

INSTRUCTIONS FOR USE

By a medical professional only.

OUTLINE

Definitions

General Product Information

1. Device Description
2. Intended Use
3. Procedure
4. Contraindications
5. Handling & Sterilization
6. Storage Conditions

Contents

For a more detailed description of the system and its utilization, please go to:

www.mphze.com or contact your Multiphze representative.

GENERAL PRODUCT INFORMATION

1. DEVICE DESCRIPTION

The Multiphze Enclosed Bladder Irrigation System features a rotatable syringe with independent ports used to manage the FILL, IRRIGATE & DRAIN functions associated with a manual bladder irrigation procedure. It is designed to mitigate the need for repeatedly disengaging the syringe from the urinary catheter and prevent the splashing, spraying, and spilling of bloody urine during the procedure.

2. INTENDED USE

The Multiphze Enclosed Bladder Irrigation System is a single-use, sterile, disposable device designed for use with an indwelling catheter for irrigation and/or drainage.

3. PROCEDURE

















The Multiphze Enclosed Bladder Irrigation System should only be used by physicians, nurses and other health care professionals trained to perform manual bladder irrigation procedures.

DEFINITIONS

Symbols and abbreviations may be used on the package label.

The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Title of Symbol	Description of Symbol	ISO 15223-1* Reference Number
	Prescription Use Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.	N/A
	Manufacturer	Indicates the medical device manufacturer	5.1.3
	Use by Date	Indicates the date after which the medical device is not to be used.	5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalogue Number	Indicates the manufacturer's catalogue number so the batch or lot can be identified.	5.1.6
	Country of Manufacture	Identifies the country of manufacture. "CC" shall be replaced by either the two-letter country code or the three-letter country code defined in ISO 3166-1.	5.1.11
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.	5.2.13
	Sterilized using Ethylene Oxide (EO)	Indicates a medical device that has been sterilized using Ethylene Oxide (EO).	5.2.3
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized or autoclaved.	5.2.6
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Temperature Limit	Indicates the maximum and minimum temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the full electronic Instructions For Use (i.e. eIFU).	5.4.3
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	5.7.10
	Medical Device	Indicates the item is a medical device.	5.7.7
	Quantity	To indicate the number of devices per package.	N/A

Source: *ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.

3. PROCEDURE (cont.)

STEP 1

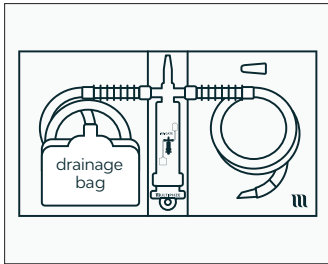
Prior to use, carefully inspect that Multiphze Enclosed Bladder Irrigation System packaging is not damaged.

STEP 2

Using sterile technique, open pouch, remove contents and unfold sterile drape to form sterile field.

STEP 3

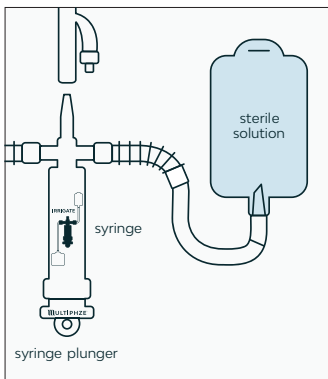
The Multiphze irrigating syringe comes pre-packaged in the IRRIGATE position and should be oriented as depicted here in preparation for procedure.



Irrigation Tubing is DEHP-free.

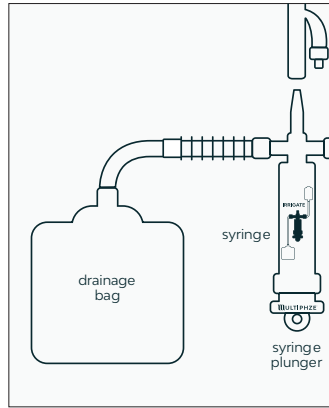
STEP 4

Spike system's irrigation line into sterile solution container provided by facility.



