

Nexus TKO[®]

Anti-Reflux Device

NEXUS TKO[®]-6P Hi-Visibility TECHNICAL SPECIFICATION SHEET

Nexus Medical 510(k): K130416



Technical Specifications

- Swabbable, luer accessible septum
- Average flow rate is 4500 mL/hour with low viscosity fluids at 1M head height
- Cracking pressure (opening pressure) no greater than 20 in/H₂O (~0.7 psi)
- Allows no reflux (fluid retrograde) upon disconnection of standard syringe
- Aspiration pressure is no less than 3.5 psi and no greater than 9.5 psi when using standard flushing syringe
- Withstands pulsating back pressure of 0.3 to 0.5 psi for 96 hours without leaking
- Withstands distal vacuum pressures up to 10 psi without leaking when proximal end is and is not connected to a standard male luer lock
- Luer lock insertion force of less than 5 pounds force
- Compatible with all ANSI and ISO 594 compliant female and male connectors
- Power injectable to 325 psi or 10 mL/second
- Average priming volume: 0.13 mL

Materials

- Materials used in the TKO products, including extension sets, are medical grade and have been utilized in other legally marketed devices throughout the industry. These include polycarbonates, ABS, silicones, isoprene and non-phthalate PVC.
- Materials are Latex-Free and DEHP-Free
- Additionally, the materials meet ISO 10993-1 standards for external communicating devices, specifically blood path/indirect devices, with prolonged exposure (24 hrs to 30 days). This includes testing for cytotoxicity, sensitization, subacute and subchronic toxicity and hemocompatibility. These tests determine additional biological responses to the materials using standard laboratory tests.

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