




## The Catheter Technology Center

# HISTORY

Specialized Engineering started in Palo Alto in 1996 already having over 10 years experience in catheter assembly processes, braiding, coiling, tipping, insert molding, 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.

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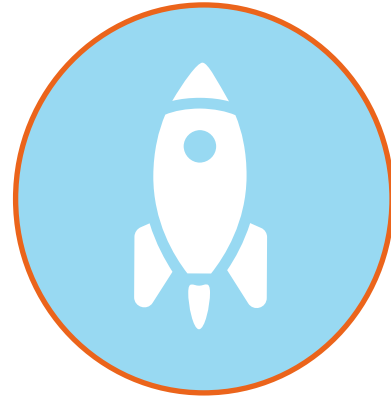


In 2000, Specialized Engineering moved to Stockton, CA. expanding manufacturing operations to 10,000 square feet. With ISO 9001: 2015 certification, Specialized Engineering is dedicated to quality and lean manufacturing with robust engineering support.



## 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

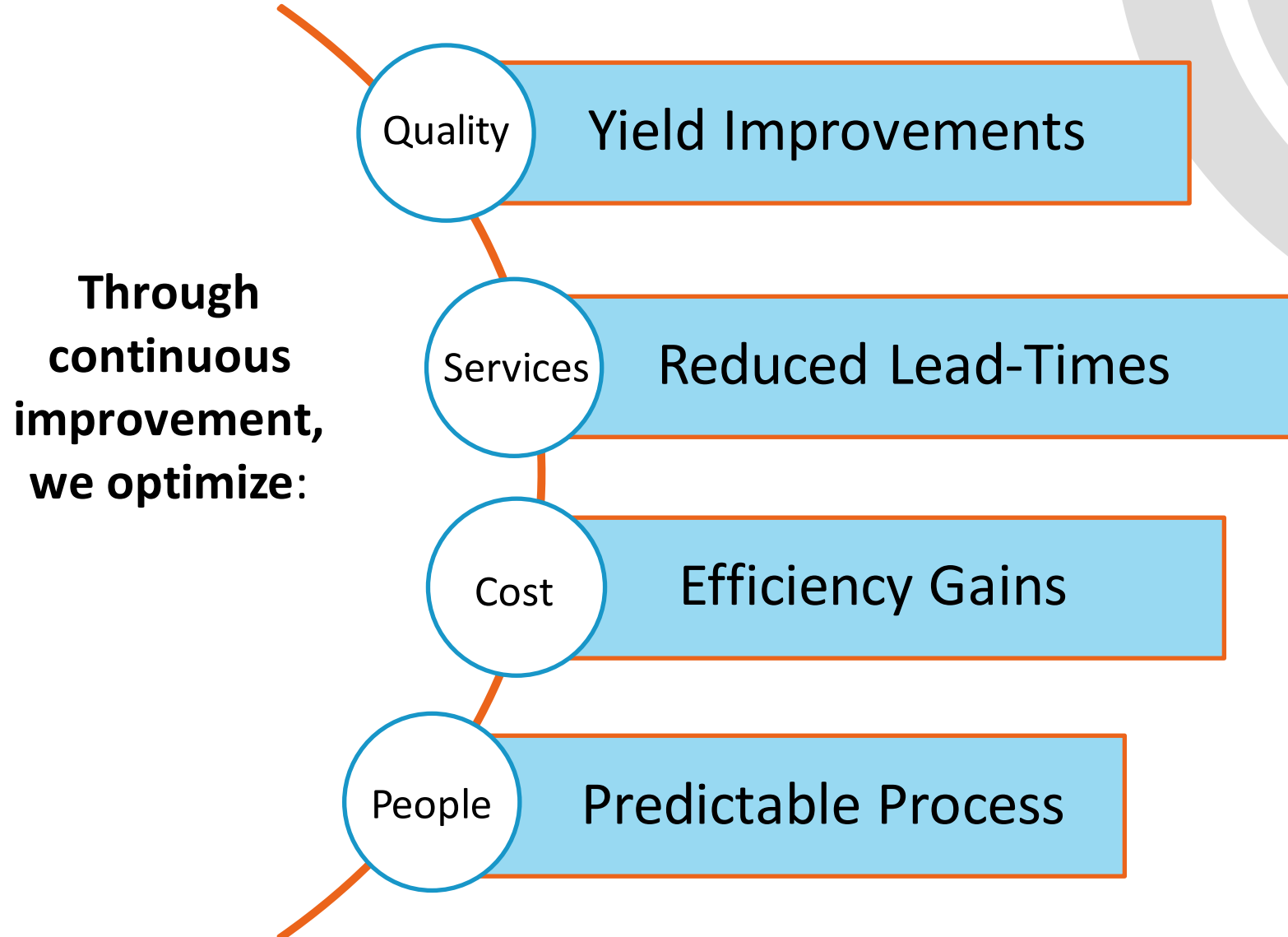
Our business strategy is to implement lean manufacturing with robust engineering support, reducing lead times and costs.



## GOAL

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

# VALUE PROPOSITION



# SENIOR STAFF



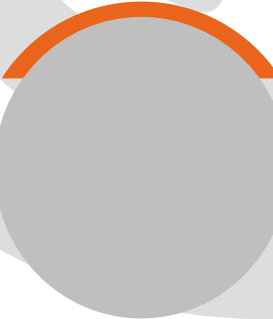
**PAUL ALBA**

President and Founder of Specialized Engineering, Paul Alba has worked in the medical device industry for over thirty years. Extensive work experience at ACS, Mallinckrodt Medical, Baxter Medical, AVE and Localmed/Perclose gives him unparalleled expertise that has catapulted Specialized Engineering to market leadership in the medical device industry.



**AGGIE ALBA**

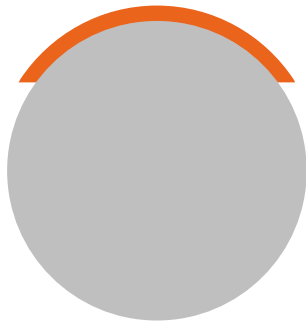
VP of Operations, pursued her Bachelor of Science Degree in Marketing from California State University, Sacramento. Aggie joined the company in 2006 and has made tremendous efforts in guiding the brand and team in advancing our presence in the medical marketplace.



**R&D ENGINEER**

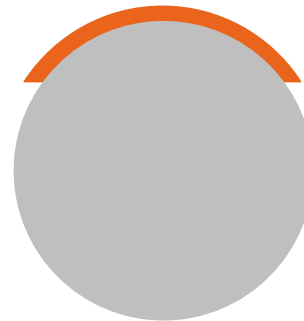
Specialized Engineering's R&D Engineer has experience in new product development throughout early stage start-up companies. She has worked in design, prototyping, preclinical testing and first in-human trials. Her hands on practical experience reliably brings customer projects to completion.

# SENIOR STAFF



## VACANT

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.



## JONATHAN TUPAS

Quality Assurance Manager, Jonathan is trained in ISO 9001:2015 Quality Assurance protocols. His constant focus is on attention to detail, the manufacture of quality product, and dedication to customer satisfaction.



## ANAIS PONCE

Administrative Assistant, Anais plays a key role in Specialized Engineering's operations. She has built and maintained strong relationships with our customer base while managing inventory, quotations, and document control.

