



URGENT PRODUCT RECALL

FEBRUARY 2016 (REVISED AUGUST 2016)

Product Name	Cat. Number	Unit	UDI	Lot Number	Exp. Date
BD SurePath™ Preservative Collection Vial	490527	500 ea.	Refer to attached list		
	490505	100 ea.			
	491095	500 ea.			
	491096	500 ea.			
	491097	500 ea.			

Dear Valued Customer,

BD initially conducted a field action and communicated to you in February 2016 the potential for leaking caps. BD has determined that the initial scope of the recall shall be extended to include additional lots of product. Please see the attached list of product impacted referencing the additional material highlighted in yellow. The same precautions will apply as noted below from the original communication.

BD has confirmed that a portion of BD SurePath™ collection vials associated with specific production lots may contain caps that are cracked which can lead to leaking of the preservative fluid. Our records indicate that you may have received vials from the affected lots specified in the attached table.

BD recommends that you check current unused inventory prior to use, identify affected vials and discard per standard lab practices. BD will issue replacements for the discarded material. Additionally, please wear suitable protective clothing, gloves, and eye/face protection and follow appropriate biohazard precautions when handling all samples, as leaking caps may increase the risk of chemical or biological exposure. Cytological specimens may contain infectious agents.

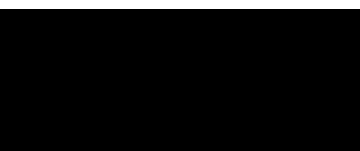
If leaking is observed after specimen collection, it is important to verify that adequate volume is available before continuing with the test. Vials from the affected lots should be processed normally if sufficient volume is present as determined through your routine laboratory procedures.

Please complete the attached form **whether or not you have any inventory remaining** so that BD may acknowledge your receipt of this notification. It is not necessary to contact BD by telephone to receive replacements. The completed form should be returned to: BDDS Regulatory Compliance, Fax: 410-316-4258 or Email: BDRC2@bd.com.

Any adverse health consequences experienced with the use of this product should be reported to BD and may be reported to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/medwatch/report.htm.

For any product inquiries, please contact BD Technical Services Department at 1-800-638-8663 ext. 2.

Please accept our apology for any inconvenience this may cause. BD is committed to providing you with the highest quality products. Thank you for your continued support.



Gail Griffiths
Sr Director, Regulatory Compliance

Fax or Email to: BD Regulatory Compliance

Fax #: 410-316-4258

Email: BDRC2@bd.com

**PLEASE RETURN THIS FORM SO THAT BD MAY ACKNOWLEDGE YOUR RECEIPT OF
THIS NOTIFICATION (MC 640)**

Please do not send multiple forms.

Facility: _____

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

Street Address: _____

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

Contact Person: _____

Telephone No.: _____ **Fax No.:** _____

Total number of affected vials discarded for replacement:

Product Name(Revised Aug 2016)	Cat. Number	Unit	Lot Number(s)	No. of Vials
BD SurePath™ Preservative Collection Vial	490527	500 ea.		
	490505	100 ea.		
	491095	500 ea.		
	491096	500 ea.		
	491097	500 ea.		

FOR BD USE ONLY

BILL TO ACC'T NO. 9000000446	ORDER REASON 517	DELIVERY P.O. NO.
SHIP TO ACC'T NO.	JUSTIFICATION CODE	INVOICE P.O. NO.

