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 occlusions17,18
- 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)
Blood reflux is the leading cause of occluded catheters

- Occlusions may result in delayed therapy.  
  - Occlusions increase the risk of CRBSI's.  
- Occlusions created the need for catheter replacement or exchange.  
- 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.  
- This can damage the intima of the vein wall and end in an IV complication which resembles an IV infiltration.  

Clotted Catheters are known contributors to catheter-related bloodstream infections (CRBSIs)

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

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.”

*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 open 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

- **Opening Pressure:** 15mmHg 0.3 psi
- **Aspiration Pressure:** 300mmHg 6.0psi

**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

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

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**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

<table>
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<tr>
<th>Specification</th>
<th>Value</th>
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<tbody>
<tr>
<td>Flow Rate at Gravity</td>
<td>75 mL/min or 3500 mL/hr.</td>
</tr>
<tr>
<td>Approx. Priming Volume6</td>
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<tr>
<td>Functional Activations</td>
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<td>Smooth Swab Able</td>
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<td>Microbial Barrier (Ingress)</td>
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<td>Mechanical Hemolysis6</td>
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<td>Blood Compatible</td>
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<td>Materials</td>
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<td>MRI Compatible</td>
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<td>Direct Fluid Path</td>
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<td>Clear Fluid Path</td>
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</table>

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.


References

3. Raad II, Luna M, Khalil SM, Costerton JW, Lam C, Bodey GP,
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,
28. Hadaway, Development of an Infusion Alliance, INS Sept-Oct, Vol (33)5 278-290