The TubeClear® System

VALUE ANALYSIS

Product Information Guide

TubeClear®

Feeding Tube Clearing System

TubeClear®

BETTER PATIENT CARE

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MADE IN U.S.A.

What's Inside:

Tubes get sluggish and clog. It's as simple as that.

The TubeClear System was developed to assist healthcare practitioners with maintaining enteral medication and nutrition therapy. During delivery, medication and nutrition materials often buildup on the inner walls of feeding and decompression tubes (Tubes). Over time, this buildup narrows the inner diameter and causes the Tube to become sluggish and/or clog which impedes critical enteral therapy delivery. Using the TubeClear System **REGULARLY** while the Tube remains in the patient and at beside helps to keep enteral therapy on schedule. And using TubeClear quickly on clogged Tubes restores patency and enteral therapy schedules which helps to keep the Tube in the patient to continue to deliver enteral therapies.

Recipient of SBA's Tibbetts Award
The commercial success of the TubeClear System led to the U.S. Small Business Administration (SBA) presenting Actuated Medical with the Tibbetts Award. The TubeClear System was developed using National Science Foundation and National Institutes of Health Small Business Innovation Research (SBIR) grants. The Tibbetts Award exemplifies the very best of the SBIR program.

Finalist for the Life Sciences Pennsylvania (formerly Pennsylvania Bio) Patient Impact Award
TubeClear System was chosen as one of three finalists for the 2013 Pennsylvania BIO Patient Impact Award. This award recognizes Life Sciences innovations (medicine, therapy, device or organization) in Pennsylvania that have made a significant contribution to the quality of health care or the life of patients.

The TubeClear® System
OVERVIEW

TubeClear System Clinical Advantages:

1 Works on Various Types of Clogs*

+ Medication and formula
+ Formula, fiber and medication
+ Coagulated protein and medication
+ Ground food

2 Requires Less Time Compared to Other Common Practices[10]

+ TubeClear System: **8.8 minutes**
+ Warm Water: **110.3 minutes**
+ Enzyme Treatment: **121.9 minutes**

3 Minimizes the Need to Replace the Tube

+ Reduces risks associated with Tube replacement – Nasoenteral feeding tube placement can result in tracheal malposition. This has been reported to occur in 2 - 3.2% of cases, and could lead to major morbidity and/or death[1,2,3,4]
+ May reduce risks and costs of radiography to confirm proper Tube placement
+ Reduces the risks of invasive interventions to replace Tubes

4 Works at Patient's Bedside

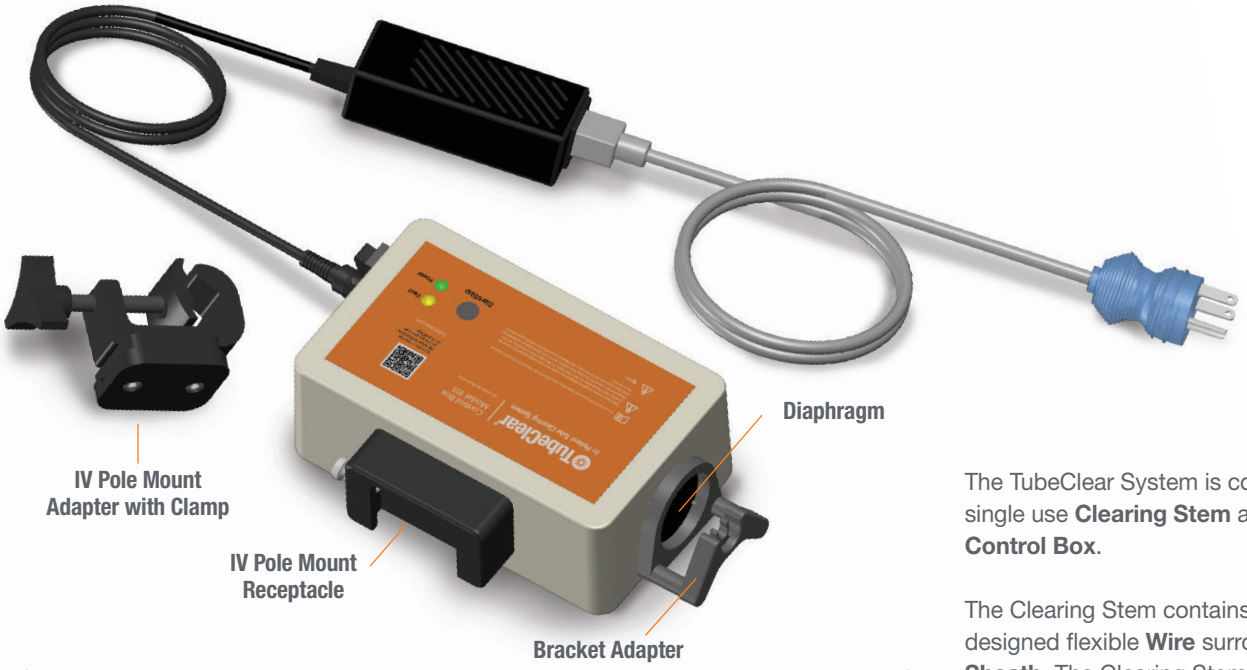
+ Can allow medication and nutrition therapy to be delivered as scheduled
+ Minimizes the need to transport patients
  - To the Interventional Radiology (IR) suite (for hospital patients)
  - To the hospital (for extended care patients)

