



The Significance of Color as a Functional Property of Critical Medical Devices

Including Examples
Where the Color Affects Performance

Outline

1. Introduction
2. Why color and how is it used?
3. When color happens & what it means
 - Example – PVC, Natural Rubber Latex & other aged materials
 - Example – Inherent color affects patient safety
4. Color as functional part of the product
 - Size indicator
 - Product identifier
 - Quality check
5. Summary / Recommendations



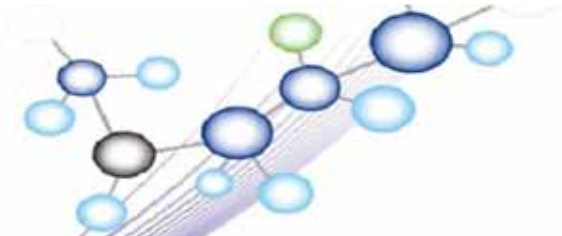
Medical Device Industry Experience

Introduction



My background:

- 20 years with Baxter Healthcare
- 15 US patents (10 for flexible PVC replacements)
- Consulting on materials, design & processing
- Expert witness (patent defense, design interpretation, etc.)
- Seminar instructor, conference planner & speaker
- Member of SPE since 1975
- SPE International President 2005 - 2006
- Distinguished, Honored Service, Fellow of SPE



Outline

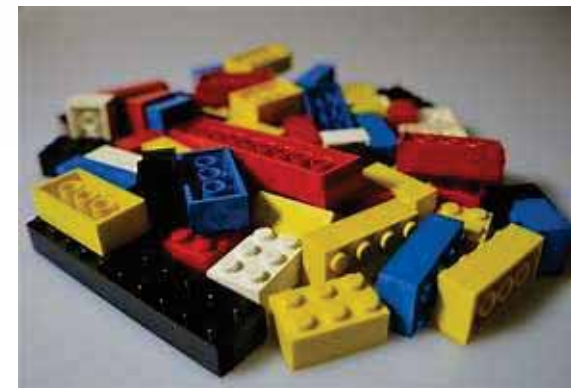
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Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

1. Color sends a message
2. To enhance appearance
3. Identifies one brand or type from another
4. Indication of quality





Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

1. Color sends a message





Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

1. Color sends a message



Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

1. Color sends a message
2. To enhance appearance: Generic vs Brand names





Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

1. Color sends a message
2. To enhance appearance
3. Identifies one brand or type from another



UNKI

The UNKI logo, consisting of the word "UNKI" in a bold, orange, sans-serif font.



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UNKI





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UNKI



A graphic of a molecular structure with blue, green, and black spheres connected by lines, positioned in the top left corner.

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A ball-and-stick molecular model showing a network of atoms. A central grey atom is bonded to several blue atoms, which are further bonded to other blue and green atoms. The structure is set against a background of light blue and purple wavy lines.

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Color in Medical Devices & the Healthcare Industry

Why color and how is it used?

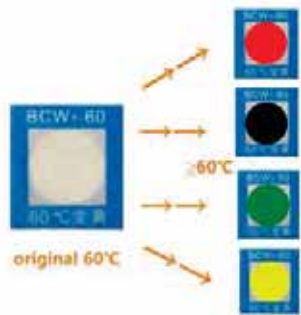
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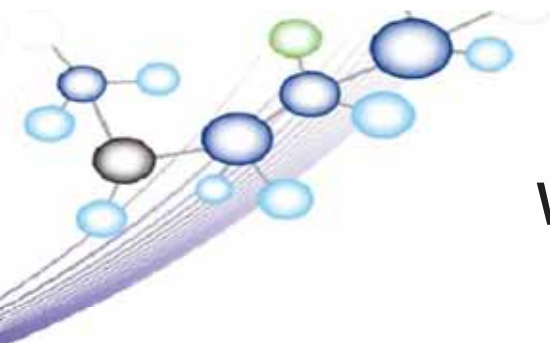
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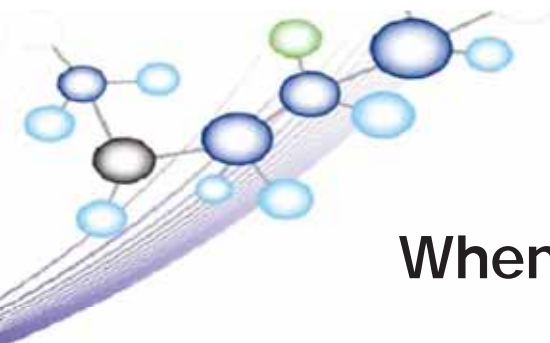


