

## **Urgent Field Safety Notice**

### **ARTISET HD DNL HC FA-2020-020 Safety Alert**

April, 2020

Dear Healthcare Provider:

**Problem Description** Baxter Healthcare Corporation has received customer complaints of various disconnection events with Artisets blood tubing sets and Cartridge blood tubing sets. The issue has been isolated to a subset of lots, based on production dates.

Currently the demand for this product has greatly exceeded supply and there are no alternative suppliers of this product. The product quality issue can be detected during set-up or priming of the device. Baxter is asking that customers perform product inspections to check the sets for disconnections prior to use to minimize the disruption of required hemodialysis treatments.

Baxter has implemented corrective actions to mitigate the occurrence of disconnections in newly manufactured sets.

<b>Product Code</b>	<b>Product Description</b>	<b>Lot number</b>
113898	EVOSET AFB K INFUSION	Refer to Attachment A
114510	CARTRIDGE WITH HEMOSCAN	Refer to Attachment A
114533	ARTISET HD SN HC	Refer to Attachment A
114598	CARTRIDGE EXTENDED PATIENT LINES	Refer to Attachment A
114599	CARTRIDGE EXT/ PATIENT LINES + INFUSION	Refer to Attachment A
114611	CARTRIDGE STANDARD	Refer to Attachment A
114613	CARTRIDGE LOW WEIGHT LOW VOLUME	Refer to Attachment A
114614	CARTRIDGE SINGLE NEEDLE	Refer to Attachment A
115283	ULTRA HDF LINE	Refer to Attachment A
955037	ULTRA HDF POST LINE	Refer to Attachment A
955075	ARTISET HD DNL HC	Refer to Attachment A
955077	ARTISET PREPOST	Refer to Attachment A
955526	PHYSIOSET HD DNL HC	Refer to Attachment A

<b>Hazard Involved</b>	A disconnection event may result in external blood loss, air embolism, or delay in therapy. Baxter has received three reports of serious injury related to blood loss as a result of disconnection events.
<b>Actions to be taken by Customers</b>	<ol style="list-style-type: none"><li>1. Prior to use, thoroughly inspect each connection of the set to check for any detachments in the tubing. Operators may continue to safely use affected sets if no detachments are observed. Additionally, per the Instructions for Use (IFU), users should observe carefully for leaks during priming and use and examine the tubing carefully to be certain that all connections are secure, all lines are unobstructed and that there are no kinks or leaks in the tubing.</li><li>2. If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter by faxing it, or scanning and e-mailing it, even if you do not have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.</li><li>3. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.</li><li>4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.</li><li>5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers and check the associated box on the reply form.</li></ol>

We apologize for any inconvenience this may cause you, your team, and our patients.

Sincerely,

Baxter Healthcare Corporation

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 955077 Artiset Prepost</b>	
<b>Lot Number</b>	<b>Lot Number</b>
1000198924	1000218874
1000198925	1000218875
1000198955	1000218876
1000200713	1000221645
1000200714	1000226118
1000204801	1000226119
1000204802	1000226121
1000204803	1000226122
1000204804	1000226690
1000206878	1000226691
1000206879	1000226692
1000206880	1000229606
1000206881	1000229607
1000206882	1000229608
1000208251	1000229609
1000210325	1000232235
1000210326	1000232236
1000210327	1000232237
1000210330	1000232238
1000211225	
1000211226	
1000214251	
1000214252	
1000214640	
1000214641	
1000216199	
1000216200	
1000216201	
1000216202	
1000217984	
1000217985	

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 955526 Physioset HD DNL HC</b>
<b>Lot Number</b>
1000209532
1000210942
1000216086
1000218889
1000228170
1000228811
1000231596

<b>Product Code: 114510 Cartridge with Hemoscan</b>
<b>Lot Number</b>
1000200968
1000203116
1000221405
1000225432

<b>Product Code: 113898 Evoset AFB K Infusion</b>
<b>Lot Number</b>
1000217172
1000217978
1000217981
1000218878
1000218881
1000218884
1000218887
1000221052
1000225271
1000225272
1000225273
1000226884
1000226885
1000226886
1000226888
1000227469
1000227470

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 114533 Artisat HD SN HC</b>
<b>Lot Number</b>
1000217170
1000217977
1000218877
1000218880
1000218883
1000221055
1000221056
1000221057
1000221058
1000222402
1000222403
1000222404
1000222405
1000225449
1000225450
1000225452
1000228183
1000228184
1000228185
1000228186
1000228187
1000230339
1000230340
1000230937

<b>Product Code: 114613 Cartridge Low Weight Low Volume</b>
<b>Lot Number</b>
1000204787

<b>Product Code: 114598 Cartridge Extended Patient Lines</b>
<b>Lot Number</b>
1000201541
1000225311
1000225883
1000230325

<b>Product Code: 114599 Cartridge Extended Patient Lines plus</b>
<b>Lot Number</b>
1000208818
1000222376
1000231585