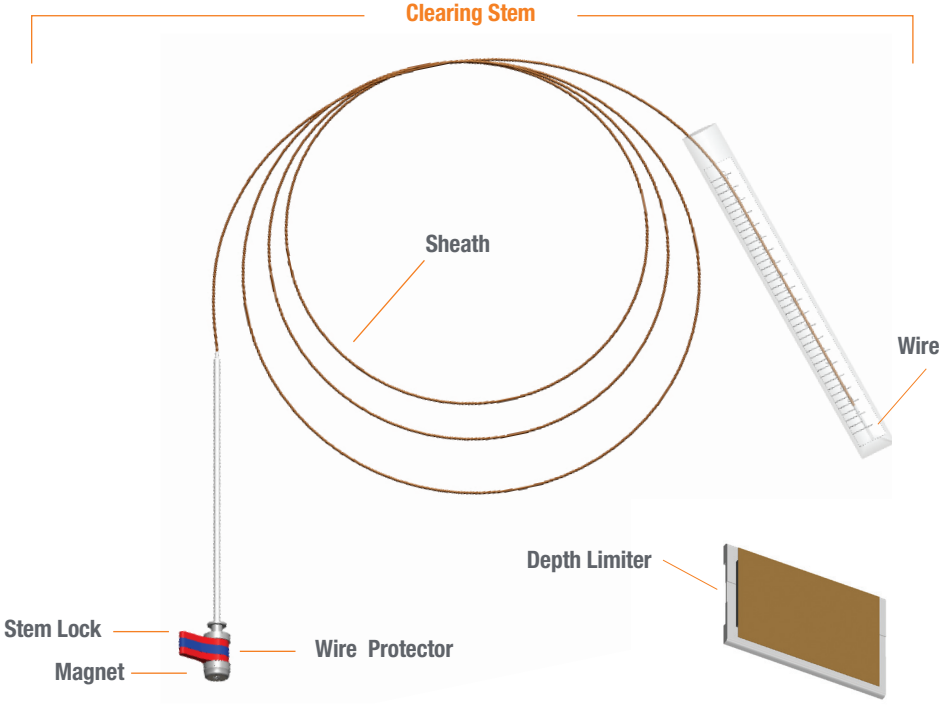
5 Improves Patient Outcomes

+ Reduces interruption of medication and nutrition therapy
+ Reduces the number of painful Tube replacements[5,6]
+ May improve patient quality scores

* As per benchtop testing

The TubeClear® System
COMPONENTS





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

The Clearing Stem contains a specifically designed flexible **Wire** surrounded by a **Sheath**. The Clearing Stem connects to the Control Box at the **Diaphragm** via the **Magnet**.

The Control Box contains a motor that moves the Clearing Stem Wire backward and forward inside the Clearing Stem Sheath.

The Wire moves approximately 0.4 - 1.0 cm (1/8 - 3/8 in). The movement of the Wire mechanically breaks up and clears the material buildup on the inside Tube walls.

The Clearing Stem has a **Depth Limiter** which limits the insertion depth of the Clearing Stem within the patient's Tube.

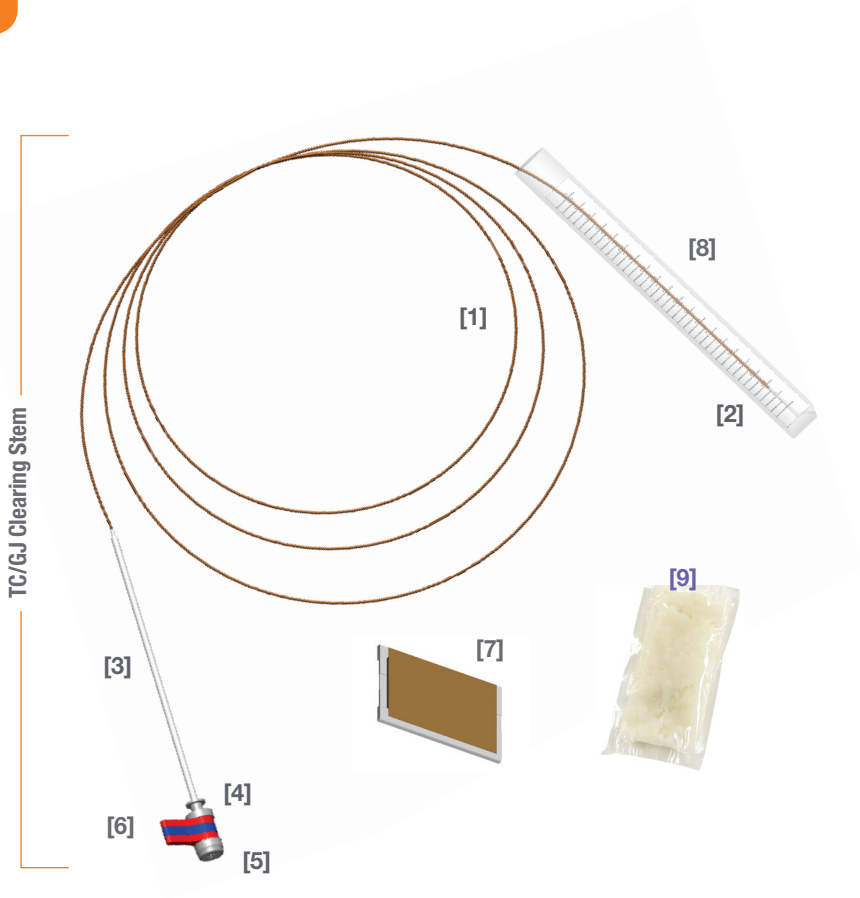
During TubeClear operation, the Tube remains in the patient.

The TubeClear System can be used at the patient's bedside.

The TubeClear System Clearing Stems are SINGLE USE. Reuse of the TubeClear Clearing Stems is prohibited and could compromise the patient.

