

STERICHECK™ OVP-C USER INSTRUCTIONS

These instructions are designed as a guideline to illustrate the standard use of components in STERICHECK™ OVP-C. The STERICHECK™ packs have been specifically designed to provide all the culture media components required to perform the UNIVERSAL OPERATOR BROTH TRANSFER VALIDATION test according to the NHS UK Pharmaceutical Aseptic Services Committee. This test is designed to confirm satisfactory aseptic technique required to maintain sterility during the preparation and manipulation of aseptically prepared injectable dose forms.

Each STERICHECK™ OVP-C pack contains the following sterile components.

- 1 x 100ml tryptone soya broth (TSB) in infusion bag with spike port + needle-free port
- 1 x 50ml tryptone soya broth (TSB) in injection vial with rubber stopper and crimped flip top cap
- 1 x 10ml tryptone soya broth (TSB) in ampoule
- 3 x Empty irradiated 20ml capacity injection vials with rubber stopper and crimped flip top cap

All components are securely held in a moulded plastic foam insert which sits in a sealed plastic box. This sealed box is wrapped in an outer plastic pouch.

The following instructions are based on Version 09 of the Universal Operator Broth Transfer Validation test together with instructions for using the STERICHECK™ OVP-C components.

Opened Box Contents



In order to equalize the pressure inside both the TSB injection vial and empty injection vials it is recommended to use vented needles or a similar pressure equalization technique when accessing the contents - refer to individual user's local procedures as applicable. If using standard hypodermic needles or similar, it is recommended to withdraw the tip slowly to minimise the potential for the contents to blow out under pressure.

1. Discard the outer plastic pouch of the STERICHECK™ OVP-C box
2. The box and external surfaces of the components are non-sterile and should be sanitized according to the user's local sanitisation procedures before entry to the aseptic preparation area or Isolator.
3. Prior to transfer to the aseptic preparation area or Isolator, remove the outer plastic pouch covering the TSB infusion bag by tearing at the notch cut into the seal. In addition, remove the flip top caps covering the TSB injection vial and the empty injection vials by pushing the edge of the flip top cap upwards to expose the grey rubber seal.

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Removing flip top cap from injection vial



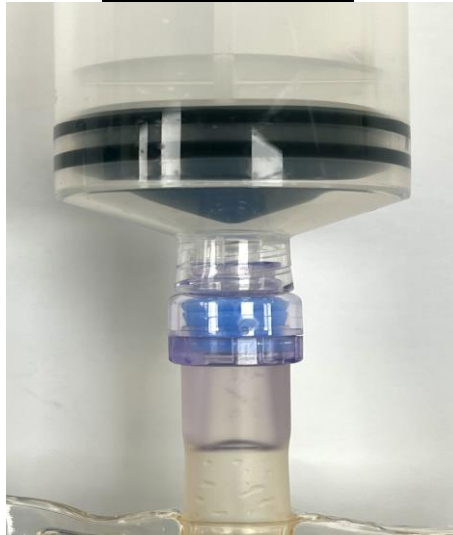
4. Label the 3 x empty injection vials as A, B and C.
5. Transfer the individual components to the aseptic preparation area or Isolator following the user's local procedures.
6. Take the 100ml TSB infusion bag. Sanitise if required according to the user's local procedures.