<b>Product Code: 114611 Cartridge Standard</b>
<b>Lot Number</b>
1000202301
1000208207
1000221644
1000222520
1000228172

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 114614 Cartridge SN</b>
<b>Lot Number</b>
1000202543
1000208817
1000222087
1000228808
1000232905

<b>Product Code: 115283 Ultra HDF Line</b>
<b>Lot Number</b>
1000230899
1000233427

<b>Product Code: 955037 Ultra HDF Post Line</b>	
<b>Lot Number</b>	<b>Lot Number</b>
1000217173	1000233895
1000217979	1000233896
1000217982	
1000218879	
1000218882	
1000218885	
1000218888	
1000222394	
1000222395	
1000222396	
1000222397	
1000222398	
1000222399	
1000222400	
1000222401	
1000226213	
1000226214	
1000226215	
1000229626	
1000229627	
1000230892	
1000230893	
1000230894	
1000230895	
1000230896	
1000232239	
1000232240	
1000232241	
1000232242	

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 955075 Artiset HD DNL HC</b>		
<b>Lot Number</b>	<b>Lot Number</b>	<b>Lot Number</b>
1000198176	1000205908	1000208227
1000198911	1000205909	1000208232
1000198914	1000205910	1000208233
1000198916	1000205912	1000208236
1000198920	1000205913	1000208239
1000198921	1000205914	1000208240
1000198926	1000205915	1000210328
1000198928	1000205916	1000210329
1000198929	1000205917	1000210332
1000198930	1000205919	1000210335
1000198932	1000205920	1000210336
1000198933	1000205921	1000210337
1000198934	1000206883	1000210339
1000198935	1000206884	1000210341
1000198938	1000206885	1000210342
1000198941	1000206887	1000210343
1000198943	1000206888	1000210345
1000198944	1000206889	1000210346
1000198947	1000206890	1000210347
1000198950	1000206892	1000210348
1000198951	1000206893	1000210349
1000198952	1000206894	1000210350
1000198953	1000206896	1000210351
1000203372	1000208210	1000211292
1000204788	1000208214	1000211293
1000204789	1000208215	1000211294
1000204791	1000208216	1000211295
1000204792	1000208217	1000211296
1000204793	1000208222	1000211297
1000204794	1000208223	1000211706
1000204800	1000208226	1000211710

**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 955075 Artiset HD DNL HC</b>		
<b>Lot Number</b>	<b>Lot Number</b>	<b>Lot Number</b>
1000211712	1000215506	1000220523
1000211714	1000217367	1000220524
1000211715	1000217369	1000220525
1000211717	1000217370	1000220526
1000212320	1000217372	1000220527
1000212321	1000217373	1000222879
1000212322	1000217374	1000223055
1000212323	1000217376	1000223056
1000212324	1000218854	1000223057
1000212325	1000218855	1000223058
1000214237	1000218856	1000223061
1000214240	1000218857	1000223062
1000214241	1000218858	1000223064
1000214245	1000218859	1000223068
1000214247	1000218860	1000223069
1000214248	1000218861	1000224759
1000214249	1000218862	1000224760
1000214633	1000218863	1000224761
1000214634	1000218864	1000224763
1000214635	1000218865	1000224764
1000214636	1000220508	1000224765
1000214638	1000220509	1000224766
1000215491	1000220510	1000224767
1000215492	1000220511	1000224770
1000215493	1000220513	1000224771
1000215496	1000220516	1000224772
1000215497	1000220517	1000224773
1000215502	1000220518	1000225434
1000215503	1000220520	1000225436
1000215504	1000220521	1000225437
1000215505	1000220522	1000225438



**Attachment A: Affected Lot Numbers (to be adapted locally)**

<b>Product Code: 95505 Artiset HD DNL HC</b>
<b>Lot Number</b>
1000225445
1000225446
1000226693
1000226694
1000226695
1000226696
1000226699
1000226700
1000226702
1000226704
1000226705
1000226708
1000229610
1000229611
1000229614
1000229615
1000229619
1000229621
1000229625
1000231277



## CUSTOMER REPLY FORM

(SAFETY ALERT LETTER DATED XXXXXX (TO BE COMPLETED LOCALLY))

**Product Name:** Artiset blood tubing sets, Cartridge Sets

**Product code:** To be adapted locally

**Batch Number:** To be adapted locally

Please complete and return one copy of this form per facility either by fax (Fax : \_\_\_\_\_) or by e-mail ( \_\_\_\_\_ ) as confirmation that you have received this notification.  
A fax cover sheet is not required.

*(Can be adapted locally)*

Facility Name and Address:  <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title:  <i>(Please Print)</i>	
Email and/or Telephone Number (Including Area Code):	

- ☐ We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.
- ☐ We have received the above mentioned letter and have disseminated this information to customers/Home Patients. *(to be adapted locally)*
- ☐ We have received the above mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients. *(to be adapted locally)*

<b>Signature/Date:</b> REQUIRED FIELD	<hr/>
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Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.