TubeClear®

The TubeClear® System Clearing Stem
FEATURES



[1] Sheath
+ Low friction surface allows for easy advancement through the Tube.
+ Color is dependent on the Clearing Stem Model for easy identification.

[2] Wire
+ Moves backward and forward to break up the clog.
+ Clearing Stem Wire Tip is engineered with a rounded and flexible design.

[3] Stem Label
+ Describes the Clearing Stem Model.
+ Color represents intended Tube type.

[4] Stem Lock
+ Snaps into the Bracket Adapter to secure the Clearing Stem during use.

[5] Magnet
+ Allows for easy attachment to the Control Box.
+ Allows the motor to move the Clearing Stem Wire.

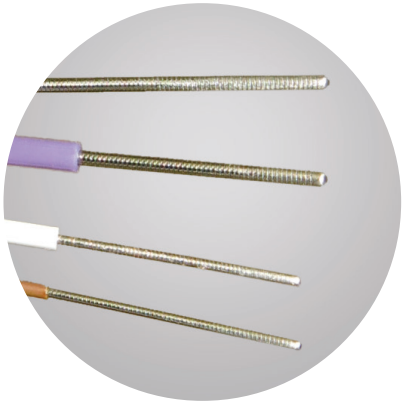
[6] Red and Blue Plastic Wire Protector
+ Packaging feature that protects the Wire during storage and attachment to the Control Box.

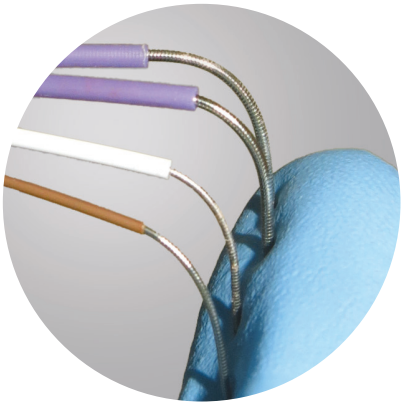
[7] Depth Limiter (Operator-Set)
+ Limits insertion depth of the Clearing Stem within the Tube.
+ Set in place by the Operator.

[8] Paper Measuring Tape
+ Used to measure placement for the Depth Limiter.

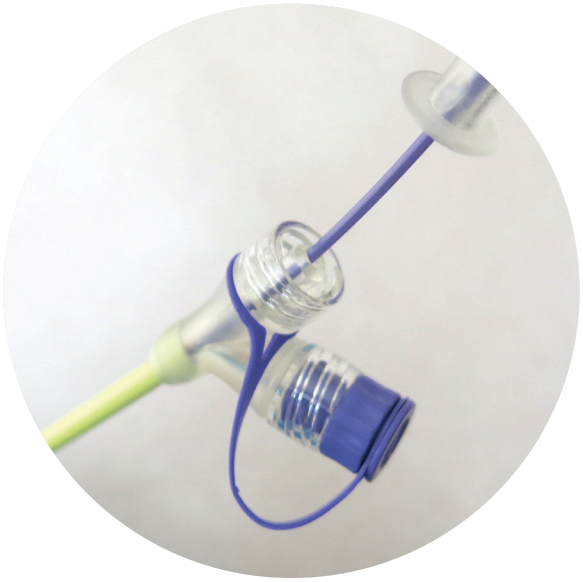
[9] Coconut Oil (GJ-1422 only)
+ Used as lubricant for the Clearing Stem Model GJ-1422. *Packaging may appear different than pictured.*

Closeups of the Clearing Stems' rounded, flexible Wire Tips.





The TubeClear® System Clearing Stem
ENFIT COMPATIBLE



The TubeClear System is compatible with the ENFit Connectors.

Source: Actuated Medical, Inc. Internal Test Report TR-4010-035

The TubeClear® System Clearing Stem
MODEL SELECTION

The TubeClear System is indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adult patients that have a Tube of size 6 to 18 Fr and length of 20 cm (8 in) to 140 cm (55 in), or have an Applied Medical Technology (AMT) G-Jet® Button, Traditional G-Jet®, Avanos MIC® or MIC-KEY® gastrojejunostomy (GJ) Tube size 14 to 22 Fr and jejunal length of 15 cm (6 in) to 45 cm (18 in).

The label on the Clearing Stem Packaging identifies the Clearing Stem Model. It also indicates the Tube type, size (Fr), and length that the Clearing Stem Model can be used. Material/manufacturer specifications are also listed on the Clearing Stem Models.

