**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:**

* Distributor

**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:**

The following actions are required of you:

* Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed below, and quarantine product subject to the recall.
* Identify and inform all your customers who receive the below products and send them a copy of the attached customer Field Safety Notice (FSN).
* Verify, through whichever means you deem appropriate, that each of these customers receives the FSN.
* Maintain all records associated with this FSCA.
* **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.

**Transmission of this Field Safety Notice**

Please distribute this communication to all customers of the BD Plastipak 100mL 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,

ppa Dr. Bernd Peschke
Director Regulatory Compliance
BD Medical MPS - EEMA **(Name & Signature of Local Contact)**

Attachment 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 |

Attachment 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 |  |  |  |

**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.

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| **Required Information:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_Company 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*