



BD PhaSeal™ System

Procedures



The BD PhaSeal™ System is a closed system drug transfer device that reduces healthcare workers' exposure to hazardous drugs, from preparation to administration and disposal.¹⁻³

Airtight and leak-proof,^{4,5} the BD PhaSeal™ System mechanically prohibits the transfer of environmental contaminants into the system.⁶ At the same time, it eliminates the escape of hazardous drug or vapor concentrations, minimizing individual and environmental exposure to hazardous drugs.^{2,3}

The BD PhaSeal™ System is engineered to common International Standards Organization (ISO) standards, simplifying connections with luer fittings, standard-size drug vials and IV administration sets.

This booklet is intended to illustrate how your facility might implement the BD PhaSeal™ System components into your procedures, but is not intended as a substitute for local guidelines, regulations or your facility's policies.

- Always follow aseptic technique and adhere to local guidelines, regulations and your facility's policies for the safe handling of hazardous drugs including the use of Personal Protective Equipment (PPE) and visual inspection.
- During IV administration, follow your facility's protocols for IV drug delivery, including disinfection of IV access ports, use of Personal Protective Equipment (PPE), and visual inspection.
- Always handle hazardous waste items according to your facility's protocol.
- To ensure safety and maintain a closed system, discard empty or unneeded syringe units without disassembling.
- Discard administration sets intact without removing the BD PhaSeal™ System Connectors.
- Discard or store vial assemblies without detaching the BD PhaSeal™ Protector.
- Ensure all Luer Lock connections are securely tightened.

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Preparation



1.1

Building the syringe unit

Equipment necessary:

1. BD PhaSeal™ Injector (N35)
2. Syringe, size dependent on dose

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. Aspirate air equal to drug dose or diluent required to reconstitute the drug.
2. Luer Lock Injector onto syringe. Syringe unit is now complete.



1.2

Engaging and disengaging the injector (N35)

Equipment necessary:

1. BD PhaSeal™ Injector (N35) or syringe unit
2. Select mating component(s): BD PhaSeal™ Protector (P14, P21, P28, P50, P55), Infusion Adapter (C100), Infusion Sets

Engage

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.



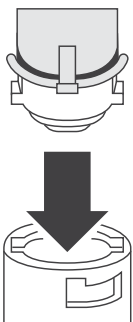
Push

Turn

Push

1. **PUSH-TURN-PUSH.** Hold white finger grips on injector and mating component. Line up wings of injector to indents of mating component. Push injector into the connection interface.

Note: Avoid touching blue portion of injector.



Hold white finger grip and turn clockwise.
Push down to engage.

Disengage



Pull

Turn

Pull

1. **PULL-TURN-PULL.** Pull injector away from connection interface until blue portion of injector is exposed. Turn counterclockwise. Pull injector to remove from mating component.

1.3

Building the Vial Assembly using the assembly fixture (M12)

Equipment necessary:

1. BD PhaSeal™ Protector according to neck size of the vial and volume to be used (P14, P21, P28, P50, P55)
2. BD PhaSeal™ Assembly Fixture (M12)
3. Drug vial(s)

Procedure:

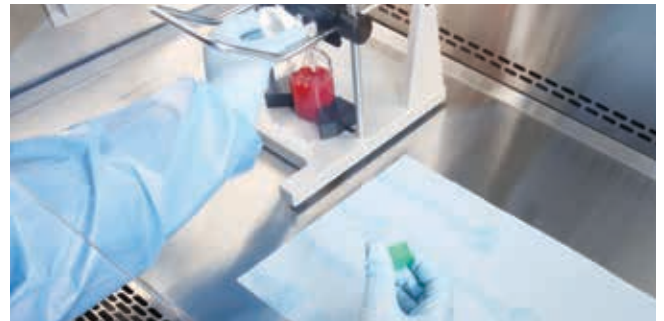
Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

Select a Protector according to neck size of vial and volume of drug to be prepared.

1. Place assembly fixture on work surface.



3. Remove cap from Protector and slide into top of assembly fixture with expansion chamber facing forward.



2. Remove vial cap, disinfect per facility protocol. Place vial on assembly fixture base between slide clamps.



4. Using downward force on handle, attach Protector onto vial to create Vial Assembly. Remove Vial Assembly from assembly fixture.