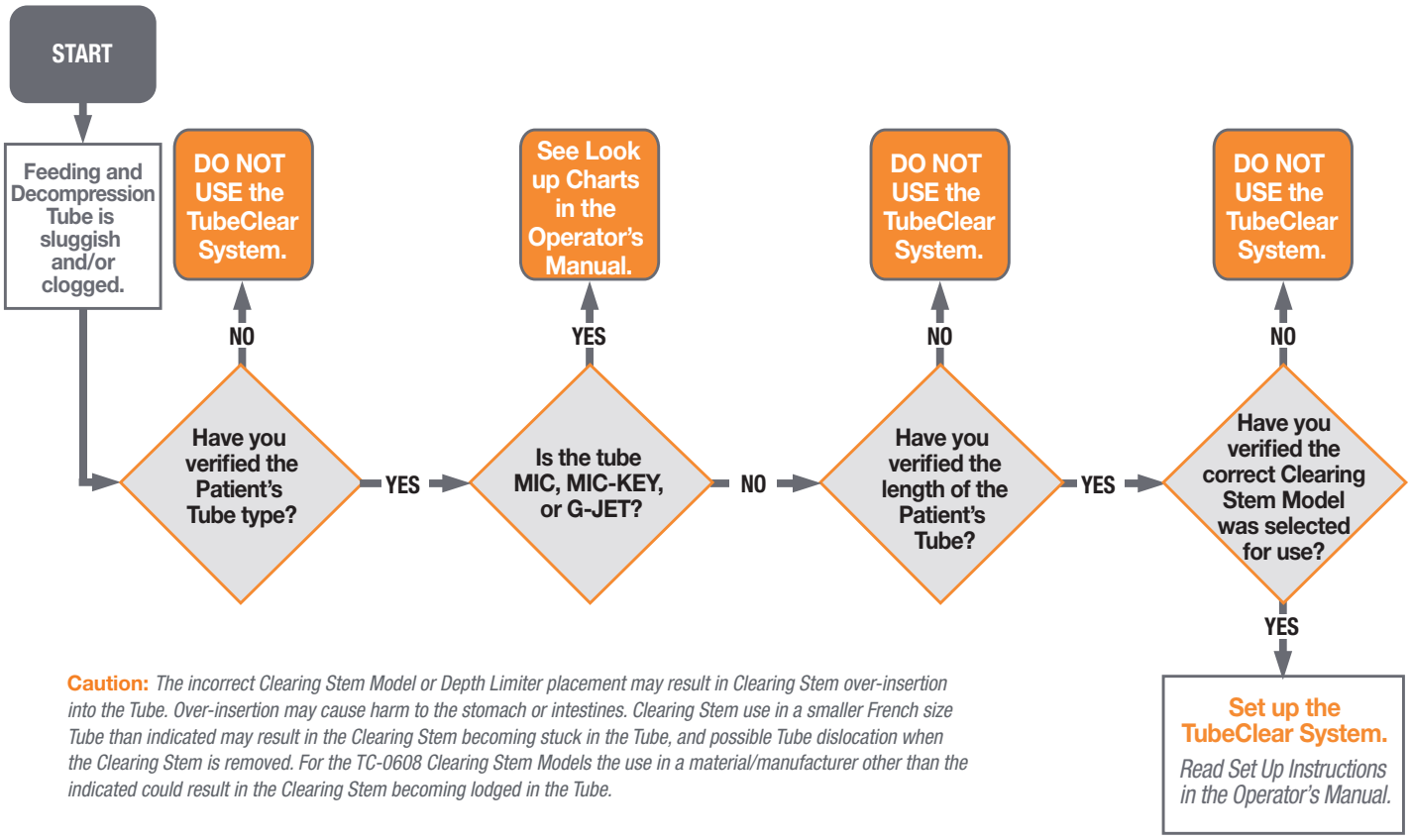
The TubeClear System Clearing Stems are SINGLE USE. Reuse of the TubeClear Clearing Stems is prohibited and could compromise the patient.

Tube Type	French Size (Fr)	Tube Material or Manufacturer	Tube Length (cm)	Tube Length (in)	Model #	Stem Color	Stem Label
NE, NG, G(PEG), or J	10 - 18	ANY	20 - 140	8 - 55	**TC-1018**	**Purple**	**Black**
NE or NG	6 - 8	PVC or Polyurethane	38 - 140	15 - 55	**TC-0608**	**Brown**	**White**
GJ	14 - 22	AMT* or Avanos**	15 - 45	6 - 18	**GJ-1422**	**Brown**	**Blue**

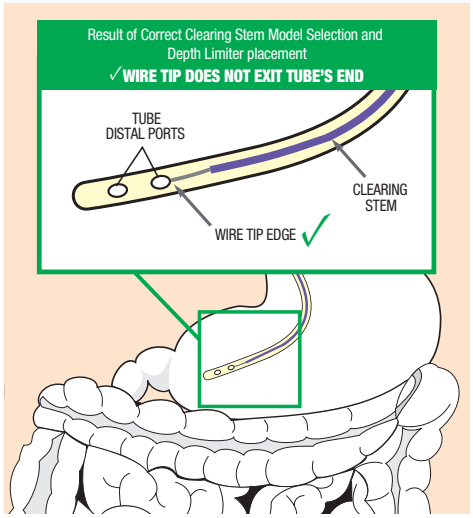
See appendix A for additional available models.

*** AMT: Applied Medical Technology, Inc. (Brecksville, OH)**
**** Avanos Medical, Inc. (Alpharetta, GA)**

Flow Diagram for Correct TubeClear Model Selection



Caution: *The incorrect Clearing Stem Model or Depth Limiter placement may result in Clearing Stem over-insertion into the Tube. Over-insertion may cause harm to the stomach or intestines. Clearing Stem use in a smaller French size Tube than indicated may result in the Clearing Stem becoming stuck in the Tube, and possible Tube dislocation when the Clearing Stem is removed. For the TC-0608 Clearing Stem Models the use in a material/manufacturer other than the indicated could result in the Clearing Stem becoming lodged in the Tube.*



Model Selection – The Clearing Stem Model TC-1018 is designed with a Depth Limiter, whose length to the distal tip of the Clearing Stem should correspond to the Tube length. The Clearing Stem Model GJ-1422 is designed with a Depth Limiter whose placement corresponds to look up charts in the Operator's Manual. Correct model selection and measurement ensures that the Clearing Stem is **NOT** longer than the patient's Tube and the Clearing Stem does **NOT** exit the Tube's distal end.

Patients may experience a tickling sensation during operation. Please review the Operator's Manual for full indications, contraindications, warnings, and cautions.

Download the Operator's Manual by visiting: https://www.TubeClear.com/Support/

The TubeClear® System

BENCHTOP TESTING

Effectiveness of Proactive Use

How well does the TubeClear System perform when used proactively on material buildup along Tube walls?