PRODUCT LIST- EXPANDED LOTS HIGHLIGHTED IN YELLOW

Product Name	Cat. #	Lot No.	Exp. Date	UDI
SurePath Collection Vial Replacement Cap	490505	5029674	N/A	N/A
		5051867	N/A	N/A
		5068841	N/A	N/A
		5083935	N/A	N/A
		5117561	N/A	N/A
		5117563	N/A	N/A
		5148682	N/A	N/A
		5148969	N/A	N/A
		5176869	N/A	N/A
		5198835	N/A	N/A
		5202623	N/A	N/A
		5232641	N/A	N/A
		5254895	N/A	N/A
		5274715	N/A	N/A
		5274717	N/A	N/A
		5288921	N/A	N/A
		5300861	N/A	N/A
		5300864	N/A	N/A
		5315568	N/A	N/A
		5315576	N/A	N/A
		6005811	N/A	N/A
		6034570	N/A	N/A
		6049623	N/A	N/A
		6053616	N/A	N/A
		6070694	N/A	N/A
SurePath GYN Preservative Vial Kit	490527	5021971	1/31/2018	(01)30382904905270(17)20180131(10)5021971(30)500
		5026951	1/31/2018	(01)30382904905270(17)20180131(10)5026951(30)500
		5027504	1/31/2018	(01)30382904905270(17)20180131(10)5027504(30)500
		5036617	1/31/2018	(01)30382904905270(17)20180131(10)5036617(30)500
		5036618	1/31/2018	(01)30382904905270(17)20180131(10)5036618(30)500
		5040883	2/28/2018	(01)30382904905270(17)20180228(10)5040883(30)500
		5042818	2/28/2018	(01)30382904905270(17)20180228(10)5042818(30)500
		5051789	2/28/2018	(01)30382904905270(17)20180228(10)5051789(30)500
		5054611	2/28/2018	(01)30382904905270(17)20180228(10)5054611(30)500
		5056854	2/28/2018	(01)30382904905270(17)20180228(10)5056854(30)500
		5058537	2/28/2018	(01)30382904905270(17)20180228(10)5058537(30)500
		5062884	2/28/2018	(01)30382904905270(17)20180228(10)5062884(30)500
		5072995	3/31/2018	(01)30382904905270(17)20180331(10)5072995(30)500
		5076742	3/31/2018	(01)30382904905270(17)20180331(10)5076742(30)500
		5077674	3/31/2018	(01)30382904905270(17)20180331(10)5077674(30)500
		5077993	3/31/2018	(01)30382904905270(17)20180331(10)5077993(30)500
		5079940	3/31/2018	(01)30382904905270(17)20180331(10)5079940(30)500
		5091576	3/31/2018	(01)30382904905270(17)20180331(10)5091576(30)500
		5091595	3/31/2018	(01)30382904905270(17)20180331(10)5091595(30)500
		5092812	3/31/2018	(01)30382904905270(17)20180331(10)5092812(30)500

