



URGENT PRODUCT RECALL

09 February 2017

Product Name	Catalog No.	Lot No.
BD Plastipak™ 100mL Syringe, Catheter tip with Luer slip adaptor	300605	Refer to Table A below

Dear Customer,

Description of the problem:

BD is conducting a voluntary field action for all lots of BD 100mL Plastipak Catheter Tip (CT) syringe labeled with a 5-year expiration date. The syringes are being recalled due to leakage past stopper failures during internal routine real time stability tests, with failures beginning at the 2-year time point. No adverse event has been reported for this issue at this time.

Although the product can safely be used for 18 months after manufacturing, to avoid mistakes, we are recalling all lots labelled with a shelf life of 5 years. All affected lots are listed in table A below. Users should stop using these lots immediately.

Potential hazard and potential risk to patients

As mentioned, there is an increased risk of leakage past the stopper starting at 18 months after production. In exceptional cases, this might result in delay in therapy, underdosing of the patient or exposure of clinicians or patients to drugs.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed in table A below. Please discontinue use, quarantine and return the product subject to the recall from inventory to your distributor for destruction. Upon receipt of the returned product, we will issue replacement product.



2. As a requirement of our Regulatory Tracking Process, we request that you complete the enclosed form, even if you no longer have the affected lot listed in your inventory. Please sign and fax the completed form to your local BD contact confirming that you have read and understood this notice.

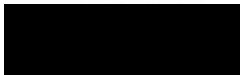
We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

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

The safety and well-being of patients and healthcare workers is the primary objective for BD and we aim to ensure that only the highest quality product is used by our customers. 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,



Rose Kwong
Senior Regulatory Affairs and Compliance Executive
South East Asia

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Table A:

LOT	LABELED EXP DATE	LOT	LABELED EXP DATE	LOT	LABELED EXP DATE	LOT	LABELED EXP DATE
1201207	DEC-2016	1206284	MAY-2017	1302257	JAN-2018	1308238	JUL-2018
1201226	DEC-2016	1206300	MAY-2017	1302271	JAN-2018	1309200	AUG-2018
1201242	DEC-2016	1206302	MAY-2017	1302282	JAN-2018	1309223	AUG-2018
1201252	DEC-2016	1207221	JUN-2017	1302301	JAN-2018	1309248	AUG-2018
1201267	DEC-2016	1207310	JUN-2017	1303203	FEB-2018	1309272	AUG-2018
1201281	JAN-2017	1207323	JUN-2017	1303215	FEB-2018	1310203	SEP-2018
1202210	JAN-2017	1209201	AUG-2017	1303233	FEB-2018	1310213	SEP-2018
1202224	JAN-2017	1209214	AUG-2017	1303246	FEB-2018	1310232	SEP-2018
1202227	JAN-2017	1209230	AUG-2017	1303263	FEB-2018	1310244	SEP-2018
1202250	JAN-2017	1209249	AUG-2017	1303275	FEB-2018	1310256	SEP-2018
1202265	JAN-2017	1209263	AUG-2017	1303293	FEB-2018	1310270	SEP-2018
1202291	JAN-2017	1210206	SEP-2017	1304218	MAR-2018	1310288	SEP-2018
1203216	FEB-2017	1210211	SEP-2017	1304234	MAR-2018	1311203	OCT-2018
1203235	FEB-2017	1210243	SEP-2017	1304254	MAR-2018	1311212	OCT-2018
1203252	FEB-2017	1210289	SEP-2017	1304267	MAR-2018	1311231	OCT-2018
1203269	FEB-2017	1210305	SEP-2017	1304285	MAR-2018	1311233	OCT-2018
1203283	FEB-2017	1211204	OCT-2017	1304287	MAR-2018	1311243	OCT-2018
1203310	FEB-2017	1211240	OCT-2017	1304299	MAR-2018	1311257	OCT-2018
1204213	MAR-2017	1211251	OCT-2017	1304600	MAR-2018	1311277	OCT-2018
1204238	MAR-2017	1211272	OCT-2017	1305210	APR-2018	1311278	OCT-2018
1204255	MAR-2017	1211296	OCT-2017	1305226	APR-2018	1312200	NOV-2018
1204273	MAR-2017	1211301	OCT-2017	1305715	APR-2018	1312210	NOV-2018
1204289	MAR-2017	1212202	NOV-2017	1305730	APR-2018	1312216	NOV-2018
1205211	APR-2017	1212226	NOV-2017	1305740	APR-2018	1312221	NOV-2018
1205228	APR-2017	1212248	NOV-2017	1305748	APR-2018	1401202	DEC-2018
1205236	APR-2017	1301200	DEC-2017	1306206	MAY-2018	1401203	DEC-2018
1205253	APR-2017	1301209	DEC-2017	1306226	MAY-2018	1401211	DEC-2018
1205265	APR-2017	1301210	DEC-2017	1306263	MAY-2018	1401300	DEC-2018
1205288	APR-2017	1301230	DEC-2017	1306283	MAY-2018	1401349	DEC-2018
1205307	APR-2017	1301253	DEC-2017	1306297	MAY-2018	1401351	DEC-2018
1205327	APR-2017	1301263	DEC-2017	1307214	JUN-2018	1401364	DEC-2018
1206217	MAY-2017	1301279	DEC-2017	1307244	JUN-2018	1401378	DEC-2018
1206233	MAY-2017	1302208	JAN-2018	1307263	JUN-2018	1402207	JAN-2019
1206251	MAY-2017	1302223	JAN-2018	1307282	JUN-2018	1402309	JAN-2019
1206266	MAY-2017	1302238	JAN-2018	1308207	JUL-2018	1402317	JAN-2019

