



September 15, 2023

RE: Revised instructions for use and launch of eIFU (electronic instructions for use) for **BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, BD Vacutainer® Push Button Blood Collection Set, BD Vacutainer® Luer Lok Access Device and BD Vacutainer® Blood Transfer Device**

Dear Valued Customer:

We would like to inform you that the **instructions for use** of BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, BD Vacutainer® Push Button Blood Collection Set, BD Vacutainer® Luer Lok Access Device and BD Vacutainer® Blood Transfer Device have been revised and updated. The purpose of this letter is to give you an overview of these changes that will go into effect.

The following SKUs are impacted:

SKU	Description
36490200	BD Vacutainer® Luer-Lok™ Access Device
36488000	BD Vacutainer® Blood Transfer Device
367363	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 25G, 12" tubing
367364	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 23G, 12" tubing
367365	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G, 12" tubing
368687	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Preattached Holder, 25G, 12" tubing
368688	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Preattached Holder 23G, 12" tubing
368689	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Preattached Holder 21G, 12" tubing
367341	BD Vacutainer® Push Button Blood Collection Set, 25G, 12" tubing
367342	BD Vacutainer® Push Button Blood Collection Set, 23G, 12" tubing
367344	BD Vacutainer® Push Button Blood Collection Set, 21G, 12" tubing
367324	BD Vacutainer® Push Button Blood Collection Set, 23G, 12" tubing, w/o Luer Adapter
367352	BD Vacutainer® Push Button Blood Collection Set with Preattached Holder, 21G, 12" tubing
368656	BD Vacutainer® Push Button Blood Collection Set with Preattached Holder, 23G, 12" tubing
368659	BD Vacutainer® Push Button Blood Collection Set with Preattached Holder, 25G, 12" tubing


#### Instructions for Use in Electronic Format (eIFU)

To access the eIFUs, please go to <https://eifu.bd.com/>. This website URL will also be available on the case label for the product.

Please note that during our transition to this updated content, the product inserts in the product cases may still hold the previous revision of the IFU. **We kindly ask you to refer to the eIFU for the most up-to-date product information** and thank you for your understanding during this transition.

## Changes to Package Insert and Package Labels

The changes to the package insert (including the instructions for use) and the package labels for the abovementioned SKUs include but are not limited to:

1. Updates to intended use statement,
2. Updates to procedural instructions,
3. Updates to precaution statements and warnings,
4. Added date of manufacture,
5. Clarification of *Required Equipment Provided* and *Required Equipment Not Provided*,
6. Added/updated addresses for *Authorized Representatives*,
7. Inclusion of symbols in accordance with ISO 15223-1 on various levels of packaging,
8. Added language translations,
9. Added symbol indicating use of blood collection is unsafe during magnetic resonance imaging procedure, to IFUs of BD Vacutainer® UltraTouch™ Push Button Blood Collection Set and BD Vacutainer® Push Button Blood Collection Set: 

**The symbols glossary and the eIFUs of the products listed above are attached for your reference.**

We understand the important role that our products play in ensuring accurate diagnostic test results for your patients as well as safety and confidence for your clinical staff. We are here to support you. These updates help to ensure compliance with regulations and improve the experience of BD customers.

For more information about these changes, please reach out to your BD Sales Consultant or our BD Technical Services Team at 1.800.631.0174 or via email at [ProductComplaints@bd.com](mailto:ProductComplaints@bd.com). For non-technical, product related questions, please contact BD Customer Service at 1.844.8.BD.LIFE (1.844.823.5433) or via email at [bd\\_customer\\_service@bd.com](mailto:bd_customer_service@bd.com).

Sincerely,

Amanda Black  
Global Platform Leader, Specimen Acquisition  
BD Life Sciences - Integrated Diagnostic Solutions