



November 28, 2006

To: Quest Medical Customers

**Re: Microbial Barrier and Hemolysis Results for the Q2<sup>®</sup> Injection Site**

During the 510(k) testing for the Q2<sup>®</sup> injection site, 7 day microbial barrier testing was performed on the product with passing results. The purpose of the test was to demonstrate the integrity of the luer activated valve microbial barrier properties under simulated worst case clinical use using a common nosocomial infection organism, Staphylococcus aureus. The results showed the product samples and negative controls demonstrated no growth of the challenge organism when used with an adequate disinfection procedure per our instructions. The product received clearance from the FDA for 510(k), K002689, in March 2001. The Q2<sup>®</sup> injection site passed additional microbial barrier testing on product cleared by FDA in 510(k) K040634 in 2004.

Recently, Quest Medical's newest products integrating the Q2<sup>®</sup> injection site were tested to evaluate the hemolytic potential of the product when subjected to simulated clinical use conditions for both infusing and extracting blood products. The results indicated the product was non-hemolytic for both infusing and extracting blood through the Q2<sup>®</sup> injection site.

It is important to note the Q2<sup>®</sup> injection site is not a positive displacement valve and does not contain mechanical parts designed to control pressure upon syringe release. The fluid path within the Q2<sup>®</sup> valve is different from many on the market in that it is a straight path through the center of the product. This provides a less tortuous, higher flow path that is easily flushed. Fluids are not trapped between the sides of the valve and the silicone housing. Millions of these valves have been used clinically over the past six years.

We will keep you advised of future developments.

Regards,

Douglas Bryan  
Director, Quality Assurance and Regulatory Affairs