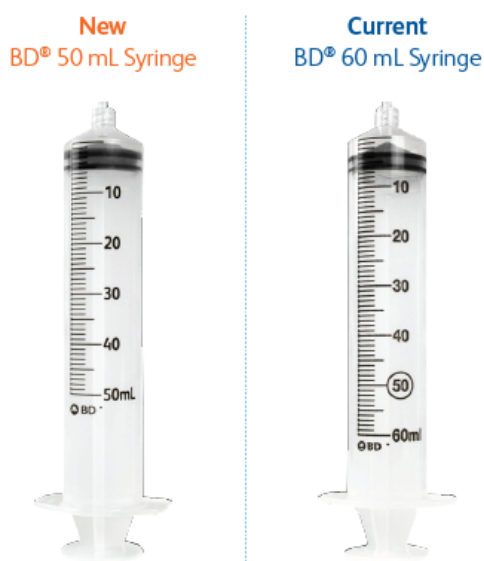


BD® 60 mL Syringes will now be 50 mL

Background

- BD is standardizing its global portfolio of BD® Syringe sizes to the following:
 - 1 mL, 3 mL, 5 mL, 10 mL, 20 mL, 30 mL and 50 mL
- As a result, the 60 mL BD® Syringe will be relabeled and sold as a 50 mL BD® Syringe
- The change being made to the device is only on the graduation scale marking, which will no longer extend beyond 50 mL
- Catalog/order numbers will remain the same



- The following table provides a summary of the change:

Syringe feature	Scope of change (<i>no change to form, fit, function or raw materials</i>)
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

*BD® Syringes are not formulated with natural rubber latex.

- The new BD® 50 mL syringe will be released by BD manufacturing plants in October 2019

Frequently Asked Questions

1. Why is BD making this change?
 - A. BD is implementing this change for three main reasons:
 - i. Help drive safe sterile compounding practice by preventing overfill of medications and complying with aseptic technique.¹⁻³
 - ii. Standardize the BD® large volume syringe offering to better manage market supply and mitigate the risk of product shortages resulting from market related events.
 - iii. 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.
2. What exactly is changing?
 - A. The only change to the device is the graduation scale marking where the scale markings will no longer extend beyond 50 mL.
 - B. All packaging labels indicating a 60 mL syringe will be updated to 50 mL.
 - C. Syringe dimensions will remain the same.
 - D. Catalog numbers will remain the same.
 - E. 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.).
3. How will this change impact me?
 - A. Fluids being aspirated or injected using the new 50 mL syringe should not exceed 50 mL of volume. As a result, please review any procedures requiring greater than 50 mL of fluid to be aspirated or injected.
 - B. If using the syringe for syringe pump infusion, then continue to use the 60 mL BD® Syringe setting on the syringe pump if 50 mL BD® Syringe is not an option. BD is working with major syringe pump manufacturers globally to update settings to provide 50 mL BD® Syringe as an option.
 - C. Similarly, for any automated or semi-automated robotics being used for medication preparation, you can continue using the existing syringe size setting.
4. When will this change occur?
 - A. BD distribution centers will release the 50 mL syringe in October 2019. Depending on BD's inventory position at that time as well as its distribution partners' inventory position, your site may start receiving the new syringe between October and December.

5. How long can I continue to receive 60 mL syringes from BD?
 - A. Following release of the 50 mL BD® Syringe into the market, we anticipate that it will take 1-2 months to deplete the 60 mL BD® Syringe inventory. Once inventory has been depleted, it will not be possible to order or receive the 60 mL BD® Syringe.

6. Can I stock up on 60 mL syringes by placing a bulk order?
 - A. In order to prevent any supply disruptions and provide a seamless transition in supply from 60 mL to 50 mL, some 60 mL syringe catalog numbers are being manually allocated. Any orders for quantities outside of your normal ordering quantities will be rejected by BD and only your normal order quantity will be shipped and invoiced.

7. Can you provide me with some samples of the 50 mL BD® Syringe?
 - A. Samples will be made available upon product release in October 2019 and can be provided at that time.

