



Urgent Medical Device Recall

Alaris™ Pump Infusion Sets

Infusion Set Model Codes- See details in Affected Product Table					
10010453	10010454	10012144	10015294	10015414	10933805
11171447	11404930	11522558	11607704	10013361T	2110-0500
2126-0500	2200-0500	2411-0500	2419-0007	2420-0007	2420-0500
2421-0500	2426-0007	2426-0500	2429-0500	2433-0007	2477-0000
2477-0007	2478-0000	C24116E			

May 06, 2019

For the Attention of:

Recall Coordinator, Director of Nursing, Director of Risk Management, and Director of Materials Procurement/Supply Chain

BD is conducting a voluntary medical device recall for certain model codes and lot numbers of the Alaris™ Pump Infusion Sets used with the Alaris™ Pump Model 8100. (see Affected Product Table on pages 4-9). BD distributed the affected lots beginning in August 2018.

In addition, out of an abundance of caution and to minimize the overall impact on affected customer sites while internal testing is on-going, BD is instructing customers to discard **all** product model codes, as noted in Attachment 1, with expiration dates between and including 05/2019 and 08/2020 (manufactured between and including 05/2016 and 08/2017). BD will provide replacement for all discarded inventory.

Our records indicate you may have received product from the lots referenced in the Affected Product Table and/or the products listed in Attachment 1.

The following information details the issue and required customer actions.

Description of the problem and health hazard(s):

BD has confirmed that an incomplete occlusion can occur on the pumping segment of affected Alaris™ Pump Model 8100 infusion sets. This is caused by a variation in the wall thickness of the pumping segment of the affected infusion sets. The issue has the potential to lead to unintended delivery of medication when the pump module is not in running status or can result in faster than expected drug delivery flow when the pump is infusing.

This issue may lead to flow inaccuracies through the pumping cycle process resulting in an over-infusion and the potential for serious patient injury depending on the type of medication that is being delivered.

BD is continuing its investigation and is working in collaboration with the supplier of the extruded tubing to assure corrective actions are taken to prevent recurrence of this issue.



Please Take the Following Actions:

1. Immediately review your inventory for the specific model codes and lot numbers listed in the Affected Product Table below. Destroy all product subject to the recall based on the affected product table on pages 3 & 4 following your institutions process for destruction.
2. BD is instructing customers to discard **all** model codes and lot numbers with an expiration date between and including 05/2019 and 08/2020 (See attachment 1) in addition to the Affected Product List in this communication.
3. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.
4. Until all affected product has been discarded and is no longer in use, please follow the instruction below:
 - During infusion of critical medications, check the medication bag more frequently than normal to ensure that the remaining volume corresponds to the expected delivery time.
5. As always, review and follow the Instructions for Use provided with the product and the Alaris System, which includes the following:
 - After the infusion set is loaded into the pump with the door closed, open the roller clamp and verify that no fluid is dripping through the drip chamber. If drips are observed, do not initiate infusion with the Pump Module unit and infusion set.
 - Ensure that the clamp on the Alaris Pump Module Infusion Set is closed whenever infusion is not intended.
6. Any case of over-infusion or other serious or unexpected medical device incidents in patients receiving infusions with these Infusion Sets should be reported to Becton Dickinson. When reporting, please identify the model code and lot number to aid in the investigation process.
7. Complete the attached Customer Response Form and return to the BD contact noted on the form **whether you have any of the impacted material or not**, so that BD may acknowledge your receipt of this notification and provide product replacement.
8. Any adverse reactions/events experienced with the use of this product should also be reported to the FDA's MedWatch Program by:
 - Web: MedWatch website at www.fda.gov/medwatch
 - Phone: 1-800-FDA-1088 Fax: 1-800-FDA-0178
 - Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

Actions Taken by BD:

1. BD will provide replacement sets for all discarded inventory.
2. BD and the raw material supplier have implemented corrective actions including improved process controls and enhanced inspection criteria to prevent recurrence. Additional actions maybe implemented upon completion of the investigation.



