rtpcompany.com

Compounding for Healthcare

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Product Development Engineer - Healthcare

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RTP COMPANY OVERVIEW

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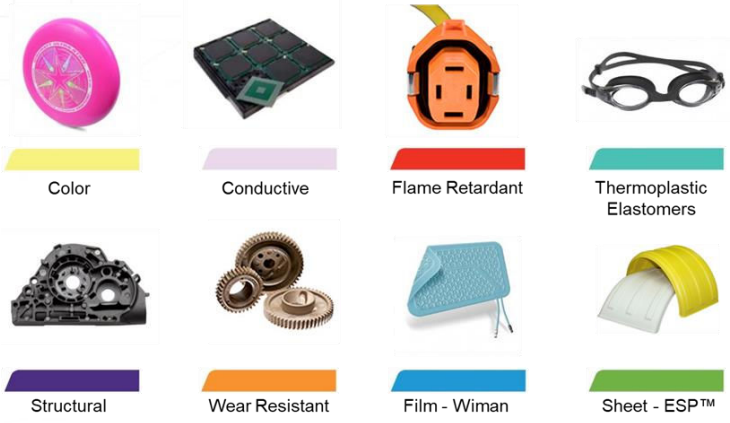
PRODUCT FAMILIES

RTP Company provides compounds for the healthcare industry across all product families



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COLOR

Color technologies add function and aesthetics to healthcare applications

- Color for identification
- Laser marking for Unique Device Identifier (UDI)
- Laser welding for joining parts with hermetic seals

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COLOR

Custom Precolors

- RTP Company's Color Lab has capabilities to match samples, Pantone selections, or many other color standards
- This ensures colors of the compound match marketing materials
- Can usually be combined with other technologies (Wear, Structural, TPE, etc.)

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COLOR

Color for Identification

- Allows for quick and easy differentiation of components
- Examples
  - Test tube caps
  - Surgical sizers

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COLOR

Laser Marking

- Laser marking pigment works in nearly all polymer systems
- Can laser mark light marks on dark surfaces or dark marks on light surfaces
- Used for UDI (Unique Device Identifier) codes
- Can be used to replace labels or printed text that could easily wear off

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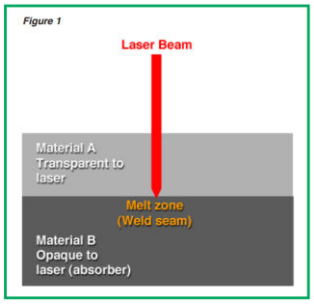
COLOR

Laser Welding

- Two parts (IR Transparent & IR Absorbing) combined through laser melting along the weld seam.
- Can be used to create hermetic seals



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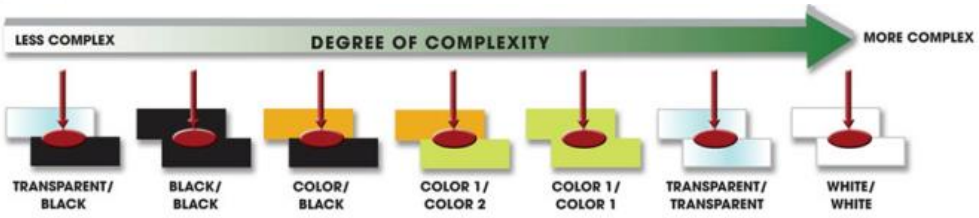
COLOR

Laser Welding

- Beneficial when other joining techniques are not viable
  - Ultrasonic welding near electrical components
  - Contamination from glues or adhesives



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STRUCTURAL

Broad use technologies for healthcare

- Non-FR housings
- Patient mobility devices (beds, wheelchairs)
- Radiopaque surgical tools

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STRUCTURAL

Radiopacity

- For use in surgical devices that need to appear on an x-ray
- For use as an x-ray shield to prevent unintended damage
  - Can be used to replace lead
- Amount of additive can be tuned for wall thickness to achieve the desired radio-density.

