

Extrusion Center of Excellence

HISTORY

Specialized Engineering started in Palo Alto in 1996 already having over 10 years experience in catheter assembly processes, engineered extrusion, and balloon blowing. With one Harrel extruder, one employee, a reputation for quality and quick turn around, the business quickly built up a tier-one client base.

In 2000, Specialized Engineering moved to Stockton, CA. expanding manufacturing operations to 10,000 square feet. With ISO 9001: 2015 certification, Specialized Engineering is dedicated to quality, lean manufacturing with robust engineering support.





VISION

To partner with global leaders in the healthcare industry to provide for the wellbeing of their patients.



MISSION

Specialized Engineering is committed to providing the highest quality engineered products in the medical device market to create added value for our customers.



STRATEGY

Our business strategy is to implement lean manufacturing with robust engineering support, reducing lead times and costs.

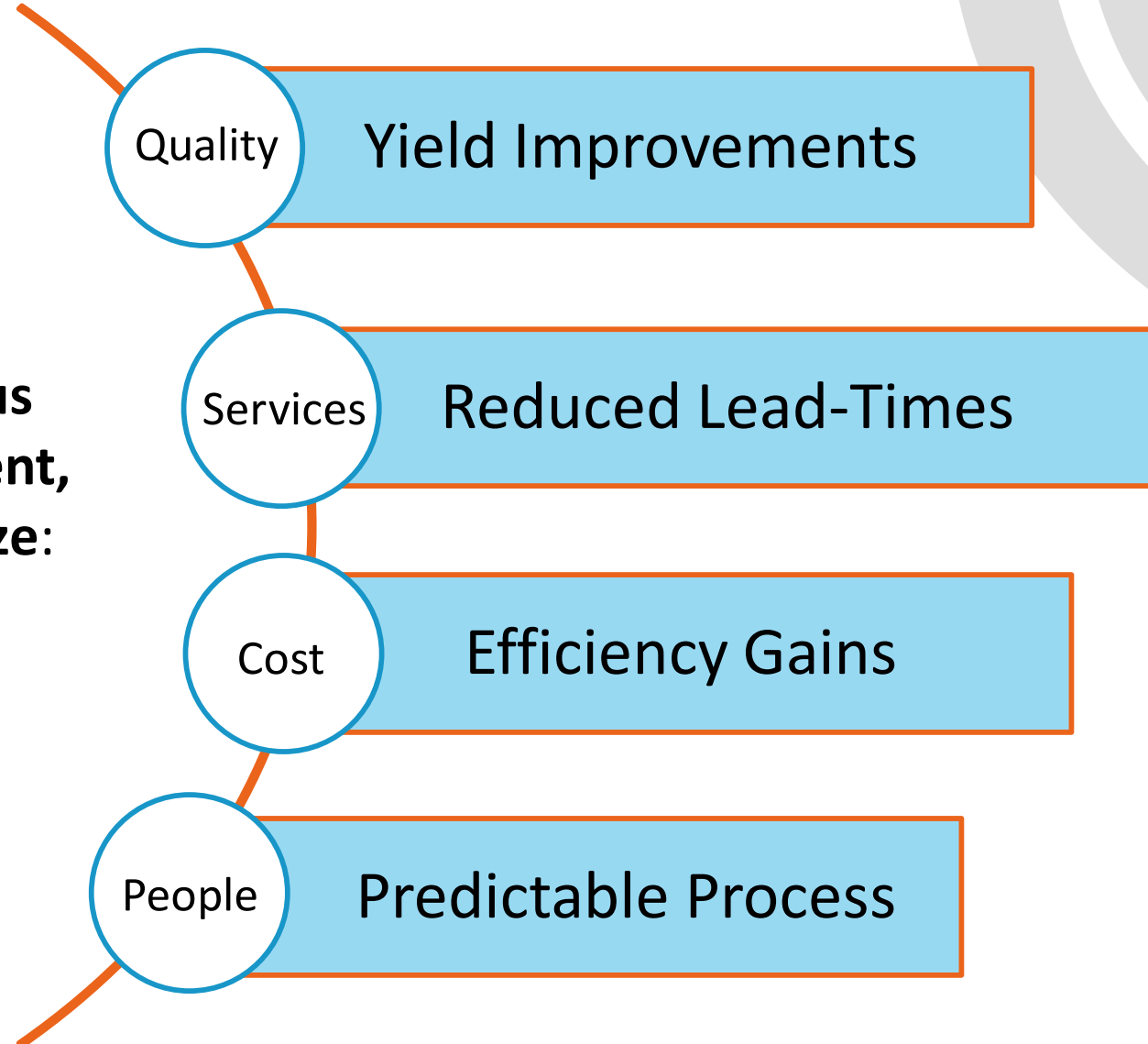


GOAL

Our goal through continuous improvement is to be a technology center of excellence to support the medical device market.

VALUE PROPOSITION

**Through
continuous
improvement,
we optimize:**



SENIOR STAFF



PAUL ALBA

President, Founder of Specialized Engineering, has been in the medical disposables industry for over thirty years. His work experiences at ACS, Mallinckrodt Medical, Baxter Medical, AVE and Localmed/Perclose give him an unparalleled perspective that has catapulted Specialized Engineering to market leadership in the medical device industry.



TIM CORTEZ

Director of Operations, has been a Senior Manager and Director for nearly thirty years within the medical device arena. He is highly knowledgeable and experienced in all facets of product development, engineering, new technology assessment, six sigma methodologies and manufacturing scale-up.



AGGIE ALBA

Marketing Director, pursued her Bachelor of Science Degree in Marketing from California State University, Sacramento. Aggie joined the company in 2006 and has made tremendous efforts in guiding the brand and team in advancing our presence in the medical marketplace.

