

A Study of Neutral Displacement Needle-Free Connectors

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An *in vitro* study was conducted that examined the performance of a select group of commercially available needle-free connectors claiming neutral displacement capability. Neutral displacement connectors are principally designed to prevent the backflow of blood into an IV catheter, also known as blood reflux, upon disconnection of a Luer device such as a medication syringe or IV administration set. Theoretically, blood reflux into an IV catheter increases both the risk of occlusion and biofilm formation.¹ A needle-free connector with no blood reflux is preferred.¹

OBJECTIVE: Evaluate the disconnection displacement performance of the following needle-free connectors:

- 1) InVision-Plus® Neutral® (REF RYM-5001) from RyMed Technologies
- 2) nPulse™ Neutral Connector (REF K100) from NP Medical
- 3) MicroCLAVE® Clear Connector (REF 12512-01) from ICU Medical
- 4) One-Link Needle-free IV Connector (REF 7N8399) from Baxter

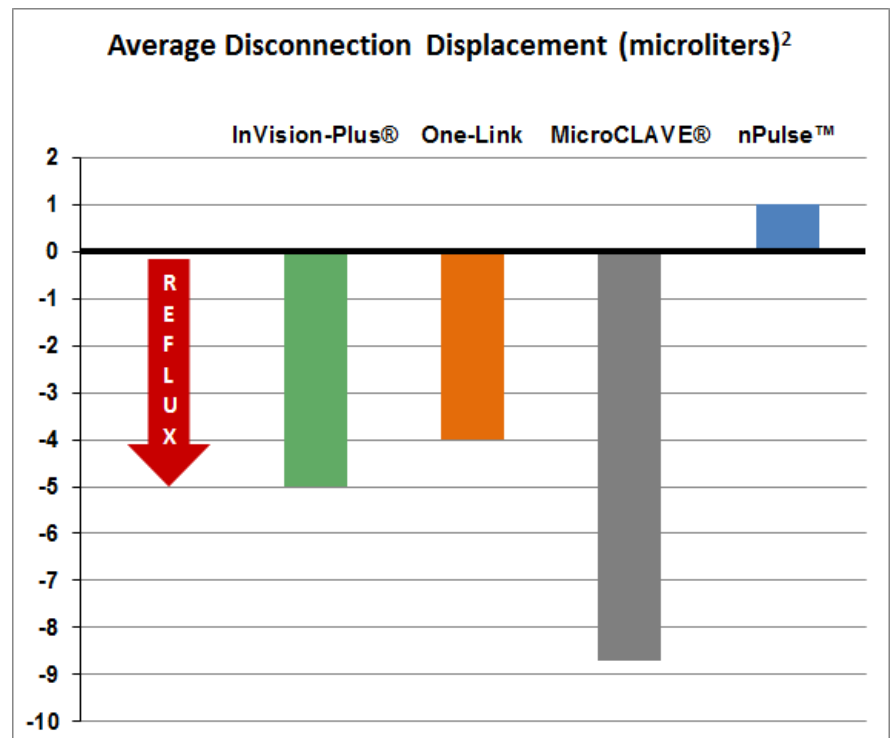
METHODS: The study population consisted of thirty (30) commercially obtained samples of each brand of needle-free connector. Each connector under test was randomly selected from the study population and connected at its distal end to a volumetrically-calibrated glass pipette. The fluid displacement in the pipette is analogous to what would be experienced in an IV catheter. Prior to the testing of each connector, air within the fluid path of the connector was purged and the septum was swabbed with an alcohol prep pad to simulate catheter priming and swabbing in the clinical setting. An ISO 5mL male Luer lock syringe filled with DI water was then connected to the connector, fluid was administered through the connector, a baseline (zero) position was established within the pipette, and then the syringe was disconnected from the connector. The amount of disconnection displacement within the pipette was then observed and recorded. Handling precautions were taken to ensure that the observed displacement was truly a function of syringe disconnection.

RESULTS³: The average disconnection displacement that was observed for each brand of needle-free connector is shown in the adjacent chart and ranged from a maximum amount of -8.7 µl for MicroCLAVE® Clear to a minimum amount of +1.0 µl for the nPulse™ Neutral Connector.

All thirty (30) test samples for InVision-Plus®, One-Link, and MicroCLAVE® Clear produced a measurable amount of fluid reflux or negative displacement within the calibrated pipette following Luer disconnection.

The slight forward pulse observed with the nPulse™ Neutral Connector prevented fluid reflux upon Luer disconnection while avoiding the product characteristics of commercially available positive displacement connectors.

The ability of the nPulse™ Neutral Connector to produce a virtually neutral and non-refluxing fluid displacement was unique amongst the split septum devices tested.



CONCLUSION: The nPulse™ Neutral Connector from NP Medical had the lowest fluid displacement amongst the devices tested and was the only device capable of exhibiting no fluid reflux during Luer disconnection.

1. Jarvis W., MD. Choosing the Best Design for Intravenous Needleless Connectors to Prevent Bloodstream Infections. Infection Control Today, July 2010, <http://www.infectioncontroltoday.com/articles/2010/07/choosing-the-best-design-for-intravenous-needleless-connectors-to-prevent-bloodstream-infections.aspx>
2. For an *in vivo* correlation, -2 microliters of blood reflux within a typical 3 Fr silicone PICC would be approximately 1 cm of length up the lumen of the catheter.
3. Data on file at NP Medical. Study Record SR20130016.