A Practical Guide for the selection and use of prefilled Syringes for flushing vascular access devices.

Paul Parisien, MedXL inc., Montreal, Canada.

OBJECTIVE

The objective of this report is to provide clinicians with important information concerning the design and function features that should be considered during the selection and use of prefilled syringes for flushing vascular access devices.

INTRODUCTION

INS standards (1) for flushing vascular access devices (VAD's) stress the importance of positive pressure flushing techniques. This standard is well recognized and widely supported. Positive pressure flushing while using a prefilled flush syringe is the most effective method of maintaining a VAD patent. However when positive pressure flushing is performed incorrectly through the use of inappropriately designed syringes or the application of excessive injection pressure there is potential for complications. These may include catheter occlusion by fibrin or thrombus formation due to blood reflux in the catheter (2), catheter damage or rupture or even vein wall rupture due to the application of excessive injection pressure (3). In order to minimize these serious complications, the selection of appropriately designed syringes and the use of a correct flushing technique is very important. There are six important criteria to consider when selecting and using prefilled syringes for VAD flushing:

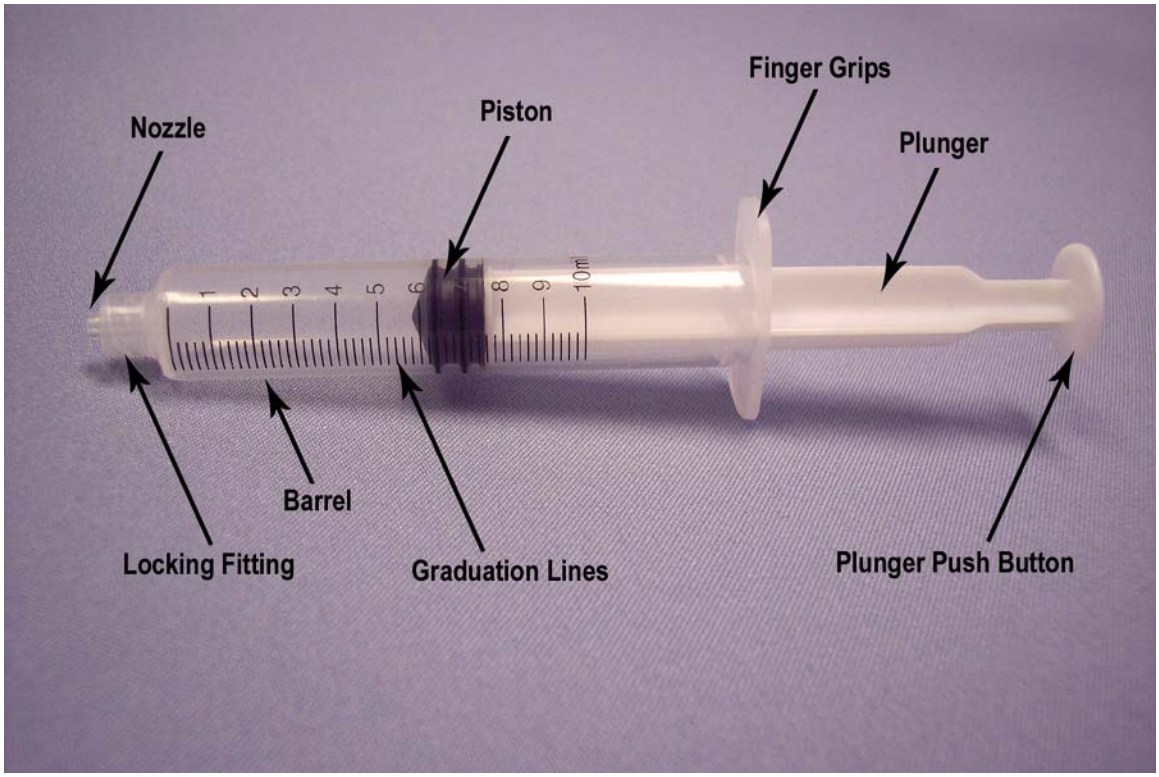
1-Syringe design.
2-Injection rate during the flushing procedure (Flush Rate).
3-Product Specifications and indications for use.
4-Product Packaging and Labeling.
5-Blood reflux into the catheter at the end of the VAD flushing procedure.
6-The time required to clamp off the catheter or the extension set.

