EQUASHIELD® CSTD

Technical Specification

- FDA ONB code cleared*
- Tested for leak-free disconnects*
- Tested for airtight vapor containment*
- Substantiated to prevent microbial ingress 10x accesses for up to seven days*

* NOTE: Data on file at EQUASHIELD®.

Superior Safety and Ease of Use

EQUASHIELD®'s

Closed System Transfer Device

Safe.

Covers More Routes of Exposure Than Alternative Systems

- The only system that prevents syringe plunger contamination (repeatedly identified as a major route of exposure to hazardous drugs).*
- Closed pressure equalization prevents the escape of drug or drug vapors.
- Dry connectors that remain free of drug residues upon disconnects.
- Cleared by the FDA under the ONB code and substantiated to prevent microbial ingress for 10x accesses up to 7 days.
- Clinically proven in peer-reviewed studies to be safe and efficacious.*

Simple.

Faster and Easier to Use

- The system was deemed the fastest to use, requiring the fewest steps and least time in independently published data.*
  A fully preassembled syringe with connector, requiring no further setups or off-the-shelf syringes.
- Easy to use single motion sliding connectors.
- Locking indication to signal secure connection during drug administration.
- Intuitive accessories such as catheter connector and syringe to syringe connector to ensure simplification of workflow.

Closed.

The Most Closed CSTD on the Market

- The only system with an encapsulated syringe barrel.
- Closed internal pressure equalization built into the syringe.
- Connector is permanently welded to a syringe to ensure protection across the hazardous drug handling process.
- Encapsulated plunger rod that cannot be detached from the barrel allowing safe use of the full volume of the syringe.
- Pre-bonded accessories such as Y-Site maintain a closed system to reduce exposure.

* NOTE: Data on file at EQUASHIELD®.



Syringe Units

EQUASHIELD®'s fully encapsulated Syringe Units prevents the exposure to syringe plunger and barrel contamination caused by hazardous drug handling. The system is equipped with a built-in closed pressure equalization with sterile air. The connector is permanently bonded onto the syringe body preventing accidental disconnections and house shielded needles to prevent the risk of accidental needle sticks.



SU-1/2
Syringe Unit
1mL



SU-3/2
Syringe Unit
3mL



SU-5/2
Syringe Unit
5mL



SU-10/2
Syringe Unit
10mL



SU-20/2
Syringe Unit
20mL



SU-35/2
Syringe Unit
35mL



SU-60/2
Syringe Unit
60mL



SU-EZ60/2
Syringe Unit
60mL



Vial Adaptors

EQUASHIELD®'s Vial Adaptor firmly snaps onto a standard vial with a unique mechanism that prevents angled or non-centered spiking. The vial adaptor provides a safe and contamination-free vial access port for the Syringe Unit. As part of EQUASHIELD®'s connector system, the vial adaptor's elastomeric membrane serves a dual purpose; to serve as a microbial barrier preventing microbial ingress, remaining drug residue-free for up to 10 repeated connections in 7 days.



VA-13/2
Vial Adaptor
13mm



VA-13C/2
Vial Adaptor
13mm Concave



VA-20/2
Vial Adaptor
20mm



VA-20C/2
Vial Adaptor
20mm Concave



VA-28/2
Vial Adaptor
28mm



Spike Adaptors

EQUASHIELD®'s Spike Adaptors are designed to firmly connect between any standard IV bag and tubing set, enabling the safe transfer of medication dose into the IV Bag.

The SA-EZ is designed to securely fit standard IV Bag ports and contains a Unique locking mechanism, preventing IV Tubing from disconnecting from the Spike Adaptor.

The SA-EZ/D is designed for versatile use, enabling the withdrawal of nonhazardous diluent and the ability to prepare and administer hazardous drugs. Facilities reduce costs and streamline inventory management by reducing the required SKUs.

The SA-EZ/W is designed for safe and cost-effective withdrawal of diluent for reconstitution with EQUASHIELD® Syringe Units (SU

SA-180 was designed to work in conjunction with FC-180 to cost-effectively administer multiple consecutive medications to a patient while maintaining a closed system.



