



Provincial Health Services Authority

# Bacillus Calmette–Guérin (BCG) Preparation Instructions during BCG Shortage Use of ChemoLock™ OUTSIDE of the Biological Safety Cabinet

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## Reconstitution and Withdrawal of Bacillus Calmette–Guérin (BCG) into a 60 mL Syringe

### Supplies:

- ✓ 1 x Bacillus Calmette–Guérin (BCG) Vial
- ✓ 1 x 250 mL Intravenous solution bag of preservative-free Normal Saline 0.9% - 'NS'
- ✓ 1 x BCG Medication Administration Kit – 'BCG Kit'
- ✓ 1 x ChemoLock™ Bag Spike (CL-10)
- ✓ 1 x ChemoLock™ Spinning Injector (CL-2000S)
- ✓ 1 x ChemoLock™ Port (CL-2100)
- ✓ 1 x 60 mL syringe

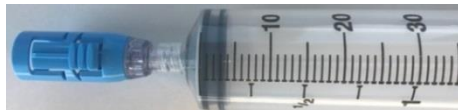
### Note:

- ✗ do **NOT** remove any ChemoLock™ device from any supply used during reconstitution of BCG as this will open the system, increasing the chance of exposure to BCG

1. insert a ChemoLock™ Bag Spike firmly into the administration port of the intravenous solution bag of NS (up to the shoulder of the ChemoLock™ Bag Spike)



2. luer the ChemoLock™ Injector onto a 60 mL syringe (rotate the Injector onto the syringe tip until an audible click is heard and it spins freely)



3. attach the ChemoLock™ Injector / syringe assembly to the ChemoLock™ Bag Spike in the NS bag by pushing the two pieces straight together until an audible click is heard



4. withdraw 50 mL of NS into the syringe; remove air from the syringe while the ChemoLock™ Injector/syringe is still attached to the ChemoLock™ Bag Spike
5. disconnect the ChemoLock™ Injector from the ChemoLock™ Bag Spike by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
6. attach a ChemoLock™ Port to the BCG Kit; align the 'OFF' arrow with the catheter tip
7. attach the BCG vial to the Medication Administration Kit



8. attach the ChemoLock™ Injector on the NS syringe to the ChemoLock™ Port on the BCG Kit by pushing the two pieces together until an audible click is heard
9. with the vial in an upright position, withdraw about 1 mL of air from the vial into the syringe and allow about 1 mL of NS to flow back into the vial (negative pressure technique) as pressure in the vial equalizes; gently swirl the vial contents (BCG suspension)
10. invert the vial/BCG Kit/syringe assembly and withdraw the BCG suspension into the syringe
11. with the vial in an upright position, withdraw another 1 mL of air from the vial into the syringe and allow about 1 mL of NS to flow back into the vial; gently swirl the contents. Withdraw the BCG suspension into the syringe; repeat as necessary (2 or 3 times) until all drug from the vial has been withdrawn into the syringe; ensure the final volume in the syringe equals 50 mL
12. remove the ChemoLock™ Injector/syringe attachment from the ChemoLock™ Port on the BCG Kit by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
13. the BCG-filled syringe MUST be labelled with the **beyond use (expiry) date and time**
14. the contents of the syringe MUST be immediately divided into patient-specific doses (see **Dividing Reconstituted Bacillus Calmette–Guérin (BCG) into Three Equal (1/3) Doses**) and administered to patients already in the facility ready for their treatment. Leftover BCG must **NOT** be saved for future patients
15. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures



**Note:**

- **BCG prepared outside of a biological safety cabinet must be administered within 1 hour of the start of reconstituting the contents of the vial (even when using a closed system drug transfer device)**

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**

## Dividing Reconstituted Bacillus Calmette–Guérin (BCG) into Three Equal (1/3) doses

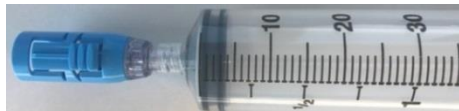
### Supplies:

- ✓ 1 x 60 mL syringe containing 50 mL of reconstituted BCG (prepared following **Reconstitution and Withdrawal of Bacillus Calmette–Guérin (BCG) into a 60 mL Syringe**)
  - ensure the divided doses will be administered to patients before the beyond use (expiry) date and time written on the syringe
- ✓ 3 x 60 mL syringes
- ✓ 3 x ChemoLock™ Spinning Injectors (CL-2000S)
- ✓ 1 x ChemoLock™ Double Port Syringe Transfer Set (CL-33)

### Note:

- ✗ do **NOT** remove any ChemoLock™ device from any supply used during division of BCG as this will open the system, increasing the chance of exposure to BCG

1. attach a ChemoLock™ Spinning Injector to each of the three empty 60 mL syringes



2. record the same **beyond use (expiry) date and time** that is recorded on the 50 mL syringe of BCG onto each of the three syringes
3. attach the ChemoLock™ Injector on the BCG-filled syringe to one end of the ChemoLock™ Double Port Transfer Set by pushing the Injector onto the Port until an audible click is heard
4. attach the ChemoLock™ Injector on one of the empty syringes to the other end of the ChemoLock™ Double Port Transfer set by pushing the two pieces straight together until an audible click is heard



5. transfer 16.7 mL (1/3) of BCG suspension into the empty syringe; remove all air from the syringe while the entire system is still attached
6. disconnect the syringe containing the 1/3 dose of BCG from the ChemoLock™ Double Port Transfer Set by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
7. repeat steps 4-6 to prepare each syringe containing 1/3 of the full dose of BCG
8. dispose of all supplies used to divide a vial of BCG into three equal doses as biohazardous waste according to site-specific policies and procedures

### Note:

- **BCG prepared outside of a biological safety cabinet must be administered within 1 hour of the start of reconstituting the contents of the vial (even when using a closed system drug transfer device)**

- **USE ASEPTIC TECHNIQUE THROUGHOUT**

## Dilution of 1/3 Doses of Bacillus Calmette–Guérin (BCG) using Normal Saline 0.9%

### Supplies:

- ✓ 3 x 60 mL syringes containing 1/3 dose of reconstituted BCG (16.7 mL)
- ✓ 1 x 250 mL Intravenous (IV) bag of preservative-free Normal Saline 0.9% with a ChemoLock™ Bag Spike inserted into the administration port (can use the same IV bag that was used to reconstitute the BCG)

### Note:

- ✗ do **NOT** remove any ChemoLock™ device from any supply used during dilution of BCG as this will open the system and increase the chance of exposure to BCG

1. attach the Injector on one of the 1/3 dose syringes to the ChemoLock™ Bag Spike in the Normal Saline bag by pushing the two pieces straight together until an audible click is heard
2. withdraw Normal Saline into the syringe until the total volume in the syringe is 50 mL
3. carefully remove air only (NOT drug) from the syringe while the ChemoLock™ Injector/syringe is still attached to the ChemoLock™ Bag Spike
4. disconnect the ChemoLock™ Injector from the ChemoLock™ Bag Spike by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
5. repeat steps 1-4 until all three syringes contain 1/3 BCG doses diluted to 50 mL with Normal Saline
6. dispose of all supplies used to dilute BCG as biohazardous waste according to site-specific policies and procedures



### Note:

- **BCG prepared outside of a biological safety cabinet must be administered within 1 hour of the start of reconstituting the contents of the vial (even when using a closed system drug transfer device)**

