



americhem[®]
HEALTHCARE

JNJ Mini-Conference II

Raphael Delgado
Sr. Business Development Manager:
Americhem Healthcare



Presenter Bio



Raphael Delgado

*Sr. Business Development
Manager- Americhem
Healthcare*

RDelgado@Americhem.com

2003 to 2006 – General Electric Plastics(LNP)- Plastic Engineer
2006 to 2009 – Milacron – Southwest Sales Engineer
2009 to Present – Americhem Healthcare

Skill Sets / Responsibilities

- Healthcare Specifications
 - Providing unbiased material selection (Polymer + Fillers/ Additives + Pigments) assistance at the OEM based on requirements including physical properties, sterilization, FDA compliance
 - Color matches (Pre- colored + Color Concentrate)
 - Solving quality issues with warping, cracking, part dimensions big/ small, or any failures with material composition tweaking
- Scientific Molding
 - Supporting molding trials at injection molder
 - Solving mold/ Tooling issues



Topics

- **Regulatory and product registration requirements**
- **Packaging and transporting requirements**
- **Supplier – Relationship expectations**





ABOUT AMERICHEM

Americhem is your global partner in manufacturing polymer solutions

Americhem is focused on optimizing performance, innovating solutions and earning trust. Our premium brands help solve the most unique challenges through groundbreaking technology and total responsiveness. The range of industries we serve offers new opportunities through cross-market innovation.

