

# Nexus TKO<sup>®</sup>

## Anti-Reflux Device

### Nexus TKO<sup>®</sup>-6P: Technical Specification

#### Nexus Medical 510(k): K130416



#### Technical Specifications

- Septum surface is flat, smooth and proven to provide microbial barrier protection.<sup>1</sup>
- Septum seals 360° compressing against the female luer housing which has been proven to provide safe and effective microbial barrier.<sup>1</sup>
- Saline only, TKO has been proven in clinical trials eliminate heparin and corresponding drip in tPA has occurred.<sup>3,4,5</sup>
- 100% Clear fluid pathway provides Caregiver complete visibility to access a productive flush.<sup>2</sup>
- No dead space or torturous fluid pathway, complete laminar flowing fluid pathway.<sup>2</sup>
- No internal mechanism, TKO is a single piece, clear, dome shaped silicone diaphragm <sup>2</sup>
- Clear, direct, rigid fluid provides complete laminar flow from top of bottom of male luer.
- No clamping sequence, the TKO diaphragm is designed to automatically close.
- Blood Reflux Protection 24/7, TKO diaphragm is proven to reduce tPA greater than 58% <sup>3,4,5</sup>.
- Average flow rate is 4500 mL/hour with low viscosity fluids at 1M head height.<sup>2</sup>
- Cracking pressure (opening pressure) no greater than 20 in/H<sub>2</sub>O (~0.7 psi)
- 7-Day use, is support by design validation and microbial ingress testing.
- Aspiration pressure is no less than 3.5 psi and no greater than 9.5 psi when using standard flushing syringe
- 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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1. GLP-Study, Nexus TKO-6P, 96-Activation microbial Barrier Performance Study on file or on our website above, 2. Lab results on file at Nexus Medical, 3. Mitch S, Brandmeyer B, PICC and Midline Catheter Occlusion Rates: a prospective study comparing the Interlink split – septum to the TKO-5Pressure Activated Anti-Reflux value, white paper 2007 4. Jasinsky L, Wurster J, Occlusion reduction and heparin elimination trial using anti-reflux device on PIVC, PICC and CVC, Jour. IV Nurs. 2009, 5. Shomo J, Reynolds c, Gilbert L, Anti-reflux technology reduces catheter complications and provides significant cost savings, Poster Board, INS National Conf. 2014.

