2. Do not attempt to flush contrast media or air bubbles back into the Check Valve Tubing Assembly line.
3. Spike contrast container only one (1) time. Dispose of spike assembly when the contrast container is depleted. Do not use the spike assembly on more than one (1) bottle of contrast media.
4. Do not leave the contrast control system intact for longer than six (6) hours.
5. Do not use the Check Valve Tubing Assembly on more than one patient. Do not replace the Check Valve Tubing Assembly more than two (2) times.

Manufacturer
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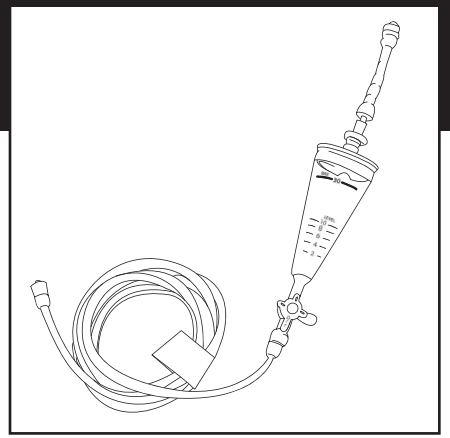
Part #5-20554 Revised 6/10

LATEX SAFE

Contrast Control Device



Single Patient Use Only
Disposable • Non-Sterile
Rx Only

IMPORTANT
Read carefully and completely before using or applying.

INTENDED USE
The DeRoyal Contrast Control Device is intended for use as a dye savings and administration system. The system consists of (2) parts described below:

Spike Assembly (Part A): All versions of Spike Assembly consist of a fluid spike and means of delivering fluid to the Disposable Check Valve Tubing Assembly (Part B). This spike assembly is intended to be used on only one bottle of contrast media. Do not spike a second bottle of contrast media with the spike currently in use. Use only a new sterile spike assembly when entering a new contrast container. Spike using hospital protocol and aseptic technique. To maintain sterility of this assembly, a sterile port dead ender (small separate package) will be provided within this package.

Disposable Check Valve Tubing Assembly (Part B): Consists of a fluid delivery line with an in line check valve which eliminates cross contamination possibilities associated with fluid back flow. The Check Valve Tubing Assembly of this system is system is intended for use on one (1) patient only and is to be replaced prior to the next patient procedure. Discard all components on the downstream side of the spike assembly when the case is completed.

DIRECTIONS FOR SPIKE ASSEMBLY DRIP CHAMBER WITH BLUE BALL

Set-Up Procedure

1. Inspect this device prior to use to verify that no damage has occured during shipping.
2. Place air vent on the contrast spike in the desired position (Open for bottles/Closed for bags).
3. Close pinch clamp or one-way stopcock (depending on set configuration).
4. Attach drip chamber assembly to the stopcock end of the Check Valve Tubing Assembly (provided separately).
5. Attach Check Valve Tubing Assembly to a manifold port.
6. Check all connections for lightness before beginning priming procedure.

Priming Procedure

7. Spike container of contrast media with the spike of the drip chamber assembly using aseptic technique.
8. Fill the drip chamber approximately 2/3 full. If necessary, float blue ball by squeezing base of drip chamber. NOTE: The contrast in the drip chamber will self-level to approximately the same level until the contrast container is depleted.
9. Open pinch clamp or one-way stopcock (depending on set configuration).
10. Prime entire assembly, (including stopcock side port if applicable), using hospital priming protocol.
11. Ensure that tubing is inspected for “air in line” before beginning procedure.
12. Contrast media can now be drawn from the system according to hospital protocol.

The set is now ready to use.

At the Conclusion of the Patient Procedure

13. If contrast media remains in container, (provided the Check Valve Tubing Assembly has not been replaced more than two (2) times and six (6) hours has not elapsed) the drip chamber assembly of the system can remain intact, as this is an extension of the contrast container.

14. Close pinch clamp or one-way stopcock, (depending on set configuration), and dispose of all components downstream of the drip chamber assembly according to hospital protocol.

15. Attach a new sterile dead end plug to the distal port of the drip chamber assembly. NOTE: Separately packaged sterile dead end plug provided within this package.

Following Patient Procedure

16. If the contrast media has been spiked within six (6) hours and the Check Valve Tubing Assembly has not been replaced more than two (2) times, continue with instructions; otherwise, dispose of the entire system according to hospital protocol.

17. Open a sterile packaged Check Valve Tubing Assembly and attach to the drip chamber assembly and the manifold per steps four (4) through six (6).

