smiths medical

portex®

Dry Heparin Arterial Blood Sampling Kit
for Gases and Electrolytes

en	Instructions for use	nl	Gebruiksaanwijzing
fr	Mode d'emploi	sv	Bruksanvisning
de	Gebrauchsanweisung	da	Brugsanvisning
it	Istruzioni per l'uso	no	Bruksanvisning
es	Instrucciones de uso	fi	Käyttöohjeet
pt	Instruções de utilização	el	Οδηγίες χρήσης

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en ENGLISH

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient and/or clinician.

NOTE: DISTRIBUTE THIS INSERT SHEET TO ALL PRODUCT LOCATIONS.

1. DESCRIPTION:
The Dry Heparin Arterial Blood Sampling Kit is a single-use, in-vitro diagnostic device designed for the drawing of arterial blood. See product package for a list of components. This product is not for injection.

2. INDICATIONS:
The arterial blood sampling syringe for Calcium Neutralized Dry Lithium Heparin syringes is intended for sampling of arterial blood for the measurement of pO_2, pCO_2, pH, CO-oximetry, electrolytes (Ca++, Na+, K+, Cl-, and Mg++), Total Magnesium, and the metabolites (Glucose and Lactate). Dry Lithium Heparin is neutralized for Ionic Calcium. The syringe is heparinized for anticoagulant effect.

3. CONTRAINDICATIONS:
3.1 Anticoagulant therapy
3.2 Severe peripheral arteriosclerosis
3.3 History of clotting disorders
3.4 History of arterial spasm following puncture

4. WARNINGS:
4.1 Bent or damaged needles can result in breakage, or damage to the tissue, or accidental needle stick. If needle is bent or damaged, immediately discard device into an approved sharps container.
4.2 Mishandling of procedural needle(s) may result in a needle stick with a contaminated needle which may result in infectious diseases.
4.3 Inadvertent injection of heparin may result in abnormal clotting.

5. CAUTIONS:
5.1 Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.
5.2 Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

6. PRECAUTIONS:
6.1 Procedure should be performed only by a trained and properly qualified person.
6.2 Check patient chart for record of anticoagulation therapy or bleeding abnormalities.
6.3 Check to determine if patient was recently suctioned or, if patient is on a ventilator, check to determine if settings were recently changed. Either may result in changes to blood gas results; therefore wait 20 minutes before drawing sample.
6.4 Blood gas values only represent the patient's condition at the time when the sample was drawn.
6.5 Confirm needle straightness, point, and attachment.
6.6 Note syringe plunger position before using.

7. INSTRUCTIONS FOR USE:
7.1 Prepare patient label. Indicate patient's age and temperature. Indicate if patient is on a ventilator, including the % O_2 and level of PEEP.
7.2 Explain procedure to patient and caution patient to breathe normally, avoiding hyperventilation, throughout the procedure.
7.3 Select puncture site. The three most common, in order of preference, are: radial artery, brachial artery, and femoral artery. Note: If radial artery is selected, confirm existence of ulnar collateral circulation.
7.4 Palpate artery and prep puncture site according to standard practice.
7.5 Prepare syringe:
7.5.1 Pulsator® Syringe:
Draw plunger back and forth two to three times to uniformly spread lubricant, then push plunger all the way to front.
7.5.2 Pro-Vent® Syringe:
Preset the plunger to desired sample volume.
7.6 Attach desired needle. With an easy twisting motion, seat needle to syringe.
7.7 Collect specimen:
7.7.1 Insert needle at a flat angle to achieve an oblique entry with easier hemostasis.
7.7.2 **OBSERVE NEEDLE HUB FOR FLASH OF BLOOD** and immediately stop advancing syringe.
7.7.3 Allow syringe to fill to desired volume.
7.7.4 With free hand, prepare to press on puncture site with gauze pad upon needle removal.
7.7.5 Remove needle and apply and maintain moderate pressure on puncture site for 3 to 10 minutes, depending on the patient, checking periodically for stoppage of bleeding. Check patient's pulse at puncture location at appropriate intervals.

See illustrated procedures that follow for use of Needle-Pro® EDGE™ and Filter-Pro® device.

7.8 Ensure thorough mixing of blood sample with heparin in syringe by holding syringe in hand and rotating wrist back and forth for 20 to 30 seconds.
7.9 Sample should be analyzed within 30 minutes. Time may need to be adjusted if other analytes are included in the specimen analysis. Follow NCCLS guidelines or health care facility protocol.

8. POSSIBLE SOURCES OF ERROR AND LIMITATIONS:
8.1 Inadequate mixing of blood sample with heparin in syringe.
8.2 Analyzer inaccuracy.
8.3 Unadjusted values when abnormal temperatures are observed.
8.4 Obtaining venous or mixed venous sample.
8.5 Air bubbles must be eliminated as soon as possible. Do not send sample to lab with any air.
8.6 Patient temperature not corrected for.
8.7 Lack of adjustment for patient receiving O_2 therapy.
8.8 Patient hyperventilation during procedure.
8.9 Lactate analysis should be performed as soon as possible.
8.10 Therapeutic levels of aspirin (up to 30 mg/dl plasma) and acetaminophen (up to 2 mg/dl plasma) will not interfere with obtained values.
8.11 Ascorbate may interfere, but is mostly cleared through urine within 4 hours of ingestion. At tissue saturation levels, ascorbate is reported to have a plasma concentration of 1 - 1.5 mg/dl. It has been demonstrated that ascorbate at this level will not interfere with the results.
8.12 Markedly hemolyzed samples should be avoided. Hemolyzed samples may contribute to spuriously high values.
8.13 Since one-third of serum magnesium is bound to albumin, serum values may be falsely elevated in dehydration and falsely decreased in hemodilution with or without clinical edema or hypoalbuminemia.
8.14 Certain drugs and other substances are known to influence circulating magnesium levels.

