

Needleless Connectors: A Primer on Terminology

ABSTRACT

Within the past 20 years there has been an explosion of devices designed to allow connection of multiple intravenous sets and catheter hubs without the use of needles. Currently, the number of devices, their internal and external designs, and their functions can be quite confusing. There is a lack of clear definitions and terminology universally accepted by all professionals involved, leading to additional confusion. The purpose of this article is to provide an overview of the many types of technological designs, clarify the characteristics, and recommend clear and concise definitions.

Within the past 20 years, we have witnessed an explosion of devices designed to allow connection of multiple intravenous (IV) administration sets and catheter hubs to administration sets without the use of needles. The use of needles for this purpose was deemed to be a risk for needlestick injuries with the inherent potential for occupationally acquired bloodborne diseases.¹

The original change from small-gauge needles to large blunt plastic cannulas generated anecdotal reports of increases in catheter lumen occlusion. Using colored fluid, reflux could easily be demonstrated in laboratory tests; however, very little clinical data can be found to

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actually document the reflux of blood caused by these devices. One classic study involving dye injection through 200 central vascular catheters used for parenteral nutrition and cancer chemotherapy documented a 3% (6/200) intraluminal occlusion rate, preventing dye injection. The obstructing material was removed by guidewire manipulation through the catheter lumen, and the study did not report the content of the occluding material.²

Device manufacturers, intent on meeting clinical needs, began to develop numerous types of these products with a variety of features. Currently, the number of devices, their internal and external designs, and their functions can be quite confusing. There is a lack of clear definitions and terminology universally accepted by all professionals involved, leading to additional confusion.

Since these devices were first introduced, concern about the risk of catheter-related bloodstream infections (CR-BSIs) associated with their use has appeared in the literature.³⁻⁵ More recently, there have been additional reports of increased CR-BSIs following a change from one product type to another.⁶⁻⁹ These reports use a variety of terms to describe the products being used, also leading to confusion and making it very difficult to compare outcomes. Recent guidelines place all brands of one category of these devices into the same risk group when the published reports have not included all of the designs in this category.

Many studies, abstracts, and poster presentations about these devices are available and contain even more confusing descriptions of the types and design features. Finally, the device manufacturers produce marketing materials that may use these terms in a manner that varies from the authors of the publications, creating mass confusion among healthcare professionals attempting to glean a true understanding about these devices.

The purpose of this article is to review the many types of technological designs, clarify the numerous characteristics, and recommend clear and concise definitions. To begin, the authors propose the term *needleless connector* as the one that best describes the entire group of these devices. This term indicates that the purpose of these devices is to allow connection of catheters, administration sets, and syringes. This could be a

primary administration set with a secondary set piggy-backed to it, a continuous or intermittent administration set attached to the catheter, or a syringe attached either to the administration set or directly to the catheter hub. All of these connections involve the potential for blood contact; therefore, the junction should be attained without the use of needles.

The current *Infusion Nursing Standards of Practice* (the *Standards*) has 2 sections that address these devices. Standard 29 addresses add-on devices and lists injection or access caps and needleless systems, while Standard 35 specifically addresses injection and access caps.¹⁰ Needles should not be used while making any of the required connections; consequently, it would seem reasonable to retitile this standard as “needleless connectors.”

The Bloodborne Pathogens Standard (29 CFR 1910.1030) from the Occupational Safety and Health Administration includes a definition of *needleless systems* as devices that provide an alternative to needles for various procedures to reduce the risk of injury involving contaminated sharps and include

- IV medication systems that administer medication or fluids through a catheter port using non-needle connections and
- jet injection systems that deliver liquid medication beneath the skin or through a muscle.¹¹ The use of *needleless connectors* would apply to those devices used for the purposes of infusion therapy, but *needleless system* is a broader term encompassing other devices for subcutaneous or intramuscular injection.

In addition, the ECRI Institute has adopted *needleless connectors* as the term encompassing this entire category of devices used for infusion therapy.¹²

TYPES OF NEEDLELESS CONNECTORS

Needleless connectors can be categorized by the complexity of their internal mechanisms and by how they function (Table 1).

Categorizing these devices by their internal mechanism creates 2 groups: simple and complex. Simple devices have no internal mechanism and include devices with an external split septum. One design requires the use of a blunt plastic cannula attached to the administration set or syringe and inserted through the prepierced septum of the needleless connector. A second design eliminates the blunt plastic cannula and allows the male luer end of an administration set or syringe to be inserted into the prepierced septum. Neither of these designs has any internal moving pieces, allowing the fluid to flow straight through the device lumen.

Complex needleless connectors contain some type of internal mechanism, and this group is commonly called a

mechanical valve. *Valve* is defined as a mechanical device that controls the flow of fluid within a system.¹³ The internal mechanism in this group of needleless connectors must be capable of allowing fluid to flow in both directions for infusion and aspiration. There are a wide variety of internal mechanisms currently used in this group, and they are discussed in detail in the sections that follow.

Another way to categorize needleless connectors is by how they function. This involves the presence of fluid displacement inside the device. Many devices allow for negative fluid displacement, meaning that blood will be pulled back into the catheter lumen. Negative fluid displacement occurs while the administration set is attached, as in the case of an empty fluid container allowed to remain connected, and upon disconnection of the administration set, syringe, or blunt cannula. With split-septum systems, blood is pulled back into the catheter lumen as the blunt cannula or male luer end of the administration set is withdrawn from the septum. With mechanical valves, blood is pulled into the catheter lumen by the movement of the valve mechanism. Blood allowed to reside inside the lumen will lead to partial or complete lumen occlusion; therefore, this category of devices mandates the use of flushing techniques to overcome this blood reflux.