SA-EZ
EZ Spike Adaptor



SA-EZ/D
EZ/D Spike Adaptor



SA-EZ/W
Spike Adaptor EZ Withdraw



SA-180
Spike Adaptor 180



Luer Lock Adaptors & Connectors

EQUASHIELD®'s luer lock adaptors and connectors are designed to convert any standard luer lock port into a closed system connection for leak-free and dry connection.

EQUASHIELD®'s Luer Lock Adaptors, LL-2 and LL-2S are secured onto a patient line for safe injection via an EQUASHIELD® Syringe Unit (SU) or safe infusion via an FC-1 or FC-1S. While LL-2 and LL-2S safely and securely attach to any standard luer lock access port, the LL-2 remains stationary, and the LL-2S spins freely when attached; both are designed for safe and secure administration of hazardous drugs.

EQUASHIELD®'s Female Luer Lock Connectors, FC-1 and FC-1S provide a connection at the end of an IV line ensuring compliance during administration and reducing the risk of accidental disconnections. FC-1 is a standard connector, while FC-1S is a free swiveling connector; both are designed safe and secure administration of hazardous drugs.



LL-2
Luer Lock Adaptor 2



LL-2S
Luer Lock Adaptor 2 Swivel



FC-1
Female Luer Lock Connector



FC-1S
Female Luer Lock Connector Swivel



IV Tubing Sets

EQUASHIELD®'s Tubing Sets contain EQUASHIELD®'s Spike Adaptor EZ or Luer-Lock Adaptor integrated with a tubing set. These sets are designed to fit into any standard IV bag, enabling safe and efficient transfer of medication dose into the IV Bag. The SA-EZ/ST is designed to securely fit standard IV Bag ports enabling safe and efficient transfer of medication dose into the IV Bag. These sets help optimize the time and cost of drug delivery via Secondary IV Infusion. LL-1Y is a Y-Site Tubing with EQUASHIELD® Luer Lock Adaptor, a female luer lock, a clamp, and a male luer lock with a vented cap.



SA-EZ/ST
Secondary
Tubing EZ



LL-1Y
Luer Lock
Y-Site



Accessories

EQUASHIELD®'s Catheter Adaptor is ideal for administering drugs using a Foley catheter for bladder instillation procedures. The LL-2C adaptor comes with a pre-bonded EQUASHIELD® Luer Lock Adaptor to a conical catheter adaptor, saving valuable setup time and preventing opportunities for accidental luer disconnections and spills.

EQUASHIELD®'s Luer Lock Adaptor DC is ideal for connecting and safely transferring medication between EQUASHIELD® Syringe Units, also known as the QS procedure. This adaptor makes transferring between Syringe Units easy with fewer components to retrieve, open and assemble. The adaptor has two access ports for EQUASHIELD® Syringe Units at nominal priming volume.

EQUASHIELD®s Female Connector 180 contain a pre-bonded Female Connector to IV tubing port. When attached to FC-180 and SA-180 reduce the number of components involved in treating patients with multiple chemotherapy doses.



