

MicroClave® Clear vs. NeutraClear® Needlefree Connector Performance Comparison

INTRODUCTION

ICU Medical is an established world leader in the design, manufacture, and support of advanced needlefree connectors for use in IV therapy. Clave® connector technology has been optimized over two decades to offer unmatched reliability, cost, and clinical efficacy^{1,2,3,4}; however, during that time, other manufacturers have made attempts to imitate its patented design. This paper explores one such example of design and performance differences between the market-leading MicroClave connector and the Cair Drive and NeutraClear needlefree connectors (distributed by Becton, Dickinson and Company).⁵ These notable design differences make clinical or laboratory data derived using Clave or Clave technologies (i.e., MicroClave) irrelevant to the Cair NeutraClear design, and any such surrogacy of product and data should not be considered when making decisions based on clinical evidence.

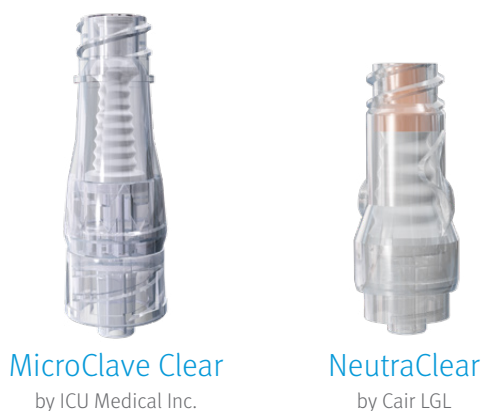
Notable design differences make clinical or laboratory derived data using Clave or Clave technologies (i.e., MicroClave) irrelevant to the Cair NeutraClear design.

TECHNOLOGY OVERVIEW

Both MicroClave and NeutraClear needlefree connectors utilize design features originally developed by ICU Medical, including an internal blunt cannula, a silicone compression seal, and a clear housing (see Figure 1). However, the NeutraClear connector is designed with an additional guiding ring component, which, according to BD marketing materials, is used “...to maintain the integrity of the silicone...guarantee[ing] a better sealing of the ‘split-septum’ after multiple activations.”⁶ In contrast, the

MicroClave connector holds pressure or “maintains integrity” by virtue of a set of O-rings built into the connector’s silicone sleeve above and below the spike windows that ensure the fluid path remains closed, rather than relying on a guiding ring to help the silicone maintain back pressure integrity.

FIGURE 1. MICROCLAVE CLEAR AND NEUTRACLEAR NEEDLEFREE CONNECTORS



The presence of the additional guiding ring component in the Cair Drive and NeutraClear connector design introduces a new variable into critical design elements, as it is an integral component surrounding the split-septum of the silicone sleeve and is directly related to the connector’s only portal of entry. As a result, its impact on both the ability to disinfect the silicone septum and bacterial transfer cannot be inferred from Clave or MicroClave studies that use a different technology.

Consequently, the use of clinical or laboratory data derived from Clave technology cannot be attributed to Cair Drive or Cair NeutraClear designs, and research data that examines and validates the Clave design is not transferable to the Cair designs (i.e., Brown, Yebenes, Ryder studies, among others).

Given their notable design differences of components integral to the connector's activation and access, Cair Drive and NeutraClear connector performance involving these components cannot be considered equivalent to studies involving MicroClave connector performance. Unlike the NeutraClear connector, the MicroClave connector is supported by more than two decades of clinical experience and billions of units manufactured, which has resulted in excellent reliability and clinical efficacy.

COMPARISON OF FLOW RATE, BACK PRESSURE LEAKAGE, AND ANGLED ACCESS LEAKAGE

Flow Rate

The MicroClave connector has been validated to ensure adequate flow during clinical applications. The connector's validated flow rate at gravity is specified at 165 mL/min, and extended-use testing shows that after seven days and 700 activations, MicroClave's flow rate at gravity averages 156 mL/min. This flow rate after a high number of activations used for validation testing of MicroClave illustrates the robustness of the product design and manufacture. The MicroClave connector will also tolerate a maximum of 400 psi, or a flow rate of 10 milliliters per second of room temperature contrast media, making it suitable for use in power injector procedures and emergency rapid fluid infusions when required. In contrast, lab testing reveals that NeutraClear connector flow rates vary considerably from unit to unit, as well as from activation to activation within the same unit (see Table 1). Overall, Cair Drive and NeutraClear connector flow rates are considerably lower than MicroClave.

