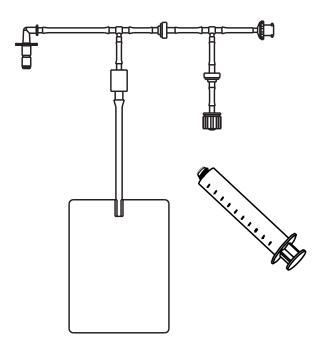


GastroFlush™ Instructions For Use



PRODUCT OFFERING

#9510 - GastroFlush™ (10/box) #9500 - Relish RL1501 Jet Lavage

Bionix® GastroFlush™ Instructions for Use

Indications for Use:

GastroFlush is indicated for use in clearing occlusions/clogs from enteral feeding tubes placed for nutrition and/or decompression in adult or adolescent patients that have tube size 8Fr-24Fr and tube length no longer than 42 inches.

Contraindications:

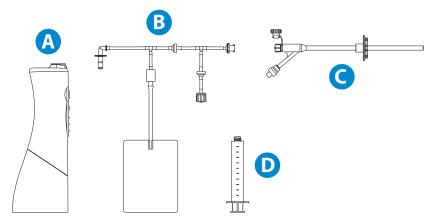
- 1. GastroFlush is for enteral feeding tubes with integral ENFit connectors only. It is NOT to be used with Drain Tubes or ENFit transition adapters.
- 2. GastroFlush is only for use with Relish RL1501 Jet Lavage (accessory)
- 3. Before proceeding with un-clogging the tube, ensure that the tube placement and position are correct. If concern exists as to tube placement or positioning, an x-ray or other verification procedure should be performed to ensure that:
 - a. Tube is correctly situated in the body.
 - b. Tube orientation is correct.
 - c. Tube has not migrated from its initial placement site.

If there is any reason to suspect that the tube has been incorrectly placed or has moved or migrated from its initial placement site in the body, REMOVE and REPLACE the tube. DO NOT attempt the un-clogging procedure.

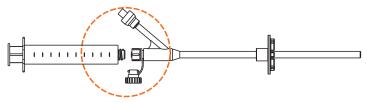
4. If the integrity of the tube is compromised (example: a weakening or aneurism in the tube wall, a rip, or break, REMOVE and REPLACE the tube. DO NOT attempt the un-clogging procedure.)

Please review the following parts before assembly.

- A. Relish RL1501 Jet Lavage (ACCESSORY NOT INCLUDED)
- B. GastroFlush™ (Disposable Assembly)
- C. ENFit® Feeding Tube (IN DWELLING NOT PROVIDED WITH PURCHASE)
- D. ENFit Syringe (5ml)

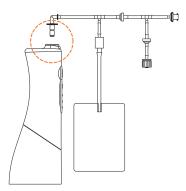


1 Use your ENFit® feeding syringe (D) to flush the clogged tube with water (C).

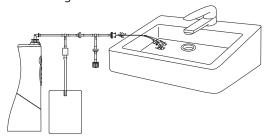


- 2 Disinfect the jet lavage prior to first use. Refer to product cleaning instructions.
- Fill the jet lavage reservoir with 50-60 mL (1/3 of reservoir) of room temperature water.

 Open hatch to fill reservoir with water.
- 4 Attach GastroFlush (B) by inserting the white irrigation adapter into the jet lavage (A) You should hear an audible click when secured.

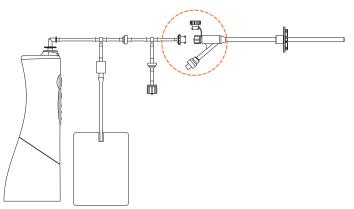


- (5) GastroFlush needs to be primed before attaching to the feeding tube.
 - a. To prime GastroFlush, attach the GastroFlush disposable assembly (B) to the jet lavage (A).
 - b. Activate the jet lavage into the sink for 1-2 seconds.
 NOTE: If you're not getting water out of your jet lavage, prime GastroFlush again.



Attach GastroFlush to the feeding tube by twisting the <u>clear</u> female ENFit Connector onto the feeding tube (C) until snug.