Summary

The TubeClear System was more effective compared to standard water flushing at removing material buildup along Tube walls in a proactive use test. §

Experimental Design (N = 22 individual tests)

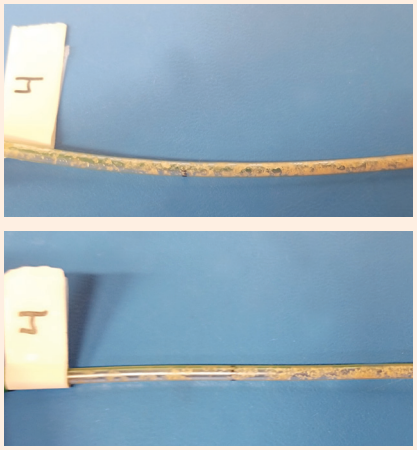
+ A weight was recorded for each feeding tube when it was empty and dry.
+ Each tube was then partially clogged and that weight was recorded.
+ Feeding formula was pumped through each tube followed by a 30-mL water flush.
+ N = 22 individual tests
  - 11 control group (only water flush).
  - 11 treatment group (water flush then insertion of a TubeClear NE-1043 Clearing Stem followed by a second water flush.
+ A final weight was recorded for each tube after test.

Results

+ On average, control group increased the Tube weight by 68.5%.
+ On average, the treatment group reduced the Tube weight by 77.1%.
+ The weight decrease of the treatment group indicated that the TubeClear System removed the material along the inside Tube walls.
+ The weight increase in control group was mostly likely caused by the remaining material along the inside Tube walls absorbing moisture.

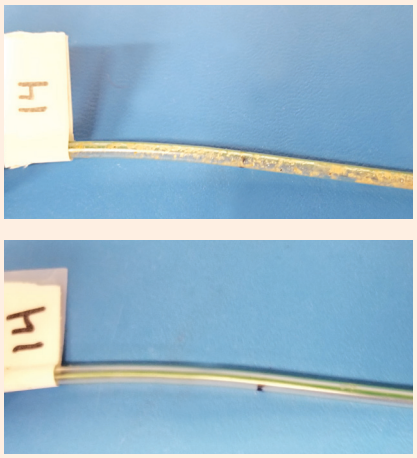
These results indicate that TubeClear is more effective at removing material buildup than the standard practice of water flushing in Tubes.

Partially Clogged Feeding Tube Treated with 30-mL Water Flush Only



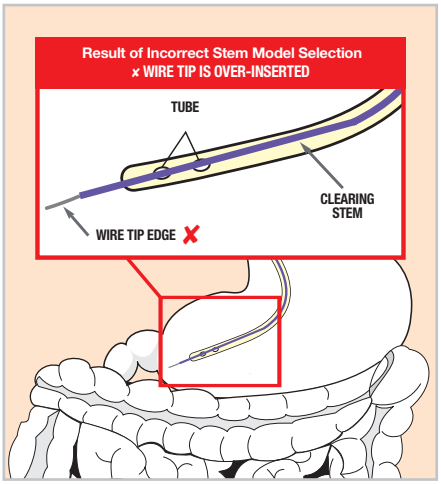
Standard Water Flush – Visual results showed material remaining in the Tube (bottom).

Partially Clogged Feeding Tube Treated with the TubeClear System



TubeClear – Visual results showed nominal, if any, material remaining in the Tube (bottom).

§ Benchtop testing does NOT guarantee the same results when used with human patients.
Source: Actuated Medical, Inc. Internal Test Report Doc. No. 1100791569-000.



Incorrect Model Selection – the Clearing Stem is longer than the patient's Tube and the Clearing Stem exits past the distal end of the Tube (i.e., over-insertion).

Over-insertion Evaluated in Porcine Gastrointestinal (GI) Tissue

In the case of *incorrect* operation,* does the TubeClear System cause a puncture in excised porcine gastrointestinal (GI) tissue?†

Summary

The Clearing Stem is designed not to exit the distal end of the Tube. However, incorrect* use may lead to over-insertion where the Clearing Stem Tip exits the distal Tube end and makes contact with GI tissue. To answer the above question, the interaction between the Clearing Stem Tip and excised porcine GI tissue was tested.

The test was conducted in two parts. Part A measured the force required to puncture porcine tissue tested in a 'non-clinical' situation.† Part B, measured the force generated at the Clearing Stem's distal tip during over-insertion using excessive User force.

During Part A testing, the Clearing Stem Tip flexed (i.e., buckled) as it made contact with the tissue, not producing any higher measurable forces after flexing. Therefore, the maximum force measured was the flexion force rather than the puncture force. During all benchtop testing, **no punctures occurred**.§

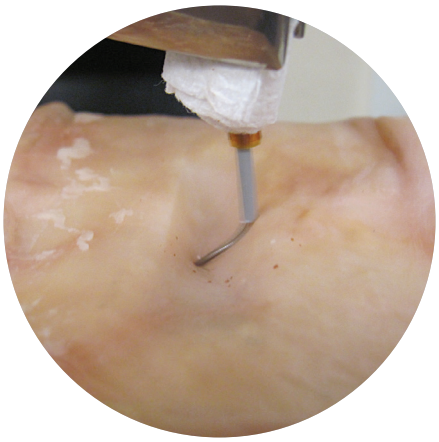


Figure A: Clearing Stem Tip Flexing Upon Contact (Part One)

PART A: What force is required for the Clearing Stem to puncture porcine GI tissue while driven by TubeClear?

