

## WHITE PAPER

## Freudenberg Medical Achieves Break-through in Measurement Technology for Silicone Tubes with Helix iMC™

*New inline process provides precise geometric measure of inner diameter*

**In a worldwide first, Freudenberg Medical introduces a ground-breaking new technology to continuously measure the inner geometry of silicone tubes. The new technology significantly increases product quality for high precision applications such as pacemaker lead insulation and dramatically cuts down on material usage and process time.**

Silicone extrusion is a continuous process and samples are taken intermittently throughout the extrusion line to verify consistent dimensions for the inner and outer geometries of a tube. In order to manufacture silicone tubes, high consistency silicone is fed into an extruder which continuously extrudes the material through a die and mandrel configuration, giving it the desired geometry. After passing through a heat curing process, e.g. by inline IR heaters, the silicone tube usually undergoes inline measurement of the outer geometry by laser as an industry standard. Unfortunately, this does not provide any information on the inner geometry of the tube, e.g. the ID of a single lumen or multi-lumen. Therefore, the quality checks for inner geometry are usually made in an off-line process by manual cuts at discrete cross sections of a tube.

This process often requires multiple iterations to “dial in” the precise tubing geometry to finally achieve the specified dimensions. Once the dimensions are in specification and good product is manufactured, additional measurements can be taken to get more data points. For a standard tubing coil of 25 or 50 ft this results in just two data points. Hence, it is assumed that all product between these two data points is in specification, provided there is no fluctuation in other process parameters. With longer length tubing additional data points are desired to ensure that the entire extrusion remains within specification, otherwise the total product would need to be scrapped.

For thermoplastic extrusion, dimensional checks for inner geometries can be made using ultrasound in a water bath, which is not applicable when processing silicones. Other options for measurement include x-ray, but this process will not work with multi-lumen tubing due to the cross fade of the overlaying inner lumen. For single lumen tubing x-ray might be technically feasible but it is rather slow and does not generate enough data points to truly be considered continuous.



Freudenberg Medical has developed, in close collaboration with a leading-edge measurement technology supplier, a system to continuously measure the inner geometry of extruded products such as single- or multi-lumen IDs, wall thickness, or concentricity as an inline process. Freudenberg's innovative measurement system for medical tubing is called Helix iMC™, it stands for inner measurement and control, and it is unique to the medical market. Helix iMC uses specific sensor technology to deliver a cross section view of the product. The displayed and documented measurement values are acquired by sensor and calculated by an algorithm; stitching together different pictures provided by each sensor into one cross-section view which provides an accurate and continuous read - of ID, OD, and wall thickness - during a complete production run. This approach enables process engineers to view the inner geometry of a tube inline, which was previously not possible using traditional laser sensor-based inline measurement systems.

The benefit to customers is continuous data monitoring resulting in a potential reduction in validation time and time to market. This new technology offers quality assurance through consistent measurement and data monitoring which leads to leaner and more efficient production. For critical medical devices, such as pacemaker lead insulation or silicone tubing for pump applications, it is highly beneficial to 100% control and document every critical dimension throughout the entire production run and not only on a sample basis.

### THE RESULT

Freudenberg Medical's Helix iMC silicone extrusion measurement solution saves time and increases efficiencies, but even more important it delivers continuous data across a complete production run without interruption and sample cuts. By providing customers with full documentation of measurement data, customers can reduce or even eliminate their incoming inspection routines. Validation efforts can be significantly reduced allowing them to get new products to market faster.

### Single lumen: effect of wall thickness adjustments made during production run

