English

Monitoring Life™

Safedraw™-M Minimally Residual Volume Luer Activated Stopcock Blood Sampling Components

INSTRUCTIONS FOR USE

Safedraw™-M minimally residual volume luer activated stopcock blood sampling components are included in select Safedraw™ blood sampling sets. These suggestions for use supplement the current instructions by providing information specific to the use of these components within the blood sampling set.

INTENDED USE
The Safedraw™-M blood sampling system is intended to be used to withdraw blood from a patient without exposing the patient to the outside environment (closed loop blood sampling), when used in conjunction with a pressure monitoring set.

INDICATIONS FOR USE
The Safedraw™-M blood sampling system is indicated for use in conjunction with pressure monitoring set for patients who require repeated venous or arterial blood sampling.

USER / PATIENT / CLINICAL
User: Qualified nurses, clinicians and physicians

Patient: Pediatric and adult applications

Clinical: Hospitals or appropriate clinical environments

CAUTIONS
- Tighten all connections before use. Do not overtighten connections as this may crack the connection leading to leaks, air embolism, bleed backs or loss of pressure waveforms.
- Air can enter the system and ultimately the patient through stopcocks inadvertently left open from accidental disconnection of monitoring system or from flushing residual air bubbles into the patient and cause air embolism.

TO CLEAN
Clean and disinfect the device per standard hospital protocol. Use aseptic technique when handling the device.

HOW TO MONITOR
Turn the handle to the "Monitoring" position (Fig. 1) (All pictures are for illustrative purposes only). Monitoring can be done using the Safedraw™-M without any risk of signal damping, (valve is closed to the flow-path).

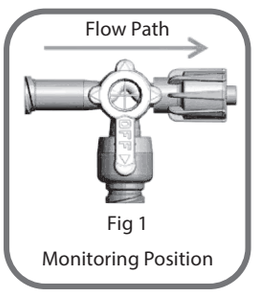


Fig 1
Monitoring Position

HOW TO PRIME
For priming turn the handle to the "Priming/Flushing" position (Fig. 2), this way the flow in the line passes through the internal volume of the valve and allows it to prime.

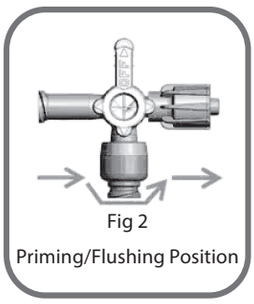


Fig 2
Priming/Flushing Position

HOW TO TAKE A BLOOD SAMPLE
Blood sampling using the Safedraw™-M is done almost identically to standard stopcocks with luer activated valves and is divided into four main stages:

1. Wiping the closed port according to institute policy
2. Dead space removal
3. Taking the blood sample
4. Line Flushing

Steps 2-3 are performed in the same manner as with other stopcocks with luer- activated valves:

a. Turn the handle to the "Sampling" position (Fig. 3) and aspirate the dead space/ blood sample to the attached syringe.
b. Prior to syringe removal, the Safedraw™-M handle should be turned to the "Monitoring" position (Fig. 1)

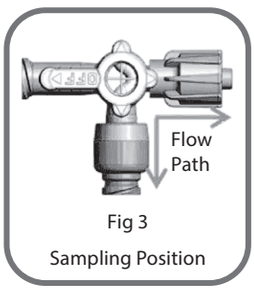


Fig 3
Sampling Position

Step 4 (line flushing) **HOW TO FLUSH:**

For cleaning blood or drug residues, the volume should be flushed according to institute policy. When flushing the line, the Safedraw™-M handle should be directed in the "Priming/Flushing" position (Fig. 2); **the residual volume is removed by the flow!**

IV INFUSION/ TRANSFUSION
The Safedraw™-M handle should be turned to the "Priming/Flushing" position (Fig. 2)

IV BOLUS ADMINISTRATION
For bolus administration, the handle of the Safedraw™-M should be turned to the "Sampling" position (Fig. 3)

For line flushing after IV bolus administration see instructions "How to Flush".

NOTE:
- The only significant change in operating the Safedraw™-M compared with a standard stopcock with a luer activated valve is that when the handle is turned to 45° the Safedraw™-M does not necessarily maintain an "all-closed" position (Fig. 4).

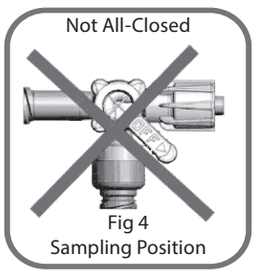


Fig 4
Sampling Position

- Do not use needles to access the valve port.
- No need for caps, plugs, “Heparin locks”, cannulas or any other add-on components to close the valve port.

Important Note!
These instructions for the Safedraw™-M are NOT meant to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be used with this product.

COMPLICATIONS
Risks associated with the use of this product include: sepsis/infection, other illness and injury, air emboli, bleed-back, and loss of pressure waveform. For further information regarding complications, contact your Merit representative.

CLINICAL BENEFIT
- Allow blood sampling

STORAGE CONDITIONS
Store in cool dry place away from direct sunlight.

STERILE and non-pyrogenic in unopened, undamaged package. For single use only. Check integrity of the individual package before use. After use, dispose of device in a manner consistent with standard protocols for waste disposal. Do not resterilize.

Device lifetime is 72 - 96 hours base on CDC & Joint Commission Intl (JCI) recommendation.

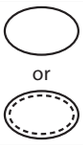
Re-use may lead to infection or other illness / injury.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

For reordering information or assistance, please contact local representative.

SPECIFICATION

Leak Resistance	Withstand fluid-filled pressure of 29 psi
Flow Performance	Allow flow ≥ 50ml/min saline with a differential infusion pressure of 200 mmHg
Septum Endurance Performance	100 times

	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Do not resterilize
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Keep Dry
	Keep away from sunlight
	Non-pyrogenic
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
STERILE EO	Sterilized using ethylene oxide
MD	Medical Device
 or	Single Sterile Barrier System or Single sterile barrier system with protective packaging inside
UDI	Unique Device Identifier
	Does not Contain DEHP, DIBP, DBP, BBP
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within 7 calendar days, call U.S.A. or EU Customer Service.
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog number
LOT	Batch code

CE 2797

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