

Custom Pre-Color Compounds Using FDA Certified Medical Device Pigments

Foster Corporation offers pre-colored compounds using FDA 21 CFR 73 Subpart D compliant medical device pigments. The colors shown below are examples of available base color options, matched using the Pantone Matching System (PMS) to the nearest Pantone number (PMS#), using pigments listed under FDA 21 CFR 73 Subpart D. Custom blends using these colorants are also available upon request.

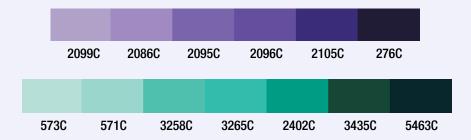
Please note that colors may vary due to computer monitor and printer color restrictions. Additional materials, such as radiopaque fillers may also affect the color of a custom compound. High temperature polymers may limit colorant options.

*For more information on FDA 21 CFR 73 Subpart D, please refer to page 2.

High Purity Inorganic Pigments



High Purity, High Strength Organic Pigments



ABOUT FDA 21 CFR 73 SUBPART D

The Food, Drug and Cosmetic (FD&C) Act, initiated by the FDA limits the use of non-certified color additives in medical devices and surgical tools that may be in contact with the human body for an extended period of time. Pigments listed under Title 21 of the Code of Federal Regulations (CFR) Parts 73 & 74, Subpart D are certified by the FDA as safe for use in such devices. Unlike those listed under 21 CFR 74, Part 73 pigments are exempt from batch certification. Please note however, that finished medical device manufacturers are still required to complete FDA submission and any associated testing on the final device.

ABOUT FOSTER CORPORATION

Since 1989, Foster Corporation has been serving medical device manufacturers with industry leading technology and service in biomedical polymer compounding. Within two ISO 13485:2016 certified facilities, Foster offers expert formulation, development and processing of medical polymers and enhancements, including radiopaque fillers, custom colors, lubricants, reinforcements and other specialty additives.



Foster Corporation

45 Ridge Road, Putnam, CT 06260 • P: 860.928.4102 F: 860.928.4226 www.fostercomp.com

Foster Corporation (Foster) believes that the information contained in this document is an accurate description of the typical characteristics and/or uses of the product or products, but it is the customer's responsibility to thoroughly test the product in each specific application to determine its performance, efficacy and safety for each end-use product, device or other application. Suggestions of uses should not be taken as inducements to infringe any particular patent. The information and data contained herein are based on information we believe reliable. Mention of a product in this documentation is not a guarantee of availability. Foster reserves the right to modify products, specifications and/or packaging as part of a continuous program of product development.

FOSTER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF INTELLECTUAL PROPERTY NON-INFRINGEMENT, INCLUDING, BUT NOT LIMITED TO PATENT NON-INFRINGEMENT, WHICH ARE EXPRESSLY DISCLAIMED, WHETHER EXPRESS OR IMPLIED, IN FACT OR BY LAW. FURTHER, FOSTER MAKES NO WARRANTY TO YOUR CUSTOMERS OR AGENTS, AND HAS NOT AUTHORIZED ANYONE TO MAKE ANY REPRESENTATION OR WARRANTY OTHER THAN AS PROVIDED ABOVE. FOSTER SHALL IN NO EVENT BE LIABLE FOR ANY GENERAL, INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR SIMILAR DAMAGES, INCLUDING WITHOUT LIMITATION, DAMAGES FOR HARM TO BUSINESS, LOST PROFITS OR LOST SAVINGS, EVEN IF FOSTER HAS BEEN ADVISED OF THE