

Nexus TKO®-5 Anti-Reflux Technology

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

Nexus TKO®-5 is the only Anti-Reflux technology which utilizes a Blunt Plastic Cannula. The TKO-5 provides **Blood Reflux Protection 24/7™** for all Peripheral, PICC and CVC Catheters while delivering a safe and effective microbial barrier. TKO-5 offers your patients a new level of safety and protection against unwanted catheter occlusions.

- Flat, smooth, swabable septum surfaces assures provides Microbial Barrier Protection 24/7™
- Reduce the high cost of occlusions in PICC, CVC & PIVC catheter
- Reduces unscheduled I.V. catheter restart
- Decreases I.V. supply costs and pharmacy costs
- Has been proven to reduce central line occlusion by 85%
- Eliminate the risk and high cost of Heparin

Nexus TKO®-5 Anti-Reflux Technology Overview

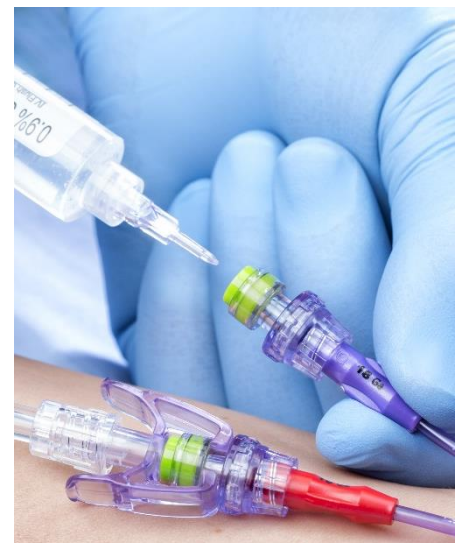
Catheter occlusions cause serious problems for caregivers and their patients

Catheter occlusions are difficult to avoid and create unwanted complications

- 25% of all central venous catheter (CVC) develop partial or full occlusions^{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)

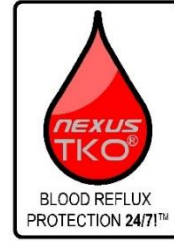


**Nexus TKO-5 Anti-Reflux
Technology**



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 flushing¹⁰
- This can damage the intima of the vein wall and 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 US¹³
- "Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for vascular catheter-associated infections (initiated October 2008)"²⁰



Nexus TKO®-5 is your proven Solution in providing "IV Catheter Patency 24/7™"

Nexus TKO®-5 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-5 with Power Injectable Kink-Free Microbore Tubing
325psi at 10 mL's per second**

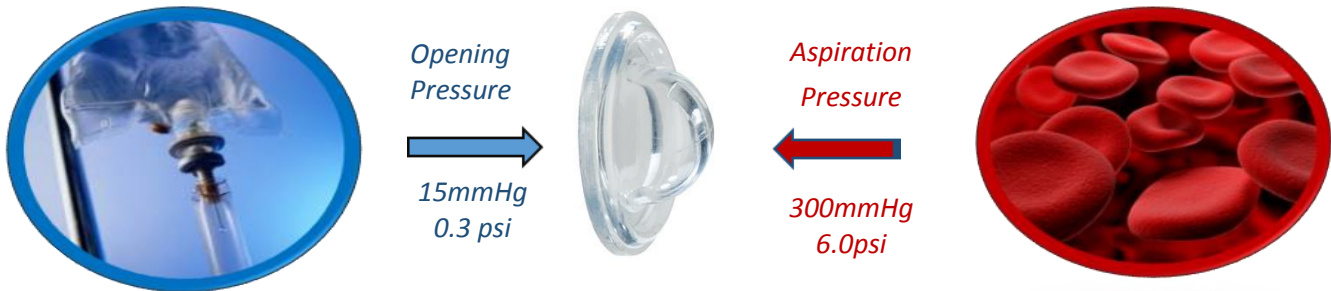
How The Nexus TKO[®]-5 Anti-Reflux Diaphragm Works

Nexus TKO[®]-5 Anti-Reflux Technology Provides “**Blood Reflux Protection 24/7™**”!