TABLE 1. TESTED FLOW RATES

Connector	Tested Flow Rate*	High Pressure Compatibility Claim
MicroClave Clear	156 mL/min	400 psi or 10 mL/sec
NeutraClear	2010: 85 mL/min 2015: 133 mL/min	325 psi or 10 mL/sec

*Based on internal testing of 7 days and 700 activations

Back Pressure Leakage

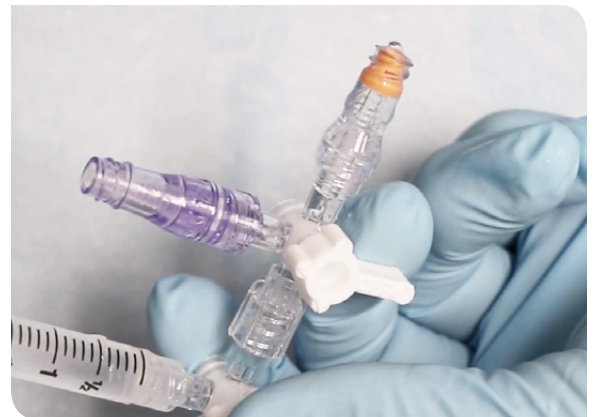
The MicroClave connector is validated to hold back pressure of greater than 60 psi for five seconds and greater than 45 psi for 30 seconds, enabling leak-free performance in multiple clinical scenarios.⁷ Testing shows that the MicroClave connector easily meets this industry guideline, holding extended back pressures of more than 75 psi.

In contrast, the NeutraClear connector begins to leak under pressure of approximately 37 psi, and in lab tests, all samples evaluated failed below the industry guideline of 45 psi for five seconds (see Figure 2). This suggests that NeutraClear

FIGURE 2. NEUTRACLEAR BACK PRESSURE LEAKAGE



FIGURE 3. NEUTRACLEAR BACK PRESSURE LEAKAGE



product performance is not in line with generally accepted performance guidelines in regard to back pressure.* Pressures like these are common in clinical practice and are easily demonstrated with a simple stopcock and a standard three mL syringe (see Figure 3).

*In the current ISO standard that the majority of IV accessory manufacturers follow to ensure luer connections are appropriate and safe (ISO 594), the standard that must be met is that when luer connections are made, the connection must withstand back pressure of 45 psi for 30 seconds. This standard does not specifically pertain to needlefree connectors, although manufacturers typically understand that to avoid leakage under this pressure in normal clinical use, needlefree connectors must also hold back pressures of this magnitude when not connected to another ISO standard luer. Therefore, industry generally uses the 594 standard as guidance for internal standards of 45 psi for five seconds. Five seconds is common partially because if an un-actuated needlefree connector on a pump set begins to fail and leak in under five seconds (depending on the pressure setting of an IV pump) the pump will not recognize pressure built up in the line and may continue to pump without alarm even when a line is occluded. There may also be more detail in the intricacies of why the industry typically uses this standard.

Angled Access Leakage

The sterility of an infusion system can be compromised when connector design and manufacturing are not optimized. MicroClave design and manufacturing tolerances ensure that as a male luer contacts the sterile silicone surface and begins to compress the septum, a dynamic seal is created before the fluid path is opened, and the internal blunt cannula begins to pass through the split-septum.

The fluid path is not accessed until the silicone is compressed to a controlled and specified depth and the windows of the cannula become exposed in the internal diameter of the access luer. This creates the dedicated internal fluid path, where

at no point does the exterior of the access luer, split-septum, or housing come in contact with the fluid path (see Figure 4).

Executed correctly, this internal fluid path technology helps protect patients and caregivers from potential exposure to blood and blood-borne pathogens, while ensuring that the sterility of the fluid path is not compromised by becoming open to the outside environment during connection and disconnection.

