

Nexus TKO[®]

Anti-Reflux Device

NEXUS NIS[®]-5 TECHNICAL SPECIFICATION SHEET

Nexus Medical 510(k): K092527



Technical Specifications

- Swabbable, plastic cannula accessible septum
- Average flow rate is 4500 mL/hour with low viscosity fluids at 1M head height
- Withstands backpressure of 45 psi
- Withstands pressures up to 325 psi during power injections at maximum flow rate of 10 mL/second
- 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 connectors
- Average priming volume: 0.1 mL

Materials

- Materials used in the Nexus NIS[®] 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.

www.nexusmedical.com
11315 Strang Line Road
Lenexa, Kansas 66215
tel (913)-451-2234
fax (913)-451-2363

