

## Nexus TKO<sup>®</sup>-6P *Anti-Reflux* Technology

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

Nexus TKO<sup>®</sup>-6P is fighting Infection every second, of every minute, of every hour, every day 24/7. Our patented Tri-Seal™ design provides proven Microbial Barrier Protection 24/7™ against bacteria transfer and colonization. TKO is a performance driven solution designed to reduce occlusions and the high cost of tPA, Heparin and catheter replacements.

- TKO provides *Blood Reflux Protection 24/7™*
- *Blood Reflux is a known contributor to CRBSI's.* <sup>1,2,3,4,</sup>
- Power injectable to 325 psi or 10 mL per second <sup>10</sup>
- Proven to reduce central line occlusions by up to 85%<sup>8</sup>
- Substantially reduces the cost of tPA (Cathflo<sup>®</sup>) and Heparin<sup>8</sup>
- Diminishes the need for expensive drugs to declot PICC/CVC catheter<sup>8</sup>

### Nexus TKO<sup>®</sup>-6P *Anti-Reflux* Technology Overview

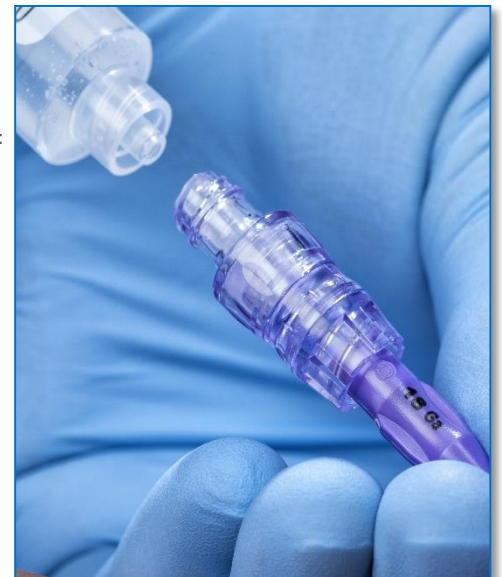
Catheter occlusions cause serious problems for caregivers and their patients

#### *Catheter occlusions are difficult to avoid and create unwanted complications*

- 25% of all central venous catheter (CVC) develop partial or full occlusions<sup>16,17,18</sup>
- 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)

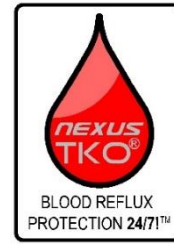


**Nexus TKO-6P *Anti-Reflux* Technology**



**Blood reflux is the leading cause of occluded catheters**

- Occlusions may result in delayed therapy,<sup>13</sup>
- Occlusions increases the risk of CRBSI's, <sup>1,2,3,4,17,18</sup>
- Occlusions created the need for catheter replacement or exchange,<sup>13</sup>
- Occlusions prevent blood sample 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.<sup>10</sup>



**Clotted Catheters are known contributors to catheter-related bloodstream infections (CRBSIs) <sup>1,2,3,4,</sup>**

- 87% percentage of all bloodstream infections involve some type of IV device<sup>21</sup>
- Catheter occlusions lead to catheter replacement, increased risk of complications, added patient stress and risk of infection<sup>13</sup>
- CRBSIs are the most costly and life threatening of all healthcare-acquired infections<sup>13</sup>
- CRBSIs cost up to \$35,000 per episode, with more than 250,000-500,000 episodes per year in the US<sup>19</sup>
- "Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for vascular catheter-associated infections (initiated October 2008)"<sup>20</sup>



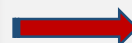
**Nexus TKO®-6P is your proven Solution in providing "IV Catheter Patency 24/7™"**

**Nexus TKO®-6P 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."<sup>11</sup>**

**William R. Jarvis MD**



**Nexus TKO®-6P with Power Injectable Kink-Free Microbore Tubing**

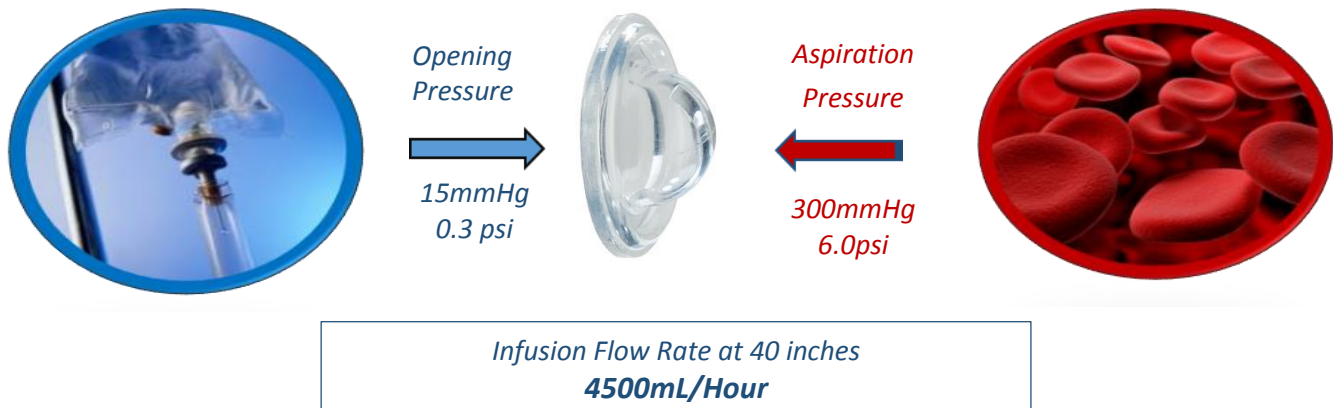
## How The Nexus TKO<sup>®</sup>-6P Anti-Reflux Diaphragm Works

Nexus TKO<sup>®</sup>-6P Anti-Reflux Technology Provides **"Blood Reflux Protection 24/7™"**!