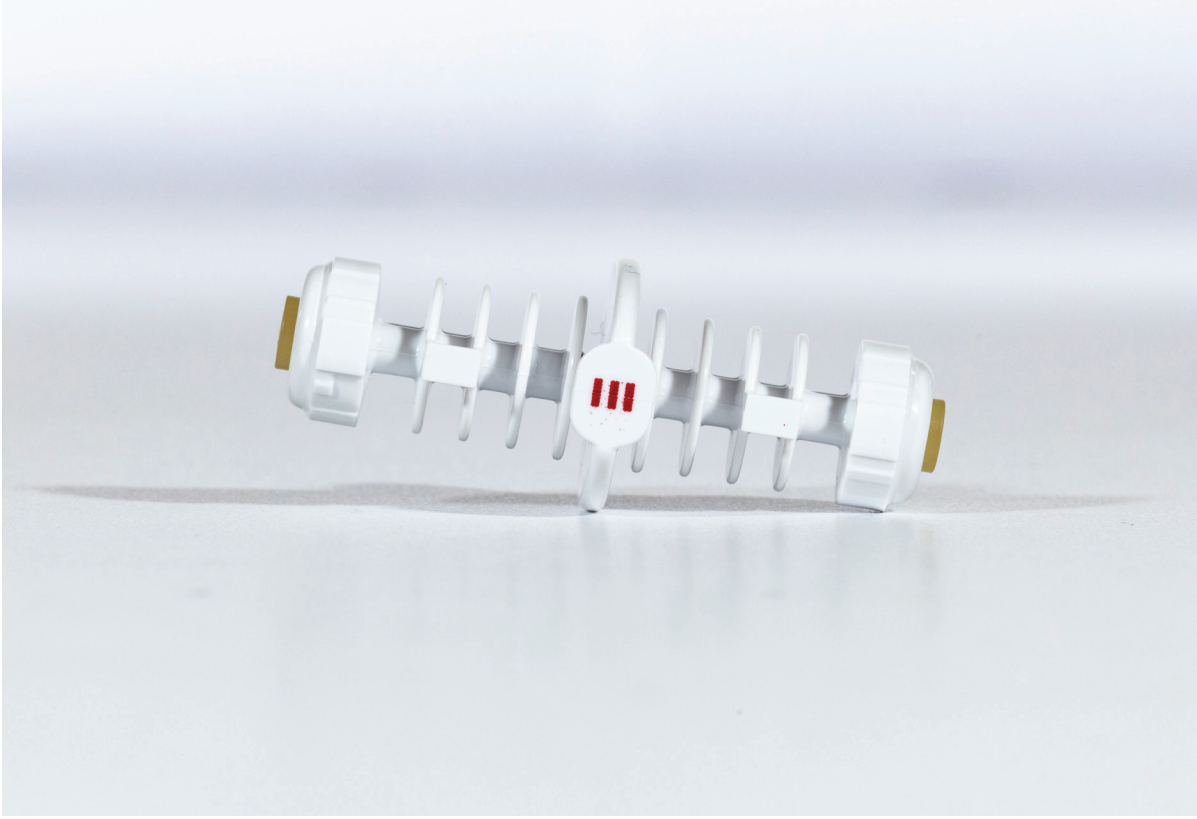
LL-2C
Luer Lock
Adaptor C



LL-1DC
Luer Lock Adaptor DC
(Double Connector)



FC-180
Female Luer Lock
Connector 180



Accessories

EQUASHIELD®'s Protective Plug is designed to cover the opening of EQUASHIELD® Female Connectors (FC-1 and FC-1S) and Syringe Units. PP-2 is pre-assembled onto EQUASHIELD® Female Connectors and is available in individually wrapped packaging for additional administration needs.

EQUASHIELD®'s Male Priming Connector is designed to enable priming of primary and secondary lines an EQUASHIELD® Female Connector effortless and free of spills.



PP-2
Protective Plug



MC-2
Male Priming Connector

CE 0483

Product Indications and Labeling

FDA 510(k) clearance: K170706

Product Code: ONB
Classification Name: Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System

Instructions for Use:

- This device should only be used under the supervision of a Pharmacist or Health Care Professional upon careful review of the instructions for use.
- This device is not intended to be used with blood or blood products.
- This device is not to be used with high-pressure infusion systems.
- Prevention of microbial ingress has been substantiated to a time period of 7 days.
- Multiple reconnections of components have been substantiated up to 10 times.
- Disinfect the device's access port septum before each repeated connection by wiping the septum in circular motions for at least 5 seconds with a sterile 70% isopropyl alcohol prep pad. Allow the alcohol to dry sufficiently before re-accessing. Do not use a pad if the packaging is damaged, as the pad may not be sterile.
- Caution: U.S. law restricts this device to sale by or on the order of a pharmacist or health care professional. RX Only.

Indications for Use (FDA):

“Closed System drug Transfer Device (CSTD) for preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills and also prevents microbial ingress up to 7 days.” The system’s closed Syringe Unit prevents intended and unintended syringe plunger detachment and can be used safely up to its maximal nominal volume with hazardous drugs.



