ΔVΔNOS

COLOR VARIATION

LATEX BLADDER, EXTERNAL PVC COVER AND PUMP TUBING

LATEX BLADDER

Testing has been conducted on Avanos elastomeric infusion pumps to determine whether the color variation of the outer latex bladder on the elastomeric infusion pump affects the form, fit or function of the device. Flow rate accuracy testing on pump bladders of various color ranging from light in color to dark in color demonstrated that all pumps regardless of color were similar in performance and within specification.

EXTERNAL PVC COVER AND PUMP TUBING

Changes in physical properties such as discoloration are a known occurrence after gamma irradiation and aging. The color change is a cosmetic defect with no effect to product performance and physical/chemical properties. In conclusion the color variation in the external PVC cover, pump tubing or latex bladder does not affect the form, fit or function of the device.

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications**, **Cautions**, **Warnings** and **Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to **www.avanosmedicaldevices.com** for additional product safety Technical Bulletins.

Please contact the Clinical Services Department at **800-444-2728** or **949-923-2400** if you have any questions regarding this information.



