Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
Bdbiosciences.com
bd.com

URGENT PRODUCT SAFETY ALERT

28 November 2018

Product Name	Catalog (Ref) No.	Serial Nos.
BD FACSAria™ II	See Attached Listing for Affected Catalog Numbers and Serial Numbers	
BD FACSAria™ III		
BD FACSAria™ Fusion		

For the Attention of: Lab Manager

Description of the problem:

BD has recently confirmed a potential for ethanol to spray from the ethanol filter during the weekly filter purge and/or the 6 month filter change maintenance activities. The ethanol spray may occur if the filter has been damaged from impact with a hard surface during bubble removal or if the connector is not fully engaged in the fitting.

Our records indicate you have been shipped one or more of the attached referenced serial number(s) of product.

Please Take the Following Actions:

1. BD recommends that you retain this letter with the instrument records maintained by your facility.
2. Share this Product Safety Alert with all users to ensure they are aware of this safety alert.
3. Complete the attached Customer Response Form and return to the contact noted so that BD may acknowledge your receipt of this notification.

Actions Taken by BD:

BD has provided detailed use instructions (attached) to minimize the potential for ethanol spray to occur.

Contact Information

If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
BD Customer/Technical Support	BD Customer Support at 855.236.2772 (prompt 2) for instruments in the United States	For customers outside the US, contact your local BD representative or distributor.

BD is committed to advancing the world of health. Our primary objective is 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.

Sincerely,

Gail Griffiths
Sr. Director, Regulatory Compliance
US Region

Kevin Judge, MD
Vice President Medical Affairs

CUSTOMER RESPONSE FORM

BD FACSAria™ II
BD FACSAria™ III
BD FACSAria™ Fusion

Please assist BD by promptly returning this form to:
BD Regulatory Compliance
Email: BDBRC@bd.com

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No.: _____**Email Address**: _____

Fax No.: _____

☐ I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

☐ We no longer have this equipment on hand.

AFFECTED PRODUCTS AND SERIAL NUMBERS

Product Name	Catalog (Ref) No.	Serial Nos.
BD FACSAria™ II Flow Cytometer 2 Laser Base	643177	P64317700076 P64317700075 P64317700077
BD FACSAria™ II Cytometer 3 Laser W/Blue/Violet	643180	P64318000028 P64318000029 P64318000030
BD FACSAria™ III 6B/2R BASIC	64828201	R648282010002 R648282010003 R648282010004 R648282010005
BD FACSAria™ III 6B/2R ACDU BASIC	64828202	R64828202012 R64828202013
BD FACSAria™ III 6B/2R/2V BASIC	64828203	R648282030006 R648282030007 R648282030008 R648282030009 R648282030010 R648282030011 R648282030012
BD FACSAria™ III 6B/2R/2V ACDU BASIC	64828210	R648282100004 R648282100005 R648282100006 R648282100007 R648282100008 R648282100009
BD FACSAria™ III 6B/2R/2NUV ACDU BASIC	64828211	R648282110003 R648282110004
BD FACSAria™ III 3B/2R/2V/4YG BASIC	64828217	R648282170002
BD FACSAria™ III 6B/2R/2NUV/2BV ACDU BASIC	64828222	R648282220001
BD FACSAria™ III 3B/2R/2V/2NUV/4YG/2BV ACDU BSC	64828235	R64828235002
BD FACSAria™ III ACDU 6B/3R	648282A2	R648282A20040
BD FACSAria™ III 6B/3R	648282A3	R648282A3007
BD FACSAria™ III ACDU 3B/3R/5YG	648282B1	R648282B1001
BD FACSAria™ III ACDU 6B/3R/3V	648282B3	R648282B3007 R648282B3008 R648282B30009 R648282B30010 R648282B30011 R648282B30012 R648282B30013 R648282B30014 R648282B30015 R648282B30016 R648282B30017 R648282B30018 R648282B30019
BD FACSAria™ III ACDU 6B/3R/6V	648282B4	R648282B40003 R648282B40004 R648282B40005 R648282B40006
BD FACSAria™ III ACDU 3B/3R/3V/5YG	648282C1	R648282C1003 R648282C10004 R648282C10005 R648282C10006 R648282C10007 R648282C10008 R648282C10009

		R648282C10010 R648282C10011 R648282C10012 R648282C10013
BD FACSAria™ III ACDU 3B/3R/6V/5YG	648282C2	R648282C20008 R648282C20009 R648282C20010 R648282C20011 R648282C20012 R648282C20013
BD FACSAria™ III ACDU 3B/3R/5YG/2NUV	648282C3	R648282C30003
BD FACSAria™ III ACDU 6B/3R/3V/2NUV	648282C4	R648282C40002
BD FACSAria™ III ACDU 6B/3R/6V/2NUV	648282C5	R648282C5004
BD FACSAria™ III 3B/3R/2V/5YG	648282C6	R648282C6001
BD FACSAria™ III 3B/3R/3V/5YG/2UV ACDU	648282D7	R648282D70001
BD FACSAria™ III ACDU 3B/3R/8V/2nUV/5YG/2BV	648282E1	R648282E1002
BD FACSAria™ III 3B/3R/6V/5YG	648282F1	R648282F10003
BD FACSAria™ Fusion	656700	R656700000013 R656700000014 R656700000015 R656700000016 R656700000017 R656700000018 R656700000019 R656700000020 R656700000021 R656700000022 R656700000023 R656700000024 R656700000025 R656700000026 R656700000027 R656700000028
BD FACSAria™ Fusion 6B/2R/3V ACDU	65670010	R656700100002
BD FACSAria™ Fusion 3B/2R/3V/4YG	65670017	R656700170002 R656700170003
BD FACSAria™ Fusion 3B/2R/3V/4YG ACDU	65670023	R656700230001
BD FACSAria™ Fusion 6B/3R/6V ACDU	656700B4	R656700B40005 R656700B40006 R656700B40007 R656700B40008
BD FACSAria™ Fusion 3B/3R/6V/5YG ACDU	656700C2	R656700C20007 R656700C20008 R656700C20009 R656700C20010
BD FACSAria™ Fusion 6B/3R/3V ACDU w/Hood	656700G2	R656700G20001
BD FACSAria™ Fusion 6B/3R/6V ACDU w/Hood	656700G3	R656700G30013
BD FACSAria™ Fusion 3B/3R/6V/5YG ACDU w/Hood	656700G5	R656700G5007 R656700G5008 R656700G5009 R656700G5011 R656700G5013 R656700G5014 R656700G5015 R656700G5016 R656700G5017 R656700G5018 R656700G5019

BD FACSAria™ Fusion 3B/3R/6V/5YG/3NUV ACDU w/Hood	656700H3	R656700H30002 R656700H30003
BD FACSAria™ Fusion 6B/3R/3UV ACDU with Hood	656700K6	R656700K60001
BD FACSAria™ Fusion 3B/3R/6V/3UV/5YG ACDU with Hood	656700L5	R656700L50001