



# PEEK & Bioresorbable Molding Workshop



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MEDICAL TECHNOLOGIES

# Overview

**+34**

YEARS IN BUSINESS

**<4%**

EMPLOYEE TURNOVER

**2**

FACILITIES

**3**

ISO 7 (CLASS 10,000)  
CLEANROOMS

**+130**

EMPLOYEES

**+1000**

SUCCESSFUL PROJECTS

**+7000**

MOLDS BUILT

**13485**

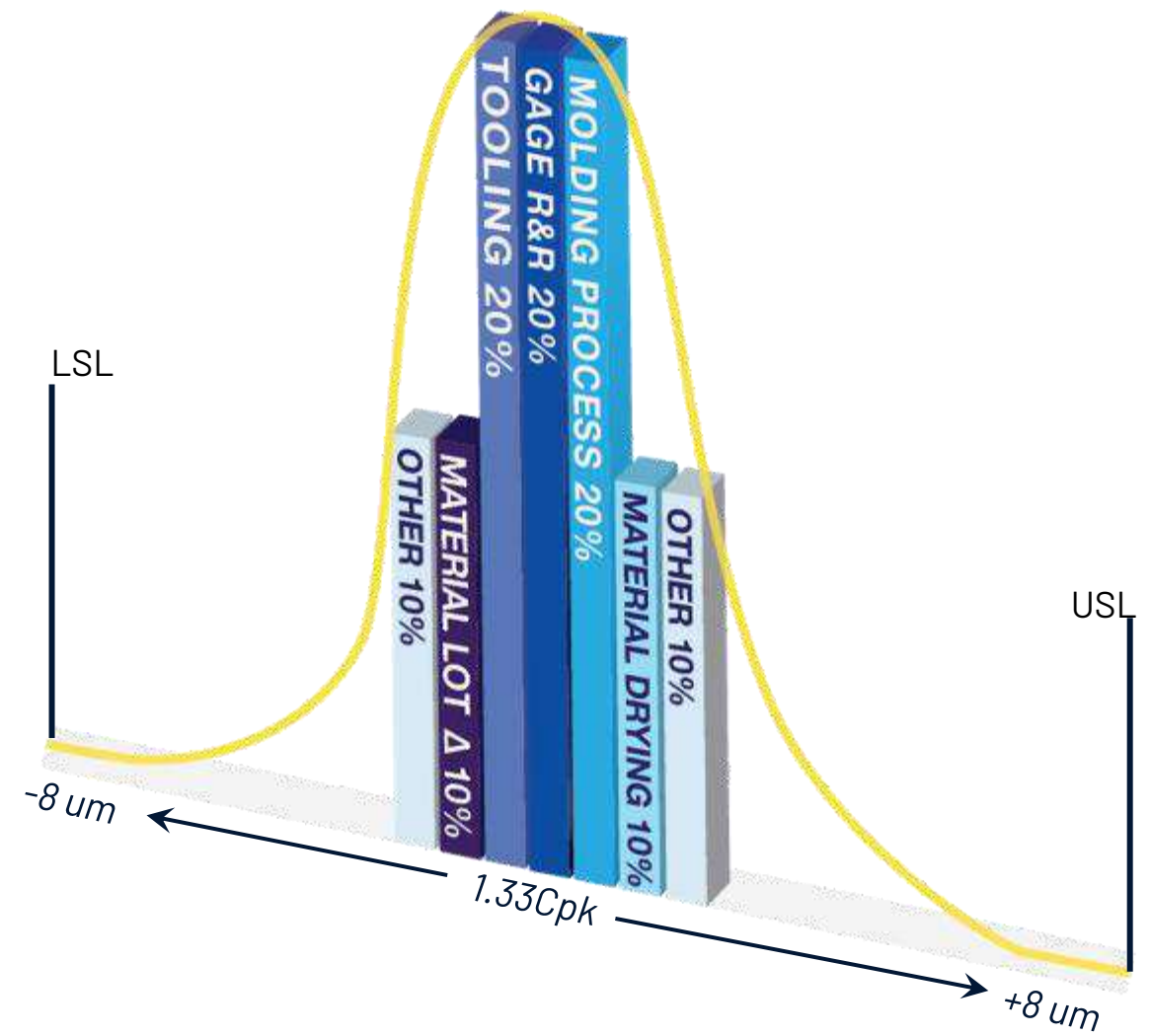
ISO CERTIFIED

# Factors That Affect the Quality of Molded Parts (Partial List)



# Key Factors That Affect the Quality of Molded Parts –

- Tooling <20%
- Micro Molding Process <20%
- Gage R&R <20%
- Material Lot-to-Lot <10%
- Material Drying <10%
- Other <20%



# Material Expertise

## - Internally Developed Resin Characterization

- Isometric created a Micro Molding Material Library of empirical resin data
- Thickness range from 0.001" - 0.015" (25-375 microns) at 0.200" in micro tensile bar length
- Gate Types: Pin, Edge
- Outputs:
  - Actual shrink (not estimated)
  - Gate style effectiveness to fill
  - Gate vestige with actual gate size/material
  - Thin wall molding test prior to mold building

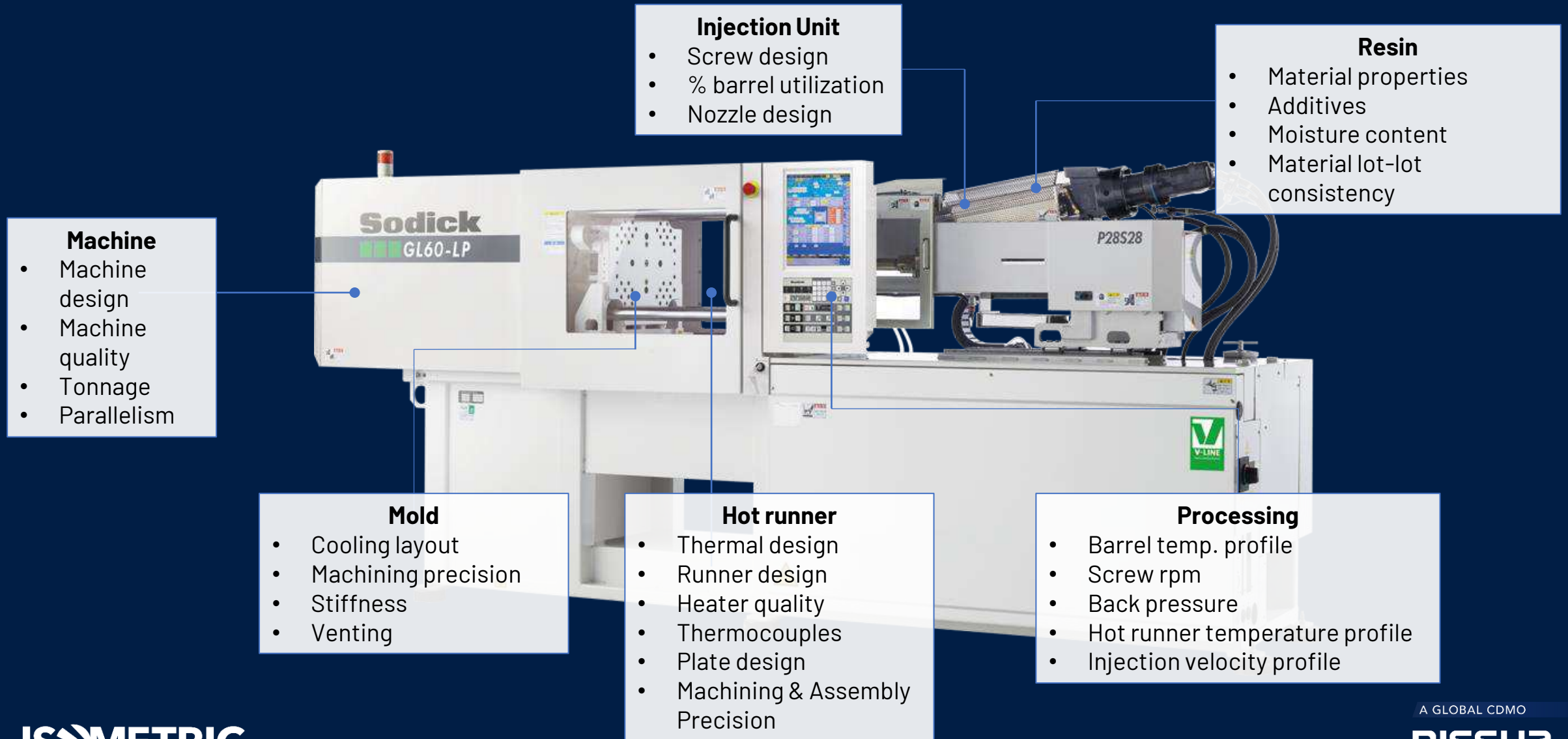


# Precision Tooling

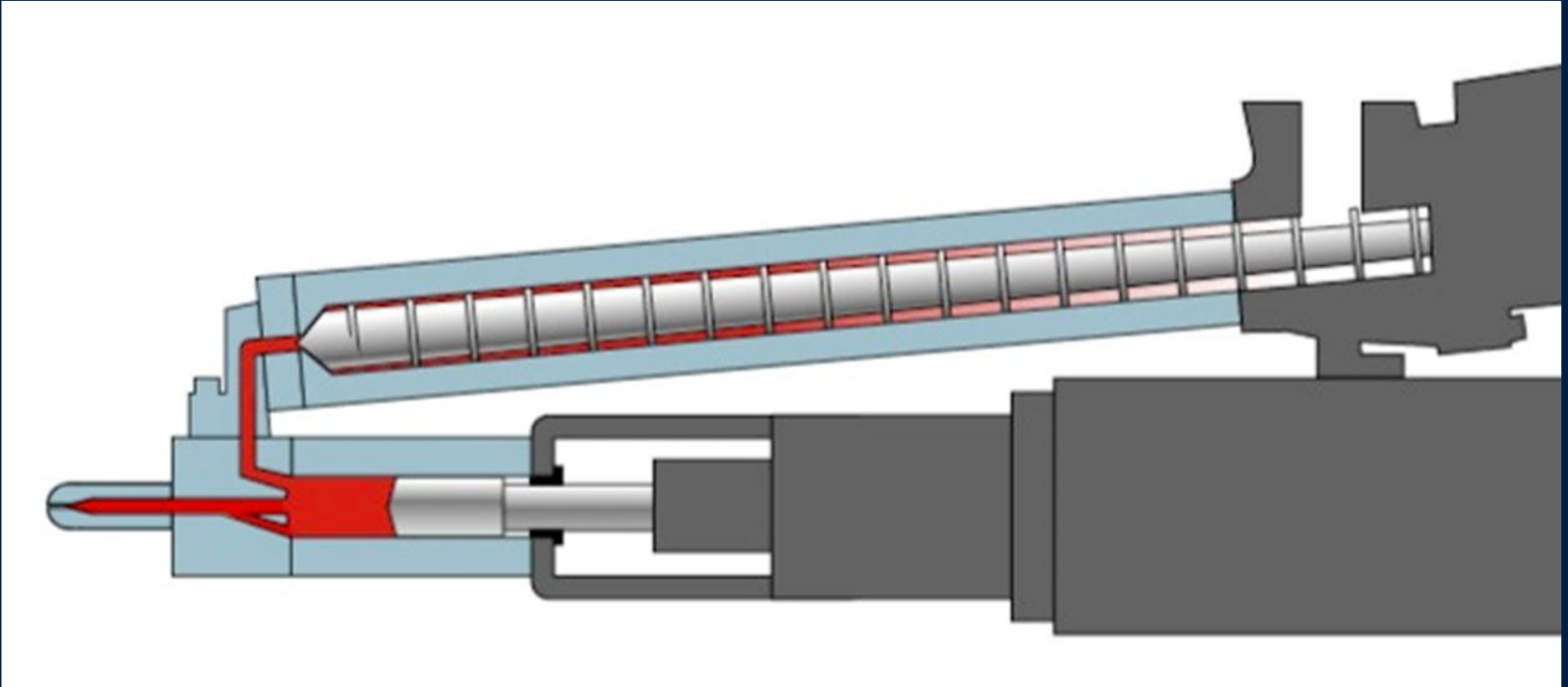
- +/- 1 micron precision or lower
- Surface finish critical to success – A2 capable
- Scalability
- Expertise in hardened steel combinations
- Development, single cavity, multi-cavity, 2-shot, insert and overmold tooling
- Precision threads/gears
- Core pin diameters less than 0.002" (50 microns)
- Venting capable at 0.0001-0.0002" (3-4 microns)
- Feature sizes of 0.0001" (3 microns)
- Ejector pins to 0.003" (75 microns)



# Precision Molding



# Decoupled Plastication & Injection – Sodick





# Fast Response Time – Sodick

Injection Step Response Comparison

	LDDV	LSV	Electric Injection Machine
Drive System	Double Linear Motor Direct	Linear Motor + Pilot Valve	AC Servo + Pulley & Belt
			AC Servo + Ball Screw Drive
Step Response(ms)	<b>2~3</b>	<b>15~20</b>	<b>25~40</b>
NC Loop Control (micro second)	<b>50(0.05ms)</b>	<b>50(0.05ms)</b>	<b>62.5-100 (0.062-0.1ms)</b>