Experimental Design (N = 30 individual tests)

+ In an attempt to cause puncture, a purposefully over-inserted Clearing Stem was advanced at a controlled rate in a 'non-clinical situation,‡ (i.e., gripping the Clearing Stem approximately 5 cm (2 in) from the Clearing Stem Tip to minimize flexion) into a piece of porcine GI tissue until the Clearing Stem Tip either punctured the porcine GI tissue or the Clearing Stem Tip flexed.
+ The maximum force was recorded using a Force Gauge.

Results§

+ The Clearing Stem Tip flexed upon contact with the tissue and no higher forces were recorded after flexing (**see Figure A**).
+ Maximum flexion force recorded was 3.270 N.
+ No punctures were observed in any trial.

* Incorrect Operation: Clearing Stem is longer than the Tube and is over-inserted past the end of Tube.
† Porcine jejunum tissue was used in the benchtop testing as it is considered a suitable human intestinal tissue model.[7,8]
‡ The described non-clinical situation would not occur during clinical use because the Clearing Stem was held closer to the distal tip than could be done in practice.
§ Benchtop testing does NOT guarantee the same results when used with human patients.
Source: Actuated Medical, Inc. Internal Test Report TR-4010-008

PART B: What is the maximum force that can be transmitted to the Clearing Stem Tip during simulated abnormal use (i.e., Operator pushes the Clearing Stem into the Tube using excessive force) while the Clearing Stem is moving forward and backward?

Experimental Design (N = 30 individual tests)

+ A Clearing Stem longer than the Tube (incorrect Clearing Stem Model) was selected to allow for over-insertion.
+ The Clearing Stem was advanced with excessive force through the Tube.
+ The maximum force exerted on the porcine GI tissue was recorded using a Force Gauge.

Results

+ Average applied force observed by the tissue was 1.357 N.
+ No punctures were observed in any trial.§

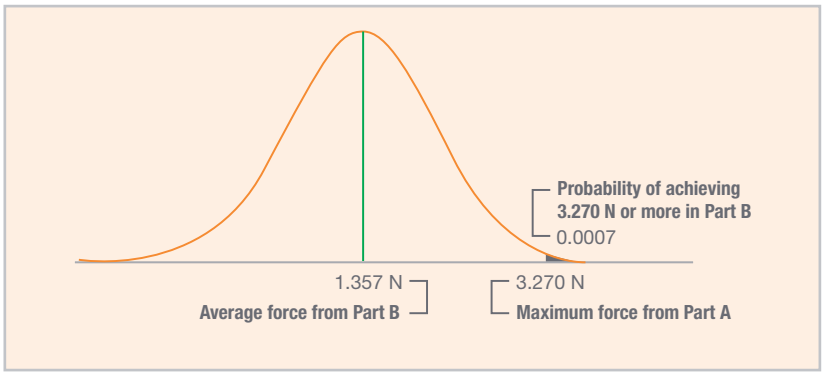


Figure B: Probability of achieving the flexion force in a simulated abnormal use situation. No puncture was observed in any trial.§

CONCLUSIONS

No punctures occurred in any of the porcine GI tissue trials.§†

A probability density function was used to demonstrate the probability of achieving the maximum force in Part A (3.270N; flexion force) compared to the forces measured in Part B (incorrect use, over-insertion situation).

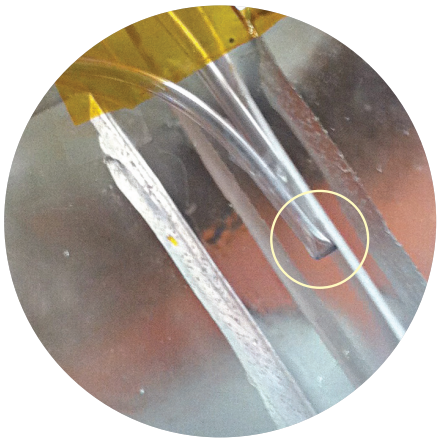
The probability of achieving a flexion force of 3.270 N or greater in an incorrect use, over-insertion situation, is 0.07% (**see Figure B**).

+ **Benchtop testing demonstrated that the TubeClear System did not cause puncture in excised porcine GI tissue during incorrect operation (over-insertion situation).§†**

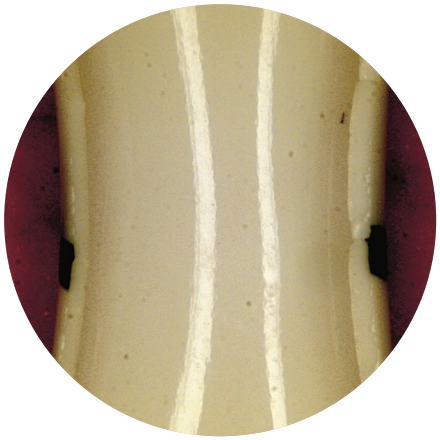
> "Great device. ICU nurses loved it."
>
> + Daria Crean, RN, BSN (research nurse at Walter Reed National Military Center)

§ Benchtop testing does NOT guarantee the same results when used with human patients.
† Porcine jejunum tissue was used in the benchtop testing as it is considered a suitable human intestinal tissue model.[7,8]

TubeClear®



Kink manually placed in the Tube.



Microscopic image of one (1) sample analyzed: Polyurethane tube (kink #3) with a feeding formula and fiber clog - No inconsistencies found.

NOTE: The white lines are the reflection of the light from the microscope.

Enteral Tube Integrity After Clearing Stem Use

Does the TubeClear System impact Tube integrity?

Summary

During correct TubeClear operation, the vibrating Clearing Stem moves along the inside of the Tube. Benchtop analysis measured inner Tube surface integrity using optical microscopy of the Tube's cross section following operation of the TubeClear System. No Tube damage was observed.

