



TubeClear[®] **Operator's Manual**

Enteral Access Clearing System

- + Read this Manual before using the TubeClear System. Failure to follow the cautions and instructions in this Manual constitutes abnormal use and can result in injury.
- + For use with TubeClear Control Box
 - Model 101
- + For use with Clearing Stem Models
 - NE-1036, NE-1042, NE-1043, NE-1045, NE-1048, NE-1050, NE-1055
 - G-1008, G-1009, G-1010, G-1011, G-1012, G-1014
 - TC-1018, TC-0812, TC-0608

Rx ONLY

NE & G Model Clearing Stem Use This Section

Use these TubeClear NE & G Clearing Stem attributes to determine your Model and the proper Operator's Instructions to follow.

Model Designation

Clear Collar



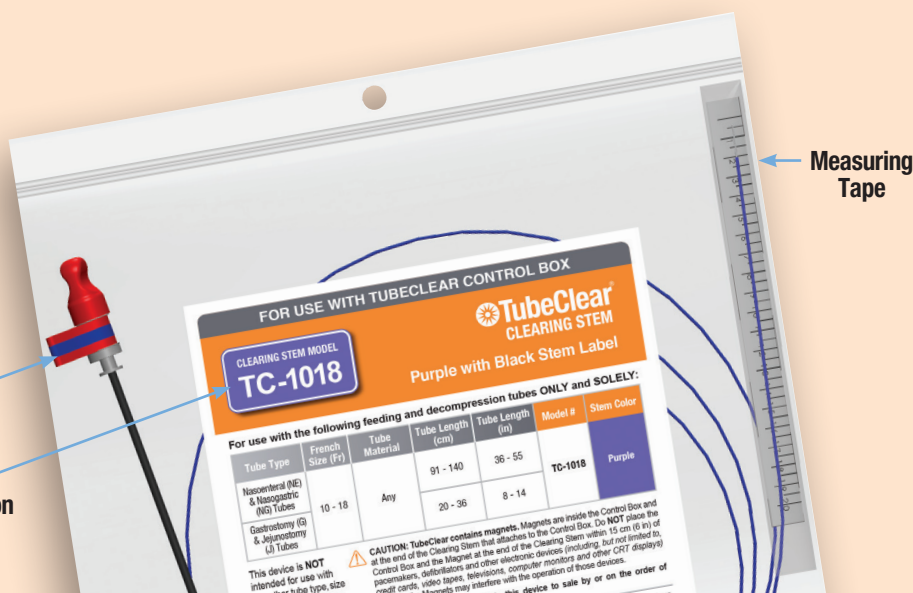
TC Model Clearing Stem Use This Section

Use these TubeClear TC Clearing Stem attributes to determine your Model and the proper Operator's Instructions to follow.

Red and Blue Plastic Protector

Model Designation

Measuring Tape



General Information on All Models

Operator Assistance Information

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

Customer Service Department at Actuated Medical, Inc.

310 Rolling Ridge Drive, Bellefonte, PA 16823

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

Training Materials

Training materials are accessible on our website at TubeClear.com.

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1.0 NE & G Model Operator's Instructions

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 Clearing Stem Models NE and G are indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adult patients that have a Tube size of 10 to 18 Fr.

The NE and G 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).
- + NE-1042, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 107 cm (42 in).
- + NE-1043, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 109 cm (43 in).
- + NE-1045, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 114 cm (45 in).
- + NE-1048, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 122 cm (48 in).
- + NE-1050, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 127 cm (50 in).
- + NE-1055, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 140 cm (55 in).
- + 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.

1.1 Cautions

Read the entire manual before using the TubeClear System. Disregarding the cautions and instructions presented in this manual constitutes ABNORMAL USE.

"Tube" as used in this manual refers to any Feeding and/or Decompression Tube, also known as an Enteral Access Device, residing in a Patient.








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





- + Use of the wrong Clearing Stem Model may result in over insertion. Over-insertion of the TubeClear Clearing Stem may cause harm to the Patient's 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 **Section 1.3** Device Description, 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 Nasoenteral (NE) Models may cause some discomfort to the nasal passage during use.
-  **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 the TubeClear System 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 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 .

1.2 Operator Profile

The TubeClear System is intended for use by Licensed Healthcare Practitioners. Training by an Actuated Medical representative or a person trained by an Actuated Medical representative is recommended in addition to reading the Operator's Manual. For information about training, contact Actuated Medical's Customer Service Department at **+1 (814) 355-0003 ext. 117** or visit the website **TubeClear.com**.

1.3 Device Description

The TubeClear System is a device for clearing clogs in Feeding and Decompression Tubes while the tube **REMAINS** in the Patient. The TubeClear System is comprised of a reusable Control Box and a single use Clearing Stem. The Clearing Stem magnetically attaches to the Control Box.

Clogs are occlusions, blockages, or obstructions of feeding formula, ground food, medications, supplements, or aspirated contents in the Patient's Tube.

The Clearing Stem consists of a 203 cm (80 in) long, flexible Wire encased in a flexible Sheath. The Wire Tip is rounded and smooth and extends approximately 1.7 cm ($\frac{2}{3}$ in) beyond the Sheath.

The Control Box contains a Motor that activates the Clearing Stem Wire. The Motor causes the Wire to move quickly backward and forward inside the Sheath. The Control Box may be mounted to an IV pole via the IV Pole Mount, which consists of the IV Pole Mount Receptacle (attached to the side of the Control Box) and the IV Pole Mount Adapter with Clamp. The Wire moves approximately 0.4 - 1.0 cm ($\frac{1}{8}$ - $\frac{3}{8}$ in) (see **Illustration right**). This backward and forward movement of the Wire allows it to break up and clear clogs while the Tube remains in the Patient. Each NE and G Model Clearing Stem has a Collar permanently attached. The Collar limits insertion depth of the Clearing Stem so that the Wire Tip does not extend beyond the end of the Tube into the Patient's stomach or intestinal lining.

Because Feeding and Decompression Tubes come in different types, sizes and lengths, several Models of TubeClear Clearing Stems are available (see **Table 1**). The label on the Clearing Stem Packaging will identify the Clearing Stem Model and indicate the Feeding and Decompression Tube type, size, and length that the Clearing Stem will clear.

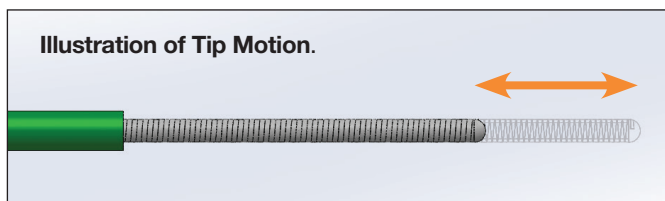


TABLE 1: TubeClear Clearing Stem NE & G Models.**Nasoenteral and Nasogastric Tubes**

French Size (Fr)	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
10 - 18	91	36	NE-1036	Yellow
10 - 18	107	42	NE-1042	Grey
10 - 18	109	43	NE-1043	Purple
10 - 18	114	45	NE-1045	Orange
10 - 18	122	48	NE-1048	Clear
10 - 18	127	50	NE-1050	Blue
10 - 18	140	55	NE-1055	Green
NE MODEL CLEARING STEMS HAVE WHITE HAND GRIPS AND STEM LABELS				

Gastrostomy and Jejunostomy Tubes

French Size (Fr)	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
10 - 18	20	8	G-1008	Yellow
10 - 18	23	9	G-1009	Grey
10 - 18	25	10	G-1010	Purple
10 - 18	28	11	G-1011	Orange
10 - 18	30	12	G-1012	Clear
10 - 18	36	14	G-1014	Blue
G MODEL CLEARING STEMS HAVE BLACK HAND GRIPS AND STEM LABELS				

EXAMPLE: If the Patient has a Nasoenteral tube, 12 Fr, 109 cm (43 in) long, select Model Number NE-1043 (Purple). If the Patient has a Gastrostomy tube, 16 Fr, 23 cm (9 in) long select Model Number G-1009 (Grey). If the Patient has a Jejunostomy tube, 14 Fr, 30 cm (12 in) long, select Model Number G-1012 (Clear).



Failure to use the correct Clearing Stem could result in over insertion of the Clearing Stem into the Patient's 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.

- + The Collar on Clearing Stem Model NE-1036 is located 91 cm (36 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1042 is located 107 cm (42 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1043 is located 109 cm (43 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1045 is located 114 cm (45 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1048 is located 122 cm (48 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1050 is located 127 cm (50 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model NE-1055 is located 140 cm (55 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1008 is located 20 cm (8 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1009 is located 23 cm (9 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1010 is located 25 cm (10 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1011 is located 28 cm (11 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1012 is located 30 cm (12 in) from the distal end of the Clearing Stem.
- + The Collar on Clearing Stem Model G-1014 is located 36 cm (14 in) from the distal end of the Clearing Stem.

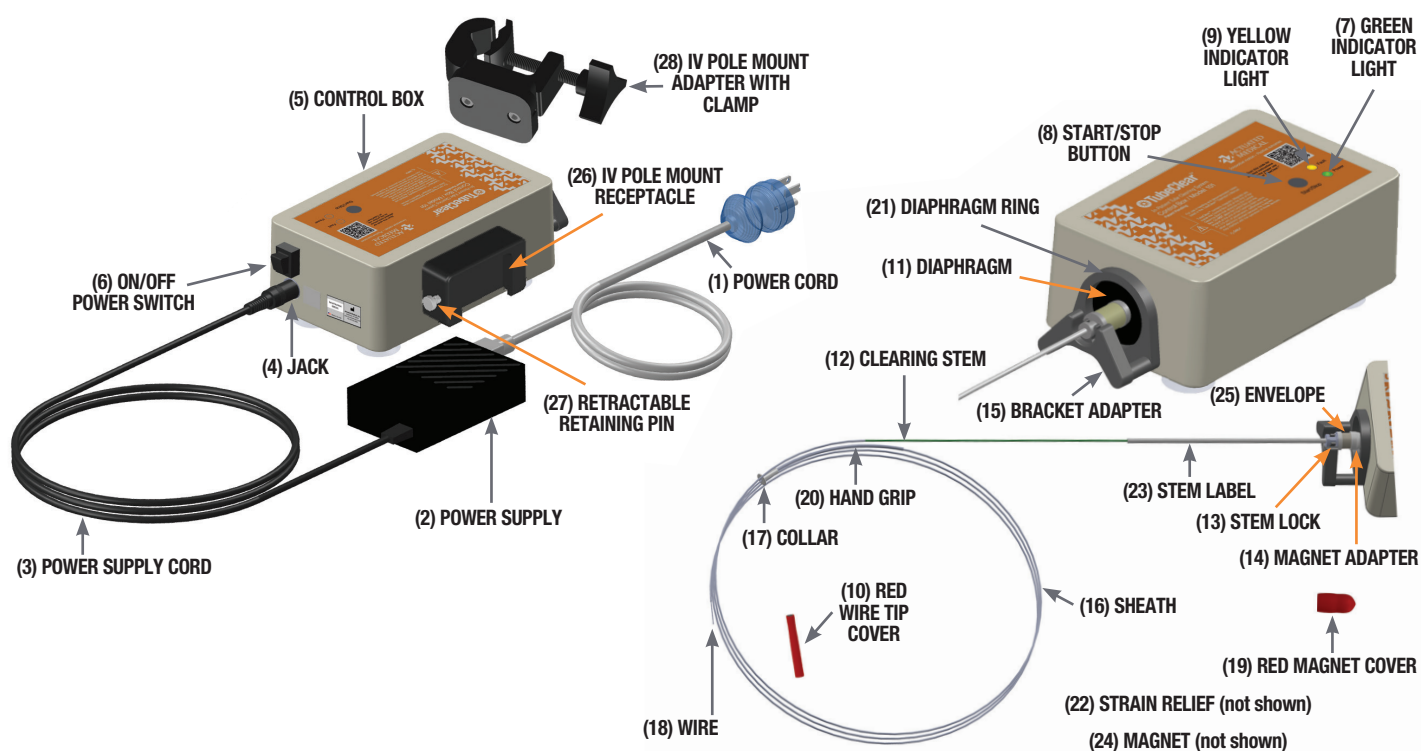
The TubeClear Control Box is externally powered. A Power Cord and a Power Supply are included with the TubeClear Control Box. The Power Cord plugs into a standard wall outlet (100 - 240 V @ 50/60 Hz). The Power Supply reduces the voltage to 24 VDC. The TubeClear System components are listed and numbered (see **Table 2** and **Figure 1**).

Symbols on Device and/or Packaging

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Do not re-use.		Prescription only		Type BF Applied Part
	Temperature Limitations		Use until		Direct Current
	WEEE Compliance		Batch		Manufactured date
NON-STERILE	Non-sterile		Class I Equipment		Manufacturer
			Read the documentation		Caution
			Ingress Protection Rating. Solid particle protection not tested. Liquid ingress protection against splashing water.		Serial Number

TABLE 2: TubeClear NE & G Models and Control Box Model 101 Components List.

