



**RE: Use of the SafeSet® Closed Blood Collection Sets and Kits for Arterial and Venous Applications.**

Dear Clinical Staff;

Thank you for your interest in the ICU Medical SafeSet Closed Blood Collection Devices. SafeSet products are designed to allow the clinician to obtain necessary blood samples within a closed system to reduce exposure and minimize blood waste. The SafeSet is described as a system for *arterial* blood collection however, the ICU Medical 510K clearance that was obtained would make it appropriate for both *arterial* and *venous* applications. Use of SafeSet products in venous applications is considered to be within the scope of the 510K clearance and therefore acceptable as an intended use.

Thank you again for your interest, if there are further questions or concerns please visit our website at [www.icumed.com](http://www.icumed.com), or contact the corporate offices at 949-366-2183.

Technical Services  
ICU Medical, Inc.