80 YEARS

Decades of growth and innovation in a privately held company

12 LOCATIONS

Multiple locations across North America, Europe, and Asia

1,000+ EMPLOYEES

Americhem employs over 1,000 employees across the globe

WORLDWIDE

Worldwide sales and technical support coverage

TECH-DRIVEN

Cutting edge organization of skilled, diverse people

LEADERSHIP

Recognized global leader in plastics technology



World

Headquarters

Cuyahoga Falls, OH, USA

Manufacturing

Concord, NC, USA

Cuyahoga Falls, OH, USA

Dalton, GA, USA

Grand Rapids, MI, USA

Liberty, NC, USA

Morrisville, PA, USA

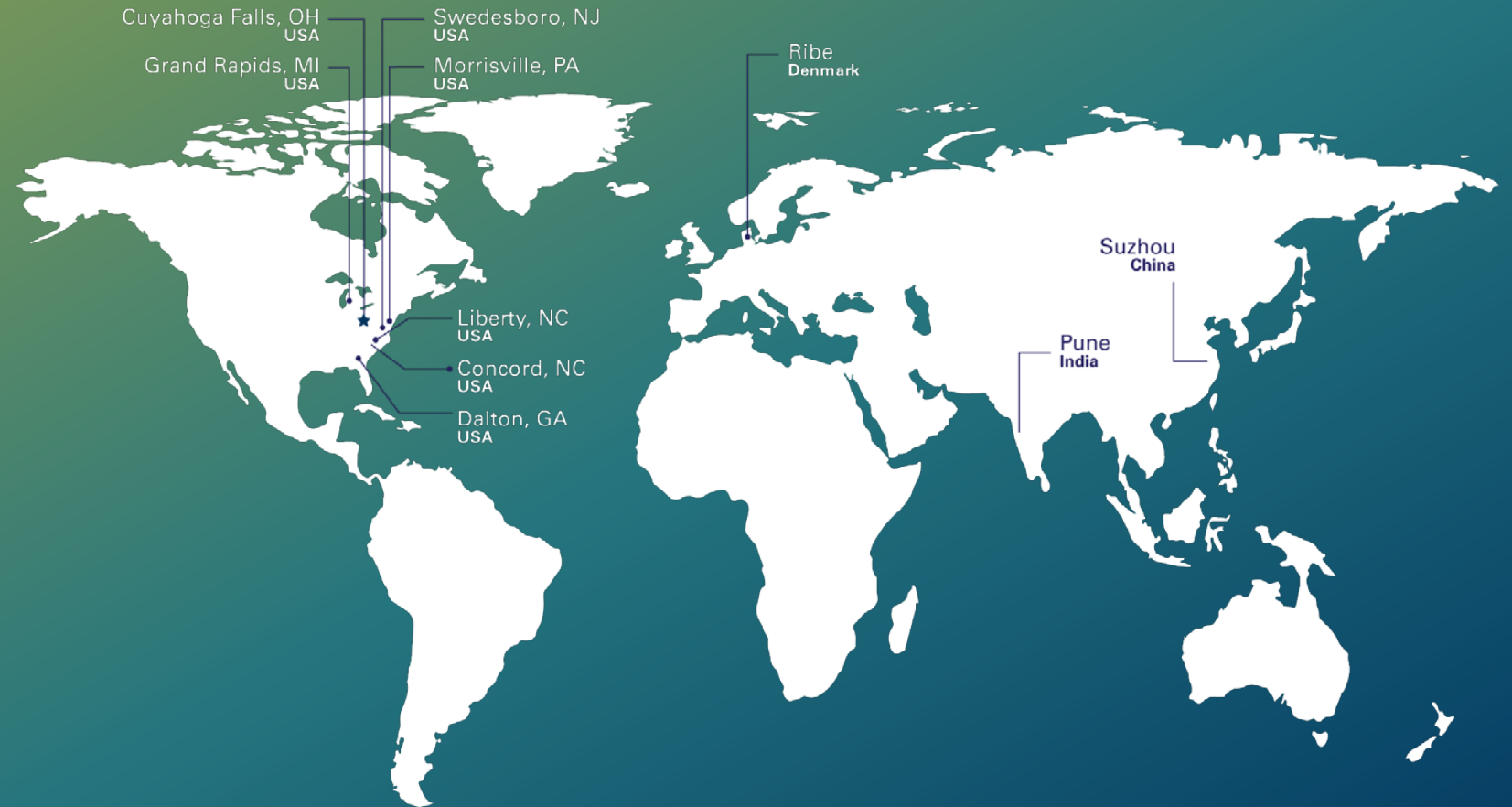
Pune, India

Ribe, Denmark

Suzhou, China

Swedesboro, NJ, USA

LOCATIONS





Regulatory and Product Registration



Industry Standards



USP Class VI



ISO 10993



FDA 21 CFR



ISO 13485 (US, Europe, Asia)



