

Advances in Needleless Connectors

Technologies assist in prevention of bloodstream infections

by Ron Stoker

December 1991, OSHA published the Bloodborne Pathogens Standard to protect workers from the risk of bloodborne pathogen exposure. The standard became effective in March 1992. The Bloodborne Pathogen Standard applied to all employers that had employees with reasonably anticipated occupational exposure to blood or other potentially infectious materials or OPIM. The Bloodborne Pathogen Standard was applied to healthcare workers and some general industries as well, e.g., first aiders. In September, 1998 California passed the first needlestick safety law requiring the use of safety products. A number of other states have passed similar legislation mandating the use of safety products.

In September 1998, following the adoption of the California law, Federal OSHA issued a Request for Information (RFI) on available safety products. The information that was gathered from the RFI indicated the feasibility and availability of a number of safer medical devices. It also showed the importance of work practice controls and training when new safety products were introduced.

In May of 1999, the Stark-Boxer Healthcare Worker Needlestick Prevention Act was introduced to Congress. A modified Needlestick Safety and Prevention Act was introduced by Congressman Cass Ballenger of North Carolina. The Act was passed unanimously in the House and Senate. President Bill Clinton signed the Act into law in November 6, 2000.

The Act required OSHA to revise the Bloodborne Pathogen Standard to mandate the use of safer products and to reduce the exposure of clinicians to bloodborne pathogens. A new definition of a needleless system was provided in this revised standard.

A needleless system was defined as a medical device that does not use a needle for the collection of bodily fluids, administration of medications, administration of fluids, and any other procedure with potential percutaneous exposures to a contaminated sharp. By using a needleless system fewer needles would be used and needlestick injuries could be avoided.

A needleless connector is still one of the best ways to prevent needlestick injuries—by eliminating as many needles as possible. By eliminating the needles and replacing them with a non-needled device means that you can't be stuck by needle that is not there. No needle—no risk!

Many changes have occurred since I started my career in the medical device industry almost 29 years ago. One of the major changes has been in the products used to accomplish intravascular infusion. Let's look at how IV infusion systems have changed over time.

Needle Access Injection Port

Almost every catheter that was used 29 years ago had an injection port placed on the proximal end. The injection port consisted of a small piece of plastic covered with latex rubber that was constricted with a small band around it. (See Figure 1.) Injections were made by inserting a sharp conventional needle into the latex dam and injecting medication. The purpose of the injection cap was to provide an avenue into the patient's venous system without having to stick another needle into the patient. The needle access injection port was easy to disinfect. The commission would simply wipe the top of the latex dam with an appropriate alcohol pad. Since only a small needle was being withdrawn from the injection port there was a minimal negative displacement of blood in the catheter. Needles were often "secured" with tape. Unfortunately, as we all know, tape did not provide very good securement and disconnection often

Figure 1.



Needleless systems used on IV tubing have made one of the greatest impacts in reducing needlestick injuries.

occurred. In addition, many healthcare workers receive needlestick injuries using this type of product. Many needles were also recapped following injection and additional needlestick injuries occurred. As we are all aware, there were no governmental or regulatory requirements to use any type of safety device at this time period.

Although needleless IV systems were available at the time, only about 50 percent of hospitals were using needleless IV systems by 1995. Many healthcare organizations were slow to adopt or did not adopt needleless systems. One of the excuses used for this was the increased cost of the devices even though the benefits were proven to save lives.

However, following the 2001 revised Bloodborne Pathogen Standard; healthcare facilities began to adopt needleless connectors in much greater numbers. Needleless systems used on IV tubing have made one of the greatest impacts in reducing needlestick injuries. The needles that were used on injection ports in IV tubing accounted for the highest rate of sharps injuries.

Pre-pierced Septum and Blunt Cannula

Injection caps began to be replaced with pre-pierced septum and blunt cannula. These consisted of a re-sealable port that attached to the hub of the patient's access device. A blunt needle or cannula could be used to repeatedly penetrate the septum. This blunt needle eliminated the need for a sharp needle and would provide intermittent access to the vascular system. (See Figure 2.)

Figure 2.



Medications would be administered inserting the blunt cannula into the pre-pierced septum. This type of system eliminates the use of a sharp needle but it also has some drawbacks. Right beneath the split septum is located an area that accommodates the introduction of the cannula. If the clinician fails to properly use a positive-pressure flush technique or a clamp on the system connection, blood can flow back up into the patient's infusion catheter. This can create a risk of clotting of the catheter and can elevate the risk of infection. Another drawback of this type of system is that conventional hypodermic needles can mistakenly be used with this system, circumventing the advantage of the blunt cannula. The split-septum products did not address the problem of catheter occlusion. Split-septum connectors created negative pressure when the blunt cannula was withdrawn. Any negative pressure at the time of disconnection can jeopardize device patency by allowing retrograde flow into the lumen of the catheter.

