

MEDIVATORS™

JET PREP®

Endoscopic Flushing Device

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INSTRUCTIONS FOR USE



Caution, refer to instructions for use.



(www.medivators.com/ifus) See instructions for use

Read the complete list of instructions before using

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. **Rx ONLY**

INTENDED USE

The JET PREP® Flushing Device is intended for use as flexible endoscope accessory to apply legally marketed solutions for washing mucosal tissue in the gastrointestinal tract.

SYMBOL LEGENDS



Caution, refer to instructions for use



Catalogue number



Lot number



Expiry date/Use by



Manufacturer



Date of manufacture



Single patient use / Do not reuse



Sterilized with ethylene oxide



Keep dry









Do not use if package is damaged or open



Temperature limit

WARNINGS & PRECAUTIONS

- Do not use this device for any purpose other than the stated intended use.
- A thorough understanding of the technical principles, clinical applications and risk associated with upper and lower GI endoscopy is necessary before using this device.
- It is essential that the endoscope, the working channel diameter and length be compatible with the JET PREP Flushing Device model prior to any procedure
- The JET PREP Flushing Device must be stored in a dry location () , and operated within the specified temperature limit. ()
- Verify that the expiration date on the JET PREP Flushing Device label () has not expired.
- The JET PREP Flushing Device is sterile () and supplied in a sealed package. Do not use the product if the package is open, damaged () or unlabeled.
- Upon removing the JET PREP Flushing Device from the package, visually inspect it with particular attention to kinks, bends or breaks, if an abnormality is detected that would prohibit proper working conditions, do not use.
- The JET PREP Flushing Device is for single use only. Do not reuse (), reprocess or re-sterilize. Reuse of the device could cause cross-contamination.
- Discard all components of the JET PREP Flushing Device after use in accordance with accepted medical practice and applicable with local, state and federal laws and regulations.
- JET PREP Flushing Device intended for use in a static position of the endoscope and should be retracted into the working channel before changing positions. During movement of the endoscope (insertion or extraction) ensure that the JET PREP Flushing Device tip position is either inside the working channel, or else removed from the working channel.

CONTRAINDICATIONS

Contraindications are in accord with those of standard endoscopic procedures.

The JET PREP® Flushing Device has not been clinically evaluated during pregnancy and consultation with an obstetrician should be considered before use.

POTENTIAL COMPLICATIONS

Potential complications associated with standard endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

INSTRUCTIONS FOR USE

1. Consult label to ensure the JET PREP Flushing Device model is compatible with the endoscope used in the procedure in terms of endoscope connector, working channel diameter and length.
2. Remove JET PREP Flushing Device from pouch.
3. Beginning at the proximal part and moving towards the distal tip, uncoil the JET PREP Flushing Device making sure not to stretch or damage the parts.
4. Prepare appropriate solutions, and connect the JET PREP Flushing Device to legally marketed endoscopic irrigation pump or manual syringe with a male luer lock connector.
5. Remove the biopsy valve from the endoscope working channel, and expose the working channel input. **NOTE:** Keep the valve within easy reach, as it will be reused to plug the entrance again at the end of the use of the device.
6. Gently insert the catheter through the working channel in small segments of approximately 2cm until the endoscope connector reaches the working channel input. The lock the device endoscope connector to the working channel input. Depending upon the JET PREP Flushing Device model used, the locking is done by: (a) screwing the male luer connector to the working channel input (for luer type connector, Figure 1); or (b) pressing the connector snap over the working channel input (for snap type connector, Figure 2).

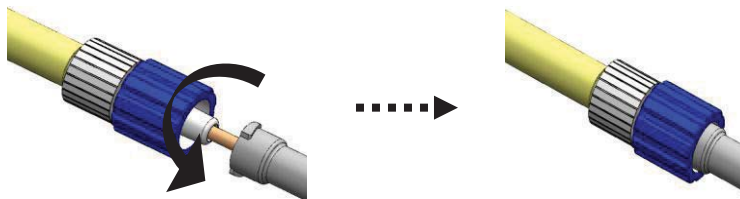


Figure 1: Locking luer type connector. Screw male luer connector to the working channel input.