# FACILITY

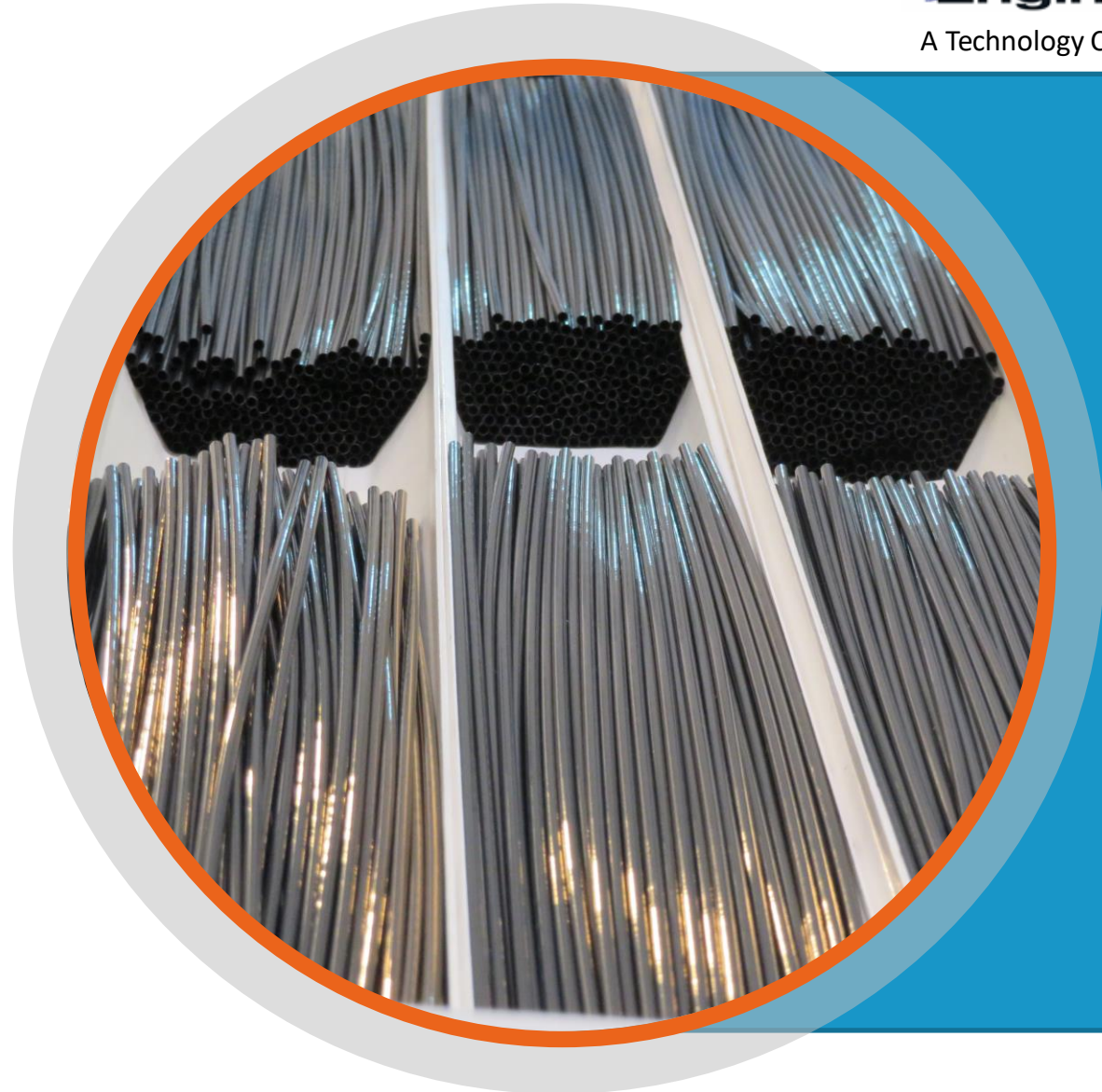
- Our facility encompasses 10,000 square feet of manufacturing space strategically located in central California's non-earthquake zone.
- The extrusion lab houses the primary manufacturing equipment which consists of 7 extrusion lines.
- Our 650 square foot pilot production lab hosts secondary processing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





