

Patient Safety Alert

Veterans Health Administration Warning System
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AL10-05

February 3, 2010

Item: Fresenius HemaClip used during dialysis

General Information: The VA National Center for Patient Safety (NCPS) analyzed reports of bleeding episodes during dialysis. Analysis of these adverse event reports with both dialysis catheter access and needle access usage revealed clinically significant bleeding episodes, some of which were catastrophic. Patient Safety Advisory AD09-02 (see Reference section) issued on 10/21/2008 outlined in detail the results of the analysis and gave recommendations for the early detection and prevention of these adverse events. The Advisory recommended that HemaClip patient connector clips be used whenever possible to decrease the possibility of loosening or disconnection of the return blood line at the dialysis catheter. After the Advisory was issued, a catastrophic event occurred in a facility that used Fresenius bloodlines but did not utilize the Fresenius HemaClip.

Dialysis machine alarms are not always reliable in preventing patient harm. In hemodialysis machines, the venous pressure monitor cannot always be relied upon for the early detection and alarm of a venous line disconnection or needle dislodgment. The analyzed reports showed that frequently, where complete disconnection occurred, the hemodialysis machine audible alarm did not sound before serious patient harm occurred. This reinforces the need to keep access sites visible as well as the protective value of utilizing the Fresenius HemaClip where Fresenius bloodlines are employed. See Attachment 1 for photos of representative catheters with the HemaClip attached.

Actions: 1. By close of business (COB) February 4, 2010, the **Facility Director (or designee)** will ensure that all Dialysis staff are made aware of this Patient Safety Alert.

2. By COB February 9, 2010, **Dialysis Unit Managers (or designee) at all facilities** must remind all dialysis personnel and patients that, as stated in the Patient Safety Advisory AD09-02, and now directed by this Alert, that the access site must remain visible, even though this may require some ingenuity, such as in the case of groin access or treatments done outside of the chronic dialysis unit. In addition, the patient should not be placed alone in a situation where the access site

cannot be seen, such as rooms which do not permit ongoing observation of the blood lines. Isolation rooms should be designed or modified to allow easy visualization of the patient during treatment.

3. By COB February 9, 2010, **Dialysis Unit Managers (or designee) at facilities that use Fresenius bloodlines** will assure that their staff have ordered the HemaClip (Part Number 04-9100-1). Note: The clips are available by the case (400 clips/case). Contact Fresenius Customer Service at (800) 323-5188. After receipt of the HemaClips, the facility shall verify the fit of the HemaClips to the catheters in use. See the Additional Information section below for the fit assessment process. Notify NCPS if the catheters and HemaClip are found to be incompatible.

4. By COB February 26, 2010, **Dialysis Unit Managers (or designee) at facilities that use Fresenius bloodlines** in conjunction with compatible dialysis catheters shall begin to use the HemaClip (Part Number 04-9100-1) on both the arterial and venous catheter connections for every patient treatment. Prior to using the clip, staff must be trained and demonstrate competency in its use and the applicable dialysis SOPs must be revised. See Attachment 2 for the Fresenius HemaClip Instructions for Use.

5. By COB March 2, 2010, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website.

<http://vaww.nbc.med.va.gov/visn/recalls/index.cfm>

Attachments:

1. Photos of representative catheters with Fresenius HemaClip attached to the venous bloodline
2. Fresenius HemaClip-Instructions for Use

Additional Information:

Fit Assessment Process: Although information currently available indicates that the clip should be suitable for virtually all catheters, there is a possibility that the HemaClip will not fit all hemodialysis catheters. Fresenius bloodlines users must verify that their existing and any new catheters are assessed for proper fit. The catheter clip part of the HemaClip should fit securely to the catheter as shown in the illustrations in the attached Instructions for Use (see Attachment 2). The catheter needs to be held snugly, so that it can't be shaken loose from the clip. Place the clip for the catheter as close as possible to the catheter/bloodline connection to assure that the plastic teeth on the HemaClip are fully engaged when the two parts are connected.

Experience has shown that blood leakage as high as 50 ml/min at the venous catheter connection does not result in the dialysis machine alarming.

