



Directions for Use

Feeding Tube Clearing System

Rx ONLY

For use with TubeClear Control Box Model 101 and Clearing Stem Models G-1008, G-1009, G-1010, G-1011, G-1012, and G-1014.

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Intended Use

The TubeClear System is intended to clear occlusions / clogs in Feeding and Decompression Tubes.

The TubeClear System is comprised of a reusable Control Box and a single use Clearing Stem.

Indications for Use

The TubeClear System is indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adult patients that have a Tube of size 10 to 18 Fr.

The Clearing Stem Models are indicated for use as follows:

- + G-1008, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 20 cm (8 in).
- + G-1009, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 23 cm (9 in).
- + G-1010, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 25 cm (10 in).
- + G-1011, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 28 cm (11 in).
- + G-1012, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 30 cm (12 in).
- + G-1014, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 36 cm (14 in).

Contraindications



Do NOT use the TubeClear System if:

- + You do **NOT** know for certain the type, size, and length of the Feeding and Decompression Tube.
- + The TubeClear Clearing Stem Model is **NOT** available for the type, size, and length of the Feeding and Decompression Tube.
- + The Feeding and Decompression Tube has been removed from the Patient.
- + The Feeding and Decompression Tube requires placement or repositioning.
- + The Feeding and Decompression Tube has been in use for longer than the Tube Manufacturer's recommendation.
- + The Patient is not permitted to receive liquids.

Troubleshooting Guide

Issue	Solution Options
If the Wire is not moving or is moving slowly.	<ul style="list-style-type: none">+ The Magnet Adapter may not be well attached to the Control Box Diaphragm.+ The Stem Lock may not be firmly clipped in the Control Box Bracket Adapter.+ The Clearing Stem may be too tightly coiled around your hand.+ The Power Cord may not be securely plugged in.
If a great amount of resistance is felt during operation.	Provided the Patient does not have an allergy to water-soluble surgical lubricant, coat the distal end (Wire Tip end) of the Clearing Stem with a water-soluble surgical lubricant. NOTE: If a water-soluble surgical lubricant is used on the Clearing Stem, the Tube must be flushed with liquid at the end of the procedure.
If the clog has not been cleared after 10 minutes of operation.	Remove the Clearing Stem and add up to 30 ml of liquid; allow the liquid to set for approximately one minute. Then repeat the procedure from Steps 13 - 24.
ANY SIGN OF KINKING DUE TO EXCESSIVE OPERATOR FORCE WILL DECREASE CLEARING EFFECTIVENESS.	<p>If the Clearing Stem keeps stopping at the same point within the Patient's Tube, there might be a clog formed from packed materials. Keep applying gentle pressure and backward and forward movements to the Clearing Stem. Effectiveness may be improved by faster backward and forward movements. However, too much force will dampen out the Wire movement and decrease Clearing Stem effectiveness. Apply gentle force allowing the Clearing Stem to break up the clog. Also, aspiration throughout the clearing process helps to break up and disperse the clog.</p> <p>If the Clearing Stem can be inserted until the Collar reaches the External Port, but the Tube is still not patent, the clog may be reforming lower down in the Tube during patency check. Repeat the procedure with several backward and forward movements of the Clearing Stem to help spread out the clog material.</p>
If the clog has not been cleared after 15 minutes of operation.	<p>Remove the Clearing Stem from the Patient's Tube and verify the Wire is moving backward and forward. If the Wire moves freely while the Clearing Stem is outside of the Patient's Tube, repeat the procedure from Steps 13 - 24. The clog may be particularly difficult to clear or there may be multiple clogs throughout the Patient's Tube.</p> <p>If the Wire is not moving backward and forward, the Clearing Stem may have become packed with clog materials or the Clearing Stem may be damaged. Replace with a new Clearing Stem and repeat Steps 13 - 24. Use less force and allow the Clearing Stem to do the work.</p>
If no progress has been made after 20 minutes of operation.	The Patient's Tube could have a kink, or the clog may be further down the Patient's Tube than the Clearing Stem can reach. Follow an alternate protocol for treating a clogged Tube.