1.4

Preparing one vial to one syringe

Equipment necessary:

1. Vial Assembly (*procedure: building the Vial Assembly*)
2. Syringe unit (*procedure: building the syringe unit*)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. Engage syringe unit to Vial Assembly.



2. Keeping vial upright, push diluent or air into vial. Expansion chamber will inflate. If reconstituting, follow drug manufacturer's package insert.



3. Invert system and aspirate drug dose into syringe unit. Expansion chamber will deflate.



4. Disengage syringe unit from Vial Assembly. Syringe unit is now ready for administration or further preparation.



Dispose of or store Vial Assembly without disassembling and in accordance with facility protocol.

1.5

Preparing two or more vials to one syringe

Equipment necessary:

1. Two or more vial assemblies (procedure: building the Vial Assembly)
2. (1) Syringe unit (procedure: building the syringe unit)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

If drug is in liquid form, draw up air equal to total dose volume required for all vials into syringe prior to preparing syringe unit. If vials are in powder form, draw up diluent needed to reconstitute for all drug vials when preparing syringe unit.

1. Engage syringe unit to first Vial Assembly.



2. Keeping vial upright, push volume of diluent or air required into the first vial. Expansion chamber will inflate. If reconstituting, follow drug manufacturer's package insert.

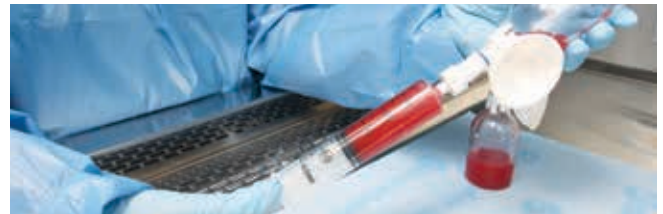


3. Disengage syringe unit from first Vial Assembly without withdrawing dose.

4. Engage syringe unit to second Vial Assembly and push remaining volume of diluent or air required into vial. If reconstituting, follow drug manufacturer's package insert. If additional vials are required, repeat step 4 as needed.



5. Invert vial and aspirate drug. Disengage syringe unit from Vial Assembly.



6. Engage syringe unit to additional vial assemblies as needed. Invert vial and aspirate drug.

7. Disengage syringe unit from Vial Assembly. Syringe unit is ready for administration or further preparation.



Dispose of or store Vial Assembly without disassembling and in accordance with facility protocol.

1.6a Preparing an IV bag using the Infusion Adapter (C100)

Equipment necessary:

1. Prepared syringe unit(s)
2. BD PhaSeal™ Infusion Adapter (C100)
3. IV bag for preparation
4. IV administration set (*optional*)
5. Injector N35 (*optional*)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. On a flat surface, spike IV bag with Infusion Adapter.

NOTE: Ensure port of IV bag is over shoulder of Infusion Adapter.



2. If priming of IV line is completed in preparation area, open blue cap on distal end of Infusion Adapter. Spike and prime administration set.

Note: If required by facility protocol, Luer Lock Injector to end of IV administration set.



3. Engage prepared syringe unit to connection interface on Infusion Adapter.



4. Push drug into IV bag. Repeat steps 3 and 4 for additional syringe units. Disengage syringe unit from connection interface on Infusion Adapter.



IV bag is now ready for administration.



Dispose of syringe unit(s) without disassembling and in accordance with facility protocol.

1.6b Preparing an IV bag using the Secondary Set (C60)

Equipment necessary:

1. Prepared syringe unit(s)
2. BD PhaSeal™ Secondary Set (C60)
3. IV bag for preparation
4. Injector N35 (optional)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. On a flat surface, spike IV bag with Secondary Set.



2. If priming of IV line is completed in preparation area, prime Secondary Set.

Note: If required by facility protocol, Luer Lock Injector to end of IV administration set.

3. Engage prepared syringe unit to connection interface on Secondary Set.



4. Push drug into IV bag. Repeat steps 3 and 4 for additional syringe units. Disengage syringe unit from connection interface on Secondary Set.