Single Use Only,
do not re-use



The device is not made
with DEHP



Do Not Use if package
is damaged



The device is not made
with natural rubber latex



Do Not
resterilize



Consult Instructions
For Use



Dispose of used materials
safely, according to your
local regulations



Non-pyrogenic



Sterilized using
ethylene oxide

Fluid Path Materials

Ref	Polypropylene	Stainless Steel	Silicone	Polyisoprene	Hydrophobic Barrier	PVC	ABS
Syringe Unit	x	x	x	x			
Vial Adaptor	x		x	x	x		
Spike Adaptors	x			x			
Female Connectors	x	x	x	x			
Secondary Tubing Set EZ	x			x		x	x
Y-Site Tubing				x		x	x
MC-2				x	x		x
SA-180	x			x			
FC-180	x	x	x	x			
LL-2	x			x			
LL-2S	x		x	x			
LL-1DC				x			x
LL-2C	x			x			
Materials Compatibility Statement	- Complies with USP Class IV guidelines - Compatible with use in Chemotherapy Compounding and Administration - DEHP, Latex and BPA free - Substantiated for use with Busulfan, Etoposide, Paclitaxel and Treanda						

Technical Specification

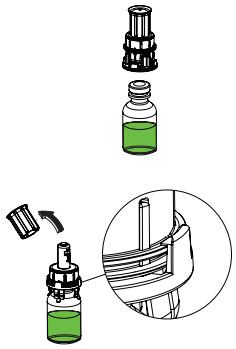
Ref	Priming Volume	Needle Size	Needle Length	Tubing Length	Gravity Flow Rate
Syringe Unit	0.07 ml for syringe 1 ml to 10 ml and 0.08 ml for all other syringes	17G (1.5 mm)	1.2" (30 mm) Non-Coring pencil point tip: needle never penetrates vial rubber stopper.		
SA-EZ & SA-EZ/D	0.15 ml				
Spike Adaptor W	0.2 ml				
Female Connectors	0.06 ml 0.065 ml for FC-1S	17G (1.5 mm)	1.2" (31 mm) Non corning pencil point tip: needle never penetrates vial rubber stopper.		A minimum flow rate of 1000 ml of sodium chloride in 10 minutes*
Secondary Tubing EZ	6 ml (excluding drip chamber)			42" (1,066.8 mm)	
Y-Site Tubing	1.6 ml			8.3" (210 mm)	
SA-180	Approximately 0.47 ml				
FC-180	0.09 ml	17G (1.5 mm)	1.2" (31 mm) Non corning pencil point		
LL-2	0.11 ml				
LL-2S	0.10 ml				
LL-1DC	0.1 ml				
LL-2C	0.1 ml				

* According to ISO 8536-4.

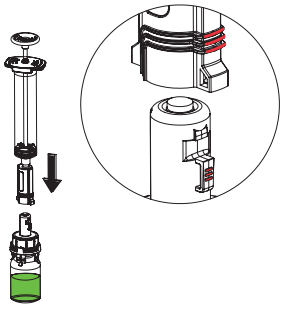
Instructions for Use

Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

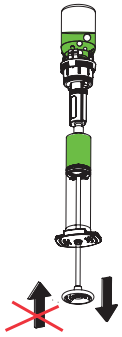
Transfer from Vial to Syringe Unit



01 Click the Vial Adaptor firmly onto the vial and ensure snapping of all 4 locking elements. Remove the protective cap.



02 Align red orientation marks and slide the Syringe Unit over the adaptor.

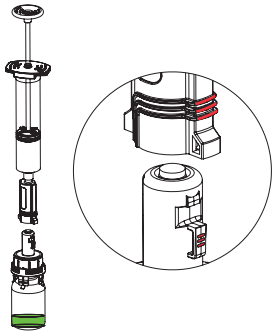


03 Invert and withdraw the liquid. Inject only to discard air and continue withdrawal.

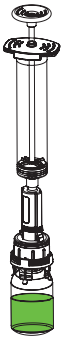


04 Pull the Syringe Unit from the Vial Adaptor.

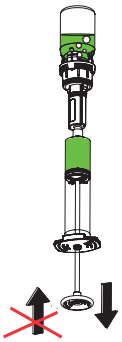
Drug reconstitution with transfer from Syringe Unit to Vial