The Nexus TKO[®]-5 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 prevention 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 with 18 gauge Catheters
3500mL/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

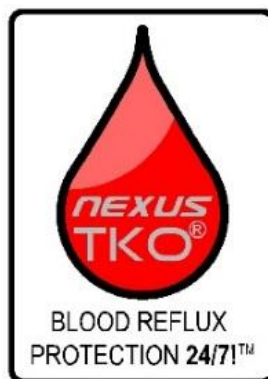


NOTE: Dome Shaped TKO Diaphragm shown in Green for Contrast & Clarity

No clamping sequence required:

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

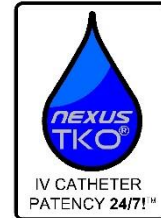
Blood Reflux Protection 24/7!



Nexus TKO®-5 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 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®-5 Tri-Seal™ Design provides Microbial Barrier Protection 24/7™

Our patented *Tri-seal™* Design with *Slit Lock™* technologies 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 group with 4-separate bacteria by an outside GLP laboratory using a 96-activations protocol over 96-hours with 3-18 hour incubation cycles on 3 separate days.

The Nexus TKO® 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

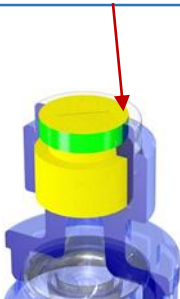
Second Level of Protection:

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

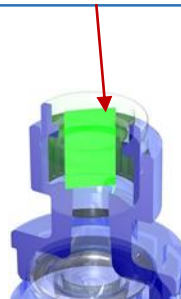
Third Level of Protection:

The *Slit-Lock™* septum protects the internal fluid path from microbial ingress while not accessed

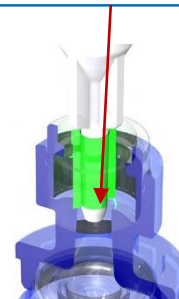
When not accessed, the Nexus Tri-Seal™ design forms a safe and effective microbial barrier



Our Slit Lock™ technology has a rigid band to form a compression seal providing Microbial Barrier Protection 24/7™



The Slit-Lock™ remains sealed until plastic blunt cannula open the slit deep inside the fluid path.



Nexus TKO®-5 Technical specifications:



Nexus TKO®-5 Anti-Reflux Technology Specification

Nexus TKO®-5 Performance Specifications

510K	K053129
Flow Rate at Gravity	75 mL/min or 3500 mL/hr.
Approx. Priming Volume ⁶	0.1 mL
Functional Activations	100
Smooth Swab Able	Yes
Microbial Barrier ⁶ (Ingress)	Yes
Mechanical Hemolysis ⁶	No
Flushing Efficacy	<5 mL

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

Nexus TKO®-5 Product Literature



Nexus TKO®-5 Anti-Reflux Technology

Nexus TKO®-5 Clinical Evidence



Nexus TKO®-5: 96-Activation Microbial Performance Study by Nelson Laboratories, Salt Lake City, Utah



Nexus TKO®-5: Mechanical Hemolysis Study by Toxikon Corporation, Bedford, Massachusetts.



Nexus TKO®-5: 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

References

1. Timisit JF, Missett b, Carlet J, et al. Central vein catheter-related thrombosis in intensive care patients, risk factors, and relationships with catheter-related sepsis. *Chest*. 1998;114(1):207-213.
2. Mehall JR, Saltzman DA, Jackson RJ, Smith SD, Fibrin sheath enhances central venous infection. *Critical Care Med*. 202;30(4); 908-912.
3. Raad II, Luna M, Khalil SM, Costerton JW, Lam C, Bodey GP,
4. Nakazama N. Infectious and thrombotic complications of central venous catheters. *Semin Oncology Nurse*, 2010;26(2) 121-131.
5. Lordick F, Hentrich M, Decker T, et al, Ultrasound screening for internal jugular vein thrombosis aids the detection of central venous catheter-related infections in patients with haemato-oncological diseases: a prospective observational study. *Br J Haematol* 2003;120:1073-1078.
6. Moureau N, Catheter-related infections and thrombosis: A proven relationship, Arrow, Teleflex, White Paper 2013,