IV bag is now ready for administration.



Dispose of syringe unit(s) without disassembling and in accordance with facility protocol.

1.7

Preparing/reconstituting with 100 mL of diluent

Equipment necessary:

1. Vial Assembly with BD PhaSeal™ Protector (P50) (procedure: building the Vial Assembly)
2. (2) Syringe units prepared with 60 mL syringes containing 50 mL of diluent (procedure: building the syringe unit)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

Syringe unit 1

1. Engage syringe unit 1 onto Vial Assembly. With vial on a flat surface, inject 50 mL of diluent. Expansion chamber of Protector will inflate to full capacity.



2. While syringe unit 1 is engaged and vial remains on flat surface, pull back 50 mL of air into syringe unit. Expansion chamber will deflate.



3. Disengage syringe unit 1 from Vial Assembly.

Note: If final dose is greater than 50 mL, syringe unit 1 may be saved for further preparation.

Syringe unit 2

4. Engage syringe unit 2 onto Vial Assembly.

With vial on a flat surface, inject 50 mL of diluent. Expansion chamber of Protector will inflate to full capacity. If reconstituting, follow drug manufacturer's package insert.



5. Invert Vial Assembly and aspirate drug dose into syringe unit 2, and disengage.

Note: If dose required is greater than 50 mL, engage syringe unit 1 to Vial Assembly, inject air then repeat step.



Dispose of or store Vial Assembly without disassembling and in accordance with facility protocol.

1.8

Circle priming: priming with drug in line

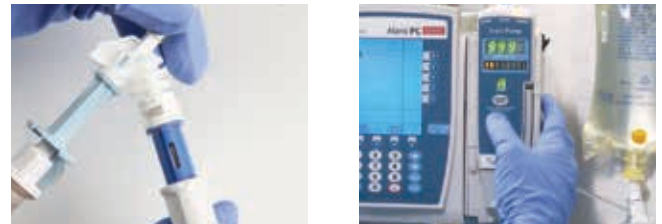
Equipment necessary:

1. Prepared IV bag (*with drug*) with BD PhaSeal™ Infusion Adapter (C100) attached
2. Primary IV administration set
3. IV pump

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol on drug administration, including disinfection of the connections, use of Personal Protective Equipment (PPE), and visual inspection.

1. Close clamp on IV administration set. While on a flat surface, spike administration set into Infusion Adapter.
2. Prime IV drip chamber per manufacturer's IFU. Slowly open clamp on IV administration set and manually prime line, allowing fluid to only flow past cassette/air sensor on administration set. Close clamp and Luer Lock Injector onto end of set.
3. With IV bag **below eye level** and on a flat surface, engage injector to Infusion Adapter interface. Hang and place IV set into pump mechanism. Set pump to prime (*i.e., rate of 999 mL/hr and VTBI at 20 mL*) and start pump.



Note: Ensure that drip chamber remains $\frac{2}{3}$ full during priming process.

4. When line is primed, stop pump and clamp IV administration set. With IV bag on a flat surface and **below eye level**, disengage injector from Infusion Adapter. Primed IV bag and administration set containing hazardous drug is now ready for administration.



1.9

Transferring hazardous drug from syringe to syringe (*QS-ing*)

Equipment necessary:

1. (2) BD PhaSeal™ Connectors (C35 or C45)
2. (2) Syringe units: one with hazardous drug; one empty or with drug/diluent, dependent on procedure
3. Luer Lock to Luer Lock transfer device connector (such as a rapid-fill connector)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. Luer Lock connectors onto each side of a Luer Lock transfer device.



2. Engage syringe units to connectors.



3. Transfer drug/diluent from one syringe to the other (*QS-ing*).



4. Disengage prepared syringe unit from connector.



Syringe unit is now ready for administration.



Dispose of Luer Lock transfer device without disassembling BD PhaSeal™ Connector/Syringe Unit and in accordance with facility protocol.

