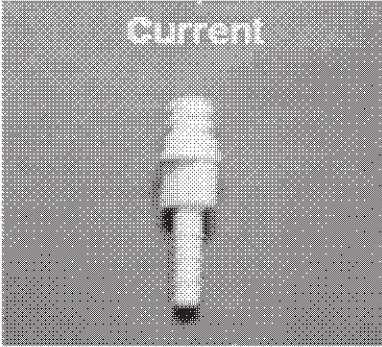
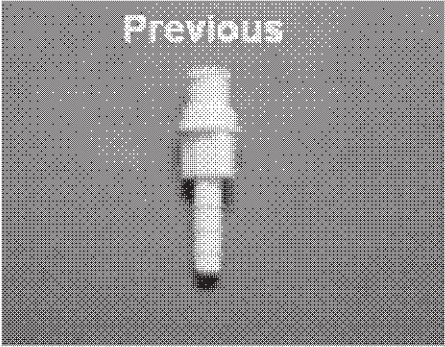




**IMPORTANT  
PRODUCT  
INFORMATION**

Oct. xx, 2011

Dear ..., (to be adapted locally)

Affected Product	Baxter Healthcare Corporation is informing you of a supplier modification regarding the Quinton BETA-CAP™ adapter (Product Code: 8814-661001) from Covidien.
Problem Description	<p>Baxter has received complaints in the US regarding the Quinton BETA-CAP™ (available from Baxter in Covidien Catheter PD kits – product code(s) : ... (to be completed locally or refer to attachment 1 if too many codes)</p> <p>The Quinton BETA-CAP™ is an adapter used to connect the patient PD catheter to the Baxter Transfer Set.</p> <p>These reports indicated that this connection was not secure and appeared loose.</p> <p>A thorough technical investigation by Baxter has confirmed the potential for a reduction in thread engagement when Baxter transfer sets are connected to the current (Covidien) Quinton Beta-cap adapter.</p>
Hazard Involved	The reduction in thread engagement may lead to an increased risk of separation resulting in the potential for developing peritonitis.
How to Identify Affected Products	<p>A reduced thread engagement results from a change made to the thread geometry to the Quinton BETA-CAP™ (8814-661001) as shown in the picture labeled Current (first distributed by Covidien June 9, 2009, lot#, 914961). Although the current BETA-CAP™ adapter has more threads compared to the previous design, Baxter engineering analysis has shown that the thread start position was altered and may result in less thread engagement.</p> <div style="display: flex; justify-content: space-around; align-items: center;"><div style="text-align: center;"><p>Current</p></div><div style="text-align: center;"><p>Previous</p></div></div>



<p>Actions to be Taken by Customer</p>	<p>If you don't use the Covidien adapter, there is no action required.</p> <p>If you use the Covidien adapter, please read carefully the below.</p> <p>Patients currently using a Quinton BETA-CAP™ adapter should be contacted to schedule an office visit with their attending physician as soon as practical to have the connection inspected or replaced. If you choose to continue use of the Quinton BETA-CAP™ adapter, Baxter recommends the clinician exercises extra caution and vigilance to ensure the connection between the Quinton BETA-CAP™ adapter and the Baxter Transfer Set is secured and tight.</p>
<p>Actions Planned by Baxter</p>	<p>Baxter would like to reinforce the recommendation to use with Baxter transfer sets exclusively the Titanium Adapter (Baxter product code 5C4129) which has sufficient thread geometry for maintaining a secure connection with the Baxter transfer sets.</p>
<p>Further Information and Support</p>	<p>Thank you for your cooperation. We look forward to continuing to serve your dialysis needs.</p> <p>If you have any questions, please call ... at .... <i>(to be adapted locally)</i></p> <p><i>The Local MOH has been notified of this action. (to be adapted/removed locally)</i></p>

Sincerely,

*Name*

*Title*

*Baxter Healthcare (to be adapted locally)*

*Division or Region (to be adapted locally)*