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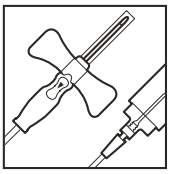
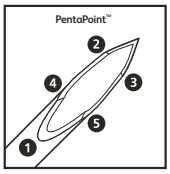
BD Vacutainer®

UltraTouch™ Push Button

Blood Collection Set with Pre-Attached Holder





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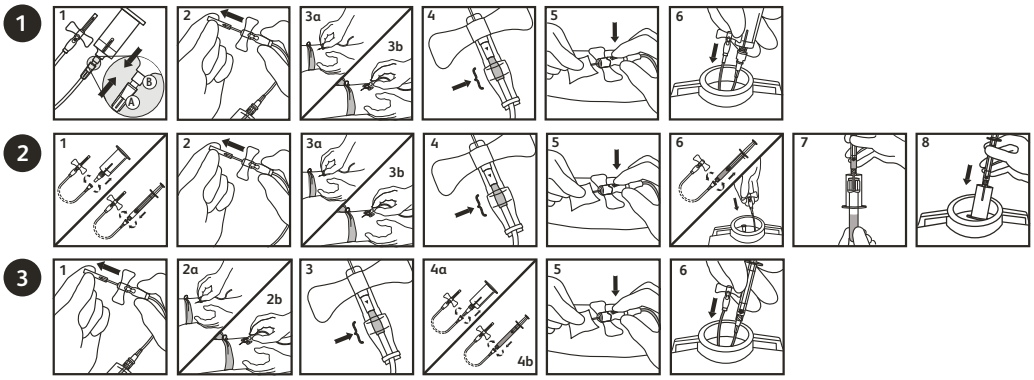


Table 1: Priming Volume		
Gauge (G)	Tubing Length (inch/mm)	Volume (mL)
21	7/177.8	0.232
23	7/177.8	0.229
25	7/177.8	0.226
21	12/304.8	0.357
23	12/304.8	0.354
25	12/304.8	0.351

INTENDED USE/INDICATIONS FOR USE

The BD Vacutainer® *UltraTouch*™ Push Button Blood Collection Set with Pre-Attached Holder is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced with venipuncture to obtain blood specimens from patients, including those with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience for short-term, single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and is to remain under the direct supervision of a clinician.

The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of an accidental needlestick injury.

NEEDLE GAUGE SELECTION

The healthcare professional should select the needle gauge depending on:

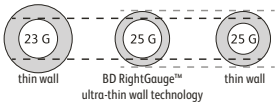
- the patient condition (such as age, weight, pre-existing conditions),
- physical characteristics of the vein (such as size, location, and accessibility),
- for blood collection, the volume of blood needed to be collected,[1,2]
- for infusion, the prescribed therapy and patient need.[3]

Choose the needle gauge that fits comfortably into the most prominent vein with little discomfort. The following are recommended needle gauges for venipuncture or infusion procedures for different age groups;

- 21G is recommended for adults[1]
- 23G and 25G are recommended for adults, pediatrics, elderly or patients with small, fragile veins, and neonates.[1,2,3]

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

1. Single handed, in-vein needle retraction aids in the prevention of an accidental needlestick and blood splatter.
2. Flashback visualization indicates vein entry.
3. Non-patient needle sleeve enables a multi-sample blood collection.
4. BD RightGauge™ technology reduces the cannula wall thickness and increases the inner diameter of the cannula.



5. Ultra-thin wall cannula enables use of a smaller needle for blood collection in all patients, including those with difficult venous access, such as pediatric, oncology and geriatric without compromising sample quality.

Required Equipment Provided

- BD Vacutainer® *UltraTouch*™ Push Button Blood Collection Set with Pre-Attached Holder.

Required Equipment Not Provided

- BD BACTEC™ brand blood culture bottles and/or BD Vacutainer® brand blood collection tubes, as dictated by test request.
- Approved biohazard container and other supplies, such as tourniquet, gloves, skin disinfectant, and sterile gauze.
- BD Vacutainer® Blood Transfer Device for syringe blood collection.
- Devices with Luer connection for IV administration and syringe blood collection.

Procedure For Blood Collection (see Diagram ❶)

1. Check to ensure that the female Luer adapter Ⓐ is securely attached to the male Luer adapter Ⓑ.
2. Apply tourniquet, disinfect the venipuncture site and remove needle sheath.
3. Perform venipuncture by holding either wings or body of the device.
4. Observe for the presence of blood in the flash chamber prior to collecting blood specimen to indicate venous access. Release tourniquet as soon as blood flow is established. Collect blood specimen(s) in accordance with the tube manufacturer's order of draw and recommended fill volumes and/or the blood culture bottle manufacturer's instructions for use.
5. Retract the needle: Place sterile gauze over the venipuncture site while the needle is still in the vein and then depress the button. The needle will slide out of the venipuncture site and lock into place. Do not impede needle retraction. Cover the puncture site with a sterile gauze and apply pressure.
6. Dispose of all used materials in an approved biohazard container.

Procedure For Blood Collection Using A Syringe (see Diagram ❷)

1. Remove the Luer Adapter and attach syringe.

Follow Blood Collection Steps 2–5.

6. Detach syringe and dispose of needle and tubing in an approved biohazard container.
7. Use the BD Vacutainer® Blood Transfer Device to transfer blood from the syringe to the evacuated tube(s) in accordance with the tube manufacturer's order of draw and recommended fill volumes and/or the blood culture bottle manufacturer's instructions for use.
8. Dispose of syringe and all used materials in an approved biohazard container.

