INSTRUCTION FOR USE OF CLOSED BLOOD SAMPLING SYSTEM - ACCUTRANS & BIOTRANS READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

ADDENDUM to INSTRUCTION SHEET

This copy only serves as an addendum to the enclosed Instruction Sheet in the same package for BIOTRANS™ and ACCUTRANS™ Pressure Monitoring systems and Kits. For Biotrans (BT) and Accutrans (AT) kit with Closed Blood Sampling System, the model numbers are further denoted by BP2 or MV (eg. BTR-XXXX–BP2, BTR-XXXX-MV, AT BC-XXXX , AT-XXXX– BP2 and AT-XXXX– MV)

DEVICE DESCRIPTION

The Closed Blood Sampling System is an add-on convenience kit that comprises pressure tubing that is connected to blood access site(s) and stopcock(s) and is supplied with components that allow blood drawing and flushing to the arterial and/or venous blood as well as medication delivery for pump or pressure bag.

INTENDED USE AND INDICATIONS

The Closed Blood Sampling system is intended for blood waste holding and returning, blood sampling, fluid administration and closed medication delivery.

The BP2 and MV systems are designed for use in conjunction with blood pressure monitoring system and for connection to central line catheters and arterial line catheters.

READ the following carefully for each Closed Blood Sampling system:

- BP2 system is intended for blood draw and flush. It is designed for the access of undiluted blood from Arterial Catheters not longer than 6.4 cm (2.5“). All diluted blood is drawn beyond the valve blood sample site into the reservoir syringe to permit withdrawal of undiluted blood from the valve using a blood-sampling syringe of any type. After the sample is drawn, the diluted blood is re-infused through the site and into the patient to reduce fluid loss.
- MV system is intended for blood management during pressure monitoring. The extension set with two stopcocks with access sites, clamp and infusion tubing for attachment to Venous Catheters or Arterial Catheters, and are for administration of fluids to patient’s vascular system and for blood sampling. The MV system is made with NON-DEHP tubing and CONTAINS NO LATEX.

POTENTIAL COMPLICATIONS

Retrograde air embolism, vaso-vagal reaction, hemolysis, sepsis/infection, thrombosis and bacteremia.

CONTRAINDICATIONS

- DO NOT use BP2 system for Venous Access. BP2system is not recommended for use with Central Venous Catheters, as withdrawal volumes required to obtain an undiluted blood sample have not been determined.
- The MV system should not be used with neonatal PICC lines.

WARNING

1. This device is intended for single patient use only.
2. **DO NOT** re-sterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and re-sterilization bear the risk of cross contamination, cross-patient infection, pyrogenic reactions and may also cause transmission of an infectious agent.
3. Used the Closed Blood Sampling system must be properly disposed as biohazard material and processed accordingly to the accepted practice and applicable local, state and federal laws and regulations.
4. For unattended medication or blood delivery,MV system: only *Luer slip or Luer locking syringes* or Luer locking tubing should be used with the access sites. It is not recommended to draw blood from catheters smaller than 3.0 French or peripheral arterial catheters smaller than 24g using the BP-MV system due to the risk of hemolysis of blood samples.
5. BP2 and MV systems are not recommended for neonatal PICC line blood draws.

CAUTIONS

1. RX only.

2. This product is designed for SINGLE USE only. DO NOT reuse or resterilize the product.

3. DO NOT use the product after indicated expiration date printed on the tyvek lid of the package.

4. DO NOT use the product if package is opened or damaged as contents may lose sterility.

5. DO NOT use needles on any access sites.

6. For MV system: DO NOT use a blunt cannula on the access sites. Use only Luer slip syringes on access sites.

7. For BP2 system: Use only a blunt cannula on the access sites.

8. For BP2 system: use a syringe with a stainless steel needle on the access site.(the syringe is equivalent to BP2 syringe during the operation)

9. Replace all Closed Blood Sampling System components per hospital protocols or CDC guidelines.

10. Flush access sites in accordance with hospital policy after or between accesses.

11. For MV system: Positive pressure is not needed during removal of syringe after blood draw or after flushing, but flushing is recommended with the stopcock lever in opposite position to valve to allow auto flushing of valve after a blood draw.

PRECAUTIONS

• DO NOT use BP2 System for infusion of medications or other fluids.

DO NOT use excessive force on any attached syringes. Doing so may damage the catheter and/or sensor.

• DO NOT use excessive force on any attached syringes to the MV system. Doing so may damage the catheter, the valves, and/or sensor. The MV valves are designed to withstand 35 psi.

MAINTAINING DEVICE EFFECTIVENESS

Exchange all Closed Blood Sampling System components according to facility protocols or CDC guidelines. In order to reduce potential contamination of system, always wipe the exposed access sites with preferred antiseptic (isopropyl alcohol or betadine) and allow to completely air dry before and after attempting blood access.

