



Directions for Use

Feeding Tube Clearing System

For use with TubeClear Control Box Model 101 and Clearing Stem Model TC-0608.

Pat. actuatedmedical.com/ip

Rx ONLY

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

TubeClear Clearing Stem Model TC-0608 is indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adults that have the following Tube type, size (French and length), and material.

- + TC-0608, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 6 - 8 Fr and have a length of 38 -140 cm (15 - 55 in).

Contraindications

 **Do NOT use TubeClear Model TC-0608 if:**

- + You do **NOT** know for certain the type, size (French and length), and material of the Feeding and Decompression Tube.
- + The TubeClear Clearing Stem Model is **NOT** indicated for the type, size (French and length), and material 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 Feeding and Decompression Tube is composed of silicone.
- + The Patient is not permitted to receive liquids.

Cautions

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
















In addition to reading the Operator's Manual, it is also required to watch the TubeClear training video before using the device. (Video is provided on a DVD with the device, and can also be found using the QR code or visiting http://www.actuatedmedical.com/AMI/TubeClear_Videos/).

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

- + Improper placement of the Depth Limiter may result in over insertion. Over insertion of the TubeClear Clearing Stem may cause harm to the Patient's gastrointestinal (GI) system.
- + 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.
- + Use of a Clearing Stem in a different type of material 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 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.
-  TubeClear Clearing Stem may cause some discomfort to the nasal passage during use in a Nasoenteral 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 the TubeClear System in any manner that would require sterile conditions.
-  **TubeClear Clearing Stems are SINGLE USE.**
-  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 the TubeClear System 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 .

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.	<p>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.</p> <p>NOTE: <i>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.</i></p>
<p>If the clog has not been cleared after 10 minutes of operation.</p> <p>ANY SIGN OF KINKING DUE TO EXCESSIVE OPERATOR FORCE WILL DECREASE CLEARING EFFECTIVENESS.</p>	<p>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 18 - 22.</p> <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 Depth Limiter 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 18 - 22. 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 18 - 22. Use less force and allow the Clearing Stem to do the work.</p>
If no progress has been made after 20 minutes of operation.	<p>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.</p>

Set-up & Operating Instructions

For use with TubeClear Control Box Model 101 and Clearing Stem Model TC-0608.

Pat. actuatedmedical.com/ip

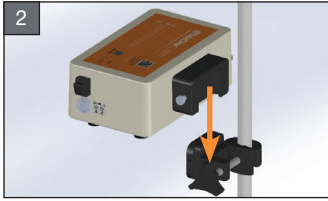
Rx ONLY

CONTROL BOX SET UP

1

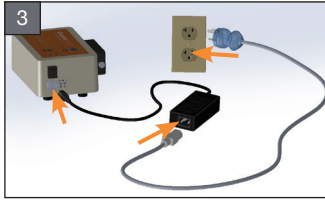
Verify that you have the correct Clearing Stem Model for the type, size (French and length), and material of the Patient's Tube.

2



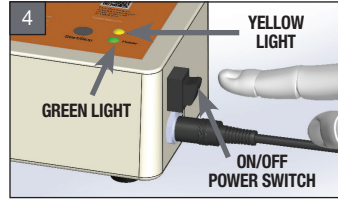
If using the IV Pole Mount, tighten the IV Pole Clamp onto an IV pole. Then slide the IV Pole Mount Receptacle over the Adapter making sure the Retractable Retaining Pin clicks.

3



Plug the Power Supply into the jack of the Control Box. Connect one end of the Power Cord into the Power Supply and the other end into a wall outlet.

4



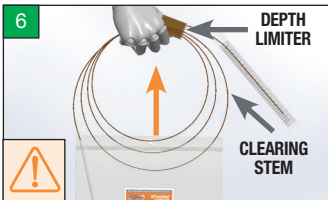
Turn the On/Off Power Switch to On. Verify the Green Light illuminates. If Yellow Light illuminates refer to Operator's Manual Section 2.4.9.

CLEARING STEM SETUP

5

Identify the length of the Patient's Tube.

6



Remove all contents from the package. Keep the Packaging for later use.

Clean technique should be used when handling the Clearing Stem.

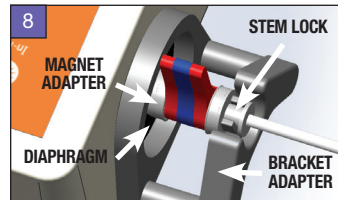
7



Remove the Red Magnet Cover from the Magnet Adapter.