Item No.	Name	Description	Item No.	Name	Description
1	Power Cord	Plugs into a standard outlet and into the Power Supply.	16	Sheath	The flexible tubing that surrounds the Wire.
2	Power Supply	Reduces voltage to the Control Box.	17	Collar	Feature limits insertion depth of the Clearing Stem.
3	Power Supply Cord	Plugs into the Jack on the Control Box.	18	Wire	Feature that interacts with the clog material.
4	Jack	Connector for Power Supply.	19	Red Magnet Cover	Covers and protects Magnet Adapter during storage.
5	Control Box	Contains the Motor and drive electronics.	20	Hand Grip	Feature for positioning hand during insertion.
6	On/Off Power Switch	Allows power to the Control Box.	21	Diaphragm Ring	Feature to secure Diaphragm to Control Box.
7	Green Indicator Light	Indicates power is available and is ready to start.	22	Strain Relief	Feature to minimize Clearing Stem bend at Control Box.
8	Start/Stop Button	Starts and stops the Motor inside the Control Box.	23	Stem Label	Describes Model and intended Feeding and Decompression Tube.
9	Yellow Indicator Light	Indicates an electrical fault. TubeClear will not operate when the yellow light is on.	24	Magnet	Feature to attach Clearing Stem to Control Box.
10	Red Wire Tip Cover	Covers and protects Wire Tip during storage.	25	Envelope	Covers Wire between Magnet Adapter and Stem Lock.
11	Diaphragm	Clearing Stem attachment point.	26	IV Pole Mount Receptacle	Feature that slides over the IV Pole Mount Adapter to hold the Control Box on an IV pole.
12	Clearing Stem	Inserts into the Patient's Tube to clear clogs, while the Tube remains inside the Patient.	27	Retractable Retaining Pin	Secures the IV Pole Mount Adapter in the IV Pole Mount Receptacle.
13	Stem Lock	Clips into the Bracket Adapter, secures the Clearing Stem.	28	IV Pole Mount Adapter with Clamp	Mounts to an IV pole and holds the Control Box via the IV Pole Mount Receptacle.
14	Magnet Adapter	Secures the Magnet on the end of the Clearing Stem.			
15	Bracket Adapter	Holds and positions the Clearing Stem during use.			

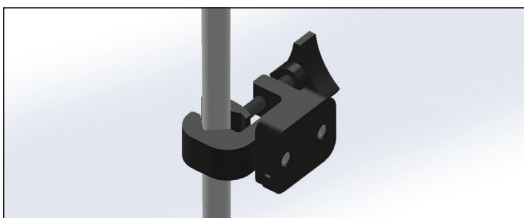
FIGURE 1: TubeClear Models NE & G Component Locations.

1.4 Control Box Set-up Instructions

1.4.1) Verify that you have the correct TubeClear Clearing Stem Model for the type, size, and length of the Patient's Tube. Refer to **Table 1** in **Section 1.3** for Model selection.

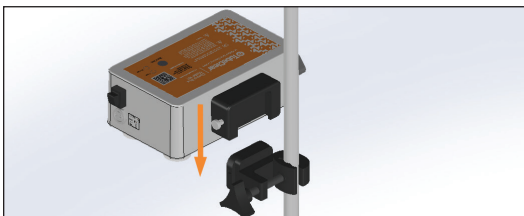
1.4.2) Place the Control Box on a level table, IV pole tray, or use the IV Pole Mount (see 1.4.2a - c) to reduce the risk of the Control Box falling. Select the side of the Patient's bed where you can easily access the Tube's ports. Position the Control Box within about 1/2 m (2 ft) of the Patient. Adjust the height of the Control Box to allow comfortable use of the TubeClear System.

1.4.2a)



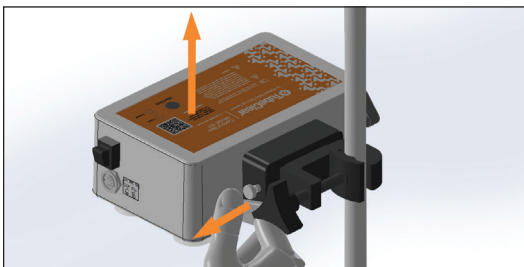
Tighten the IV Pole Clamp onto an IV pole.

1.4.2b)



Slide the IV Pole Mount Receptacle over the Adapter. Be sure that the Retractable Retaining Pin clicks.

1.4.2c)

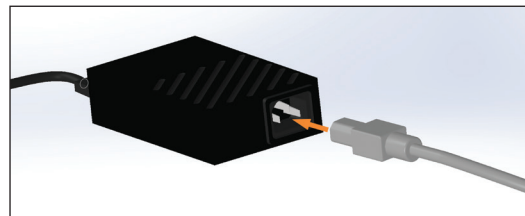


To remove Control Box from the IV Pole Mount Adapter, pull outward on the knob of the Retractable Retaining Pin while simultaneously lifting the Control Box upward and off of the IV Pole Mount Adapter.

1.4.3) It is recommended that the Operator wear eye protection and gloves when operating the TubeClear System.

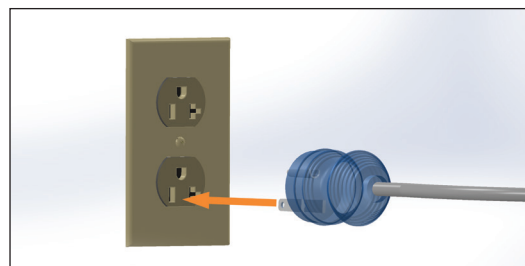
1.4.4) It is recommended that a disposable pad be placed over the Patient's chest and stomach area during use of the TubeClear System to keep the Clearing Stem from touching the Patient or bedding.

1.4.5)



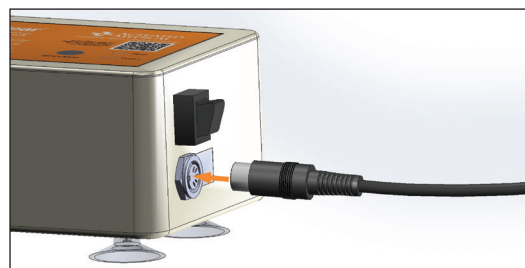
Verify that the Power Cord is securely plugged into the Power Supply.

1.4.6)



Plug the Power Cord into a standard 100 - 240 V @ 50/60 Hz outlet.

1.4.7)



Plug the Power Supply Cord into the Jack on the Control Box being sure to line up the pins.

1.4.8)

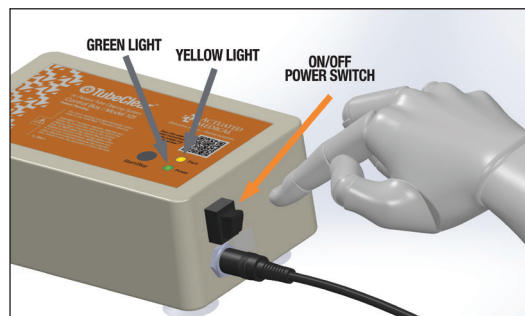
Verify that the Control Box is operational by turning the On/Off Power Switch to the **On** position.

1.4.9)

The Green Indicator Light will illuminate when the Control Box is ready for use.

NOTE: The Control Box Motor will not start at this time. The Start/Stop Button needs to be pushed down before the Control Box Motor will operate.

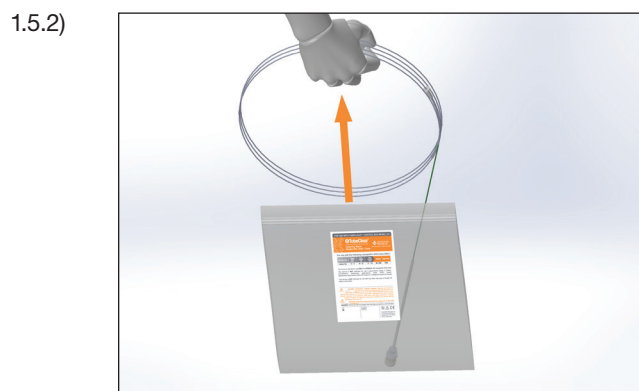
1.4.10)



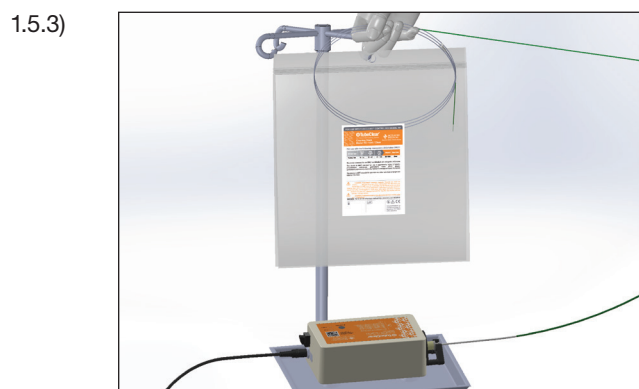
If the Yellow Indicator Light illuminates, do **NOT** use the Control Box. Turn the power **Off** and then back **On** (cycle the power). If the Yellow Indicator Light remains on, see **Section 6.0** Return Policy.

1.5 Clearing Stem Set-up Instructions

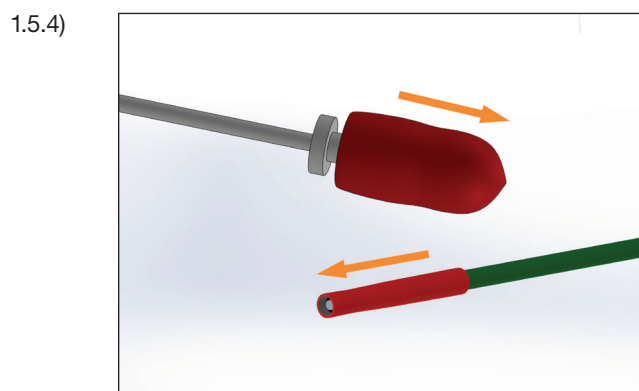
- 1.5.1) Verify that you have the correct TubeClear Clearing Stem Model for the type, size, and length of the Patient's Tube. Refer to **Table 1** in **Section 1.3** for Model selection.



Remove the Clearing Stem from its Packaging. Keep the Packaging for later use.

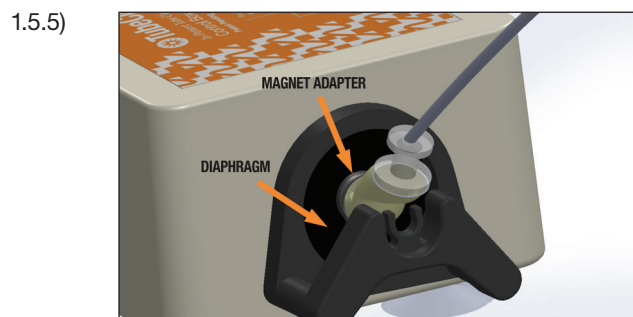


Anytime the Clearing Stem is not in the Patient's Tube, loosely coil it and place it into the Packaging.

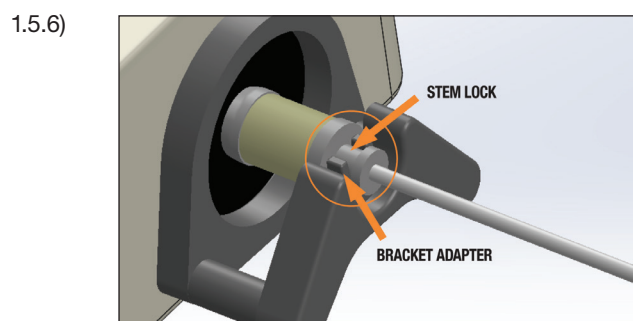


Pull the Red Magnet Cover from the Magnet Adapter at the end of the Clearing Stem. Similarly, pull the Red Wire Tip Cover from the other end of the Clearing Stem. Place Red Magnet Cover inside the Packaging. The Red Magnet Cover will be needed later.

(Clearing Stem color is dependent on Model specific to Patient's Tube.)

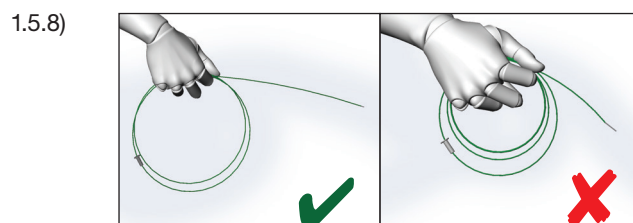


Directly place the Clearing Stem Magnet Adapter to the center of the Control Box Diaphragm. The Magnet Adapter will adhere magnetically to the center of the Diaphragm. Pull gently on the Magnet Adapter to confirm that it is securely attached. There will be resistance if the Magnet Adapter is properly attached. If the Magnet Adapter is not attached securely, reposition the Magnet Adapter onto the Diaphragm center.



