URGENT: FIELD SAFETY NOTICE
MSS-16-730-FA

Voluntary Product Recall

Date: <<insert date here>>

BD Plastipak™ Syringe, Catheter tip with Luer slip adaptor
Catalogue Number: 300605

For the Attention of:

- Procurement, Medical Director, Risk Manager, Head of Pharmacy, Medical Device Safety Officer

Description of the problem:

BD is conducting a voluntary field safety corrective action for all lots of BD 100ml Plastipak Catheter Tip (CT) syringe labeled with a 5yr 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 2yr 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.

Actions:

1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed below, and quarantine product subject to the recall.

2. **Complete the Recall Response Card form and fax it back to BD at xxx-xxx-xxxx or email the completed form to yyyy@yy.com**

Upon receipt of the Notice of Return BD will contact you to organize the replacement of the recalled product at no charge.

NOTE: If you do not have any of the affected lots in your inventory, please complete the Notice of Return form indicating you have zero (0) quantity and return the completed form back to BD at **(BD office contact fax. number).**

Transmission of this Field Safety Notice

Please distribute this communication to all users of the BD Plastipak 100mL Catheter Tip (CT) Syringes affected.

Contact Reference Person

If you have any questions, or would like to discuss this issue further, please feel free to contact your local BD Account Manager **add contact details**

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,

[redacted]

BD Medical MPS - EEMA

(Name & Signature of Local Contact)

Attachment A:

LOT	LABELED EXP DATE
1201207	DEC-2016
1201226	DEC-2016
1201242	DEC-2016
1201252	DEC-2016
1201267	DEC-2016
1201281	JAN-2017
1202210	JAN-2017
1202224	JAN-2017
1202227	JAN-2017
1202250	JAN-2017
1202265	JAN-2017
1202291	JAN-2017
1203216	FEB-2017
1203235	FEB-2017
1203252	FEB-2017
1203269	FEB-2017
1203283	FEB-2017
1203310	FEB-2017
1204213	MAR-2017
1204238	MAR-2017
1204255	MAR-2017
1204273	MAR-2017
1204289	MAR-2017
1205211	APR-2017
1205228	APR-2017
1205236	APR-2017
1205253	APR-2017
1205265	APR-2017
1205288	APR-2017
1205307	APR-2017
1205327	APR-2017
1206217	MAY-2017
1206233	MAY-2017
1206251	MAY-2017
1206266	MAY-2017

LOT	LABELED EXP DATE
1206284	MAY-2017
1206300	MAY-2017
1206302	MAY-2017
1207221	JUN-2017
1207310	JUN-2017
1207323	JUN-2017
1209201	AUG-2017
1209214	AUG-2017
1209230	AUG-2017
1209249	AUG-2017
1209263	AUG-2017
1210206	SEP-2017
1210211	SEP-2017
1210243	SEP-2017
1210289	SEP-2017
1210305	SEP-2017
1211204	OCT-2017
1211240	OCT-2017
1211251	OCT-2017
1211272	OCT-2017
1211296	OCT-2017
1211301	OCT-2017
1212202	NOV-2017
1212226	NOV-2017
1212248	NOV-2017
1301200	DEC-2017
1301209	DEC-2017
1301210	DEC-2017
1301230	DEC-2017
1301253	DEC-2017
1301263	DEC-2017
1301279	DEC-2017
1302208	JAN-2018
1302223	JAN-2018
1302238	JAN-2018

LOT	LABELED EXP DATE
1302257	JAN-2018
1302271	JAN-2018
1302282	JAN-2018
1302301	JAN-2018
1303203	FEB-2018
1303215	FEB-2018
1303233	FEB-2018
1303246	FEB-2018
1303263	FEB-2018
1303275	FEB-2018
1303293	FEB-2018
1304218	MAR-2018
1304234	MAR-2018
1304254	MAR-2018
1304267	MAR-2018
1304285	MAR-2018
1304287	MAR-2018
1304299	MAR-2018
1304600	MAR-2018
1305210	APR-2018
1305226	APR-2018
1305715	APR-2018
1305730	APR-2018
1305740	APR-2018
1305748	APR-2018
1306206	MAY-2018
1306226	MAY-2018
1306263	MAY-2018
1306283	MAY-2018
1306297	MAY-2018
1307214	JUN-2018
1307244	JUN-2018
1307263	JUN-2018
1307282	JUN-2018
1308207	JUL-2018

LOT	LABELED EXP DATE
1308238	JUL-2018
1309200	AUG-2018
1309223	AUG-2018
1309248	AUG-2018
1309272	AUG-2018
1310203	SEP-2018
1310213	SEP-2018
1310232	SEP-2018
1310244	SEP-2018
1310256	SEP-2018
1310270	SEP-2018
1310288	SEP-2018
1311203	OCT-2018
1311212	OCT-2018
1311231	OCT-2018
1311233	OCT-2018
1311243	OCT-2018
1311257	OCT-2018
1311277	OCT-2018
1311278	OCT-2018
1312200	NOV-2018
1312210	NOV-2018
1312216	NOV-2018
1312221	NOV-2018
1401202	DEC-2018
1401203	DEC-2018
1401211	DEC-2018
1401300	DEC-2018
1401349	DEC-2018
1401351	DEC-2018
1401364	DEC-2018
1401378	DEC-2018
1402207	JAN-2019
1402309	JAN-2019
1402317	JAN-2019

