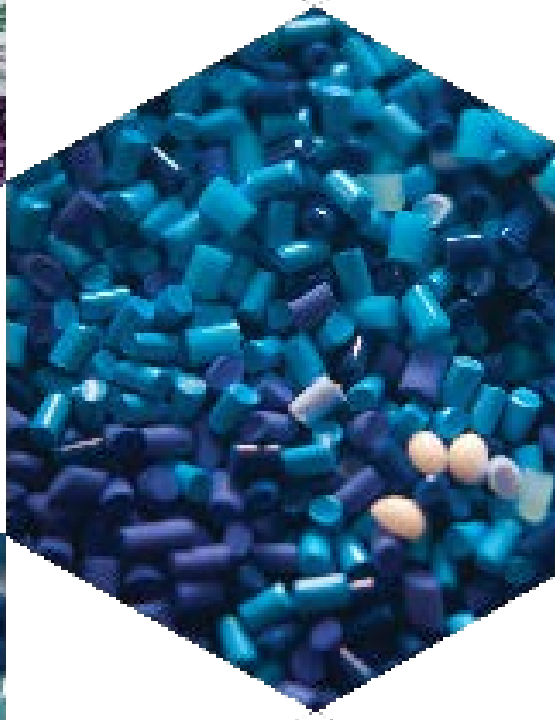
Medical Color Solutions







Foster®
PERFORMANCE SOLUTIONS BY GEON

Color Solutions Designed to Accelerate Medical Device Development

FOSTER MEDICAL COLOR CONCENTRATES AND CUSTOM PRE-COLORED AND COLOR CONCENTRATE COMPOUNDS

Foster, LLC helps medical device manufacturers reduce development risk, simplify sourcing, and accelerate regulatory pathways through proven, compliant color solutions. By combining regulatory expertise with advanced compounding capabilities, Foster enables efficient product development from prototyping through commercialization.

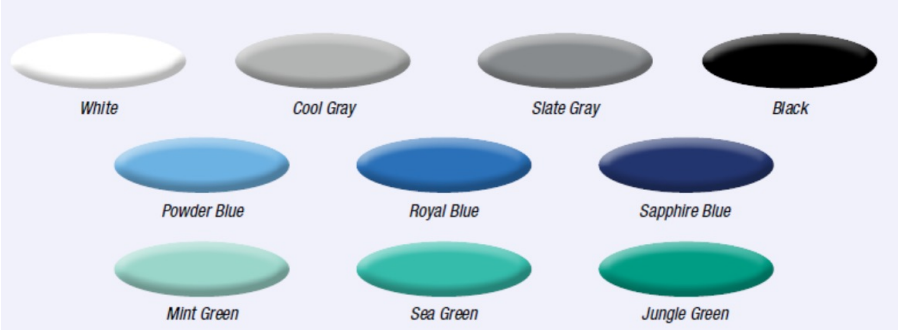
Our comprehensive portfolio of medical device–compliant color solutions are designed to support regulatory compliance, performance, and efficient manufacturing. These solutions include MediBatch™ color concentrates and custom pre-colored and color concentrate compounds, all formulated using FDA-certified medical device and food contact grade pigments to support FDA submissions and accelerate device approval.

Foster operates ISO 13485:2016–certified facilities and has supported medical device manufacturers since 1989 with advanced biomedical polymer compounding and color technologies.

MEDIBATCH™ MEDICAL COLOR CONCENTRATES

Foster MediBatch™ is a line of small-lot, medical device–compliant color concentrates developed specifically for medical applications.

Standard MediBatch™ Colors



Key Features

- Formulated with medical device pigments compliant with FDA 21 CFR 73 & 74 Subpart D
- Universal carrier resin that passed USP Class VI biocompatibility testing
- Designed to support FDA submissions and accelerate approval timelines
- Available in 25 lb. and 50 lb. lots, ideal for prototyping and early production
- Recommended let-down ratio of 25:1 for extrusion and injection molding

Universal Carrier Compatibility

MediBatch™ universal color concentrates are designed for broad compatibility with commonly used medical-grade polymers, helping simplify material selection and processing. Compatible resin families include:

- PEBA
- TPU
- PA 11/PA 12
- EVA
- Polyethylene (PE)
- Polypropylene (PP)

CUSTOM PRE-COLORED AND COLOR CONCENTRATE COMPOUNDS

Custom color concentrate and pre-colored medical compounds provide uniform, ready-to-process materials without the need for downstream color addition.