SurePath GYN Preservative Vial Kit	490527	5096907	4/30/2018	(01)30382904905270(17)20180430(10)5096907(30)500
		5098734	4/30/2018	(01)30382904905270(17)20180430(10)5098734(30)500
		5098998	4/30/2018	(01)30382904905270(17)20180430(10)5098998(30)500
		5099700	4/30/2018	(01)30382904905270(17)20180430(10)5099700(30)500
		5103806	4/30/2018	(01)30382904905270(17)20180430(10)5103806(30)500
		5111748	4/30/2018	(01)30382904905270(17)20180430(10)5111748(30)500
		5114611	4/30/2018	(01)30382904905270(17)20180430(10)5114611(30)500
		5118509	4/30/2018	(01)30382904905270(17)20180430(10)5118509(30)500
		5119815	4/30/2018	(01)30382904905270(17)20180430(10)5119815(30)500
		5120573	4/30/2018	(01)30382904905270(17)20180430(10)5120573(30)500
		5124528	4/30/2018	(01)30382904905270(17)20180430(10)5124528(30)500
		5132801	5/31/2018	(01)30382904905270(17)20180531(10)5132801(30)500
		5133585	5/31/2018	(01)30382904905270(17)20180531(10)5133585(30)500
		5135799	5/31/2018	(01)30382904905270(17)20180531(10)5135799(30)500
		5139714	5/31/2018	(01)30382904905270(17)20180531(10)5139714(30)500
		5141835	5/31/2018	(01)30382904905270(17)20180531(10)5141835(30)500
		5152978	5/31/2018	(01)30382904905270(17)20180531(10)5152978(30)500
		5153808	5/31/2018	(01)30382904905270(17)20180531(10)5153808(30)500
		5155575	5/31/2018	(01)30382904905270(17)20180531(10)5155575(30)500
		5155636	6/30/2018	(01)30382904905270(17)20180630(10)5155636(30)500
		5159991	6/30/2018	(01)30382904905270(17)20180630(10)5159991(30)500
		5160987	6/30/2018	(01)30382904905270(17)20180630(10)5160987(30)500
		5162962	6/30/2018	(01)30382904905270(17)20180630(10)5162962(30)500
		5181934	6/30/2018	(01)30382904905270(17)20180630(10)5181934(30)500
		5182916	6/30/2018	(01)30382904905270(17)20180630(10)5182916(30)500
		5183715	6/30/2018	(01)30382904905270(17)20180630(10)5183715(30)500
		5187810	6/30/2018	(01)30382904905270(17)20180630(10)5187810(30)500
		5224627	8/31/2018	(01)30382904905270(17)20180831(10)5224627(30)500
		5229676	8/31/2018	(01)30382904905270(17)20180831(10)5229676(30)500
		5230761	8/31/2018	(01)30382904905270(17)20180831(10)5230761(30)500
		5245805	8/31/2018	(01)30382904905270(17)20180831(10)5245805(30)500
		5254963	9/30/2018	(01)30382904905270(17)20180930(10)5254963(30)500
		5254975	9/30/2018	(01)30382904905270(17)20180930(10)5254975(30)500
		5257946	9/30/2018	(01)30382904905270(17)20180930(10)5257946(30)500
		5259923	9/30/2018	(01)30382904905270(17)20180930(10)5259923(30)500
		5260633	9/30/2018	(01)30382904905270(17)20180930(10)5260633(30)500
		5261780	9/30/2018	(01)30382904905270(17)20180930(10)5261780(30)500
		5265751	9/30/2018	(01)30382904905270(17)20180930(10)5265751(30)500
		5286992	10/31/2018	(01)30382904905270(17)20181031(10)5286992(30)500
		5287842	10/31/2018	(01)30382904905270(17)20181031(10)5287842(30)500
		5289906	10/31/2018	(01)30382904905270(17)20181031(10)5289906(30)500
		5292932	10/31/2018	(01)30382904905270(17)20181031(10)5292932(30)500
		5299846	10/31/2018	(01)30382904905270(17)20181031(10)5299846(30)500
		5307889	10/31/2018	(01)30382904905270(17)20181031(10)5307889(30)500
		5309977	11/30/2018	(01)30382904905270(17)20181130(10)5309977(30)500
		5310989	11/30/2018	(01)30382904905270(17)20181130(10)5310989(30)500
		5313772	11/30/2018	(01)30382904905270(17)20181130(10)5313772(30)500
		5314548	11/30/2018	(01)30382904905270(17)20181130(10)5314548(30)500
		5329722	11/30/2018	(01)30382904905270(17)20181130(10)5329722(30)500