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STRUCTURAL

Radiopacity

- Barium Sulfate
  - Widely used radiopaque additive
  - Cost effective
  - Colorable
  - USP grades available
- Bismuth Compounds
  - Higher density than BaSO4
  - Brighter/higher contrast & sharper image
- Tungsten
  - Twice as dense as Bismuth, high level of radiopacity
  - Raw material is dark gray, color limitations
  - Cost considerations

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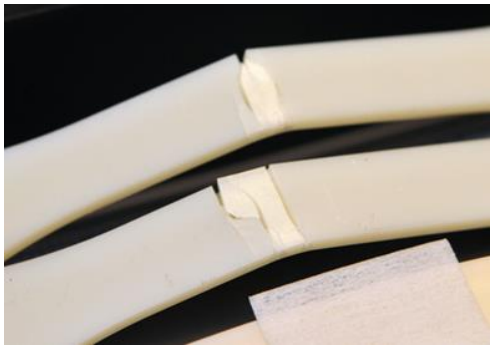
STRUCTURAL

Cost Effective Chemical Resistance

- Historically PC/ABS
- Amorphous = poor chemical resistance
- High temp amorphous (PPSU) = High cost
- Hospitals work to reduce infections
  - More rigorous cleaning schedules



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STRUCTURAL

Cost Effective Chemical Resistance

- Developed copolyester alloys
  - Amorphous
  - Good chemical resistance
  - Lower cost than high temp polymers
- Custom alloys on demand
  - Structural
  - FR

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STRUCTURAL

Cost Effective Chemical Resistance

- Developed an in-house test regime to compare performance of materials to a range of chemicals
- Continuing development focus in this area

Figure 5: Pass/Fail, ASTM D638 Tensile Strength/Elongation

Disinfectant	RTP 2000 HC Series	Standard PC/ABS
Birex® - Phenol	✓	✓
CaviCide 1® - Alcohol	✓	✗
Cidex Plus® - Glutaraldehyde	✓	✗
Incides N® - Alcohol	✓	✗
Incidin Plus® - Glucoprotamin	✓	✗
Incidin Pro® - Alcohol	✓	✗
Sani-Cloth Active® - Quarternary Compound	✓	✗
Sani-Cloth Bleach® - Chlorine	✓	✓
Sani-Cloth Plus® - Alcohol	✓	✗
Super Sani-Cloth® - Alcohol	✓	✗
T-Spray II™ - Chlorine	✓	✗

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STRUCTURAL

Sterilization – Ethylene Oxide (EtO) Gas

- Toxic gas
  - Disposal considerations
- Polymers require chemical resistance

Not Recommended
- Some ABS grades (stress cracking)
- Some TPE grades

Most polymers are unaffected by EtO gas

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STRUCTURAL

Sterilization – Steam/Autoclave

- Commonly used for quick & easy disinfection
- Used in healthcare facilities
- 30-minute cycles at 121 Celsius
- Stress relaxation (annealing) can occur

Not Recommended
- ABS/Polystyrene
- Polyesters (PET, PBT)

Fair - Good
- Nylon
- Polycarbonate
- Polypropylene

Best
- PPSU
- PEEK

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STRUCTURAL

Sterilization – High Energy Radiation

- Gamma & E-Beam
- Damages polymers via:
  - Chain scission
  - Crosslinking
- Cumulative Damage
- Can be both mechanically and visually damaging

Not recommended
- Acetal
- PTFE

Stabilization Required
- Polypropylene
  - Color & Impact
- Polycarbonate
  - Color

Good (<80 kGy)
- Polyethylene*
- Liquid crystal polymer
- Polysulfones

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STRUCTURAL

Sterilization – Vaporized Hydrogen Peroxide (VHP)

- Low temperature process
- Broader range of polymer compatibility compared to steam
- Some chemical resistance is needed
- Uptick due to constraints in EtO capacity

Not Recommended (Some Cycles)
- Polyurethane
- Nylon
- Acetal

Limited after repeat sterilization
- Nylon
- Acetal
- PMMA

Best (Multiple Cycles)
- PPSU (200+ Cycles)
- PEEK (200+ Cycles)
- PEI (300+ Cycles)

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THERMOPLASTIC ELASTOMERS (TPE)

Provides soft-touch over molded surfaces in addition to standalone devices

- tubing
- catheters
- grips (toothbrushes, razors, surgical tools)
- seals
- vial closures
- drug delivery or monitoring patches
- connectors

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THERMOPLASTIC ELASTOMERS (TPE)

