

INNOVAC QUICK-DRAW

INTENDED USE

The Innovac® Quick-Draw® Capillary Whole Blood Collection System is intended for in-vitro diagnostic use to facilitate the collection of whole blood specimens from a capillary puncture site, i.e., finger or heel-stick. The system is composed of a capillary collection container, (BD Microtainer® or Greiner Bio-One Mini Collect®, sold separately), with a Quick-Draw adapter assembled to it. This assembly is attached to the Innovac Vacuum Handle, a battery operated vacuum device. When assembled and activated, the system aspirates blood specimens from the puncture site into the collection container.

WARNING: The Innovac® Quick-Draw® Capillary Whole Blood Collection System has not been validated on the following patient groups to determine red blood cell membrane integrity: hereditary elliptocytosis, hereditary spherocytosis, stomatocytosis resulting from excessive alcohol consumption, anemia due to hypophosphatemia as a result of alcoholic withdrawal states, and recovery phase after severe burns.

Replace the disk filter in the Innovac Vacuum Handle if it should become contaminated in the unlikely failure of the primary filter located inside each Quick-Draw Adapter. Replace the disk filter as outlined in the Innovac Vacuum Handle instruction guide.

INSTRUCTIONS FOR USE

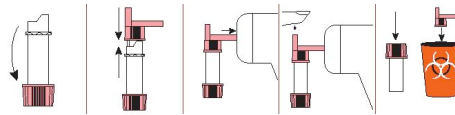
CAUTION: Handle all biological samples carefully. Exposure to such samples may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. All samples and collection materials must be disposed of according to the policies and procedures of your facility. If exposure occurs, obtain appropriate medical attention.

COLLECTOR ASSEMBLY

GREINER MINICOLLECT®

- PUSH THE Q-D ADAPTER THROUGH THE PIERCABLE CAP
- PUSH ON COMPLETELY AND THEN GIVE A FIRM 1/2 TWIST WHILE PUSHING IN
- **BE SURE THAT THE ADAPTER SEATS COMPLETELY FLAT ONTO THE RUBBER CAP. AN AIR TIGHT SEAL IS REQUIRED.**
- If multiple draws are needed, assemble all collectors prior to skin puncture and set aside until needed.
- AFTER COLLECTION, TWIST OFF THE QUICK-DRAW ADAPTER ONLY AND DISCARD INTO A BIOHAZARD CONTAINER
- THE RUBBER CAP RE-SEALS ITSELF
- MIX ACCORDING TO MFR INSTRUCTIONS

BD MICROTAINER®



- Remove the cap from the collection container (Microtainer®) and set aside.
- Push on completely the Quick-Draw Adapter to the collection container. **Be sure the Adapter is pushed on completely.** Give the Q-D adapter ¼ turn on the Microtainer to seat completely.
- If multiple draws are needed, assemble all collectors prior to skin puncture and set aside until needed.
- AFTER COLLECTION, TWIST OFF THE QUICK-DRAW ADAPTER AND DISCARD INTO A BIOHAZARD CONTAINER
- REPLACE THE ORIGINAL CAP
- MIX ACCORDING MFR INSTRUCTIONS

COLLECTING SAMPLES



- Attach the Quick-Draw assembly to the male luer fitting of the disk filter on the front of the Innovac Vacuum Handle as shown.
- Rotate the Quick-Draw assembly on the Innovac Vacuum Handle to desired position. Best results are obtained with the Quick-Draw assembly held in a near vertical orientation during collection.
- Use your facility's procedure to perform a skin puncture. Use a lancet designed for the volume of sample you are collecting.
- Press and release the blue button on the Innovac Vacuum Handle to start the vacuum. Press the button again to stop the vacuum. You don't have to hold the button in to activate the vacuum. This allows you to hold the Innovac in a position that is most comfortable to you. This also allows the use of extension tubing for the collection procedure (see **Extension Tubing Use** below).
- With the vacuum running, touch the tip of the Quick-Draw assembly to the puncture site as the blood drop forms. Blood will be drawn into the collection container. Avoid squeezing the heel / finger excessively as this may introduce tissue fluids into the sample. **Avoid scooping the sample as this may lead to a hemolyzed or clotted sample.**
- Fill collection container to desired level. To check the sample volume collected, stop the vacuum so the blood level settles inside the vessel. You can also remove the Q-D assembly from the Innovac if that is easier for you. Reattach or reactivate the vacuum to collect more sample.
- After sample collection, remove the Quick-Draw assembly from handle by turning clockwise while pulling away from the handle.