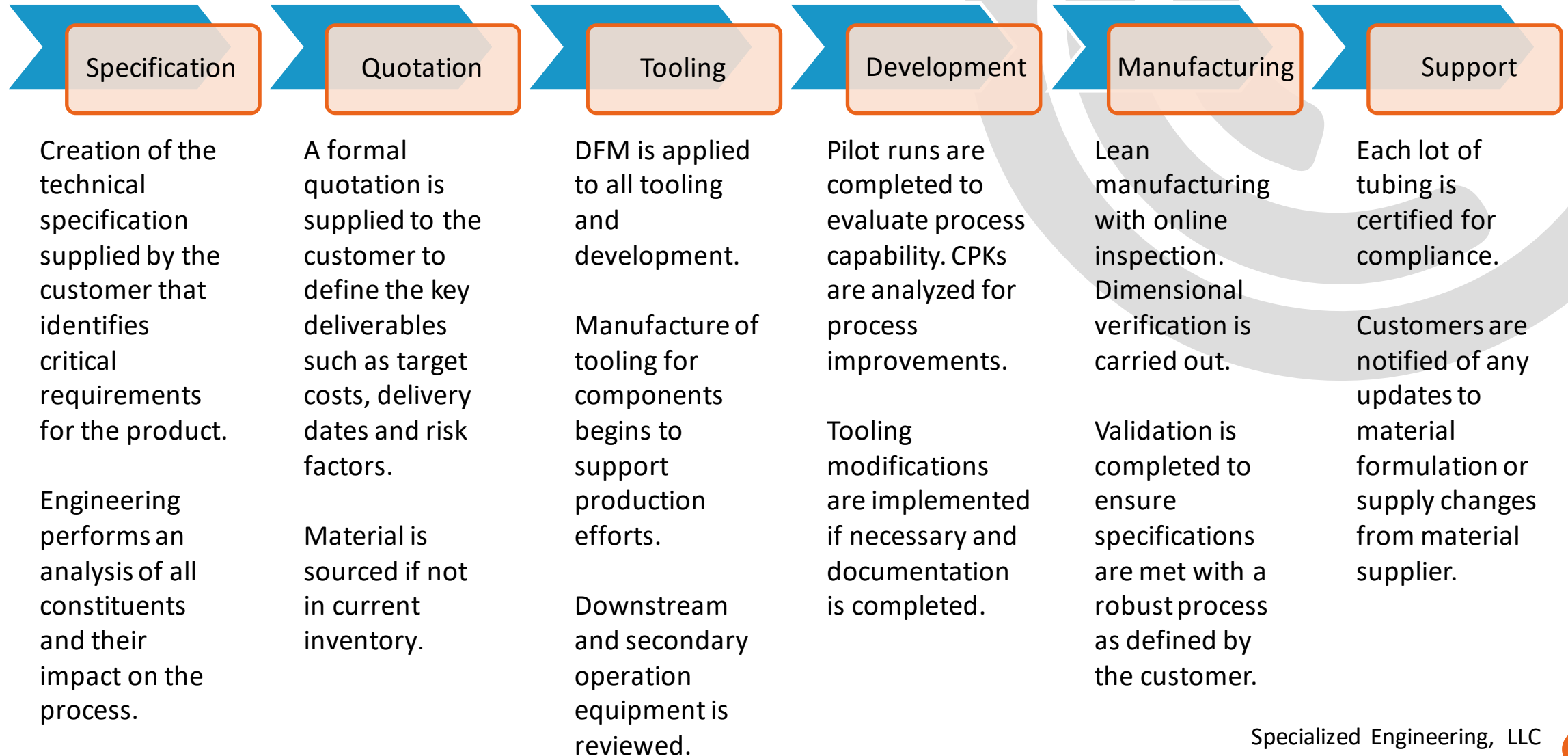
# CAPACITY

- 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



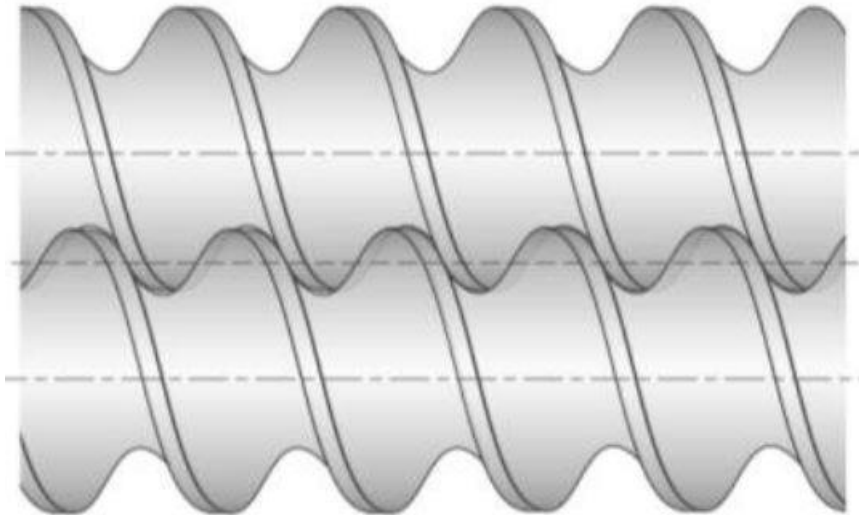
A Technology Center of Excellence

- Beading
  - 0.007" minimum OD
  - 0.175" maximum OD
- Tubing
  - 0.004" minimum ID
  - 0.375" maximum OD
  - 0.002" minimum wall
  - 0.050" maximum wall



# ON A BUDGET? QUICK TURN? SMALL BATCH COLOR. HAND BLENDS AND MACHINE COMPOUNDING 5 TO 25LBS.

- Pebax
- Nylon 11, 12, 6/6
- HDPE
- LDPE
- LLDPE
- Pellethane
- Polyurethane
- PVC
- Polypropylene
- PET Polyester
- AND MANY MORE



Please send your request to [info@meditube.com](mailto:info@meditube.com).

Please review <https://chamfr.com/> as we continue to build our current stock items for immediate shipping.



# THIN WALLED POLYESTER (PET) EXTRUSION CAPABILITIES



A Technology Center of Excellence



## 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
- Insert molding
- Burst Testing
- Tensile Testing
- Moisture Analysis

# HIGH PERFORMANCE BRAIDED & COILED SHAFTS

High performance catheter shafts are often required for tortuous and complex procedures.

**We manufacture our own Shrink FEP for lamination this enables us to have better quality, a quicker turn around, and lower costs than our competitors.**

Braid and coil reinforcements are used to increase torque transmission and hoop strength.

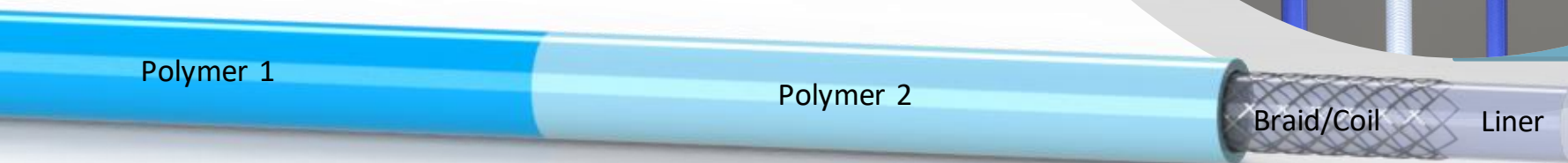
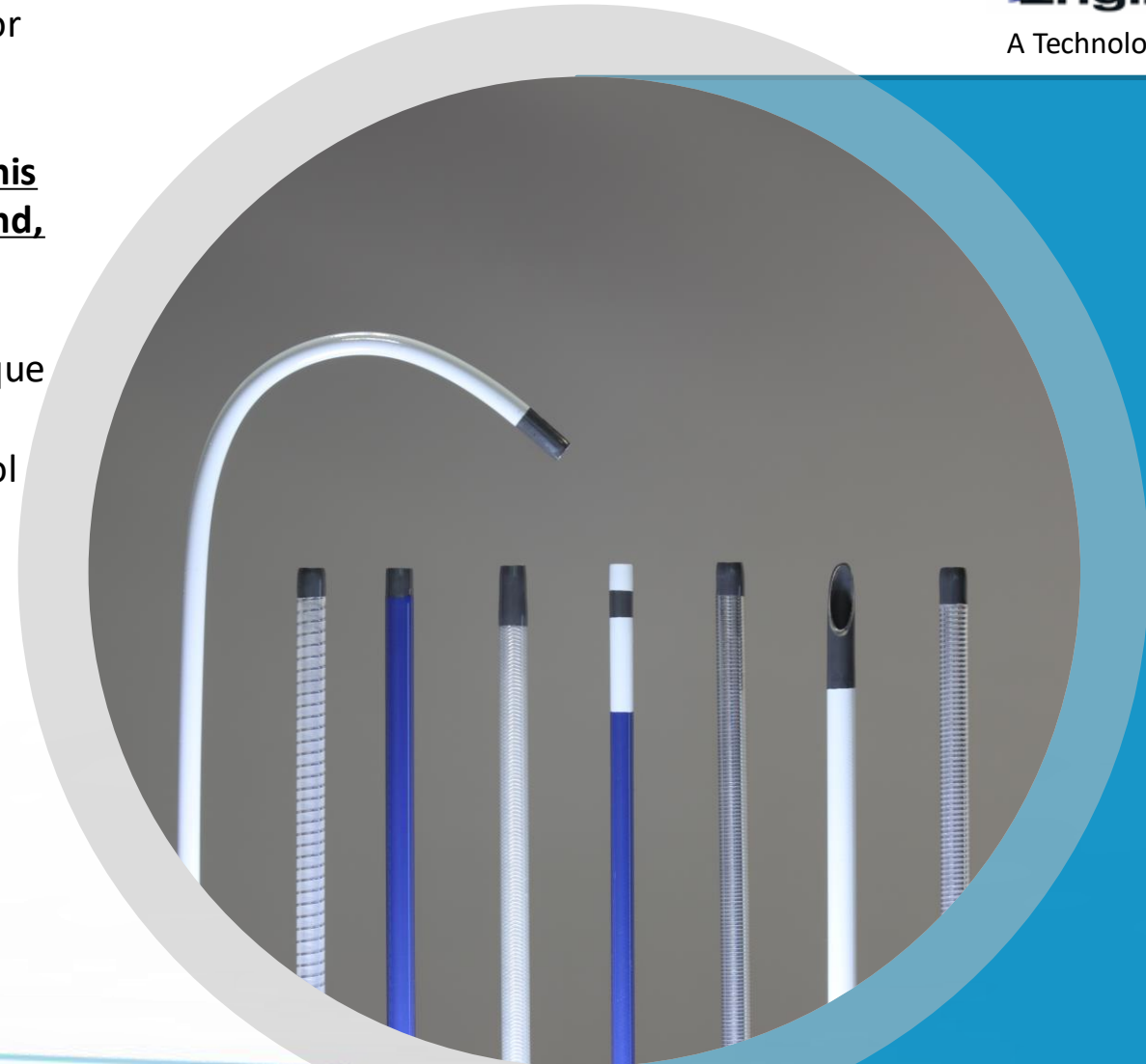
**Reinforcement Materials:** Stainless Steel, Kevlar, Nitinol

**Liner Materials:** FEP, PTFE, HDPE, Pebax, Nylon Single and Multilumen Profiles

Variable durometers, pick counts and TPI.