If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
Regional Customer Quality	888-237-2762 OPT 3, OPT 2 Monday – Friday between the hours of 8:00am and 5:00pm (CT)	Recall Inquiries
Customer Advocacy	Call 888-812-3266 between 7AM-5PM Monday-Friday PST or Email: customerfeedback@BD.com	Product Complaints Adverse Event Reports

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Idal Beer, MD
VP, Medical Affairs
BD Medication Management Solutions

Gail Griffiths
Sr. Director, Corporate Regulatory Compliance
BD US Region



Affected Product Table

Model Code	Product Description and UDI	Lot Number	Expiration Date (MM/YYYY)
10010453	BD Alaris™ Pump Infusion Set UDI: 07613203021135	18096166	09/2021
		18096167	09/2021
		18096235	09/2021
		18096236	09/2021
		18096294	09/2021
		18096295	09/2021
		18096301	09/2021
		19026173	02/2022
10010454	BD Alaris™ Pump Infusion Set UDI: 07613203015806	17087410	08/2020
		17087411	08/2020
		18096003	09/2021
10012144	BD Alaris™ Pump Infusion Set UDI: 07613203021159	18096803	09/2021
		18096804	09/2021
10013361T	BD Alaris™ Pump Infusion Set UDI: 10885403223204	18095427	09/2021
		18095428	09/2021
10015294	BD Alaris™ Pump Infusion Set UDI: 10885403227981	18096296	09/2021
		18096293	09/2021
		18096273	09/2021
		18096272	09/2021
		18096229	09/2021
		18096228	09/2021
10015414	BD Alaris™ Pump Infusion Set UDI: 10885403233999	17087192	08/2020
		17087329	08/2020
		17087330	08/2020
		17087331	08/2020
		18036906	03/2021
		18036907	03/2021
10933805	BD Alaris™ Pump Infusion Set UDI: 07613203019088	18116304	11/2021
11171447	BD Alaris™ Pump Infusion Set UDI: 07613203021234	18096302	09/2021
		18096422	09/2021



11404930	BD Alaris™ Pump Infusion Set UDI: 07613203021197	19025787	02/2022
11522558	BD Alaris™ Pump Infusion Set UDI: 10885403232305	18096500	09/2021
		18096501	09/2021
		18096611	09/2021
11607704	BD Alaris™ Pump Infusion Set UDI: 10885403228001	18015347	01/2021
		18076591	07/2021
		18076660	07/2021
2110-0500	BD Alaris™ Pump Infusion Set UDI: 07613203012713	17087446	08/2020
2126-0500	BD Alaris™ Pump Infusion Set UDI: 07613203012638	18095286	09/2021
		18095287	09/2021
		18095355	09/2021
2200-0500	BD Alaris™ Pump Infusion Set UDI: 07613203012638	17087336	08/2020
		17087337	08/2020
		17087412	08/2020
2411-0500	BD Alaris™ Pump Infusion Set UDI: 10885403226090	18096312	09/2021
		18096313	09/2021
		18094358	09/2021
2419-0007	BD Alaris™ Pump Infusion Set UDI: 10885403227950	18096609	09/2021
		18096610	09/2021
2420-0007	BD Alaris™ Pump Infusion Set UDI: 07613203021012	17077279	07/2020
		17077398	07/2020
		17113133	11/2020
		17113134	11/2020
		17118801	11/2020
		17118810	11/2020
		18015266	01/2021
		18015267	01/2021
		18015351	01/2021
		18015353	01/2021
		18015458	01/2021
		18015459	01/2021
		18015568	01/2021
		18026598	02/2021
		18026601	02/2021



2420-0007	BD Alaris™ Pump Infusion Set UDI: 07613203021012	18036759	03/2021
		18036760	03/2021
		18036761	03/2021
		18036941	03/2021
		18036965	03/2021
		18036966	03/2021
		18036967	03/2021
		18037062	03/2021
		18037063	03/2021
		18037064	03/2021
		18075677	07/2021
		18075700	07/2021
		18075709	07/2021
		18075714	07/2021
		18075715	07/2021
		18075716	07/2021
		18076779	07/2021
		18076784	07/2021
		18076830	07/2021
		18086266	08/2021
		18086339	08/2021
		18093065	09/2021
		18093066	09/2021
		18093070	09/2021
		18093076	09/2021
		18093077	09/2021
		18095339	09/2021
		18095354	09/2021
		18095359	09/2021
		18095360	09/2021
		18095412	09/2021
		18095889	09/2021
		18095980	09/2021
		18095991	09/2021
18095996	09/2021		
18096179	09/2021		
18096180	09/2021		
18115088	11/2021		
18115135	11/2021		
18116622	11/2021		
18116623	11/2021		
18116624	11/2021		
18116707	11/2021		
19013154	01/2022		
19013155	01/2022		
19023000	02/2022		



