

CultureSafe™ | Blood Culture Bottle Dispensing Device

Instructions for Use

Indications for Use

CultureSafe™ is a dispensing device designed to help reduce the risk of needlestick injuries during the transfer of samples from a blood culture bottle for further testing. The device can be used with either the **Drop Technique** or **Syringe Draw Technique**. There are no known contraindications for CultureSafe; however, care should be taken per the Warnings and Precautions included in this Instructions for Use.

Warnings and Precautions

CultureSafe should not be used if the sterile packaging is damaged. Be careful when removing the device from its packaging, as to not make contact with a non-sterile surface. The device should be used in an enclosed, well ventilated laboratory workspace (as defined by facility protocol), along with required protective apparel. The absorbent cap should remain attached and in place during puncture of the blood culture bottle, as the bottle may contain gas-producing organisms that can cause internal pressure to build. This will also help protect the dispensing tip from non-sterile contact.

Instructions for Assembly

Please refer to the Warnings and Precautions before using this product.

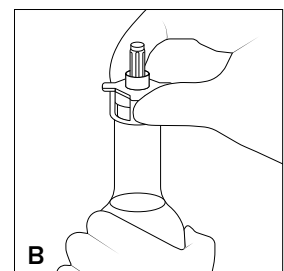
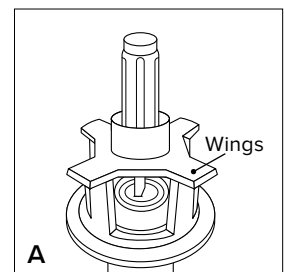
1. Gently shake the blood culture bottle to mix its contents.
2. Disinfect the rubber cap and blood culture bottle according to your facility's protocol.

Note: If using an alcohol pad to disinfect the rubber cap, please remove it from the top of the blood culture bottle and dispose of it prior to Step 5.

3. Peel open the CultureSafe packaging, starting from the side with arrows.
4. Carefully remove CultureSafe from its packaging. Do not touch the cannula or dispensing tip.
5. Position the device over the blood culture bottle's rubber septum, centering the cannula over the disinfected cap. *(Image A)*
6. Holding the blood culture bottle steady with one hand, use your other hand to press down firmly, pierce the blood culture bottle, and twist slightly. Press the device firmly until the rubber cap is punctured. *(Image B)*

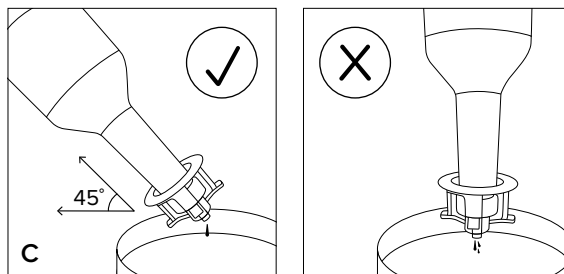
Note: The device may not sit flush with the top of the cap.

7. Twist to remove the white absorbent cap from the device. Properly dispose of the absorbent cap per your facility's protocol.
8. Obtain culture sample by using either the **Drop Technique** or **Syringe Draw Technique**, described below.



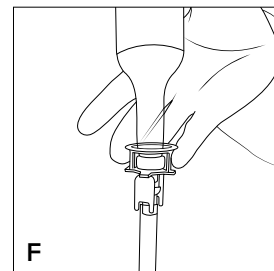
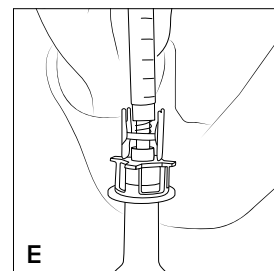
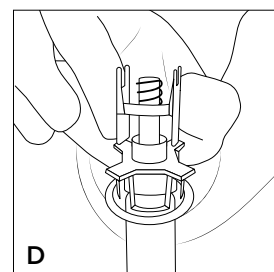
Drop Technique

1. Arrange the device's dispensing tip to be close to your slide, plate, or tube.
2. **Slowly** tilt the blood culture bottle downward to an approximate 45° angle and dispense the required number of sample drops. (*Image C*)
3. Turn the blood culture bottle upright.
4. Carefully remove the CultureSafe unit by holding the blood culture bottle with one hand as you use the other hand to slightly twist and pull up on the device's wings. (*Image A*) This will help to reduce potential spatter.
5. Dispose of CultureSafe according to your facility's protocol.







Syringe Draw Technique

1. Insert the sterile female-to-female adapter (or a female luer syringe) into the male luer of the CultureSafe with a slight twist. (*Image D*)
2. If using the female-to-female adapter, insert the male end of a sterile male luer syringe into the female luer of the adapter with a slight twist. (*Image E*)
3. Invert the blood culture bottle and draw the required sample amount into the syringe. (*Image F*)
4. Upright the blood culture bottle and pull back slightly on the syringe plunger to remove any sample remaining in the CultureSafe.
5. Remove the syringe from the adapter and CultureSafe.
6. Dispense the sample from the syringe. Dispose of the syringe according to your facility's protocol.
7. Carefully remove the CultureSafe unit by holding the blood culture bottle with one hand as you use the other hand to slightly twist and pull up on the device's wings (*Image A*). This will help to reduce potential spatter.
8. Dispose of CultureSafe and adapter according to your facility's protocol.



CAUTION: Do not use CultureSafe using the Drop Technique after using the Syringe Draw Technique.

Symbols Glossary

Symbol	Meaning	Description of Symbol	ISO 15223-1
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	5.1.6
	Date of Manufacture	Indicates the date when the medical device was manufactured	5.1.3
	Do Not Reuse	Indicates a medical device that is intended for one single use only	5.4.2
	In Vitro Diagnostic Device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	5.5.1
	Keep Dry	Indicates a medical device that needs to be protected from moisture	5.3.4
	Manufacturer	Indicates the medical device manufacturer	5.1.1
	Contains Sufficient for Tests	Indicates the total number of tests that can be performed with the medical device	5.5.5
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use	5.4.3
	Do Not Re-Sterilize	Indicates a medical device that is not to be re-sterilized	5.2.6
	Do Not Use If Package Is Damaged and Consult Instructions for Use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information	5.2.8
	Keep Away From Sunlight	Indicates a medical device that needs to be protected from light sources	5.3.2
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	5.4.4
	Prescription Device	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	N/A
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide	5.2.3
	Use by Date	Indicates the date after which the medical device is not to be used	5.1.4