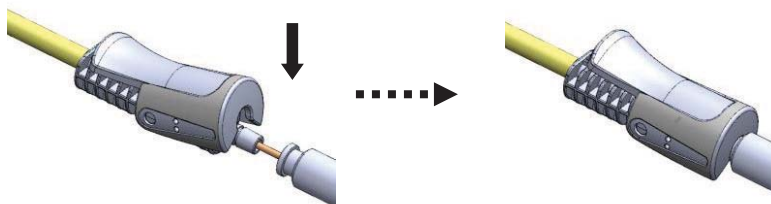


Figure 2: Locking snap type connector. Press snap over working channel input.

7. Switching between the different modes of the device (i.e. spraying, irrigation/aspiration, and flushing of working channel), is done by moving the handle slider back and forth to place the JET PREP Flushing Device distal tip in the required position, as depicted below:

- 7.1 For spraying, place the JET PREP Flushing Device distal tip on the distal end of the working channel by adjusting the handle slider to position B (see Figure 3), and deliver fluid.

Irrigation - Position B

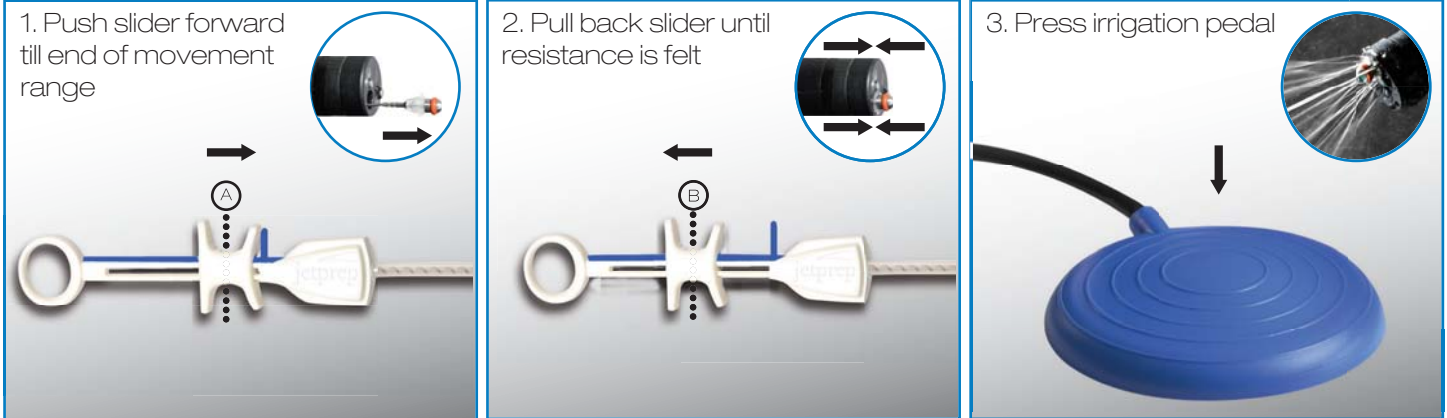


Figure 3: For spraying, handle slider is moved to Position B.

NOTE: If distal tip does not appear on the video monitor (i.e. distal tip remains inside the endoscope), push the slider fully forward (to position A, as depicted in Figure 4). If the distal tip does not appear when slider is located in position A as well, deliver a small volume (several ml) of fluid to aid in tip positioning, as fluid will push the tip out.

- 7.2. To allow aspiration, place the JET PREP® Flushing Device distal tip outside the working channel by pushing the handle slider all the way forward to position A (see Figure 4), and vacuum.

Suction - Position A

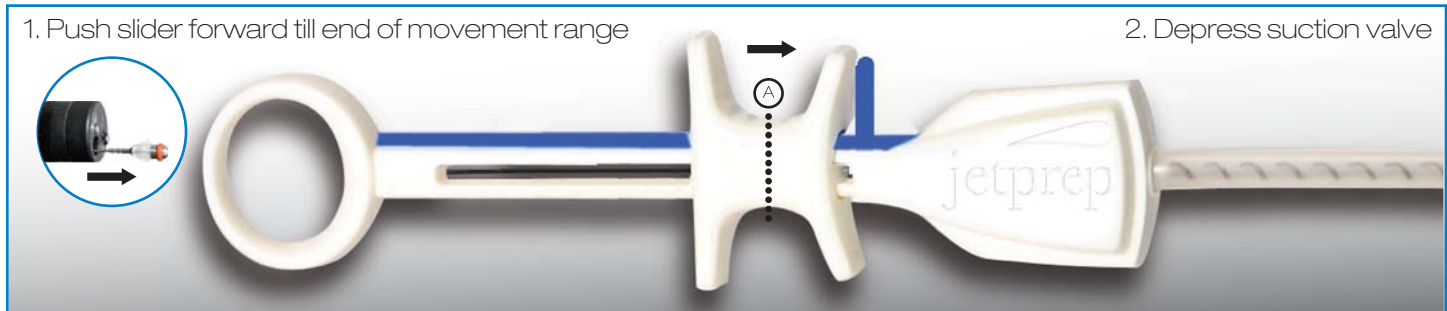


Figure 4: For aspiration, handle slider is moved to Position A.

