

Nexus TKO[®]-6 *Anti-Reflux Technology*

The Nexus TKO[®] (*"To Keep Open"*) *Anti-Reflux* technology is designed to deliver I.V. Catheter Patency 24/7™!

Nexus TKO-6 offers your patients a new level of safety and protection against unwanted catheter occlusions. The TKO provides *Blood Reflux Protection 24/7™* for all Peripheral, PICC and CVC Catheters while delivering a safe and effective microbial barrier.

- Reduces potential delays in delivering IV therapy
- Reduces unscheduled I.V. *catheter* restarts
- Minimizes trauma to the patient
- Diminishes the need for expensive drugs to declot PICC/CVC catheter

Nexus TKO[®]-6 Anti-Reflux Technology Overview

Catheter occlusions cause serious problems for caregivers and their patients

Catheter occlusions are difficult to avoid and create unwanted complications

- 25% of all central venous catheter (CVC) develop partial or full occlusions ^{16,17,18}
- Blood can inadvertently reflux into a catheter in multiple ways
- Current needle free injection sites do not effectively address the many causes of blood reflux
- Blood reflux may lead to several unintended IV complications, including the following:
 - occlusions
 - infiltrations
 - phlebitis
 - costly catheter restarts
 - catheter-related bloodstream infections (CRBSIs)

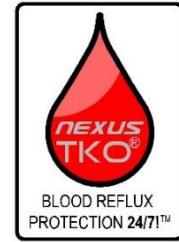


Nexus TKO-6 Anti-Reflux Technology



Blood reflux is the leading cause of occluded catheters

- Occlusions may result in delayed therapy,¹³
- Occlusions increases the risk of CRBSI's,^{1,2,3,4,17,18}
- Occlusions created the need for catheter replacement or exchange,¹³
- Occlusions prevent blood sampling from CVC/PICC catheter
- When blood refluxes into a catheter, there is the potential for clinicians to force the syringe plunger forward when flushing and damage the intima of the vein wall. Which may end in an IV complication which resembles an IV infiltration.¹⁰



Clotted Catheters are known contributors to catheter-related bloodstream infections (CRBSIs)^{1,2,3,4,}

- 87% percentage of all bloodstream infections involve some type of IV device²¹
- Catheter occlusions lead to catheter replacement, increased risk of complications, added patient stress and risk of infection¹³
- CRBSIs are the most costly and life threatening of all healthcare-acquired infections¹³
- CRBSIs cost up to \$35,000 per episode, with more than 250,000-500,000 episodes per year in the US¹⁹
- "Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for vascular catheter-associated infections (initiated October 2008)"²⁰



Nexus TKO®-6 is your proven Solution in providing "IV Catheter Patency 24/7™"

Nexus TKO®-6 Anti-Reflux Technology Provides "Blood Reflux Protection 24/7™"!

Causes of Blood Reflux & Catheter Occlusions:

PHYSIOLOGICAL:

- Patient Movement
- Crying
- Coughing
- Sneezing
- Respiration
- Vomiting



MECHANICAL:

- Syringe connection/disconnection
- Syringe plunger rebound
- Venous pressure changes
- IV bag runs dry
- Low KVO/flow rates
- Ventilators & IV Pumps

"Theoretically, Blood Reflux into either the IV catheter or the needleless connector increases both the risk of occlusion and biofilm formation."¹¹

William R. Jarvis MD



**Nexus TKO-6 with Power Injectable Kink-Free Microbore Tubing
325psi at 10 mL's per second**

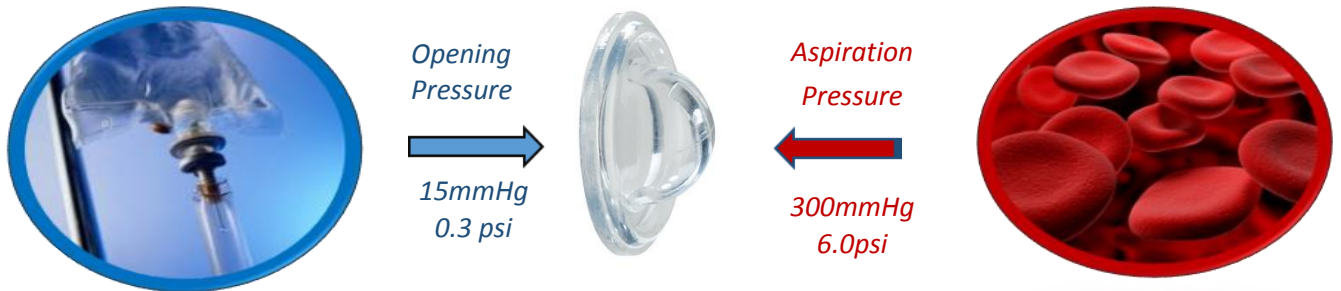
How The Nexus TKO[®]-6 Anti-Reflux Diaphragm Works

