

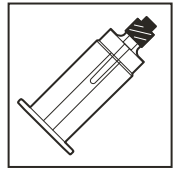


Vacutainer®

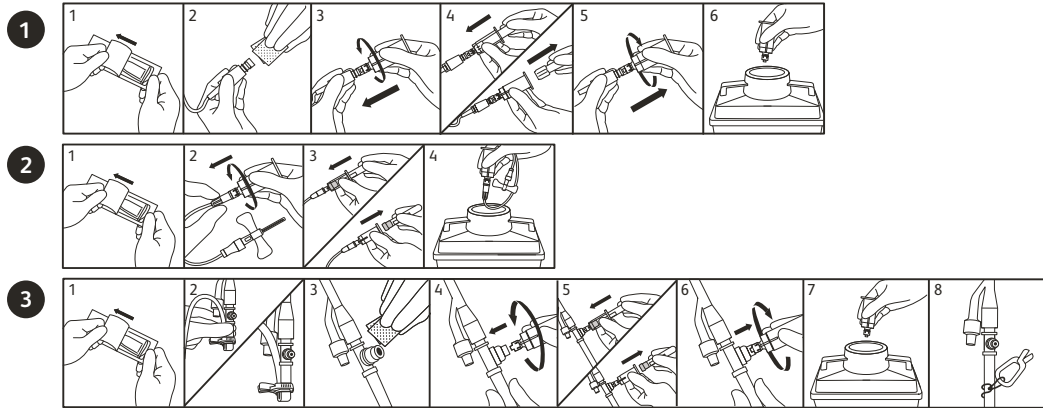
Luer-Lok™ Access Device

Holder with Pre-Attached Multiple Sample Adapter

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REF 36490200



INTENDED USE/INDICATIONS FOR USE

The BD Vacutainer® Luer-Lok™ Access Device is a sterile, single-use, non-invasive device intended to be used by healthcare professionals for safe, closed-system venous blood or urine collection from a female Luer of a catheter port, blood collection set or sampling port connected to the urinary catheter, directly into an evacuated blood collection or urine collection tube(s) for in vitro diagnostic testing. This device may also be used with a blood collection set with a female Luer to collect blood cultures.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

- The BD Vacutainer® Luer-Lok™ Access Device provides a standard Luer connection for a multi-sample, direct blood or urine transfer from a female Luer port of a catheter/ blood collection set or sampling port connected to the urinary catheter.
- The BD Vacutainer® Luer-Lok™ Access Device is a needleless, closed-system, direct transfer device which may minimize the potential risk of needlestick injuries by eliminating the need for a blunt or hypodermic needle for catheter blood or urine specimen collection.

SAFETY PRECAUTIONS AND WARNINGS

Precautions

1. Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to blood borne pathogens.
2. Do not use the device past the printed expiration date.
3. The device is designed and intended for use in combination with intravenous or urinary catheters incorporating compatible Luer connectors, BD Vacutainer® brand blood collection sets without a Luer adapter, BD Vacutainer® brand blood and urine collection tubes, and/or BD BACTEC™ blood culture bottles (when used with a blood collection set). The safety and performance of the device has not been established for use in combination with other devices.
4. Follow evacuated tube(s) and/or blood culture bottle(s) manufacturers' instructions for recommended tube order of draw and fill volume(s). Incomplete fill could lead to erroneous results which may potentially result in improper diagnosis or treatment.
5. BD Vacutainer® Luer-Lok™ Access Device is not recommended for use with Sysmex UF-1000i and UX-2000 analyzers as it may falsely identify contaminant particles as Red Blood Cells. NOTE: The Sysmex UF-1000i is an integral part of the CLINITEK® AUWi™ PRO Automated Urine Workstation and the CLINITEK® AUWi™ Automated Urinalysis System. Confirm any abnormal urinalysis results with your facility's policies, procedures and best practice guidelines.
6. If using a blood culture bottle designed for direct filling from the Central Vascular Access Device (CVAD), follow your facility's instructions and the blood culture bottle manufacturer's instructions to maintain the bottle upright to avoid reflux of the broth medium into the CVAD and vein.¹

Warnings

1. Handle all biologic samples and blood collection "sharps" (needles) according to the policies and procedures of your facility as exposure to biologic samples or needlestick injury may lead to infection or seroconversion. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since samples may transmit viral hepatitis, HIV (AIDS), or other infectious diseases.
2. Discard all blood collection "sharps" in puncture resistant biohazard containers appropriate for their disposal.
3. Intended for single-use only. Reuse may lead to infection and/or sample contamination.
4. Do not use if foreign matter is present as it may lead to sample contamination.

EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

STORAGE

Store at room temperature and keep away from sunlight.