Firmly clip the Stem Lock into the Bracket Adapter and verify the connection is secure. Proper placement of the Stem Lock is necessary for effective operation.

- 1.5.7) Do **NOT** operate the TubeClear System if Stem Lock is not securely clipped in Bracket Adapter.



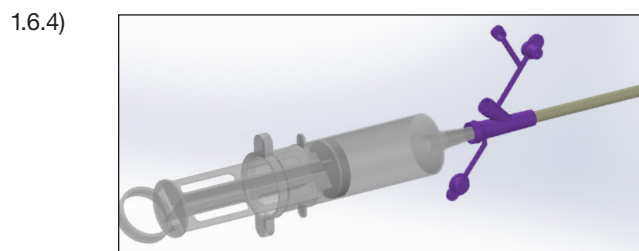
You may loosely coil the Clearing Stem around your hand to help control the Clearing Stem length while inserting it into the Patient's Tube. Do **NOT** tightly coil the Clearing Stem around your hand before or during use because this will slow the Wire motion inside the Sheath and decrease efficacy.

1.6 Operating Instructions

- 1.6.1) Read the Operating Instructions and review **Flow Diagrams A and B** before operating the TubeClear System.

- 1.6.2) Set-up TubeClear Control Box and attach the Clearing Stem as directed in **Section 1.4 - Section 1.5**.

- 1.6.3) Do **NOT** press down the Start/Stop Button until Step 1.6.7.



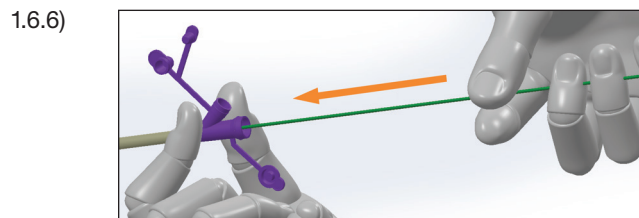
Throughout the clearing process **insert water** and **aspirate** loosened clog contents. Insert up to 30 mL of liquid at a time into the Patient's Tube.

- 1.6.5) Hold the Patient's Tube in one hand and the Clearing Stem in your other hand.

- 1.6.5a) Optional: Coat the distal end (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.

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



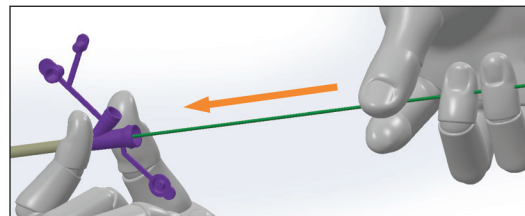
Insert the Clearing Stem into the Patient's Tube only a few centimeters (inches) at this time.



Hold both the Patient's Tube and the Clearing Stem with one hand and firmly press down the Start/Stop Button with your other hand.

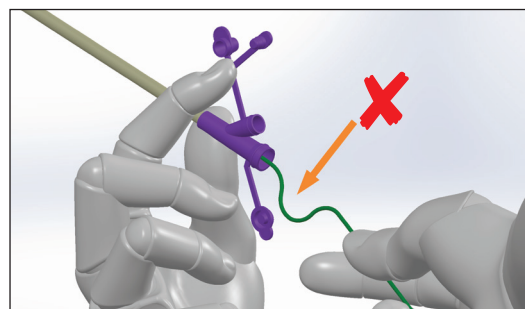
NOTE: The Control Box will automatically stop after operating for ten (10) minutes. The Control Box may be re-started by pressing down the Start/Stop Button again.

1.6.8)



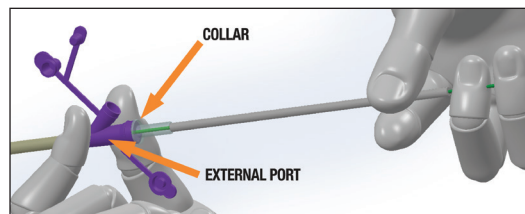
Manually advance the Clearing Stem until you encounter resistance from the clog. Continue to apply gentle forward force to the Clearing Stem to break up the clog. Manual backward and forward movement of the Clearing Stem is helpful in breaking up the clog.

1.6.9)



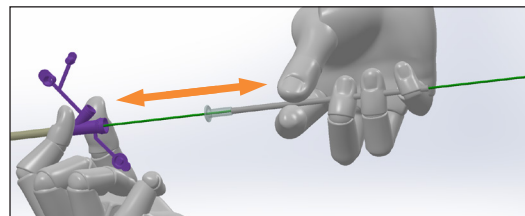
DO NOT APPLY EXCESSIVE FORCE TO THE CLEARING STEM. ANY SIGN OF KINKING DUE TO OPERATOR FORCE WILL DECREASE EFFECTIVENESS.

1.6.10)



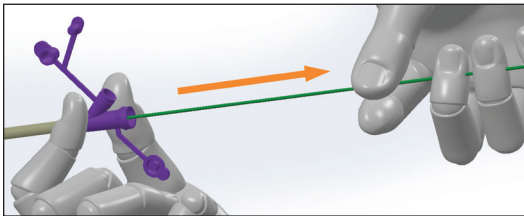
Continue forward advancement of the Clearing Stem until the Collar reaches the Tube's External Port. If this does not occur within ten (10) minutes, refer to **Section 8.0** Troubleshooting Guide.

1.6.11)



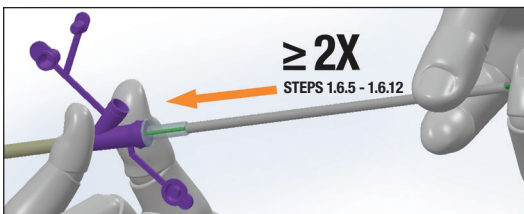
After the Collar reaches the Tube's External Port, move the Clearing Stem backward approximately 10 cm (4 in) then forward until the Collar reaches the Tube's External Port again several times.

1.6.12)



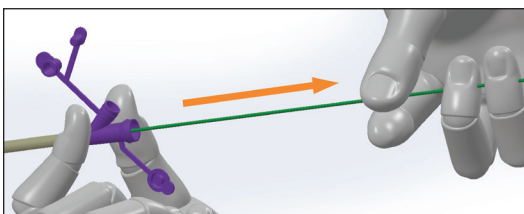
With the Control Box **On**, hold the Patient's Tube with one hand and slowly remove the Clearing Stem from the Tube with the other hand.

1.6.13)



Reinsert the Clearing Stem until the Collar reaches the Tube's External Port **at least two (2) more times** (Steps 1.6.5 - 1.6.12). This will help to clear any material that remains at the distal end of the Patient's Tube. Additional backward and forward movement may be necessary to clear clogged material.

1.6.14)



With the Control Box **On**, hold the Patient's Tube with one hand and slowly remove the Clearing Stem from the Tube with the other hand.

1.6.15)

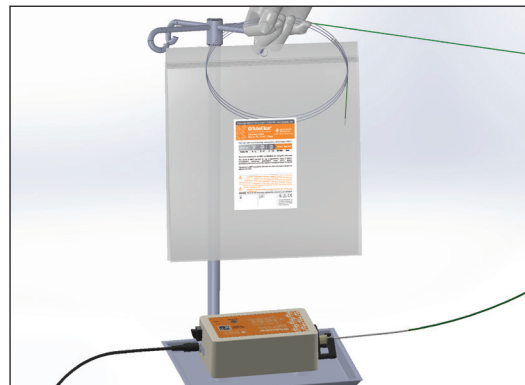


Stop the Control Box by pressing down the Start/Stop Button.

1.6.16)

Do NOT detach the Clearing Stem from the Control Box at this time as you may need to reinsert it if the Tube is not yet clear.

1.6.17)

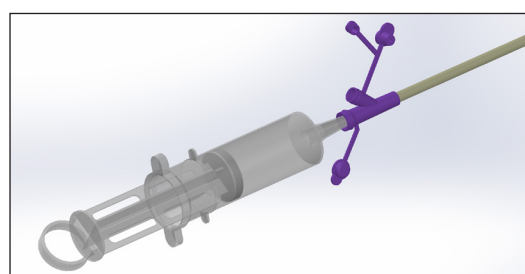


With the Magnet Adapter attached to the Control Box, loosely coil the Clearing Stem and place it back into the Packaging during patency confirmation.

1.6.18)

Verify that the Patient's Tube is properly placed using your Institution's Protocol.

1.6.19)



Use the enteral syringe to aspirate or flush loosened clog contents out of the Tube.

NOTE: 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.

1.6.20)

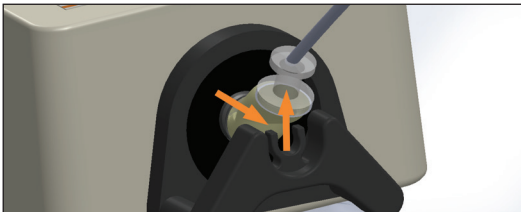
Verify that the Patient's Tube is clear using your Institution's Protocol.

1.6.21)



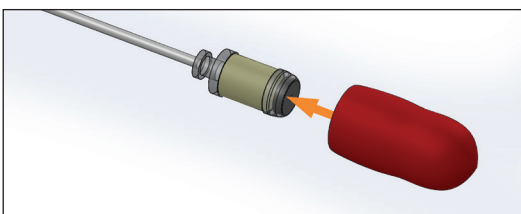
If the Patient's Tube is still clogged, repeat Steps 1.6.5 - 1.6.20 until the clog is removed. If this does not occur within ten (10) minutes or if progress is not made, refer to **Section 8.0** Troubleshooting Guide.

1.6.22)



After verifying the Patient's Tube is clear, disconnect the Clearing Stem from the Control Box by unclipping the Stem Lock from the Bracket Adapter. Then gently pull upward on the Magnet Adapter to remove it from the Diaphragm.

1.6.23)



Immediately replace the Red Magnet Cover on the Magnet Adapter of the Clearing Stem prior to disposal.

1.6.24)

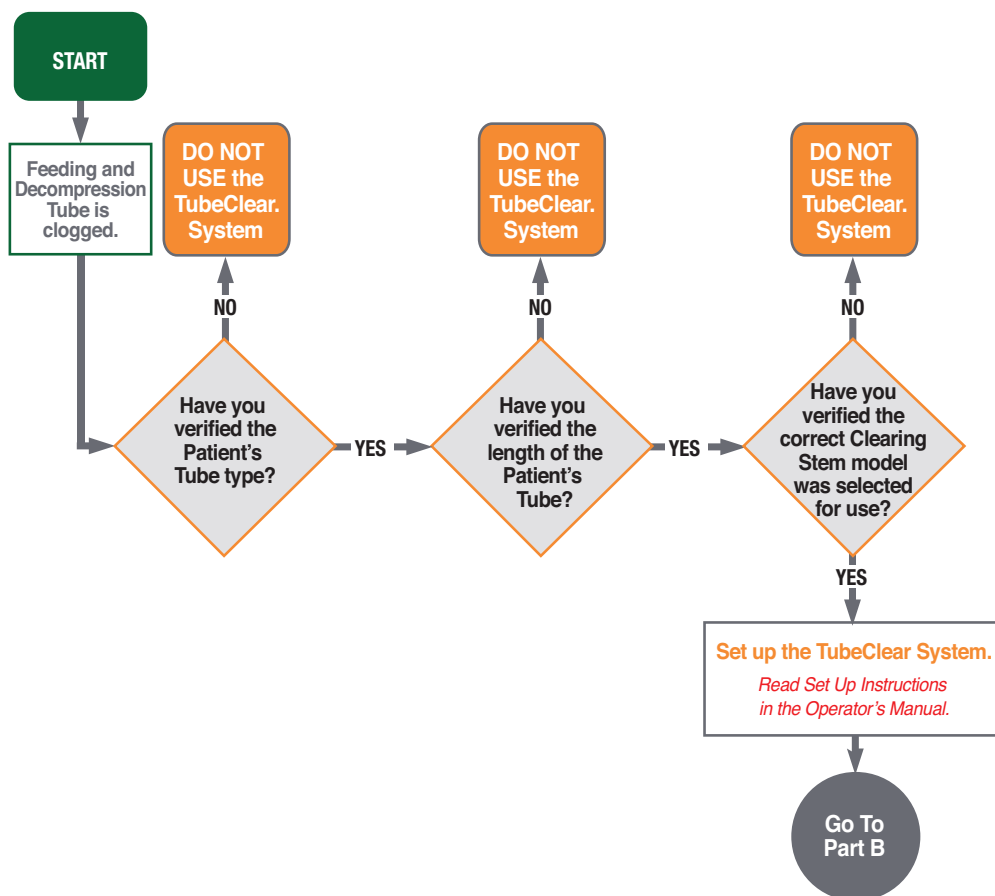


Do **NOT** dispose of the Clearing Stem with ordinary waste. Dispose of the Clearing Stem as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.

