Performance Solutions

Designed to Deliver

IV Catheter Patency 24/7!

--Nexus Medical Since 2001

The Beginning - 2000

Nexus Medical LLC began in 2000 when the Company was awarded a grant from the US Army Medical Material Command in Fort Detrick Maryland to solve the problems associated with unintentional "Blood Reflux" into I.V. catheters and the many unintended consequences it caused for the wounded Army Soldier, Marine and Military Clinicians.

Research - 2001

Nexus Medical's Engineers learned "Blood Reflux" was caused by a multiplicity of external and internal conditions which occurred during the helicopter airlift evacuation or in the first MASH field hospital.

Study and Develop - 2002

Nexus Medical's Engineers lab tested and studied the human factors associated with the internal and external pressures which cause "Blood Reflux" into PIV, Medline, PICC and CVC Catheters. The root causes of "Blood Reflux" can be characterized in two very clear categories which we refer to as mechanical and physiological conditions.

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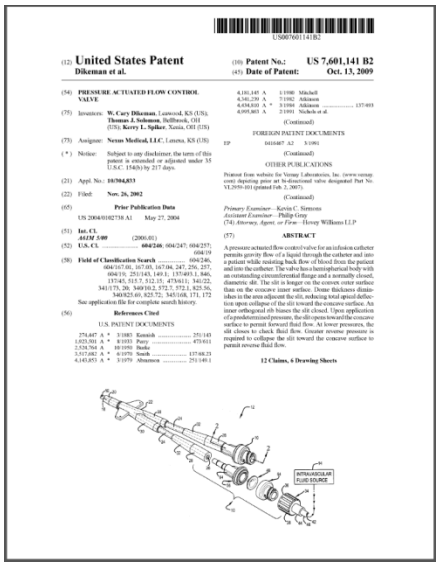
Patent - 2002

Nexus Medical filed the first of many Nexus TKO® US and Foreign patent in 2002 for our Dome Shaped Pressure Activated Anti-Reflux Valve Technology



(12) **United States Patent**
Dikeman et al.

(10) **Patent No.: US 7,601,141 B2**
(45) **Date of Patent: Oct. 13, 2009**

(54) **PRESSURE ACTUATED FLOW CONTROL VALVE**

(75) Inventors: **W. Cary Dikeman**, Leawood, KS (US); **Thomas J. Solomon**, Bellbrook, OH (US); **Kerry L. Spiker**, Xenia, OH (US)

(73) Assignee: **Nexus Medical, LLC**, Lenexa, KS (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 217 days.

(21) Appl. No.: **10/304,033**

(22) Filed: **Nov. 26, 2002**

(65) **Prior Publication Data**
US 2004/0102710 A1 May 27, 2004

(51) **Int. Cl.**
A61M 5/00 (2006.01)

(52) **U.S. Cl.** **604/246**; 604/247; 604/257; 604/19

(58) **Field of Classification Search** 604/246, 604/167.01, 167.03, 167.04, 247, 256, 257, 604/19, 251/145, 149.1, 157/493.1, 846, 137/45, 515.7, 512.15, 473/611; 341/22, 341/175, 20; 340/1912, 572.7, 572.1, 825.56, 340/825.69, 825.72; 345/168, 171, 172
See application file for complete search history.

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(Continued)

Primary Examiner—Kevin C. Sirmons
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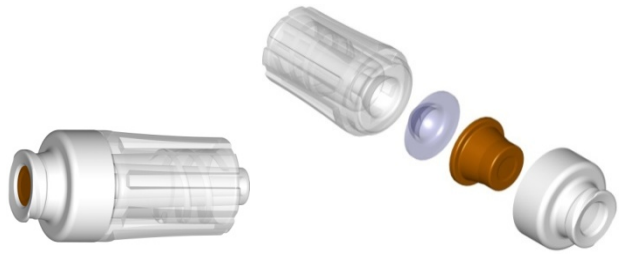
(74) *Attorney, Agent, or Firm*—Hovey Williams LLP

(57) **ABSTRACT**

A pressure actuated flow control valve for an infusion catheter permits gravity flow of a liquid through the catheter and into a patient while resisting back flow of blood from the patient and into the catheter. The valve has a hemispherical body with an outstanding circumferential flange and a normally closed, diametric slit. The slit is longer on the convex outer surface than on the concave inner surface. Dome thickness diminishes in the area adjacent the slit, reducing total apical deflection upon collapse of the slit toward the concave surface. An inner orthogonal rib biases the slit closed. Upon application of a predetermined pressure, the slit opens toward the concave surface to permit forward fluid flow. At lower pressures, the slit closes to check fluid flow. Greater reverse pressure is required to collapse the slit toward the concave surface to permit reverse fluid flow.