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A NISSHA MEDICAL TECHNOLOGIES COMPANY

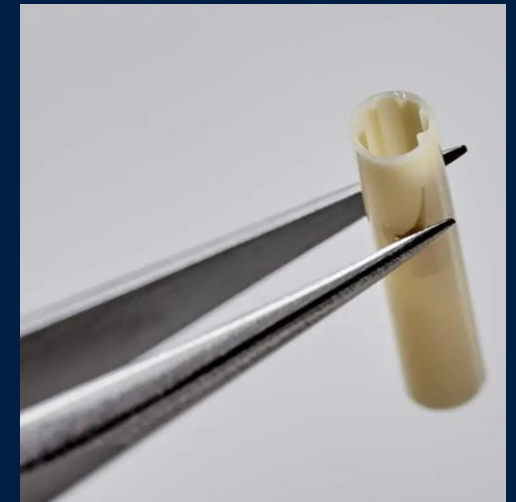
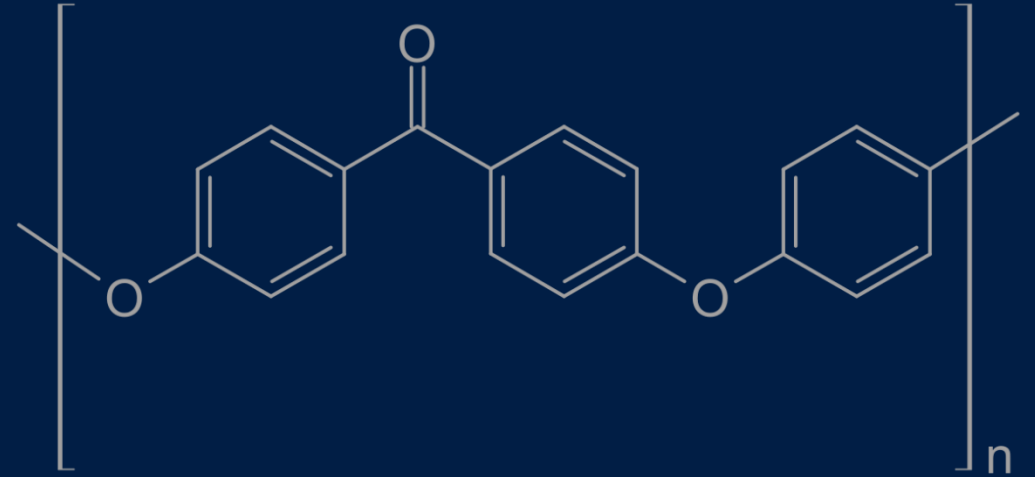
# PEEK Molding

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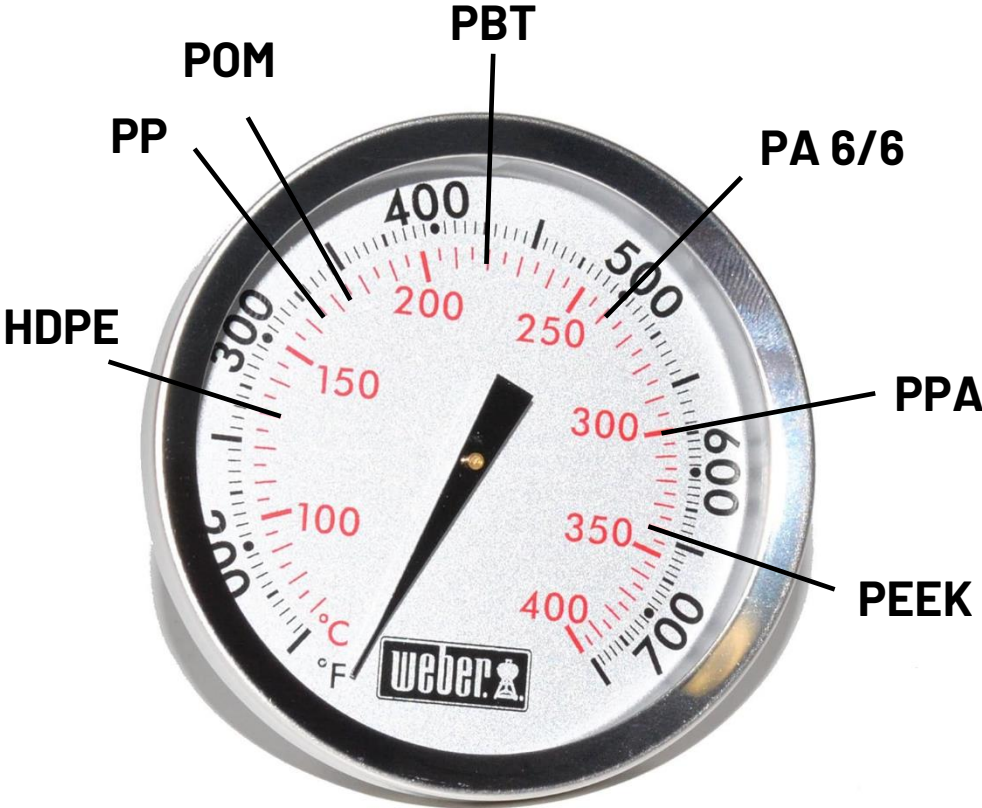
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# Challenges with PEEK

- High Melting Point
- High Viscosity
- High Melt and Mold Temperatures
- Semi-Crystalline Material
- % Crystallinity
- Fillers/Additives



# Challenges with PEEK – High Melting Point



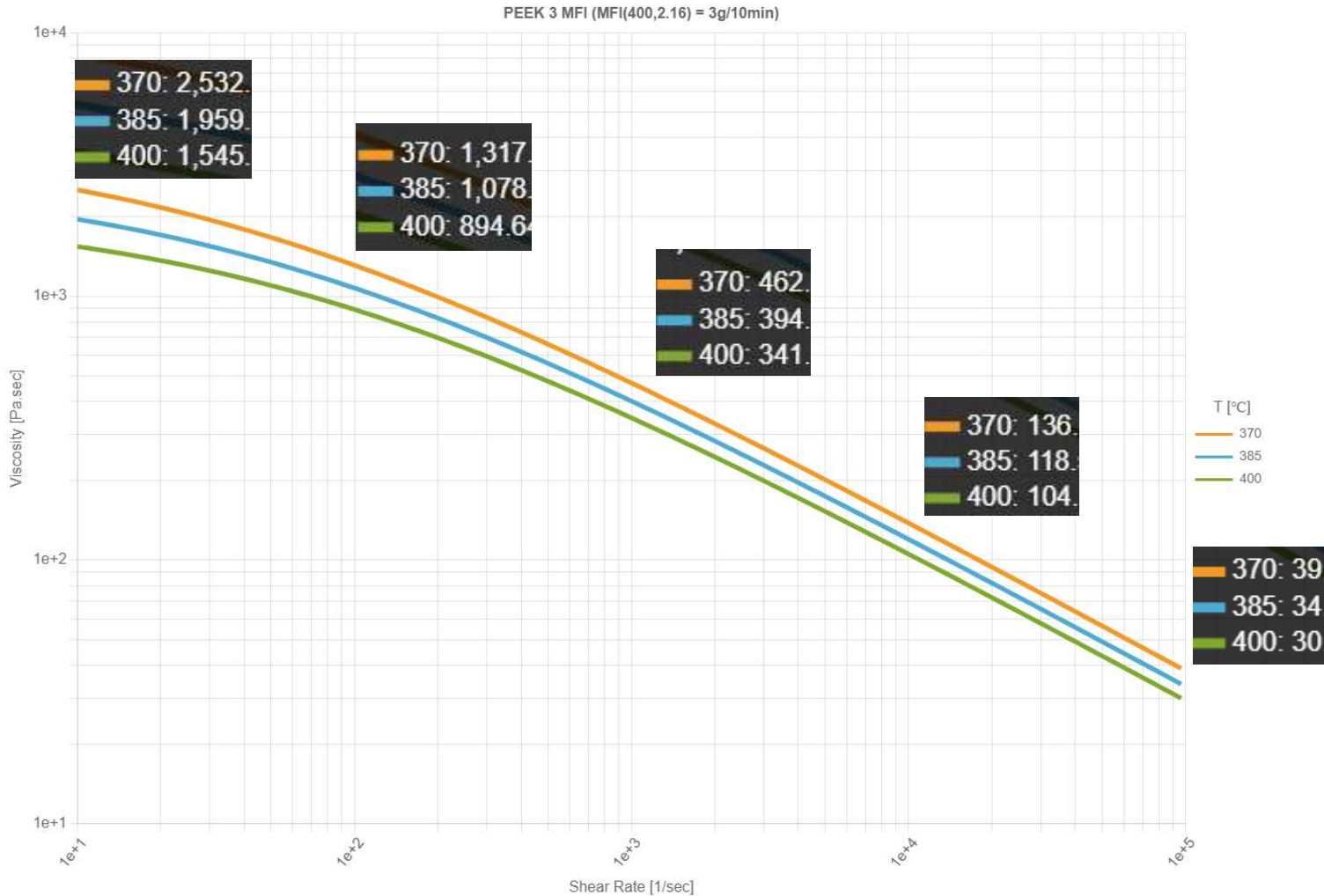
# Approximate Viscosities of Common Materials

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<b>Material</b>	<b>Viscosity @ 70°F Pa.s</b>
Water	0.001
Milk	0.003
SAE 40 Motor Oil	0.67
Castrol Oil	1
Honey	10
Chocolate	25
Ketchup	50
Mustard	70
Sour Cream	100
Peanut Butter	250

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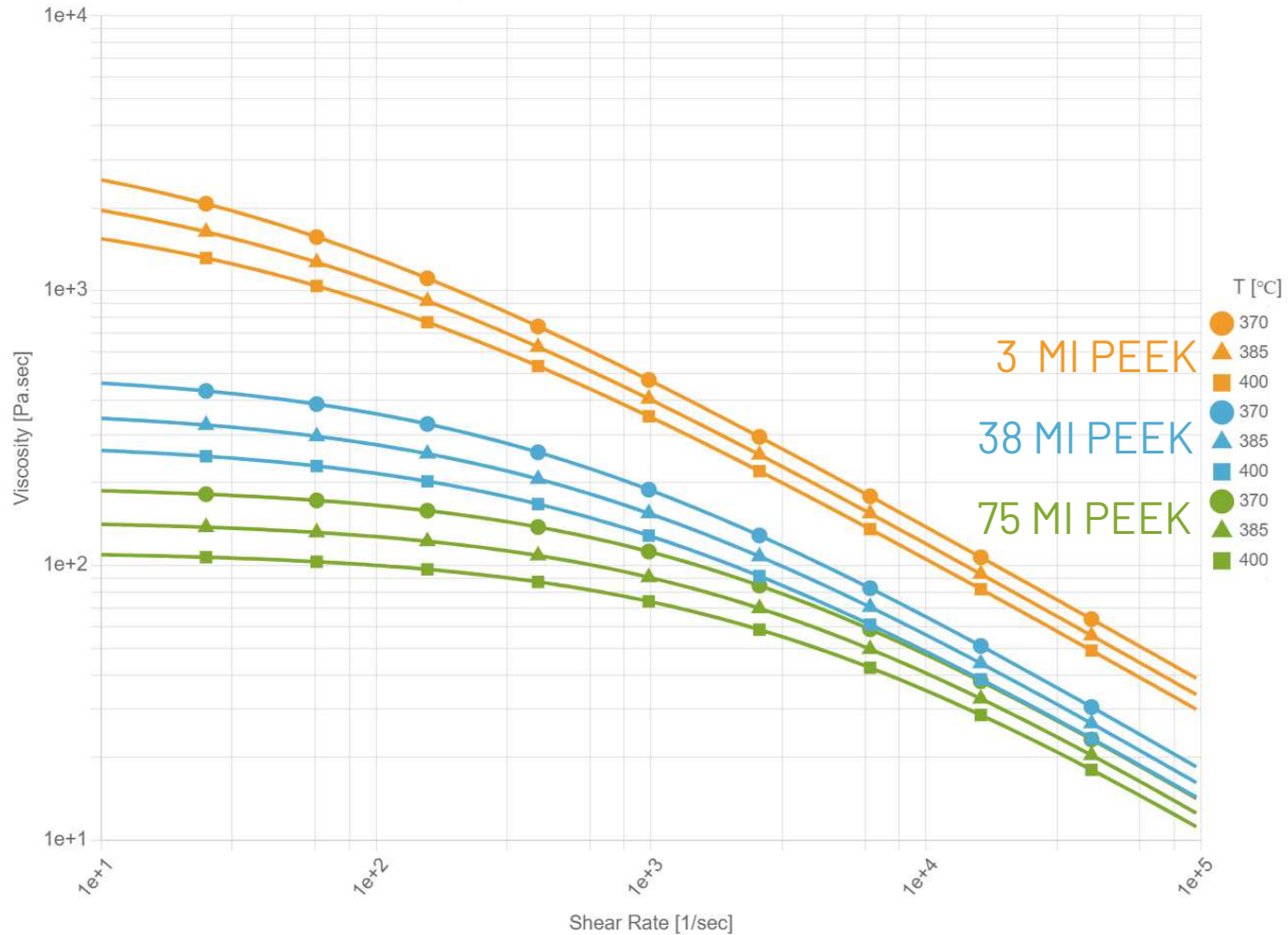
# Challenges with PEEK – High Viscosity