		19026122	02/2022
		19026123	02/2022
		19026211	02/2022
		19033033	03/2022

2420-0500	BD Alaris™ Pump Infusion Set UDI: 07613203012430	17077358	07/2020
		17113141	11/2020
		17113142	11/2020
		17113146	11/2020
		18023014	02/2021
		18076737	07/2021
		18076738	07/2021
		18076739	07/2021
		18076740	07/2021
		18076741	07/2021
		18086332	08/2021
		18086333	08/2021
		18086334	08/2021
		18093055	09/2021
		18093056	09/2021
		18093057	09/2021
		18093072	09/2021
		18093073	09/2021
		18093074	09/2021
		18093075	09/2021
		18095068	09/2021
		18095357	09/2021
		18095358	09/2021
		18095417	09/2021
		18116640	11/2021
		18116641	11/2021
18116703	11/2021		
19026180	02/2022		
19026215	02/2022		
19026262	02/2022		

2421-0500	BD Alaris™ Pump Infusion Set UDI: 07613203019149	18096445	09/2021
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2426-0007	BD Alaris™ Pump Infusion Set UDI: 10885403227998	17077131	07/2020
		17077313	07/2020
		17087341	08/2020
		17125017	12/2020
		18015417	01/2021
		18015453	01/2021
18015454	01/2021		



		18026723	02/2021
		18026724	02/2021
		18026754	02/2021
		18036897	03/2021
		18075724	07/2021
		18076609	07/2021
		18076610	07/2021
		18076611	07/2021
		18086142	08/2021
		18086230	08/2021
		18086259	08/2021
		18086330	08/2021
		18095280	09/2021
		18115006	11/2021
		18115007	11/2021
		18115132	11/2021
		18116575	11/2021
		18116635	11/2021
		18116647	11/2021
		18116648	11/2021
		18116657	11/2021
		18116658	11/2021
		18116659	11/2021
		18116754	11/2021
		18116755	11/2021
		18116762	11/2021
		19026002	02/2022
		19026003	02/2022
2426-0500	BD Alaris™ Pump Infusion Set UDI: 07613203020992	17077013	07/2020
		17077267	07/2020
		17077268	07/2020
		18015449	01/2021
		18015450	01/2021
		18023011	02/2021
		18023012	02/2021
		18023013	02/2021
		18026479	02/2021
		18026729	02/2021
		18026731	02/2021
		18026732	02/2021
		18036894	03/2021
		18036995	03/2021
		18037027	03/2021
		18037029	03/2021
		18037048	03/2021
		18037051	03/2021



		18076650	07/2021
		18076675	07/2021
		18076676	07/2021
		18086146	08/2021
		18095276	09/2021
		18095352	09/2021
		18115003	11/2021
		18115004	11/2021
		18115129	11/2021
		19013152	01/2022
		19013153	01/2022
		19023004	02/2022
		19023005	02/2022
2429-0500	BD Alaris™ Pump Infusion Set UDI: 10885403228018	18095992	09/2021
		18095998	09/2021
		18096112	09/2021
		18096113	09/2021
		18096314	09/2021
2433-0007	BD Alaris™ Pump Infusion Set UDI: 10885403227974	18096269	09/2021
		18096271	09/2021
2477-0000	BD Alaris™ Pump Infusion Set UDI: 07613203011310	18015339	01/2021
		18036908	03/2021
		18115199	11/2021
		18115200	11/2021
2477-0007	BD Alaris™ Pump Infusion Set UDI: 07613203019460	18116521	11/2021
		18116637	11/2021
		18116638	11/2021
		18116751	11/2021
		18116752	11/2021
2478-0000	BD Alaris™ Pump Infusion Set UDI: 10885403235122	17087193	08/2020
		17087334	08/2020
		18116061	11/2021
		18116062	11/2021
C24116E	BD Alaris™ Pump Infusion Set UDI: 07613203021098	18096030	09/2021
		18096110	09/2021