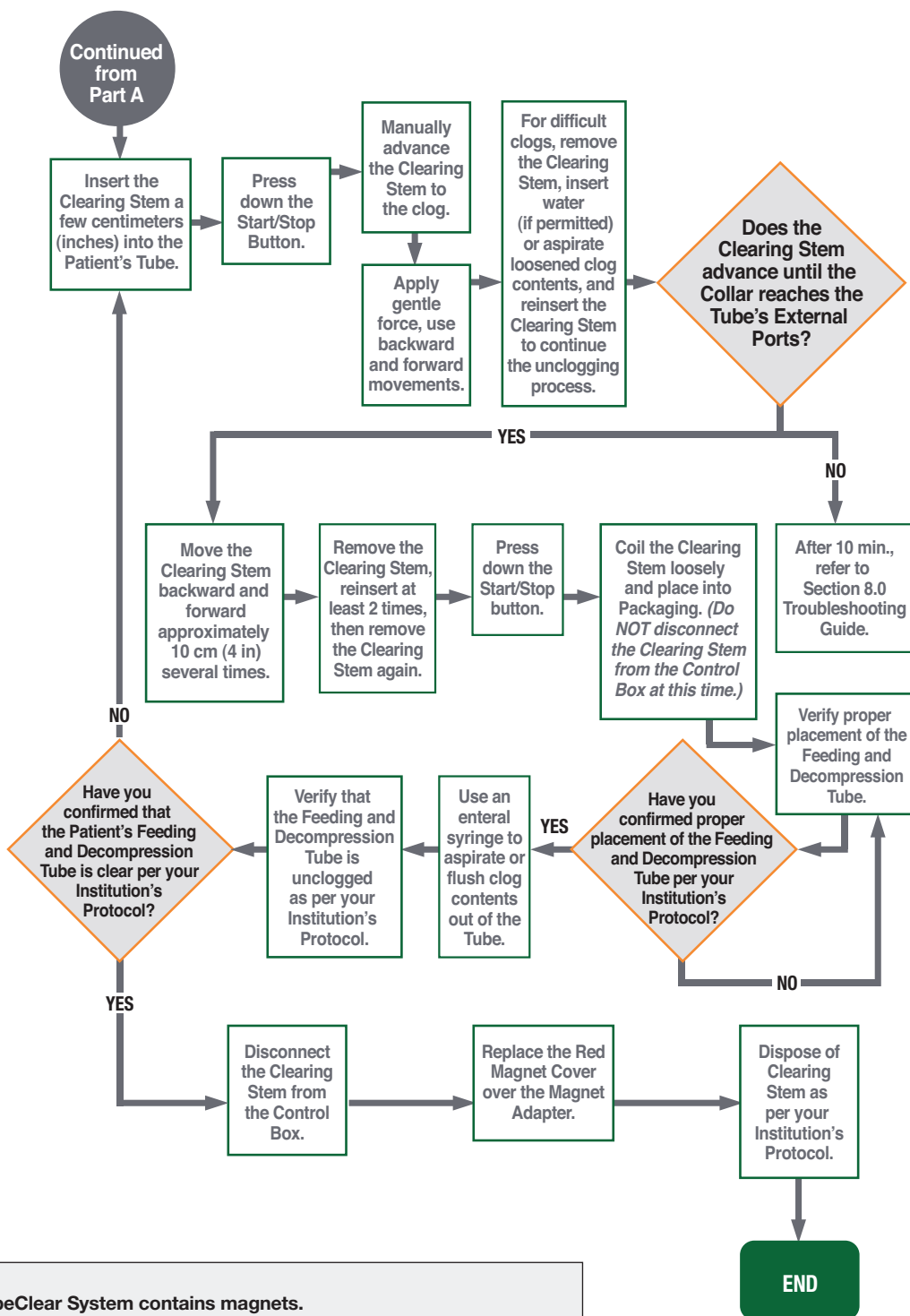
1.6.25)

If any of the de-clogged contents from the Patient's Tube come into contact with the Patient or any surfaces, consider the de-clogged contents to be similar to vomitus. Clean the Patient and surfaces in accordance with your Institution's Protocol.

FLOW DIAGRAM PART A: Flow Diagram for Operation of the TubeClear System.



FLOW DIAGRAM PART B: Flow Diagram for Operation of the TubeClear System.

**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.

2.0 TC Model Operator's Instructions

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.

TC-1018 Clearing Stem Model Indications for Use

TubeClear Clearing Stem Model TC-1018 is indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adults that have the following Tube type and size (French and length).

- + TC-1018, for Nasoenteral and Nasogastric Tubes that are size 10 - 18 Fr and have a length of 91 - 140 cm (36 - 55 in); and Gastrostomy and Jejunostomy Tubes that are size 10 - 18 Fr and have a length of 20 - 36 cm (8 - 14 in).

TC-1018 Clearing Stem Model Contraindications



Do NOT use TubeClear Clearing Stem Model TC-1018 if:

- + You do **NOT** know for certain the type and size (French and length) of the Feeding and Decompression Tube.
- + The TubeClear Clearing Stem Model is **NOT** indicated for the type and size (French 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.

TC-0812 Clearing Stem Model Indications for Use

TubeClear Clearing Stem Model TC-0812 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-0812, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 8 - 12 Fr and have a length of 38 - 140 cm (15 - 55 in).

TC-0812 Clearing Stem Model Contraindications



Do NOT use TubeClear Clearing Stem Model TC-0812 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.

TC-0608 Clearing Stem Model 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).

TC-0608 Clearing Stem Model Contraindications



Do NOT use TubeClear Clearing Stem 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.

2.1 Cautions

Read the entire manual before using the TubeClear System. Disregarding the cautions and instructions presented in this manual constitutes ABNORMAL USE.



In addition to reading this 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/).

A "Directions for Use" insert is included in the Clearing Stem bag for quick reference.

"Tube" as used in this manual refers to any Feeding and/or Decompression Tube, also known as an Enteral Access Device, residing in a Patient.

Make certain that the correct Clearing Stem Model has been selected or type, size (French and length), and material of the 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 **Section 2.3 Device Description**, 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, fluoroene, 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 .

2.2 Operator Profile

The TubeClear System is intended for use by Certified or Licensed Healthcare Practitioners. Reading the Operator's Manual and watching the TubeClear Training Video is required before using the TubeClear System. For information about additional training, contact Actuated Medical's Customer Service Department at +1 (814) 355-0003 ext. 117 or visit the website **TubeClear.com**.

2.3 Device Description

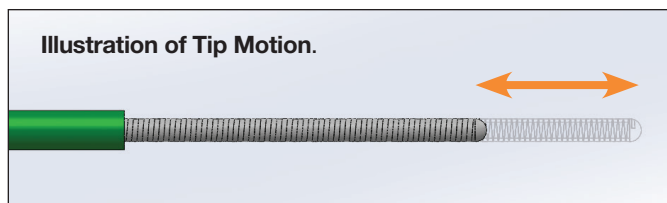
The TubeClear System clears clogs in Feeding and Decompression Tubes while the tube **REMAINS** in the Patient. The TubeClear System is comprised of a reusable Control Box and a single use Clearing Stem. The Clearing Stem magnetically attaches to the Control Box.

Clogs are occlusions, blockages, or obstructions of feeding formula, ground food, medications, supplements, or aspirated contents in the Patient's Tube.

The Clearing Stem consists of a 203 cm (80 in) long, flexible Wire encased in a flexible Sheath. The Wire Tip is rounded and smooth and extends approximately 1.7 cm ($\frac{2}{3}$ in) beyond the Sheath.

The Control Box contains a Motor that activates the Clearing Stem Wire. The Motor causes the Wire to move quickly backward and forward inside the Sheath. The Control Box may be mounted to an IV pole via the IV Pole Mount, which consists of the IV Pole Mount Receptacle (attached to the side of the Control Box) and the IV Pole Mount Adapter with Clamp. The Wire moves approximately 0.4 - 1.0 cm ($\frac{1}{8}$ - $\frac{3}{8}$ in) (see **Illustration right**). This backward and forward movement of the Wire allows it to break up and clear clogs while the Tube remains in the Patient.

Each Clearing Stem has a Depth Limiter that the Operator sets. When the Depth Limiter reaches the Tube's external port, the Clearing Stem cannot be inserted further into the Tube. The Depth Limiter properly set by the Operator minimizes the risk of the Clearing Stem exiting the end of the Tube.



Because Feeding and Decompression Tubes come in different types, sizes (French and length), and materials, several Models of the TubeClear Clearing Stems are available (see **Table 3 - 5**). The label on the Clearing Stem Packaging will identify the Clearing Stem Model and specify the Feeding and Decompression Tube type, size (French and length), and material (when applicable) for which the specific Clearing Stem Model is indicated.

TABLE 3: TubeClear Clearing Stem Model TC-1018.

Tube Type	French Size (Fr)	Tube Material	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
Nasoenteral (NE) & Nasogastric (NG) Tubes	10 - 18	ANY	91 - 140	36 - 55	TC1018	Purple
Gastrostomy (G) & Jejunostomy (J) Tubes			20 - 36	8 - 14		
TC-1018 MODEL CLEARING STEM HAS A BLACK STEM LABEL						

EXAMPLE: Patient has a Nasoenteral tube, 14 Fr, PVC, 109 cm (43 in) long - select Model Number TC-1018.

TABLE 4: TubeClear Clearing Stem Model TC-0812.

Tube Type	French Size (Fr)	Tube Material	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
Nasoenteral (NE) & Nasogastric (NG) Tubes	8 - 12	PVC or Polyurethane	38 - 140	15 - 55	TC-0812	White
TC-0812 MODEL CLEARING STEM HAS AN ORANGE STEM LABEL						

EXAMPLE: Patient has a Nasogastric tube, 8 Fr, PVC, 91 cm (36 in) long - select Model Number TC-0812. (Model Number TC-0608 may also be selected for this example.)

TABLE 5: TubeClear Clearing Stem Model TC-0608.

Tube Type	French Size (Fr)	Tube Material	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
Nasoenteral (NE) & Nasogastric (NG) Tubes	6 - 8	PVC or Polyurethane	38 - 140	15 - 55	TC-0608	Brown
TC-0608 MODEL CLEARING STEM HAS A WHITE STEM LABEL						

EXAMPLE: Patient has a Nasoenteral tube, 6 Fr, polyurethane, 56 cm (22 in) long - select Model Number TC-0608.



Failure to set the Depth Limiter to the correct position could result in over insertion of the Clearing Stem into the Patient's gastrointestinal (GI) system.



Use of a Clearing Stem in a smaller French size Tube than indicated or in a Tube made of a non-indicated material 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 larger French size Tube than indicated may result in a non-effective clearing attempt.

TABLE 6a: TubeClear Clearing Stem Selection Chart for NE Tube Types.

Tube Type	French Size	Tube Material	Tube Length (cm)	Tube Length (in)	Model TC-1018	Model TC-0812	Model TC-0608
NE or NG	12.5 - 18	ANY	91 - 140	36 - 55	✓	✗	
	10 - 12	ANY	91 - 140	36 - 55	✓	✗	
		PVC or Polyurethane	91 - 140	36 - 55	✓	✓	✗
			38 - 90.9	15 - 35.9	✗	✓	
		Silicone	91 - 140	36 - 55	✓	✗	✗
			38 - 90.9	15 - 35.9	✗		
	8.5 - 9.5	PVC or Polyurethane	38 - 140	15 - 55	✗	✓	✗
		Silicone	ANY	ANY	✗		
	8	PVC or Polyurethane	38 - 140	15 - 55	✗	✓	✓
		Silicone	ANY	ANY		✗	
	6 - 7.5	PVC or Polyurethane	38 - 140	15 - 55	✗	✗	✓
		Silicone	ANY	ANY		✗	
KEY ✓ = Clearing Stem for use with listed specifications ✗ = Clearing Stem NOT for use with listed specifications							

TABLE 6b: TubeClear Clearing Stem Selection Chart for G and J Tube Types.

Tube Type	French Size	Tube Material	Tube Length (cm)	Tube Length (in)	Model TC-1018	Model TC-0812	Model TC-0608
G	10 - 18	ANY	20 - 36	8 - 14	✓	✗	✗
J	10 - 18	ANY	20 - 36	8 - 14	✓	✗	✗
KEY					✓ = Clearing Stem for use with listed specifications		
					✗ = Clearing Stem NOT for use with listed specifications		



If your Patient's Tube does not meet any of the criteria listed in **Table 6a** and **Table 6b** or you do not know any of the information listed above, do **NOT** use the TubeClear System.

The TubeClear Control Box is externally powered. A Power Cord and a Power Supply are included with the Control Box. The Power Cord plugs into a standard wall outlet (100 – 240 V @ 50/60 Hz). The components of the TubeClear System are listed and numbered (see **Table 7** and **Figure 2**).