Viscosity of 3 MFI PEEK at 400 °C

Shear rate 1/s	Viscosity Pa.s
10	1,545
100	895
1,000	341
10,000	104
100,000	30

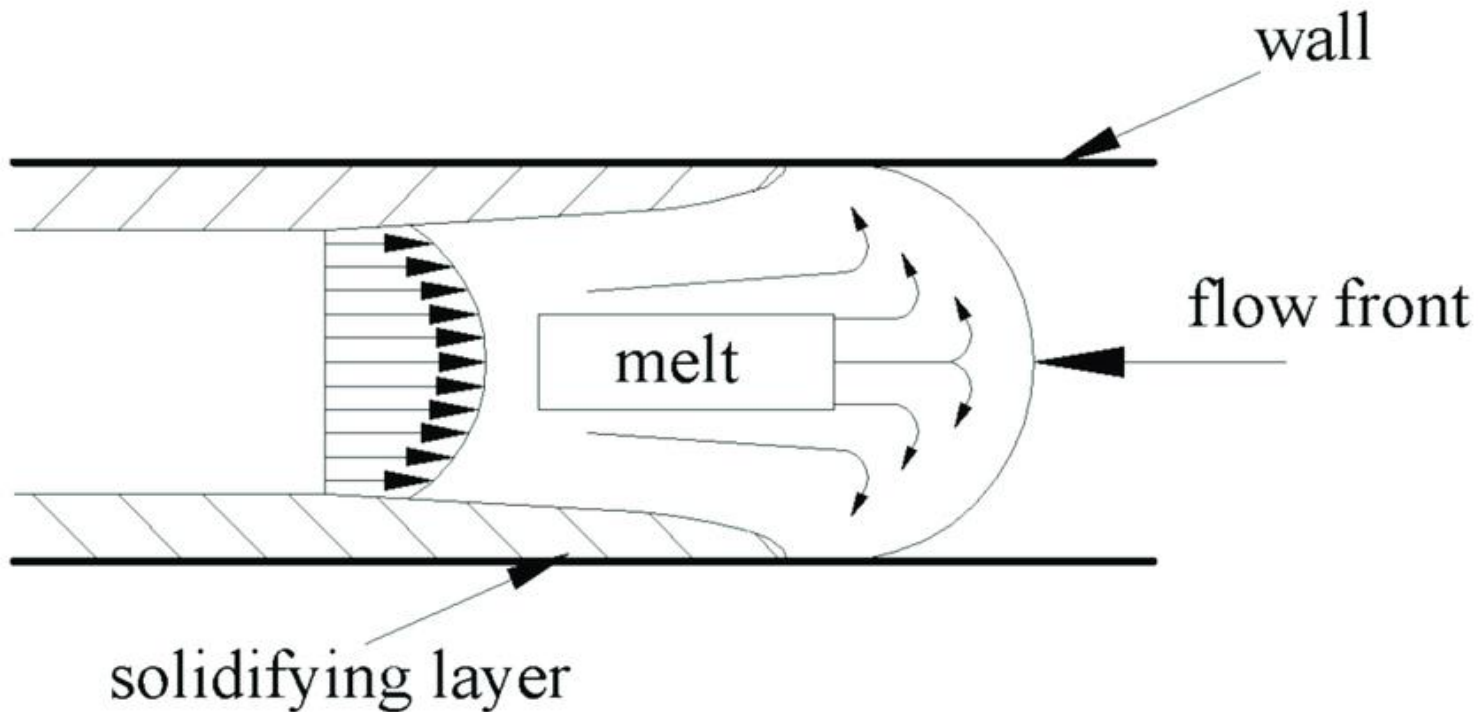
# Challenges with PEEK – High Viscosity



Viscosity @1000s<sup>-1</sup>, 400 °C

Material	Viscosity Pa.s
3 MFI PEEK	357
38 MFI PEEK	130
75MFI PEEK	74

# Challenges with PEEK – High Pressure Drop



$$\Delta P_r = \frac{8 \cdot Q \cdot \eta \cdot L}{\pi R^4}$$

Where,

$\Delta P_r$  - pressure drop in a round channel

$Q$  - Volumetric flow rate

$\eta$  - Viscosity

$L$  - length of channel

$R$  - radius of channel



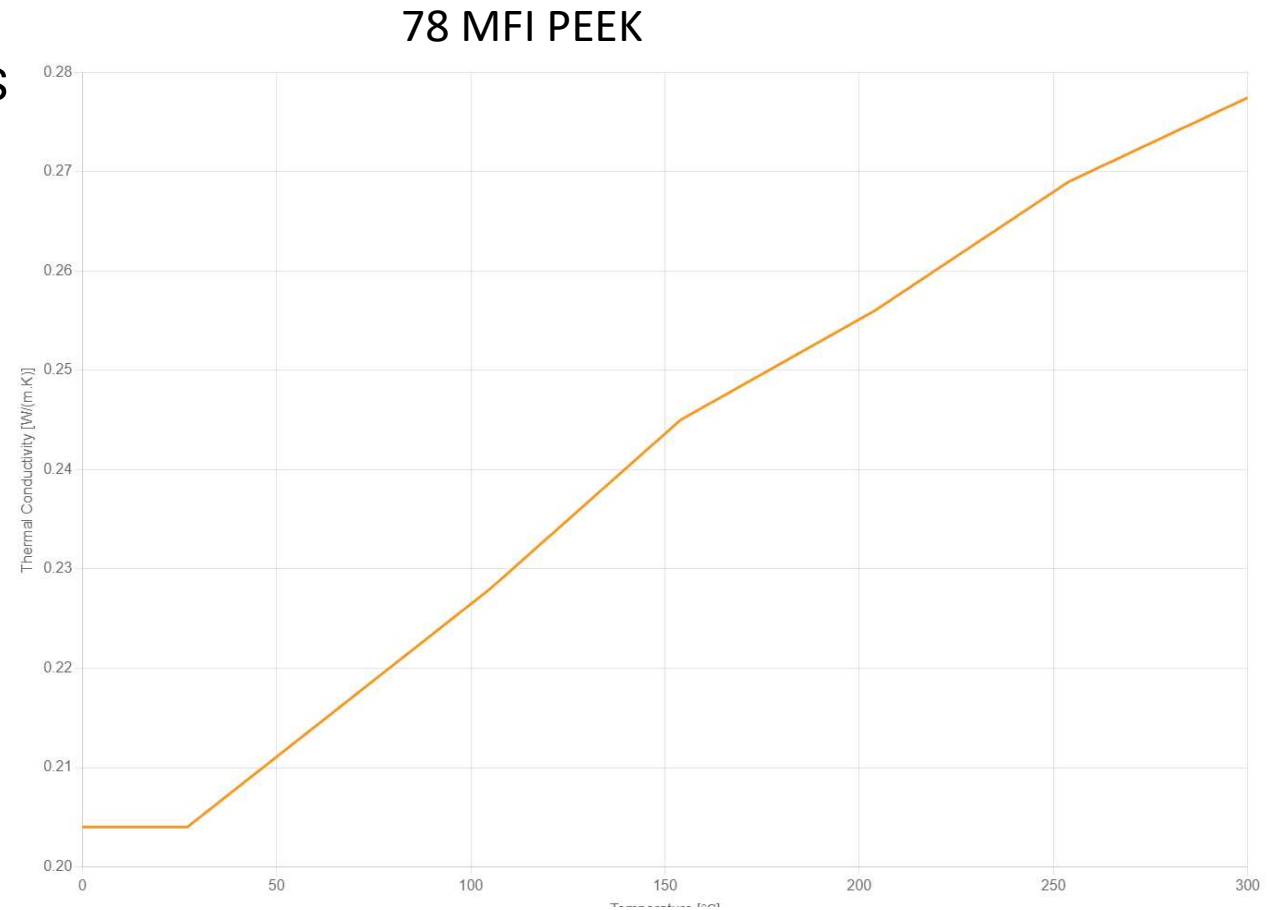
# Challenges with PEEK - High Melt & Mold Temps

VESTAKEEP*	Tool temperature [°C]	Die [°C]	Zone 3 [°C]	Zone 2 [°C]	Zone 1 [°C]	Hopper [°C]
1000 G	160 - 200	380	370	360	350	40 - 100
1000 CF 30	160 - 210	390	380	4/160	360	40 - 100
1000 CF 40	160 - 210	390	380	4/160	360	40 - 100
2000 G	160 - 200	380	370	4/160	350	40 - 100
2000 GF 30	160 - 200	380	370	4/160	350	40 - 100
2000 FC 30*	160 - 200	380	370	4/160	350	40 - 100
2000 CF 30	160 - 210	390	380	4/160	360	40 - 100
2000 CF 40	160 - 210	390	380	4/160	360	40 - 100
3300 G	160 - 200	390	380	4/160	360	40 - 100
4000G	160 - 200	390	380	4/160	360	40 - 100
4000 GF30	160 - 200	400	385	4/160	360	40 - 100
4000 FC 30*	160 - 200	380	370	4/160	350	40 - 100
4000 CF 30	160 - 210	400	385	4/160	360	40 - 100
4000 CC 20 (TiO2)	160 - 200	400	385	4/160	360	40 - 100
Ultimate	160 - 210	390	380	4/160	360	40 - 100

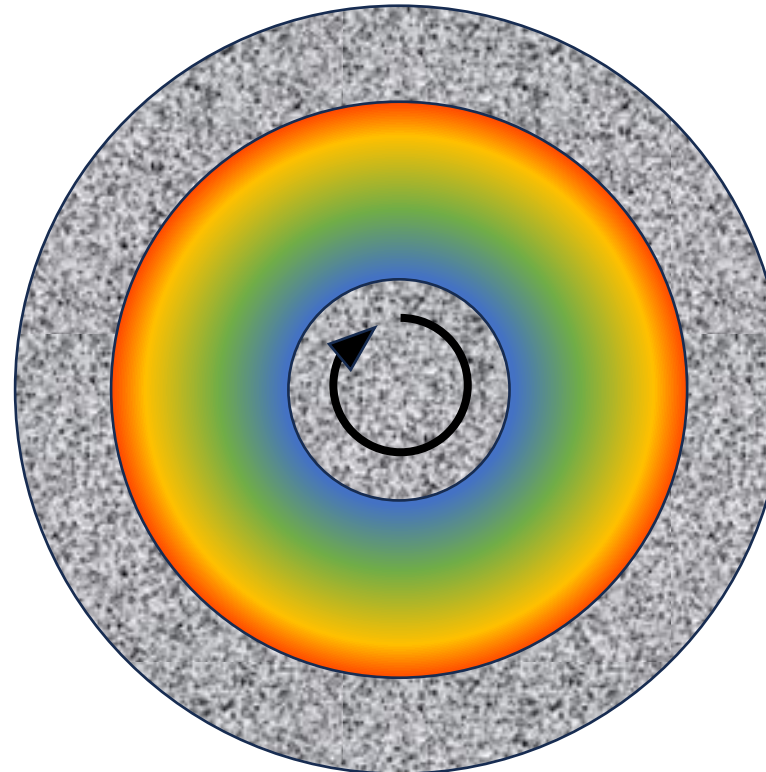
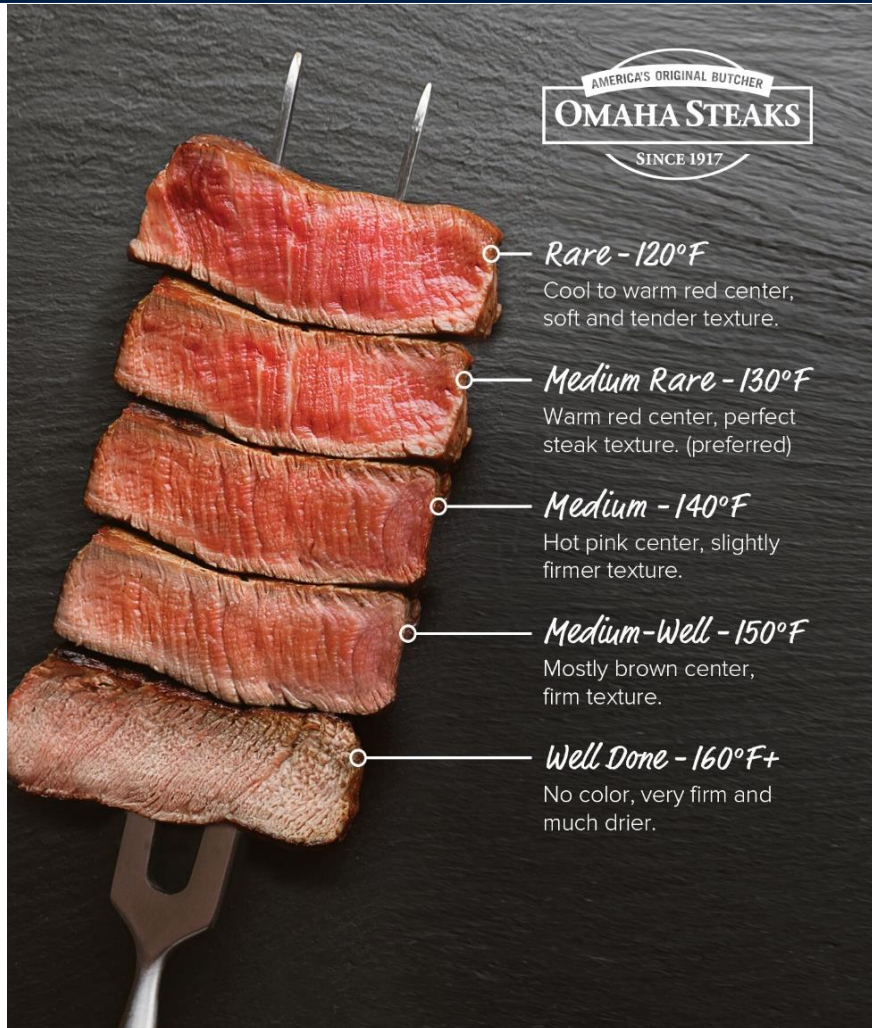
# Challenges with PEEK – Low Thermal Conductivity

