



*Connecting People, Science and Regulation*

# COC/COP Characteristics & Considerations

**Scott R. Smith**  
**VP Sales & Marketing**  
**Plas-Tech**  
**Engineering**  
**USA**



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# THE FUTURE IS NOW!

# PLASTICS

VIDEO CLIP



# CUSTOM SYRINGE



**COC C-09-5-1 CUSTOM SYRINGE**

[www.plastechengineering.com](http://www.plastechengineering.com)



# WHY ARE WE HERE?

- Custom injection molding contract manufacturing firm focused on medical device and pharmaceutical industry needs.
- We have designed, tooled and molded custom syringes for the pre-filled sector for over 12 years.
- We have been working with COC/COP design/tooling/processing for seven years.

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# MATERIAL SUPPLIERS

- COC (Cyclic Olefin Co-Polymer)
  - Supplier:



- COP (Cyclo Olefin Polymer)
  - Supplier:

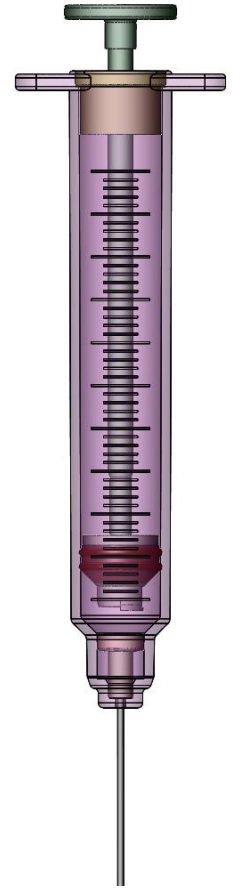


ZEON CHEMICALS



# SYSTEM APPLICATIONS

- Pre-Filled Syringes
- Auto-Injection Devices
- Lypholization Devices
- Diagnostic Devices
- Auto-Retractable Safety Syringes  
in a Pre-Filled Format





# GENERAL

- REGARDLESS OF MATERIAL & GRADE (COC/COP)
  - Low water absorption
  - Low protein absorption
  - High resistance to chemicals
  - Biocompatibility with drugs
  - High transparency
  - Less than half the weight of glass packaging (shipping \$)
  - No accidental breakage (glass shattering)
  - No surface delamination (glass flakes contamination)





# PROPERTY CHARACTERISTICS

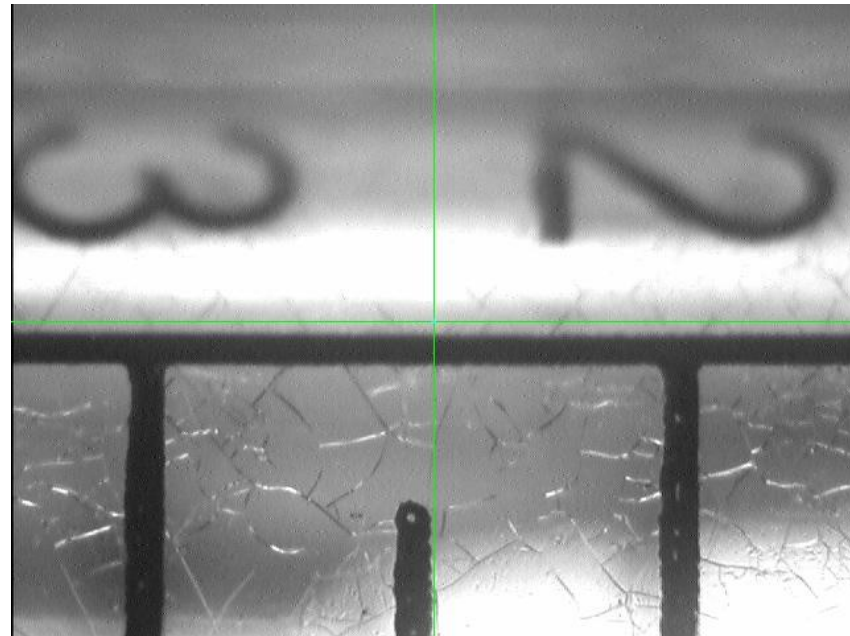
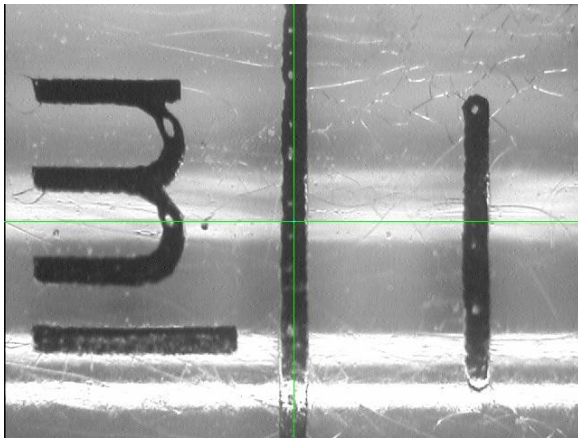
- Flexural Modulus