Please send your request to [info@meditube.com](mailto:info@meditube.com).

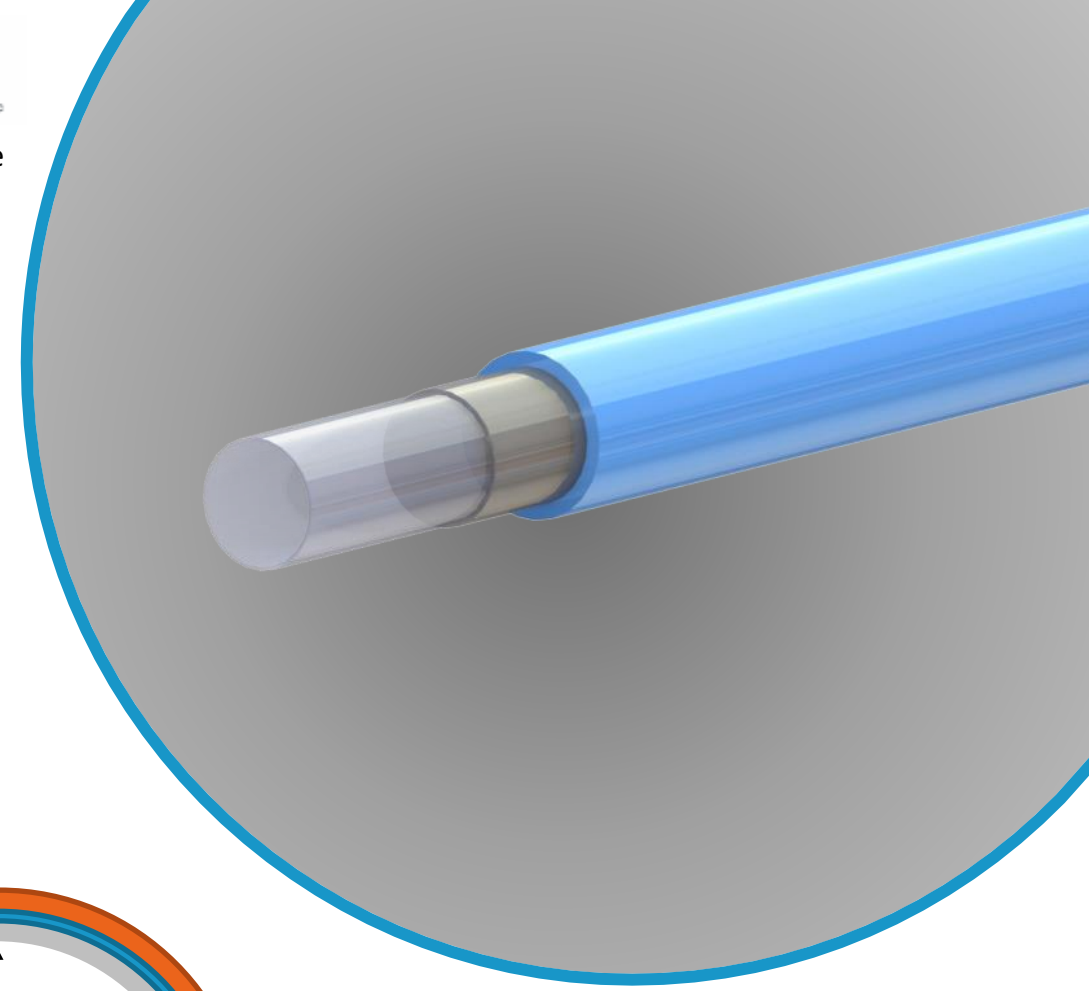
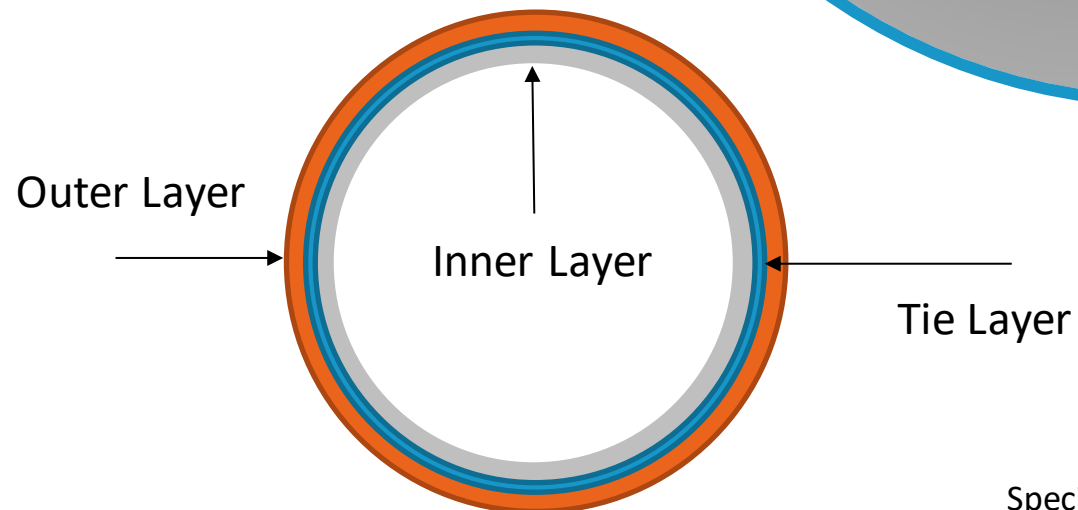
Please review <https://chamfr.com/> as we continue to build our current stock items for immediate shipping.



# 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
- FEP





# ALTERNATIVE TO PTFE LINERS:

THE BENEFITS ARE LEADTIME, PRICING, SIMILAR LUBRICITY

Coextruded or ultra thin wall HDPE or FEP 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, inner liner lubricity with no guidewire lock up. Common polymers used with this type of construction include:

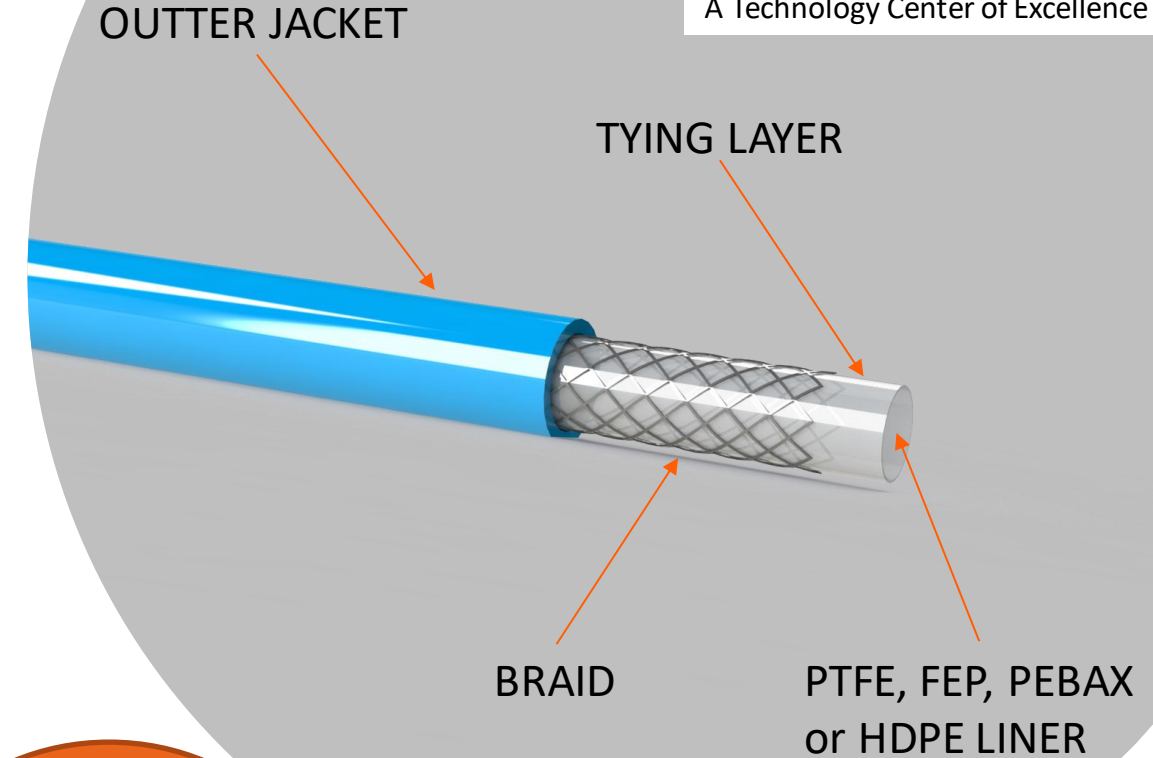
- HDPE
- FEP
- LDPE
- TYING LAYER
- NYLON
- POLYURETHANE
- PEBAX



Outer Layer

Inner Layer

Tie Layer & Braid



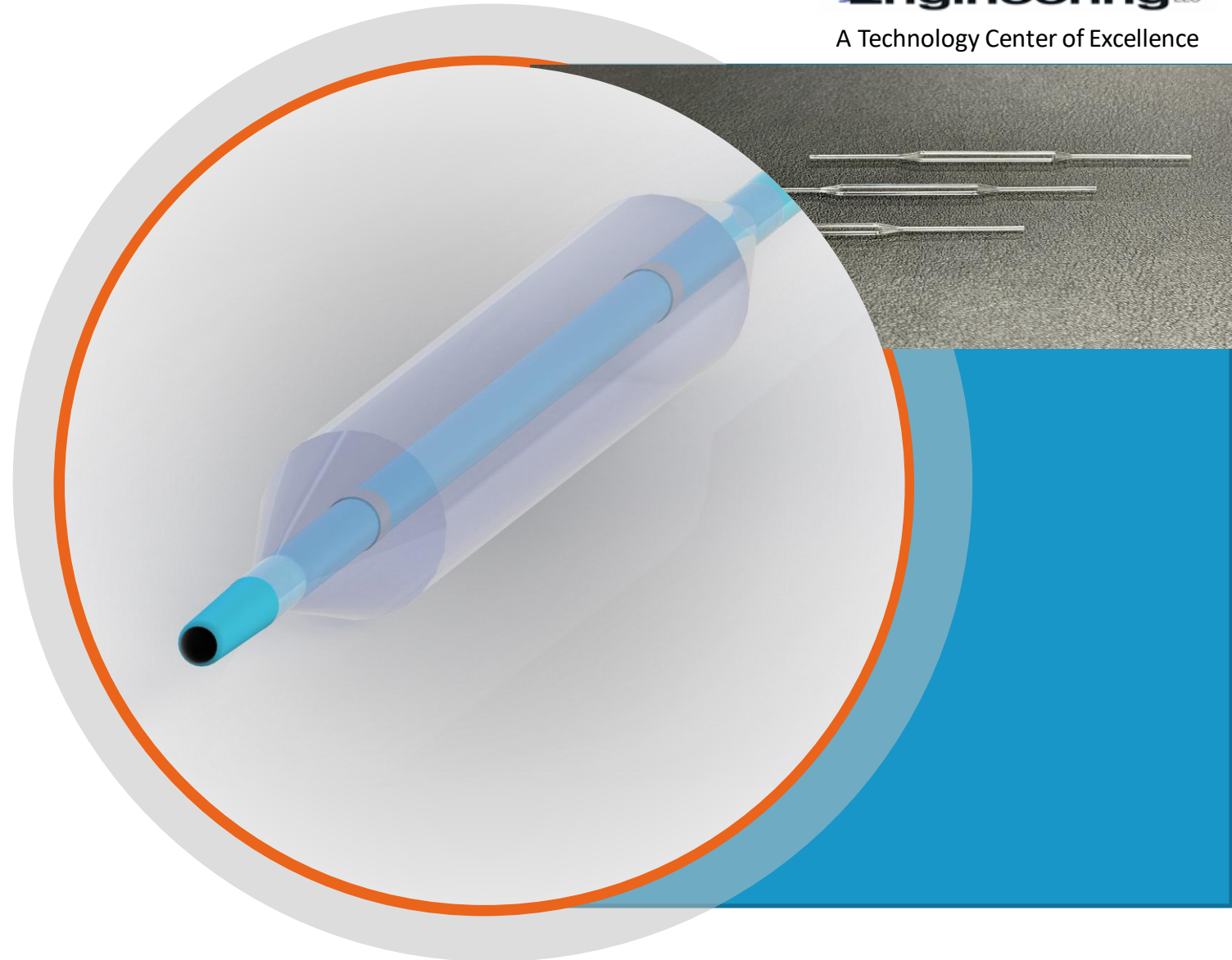
# HIGH PERFORMANCE BALLOONS & BALLOON TUBING

## Our Service & Equipment Includes

We offer expert balloon extrusion and balloon blowing service, we have helped customers increase their balloon blowing yields from 50% to over 90% taking the frustration out of balloon blowing and making it a repeatable process.