The importance of each of these criteria is reviewed and discussed in this report.

SYRINGE DESIGN

The design of syringes has been an ongoing process requiring several decades of testing, consultation and input from clinicians and engineers from around the world. The culmination of all this effort has been an International Standard called ISO 7886-1 (Sterile hypodermic syringes for single use – part 1. Syringes for manual use.) which was released in 1993. Since then the ISO standard has insured that manual injection syringes, manufactured by companies that have adopted the standard, are made according to specifications that make them easy to recognize and use by healthcare professionals around the world.

Figure 1. An example of an ISO compliant ‘’Manual Use Syringe’’ and it’s parts



An important part of the ISO standard is the syringe design specifications. These specifications ensure that syringes are safe, easy to use, allow the user to have proper control over the syringe barrel during injection and ensure a constant injection pressure when the plunger is depressed. Important design criteria to consider when selecting prefilled flush syringes and that are defined in the ISO standard include:

1-Finger grip design and size.

2-Distance of the plunger push button from the finger grips at the empty position.

3-Graduations

Finger grip design and Size
A correct finger grip design will give the user more control over the syringe during flushing. A poor finger grip design makes the syringe barrel difficult to hold and control during flushing.

FIGURE 2. Examples of different finger grips. The ISO specification requires that the finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.

	
Well designed finger grips that give the user good control over the syringe when flushing a VAD.	Poorly designed finger grips that make the syringe difficult to control when flushing a VAD

Distance of the plunger push button from the finger grips at the empty position
Another important design criteria that is specified in the ISO standard is the plunger push button to finger grip length when the piston coincides with the zero graduation line. This optimal length ensures that there is no unwanted increase in injection pressure during injection of the last few mL's of solution. Elimination of the length between the finger grip and the plunger push button at the end of the injection stroke makes it more difficult for the user to apply a constant injection pressure during the flushing procedure and especially at the end of the injection.

FIGURE 3. Examples of different plunger push button to finger grip distances when the syringe is empty. The ISO specification requires the distance to be a minimum of 12.5 mm for syringes of 5 mL or greater nominal capacity.