01 Align red orientation marks and slide the Syringe Unit with the diluent or drug over the adaptor.



02 Inject diluent or drug into the vial.

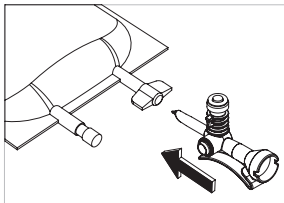


03 After dilution invert and withdraw the diluted drug. Inject only to discard air and continue withdrawal.

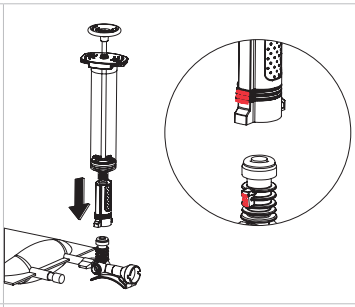


04 Pull the Syringe Unit from the Vial Adaptor.

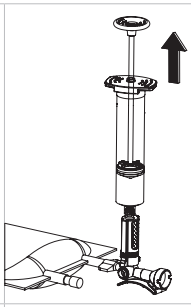
Withdrawal of diluent form a bag



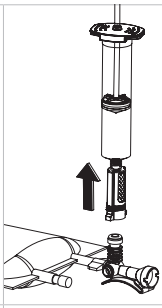
01 Connect Spike Adaptor-W to a diluent bag. Spike Adaptor-W may only be used with non-hazardous fluids.



02 Using a new/unused Syringe Unit, align red orientation marks and slide Syringe Unit over Spike Adaptor-W.



03 Withdraw desired amount of diluent.

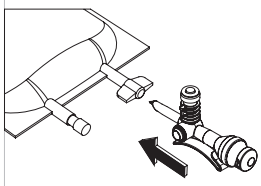
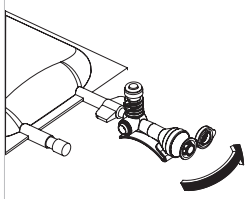
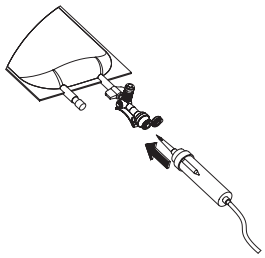
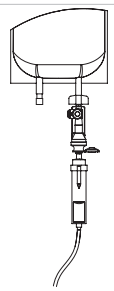


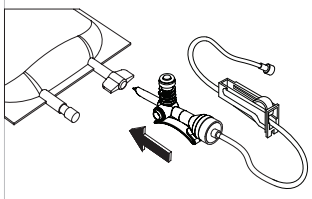
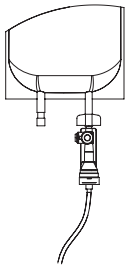
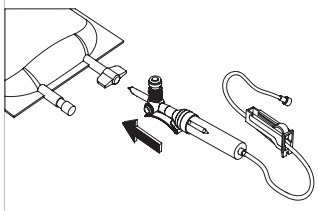
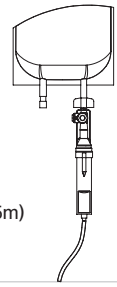
04 Pull the Syringe Unit from Spike Adaptor-W.

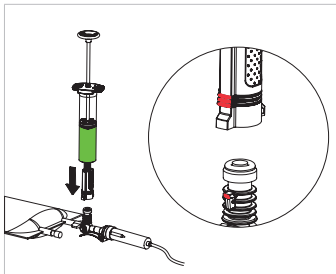
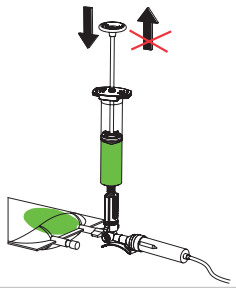
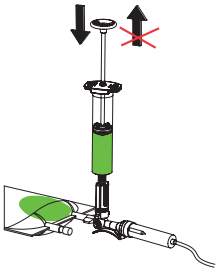
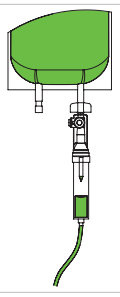
Instructions for Use

Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

Injection into an infusion bag and infusion administration

			
1a.1 Option a: Using Spike Adaptors (SA-1 or SA-1T). Connect Spike Adaptor to the infusion bag.	**1a.2** Open the spike port cap.	**1a.3** Insert tubing set spike into the spike port.	**1a.4** Prime the IV line.