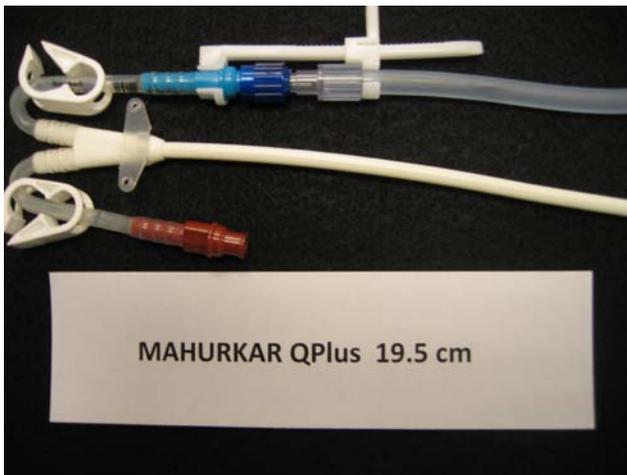
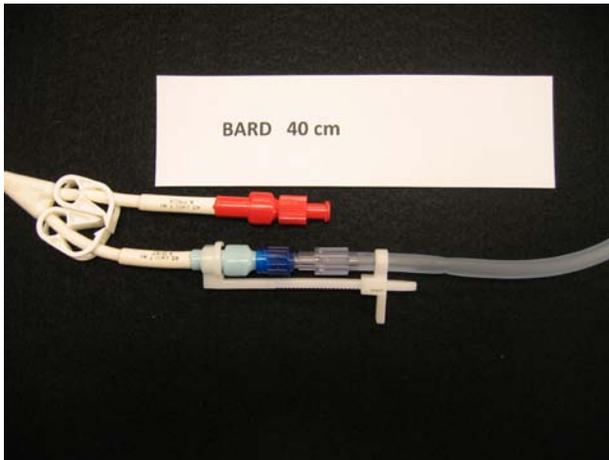
The HemaClip should prevent a catastrophic disconnection and blood loss at the dialysis machine pump rate, which is typically 400 to 500 ml/min. However, even with use of the HemaClip, dialysis staff must continue to use the correct technique firmly attaching the bloodline locking Luer connector to the catheter.

Reference: Patient Safety Advisory, AD09-02, Bleeding episodes during dialysis
<http://www.patientsafety.gov/alerts/BleedingEpisodesDuringDialysisAD09-02.pdf>

Source: VA Medical Centers

Contact: Thomas Bauld, PhD, or Judith Anderson, M.D., VA National Center for Patient Safety (NCPS) at (734) 930-5890.

Attachment 1 - Photos of representative catheters with Fresenius HemaClip attached to the venous bloodline



Attachment 2 - Fresenius HemaClip Instructions for Use

**Fresenius® HemaClip
Bloodline Connector Clip
for Hemodialysis**

Catalog No. 04-9100-1

NON STERILE

Use only with Fresenius manufactured bloodlines

CAUTION:

- This device does not work with all catheter types. Contact the catheter manufacturer to determine if this device is compatible before use.
- For use only with Fresenius manufactured bloodlines when used in conjunction with hemodialysis catheters. The device is not intended for use with other manufacturer's bloodlines.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS:

- Do not reuse or alter this device.
- Ensure visibility of bloodline connection to catheter at all times during the treatment. Do not cover the access or bloodlines with a blanket or clothing prior to or during the treatment.
- Ensure all connections are secure before use, and monitor for leaks regularly during patient use. Blood leaks can result if connections are not secure. Any air entering the extracorporeal circuit during dialysis may result in serious patient injury or death.
- If any disruption to the dialysis treatment occurs, it is imperative that the Fresenius® HemaClip be re-applied if removed, or re-examined for proper connection if manipulated in any way.
- Always use aseptic technique when making or breaking any fluid path connection.

INDICATIONS FOR USE:

The Fresenius® HemaClip is intended to decrease the possibility of a complete disconnection of dialysis catheters from blood tubing during the hemodialysis treatment. It is not intended to replace a properly made bloodline catheter connection or the function of the bloodline luer or the rotating collar of the bloodline patient connector.

NOTE:

For single use only. Do not reuse.

This product does not contain latex.



Fresenius Medical Care
95 Hayden Ave
Lexington, MA 02420
1-800-662-1237

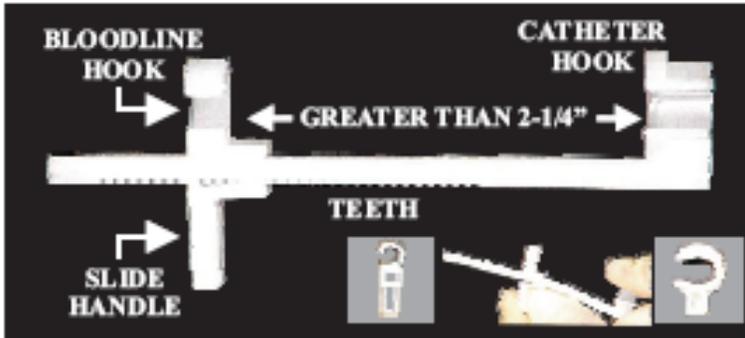
Assembled in Mexico

71-390603

Attachment 2 - Fresenius HemaClip Instructions for Use (continued)

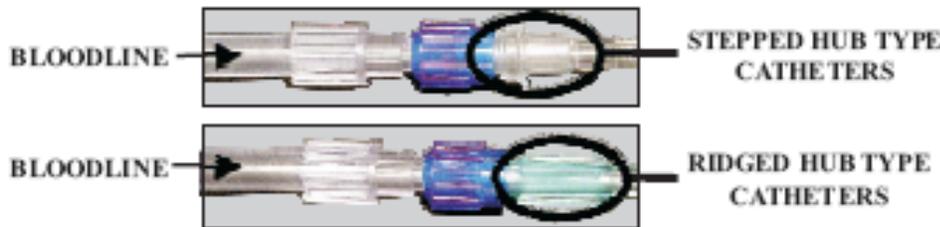
CONNECTION INSTRUCTIONS:

- 1 Remove Fresenius® HemaClip from its package.