Mpa	MATERIAL	GRADE
2900	COC	6013S-04
2600	COC	8007S-04
2600	COP	790R
2380	PC	Medical
2200	COP	690R
2120	COC	C-09-5-1
2100	COP	1020R

EASIER  
PROCESSING  
AND  
MORE OPTIONS



- Mineral Oil will “craze” the barrel



- Lubricants
- Coatings
- Sterilization

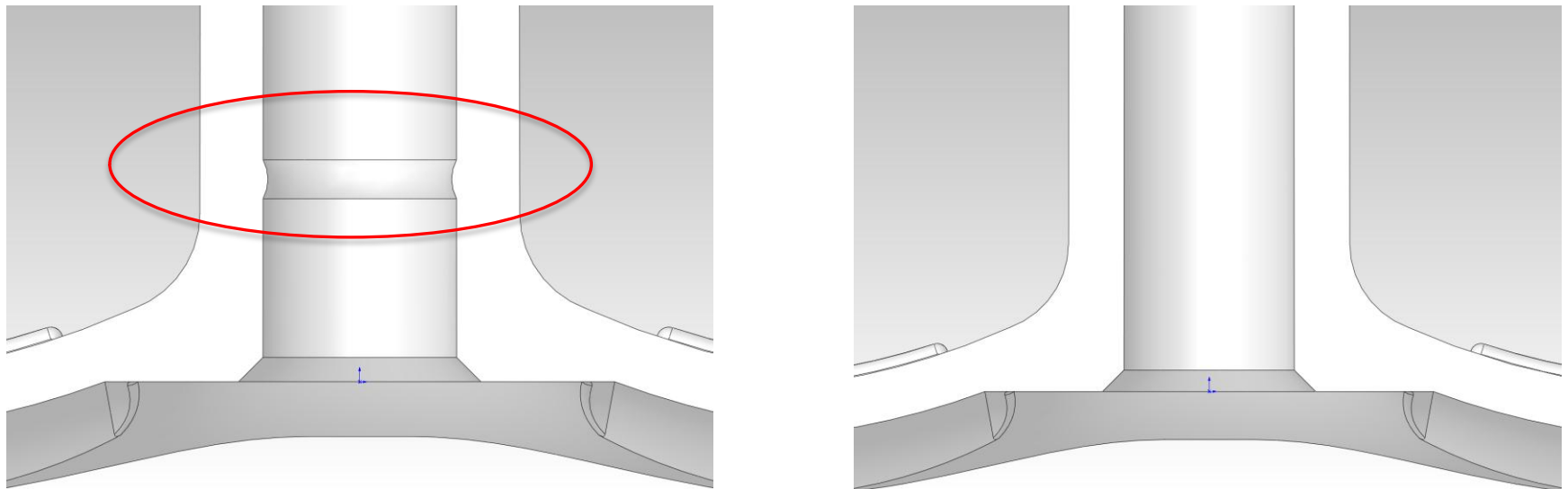


# LEACHING CHARACTERISTICS

- BPA FREE
- PLASTICIZER FREE  
(no phthalates in manufacturing of these resins)
- NO METALS (As would be the case with glass)



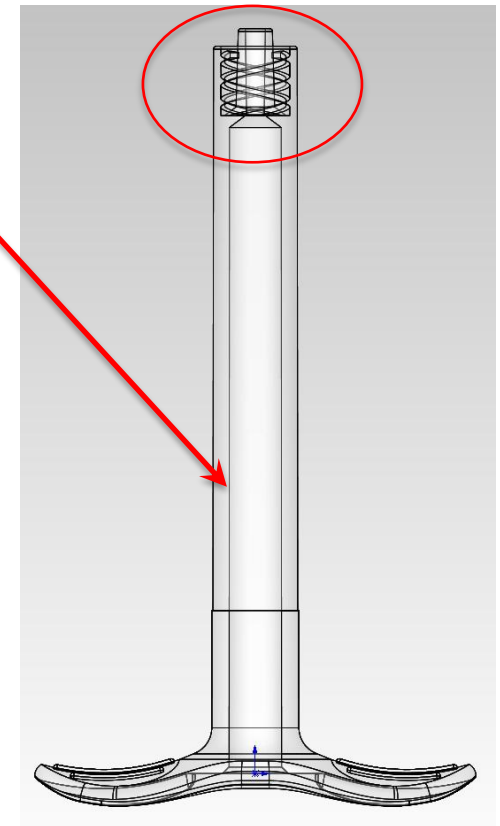
- DESIGN FEATURES
  - Controlled Syringe or Non-controlled Syringe



