EQ JASHIELD® PROCEDURES M A N U A L

For Using EQUASHIELD Closed System Drug Transfer Device

EQUASHIELD® AN INNOVATIVE CLOSED SYSTEM TRANSFER DEVICE

Equashield, LLC is a privately held medical device company with in-depth experience in the design, production and supply of drug admixing and transfer systems. The company's proprietary product, EQUASHIELD®, is a Closed System Transfer Device for hazardous drugs that exemplifies our credo and commitment to safety and simplicity through innovation.

EQUASHIELD® provides unprecedented protection to healthcare workers and their patients, while remaining affordable and simple to use. All products are FDA cleared and CE approved, complying with the strictest regulatory requirements. Our ISO13485 production facility, is equipped with class 100,000 (ISO-8) clean rooms, and works in full compliance with U.S. Good Manufacturing Practices.

Equashield, LLC provides extensive in-house service and easily accessible local support. By designing and producing innovative protection products, Equashield is creating an environment where medical professionals have the confidence to serve others without compromising their own health and safety. We strive to provide superior innovative solutions for the protection of healthcare workers around the globe.

This procedural book provides suggested instructions on how to use Equashield products within your hazardous drug handling workflow policies. This book is not intended to substitute your facility policies and procedures, but instead, complement them. Local guidelines, regulations or your facility policies should always be followed as it relates to aseptic compounding of hazardous drugs, disinfection procedures for IV access ports, hazardous waste disposal, storage and disposal of used CSTD components and partially used vials.

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PREPARATION

1. Basic Pharmacy Procedures

1 Engaging and Disengaging System Components

Engage:

All Equashield components are engaged by aligning the red marks on each component and sliding components together (Push On)



DO NOT TWIST OR ROTATE SYSTEM COMPONENTS DURING OR AFTER ENGAGEMENT

Disengage:

All Equashield components are disengaged by pulling apart the Syringe Unit from its mating component (Pull Off)



Note: All Equashield membranes are cleared for up to 10 disengagements

1.2 Preparing a Vial Assembly

Equashield Vial Adaptors are available in five configurations



Equipment:

- 1. Drug Vial or Diluent Vial
- 2. Equashield Vial Adaptor, Appropriate for Vial Closure Size

Adaptor:



1.3 Preparing a Simple Dose

Equipment:

- 1. Assembled Drug Vial (Refer to: Preparing a Vial Assembly)
- 2. Equashield Syringe Unit

Procedure:



Dispose of or store Vial Assembly per facility protocol



1.4 Preparing a Dose With Multiple Vials

Equipment:

- 1. Assembled Drug Vial (Refer to: Preparing a Vial Assembly)
- 2. Equashield Syringe Unit

Procedure:



Reconstituting Lyophilized Powder Using a Diluent Vial

Equipment:

- 1. Assembled Lyophilized Drug Vial (Refer to: Preparing a Vial Assembly)
- 2. Assembled Diluent Vial (Refer to: Preparing a Vial Assembly)
- 3. Equashield Syringe Unit

Procedure:



Dispose of or store Vial Assembly per facility protocol

Reconstituting Lyophilized Powder Using a Diluent Bag

Equipment:

- 1. Assembled Lyophilized Drug Vial (Refer to: Preparing a Vial Assembly)
- 2. Diluent Bag
- 3. Equashield Syringe Unit
- 4. Equashield Spike Adaptor W (SA-W)

Spike Adaptor W (SA-W) is a spike adaptor specifically designed to withdraw diluent from IV bags for reconstitution. NEVER engage a Syringe Unit to the SA-W, if the Syringe Unit was previously engaged to a hazardous drug vial.



6

Invert vial and withdraw required dose. Disengage Syringe Unit from Vial Assembly

Syringe Unit is now ready for administration or downstream preparation



7

Dispose of or store Vial Assembly per facility protocol



1.7 Preparing an IV Bag Using an Equashield Spike Adaptor

Equipment:

- 1. Equashield Syringe Unit With Required Drug Dose
- 2. Equashield Spike Adaptor (SA-1/SA-1T)
- 3. IV Bag

This preparation assumes that pharmacy does not connect the tubing set.