Color in Medical Devices

When color happens & what it means

Examples: PVC, NRL & other materials show discoloration with processing or aging





Color in Medical Devices

When color happens & what it means

Examples: PVC shows discoloration

with age & sometimes when sterilized



Color in Medical Devices

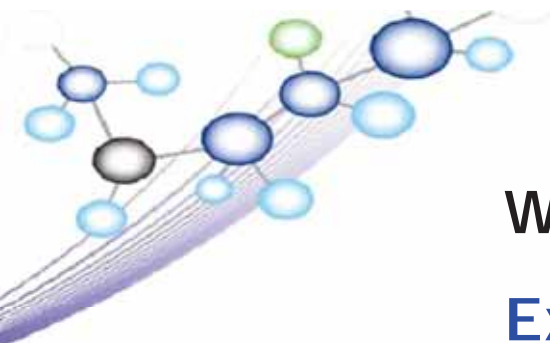
When color happens & what it means

Examples: Other materials show color shift
discoloration when radiation sterilized



Polyester

Polycarbonates



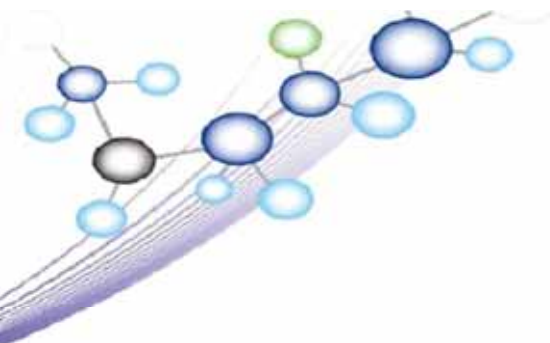
Color in Medical Devices

When color happens & what it means

Examples: NRL gloves show discoloration with age



Natural Rubber Latex gloves



Color in Medical Devices

When color happens & what it means

Examples: Inherent PVC color & clarity
can show problem-free dialysis

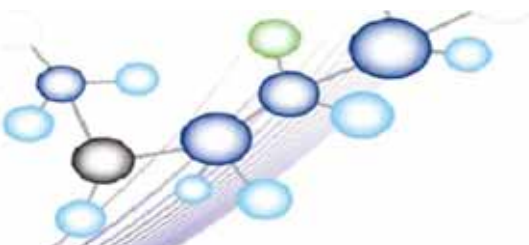


Clear colorless PVC will show cloudiness in solution



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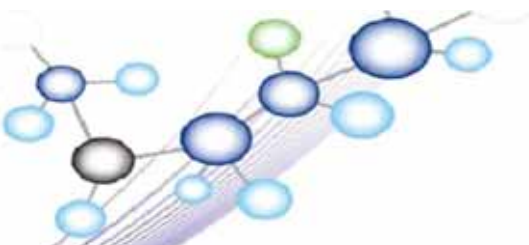
Color in Medical Devices & the Healthcare Industry

Color as functional part of the product

- Size indicator:

Needle Cannula sizes





Color in Medical Devices & the Healthcare Industry

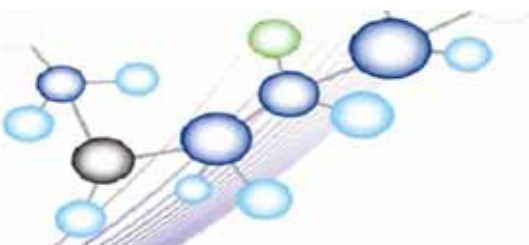
Color as functional part of the product

- Size indicator:

18 Gauge

Needle Cannula sizes





Color in Medical Devices & the Healthcare Industry

Color as functional part of the product

- Size indicator:

20 Gauge

Needle Cannula sizes



Color in Medical Devices & the Healthcare Industry

Color as functional part of the product

- Product identifier:

Blood Collection Vacuum Tubes

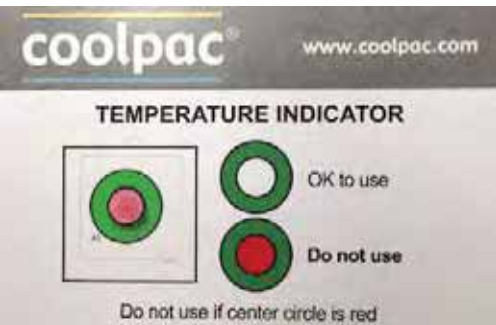


Color in Medical Devices & the Healthcare Industry

Color as functional part of the product

- Quality check:

Temperature indicators



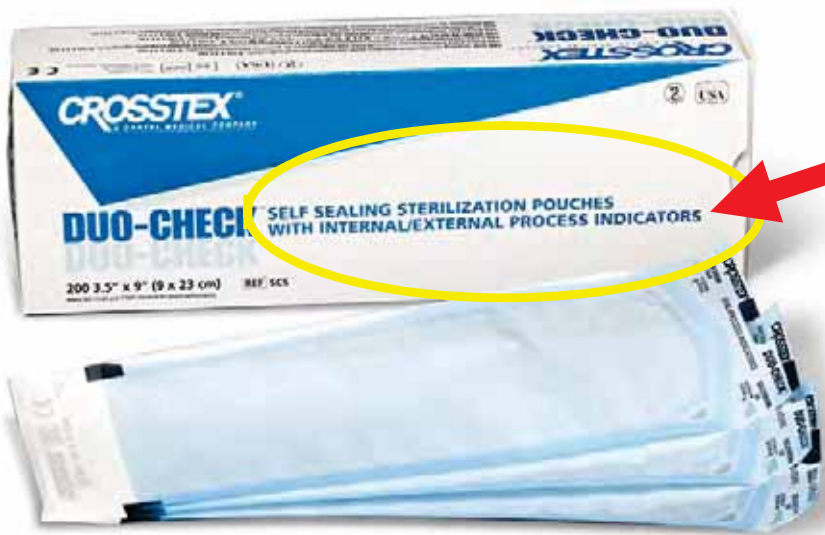


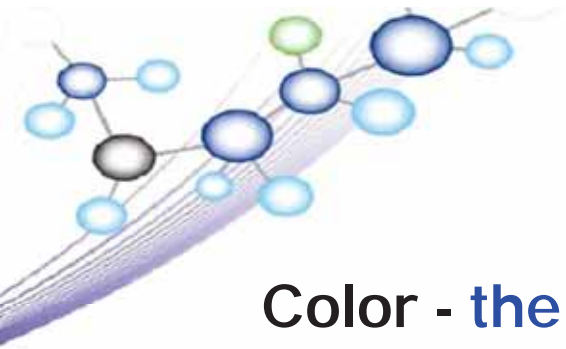
Color in Medical Devices & the Healthcare Industry

Color as functional part of the product

- Quality check:

Sterilization indicators

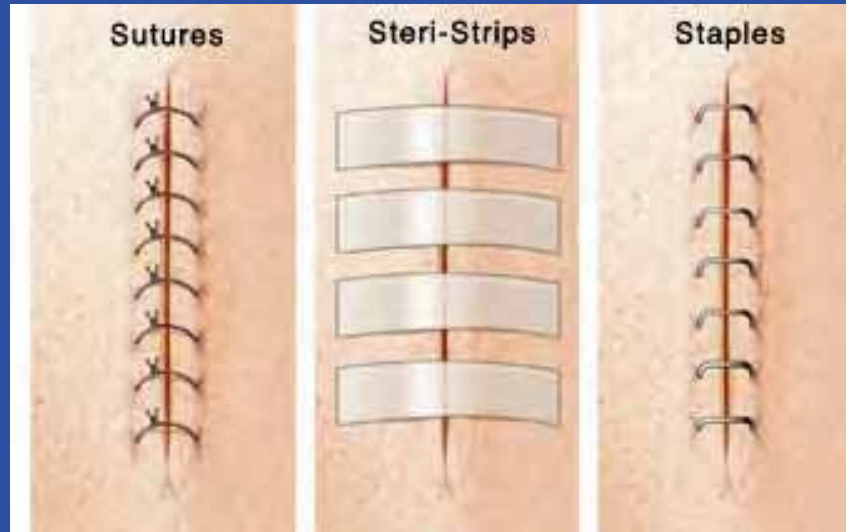




Color in the Healthcare Industry

Color as functional part of the product

Color - the difference between a Functional Product & a "Dud"!

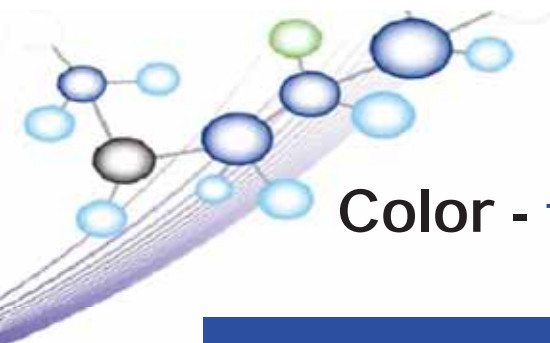




Color in the Healthcare Industry

Color - the difference between a Functional Product & a "Dud"!

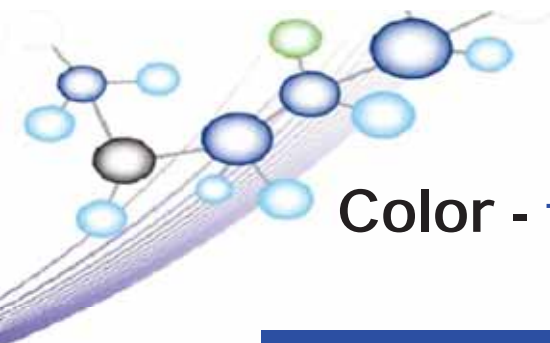




Color in the Healthcare Industry

Color - the difference between a Functional Product & a "Dud"!





Color in the Healthcare Industry

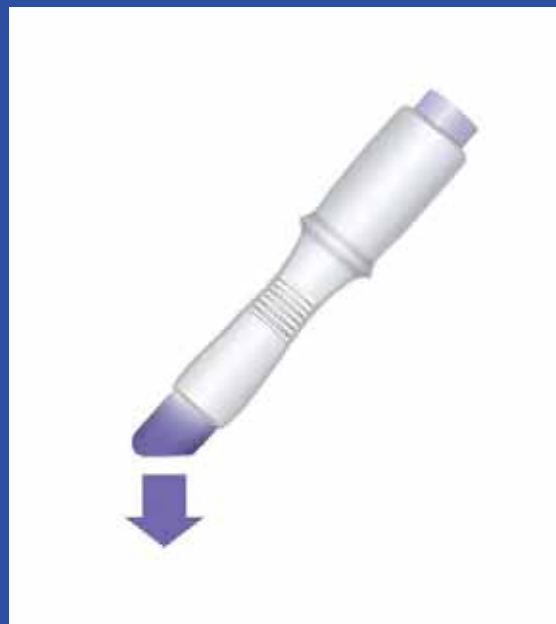
Color - the difference between a Functional Product & a "Dud"!