- **USE ASEPTIC TECHNIQUE THROUGHOUT**

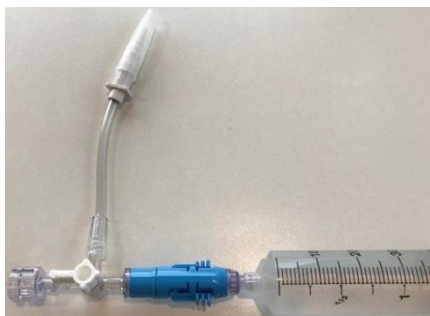
## Administration of 1/3 Diluted Doses of Bacillus Calmette–Guérin (BCG)

### Supplies:

- ✓ 3 x 60 mL syringes containing 50 mL of 1/3 dilute BCG suspension (labelled with the **beyond use (expiry) date and time**) attached to ChemoLock™ Injectors
- ✓ 3 x BCG Medication Administration Kits
- ✓ 3 x ChemoLock™ Ports (CL-2100)

### Note:

- ✗ do **NOT** remove any ChemoLock™ device from any supply used during administration of BCG as this will open the system, increasing the chance of exposure to BCG
1. check to ensure the syringe of dilute 1/3 BCG suspension has not expired (not past the **beyond use (expiry) date and time** written on the barrel of the syringe)
  2. luer lock one ChemoLock™ Port to a BCG Medication Administration Kit; align the 'OFF' arrow with the vial adapter end of the BCG Medication Administration Kit



3. **immediately before** administering the dose to the patient, attach the ChemoLock™ Injector on a syringe containing the diluted 1/3 dose of BCG to the ChemoLock™ Port on the BCG Medication Administration Kit by pushing the two pieces straight together until an audible click is heard
4. administer the BCG to the patient as per site protocol
5. dispose of all supplies used to administer BCG as biohazardous waste according to site-specific policies and procedures

### Note:

- BCG prepared outside of a biological safety cabinet **must** be administered within 1 hour of the start of reconstituting the drug in the vial (even when using a closed system drug transfer device)

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**

## Appendix 1: Supplies & Devices

### ICU Medical's ChemoLock™

For more information on ICU Medical's ChemoLock™ supplies visit: <http://www.icumed.com/products/oncology/hazardous-drug-closed-systems-and-cstds/chemolock.aspx>

#### ***ChemoLock™ Spinning Injector (CL-2000S)***



The ChemoLock™ Injector ensures a **closed drug transfer**. The Injector is attached to a standard luer lock syringe. The Injector is available in a spinning and non-spinning design. The spinning design prevents accidental disconnection of the Injector during hazardous drug preparation and administration. The priming volume of the ChemoLock™ Injector is 0.3 mL. The ChemoLock™ Injector has been tested to and is approved for up to 10 activations.

#### ***ChemoLock™ Bag Spike (CL-10)***



The ChemoLock™ Bag Spike is inserted into the administration port of an infusion solution bag. It has a built-in ChemoLock™ Port to facilitate a **leak-proof connection** for transfer of solution into and out of an infusion solution bag. The Port on the ChemoLock™ Bag Spike has been tested to and is approved for up to 10 activations.

#### ***ChemoLock™ Port (CL-2100)***



The ChemoLock™ Port attaches to the same luer locking device that syringes luer lock onto, providing a **leak-proof connection** for safe drug transfer via injection or infusion. The priming volume of the Port is 0.1 mL. The Port has been tested to and is approved for up to 10 activations.

#### ***ChemoLock™ Double Port Syringe Transfer Set (CL-33)***



The ChemoLock Double Port Syringe Transfer Set facilitates a safe and efficient transfer of solution from one syringe to another. The Ports on the ChemoLock Double Port Syringe Transfer Set have been tested and are approved for up to 10 activations.

### Non- ChemoLock™

Bacillus Calmette–Guérin (BCG)- 1 to  $8 \times 10^8$  CFU which is approximately 50mg/vial

Bacillus Calmette–Guérin (BCG) Medication Administration Kit (used to facilitate reconstitution and withdrawal of BCG)



250 mL Intravenous Bag of Normal Saline 0.9%

60 mL Syringes