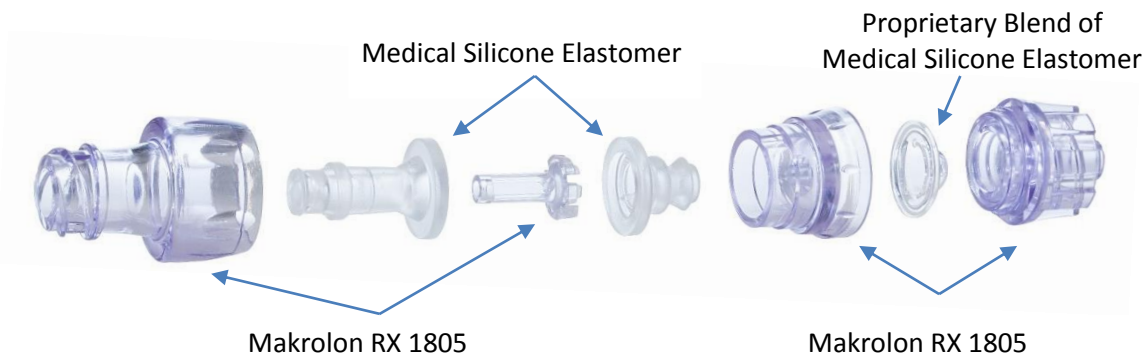


Nexus TKO®

Anti-Reflux Device

Nexus TKO®-6P: Biocompatibility & Chemical Compatibility Technical Specification

Nexus Medical 510(k): K130416



The Nexus TKO® family of infusion therapy product has been performance engineered to meet or exceed ISO, FDA and USP requirements for arterial and venous infusions of IV fluids, medication, drugs, blood and blood products. In order to meet the rigid requirements for biocompatibility and chemical compatibility, proper materials must be selected. Nexus has chosen two materials which are Bayer Makrolon RX1805 and Medical Grade Silicone Rubber which all have been proven over decades of safely delivering Infusion Therapy in oncology, bone marrow transplant, adult and neonatal intensive care units, surgery and dialysis to name a few specialty areas. Nexus has tested all of our materials to be biocompatible and chemically compatible to meet infusion therapy standards for clarity, pressure, antiseptic cleaning, impact strength, chemical and drug resistance.

Technical Specifications:

- Septum surface and TKO male and female housing can be disinfected with 70% isopropyl alcohol, Betadine®, chlorhexidine gluconate, Chloraprep®, Clorascrub® and 3% Hydrogen Peroxide.¹
- Nexus TKO and related tubing sets are lipid, alcohol and Taxol® compatible.
- Nexus TKO materials have been tested to 10mL per second or 325 psi.³
- Bayer Makrolon and medical grade silicones provide a level of chemical resistance required for use with cytotoxic and nuclear.
- Medical Silicone Elastomers have more than 60-years of history in medical device engineering due to polymers.²
- Medical Silicone Elastomers meet ISO 10993, USP (87), (88) and USP Class VI.²
- Nexus TKO and related tubing sets offer safety and convenience for healthcare workers dispensing, transferring and administering cytotoxic drugs to patients.¹
- Heat compatibility with ethylene oxide (ETO) Steam 121°C Gamma radiation and Electron beam.¹
- High heat resistance and dimensional stability with thermal properties to 135°C.¹
- Meet biocompatibility requirements of USP Plastics Class VI and ISO 10993-1 for the categories of Cytotoxicity, Klignan Maximization, Intracutaneous Injection, Pyrogenicity, Ames Reverse Mutation, Muscle Implantation,

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-5 Pressure Activated Anti-Reflux valve, 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.



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- in-vitro hemocompatibility, USP Physicochemical Test, Heavy Metals Analysis- Acid digest and extraction.¹
Hemolysis-direct and indirect, Luer lock insertion force of less than 5 pounds force
- Material rigidity meets compatibility with all ANSI and ISO 594 compliant female and male connectors.³
- Material pressure compatibility with Power injectable to 325 psi or 10 mL/second.³
- Material ultrasonic weld integrating validation tested to 40 feet pounds.³

References

1. Bayer Medical Reference Guidance for High Performance Materials for the Healthcare Industry Aug. 2009
www.plastics.bayer.com
2. Momentive Silicone Elastomers, Silicone Rubbers in Medical Application Dr. Ludwig, EMEA Manager of
Consumer Goods and Healthcare
3. Nexus Medical Technical Data and FDA 510K

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-5 Pressure 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.

