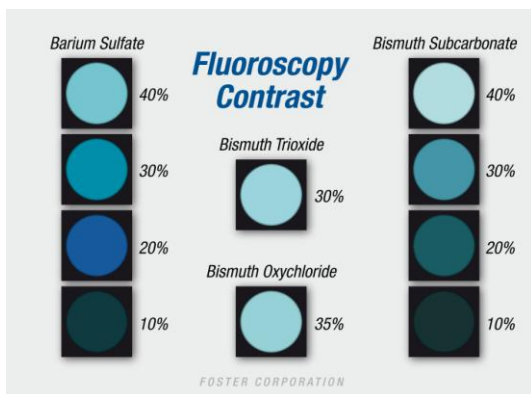


TECHNOLOGY UPDATE

Effect of Radiopaque Fillers on Mechanical Properties

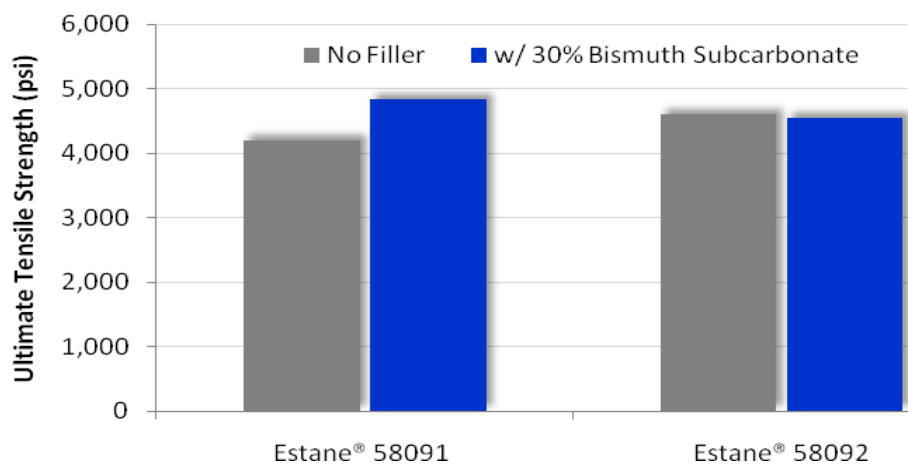
For more than three decades, radiopaque fillers have been added to plastics to provide visibility under x-ray for minimally invasive devices such as catheters. This visibility ensures accurate placement of the device during diagnostic or therapeutic procedures. The impact of such additives on mechanical properties has been reported to a lesser degree.

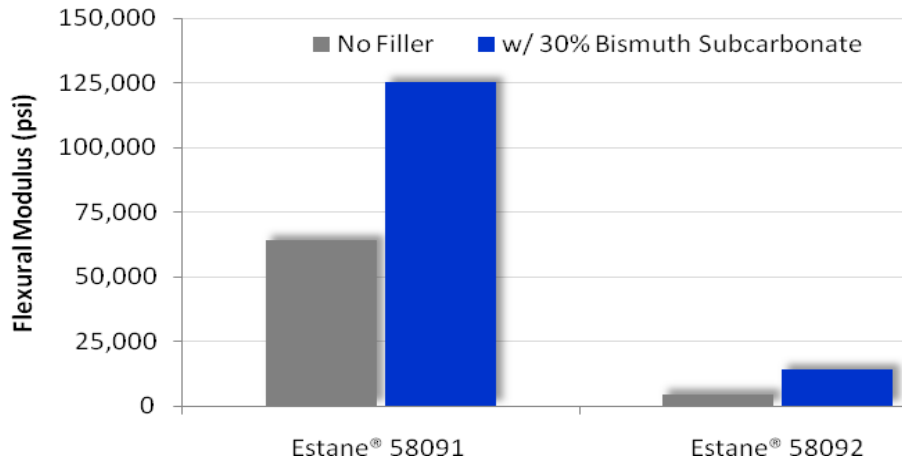
Our engineering team has recently undertaken studies to better understand the effects of radiopaque fillers on tensile properties and flexural properties, which are used in engineering formulas to calculate burst pressure and rigidity, respectively. Cardiovascular catheters are often required to withstand burst pressure in order to inflate balloons. Thus, improvement in tensile can be advantageous. However, if this occurs in conjunction with an increase in flexural modulus the catheter may become too stiff to navigate the vascular channels.



In a recent study, our engineers measured the effects on tensile modulus and flexural modulus when adding 30% bismuth subcarbonate to two different durometers of thermoplastic polyurethane. This percent filler represents a common loading level required for radiopacity in cardiovascular applications. The polyurethane was an aromatic polyester-based produced by Lubrizol and sold under the tradename of Estane®. We selected two durometers: 70D and 95A.

The resulting change in tensile properties for the 30% bismuth filler polyurethane was minimal with only a 15% increase to the 70D resin and a 1% decrease in the 95A resin. Flexural modulus, on the other hand, increased 95% in the 70D resin and 213% in the 95A resin. Knowing this, engineers can manage flexural modulus by selecting a softer resin initially.





This limited study may suggest that the addition of 30% bismuth subcarbonate to polyurethane may not effect the burst pressure performance of catheters substantially since tensile strength is relatively unchanged. However, it will likely increase the stiffness of a catheter since flexural modulus more than doubles in two durometers. Yet, selecting a lower durometer base resin can mitigate this increase such that the final compound has a stiffness suitable for the application. For example, 30% filler in the 95A resin has a flexural modulus 78% less than the unfilled 70D resin.

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