8. What alternate options do I have if I do not want to use the 50 mL BD® Syringe?
 - A. If you find that the clinical procedures you are doing can only be done with a 60 mL syringe, then please let us know the clinical details and the unmet need that specifically requires a 60 mL syringe.

9. What is the price for these new 50 mL syringes?
 - A. The price will not change, and you will continue to receive the same exact quantity under the same catalog numbers.

10. If you are replacing the 60 mL syringe with a smaller size syringe, shouldn't I be paying less?
 - A. As design, dimensions and raw materials remain the same, our cost to produce the 50 mL syringe is no different than the cost to produce a 60 mL syringe.

11. Does BD intend on launching a separate 60 mL syringe?
 - A. For the reasons stated (*FAQ 1*), BD currently has no immediate plans to develop a separate 60 mL syringe. We believe this change addresses the evolving needs of the market by promoting safe medication preparation practices by healthcare workers globally and increases our capability to ensure continuity of product supply.

12. Will this change apply to 60 mL BD® oral or enteral syringes?
 - A. Yes, the change to 50 mL scale marking will be applied across all BD® 60 mL Syringes including luer slip tip, BD Luer-Lok™ tip, catheter tip, eccentric tip, oral/enteral syringes, convenience trays, bulk non-sterile syringes and closed system transfer devices (*CSTDs*).

13. We currently use 60 mL oral and/or enteral syringes, which are not used for compounding sterile products and therefore do not require proper aseptic technique. Why are you changing the oral/enteral syringes?
- A. BD produces the 60 mL oral and enteral syringes on the same manufacturing lines as the general use syringes. BD will need to standardize this change across all existing 60 mL manufacturing lines in order to maintain the quantity of supply, which is needed to meet increasing global demand for oral and enteral syringes.
 - B. If considering changing your oral and/or enteral syringes to source from an alternate supplier, please keep in mind that alternate suppliers do not offer the same sizes as BD® Syringes, and changes may be required to your feeding schedules and protocols by migrating to 12 mL and 35 mL syringes offered by alternate suppliers instead of 10 mL and 30 mL that is offered by BD.
14. If this change is to help users comply with proper aseptic technique, how come BD is not changing the other size syringes?
- A. Recommendations around proper aseptic technique¹⁻³ suggest moving to a larger size syringe if more than $\frac{3}{4}$ of the syringe needs to be filled. As 60 mL is the largest syringe offered by BD, users do not have the option to move to a larger volume syringe thereby compromising aseptic technique. Due to this, BD felt it necessary to do its part in helping to ensure proper aseptic technique is being followed.
15. Some of my medications indicate the usage of a 60 mL syringe for preparation, I have to follow the manufacturer's instructions for use.
- A. BD is unaware of medications indicating the specific usage of a 60 mL syringe. Any such evidence that you are able to provide will be greatly appreciated.
16. What if I want 50 mL syringes, but distributor is depleting all 60 mL syringes first?
- A. BD and our channel partners/distributors will be depleting 60 mL syringe inventory before shipping out 50 mL syringe inventory, following normal batch management practices (*first in, first out process*).
17. What is the return policy for the 60 mL syringes?
- A. BD will not be accepting 60 mL syringe returns outside the normal return policy. Channel partners/distributors should not be returning 60 mL syringes to replace with 50 mL syringes.
18. Will BD be changing existing 60 mL catalog numbers (SKUs) for the 50 mL product?
- A. In order to minimize any disruption related to this change, BD will maintain existing 60 mL catalog numbers (SKUs) for the 50 mL product. This will mean that you will not have to change anything related to your ordering processes and can continue to order product as is. Depending on your distributor's inventory-on-hand and the method by

which they receive and ship, you may continue to see 60 mL within your facility following October 2019, when BD will have implemented and released this change.

19. With the scale marking being reduced to 50 mL, doesn't that mean I should only fill up to $\frac{3}{4}$ of the syringe barrel if aligning to proper aseptic technique?
- A.** As length of the barrel is not changing, compliance to proper aseptic technique would mean not filling more than $\frac{3}{4}$ of the entire barrel length. Therefore, all medications can be filled up to 50 mL.

References:

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 <http://www.ashpmedia.org/bookstore/P2074/Chpt-16.ppt>.