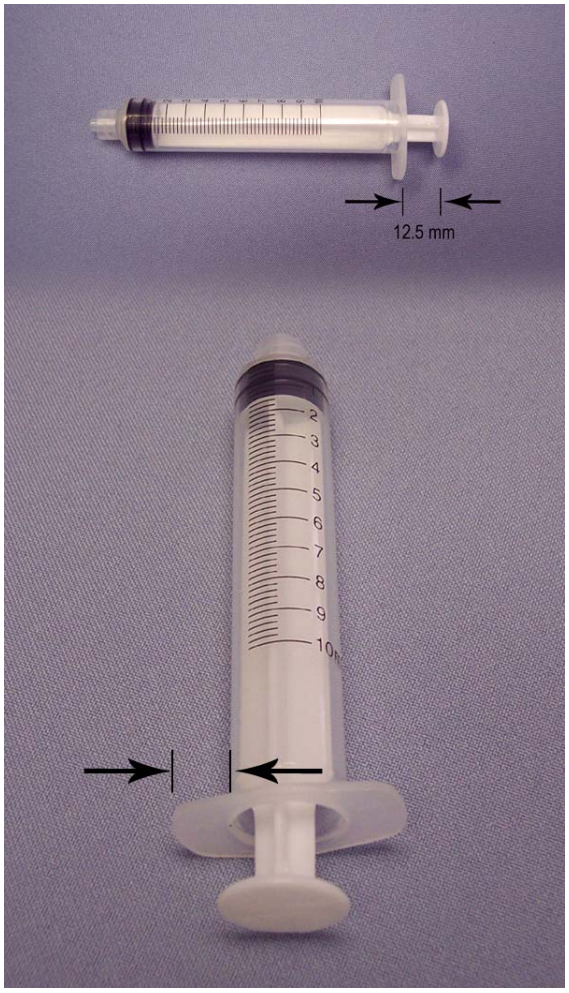
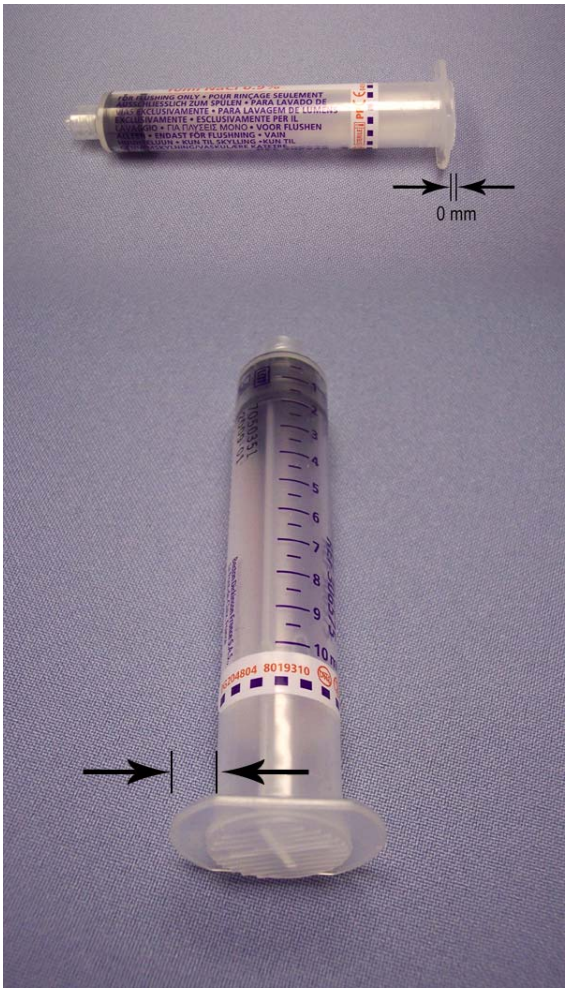
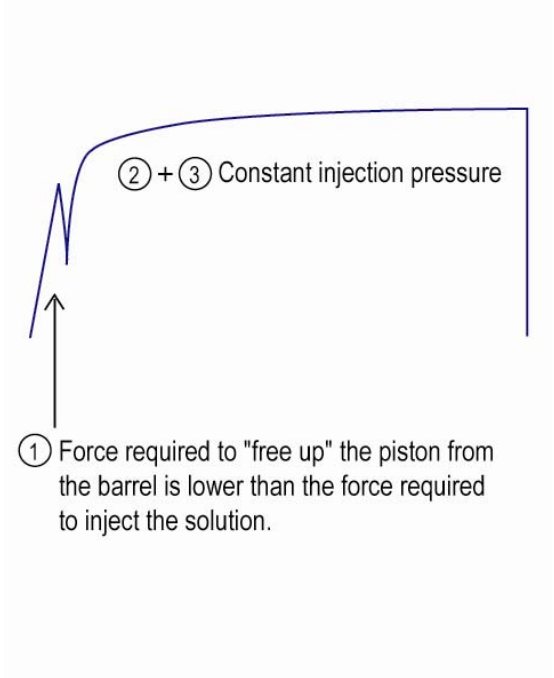
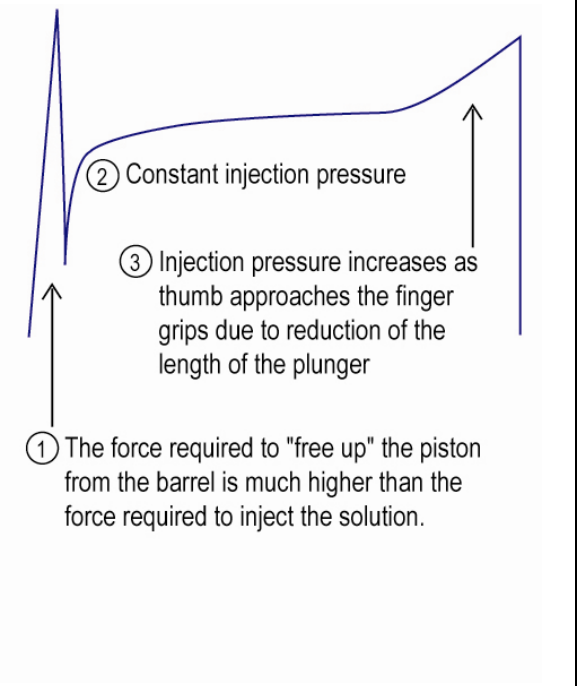
	
A syringe that meets the ISO requirements and consequently ensures a more continuous injection pressure by the user.	The worst case scenario of a syringe design in which the length has been reduced to zero and hence makes it harder for the user to maintain a continuous injection pressure especially when injecting the last few mL's of solution. The problem is compounded by the short finger grips.

