Needle-Free Valve Improves Medicine's Ability to Go with the Flow

SmartSite Plus Needle-Free Valve with Positive Displacement

Submitted and manufactured by Alaris Medical Systems Inc. (San Diego)

any companies have added needle-free access valves to their product lines to meet healthcare institutions' needs after the November 2000 passage of the Needlestick Safety and Prevention Act. However, no one product combined several noteworthy capabilities: a small number of parts, a simple snap-together design, and positive displacement of a nontortuous fluid path to help prevent clotting in catheters.

Alaris Medical Systems' Smart-Site Plus Needle-Free Valve incorporates all of these features. The company's goal is to deliver the best medical care to patients while simplifying use for clinicians. The product provides needle-free access to an IV set or catheter site that allows a one-time positive bolus of fluid.

"This positive displacement of fluid helps alleviate clotting that can occur in catheters, which is a common problem for patients. Blood backflow can allow blood to form a fibrin clot in the catheter, necessitating the insertion of a new catheter," says Ted Mosler, the company's senior design engineer. The design of SmartSite Plus helps reduce that problem. It also makes work a snap—literally—for clinicians.

"Its unique, three-component design snaps together," Mosler says. "Current systems have three to seven components, including caps or cannulae. We've eliminated those extra parts. One other system has a snaptogether design, but it doesn't have

def a e-

> a positive displacement feature. Our product is one of the most advanced as far as technology goes, but it's simple to use."

Its three injection-molded components snap together in seconds. The female luer housing is constructed of white polycarbonate, the male luer housing is clear ABS, and the internal piston is made from silicone. The valve's female luer opening may be connected directly to the male luer tip at the end of a syringe or secondary line. When the male connector is pushed into the valve, the rubber piston compresses and opens a straight, nontortuous fluid path.

"This fluid path is desirable from a clinical viewpoint, to help reduce the chances of damaging blood cells. Clinicians want to keep blood cells whole to ensure accurate blood tests, and this path allows that," explains David McMahon, senior manager, marketing.

The company says creating the device was challenging on several levels. Its SmartSite Needle-Free Valve already is the market leader, and it won an MDEA gold award in 1998.

"This new product had to incorporate all of the features that made the SmartSite Needle-Free Valve a leader, but add positive displacement to reduce catheter occlusions. Further, the technology had to be packaged in a

small size while still providing better patient comfort, a straight flow-through path, and an easy-to-disinfect design," McMahon says.

"We went through lots of versions before we found one that exceeded expectations," Mosler reports. "We had to find highly chemically resistant resins with good material properties that lent themselves to high-stress applications like disinfecting, snapping, and connecting with male luers."

"Understanding users' needs—the need to put together a system easily and quickly while lowering the incidence of clotting—was vital to creating a successful design," McMahon concludes.

Supply and design credit: Karl Leinsing (Hampton, NH).