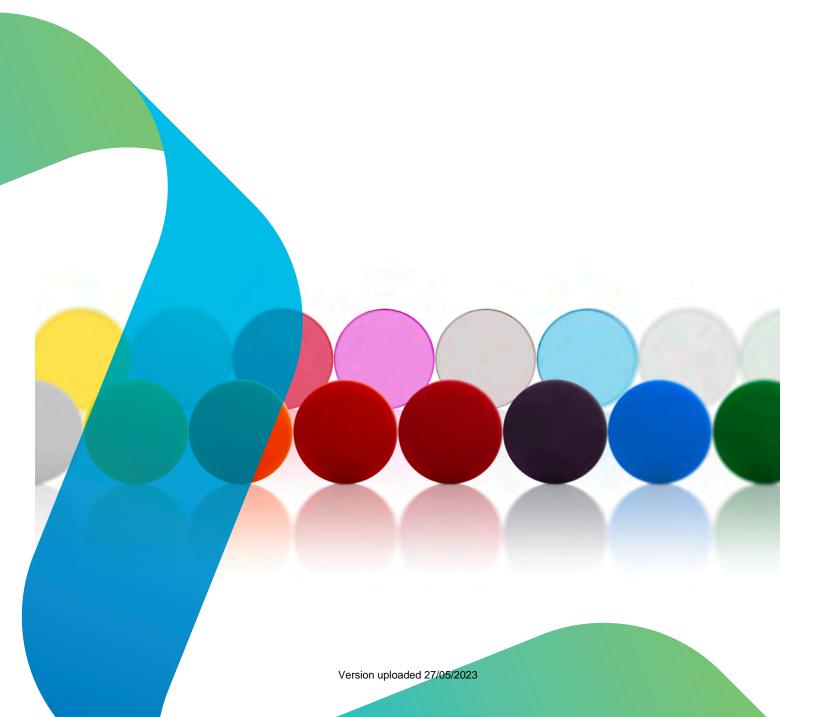




Color masterbatch line



Color masterbatches

The Nusil® brand offers a wide range of masterbatches to provide off-the-shelf pigmenting options for silicones used in medical devices.

NuSil masterbatches are designed for use with platinum-catalyzed liquid silicone rubbers (LSRs) and high consistency silicone rubbers (HCRs). They consist of pigments dispersed in a vinyl-functional silicone polymer which covalently bonds into the matrix of the platinum-catalyzed silicone systems.

BENEFITS OF USING COLOR MASTERBATCHES

Processing

- Provides a means to easily pigment silicone elastomer systems
- Eliminates dry pigment contamination in cleanroom environments
- Reduces costly cleaning time

Performance

- Unparalleled color consistency
- Improved device aesthetics
- No color "bleed out" in the final cured state
- Minimal impact to physical properties

Color options

- Custom colors available upon request
- NuSil has the capability to provide pre-pigmented versions of our LSRs, HCRs, adhesives, low viscosity elastomers and gels

Regulatory support

NuSil color masterbatches are supported with a level of biological testing unique to the industry: They are offered with comprehensive Master Files (MAF) submitted to the FDA and meet the test requirements listed below.

BIOLOGICAL ENDPOINT	STUDY	STANDARD
Cytotoxicity	Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5
Hemolysis	Hemolysis (Extract)	ISO 10993-4
Acute Systemic Toxicity	Acute Systemic Toxicity (Extract)	ISO 10993-11
		ISO 10993-6
Subchronic Systemic Toxicity	Systemic Toxicity Following Four Week Subcutaneous Implant	ISO 10993-11
Intracutaneous Irritation	Intracutaneous Study (Extract)	ISO 10993-10
Implantation (One week)	One Week Muscle Implantation Study	ISO 10993-6
Implantation (Twelve weeks)*	Twelve Week Muscle Implantation Study	ISO 10993-6
Genotoxicity	Bacterial Reverse Mutation Method (Extract)	ISO 10993-3
Pyrogenicity	Pyrogenicity – Material Mediated (Extract)	ISO 10993-11
Skin Sensitization	Maximization Sensitization (Extract)	ISO 10993-10

^{*} Implant line products only

Instructions for use:

The color masterbatches are supplied as a single component material. Depending on the masterbatch chosen, they can either be combined manually, on a two-roll mill or by third stream when using a dosing system. To achieve the colors shown in this guide and for minimal impact to physical properties, suggested concentration is 2pph masterbatch by weight.

SOLID COLOR		TRANSI		LUCENT COLOR	
LSR	HCR				LSR
MED-4800-1 MED-4900-1	MED-4502-1 MED-4102-1		WHITE		MED50-4800-1 MED50-4900-1
MED-4800-2 MED1-4800-2 MED-4900-2 MED1-4900-2	MED-4502-2 MED1-4502-2 MED-4102-2 MED1-4102-2		BLACK		MED50-4800-2 MED-51-4800-2 MED50-4900-2 MED-51-4900-2
MED-4800-3 MED-4900-3	MED-4502-3 MED-4102-3		RED		MED50-4800-3 MED50-4900-3
MED-4800-4 MED-4900-4	MED-4502-4 MED-4102-4		ORANGE		MED50-4800-4 MED50-4900-4
MED-4800-5 MED-4900-5	MED-4502-5 MED-4102-5		YELLOW		MED50-4800-5 MED50-4900-5
MED2-4800-6 MED2-4900-6	MED2-4502-6 MED2-4102-6		GREEN		MED52-4800-6 MED52-4900-6
MED-4800-6 MED-4900-6	MED-4502-6 MED-4102-6		DARK GREEN		MED50-4800-6 MED50-4900-6
MED1-4800-7 MED1-4900-7	MED1-4502-7 MED1-4102-7		BLUE		MED51-4800-7 MED51-4900-7
MED-4800-7 MED-4900-7	MED-4502-7 MED-4102-7		DARK BLUE		MED50-4800-7 MED50-4900-7
MED3-4800-8 MED3-4900-8	MED3-4502-8 MED3-4102-8		VIOLET		MED53-4800-8 MED53-4900-8

IMPLANT LINE: Implantable >29 days PREMIUM CARE LINE: Non-implant



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