



MEDICAL DEVICE PRODUCT DEVELOPMENT

PLASTIC COMPOUND SELECTION & CHANGE MANAGEMENT

- ▶ Formulations using pre-tested ISO 10993 biocompatible materials
- ▶ Experience with all resin systems and additives
- ▶ Formulation control and change management

ADDITIONAL BENEFITS

- Plastic selection assistance to optimize properties and cost (white paper available)
- Ability to provide material samples during the prototype phase
- ISO 9001 quality system to manage formulation changes
- Extensive history of successful medical device applications
- Commodity plastics, engineered compounds and thermoplastic elastomers available
- No Substitutions service to protect your custom formulation

Imagine the development of a new medical device in which you work directly with your plastics supplier to establish your specific material needs. A custom compound is developed using known biocompatible materials, focusing on your requirements for color and functionality, all while using the most cost effective raw materials. At RTP Company we have not only imagined this scenario, we make it a reality everyday.

Based on decades of experience, RTP Company's engineers will formulate a custom compound ideally suited for your medical device. Our engineers select materials from our database of base resins, pigments, dyes, lubricants, reinforcements and a variety of other additives that have successfully passed biocompatibility testing. This allows us to create plastic compounds with confidence that you will pass your ISO prescribed biocompatibility testing requirements.

Formulation Control

We also understand the need to maintain control of the materials in your custom formulation in order to preserve the testing integrity of your finished molded and assembled device. For these situations, RTP Company has established a No Substitution policy which is applicable only if requested by the customer at the beginning of the formulation process. Using our ISO 9001 quality system procedure we can insure your custom formulation is maintained by using a specific nomenclature that signifies that no raw material changes or substitutions are allowed unless authorized.

Change Management

Should a need to change your custom formulation occur, the following steps are taken:

1. Notify you of the change as soon as detected
2. Provide you with information regarding the type of change
3. Provide you with timing on the change
4. Provide you with options to manage the change

This No Substitutions service provides an additional layer of protection to your custom formulation to help insure that the product you specified and qualified is the same product you get on each order.

Custom compounds for medical devices...another innovation from RTP Company your global leader of custom engineered thermoplastics.



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Medical Device Resin Selection

Resin Systems Used for Medical Devices

Selecting the base resin to optimize performance and cost of your medical device can be a daunting task. At RTP Company, we start by listening to your needs and design requirements, then we select the best resin to optimize your cost, physical properties and aesthetics.

Knowing how a material will be used in its end-use application is imperative during the material selection process. RTP Company product development engineers are well versed in seeking out the information necessary to ensure an appropriate material is recommended. This healthcare application checklist has been developed to help you prepare thoughtful answers to common questions.

Will you perform biocompatibility testing?

Will you obtain a 510(k) or CE mark?

Sterilization Method:

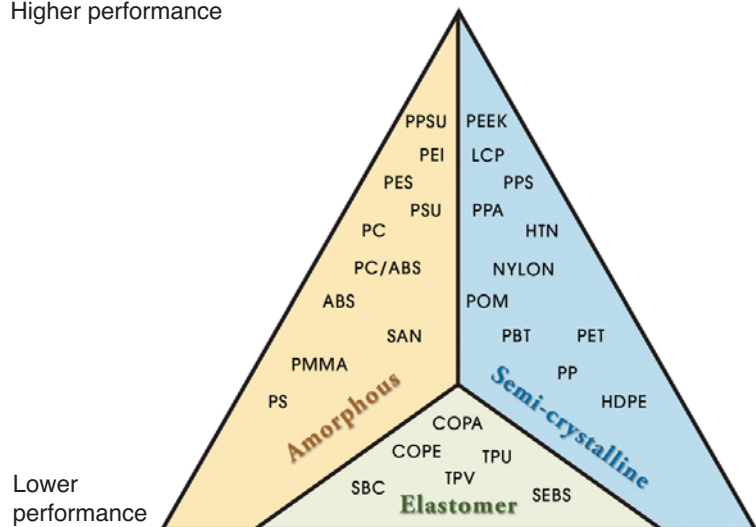
Gamma or E-Beam

ETO

Autoclave

Will this come in contact with body fluid?

Higher performance



PLASTIC TECHNOLOGIES

Color	Structural	Conductive	Wear	Flame Retardant	Elastomer
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MEDICAL PORTFOLIO

Bio-Compatible Color	Radiopaque	Static dissipative	Bondable TPEs	Friction/Wear Reduction	Sheet & Film
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Known bio-compatible database					
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This diagram illustrates how we start to narrow the base resin choices for your medical device by taking into consideration features such as environmental exposures (chemical resistance, temperature and humidity for example), lifecycle of the device, and overall function of the device. Once a base resin is selected, we look at additional technologies required such as color or structural reinforcement, and then start to develop a custom formulation from products in our medical portfolio. The foundation of our medical portfolio is our database of known biocompatible tested and FDA compliant materials which we use to develop custom formulations to meet the specialized requirements for medical devices such as biocompatibility, radio opacity, static dissipation, elastomers for ergonomics, low friction, medical films, chemical resistance, and sterilization.

Additional information on the resin selection process for medical devices can be found in our white paper: Selection of Materials for Medical Applications www.rtpcompany.com/info/papers.

RTP Company: Your Global Compounder Of Custom Engineered Thermoplastics

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