- 7.3. To clean the aspiration channel, in case the working channel is blocked during aspiration, place the distal tip inside the working channel by pulling the handle slider all the way back to position C (see figure 5), pull trigger back, and deliver fluid together with vacuuming.

Working Channel Clearing - Position C

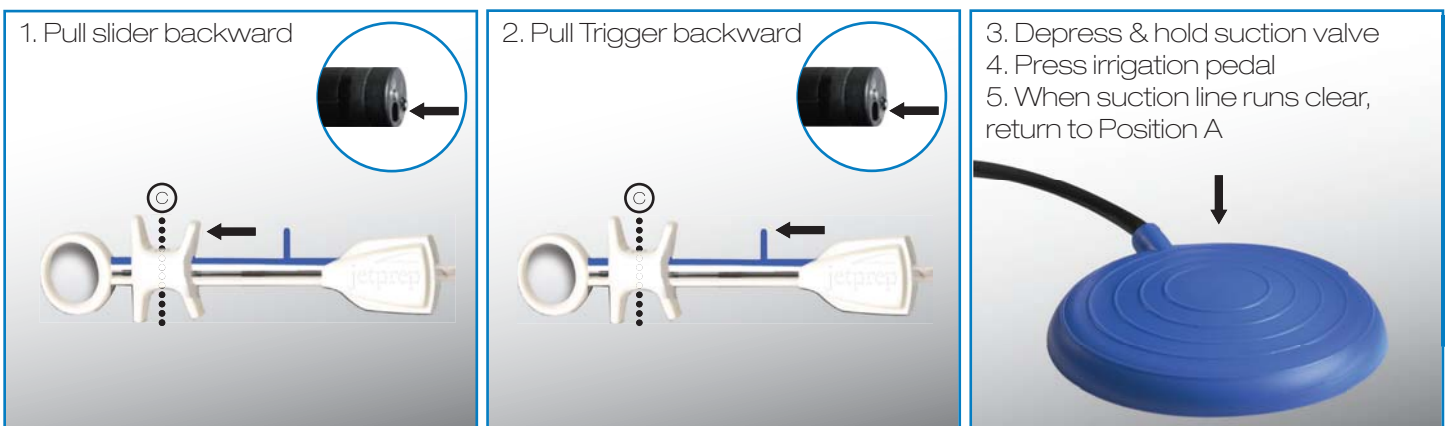


Figure 5: For cleaning the aspiration channel, handle slider is moved to Position C.

NOTE: Use the video monitor to control the JET PREP Flushing Device distal tip position.

8. Upon completion of the procedure, disconnect the JET PREP Flushing Device endoscopic connector from the endoscope working channel input and replace the biopsy valve.

NOTE: You may place the JET PREP® Flushing Device on a clean surface for repeated use should this be necessary during the same procedure with the same patient.

9. Discard the JET PREP Flushing Device in accordance with accepted medical practice and applicable with local, state and federal laws and regulations.

Part Number	Model Type	Scope Type	Channel Diameter (mm)	Scope Length (mm)
JP30022	OLYMPUS®	Adult Colonoscope - Long	3.7	1680
JP30016	OLYMPUS	Adult Colonoscope - Short	3.7	1330
JP30069	OLYMPUS	Pediatric Colonoscope - Long	3.2	1680
JP30068	OLYMPUS	Pediatric Colonoscope - Short	3.2	1330
JP30050	OLYMPUS	Gastroscope	3.7	1030
JP30064	PENTAX®	Adult Colonoscope - Long	4.2	1700
JP30063	PENTAX	Adult Colonoscope - Short	4.2	1500
JP30024	PENTAX	Pediatric Colonoscope - Long	3.8	1700
JP30023	PENTAX	Pediatric Colonoscope - Short	3.8	1500
JP30051	PENTAX	Gastroscope	3.8	1050
JP30052	FUJIFILM®	Adult Colonoscope - Long	3.8	1690



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