Empis® Serum Vial Kit

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CX-5040

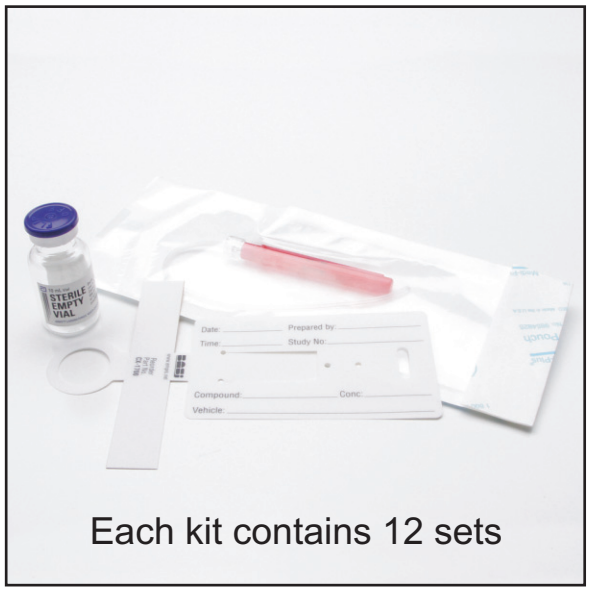
Version 1.0

CX-5040 Serum Vial Kit

The Serum Vial Kit provides sufficient sterile serum vials, vent lines and serum bottle holders to prepare and install 12 dosing solutions on the Empis Automated Drug Infusion system. The kit components can be ordered separately as needed to replenish the kit.

Contents of this Kit

Qty	Part No.	Description
12	MR-5240	SterileVial, 10 mL capacity
12	CX-1701	Sterile vent line with 5 cm needle
12	CX-1700	Empis vial holder



Each kit contains 12 sets

When should I use a vial?

The Empis System will deliver a test article from either a loaded syringe, or an automatically refillable syringe. With a refillable syringe, there is a refill line which connects to either a sterile bag of fluid, or a sterile serum vial containing fluid.

Bags of fluid can be used when the test article solution is plentiful and inexpensive. An example would be a bag containing 150 mL of normal saline or water, that would be used to flush a bolus dose through the catheter.

A serum bottle is a better choice when there is a limited amount of solution available, as would be the case for several mL of a drug used in a continuous infusion, or dose-ranging study.. Bags contain an extra fill port which can trap solution, leaving it unavailable for dosing. Bottles will direct all of the solution towards the refill needle inserted in the bottle septum.

What about sterile solutions?

We provide no means to sterilize dosing solutions, although the components of this kit are sterile and suitable for use with sterile solutions. This task is usually done during formulation, using a syringe-mounted, sterile filter or another sterile apparatus with a 0.2 µm filtration membrane. The decision on whether or not to prepare a sterile dosing solution depends on the species of animal and the location of the catheter. A solution delivered to the stomach or duodenum, for example, would generally not require sterilization since neither of those destinations would be considered sterile. A continuous, intravenous infusion over a period of several days would have to be considered from multiple perspectives, only one of which is sterility. The stability of the solution, the chemical stability of the test article, and binding or other interactions with the drug delivery stem would be equally important considerations.

Please consult your drug formulations group and animal use and care committee for guidance.

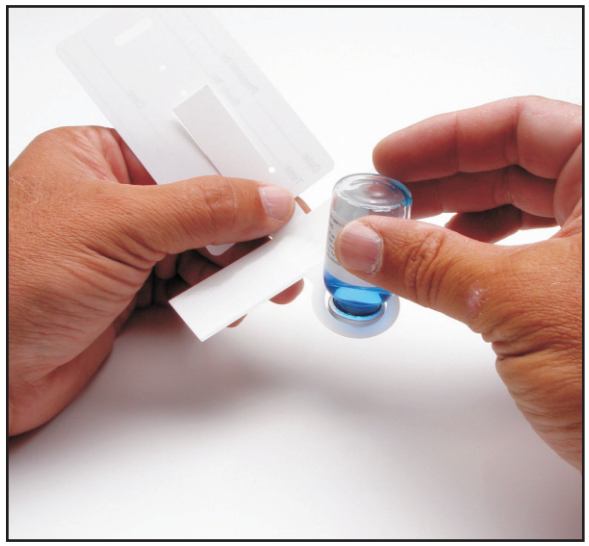
Assembly of a Serum Vial for Installation on the Empis system

