



**RONCELLI PLASTICS**

FAST | CLEAN | PRECISE

# MEDICAL & LIFE SCIENCE

PRECISION PLASTIC MACHINING FOR MEDICAL & LIFE SCIENCE APPLICATIONS

1-800-250-6516  
[WWW.RONCELLI.COM](http://WWW.RONCELLI.COM)



## MANUFACTURING CAPABILITIES

### CNC Machining (Temperature Controlled Machining Center)

- 5 Axis CNC Milling (up to 21")
- 3 Axis CNC Milling (up to 30"x60")
- CNC Turning (up to 18" in diameter)
- CNC Swiss (30mm in diameter)
- Small hole drilling (.004" capable)
- Die Cutting / Stamping

### Rapid Prototype Management

- Quick Turn Machining Cell
  - 5 Axis CNC Mills
  - Tolerances +/- .0005"
  - Turnaround time < 1 week
- Fusion Deposition Manufacturing (FDM)
  - 3D printed precision parts from Ultem® & Polycarbonate
  - Tolerances +/- .0015"
  - 2-3 day turnaround time



### Quality Practices & Assembly

- ISO 13485 Certified
- Class 1000 Clean Room packaging & assembly
- Class IV laser part marking
- Copy Exact
- Material is certified and lot traceable
- First article, in-process, and final inspections on all part orders

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# MEDICAL & LIFE SCIENCE MATERIALS

## Compatibility With Common Sterilization Methods

Life Science Grades	Sterilization Method				
	Ethylene Oxide Gas	Steam 134° C	Dry Heat 160° C	Plasma	Gamma Irradiation
PEEK	VG	VG	VG	VG	VG
PPS	VG	G	VG	G	VG
PPSU	VG	VG	VG	VG	G
PEI	G	G	VG	G	G
PSU	G	G	G	G	G
PC	G	NS	NS	G	G
POM-C	G	P	NS	G	NS
PPE	G	G	NS	G	G
PP	G	P	NS	G	NS
PTFE	G	VG	VG	G	NS
PES	G	G	G	G	G
PVDF	G	G	NS	G	G
PET	G	NS	NS	G	G

VG = Very Good, G = Good, P = Poor, NS = Not Suited

## Medical Plastics Chemical Compatibility

Chemical Resistance* Against	Material								
	PEEK	PPS	PPSU	PEI	PSU	PC	POM-C	PPE	PP
Weak Acids	A	A	A	A	A	A	L	A	A
Strong Acids	L	L	L	U	U	U	U	L	L
Weak Alkalis	A	A	A	A	A	L	A	A	A
Strong Alkalis	A	A	A	U	L	U	A	L	A
Water	A	A	A	A	A	A	A	A	A
Hot Water (80-90° C)	A	A	A	A	A	L	A	A	A
Alcohol	A	A	A	A	L	A	A	A	A
Esters	A	A	L	L	U	U	A	L	L
Ether	A	A	L	L	L	U	L	L	L
Ketones	A	A	U	U	U	U	A	L	L
Aromatic Hydrocarbons	A	A	L	U	U	U	A	L	L
Alipatic Hydrocarbons	A	A	A	A	A	A	A	L	L

\* = at normal room temp (15-25° C), unless otherwise stated

A = Acceptable Use, L = Limited Use, U = Unacceptable

# MEDICAL & LIFE SCIENCE APPLICATIONS

## SPINAL IMPLANTS

- Application
  - Spinal Fusion Cages, Cervical Spacers, Thoracolumbar & Cervical Sizers
- Material
  - PEEK Optima® (implantable grade), Virgin PEEK, UHMW-PE
- Requirements
  - Biocompatible
  - Radiolucency
  - Stress crack resistance
  - High-load capability
  - Strong chemical resistance
  - Thermal degradation resistance

Spinal implants for the human body place heavy demands on the materials used. For years, the primary materials being used were titanium and cobalt chromium. Now, high performance thermoplastics like PEEK Optima® and virgin PEEK are gaining significant traction due to its capability in high-load, high temperature applications, and its compatibility with diagnostic imaging including MRI and CT scans that are critical for visualizing changes to the spinal cord and soft tissue structures of the spine.