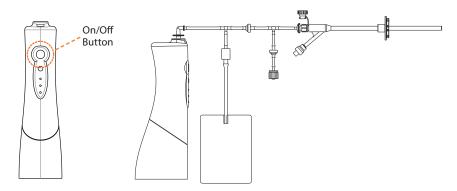
NOTE: If your feeding tube has multiple input lines, ensure that all but one line is closed using the proper ENFit cap. If more than one line needs unclogged, repeat the unclogging process (Steps 6-9) separately for each line.



Once both ends of GastroFlush are attached, turn the jet lavage on to begin procedure.

NOTE: The on button is on the front side of the jet lavage. Press the button once to activate (Turn On). Once the procedure is complete, press the button again to deactivate (Turn Off).

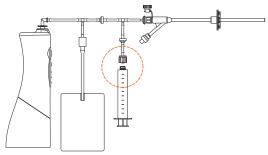
NOTE: Irrigation water may flow into the overflow bag during the procedure. Be sure to note amount of water in overflow bag.



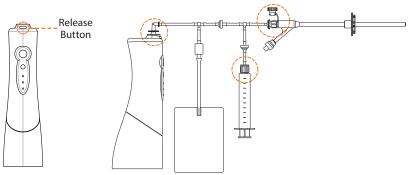
- 8 Deactivate jet lavage when one of the following occurs:
 - a. Water is no longer flowing into the overflow bag.
 - b. Jet lavage is empty.

- After deactivating the jet lavage, connect ENFit 5ml syringe to the Male ENFit Connector and flush with water (D).
 - a. If you cannot flush with water, repeat steps 2-7 a maximum of 2 times.

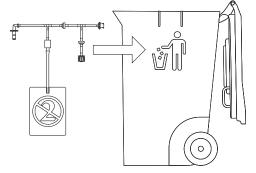
NOTE: You should not introduce more than 50-60 ml of water into the feeding tube once patency is restored. Jet lavage Reservoir volume is 160 ml. Overflow volume is 1 L.



Once you can flush with water, untwist the female ENFit connector from the feeding tube and disconnect irrigation adapter from jet lavage using release button on front of unit.



GastroFlush is a single-use, disposable device.
Dispose of GastroFlush according to hospital guidelines.



12 Completely empty jet lavage and clean according to instructions provided.

Jet Lavage Cleaning Instructions

After Each Use

- Dispose of any used irrigation assemblies.
- Empty any liquid left in the tank.
- Run the appliance for 2 to 3 seconds on 'Normal' until no liquid comes out.
- Fill tank approximately ½ full of 5% vinegar (acetic acid solution), then run unit on 'Normal' until no liquid comes out.
- Fill tank with sterile water, then run unit until no liquid comes out.
- Allow unit to dry completely with cap open before storing.

Disinfection

- Wipe the exterior when necessary with a soft cloth and mild non-abrasive cleanser.
- Do not wipe the appliance with solvents or alcohol.
- Do not wash using hot water (over 120°F (50°C)).
- Allow exterior to dry after washing with water.
- Empty any liquid left in the tank.
- Run the appliance for 2 to 3 seconds on 'Normal' until no liquid comes out.
- Prepare at least 1 cup of .55% Ortho-Phthalaldehyde solution.
- Fill tank approximately $\frac{1}{2}$ full with the OPA solution.
- Run jet lavage until a small amount of OPA solution exits irrigation port on top of unit. When solution is visible from irrigation port, deactivate unit.
- Follow the manufacturers recommendations on soak times for disinfection.
- When disinfection is complete, empty OPA solution from tank, then run unit until no liquid can be seen exiting the irrigation port.
- Fill tank approximately ½ full of sterile water, then run unit until no liquid exits the irrigation port.
- Repeat sterile water rinse 2 times.
- Allow unit to dry with tank port open when not using for a long period.
- · Never immerse the unit in water.
- Do not clean the unit while it is connected to the charger.
- Store unit with reservoir cap *open*\) as these may damage the unit.







5154 Enterprise Blvd. • Toledo, Ohio 43612 Phone: 800.551.7096 • Fax: 800.455.5678 www.Bionix.com

©2018 Bionix Development Corp. RM95-0950 • Rev. A • *Patent Pending *ENFit® and NRFit™ are trademarks of GEDSA.