



URGENT: PRODUCT RECALL

PRODUCT: BD 60 ml Luer-Lok™ Syringes, Reorder Number 309653
Please see attached list of affected lot numbers

July 15, 2008

Attention: BD Syringe Customer

BD is conducting a recall on the above referenced product. BD has determined that unit package seal integrity (and resulting product sterility) can be adversely affected when the product is exposed to low atmospheric pressure experienced at high altitudes (e.g. during product shipping).

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory and determine if you have any of the affected product. If so, please remove it from inventory. Please reference the attached illustrations to locate the product catalog, description and lot number.
2. Complete the enclosed Customer Packing List. The product can be returned by following the instructions on the packing list. Upon receipt of returned product, BD will send you replacement product (replacement product is readily available).

This recall only affects products identified on the attached list.

Representatives are available to assist you in this process and answer any questions you may have about this recall, the product return procedure, and how to obtain replacement product. Please contact the BD Recall Hotline at 866-421-1675, Monday – Friday, 8:00 AM – 6:00 PM Central Time.

Please accept our apology for any inconvenience this recall may cause. We at BD are committed to providing our customers with the highest quality products and appreciate your continued support.

Sincerely,

A handwritten signature in blue ink that reads "Greg Morgan".

Greg Morgan
BD Regulatory Compliance

Product Recall
Customer Packing List



BD 60 ml Luer-Lok™ Syringes (Reorder#309653): Please see attached list of affected lot numbers.

Product Return Instructions:

1. Enclose this Packing List with the shipment, and provide a contact name and number.
2. Please enter quantity of product to be returned.
3. The simplest way to return product would be to access the following UPS website:
<http://www.upsrow.com/bd>
User name: bd, Password: bd
When you access the site, you can select among 3 UPS shipping options. If you select the initial option, "Display Return Label Only", you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select the either of the other two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.
4. If you do not have access to the internet you can call UPS at: 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: 0ER739. Product should be returned to:
BD Distribution Center
200 Birch Creek Road
Swedesboro, NJ 08085
5. Upon receipt of returned product BD will provide replacement product (please allow 4-6 weeks for shipment of replacement product). A returned goods authorization is NOT required for this recall return process.

Please check your return carefully and fill out below. Enclose a copy of this packing slip with your shipment. Please indicate the number of syringes you are returning: _____
Please return only syringes from the lots referenced on the attached list, you will only receive replacement for recalled product that you return.

Contact Information:

Facility Name:

Contact person:

Phone#:

Address (no P.O. Boxes)

City:

State:

Zip Code:

Distributor Name (from who you purchased product):

Address:

List of Affected Lot Numbers:


BD has a 7 digit lot numbering system. This recall impacts lot numbers beginning with the numbers 5, 6, or 7. It also impacts the following lot numbers:

| | |
|---------|---------|
| 8010954 | 8058890 |
| 8014571 | 8058896 |
| 8031115 | 8058898 |
| 8031117 | 8058900 |
| 8031119 | 8058902 |
| 8031124 | 8072401 |
| 8031133 | 8072409 |
| 8038154 | 8072414 |
| 8038158 | 8072419 |
| 8045564 | 8079645 |
| 8045567 | 8079656 |




(Note: In order to make the recall practical for customers to implement, BD has requested the return of lots beginning with the numbers 5, 6, or 7. While not all lots beginning with the digits 5, 6 and 7 exhibit the issue, it is much easier to instruct customers to return these lots, rather than have customers examine/check a more comprehensive list of affected and unaffected lots.)

Please see the attached illustrations for locating product lot numbers.

Case Label

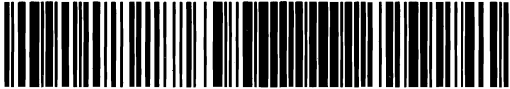
 **BD 60ml Syringe**
Luer-Lok™ Tip


Jeringa • Seringa • Seringue • Spritze • Siringa • Spult
Spruta • Sprøjte • Ruisku • Σύριγγα • Sprøyte • Strzykawka
Injekcijska brizgalka • Injekčná striekačka • Süstäl
Fecskendő • Švirkštas • Stříkačka • Šjirce • Şiringa • Шприц
Štrcaljka • Seringã • Спринцовка • Шприц


 **STERILE**  Do Not Reuse  **CE** 0050

BD, Franklin Lakes, NJ, 07417 USA. Made in USA. www.bd.com
Authorized Representative: BD, Laagstraat 57, B-9140, Temse, Belgium
BD, BD Logo and Luer-Lok are trademarks of Becton, Dickinson and Company. ©2005 BD

160(4 x 40) **REF 309653**



(17) 120600 (10) 7179827 (30) 160


(01) 5038290 309653 9

 2012-06


DG561604

LOT 7179827



Reorder Number

Lot Number

Shelf Carton Label


 **BD 60ml Syringe**
Luer-Lok™ Tip

Jeringa • Seringa • Seringue • Spritze • Siringa • Spuit
Spruta • Sprøjte • Ruisku • Σύριγγα • Sprøyte • Strzykawka
Injekcijska brizgalka • Injekčná striekačka • Süstäl
Fecskendő • Švirkštas • Stříkačka • Šjirce • Şiringa • Шприц
Štrcaljka • Seringã • Спринцовка • Шприц



40 **REF 309653**


(17) 120900 (10) 7291706 (30) 40


(01) 3038290 309653 5

 2012-09

DG567805

LOT 7291706


Reorder Number

Lot Number

Unit Package

Top



Reorder Number

Bottom



Lot Number