FIGURE 4. graphical representation of Injection pressures exerted by the thumb of a clinician as the plunger is depressed at a constant rate on different brands of syringes

	
The injection pressure is constant over the entire length of the syringe barrel	The injection pressure spikes above the constant pressure line due to the ‘’piston Lock effect’’ followed by a constant injection pressure until the last few mL’s as the users thumb approaches the finger grips. At this point injection pressure will again increase. This is due to the reduction of the length from the finger grip to the plunger push button when the piston reached the zero graduation mark on the barrel.

Graduations
Clear, concise and accurate graduations on the syringe barrel are always an added benefit. This is especially important when a precise volume of solution is required to be delivered.

FIGURE 5 Examples of ISO compliant and non compliant syringe barrel graduations

	
A graduated syringe that meets ISO standards with respect to graduations	A graduated syringe that fails to meet ISO standards with respect to graduations.

The recommendation when reviewing the design of a flush syringe is to select a supplier with a product that is designed according to ISO standards. Unless there is objective evidence, avoid selecting flush syringes with design features that have been modified or altered as compared to the ISO standard. The ISO design specifications are tried and true and are the result of years of testing and development by experts around the world.

INJECTION RATE DURING THE FLUSHING PROCEDURE (Flush Rate)
The flush Rate is the time it takes to empty the solution out of the syringe. The rate at which a syringe is emptied directly affects the dynamic injection pressure that is generated during flushing. All things being equal, the faster the syringe is emptied, the higher the observed dynamic injection pressure will be. The flush rate is a convenient parameter to use when flushing since it can be directly observed AND controlled by the clinician. For example: in order to obtain a flush rate of 1mL per second when using a 10mL prefilled flush syringe, a clinician would simply count to 10 seconds while injecting the 10 mL's of solution or alternatively simply observe the piston descending past every 1 mL graduation on the syringe barrel each second. Fast flush rates can generate high dynamic injection pressures (above 40 psi). Since dynamic injection pressures depend on the diameter of the syringe barrel, flush rates should be recommended by the manufacturer of the flush syringe.

Table 1 Average pressure generated (excluding the ‘’piston lock effect’’) at different flush rates for 2 different prefilled flush syringe brands.

Flush Rate	Average Dynamic Pressure MedXL Praxiject™	Average Dynamic Pressure BD Posiflush™
0.5 mL/second (10 mL in 20 seconds)	7.3 Psi	8.9 Psi
0.67 mL/second (10 mL in 15 seconds)	10.5 Psi	12.8 Psi
1 mL per second (10 mL in 10 seconds)	17.1 Psi	18.7 Psi
1.5 mL per second (10 mL in 6.7 seconds)	32.0 Psi	32.0 Psi
2.0 mL per second (10 mL in 5.0 seconds)	51.8 Psi	55.5 Psi
RANK	1st	2nd

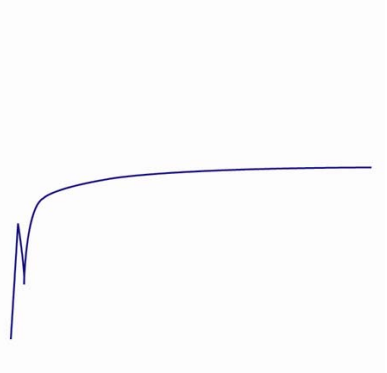
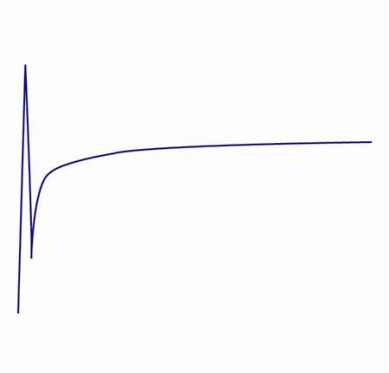
The best flush syringe generates the lowest dynamic pressure at the various measured flush rates.