STEP 5

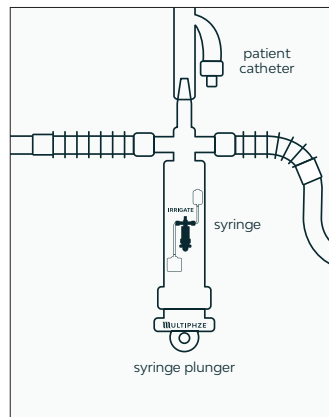
Hang system's pre-attached drainage bag below level of irrigation. (Do not lay drainage bag on the floor.) Disconnect patient's drainage tube from their catheter. Drainage bag cap provided in packaging.



STEP 6

Insert the Multiphze syringe tip into the drainage line of the patient's indwelling urinary catheter.

Begin procedure by pulling syringe plunger out to remove excess fluids/clots from bladder. Rotate syringe to DRAIN position and push plunger into syringe to move contents into attached drainage bag.



STEP 7: FILL PHASE

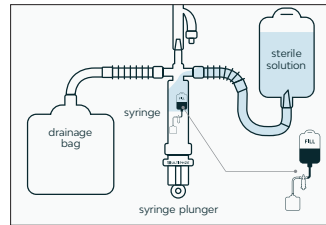
Rotate Multiphze irrigating syringe to FILL position.

Pull plunger back to fill syringe with sterile solution.

If plunger feels stuck within syringe, simply push it forward and then pull it back to continue.

If air is encountered during initial fills, then rotate immediately to DRAIN position and push plunger into syringe barrel to evacuate air into drainage bag.

If no air is encountered, fill barrel with sterile solution while in "FILL" position before proceeding to next phase.



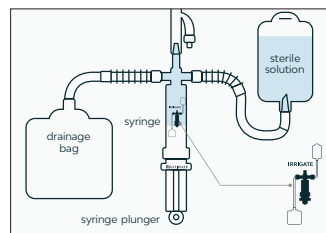
STEP 8: IRRIGATE PHASE

Rotate syringe to IRRIGATE position.

Push plunger into syringe to advance sterile solution into patient's bladder.

Pull plunger back to draw out bladder contents into syringe.

Manually irrigate bladder by pushing fluids back and forth with plunger through syringe tip as needed.

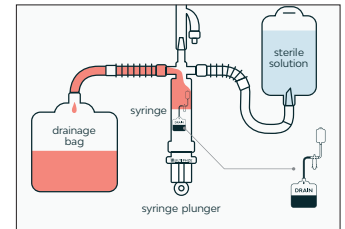


STEP 9: DRAIN PHASE

To drain contents, rotate syringe to DRAIN position.

Push plunger into barrel to empty its contents into attached drainage bag.

Repeat STEPS 7 through 9 as needed to complete procedure.



STEP 10: OFF PHASE

When procedure is complete, rotate syringe to OFF position before disengaging system from patient's catheter.

STEP 11: OPTIONAL STEP

After the manual bladder irrigation procedure is completed, the Multiphze irrigation line and drainage bag are immediately transferable with the patient if continuous bladder irrigation, via a 3-way catheter is needed.

4. CONTRAINDICATIONS

Contraindications include:

- Do not use with clogged catheter/tubing system or if suspected cavity perforation.

WARNING:

- Use system per instructions. Avoid excessive forces when pushing or pulling fluids through syringe to prevent potential unintended injury to patient or damage to system that could cause it to leak.
- Avoid excessive syringe pull pressure when using plunger, as syringe may inadvertently dislodge from catheter.
- It is advisable to first draw fluid out of the bladder before beginning any irrigation or instilling more fluid into bladder due to potential harm/discomfort it may cause patient.
- Do not re-sterilize or autoclave system.

5. HANDLING & STERILIZATION

- The Multiphze Enclosed Bladder Irrigation System has been sterilized with Ethylene Oxide (EO).
- Handle with care.
- Do not use any sterile product if packaging has been opened, damaged or has an expiration date that has lapsed.

6. STORAGE CONDITIONS

- All Multiphze Enclosed Bladder Irrigation Systems must be stored in their original sealed packaging.
- This product must be stored in a clean, dry environment and be protected from direct sunlight and extreme temperatures.

CONTENTS

- 1 Four Phase Irrigating Syringe (Off, Fill, Irrigate, Drain)
- 1 4L Urine Drainage Bag and Cap
- 1 DEHP-free Irrigation Line with Spike, Drip Chamber, Roller Clamp, Check Valve and Barbed Connectors
- 1 Sterile Drape