1.10 Filtering with a vial

Equipment necessary:

1. Vial Assembly (*procedure: building the Vial Assembly*)
2. BD PhaSeal™ Injector (N35)
3. BD PhaSeal™ Connector (C35 or C45)
4. Nonvented disc filter (*size per facility protocol*), Luer Lock on both ends
5. Syringe unit prepared without air or diluent

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

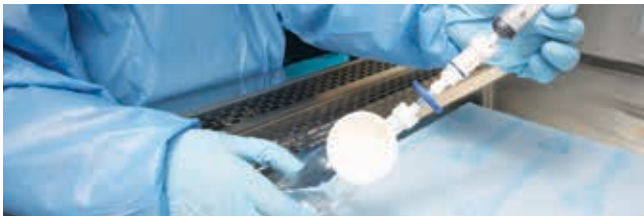
1. Luer Lock Injector onto one side of disc filter and connector to other side.



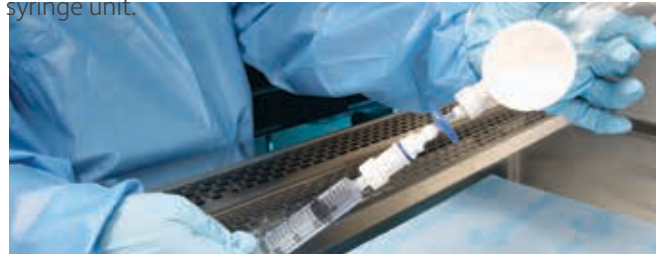
2. Engage this assembly onto Vial Assembly to create filter assembly.



3. Engage syringe unit to connector on filter assembly.



4. Invert Vial Assembly and aspirate drug dose into syringe unit.



5. Disengage syringe unit from connector on filter assembly. Syringe unit is now ready for administration or further preparation.



Dispose of vial/filter assembly without disassembling and in accordance with facility protocol.

1.11 Filtering with a syringe

Equipment necessary:

1. (2) Syringe units: syringe unit 1 (*with drug*) and syringe unit 2 (*empty*)
2. Nonvented Luer Lock disc filter
3. (2) BD PhaSeal™ Connectors (C35 or C45) Luer Lock to Luer Lock transfer device connector (*such as a rapid-fill connector*)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

1. Luer Lock a connector to each side of disc filter to create filter/connector assembly.



2. Engage syringe units to each side of filter/connector assembly. Filter drug from syringe unit 1 (*syringe with drug*) into syringe unit 2 (*empty syringe*).



3. Disengage syringe unit 2 from filter/connector assembly. syringe unit 2 is now ready for administration or further preparation.



Dispose of remainder of filter/connector assembly transfer device without disassembling and in accordance with facility protocol.

1.12 Filtering into an IV bag

Equipment necessary:

1. BD PhaSeal™ Injector (N35)
2. BD PhaSeal™ Connector (C35 or C45)
3. Disc filter per facility protocol (*Luer Lock on both sides*)
4. IV bag for drug preparation
5. Prepared drug in syringe units

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs, including the use of Personal Protective Equipment (PPE) and visual inspection.

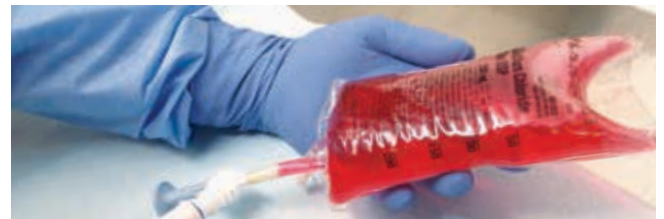
1. Luer Lock Injector on to one side of disc filter and connector to other side (*disc filter assembly*).



2. Engage injector of disc filter assembly to interface on Infusion Adapter.



3. Engage prepared syringe unit to connector on disc filter assembly. Push drug into IV bag (*filtering*).



Note: For multiple syringes, disengage first syringe unit and engage additional syringe units.

4. After all drug syringe units have been added to IV bag, disengage injector on disc filter assembly from Infusion Adapter.

IV bag is now ready for administration.



Dispose of disc filter assembly and syringe units without disassembling and in accordance with facility protocol.