Cautions

Reading this document does not substitute for reading the Operator's Manual before use. **Read the Operator's Manual in its entirety before using TubeClear. Disregarding the cautions and instructions presented in this document constitutes ABNORMAL USE.**

Make certain that the correct Clearing Stem Model has been selected for type, size, and length of the Feeding and Decompression Tube (i.e., Tubes).

- + Use of the wrong Clearing Stem Model may result in over insertion. Over insertion of the TubeClear Clearing Stem may cause harm to the stomach or intestines.
- + Use of a Clearing Stem in a smaller French size Tube than indicated may result in the Clearing Stem becoming lodged in the Tube, and possible Tube dislocation when the Clearing Stem is removed.

Refer to **Table 1**, in the TubeClear Operator's Manual for guidance on verifying correct selection of the Clearing Stem.



If the Patient's Tube is removed, do **NOT** clear and re-insert the same Tube. The TubeClear System is intended to be used with the Tube residing **IN THE PATIENT**. If the Tube has been removed from the Patient, follow your Institution's Protocol for insertion of a new Tube.



The TubeClear System contains magnets. Magnets are inside the Control Box and at the end of the Clearing Stem that attaches to the Control Box. Do **NOT** place the Control Box and the Magnet at the end of the Clearing Stem within 15 cm (6 in) of pacemakers, defibrillators and other electronic devices (*including, but not limited to, credit cards, video tapes, televisions, computer monitors and other CRT displays*) because the Magnets may interfere with the operation of those devices.



Ensure that the Control Box is securely mounted to a level table, IV pole tray, or use TubeClear IV Pole Mount to reduce the risk of the Control Box falling.



The TubeClear System is non-sterile. It is intended to be used with Feeding and Decompression Tubes and does **NOT** require sterile conditions for its intended purpose. Do **NOT** use TubeClear in any manner that would require sterile conditions.



Use of liquids to flush and aspirate throughout the procedure is essential to the effective use of the TubeClear System.



No modification of this equipment is allowed.



Federal law (U.S.) restricts TubeClear to sale by or on the order of a physician.

	Attention, read instructions before use.
	Do NOT operate in the presence of flammable anesthetics. (<i>Flammable anesthetics are gases or vapors, including, but not limited to, fluroxene, ethyl chloride, ethyl ether and ethylene, which may form flammable or explosive mixtures with air, oxygen or reducing gases such as nitrous oxide.</i>)
	Do NOT dispose of the Clearing Stem or any de-clogged contents from the Feeding and Decompression Tube with ordinary waste. Dispose as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.
	The TubeClear Clearing Stems are SINGLE USE .

