INSTECH

INSTRUCTIONS FOR USE (IFU)

CATHETER LOCK SOLUTIONS IN VIALS

HEPARIN IN DEXTROSE, USP
HEPARIN IN GLYCEROL, USP
HEPARIN IN SALINE (0.9% NaCl), USP

PRODUCT PART NUMBERS AND SPECIFICATIONS

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For lab animal research use only.
Not intended for human use.

Description and Intended Use
These pharmaceutical-grade preservative-free sterile grade solutions in vials are intended to maintain patency of catheters and vascular access devices used in pre-clinical research. The lock solution occupies the dead space within the catheter inhibiting intraluminal blood clot formation.

How Supplied
Supplied clear and colorless. Each mL contains the indicated USP (United States Pharmacopeia) units/mL heparin sodium USP (derived from porcine intestinal mucosa), plus either 0.5g dextrose anhydrous USP for 50% dextrose, 0.5 mL glycerol USP for 50% glycerol, or 0.9 mg NaCl for Saline. Lastly, WFI (water for injection) USP, sterile grade, is added to achieve stated concentration. The pH range is 5.0 to 7.5. All materials are USP grade with lot traceability and solution filtered for sterility.

50mL and 10mL USP Type 1 borosilicate glass serum vials feature recessed Instech PinPorts™ for convenient aseptic access or butyl rubber stoppers, both of which meet USP Class VI requirements. All products feature USP grade materials and are sealed to maintain product integrity and sterility, then individually placed in labeled boxes.

Precautions
Prior to infusing compounds or withdrawing blood, the lock solution must be withdrawn from the catheter.

- Use recommended withdraw technique to avoid coring when accessing butyl rubber stoppers with a needle (see below).
- Know and understand the dead volume of the catheter and access device you intend to lock. Catheter lock solution contains high concentrations of anticoagulant heparin sodium. If administering a volume that is significantly greater than the dead volume of the catheter, injuries i.e., hemorrhaging, may occur to the animal.
- However, due to laminar flow, it generally requires 1.7x the dead volume to fully fill the catheter and replace the prior volume when using higher viscosity i.e., with dextrose or glycerol, lock solutions.[1] Therefore, some portion of this will be infused into your animals; check with your veterinary staff for what is safe for your animals and will not compromise your research.
- Discard if the solution is not clear or suspected to be contaminated.

Usage
Aseptic technique in a clean environment is recommended when handling PinPorts™, VABs™ and lock solution to prevent infection and contamination.

1. Follow vascular device instructions. Instech product manuals available at https://www.instechlabs.com/resources/manuals.
2. The vascular device should be completely flushed clear of the infusion solution or blood (in the case of sampling) with a physiological solution, e.g. 0.9% Sodium Chloride (Normal Saline), USP Sterile Grade prior to instilling catheter lock solution.
3. Under aseptic conditions, withdraw lock solution from the vial using sterile Instech™ injector (PNP3M) and sterile syringe (or sterile beveled needle and sterile syringe if accessing butyl rubber stopper).
4. Using the appropriate needle or connection for accessing the vascular access device, inject lock solution to the specific dead volume of the device catheter, vascular access port and other extension tubing.
5. The injected lock solution is intended to remain within the vascular device until the subsequent treatment or flushing event.
6. Prior to infusing compounds or withdrawing blood within the vascular device, the lock solution must be withdrawn.

Accessing Recessed PinPorts™

1. Remove and discard the Steri-Tamp® seal from the top of the vial.
2. Disinfect the recessed PinPort™ on the vial and the PinPort™ on the vascular access device with sterile 70% isopropyl alcohol or sterile 70% denatured ethanol (EtOH). Allow to dry.
3. Use positive pressure by drawing into the syringe a volume of air equal to the volume of lock solution to be withdrawn from the vial.
4. Place the vial on the work area surface and insert syringe with PinPort™ injector into the recessed PinPort™.

Recessed PinPort™ accessed with PinPort™ injector

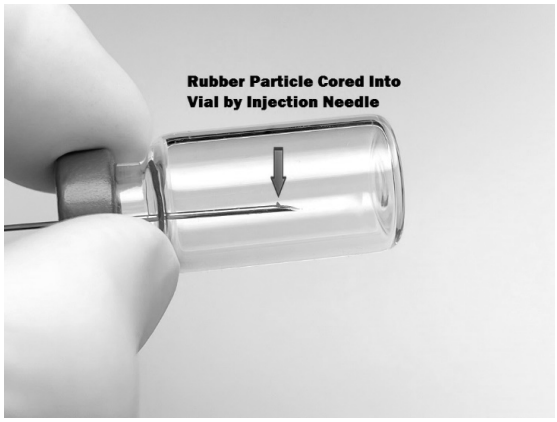
5. Invert the vial, hold the vial with one hand and with the other hand hold the barrel of the syringe, keeping the syringe and PinPort™ injector attached to the recessed PinPort™ on the vial.

