Baxter Healthcare Corporation 847.546.6311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

Urgent Product Recall

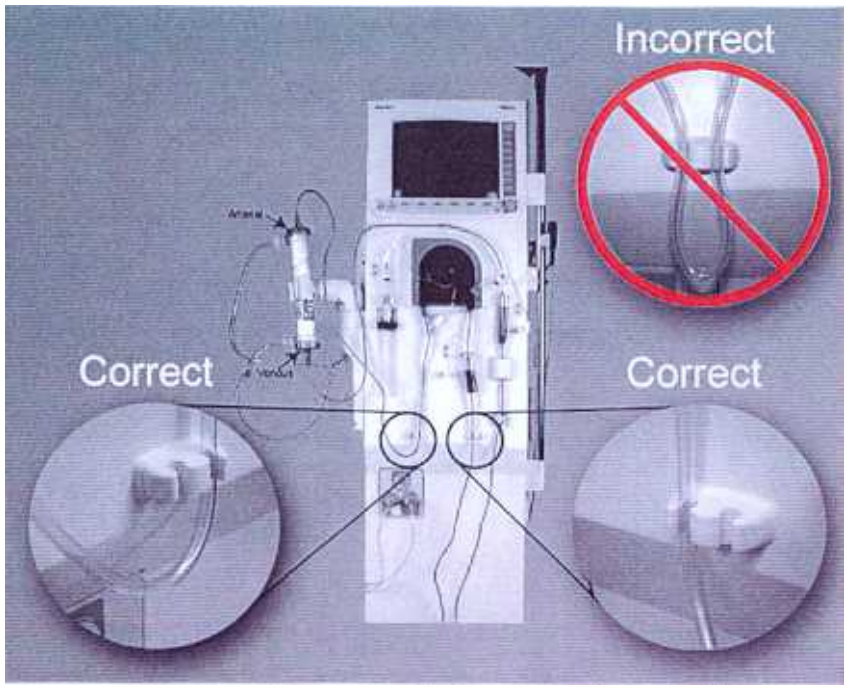
September 28, 2005

Re: Proper Routing of Blood Tubing Set for MERIDIAN Instruments to Prevent Potential Kinking (Product Codes: 5M5576 and 5M5576R)

Dear Hemodialysis Administrator:

Baxter has received reports of hemolysis related to kinks in blood tubing sets used on the MERIDIAN instrument, which has contributed to a death and a serious injury. It has been determined that there is an increased risk for kinks to occur at the double-tubing clips mounted on the front of the MERIDIAN instrument. The risk increases when a single tubing line is routed through both retainers on either clip (please see 'Incorrect' view in picture below). Baxter Healthcare Corporation is providing you with the following information to ensure the safe and effective use of recommended blood tubing sets:

- When setting up a recommended blood tubing set for the MERIDIAN Instrument, ensure that the arterial tubing between the blood pump and dialyzer and between the blood pump and the patient is routed through **only one of the two retainers in the double-tubing clip** (see 'Correct' views in picture below).



- Looping the arterial blood tubing set through both retainers of the double-tubing clip increases the risk of the blood tubing set kinking (see 'Incorrect' view in picture above), which could cause hemolysis. The clinical implication of returning hemolyzed blood to a patient is variable but ranges from no adverse effect, to symptoms including back pain, abdominal pain and shortness of breath, and ultimately, in the worst case, could lead to death.

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To correct this issue, Baxter is providing you and your staff with this letter and labels to be affixed to all your MERIDIAN instruments that provide proper instruction to route tubing through the tubing clips. In addition, Baxter will be providing an upgrade kit for both the pre- and post-blood pump double-tubing clips. Additional information regarding this kit will be communicated to you as it becomes available.

In the interim, there is no need to remove your instrument from service, however **IT IS CRITICAL** that you take the following actions:

1. Affix one of the enclosed labels to each MERIDIAN instrument in your possession, as per the instructions accompanying this letter
2. Assure that all care providers are trained and follow the proper setup as outlined above and are using **only one of the two retainers in each of the double-tubing clips** during treatment.
3. Confirm that these two actions have been performed using the attached reply forms.

This instruction supercedes all instructions previously issued regarding use of the double-tubing clips for this product, or that appear in the current version of the Operator's Manual.

If you have provided Baxter MERIDIAN instruments to other services, facilities, or home patients, please forward this information including labels and label instructions as appropriate.

Please complete the attached reply form confirming your receipt of this letter and return it to Baxter using the fax number provided on the form. Returning the customer reply forms promptly will prevent you from receiving a repeat notice.

