

February 3rd, 2020

URGENT: FIELD SAFETY NOTICE – MDS-19-1685

Alaris® Extension Sets, Low Sorbing (PE)

REF & Lot Numbers: Refer to Attachment 1

Type of Action: Product Removal

Attention: Nurse Managers, Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing a Field Safety Notice to remove specific lots of Alaris® Extension Sets, Low Sorbing (PE), manufactured by Shanghai Kindly Enterprise Development Group (KDL) and distributed by CareFusion (now part of BD) as listed in Attachment 1. Attachment 2 of this Field Safety Notice contains an example of the product label to assist you in identifying the product. According to our distribution records your organisation may have received these devices.

Description of the Problem

Through customer feedback, BD has confirmed that there is the potential for the male luer of the extension set to become disconnected from the female luer of the connecting device. The disconnection can occur upon initial connection and/or during infusion, resulting in leakage of medication and potential interruption of the therapy being administered.

Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate and quarantine any units of the impacted devices as listed in Attachment 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them return the affected product to your facility.
3. Destroy all unused units of the product listed in Attachment 1.
4. Complete the Customer Response Form on page 3 together with Attachment 1 on page 4, as applicable, indicating:
 - the quantities destroyed **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed Customer Response Form to BDUKFieldAction@bd.com **as soon as possible or no later than February 28th, 2020.**



1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

Should you have any questions or require assistance relating to this Field Safety Notice, please contact BDUKFieldAction@bd.com.

We confirm that the appropriate regulatory agencies have been informed of these actions.

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 you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

A handwritten signature in blue ink that reads "William David".

William David
Senior Director, Quality Compliance EMEA

Attachment 1: Affected Product Code / Lot Number Combinations

Attachment 2: Example of product label



Customer Response Form – MDS-19-1685

Alaris® Extension Sets, Low Sorbing (PE)

REF & Lot Numbers: Refer to Attachment 1

Please read in conjunction with Field Safety Notice MDS-19-1685 and return, completed and signed, as soon as possible or **no later than February 28th, 2020** to BDUKFieldAction@bd.com.

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below:

We do not have any of the affected product as listed in Attachment 1 in our possession. *(Please complete the table below with your contact information and return to the email address listed above.)*

OR

We have units of the affected product as listed in Attachment 1 in our possession and I confirm that the units have been destroyed. *(Please complete Attachment 1 with the quantity of units destroyed. Then complete the table below with your contact information and return both documents to the email address listed above.)*

Name of Trust <i>(if applicable)</i>			
Name of <u>all</u> Facilities / Hospitals covered by this response <i>(e.g. other hospitals within your Trust)</i>			
Facility / Hospital address			
City		Postcode	
Contact telephone number		E-mail address	
Contact name			
Job title			
Signature		Date	

This form must be returned to BD before this action can be considered closed for your account.

Attachment 1: Affected Product Code / Lot Number Combinations

REF	LOT	Quantity destroyed	REF	LOT	Quantity destroyed
04105001509K	20170706		G40215K	20180325	
	20170914			20180514	
	20171122		G40615K	20170504	
04105003509K	20190305			20170602	
	20190415			20170805	
	20190806			20170918	
04105005509K	20170601			20171126	
	20170804			20180122	
	20170915			20180306	
	20171015			20180326	
	20171123			20180418	
	20180301			20180515	
	20190110			20181123	
	20190306			20190112	
04105007509K	20171016			20190722	
	20180302		G40620K	20170603	
04105010509K	20170916			20170708	
	20171124			20170806	
	20180303			20170919	
	20190111			20171020	
	20190307			20171127	
	20190419			20180123	
04105025509K	20171017			20180307	
	20180304			20180327	
G40215K	20170707			20180419	
	20170917			20180516	
	20171018			20180609	
	20171019			20181124	
	20171125		20190113		
	20180121		20190416		
	20180305		20190723		

Attachment 2: Example of product label

Alaris® Products

en EXTENSION SET. LOW SORBING (PE)	bg УДЪЛЖИТЕЛ. НИСКА СОРБЦИЯ (PE)
cs PRODLUŽOVACÍ SOUPRAVA. NÍZKÁ ABSORPCE (PE)	et PIKENDUSLIIN. VÄHESE SORPTSIOONIGA (PE)
da FORLÆNGERSÆT. LAV ABSORPTION (PE)	hu HOSSZABBÍTÓ SZERELÉK. ALACSONY SZORPCIÓJÚ (PE)
de VERLÄNGERUNGSLEITUNG. GERINGE AD- UND ABSORPTION (PE)	it PAILGINIMO SISTEMA. MAŽAI SUGERIANTIS (PE)
el ΣΕΤ ΕΠΕΚΤΑΣΗΣ. ΧΑΜΗΛΗΣ ΑΠΟΡΡΟΦΗΣΗΣ (PE)	lv PAGARINĀŠANAS KOMPLEKTS. MAZABSORBĒJOŠS (PE)
es ALARGADERA. BAJA ABSORCIÓN (PE)	pl ZESTAW PRZEDŁUŻAJĄCY. NISKOABSORPCYJNE (PE)
fi JATKOLETKU. VÄHÄINEN ABSORBOITUMINEN (PE)	ro PRELUNGITOR. CU ABSORBȚIE REDUSĂ (PE)
fr PROLONGATEUR. FAIBLE SORPTION (PE)	ru УДЛИНИТЕЛЬНЫЙ НАБОР. НИЗКАЯ АБСОРБЦИЯ (ПЭ)
it PROLUNGA. A BASSO ASSORBIMENTO (PE)	sk PREDLŽOVACIA SÚPRAVA. NÍZKA ABSORPCIA (PE)
nl EXTENSIESET. LAAG-ABSORBEREND (PE)	sl PODALJŠEK ZA INFUZIJO. NIZKO VSRKAVANJE (PE)
no FORLENGELSESETT. LAVTABSORBERENDE (PE)	sr SET ZA EKSTENZIJU. NISKA SORPCIJA (PE)
pt PROLONGAMENTO. BAIXA ABSORÇÃO (PE)	tr UZATMA SETİ. DÜŞÜK EMİLİM (PE)
sv FÖRLÄNGNINGSSAGGREGAT. LÅGABSORBERANDE (PE)	ja 延長チューブ. 低吸収 (PE)
	zh 延长管路. 低吸收 (PE - 聚乙烯)



Distributed by



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 Shanghai, P.R.C.
 EC REP Shanghai International Holdings Corp.
 GmbH(Europe), Addr: Eiffestrasse 80,20537
 Hamburg Germany
 Tel:0049-40-2513175



Rev. 05/2015

150 cm

1.4 ml

REF XXX

LOT 20141226

2019-11