Some mechanical valves are designed to produce a positive fluid displacement upon disconnection of the administration set or syringe from the device. These valves have a reservoir for holding a small amount of fluid. Upon disconnection, this fluid is pushed out to the catheter lumen to overcome the reflux of blood that has occurred. Blood can still move into the catheter lumen, but the displacement mechanism prevents it from residing in the catheter lumen after disconnection. While the administration set is attached to this device, the valve remains open. The positive displacement occurs only upon administration set or syringe disconnection. Consequently, an empty fluid container allowed to remain connected will allow blood to reflux into the catheter. The length of catheter lumen affected by this reflux depends on many variables such as the catheter lumen size, vein lumen size, venous pressure, and changes in intrathoracic venous pressure produced by coughing, vomiting, or sneezing.

Some mechanical valves are labeled as *neutral devices*, indicating that the device prevents blood reflux upon connection and disconnection. There can be a very small amount of blood reflux (eg, up to 0.02 mL), and some have purported that this indicates it is not neutral. The terms *negative*, *positive*, and *neutral displacement* are marketing terms, and there are no documents from any regulatory organizations providing guidance on the use of these terms.

One other type of device that could be included in the neutral group is a cupped silicone membrane with a slit that acts as a valve. This device operates by pressure

TABLE 1
Needleless Connector Devices^a

Brand of Device	Type of Displacement	Priming Volume	Luer Access or Luer Activated	Internal Mechanism
Antimicrobial CLAVE [®] , ICU Medical, Inc	Negative	0.06 mL/0.04 mL	Luer activated	Mechanical valve with internal blunt cannula
CLEARLINK [®] V-Link, Baxter	Negative	0.25 mL	Luer activated	Mechanical valve
INTERLINK [®] , Baxter	Negative	0.2 mL	No luer—blunt cannula access	None
Q-Syte [™] , BD Medical	Negative	0.10 mL	Luer access	None
SmartSite [®] , CareFusion	Negative	0.1 mL	Luer activated	Mechanical valve
CLC2000 [®] , ICU Medical, Inc	Positive	0.09 mL	Luer activated	Mechanical valve
FLOLINK [®] , Baxter	Positive	0.25 mL	Luer activated	Mechanical valve
MaxPlus [®] /MaxPlus Clear [®] /MaxGuard [®] , Maximus Medical	Positive	0.28 mL (all)	Luer activated	Mechanical valve
Posiflow [™] , BD Medical	Positive	0.06 mL	Luer activated	Mechanical valve
SmartSite [®] Positive Bolus, CareFusion	Positive	0.12 mL	Luer activated	Mechanical valve
Ultrasite [®] /Ultrasite [®] Ag, B Braun Medical	Positive	0.35 mL (both)	Luer activated	Mechanical valve with internal spring
Bionector [®] , Vygon	Neutral	0.018 mL	Luer activated	Mechanical valve with internal blunt cannula
InVision-Plus [®] /InVision-Plus [®] Junior [™] , RyMed Technologies Inc	Neutral	0.027 mL/0.022 mL	Luer activated	Mechanical valve with internal blunt cannula
Nexus TKO [®] -4 Nexus TKO [®] -5 with split septum Nexus TKO [®] with CLAVE [®] , Nexus Medical	Neutral	<0.10 mL 0.10 mL 0.15 mL	Requires addition of another connector No luer—blunt cannula access Luer activated	Pressure-sensitive valve in all types
MicroCLAVE [®] , ICU Medical, Inc	Neutral	0.02 mL	Luer activated	Mechanical valve with internal blunt cannula

^aData per the manufacturer's Web site or personal communication.

and is the only add-on connector that will automatically close when the fluid container empties.

Needleless connectors have also been associated with the word *pressure*; however, there is no pressure or force generated when the fluid movement occurs. The focus is on fluid displacement inside the device and attached catheter.

MATERIALS IN NEEDLELESS CONNECTORS

A wide variety of plastics are commonly used to manufacture the external housing, septum, and external and internal mechanism of needleless connectors, although other materials such as silicone and stainless steel are

also used. Plastics are lightweight, waterproof, moldable, typically resistant to chemicals, can be colorized, and fall into 2 categories: thermoplastics and thermosetting.¹³ Thermoplastics, such as polyester and polyethylene, are capable of becoming hard or soft as they are heated or cooled, while thermosetting material remains permanently rigid at all temperatures.¹³ The biomaterials used in the manufacturing of needleless connectors include, but are not limited to, the following products: silicone, polyester, polyethylene, polycarbonates, and stainless steel. Also, it is important to note that all of the devices are free of latex and di(2-ethylhexyl)phthalate.¹²

Silicone, a group of polymer organic compounds of silicon, carbon, hydrogen, and oxygen, is used in many different types of IV products. It has a variety of positive attributes such as heat resistance, repelling water, flexibility, good tensile strength, resilience, and lubricating properties.^{13,14} Silicone is an integral polymer used in the manufacturing of needleless connector components.

Polyester is a synthetic polymer derived from coal, air, water, and petroleum. While commonly used in fabric for clothing, it is also a plastic material that is used in the manufacturing of the external housing for needleless connectors. Polyester is resistant to corrosion, chemicals, solvents, etc.¹⁵

Polyethylene is a major synthetic thermoplastic polymer commonly used in IV administration sets. Polyethylene is tough, water and chemical resistant, and easily molded.¹³ It has been used in the manufacturing of some of the needleless connector fluid pathways.

Stainless steel is a steel alloy, which means it is a substance that is a mixture of 2 or more metals and is the most widely used alloy. Stainless steel attributes are its resistance to rust, stains, and corrosion, as well as its strength, impact resistance, fire and heat resistance, and fabrication ease.¹⁶ Stainless steel has been used in the manufacturing of some needleless connectors' fluid pathway components; however, fluid does not come into contact with the stainless steel.