18. Continue with steps nine (9) through twelve (12).

DIRECTIONS FOR SPIKE ASSEMBLY WITH BURETTE

Set-Up Procedure

1. Inspect this device prior to use to verify that no damage has occured during shipping.

2. Place air vent on the contrast spike in the desired position (Open for bottles/Closed for bags).

3. Close the "normally open pinch clamp" on the sterile air vent of the burette assembly.

4. Close lower pinch clamp or turn stopcock "OFF" to the burette assembly (depending on set configuration).

5. Attach burette assembly to the stopcock end of the Check Valve Tubing Assembly (provided separately).

6. Attach Check Valve Tubing Assembly to a manifold port.

7. Check all connections for tightness before beginning priming procedure.

Priming Procedure

8. Spike container of contrast media with the spike of the burette assembly using aseptic technique.

9. Open pinch clamp on sterile air vent port on the burette assembly to allow contrast media to flow into the burette.

10. Fill burette to the desired level and close same pinch clamp. NOTE: The contrast in the burette will self-level to approximately the same level until the contrast container is depleted.

11. Open lower pinch clamp or turn stopcock "OPEN" to the burette assembly (depending on set configuration).

12. Prime entire assembly (including stopcock side port if applicable) using hospital priming protocol.

13. Ensure that tubing is inspected for "air in line" before beginning procedure.

14. Contrast media can now be drawn from the system according to hospital protocol.

The set is now ready to use.

At the Conclusion of the Patient Procedure

15. If contrast media remains in container, (provided the Check Valve Tubing Assembly has not been replaced more than two (2) times and six (6) hours has not elapsed) the burette assembly of the system can remain intact, as this is an extension of the contrast container.

16. Close lower pinch clamp or turn stopcock "OFF" to the burette assembly (depending on set configuration) and dispose of all components downstream of the burette assembly according to hospital protocol.

17. Attach a new sterile dead end plug to the distal port of the burette assembly. NOTE: Separately packaged sterile dead end plug provided within this package.

Following Patient Procedure

18. If the contrast media has been spiked within six (6) hours and the Check Valve Tubing Assembly has not been replaced more than two (2) times, continue with instructions; otherwise, dispose of the entire system according to hospital protocol.

19. Open a sterile packaged Check Valve Tubing Assembly and attach to the burette assembly and the manifold per steps five (5) through seven (7).

18. Continue with steps eleven (11) through fourteen (14).

DIRECTIONS FOR SPIKE ASSEMBLY WITHOUT BURETTE OR DRIP CHAMBER

Set-Up Procedure

1. Inspect this device prior to use to verify that no damage has occured during shipping.

2. Place air vent on the contrast spike in the desired position (Open for bottles/Closed for bags).

3. Close pinch clamp or one-way stopcock (depending on set configuration).

4. Attach the spike assembly to the stopcock end of the Check Valve Tubing Assembly (provided separately).

5. Attach Check Valve Tubing Assembly to a manifold port.

6. Check all connections for tightness before beginning priming procedure.

Priming Procedure

7. Spike container of contrast media with the spike assembly using aseptic technique.

8. Open lower pinch clamp or turn stopcock "OPEN" to the spike assembly (depending on set configuration).

9. Prime entire assembly (including stopcock side port if applicable) using hospital priming protocol.

10. Ensure that tubing is inspected for "air in line" before beginning procedure.

11. Contrast media can now be drawn from the system according to hospital protocol.

The set is now ready to use.

At the Conclusion of the Patient Procedure

12. If contrast media remains in container, (provided the Check Valve Tubing Assembly has not been replaced more than two (2) times and six (6) hours has not elapsed) the spike assembly of the system can remain intact, as this is an extension of the contrast container.

13. Close lower pinch clamp or turn stopcock "OFF" to the spike assembly (depending on set configuration) and dispose of all components downstream of the spike assembly according to hospital protocol.

14. Attach a new sterile dead end plug to the distal port of the spike assembly. NOTE: Separately packaged sterile dead end plug provided within this package.

Following Patient Procedure

15. If the contrast media has been spiked within six (6) hours and the Check Valve Tubing Assembly has not been replaced more than two (2) times, continue with instructions; otherwise, dispose of the entire system according to hospital protocol.

16. Open a sterile packaged Check Valve Tubing Assembly and attach to the spike assembly and the manifold per steps four (4) through six (6).

17. Continue with steps eight (8) through eleven (11).

CAUTION

- Federal (USA) law restricts this device to use by or under the direction of a physician.
- Maintenance of sterility can only be achieved through proper set up and use.
- Do not add a secondary fluid line or inject into the side-port of the stopcock on the Check Valve Tubing Assembly.
- When venting the Check Valve Tubing Assembly through the side port of the stopcock, do not allow non-sterile air to pass the check valve.

1. Use proper aseptic technique when handling this device.