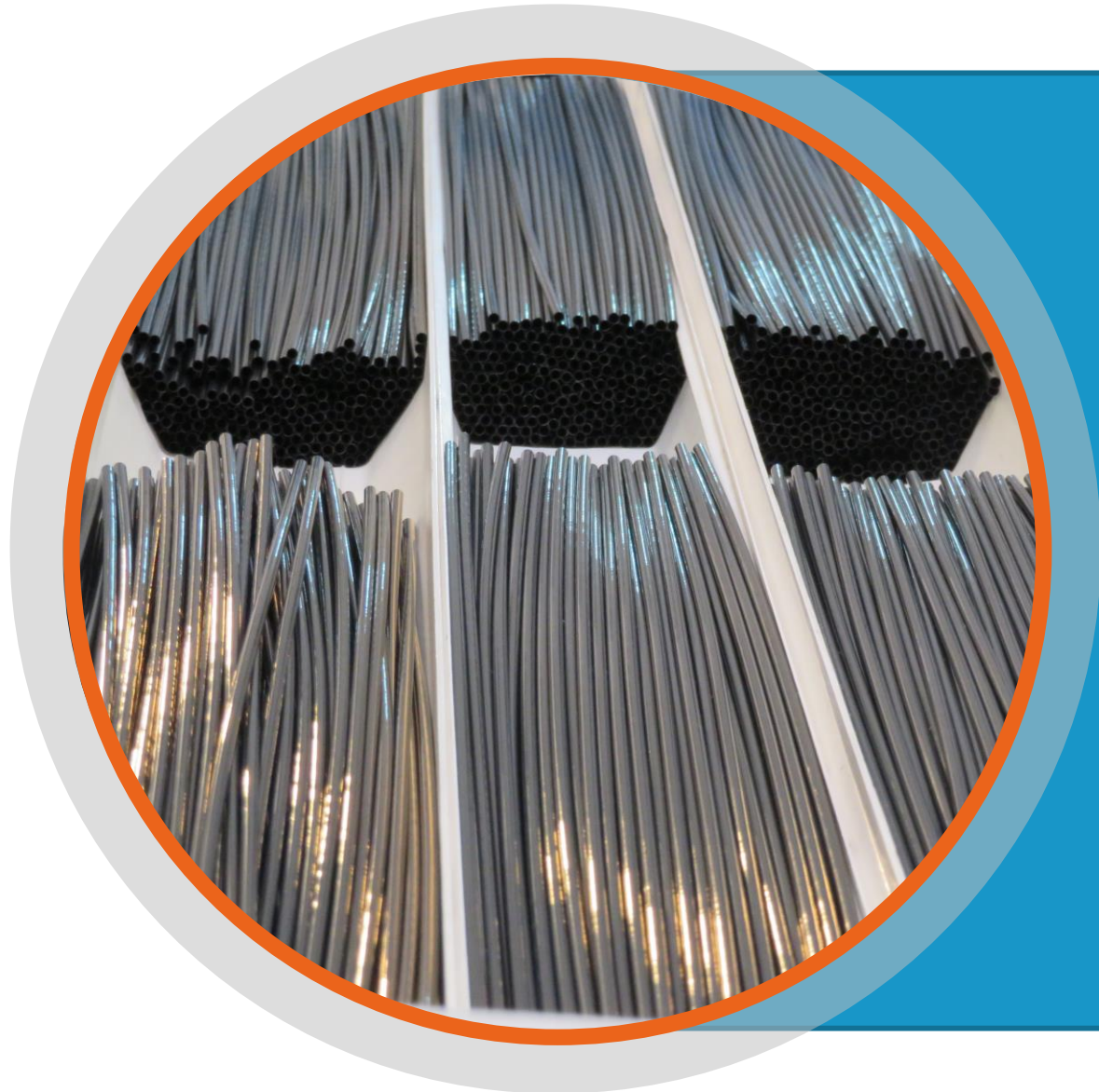
FACILITY

- Our facility encompasses 10,000 square feet of manufacturing space strategically located in central California's non-earthquake zone.
- The extrusion lab houses the primary manufacturing equipment which consists of 7 extrusion lines.
- Our 650 square foot pilot production lab hosts secondary processing equipment including a 16 carrier braider, RF & thermal tipping machines, split die forming, automated precision cutting and hole punching tools.