Polycarbonate is a very popular resin used in the development and manufacturing of medical devices. This type of thermoplastic polymer is easy to work and mold but combines strength, impact and temperature resistance, toughness, and clarity, which are important characteristics.¹⁷

It is a popular polymer in the development of medical devices because of its clarity and strength. This polymer gives IV components, such as needleless connectors, the ability to form secure, tight connections, and/or seals to decrease risk of leaking and clear components that permit the clinician to assess visually blood, particulate matter, or debris within the internal mechanism of the needleless connector. Another significant advantage to polycarbonate is that it can be sterilized by using the ethylene oxide, irradiation, or steam autoclaving methods.¹⁷

So, as one can see, there are a variety of polymers that can be employed to manufacture the internal and external components of needleless connectors. This brief overview offers a look into not only what type of material can be used for the different components but also some interesting characteristics or features of each, which provides important knowledge and facts in supporting informed product selection decisions and use.

THE EXTERNAL DESIGN OF THE CONNECTOR

The characteristics of the connector's external housing is critical for the clinician to meet the national standard of practice. INS Standard 35: Injection and Access Caps has the following statement in the practice criteria: "If the integrity of the injection or access cap is compromised or if residual blood remains within the cap, it should be replaced immediately and consideration should be given to changing the catheter and administration set."^{10(p536)} If the clinician is unable to determine whether the needleless connector is clearly and completely flushed, the connector should be changed.

Needleless connector housing is characterized as having an opaque, clear, or partial visualization (Figure 1). *Opaque* comes from the Latin word *opacus*, meaning "shaded or dark," not transparent, impenetrable by visible light, or unable to see through.¹³ Based on this definition, a needleless connector with opaque housing prevents the nurse from being able to see inside to determine if there is any residual solution, blood, or debris remaining inside.

The word *clear* comes from the Latin word *clarus*, meaning transparent, easily seen, or distinct. Transparent means the object is free of anything that blocks it and suggests it allows objects to be seen distinctly.¹³ Needleless connectors with clear housing provide an unobstructed, transparent view of the complete device, which allows the nurse to see distinctly any objects, such as mechanical components, and fluids (Figure 2).

A needleless connector designed with partial visualization would allow the practitioner a limited visual area. Some devices have a colorized plastic housing that



Figure 1 Opaque device. (Courtesy of Lynn Hadaway.)

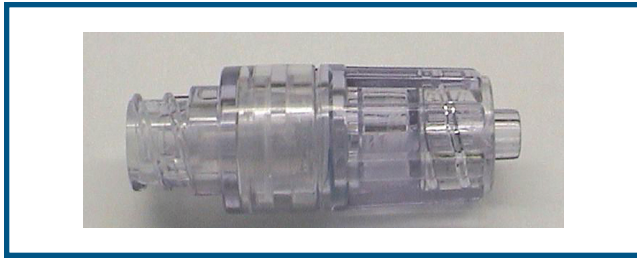


Figure 2 Clear device. (Courtesy of Lynn Hadaway.)

allows some visualization of the internal housing but limits a distinct, clear view.

THE CONNECTION SURFACE

The configuration of the external connection surface can have a direct impact on the outcome with the device. Needleless connectors can have a relatively flat surface, an area of indentation in the center of the surface, an angled post in the center, or some other form of irregular surface. There is also a category of mechanical valves that requires closure with a new sterile end cap.

The surface design is thought to be one factor in the controversy over the infection risk associated with each device. The more intricate designs could present difficulty in reaching all surfaces to clean adequately before each use.

Nurses may also have difficulty in making the connection between the male luer end of an administration set or syringe due to these angles or irregularities. This difficulty increases the potential for inadvertent contamination of the set or syringe and requires additional nursing time to ensure patient safety.

Needleless connectors requiring closure with an end cap means that sterile caps must be made readily available in the patient care area; otherwise, the connector could go uncapped and increase the risk of intraluminal contamination.

ACCESS TO THE FLUID PATH

The mechanism to access the fluid pathway includes 2 types—the external blunt plastic cannula and luer access. The blunt cannula is pushed through the split septum. These cannulas can either be manually held in place during injection or have some type of locking mechanism to prevent accidental disconnection.

Devices that use a luer-access mechanism include both the mechanical valves and the split-septum groups. The male luer end of an administration set or syringe is luer-locked or screwed onto the needleless connector. In the case of a split septum, this male luer end simply pushes open the sides of the split septum (Figure 3a and 3b). For a mechanical valve, this male luer end is what moves the centerpiece or post to open and allow fluid to flow through the device.