7. Jasinsky RN BSN, J Wurster RN MSN, "Occlusions Reduction and Heparin Elimination Trial using an Anti-Reflux Device on Peripheral and Central Intravenous Lines", Intravenous Nurses Society
8. S Mitch RN CRNI, B Brandmeyer RN BSN, "PICC and Midline Catheter Occlusion Rates: A Prospective Study Comparing the Interlink Split Septum Device versus Nexus TKO Split Septum Pressure Activated Anti-Reflux Diaphragm".
9. GLP-Study, Nexus TKO®, 96-Activation Microbial Barrier Performance Study, on file at Nexus Medical LLC,
10. Lab results on file at Nexus Medical, LLC,
11. Jarvis, W. Choosing the best design for the Intravenous needleless connection to prevent HA-BSI's. *Infection Control Today*, 2010 Aug.
12. Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008.
13. Hadaway L. Reopen the pipeline for IV therapy. *Nursing*. 2005; 35(8):54-61.
14. O'Grady NP, Alexander M, Dellinger EP, et al. Guidelines for the prevention of intravascular catheter-related infections. *MMWR Recomm Rep*. 2002;51(RR-10):1-26.
15. Haire WD, Atkinson JB, Stephen LC, Kotulak GD, et al. Urokinase versus recombinant tissue plasminogen activator in thrombosed central venous catheters: a double-blinded, randomized trial. *Thromb Haemost*. 1994;72(4):543-7.
16. Deitcher S, et al. Safety and efficacy of alteplase for restoring function in occluded central venous catheters: results of the cardiovascular thrombolytic to open occluded lines trial. *J Clin Oncol*. 2002;20(1): 317-24.
17. Ryder, M. *Catheter-related infections: It's all about biofilm. Topics Adv. Practice of Nursing Journal*. 2005 5(3)
18. Timoney JP, Malkin MG, Leone DM, Groeger JS, Heaney ML, Keefe DL, Klang M, Lucarelli CD, Muller RJ, Eng SL, Connor M, Small TN, Brown AE, Saltz LB. Safe and cost effective use of alteplase for the clearance of occluded central venous access devices, *JCO*. Apr 1, 2002:1918-1922; DOI:10.1200/JCO.2002.07.131.
19. Ponec D, Irwin D, Haire WD, Hill PA, Li X, McCluskey ER; COOL Investigators. Recombinant tissue plasminogen activator (alteplase) for restoration of flow in occluded central venous access devices: a double-blind placebo-controlled trial—the Cardiovascular Thrombolytic to Open Occluded Lines (COOL) efficacy trial. *J Vasc Interv Radiol*. 2001 Aug;12(8):951-5.
20. Hadaway L. Heparin locking for central venous catheters. *Journal of the Association for Vascular Access*, 11 (4) 224-231. 2006.
21. Moureau N, Poole S, et al. *Central Venous Catheters in Home Infusion Care: Outcomes Analysis in 50,470 Patients 13-10:1009-1016, October 2002*
22. Kokotis K. Cost containment and infusion services. *Journal of Infusion Nursing*. (2005) 28(3 Suppl.), S22-S32.
23. Cummings-Winfield C, Mushani-Kanji T. Restoring patency to central venous access devices. *Clin J Oncol Nurs*. 2008; 12(6):925-935
24. Richardson DK. Vascular access nursing-practice, standards of care, and strategies to prevent infection: a review of flushing solutions and injection caps (part 3 of a 3-part series). *J Assoc Vasc Access*. 2007;12(2):74-84.
25. Gorski, Lisa A MS, RN, CS, CRNI. *Central Venous Access Device Occlusions: Part 1: Thrombotic causes and treatment. Home Healthcare Nurse*. 21:2;115-121, February 2003.
26. Cummings-Winfield C, Mushani-Kanji T. Restoring patency to central venous access devices. *Clin J Oncol Nurs*. 2008; 12(6):925-934.
27. Wingerter L. Vascular access device thrombosis. *Clin J Oncol Nurs*. 2003;7(3):345-348.
28. Hadaway, *Development of an Infusion Alliance, INS Sept-Oct, Vol (33)5 278-290*
29. Perucca, *Financial Analysis for the Infusion Alliance, INS Sept-Oct 2011, (33)5 304-309*