competitive material compared to many other flexible material options, like TPUs. This blend of benefits allows flex-PVC to find a home in applications ranging from IV tubing and drug delivery to respiratory tubing and insufflation applications.

Unfortunately, to make flex-PVC flexible, it is blended with a variety of additives including plasticizers. Some of these additives and plasticizers can leach out of the tubing over time creating a variety of issues. There is growing environmental and regulatory concern about the persistence of some phthalate plasticizers, especially DEHP (di-ethyl-hexyl phthalate), that have

been shown to have negative environmental effects. Therefore the medical industry has been searching for an alternative material that will meet the requirements of the tubing application, yet be compliant with environmental and health regulations environmentally and regulatory friendly. Styroflex 4G80 addresses these concerns, possesses very similar material properties, and can be processed on established production and assembly equipment.

New Material Idea

INEOS Styrolution has a vision to offer alternatives to common materials on the market, such as PVC, for tubing and infusion applications. Their goal was to create a material that meets all customer application and processing needs for medical tubing.

- Can be processed on existing tubing equipment
- Offer processing advantages to incumbent and competitive materials
 - Meet processing speeds of incumbent and competitive materials
 - Offer a density advantage to incumbent and competitive materials
 - Process at a lower temperature
- Improve bondability of tubing to other fluid delivery devices
 - Increased bond strength
 - Compatibility with common bonding systems
- Offer key material characteristics and performance
 - Maintain clarity of material (especially for air bubble visibility)
 - Maintain tubing lubricity
 - Produce material with low blocking
 - Sufficient kink resistance in tubing
 - Sufficient roller clamp performance
 - IV pump Stability
 - High burst strength
- Alternative to DEHP based materials

Production Development

After receiving samples, Teel and INEOS Styrolution collaboratively developed process specifications and parameters. They started with a standard, general-purpose screw and vacuum sizing tank with a wafer bushing sizer very similar to what would be used for flex-PVC. The die was custom designed with a higher draw-down than is typically used for flex-PVC. Melt temperatures were carefully adjusted to ensure stability and a standard mesh screen pack generated stable backpressure.

The Styroflex® 4G80 extruded with a few minor adaptations to a standard extrusion process. Water temperature needed to be correctly controlled and the cutter blade was a custom design. Once these adaptations were complete, the process was very stable. Teel continued to work to improve their extrusion capabilities for the 4G80 and define conditions for spooling and conveying to handle parts post extrusion.

The Styroflex® 4G80 created both thin walled parts, with a 0.161" OD and a 0.022" wall, and thick walled parts, with a 0.395" OD and 0.090" wall, using similar run conditions and properly

sized tooling. This is a wide range of medical tubing sizes for different applications where PVC is commonly used today. All of which are within the capabilities of Styroflex® 4G80.

0.395" x 0.090" Wall



0.161" OD x 0.022" Wall



Conclusion

Medical OEMs and medical designers who have made the decision to use new materials or alternatives to PVC should consider Styroflex® 4G80 for their tubing needs. Teel Plastics has experience and the expertise to process Styroflex® 4G80 on their existing extruders, with minimal adjustments. The material processes well, and can be made in a wide range of wall thicknesses and sizes. Testing has been conducted on Styroflex 4G80 tubing, and the material meets or exceeds specific medical tubing requirements.

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