CLEARING STEM TO CONTROL BOX

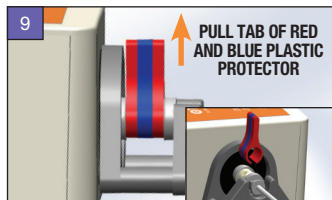
8



Place the Magnet Adapter onto the black rubber Diaphragm of the Control Box, and firmly clip the Stem Lock into the Bracket Adapter. Verify connection is secure.

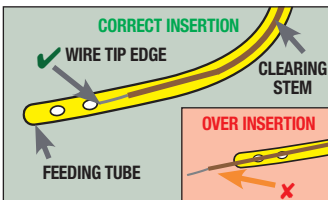
MEASURING AND PLACING THE CLEARING STEM'S DEPTH LIMITER

9



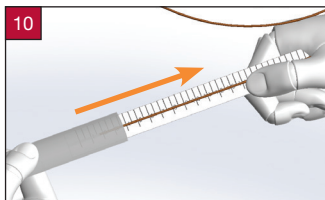
Remove the Red and Blue Plastic Protector by pulling directly up on the tab. Then, confirm Stem Lock is still clipped in.

10



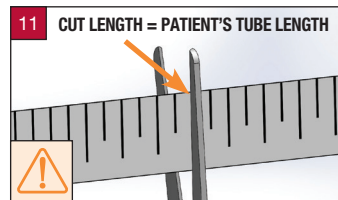
Steps 10 through 14 help to ensure proper placement of the Depth Limiter. Proper placement of the Depth Limiter minimizes the risk of the Clearing Stem exiting the end of the Tube.

11



Remove the Measuring Tape / Clearing Stem Assembly from the clear plastic sleeve.

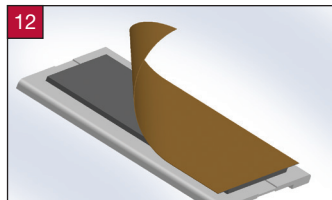
11



Cut or tear the Measuring Tape at the location that matches the Patient's Tube length.

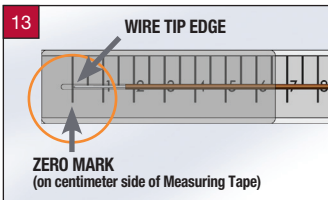
Confirm centimeter or inch side of Measuring Tape before cutting.

12



Remove the brown backing from the tape section on the Depth Limiter.

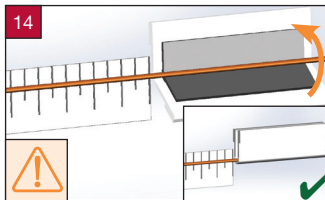
13



Verify that the edge of the Wire Tip is lined up with the zero mark on the Measuring Tape.

While holding the Measuring Tape tightly against the Clearing Stem, slide your fingers to the cut edge of the Measuring Tape.

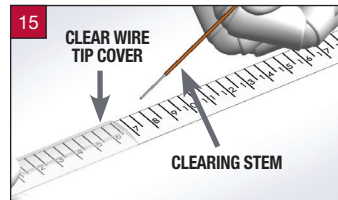
14



Place the Clearing Stem within the adhesive section of the Depth Limiter. Fold the Depth Limiter in half and press firmly for five seconds.

Gently pull on the Depth Limiter to ensure it is attached/adhered to the Clearing Stem.

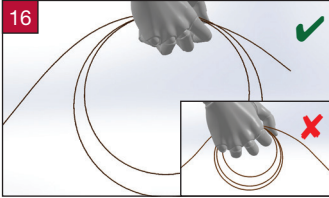
15



Remove the Clearing Stem from the Clear Wire Tip Cover on the Measuring Tape.

Continued on next page

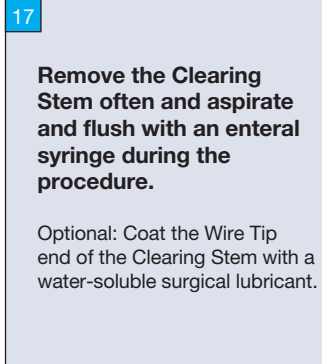
OPERATING INSTRUCTIONS



Do NOT tightly coil the Clearing Stem during use as it will decrease effectiveness

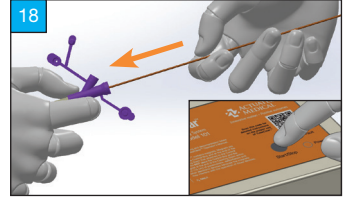
Check to make sure the following steps have been completed prior to proceeding to the operating instructions:

- ✓ Clearing Stem is attached to the Control Box with the Stem Lock firmly clipped in the Bracket Adapter.
- ✓ The Depth Limiter is attached to the Clearing Stem at the location that corresponds to the Patient's Tube length.
- ✓ The Clearing Stem has been removed from the Clear Wire Tip Cover.