Accessing contents from needle-free port on TSB infusion bag

Syringe without luer lock



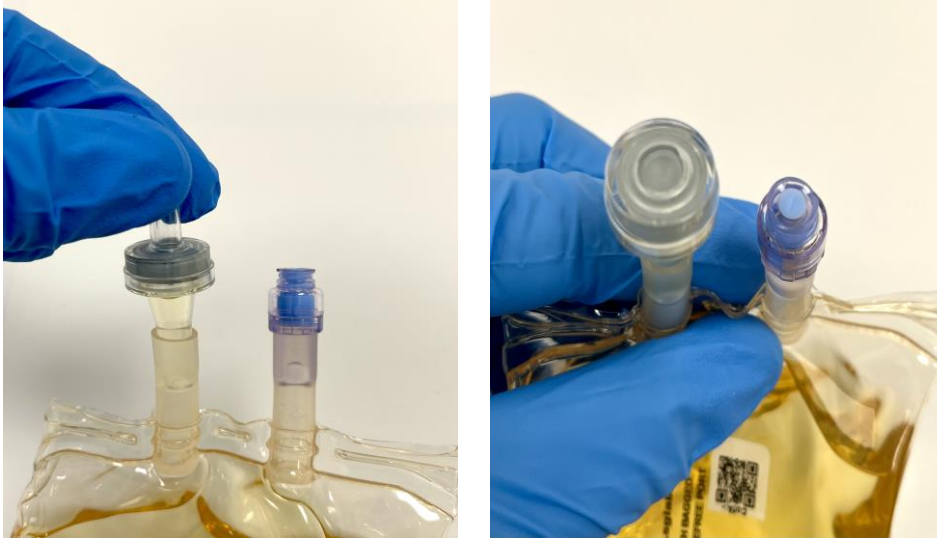
Syringe with luer lock



7. Using a minimum 5ml volume syringe, push the syringe tip into the blue seal on the needle-free port and withdraw a 5ml TSB aliquot. It is recommended to use a luer lock syringe and to screw the syringe to the base. This will provide a better seal.
8. Remove and cap the syringe.
9. Repeat Stages 7 and 8 a further four times to form 5 x 5ml TSB filled syringes
10. Sanitise the grey seal of the 50ml TSB injection vial according to the user's local procedures.
11. Using a needle connected to a minimum 5ml volume syringe, pierce the grey seal and remove a 5ml aliquot of TSB from the vial[.

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Accessing the grey rubber seal on TSB infusion bag



12. Transfer the 5ml withdrawn TSB from the syringe into the 100ml TSB infusion bag by piercing the grey rubber seal on the spike port. The seal is exposed by snapping off the extended clear plastic point. Discard the needle and syringe.
13. Repeat Stage 11 and 12 a further four times. This will restore the bag volume back to 100ml.
14. Sanitise the 10ml TSB ampoule according to the user's local procedures.
15. Sanitise the grey rubber seal on the empty injection vial labelled "A" according to the user's local procedures
16. Hold the ampoule securely at the base and, with the other hand, pull the neck backwards to snap the top. The white line around the ampoule neck is the weakest point and should break easily to expose the TSB contents.

Breaking ampoule seal



17. Using a needle connected to a minimum 5ml volume syringe or similar device, remove a 5ml aliquot of TSB from the ampoule and transfer to injection vial "A" by piercing through the grey rubber seal. Discard the needle, syringe and opened ampoule safely.
18. Using a needle connected to a minimum 5ml volume syringe, remove a 5ml TSB aliquot from the 100ml TSB infusion bag by piercing the grey rubber seal. Transfer the TSB aliquot to injection vial "A". Discard the needle and syringe safely
19. Repeat Stage 18 a further two times to transfer TSB from the infusion bag to injection vial "A" to bring the final volume in the vial to 20ml.

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20. Sanitise the grey rubber seal on the empty injection vial labelled “B” according to the user’s local procedures
21. Using a new needle connected to a minimum 5ml volume syringe, remove a 5ml aliquot of TSB from injection vial “A” and transfer to injection vial “B”. Discard the needle and syringe safely.
22. Repeat Stage 21 once to add a further 5ml TSB aliquot from injection vial “A” to injection vial “B”. Injection vials “A” and “B” will now contain 10ml TSB.
23. Sanitise the grey rubber seal on the empty injection vial labelled “C” according to the user’s local procedures
24. Using a new needle connected to a minimum 5ml volume syringe, remove a 5ml aliquot of TSB from injection vial “B” and transfer to injection vial “C”. Discard the needle and syringe safely. Injection vials “B” and “C” will now contain 5ml TSB.
25. The filled components to be incubated are as below
 - 5 x capped syringes from Stage 9
 - 3 x injection vials “A”, “B” and “C”
 - 1 x 100ml TSB infusion bag
 - 1 x 50ml TSB injection vial
26. Incubate according to the user’s local procedures. In absence of local procedures, it is recommended to incubate at 30 - 35°C for 14 days with daily inspection to check for signs of turbidity that indicates the presence of microbial growth.