CUSTOMER RESPONSE FORM

MDS-19-1531-FA
Alaris™ Pump Infusion Sets

Infusion Set Model Codes- See details in Affected Product Table					
10010453	10010454	10012144	10015294	10015414	10933805
11171447	11404930	11522558	11607704	10013361T	2110-0500
2126-0500	2200-0500	2411-0500	2419-0007	2420-0007	2420-0500
2421-0500	2426-0007	2426-0500	2429-0500	2433-0007	2477-0000
2477-0007	2478-0000	C24116E			

Please assist BD by promptly returning this form to:

BD Regulatory Compliance

Email: BD3973@stericycle.com

Fax No: 888-202-3822

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ State: _____ Zip: _____

Contact Person: _____

Telephone No.: _____ Email Address: _____

Fax No.: _____

Check all that apply:

I have read and understood the attached notice.

This facility does not have any of the affected product(s) on hand.

I certify that all impacted products on hand have been discarded and request replacement for the following products.

Model Code	Lot Number	Quantity- Each	Quantity- Case/20

Name:	_____
Title:	_____
Signature/Date:	_____

Attachment 1
BD Alaris™ Pump Infusion Sets

All product model codes with expiration dates between and including 05/2019 and 08/2020 (manufactured between and including 05/2016 and 08/2017)
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10010453	10010454	10010483	10010541	10010761
10010871	10011301	10011462	10012144	10012182
10012283	10012293	10012645	10013034	10013037
10013072	10013186	10013361	10013361T	10013854
10013889	10013890	10014035	10014855A	10015012
10015294	10015312	10015414	10015489	10015645
10015861A	10015862	10015896	10031773	10061661A
10062818	10074281A	10137405	10142568	10178573
10321213	10321213T	10382963	10404198	10406194
10408730	10561554	10779313	10813621	10817613
10817920	10821753	10863358	10879047	10879391
10927766	10933805	10934345	10942011	11045328
11059729	11063735	11118122	11130148	11133698
11147991	11171447	11258588	11287205	11401542
11404930	11419365	11426964	11426965	11484001
11522558	11532269	11582773	11590100	11607704
11607787	11609481	11612593	11613191	2107-0500
2110-0500	2111-0500	2120-0007	2120-0500	2122-0007
2123-0007	2125-0500	2126-0007	2126-0500	2129-0500
2130-0500	2131-0500	2140-0600	2141-0600	2171-0007
2177-0000	2200-0500	22000-B007T	2202-0007	2202-0500
2203-0500	2204-0007	2205-0000	2206-0007	2207-0007
2210-0500	2211-0500	2220-0500	2232-0007	22600-0007T
2260-0500	22601-B007T	22602-B007T	22603-B007T	2270-0500
2278-0500	2280-0000	2280-0006	2280-0008	24001-0007
24008-0007	24010-0007T	2401-0500	2403-0000	2403-0007
2406-0500	2408-0500	2409-0500	2410-0500	2411-0500
2412-0500	2413-0007	2414-0500	2416-0007	2419-0007
2420-0007	2420-0500	2421-0500	2422-0007	2423-0007
2424-0007	2425-0500	2426-0007	2426-0500	2428-0007
2429-0007	2429-0500	2430-0500	24301-0007T	2432-0007
2433-0007	2434-0007	2435-0007	2436-0500	2440-0600
2441-0007	2441-0600	2442-0007	2443-0600	2444-0007
2447-0007	2447-0600	2448-0007	2448-0600	2449-0600
2450-0500	2451-0007	2452-0007	2455-0500	24601-B007T
2461-0007	2463-0007	2465-0007	2466-0007	2477-0000
2477-0007	2478-0000	2929-0500	2941-0500	2942-0500
C24101E	C24103E	C24104E	C24105E	C24106E
C24107E	C24111E	C24112	C24116E	C24117
10010541-07	10074281	11147992	2438-0500	24600-0007
C24119E				