Administration



2.1

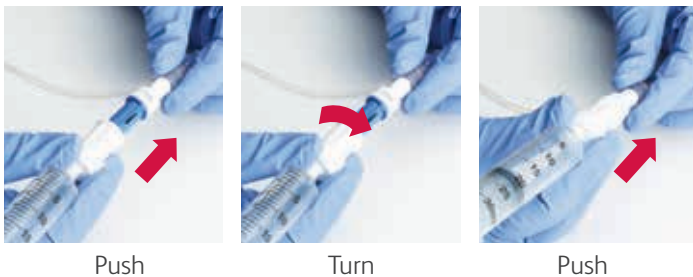
Engaging and disengaging the injector (N35)

Equipment necessary:

1. BD PhaSeal™ Injector (N35) or syringe unit
2. Select mating component(s): BD PhaSeal™ Connector (C35 or C45), Infusion Adapter (C100), Infusion Sets, Y-site connector (C80)

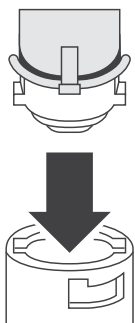
Engage

NOTE: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of personal protective equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.



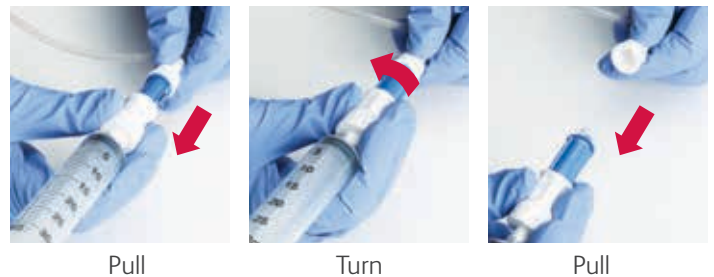
1. **PUSH-TURN-PUSH.** Hold white finger grips on injector and mating component. Line up wings of injector to indents of mating component. Push injector (N35) into connection interface.

Note: Avoid touching blue portion of injector.



Hold white finger grip and turn clockwise.
Push down to engage.

Disengage



1. **PULL-TURN-PULL.** Pull injector away from connection interface until blue portion of injector is exposed. turn counterclockwise. Pull injector to remove from mating component.

2.2

Administering an IV push

Equipment necessary:

1. BD PhaSeal™ Connector (C35 or C45), or BD PhaSeal™ Y-Site Connector (C80)
2. Syringe unit(s) prepared with drug

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock connector onto patient's IV line or access port per facility protocol, or access connector on the Y-site.



2. Engage syringe unit delivered from preparation area to connector or Y-site connector.



3. Hold connector or Y-site connector while administering the drug.



4. When IV push administration is complete, disengage syringe unit from connector or Y-site connector. Repeat for remaining syringe units or IV infusions.



Note: BD PhaSeal™ Connector or Y-site connector should remain connected to IV line and may be used for additional IV administration or IV push procedures. Connectors should be disinfected following aseptic technique and facility protocol and should be disposed of without disconnecting from tubing.



Dispose of syringe unit without disassembling and in accordance with facility protocol.

2.3

Flushing the connector (C35, C45 or C80) with saline

Equipment necessary:

1. BD PhaSeal™ Connector or Y-site connector (C35, C45 or C80) on an IV line
2. BD PhaSeal™ Injector (N35)
3. Flush syringe per facility protocol

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock an injector onto flush syringe to create a syringe unit. Engage syringe unit to connector on IV line.



2. Flush per facility protocol. Disengage syringe unit from connector.



Dispose of syringe unit without disassembling and in accordance with facility protocol.

2.4

Flushing through the Infusion Adapter (C100)

Equipment necessary:

1. Saline syringe per facility protocol
2. BD PhaSeal™ Injector (N35)
3. IV bag with Infusion Adapter (C100) already attached

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock Injector to flush syringe to create a syringe unit. **Below eye level**, engage syringe unit to connection interface on Infusion Adapter.
2. Instill saline into IV bag. Disengage syringe unit from Infusion Adapter interface, then flush IV administration set according to facility protocol.



Dispose of syringe unit, hazardous drug IV bag and IV administration set without disassembling and in accordance with facility protocol.