Key Features

- Colored using pigments compliant with FDA 21 CFR 73, 74 Subpart D and FDA 21 CFR 173- 178
- Matched using the Pantone Matching System (PMS)
- Available across a broad range of polymer platforms
- Scalable from small development lots to large-volume commercial production
- Suitable for extrusion and injection molding applications
- Designed for applications requiring tight color control and lot-to-lot consistency

Pigment Technologies

- High-purity inorganic pigments for stability and durability
- High-purity, high-strength organic pigments for enhanced chromatic performance
- Selected dyes, where appropriate, to achieve specific transparency or aesthetic requirements, subject to regulatory and application considerations

Additional materials such as radiopaque fillers, low friction additive or high-temperature polymers may influence color availability and final appearance.

Color Match Procedure for Custom Formulations

Foster's color match process applies to both custom color concentrates and pre-colored compounds, ensuring consistent color development regardless of the chosen solution.

01

The process begins with a color match worksheet where the customer defines critical parameters such as resin type, processing method (extrusion or molding), regulatory requirements, and target color. Color references may include Pantone numbers, physical part samples, or visual standards.

02

Using a computerized color-matching system, Foster's color specialists develop precise formulations utilizing FDA-compliant medical device pigments and food-contact–grade pigments.

03

Prototype color-matched samples are then produced and submitted for customer review and approval prior to scale-up and production.

REGULATORY CONSIDERATIONS

FDA Colorant & Food Contact Regulations

Foster can formulate color concentrates and pre-colored compounds using pigments suitable for medical device applications depending on material selection and end-use requirements. Many commonly used food-contact–grade pigments utilized by Foster have also been tested for biocompatibility, supporting their use across a broad range of applications.

Under the Food, Drug, and Cosmetic (FD&C) Act, the FDA regulates color additives and materials used in medical devices, food-contact applications, and other products that may contact the human body. FDA standards we follow:

- **21 CFR 73 – Color Additives Exempt from Certification:** FDA-certified pigments that do not require batch certification and are commonly used in medical devices and certain food-contact applications.
- **21 CFR 74 – Color Additives Subject to Certification:** Pigments that require FDA batch certification prior to use.
- **21 CFR 173 – Secondary Direct Food Additives:** Covers additives, including colorants and processing aids, that may become components of food through indirect use.
- **21 CFR 174 – Indirect Food Additives: General:** Governs materials and additives intended for use in food-contact polymers, coatings, and processing equipment.
- **21 CFR 175–178 – Indirect Food Additives:** Addresses specific food-contact materials, including polymers, adjuvants, and colorants used in articles intended for food contact.

While Foster materials are formulated with compliant pigments, finished product manufacturers remain responsible for FDA submissions, regulatory determinations, and validation testing of the final device or food-contact article.

ABOUT FOSTER, LLC

Foster, LLC, a Geon® Performance Solutions company, serves medical device and pharmaceutical manufacturers with industry-leading technology and service in biomedical materials. Our lifesaving and life-enhancing applications include custom medical compounds, implantable materials, drug/polymer blends, and polymer distribution. Backed by ISO 13485:2016 and ISO 14001:201 certifications, Foster ensures exceptional quality, safety, and sustainability at every step. Through global supply partnerships and U.S.-based manufacturing locations, distribution centers, and an innovation center, Foster offers comprehensive support to customers from formulation development through production.

Important Notice

All information provided represents typical characteristics and is intended as guidance only. Customers are responsible for validating performance, safety, and regulatory compliance in their specific applications. Foster, LLC makes no express or implied warranties and reserves the right to modify products, specifications, or packaging as part of ongoing product development.

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