Nexus TKO®-6P Hi-Visibility Anti-Reflux Technology

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

Nexus TKO®-6P Hi-Visibility provides the same Anti-Reflux protection with the added value of a bright Highly Visible green band which was specifically designed to meet the special needs of Home Infusion Patients. The bright green color easily allows Home Infusion Patients to visually distinguish the Extension Set and the TKO! This safe and practical solution assists care providers in patient and family training procedure.

- **TKO Hi-Visibility** provides **Blood Reflux Protection 24/7™**
- **TKO Hi-Visibility** is proven to reduce central line occlusions by up to 85%
- **TKO Hi-Visibility** substantially reduces the cost of tPA (Cathflo®) and Heparin
- **TKO Hi-Visibility** diminishes the need for expensive drugs to declot PICC/CVC catheter

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**Nexus TKO®-6P Hi-Visibility 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
- 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 CRBSIs,  
- Occlusions created the need for catheter replacement or exchange,  
- Occlusions prevent blood sample from CVC/PICC catheter  
- When blood reflexes 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. 

**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®-6P **Hi-Visibility** is your proven Solution in providing “IV Catheter Patency 24/7™”

Nexus TKO®-6P **Hi-Visibility** 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®-6P **Hi-Visibility** with Power Injectable Kink-Free Microbore Tubing
How The Nexus TKO®-6P Hi-Visibility Anti-Reflux Diaphragm Works

Nexus TKO®-6P Hi-Visibility Anti-Reflux Technology Provides “Blood Reflux Protection 24/7™”!

The Nexus TKO®-6P Hi-Visibility 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

Opening Pressure
15mmHg
0.3 psi

Aspiration Pressure
300mmHg
6.0psi

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

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**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!*
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®-6P Hi-Visibility 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®-6P 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.
Nexus TKO®-6P *Hi-Visibility* Technical specifications:

**Nexus TKO®-6P Hi-Visibility Anti-Reflux Technology**

Nexus TKO®-6P *Hi-Visibility* Performance Specifications:

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Flow Rate at Gravity</td>
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<tr>
<td>Approx. Priming Volume</td>
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<tr>
<td>Functional Activations</td>
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<tr>
<td>Smooth Swabable</td>
<td>Validated to 96 Activations</td>
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<td>Direct Fluid Path</td>
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<td>Clear Fluid Path</td>
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Nexus TKO®-6P *Hi-Visibility* Product Literature

**Nexus TKO®-6P Anti-Reflux Technology**
Nexus TKO®-6P Hi-Visibility Clinical Evidence

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

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

Nexus TKO®-6P: 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,

References

3. Raad II, Luna M, Khalil SM, Costerton JW, Lam C, Bodey GP.
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,