



October 2, 2009

Dear Alcavis HDC Customer,

Alcavis HDC is committed to providing our customers with innovative and progressive solutions for their infection control needs. We have performed numerous market studies working with clinicians (doctors and nurses) to identify products that satisfy their particular needs. ExSept Plus is one such product, used routinely to clean the exit sites of catheter patients. In addition to the effectiveness of ExSept Plus at cleaning the exit site, it also has the benefit of catheter compatibility. This is extremely important in dialysis where dialysis catheters, hemodialysis and peritoneal dialysis catheters, are in the body for a period of months or longer.

We have recently received a new FDA 510K clearance for the ExSept Plus. This new clearance allows us to specifically put on the label the care of catheter “exit sites”, which will provide a very clear indication for use for your clinical team. We plan to introduce this new labeling in November 2009 and we want to work with your clinic to make sure the transition is seamless.

The ExSept Plus for catheter exit site care that we will be rolling out is IDENTICAL to the ExSept Plus that has been on the market for the past 10 years. The advantage is that the product is clearly indicated for the care of catheter “Exit Sites”. Due to our expanded claims, the product is now also considered a prescription product/ by order from a physician. **To comply with the regulatory requirements, all you will need to do is add the use of the ExSept Plus to the physician’s standing orders for the dialysis treatment.** A noted benefit, as explained by many clinicians, is that the “by order of a physician” label is preferred so that tracking of use can be entered into your patient database.

I have attached copies of our existing label and of our new label with expanded claims. The instructions for use are nearly identical. We have also attached the FDA 510K listing, printed from the FDA website (ExSept Plus is also called ExSept WC).

We would be pleased to answer any questions you may have. Please contact me or Shelly Padovan, our clinical nurse, at your convenience: 1-800-726-2308. We look forward to working with you and rolling out this product to better satisfy the needs of your patients.

Regards,

Richard Moncure  
National Sales and Marketing Manager  
Alcavis HDC, LLC