Attachment A (Continuation):

LOT	LABELED EXP DATE
1402338	JAN-2019
1402356	JAN-2019
1402375	JAN-2019
1403219	FEB-2019
1403248	FEB-2019
1403267	FEB-2019
1403277	FEB-2019
1403306	FEB-2019
1404208	MAR-2019
1404228	MAR-2019
1404257	MAR-2019
1404279	MAR-2019
1404301	MAR-2019
1404601	MAR-2019
1405216	APR-2019
1405242	APR-2019
1405266	APR-2019
1405294	APR-2019
1405313	APR-2019
1406218	MAY-2019
1406244	MAY-2019
1406274	MAY-2019
1407220	JUN-2019
1407240	JUN-2019
1407266	JUN-2019
1407286	JUN-2019
1407311	JUN-2019
1408209	JUL-2019
1408257	JUL-2019
1408274	JUL-2019
1409202	AUG-2019
1409228	AUG-2019
1410200	SEP-2019
1410220	SEP-2019
1410243	SEP-2019

LOT	LABELED EXP DATE
1410263	SEP-2019
1410276	SEP-2019
1410294	SEP-2019
1410314	SEP-2019
1411212	OCT-2019
1411238	OCT-2019
1411260	OCT-2019
1411277	OCT-2019
1411303	OCT-2019
1411318	OCT-2019
1412211	NOV-2019
1412237	NOV-2019
1412251	NOV-2019
1412275	NOV-2019
1501200	DEC-2019
1501208	DEC-2019
1501245	DEC-2019
1501257	DEC-2019
1501276	DEC-2019
1501286	DEC-2019
1501299	DEC-2019
1502200	JAN-2020
1502217	JAN-2020
1502230	JAN-2020
1502244	JAN-2020
1502257	JAN-2020
1502270	JAN-2020
1502285	JAN-2020
1503208	FEB-2020
1503230	FEB-2020
1503246	FEB-2020
1503264	FEB-2020
1503277	FEB-2020
1503298	FEB-2020
1504216	MAR-2020

LOT	LABELED EXP DATE
1504242	MAR-2020
1504257	MAR-2020
1504276	MAR-2020
1505202	APR-2020
1505232	APR-2020
1505242	APR-2020
1505267	APR-2020
1505290	APR-2020
1506200	MAY-2020
1506216	MAY-2020
1506217	MAY-2020
1506269	MAY-2020
1506270	MAY-2020
1507200	JUN-2020
1507201	JUN-2020
1507202	JUN-2020
1507203	JUN-2020
1507305	JUN-2020
1508245	JUL-2020
1508253	JUL-2020
1508267	JUL-2020
1509207	AUG-2020
1509208	AUG-2020
1509209	AUG-2020
1509210	AUG-2020
1509268	AUG-2020
1510200	SEP-2020
1510201	SEP-2020
1510250	SEP-2020
1510251	SEP-2020
1510252	SEP-2020
1510297	SEP-2020
1511200P	OCT-2020
1511201P	OCT-2020
1511202P	OCT-2020

LOT	LABELED EXP DATE
1511203P	OCT-2020
1511204P	OCT-2020
1511205P	OCT-2020
1511277P	OCT-2020
1512200P	NOV-2020
1512201P	NOV-2020
1601200P	DEC-2020
1601215P	DEC-2020
1601216P	DEC-2020
1601254P	DEC-2020
1601273P	DEC-2020
1602200P	JAN-2021
1602201P	JAN-2021
1602202P	JAN-2021
1602203P	JAN-2021
1602204P	JAN-2021
1603200P	FEB-2021
1603201P	FEB-2021
1603202P	FEB-2021
1603203P	FEB-2021
1604200P	MAR-2021
1604201P	MAR-2021
1604202P	MAR-2021
1604203P	MAR-2021
1604204P	MAR-2021
1604205P	MAR-2021
1605200P	APR-2021
1605201P	APR-2021
1605202P	APR-2021
1605203P	APR-2021

NOTICE OF RETURN

BD Plastipak™ Syringe, Catheter tip with Luer slip adaptor
Catalogue Number: 300605

Check inventory and complete the information below, even if you do not have or are not returning the affected product.
Failure to complete all sections of this page may result in improper or delayed of replacement product.

Fax the completed form to{ Contact Name} at {Fax Number} **or email the completed form to (BD country contact email).**

Upon receipt of the Notice of Return BD will contact you to organize the replacement of the recalled product at no charge.

Please check your return carefully and complete the contact information below. Only return product from the lots referenced in the recalled letter, you will only receive replacement for recalled product that you return.