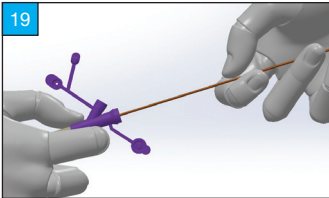


Remove the Clearing Stem often and aspirate and flush with an enteral syringe during the procedure.

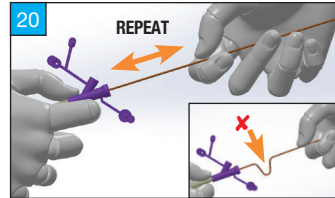
Optional: Coat the Wire Tip end of the Clearing Stem with a water-soluble surgical lubricant.



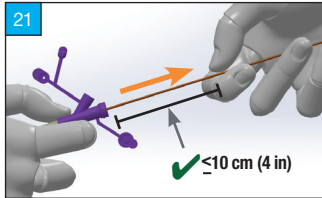
Insert the Clearing Stem a few centimeters into the Tube. Then press the Start/Stop Button to activate the Control Box.



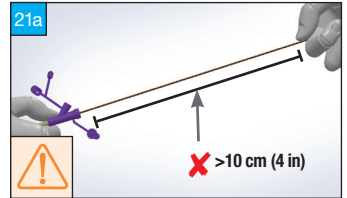
Manually advance the Clearing Stem until you encounter resistance from the clog.



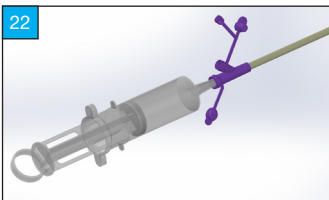
Work on the clog using varying speeds of backward and forward motions. DO NOT apply excessive force to the Clearing Stem. Any sign of kinking will decrease effectiveness.



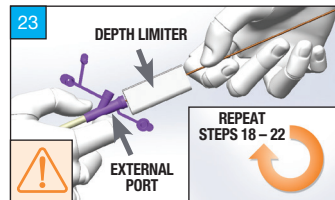
If Clearing Stem is not easily advancing through the clog within 1-2 minutes, remove the Clearing Stem from the Tube by holding the Tube with one hand and slowly retracting the Clearing Stem with the other hand.



Allow no more than 10 centimeters (4 inches) between hand and port.

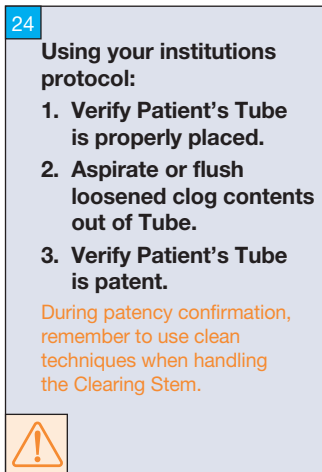


After removal, stop the Control Box by pressing the Start/Stop Button. Then aspirate and flush with an enteral syringe.



If clog is still present, re-insert the Clearing Stem into the Tube and repeat Steps 18 - 22 until patency is restored or the Depth Limiter reaches the Tube's external port.

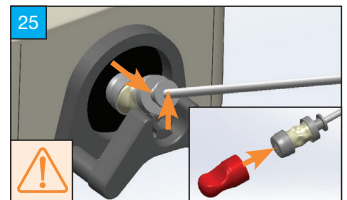
If a water-soluble surgical lubricant is used on the Clearing Stem, the Tube must be flushed with liquid at the end of the procedure.



Using your institutions protocol:

1. Verify Patient's Tube is properly placed.
2. Aspirate or flush loosened clog contents out of Tube.
3. Verify Patient's Tube is patent.

During patency confirmation, remember to use clean techniques when handling the Clearing Stem.



After confirming Patient's Tube is patent, disconnect the Clearing Stem, replace the Red Magnet Cover and dispose as regulated medical waste.

The Clearing Stem is a single use device.

Operator Assistance Information

If you have questions regarding the use of the TubeClear System, 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.