

# IMPLANT LINE COLOUR MASTERBATCHES

NuSil<sup>TM</sup> colour masterbatches offer off-the-shelf pigmenting options for silicone elastomers intended for the medical device market.

NuSil<sup>TM</sup> and GSDI co-developed a line of silicone masterbatches for colouring liquid silicone rubbers (LSRs) and high consistency silicone rubbers (HCRs)

These colour masterbatches can be used with NuSil<sup>TM</sup> Medical Implant (long-term implantable) silicone products.

The colour masterbatches consist of pigments dispersed in vinyl functional silicone polymers that when used in conjunction with platinum cure systems will participate in an elastomer's curing process, becoming part of the polymer matrix.

#### BENEFITS OF USING COLOUR MASTERBATCHES

#### PROCESSING

- · Eliminate dry pigment contamination in clean room environments
- · Reduce costly cleaning time
- · Provide a means to easily pigment silicone elastomer systems

#### PERFORMANCE

- · Unparalleled colour consistency
- · Improved device aesthetics
- · No 'bleed' out will occur in the final cured state
- · Maintains good physical properties

#### REGULATORY SUPPORT

What differentiates NuSil<sup>TM</sup> colour masterbatches from other colour options in the medical device market is the level of biological testing performed on these materials. Our colour masterbatches are supported by the following biological test data and comprehensive Master Files (MAF) submitted to the FDA

SECTION	BIOLOGICAL TEST
1	In Vitro Hemolysis Study (Modified ASTM - Extraction Method)
2	USP and ISO Systemic Toxicity Study Extract
3	ISO Intracutaneous Study Extract
4	ISO Muscle Implantation Study (1 week)
5	ISO Muscle Implantation Study (12 weeks)
6	Genotoxicity: Bacterial Reverse Mutation Study (DMSO Extract) (Saline Extract)
7	USP Pyrogen Study Material Mediated
8	ISO Maximization Sensitization Study

#### COLOUR OPTIONS

- · Opaque Colours (HCR and LSR): white, black, red, orange, yellow, green, dark green, blue, dark blue and violet
- · Translucent Colours (LSR only): white, black, red, orange, yellow, green, dark green, blue, dark blue and violet
- · Custom Colours are available upon request
- · We also have the capability to provide pre-coloured versions of our LSRs, HCRs and adhesives

NuSil

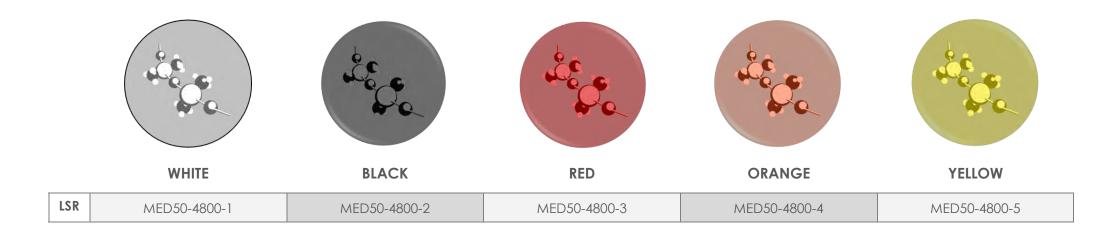


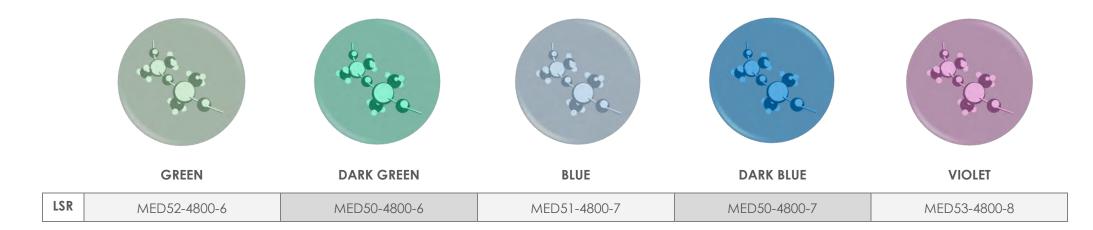
## OPAQUE COLOUR



Our colour masterbatches are comprised of pigments blended into vinyl functional polymers. The dispersion process and focus on pigment particle size ensures unparalleled lot to lot consistency. We recommend adding these colour and translucent colour masterbatches at 2 parts per hundred. Customized colours are obtained by a process of blending qualified base colours and are available upon request. It is the sole responsibility of each purchaser to ensure that any use of these materials is safe and complies with all applicable laws and regulations. It is the user's responsibility to adequately test and determine the safety and suitability for their applications and NuSil Technology LLC makes no warranty concerning fitness for any use or purpose.

### TRANSLUCENT COLOUR





Our colour masterbatches are comprised of pigments blended into vinyl functional polymers. The dispersion process and focus on pigment particle size ensures unparalleled lot to lot consistency. We recommend adding these colour and translucent colour masterbatches at 2 parts per hundred. Customized colours are obtained by a process of blending qualified base colours and are available upon request. It is the sole responsibility of each purchaser to ensure that any use of these materials is safe and complies with all applicable laws and regulations. It is the user's responsibility to adequately test and determine the safety and suitability for their applications and NuSil Technology LLC makes no warranty concerning fitness for any use or purpose.



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# ABOUT POLYMER SYSTEMS TECHNOLOGY LIMITED

Polymer Systems Technology Limited was established in 1994, and is located in High Wycombe, approximately 25 miles west of London.

The company has grown progressively since then, moving to newly built premises consisting of 6,000 square feet in 2005.

PST is a company committed to meeting the agreed requirements of our customers, both internal and external, on time, every time, and to be a diligent supplier of polymers without detrimental harm to the environment.

Product quality and safety in use are of paramount concern to us. It is for this reason that registration to the approved quality standards was sought.

#### POLYMER SYSTEMS TECHNOLOGY LIMITED

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