The fluid path of the MicroClave connector remains closed until the dynamic seal is achieved between the syringe luer and the sterile silicone surface of the connector, even when challenged with an angled luer insertion. In contrast, a dynamic seal can only be created when accessing the NeutraClear connector with a precise, straight-on male luer insertion, creating opportunities for improper connections and leaking from the connector if accessed at an angle.

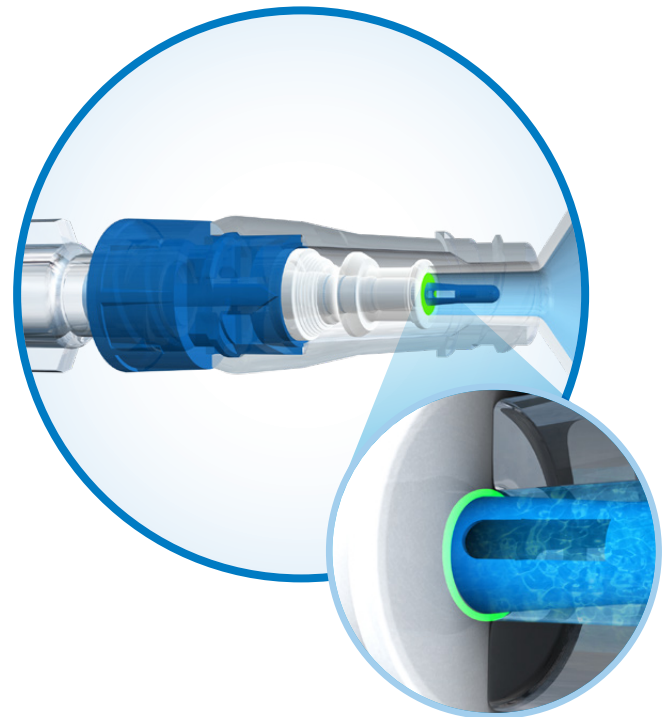
CONCLUSION

Given notable differences to critical design features as well as the performance differences described, Cair Drive and NeutraClear connector cannot be considered mechanically or clinically equivalent to the MicroClave connector. These design and performance differences

also make clinical or laboratory data derived using products with Clave technology irrelevant to the Cair design, and research data that examines and validates the Clave technology design is not transferable to the Cair designs.

Cair Drive and NeutraClear connector performance cannot be considered equivalent to MicroClave connector performance, and therefore cannot be considered clinically equivalent to MicroClave.

FIGURE 4. MICROCLAVE SPLIT-SEPTUM SILICONE SEAL



Specifically designed to minimize contact between the connector's external surface and the internal fluid path upon luer activation, this proven Clave technology minimizes entry points for bacteria. Several studies have attributed this feature to a significant reduction in bacterial contaminants passed through the connector.^{2,3,8}

References

1. Bouza E, Munoz P, Lopez-Rodriguez J, Jesus Perez M, Rincon C, et al. *J Hosp Infect.* 2003; 54:279–287.
2. Yebenes J, Delgado M, Sauca G, Serra-Prat M, Solsona M, Almirall J, et al. Efficacy of three different valve systems of needlefree closed connectors in avoiding access of microorganisms to endovascular catheters after incorrect handling. *Crit Care Med* 2008;36: 2558–2561.
3. Ryder M, RN, PhD. Bacterial transfer through needlefree connectors: Comparison of nine different devices. Poster presented at the Annual Society for Healthcare Epidemiology of America (SHEA) conference 2007.
4. Moore C, RN, MBA, CIC. Maintained low rate of catheter-related bloodstream infections (CR-BSIs) after discontinuation of a luer access device (LAD) at an academic medical center. Poster presented at the annual Association for Professionals in Infection Control and Epidemiology (APIC) Conference 2010, Abstract 4-028.
5. Note that a technical comparison video of these performance characteristics is available at <http://go.icumed.com/microclave-clear-videos>.
6. CareFusion NeutraClear® IV Connector brochure. 0000CF02294 Issue 1. August 2014.
7. Performance data on file at ICU Medical Inc. San Clemente, CA 92673. Reference ENG-433.
8. JD Brown, HA Moss, TSJ Elliott. The potential for catheter microbial contamination from a needleless connector. *J Hosp Infect.* 1997; 36:181-189.