Set-up and Operating Instructions

- 1 **Verify that you have the correct Clearing Stem Model for the type, size, and length of the Patient's Tube.**
- 2a **IF USING THE IV POLE MOUNT FOLLOW STEPS 2a-c.**
Tighten the IV Pole Clamp onto an IV pole.
- 2b Slide the IV Pole Mount Receptacle over the Adapter. Be sure that the Retractable Retaining Pin clicks.
- 2c To remove the Control Box from the IV Pole Mount Adapter pull out on the knob while simultaneously lifting the Control Box upward.
- 3 Plug the Power Cord into the Power Supply.
- 4 Plug the Power Cord into the wall outlet.
- 5 Plug the Power Supply Cord into the Jack below the ON/OFF Power Switch being sure to line up the pins.
- 6 Turn the ON/OFF Power Switch to On. Verify the Green Light illuminates.
If the Yellow Light illuminates, turn the ON/OFF Power Switch to Off and then back to On. If the Yellow Light remains on, do not use the Control Box and refer to Operator's Manual.
- 7 Remove the Clearing Stem from the Packaging. Keep the Packaging for later use.
- 8 Anytime the Clearing Stem is not in the Patient's Tube, loosely coil it and place it into the Packaging.
- 9 Remove the Red Plastic Covers from the Magnet Adapter and the Wire Tip. Place the Red Plastic Cover inside the Packaging as it will be needed later.
Clearing Stem color is dependent on Model specific to Patient's Tube.
- 10 Directly place the Magnet Adapter on the center of the Diaphragm.
- 11 Clip the Stem Lock into the Bracket Adapter.
Proper placement of the Stem Lock is necessary for effective operation.
- 12 You may loosely coil the Clearing Stem around your hand to help control the length during insertion. (Do NOT tightly coil the Clearing Stem as it will decrease effectiveness.)
- 13 Throughout the clearing process insert water and aspirate loosened clog contents. Insert up to 30mL of liquid at a time into the Patient's Tube.
- 14 **Optional: Coat the Wire Tip end of the Clearing Stem with a water-soluble surgical lubricant.**
If a water-soluble surgical lubricant is used on the Clearing Stem, the Tube must be flushed with water at the end of the procedure.
- 15 While holding the Patient's Tube in one hand, insert the Clearing Stem a few centimeters (inches) into the Tube with the other hand.
- 16 While holding the Patient's Tube and the Clearing Stem with one hand, firmly press down the Start/Stop Button with your other hand.
After ten (10) minutes the Control Box will automatically stop. It can be re-started by pressing the Start/Stop Button again.
- 17 Manually advance the Clearing Stem until you encounter resistance from the clog. Continue to apply gentle forward force to the Clearing Stem to break up the clog.
Manual backward and forward movement of the Clearing Stem may be helpful in breaking up the clog.
- 18 **DO NOT APPLY EXCESSIVE FORCE TO THE CLEARING STEM. ANY SIGN OF KINKING DUE TO OPERATOR FORCE WILL DECREASE CLEARING EFFECTIVENESS.**
- 19 Continue until the Collar reaches the Tube's External Port. If this does not occur within ten (10) minutes refer to the Troubleshooting Guide.
- 20 Move the Clearing Stem backward and forward about 10 cm (4 in) several times.
- 21 Hold the Patient's Tube with one hand and slowly remove the Clearing Stem from the Tube with the other hand.
- 22 Reinsert until the Collar reaches the Tube's External Port at least two (2) more times. (Steps 15-19) $\geq 2X$ STEPS 15-19
- 23 Hold the Patient's Tube with one hand and slowly remove the Clearing Stem from the Tube with the other hand.
- 24 Stop the Control Box by pressing the Start/Stop Button.
Do NOT detach the Clearing Stem from the Control Box at this time as you may need to reinsert if the Tube is not patent.
- 25 Loosely coil the Clearing Stem and place into the Packaging during patency confirmation.
- 26 **Verify that the Patient's Tube is properly placed using your Institution's protocol.**
Use an enteral syringe to aspirate or flush loosened clog contents out of the Tube.
Verify that the Patient's Tube is patent using your Institution's protocol.
- 27 **REPEAT STEPS 13-24**
If Patient's Tube is still clogged, repeat Steps 13-24 until clog is removed. If this does not occur within ten (10) minutes, refer to Troubleshooting Guide.
- 28 After confirming the Patient's Tube is patent, disconnect the Clearing Stem by unclipping the Stem Lock from the Bracket Adapter. Then pull up on the Magnet Adapter to remove it from the Diaphragm.
- 29 **Replace the Red Magnet Cover prior to disposal as regulated medical waste.**

Operator Assistance Information

If you have questions regarding the use of TubeClear, please contact:

Customer Service Department at Actuated Medical, Inc.

Phone +1 (814) 355-0003 ext. 117 / Fax +1 (814) 355-1532

Monday through Friday

8:00am - 5:00pm U.S.A. Eastern Standard Time

Additional training materials are accessible on our website at TubeClear.com.

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