PISTON LOCK EFFECT

High dynamic injection pressures can also be attained with certain flush syringe brands, if they are inadvertently used before the piston is released from the barrel. The high dynamic injection pressures generated by this effect are caused by ‘’the piston lock effect’’ a phenomenon which occurs when prefilled syringes are steam sterilized by the manufacturer. The heat during sterilization causes the piston to ‘’stick’’ to the syringe barrel. A disconcerting amount of dynamic injection pressure beyond 40 psi is required to release the piston from the barrel. (See figure 6)

Other factors that will affect the dynamic injection pressure at a given flush rate include restrictions to flow such as smaller diameter catheters or longer catheters as well as venous occlusions such as venous spasms or muscle contractions. Also, the smaller the barrel diameter of the syringe, the higher the dynamic pressure will be for a given flush rate. Hence smaller diameter syringes should be used with a slower flush rate. Complications due to high injection pressures include catheter damage or rupture and/or vein damage or rupture.

FIGURE 6. Graphical representation of the ‘’Piston Lock Effect’’

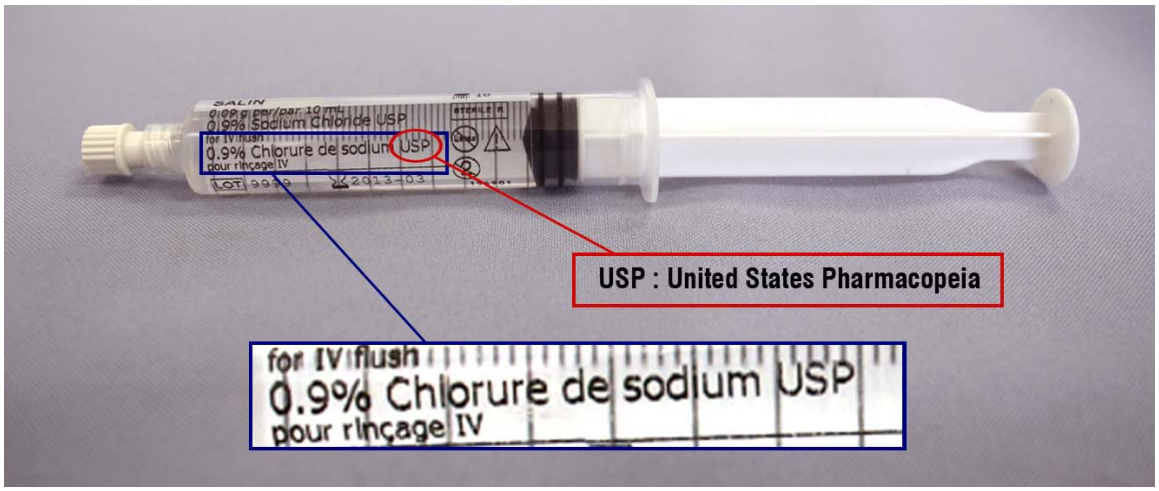
	
The piston Lock effect is less than the pressure required to inject the solution. The pressure required to free the piston from the barrel is less than the injection pressure. (MedXL Praxiject™ 0.9% Sodium Chloride USP syringe)	The Piston Lock Effect is greater than the pressure required to inject the solution. A disconcerting amount of dynamic injection pressure (beyond 40 psi) is required to release the piston from the barrel. Note the very high pressure required to free the piston from the barrel. (BD Posiflush™ saline flush syringe)

A careful selection of prefilled flush syringe brands is highly recommended in order to avoid syringes that are steam sterilized and which require high injection pressures to overcome the piston lock effect. There is a risk involved when using these products especially if the syringe is used to flush a VAD before the piston is released from the barrel. Always Flush at the manufacturers recommended rates. Pay careful attention to the feeling your fingers experience when flushing. An occlusion in the vein or the catheter will cause the pressure to build. When increased resistance is felt, it is important not to increase the force exerted against that resistance.

PRODUCT SPECIFICATIONS AND INDICATIONS FOR USE

Undoubtedly the most important question that needs to be answered is ‘’To what standards is the saline flush syringe and it’s solution manufactured’’. USP or better would be the ideal choice. Beware, some products do not meet the USP standard. Instead other unrecognized standards such as SP have been used.