The Nexus TKO<sup>®</sup>-6P 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.

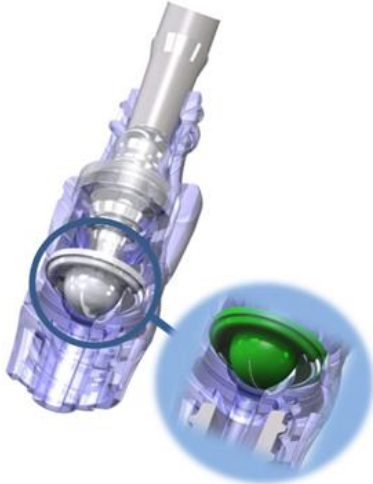
### **Bi-Directional Flow Control 24/7™**

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



**Normally Closed Position:**

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



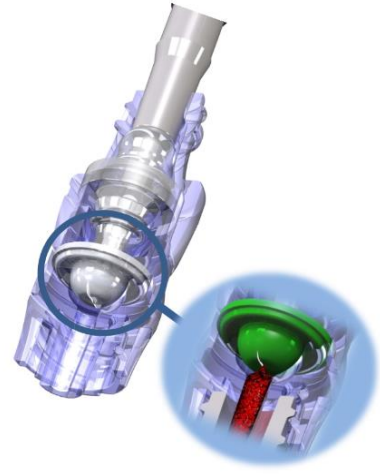
**Flush/Infusion:**

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

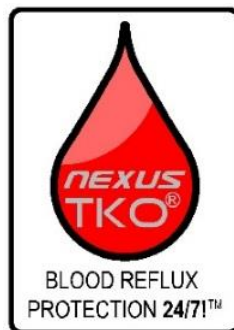


*NOTE: Dome Shaped TKO Diaphragm shown in Green for Contrast & Clarity*

**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®-6P 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.<sup>7,8,9,10,11</sup>
- Nexus TKO® is proven to reduce central line occlusions by up to 85%<sup>8</sup> and at the same time eliminate Heparin flushing from the formulary.<sup>8</sup>
- Nexus TKO® with its patented Tri-Seal™ design provides proven microbial barrier protection against bacterial transfer and colonization.<sup>9,10</sup>



### ***Nexus TKO®-6P 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

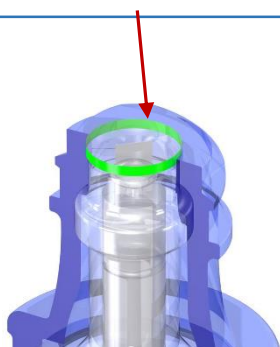
#### ***Second Level of Protection:***

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

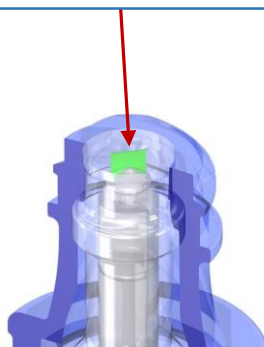
#### ***Third Level of Protection:***

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

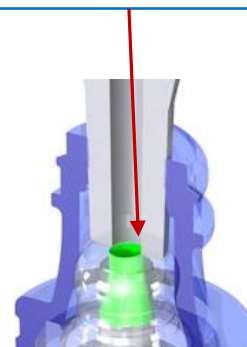
*When not accessed, the Nexus Tri-Seal™ design forms a safe and effective microbial barrier*



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

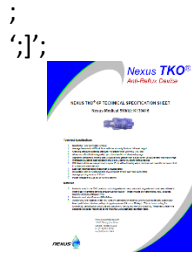


*The Slit-Lock™ septum remains sealed until fully compresses deep inside the fluid path. (Self-Opening Slit Septum)*



## Nexus TKO®-6P Technical specifications:

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### *Nexus TKO®-6P Anti-Reflux Technology Specification*

## Nexus TKO®-6P Performance Specifications

<b>510K</b>	<b>K130416</b>
<b>Flow Rate at Gravity</b>	<b>75 mL/min or 4500 mL/hr.</b>
<b>Approx. Priming Volume</b>	<b>0.12 mL</b>
<b>Functional Activations</b>	<b>100</b>
<b>Smooth Swappable</b>	<b>Validated to 96 Activations</b>
<b>Microbial Barrier (Ingress)</b>	<b>Validated to 96 Activations</b>
<b>Mechanical Hemolysis</b>	<b>No Mechanical Hemolysis</b>
<b>Flushing Efficacy</b>	<b>≤ 5 mL</b>

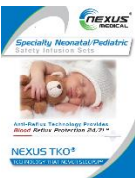
<b>Latex Free</b>	<b>No Latex</b>
<b>DEHP Free</b>	<b>No Phthalates</b>
<b>Blood Compatible</b>	<b>Yes</b>
<b>Lipid Compatible</b>	<b>Yes</b>
<b>Materials</b>	<b>Polycarbonate, Silicone</b>
<b>MRI Compatible</b>	<b>Yes</b>
<b>Direct Fluid Path</b>	<b>Yes</b>
<b>Clear Fluid Path</b>	<b>Yes</b>

## Nexus TKO®-6P Product Literature

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### *Nexus TKO®-6P Anti-Reflux Technology*



### *Nexus Medical Neonatal/Pediatric Safety Infusion Sets*

## Nexus TKO®-6P Clinical Evidence

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*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, Jasinsky L, Wurster J, Journal of Intravenous Nursing, vol.32 Num. 1 Jan/Fed 2009. 33-40*

## References

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