12 Claims, 6 Drawing Sheets



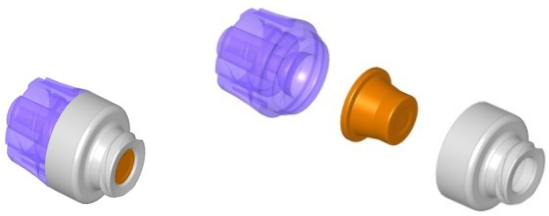
FDA Approved Nexus TKO®-1 – 2003

510K: K024363

Nexus Medical submitted the first FDA 510K for a Luer-Activated Needle Free Device which had the Pressure Activated Anti-Reflux Valve feature. We called this new “Anti-Reflux” device the TKO (To Keep Open)

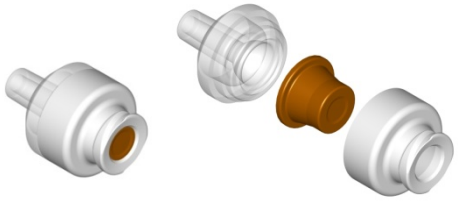
1st Clinical Trial – 2004

Clinical Trial for the Nexus TKO®-1 was conducted at Wilford Hall Medical Center, San Antonio, Texas in the Bone Marrow Transplant Area



Nexus NIS-2 & NIS-7 – 2004

NIS-2 and NIS-7 Luer-Activated Injection Site Devices (Non TKO)



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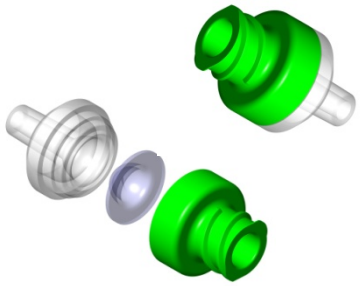
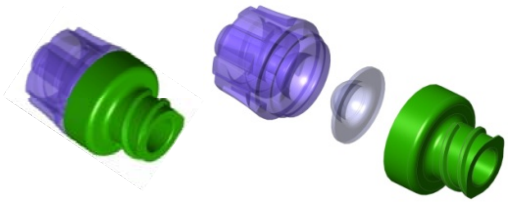




FDA Approved Nexus TKO®-3, Nexus TKO®-4 & Nexus TKO®-4S – 2004

510K: K041845

Nexus TKO®-3, Nexus TKO®-4 & Nexus TKO®-4S Luer Lock Devices

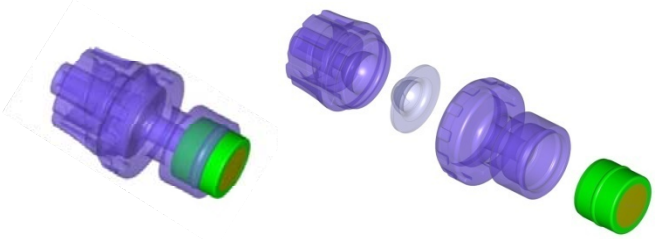
Nexus TKO®-5 – 2005

While using the Nexus TKO®-5 on PICC and CVC lines, Wesley Medical Center reduced tPA usage by over 71% while eliminating Heparin on all flush procedures

FDA Approved Nexus TKO®-5 – 2005

510K: K053129

Nexus TKO®-5 Split Septum Anti-Reflux Device



FDA Approved Pressure-Rated Extension Sets – 2009/2011

Maximum Pressure = 325 psi

510K: K092382

In 2009 Nexus developed a Standardbore line of pressure-rated extension sets, in 2011 the line was extended with Microbore extension sets

510K Approved Nexus TKO®-6 – 2012

510K: K113398

Nexus TKO®-6 launched in 2012 with the introduction of the markets first crystal clear neutral pressure anti-reflux technology. Nexus has been committed to a crystal clear fluid pathway from the very first Nexus TKO®-1 in 2003