

Nexus TKO[®]

Anti-Reflux Device

NEXUS TKO[®]-5 TECHNICAL SPECIFICATION SHEET

Nexus Medical 510(k): K053129



Technical Specifications

- ☞ Swabbable, plastic cannula accessible septum
- ☞ Average flow rate is 3500 mL/hour with low viscosity fluids at 1M head height
- ☞ Cracking pressure (opening pressure) no greater than 20 in/H₂O (~0.7 psi)
- ☞ Allows less than 0.01 cc of reflux (fluid retrograde) upon disconnection of flushing syringe
- ☞ Aspiration pressure is no less than 3.5 psi and no greater than 9.5 psi when using flushing syringe
- ☞ Withstands pulsating back pressure of 0.3 to 0.5 psi for 96 hours without leaking
- ☞ Withstands pressures up to 325 psi during power injections at maximum flow rate of 5 mL/sec
- ☞ Withstands distal vacuum pressures up to 10 psi without leaking when proximal end is and is not connected to a locking cannula
- ☞ Cannula attachment and detachment is less than 8 pounds force
- ☞ Compatible with all ANSI and ISO 594 compliant female and male connectors
- ☞ Average priming volume: 0.1 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
- ☞ Materials meet the requirements of US Pharmacopeia Class VI which includes testing for acute systemic toxicity, intracutaneous toxicity and implantation test. These tests measure and determine the biological response of animals to the plastic by either direct or indirect contact, or by injection of the specific extracts prepared from the material under test.
- ☞ 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 additional testing for cytotoxicity, sensitization, subacute and subchronic toxicity and hemocompatibility. These tests determine additional biological responses to the plastic using standard laboratory tests.



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