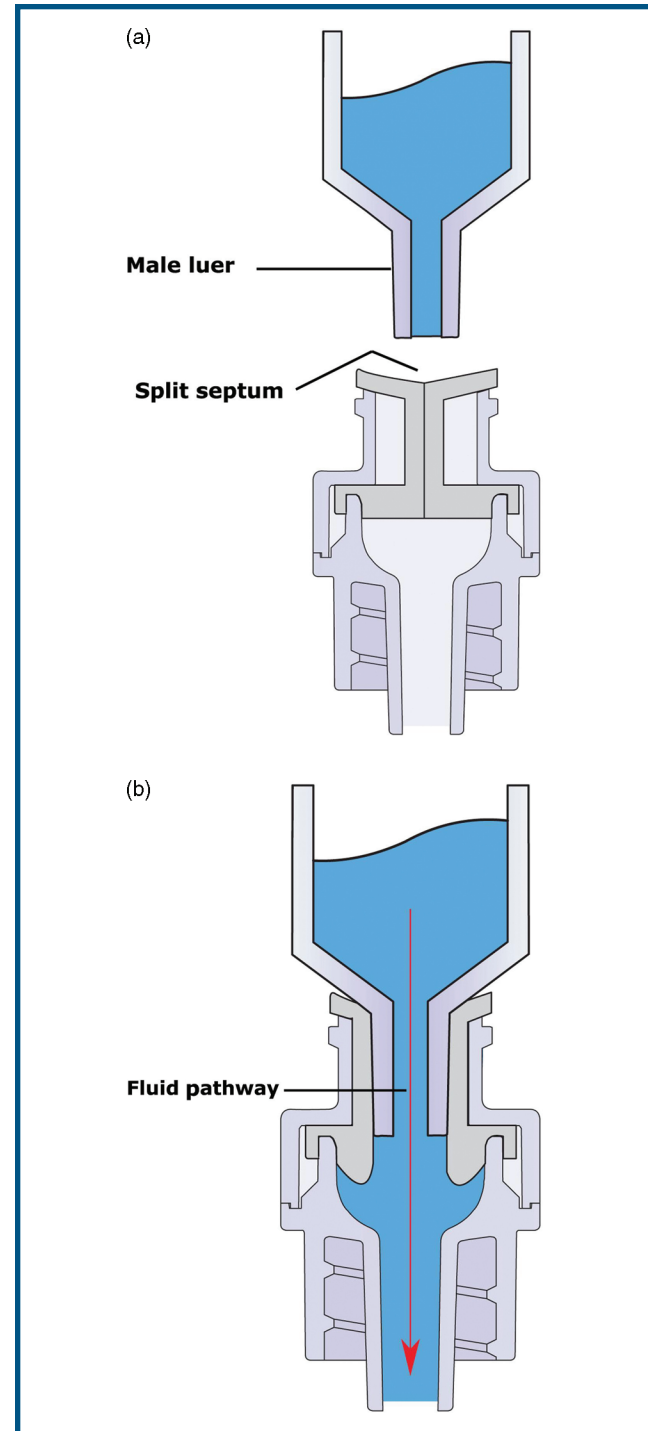


Figure 3a and 3b Luer access split septum with negative displacement. (Courtesy and © Becton, Dickinson and Company.)

THE INTERNAL DESIGN OF THE CONNECTOR

The Fluid Path

As discussed with both types of split-septum devices, the pathway of fluid flow through the device is straight because there are no internal mechanisms (Figure 4a and 4b). Mechanical valves have a variety of internal

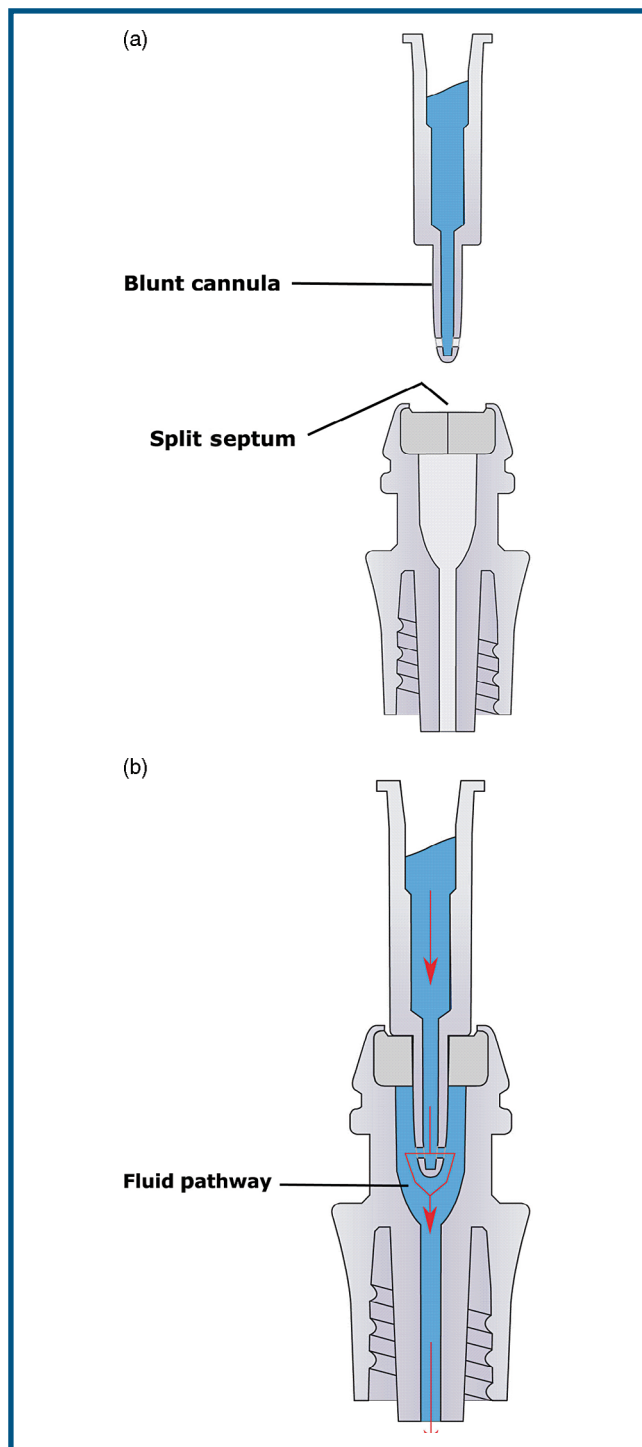


Figure 4a and 4b Split septum opened by blunt cannula. (Courtesy and © Becton, Dickinson and Company.)

designs with moving parts. Fluid must flow either through or around these moving parts. A mechanical valve with a positive displacement mechanism would have a small reservoir to hold fluid until the administration set or syringe is disconnected.

Fluid flowing in a laminar manner will move in a smooth, constant pattern. This describes blood flow through vessels as the flow actually occurs in concentric

layers with the fluid in the center of the vessel moving the fastest. The layers closest to the vessel wall will have the slowest flow; however, all layers are moving forward in an uninterrupted pattern.

Turbulent flow occurs when there is some force to create swirls, eddies, or vortices, causing the fluid to move in random patterns with much fluctuation. One blunt plastic cannula is designed with fluid exit holes on 2 sides of the cannula for the express purpose of creating turbulent fluid flow (Figure 4a and 4b). Other internal mechanisms may have complex fluid pathways that create turbulent flow.

