

## Bacillus Calmette-Guérin (VERITY-BCG®)

### Preparation of a Full Dose and a Half Dose of VERITY-BCG® Using the ChemoLock™ Closed System Drug Transfer Device

#### Table of Contents

<i>Preparation of a Full Dose (80 mg / 2 Vials) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit and ChemoLock™</i> .....	1
<i>Preparation of a Full Dose (80 mg / 2 Vials) of Bacillus Calmette-Guérin (VERITY-BCG®) Using ChemoLock™</i> ..	3
<i>Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit and ChemoLock™</i> .....	4
<i>Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using ChemoLock™</i> ...	6
<i>Administration of Bacillus Calmette-Guérin (VERITY-BCG®) Using Using a MEDXL BCG Medication Administration Kit and ChemoLock™</i> .....	7
<i>Administration of Bacillus Calmette-Guérin (VERITY-BCG®) Using a ChemoLock™ BCG Kit</i> .....	8
<i>Appendix 1: Supplies &amp; Devices</i> .....	9
<i>References</i> .....	10

The typical dose used for intravesical instillation is dictated by brand (*refer to protocol by which patient is being treated*):

**VERITY-BCG®** (Russian BCG-I strain) 1 vial = 40 mg = 1 to 8 x 10<sup>8</sup> CFU;  
 • *full dose* = 80 mg (2 x 40 mg vials)


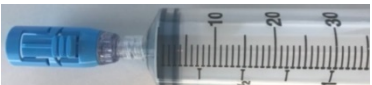
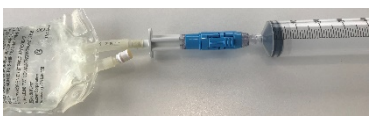
The instructions described in these checklists are by no means intended to be regarded as the only acceptable method of preparing a full or half dose of VERITY-BCG®.

## Preparation of a Full Dose (80 mg / 2 Vials) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit and ChemoLock™


### Supplies:

- ✓ 2 x VERITY-BCG® 40 mg vials
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 1 x 50 mL BD syringe
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x MEDXL BCG Medication Administration Kit (BCG Kit)
- ✓ 1 x ChemoLock™ Bag Spike (CL-10)
- ✓ 1 x ChemoLock™ Spinning Injector (CL-2000S)
- ✓ 1 x ChemoLock™ Vial Spike (CL-82)
- ✓ 1 x ChemoLock™ Port (CL-2100)


### 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 50 mL (BD) 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 45 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)

### Reconstituting the drug in the first vial

6. attach a ChemoLock™ Vial Spike to a VERITY-BCG® vial
  7. attach the ChemoLock™ Injector / NS-filled syringe assembly to the ChemoLock™ Vial Spike by pushing the two pieces straight together until an audible click is heard
  8. with the vial in an upright position, inject approximately 1 mL of NS into the vial
  9. allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend
  10. withdraw the VERITY-BCG® suspension into the syringe; repeat step 8 as necessary until all drug from the vial has been withdrawn into the syringe
  11. disconnect the ChemoLock™ Injector from the ChemoLock™ Vial Spike by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
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### Reconstituting the drug in the second vial

12. attach a ChemoLock™ Port to the luer lock end of the BCG Kit; align the 'OFF' arrow with the catheter tip
  13. attach the other VERITY-BCG® vial to the other end of the BCG Kit
  14. attach the ChemoLock™ Injector on the syringe containing the contents of the first VERITY-BCG® suspension to the ChemoLock™ Port on the BCG Kit by pushing the two pieces together until an audible click is heard
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15. with the vial in an upright position, withdraw approximately 1 mL of air from the vial into the syringe and allow approximately 1 mL of VERITY-BCG® suspension to flow back into the vial as pressure in the vial equalizes
16. allow the VERITY-BCG® suspension in the vial to stand for a few minutes, then gently swirl to suspend
17. withdraw the VERITY-BCG® suspension into the syringe; repeat step 15 as necessary until all drug from the vial has been withdrawn into the syringe
18. do not detach the syringe or the vial from the BCG Kit
19. the VERITY-BCG®-filled syringe **MUST** be labelled with the **beyond use (expiry) date and time**; the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
20. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures



**Note:**

- BCG *must* be administered within 2 hours of the start of reconstituting the drug in the vial<sup>1,2</sup>

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**

## Preparation of a Full Dose (80 mg / 2 Vials) of Bacillus Calmette-Guérin (VERITY-BCG®) Using ChemoLock™

### Supplies:

- ✓ 2 x VERITY-BCG® 40 mg vials
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 1 x 50 mL BD syringe
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x ChemoLock™ Bag Spike (CL-10)
- ✓ 1 x ChemoLock™ Spinning Injector (CL-2000S)
- ✓ 2 x ChemoLock™ Vial Spikes (CL-82)

