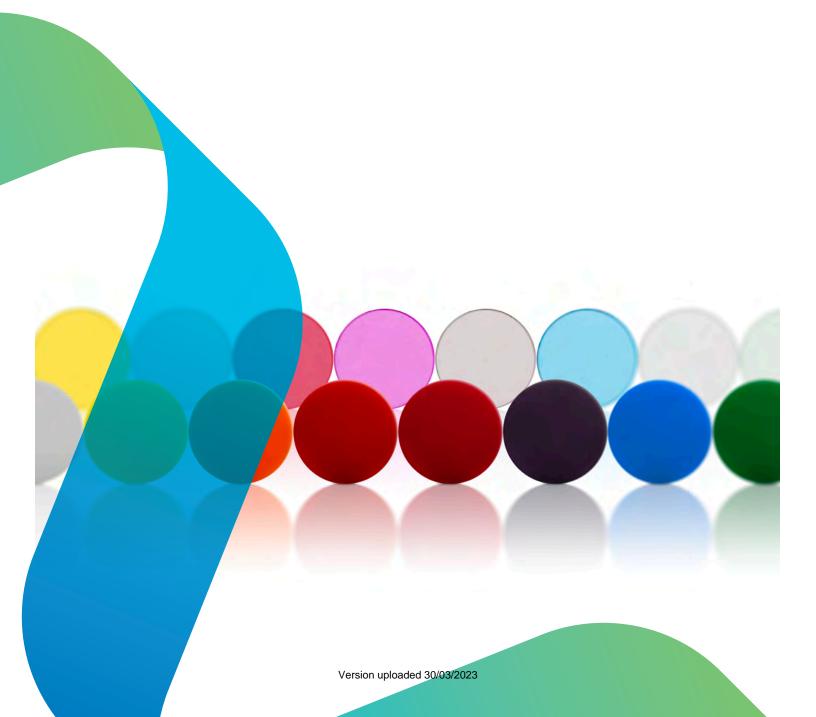




# Color masterbatch line



## 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                |
| Subchronic Systemic Toxicity | Systemic Toxicity Following Four Week Subcutaneous Implant | ISO 10993-6<br>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                |

<sup>\*</sup> 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  |  | l | TRANSLUCE  | NT COLOR |  |
|--|--|---|------------|----------|--|
| LSR  | HCR  |   |            |          | LSR  |
| MED-4800-1<br>MED-4900-1                               | MED-4502-1<br>MED-4102-1                               |   | WHITE      |          | MED50-4800-1<br>MED50-4900-1                                   |
| MED-4800-2<br>MED1-4800-2<br>MED-4900-2<br>MED1-4900-2 | MED-4502-2<br>MED1-4502-2<br>MED-4102-2<br>MED1-4102-2 |   | BLACK      |          | MED50-4800-2<br>MED-51-4800-2<br>MED50-4900-2<br>MED-51-4900-2 |
| MED-4800-3<br>MED-4900-3                               | MED-4502-3<br>MED-4102-3                               |   | RED        |          | MED50-4800-3<br>MED50-4900-3                                   |
| MED-4800-4<br>MED-4900-4                               | MED-4502-4<br>MED-4102-4                               |   | ORANGE     |          | MED50-4800-4<br>MED50-4900-4                                   |
| MED-4800-5<br>MED-4900-5                               | MED-4502-5<br>MED-4102-5                               |   | YELLOW     |          | MED50-4800-5<br>MED50-4900-5                                   |
| MED2-4800-6<br>MED2-4900-6                             | MED2-4502-6<br>MED2-4102-6                             |   | GREEN      |          | MED52-4800-6<br>MED52-4900-6                                   |
| MED-4800-6<br>MED-4900-6                               | MED-4502-6<br>MED-4102-6                               |   | DARK GREEN |          | MED50-4800-6<br>MED50-4900-6                                   |
| MED1-4800-7<br>MED1-4900-7                             | MED1-4502-7<br>MED1-4102-7                             |   | BLUE       |          | MED51-4800-7<br>MED51-4900-7                                   |
| MED-4800-7<br>MED-4900-7                               | MED-4502-7<br>MED-4102-7                               |   | DARK BLUE  |          | MED50-4800-7<br>MED50-4900-7                                   |
| MED3-4800-8<br>MED3-4900-8                             | MED3-4502-8<br>MED3-4102-8                             |   | VIOLET     |          | MED53-4800-8<br>MED53-4900-8                                   |

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



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