Experimental Design (N = 90 individual tests)

+ A kink was manually placed in the Tube.
+ A Clearing Stem was used to break up an *in vitro* produced clog and then driven into the kink.*
  - 30 tests conducted with Clearing Stem NE-1055
  - 30 tests conducted with Clearing Stem TC-0812
  - 30 tests conducted with Clearing Stem TC-0608
+ The Clearing Stem was operated and advanced per normal use for a total of 30 minutes within the Tube.
+ The Tube was cross sectioned at the kink.
+ The Tube's internal surface was analyzed using optical microscopy.

Results

+ NE-1055 Clearing Stems: Thirty (30) out of thirty (30) sections analyzed showed no visual inconsistencies caused by the TubeClear System:
  - **No Tube puncture, marring, scratching, or other visual damage.**
+ TC-0812 and TC-0608 Clearing Stems: Thirty (30) out of thirty (30) sections analyzed showed consistent marks or blemishes caused by the TubeClear system. Further examination via microscope show no material was removed from the Tube by the Clearing Stem:
  - **No Tube puncture or structural damage to the Tube.**
+ Benchtop testing demonstrated the use of the TubeClear System did not compromise the Tube's integrity.§

* Driving the Clearing Stem into a kink represents the use scenario that produces the most repetitive direct contact of the Clearing Stem Tip against the Tube that may affect Tube integrity.
§ Benchtop testing does NOT guarantee the same results when used with human patients.
Source: Actuated Medical, Inc. Internal Test Reports TR-4010-026, TR-4017-009, and TR-4021-019.

Enteral Tube Vibration During Clearing Stem Use

How much does the TubeClear System cause the Tube to vibrate?

Summary

During correct TubeClear operation, the vibrating Clearing Stem† moves along the inside of the Tube. Benchtop analysis measured vibration of the Tube during Clearing Stem operation. The maximum Tube vibration during Clearing Stem operation was 1.98 mm (0.08 in) with an average of less than 1 mm (0.04 in).

Experimental Design (N = 22 individual tests)

+ A clogged Tube was placed through a linear variable differential transformer (LVDT) sensor, located at the pharynx of the test model.
+ A Clearing Stem was used to clear the clogged Tube.
+ The Tube vibration caused by the Clearing Stem during operation was recorded by the LVDT sensor.
+ N = 22 individual tests.
  - 11 coagulated protein and medication clogs.
  - 11 feeding formula and fiber clogs.

Results

+ Coagulated protein and crushed medication clogs:
  - Maximum vibration recorded = 1.98 mm (0.08 in).
  - Average vibration recorded = 0.81 mm (0.03 in).
+ Feeding formula and fiber clogs:
  - Maximum vibration recorded = 1.18 mm (0.05 in).
  - Average vibration recorded = 0.59 mm (0.02 in).
+ **The small-scale vibration movement is not expected to cause patient pain.***§

> "TubeClear has been a great tool for the care of both our inpatient and outpatient enteral feed patients. Whereas we used to spend exorbitant amounts of time trying to clear clogged tubes, we now can clear them in a minute or two. Easy, intuitive and functional – the perfect combination."
>
> + Jim Mercer, RN, BSN (Veteran Affairs Salt Lake City Health Care System)

† Study conducted with NE-1043 and NE-1036 Clearing Stems. Repeat studies with TC-0812 and TC-0608 did not find any statistically significant difference.
* See the Case Study Report for clinical relevance.
§ Benchtop testing does NOT guarantee the same results when used with human patients.
Source: Actuated Medical, Inc. Internal Test Report TR-4010-009-2

TubeClear®

Enteral Tube Movement During Clearing Stem Use

Does the TubeClear System cause the Tube to stretch or move lengthwise through the GI tract?

Summary

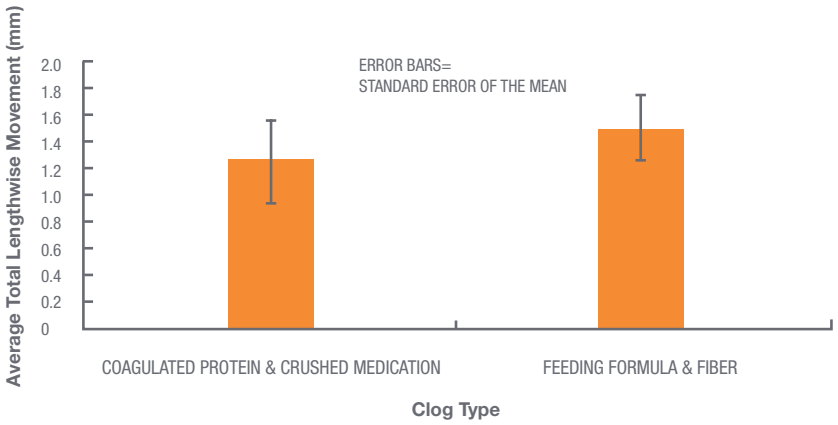
During correct TubeClear operation, the vibrating Clearing Stem† moves along the inside of the Tube. Benchtop analysis measured the maximum lengthwise movement of the Tube during Clearing Stem operation. The maximum lengthwise movement during Clearing Stem operation was 2.54 cm (1 in).

Experimental Design

+ A ruler was placed to the side of the benchtop esophagus model in order to analyze the lengthwise movement of the Tube.
+ A Clearing Stem was used to clear the clogged Tube.
+ The clearing process was recorded by a video camera.
+ Following testing, the video was analyzed for lengthwise movement of the Tube caused during operation.
+ N = 22 individual tests.
  - 11 coagulated protein and medication clogs.
  - 11 feeding formula and fiber clogs.