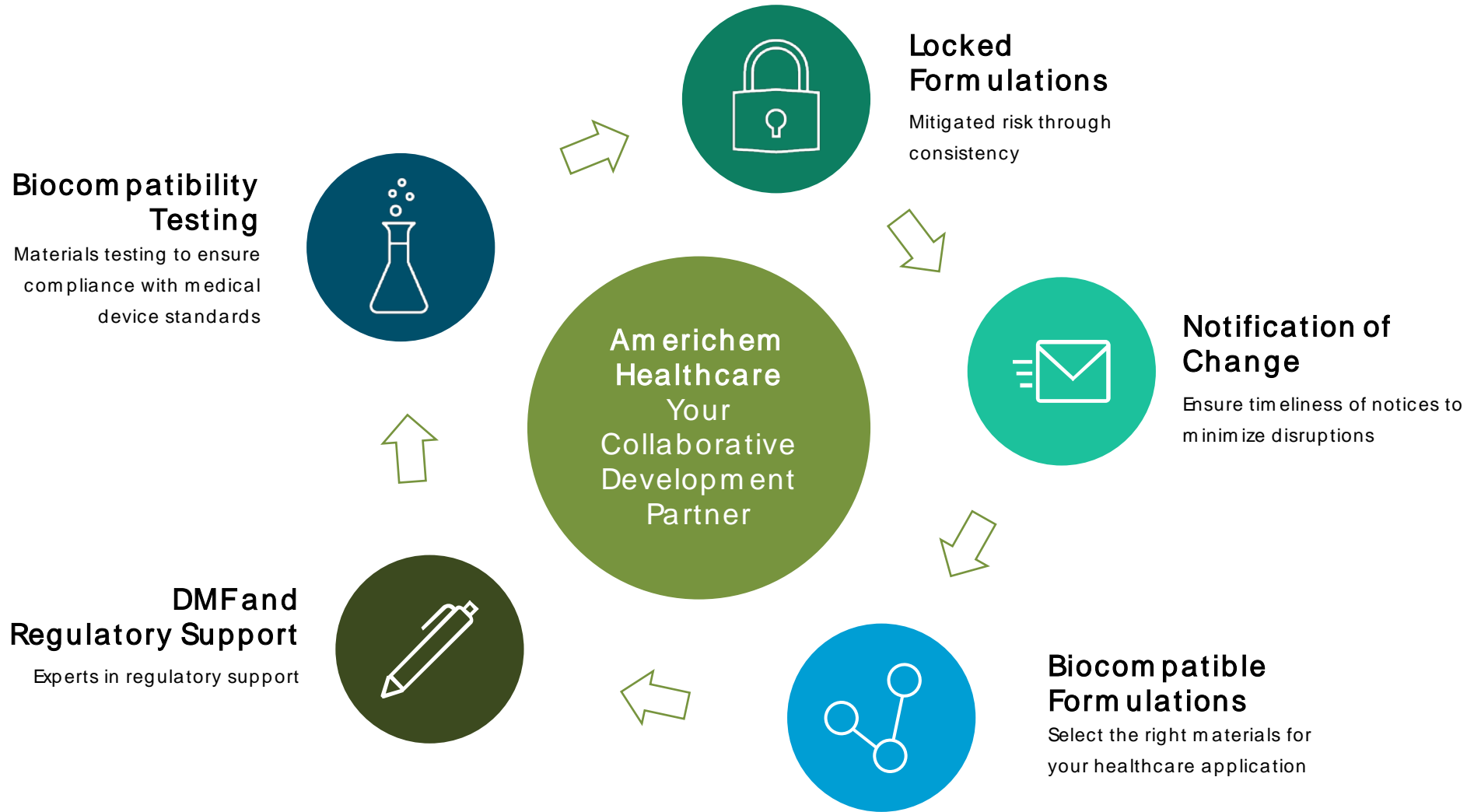
UL 94 Listings





Regulatory and Product Registration

GLOBAL REACH. REGIONAL FOCUS.





Packaging and Transporting Requirements



Packaging and Transporting Requirements

- **Quality**

Will follow OEM specifics for packaging, shipping and logistics

Automated Material conveyance

Example- Sealed samples from Silos provided to trucker with paperwork

- **Best Practices**

Quarter boxes / Gaylords / Drums / Foil Lined Drums / Foil Bags / Dedicated

Polymer bulk trucks

- **Communication with Audit Trail**

We keep informed every step of the way.

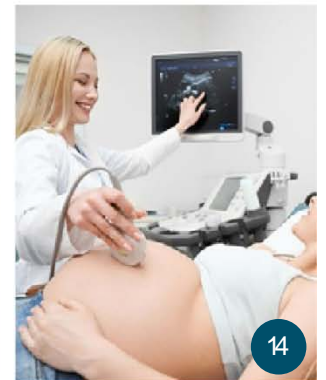
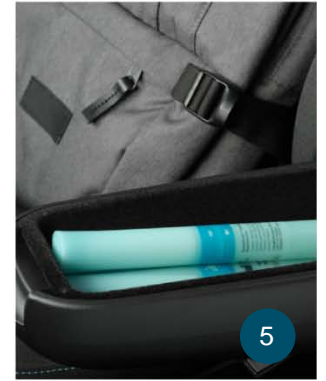
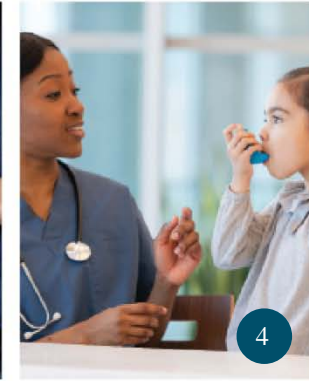
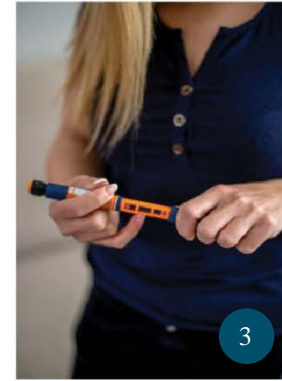
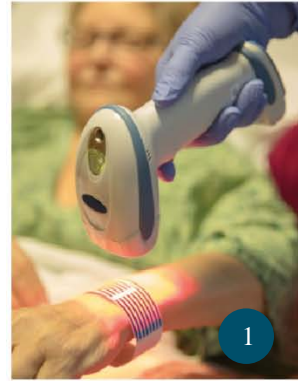


Supplier – Relationship Expectations



Market Segments

- Clinical Mobility 7
- Critical Care 2
- Diabetes Management 3,13
- Diagnostics 8
- Drug Delivery 4,6
- Lifestyle 5,13
- Patient Monitoring 6
- Point of Care 1,7
- Respiratory 10
- Surgical 9,12
- Women's Health 14