Symbols on Device and/or Packaging

















Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Do not re-use.		Prescription only		Type BF Applied Part
	Temperature Limitations		Use until		Direct Current
	WEEE Compliance		Batch		Manufactured date
	Non-sterile		Class I Equipment		Manufacturer
			Read the documentation		Caution
			Ingress Protection Rating. Solid particle protection not tested. Liquid ingress protection against splashing water.		Serial Number

TABLE 7a: TubeClear Control Box Model 101 Components List.

Item No.	Name	Description
1	Power Cord	Plugs into a standard outlet and into the Power Supply.
2	Power Supply	Reduces voltage to the Control Box.
3	Power Supply Cord	Plugs into the Jack on the Control Box.
4	Jack	Connector for Power Supply.
5	Control Box	Contains the Motor and drive electronics.
6	On/Off Power Switch	Allows power to the Control Box.
7	Green Indicator Light	Indicates power is available and is ready to start.
8	Start/Stop Button	Starts and stops the Motor inside the Control Box.
9	Yellow Indicator Light	Indicates an electrical fault. TubeClear will not operate when the yellow light is on.
10	Bracket Adapter	Holds and positions the Clearing Stem during use.
11	Diaphragm	Clearing Stem attachment point.
12	Diaphragm Ring	Feature to secure Diaphragm to Control Box.
13	IV Pole Mount Receptacle	Feature that slides over the IV Pole Mount Adapter to hold the Control Box on an IV pole.
14	Retractable Retaining Pin	Secures the IV Pole Mount Adapter in the IV Pole Mount Receptacle.
15	IV Pole Mount Adapter with Clamp	Mounts to an IV pole and holds the Control Box via the IV Pole Mount Receptacle.

TABLE 7b: TubeClear TC Model Clearing Stem Components List.

Item No.	Name	Description
16	Clearing Stem	Inserts into the Patient's Tube to clear clogs, while the Tube remains inside the Patient.
17	Wire	Feature that interacts with the clog material.
18	Sheath	The flexible tubing that surrounds the Wire.
19	Stem Lock	Clips into the Bracket Adapter, secures the Clearing Stem.
20	Magnet Adapter	Secures the Magnet on the end of the Clearing Stem.
21	Magnet	Feature to attach Clearing Stem to Control Box.
22	Envelope	Covers Wire between Magnet Adapter and Stem Lock.
23	Stem Label	Provides product name and intellectual property information.
24	Strain Relief	Feature to minimize Clearing Stem bend at Control Box.
25	Red Magnet Cover	Covers and protects Magnet Adapter during storage.
26	Depth Limiter	Feature that Operator manually sets that corresponds to the length of the Tube to limit insertion depth of the Clearing Stem.
27	Red and Blue Plastic Protector	Packaging feature that protects Wire during storage and attachment to the Control Box.
28	Clear Wire Tip Cover (on centimeter scale side)	Packaging feature that protects Wire Tip during storage.
29	Paper Measuring Tape	Measuring Tape used to set Depth Limiter.

FIGURE 2a: TubeClear Control Box Model 101 Components.

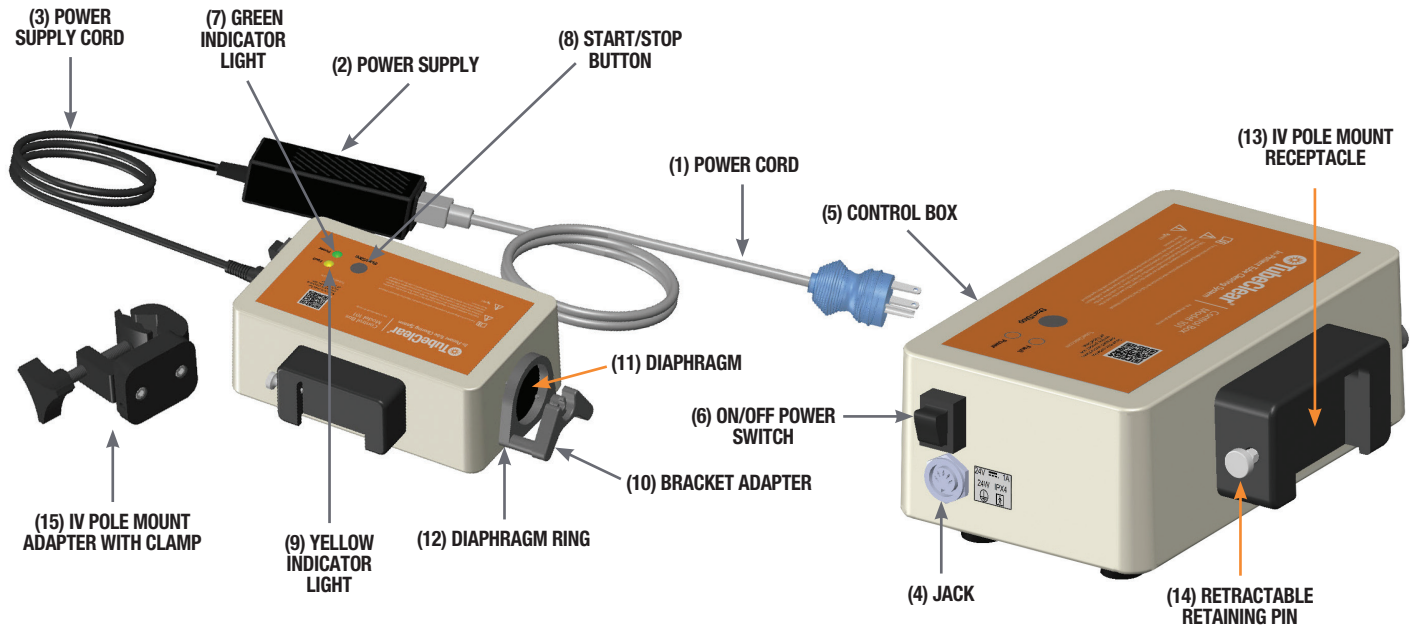
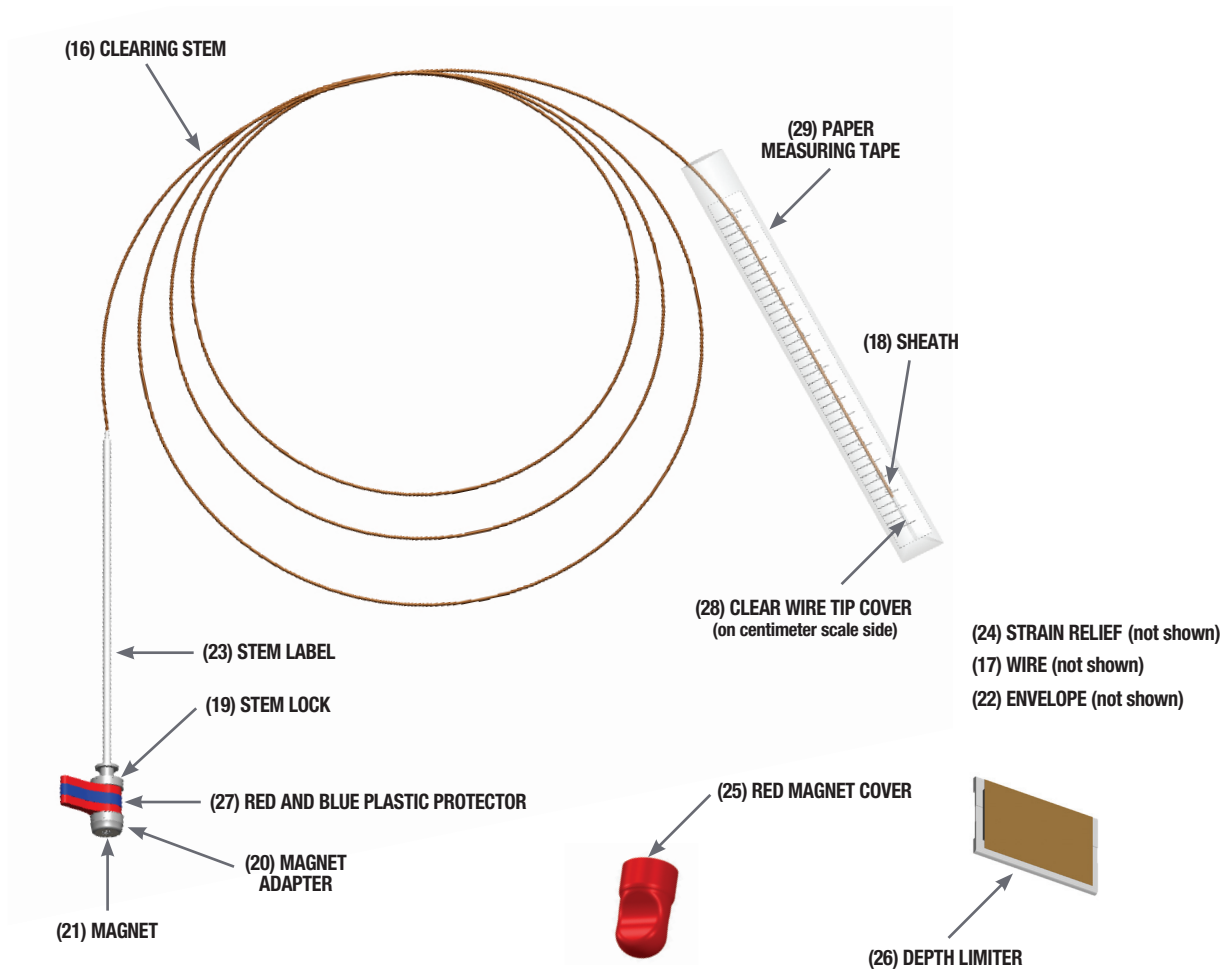


FIGURE 2b: TubeClear TC Model Clearing Stem Components. NOTE: Color of Sheath (18) and Stem Label (23) will vary between Models.

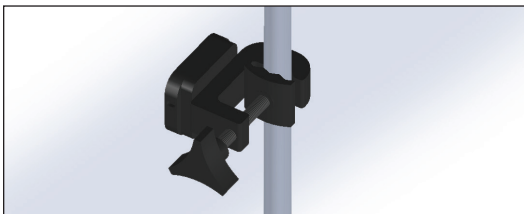


2.4 Control Box Set-up Instructions

- 2.4.1) Verify that you have the correct TubeClear Clearing Stem Model for the type, size (French and length), and material of the Patient's Tube. Refer to **Table 6** in **Section 2.3** for Model selection.

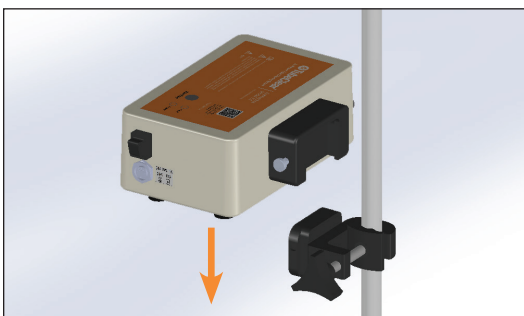
- 2.4.2) Place the Control Box on a level table, IV pole tray, or use the IV Pole Mount (see 2.4.2a - c) to reduce the risk of the Control Box falling. Select the side of the Patient's bed where you can easily access the Tube's ports. Position the Control Box within about 1/2 m (2 ft) of the Patient. Adjust the height of the Control Box to allow comfortable use of the TubeClear System.

2.4.2a)



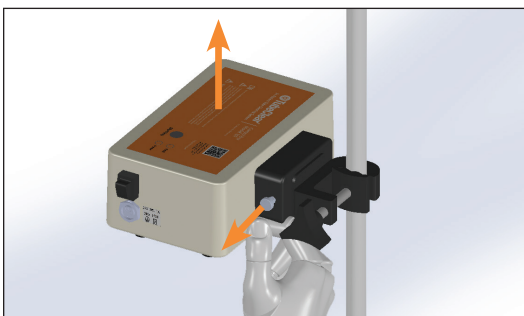
Tighten the IV Pole Mount Adapter with Clamp onto an IV pole.

2.4.2b)



Slide the IV Pole Mount Receptacle over the Adapter. Be sure that the Retractable Retaining Pin clicks.

2.4.2c)

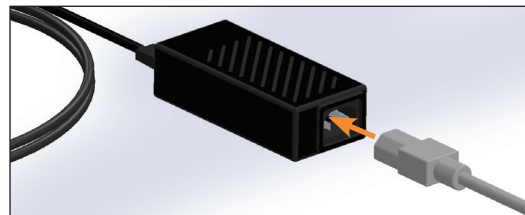


To remove the Control Box from the IV Pole Mount Adapter, pull outward on the knob of the Retractable Retaining Pin while simultaneously lifting the Control Box upward and off of the IV Pole Mount Adapter.

- 2.4.3) It is recommended that the Operator wear eye protection and gloves when operating the TubeClear System.