- Finger grip design options

- **TOOL DESIGN and PROCESSING**

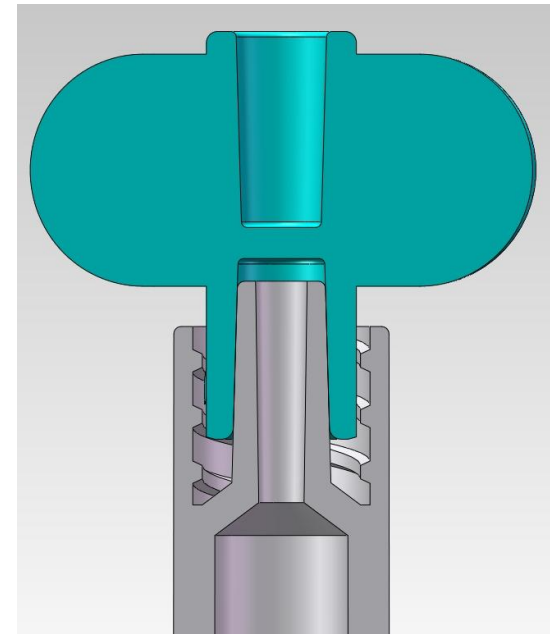
- Gating location is important
- Draft angle is important
  - No Draft May be Allowable
- Heating of mold (not cooling) is critical with these materials
- Leaving material idle in barrel



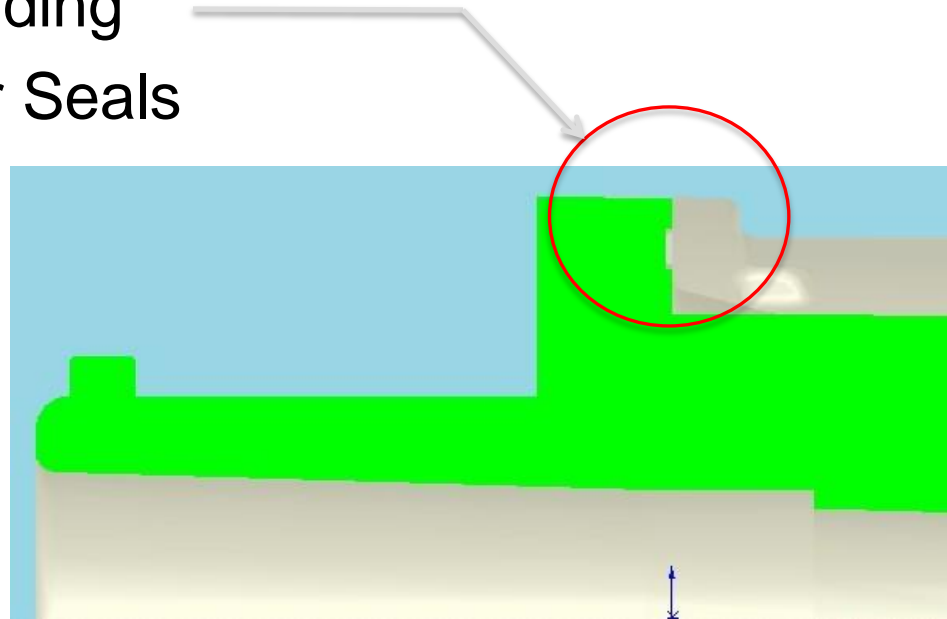


# ASSY CONSIDERATIONS

- ASSEMBLY REQUIREMENTS
  - Luer Lock Cap (w/torque specification)
    - Dissimilar flex modulus
    - Maintains packaging benefits
  - Push on Elastomer Cap
    - Chemical Compatibility
    - Sterilization Compatibility
    - Compromises Benefits
      - Elastomers are hydroscopic



- ASSEMBLY REQUIREMENTS
  - Hermetic Sealing
    - Sonic Welding
    - Elastomer Seals





# STERILIZATION

- **OPTIONS INCLUDE**

- Steam, ETO, EB, GAMMA
- H<sub>2</sub>O<sub>2</sub> (Hydrogen Peroxide)
- NO<sub>2</sub> (Nitrogen Dioxide)



- **CONSIDERATIONS**

- Material Discoloration
- Material Breakdown
- Residuals
- Barrel, Plunger Tip, Cap, Lubricant, Drug



# SUMMARY

- **TO GET IT RIGHT!**

- Commit to an experienced supplier early in the process.
- Design options are extensive as compared to traditional glass packaging.
- **Safety** at all stages of the product life cycle should be in your formal **GMP Risk Analysis** process.
- Plastic is the right solution when you calculate the **TOTAL COST OF OWNERSHIP.**



# PLASTICS IS THE FUTURE

## THANK YOU

- **PRESENTER**

**Plas-Tech Engineering, Inc.**

**875 Geneva Parkway N**

**Lake Geneva, WI 53147 USA**

**Scott R. Smith**

**[scotts@plastecheengineering.com](mailto:scotts@plastecheengineering.com)**

**262-745-1428 Mobile**

**AND THE FUTURE IS NOW!**