## Thermal Conductivity of Different Materials

- Copper: ~390-400 W/m·K
- Aluminum: ~205-235 W/m·K
- Stainless Steel: ~14-20 W/m·K
- Steak: ~0.49 W/m·K
- PEEK: ~0.25 W/m·K
- PC: ~0.19-0.22 W/m·K
- PP : ~0.15-0.22 W/m·K
- Air: ~0.024-0.03 W/m·K



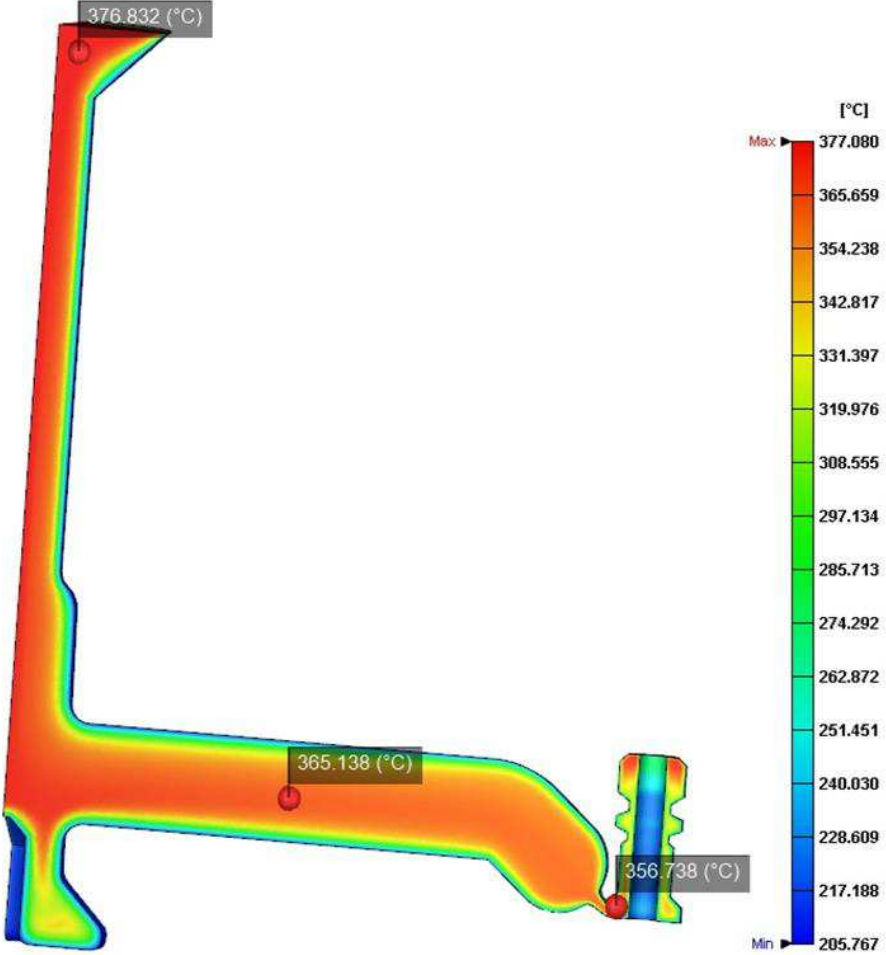
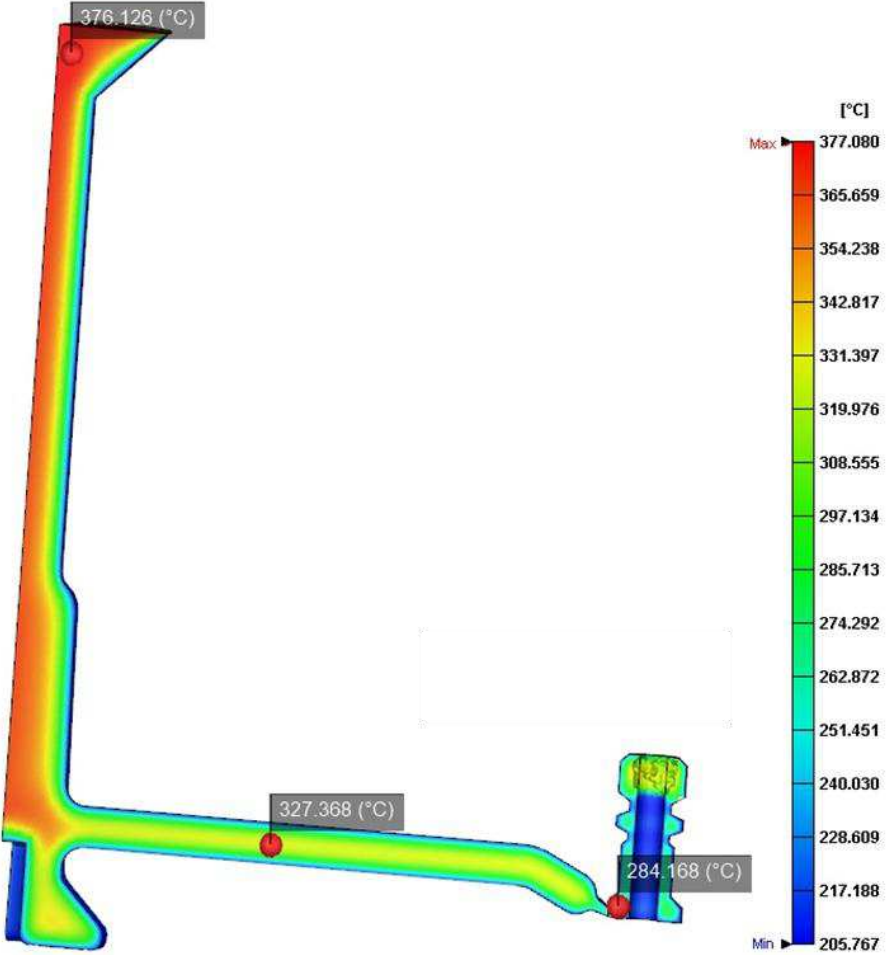
# Challenges with PEEK – Low Thermal Conductivity



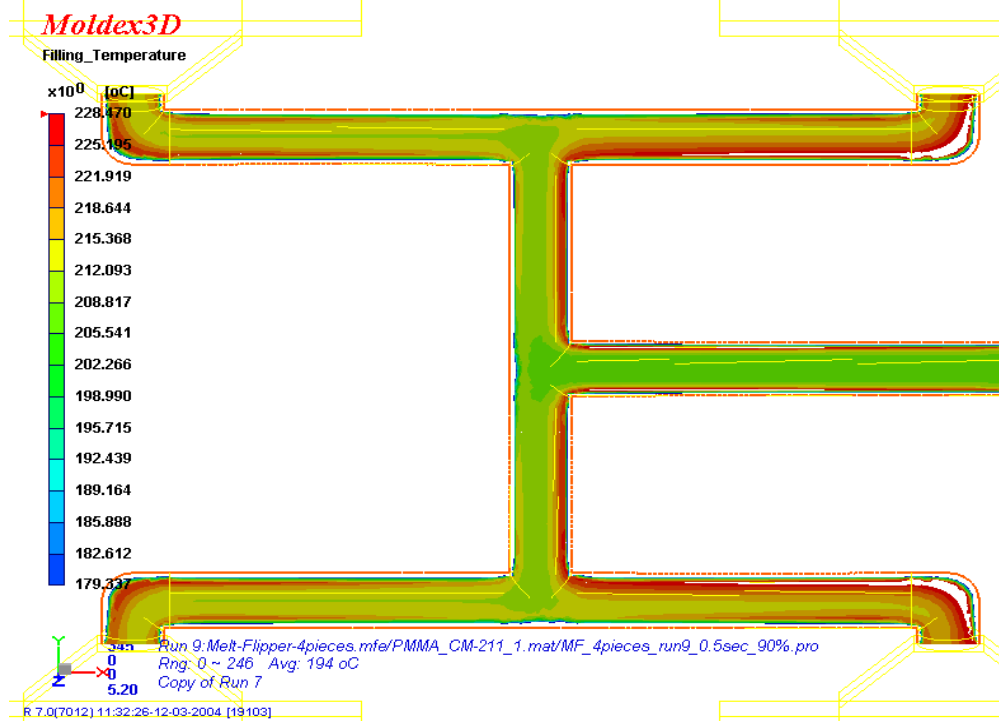
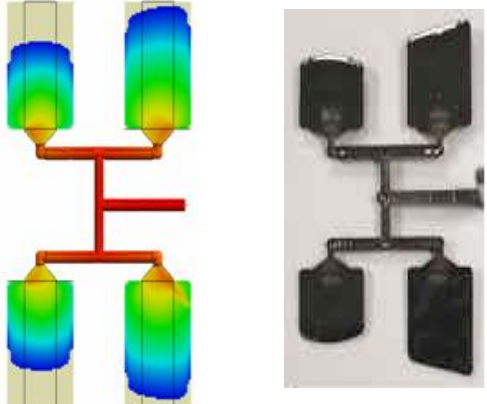
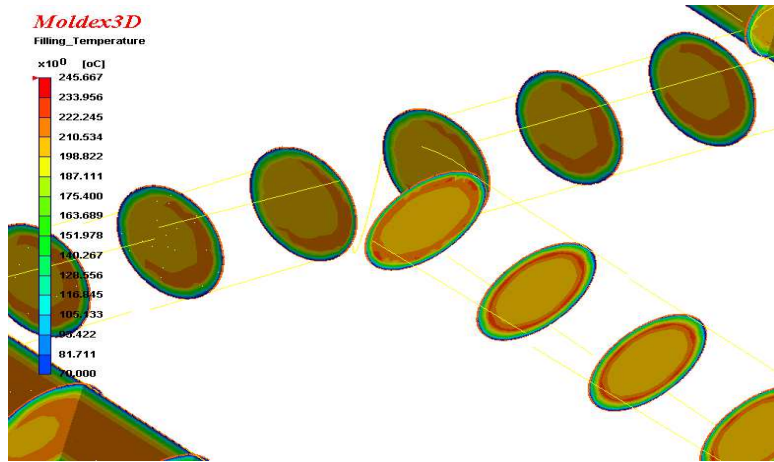
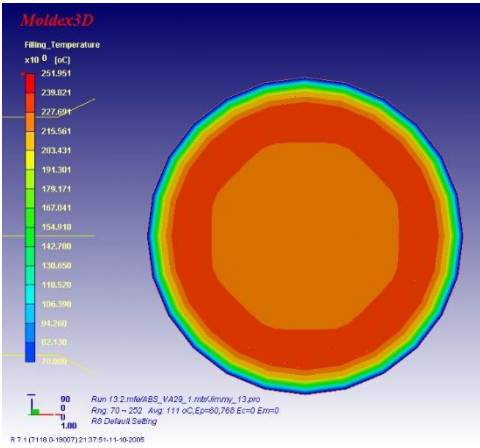
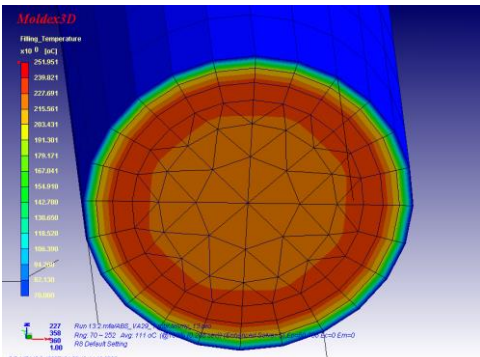
Melt Temperature Profile Depends on:

- Barrel temperature profile
- Screw design
- Material viscosity
- Screw RPM
- Back Pressure
- Cycle Time