Am erichem Healthcare Solutions



- **Unbiased Material Selection**
 - *(ABS to PEEK)*
 - *Fillers / Additives / Pigments*
 - *Strong producer relationships*
- **ISO13485 Global Manufacturing Plants**
 - *Clean Compounding facilities*
 - *Global formulation language Biocompatible Compounds*
 - *ColorRx- Biocompatible Tested Base resins / Compounds*
- **Small MOQ (25 lbs)**
- **Speed for samples**
 - *NPI projects*
 - *Tribology projects*
- **Formulation development**
 - *Alloys*
 - *Light transmission*



Clean Compounding Morrisville, PA USA

Benefits of Americhem Healthcare Clean Compounding

- 62,000 ft² clean compounding facility
- 6 production line compounding capacity
- Dedicated medical application compounds
- ISO13485 positive pressure cGMP facility
- World- class customer design space
- Suzhou, China and Ribe, Denmark facilities expansions ongoing
- Capabilities highlighted in [video](#)



Biocompatible Healthcare Specialty Solutions



- **Color Expertise**
Small lot, pre-color, masterbatch, Gamma stable, UV stable
- **Impact / Chemical Resistance**
Inhouse testing
- **Electrical/ Thermal Conductive**
Conductive, shielding properties, anti-static, Radiopaque
- **Friction Reduction**
Lubricity, low COF
- **Structural / Reinforced / Warpage Control**
Glass and carbon fiber reinforcements
- **Antimicrobial**
compounds and masterbatch
- **Branded resins**



Healthcare Product Lines

ColorFast™	Custom Color Compounds & Alloys
ColorRx®	Biocompatible Compounds & Alloys
InStruc™	Structural Compounds
InLube™	Wear & Friction Compounds
InElec™	Electrically Active Compounds & Alloys
nShield™	Antimicrobial Masterbatch
nBalance™	Sustainable Masterbatch
Americhem	Color Masterbatch Technology



Services

- Compound Development
 - Fully Equipped Testing Labs
 - IQ / OQ / PQ Technical Molding Support
 - Fast Product Development & Prototyping
 - Customer Toll Processing
 - Customer Trials
 - R&D Sampling
- Material Selection Expertise
 - Color Design Expertise
 - Testing Capabilities
 - ✓ Biocompatibility
 - ✓ Chemical Resistance
 - ✓ UL Testing
 - ✓ Physical & Mechanical Testing
 - ✓ Analytical Testing





Supplier – Relationship Expectations

Application Requirements

- Temperature
 - Short term / Long Term
- Strength requirement (Loads / Forces)
 - Tensile Strength Elongation / Flexural / Impact
- Chemical exposure
- Sterilization / Autoclave
- Agency requirements –
 - FDA / ISO10993 Classification / USP
 - UL,EU,CSA