Nexus TKO[®]-6 Anti-Reflux Technology Provides “**Blood Reflux Protection 24/7™**”!

The Nexus TKO[®]-6 Anti-Reflux diaphragm automatically opens and closes based upon fluid pressure. The TKO diaphragm opens towards the patient when fluid pressure from sources such as IV pump, syringe pump, IV bag, flushing or medication syringe are used. When the fluid pressure drops the TKO diaphragm instantly and automatically closes preventing blood reflux into the catheters.

Bi-Directional Flow Control 24/7™

*DOME SHAPED TKO™ Diaphragm
Single Piece-Crystal Clear
3-Position*

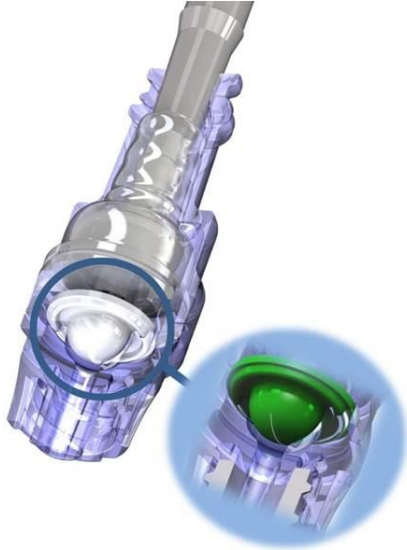


Infusion Flow Rate at 40 inches
4500mL/Hour



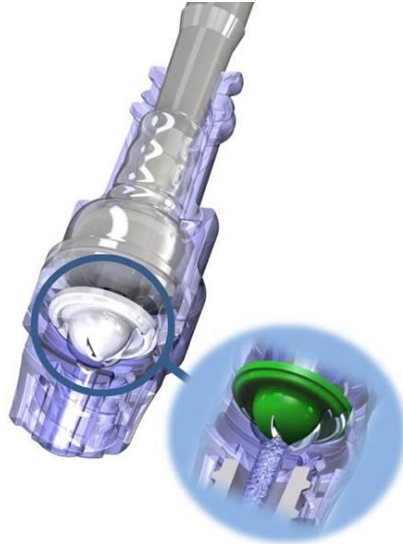
Normally Closed Position:

The TKO Diaphragm provides
Blood Reflux Protection 24/7™!



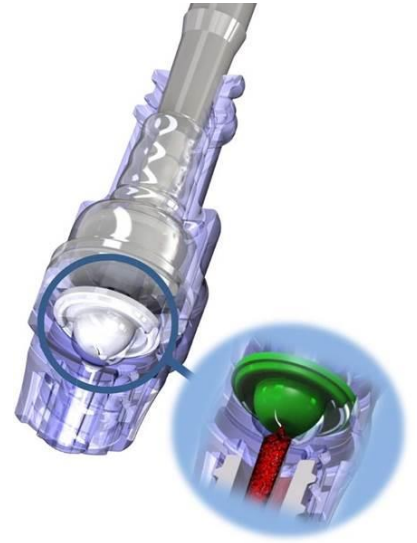
Flush/Infusion:

The TKO Diaphragm opens forward
with normal gravity pressure



Blood Sampling/Patency Check:

The TKO Diaphragm opens in reverse
for safe and easy blood sampling

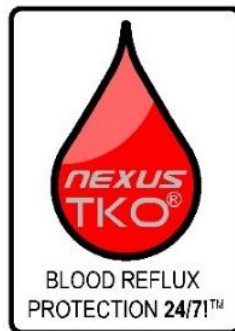


NOTE: Dome Shaped TKO Diaphragm shown in Green for Contrast & Clarity

No clamping sequence required:

The Nexus TKO® Anti-Reflux technology requires
NO CHANGE in practice or clamping sequence, the TKO automatically provides

Blood Reflux Protection 24/7!



