Nexus TKO®-6P

Frequently Asked Questions (FAQs)

Nexus TKO®-6P

Functional FAQs

Q. Is the Nexus TKO®-6P power injectable?

A. Yes. The device is injectable to 325 psi at 10ml's/second

Q. What is the minimum fluid flow rate of the Nexus TKO®-6P?

A. The minimum flow rate on average is 4,500 mL/hour with standard I.V. fluids (D5W, saline, ringers lactate, TPN) I.V. medications and drugs at 36 inch head height.

Q. At what pressure does the Nexus TKO®-6P Anti-Reflux valve open?

A. The TKO opens (forward flow) on average with 10 inches of water column or 18 mmHG.

Q. Can a clinician perform a draw blood with the Nexus TKO®-6P?

A. Yes. The TKO easily opens in reverse to aspirate blood to confirm catheter patency and/or draw blood specimens with either syringes or blood tubes.

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Frequently Asked Questions (FAQs)

Functional FAQs Cont...

Q. How sensitive is the Nexus TKO®-6P to changes in the patient's vascular pressure?

A. The TKO remains in the closed position on average up to 20 times the patient's vascular resistance which is 300 mmHg or 6 psi. With this superior design feature the clinician is assured the TKO will stay in the closed position and prevent blood reflux from patient movement, thoracic pressures from ventilators, sneezing, vomiting, chest compressions or other changes in vascular pressure.

Q. What is the priming volume of the Nexus TKO®-6P?

A. The Nexus TKO®-6P has an approximate priming volume of 0.10 mL.

Q. Is the Nexus TKO®-6P compatible with peripheral, PICC and CVC catheters on the market?

A. Yes. All TKO I.V. connections comply with ANSI and ISO 594 luer dimensions.

Q. Is the Nexus TKO®-6P a positive pressure, neutral pressure, or negative pressure device?

A. Neither – The Nexus TKO®-6P is a truly neutral pressure anti-reflux device that prevents blood reflux 24/7 and not just when the syringe is removed.

Q. What tubing set configurations are available with the Nexus TKO®-6P?

A. The Nexus TKO®-6P is available individually packaged and attached to a wide variety of macrobore, microbore, ultra-microbore extension sets in various lengths and with slide clamp or pinch clamp options.

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Clinical FAQs

Q. Can the Nexus TKO®-6P be used for blood draws or blood transfusions without causing hemolysis?

A Yes, the Nexus TKO®-6P has been used for many years, in many hospitals without any issues of hemolysis for blood draws or transfusions. Independent lab studies verify these results and are available upon request. **See: Nexus Mechanical Hemolysis Study**

Q. How much saline flushing solution is required to effectively clear the Nexus TKO®-6P after a blood draw?

A. The fluid path of the Nexus TKO®-6P may be cleared of residual blood with less than 0.09mL of saline flush. **See: Nexus Flush Efficacy Study**

Q. Can the Nexus TKO®-6P be used to deliver all types of I.V. fluids, medication, drugs or TPN without any issues?

A. Yes, there is no known fluid, medication, drug or TPN limitation with the Nexus TKO®-6P. All Nexus TKO devices are manufactured from medical grade materials which have a long history of clinical success in all facets of I.V. fluid and drug delivery.

Q. Can the Nexus TKO®-6P be used for neonatal infusions?

A. Yes, the TKO has passed all syringe pump testing for rate consistency with the infusion rate set at the lowest setting of 0.01 mL per hour.

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Regulatory FAQs

Q. Is the Nexus TKO®-6P FDA approved?

A. Yes, the Nexus TKO®-6P has cleared by the FDA and has an FDA 510K number of **K130416**.

Q. What materials are used in the Nexus TKO®-6P?

A. The plastic molded components are manufactured from Bayer Makrolon, a common and widely used medical grade polycarbonate. The internal Anti-Reflux bi-directional value and septum is molded from medical grade silicone rubber. All components are DEHP free and are not manufactured with natural rubber latex.

Q. Are the materials in the Nexus TKO®-6P biocompatible?

A. Yes, all materials used in the manufacture of the devices have undergone extensive biocompatibility testing and meet the requirements of US Pharmacopeia Class VI. These tests include acute systemic toxicity, intracutaneous toxicity and implantation tests. These tests measure and determine the biological response of animals to the materials used in the device.

In addition, all materials used in the manufacture of the Nexus TKO®-6P devices meet the requirements of ISO 10993-1 standards for external communicating devices with prolonged exposure (24 hours – 30 days). Materials used in the devices have been tested for cytotoxicity, sensitization, subacute and subchronic toxicity and hemocompatibility.

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Frequently Asked Questions (FAQs)

Regulatory FAQs Cont…

Q. How is the Nexus TKO®-6P sterilized?

A. The Nexus TKO®-6P devices along with any bonded extension set are individually packaged in sterile, single use pouches that have been sterilized using EO gas.

Q. Is the Nexus TKO®-6P patented?

A. Yes, various components of the devices are covered by issued US patents, foreign patents as well as various patents pending.