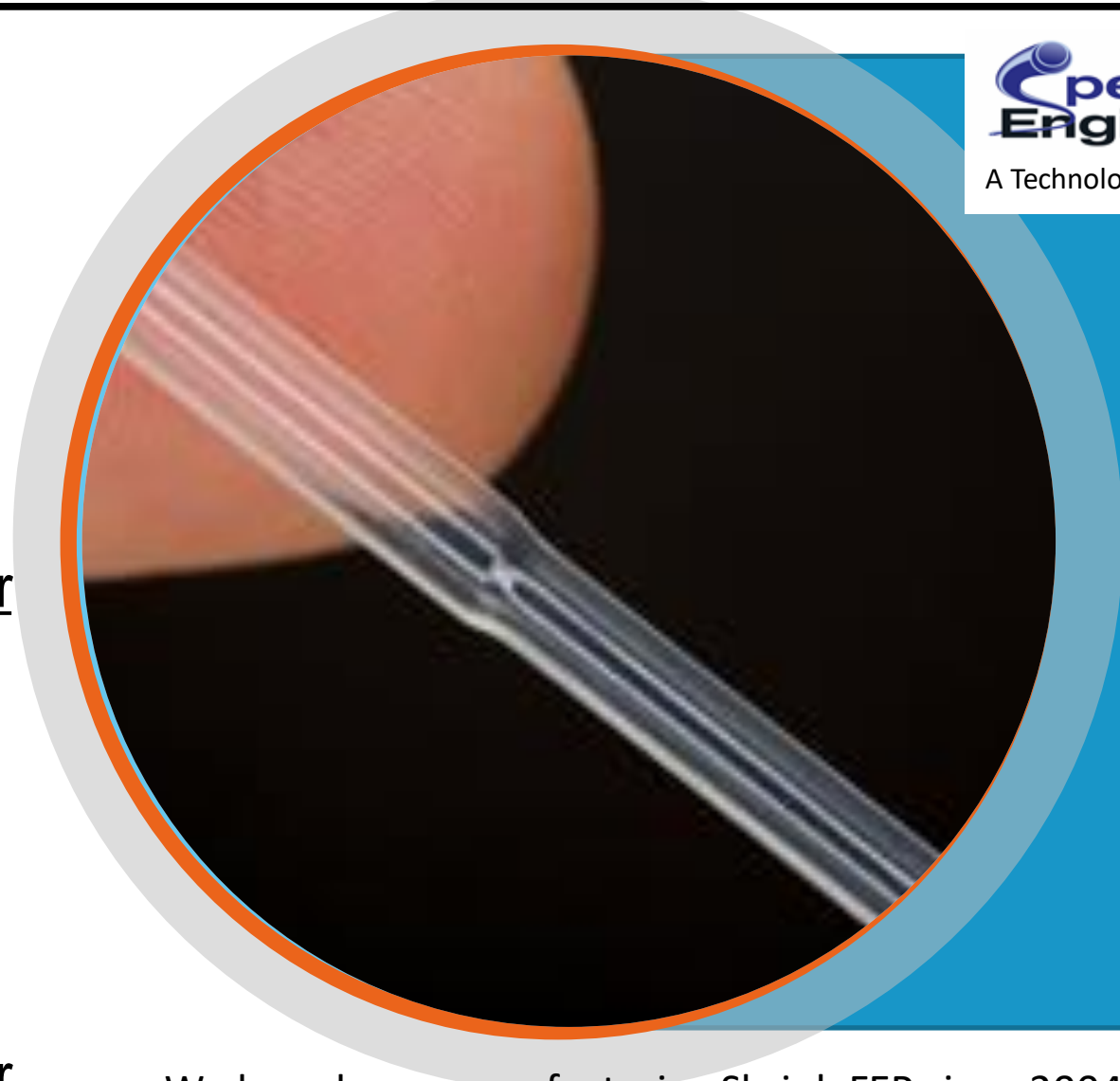
We have also increased their burst strength 3+ ATMs and reduce fish eyes in the finished balloons. Giving our customers superior balloon tubing to make balloons that exceed their customers expectations. Please contact us to help solve your balloon blowing processes. Instron 3343 Single Column Testing System

- MicroVu Vertex 311 Automated Precision Measurement System  
Optical measurement system for reliable non contact inspection
- CEM LabWave 9000 Moisture content analysis for raw material analysis
- 1000 PSI Crescent Design Hydraulic Burst-Leak Tester
- 4+ Interface balloon Blowers and many assorted balloon molds.



# ULTRA-THIN WALLED .0025" SHRINK FEP

- Exceeding 2 : 1 recovery ratio.
- Cut lengths up to 8'+.
- Expanded ID's over 0.300"
- Recovered ID's under .015"
- Single walls from .015" to .003"
- With our 4 week lead time, we can get your manufacturing and development back on track. "Expedite Available"
- Please send your request to [info@meditube.com](mailto:info@meditube.com) .
- Please review <https://chamfr.com/> as we continue to build our current stock items for immediate shipping.



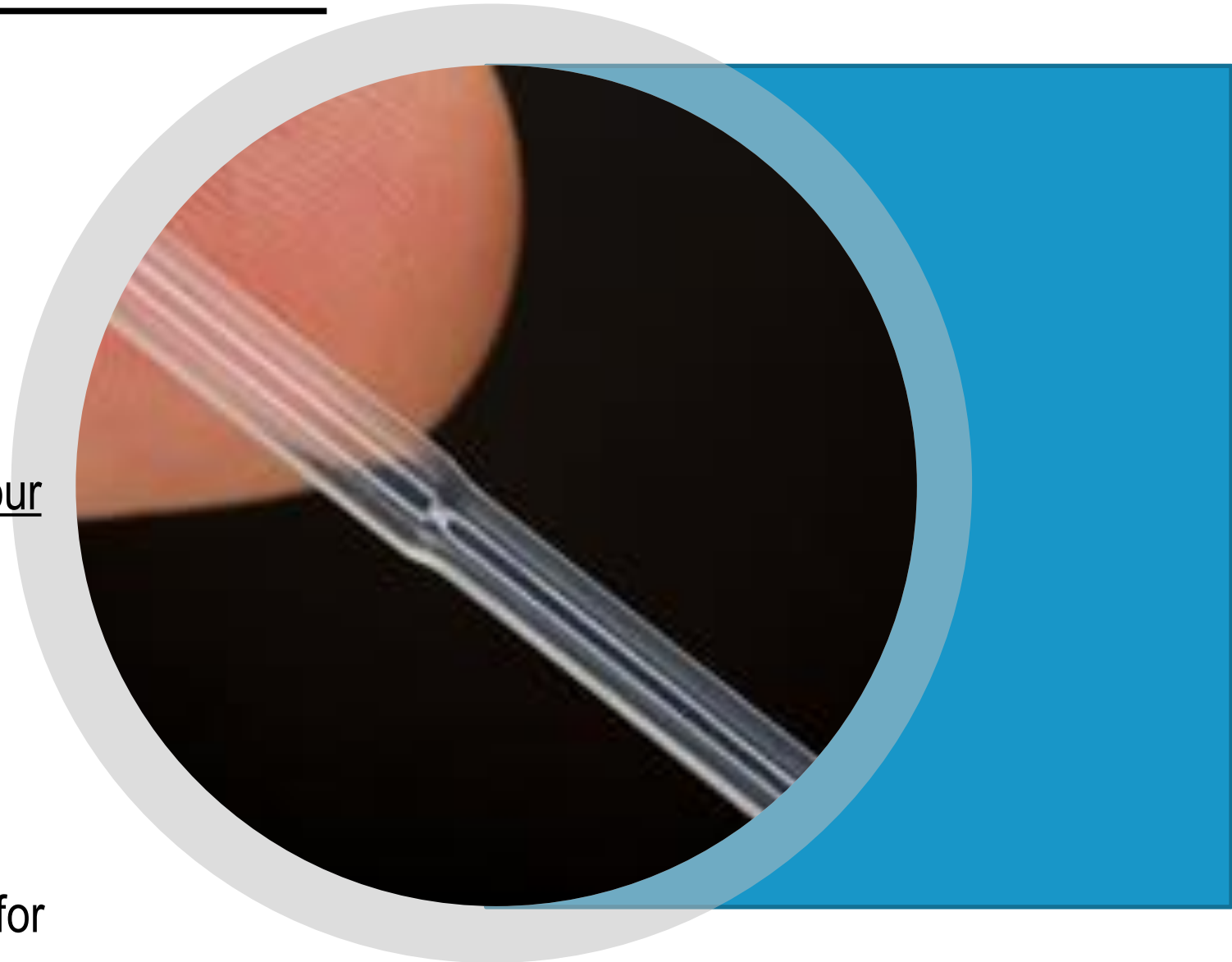
**Specialized Engineering LLC**  
A Technology Center of Excellence

We have been manufacturing Shrink FEP since 2004.