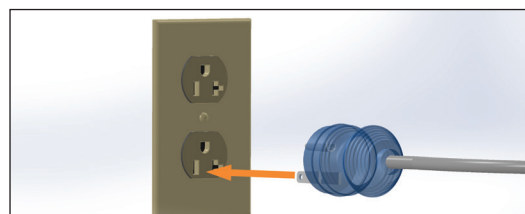
- 2.4.4) It is recommended that a disposable pad be placed over the Patient's chest and stomach area during use of the TubeClear System to keep the Clearing Stem from touching the Patient or bedding.

2.4.5)



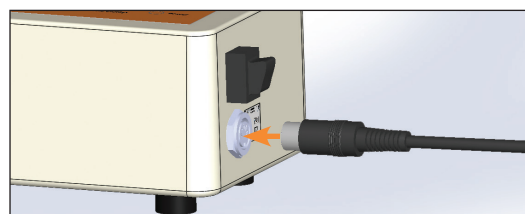
Verify that the Power Cord is securely plugged into the Power Supply.

2.4.6)



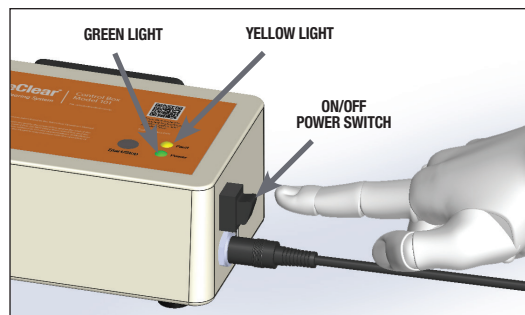
Plug the Power Cord into a standard 100 - 240 V @ 50/60 Hz outlet.

2.4.7)



Plug the Power Supply Cord into the Jack on the Control Box being sure to line up the pins.

2.4.8)



Verify that the Control Box is operational by turning the On/Off Power Switch to the **On** position. The Green Indicator Light will illuminate when the Control Box is ready for use.

NOTE: The Control Box Motor will not start at this time. The Start/Stop Button needs to be pushed down before the Control Box Motor will operate.

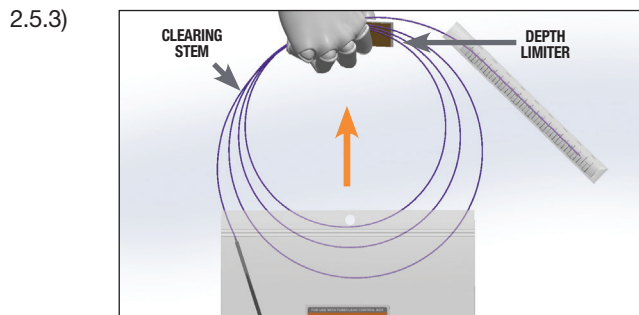
2.4.9)

If the Yellow Indicator Light illuminates, do **NOT** use the Control Box. Turn the power **Off** and then back **On** (cycle the power). If the Yellow Indicator Light remains on, see **Section 6.0** Return Policy.

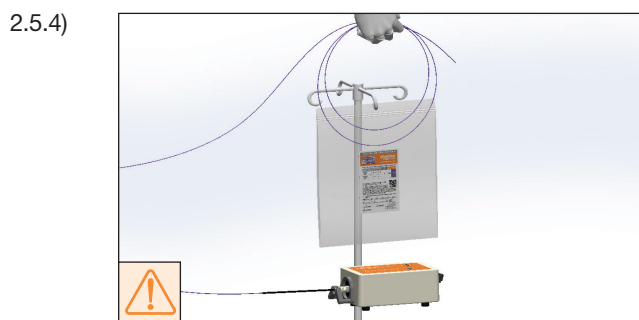
2.5 Clearing Stem Set-up Instructions

2.5.1) Verify that you have the correct TubeClear Clearing Stem Model for the type, size (French and length), and material of the Patient's Tube. Refer to **Table 6** in **Section 2.3** for Model selection.

2.5.2) Identify the length of the Patient's Tube.

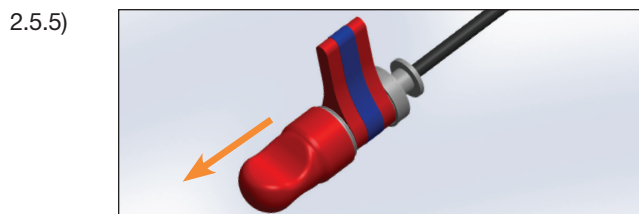


Remove the Clearing Stem and Depth Limiter from the package. Keep the Packaging for later use. (Clearing Stem color is dependent on Model specific to the Patient's Tube.)



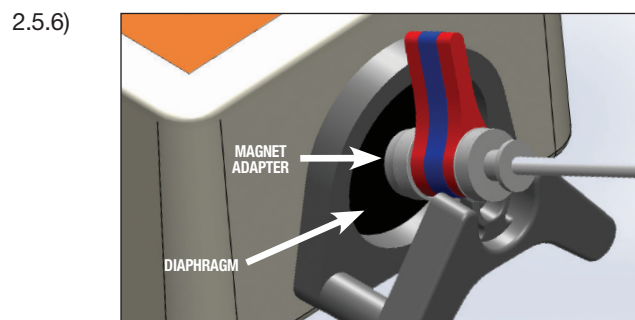
Anytime the Clearing Stem is not in the Patient's Tube, loosely coil it and place it into the Packaging. This will help to prevent the Clearing Stem from falling to the floor or another potentially contaminated surface.

Clean technique should be used when handling the Clearing Stem.

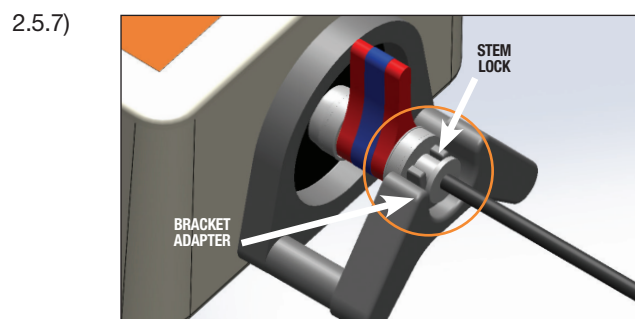


Pull the Red Magnet Cover from the Magnet Adapter at the end of the Clearing Stem. Place the Red Magnet Cover inside the Packaging. The Red Magnet Cover will be needed for disposal.

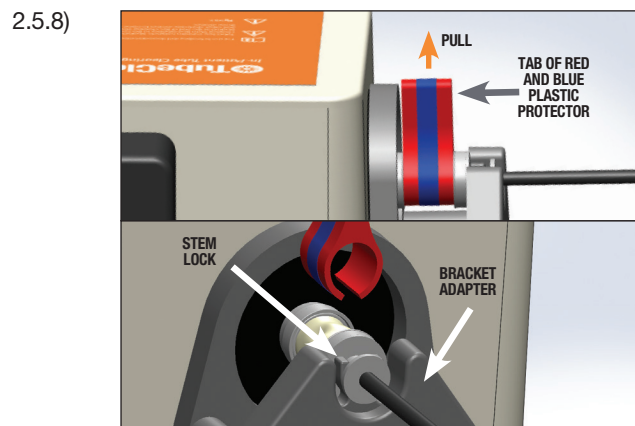
Attaching Clearing Stem to Control Box



Directly place the Magnet Adapter of the Clearing Stem on the center of the Control Box Diaphragm. If necessary, rotate the Clearing Stem so that the red and blue tab is facing directly up.



Firmly clip the Stem Lock (by pressing down) into the Bracket Adapter and verify the connection is secure. Proper placement of the Stem Lock is necessary for effective operation.



Remove the Red and Blue Plastic Protector from the Clearing Stem by pulling directly up on the tab. This releases the Plastic Protector by breaking the blue tape at the other end of the Plastic Protector. Then, confirm that the Stem Lock is still clipped in the Bracket Adapter.

2.5.9) Do **NOT** operate the TubeClear System if the Stem Lock is not securely clipped in the Bracket Adapter.

Measuring and Placing the Clearing Stem's Depth Limiter

Steps 2.5.10 through 2.5.15 help to ensure proper placement of the Depth Limiter. The Depth Limiter must be properly set by the Operator to the location that equals the Patient's tube length to minimize the risk of the Clearing Stem exiting the end of the Tube.

Importance of Correct Depth Limiter Placement

Illustration of Proper Depth Limiter Placement on Clearing Stem.

- ✓ Depth Limiter is placed at the correct location that corresponds to the length of the Patient's Tube.

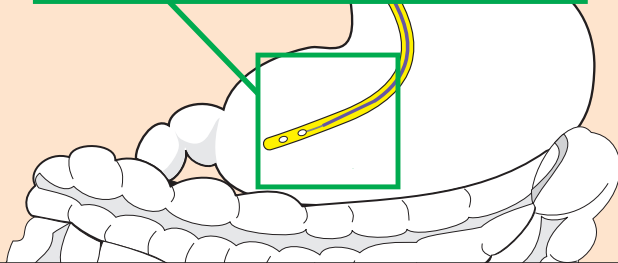
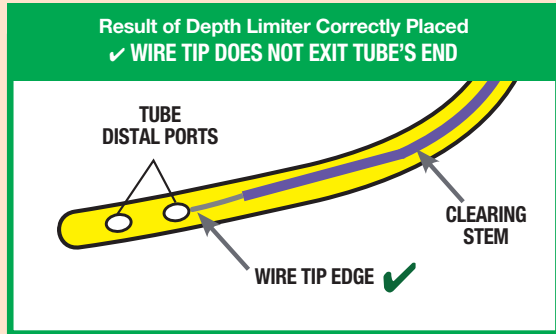
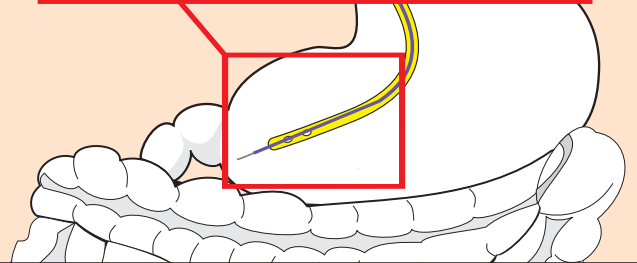
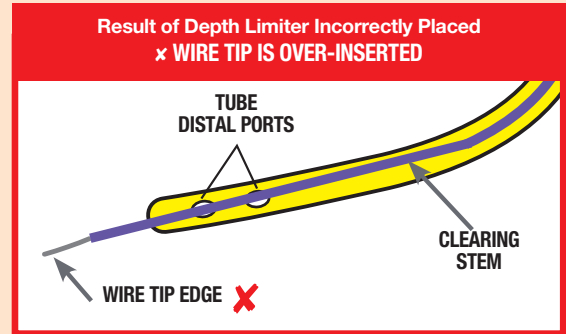
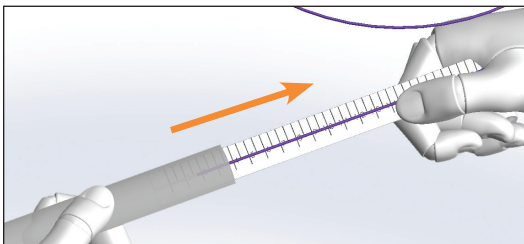


Illustration of Improper Depth Limiter Placement on Clearing Stem.

- ✗ Depth Limiter is placed at the incorrect location that is longer than the length of the Patient's Tube causing over-insertion of the Clearing Stem.

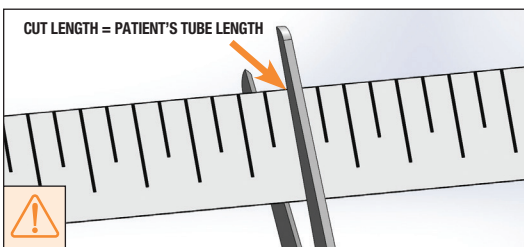


2.5.10)



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

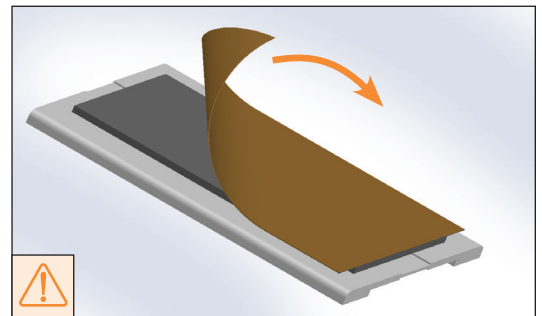
2.5.11)



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

Verify if the Tube length is specified in centimeters or inches. Then use the corresponding side of the Measuring Tape.