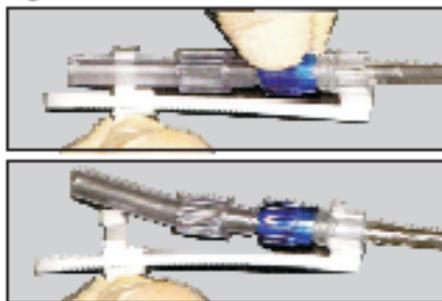
- 2 Check that bloodline hook is at least 2 ¼" from catheter hook. To back off slide handle, bend bottom of handle towards catheter hook to disengage slide handle from teeth (see above).

- 3 Connect bloodline to catheter, and secure connection using blue luer lock.



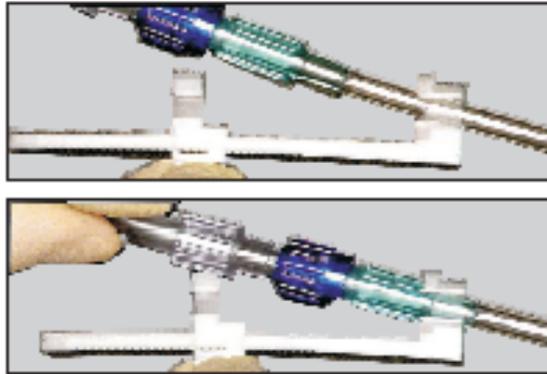
- 4 Grasp slide handle between thumb and index finger of RIGHT hand. Hook openings should be facing upwards.

- 5 (Skip to #6 for Ridged Hub Type). If using device with Stepped Hub Type catheter, grasp catheter/bloodline connection with left hand & gently snap catheter hub down into catheter hook. Catheter hook is grooved for snug fit with most catheter hubs.



Attachment 2 - Fresenius HemaClip Instructions for Use (continued)

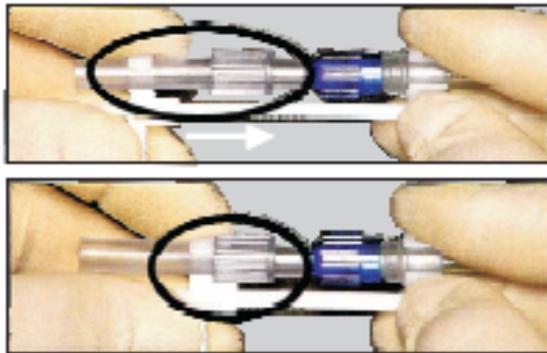
- ⑥ If using device with a **Ridged Hub Type** catheter, slide catheter hub so it fits snugly within catheter hook.



- ⑦ Gently snap bloodline into bloodline hook.



- ⑧ Grasp both hooks with thumb and index finger of both hands, and push hooks toward each other. A clicking sound will be heard.



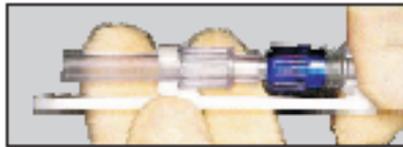
- ⑨ Push hooks together a final time to ensure that teeth are fully engaged and connection is secure.

Attachment 2 - Fresenius HemaClip Instructions for Use (continued)

DISCONNECTION INSTRUCTIONS:

PRIOR TO disinfection of catheter/bloodline connection:

- ❶ After the dialysis treatment has been discontinued and the patient's blood has been returned, check catheter/bloodline connections for tightness.
- ❷ With **LEFT** hand, firmly grasp catheter hook between thumb and index finger. With **RIGHT** hand: place thumb against slide handle, index finger behind clear bloodline collar, and middle finger behind handle.



- ❸ Push against bloodline collar and bloodline with index and middle fingers until bloodline is released from bloodline hook.



- ❹ Gently slide catheter hook off of catheter hub, and slide catheter hook down the catheter tubing.



- ❺ Remove catheter hook from catheter tubing.
- ❻ Check catheter/bloodline-luer connection for tightness after removal of Fresenius® HemaClip connector.
- ❼ Follow facility procedure for treatment termination using a catheter.

CAUTION

*Close mainline clamp on bloodline
and clamp on catheter before disconnection.
Care should be taken to avoid pulling on the catheter.*