INSTRUCTIONS FOR USE

Set up the pressure monitoring system per instructions in BIOTRANS™ or ACCUTRANS™ Instruction Sheet.

PRECAUTIONS

• Do not wrap strap tightly, as this can restrict blood flow in the patient's arm.

• Leave distal vented cap in place to prevent contamination of Luer connector.

Closed Blood Sampling System (BP2)

A. Priming System (Best if primed under gravity flow or low bag pressure):

1. Open package in aseptic manner. Tighten all connections.

2. Turn the stopcock on BP2 blood draw syringe off to the syringe.

3. Spike bag, remove air and prime IV spike chamber.

4. Squeezing flush device, prime the dome, zero port stopcock, and tubing, until saline reaches the lower stopcock with valve area.

5. Release flush device, and turn the stopcock on the BP2 blood draw syringe off to the patient side.

6. Holding the blood draw syringe nose up (like a T), Squeeze the flush device and allow 2-3 cc saline to fill into the syringe. Hold the BP2 syringe upright to allow/assist any air to rise to the nose of the syringe.

7. Turn the stopcock on the BP2 off to the transducer side.

8. Holding the nose in the up position, push the syringe plunger down completely to push all air and all saline out of the BP2 syringe into the tubing below the syringe. This primes the dead space in the nose of the syringe.

9. Turn the stopcock off to the BP2 syringe.

10. Squeeze the flush device and continue priming, removing all air from the tubing below the blood draw syringe until the tubing is fully primed.

11. Open the stopcock on the dome to air and attach the dome to the transducer and lock on.

12. Attach extension set to patient's catheter.

13. Flush to clear the catheter.

14. Zero the transducer. Begin monitoring pressure.

B. Arterial Blood Sampling Procedure using Aseptic Technique:

PRECAUTIONS

• If a Luer slip sample syringe is used with the valve sample site, be sure to insert the syringe firmly into the valve to avoid disconnect.

15. Swab the valve on stopcock to be used for blood draw. Turn stopcock handle opposite valve to be used for blood draw.

16. Turn the stopcock on the blood draw syringe off to the transducer. Pull the blood draw syringe barrel with sheath back slowly to draw blood off the patient's catheter. Draw 5-10 cc of holding blood to clear the catheter and stopcock with valve area.

17. Turn the stopcock handle on stopcock with sample valve off to the transducer.

18. Attach the desired type and size of blood draw syringe to the valve sample site. Draw the desired amount of blood slowly into the syringe and then remove the syringe from the valve. Turn the stopcock handle on the valve sample site to the access position, opposite the valve.

19. Go to the BP2 syringe. Slowly re-infuse the holding blood into the patient, holding the syringe in a vertical, nose down position.

20. After re-infusing holding blood completely, turn the stopcock handle on the BP2 syringe opposite the BP2 syringe.

21. Squeeze the flush device to fill the BP2 syringe with approximately 3-4 cc of fluid. Some flush will also travel down the line.

22. Push the blood saline mixture in the BP2 syringe out into the line, and turn the BP2 stopcock handle off to the BP2 syringe.

23. Continue to flush the line using the squeeze flush wings on the transducer until line is sufficiently clear. Flush enough to also clear the catheter.

24. Swab the valve sample site to remove any blood residue.

25. Resume normal pressure monitoring.

PRECAUTIONS

If blood collects in the nose of the holding syringe, to flush out:

1. Close the stopcock on the holding syringe to the transducer.
2. Draw up 1-2 cc saline from the line, and holding the syringe nose down, re-infuse into the line.
3. Turn the stopcock off to the holding syringe and give a brief flush by squeezing the flush device to clear the line and the catheter.

Alternate Method to flush out:

1. Close the stopcock on the holding syringe to the patient line.
2. While squeezing the flush device, allow 1-2 cc saline to fill into the holding syringe.
3. Holding the nose of the holding syringe down, turn the stopcock on the holding syringe off to the transducer, and infuse the saline/mixture into the line.
4. Turn the stopcock on the holding syringe off to the holding syringe and squeeze the flush device to clear the line and the catheter.

Closed Blood Sampling System with marvelous stopcock

A. Priming System (Best if primed under gravity flow or low bag pressure):

1. Open package in aseptic manner. Tighten all connections.

2. Turn the stopcock on MV blood draw syringe off to the syringe.

3. Spike bag, remove air and prime IV spike chamber.

4. Squeezing flush device, prime the dome, zero port stopcock, and tubing, until saline reaches the lower stopcock with valve area.

5. Release flush device, and turn the stopcock on the MV blood draw syringe off to the patient side.

6. Holding the blood draw syringe nose up (like a T), Squeeze the flush device and allow 2-3 cc saline to fill into the syringe. Hold the MV syringe upright to allow/assist any air to rise to the nose of the syringe.

