

## **URGENT- Field Safety Notice**

CRIT-LINE® Blood Chamber  
Possible Blood Chamber Connection Leaks  
Field Action Number: **FA-2015-6 REV C**

Dear Valued Customer/Medical Device Liaison Officer,

The purpose of the notification is to inform you that Fresenius Medical Care Renal Therapies Group, LLC (FMCRTG, LLC) had initiated a voluntary **recall of all lots** for Product Code CL10021021 of the CRIT-LINE® Blood Chamber, due to the possibility of blood chamber connection leaks associated with the use of the CRIT-LINE® Blood Chamber.

Health consequences from blood loss may include low blood pressure, dizziness, shortness of breath, confusion, chest pain, loss of consciousness, shock, and, in extreme cases, excessive blood loss may lead to death. Separation in the connection of the blood circuit that allows blood loss could provide entry for bacteria with resultant risk of bacteremia, blood stream infection, and sepsis that may lead to death.

**We ask that you please do the following:**

- **Immediately examine your stock to determine whether you have any CRIT-LINE® Blood Chambers.**
- **If any product of this lot is found, discontinue use *immediately*.**
- **Place all units in a secure, segregated area.**
- **Please fill out and return the attached Reply Form at your earliest convenience.**
- **Contact Materials Management: Lindsey Trett ([Lindsey.Trett@fmc-na.com](mailto:Lindsey.Trett@fmc-na.com)) for instructions on how to return the recalled product.**

If you need any further information or support concerning this issue, please contact the Customer Service Care Team at +1-800-323-5188 and reference the Field Action Number listed above.

If you have any additional medical concerns or questions, please contact Medical Information and Communication: +1-855-616-2309 or Website: [www.fresenius-medinfo.com](http://www.fresenius-medinfo.com).

We apologize for any inconvenience this product recall may cause.

**Please forward this FIELD SAFETY NOTICE to all those who need to be aware of this issue within your organization.**

**Please pass this Field Safety Notice to all who received affected devices.**

Sincerely,



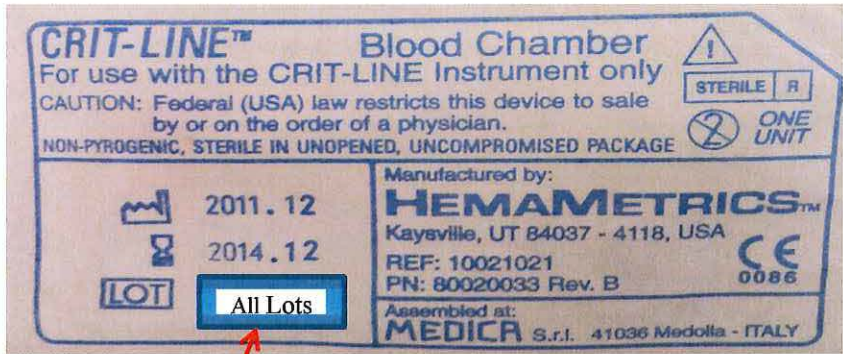
Dirk E. Stevens, Ph.D.  
SVP Quality and Regulatory Affairs, FMCRTG, LLC

**Fresenius Medical Care North America**

**Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000**

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Field Action Number: FA-2015-6 REV C

Affected Products	<p><b>Part Number</b> - CL10021021</p> <p><b>Product</b> - CRIT-LINE® Blood Chamber</p> <p><b>Lots</b>- See Attachment</p> <div style="text-align: center;">  <p style="color: red; font-weight: bold;">Sample Label Only- All lots are being recalled</p> </div>
Problem Description	Fresenius Medical Care Renal Therapies Group, LLC has received an increased number of complaints pertaining to blood chamber connection leaks during the use of the CRIT-LINE® Blood Chamber.
Hazard Involved	Health consequences from blood loss may include: low blood pressure, dizziness, shortness of breath, confusion, chest pain, loss of consciousness, shock, and, in extreme cases, excessive blood loss may lead to death. Separation in the connection of the blood circuit that allows blood loss could provide entry for bacteria with resultant risk of bacteremia, blood stream infection, and sepsis that may lead to death.
Actions to be taken by Customer/Clinic/Patient	<p><b>We ask that you please do the following:</b></p> <ul style="list-style-type: none"> <li>• <b>Immediately examine your stock to determine whether you have any CRIT-LINE® Blood Chambers.</b></li> <li>• <b>If any product of this lot is found, discontinue use immediately.</b></li> <li>• <b>Place all units in a secure, segregated area.</b></li> <li>• <b>Please fill out and return the attached Reply Form at your earliest convenience.</b></li> <li>• <b>Contact Materials Management: Lindsey Trett</b></li> </ul>

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	<b>(<a href="mailto:Lindsey.Trett@fmc-na.com">Lindsey.Trett@fmc-na.com</a>) for instructions on how to return the recalled product.</b>
Actions planned by Fresenius	<ul style="list-style-type: none"> <li>• Fresenius (FMCRTG, LLC) has sent this Customer Notification to all facilities that have been sent the affected lots of CRIT-LINE® Blood Chambers.</li> <li>• Fresenius (FMCRTG, LLC) has notified all applicable Competent Authorities of this recall.</li> </ul>
Further Information and Support	<p>If you need any further information or support concerning this issue, please contact the Customer Service Care Team at +1-800-323-5188 and reference the Field Action Number listed above.</p> <p>If you have any additional medical concerns or questions, please contact Medical Information and Communication: +1-855-616-2309 or Website: <a href="http://www.fresenius-medinfo.com">www.fresenius-medinfo.com</a>.</p>



## Reply Form

**Please Complete and Return This Form.**  
**Please fill out and fax/mail this confirmation at your earliest convenience.**

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Date: \_\_\_\_\_

**Please check the following:**

I have read the attached Notification and understand the instructions that I am given.

