# Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

September 13, 2002

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| Item: | **MEDISYSTEMS Corp., blood tubing for dialysis, Product code D3-9694/9793 or K3-9694/9793, BAXTER Product Code 5M9694.** |
| Specific Incident: | See the attached FDA News Release. There are reports outside the VA healthcare system that this blood tubing may be linked to deaths and injuries when used with the Meridian model of dialysis machines manufactured by Baxter Healthcare Corporation. |
| Action: | Check your inventory for the affected products, Medisystems Product code D3-9694/9793 or K3-9694/9793, Baxter Product code 5M9694. Contact the manufacturer for alternative blood tubing products so that you will not compromise needed dialysis treatments. Immediately (within 24 hours) remove affected tubing from service in a manner that does not compromise the provision of necessary dialysis treatment. |
| Source: | FDA and Baxter Healthcare Corporation. |
| Contact: | For return of blood tubing products and shipment of alternate blood tubing products contact Baxter, Hospital Order Support (7am-6pm CST) at 1-888-229-0001, select option 3 and next select option 2.<br><br>For other questions/guidance contact Baxter, Renal Division (7:30am-5pm) at 1-888-736-2543 select option 3. |

U.S. Food and Drug Administration
FDA News

Department of Health and Human Services

FOR IMMEDIATE RELEASE
P02-33
September 12, 2002

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

# FIVE KIDNEY DIALYSIS DEATHS PROMPT BAXTER/FDA ACTION

The Food and Drug Administration (FDA) today announced that Baxter Healthcare Corporation has notified dialysis centers that certain blood tubing used with Baxter's Meridian dialysis machines may possibly be linked to five patient deaths and two injuries. These occurred at two kidney dialysis centers in late August.

Although the cause of the deaths has not yet been determined, Baxter on September 6 notified hemodialysis centers that it is exploring the possibility that the patients' hemodialysis treatments may have used the same model dialysis machine and bloodline set. Baxter told customers to immediately discontinue use of certain models of Medisystems blood tubing in conjunction with Meridian dialysis machines and use other Medisystems blood tubing instead.

FDA is working closely with both Baxter Healthcare of Roundtop, Ill., and Medisystems Corporation of Seattle, to identify the exact cause of the problem.

"FDA is alerting the public and the medical community to this problem in an effort to prevent other deaths and injuries," said FDA Deputy Commissioner Dr. Lester M. Crawford. "Although details are still sketchy, in the interest of patient safety, FDA wants to make certain that dialysis patients and the wider medical community are aware of these incidents."

Baxter's preliminary investigation found that the two hemodialysis centers where the incidents occurred may have been using the following:

**Blood tubing--Medisystems Corp., Product Code D3-9694/9793 or K3-9694/9793, Baxter Product Code 5M9694**

**Hemodialysis Machine--Meridian**

Alternate Medisystems blood tubing is available.

The incidents occurred at Nephrology, Inc., in Mishawaka, Ind., and Physicians Dialysis, Inc., in Grand Rapids, Mich.

Further details can be obtained from Baxter's Postmarket Surveillance Group at 1-888-736-2543, option 3.

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