Looking forward, medical engineers are focusing more on incorporating biomaterials with regenerative properties that can play an integral role in the healing process. Advanced polymers like PEEK Optima® can be coated to enhance PEEK's osseo-conductivity in order to actively encourage bone growth.



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## SURGICAL TOOLS

- Application
  - Surgical driver handles
- Material
  - Radel® (PPSU), PEEK
  - 30% glass filled
- Requirements
  - Autoclavable
  - Excellent impact resistance
  - High polished surface finishing
  - Intensive biocompatibility testing
  - Color options



Medical instruments and tools must retain performance after multiple autoclave cycles without degradation of color or dimensional stability. Now, with advancements in life science grade plastics that can withstand repeated autoclaving cycles in addition to harsh cleaning agents, new opportunities are available to develop your next surgical tool out of plastics instead of metal.

## ENDOSCOPY INSTRUMENTS

- Application
  - Camera head coupler, trays, covers, spacers, handles,
- Material
  - Filled & unfilled grades of PEEK & Ultem®
- Requirements
  - Biocompatibility
  - Repeat sterilization
  - High temperature capability
  - Excellent chemical resistance
  - Lightweight



With the growing demand for repeated use medical devices and instruments, endoscopic applications utilizing PEEK and/or Ultem® benefit from strong physical properties and steam sterilization resistance for more than 1000 cycles. Additionally, a medical device conversion from metal to plastic provides weight reduction advantages without sacrificing performance requirements.

Since 1969, Roncelli Plastics has specialized in Precision Fabrication, CNC Machining, Die Cutting, Rapid Prototyping and Clean Room Assembly of plastic and non-metallic components. Our highly experienced staff of machinists, quality personnel, and supervisors is dedicated to delivering the best quality plastic and non-metallic components in the industry. We're proud to deliver finished components to some of the largest and most well-known organizations in the world.

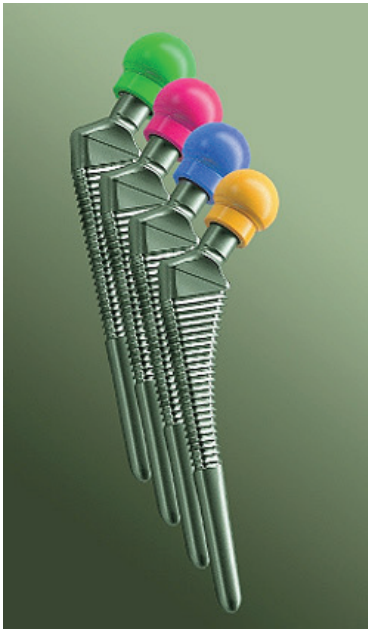


# MEDICAL INSTRUMENTS

- Application
  - Trauma Target Guide
- Material
  - PEEK, Carbon-filled PEEK (CA30 & CC60)
- Requirements
  - Extreme stiffness (high flex modulus)
  - Biocompatibility for body contact up to 24 hours
  - Radiopaque
  - Elongation modulus 9,200 MPa (at 23° C)



When an application like trauma target guides require extreme dimensional stability even at elevated temperatures, advanced polymers like PEEK CC60 and PEEK CA30 provide a solution. Additional characteristics like radiopaqueness provide surgeons visibility during surgery to accurately insert guide pins on the first take, regardless of the variety of sizes and shapes of the patients.



- Application
  - Orthopedic Trial
- Material
  - Radel® (PPSU)
- Requirements
  - Biocompatible
  - Autoclavable
  - Dimensionally stable
  - Various color grades
  - Made from USP & FDA compliant resin

Orthopedic trials are utilized in surgical joint replacement surgeries as a gauge to determine which size of a permanent implant should be implemented. Recently, Radel (PPSU) has become the most commonly used plastic for this application, specifically due to its longer autoclave life versus traditionally used materials like Acetal (POM).

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