smiths medical

portex®

Line Draw Arterial Blood Sampling Kit
with Dry Lithium Heparin for Gases and Electrolytes

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no Bruksanvisning
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el Οδηγίες χρήσης

Rx ONLY

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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 Line Draw Arterial Blood Sampling Kit with Dry Lithium Heparin is a single-use, latex-free, in-vitro diagnostic device designed for the drawing of arterial blood via an arterial line. See product package for a list of components. This product is not for injection.

Note: A waste syringe is required for performance of this procedure and is not included with this kit.

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 Mishandling of procedural needle(s) may result in a needle stick with a contaminated needle which may result in infectious diseases.
4.2 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.

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 Clear heparin lock (with a waste syringe) per health care facility protocol.
7.4 REMOVE STOPPER/TIP CAP FROM SYRINGE AND PLACE NEARBY.
7.5 Push syringe plunger fully forward.
7.6 Draw desired sample and, with syringe in vented position, expel any air.
Note: Do not overfill syringe.
7.7 Cap syringe with stopper/tip cap or Filter-Pro® device. **See illustrated procedure that follows for use of 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.
7.10 Flush arterial line and heparin lock per health care facility protocol.
7.11 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.

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 Air bubbles must be eliminated as soon as possible. Do not send sample to lab with any air.
8.5 Patient temperature not corrected for.
8.6 Lack of adjustment for patient receiving O_2 therapy.
8.7 Lactate analysis should be performed as soon as possible.
8.8 Therapeutic levels of aspirin (up to 30 mg/dl plasma) and acetaminophen (up to 2 mg/dl plasma) will not interfere with obtained values.
8.9 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.
8.10 Markedly hemolyzed samples should be avoided. Hemolyzed samples may contribute to spuriously high values.
8.11 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.
8.12 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 electrolytes (Ca^{++}, Na^+, K^+, Cl^-, and Mg^{++}), Total Magnesium, and the metabolites (Glucose and Lactate). Dry Lithium Heparin is neutralized for Ionic Calcium.

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CE 98/79/EC(1)

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

CE 2797 98/79/EEC(2)

STERILITY:

REFER TO THE UNIT PACKAGE FOR APPLICABLE STERILITY STATEMENT:

STERILE EO

Sterilized by ethylene oxide; contents sterile unless device package has been opened or damaged.

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

FILTER-PRO®
AIR BUBBLE REMOVAL DEVICE

1. DESCRIPTION:

The Filter-Pro® Air Bubble Removal Device is a single-use, latex-free 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):

6.1 Firmly push Filter-Pro® device onto Luer as illustrated below. (Fig. 1)
6.2 Holding the Luer end up, tap the syringe to move air bubbles to the top.
6.3 To remove air bubbles from sample **SLOWLY** advance the plunger to expel the air from the sample.
6.4 **STOP PUSHING** the plunger when sample wets the filter. (Fig. 2)
Continued pressure may release Filter-Pro® device from syringe.
6.5 Promptly transport labeled syringe with Filter-Pro® device attached to laboratory per blood gas procedures.

Fig 1.

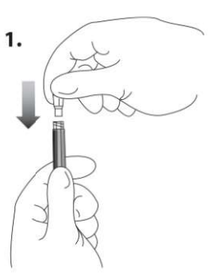

Fig 2.