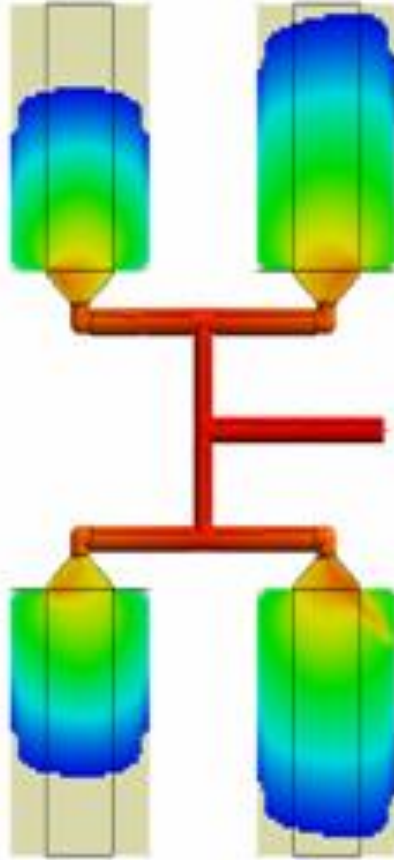
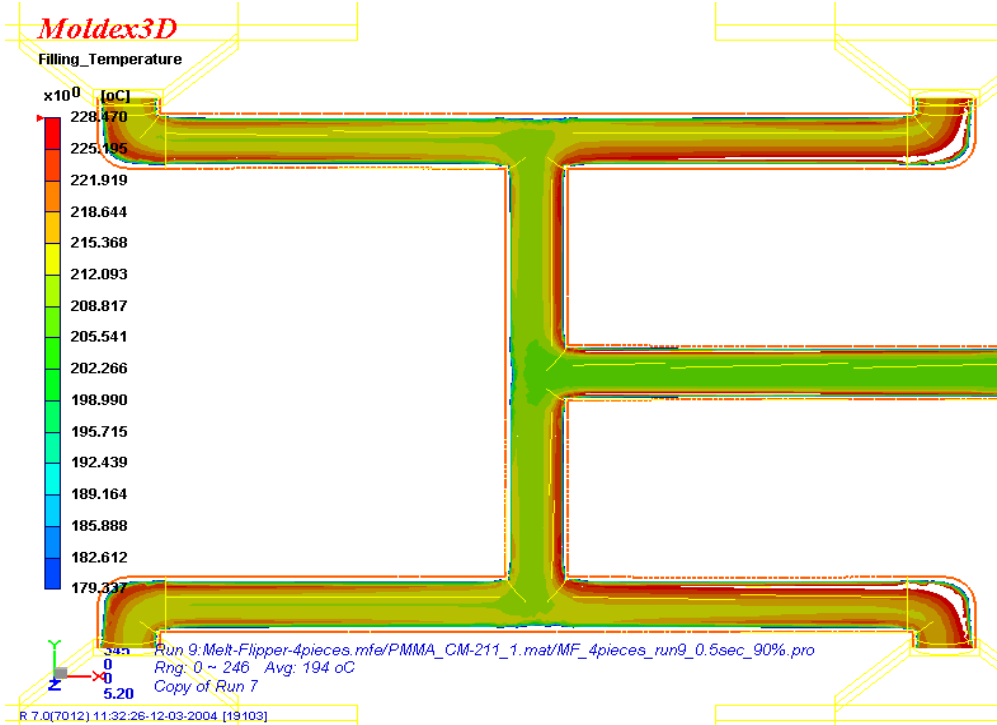
# Challenges with PEEK – Runner Sizing



# Challenges with PEEK – Filling Imbalance

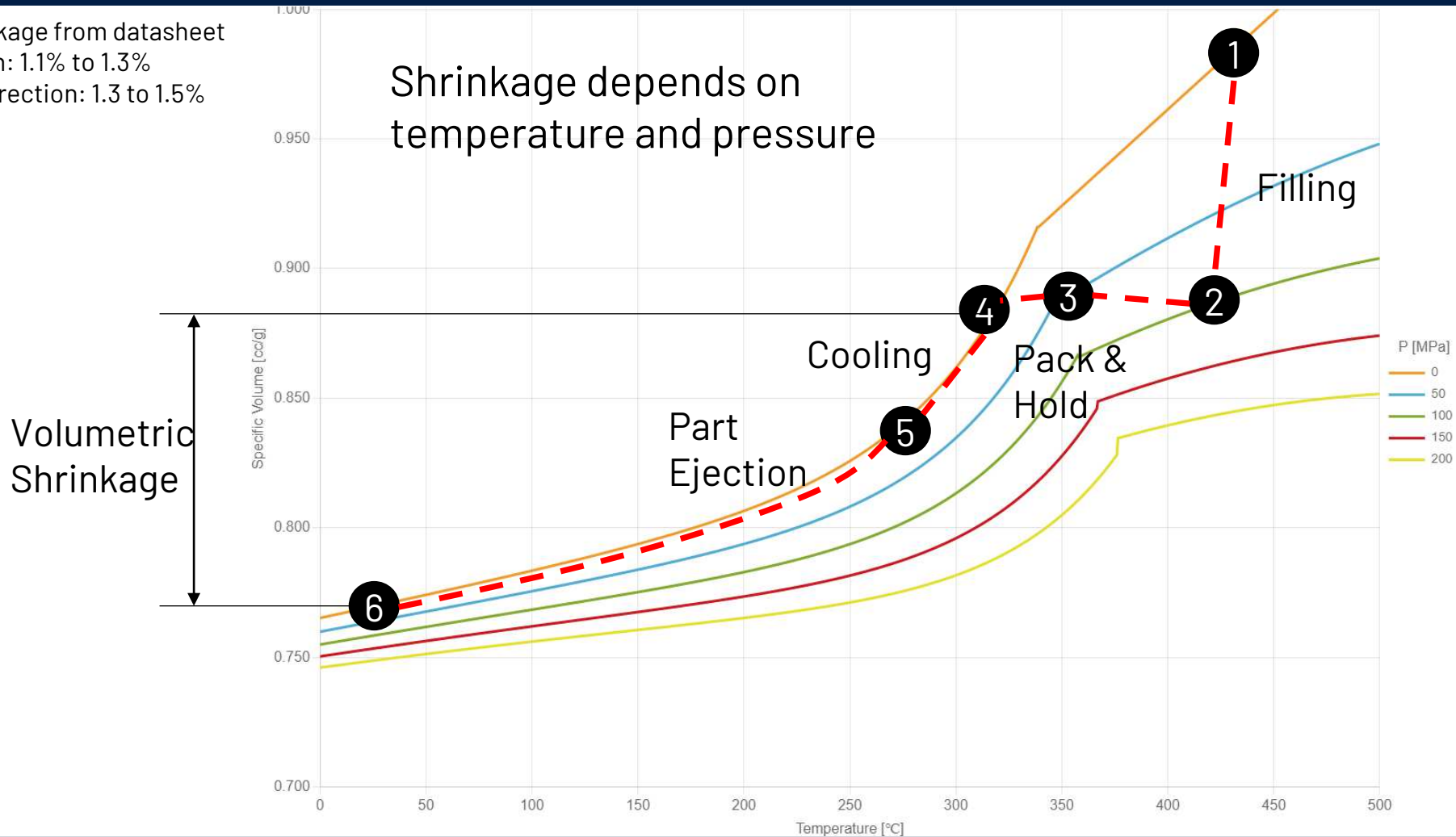


# Challenges with PEEK – Filling Imbalance

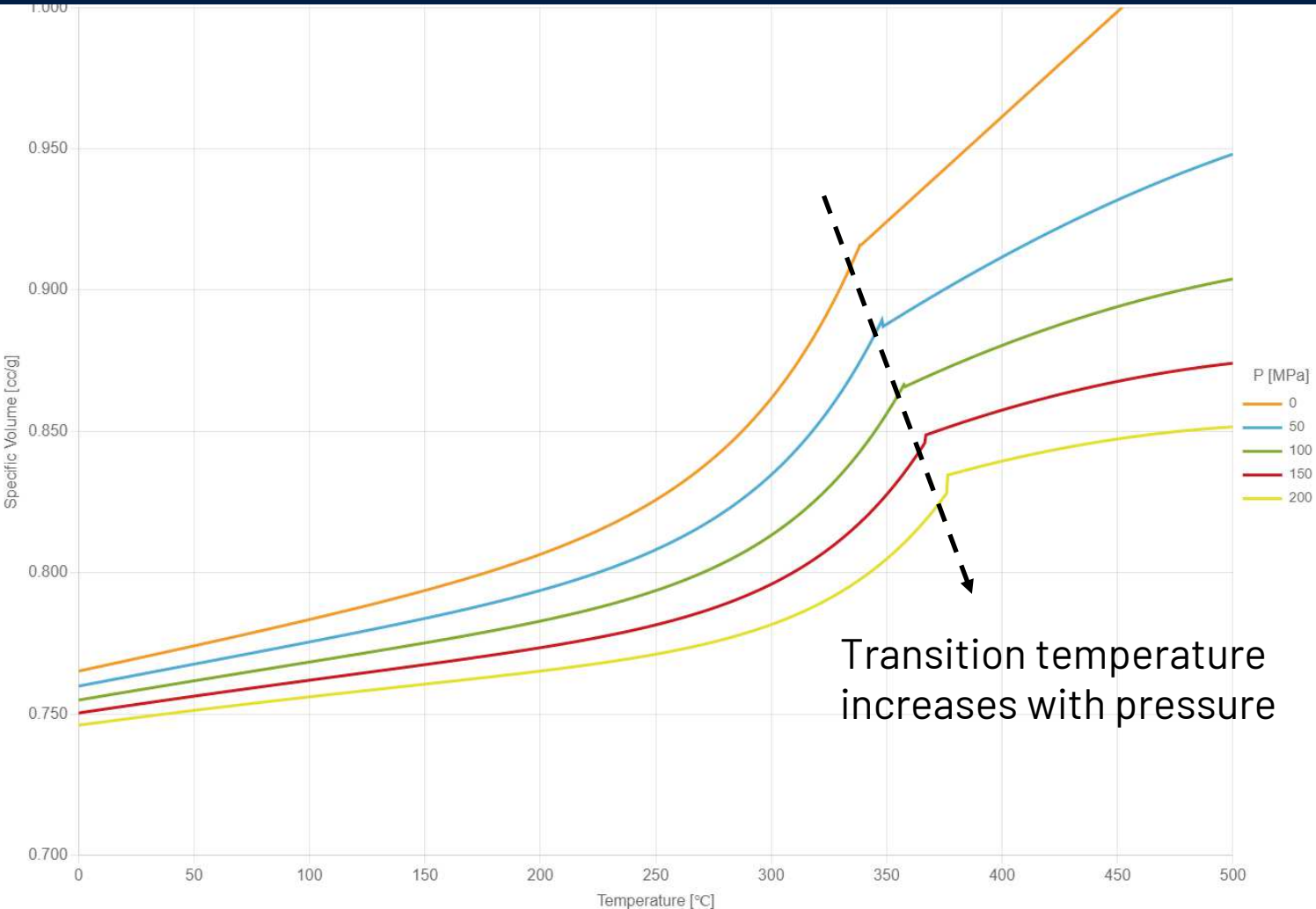


# Challenges with PEEK – Shrinkage

Molding Shrinkage from datasheet  
Flow Direction: 1.1% to 1.3%  
Transverse Direction: 1.3 to 1.5%



# Challenges with PEEK – Transition Temperature



Transition temperature increases with pressure



# Challenges with PEEK – % Crystallinity

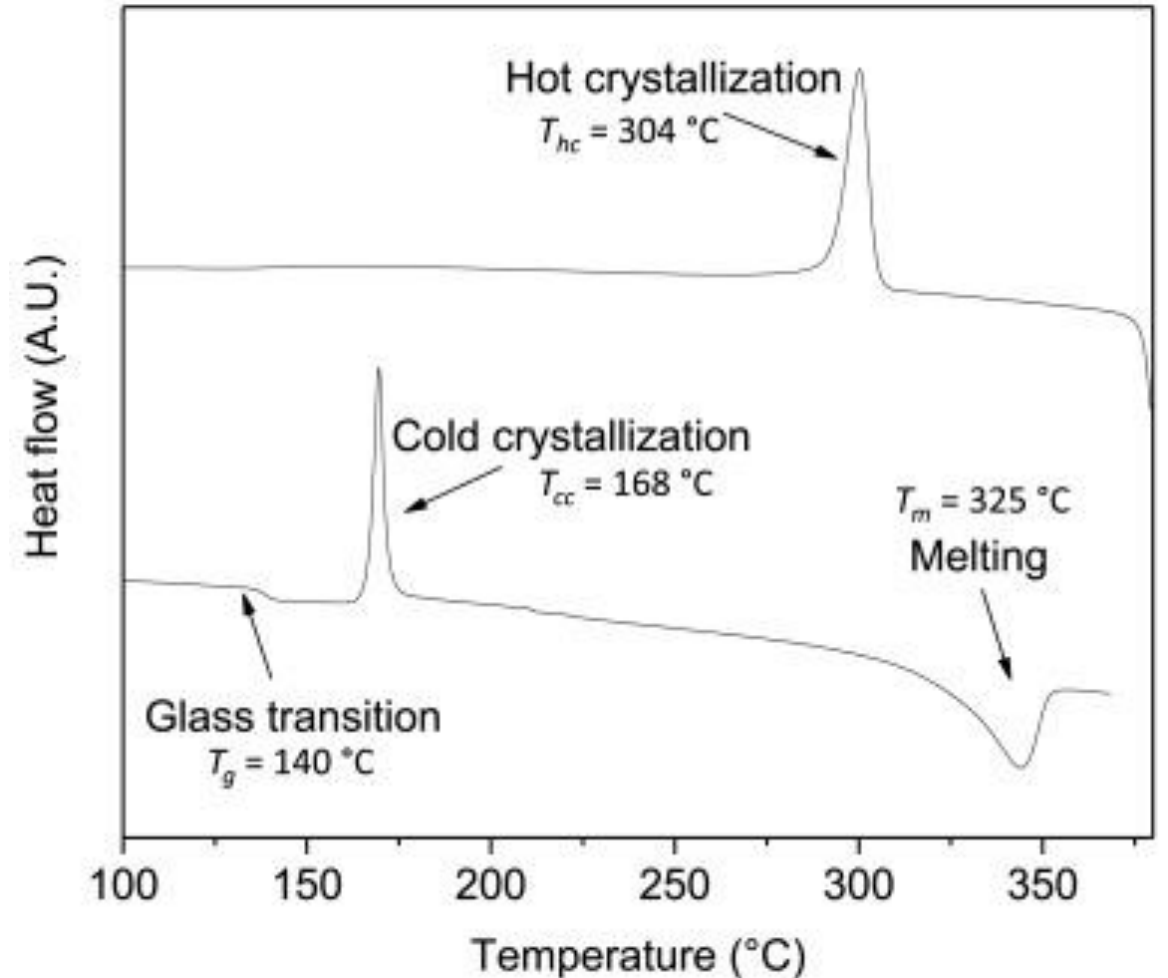
The percent crystallinity is directly related to many of the key properties exhibited by a semi-crystalline polymer including:

- Brittleness
- Toughness
- Stiffness or modulus
- Optical clarity
- Creep or cold flow
- Long term stability
- Barrier resistance (ability to prevent gas transfer in or out)

The percent crystallinity is determined using the following equation:

$$\% \text{ Crystallinity} = \frac{\Delta H_m - \Delta H_c}{\Delta H_m} \times 100 \%$$

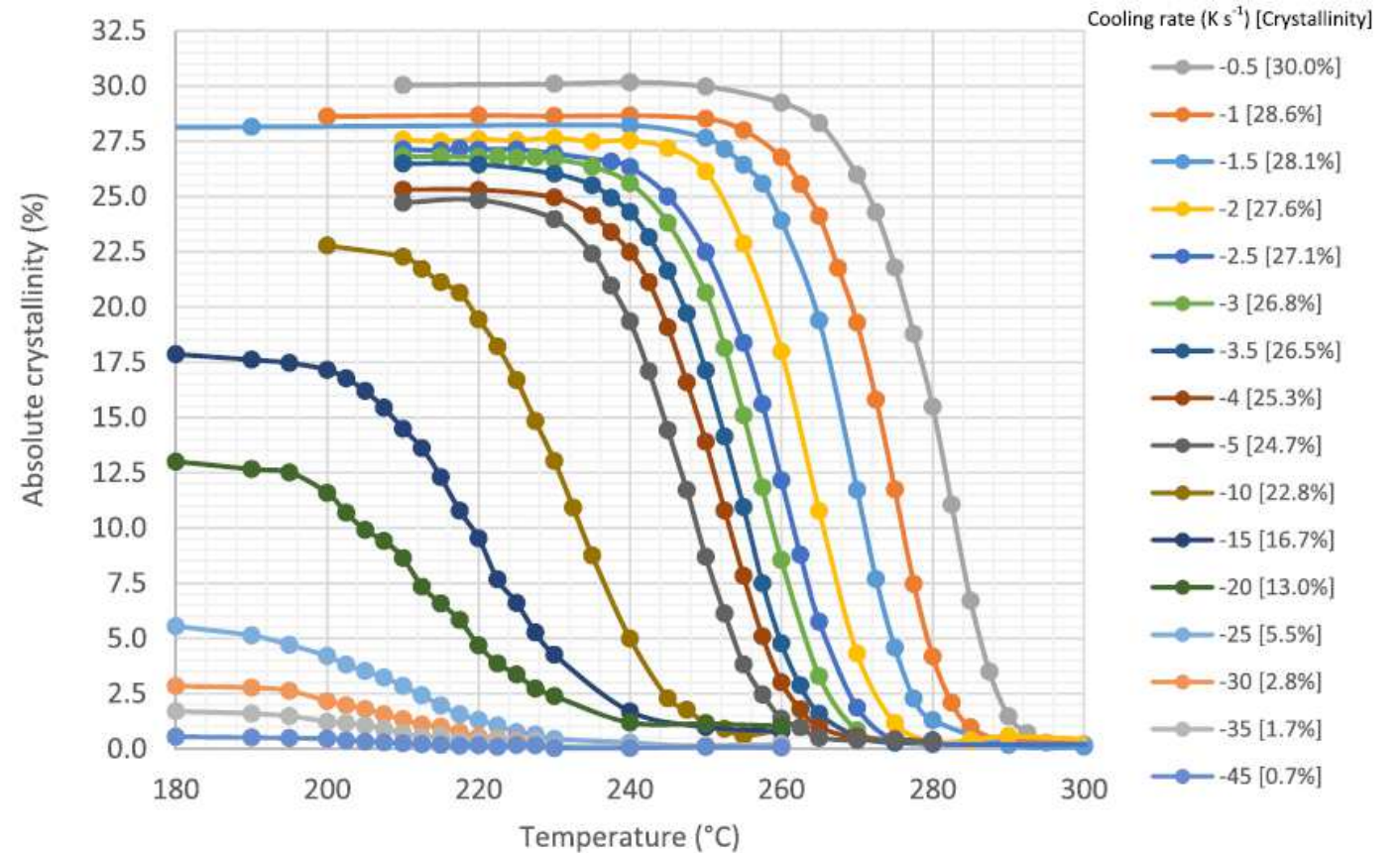
The heats of melting,  $\Delta H_m$ , and cold crystallization,  $\Delta H_c$ , are determined by integrating the areas (J/g) under the peaks.



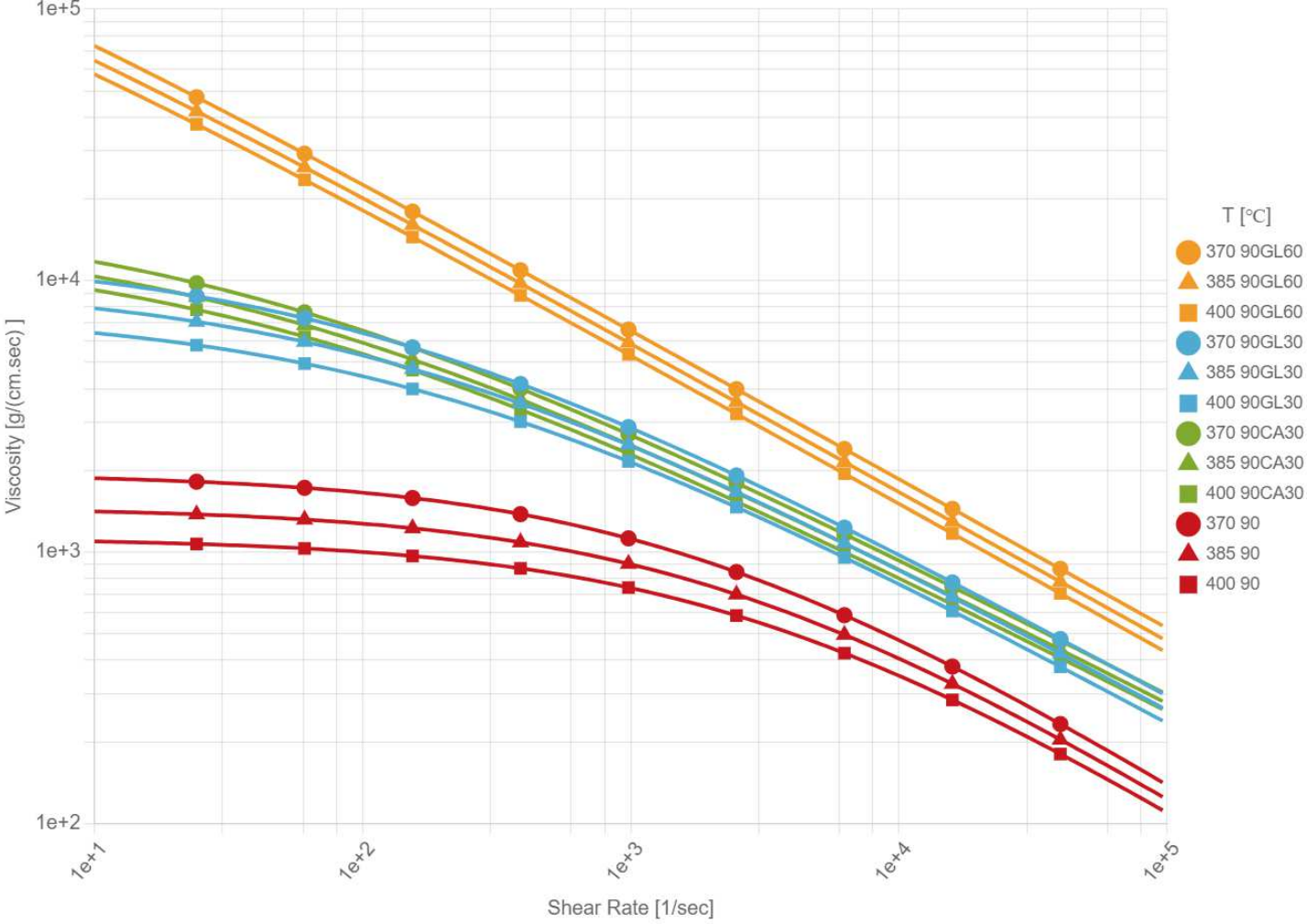
# Challenges with PEEK – % Crystallinity

The percent crystallinity of a semi-crystalline polymer primarily depends on:

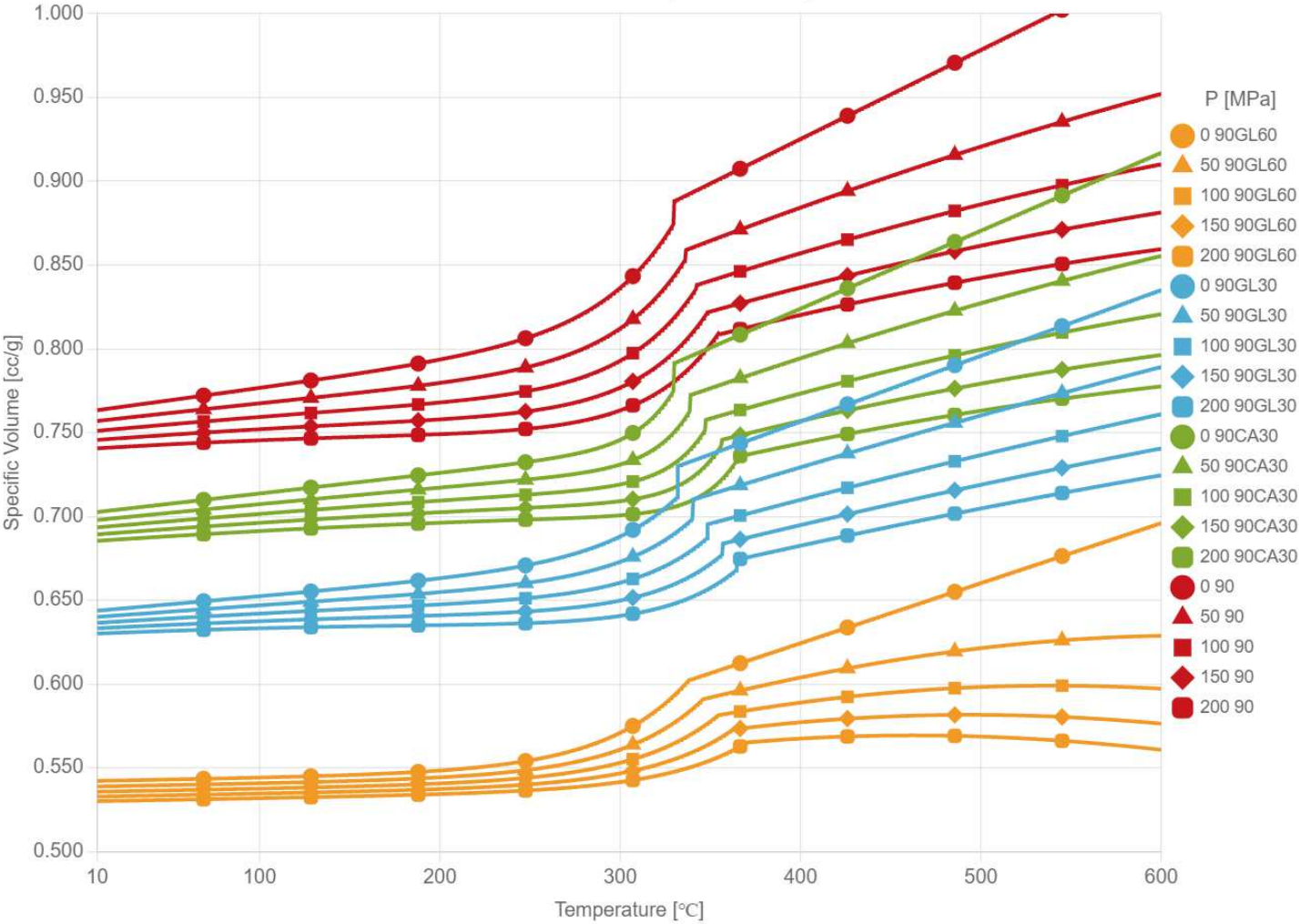
- Material properties
- Rate of Cooling
  - Mold Design
  - Processing Conditions
    - Melt Temp
    - Mold Temp
    - Screw RPM
    - Back Pressure
    - Barrel Temp Profile
    - Peak Injection Pressure
    - Pack + Hold Pressure & Time
    - Cooling Time
- Fillers / Additives
- Annealing



# Challenges with PEEK – Fillers



# Challenges with PEEK – Fillers





# Bioresorbable Molding

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# Bioresorbable Molding

- Molding in a large variety of bioresorbable resins
- Systems in place for:
  - Resin storage and handling
  - Cleaning all contact surfaces inside and outside of the press and mold
  - Specialized packaging and shipping



# Factors That Affect the Quality of Molded Parts (Partial List)



# Intrinsic Viscosity Testing

- Bioreabsorbable parts must pass Intrinsic Viscosity tests

$$[\eta] = K \cdot M^a$$

where:

- $[\eta]$  is the intrinsic viscosity,
- $M$  is the molar mass
- $K$  and  $a$  are empirical constants that depend on the specific polymer-solvent system and temperature.





