## **BD Medical**

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Tel: 201.847.6800 www.bd.com

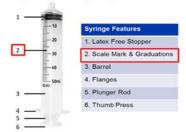
August 26, 2019



## Dear Valued Customer:

In an effort to continuously improve our offerings and address the evolving needs of the market, we are writing to inform you that BD is standardizing the recommended volumetric capacity for large volume syringes. This change will impact syringe offerings across the general use (BD Luer-Lok $^{\text{TM}}$  Tip, Luer Slip Tip, Eccentric Tip and Catheter Tip), oral and enteral syringe categories. With this change, the scale mark (Figure 1) on all 60 mL BD $^{\text{®}}$  Syringes will no longer extend beyond 50 mL (Figure 2), and the product will be labeled and sold as a 50 mL syringe globally. A summary table indicating the scope of changes can be found below (Table 1).

Figure 1: Syringe features



Scale mark for 60 mL BD® Syringes will no longer extend beyond 50 mL

Figure 2: Images of new 50 mL BD® Syringe and current 60 mL BD® Syringe



Table 1: Summary of change

| Syringe feature            | Scope of change (no change to form, fit, function or raw materials)      |  |  |
|----------------------------|--|--|--|
| Latex free rubber stopper* | No change to stopper material or dimensions                              |  |  |
| Scale mark                 | Scale mark reduced from 60 mL to 50 mL                                   |  |  |
| Graduations                | Graduations remain at 1 mL increments                                    |  |  |
| Barrel                     | No change to barrel material or dimensions                               |  |  |
| Flanges                    | No change to flange material or dimensions                               |  |  |
| Plunger rod                | No change to plunger rod material or dimensions                          |  |  |
| Thumb press                | No change to thumb press material or dimensions                          |  |  |
| Catalog / order number     | No change to catalog / order number unless otherwise noted in Appendix I |  |  |

<sup>\*</sup>BD® Syringes are not formulated with natural rubber latex.

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There are no changes to device form, fit, function or raw material composition, and therefore, the new 50 mL BD® Syringe will maintain compatibility with any ancillary devices currently being used for either preparation or administration of medications (e.g., syringe pumps, robotic filling equipment, etc.).

With the exception of the 50 mL BD® Catheter Tip Syringe (309620), it is anticipated that 50 mL BD® Syringes will arrive at your facilities between October and December 2019. Due to current demand and inventory levels, it is anticipated that the transition from 60 to 50 mL for the BD Catheter Tip Syringe (309620) may occur as early as mid-September.

We are implementing this change for three main reasons:

- 1) Help drive safe sterile compounding practice by preventing overfill of medications and complying with aseptic technique.<sup>1-3</sup>
- 2) Standardize the BD® large volume syringe offering to better manage market supply and mitigate the risk of product shortages resulting from market related events.
- 3) Align with other medication receptacles that may be in short supply (*i.e.*, 50 mL mini bags, 50% dextrose prefilled syringe, sodium bicarbonate prefilled syringe, etc.) to facilitate product substitution with no anticipated clinical impact.

Please refer to Appendix I for a list of BD catalog numbers that will be impacted as well as any substitute catalog numbers that may be introduced as part of this change.

If you have any questions, please contact the BD Customer Clinical Support hotline at 1.800.555.7422 (*U.S. and Canada only*) or medical.support@bd.com.

We thank you for your continued support of BD, its products and services.

Sincerely,

Akshay Yeshokumar

Associate Director Global Marketing

WW Hypodermic

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1. Wilson, JP, Solimando, DA. Aseptic Technique as a Safety Precaution in the Preparation of Antineoplastic Agents. *Hospital Pharmacy*. November 1981; Vol 16:575-581.

2. McElhiney LF. Aseptic Technique. In: Buchanan EC, Schneider PJ, Forrey RA, eds. *Compounding sterile preparations*. 4th ed. Bethesda, MD: American Society of Health-System Pharmacists; 2017.

3. Aseptic Technique, Sterile Compounding, and IV Admixture Programs. *Practice Basics*. American Society of Health-System Pharmacists, pp. 47; 2017. Retrieved from <a href="http://www.ashpmedia.org/bookstore/P2074/Chpt-16.ppt">http://www.ashpmedia.org/bookstore/P2074/Chpt-16.ppt</a>.

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## Appendix I

The table below indicates the existing BD catalog numbers that will be impacted by this change. Details of any replacement category numbers are also contained within the table for any instances where it has been necessary to introduce the new 50 mL syringes under a new BD catalog number. Also included are the markets where each BD catalog number is sold.

| Existing BD<br>catalog<br>number | Existing BD catalog description                        | New BD catalog description                             | Replacement BD catalog number | Markets served  |
|----------------------------------|--|--|-------------------------------|---|
| 301035                           | Syringe Non-Sterile<br>60 mL Luer-Lok™                 | Syringe Non-Sterile<br>50 mL Luer-Lok™                 | N/A                           | Canada, Europe, United<br>States  |
| 301036                           | Syringe Non-Sterile<br>60 mL Luer Slip Tip             | Syringe Non-Sterile<br>50 mL Luer Slip Tip             | N/A                           | Canada, United States   |
| 301037                           | Syringe 60 mL Non-<br>Sterile Catheter Tip             | Syringe 50 mL Non-<br>Sterile Catheter Tip             | N/A                           | Canada, United States   |
| 302827                           | Syringe 60 mL<br>Luer-Lok™                             | Syringe 50 mL<br>Luer-Lok™                             | 303552                        | Brazil  |
| 302828                           | Syringe 60 mL<br>Catheter Tip                          | Syringe 50 mL<br>Catheter Tip                          | 303553                        | Brazil  |
| 302829                           | Syringe 60 mL<br>Luer Slip Tip                         | Syringe 50 mL<br>Luer Slip Tip                         | 303554                        | Brazil  |
| 305863                           | Syringe Oral/Enteral<br>60 mL Clear                    | Syringe Oral/Enteral<br>50 mL Clear                    | N/A                           | Australia, Europe, Middle<br>East, South America,<br>United States  |
| 305864                           | Syringe Oral/Enteral<br>Non-Sterile 60 mL              | Syringe Oral/Enteral<br>Non-Sterile 50 mL              | N/A                           | Canada  |
| 309620                           | Syringe 60 mL<br>Catheter Tip                          | Syringe 50 mL<br>Catheter Tip                          | N/A                           | Australia, Canada,<br>Central America, Europe,<br>Middle East, New<br>Zealand, Southern<br>Africa, South America,<br>Southeast Asia, United<br>States                             |
| 309653                           | Syringe 60 mL<br>Luer-Lok™ Tip                         | Syringe 50 mL<br>Luer-Lok™ Tip                         | N/A                           | Australia, Canada,<br>Central America, Europe,<br>Hong Kong, Japan,<br>Korea, Middle East, New<br>Zealand, Southern<br>Africa, South America,<br>Southeast Asia, United<br>States |
| 309654                           | Syringe 60 mL<br>Luer Slip Tip                         | Syringe 50 mL<br>Luer Slip Tip                         | N/A                           | Canada, Central<br>America, United States   |
| 309680                           | Syringe Pharmacy<br>Convenience Pak<br>60 mL Luer-Lok™ | Syringe Pharmacy<br>Convenience Pak<br>50 mL Luer-Lok™ | N/A                           | Canada, Hong Kong,<br>United States   |