**And**

I am returning unused affected product. **HOW MANY** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Phone Number/Email (optional):** \_\_\_\_\_

**FAX FORM TO: +1-781-699-9796 ATTN: Quality Department**  
**OR SCAN AND E-MAIL SIGNED FORM TO: NOTIFYRA@fmc-na.com**

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**CRIT-LINE<sup>®</sup> Blood Chamber:**  
**Field Action Number: FA-2015-6 REV C**  
**LOT NUMBERS**

Lot number	Lot number	Lot number	Lot number	Lot number	Lot number	Lot number	Lot number
120301	130503	131205	14051306	14091311	15011316	14061301	14101301
120302	130601	131206	14051307	14091312	15011317	14061302	14101302
120303	130602	131207	14051308	14091313	15011318	14061303	14101303
120304	130603	131208	14051309	14091314	15011319	14061304	14101304
120305	130604	131209	14051310	14091315	15011320	14061305	14101305
120306	130605	140101	14051311	14091316	15011321	14061307	14101306
120401	130606	140102	14051312	14091317	15011322	14061308	14101307
120402	130701	140103	14061301	14091318	15011323	14061309	14101308
120403	130702	14011104	14061302	14101301	15011324	14061310	14101309
120404	130703	14010205	14061303	14101302	15021301	14061311	14101310
120405	130704	14010206	14061304	14101303	15021302	14061312	14101312
120406	130705	14011107	14061305	14101304	15021303	14061313	14111116
120501	130706	14011108	14061106	14101305	15021304	14061314	14111301
120502	130801	14011109	14061307	14101306	15021305	14061315	14111302
120503	130802	14011110	14061308	14101307	15021306	14061316	14111303
120504	130803	14011111	14061309	14101308	15021307	14061317	14111304
120505	130804	14010212	14061310	14101309	15021308	14071106	14111305
120506	130805	14021104	14061311	14101310	15021309	14071118	14111306
120601	130806	14021106	14061312	14101111	15021310	14071301	14111307
120701	130901	14020203	14071301	14101312	15021311	14071302	14111308
120702	130902	14021201	14071302	14111301	15021312	14071303	14111309
120703	130903	14021105	14071303	14111302	15031301	14071304	14111310
120704	130904	14021202	14071304	14111303	15031302	14071305	14111311
120705	130905	14021107	14071305	14111304	15031303	14071307	14111312
120801	130906	14021108	14071106	14111305	15031304	14071308	14111313
120802	131001	14021209	14061313	14111306	15031305	14071309	14111314
120803	131002	14021110	14061314	14111307	15031306	14071310	14111315
120901	131003	14021211	14061315	14111308	15031307	14071311	14111317
120902	131004	14021212	14061316	14111309	15031308	14071312	14111318
120903	131005	14021113	14061317	14111310	15031309	14071313	14121301



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Lot number	Lot number	Lot number	Lot number	Lot number	Lot number	Lot number	Lot number
121001	131006	14031101	14061118	14111311	15031310	14071314	14121302
121002	131007	14031103	14071307	14111312	15031311	14071315	14121303
121003	131008	14031202	14071308	14111313	15031312	14071316	14121304
121004	131009	14031205	14071309	14111314	14041301	14071317	14121305
121005	131010	14031304	14071310	14111315	14041302	14081301	14121306
121006	131011	14031306	14071311	14111116	14041303	14081302	15011301
121101	131012	14031307	14071312	14111317	14041304	14081303	15011302
121102	131101	14031308	14071313	14111318	14041305	14081304	15011303
121103	131102	14031309	14071314	14121301	14041306	14081305	15011304
121201	131103	14031310	14071315	14121302	14041307	14081306	15011305
121202	131104	14031311	14071316	14121303	14041308	14091301	15011306
121203	131105	14031312	14071317	14121304	14041309	14091302	15011307
130101	131106	14041301	14071118	14121305	14041310	14091303	15011308
130102	131107	14041302	14081301	14121306	14041311	14091304	15011309
130103	131108	14041303	14081302	15011301	14041312	14091305	15011310
130201	131109	14041304	14081303	15011302	14051301	14091306	15011311
130202	131110	14041305	14081304	15011303	14051302	14091307	15011312
130203	131111	14041306	14081305	15011304	14051303	14091308	15011313
130301	131112	14041307	14081306	15011305	14051304	14091309	15011314
130302	131113	14041308	14091301	15011306	14051305	14091310	15011315
130303	131114	14041309	14091302	15011307	14051306	14091311	15011316
130304	131115	14041310	14091303	15011308	14051307	14091312	15011317
130305	131116	14041311	14091304	15011309	14051308	14091313	15011318
130306	131117	14041312	14091305	15011310	14051309	14091314	
130401	131118	14051301	14091306	15011311	14051310	14091315	
130402	131201	14051302	14091307	15011312	14051311	14091316	
130403	131202	14051303	14091308	15011313	14051312	14091317	
130501	131203	14051304	14091309	15011314	14061106	14091318	
130502	131204	14051305	14091310	15011315	14061118	14101111	