6. Push the plunger to inject the air into the vial to create positive pressure. Allow the positive pressure to force the lock solution into the syringe.
7. Remove air bubbles from the syringe by tapping the syringe and expel the air bubbles into the vial. It may be necessary to use successive small injections and withdraws to exchange the air in the syringe into the vial.
8. Fill the syringe to a slight excess of the desired volume of lock solution then push the plunger the correct volume.
9. Disconnect syringe with PinPort™ injector from recessed PinPort™ on vial.

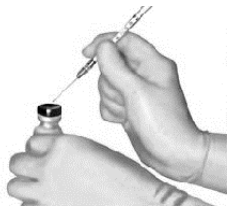
Accessing Butyl Rubber Stoppers

Vial Sealed with Butyl Rubber Stopper

1. Remove and discard the tamper-evident seal from top of vial.
2. Use positive pressure by drawing into the syringe a volume of air equal to the volume of lock solution to be withdrawn from the vial.
3. Place the vial on the work area surface and penetrate the vial without coring. Coring can occur on traditional needle accessed butyl rubber stopper when pieces of the stopper break off and fall into the extract due to repeated needle insertions. These pieces may appear as small grey or dark particles inside the vial.

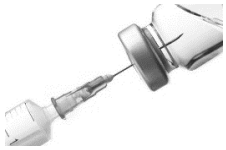


4. To prevent coring, use the following technique: Place the vial on the work area surface and position the needle point on the center of the butyl rubber stopper (within the little circle) so that the bevel opening is facing upward, and the needle is at 45° – 60° angle to the closure surface.



5. Apply downward pressure on the needle while gradually bringing the needle up to an upright position. Just before penetration is complete, the needle should be at a vertical 90° angle.

6. Invert the vial, hold the vial with one hand and with the other hand hold the barrel of the syringe. Keep the needle inserted into the vial.



7. Push the plunger to inject the air into the vial to create positive pressure. Allow the positive pressure to force the lock solution into the syringe.
8. Remove air bubbles from the syringe by tapping the syringe and expel the air bubbles into the vial. It may be necessary to use successive small injections and withdraws to exchange the air in the syringe into the vial.
9. Fill the syringe to a slight excess of the desired volume of lock solution then push the plunger the correct volume.
10. Withdraw the needle from the vial.

Considerations

When using vials sealed with butyl rubber stoppers the following should be considered:

- Accessing with higher gauge needles (between 22 to 27 gauge) is recommended. The higher the gauge, the smaller the bore. Avoid using large bore (<22 gauge) needles, as these may cause excessive damage or coring to the rubber stopper with repeated use.
- Insert the needle in the center of the butyl rubber stopper (within the little circle). This area is thinner than the edges and is designed to handle repeated insertions.
- When inserting the needle, use an angled entry with the bevel tip of the needle on the bottom, closest to the stopper (see figure). Insert carefully and try to minimize the force of entry.

- If using a 50mL vial and anticipate >10 insertions and withdraws, then consider 10mL vials. Use of smaller, lower volume vials will minimize the number of insertions into a single butyl rubber stopper.
- Consider Instech recessed PinPort™ vials accessed with PinPort™ injectors to improve safety at your facility by reducing injury risk from reduced handling of sharp needles while also eliminating risk of contamination from coring.

Storage

- Store at controlled ambient temperature of 15-25°C (59-77°F) with relative humidity of 60% or lower.
- Avoid exposure to excessive heat: >40°C (104°F).
- Do not freeze.
- Avoid exposure to UV light.
- **Expiration date is one (1) year** from date of manufacture. The expiration date is listed on the product label.
- If the vial has been opened and/or accessed, (e.g., needle-punctured) the vial should be dated and discarded within **28 days**.
- If the vial has not been opened or accessed (e.g., needle-punctured), the vial should be discarded prior to the expiration date.
- Improper storage and handling of solutions may decrease efficacy.

Disposal

Vials and lock solutions should always be disposed of properly following local waste management policies.

References

[1]Instech testing summarized in Sept 2022 blog post https://www.instechlabs.com/blog/what-does-laminar-flow-have-to-do-with-rodent-catheters

For more information go to www.instechlabs.com/manuals or scan the code or call Instech Laboratories, Inc. at 1-800-443-4227.

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