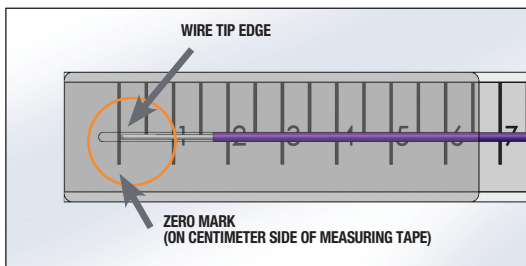
2.5.12)



Remove the brown backing from the tape section on the Depth Limiter to expose the adhesive. Set the Depth Limiter aside so that it does not adhere to anything.

The Depth Limiter will be used to set the location on the Clearing Stem that corresponds to the Patient's Tube length.

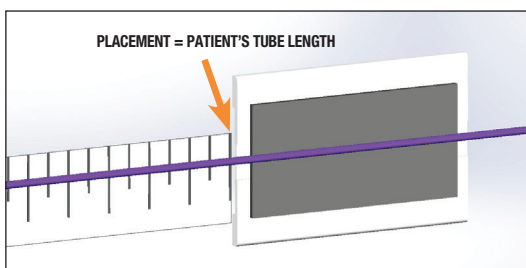
2.5.13)



Verify that the edge of the Wire Tip is lined up with the zero mark on the Measuring Tape. If not aligned, slide the Clearing Stem within the Clear Wire Tip Cover until the Wire Tip is lined up with the zero mark.

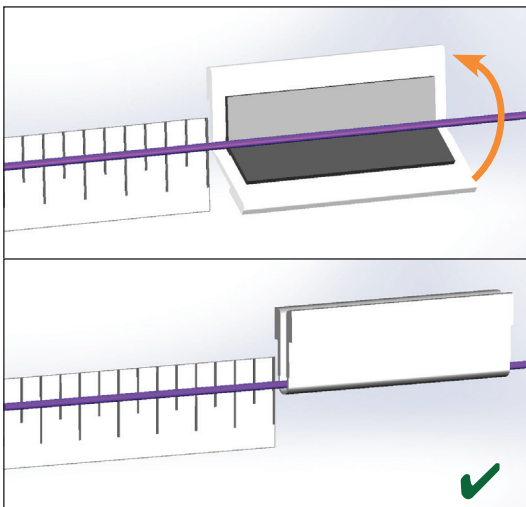
- 2.5.14a) While holding the Measuring Tape tightly against the Clearing Stem, slide your fingers to the cut edge of the Measuring Tape not allowing for any slack between the Clearing Stem and the Measuring Tape.

2.5.14b)



Place the Clearing Stem in the center of the adhesive section on the Depth Limiter, lining up the cut edge of the Measuring Tape with the edge of the Depth Limiter.

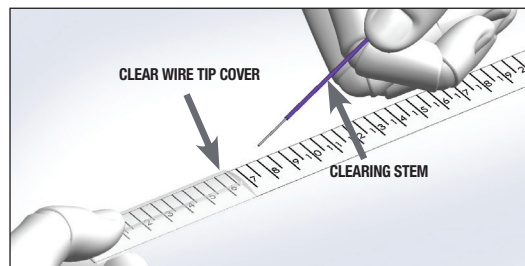
2.5.15)



Fold the Depth Limiter in half over the Clearing Stem and press firmly for approximately five (5) seconds to adhere the Depth Limiter to the Clearing Stem.

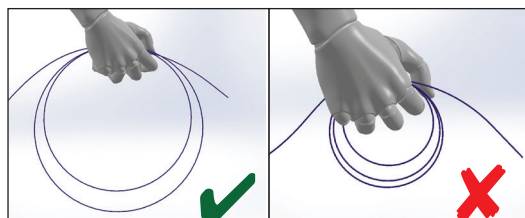
NOTE: Gently pull on the Depth Limiter to ensure it is attached / adhered to the Clearing Stem.

2.5.16)



Remove the Wire Tip end of the Clearing Stem from the Clear Wire Tip Cover attached to the Measuring Tape. Dispose of the Measuring Tape and Clear Wire Tip Cover.

2.5.17)



You may loosely coil the Clearing Stem around your hand to help control the Clearing Stem length while inserting it into the Patient's Tube. Do **NOT** tightly coil the Clearing Stem around your hand before or during use because this will slow the Wire motion inside the Clearing Stem and decrease effectiveness.

2.6 Operating Instructions

Read all the Operating Instructions before operating the TubeClear System.

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.

2.6.1) Set-up the Control Box and attach the Clearing Stem as directed in **Section 2.4 - Section 2.5**.

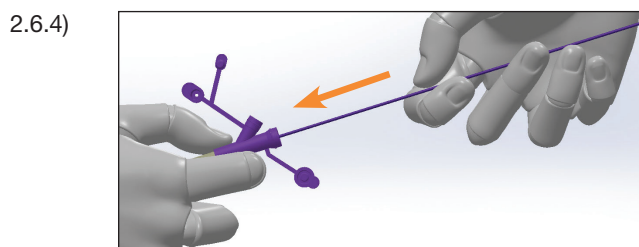
2.6.2) Do **NOT** press down the Start/Stop Button until Step 2.6.5.

2.6.3) Hold the Patient's Tube in one hand and the Clearing Stem in your other hand.

2.6.3a) Optional: 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.

⚠ *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.*

2.6.3b) **Remove the Clearing Stem often and aspirate and flush with an enteral syringe during the procedure.**



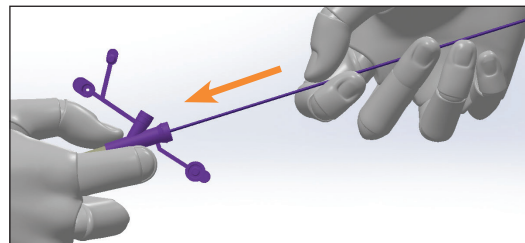
Insert the Clearing Stem into the Patient's Tube only a few centimeters at this time.



Hold both the Patient's Tube and the Clearing Stem with one hand and firmly press down the Start/Stop Button with your other hand.

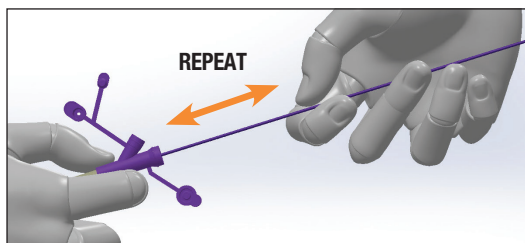
NOTE: The Control Box will automatically stop after operating for ten (10) minutes. The Control Box may be re-started by pressing down the Start/Stop Button again.

2.6.6)



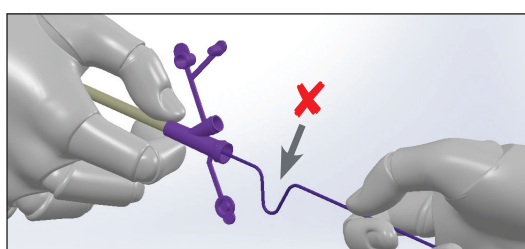
Manually advance the Clearing Stem until you encounter resistance from the clog.

2.6.7)



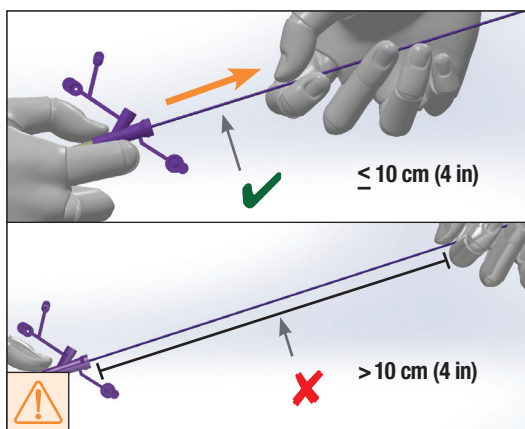
Work on the clog using varying speeds of backward and forward motions.

2.6.8)



DO NOT APPLY EXCESSIVE FORCE TO THE CLEARING STEM. ANY SIGN OF KINKING DUE TO OPERATOR FORCE WILL DECREASE EFFECTIVENESS.

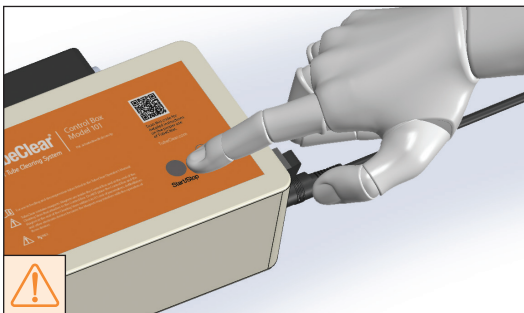
2.6.9)



Allow no more than ten (10) centimeters (four (4) inches) between hand and Tube's external port at any time.

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.

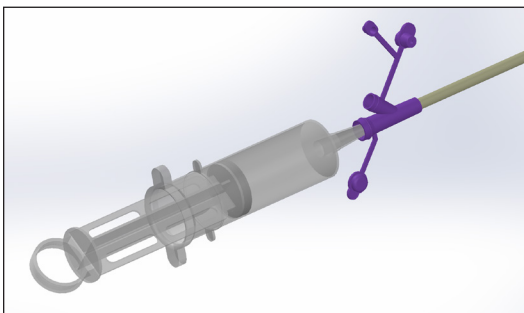
2.6.10)



Remember to use clean technique when handling the Clearing Stem.

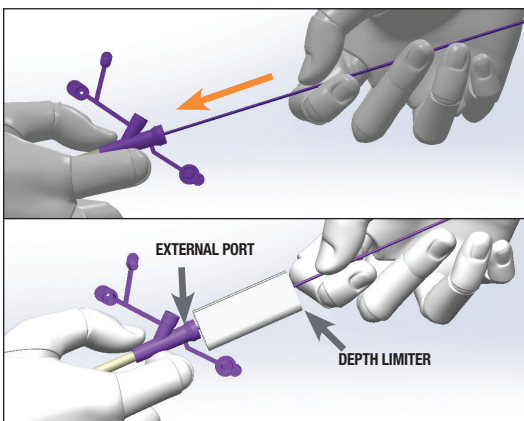
After removal, stop the Control Box by pressing the Start/Stop Button. Do **NOT** detach the Clearing Stem from the Control Box at this time as you may need to reinsert it if the Tube is not yet clear.

2.6.11)



Aspirate and flush with an enteral syringe. Insert up to 30 mL of liquid at a time into the Patient's Tube.

2.6.12)



If the clog is still present, re-insert the Clearing Stem into the Tube and repeat Steps 2.6.4 - 2.6.11 until patency is restored or the Depth Limiter reaches the Tube's external port. If patency is not restored within ten (10) minutes, refer to **Section 8.0** Troubleshooting Guide.

2.6.13)

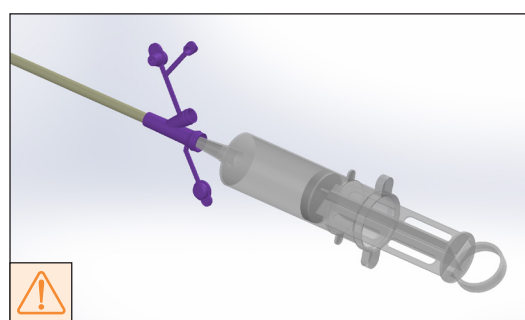


With the Magnet Adapter still attached to the Control Box, loosely coil the Clearing Stem and place it back into the Packaging during patency confirmation.

2.6.14)

Verify the Patient's Tube is properly placed using your Institution's Protocol.

2.6.15)



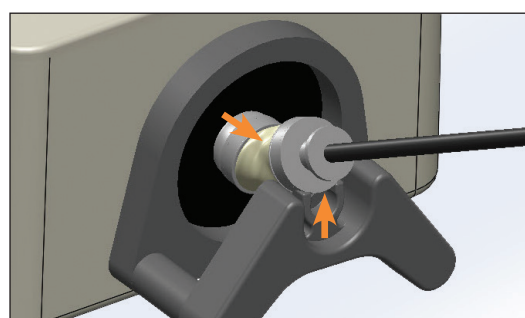
If a water-soluble surgical lubricant is used on the Clearing Stem, the Tube must be flushed with liquid at the end of the procedure.

Using your Institution's Protocol, aspirate or flush loosened clog contents out of the Tube.

2.6.16)

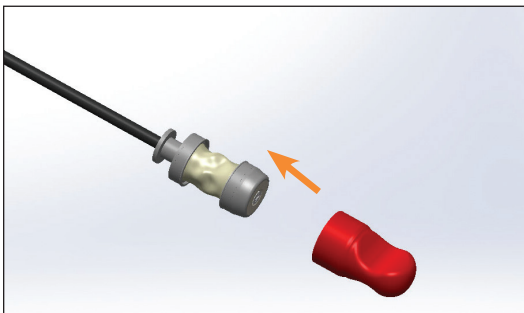
Verify that the Patient's Tube is clear using your Institution's Protocol.