The effect of turbulent flow in blood vessels can produce a negative outcome because it damages the endothelial cell layer, exposing the basement membrane, which initiates the clotting process. No studies are available to examine the impact of laminar versus turbulent flow through needleless connectors or catheters. Since blood will frequently be aspirated into needleless connectors and the internal mechanisms vary greatly, it would be beneficial to know the impact of these fluid flow patterns through all types of these devices.

Internal Volume

The internal volume of a needleless connector is the amount of fluid required to remove all air from the system. The volume for each brand will vary, and this information should be available in the product literature or on the manufacturer's Web site.

Interstitial space, sometimes called dead space, has been applied to needleless connectors through some of the research on the infection risk associated with them. Interstitial space when applied to human physiology means the space that is situated between the cells or other structures. In humans, this space is fluid with a gel-like substance. When applied to needleless connectors, it is used to indicate spaces inside the housing where fluid can leak or be flushed into, although the original design did not intend for fluid to move into these spaces.

INTERNAL MECHANISMS

This section will provide information on the internal mechanisms or components of needleless connectors. These components or mechanisms include mechanical valves, split septa with internal blunt cannulas, and pressure-sensitive valves. The following descriptions are based on the examination of disassembled needleless connectors.

Mechanical Valve

A mechanical valve is a system of interrelated parts designed to work together to open or close the fluid pathway. These systems contain a collapsible silicone sleeve with an open slit at the connection surface contained

inside the rigid plastic housing. Attaching the male end of a syringe or IV administration set opens the slit to allow fluid to flow through the center of the sleeve. The male luer end meets the slit and compresses the sleeve. The sleeve may have a small expanded area to prevent fluid from leaking into the interstitial space (Figure 5a and 5b).

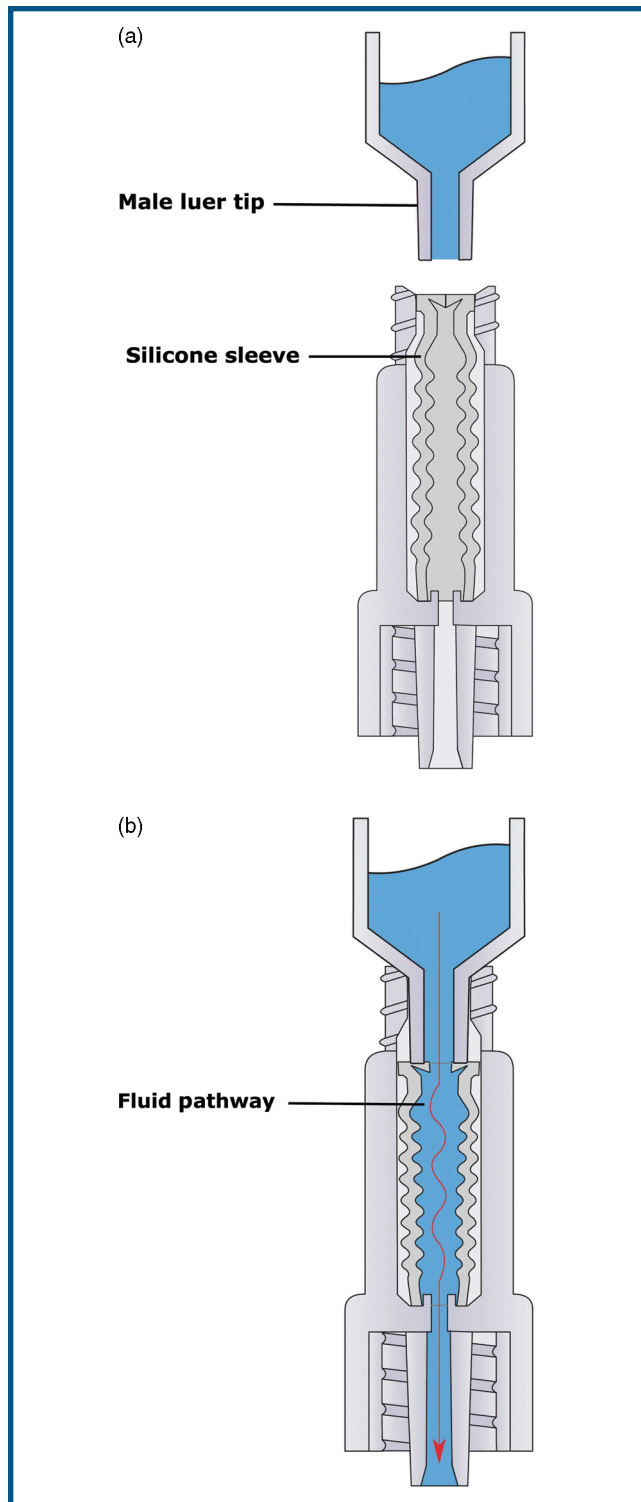


Figure 5a and 5b Luer-activated mechanical valve with negative displacement. (Courtesy and © Becton, Dickinson and Company.)

The mechanical valve design evolved to decrease the reflux of blood into the vascular access device. The goal is to eliminate or diminish occlusion episodes and reduce the use of heparin for locking catheters. Thus, these mechanical valves are known as positive displacement devices.

The compressible sleeve is larger and has an enlarged reservoir to hold a small amount of fluid. This compressible center sleeve does not have a slit in the connection surface; therefore, the fluid flows between this sleeve and the outer housing. A stainless steel spring is enclosed inside the silicone sleeve of one brand and is not in contact with the fluid. Removing the male luer tip releases the pressure on the collapsible sleeve, causing the sleeve to return to its original position. This forces the fluid being held between the sleeve and housing into the catheter lumen to overcome blood reflux (Figure 6a and 6b).

