

A Case Study of Mobilize Lubricious Compounds

Compounding Solutions hired an independent 3rd party Medical Device Contract Manufacturer specializing in catheter manufacturing and testing to conduct a case study to review the effects of Pebax 6333 SAO1 MED & Pebax 2533 SAO1 MED loaded with Mobilize, a lubricious additive, against natural Pebax resins.

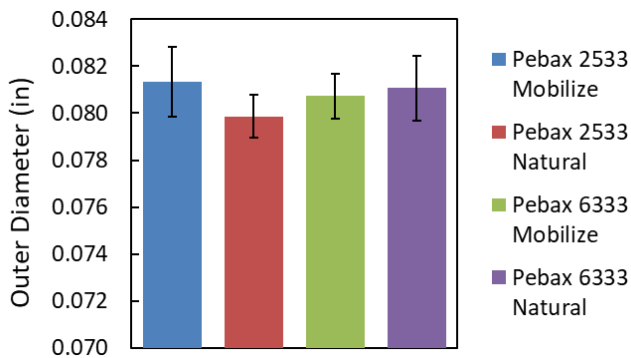
Scope:

Both Pebax 6333 and Pebax 2533 were compounded using a 27mm twin screw co-rotating extruder at Compounding Solutions. These resins were extruded into 20" long sections of tubing with outer and inner diameters of 0.081" and 0.069", respectively. The tubing was then tested for the following:

- Dimensional Stability
- Insertion Force
- Flow Rate
- Shaft Leak Test
- Tensile Strength

Results:

Figure 1 - Extruded Tubing Dimensional Stability



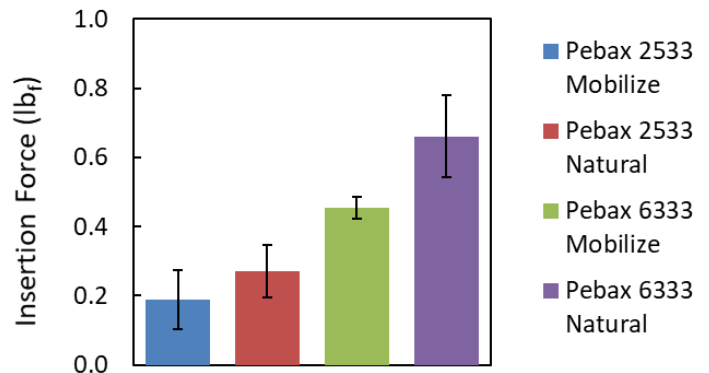
Insertion Force: The tubes were inserted through a track which simulated a fistula fixture. This contained a bend radius of 1 in and used a standard 7-French introducer. All samples were conditioned in 37°C deionized water. The average force required to insert 15 tubing shafts of each material is shown in Figure 2. A 30% reduction of required insertion force was found using the Mobilize additive in both the hard and soft grades of Pebax.

Summary:

- The natural Pebax and Mobilize compounds were extruded and laminated using the same processing parameters. No changes in processing were necessary.
- No significant effects on tensile strength, shaft leak test, flow rate or dimensional stability were observed amongst the Mobilize compounds.
- It was observed that the Mobilize compounds reduced the insertion force by 30% compared to natural Pebax.
- Incorporating Mobilize into a typical catheter build can reduce the cost of the device by as much as 50%.

Dimensional Stability: The outer diameter was measured at five points along tubes using a laser micrometer. The average diameter of 15 tubes of each material is shown in Figure 1. There is no significant difference between the various materials.

Figure 2 - Required Tube Insertion Force



A Case Study of Mobilize continued...

Flow Rate: This test observes the rate at which a set volume of water can pass through the shaft in a given time. Two Shafts were bonded onto a standard over-the-wire hub, leaving a clearance of 0.001213in². Through this clearance, 37C DI water was drawn at a constant pressure. The average time for 10mL liquid to flow is shown on the graph. There is no significant difference between the tubes.