Nexus TKO®-6 Provides “Microbial Barrier Protection 24/7™”

The Nexus TKO® technology is designed to protect both ends of your catheter. First our TKO technology reduces blood reflux from the tip of the catheter. Second our TKO technology provides microbial barrier protection which has been validated to 96-activation without microbial growth.

- Nexus TKO® Anti-Reflux Technology provides protection against the the costly risk of blood reflux.^{7,8,9,10,11}
- Nexus TKO® is proven to reduce central line occlusions by up to 85% and at the same time eliminate Heparin flushing from the formulary.⁸
- Nexus TKO® with its patented Tri-Seal™ design provides proven microbial barrier protection against bacterial transfer and colonization.^{9,10}



Nexus TKO®-6 Tri-Seal™ Design provides Microbial Barrier Protection 24/7™

Our patented *Tri-seal™* Design with *Slit Lock™* technology is designed into all of our Needle free technologies (NIS-5, NIS-6, NIS-6P, TKO-5, TKO-6 and TKO-6P). The Nexus TKO® *Tri-Seal™* Design provides **Microbial Barrier Protection 24/7™**. The *Tri-Seal™* design with *Slit Lock™* technology has been validated using 4-separate study groups with 4-separate bacteria by an outside GLP laboratory using a 96-activation protocol over 96-hours with 3-18 hour incubation cycles on 3-separate days.

The Nexus TKO®-6 Tri-Seal™ Design Provides 3-Levels of Microbial Barrier Protection 24/7™

First Level of Protection:

A 360° compressed seal proven to provide a safe and effective microbial barrier protection between the septum and the needle-free connector housing

Second Level of Protection:

A smooth, easy to disinfect septum surface, promotes a safe and effective microbial barrier.

Third Level of Protection:

The *Slit-Lock™* septum protects the internal fluid path from microbial ingress while luer is activating

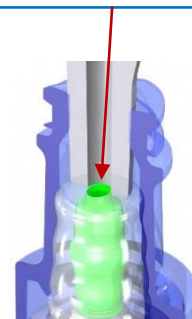
When not accessed, the Nexus Tri-Seal™ design forms a safe and effective microbial barrier



Our Slit Lock™ Technology forms an Invisible Slit Seal providing a Microbial Barrier Protection 24/7™



The Slit-Lock™ septum remains sealed until fully compresses deep inside the fluid path. (Self-Opening Slit Septum)



Nexus TKO®-6 Technical specifications:



Nexus TKO®-6 Anti-Reflux Technology Specification

Nexus TKO®-6 Performance Specifications

510K	K113398
Flow Rate at Gravity	75 mL/min or 4500 mL/hr.
Approx. Priming Volume⁶	0.1 mL
Functional Activations	100
Smooth Swab Able	Yes
Microbial Barrier⁶ (Ingress)	Yes
Mechanical Hemolysis⁶	No
Flushing Efficacy	< 5 mL

Latex Free	Yes
DEHP Free	Yes
Blood Compatible	Yes
Lipid Compatible	Yes
Materials	Polycarbonate, Silicone
MRI Compatible	Yes
Direct Fluid Path	Yes
Clear Fluid Path	Yes

Nexus TKO®-6 Product Literature



Nexus TKO®-6 Anti-Reflux Technology

Nexus TKO[®]-6 Clinical Evidence



Nexus TKO[®]-6: 96-Activation Microbial Performance Study by Nelson Laboratories, Salt Lake City, Utah.



Nexus TKO[®]-6: Mechanical Hemolysis Study by Toxikon Corporation, Bedford, Massachusetts.



Nexus TKO[®]-6: Blood Clearance Study by, Toxikon Corporation, Bedford, Massachusetts



PICC and Midline Catheter Occlusion Rates: A perspective Study Comparing the Baxter Interlink Split Septum Device versus. Nexus TKO Pressure Activated Anti-Reflux Device, Mitch S. Brandmeyer B. White Paper 2010



Occlusion Reduction and Heparin Elimination Trial Using an Anti-Reflux Device on peripheral and Central Catheters, Jasinsky L, Wurster J, Journal of Intravenous Nursing, vol.32 Num. 1 Jan/Fed 2009. 33-40

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