

# **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.

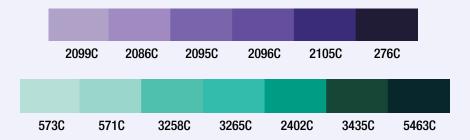
Please note that colors may vary due to computer monitor and printer color restrictions. Additional materials, such as radiopaque fillers may also affect the color of a custom compound. High temperature polymers may limit colorant options.

\*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**

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