1. Prepare the dosing solution and mark the label section of the vial holder with pertinent information.

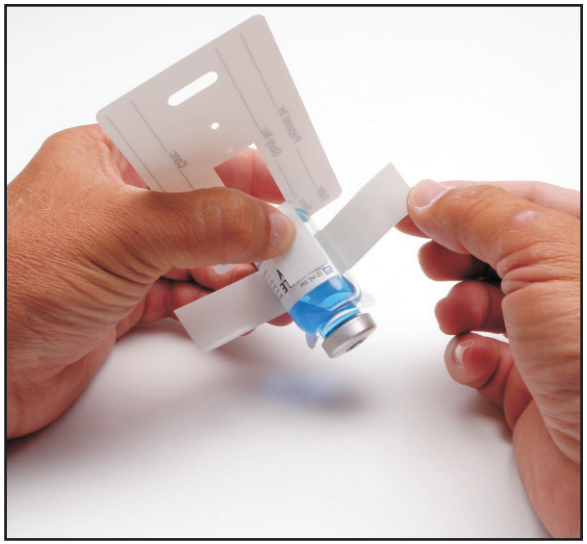
2) Remove the plastic cap covering the septum on the sterile serum vial. Fill the vial by injection.

3) Remove the backing from the adhesive strip on the back surface of the vial holder, as shown:

4) Slip the loop of the vial holder over the neck of the serum vial, as shown:



5) Pull down the central tab on the vial holder. Fold it across the bottom of the vial and then along the side.



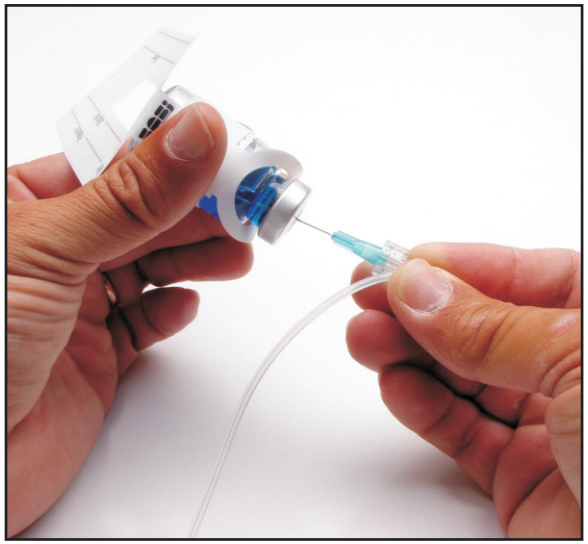
6) Secure the tab by folding the adhesive-backed arms of the holder over it, and pressing them firmly.

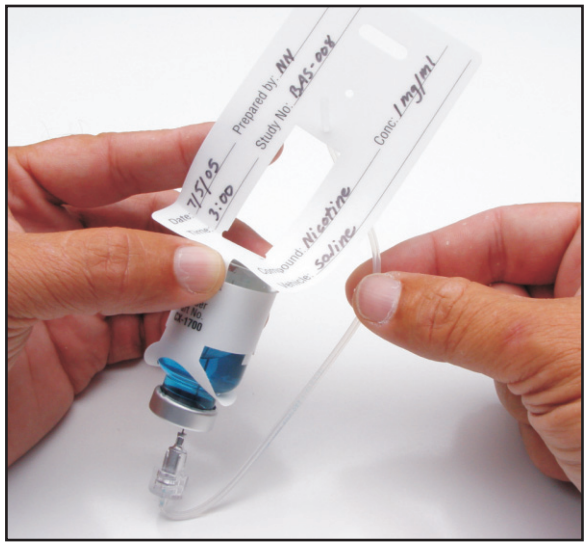
7) To maintain aseptic technique, wipe the septum with alcohol before inserting the sterile needle to the vent line.

8) Remove the vent line from the package, and then remove the needle cap.

Assembly of a Serum Vial for Installation on the Empis system (continued)

9) As you insert the needle through the septum, pinch the tubing closed with one hand. This will prevent fluid from entering the vent line as it passes through the fluid in the vial.





10) Thread the vent tube in and out of the two small holes at the top of vial holder to keep it secure and upright.

11) Hang the vial of solution on the Empis rack, as shown, and complete the connection to refill line on the appropriate syringe.

12) Ensure that the refill needle will remain below the surface of the solution in the vial. If there is too much tension on the refill line, lower the height of the rack or adjust the refill line as needed.

Questions?

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