9. HEPARIN INFORMATION:
9.1 Heparin source is porcine intestinal mucosa.
9.2 Heparin is for syringe heparinization only, not for injection.
9.3 Where indicated, Dry Lithium Heparin is used for sampling of arterial blood for the measurement of pO_2, pCO_2, pH, CO-oximetry, the major metabolites (Ca++, Na+, K+, Cl-, and Mg++), Total Magnesium, and the metabolites (Glucose and Lactate). Dry Lithium Heparin is neutralized for Ionic Calcium.

CE 98/79/EC(1)

"CE" ***WITHOUT NUMBER*** (1) COVERS IN-VITRO DIAGNOSTIC SYRINGE.
"CE" ***WITH NUMBER*** (2) COVERS OTHER MEDICAL DEVICES

CE 2797 93/42/EEC(2)

STERILITY:
REFER TO THE UNIT PACKAGE FOR APPLICABLE STERILITY STATEMENT:

STERILE EO

STERILITY:
Syringe fluid path and needle (if provided) are sterile unless individual components have been opened or damaged.

NEEDLE-PRO® EDGE™
NEEDLE PROTECTION DEVICE

1. DESCRIPTION:
The Needle-Pro® EDGE™ safety device is a single-use needle safety sheath.

2. INDICATIONS:
This device covers a needle after use to help prevent needle sticks.

3. CONTRAINDICATIONS:
None known.

4. WARNINGS:
4.1 A needle stick with a contaminated needle may cause infectious diseases.
4.2 Intentional disengagement of the Needle-Pro® EDGE™ safety device may result in a needle stick with a contaminated needle.
4.3 Bent or damaged needles can result in breakage or damage to the tissue or accidental needle stick. If the needle is bent or damaged, no attempt should be made to straighten the needle or engage the Needle-Pro® EDGE™ safety device. Immediately discard into a sharps container. The Needle-Pro® EDGE™ safety device may not properly contain a bent needle and/ or the needle could puncture the needle protection device which may result in a needle stick with a contaminated needle.
4.4 Mishandling of the needle protection device may cause needles to bend whereby they protrude from the needle protector sheath which may result in a needle stick with a contaminated needle.
4.5 Do not use free hand to press sheath over the needle. This may result in a needle stick with a contaminated needle.

5. CAUTIONS:
5.1 Follow standard infection control procedures as specified by the Centers fo Disease Control and Prevention (USA) or local equivalent.
5.2 Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

6. INSTRUCTIONS FOR USE:
6.1 After procedure is completed, press the needle into the sheath using a one-handed technique. Perform a one-handed technique by **GENTLY** pressing the sheath against a flat surface. An audible click may be heard as an indication that the needle is engaged into the needle protection device. AS THE SHEATH IS PRESSED, (Fig. 1) THE NEEDLE IS FIRMLY ENGAGED INTO THE SHEATH (Fig. 2).

Fig. 1

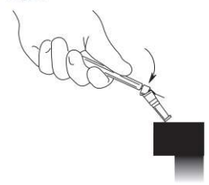
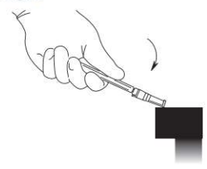
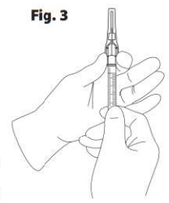


Fig. 2



6.2 Visually confirm that the needle is fully engaged into the needle protection sheath.
6.3 Remove the Needle-Pro® EDGE™ safety device with engaged needle from the syringe by grasping the Luer hub of the device with thumb and forefinger, keeping the free fingers clear of the end of the device containing the needle point. (See Fig. 3)

Fig. 3



6.4 Attach Filter-Pro® device - see below for Filter-Pro® device instructions for use.
6.5 After use, place sharps in approved sharps container. Dispose of contaminated device in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.

FILTER-PRO®
AIR BUBBLE REMOVAL DEVICE

1. DESCRIPTION:
The Filter-Pro® Air Bubble Removal Device is a single-use device. Additional dead space of the Filter-Pro® device averages 0.10ml.

2. INDICATIONS:
The Filter-Pro® device is used for the removal of air bubbles from an arterial blood sample. Upon removal of air bubbles, the Filter-Pro® device can then be utilized as a stopper/tip cap during transport to analyzer.

3. CONTRAINDICATIONS:
None known.

4. WARNINGS:
4.1 Failure to advance plunger **SLOWLY** may disengage Filter-Pro® device resulting in splashing of blood. Exposure to blood products may cause infectious diseases.
4.2 Mishandling of the Filter-Pro® device/syringe assembly may result in exposure to blood products.

5. CAUTIONS:
Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

6. INSTRUCTIONS FOR USE (After blood draw):
1. Firmly push Filter-Pro® device onto Luer as illustrated below. (Fig. 1)
2. Holding the Luer end up, tap the syringe to move air bubble to the top.
3. To remove air bubbles from sample **SLOWLY** advance the plunger to expel the air from the sample.
4. **STOP PUSHING** the plunger when sample wets the filter. (Fig. 2) Continued pressure may release Filter-Pro® device from syringe.
5. Promptly transport labeled syringe with Filter-Pro® device attached to laboratory per blood gas procedures.

Fig. 1

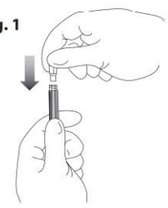


Fig. 2