Color in the Healthcare Industry

Color - the difference between a Functional Product & a “Dud”!





Color in the Healthcare Industry

Color - the difference between a Functional Product & a "Dud"!



Color in the Healthcare Industry

Color - the difference between a Functional Product & a "Dud"!

Original formula
+ color + 2 years



= Final product formula
& FDA clearance!





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Color in Medical Devices & the Healthcare Industry

Summary / Recommendations

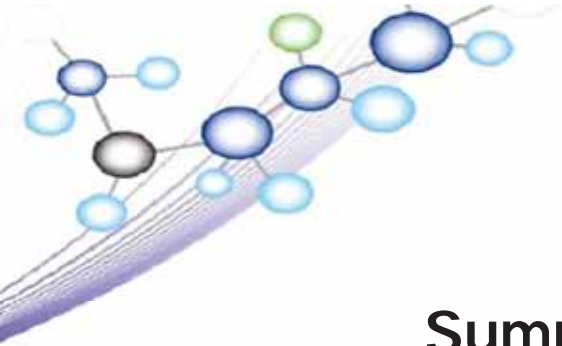
- Plan use of color based on market needs
- Should be considered part of the initial design of product
- Work with colors that are acceptable for medical devices!



Color in Medical Devices & the Healthcare Industry

Summary / Recommendations

- Work with colors that are acceptable for medical devices (no heavy metal colorants, esp. for Class 3 Implantables!)
- Do appropriate testing (physical / functional, chemical, biological)...
...to avoid surprises & delays & added cost!

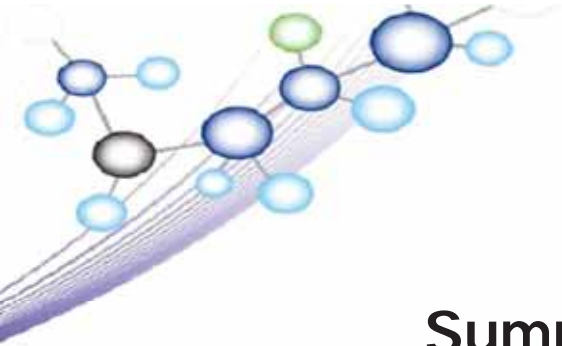


Color in Medical Devices & the Healthcare Industry

Summary / Recommendations

Do appropriate testing

- Physical / functional
- Chemical
- Biological - ISO 10993 explains requirements



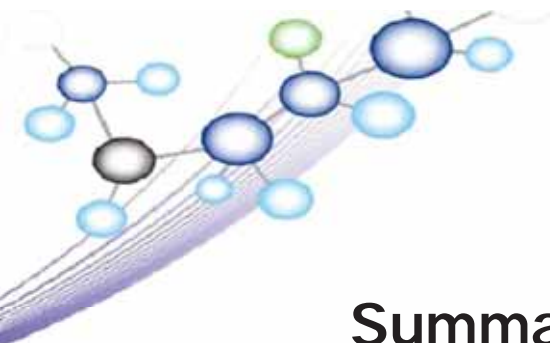


Color in Medical Devices & the Healthcare Industry

Summary / Recommendations

- Plan use of color based on market needs
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Color in Medical Devices & the Healthcare Industry

Summary / Recommendations

- Appropriate color usage can make the product successful
- The emerging "Healthcare at Home" growth needs colorful & intuitive products to help proper usage and function!
- Color helps bring "joy" to an otherwise drab environment!





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SPE Decorating & Coatings Division
TOPCON
& **IMDA** SYMPOSIUM



Sept. 16-17, 2021
Edina, Minnesota

Questions?

SPE Decorating & Coatings Division
TOPCON
& **IMDA SYMPOSIUM**

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Thank you for being here!

It's great to finally be face-to-face again!!

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Sept. 16-17, 2021
Edina, Minnesota

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