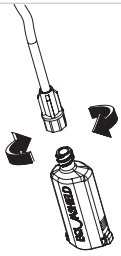
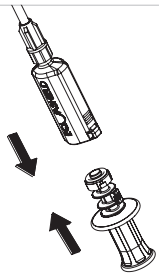
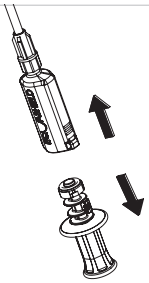
				 20 Drops/mL Approx. Length: 45" (1.15m) Approx.
1b.1 Option b: Using Spike Tubing (SA-1E). Close the clamp and insert spike into the IV bag.	**1b.2** Prime the IV line.	Or	**1c.1** Option c: Using Secondary Tubing (SA-1S or SA-1ST). Close the regulating clamp and insert spike into the IV bag.	**1c.2** Fill drip chamber partially and prime the set, purge air and close the regulating clamp.

			
02 Align red orientation marks and slide the Syringe Unit over the Spike Adaptor.	**03** Inject the drug. Aspirate at least 0.5ml and reinject to flush the channels. Do not withdraw liquids from the bag when using this adaptor.	**04** Pull the Syringe Unit from the Spike Adaptor.	**05** Administer.

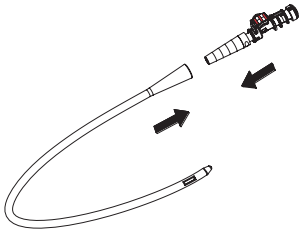
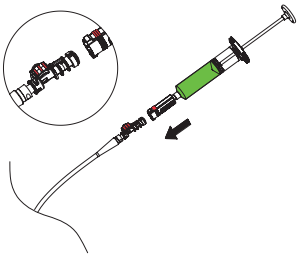
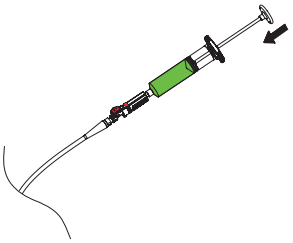
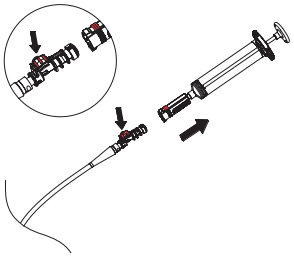
Instructions for Use

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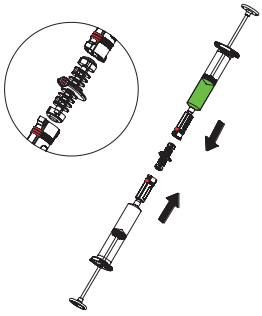
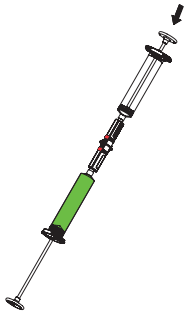
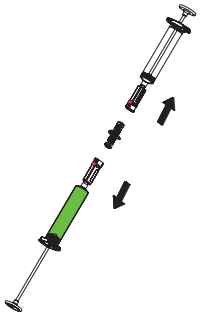
Priming of IV Line

			
01 Connect the luer lock ports of the IV tubing to the Female Luer Lock Connector.	**02** Align the red orientation marks and slide the Male Priming Connector into the Female Luer Lock Connector.	**03** Prime the IV line.	**04** Pull to disconnect.

Injecting into a Catheter

			
01 Attach catheter by sliding the catheter over the adaptor.	**02** Align red orientation marks and slide the Syringe Unit over the adaptor.	**03** Inject.	**04** Push lever to dissconnect and pull Syringe Unit from the adaptor.

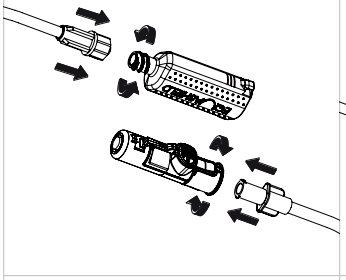
Transfer from Syringe Unit to Syringe Unit

		
01 Align red orientation marks and slide the first Syringe Unit over the adaptor followed by the second Syringe Unit.	**02** Transfer, as desired, from Syringe Unit to Syringe Unit.	**03** To disconnect, pull the syringes from the adaptor.