SurePath GYN Preservative Vial Kit	490527	5335687	11/30/2018	(01)30382904905270(17)20181130(10)5335687(30)500
		5336942	11/30/2018	(01)30382904905270(17)20181130(10)5336942(30)500
		5338670	12/31/2018	(01)30382904905270(17)20181231(10)5338670(30)500
		5338883	12/31/2018	(01)30382904905270(17)20181231(10)5338883(30)500
		5356723	12/31/2018	(01)30382904905270(17)20181231(10)5356723(30)500
		6004951	12/31/2018	(01)30382904905270(17)20181231(10)6004951(30)500
		6005549	12/31/2018	(01)30382904905270(17)20181231(10)6005549(30)500
		6006799	12/31/2018	(01)30382904905270(17)20181231(10)6006799(30)500
		6007867	1/31/2019	(01)30382904905270(17)20190131(10)6007867(30)500
		6008893	1/31/2019	(01)30382904905270(17)20190131(10)6008893(30)500
		6013992	1/31/2019	(01)30382904905270(17)20190131(10)6013992(30)500
		6035631	2/28/2019	(01)30382904905270(17)20190228(10)6035631(30)500
		6035921	1/31/2019	(01)30382904905270(17)20190131(10)6035921(30)500
		6039889	2/28/2019	(01)30382904905270(17)20190228(10)6039889(30)500
		6040847	2/28/2019	(01)30382904905270(17)20190228(10)6040847(30)500
		6041757	2/28/2019	(01)30382904905270(17)20190228(10)6041757(30)500
		6042626	2/28/2019	(01)30382904905270(17)20190228(10)6042626(30)500
		6042770	1/31/2019	(01)30382904905270(17)20190131(10)6042770(30)500
		6043808	1/31/2019	(01)30382904905270(17)20190131(10)6043808(30)500
		6048749	2/28/2019	(01)30382904905270(17)20190228(10)6048749(30)500
		6071899	3/31/2019	(01)30382904905270(17)20190331(10)6071899(30)500
		6075907	3/31/2019	(01)30382904905270(17)20190331(10)6075907(30)500
		6077898	3/31/2019	(01)30382904905270(17)20190331(10)6077898(30)500
		6078502	3/31/2019	(01)30382904905270(17)20190331(10)6078502(30)500
		6082738	3/31/2019	(01)30382904905270(17)20190331(10)6082738(30)500
		6083562	3/31/2019	(01)30382904905270(17)20190331(10)6083562(30)500
SurePath GYN Preservative Vial Kit with Cervex-Brush	491095	5019819	1/31/2018	(01)30382904910950(17)20180131(10)5019819(30)500
		5043915	2/28/2018	(01)30382904910950(17)20180228(10)5043915(30)500
		5071607	3/31/2018	(01)30382904910950(17)20180331(10)5071607(30)500
		5090525	3/31/2018	(01)30382904910950(17)20180331(10)5090525(30)500
		5125823	5/31/2018	(01)30382904910950(17)20180531(10)5125823(30)500
		5126797	5/31/2018	(01)30382904910950(17)20180531(10)5126797(30)500
		5166589	6/30/2018	(01)30382904910950(17)20180630(10)5166589(30)500
		5167807	6/30/2018	(01)30382904910950(17)20180630(10)5167807(30)500
		5233517	8/31/2018	(01)30382904910950(17)20180831(10)5233517(30)500
		5294898	10/31/2018	(01)30382904910950(17)20181031(10)5294898(30)500
		5341974	12/21/2018	(01)30382904910950(17)20181221(10)5341974(30)500
		5355511	12/31/2018	(01)30382904910950(17)20181231(10)5355511(30)500
		6027958	1/31/2019	(01)30382904910950(17)20190131(10)6027958(30)500
		6088657	3/31/2019	(01)30382904910950(17)20190331(10)6088657(30)500
SurePath GYN Preservative Vial Kit with Cervex-Brush Combi	491096	5019820	1/31/2018	(01)30382904910960(17)20180131(10)5019820(30)500
		5042809	2/28/2018	(01)30382904910960(17)20180228(10)5042809(30)500
		5098503	4/30/2018	(01)30382904910960(17)20180430(10)5098503(30)500
		5126602	5/31/2018	(01)30382904910960(17)20180531(10)5126602(30)500
		5237775	8/31/2018	(01)30382904910960(17)20180831(10)5237775(30)500
		5315970	11/30/2018	(01)30382904910960(17)20181130(10)5315970(30)500
		5355504	12/31/2018	(01)30382904910960(17)20181231(10)5355504(30)500
		6089538	3/31/2019	(01)30382904910960(17)20190331(10)6089538(30)500

SurePath GYN Preservative Vial Kit with Brush/Spatula	491097	5019816	1/31/2018	(01)30382904910970(17)20180131(10)5019816(30)500
		5019865	1/31/2018	(01)30382904910970(17)20180131(10)5019865(30)500
		5047951	2/28/2018	(01)30382904910970(17)20180228(10)5047951(30)500
		5089823	3/31/2018	(01)30382904910970(17)20180331(10)5089823(30)500
		5112617	4/30/2018	(01)30382904910970(17)20180430(10)5112617(30)500
		5126803	5/31/2018	(01)30382904910970(17)20180531(10)5126803(30)500
		5167835	6/30/2018	(01)30382904910970(17)20180630(10)5167835(30)500
		5168911	6/30/2018	(01)30382904910970(17)20180630(10)5168911(30)500
		5232660	8/31/2018	(01)30382904910970(17)20180831(10)5232660(30)500
		5292765	10/31/2018	(01)30382904910970(17)20181031(10)5292765(30)500
		5315745	11/30/2018	(01)30382904910970(17)20181130(10)5315745(30)500
		5352746	12/31/2018	(01)30382904910970(17)20181231(10)5352746(30)500
		6026695	1/31/2019	(01)30382904910970(17)20190131(10)6026695(30)500
		6049878	2/28/2019	(01)30382904910970(17)20190228(10)6049878(30)500
		6084731	3/31/2019	(01)30382904910970(17)20190331(10)6084731(30)500