Another brand contains a rigid center plastic piece positioned with an angle at the connection surface. A stainless steel spring is located behind this rigid plastic piece. Attaching the male luer tip pushes the plastic piece in and compresses the spring. Detaching the male luer tip relieves pressure on the spring, allowing the contained fluid to be pushed into the catheter lumen.

Internal Split Septum and Blunt Cannula

An external blunt cannula system requires the nurse to push this rigid plastic piece through a split septum to enter the open fluid pathway. An internal split septum is mounted at the distal end of the needleless connector and is tapered with the smaller end pointing to its connection with the male luer tip of a syringe or set. These cannulas may have an open tip or a closed tip with 2 openings on the side of the cannula. A collapsible silicone sleeve with a split covers the cannula. Attachment of the male luer tip pushes the silicone sleeve down over the blunt cannula to expose the opening(s). To avoid fluid leaking into the interstitial space, the opening(s) must meet and be completely covered by the male luer tip. Fluid flows inside the blunt cannula (Figure 7a and 7b).

Pressure-Sensitive Valve

A relatively new device is available with a pressure-sensitive valve. This device is available as a stand-alone device for use with all other needleless connectors or can be purchased with either a preattached mechanical valve or a split-septum system. The valve is a round silicone-cupped disk with a slit in the center (Figure 8).

Fluid displacement with other needleless connectors occurs only at the time of syringe or set disconnection. These systems remain an open conduit as long as the syringe or set is still attached to the needleless connector. This pressure-sensitive valve changes this process. When the fluid flow stops, the pressure on the valve is relieved and it automatically closes, thus preventing blood reflux into the catheter lumen.

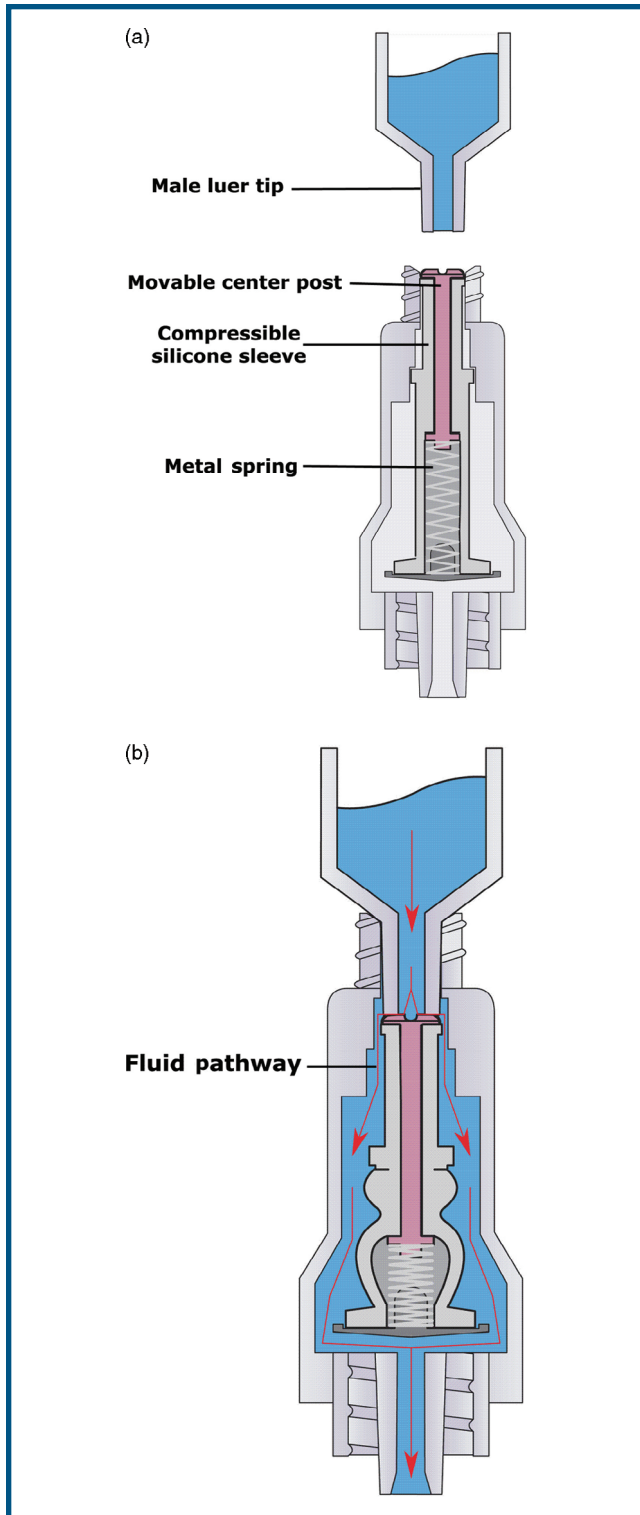


Figure 6a and 6b Luer-activated mechanical valve with positive displacement. (Courtesy and © Becton, Dickinson and Company.)

INTERNAL SPRINGS

As described above, some needleless connectors use metal internal springs inside the connector. It is important for clinicians to be aware of materials used in the

