Dear Customer; July 14, 2000

There has been much discussion concerning the use of normal saline as the exclusive flush solution for the CLC2000 on Vascular Access Device (VAD). Currently there are two manufacturers or brands of VAD which recommend the use of normal saline in flushing. The Groshong®, which has a slit like valve at the distal tip of the catheter and the Catheter Innovations, PASV™ incorporating the same type of valve in the connection hub or proximal end of the catheter. Both of these valves claim to prevent blood reflux into the catheter lumen1. For this reason, the catheters may be flushed with normal saline. Other VAD with open (non-Valved) lumens are typically flushed with a specific concentration of heparin in order to maintain Patency. Each protocol or practice is based on the assumption, if blood is present in the VAD lumen, it can potentially occlude and cause the loss of VAD patency.

There is a significant amount of literature, which argues for normal saline flushing of peripheral access devices. A literature review indicates that normal saline is an adequate flush solution for maintaining the patency of these devices and reducing phlebitis complications in some cases2-5. At a time in health care where cost control is of paramount issue, the elimination of the drug heparin for use to maintain CVAD patency would be a cost benefit to a health care provider. In addition health care providers have the need to implement needle safety devices such as the CLC2000 as recommended by OSHA and currently legislated in some states6. Further cost control programs are being explored to facilitate the move to needle safety devices.

A more significant issue regarding the use or contraindication of heparin is the potential risk of Heparin-induced Thrombocytopenia, a hyperthrombotic event resulting from a physiological reaction to heparin. Heparin used for flushing central venous catheters has resulted in reported life-threatening cases of Heparin-induced Thrombocytopenia7. Using Heparin where it is not necessary or not indicated poses the risk of this potentially life-threatening reaction. As cited in paragraph two, normal saline has been proven effective for maintaining the patency of peripheral devices. The question arises as to whether or not it is better to prevent the incidence of catheter occlusion, rather than to treat it using a medication and protocol not indicated by the manufacturer for restoration of catheter patency.

It is recommended in nursing practice to use positive pressure flush techniques in order to eliminate blood reflux8. Physically if there is no blood reflux in the catheter, then your need for heparin to maintain patency is unnecessary as recognized by published research2-5. Fortunately the CLC2000 is the only product guaranteed to eliminate blood reflux, therefore when using the CLC2000, normal saline flushing without heparin is an appropriate procedure for VAD maintenance.

ICU Medical has changed labeling for the CLC2000 in reference to the original 510K market clearance, November 1997, to recommend; **Flush CLC2000 with Normal Saline!**

Please remit any questions or concerns to ICU Medical, Inc. at 949-366-2183.