Figure 3—Flow Rate Test

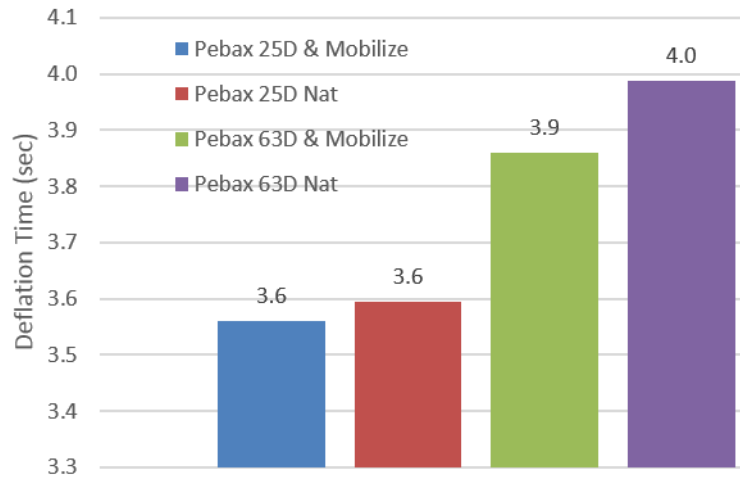
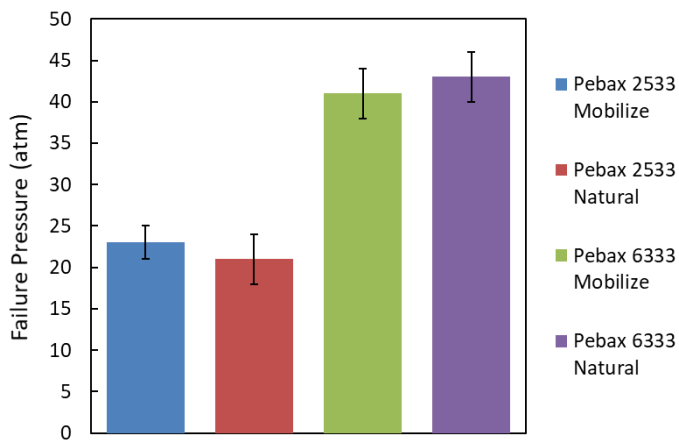


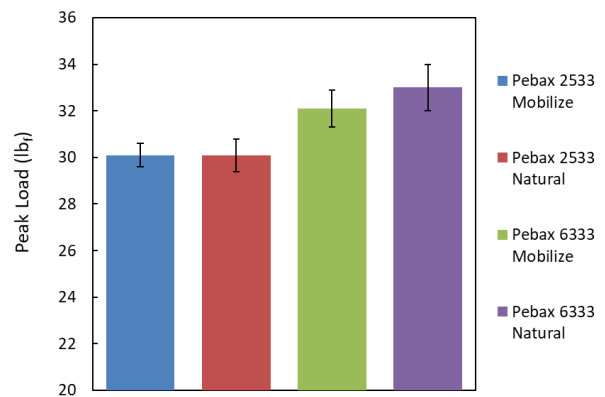
Figure 4—Shaft Leak Test



Shaft Leak Test: The tubing underwent a leak test using a HBLT leak test machine. The average failure pressure of 15 tubes is shown in Figure 4. No significant difference was found between the loaded and natural tubing.

Tensile Strength: Tubing samples were tested using the ISO-1055:2013 standard. The samples were tested until failure. The average peak load of 10 tubing samples of each material is shown in Figure 5. There is no significant difference between natural and loaded tubes.

Tensile Strength



A Case Study of Mobilize Continued...Dollarization

Compounding Solutions has presented the benefits of adding the Mobilize additive to increase lubricity, however, adding Mobilize to your catheter tubing compound can also save you money. If we look at a typical simple catheter build using an etched PTFE liner, Pebax & BaSO4 outer layer, FEP Shrink tubing and a hydrophilic coating versus a catheter build made with Pebax, BaSO4 & mobilize outer layer.

Component	Catheter Build w/o Mobilize	Catheter Build with Mobilize	Notes
PTFE Liner @ 4ft length	\$5 per length	\$0.00	The PTFE liner can be eliminated with the benefit of reduction of insertion force and ease to remove from mandrel with Mobilize
Pebax Compound Outer layer @ 4ft length	\$2.40 per length	\$2.60 per length	The cost of 50lbs of Pebax & BaSO4 compound = \$30/lb. The cost of 50lbs of Pebax, BaSO4 & Mobilize compound = \$60 /lb
FEP Shrink Tubing @ 4ft length	\$5 per length	\$5 per length	Necessary cost in building of the catheter
Hydrophilic Coating @ 4ft length	\$4 per length	\$0.00	The Mobilize additive reduce the coefficient of friction by 30% of both the inner and outer surface
Total	\$16.40 per length	\$7.60 per length	54% COST REDUCTION

The above dollarization does not figure in the most recent discovered benefit of Mobilize, increased production speed. Customers have reported a significant reduction in die head pressure, allowing for up to 15% faster line speed/output equating to reduced costs.

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See Safety Data Sheet for Health & Safety Consideration