Medical TPE Portfolio – All tested to ISO 10993 -5, -10, -11

RTP 2700 S MD	• SBC Technology • Highly Elastic • Translucent/PP Bondable • Durometers 30A – 80A
Polabond® 6042 MD	• Alloy Technology • PC, PC Alloys and ABS substrate bondable • Haptics/Tensile/Tear • Durometers 40A – 70A
Polabond® 6003 MD	• Alloy Technology • PBT and PMMA substrate bondable • Functional Elasticity • Durometers 45A, 55A and 75A

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THERMOPLASTIC ELASTOMERS (TPE)

Lubricity

- We can modify TPE alloys to shift between a 'tacky' feel and a 'silky' feel.
- Wear & Friction additives can be added to increase lubricity
  - Silicone
  - PFPE (Perfluoropolyether) Oil
  - PTFE

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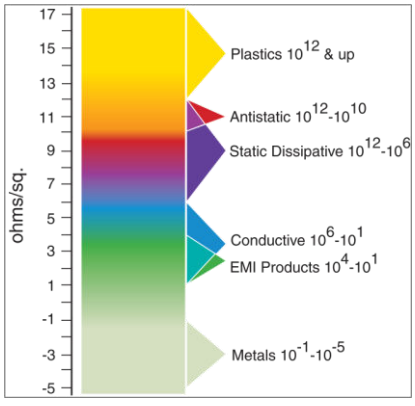
CONDUCTIVE

Provides antistatic, static dissipative, and EMI shielding performance

- Pipette tips
- Dry powder drug delivery
- EMI shielding for housings



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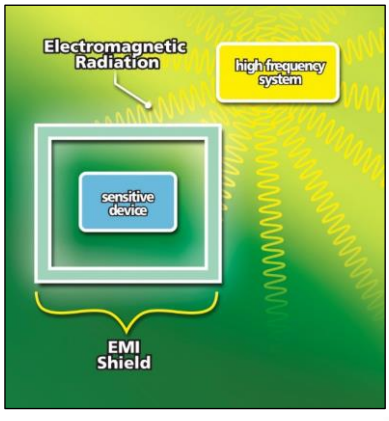
CONDUCTIVE

Electromagnetic Interference (EMI) Shielding

- EMI shields protect sensitive devices from high frequency sources in the area.



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CONDUCTIVE

Electromagnetic Interference (EMI) Shielding

Stainless Steel Fiber

- 8 µm Diameter
- 302 Tool Steel
- Very Flexible

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CONDUCTIVE

Electromagnetic Interference (EMI) Shielding

- Pre-blended mix of pellets
- Necessary to retain aspect ratio
- Evenly dispersed during molding
- SSF loading up to 20%
- Colors Possible

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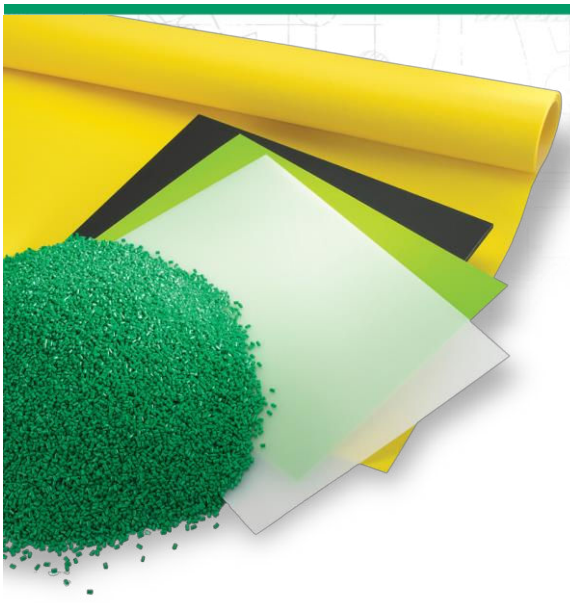
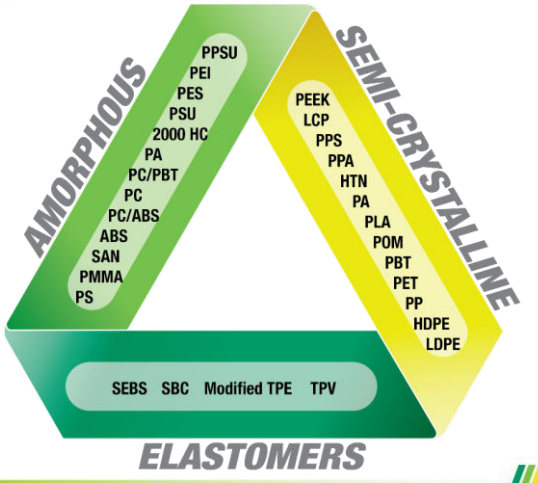


FORMULATING FOR HEALTHCARE



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FORMULATING FOR HEALTHCARE

Why the need?