# Intrinsic Viscosity Testing

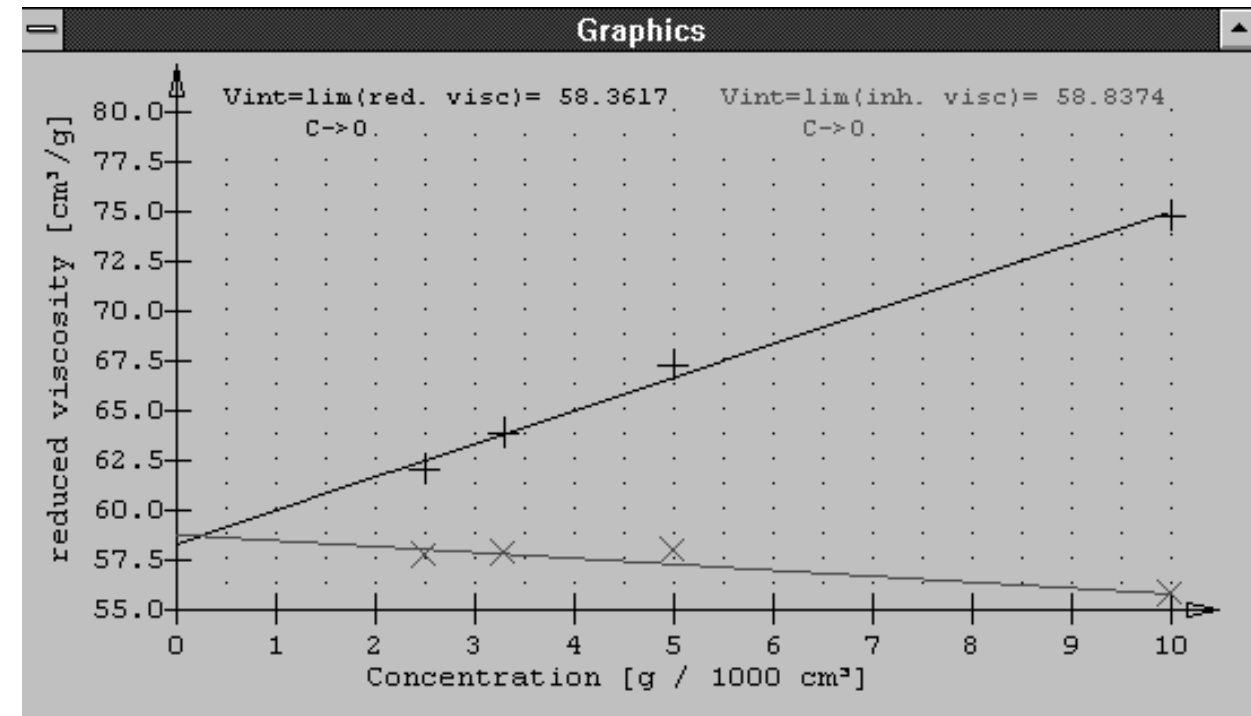
- Bioreabsorbable parts must pass Intrinsic Viscosity tests

$$[\eta] = K \cdot M^a$$

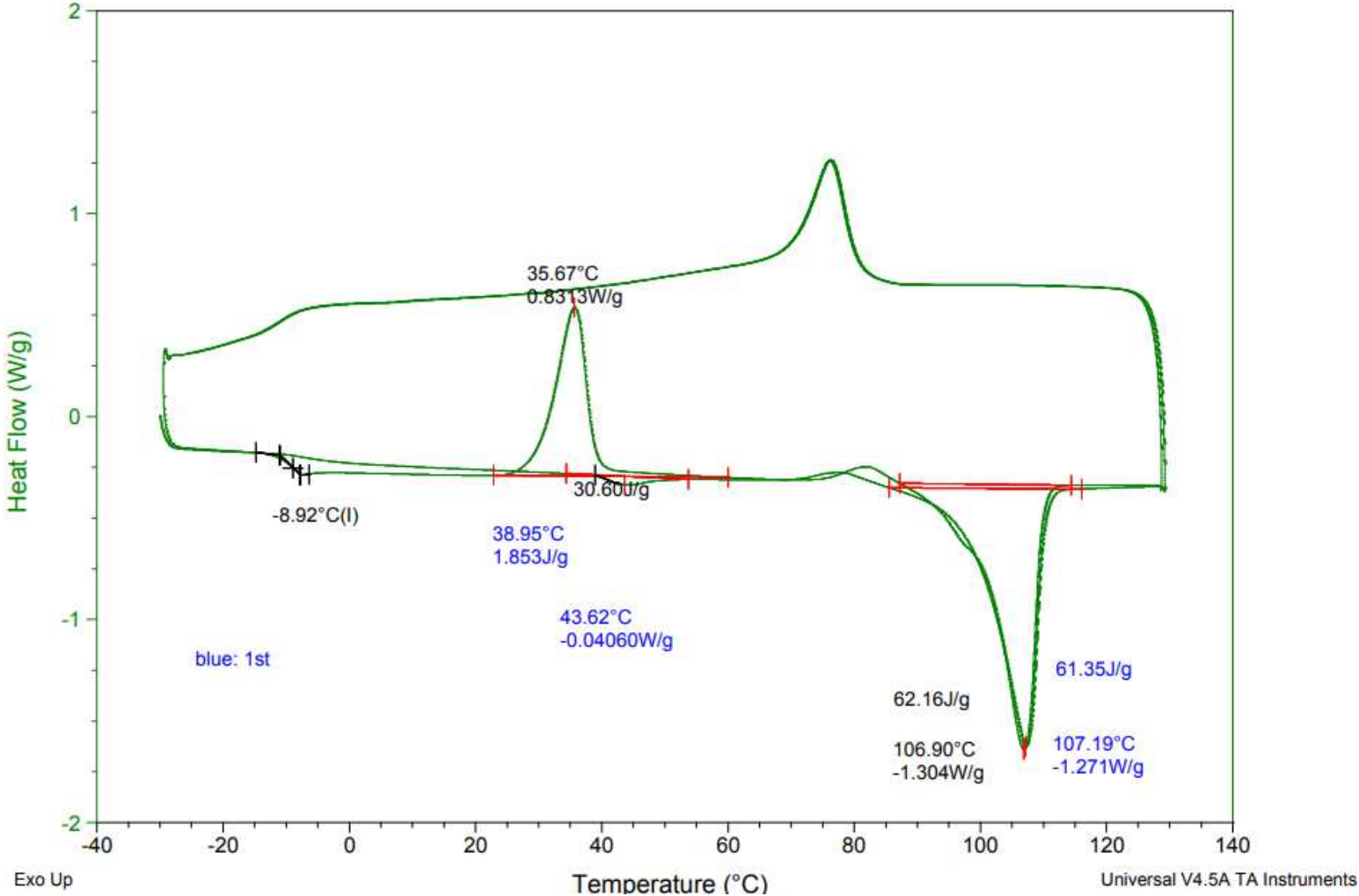
where:

- $[\eta]$  is the intrinsic viscosity,
- $M$  is the molar mass
- $K$  and  $a$  are empirical constants that depend on the specific polymer-solvent system and temperature.

Relative Viscosity:	$v_{rel} = \frac{v_{Solution}}{v_{Solvent}}$	$v_{rel}$ Relative Viscosity	---
Specific Viscosity:	$v_{spec} = v_{rel} - 1$	$v_{spec}$ Specific Viscosity	---
Reduced Viscosity: (Viscosity number, VZ)	$v_{red} = \frac{v_{rel} - 1}{C}$	$v_{red}$ Reduced Viscosity Concentration	$\frac{cm^3/g}{g/cm^3}$
Inherent Viscosity (log. Viscosity number)	$v_{inh} = \frac{\log v_{rel}}{C}$	$v_{inh}$ Inherent Viscosity Concentration	$\frac{cm^3/g}{g/cm^3}$



# Polydioxanone (RESOMER® X 206 S)



# Polydioxanone (RESOMER® X 206 S)

## DESCRIPTION

RESOMER® X 206 S is a semi-crystalline homopolymer of p-dioxanone with an inherent viscosity range of 1.5 – 2.2 dL/g (measured in HFIP). It is supplied in white to off-white granular form and may be used in medical applications.

## MECHANICAL PROPERTIES

Measurement according to DIN EN ISO 527-2:2012, test specimens A14 (ISO 20753:2008)

Tensile strength	35–45 MPa
Young's modulus	600–800 MPa
Elongation at break	ca. 250 %

## PHYSICAL PROPERTIES

Density	1.38 g/cm <sup>3</sup>
Melting point	115 °C
Glass transition temperature	-16 °C

## PROCESSING

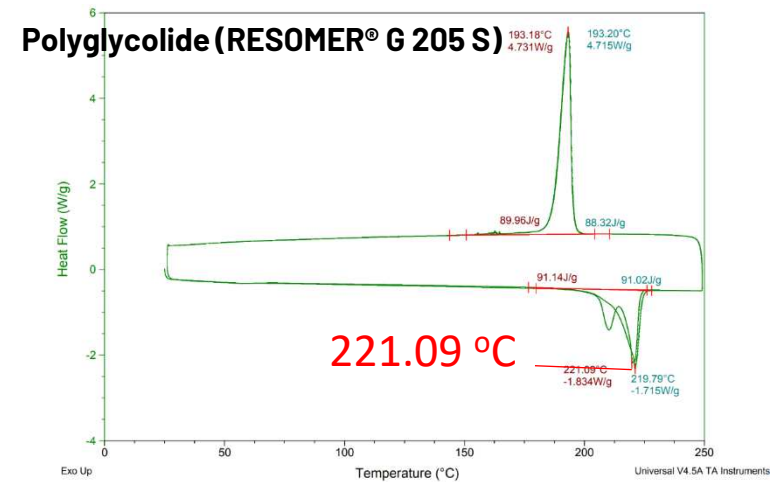
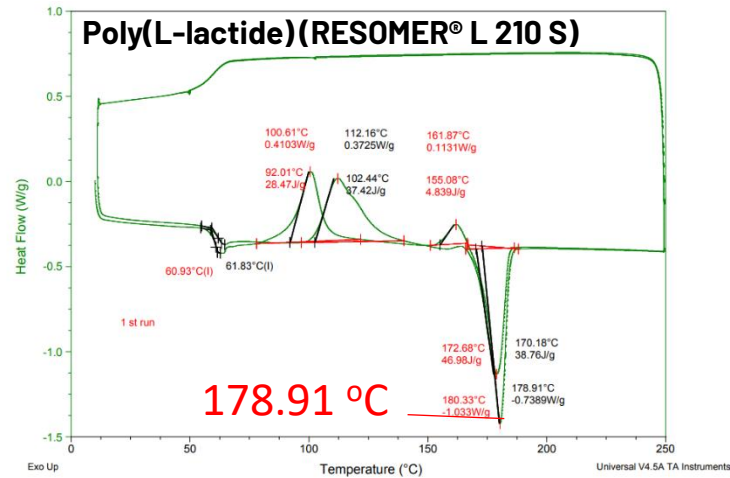
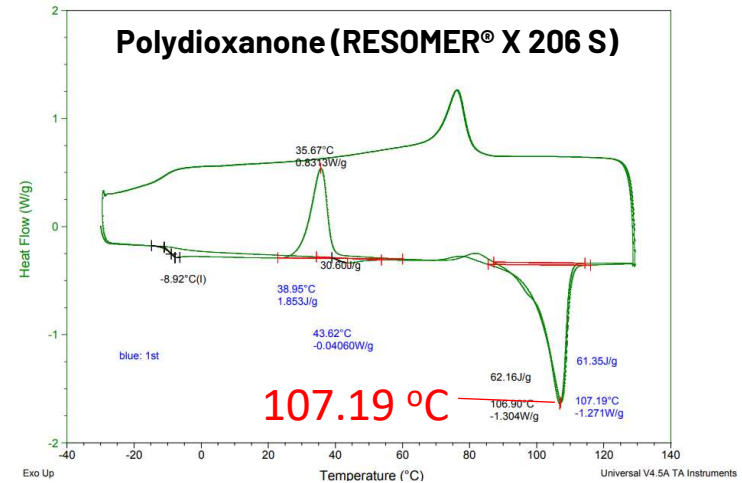
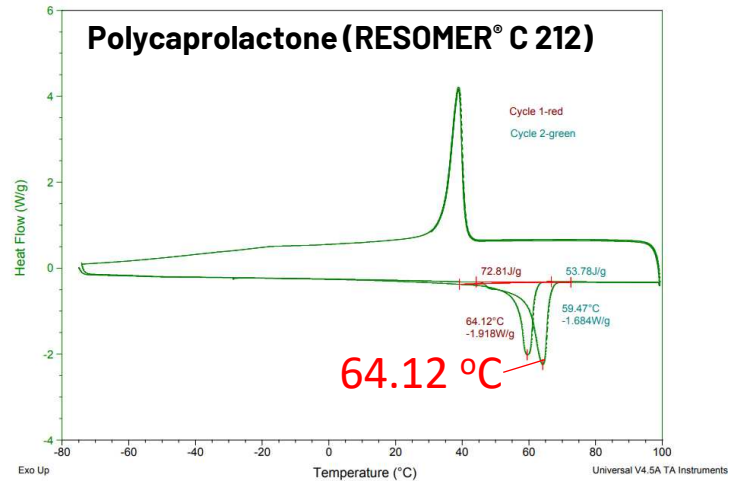
Drying/residual moisture: < 300 ppm