Americhem Healthcare Case Study

Single Use Surgical Tools

Vessel Sealing Component- Proximal End

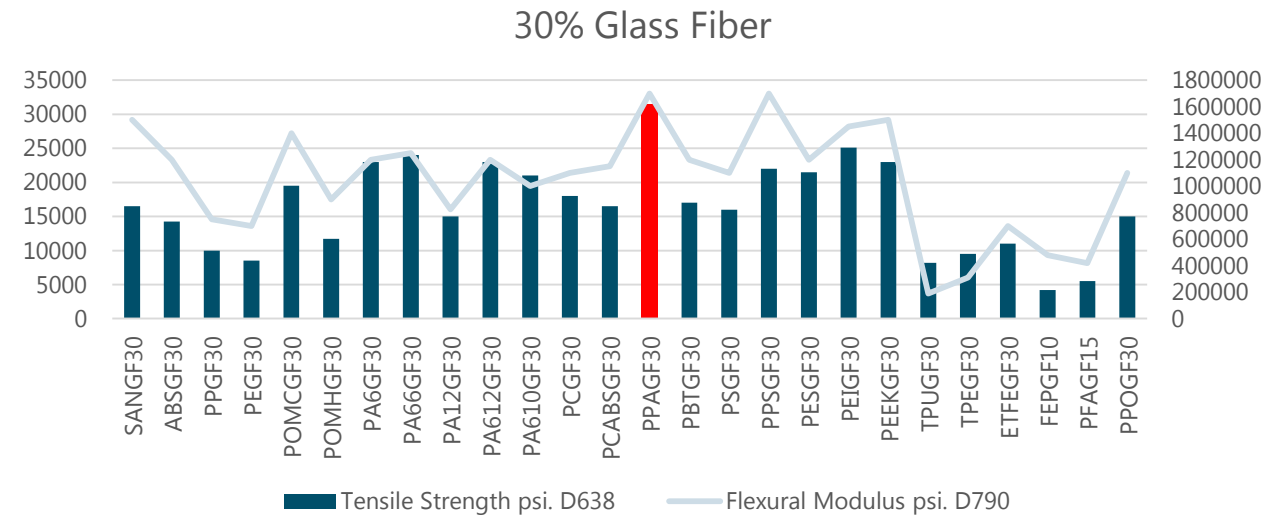
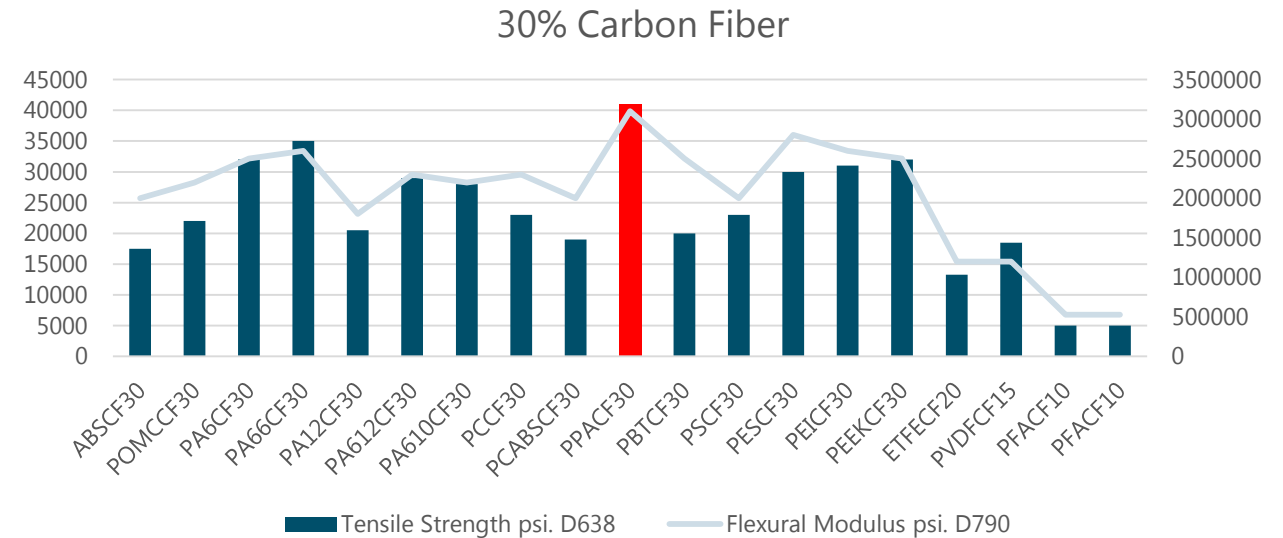
- InStruc™ PPAGF35MIN10HWMD Gray
 - Insert Molding
 - Tensile Strength
 - Dielectric Properties
 - Dimensional Control
 - Enhanced Flow Properties for thin wall

Laparoscopic internal components- Distal End

- InLube™ PPACF30TF15SI2MD
 - Structural strength
 - Excellent tribology wearing against itself

Thrust Washer Wear- 50 fpm - 40psi

MOVING	STATIONARY	Wear Factor (DYN)	Wear Factor (ST)	COF, Static	COF, Dynamic
PPACF30TF15	PPACF30TF15	16	10	0.21	0.23
PPAGF30TF13SI2	Steel	12	1	0.46	0.49
PPACF15TF15	Steel	15	0	0.50	0.50
PPAGF30TF15	Steel	18	1	0.52	0.59
PPATF10	Aluminum	8	0	0.05	0.18
PPATF20	Steel	22	0	0.27	0.36





Americhem Healthcare Case Study

Application Requirements

- Advanced Healthcare Instrument Pivot - Movement
 - Metal to Plastic conversion
 - Compression creep resistance and Tensile fatigue
 - Insert molding metal bearing shaft
 - Great long-term wear with multiple exposure to autoclaving at 134C
 - High chemical resistance



Our Solutions

- InLube™ PEEKCF40TF10
 - Over 60% weight reduction versus aluminum and steel
 - Highest mechanical strength at elevated temperatures
 - 4 million (+) psi Tensile & Flexural Modulus
 - High dimensional stability and CTE
 - Superior tribology at elevated temperatures
 - Low coefficient of friction providing accurate in movement
 - Decrease in coefficient of thermal expansion through temperature fluctuations
 - Diminishing expansion/contraction with mating metal parts and inserts



Thank You