### 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 50 mL (BD) 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 45 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™ Vial Spike to each of the VERITY-BCG® vials
7. attach the ChemoLock™ Injector / NS-filled syringe assembly to the ChemoLock™ Vial Spike in one of the vials by pushing the two pieces straight together until an audible click is heard
8. with the vial in an upright position, inject approximately 1 mL of NS into the vial
9. allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend
10. withdraw the VERITY-BCG® suspension into the syringe; repeat step 8 as necessary until all drug from the vial has been withdrawn into the syringe
11. disconnect the ChemoLock™ Injector from the ChemoLock™ Vial Spike by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
12. repeat steps 7 through 11 using the syringe containing the reconstituted contents of one vial of VERITY-BCG® suspension to reconstitute the contents of the second VERITY-BCG® vial
13. the VERITY-BCG®-filled syringe **MUST** be labelled with the **beyond use (expiry) date and time**; the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
14. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures

### Note:

- BCG *must* be administered within 2 hours of the start of reconstituting the drug in the vial<sup>1,2</sup>

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**

## Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit and ChemoLock™


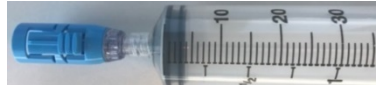


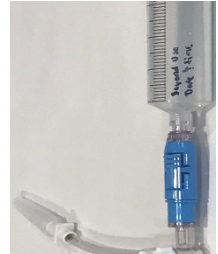
### Note:

- As long as the syringe and VERITY-BCG® vial are NOT disconnected from the MEDXL BCG Medication Administration Kit, it is not necessary to use a Closed System Drug Transfer Device to reconstitute one vial of VERITY-BCG® and dilute in 45 mL of normal saline [refer to **Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit** in the **Bacillus Calmette-Guérin (VERITY-BCG®) Preparation Instructions during BCG Shortage NOT using a Closed System Drug Transfer Device**]

### Supplies:

- ✓ 1 x VERITY-BCG® 40 mg vial
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 1 x 50 mL BD syringe
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x MEDXL 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)

### 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
- 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)
  - luer the ChemoLock™ Injector onto a 50 mL (BD) syringe (rotate the Injector onto the syringe tip until an audible click is heard and it spins freely)
  - 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
  - withdraw 45 mL of NS into the syringe; remove air from the syringe while the ChemoLock™ Injector/syringe is still attached to the ChemoLock™ Bag Spike
  - 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)
  - attach a ChemoLock™ Port to the luer lock end of the BCG Kit; align the 'OFF' arrow with the catheter tip
  - attach the VERITY-BCG® vial to the other end of the BCG Kit
  - 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
  - with the vial in an upright position, withdraw approximately 1 mL of air from the vial into the syringe and allow approximately 1 mL of NS to flow back into the vial as pressure in the vial equalizes
  - allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend
  - withdraw the VERITY-BCG® suspension into the syringe; repeat step 9 as necessary until all drug from the vial has been withdrawn into the syringe
  - do **not** detach the vial or the syringe from the BCG Medication Administration Kit

13. the VERITY-BCG® syringe **MUST** be labelled with the **beyond use (expiry) date and time** and that **the contents of the syringe contains a 40 mg (1/2 dose) of VERITY-BCG®**; the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
14. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures

**Note:**

- **BCG must be administered within 2 hours of the start of reconstituting the drug in the vial<sup>1,2</sup>**

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**






## Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using ChemoLock™

### Supplies:

- ✓ 1 x VERITY-BCG® 40 mg vial
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 1 x 50 mL BD syringe
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x ChemoLock™ Bag Spike (CL-10)
- ✓ 1 x ChemoLock™ Spinning Injector (CL-2000S)
- ✓ 1 x ChemoLock™ Vial Spike (CL-82)

### 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 50 mL (BD) 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 45 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™ Vial Spike to the VERITY-BCG® vial
7. attach the ChemoLock™ Injector / NS-filled syringe assembly to the ChemoLock™ Vial Spike by pushing the two pieces straight together until an audible click is heard
8. with the vial in an upright position, inject approximately 1 mL of NS into the vial  

9. allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend
10. withdraw the VERITY-BCG® suspension into the syringe; repeat step 8 as necessary until all drug from the vial has been withdrawn into the syringe
11. disconnect the ChemoLock™ Injector from the ChemoLock™ Vial Spike by squeezing the release clips on the ChemoLock™ Injector (the ChemoLock™ Injector will automatically disconnect; do NOT pull apart when releasing)
12. the VERITY-BCG®-filled syringe **MUST** be labelled with the **beyond use (expiry) date and time** and that **the contents of the syringe contains a 40 mg (1/2 dose) of VERITY-BCG®**; the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed  

13. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures

### Note:

- BCG **must** be administered **within 2 hours of the start of reconstituting the drug in the vial**<sup>1,2</sup>