Table A (Continuation):

LOT	LABELED EXP DATE	LOT	LABELED EXP DATE	LOT	LABELED EXP DATE	LOT	LABELED EXP DATE
1402338	JAN-2019	1410263	SEP-2019	1504242	MAR-2020	1511203P	OCT-2020
1402356	JAN-2019	1410276	SEP-2019	1504257	MAR-2020	1511204P	OCT-2020
1402375	JAN-2019	1410294	SEP-2019	1504276	MAR-2020	1511205P	OCT-2020
1403219	FEB-2019	1410314	SEP-2019	1505202	APR-2020	1511277P	OCT-2020
1403248	FEB-2019	1411212	OCT-2019	1505232	APR-2020	1512200P	NOV-2020
1403267	FEB-2019	1411238	OCT-2019	1505242	APR-2020	1512201P	NOV-2020
1403277	FEB-2019	1411260	OCT-2019	1505267	APR-2020	1601200P	DEC-2020
1403306	FEB-2019	1411277	OCT-2019	1505290	APR-2020	1601215P	DEC-2020
1404208	MAR-2019	1411303	OCT-2019	1506200	MAY-2020	1601216P	DEC-2020
1404228	MAR-2019	1411318	OCT-2019	1506216	MAY-2020	1601254P	DEC-2020
1404257	MAR-2019	1412211	NOV-2019	1506217	MAY-2020	1601273P	DEC-2020
1404279	MAR-2019	1412237	NOV-2019	1506269	MAY-2020	1602200P	JAN-2021
1404301	MAR-2019	1412251	NOV-2019	1506270	MAY-2020	1602201P	JAN-2021
1404601	MAR-2019	1412275	NOV-2019	1507200	JUN-2020	1602202P	JAN-2021
1405216	APR-2019	1501200	DEC-2019	1507201	JUN-2020	1602203P	JAN-2021
1405242	APR-2019	1501208	DEC-2019	1507202	JUN-2020	1602204P	JAN-2021
1405266	APR-2019	1501245	DEC-2019	1507203	JUN-2020	1603200P	FEB-2021
1405294	APR-2019	1501257	DEC-2019	1507305	JUN-2020	1603201P	FEB-2021
1405313	APR-2019	1501276	DEC-2019	1508245	JUL-2020	1603202P	FEB-2021
1406218	MAY-2019	1501286	DEC-2019	1508253	JUL-2020	1603203P	FEB-2021
1406244	MAY-2019	1501299	DEC-2019	1508267	JUL-2020	1604200P	MAR-2021
1406274	MAY-2019	1502200	JAN-2020	1509207	AUG-2020	1604201P	MAR-2021
1407220	JUN-2019	1502217	JAN-2020	1509208	AUG-2020	1604202P	MAR-2021
1407240	JUN-2019	1502230	JAN-2020	1509209	AUG-2020	1604203P	MAR-2021
1407266	JUN-2019	1502244	JAN-2020	1509210	AUG-2020	1604204P	MAR-2021
1407286	JUN-2019	1502257	JAN-2020	1509268	AUG-2020	1604205P	MAR-2021
1407311	JUN-2019	1502270	JAN-2020	1510200	SEP-2020	1605200P	APR-2021
1408209	JUL-2019	1502285	JAN-2020	1510201	SEP-2020	1605201P	APR-2021
1408257	JUL-2019	1503208	FEB-2020	1510250	SEP-2020	1605202P	APR-2021
1408274	JUL-2019	1503230	FEB-2020	1510251	SEP-2020	1605203P	APR-2021
1409202	AUG-2019	1503246	FEB-2020	1510252	SEP-2020		
1409228	AUG-2019	1503264	FEB-2020	1510297	SEP-2020		
1410200	SEP-2019	1503277	FEB-2020	1511200P	OCT-2020		
1410220	SEP-2019	1503298	FEB-2020	1511201P	OCT-2020		
1410243	SEP-2019	1504216	MAR-2020	1511202P	OCT-2020		



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(CUSTOMER ACKNOWLEDGEMENT)

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

Please tick as appropriate.

- ☐ We do not have any stock of the below affected products on hand.
- ☐ We have a total of _____ unit(s) of the affected product listed below in our inventory to be returned to distributor for destruction.

Note: Please provide details on the quantity of affected units as per below table.

Cat. Number	Lot Numbers	Quantity (eaches) received	Quantity (eaches) used	Remaining Quantity (eaches) in inventory to be returned to distributor for destruction
300605	1510201			

Please return only product from the lot referenced in the recall letter; you will only receive product replacement for recalled product that you return.

Completed by:

☐ I have read and understood the attached notice.

Name: _____ Signature / Date: _____

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

Street Address: _____

Telephone No.: _____ Fax No.: _____

Company stamp:

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