English

Monitoring Life™

Safedraw™-P Septum / Stopcock / Luer-Lock Adapter Blood Sampling Components

INSTRUCTIONS FOR USE

Safedraw™-P septum, stopcock and Luer-lock adaptor 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™-P 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™-P 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

CONTRAINDICATIONS
- Do not use for the purpose that involves high pressure load including angiography.
- Do not perform injection or other procedures through Safedraw™-P septum using a needle.
- Do not use povidone-iodine as a disinfectant because the septum can be stained or swollen.

CAUTIONS
- Read the directions thoroughly prior to use.
- Use aseptic technique and proper setup when handling the device.
- Disinfect the septum (A) and the cap (B) with a disinfectant such as alcohol, before and after use of the device. (See Figure 1)
- Use a syringe with Luer-slip for connecting directly to the Safedraw™-P septum.
- Only use Safedraw™-P Luer-lock adaptor to connect Luer lock components to the septum. Use of other connectors might lead to disconnection from the septum, causing infusion interruption.
- If looseness or leak is detected around the septum area after repeatedly performing blood sampling, replace with a new product.
- Perform priming under a condition which the septum is facing downward.
- 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.

A. SEPTUM ACCESS USING A LUER-SLIP DEVICE (SEE FIGURE 2)
1. Disinfect the septum and cap area.
2. Insert the male luer of a Luer-slip syringe straight into the septum until the tip does not go any further.
3. Withdraw the blood sample slowly.
4. Remove the syringe from septum by slowly pulling the syringe away from the septum.
5. Disinfect the septum and cap area.

B. SEPTUM ACCESS USING A LUER-LOCK DEVICE (SEE FIGURE 4)
1. Remove the cover from the female luer of the Safedraw™- P Luer-lock adapter (figure 3) and connect a Luer-lock syringe, or other suitable blood sampling device, to it.
2. Remove the cover from the male luer of the Safedraw™-P Luer-lock adaptor.
3. Disinfect the septum and cap.
4. Hold the Luer-lock adapter and push the male luer firmly into the septum.
5. Once the adapter is inserted into the septum, lock the adapter to the septum by rotating it 45° to 60° clock-wise.
6. Always disconnect the Luer-lock adaptor from septum before removing blood sampling device otherwise leakage of blood through the lock adapter may occur.
7. Disinfect the septum and cap area

C. USE OF THE SAFEDRAW™-P STOPCOCK SEPTUM
D is the output to the patient

E is the input side from the administration set

The tap (C) position and the flow directions of the off-directed type stopcock (Figure 5)

The tap (C) position and the flow directions of the on-directed type stopcock (Figure 6)

PRIMING
1. Perform priming under a condition which the septum is facing downward and the tap is open to three different positions (Figure 7 or Figure 11).
2. To ensure air is removed from under the septum, turn tap OFF to the patient direction (Fig.10 or Fig.14) and insert syringe into the septum. If connected to a transducer, activate the flush device while drawing the air and bubbles from inside tube and under the septum.
3. Turn tap OFF to the septum direction, and connect to the patient to measure the blood pressure (Figure 8 or Figure 12).

BLOOD SAMPLING
1. Disinfect the septum and cap.
2. Turn tap OFF to the transducer position (Figure 9 or Figure 13).
3. Insert the Luer-slip syringe, or other suitable blood sampling device, straight into the septum. The male luer should be completely inserted into the septum.
4. Slowly aspirate the blood sample.
5. Remove the sampling device and disinfect the septum and cap.
6. Open the tap to three different positions (Figure 7 or Figure 11).
7. Activate the fast flush device to return the blood from the monitoring line to the patient and clear blood from under the septum.
8. Turn tap OFF to the septum position for blood pressure measurement. (Figure 8 or Figure 12).

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 14.5 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
Rx 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
PHT DEHP DIBP DBP BBP	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

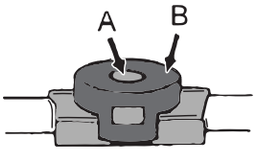
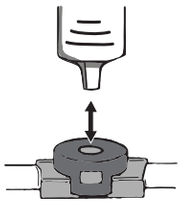


Figure 1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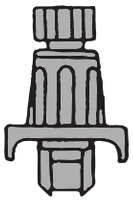
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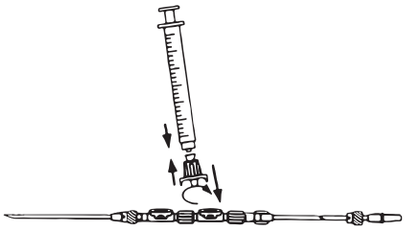
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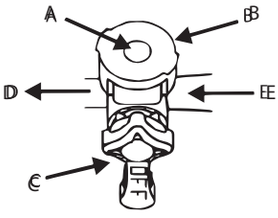

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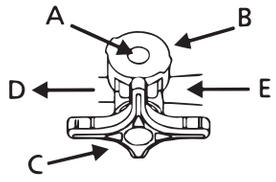

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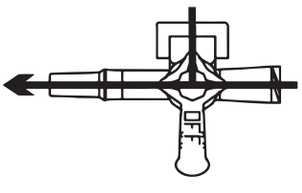
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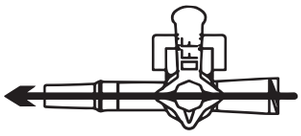

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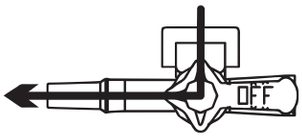

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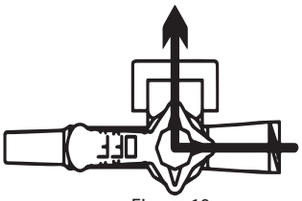

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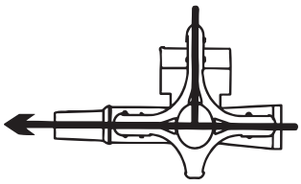

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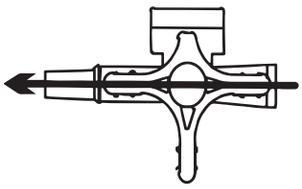

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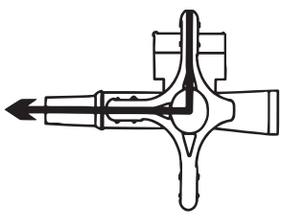

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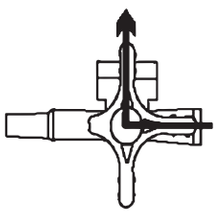

Figure 14

CE 2797

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