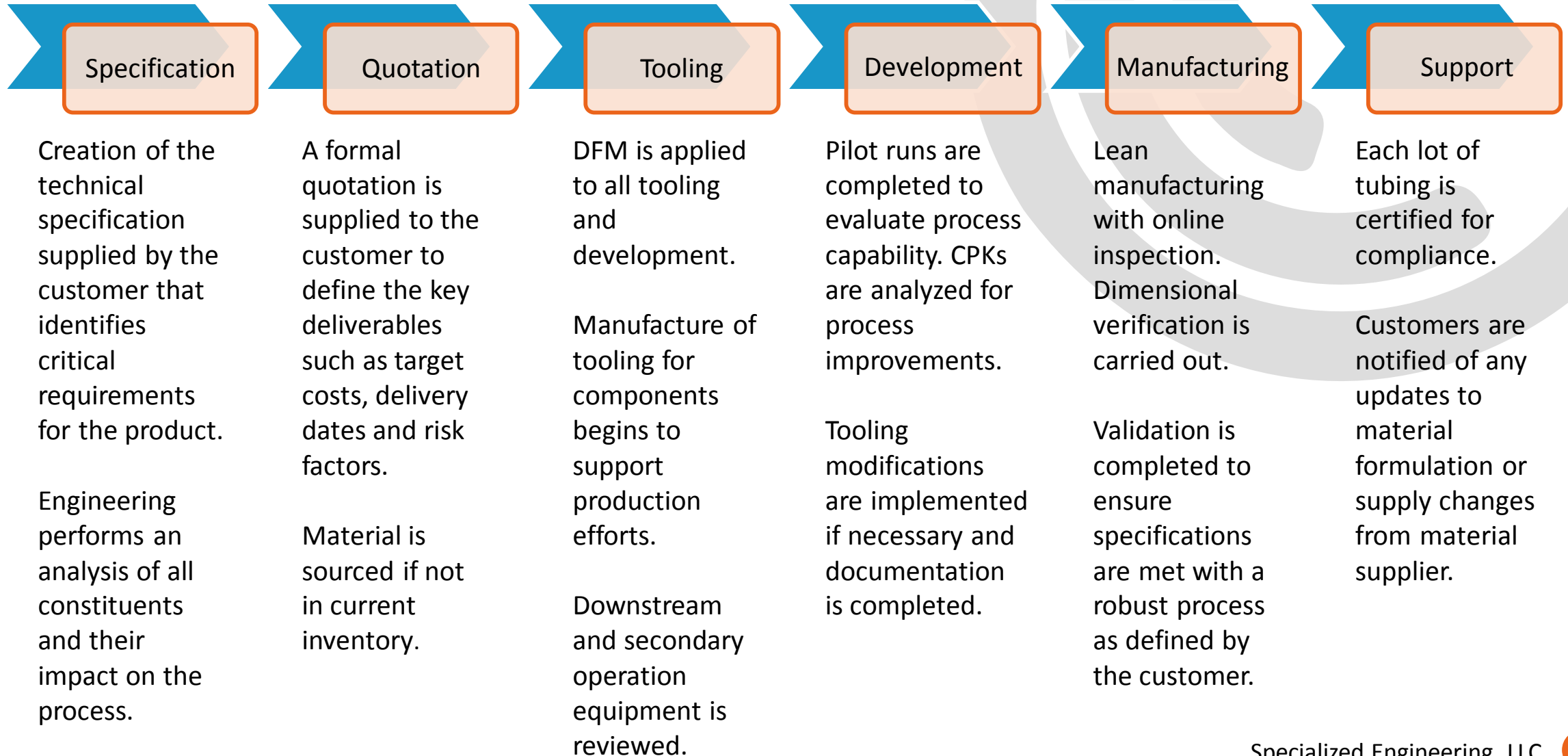


CAPACITY

- Currently Specialized Engineering is operating at 20% of the extrusion capacity. Daily throughput per extruder line is up to 50,000 feet.
- Typical usage consists of 3 extrusion lines running one shift. 5 extrusion lines are available with 2 additional lines being installed.
- Shifts can be staggered to obtain longer runs when required, up to 24 hours per day. Current staff is a total of 14 team members.



DEVELOPMENT PROCESS



MATERIALS AND SIZES OFFERED

- Pebax
- Nylon 11, 12, 6/6
- HDPE
- LDPE
- LLDPE
- Pellethane
- Polyurethane
- PVC
- Polypropylene
- PET Polyester
- PEEK
- FEP
- Ultem
- Beading
 - 0.007" minimum OD
 - 0.125" maximum OD
- Tubing
 - 0.004" minimum ID
 - 0.375" maximum OD
 - 0.002" minimum wall
 - 0.050" maximum wall



CORE COMPETENCIES

EXTRUSION TECHNOLOGY



- Single lumen
- Multi lumen
- Tri layer
- Profile
- Balloon tubing
- Bump tubing
- Beading
- Coextrusion
- Striping
- Textured ID/OD



VALUE ADDED SERVICES

- Online annealing
- Flaring
- Hole punching
- Adhesive bonding
- Precision cutting
- Fixture design
- High Temp 3D Printing, PEEK/Ultem
- Braiding
- Coiling
- Tipping
- Thermal bonding
- Catheter assemblies
- RF Bonding
- Insertmolding

HIGH PERFORMANCE SHAFTS

High performance shafts are often required for tortuous and complex procedures. Braid and coil reinforcements are used to increase torque transmission and hoop strength.

- Reinforcement Materials: Stainless Steel, Kevlar, LCP, Nitinol
- Liner Materials: FEP, PTFE, HDPE, Pebax, Nylon
- Single and Multilumen Profiles
- Variable durometers, pick counts and TPI



