Cord Stick Multiple Draw System

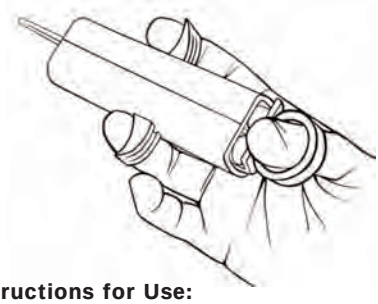
Patent No. 5,569,210

For Umbilical Cord Blood Sampling

Cord Stick® Multiple Draw System is intended for obtaining two samples of venous umbilical cord blood after delivery of a newborn infant and aids in the prevention of needle stick injury.

Manufactured for:
Cord Stick Corporation
1400 Florida Ave., Suite 205 • Modesto, CA 95350
(209) 524-2215 • 1-800-830-9118

CAUTION: Federal law restricts this device to sale by or use on the order of a physician.



Instructions for Use:

1. Peel off cover and remove device from package. ***Keep hands behind finger wings and exposed needle at all times.***
2. Place thumb in plunger ring and fingers on finger wings on barrel sides like a thumb control syringe.
3. **Pull** off exposed needle cap using other hand.
4. Insert needle into umbilical vein.
5. When needle enters vein, **immediately** press plunger tray forward with thumb until it stops.
6. Observe tubes filling. After 4-5 seconds, withdraw needle from umbilical cord. Remaining vacuum empties manifold reducing splash contamination.
7. **Keeping hands behind finger wings and exposed needle,** hold sides of barrel with one hand and with the other hand remove the plunger tray and specimen tubes from barrel assembly. This removal process locks the needles inside the barrel housing.
8. Inspect the top of the tubes to assure a needle has not detached from manifold. The sample tubes may now be removed from tray, labeled with patient information, and sent to the lab. The **Cord Stick®** Multiple Draw System parts should be disposed of in a sharps container.

Do not attempt to reassemble for more compact disposal.

For single use only.

Do not reuse.

Sterile in unopened, undamaged package.
FDA registered.
Lot No. XXXXXXX
Expiration Date: MM-DD-YY
REV. A

TROUBLESHOOTER

Cord Stick Corporation has tried to create the best possible product for umbilical cord blood sampling. We understand, however, that despite our best efforts, users may encounter difficulties. Problems are most frequently encountered during the initial phase of the learning curve. Listed below are some of the problems and how to deal with them. If you encounter problems not listed here, please contact us:

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Needle comes off manifold

If a twisting motion is used to remove the needle cover, the drawing needle may detach from the manifold. To avoid this problem be sure to
Pull off the needle cap.

Flashback not seen

If you do not see manifold flashback and are certain that the needle is in the vein, it is possible that the specimen needle is partially inserted into the stoppers of the tubes blocking air egress. If the needle is in the vein **Press the plunger tray forward and observe filling of the tubes.**

Blood leaks inside the barrel

If the plunger tray is not pressed forward quickly after the needle enters the vein, blood can drip through the manifold and specimen needles into the barrel assembly. While this is a contamination issue, it does not affect the device function. To avoid this internal contamination problem, be sure to:
Press the plunger tray forward as soon as the needle enters the umbilical vein.

Blood leaks from needle after obtaining specimen

If the specimen tubes are filled to capacity, a small amount of blood contained in the needles and manifold may escape. To avoid this contamination, remove needle from vein prior to complete filling, the small amount of remaining vacuum will empty the manifold and needles of any residual blood thus avoiding leaks. To avoid blood leaking from the drawing needle after obtaining the specimen,
Remove the needle from the vein prior to complete filling of the tubes.

Needle remains exposed after tray withdrawal

If the needle remains exposed after use, immediately dispose of the unit in a sharps container. There are two main reasons for this occurrence: First, the needle may be detached from the manifold during needle cap removal; Second, the barrel is being held incorrectly. To avoid these problems be sure to:
PULL off the needle cap and **Hold the barrel sides behind the finger wings at tray removal.**

Tubes are hard to remove from tray

To most easily remove tubes:
Roll the cap end of the tube out of the tray with your thumb.