Specialized Engineering, LLC [Info@meditube.com](mailto:Info@meditube.com)

# SHRINK PET

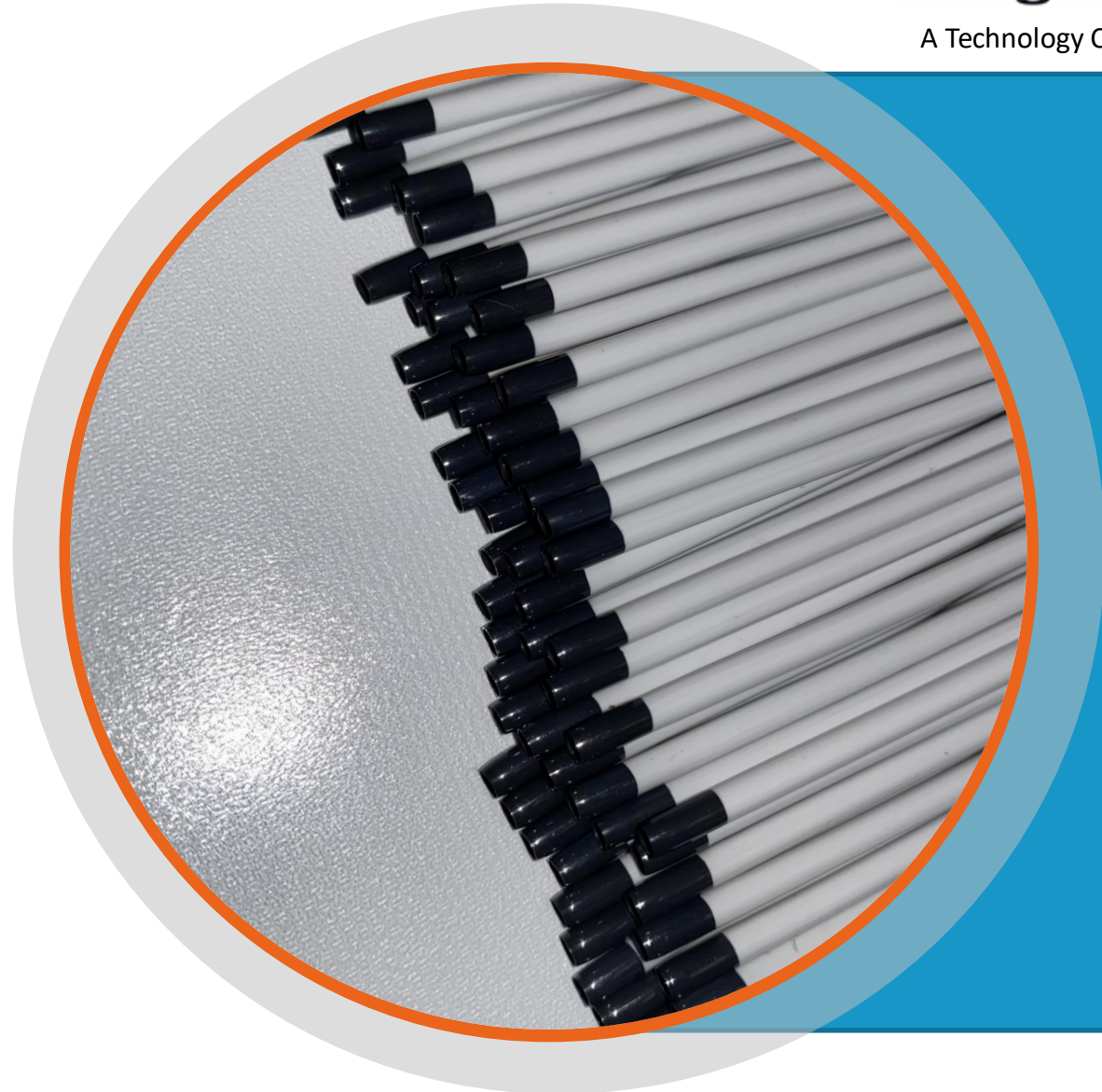
- Exceeding 1.25 : 1 recovery ratio.
- Cut lengths up to 6'+.
- Expanded ID's over 0.250"
- Recovered ID's under .025"
- Single walls from .0005" to .0020"
- With our 4 week lead time, we can get your manufacturing and development back on track. "Expedite Available"
- Please send your request to [info@meditube.com](mailto:info@meditube.com) .
- Please review <https://chamfr.com/> as we continue to build our current stock items for immediate shipping.