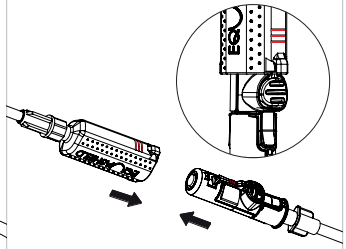
Instructions for Use

Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

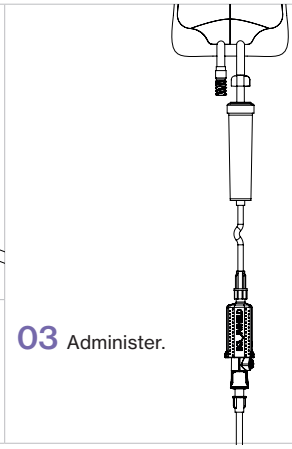
Connection of two IV tubing segments



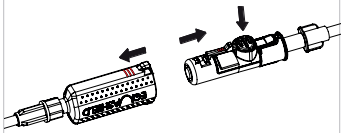
01 Connect the luer lock ports of the IV tubes to the Male and Female Luer Lock Connectors respectively.



02 Align red orientation marks and slide female connector over the male luer lock adaptor until click is heard.

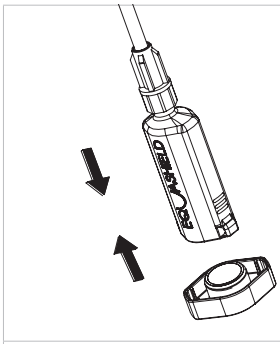


03 Administer.

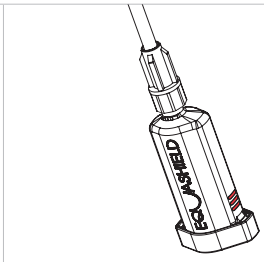


04 Push the lever to disconnect and pull components apart.

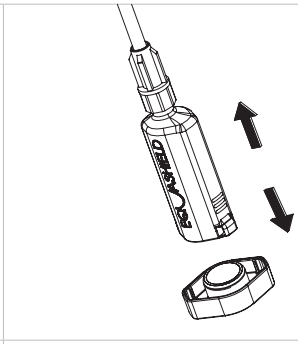
Connection of the Protective Plug



01 Place protective plug onto any EQUASHIELD® connector.



02 EQUASHIELD® connectors are now closed.

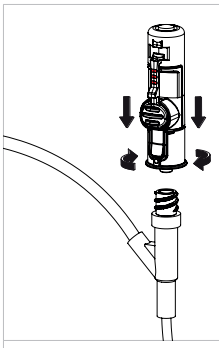


03 Pull to disconnect.

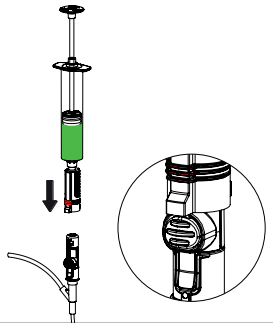
Instructions for Use

Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

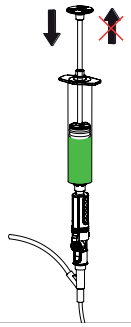
Using LL-2/LL-2S and EQUASHIELD® Syringe Unit with Hazardous Drugs



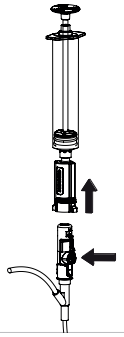
01 Connect male luer port of Luer Lock Adaptor 2 to a female luer lock port. Push firmly and tighten clockwise.



02 Align red orientation marks and slide Syringe Unit over the Adaptor until click is heard.

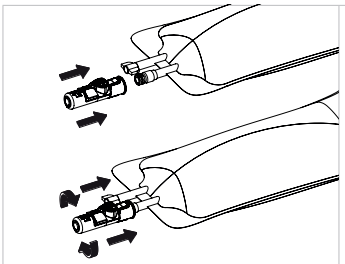


03 This device shall be used for injection only when using this adaptor with EQUASHIELD® Syringe Unit. Do not withdraw, except for blood return check or flushing the channels. To flush the channels, aspirate not more than 20% of Syringe Unit nominal volume (for 1ml SU not more than 40%) and reinject.