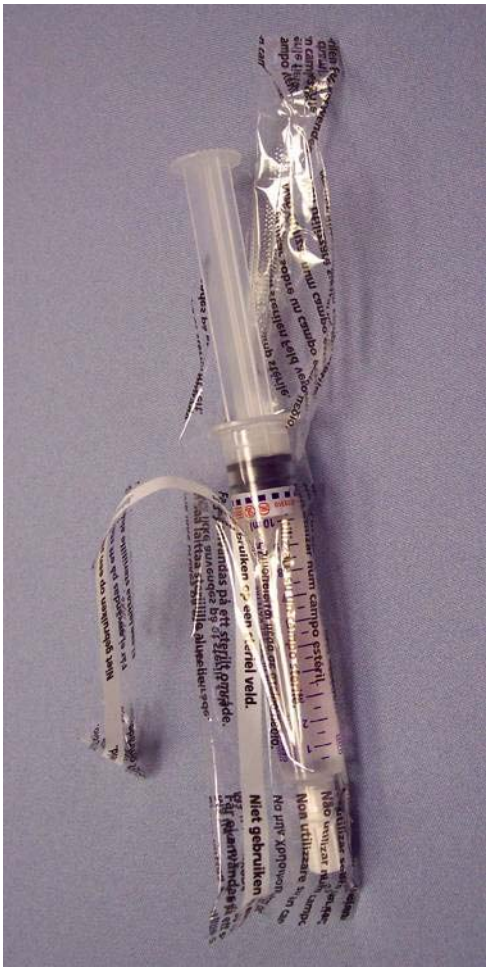
FIGURE 7. Examples of a product that meets the USP specifications and one that doesn’t.



PRODUCT PACKAGING AND LABELING

Product packaging is another important factor when selecting flush syringes or any Healthcare product for that matter. All things being equal the preferred product packaging of a flush syringe should always be sterile field compatible. This is due to the fact that flush syringes may be used in many different areas of the hospital, for different uses and under different conditions. It would therefore be better to err on the side of safety and to select a product that can be used in a sterile field than to be using ‘’non’’ sterile field compatible flush syringes that could possibly and inadvertently be used for flushing central lines, in the OR suite or the burn ward for example. With respect to product labeling, what instructions are provided on the label and product package? Are they sufficient? Do they convey all the information that is required to correctly use the product?

FIGURE 8. Examples of different product packaging and labeling

	
Example of a product that is packaged in sterile field ‘’Peel Pouch’’ compatible packaging	Example of a product that is packaged in flow wrap ‘’candy wrapper’’ packaging. The product should not be used in a sterile field.

BLOOD REFLUX

The term blood reflux refers to blood aspirated into the distal tip of a VAD after the clinician has relaxed the pressure on the syringe plunger. The injection pressure applied to the plunger at the completion of the flush procedure and piston design are two critical factors that contribute to blood reflux.

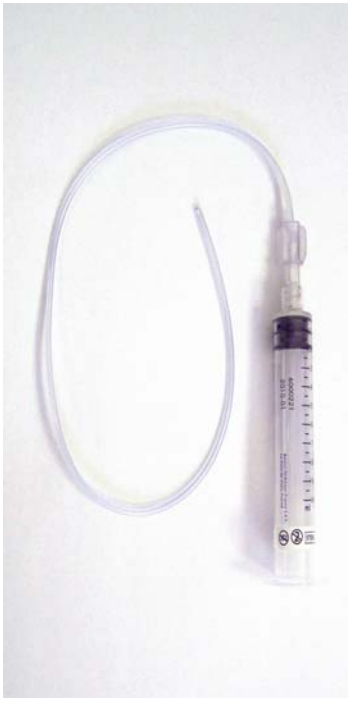
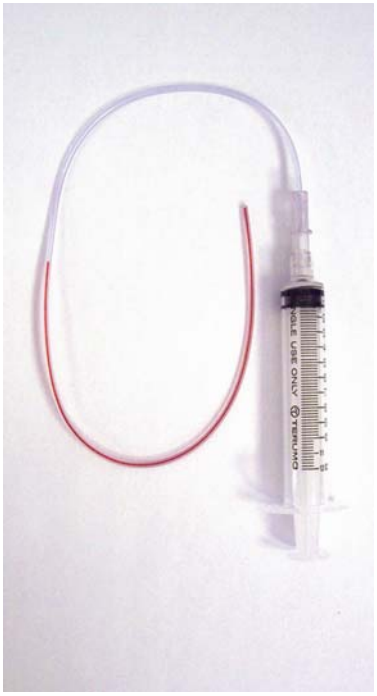
The higher the applied pressure on the piston at the end of the flush procedure the more blood will be drawn back into the catheter when the pressure is relaxed on the syringe plunger. Differences in syringe piston design will also contribute to blood reflux. The more the piston can ''bounce back'' in the barrel when the pressure is relaxed at the end of the flush procedure, the more blood will be drawn back into the catheter. Complications related to blood reflux include catheter occlusion by fibrin or thrombus formation.