Luer-Activated Ports—Negative Displacement

Following the adoption of the Needlestick Safety and Prevention Act, Luer-activated mechanical valves began to be used on a more frequent basis. When the male luer is inserted into the connector a valve opens and fluid can be infused or aspirated. Once the luer is removed the valve closes automatically. This provides intermittent access to the vasculature and removes the need for either a conventional sharp needle or a blunt needle. These were both positive steps in patient and healthcare worker safety. Needlestick injuries were reduced because the needle had been removed from the system. (See Figure 3.)

Figure 3.



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However the luer-activated design posed some other risks. One of the problems created by the luer-activated design is the inadvertent negative fluid displacement that occurs when the male luer is removed from the connector. This negative fluid displacement pulls blood into the catheter lumen and intraluminal thrombotic catheter blockages can occur. Not only does this create occlusions but increases the potential for growth of microorganisms which could flow into the patient's bloodstream. When a catheter occlusion occurs, clinicians administer anti-thrombolytic agents to de-clot the line. This increase in manipulation of the line costs the hospital time and money. It also increases the patient's risk of infection due to contamination. The catheters often have to be replaced because the blood clot could not be removed. This is both difficult for the patient and expensive. It became very important for clinicians to maintain the patency of the catheters.

Many clinicians started to note an increase in bloodstream infections with the use of these products. It has been theorized that this is due to the inability of disinfecting the surface of the device. The theory is that the lack of a flat, smooth surface where the male luer connector would be inserted could be a problem. The newer products had crevices and recesses that were supposedly difficult to disinfect on the top of the valve. Some luer-activated connectors were found to cause an increase in bloodstream infections in several studies.

Luer-activated Ports—Positive Displacement

A number of companies started to design luer-activated valves that displace fluids as the male luer was removed. The concept is that after the syringe is removed from the connector, the needleless connector pushes a small amount of solution out of the connector distally. This would then push fluid out of the distal end of the catheter and would totally fill the catheter with solution thus minimizing occlusion. This positive pulse of fluid clears the catheter tip from blood, thus making occlusions less likely to form because blood is not sitting in a catheter for an extended period of time. (See Figure 4.)

Figure 4.



An additional connector has been designed with a positive push feature that gives an overall negative fluid displacement and therefore no retrograde blood movement into the catheter lumen.

Latest Advances

Luer-Activated Ports—Clear with Anti-Microbial Technology

In the latest advance in luer-activated ports, Maximus Medical, a division of Medegen, has recently introduced the MaxGuard™ Advanced Luer Activated Device featuring Agion® antimicrobial technology. (See Figure 5.)

Figure 5.



Many hospitalized patients receive medications and nutritional support intravenously. During the process of administering intravenous medication, environmental contaminants can be introduced into the bloodstream. This is of particular concern if proper infection prevention techniques are not followed. MaxGuard with antimicrobial technology helps prevent contamination and growth of microorganisms at the point of entry into the catheter, and subsequently in the bloodstream. MaxGuard is new technology introduced to assist hospitals in reducing catheter-related

bloodstream infections. This latest advance in luer-activated needleless connectors helps clinicians prevent bloodstream infections. This will help to provide clients with a product that significantly improves their efforts to enhance patient care and positive outcomes.

The MaxGuard positive displacement connector not only contains antimicrobial technology but it is clear which provides a visualization of the fluid path. It features a positive displacement technology that provides a bolus of fluid to clear the catheter tip upon disconnection from the device. It also features Medegen's patented Tru-Swab® top which acts as a double seal barrier to contamination and allows for true disinfection during pre-access swabbing. The translucent housing provides for visualization of the fluid path allowing for complete flushing of the device.

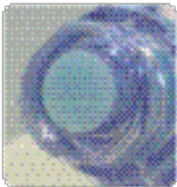
The introduction of MaxGuard comes at a time when bloodstream infection rates continue to be a major concern among hospitals. With the new federal policy restricting reimbursement

for healthcare-associated infections (HAIs), healthcare professionals are seeking techniques and technologies to assist in their bloodstream infection prevention efforts. †

Ron Stoker is the founder and executive director of the International Sharps Injury Prevention Society (ISIPS) and is a frequent contributor to Managing Infection Control magazine. He speaks frequently at national and international meetings on sharps safety, hand hygiene and infection control issues. He is co-author of the "Compendium of Infection Control Technologies." For more information on the Compendium, go to <http://kunaki.com/Sales.asp?PID=PX00OLESG1>. Mr. Stoker is providing a number of webinars focusing on a variety of sharps injury prevention safety products. For more information on the webinars, go to www.isips.org/seminars.html.

Minimize Peripheral IV Complications

The combination of MaxPlus® Clear™ positive displacement connector and Tru-Secure® Peripheral Catheter Securement minimizes complications such as occlusion and dislodgement that can lead to dangerous restarts.



MaxPlus Clear

- Flat, smooth surface for optimal disinfection
- Positive displacement technology keeps catheter patent
- Clear fluid path allows for enhanced flushing technique

Tru-Secure

- Non-irritating foam safely secures peripheral catheter
- Protects insertion site with a clear bio-occlusive dressing
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