➤ **USE ASEPTIC TECHNIQUE THROUGHOUT**



## Administration of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit and ChemoLock™

### Note:

- As long as the syringe and VERITY-BCG® vial are NOT disconnected from the MEDXL BCG Medication Administration Kit, it is not necessary to use a Closed System Drug Transfer Device to reconstitute one vial of VERITY-BCG® and dilute in 45 mL of normal saline [refer to **Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit** in the **Bacillus Calmette-Guérin (VERITY-BCG®) Preparation Instructions during BCG Shortage NOT using a Closed System Drug Transfer Device**]

### Supplies:

- ✓ 1 x 50 mL syringe containing 45 mL of a full dose (= 80 mg) OR 1/2 dose (= 40 mg) of VERITY-BCG® suspension (labelled with the **beyond use (expiry) date and time**) attached to a ChemoLock™ Injector
- ✓ 1 x MEDXL BCG Medication Administration Kit (BCG Kit)
- ✓ 1 x ChemoLock™ Port (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 VERITY-BCG® suspension has not expired (not past the **beyond use (expiry) date and time** recorded on the syringe); the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
  2. leftover BCG must **NOT** be saved for a future patient
  3. attach a ChemoLock™ Port to the luer lock end of the BCG Kit; align the 'OFF' arrow with the vial adapter end of the BCG Kit
  4. **immediately before** administering the dose to the patient, attach the ChemoLock™ Injector on a syringe containing the dose of VERITY-BCG® to the ChemoLock™ Port on the BCG Medication Administration Kit by pushing the two pieces straight together until an audible click is heard
  5. administer the VERITY-BCG® to the patient as per site protocol
  6. dispose of all supplies used to administer BCG as biohazardous waste according to site-specific policies and procedures



### Note:

- **BCG must be administered within 2 hours of the start of reconstituting the drug in the vial<sup>1,2</sup>**
- **USE ASEPTIC TECHNIQUE THROUGHOUT**



## Administration of Bacillus Calmette-Guérin (VERITY-BCG®) Using a ChemoLock™ BCG Kit

### Supplies:

- ✓ 1 x 50 mL syringe containing 45 mL of a full dose (= 80 mg) OR 1/2 dose (= 40 mg) of VERITY-BCG® suspension (labelled with the **beyond use (expiry) date and time**) attached to a ChemoLock™ Injector
- ✓ 1 x ChemoLock™ 7.5" (19 cm) Extension Set w/ChemoLock™ Port, Clamp, Graduated Adapter (CL-3967) (ChemoLock™ BCG Kit)

### 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 VERITY-BCG® suspension has not expired (not past the **beyond use (expiry) date and time** recorded on the syringe); the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
  2. leftover BCG must **NOT** be saved for a future patient
  3. Squeeze the clamp on the ChemoLock™ BCG Kit closed
  4. **immediately before** administering the dose to the patient, attach the ChemoLock™ Injector on a syringe containing the dose of VERITY-BCG® to the ChemoLock™ Port on the ChemoLock™ BCG Kit by pushing the two pieces straight together until an audible click is heard
  5. open the clamp on the ChemoLock™ BCG Kit and administer the VERITY-BCG® to the patient as per site protocol
  6. dispose of all supplies used to administer BCG as biohazardous waste according to site-specific policies and procedures



### Note:

- **BCG must be administered within 2 hours of the start of reconstituting the drug in the vial<sup>1,2</sup>**
- **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 0.34 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 priming volume of the ChemoLock™ Bag Spike is 0.43 mL. 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 ChemoLock™ 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.

#### ChemoLock™ 7.5" (19 cm) Extension Set w/ChemoLock™ Port, Clamp, Graduated Adapter (CL-3967) (ChemoLock™ BCG Kit)

The ChemoLock™ Extension Set w/ChemoLock™ Port, Clamp, Graduated Adapter may be used for bladder instillation of Bacillus Calmette-Guérin (BCG). The priming volume of the ChemoLock™ Extension Set is 1.5 mL. The Port on the ChemoLock™ Extension Set has been tested and is approved for up to 10 activations.



#### Non- ChemoLock™

Bacillus Calmette-Guérin (VERITY-BCG®)- 1 to  $8 \times 10^8$  CFU (= 40 mg/vial) (ONE-HALF [1/2] dose)

MEDXL Medication Administration Kit (used to facilitate reconstitution and withdrawal of BCG)



#### Intravenous Solution Bag of Preservative-free Normal Saline 0.9%

50 mL BD Syringes (Note that 60 mL syringes may be used in place of the 50 mL BD syringes; the total volume in the syringe(s) after dilution of the drug remains at 45 mL)

## References

1. Verity Pharmaceuticals Inc. VERITY-BCG® Product Monograph. Mississauga, Ontario; 5 January 2021
2. The United States Pharmacopeial Convention, Inc. General Chapter 797: Pharmaceutical compounding - sterile preparations Draft. USP 27-NF 22. Rockville, Maryland: The United States Pharmacopeial Convention, Inc.; 2019