We apologize for any inconvenience you may experience as a result of this communication. If you have questions regarding this communication, please use the contact numbers provided below; they will help us promptly address your concerns.

> For general communication inquiries, including questions on the reply form, call Center for One Baxter, 1-800-422-9837.
>
> For technical questions regarding the operation of your MERIDIAN instrument, call Baxter Global Technical Services, 1-800-553-6898, Technical Assistance - prompt 3, Technical or Operational Assistance in Hemo machines - option 2, MERIDIAN - choice 2.

The Food and Drug Administration has been notified of this communication.

Sincerely,

Signature

Joseph P. Sener, P.E.
Vice President Quality
Renal Division
Baxter Healthcare Corporation

cc: Chief Technician
Hemodialysis Charge Nurse

Enclosures

Baxter

Letter Response

Proper Routing of Blood Tubing Set for MERIDIAN Instruments to Prevent Potential Kinking (Product Codes: 5M5576 and 5M5576R)

Customer Reply Form
(Urgent Device Correction letter dated September 28, 2005)

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1-847-270-5457

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Telephone Number (including Area Code):	

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date:
REQUIRED FIELD

See Page 2

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Meridian Double-Tubing Clip Label Installation Instructions

1. Remove any blood tubing sets from the Meridian Instrument.

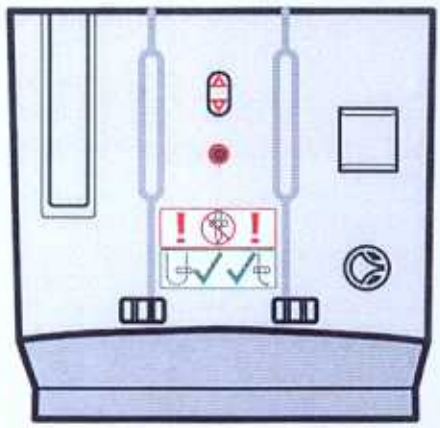
2. Wipe the Front Panel area, where the label is to be attached with isopropyl alcohol.

3. Peel off adhesive backing from label.

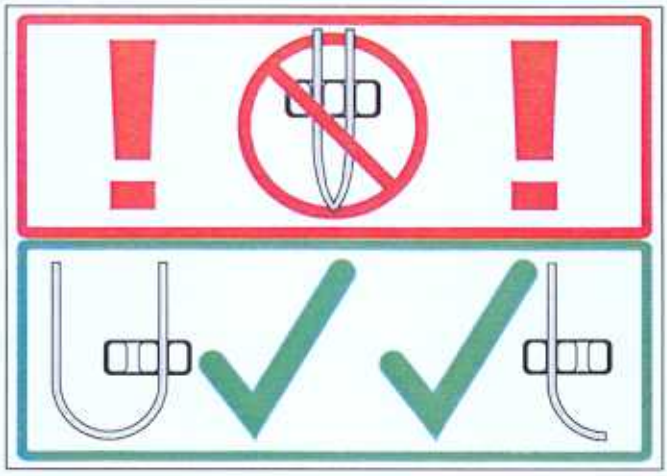
4. Make sure to orient the label with the red text at the top and attach the label to Front Panel as shown.

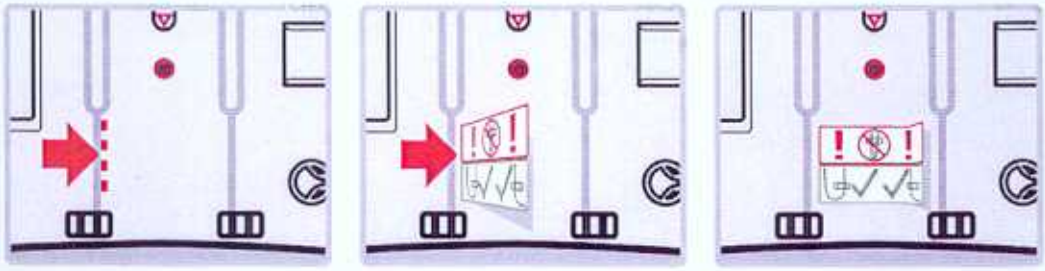
5. Align the label with the vertical line molded onto the instrument housing and press the label flat from the side.

Note: Pressing from the top may cause a wrinkle in the label. Additional labels have been enclosed for your convenience.



Proper Label Placement





Align here

Align and flatten from the side