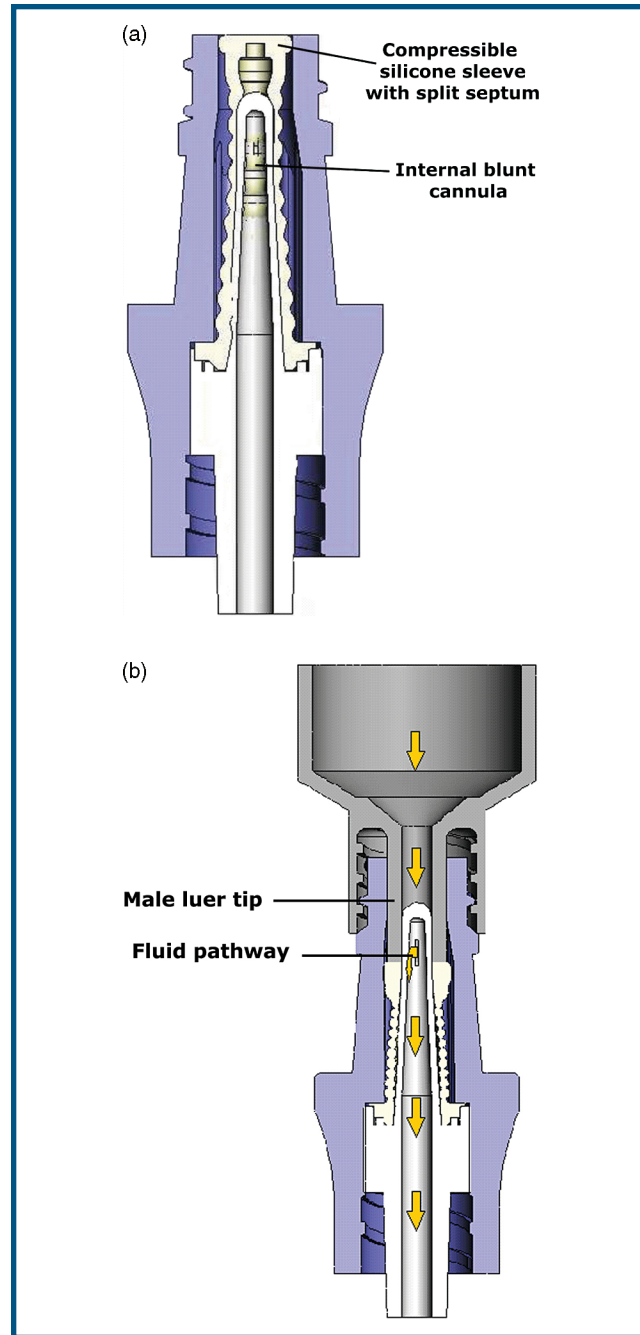


Figure 7a and 7b Luer-activated mechanical valve with neutral displacement. (Courtesy of Lynn Hadaway.)

manufacturing of a considered needleless connector as it will assist in providing and developing information on use for select procedures. For example, if the chosen needleless connector has internal metal springs, there may be issues with magnetic resonance imaging with the potential to cause image distortion, create an image artifact, or pull on the catheter.¹² However, these issues can be avoided or limited by making sure that the needleless connector is not within the imaging field, securely taping down the catheter, and making the practitioners in radiology aware of the potential artifact.

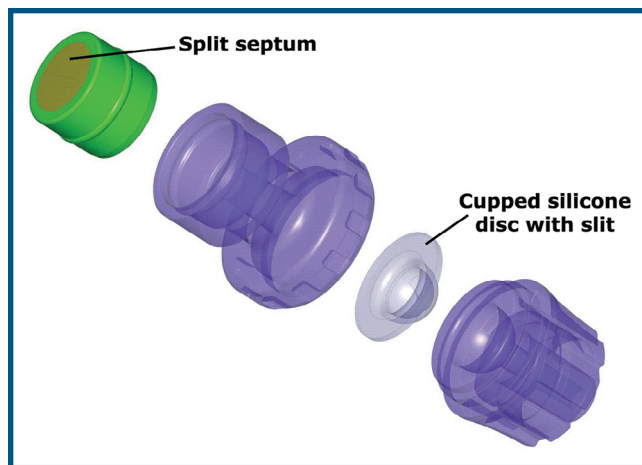


Figure 8 Pressure-sensitive valve with split septum. (Courtesy of Lynn Hadaway.)

MICROBIAL BARRIERS

Several needleless connectors have been developed to provide intraluminal and extraluminal microbial protection to decrease the risk of CR-BSIs or catheter-associated bloodstream infections (CA-BSIs) and improve patient outcomes. Currently, needleless connectors designed with microbial barriers use silver or a combination of silver and chlorhexidine as the antimicrobial agent(s) applied through either impregnated or coated technology. When a device is coated with an antimicrobial agent, the biocide or antimicrobial agent may be sprayed, painted, or dipped onto the surface of the device. An impregnated device means that the biocide or antimicrobial agent is incorporated into the device and is an intrinsic part of it. Clinicians need to obtain clear information from the manufacturer about the antimicrobial needleless connector being considered for patient care and understand whether the microbial barrier is applied to the entire device or only certain components of it.

Silver has been used in the medical arena for many years and has been found to be an effective agent. Several clinical studies have focused on its effectiveness on colonization and CR-BSIs on medical devices such as central vascular catheters and urinary catheters.¹⁸⁻²² However, the authors are unaware of published clinical studies on antimicrobial needleless connectors and the effect on colonization and CR-BSIs. In addition, there is no information on long-term effects of silver exposure, particularly in the pediatric and neonatal patient populations.¹² These devices are not considered appropriate for persons with sensitivity to silver.¹²

Clinicians can obtain more detailed information from the different manufacturers. The development of needleless connectors with microbial barriers may be a potential positive evolution in the design and technolo-

gy of these vascular access devices, but further clinical evidence is needed to prove effectiveness against CR-BSIs, internal colonization, and/or contamination.

ACTUATIONS

Actuations, or activations, are the number of times a syringe, IV administration set, or blunt cannula is attached to the needleless connector before the needleless connector is removed. Each manufacturer of needleless connectors is responsible for developing its process and testing each product design to identify the projected number of activations or actuations that can occur before the device fails. This information provides insight for clinicians into the durability, functionality, and usage of a particular needleless connector. For example, testing by BD Medical (Sandy, Utah) showed 100 actuations for the BD Q-Syte™ Luer Access Split Septum and 200 actuations with the BD Interlink® Ultrasite Needle Free IV System (M. Wise, RN, BD Medical, e-mail communication, February 16, 2009). Activations with BD Interlink® Ultrasite® Needle Free IV System from B Braun Medical are performed 216 times for design verification. A complete activation is defined by this company to include engagement of the luer access, flushing fluid through the device, aspirating from the device, and disconnection (Steve Weber, BS, B Braun Medical, e-mail communication, July 17, 2009).