Procedure:



Preparing an IV Bag Using an Equashield Spike Adaptor and IV Tubing Set

Equipment:

- 1. Equashield Syringe Unit With Required Drug Dose
- 2. Equashield Spike Adaptor (SA-1/SA-1T)
- 3. IV Bag
- 4. IV Tubing Set
- 5. Equashield Female Connector (FC-1/FC-1S)

Procedure:



3

Disinfect Spike Adaptor membrane per facility protocol



4

Engage Syringe Unit to Spike Adaptor and inject drug. Flush Spike Adaptor by aspirating at least 0.5 mL and re-inject





Disengage Syringe Unit from Spike Adaptor

IV bag is now ready for administration



Dispose of Syringe Unit per facility protocol



Preparing an IV Bag Using an Equashield Secondary Set

Equipment:

- 1. Equashield Syringe Unit With Required Drug Dose
- 2. Equashield Secondary Set (SA-1S/SA-1ST)
- 3. IV Bag
- 4. Equashield Female Connector (FC-1/FC-1S)

Procedure:



PREPARATION 2. Advanced Pharmacy Procedures

2.1 Batch Reconstituting Lyophilized Powder Using an Equashield Reconstitution Set

Equipment:

- 1. Empty IV Bag
- 2. Diluent Bag
- 3. Luer Lock Syringe
- 4. Equashield Reconstitution Set (LL-1R)
- 5. Assembled Lyophilized Drug Vials (Refer to: Preparing a Vial Assembly)

Procedure:



5

Engage Female Connector to lyophilized Vial Assembly; keep Vial Assembly in an upright position



6

Use syringe to withdraw required amount of diluent and inject into Vial Assembly



7

Disengage Female Connector from Vial Assembly. Shake, swirl or set aside per package insert



8

Repeat the process for additional lyophilized drug vials

2.2 Circle Priming

Equipment:

- 1. Assembled IV Bag (Refer to: Preparing an IV Bag Using an Equashield Spike Adaptor)
- 2. IV Tubing Set
- 3. Equashield Female Connector (FC-1/FC-1S)

Procedure:



5

Open the roller clamp gradually to prime tubing



6

Close the roller clamp, disengage Female Connector from Spike Adaptor and reattach the cap



2.3 Priming Into an Empty Bag Using an Equashield Spike Adaptor

Equipment:

- 1. Assembled IV bag (Refer to: Preparing an IV Bag Using an Equashield Spike Adaptor)
- 2. IV Tubing Set
- 3. Equashield Female Connector (FC-1/FC-1S)
- 4. Equashield Spike Adaptor (SA-1/SA-1T)
- 5. Empty IV Bag

Procedure:



2.4 Transfering From an Equashield Syringe Unit to Another Equashield Syringe Unit

Equipment:

- 1. Equashield Syringe Unit With Required Drug Dose
- 2. Equashield Syringe Unit With Required Diluent
- 3. Equashield Luer Lock Adaptor DC (LL-1DC)

Procedure:



5

Dispose of the components per facility protocol



2.5 Filtering Into an IV Bag Using a Disc Filter

Equipment:

- 1. Assembled IV Bag (Refer to: Preparing an IV Bag Using an Equashield Spike Adaptor)
- 2. Luer Lock Disc Filter
- 3. Equashield Luer Lock Adaptor (LL-1)
- 4. Equashield Female Connector (FC-1/FC-1S)
- 5. Equashield Syringe Unit With Required Drug Dose
- 6. Equashield Syringe Unit With Fluid for Flushing

Procedure:





Disinfect LL-1 membrane per facility protocol and engage the Syringe Unit with required dose



5 Inject the drug through disc filter filter Disengage Syringe Unit from the Disc Filter Assembly 7 8

Engage the Syringe Unit for flushing of Disc Filter Assembly and inject



Disengage the Disc Filter Assembly from Spike Adaptor



9

Dispose of the Syringe Units and Disc Filter Assembly per facility protocol

Always refer to disc filter manufacturer's data sheet



2.6 Preparing an Ambulatory Pump Cassette

Equipment:

- 1. Ambulatory Pump Cassette and Tubing
- 2. Equashield Luer Lock Adaptor (LL-1)
- 3. Equashield Female Connector (FC-1/FC-1S) Two Pieces
- 4. Equashield Syringe Unit With Required Dose
- 5. Luer Lock Syringe With Required Diluent

Procedure:





4 Engage Syringe Unit to LL-1 and inject drug



5

Withdraw small air bubbles, clamp and disengage the Syringe Unit from LL-1



If attaching tubing:



Prime tubing per facility protocol and attach a Female Connector to each end



7

Remove cap from Female Connector and engage to LL-1

Cassette is ready for administration



8

Dispose of Syringe Unit per facility protocol



2.7 Preparing an Elastomeric Pump

Equipment:

- 1. Elastomeric Pump
- 2. Equashield Syringe Unit With Required Dose
- 3. Equashield Luer Lock Adaptor (LL-1)
- 4. Equashield Female Connector (FC-1/FC-1S)
- 5. Luer Lock Syringe With Required Diluent

Procedure:



2 Prime tubing and attach Female Connector to the tubing end



3 Attach LL-1 to pump



4

Engage Syringe Unit to the LL-1, invert pump and inject drug



Disengage Syringe Unit from LL-1

5

Elastomeric pump is ready for administration



6

Dispose of Syringe Unit per facility protocol



ADMINISTRATION

3. Basic Nursing Procedures

3.1 Engaging and Disengaging System Components

Engage:

All Equashield components are engaged by aligning the red marks on each component and sliding components together (Push On)



DO NOT TWIST OR ROTATE SYSTEM COMPONENTS DURING OR AFTER ENGAGEMENT

Disengage:

All Equashield nursing components are disengaged by depressing the lever on the Luer Lock Adaptor (LL-1) and pulling apart (Pull Off)



3.2 Administering an IV Push (IVP)

Equipment:

- 1. Equashield Syringe Unit Prepared With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.







6 After IVP is complete,

depress lever on LL-1 and disengage Syringe Unit (Pull Off)





Dispose of per facility protocol



3.3 Administering an IV Piggyback (IVPB)

Equipment:

- 1. Equashield Prepared IV Bag With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



5

Align red to red and engage Female Connector to LL-1 (Push On)



6

After infusion is complete, depress lever on LL-1 and disengage Female Connector (Pull Off)



7 Dispose of per facility protocol



3.4 Administering a Direct Connect Infusion

Equipment:

- 1. Equashield Prepared IV Bag With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.





After infusion is complete, depress lever on LL-1 and disengage Female Connector (Pull Off)



7 Dispos

Dispose of per facility protocol



3.5 Administering Intramuscular (IM) and Subcutaneous (SQ) Injections

Equipment:

- 1. Equashield Syringe Unit Prepared With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)
- 3. Injection needle

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



3.6 Equashield Y-Site Tubing Accessory

Equipment:

- 1. Equashield Syringe Unit Prepared With Drug or Equashield Prepared IV Bag With Drug
- 2. Equashield Y-Site Tubing Accessory (LL-1Y)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.





3.7 Back Priming

Equipment:

- 1. Equashield Prepared IV Bag With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



6

Lower secondary bag below the primary bag until the secondary tubing is primed and drip chamber is filled to facility standard



Tubing is now primed and ready for administration per facility protocol

3.8 Flushing

A. With An Equashield Syringe Unit

Equipment:

1. Equashield Syringe Unit Prepared With Diluent

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



B. With Back Priming Technique

Equipment:

1. Completed IV Infusion

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



C. With Equashield Spike Adaptor

Equipment:

- 1. Equashield Syringe Unit Prepared With Diluent
- 2. Completed IV Infusion

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



ADMINISTRATION 4. Advanced Nursing Procedures

Administration Advance

4.1 Intravesical Instillation (Bladder)

A. Straight Catheter Via Push

Equipment:

- 1. Equashield Syringe Unit Prepared With Drug
- 2. Luer Lock Adaptor C (LL-1C)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



B. Indwelling Catheter Via Push

Equipment:

- 1. Equashield Syringe Unit Prepared With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



6

After instillation is complete, depress lever on LL-1 and disengage Syringe Unit (Pull Off)



7 Dispose of per facility protocol



C. Straight Catheter Via Gravity

Equipment:

- 1. Equashield Prepared IV Bag With Drug
- 2. Equashield Luer Lock Adaptor C (LL-1C)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



4.2 Ambulatory Pump

A. Administration

Equipment:

- 1. Equashield Prepared IV Bag With Drug or Equashield Prepared Cassette With Drug
- 2. Equashield Luer Lock Adaptor (LL-1)

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.



B. Disconnection

Equipment:

1. Completed Ambulatory Pump Infusion

Procedure:

Follow aseptic technique and facility guidelines for safe handling and drug administration, confirming all connections are tightened securely. Follow facility protocol for disinfection of all access ports and Equashield components.

1

After infusion is complete, depress lever on LL-1 and disengage Female Connector (Pull Off). Flush per facility protocol



2

Dispose of per facility protocol



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