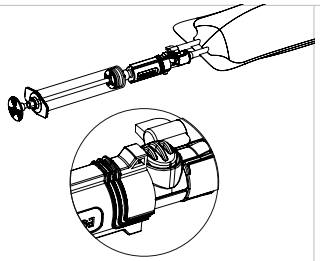


04 Push lever to disconnect and pull the Syringe Unit.

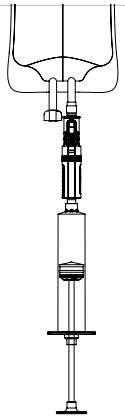
Using LL-2/LL-2S and EQUASHIELD® Syringe Unit with Non-Hazardous fluids



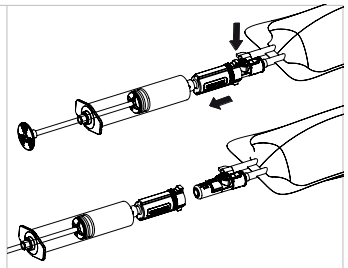
01 Connect male luer port of Luer Lock Adaptor 2 to the female luer port of the diluent bag, or of any other non hazardous source. Push firmly and tighten clockwise.



02 Using only new/unused Syringe Unit, align red orientation marks and slide Syringe Unit over Luer Lock Adaptor 2 until click is heard.



03 Withdraw desired amount of non hazardous fluid.

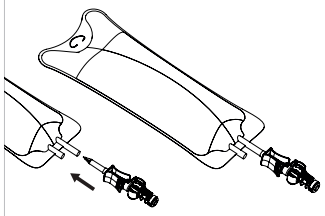
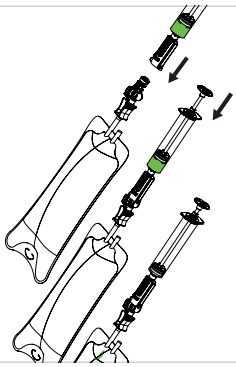
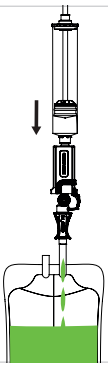
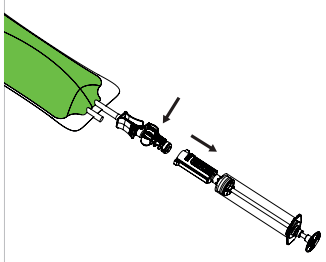


04 Push lever to disconnect and pull the Syringe Unit from Luer Lock Adaptor 2.

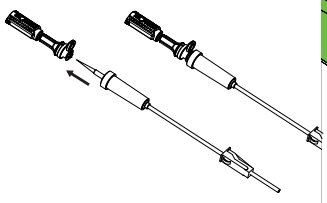
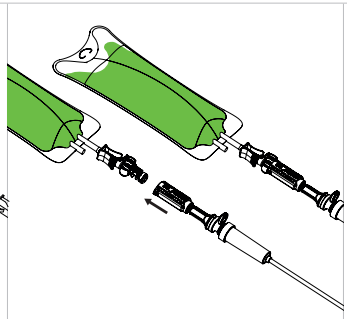
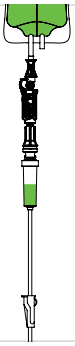
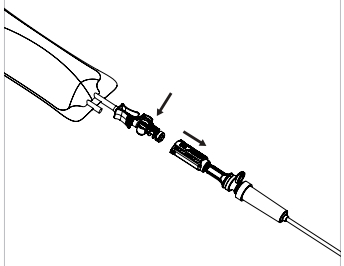
Instructions for Use

Note: For precise compounding and administration instructions, please refer to Instructions for Use supplied with the product.

Injection into infusion bag

			
01 Attach the Spike Adaptor to the infusion bag.	**02** Align red orientation marks and slide the Syringe unit over the Spike Adaptor until a click is heard. Inject the drug. Do not withdraw liquids from the bag when using this adaptor.	**03** Consider residual volume of the device and the infusion bag port. To flush, aspirate a small volume of air into the syringe by pulling the plunger, and flush downstream. Prefilled flush syringes may also be used.	**04** Push the lever to disconnect and pull the Syringe Unit from the Spike Adaptor.

Infusion Administration

			
05 Consider priming the line. Open the Twist Off cap. Insert tubing set spike into the Female Connector spike port.	**06** Align red orientation marks and slide the Female Connector over the Spike Adaptor.	**07** Administer medication as per facility protocol.	**08** Push the lever to disconnect and pull the set connected female connector from the spike adaptor.

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