MEDICAL DESIGN BRIEFS
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Herb Werner
By Herb Werner
Marketing Manager at Fluid Metering, Inc.

Micro-Volume Fluid Dispensing for Disposable Medical Component Assembly

When one thinks of the term “disposable”, the first impression might be to associate the item as one being low cost and not requiring much precision in manufacturing. However, disposable medical components most often become an integral part of the operational integrity of the device or instrument to which it is connected. Inconsistent manufacturing of the kit can have critical consequences to both the function of the device, as well as the patient to which it is connected. Therefore, in the multi-billion dollar market of single use, or disposable medical component manufacture, the challenge remains to produce production quantity products while maintaining the highest possible quality.

To ensure manufacturing integrity, disposable sets are, either manufactured and supplied direct by the device manufacturer, or through a contract manufacturer specifically licensed to produce the disposable component. In either case, the techniques, methods and production equipment used in the assembly process will directly reflect the precision, quality and consistency of the finished product.

The majority of these disposable components are not a single part, but rather an assembly of several components, most often configurations of molded or extruded plastic components (plastic tubing, connectors, fittings, syringes, cassettes, blood collection bags, etc..). To ensure quality, these components are often assembled, inspected and packaged by the manufacturer as a complete set or kit. This simplifies the final process of sterilization, as well.

During the assembly process, the individual components are bonded together using one of a variety of adhesives or using a solvent (solvent welding). Solvent Welding is a method of bonding polymer components together a solvent (typically cyclohexanone) to chemically soften the surface of the components temporarily, allowing them to bond together on contact without using an adhesive. Whether using an adhesive or solvent to bond components together, dispensing precision is critical to both the quality and function of the finished product. If too little adhesive or solvent is dispensed, partial bonding may result. Too much adhesive and the excess may occlude the tubing orifice. Too much solvent may affect the structural integrity of the components.

One of the technologies developed to meet the challenge of precision production dispensing of bonding fluids, particularly in the microliter range is the valveless piston pump, or “CeramPump®.” The pump head internals are made from chemically resistant, sapphire-hard ceramics, ideal for dispensing a broad range of fluids including cyclohexanone, UV curable adhesives, acrylic cement, and 2-part epoxy bonding agents used in the manufacture and assembly of catheters, IV tubing, and disposable tubing sets used in apheresis and blood cell processing systems. Saline, silicone lubricants, isopropyl alcohol, and

antibacterial agents are just a few of the non-bonding fluids dispensed using CeramPump® technology as well.

CeramPump® Basics

The CeramPump® is a low volume piston pump, which uses one moving part to accomplish both the pumping and valving functions thereby eliminate check valves which are present in all other reciprocating (syringe, diaphragm, bellows, piston) designs. This pump design uses a unique rotating and reciprocating ceramic piston, moving within a precision mated ceramic liner to pump fluid in one direction without allowing any backflow. The reciprocation action of the piston acts very similar to a standard piston pump. As the piston moves back, it draws fluid into the pump chamber. As it moves forward, fluid is pushed out of the pump.

However, what differentiates this design is that in addition to reciprocating, the piston also simultaneously and continuously rotates in one direction. The piston is designed with a flat cut into the end closest to the inlet and outlet port (see figure 1). As the piston rotates, the flat is alternately aligned with the inlet and outlet port, essentially functioning as a valve. At no time is the inlet and outlet ports interconnected, and therefore the need for check valves is eliminated. One complete synchronous rotation and reciprocation is required for each suction and discharge cycle as shown in figure 1. An animation of continuous metering using the CeramPump® principle can be found on the web site www.fmipump.com.

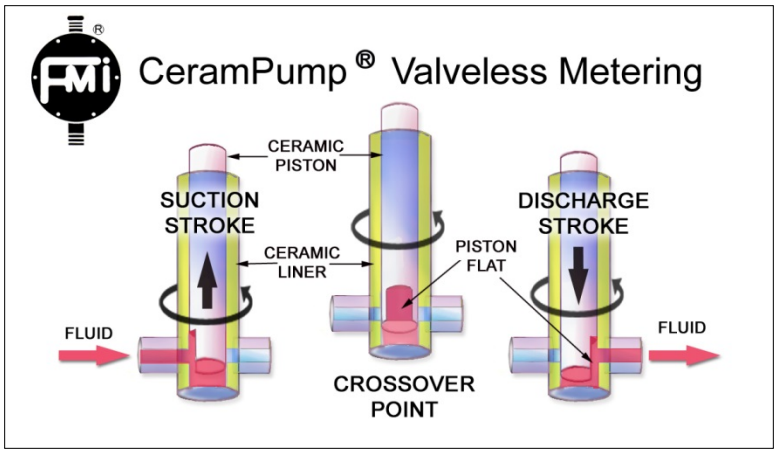

Figure 1

Adjustment of Dispense Volume

The piston displacement (or volume pumped per stroke) is variable and controlled by the angle of the pump head to the drive. When the pump angle is zero, the pump head is in straight alignment with the drive, the flow is zero. In this situation, there is no reciprocation and the piston is only rotating. As the angle of the pump head increases above zero in either direction with respect to the drive, the piston reciprocates, and fluid is moved through the pump (see figure 2). The greater the angle, the greater the displacement per stroke.. Adjustment is infinite between zero and 100% and a flow rate indicator provides for simple linear calibration. The pump is designed so that at any angle and flow rate, the piston always bottoms for maximum bubble clearance. This is especially important at very small dispenses and flow rates, as the presence of even a minute bubble will significantly affect accuracy.

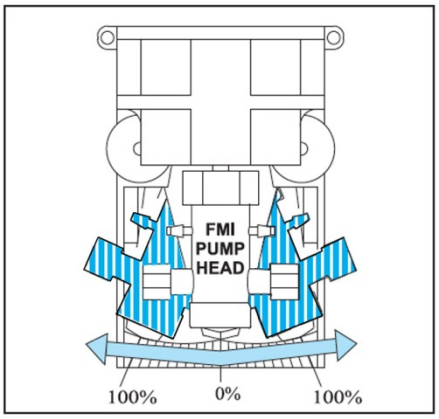

Figure2

Valveless Piston Pump (CeramPump®) Feature Summary

Valveless Design
The valveless feature of the CeramPump® design is its most significant feature. There are typically four check valves present in diaphragm, bellows, and traditional piston pumps.

Ceramic Internals
The CeramPump® uses sapphire-hard ceramics for both the piston and mated liner. These components are dimensionally stable in that they will not change shape or dimension over time.

One Moving Part
The ceramic piston is the only moving part in contact with the fluid. Dimensionally-stable and chemically inert, it will provide long-term, drift-free fluid control for millions of maintenance-free cycles.

The CeramPump® was developed by Fluid Metering, Inc. For more information, they can be contacted at 1-800-223-3388 or through their web site at www.fluidmetering.com.

About the Author
Herb Werner has been the Marketing Manager for Fluid Metering, Inc. for 19 years with over 35 years fluid control experience in chemical process, water treatment, medical & analytical instrumentation, pharmaceutical, and semiconductor industries. He has a B.S in Environmental Biology and is an active member of ISA, AWWA, & WEF societies. The CeramPump®