- RTP Company has a broad portfolio of plastics and additives for the healthcare industry
- Not all raw material suppliers support healthcare applications equally.
  - The responses ensure the proper suppliers and controls are in place
- Having this information up front helps to ensure there are no hurdles or setbacks from raw materials as the program progresses
  - Partnering with RTP Company can help offer guidance on new applications

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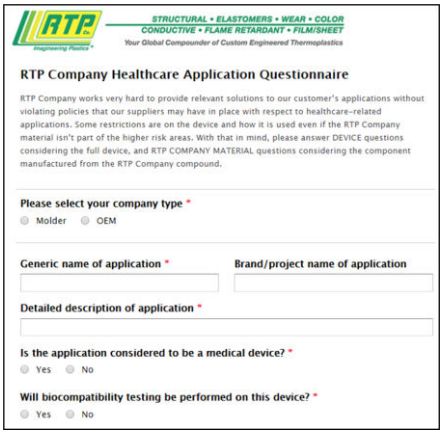
FORMULATING FOR HEALTHCARE

RTP Company Healthcare Application Questionnaire

- Online, interactive questionnaire
- Helps us categorize your application
- Ensures we comply with our suppliers' policies
- Can be filled out by anyone knowledgeable about the application


STRUCTURAL • ELASTOMERS • WEAR • COLOR
CONDUCTIVE • FLAME RETARDANT • FILM/SHEET
Your Global Compounder of Custom Engineered Thermoplastics

RTP Company Healthcare Application Questionnaire

RTP Company works very hard to provide relevant solutions to our customer's applications without violating policies that our suppliers may have in place with respect to healthcare-related applications. Some restrictions are on the device and how it is used even if the RTP Company material isn't part of the higher risk areas. With that in mind, please answer DEVICE questions considering the full device, and RTP COMPANY MATERIAL questions considering the component manufactured from the RTP Company compound.

Please select your company type *
Molder OEM

Generic name of application *
Brand/project name of application

Detailed description of application *

Is the application considered to be a medical device? *
Yes No

Will biocompatibility testing be performed on this device? *
Yes No

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FORMULATING FOR HEALTHCARE

RTP Company Healthcare Application Questionnaire

- Short and simple questionnaire intended to gather critical regulatory information.
  - Device Classification
    - US I, II, or III
  - Patient Contact Duration
    - Transient – Less than 24 hours
    - Temporary – 24 hours to 29 days
    - Permanent – 30 days or longer
  - Biocompatibility Testing

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SUMMARY

Technology + Control

- RTP Company has several product technologies that can be implemented across nearly all polymer systems for the healthcare market
- We have the capability to offer custom control schemes on formulations to fit your application

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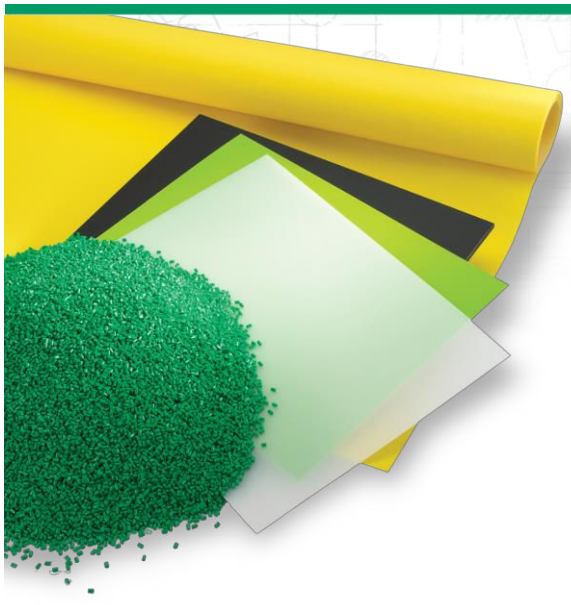

THANK YOU!

Questions?

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