SPECIMEN COLLECTION AND HANDLING

Required Materials Provided for Blood and Urine Specimen Collection

- BD Vacutainer® Luer-Lok™ Access Device

Required Materials Not Provided for Blood Specimen Collection

- Intravenous catheter or BD Vacutainer® blood collection set (wingset with female Luer)
- BD Vacutainer® brand blood collection tubes, as dictated by test request
- Blood culture bottles, as dictated by test request
- Antiseptic wipe, appropriate biohazard container

Required Materials Not Provided for Urine Specimen Collection

- BD Vacutainer® brand urine collection tubes
- Urinary catheter and urine collection bag
- Antiseptic wipe, appropriate biohazard container

PROCEDURE

❶ Intravenous catheter blood collection from a female Luer port:

When using an indwelling catheter, please follow your facility's recommended policies and procedures for clamping and unclamping, flushing and discarding the appropriate volume of blood during blood collection. An evacuated no-additive tube may be used to perform a discard prior to blood collection to prevent specimen contamination and maintain a closed system.

1. Confirm the expiration date and condition of the package. Peel off paper backing as indicated by the arrow and remove the device from package.
2. Using aseptic technique, disinfect the catheter port using an antiseptic wipe.
3. Insert the tip of the BD Vacutainer® Luer-Lok™ Access Device into the catheter port and rotate clockwise until it fits securely.
4. Collect blood specimen(s) in accordance with the tube manufacturer's order of draw.

PRECAUTION: Follow the evacuated blood collection tube(s) manufacturers' instructions for recommended fill volume(s).

5. Once collection is complete and the final tube is removed, hold the catheter port and rotate the BD Vacutainer® Luer-Lok™ Access Device counterclockwise and then pull to remove.
6. Discard all used materials into appropriate biohazard container(s) in accordance with the policies and procedures of your facility.

❷ Blood collection from a blood collection set (using wingset with a female Luer):

Follow the blood collection set manufacturer's instructions for blood collection.

1. Confirm the expiration date and condition of the package. Peel off paper backing as indicated by the arrow and remove the device from package.
2. Attach the BD Vacutainer® Luer-Lok™ Access Device to the female Luer of the blood collection set and rotate clockwise until it fits securely.
3. Collect blood specimen(s) in accordance with the tube manufacturer's order of draw.

PRECAUTION: Follow the evacuated tube(s) and/or blood culture bottle(s) manufacturers' instructions for recommended fill volume(s). Maintain the blood culture bottle(s) upright to avoid reflux of broth into the vein.

4. Once collection is complete and final tube is removed, discard all used materials into appropriate biohazard container(s) in accordance with the policies and procedures of your facility.

❸ Urine collection from the sampling port connected to the urinary catheter:

Urine should never be collected from the drainage collection bag, drainage ports, or other sites.

1. Confirm the expiration date and condition of the package. Peel off paper backing as indicated by the arrow and remove the device from package.
2. Clamp the tubing below the sampling port, and allow adequate time for urine to accumulate in catheter tubing.

3. Using aseptic technique, disinfect the sampling port with an antiseptic wipe.
4. Insert the tip of the BD Vacutainer® Luer Lok™ Access Device into the sampling port and rotate clockwise until it fits securely.

5. Collect urine specimens in accordance with the tube manufacturer's order of draw.

PRECAUTION: Follow the evacuated urine collection tube(s) manufacturers' instructions for recommended fill volume(s).

6. Once collection is complete and final tube is removed, rotate the BD Vacutainer® Luer-Lok™ Access Device counterclockwise and then pull to remove.
7. Discard all used materials into appropriate biohazard container(s) in accordance with your facility's policies and procedures.
8. Unclamp the drainage tube and ensure adequate urine flow.

TECHNICAL SERVICES AND SUPPORT

In the United States, contact BD at 1.800.631.0174 or bd.com. For regions outside of the United States, contact your local BD representative or bd.com. For U.S. patents that may apply, see bd.com/patents.

REFERENCES

¹Infusion Therapy Standards of Practice. Phlebotomy; Blood sampling via a vascular access device. Infusion Nurses Society: 2021.

Change History

Revision	Date	Change Summary
01	2023-07	Initial release.

SYMBOLS GLOSSARY

Please refer to product labeling for applicable symbols.


Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorized representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult <i>instructions for use</i>
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <n> tests
	For IVD performance evaluation only
	Non-pyrogenic
	Patient number
	This way
	Do not stack

Symbol	Meaning
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	<Box #> / <Total Boxes>
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier
	Importer
	Place patient label in framed area only
	Magnetic resonance (MR) safe
	Magnetic resonance (MR) conditional
	Magnetic resonance (MR) unsafe
	For use with
	This Product Contains Dry Natural Rubber
	For Export Only
	Instruments

Note: Text layout in symbols is determined by label design.


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