

Intended Use

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

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

Indications for Use

TubeClear 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:

NE-1036, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 91 cm (36 in).

G-1008, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 20 cm (8 in).

NE-1042, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 107 cm (42 in).

G-1009, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 23 cm (9 in).

NE-1043, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 109 cm (43 in).

G-1010, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 25 cm (10 in).

NE-1045, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 114 cm (45 in).

G-1011, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 28 cm (11 in).

NE-1048, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 122 cm (48 in).

G-1012, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 30 cm (12 in).

NE-1050, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 127 cm (50 in).

G-1014, for Gastrostomy and Jejunostomy Tubes that are of size 10-18 Fr and have a length of 36 cm (14 in).

NE-1055, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 140 cm (55 in).

Contraindications

Do NOT use TubeClear 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.








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 the Operator's Manual 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** of the 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. TubeClear 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 NE Models may cause some discomfort to the nasal passage during use.
-  **TubeClear 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.
-  **TubeClear 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.
-  **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 . Reuse of the TubeClear Clearing Stems is prohibited and could compromise patient.

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



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MADE IN U.S.A.

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