Procedure For Short Term IV Administration (see Diagram ❸)

(Up to 2 hours under direct supervision of clinician)

- When securing the device, tape the wings. Note: Taping over the button and applying pressure may cause the needle to retract.
- Prime set if necessary, in accordance with your facility's procedure (See Table 1, Priming Volume. Column 1 is gauge, column 2 is tubing length in inches/millimeters (mm) and column 3 is in mL).

1. Apply tourniquet, disinfect the venipuncture site and remove needle sheath.
2. Perform venipuncture by holding either wings or body of the device.
3. Observe for the presence of blood in the flash chamber and release tourniquet.
4. (a) Remove assembled Luer Adapter.
   (b) Attach IV line or syringe to the female Luer connector, ensure that there is no air in the system and start infusion.
   - The device should be changed in accordance with your facility's procedure and should not be used for longer than 2 hours.
5. Retract the needle. Place sterile gauze over the venipuncture site while the needle is still in the vein and then depress the button. The needle will slide out of the venipuncture site and lock into place. Do not impede needle retraction. Cover the puncture site with a sterile gauze and apply pressure.
6. Dispose of all used materials in an approved biohazard container.

SAFETY PRECAUTIONS AND WARNINGS

Precautions

1. Use product at room temperature.
2. Practice Standard Precautions.
   - Key elements include hand hygiene, cleaning of the environment, use of gloves, eye protection, other personal protective equipment, waste management and engineering controls to protect from blood splatter, blood leakage, and potential exposure to infectious agents.
   - Practice aseptic technique to minimize the risk of healthcare-associated infections.
3. Prolonged tourniquet time greater than 1–2 minutes may cause hemoconcentration which can impact test results.
4. For all infusates, adhere to all contraindications, warnings, precautions, and instructions for use, as specified by their manufacturer(s).
5. For infusion, balance the risk of infiltration against the venous trauma when choosing a needle gauge.
6. Use only compatible male Luer connectors. Non-compatible Luer connectors may cause leakage, hemolysis and incorrect draw volumes.
7. Do not over-tighten Luer connections as damage may occur.
8. Using a syringe to draw blood may result in increased hemolysis.[2]
9. Do not obstruct needle during activation. Visually confirm that the needle point is completely covered.
10. Male Luer adapter and holder are not intended to be separated.
11. The device is designed and intended for use in combination with BD Vacutainer® brand blood collection tubes, BD BACTEC™ brand blood culture bottles, and BD Vacutainer® Blood Transfer Device. The safety and performance of the device has not been established for use in combination with other devices.
12. Incomplete fill of tubes/blood culture bottles could lead to erroneous results which may potentially result in improper diagnosis or treatment.
13. This device contains the following substance defined as CMR 1B, in a concentration above 0.1% weight by weight: Cobalt, CAS Number 7440-48-4 and EC Number 231-158-0. Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effect. Note: For more information, please consult the European Chemicals Agency website: echa.europa.eu/home.

Warnings

1. 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. Utilize any safety engineered feature if the blood collection device provides one.
2. Discard all blood collection "sharps" in puncture resistant biohazard containers approved for their disposal.
3. Do not use if foreign matter is present as it may lead to infection, allergic or toxic reaction. Unintended device material or infusate exposure into the body can lead to infection, allergic or toxic reaction.
4. Intended for single-use only. Reuse may lead to infection or other illness/injury.
5. Activation of the device while the needle is still in the venipuncture site is recommended. Activation of the device after the needle is removed from the site should be performed away from self and others to avoid exposure to blood or IV fluid splatter.
6. Do not use device after its expiration date.
7. Potential adverse events associated with phlebotomy, infusion, or device malfunction such as, but not limited to, moderate discomfort, bruising, hematoma, pain, infection, hemoconcentration, nerve/vein/tissue damage, edema, accidental arterial puncture, iatrogenic anemia, vasovagal reaction, syncope, diaphoresis with near syncope, petechiae, allergies, thrombosis, phlebitis, thrombophlebitis, loss of consciousness with tonic-clonic seizures, extravasation, infiltration, or air embolism may occur due to patient physiological characteristics, chosen venipuncture/anatomic site, and clinical experience of the healthcare professional.

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.

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

1. World Health Organization (2010). WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. World Health Organization.
2. Clinical Laboratory and Standards Institute (2017). GP41 Collection of Diagnostic Venous Blood Specimens, 7th Edition. Clinical and Laboratory Standards Institute.
3. Infusion Nurses Society. Infusion Therapy Standards of Practice, 8th Edition 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
EC REP	Authorized representative in the European Community
CH REP	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
NON STERILE	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	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 *instructions for use* or consult electronic *instructions for use*
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	In vitro diagnostic medical device
CONTROL –	Negative control
CONTROL +	Positive control
Σ	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
PHT DEHP BBP	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	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
Rx Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	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
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
/	<Box #> / <Total Boxes>
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
FC	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier
	Importer
	Place patient label in framed area only
MR	Magnetic resonance (MR) safe
MR	Magnetic resonance (MR) conditional
MR	Magnetic resonance (MR) unsafe
For use with	For use with
This Product Contains Dry Natural Rubber	This Product Contains Dry Natural Rubber
For Export Only	For Export Only
Instruments	Instruments

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

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