Polymer 1

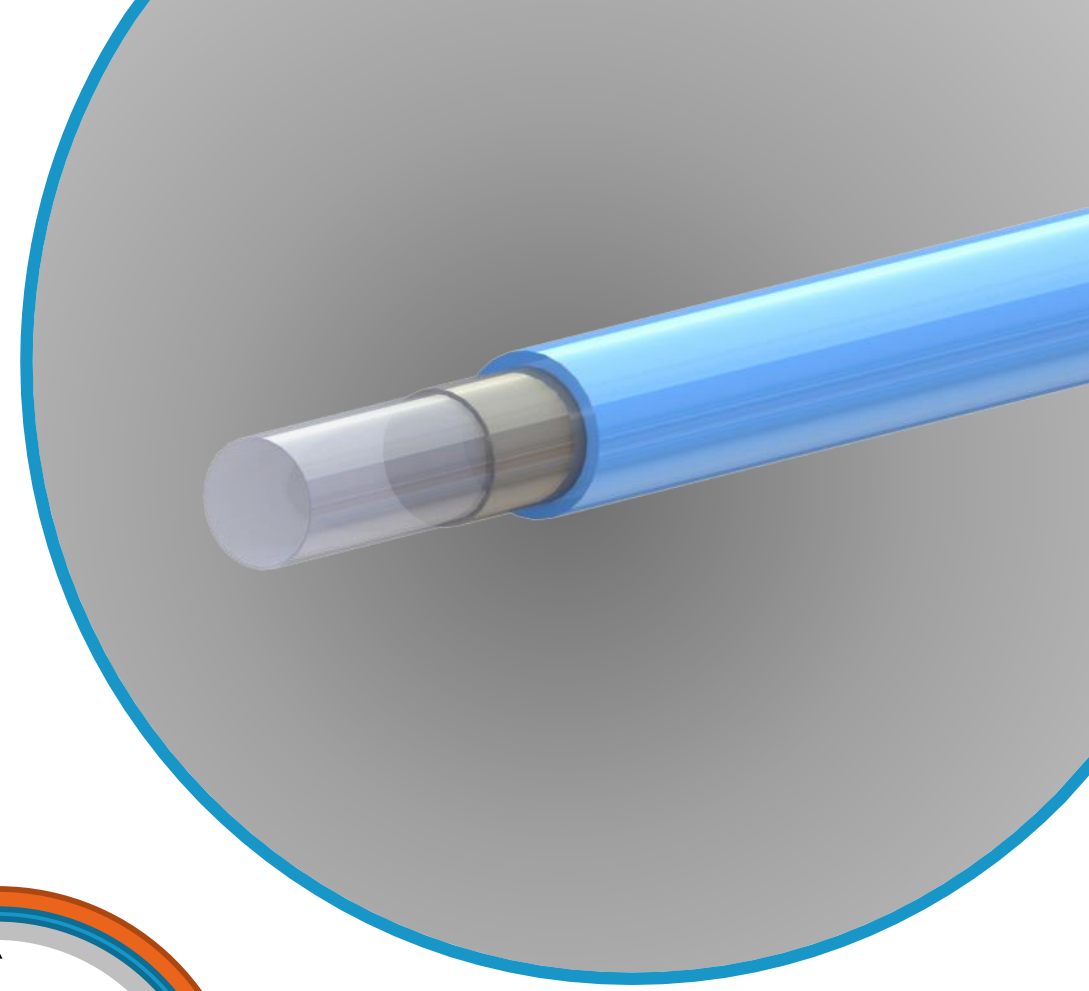
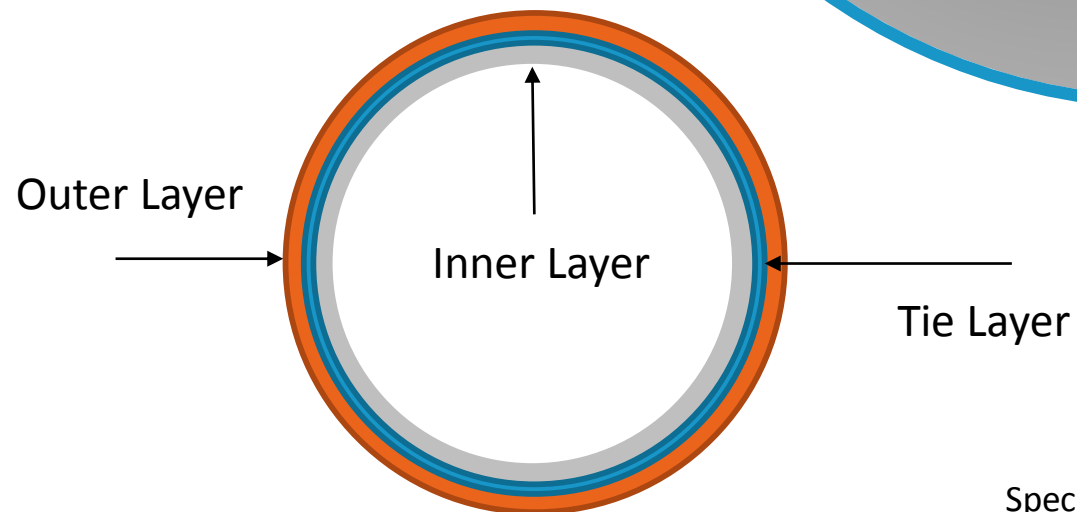
Polymer 2