2.5

Using a primary IV administration set for hazardous drug delivery

Equipment necessary:

1. BD PhaSeal™ Connectors (C35 or C45 or Y-site C80)
2. BD PhaSeal™ Injector (N35)
3. Primary IV administration set
4. IV bag prepared with BD PhaSeal™ Infusion Adapter (C100)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

IV bag spiked and primed in preparation area:

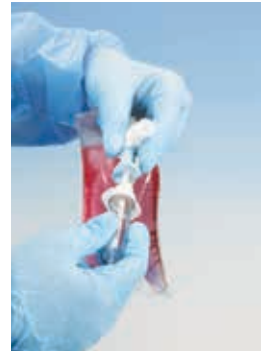
OR

IV bag needs to be primed in administration area:

- A** Luer Lock Injector to end of IV administration set if not attached in preparation area.



- A** Preprime IV administration set with saline or designated IV fluid per facility protocol. Ensure line is clamped. Spike preprimed IV administration set **below eye level** into distal end of Infusion Adapter.



- B** Luer Lock Injector to end of primary IV administration set.

- 1.** Luer Lock connector onto patient's IV line or access port per facility protocol, or access connector on Y-site.



- 2.** Engage injector to connector and administer infusion per facility protocol.



- 3.** Once infusion is completed, stop pump, clamp IV lines and disengage injector.



Note: BD PhaSeal™ Connectors should remain connected to IV line. Connector may be used for additional IV administration or IV push procedures. Connectors should be disinfected following aseptic technique and facility protocol and should be disposed of without disconnecting from tubing.



Dispose of hazardous drug IV infusion bag and primary IV administration set without disassembling and in accordance facility protocol.

2.6

Using a secondary infusion line (piggyback) for hazardous drug delivery

Equipment necessary:

1. BD PhaSeal™ Connector (C35 or C45)
2. BD PhaSeal™ Injector (N35)
3. Secondary IV administration set or BD PhaSeal™ Secondary IV Set (C60)
4. IV bag prepared with drug

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

IV bag spiked and primed in preparation area:

OR

IV bag needs to be primed in administration area:

- A** Luer Lock Injector to end of secondary IV administration set or administration set if not attached in preparation area.



- A** Prime secondary IV administration set with designated fluid per facility protocol. Ensure line is clamped. Spike secondary IV administration set into distal port of Infusion Adapter.



- B** Luer Lock Injector onto end of secondary IV administration set.



- 1.** Luer Lock connector onto patient's IV line or access port per facility protocol, or access connector on Y-site.



- 2.** Engage injector to connector and administer infusion per facility protocol.



- 3.** Once infusion is completed, stop pump, clamp IV lines and disengage injector.



Note: Connector should remain on IV line and may be used for additional IV administration. Connectors should be disinfected following aseptic technique and facility protocol and should be disposed of without disconnecting from IV administration set.



Dispose of hazardous drug IV infusion bag and primary IV administration set without disassembling and in accordance facility protocol.

2.7

Backpriming and administering a secondary (piggyback) IV administration set

Equipment necessary:

1. BD PhaSeal™ Connector or Y-site connector (C35, C45 or C80)
2. BD PhaSeal™ Injector (N35)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock Injector to end of IV administration set if not attached in preparation area.



2. Ensure line is clamped. Spike IV administration set into distal end of Infusion Adapter. Luer Lock Injector to secondary IV administration set.



3. Engage injector to connector. Release roller clamp and back prime IV line. Administer infusion.



4. Once infusion is completed, clamp Secondary Set IV line and disengage injector from connector.



Note: Connector should remain on IV line and may be used for additional IV administration. Connectors should be disinfected following aseptic technique and facility protocol and should be disposed of without disconnecting from IV administration set.



Dispose of IV administration sets without disassembling and in accordance with facility protocol.

2.8

Intravesicular administration (urine and bladder)

Equipment necessary:

1. BD PhaSeal™ Connector (C35 or C45)
2. Syringe unit prepared with drug
3. Luer Lock Foley tip adapter for administration
(brand per facility's protocol)

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock connector (C35 or C45) to Foley tip adapter.



2. Insert Foley tip adapter connector assembly into patient's Foley catheter instillation port. Engage prepared syringe unit to connector on patient's Foley catheter.