FILTER REPLACEMENT PROCEDURE FOR INNOVAC HANDLE

The disk filter is in place as a safety measure to stop any blood that may pass through should the primary filter located on the Quick-Draw Adapter fail. **To assure optimum performance, the disk filter should be visually inspected before connecting the Quick-Draw assembly to it. The filter is easily seen through the hole in the front of the Innovac Vacuum Handle. Replace the filter if it is obviously contaminated:**

- Remove the protective cover over the disk filter on the front of the Innovac Vacuum Handle by turning the cover counterclockwise.
- The disk filter should be considered potentially bio-hazardous. Therefore, precautions should be used when handling it.
- If the filter is contaminated, remove the disk filter by turning it counterclockwise. Handle the filter as potentially bio-hazardous. The filter will become firmly seated from attaching the Quick-Draw Assemblies during use. Use a haemostatic forceps or other device to grasp the filter to turn

- Attach new disk filter by turning clockwise until seated finger-tight. Replace the protective cover over the disk filter by reattaching and turning clockwise until firmly seated.
- Part No. 15-501 (10/pk)

DISINFECTION OF INNOVAC HANDLE

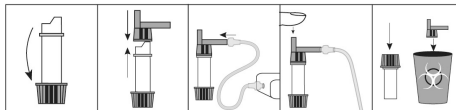
- Do not immerse.
- Wipe outside of Innovac Vacuum Handle with mild detergent solution to remove soil.
- Wipe with hospital grade disinfectant labeled for use on plastic surfaces per disinfectant label directions.

BATTERY REPLACEMENT IN INNOVAC HANDLE

- Remove battery compartment cover.
- Remove old battery.
- Replace with one 9V alkaline battery.
- Replace battery compartment cover.

NOTE : When the Innovac Handle is not to be used for a long period time, remove the battery to avoid damage caused by battery leakage and corrosion.

EXTENSION TUBING USE



Use of extension tubing with the Innovac system offers the following benefits:

1. The Innovac Vacuum is located at a distance from the patient. This is beneficial in the NICU where decibel levels are a concern, especially inside the incubator.
2. The Innovac Vacuum is not held in the hand, only the Q-D assembly is held in the hand. This may be a more natural feeling collection technique for the user.

Innovative Med Tech offers 36" (15-036) and 60" tubing (15-060). The IMT tubing has a green stripe on the tubing so that it does not get confused with other tubing being used by the patient. You may also use your own tubing, just be sure that it is not "micro-bore" tubing.

EXTENSION TUBING FAQ'S:

How often do we need to change the Extension Set Tubing?

- This is your choice based on your facility's protocol. Because changing the tubing for every patient is not cost effective, we offer the disposable sheaths (15-100). A new sheath is used for every patient.
- In the NICU or similar in-patient settings where the patient receives subsequent draws, most users leave the tubing with the patient and reuse it.

Do you recommend using a sheath over the tubing each time?

- Yes, but again this is your call.

If you can use the tubing over, can the tubing be cleaned with a Sani-Cloth type product?

- Yes, this could be an option to using the sheath. Again, it depends on what your universal precautions allow.

EXTENSION TUBING SHEATH



Figure 1

Figure 2

Figure 3

1. Tubing insertion: With the end-cap removed, slide the male luer fitting beneath the white tab into the sheath opening. Push the tubing to the end of the sheath until the male luer fitting slightly protrudes the end. (Figure 1)
2. Protective Covering Removal: Hold the tubing and the sheath as shown and pull the blue tab removing the protective cover in the direction shown. Discard cover. (Figure 2)
3. Paper Backing Removal: Beginning at the end with the male luer fitting protruding, peel the paper backing in the direction shown and discard. (Figure 3)
4. Attach the Quick-Draw collector assembly to the male luer fitting.
5. After use, remove the Quick-Draw collector assembly from the tubing. Remove the sheath from the tubing and discard properly.

THIS PACKAGE CONTAINS:

One Innovac Vacuum Handle, complete with 9V alkaline battery and one disk filter.

MANUFACTURED FOR:

Innovative Medical Technologies, Inc.
Leawood, KS 66224

WARRANTY:

The Innovac Vacuum Handle is warranted against defects in materials and workmanship for one year from date of purchase.

Protected by U.S. and foreign patents.