TRILAYER + COEXTRUSION

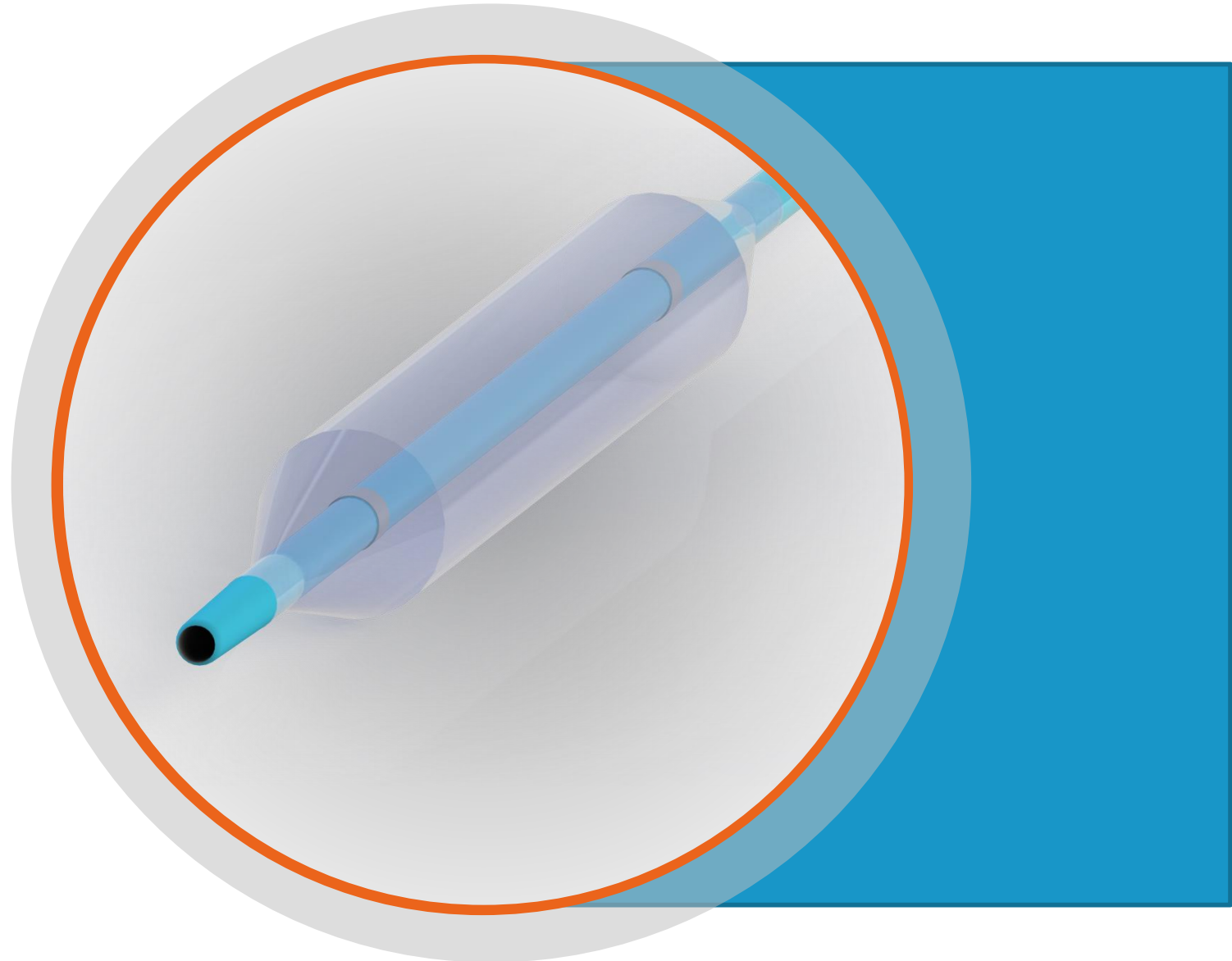
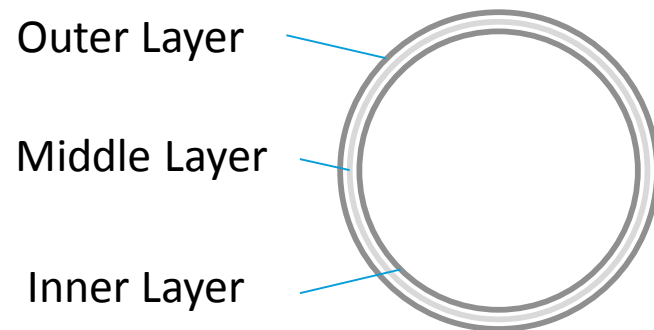
Trilayer and coextruded shafts are engineered shafts that incorporate discreet layers to suit a specific set of specifications. Our proprietary process for producing this type of tubing enables high crush strength with no guidewire lock up. Common polymers used with this type of construction include:

- HDPE
- LDPE
- Nylon
- Polyurethane
- Pebax

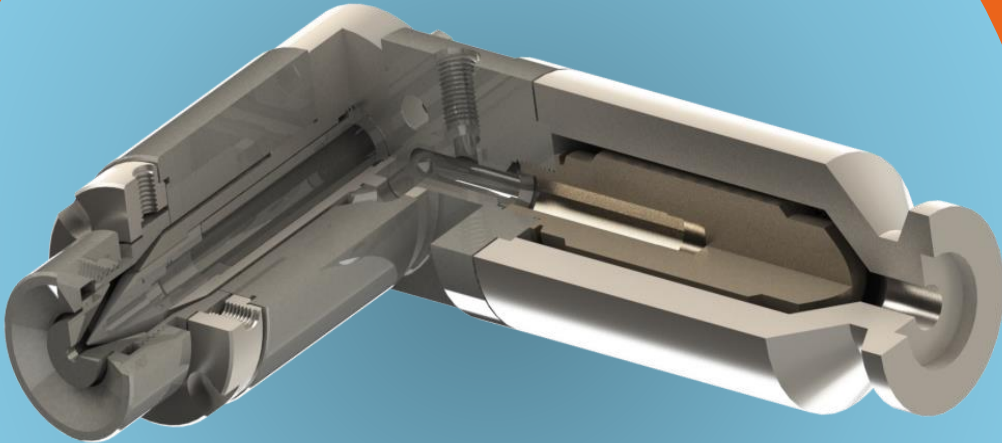


HIGH PERFORMANCE BALLOON TUBING

- Our proprietary process for manufacturing balloon tubing incorporates up to 3 polymers in individual layers to orient polymer chains in multiple directions to achieve thin wall high pressure balloons.



