

SmartSite[®] valve compatibility with male luer FAQs

The SmartSite needle-free system, a luer activated device (LAD), conforms to all International Organization for Standardization (ISO) standards, specifically ISO594 specifications for luer connectors. Incompatibilities exist when the luer connector of an IV set, stopcock or other device does not allow the valve to open and fluid to flow properly.

1. Is there a possibility of product incompatibility with some stopcocks or other male luers?

ISO standards do not address all of the characteristics that might affect compatibility between all manufacturers' valves and possible combinations of luers. SmartSite needle-free valves perform properly with luers manufactured with a wide, smooth edge surface which will fully engage the device. Internal laboratory testing revealed potential incompatibility of SmartSite valves used with sharp tip male luers, thin walled male luers, or luers without a wide, smooth edge surface.

2. How does the SmartSite valve interact with a male luer and what is the reason for a potential incompatibility?

Most syringes and other male luers work very well with the SmartSite valve. We do not anticipate incompatibility with male luers that meet ISO 594 specifications for luer connectors. However, in the manufacturing process, there may be a sharp ridge of residual plastic ("flash") that forms a thin edge on the tip of the male luer. This may occasionally cause SmartSite valve inactivation.

The design of the SmartSite valve helps keep the valve closed and resistant to leakage. However, the piston is soft silicone rubber and any sharp edge can dig into the top of the piston and prevent it from sliding against the tip of the luer. This sliding is the mechanism by which the valve opens. If the sliding is prevented, the valve will open only slightly or not at all.

3. What are common causes of potential incompatibility with the SmartSite valve and how does CareFusion address those incompatibilities?

Potential product incompatibility can be caused by factors such as the manufacturing process on male luers (flash on male luer tip), user technique, non-ISO 594 male luer configurations, among others:

- Pre-filled syringes with flash on male luer tips

- Vacutainer systems for blood draws with excessive flash or sharp tip designs on male luer tip
- Male luers on stopcock that have excessive flash or sharp tip designs on luer tip
- Male luers on IV sets with excessive flash or sharp tip designs on male luer tip
- Male luer configurations that do not meet international standards (ISO 594)

In most cases, these are isolated incidences. While the above situations have been reported, we may become aware of potential situations in the future due to vendors making a change in their manufacturing process. When possible, CareFusion has looked for opportunities to partner with other manufacturers to improve product compatibility, or correct known incompatibility between our connections, and will continue to do so in the future.

4. Who can assist me in identifying potential compatibility issues with the SmartSite valve and other manufacturers' stopcocks and male luers?

- As always, CareFusion is committed to patient safety. It is important for our customers to identify specific product incompatibility prior to the implementation of a new product, as well as products which may currently be in use.
- Your local CareFusion Sales Representative would be pleased to assist you in identifying product compatibility with the SmartSite valves.
- The Customer Advocacy Department can coordinate evaluation of compatibility questions for your facility and can be reached at 888.812.3266.

CareFusion
San Diego, CA

carefusion.com