



» APPLICATION BULLETIN

MEVOPUR™ Standard Colors for Needle and Catheter Hubs

To help our customers meet healthcare industry standards, Avient offers a range of standard colors for needle hubs, canula hubs and wings matching the color coding of the ISO 6009 standard. Available in opaque or transparent form based on PP resins, either as a masterbatch or pre-color formulation, the colors are standardized to RAL and Pantone color systems. These colors can be combined with a desired additive functionality for convenience.

KEY CHARACTERISTICS

- Manufactured at three ISO 13485 certified sites, providing global consistency and increased security of supply
- Documented change control beyond CAS Number level reducing risk of change
- Free from animal-derived substances and phthalates
- Color can be combined with additives to enhance performance and protection

REGULATORY SUPPORT

- Raw materials tested to:
 - ISO 10993-1 and USP <87> <88> biological evaluation
 - European Pharmacopeia 3.1.3/3.1.5 (polyolefin)
 - USP <661.1> (polyethylene)
 - ICH Q3D elemental impurities
- Registered Device Master File
- Food contact established with FDA/EU*

* FDA/EU compliance information available upon request

NOMINAL OUTSIDE DIAMETER OF NEEDLE (MM)	COLOR DESCRIPTION	RAL	PANTONE	TRANSPARENT PRODUCT CODE	OPAQUE PRODUCT CODE
0.4	Medium Grey	7035	423 C	PP7M665125	PP7M665127
0.45	Brown	8017	7588 C	PP8M665294	PP8M665296
0.5	Orange	2003	173 C	PP2M665298	PP2M665300
0.55	Medium Purple	4005	7676 C	PP4M665290	PP4M665292
0.6	Deep Blue	5010	288 C	PP5M665894	PP5M665896
0.7	Black	9005	Black C	PP9M664950	PP9M664952
0.8	Deep Green	6001	7483 C	PP6M665687	PP6M665689
0.9	Yellow	1021	115 C	PP1M665211	PP1M665213
1.1	Cream	1015	7401 C	PP0M665290	PP0M665292
1.2	Pink	3015	502 C	PE3M665725	PP3M665727

Healthcare use limitations apply—see below. Contact Avient for more information.

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Avient products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices categorized by either the United States Food and Drug Administration (FDA) or the International Standards Organization (ISO) as an “implant” device; or “Permanent” as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices for “Long Term” use as defined in EU Directive 93/42/EEC as amended.

Without limiting the generality of this statement, Avient products shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) “plastic” (cosmetic or reconstructive) surgery use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, and with all applicable laws and regulations.