

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:

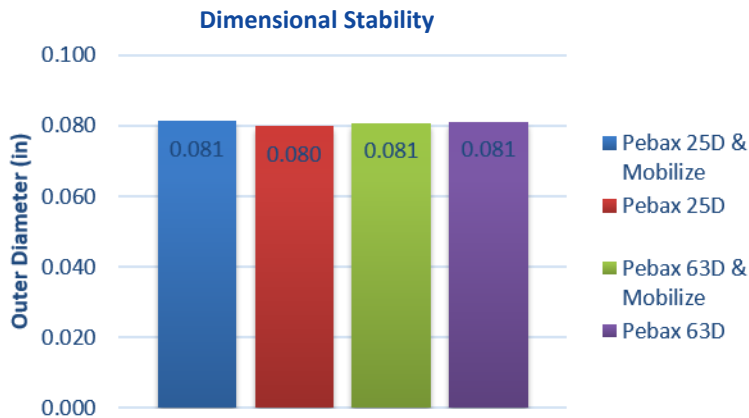
Pebax 6333 & Pebax 2533 were compounded using 27mm twin screw co-rotating extruder technology at Compounding Solutions. These resins were then extruded into 0.081in O.D x 0.069in ID x 20in Length tubing to be tested in the following:

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

Summary:

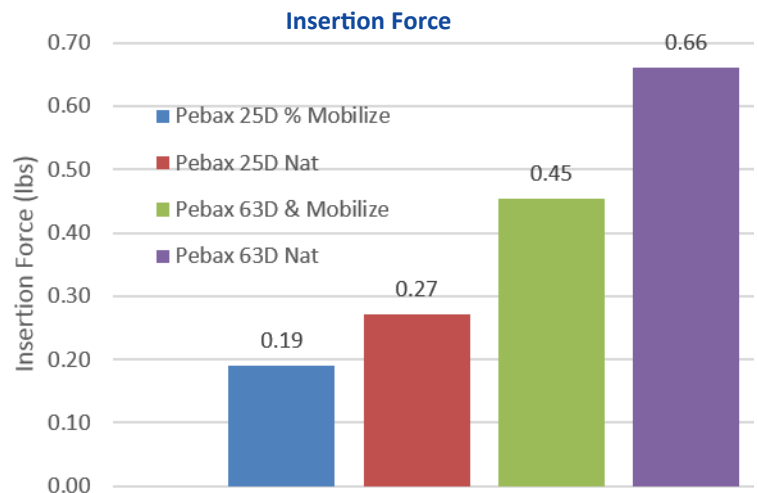
- ◆ Both natural Pebax and Mobilize compounds were extruded and laminated using the same processing parameters. No change in processing necessary.
- ◆ The Mobilize additive had no statistically significant effect on tensile strength, shaft leak test, flow rate, or dimensional stability.
- ◆ The Mobilize additive reduced the insertion force by 30% vs natural Pebax.
- ◆ Utilizing the Mobilize additive can help reduce costs of a typical catheter device by as much as 50%.

Results:



Dimensional Stability: The outer diameter was measured at five points along the tube using a laser micrometer. The average is shown on the graph. No change was found between the different materials.

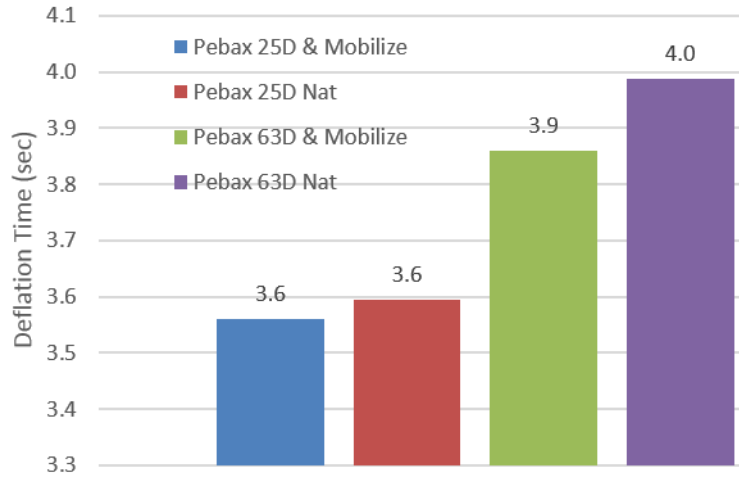
Insertion Force: Tubing was inserted through a track that simulated a fistula fixture, with a bend radius of 1in, while using a standard 7-French introducer. All samples were pre-treated in 37°C DI water to simulate use. The average force to insert the tubing shaft is shown on the graph. A reduction of 30% in force was found using the Mobilize additive.



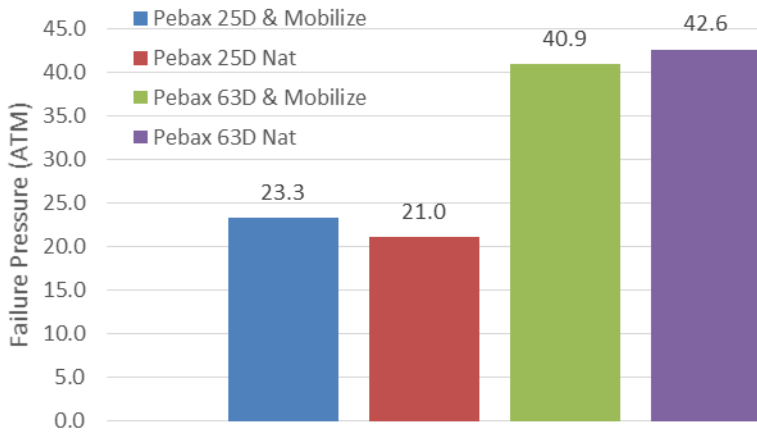
A Case Study of Mobilize continued...

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.

Flow Rate Test



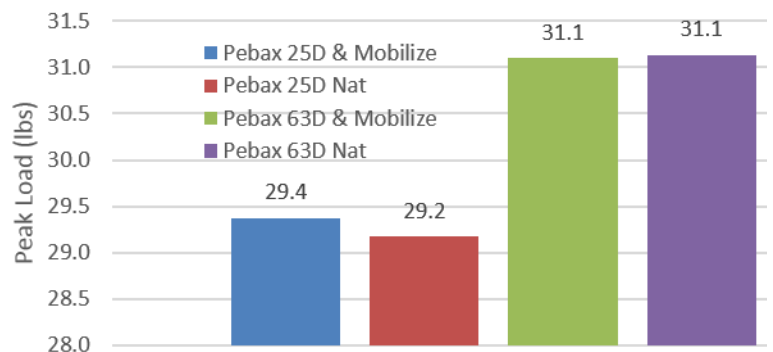
Shaft Leak Test



Shaft Leak Test: The tubing underwent a leak test using a HBLT leak test machine. The average failure pressure is shown on the graph. No statistically significant difference was found between the loaded vs. natural tubing.

Tensile Strength: Tubing samples were tested using the ISO-1055:2013 standard. The samples were tested until failure, these average values are shown on the graph.

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
Hydrophillic 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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