7. Turn the stopcock on the MV off to the transducer side.

8. Holding the nose in the up position, push the syringe plunger down completely to push all air and all saline out of the MV syringe into the tubing below the syringe. This primes the dead space in the nose of the syringe.

9. Turn the stopcock off to the MV syringe.

10. Squeeze the flush device and continue priming, removing all air from the tubing below the blood draw syringe until the tubing is fully primed.

11. Open the stopcock on the dome to air and attach the dome to the Accutrans transducer and lock on.

12. Attach extension set to patient's catheter.

13. Flush to clear the catheter.

14. Zero the transducer. Begin monitoring pressure.

B. Arterial Blood Sampling Procedure using Aseptic Technique:

PRECAUTIONS

- If a Luer slip sample syringe is used with the valve sample site, be sure to insert the syringe firmly into the valve to avoid disconnect.
- DO NOT use a blunt cannula on the access sites. Use only luer slip syringes on access sites.

15. Swab the valve on stopcock to be used for blood draw. Turn stopcock handle opposite valve to be used for blood draw.

16. Turn the stopcock on the blood draw syringe off to the transducer. Pull the blood draw syringe barrel with sheath back slowly to draw blood off the patient's catheter. Draw 5-10 cc of holding blood to clear the catheter and stopcock with valve area.

17. Turn the stopcock handle on stopcock with sample valve off to the transducer.

18. Attach the desired type and size of blood draw syringe to the valve sample site. Draw the desired amount of blood slowly into the syringe and then remove the syringe from the valve. Turn the stopcock handle on the valve sample site to the access position opposite the valve.

19. Go to the MV syringe. Slowly re-infuse the holding blood into the patient, holding the syringe in a vertical, nose down position.

20. After re-infusing holding blood completely, turn the stopcock handle on the MV syringe opposite the syringe.

21. Squeeze the flush device to fill the MV syringe with approximately 3-4 cc of fluid. Some flush will also travel down the line.

22. Push the blood saline mixture in the MV syringe out into the line, and turn the MV stopcock handle off to the MV syringe.

23. Continue to flush the line using the squeeze flush wings on the transducer until line is sufficiently clear. Flush enough to also clear the catheter.

24. Swab the valve sample site to remove any blood residue.

25. Resume normal pressure monitoring.

c: PRECAUTIONS

If blood collects in the nose of the holding syringe, to flush out:

1. Close the stopcock on the holding syringe to the transducer.

2. Draw up 1-2 cc saline from the line, and holding the syringe nose down, re-infuse into the line.

3. Turn the stopcock off to the holding syringe and give a brief flush by squeezing the flush device to clear the line and the catheter.

Alternate Method to flush out:

1. Close the stopcock on the holding syringe to the patient line.

2. While squeezing the flush device, allow 1-2 cc saline to fill into the holding syringe.

3. Holding the nose of the holding syringe down, turn the stopcock on the holding syringe off to the transducer, and infuse the saline/mix-ture into the line.

4. Turn the stopcock on the holding syringe off to the holding syringe and squeeze the flush device to clear the line and the catheter.

PACKAGING AND STERILITY

Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. The Closed Blood Sampling System are for single use only. Do not clean or resterilize used the system components.

STORAGE

Bioptimal's Closed Blood Sampling System should be stored in dry location.

SHELF-LIFE

The recommended shelf-life is indicated on each package.

WARRANTY

BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond

BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

ADVERSE EVENT REPORTING

While Bioptimal strives to produce quality Critical Care Products that are free of workmanship and product defects, the possibility of adverse events that may happen to the user due to unintended product failures, use-errors and/or user non-conformance to product information in the IFU cannot be fully mitigated. For any adverse event that may happen, please report to the manufacturer and authorized representative indicated in the IFU or product labels. Similarly, please also report any adverse event to the competent authorities of EU member states.

PRODUCT INFORMATION

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Symbols Legend

STERILE EO	**Sterilised using Ethylene Oxide in a single sterile barrier system**		**Non-Pyrogenic**
	For Single Use Only	2	**Do Not Re-sterilise**
	Fragile and handle with care		**Do Not Use If Package Is Damaged**
	Keep Dry		**Keep From Direct Sunlight**
	Temperature Limitation	%	**Humidity Limitation**
	Use by date	MD	**Medical Device**
	Manufacturer and date of manufacture	EC REP	**Authorised Representative in the European Community**
	Importer information		**Distributor information**
REF	**Catalogue number**	LOT	**Lot Number**
UDI	**Unique Device Identifier**	CE 0344	**CE conformity marking per European Council Directive 93/42/EEC**
	Consult Instruction for Use	PHT DEHP	**Contains or Presence of Phthalate**