2.6.17)



After confirming patency of the Patient's Tube, disconnect the Clearing Stem from the Control Box by unclipping the Stem Lock from the Bracket Adapter. Then gently pull upward on the Magnet Adapter to remove it from the Diaphragm.

2.6.18)



Immediately replace the Red Magnet Cover on the Magnet Adapter of the Clearing Stem prior to disposal.

2.6.19)



The Clearing Stem is a single use device.

Do **NOT** dispose of the Clearing Stem with ordinary waste. Dispose of the Clearing Stem as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.

2.6.20)

If any of the de-clogged contents from the Patient's Tube come into contact with the Patient or any surfaces, consider the de-clogged contents to be similar to vomitus. Clean the Patient and surfaces in accordance with your Institution's Protocol.

3.0 Control Box Cleaning Instructions

- 3.1) Turn **Off** and unplug the Control Box prior to cleaning.
- 3.2) Thoroughly clean the Control Box after each use.
- 3.3) Clean the Control Box by wiping all exterior surfaces with (a) a cloth dampened with isopropyl alcohol or with (b) disinfectant wipes.
- 3.4) Clean the Diaphragm by wiping the surface with either (a) a nonabrasive cloth dampened with isopropyl alcohol or with (b) disinfectant wipes.
- 3.5) Do **NOT** clean the Clearing Stem. The Clearing Stem is designed for **SINGLE USE**. It should **NOT** be reused under **ANY** condition. Dispose of the Clearing Stem as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.

4.0 Maintenance

Other than careful cleaning of the Control Box after each use, TubeClear does not require maintenance.

5.0 Storage

Store the Control Box and any unused Clearing Stems in a clean, dry area. It is recommended that the Control Box and Clearing Stems be stored at temperatures between -20°C (-4°F) to 60°C (140°F) and at a relative humidity from 10% to 90%.

6.0 Return Policy

Actuated Medical, Inc. (AMI) takes pride in the quality of our product. If the device is found to be defective within thirteen (13) months of purchase, contact our Customer Service Department at **+1 (814) 355-0003 ext. 117** for prompt replacement. You will be provided with a Return Authorization (RA) number and return shipping information. *All returns must be accompanied by an RA number and reason(s) for return.*

7.0 Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of medical device components. Prior to the disposal of your device, any possible risk of infection from blood borne pathogens must also be eliminated by appropriate disinfection.


8.0 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: 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.</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 Section 1.6 Steps 1.6.5 - 1.6.20 for NE & G Model Clearing Stems or Section 2.6 Steps 2.6.4 - 2.6.11 for TC Clearing Stem Models.</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/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 Section 1.6 Steps 1.6.5 - 1.6.20 for NE & G Model Clearing Stems or Section 2.6 Steps 2.6.4 - 2.6.11 for TC Clearing Stem Models. 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 Section 1.6 Steps 1.6.5 - 1.20 for NE & G Model Clearing Stems or Section 2.6 Steps 2.6.4 - 2.6.11 for TC Clearing Stem Models. 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.

9.0 Technical Data

9.1) Environmental Conditions that Affect Use


Operating conditions: From 0°C (32°F) to 35°C (95°F).
Relative humidity from 30% to 75%.

 Transport and storage conditions: From -20°C (-4°F) to 60°C (140°F). Relative humidity from 10% to 90%.

9.2) Classification - TubeClear is:

- + Classified as IEC Class I Equipment. 

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- + Classified as Type BF applied part.  (The applied part is the Clearing Stem.)
- + Isolated through means of double insulation.
- + An externally-powered device.
- + Type IPX4.
- + Non-sterile.

- + **NOT** suitable for use in the presence of flammable anesthetics.

- + Suitable for continuous operation.

9.3) Accessories

- + Power Cord – Hospital Grade (US), Unshielded, IEC 320 Connector, RoHS Compliant.
- + Power Supply (Transformer) – Input: 100 - 240 V, 50/60 Hz, Output: 24 VDC, up to 3.0 A, 3-pin IEC 320 Inlet, RoHS Compliant.



Use of Power Supplies and Power Cords other than those specified in **Section 1.3** or **Section 2.3** may result in improper functioning of TubeClear and increased emissions or decreased immunity of the TubeClear System.

9.4) Electromagnetic Emissions / Immunity

Guidance regarding electromagnetic emissions and electromagnetic immunity is presented in **Table 8**, **Table 9**, **Table 10** and **Table 11**.

TABLE 8: Guidance & Manufacturer's Declaration – Electromagnetic Emissions.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	TubeClear Control Box Model 101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	
TubeClear Control Box Model 101 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

TubeClear Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear Control Box Model 101 should assure that it is used in such an environment.

TABLE 9: Guidance & Manufacturer's Declaration – Electromagnetic Immunity.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4	± 2kV Mains ± 1kV I/Os	± 2kV Mains ± 1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	± 1kV differential ± 2kV common	± 1kV differential ± 2kV common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 Seconds	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the Operator of TubeClear Control Box Model 101 requires continued operation during power mains interruptions, it is recommended that TubeClear Control Box Model 101 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TubeClear Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear Control Box Model 101 should assure that it is used in such an environment.

TABLE 10: Guidance & Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-Supporting.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted EN/IEC 61000-4-6	3 Vms 150 kHz - 80 MHz	3 Vms	<p>Portable and mobile communications equipment should be separated from TubeClear Control Box Model 101 by no less than the distances calculated / listed below:</p> <p>$D = (3.5/V1)(\text{Sqrt } P)$</p> <p>$D = (3.5/E1)(\text{Sqrt } P)$ 80 - 800 MHz</p> <p>$D = (7/E1)(\text{Sqrt } P)$ 800 MHz - 2.5 GHz</p> <p>Where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	3 V/m	

TubeClear Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear Control Box Model 101 should assure that it is used in such an environment.

TABLE 11: Recommended Separation Distances for TubeClear Control Box Model 101.

Max Output Power (Watts)	Separation (m) 150 kHz - 80 MHz $D=(3.5/V1)(\text{Sqrt } P)$	Separation (m) 80 MHz - 800 MHz $D=(3.5/E1)(\text{Sqrt } P)$	Separation (m) 800 MHz - 2.5 GHz $D=(7/E1)(\text{Sqrt } P)$
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7383
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

TubeClear Control Box Model 101 is intended for use in the electromagnetic environment in which radiated disturbances are controlled.

The Operator of TubeClear Control Box Model 101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and TubeClear Control Box Model 101 as recommended above, according to the maximum output power of the communications equipment.

10.0 Limited Warranty

Actuated Medical, Inc. (“Manufacturer”) makes certain limited warranties set forth in this Limited Warranty regarding the following products (the “Products” and each a “Product”):

Product Description	
TubeClear Control Box Model 101	
TubeClear Clearing Stem Model NE-1036	TubeClear Clearing Stem Model G-1009
TubeClear Clearing Stem Model NE-1042	TubeClear Clearing Stem Model G-1010
TubeClear Clearing Stem Model NE-1043	TubeClear Clearing Stem Model G-1011
TubeClear Clearing Stem Model NE-1045	TubeClear Clearing Stem Model G-1012
TubeClear Clearing Stem Model NE-1048	TubeClear Clearing Stem Model G-1014
TubeClear Clearing Stem Model NE-1050	TubeClear Clearing Stem Model TC-1018
TubeClear Clearing Stem Model NE-1055	TubeClear Clearing Stem Model TC-0812
TubeClear Clearing Stem Model G-1008	TubeClear Clearing Stem Model TC-0608

Manufacturer warrants to the purchaser of the Products (“Customer”) that the Products will be free from defects in material and workmanship per AMI Product specifications for a period of 13 months from the date of purchase (the “Warranty Period”). The foregoing limited warranties are solely to and for the Customer’s benefit.

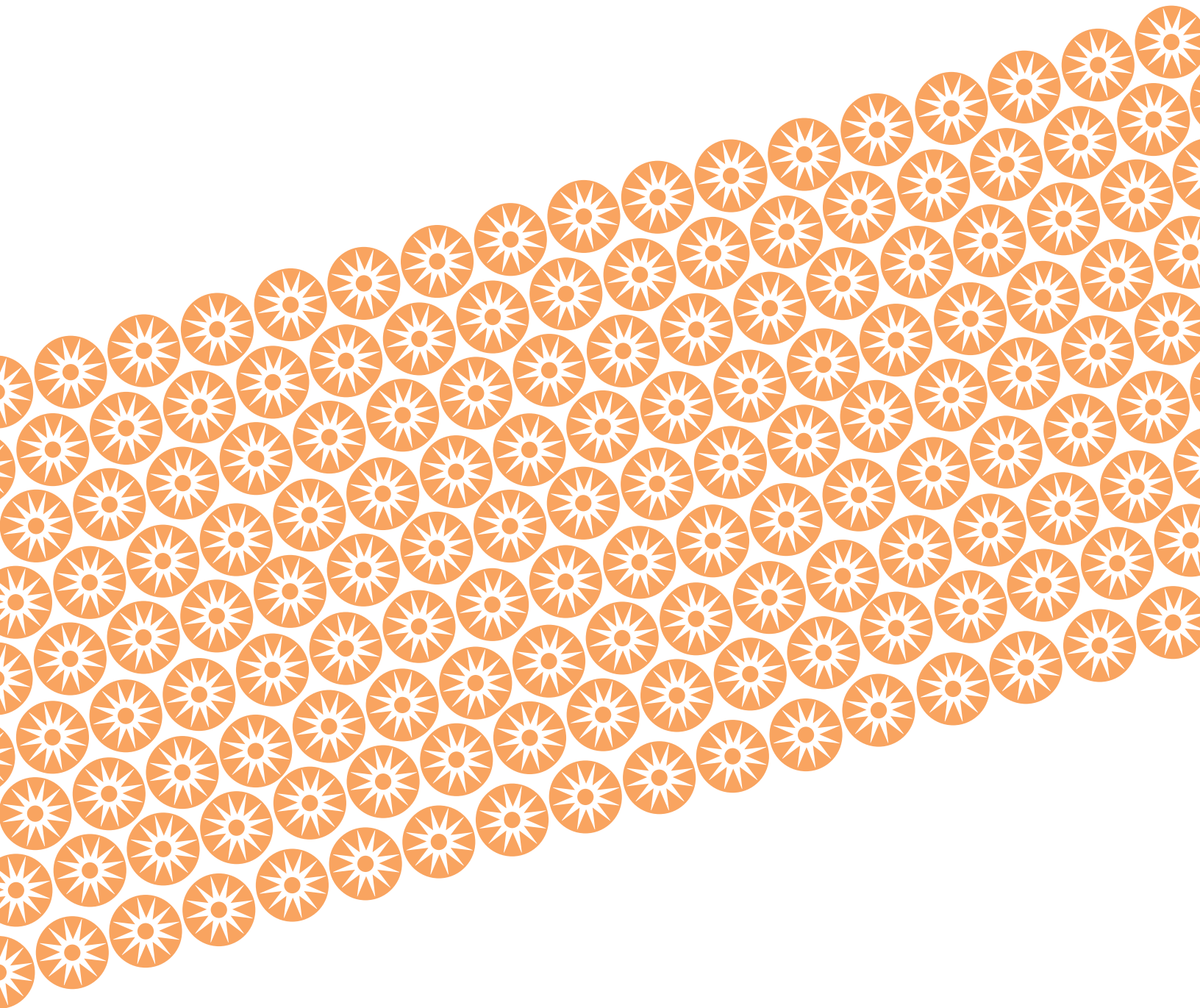
Limited Warranties do not apply where any Product (a) has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Manufacturer; or (b) has been reconstructed, repaired or altered by persons other than Manufacturer or its authorized representative.

During the Warranty Period, regarding any defective Product deemed defective by the Manufacturer, Manufacturer’s liability under any Limited Warranty is discharged, in Manufacturer’s sole discretion and at its expense, by (i) repairing or replacing the defective Product; or (ii) crediting or refunding the price of the defective Product, less any applicable discounts, rebates or credits.

All claims for breach of a Limited Warranty must be received by Manufacturer no later than fifteen (15) calendar days after the expiration of the Warranty Period.

THIS LIMITED WARRANTY SETS FORTH CUSTOMER’S SOLE REMEDY AND MANUFACTURER’S ENTIRE LIABILITY FOR ANY BREACH OF ANY WARRANTY RELATING TO THE PRODUCTS. EXCEPT FOR THE EXPRESS LIMITED WARRANTIES DESCRIBED IN THIS LIMITED WARRANTY, NEITHER MANUFACTURER NOR ANY PERSON ON MANUFACTURER’S BEHALF HAS MADE OR MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, INCLUDING ANY WARRANTIES OF: (i) MERCHANTABILITY; (ii) FITNESS FOR A PARTICULAR PURPOSE; (iii) TITLE; (iv) NON-INFRINGEMENT; OR (v) PERFORMANCE OF PRODUCTS TO STANDARDS SPECIFIC TO THE COUNTRY OF IMPORT, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED.

Notes



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