3. Administer drug and disengage injector when complete.



Note: Connector/Foley tip adapter assembly may be left in place during instillation.



Dispose of syringe unit and Foley tip adapter connector assembly without disassembling and in accordance with facility protocol.

2.9

Circle priming: priming with drug in line

Equipment necessary:

1. Prepared IV bag (*with drug*) with BD PhaSeal™ Infusion Adapter (C100) attached
2. Primary IV administration set
3. IV pump

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Close clamp on IV administration set. While on a flat surface with bag **below eye level**, spike administration set into Infusion Adapter.



3. With IV bag **below eye level** and on a flat surface, engage injector to Infusion Adapter interface. Hang and place IV set into pump mechanism. Set pump to prime (*i.e., rate of 999 mL/hr and VTBI at 20 mL*) and start pump.



Note: Ensure that drip chamber remains $\frac{2}{3}$ full during priming process. VTBI, volume to be infused.

2. Hang IV bag and prime drip chamber per manufacturer's package insert. Slowly open clamp on IV administration set and manually prime line, only past cassette/air sensor on administration set. Close clamp and Luer Lock Injector onto end of set.



4. When line is primed, stop pump and clamp IV administration set. With IV bag on a flat surface and **below eye level**, disengage injector from connection interface on Infusion Adapter. Primed IV bag and administration set containing hazardous drug are now ready for administration.



Note: If there is a need to flush postinfusion, refer to procedure: flushing through an Infusion Adapter, section 2.4.

2.10 Intramuscular (IM) and subcutaneous (SC) injections

Equipment necessary:

1. BD PhaSeal™ Connector (C35)
2. Prepared syringe unit
3. Needle for administration

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Luer Lock needle required for administration to connector.



2. Engage connector needle assembly to syringe unit and administer drug.



Dispose of syringe unit without disassembling and in accordance with facility protocol.

2.11 Using an Infusion Clamp (M25)

Equipment necessary:

1. BD PhaSeal™ Infusion Clamp (M25)
2. IV administration line with BD PhaSeal™ Injector and connector already engaged

Procedure:

Note: Follow aseptic technique and local guidelines for safe handling of hazardous drugs and facility protocol for drug administration, including disinfection of all IV access ports and BD PhaSeal™ System components, use of Personal Protective Equipment (PPE), and visual inspection. Ensure all Luer Lock connections are securely tightened.

1. Position Infusion Clamp around injector/connector assembly with correct orientation as shown in diagram on inside of clamp. Snap clamp closed, locking PhaSeal™ Injector/Connector Assembly in place.



Note: Infusion Clamp is for single patient use **only** and can be used to secure injector/connector throughout patient's hospital/clinic visit. Clamp should be discarded in accordance with facility protocol after single patient use.

References

- 1 FDA ONB Clearance Letter. 2013.
- 2 Rowe EC, Savage SW, Rutala WA, Weber DJ, Gergen-Teague M, Eckel SF. Economic and microbiologic evaluation of single-dose vial extension for hazardous drugs. *J Oncology Practice*. 2012;8(4):45e-49e.
- 3 Jorgenson JA, Spivey SM, Au C, Canann D, Ritter H, Smith B. Contamination comparison of transfer devices intended for handling hazardous drugs. *Hosp Pharm*. 2008;43(9):723-727.
- 4 Jorgenson JA. Leakproof connection integrity test for devices intended for handling hazardous drugs. Salt Lake City, UT: University of Utah Health Care. Accessed on June 7, 2018 at http://www.oncosystems.com.tr/dosyalar/Leakproof_Connection_Integrity_Test%281%29.pdf.
- 5 Nyman HA, Jorgenson JA, Slawson MH. Workplace contamination with antineoplastic agents in a new cancer hospital using a closed-system drug transfer device. *Hosp Pharm*. 2007;42(3):219-225.
- 6 Sessink PJM, Trahan J, Coyne, JW. Reduction in surface contamination with cyclophosphamide in 30 US hospital pharmacies following implementation of a closed-system drug transfer device. *Hosp Pharm*. 2013;48(3):204-212.

Consult Instructions for Use.

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