## TEMPERATURE SETTINGS

(Arburg 170 S 180-30)

Feed throat:	20 °C
Zone 1:	95–105 °C
Zone 2:	95–105 °C
Zone 3:	105–115 °C
Nozzle:	110–120 °C
Mold temperature:	25 °C

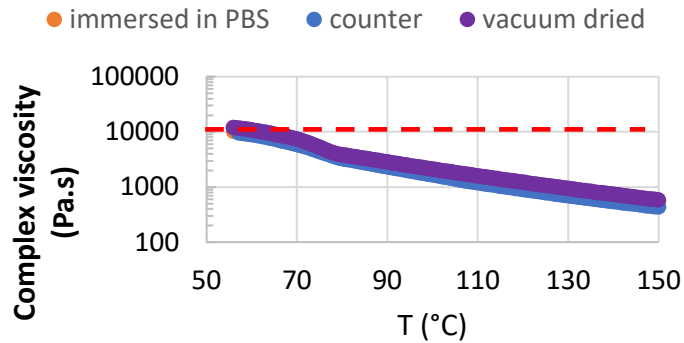
# DSC Curves



# Complex Viscosity Curves

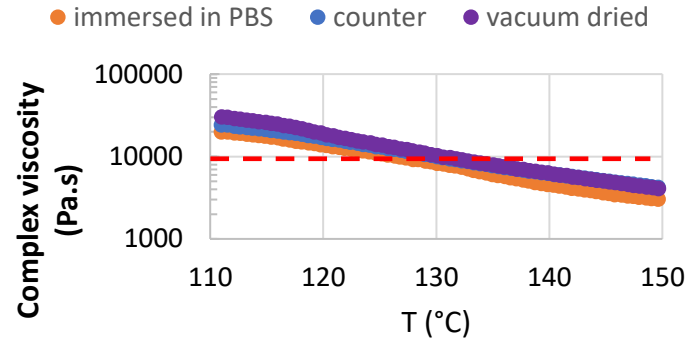
## Polycaprolactone (RESOMER® C 212)

Inherent viscosity 1.13 - 1.38 dl/g

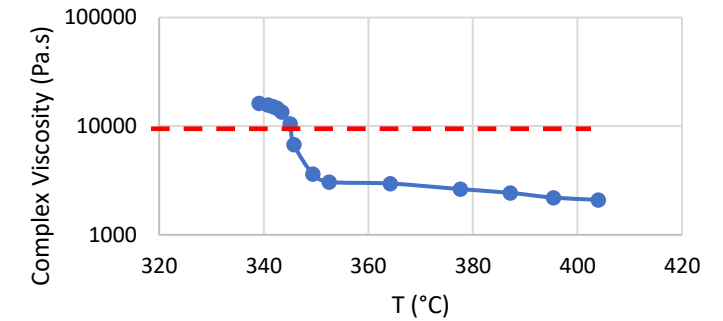


## Polydioxanone (RESOMER® X 206 S)

Inherent viscosity 1.5 - 2.2 dl/g

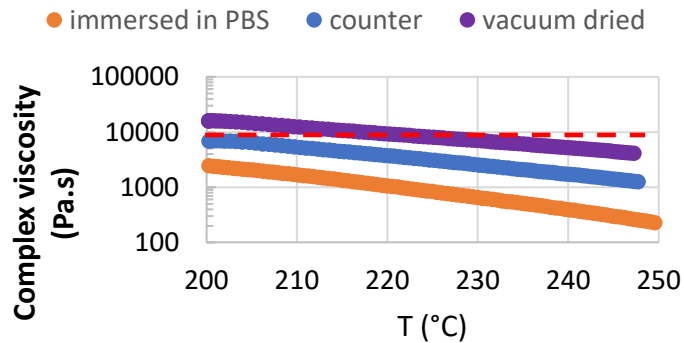


## PEEK 3 MFI



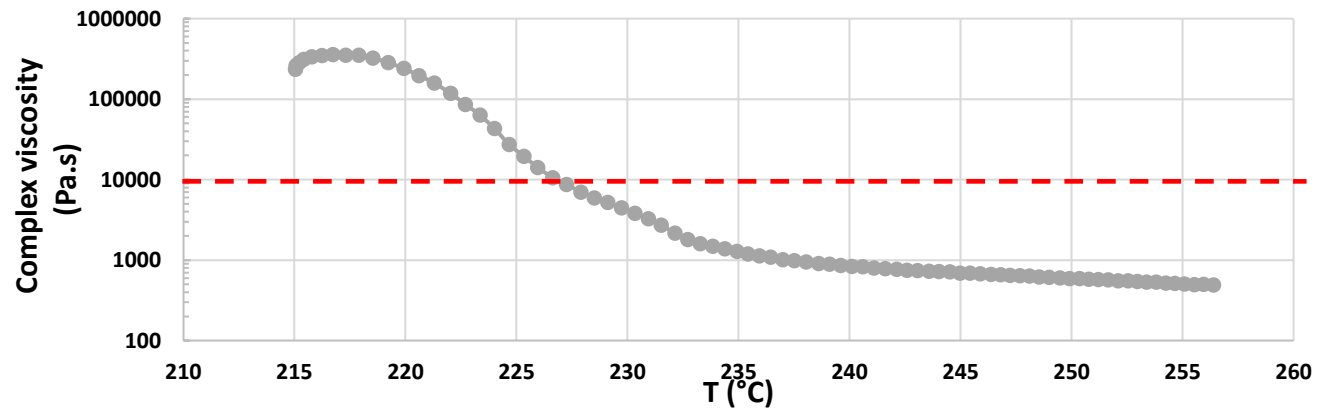
## Poly(L-lactide) (RESOMER® L 210 S)

Inherent viscosity 3.3 - 4.3 dl/g

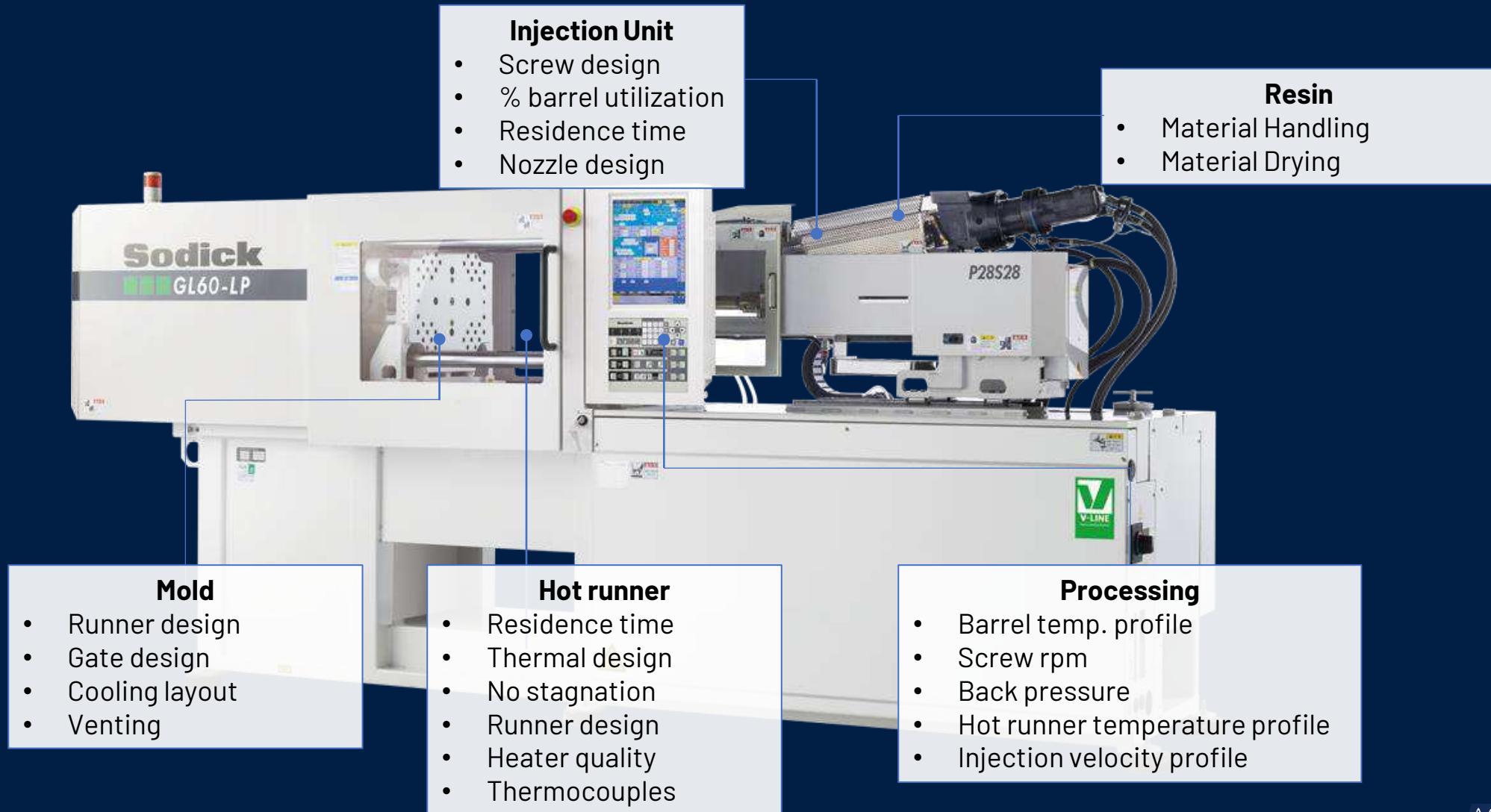


## Polyglycolide (RESOMER® G 205 S)

Inherent viscosity 1.05 - 1.25 dl/g



# Bioresorbable Molding



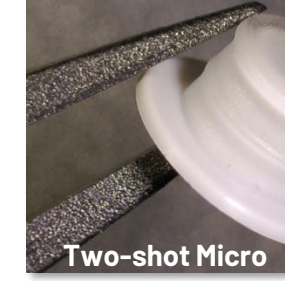
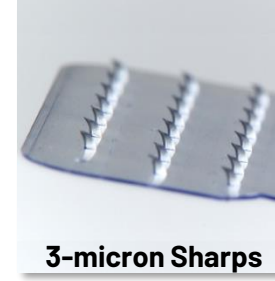
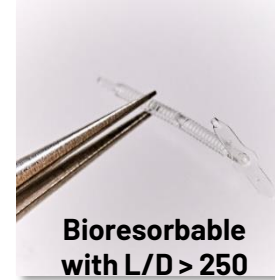
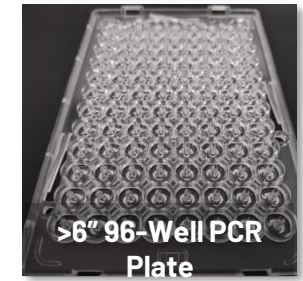
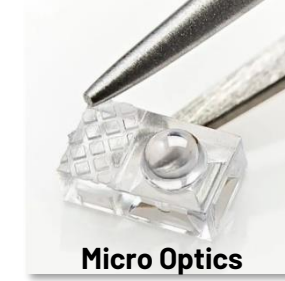
# Primary Causes of Thermal Degradation of Bioresorbable Polymers

- Moisture
- High temperatures
- Long residence time
- Excessive shear
- Stagnation
- Machine startup and shut down procedures

# Thank You!

# Questions?

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