

## HEMODIALYSIS MACHINE FAILURE



Baxter Meridian Hemodialysis Instrument

### **FDA Class I Classification Given to Baxter's September 2005 Urgent Product Recall for Meridian Hemodialysis Instrument**

FOR IMMEDIATE RELEASE -- Deerfield, IL -- December 13, 2005 -- Baxter Healthcare Corporation announced that the U.S. Food and Drug Administration (FDA) has classified a September 28, 2005 Urgent Product Recall letter from Baxter to customers regarding the company's Meridian® Hemodialysis (HD) Instrument (Product Codes 5M5576 and 5M5576R) as a Class I recall. This classification does not require the return of Meridian instruments currently in the market. In the September letter, Baxter directs customers to route blood tubing through only one channel of the two channel clips mounted on the front of the Meridian to reduce the risk of blood tubing kinks.

Specifically, there have been reports of hemolysis (broken blood cells) related to kinks in the blood tubing sets used with the Meridian . To date, there have been reports of one death and at least one serious injury, associated with kinking of blood tubing sets routed through both channels of the clips mounted on the front of the Meridian . The clinical implication of returning hemolyzed blood to a patient can range from no adverse health consequences up to and including death. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the affected product may cause serious injury or death if the problem is not corrected.

The last Meridian was manufactured in 2002. Approximately 2,100 Meridian instruments are currently in use, including 1,700 in the United States .