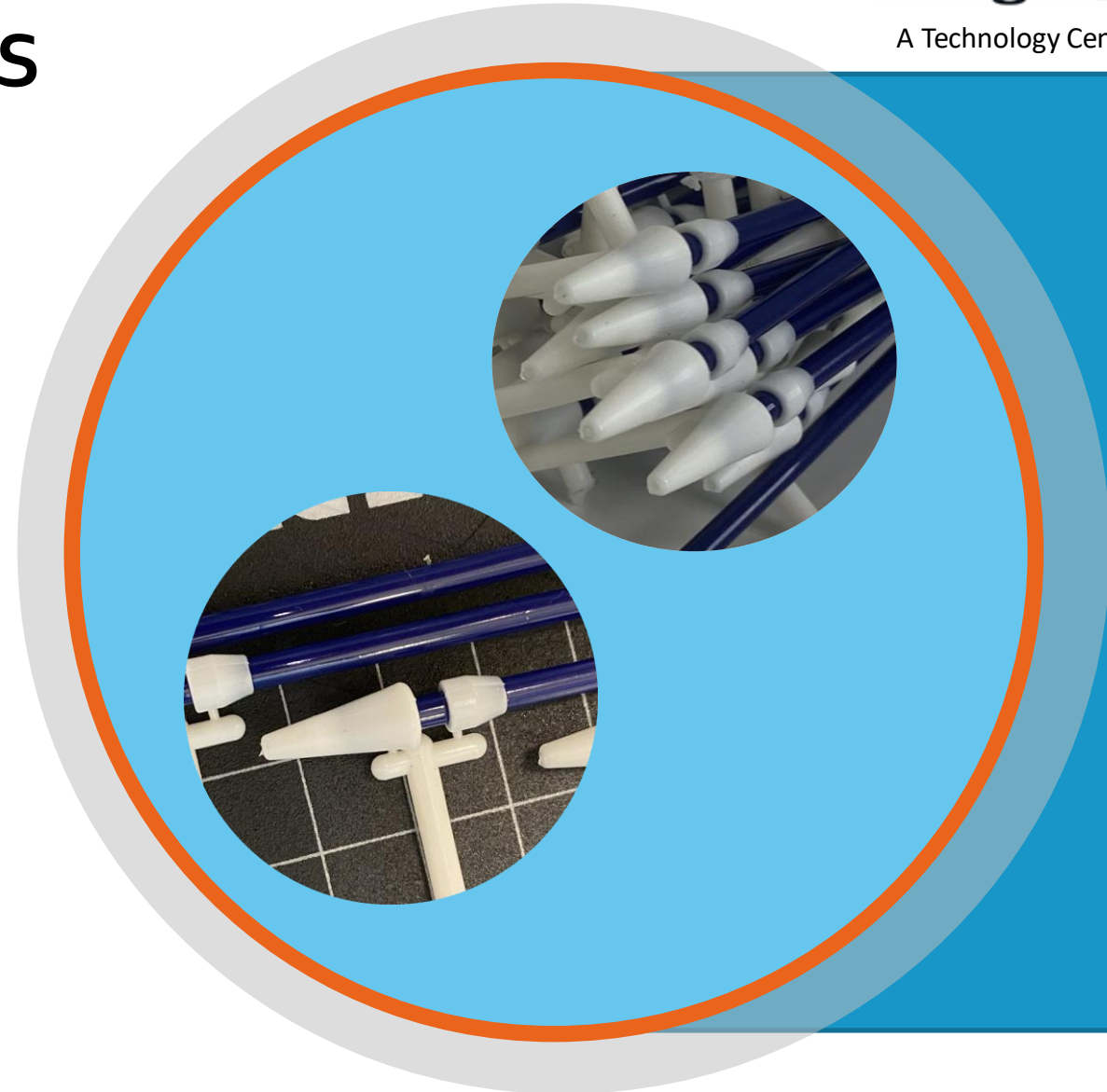
# RADIOPAQUE TIPS AND TIPPING

- Our proprietary process for manufacturing radiopaque tubing incorporates up to 80% Tungsten.
- Our Proprietary tipping processes which includes RF and Thermal heating separately as individual processes. Provides tip bonding that's well in excess the ISO standard of 15n.



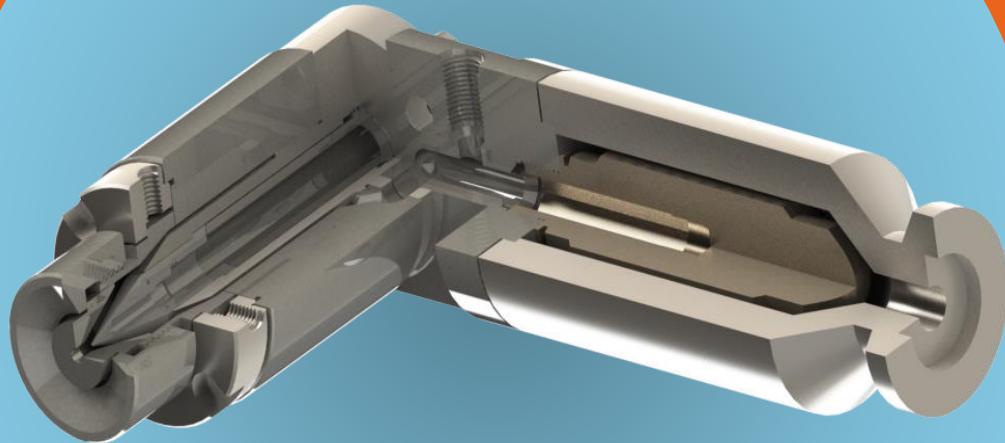
# INSERT MOLDING OF TIPS AND HUBS

- Our proprietary process for insert molding is specifically designed around catheter manufacturing.
- Our Proprietary over molding processes bonding that exceeds 15n.





## 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.

## LASER MARKING OF ALL KINDS OF MATERIALS

New developments:

We have ventured into laser marking and We can mark nearly any polymer, metal, and even cut thru glass.

There are many things we can do for instance part numbers, lot numbers, serialized numbers and logos. Just think, no pad print, no inks, no laser additives and no biocompatibility issues.

This is just a laser mark of a logo on Gray Pebax tube.



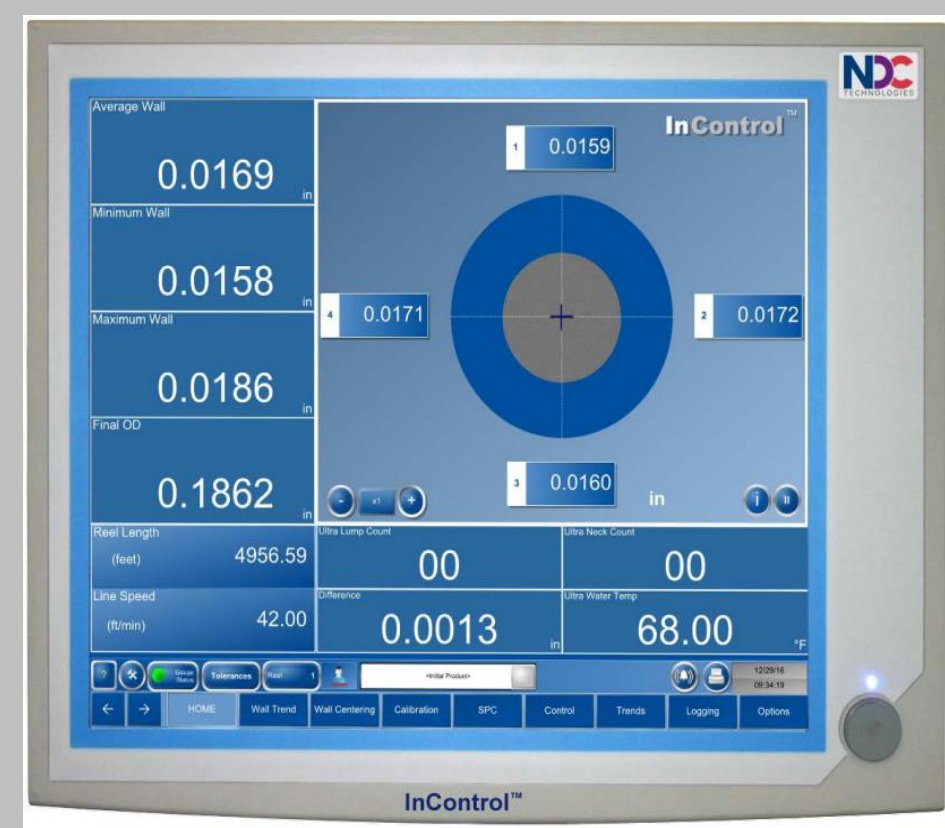
# ONLINE QUALITY ASSURANCE



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 non contact inspection
- CEM LabWave 9000  
Moisture content analysis for raw material analysis
- Crescent Design  
Hydraulic Burst-Leak Tester





# QUALITY POLICY

Specialized Engineering, LLC  
Info@meditube.com 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.



## Certificate of Registration

Specialized Engineering, LLC  
831 Performance Drive, Stockton, CA 95206, USA

have been assessed and approved to:

**ISO 9001:2015**  
Quality Management System

The approved management system applies to the following scope:

Specialized Engineering, LLC, located in Stockton, California, provides Injection Molding, Extrusion and Thermoforming Services.  
Clause 8.3, Design and development of products and services, is not applicable to the Quality Management System.

Original Approval	24 <sup>th</sup> October 2003
Current Certificate	24 <sup>th</sup> January 2023
Certificate Expiry	24 <sup>th</sup> January 2024
Certificate Number	US2091

Signed: Certification Officer



This certificate remains valid while the holder maintains their administration systems in accordance with the standards and guidelines stated above, which will be audited annually by QAS International. The holder is entitled to display the above registration mark for the duration of this certificate, which should be returned to QAS International upon reasonable request.

Issuing Office: QAS International, 5 Technology Park, Colindale Lane, London, NW9 6BX, UK

Tel: 020 31989788 • info@qas-international.com • https://www.qas-international.com





# 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



Edwards