Required Information:

_____ _____
Establishment Name : Phone Number:

_____
Address/City/Postcode :

_____
Lot Number and Quantity Returned (units) :

_____
Completed by: (Print Name/Signature/Date)

BD Office use only

_____
Lot Number and Quantity Returned (units) :

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

Medtronic
60 Middletown Avenue
North Haven, CT 06473
www.medtronic.com

URGENT: FIELD SAFETY NOTICE
Certain Covidien Procedure Packs containing BD Plastipak™ Syringe 100 ml with catheter neck

June X, 2017

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic received notification of a recall by Becton Dickinson of BD Plastipak™ Syringes 100 ml with catheter neck that are contained in specific procedure packs manufactured by Covidien, now a part of Medtronic. The attached Urgent Field Safety Notification MSS-16-730-FA contains pertinent information related to this recall. The specific Covidien kits that are affected are listed on Attachment A contain the affected syringes.

Medtronic is requesting that customers do not use the BD Plastipak™ Syringes 100 ml with catheter neck contained in the product kits listed on Attachment A and discard the affected syringes. The BD Plastipak™ syringes included in these kits does not impact the integrity of the remaining products in the kit.

Actions:

1. Please do not use the BD Plastipak™ Syringes 100 ml with catheter neck contained in the affected item codes/lots listed on Attachment A. Customers are requested to discard affected syringes.

2. Please complete the attached form and send it to XXXXXX@Medtronic.com or fax to XXX) XXX-XXXX.

This action is being taken with the knowledge of (Insert local Competent Authority name) . We request you report any quality problems experienced with the use of this product to Medtronic:

- Email your local Medtronic representative at: XXXXXXXXX@Medtronic.com

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

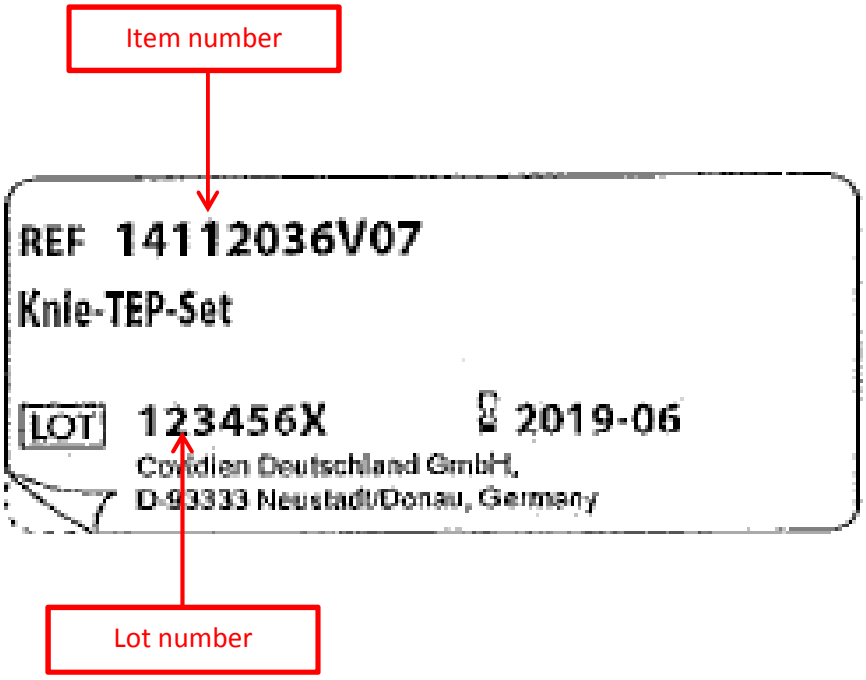
Sincerely,

Medtronic

Attachment A

Item Code	Description	Lots						
14112033-08	Laparotomie-Set	234395X	240210X	245184X	253462X	262055X	268401X	276732
14112033-07	Laparotomie-Set	162020X	176361X	182961X	188674X	205968X	214822X	223113X
1419889-08	Offene rad. Prostatektomie-Set	159265X	180467X	203403X	246108X	263901X	225717X	278188
1417562-10	Großes-Set Hüfte u. Knie Univers	164104X	192552X	208089X	224726X			
14112036-06	Knie-TEP-Set [redacted]	196721X	219653X	229970X	244085X			
14113142-11	BAA Set [redacted]	227714X	244259X	255217X	263768X			
14112036-05	Knie-TEP-Set	159758	159758X	181738X				
14113603-07	MIC-MK-Set	173088X						
14113603-08	MIC-MK-Set	223110X						
14113603-10	MIC-MK-Set [redacted]	251619X						
14112036V07	Knie-TEP-Set [redacted]	262301X						

Attachment B



Acknowledgement and Receipt Form—Response is Required

Certain Coviden Deutschland Procedure Packs containing BD Plastipak™ Syringe 100 ml with catheter neck

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone#: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the Urgent Field Safety Notice regarding BD Plastipak™ Syringes 100 ml with catheter neck by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

_____	_____	_____	_____
Name: (print)	Signature:	Telephone:	Date:

If you have any questions regarding this Medical Device Correction, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

local Medtronic representative at: XXXXXXXX@Medtronic.com **or XXXXXX XXXX**