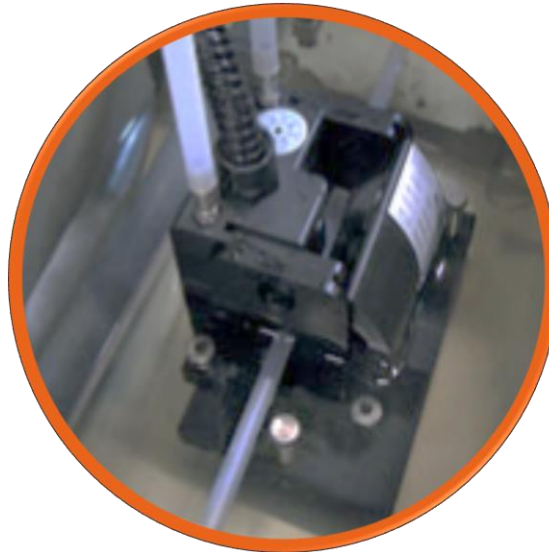
EXTRUSION TOOL DESIGN



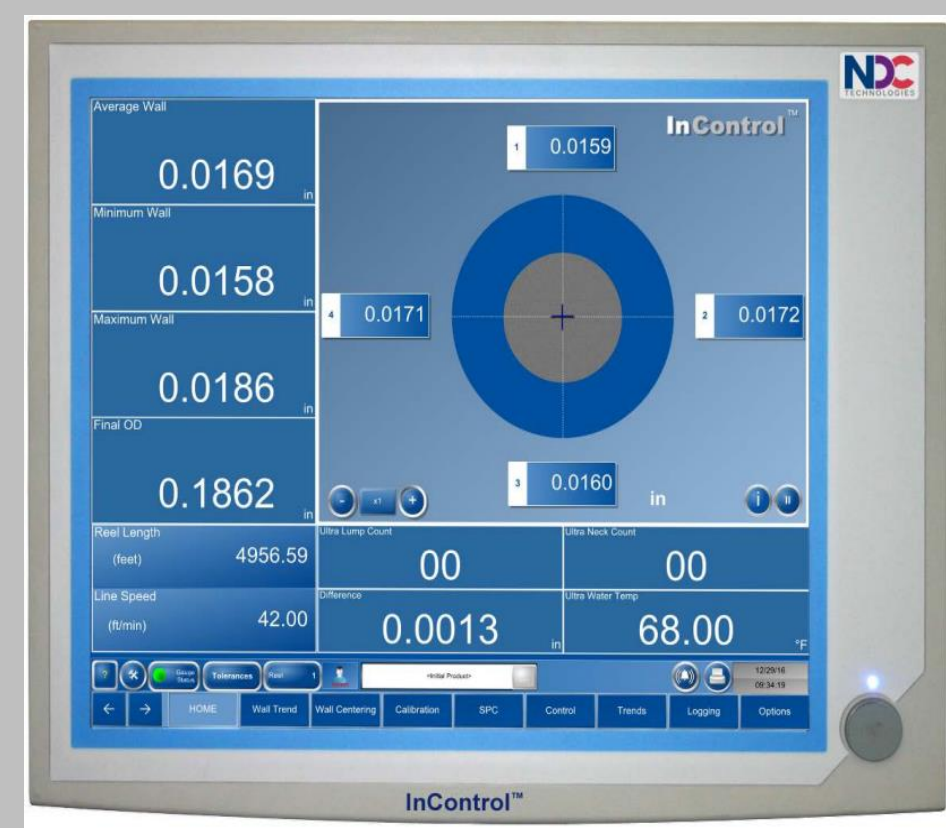
- Custom tooling is often necessary to meet the high-end specifications required in today's competitive market.
- Our in-house engineering team has developed material specific draw down ratios along with high flow inline material filtering to ensure the highest quality components that meet exacting specifications.

ONLINE QUALITY ASSURANCE

The addition of online ultrasonic gauging has enabled Specialized Engineering to increase yields and reduce touch time during inspection. Live scanning of wall thickness enables closed loop control of outputs. 8 channel SPC data analysis generates reports for each lot.



Inline Measurement Head



METROLOGY

Our metrology lab houses the following equipment for characterization and analysis:

- Instron 3343 Single Column Testing System
Tensile, Compression, Strain, Cyclic Conditioning
- MicroVu Vertex 311 Automated Precision Measurement System
Optical measurement system for reliable noncontact inspection
- CEM LabWave 9000
Moisture content analysis for raw material analysis



QUALITY POLICY

Specialized Engineering, LLC is committed to providing our customers with superior personalized service.

We strive to be a technology center of excellence and a leader of engineered solutions for the medical device industry through customer service, technical excellence and continuously improving the effectiveness of our quality management system in accordance with industry, applicable regulatory and statutory requirements.



STRIVING FOR EXCELLENCE

Quality is paramount at Specialized Engineering. Through years of experience we have developed a process for continuously creating quality products. This development process has produced millions of feet of precision tubing used in many commercial devices over the years by large and small companies alike. Through driving culture change this process has enabled us to focus on throughput, quality, reducing costs and lead times while developing a lean manufacturing methodology.

CUSTOMERS