The US Food and Drug Administration does not set forth specific requirements in this arena; however, this is addressed in a guidance document from the Food and Drug Administration containing nonbinding recommendations. Bench testing in both dry and wet conditions is recommended. Repeated connections should be made until the point of failure.²³ This process is left up to the manufacturer to provide testing that supports the “instructions for use.” Most manufacturers will provide some established time frame for use or direct clinicians to follow the Centers for Disease Control and Prevention guidelines, which direct the use of such devices to a time frame. It is important to note here that an identified time frame does not necessarily correlate to the number of actuations. It is clear that in the clinical setting, end users are not counting how many actuations have actually occurred with the product.

CONCLUSION

This article has attempted to provide an overview of common terminology and definitions related to needleless connectors, design, components, and function. It has focused on generic information, and the authors recommend that each decision maker understand all

factors in the products being used. Many critical aspects of the use of these devices remain to be answered. Clinical research is required to answer these questions; however, researchers must enhance their knowledge of product design as research is planned. As busy clinicians struggle with product decisions, it is the authors' hope that this information will prove beneficial to improving clinical outcomes with these devices. Finally, speaking a common language about these devices can enhance communication among clinicians, manufacturers, and regulatory agencies.

REFERENCES

1. Food and Drug Administration. *Needlestick and Other Risk From Hypodermic Needles on Secondary IV Administration Sets: Piggyback and Intermittent IV*. Rockville, MD: Food and Drug Administration; 1992.
2. Stephens LC, Daire W, Kotulak G. Are clinical signs accurate indications of the cause of central venous catheter occlusions? *J Parenter Enteral Nutr*. 1995;19(1):75-79.
3. Danzig L, Short L, Collins K, et al. Bloodstream infections associated with a needleless intravenous infusion system in patients receiving home infusion therapy. *JAMA*. 1995;273:1862-1864.
4. Do A, Ray B, Banerjee S, et al. Bloodstream infection associated with needleless device use and the importance of infection-control practices in the home health care setting. *J Infect Dis*. 1999;179(2):442-448.
5. Kellerman S, Shay D, Howard J, et al. Bloodstream infections in home infusion patients: the influence of race and needleless intravascular access devices. *J Pediatr*. 1996;129:711-717.
6. Maragakis LL, Bradley KL, Song X, et al. Increased catheter-related bloodstream infection rates after the introduction of a new mechanical valve intravenous access port. *Infect Control Hosp Epidemiol*. 2006;27(1):67-70.
7. Field K, McFarlane C, Cheng A, et al. Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit. *Infect Control Hosp Epidemiol*. 2007;28(5):610-613.
8. Salgado C, Chinnes L, Paczesny T, Cantey R. Increased rate of catheter-related bloodstream infection associated with use of a needleless mechanical valve device at a long-term acute care hospital. *Infect Control Hosp Epidemiol*. 2007;28(6):684-688.
9. Rupp M, Sholtz L, Jourdan D, et al. Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. *Clin Infect Dis*. 2007;44(11):1408-1414.
10. Infusion Nurses Society. *Infusion Nursing Standards of Practice*. *J Infus Nurs*. 2006;29(1S):S32, S35.
11. Occupational Safety and Health Administration. *Revision to OSHA's Bloodborne Pathogens Standard: Technical Background and Summary*. Washington, DC: Occupational Safety and Health Administration; 2001.
12. ECRI Institute. Evaluation: needleless connectors. *Health Devices*. 2008;37(9):261-283.
13. *Merriam-Webster's Medical Dictionary*. Springfield, MA: Merriam-Webster Inc; 2003.
14. Thomas J. The use of polymers in IV catheters. *J Vasc Access Devices*. 2002;7(1):25-33.
15. Considine G, ed. *Van Nostrand's Scientific Encyclopedia*. 10th ed. Hoboken, NJ: John Wiley & Sons; 2008.
16. Stainless Steel Information Center. Specialty Steel Industry of North America. Stainless steel overview: features and benefits. <http://www.ssina.com/overview/features.html>. Accessed March 30, 2009.
17. Powell D. Medical applications of polycarbonate. *Med Plast Biomater* 1998; September: 38.
18. Bach A, Eberhardt H, Frick A, Schmidt H, Bottiger BW, Martin E. Efficacy of silver-coating central venous catheters in reducing bacterial colonization. *Crit Care Med*. 1999;27(3):515-521.
19. Bong JJ, Kite P, Wilco MH, McMahan MJ. Prevention of catheter related bloodstream infection by silver iontophoretic central venous catheters: a randomised controlled trial. *J Clin Pathol*. 2003;56(10):731-735.
20. Fraenkel D, Rickard C, Thomas P, Faoagali J, George N, Ware R. A prospective, randomized trial of rifampicin-minocycline-coated and silver-platinum-carbon-impregnated central venous catheters. *Crit Care Med*. 2006;34(3):668-675.
21. Saint S, Elmore JG, Sullivan SD, Emerson SS, Koepsell TD. The efficacy of silver alloy-coated urinary catheters in preventing urinary tract infection: a meta-analysis. *Am J Med*. 1998;105(3):236-241.
22. Johnson JR, Kuskowski MA, Wilt TJ. Systematic review: antimicrobial urinary catheters to prevent catheter-associated urinary tract infection in hospitalized patients. *Ann Intern Med*. 2006;144(2):116-126.
23. US Food and Drug Administration. Guidance for industry and FDA staff: intravascular administration sets premarket notification submissions. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070844.htm>. Published July 11, 2008. Accessed July 15, 2009.