THERMOPLASTIC ELASTOMERS • STRUCTURAL • WEAR
CONDUCTIVE • COLOR • FLAME RETARDANT

Medical Grade Colors
Dean Fosbury
September, 2015
Today’s Topics

- Intro to RTP Color
- Biocompatibility
  - Statements
  - Color Packages
- Additive Masterbatch
  - Laser Marking
  - Laser Welding
- Conclusion

BRANDING OF MEDICAL DEVICES

Color Increases Brand Recognition
Up To 80%

Brand Recognition Increases Company Value
RTP Company Color Division
YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

• Color virtually all resins
  – Engineering resins
  – Styrenic resins
  – Polyolefin resins

• Color in multiple formats
  – Masterbatches
  – Precolored resins
  – Cube blends

• Global color management
  – Global color synchronization
  – Color standards
  – Fast color matching service

Coloring Options
YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

• Masterbatches
  – Additive Masterbatches
  – Custom
  – Standard Engineering
  – Unicolor
  – Commodity Blacks & Whites

• Precolor
• Cube blend

Your Color – Your Way
Numeric Color Modeling

- CIE L*a*b* is most popular
- Numeric model provides
  - 3 dimensional color space
  - Quantify colors numerically
  - Can be used for specification, identification, comparison
- Identified by L* a* b* values
  - L* = lightness to darkness
  - a* = redness to greenness
  - b* = yellowness to blueness
  - DE = total color difference

\[ DE = \sqrt{D_L^2 + D_a^2 + D_b^2} \]
Color Evaluation & Control
YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

Visual Color Evaluation
• Confirmed color vision
• Color standards for reference
• Controlled light
• Agreed upon color space

Instrumental Color Evaluation
• Calibrated machine
• Color standards for reference
• Controlled temperature
• Agreed upon color space

Statement of Biocompatibility
YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

Statement of Biocompatibility
ISO 10993-1: Biocompatibility Tests, In Vivo and In Vitro

This is to confirm that the pigments, resin(s), and additive(s) used in the following product manufactured by RTP Company,

EMD-XXXX MB Unicolor 5D Green

have been used in compounds that have undergone the following studies by NAMSA, an independent laboratory. The tested compounds have been found to meet ISO 10993-1 and/or USP requirements.

ISO In Vitro Mutagenicity Study: Extract, ISO 10993: Biological Evaluation of Medical Devices, Part 10, Test for Genetic and Reproductive Toxicity. The mutagenic extract met the requirements of the test. There was no significant difference between the mean score of the test extract and the mean score of the corresponding controls.

USP and ISO Systemic Toxicity Study: Extract, United States Pharmacopeia and ISO 10993: Biological Evaluation of Medical Devices, Part 11, Tests for Systemic Toxicity (ISO). Each test article extract met the test requirements. Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts.

Cutaneous Study Using the ISO Elution Method (IX MEM Extract), ISO 10993: Biological Evaluation of Medical Devices, Part 5, Test for Delayed Hypersensitivity, in 2009
Methods and Results. Under the conditions of this study, the IX MEM test extract showed no evidence of eliciting cell lysis or toxicity. The IX MEM test extract met the requirements of the test since the grade was less than 2 (mild reactivity).
Standard Medical Colours

- 18 Standard Colors that have passed ISO 10993-1
- Unicolor™ - Universal carrier
- Styrenics, Olefins, Elastomers, Nylons, PVC, Engineering Resins, Radel® R and other high temperature resins
- Low letdown ratio 1-2%

Plastic Formulation Selection

Up Front Material Selection Criteria:
- Ability to pass ISO biologic testing
- Global availability
- High commercial viability
- Sterilization process
- Mechanical/Chemical requirements
- Branding

Paproing the File:
- Statement of biocompatibility
- Technical datasheet
- MSDS

Goal:
- To demonstrate to your regulatory reviewer a documented pattern of concern for safety issues.
Insight to RTP Color Number Nomenclature

Color number Prefixes:

• SC - Standard nomenclature
• ZC - FDA ingredients
• EC - No substitute formula
• EMD - No substitute formula
  - Uses resin, additives, and pigments known to pass ISO:10993 or USP VI

Additive Masterbatch

• Antistatic
• Flame Retardant
• Foaming
• Glow in the Dark
• Laser Marking
• Laser Welding
• Stabilizers
  – UV
  – Heat
• Clarifiers
Laser Marking

Basic mechanism

Laser energy absorbed causing a reaction
- Charring (dark mark)
- Foaming (light mark)
- Ablation (removal of layer, ex. Paint)

One Light – Two Marks

Dark Marks

Light Marks
Laser Marking

• Different lasers can be used, but Nd:YAG (Neodymium doped Yttrium Aluminum Garnet) is the best compromise of...
  – Speed
  – Flexibility
  – Marking quality

Advantages

• Permanent Marks
  – Bar codes
  – Serial marks
• No consumables (labels)
• FDA and BIO compounds available
• Combine with other technologies
• Unique colors achievable
• Dark or light marks
Laser Welding

Method for joining thermoplastic parts by using the thermal power of laser to bond materials

Laser Beam

Material A: Transparent to Laser

Melt Zone (Weld Seam)

Material B: Opaque to Laser (Absorber)

Laser Welding of Thermoplastics

• The below chart indicates the degree of complexity for laser welding of various colors combinations

• RTP Company has experience with pigment/filler combinations, and loading levels, to support successful welding using both Diode and Nd:YAG lasers
## Laser Welding of Thermoplastics

### Advantages

- No contact with plastic part
- Relatively high speed
- Can weld complex parts
- No flash is produced
- High-precision joints can be produced
- Gas-tight, hermetic seals are possible
- Thermal distortion is minimal
- Resins of different compositions can be joined
- No consumables (adhesives, fasteners, etc.)

### Conclusion

- Regulatory bodies are placing increased scrutiny on colorants for plastics to pass biologic testing
- Color selection for drug delivery, surgical tools and other medical devices is a critical skill and key to Branding
- Laser marking provides a permanent, rapid, and precise way to mark devices
- Additive Masterbatch can enhance commodity resin properties and function
- Selecting a skilled color compounding with a history of success in medical devices can speed application development and help reduce risk