One syringe manufacturer has eliminated both effects by ensuring that the piston stops or ''bottoms out'' before actually reaching the bottom of the syringe barrel. Although this is an interesting concept it creates other problems such as variability in injection pressure as discussed above and is not particularly desirable as a design feature because it does not comply with the ISO syringe design standard and all the design benefits that result from compliance with the standard.

TABLE 2 Solution reflux length in a 4 French catheter at different applied pressures

Applied Force (Pounds)	**MedXL Praxiject™ Solution reflux length (Applied Pressure-psi)**	**BD PosiFlush™ Solution reflux length (Applied Pressure-psi)**	**Terumo™ Solution reflux length (Applied Pressure-psi)**
5	0 cm (18 psi)	0 cm (19 psi)	8 cm (17 psi)
10	0 cm (36 psi)	0 cm (38 psi)	20 cm (33 psi)
15	0 cm (55 psi)	0 cm (58 psi)	25 cm (50 psi)
20	0 cm (73 psi)	0 cm (78 psi)	35 cm (67 psi)
25	0 cm (91 psi)	1 cm (97 psi)	›35 cm (83 psi) (solution refluxes back into luer hub on catheter)
Rank	1st	2nd	3rd

FIGURE 10. Solution reflux in a 4Fr catheter at 10 pounds of force from various syringes

		
Figure 1. An example of a Flush Syringe (MedXL Praxiject™) which has minimal blood reflux because it has been designed for flushing VAD's.	Figure 2. An example of a Flush Syringe (BD PosiFlush™) which has minimal blood reflux because it has been designed for flushing VAD's.	Figure 3. An example of a standard syringe (Terumo™) that has significant blood reflux due to the fact that it is not designed for flushing VAD's.
Rank : 1st	2nd	3rd

The recommendation when selecting flush syringes is to select a product that is designed to generate minimal blood reflux while satisfying the requirements of the ISO standard. Unless objective evidence is available avoid prefilled flush syringes with design features which do not meet the ISO standard. The ISO design specifications are tried and true and are the result of years of testing and development. The ideal flushing syringe respects the design features and specifications AND has minimal blood reflux due to the appropriate design of the syringe piston. It is important to note that there are other factors which are not discussed here that may be just as important contributors to blood reflux, such as the use of needleless canula and needleless injections sites.

CLAMP OFF TIME

This is the time required to clamp off a VAD after the flushing procedure. This parameter is important if the VAD or the extension set is equipped with a clamp. Since many peripheral catheters are simply equipped with some form of an injection site and there is no clamp available, this parameter is of no consequence. There is however no doubt that the time required to close the clamp is important in the extremes. For example, leaving a clamp in the open position after a flushing procedure would be an open invitation for subsequent complications. On the other hand, instantaneously closing the clamp at the end of the flushing procedure would essentially eliminate any potential for complications. The effect of clamping time on blood reflux is difficult to measure and control. A difference of 1 or 2 seconds in clamp off time may be due to many factors, including the manual dexterity of the clinician. The issue is that the clamp on devices used for flushing should be closed as soon as possible immediately after completing the flush procedures or even before the syringe is empty.

CONCLUSION

In addition to the many features discussed in this report there are other factors to consider when selecting a prefilled flush syringe supplier. However and in our opinion these are the most critical. The overall results indicate that MedXL prefilled saline Flush syringes, when used as directed, are among the best currently available on the market for meeting ISO design specifications, minimizing injection pressure variations, are easy to use from a safety and design perspective, are ISO compliant with respect to product design and do not generate any injection pressure spikes due to the piston lock effect and finally exhibit minimal blood reflux.

1. Mayo D.J. Reflux in Venous Access Devices. A Manageable problem. Journal of Vascular Access Devices, Winter 2001.
2. Hadaway L.C. Major Thrombotic and Nonthrombotic Complications. Journal of Intravenous Nursing, Vol. 21, No 5S, Sept/Oct 1998.
3. Journal of Vascular Access Devices. Summer 1999.