Results

+ During correct TubeClear operation, Tube lengthwise movement ranged from 0 - 2.54 cm (0 – 1 in) for both clog types.
+ Average lengthwise Tube movement recorded:
  - Coagulated protein and crushed medication clog = 1.27 cm (0.5 in).
  - Feeding formula and fiber clog = 1.52 cm (0.6 in).
  - The detected Tube movement and stretching may have been caused by the Clearing Stem pushing on the clog and the Tube's own elastic properties.
+ **No permanent changes to the Tube's length were measured.** §



† Study conducted with NE-1043 and NE-1036 Clearing Stems. Repeat studies with TC-0812 and TC-0608 did not find any statistically significant difference.

§ Benchtop testing does NOT guarantee the same results when used with human patients.

Source: Actuated Medical, Inc. Internal Test Report TR-4010-009-2

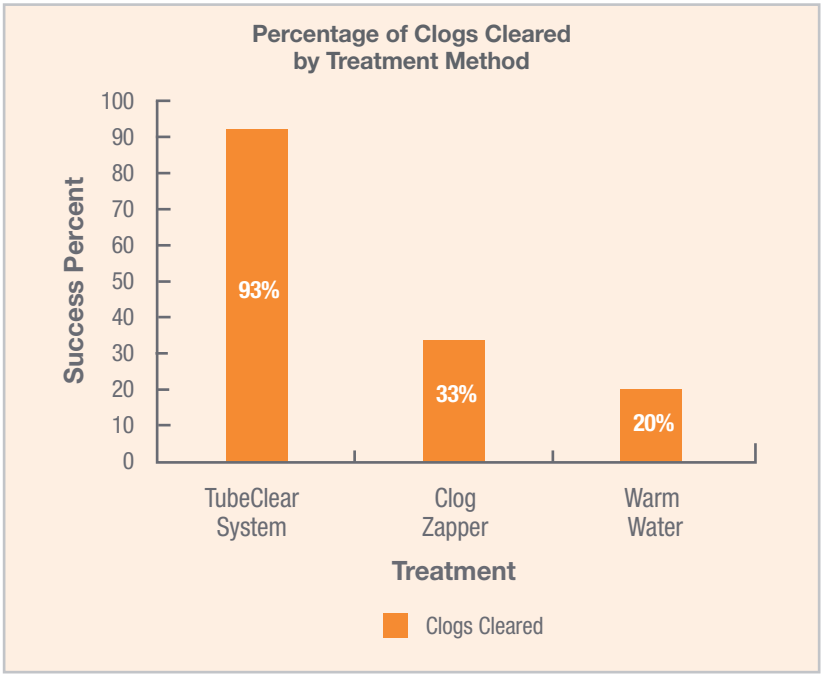
TubeClear System Comparison

How does the TubeClear System compare to current practices?

In benchtop testing published in Nutrition in Clinical Practice by a research nurse[10], the TubeClear System was found to be faster and more effective than both commercially available enzyme treatments and standard water flushes.§

Tubes: 8 Fr, 42 inch nasogastric tubes were tested.

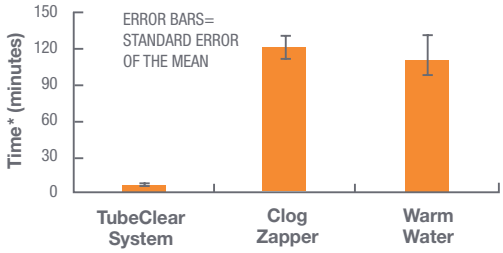
+ Clearing Stem Model TC-0812 was used with the TubeClear System.
+ Clog Zapper (Avanos Medical, Inc., Alpharetta, GA) was used for the enzyme treatment.



> "It is a good [TubeClear] system for clearing feeding tubes and most of the ones that we use have a small bore. It saves a significant amount of time having to pull the tube and have a new one re-inserted."

+ Len Sterling, RN
  Director of a Level 1 Regional Burn Unit

Clog Clearing Time* Comparison

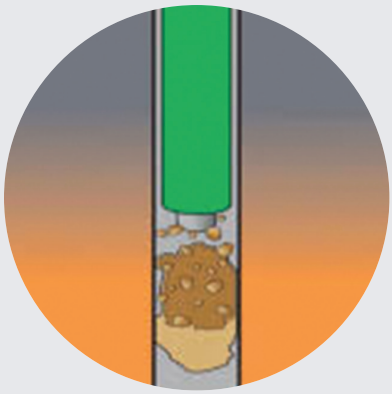


+ The TubeClear System was more than 13x faster than Clog Zapper. †
+ The TubeClear System was more than 12x faster than Warm Water. †

§ Benchtop testing does NOT guarantee the same results when used with human patients.
* Time - includes set-up, active nursing and dwell times for each treatment.
† *Source: Unpublished data by Garrison, C.M.*

The TubeClear® System

EXTERNAL ABSTRACTS



+ **Clinical Nutrition Week**
  "Effectiveness of five methods to clear four types of occlusions in 10 French feeding tubes." [11]

+ **Practical Gastroenterology**
  "Clogged Feeding Tubes: A Clinician's Thorn." [12]

+ **Nutrition Science & Practice**
  "Evaluation of a tube declogging system in clearing occluded small bore nasoenteric feeding tubes." [13]

The TubeClear® System

CLINICAL DATA

IRB Approved Clinical Studies

+ **Walter Reed National Military Medical Center**
  - Approved IRB clinical study.
  - First successful use on a soldier in the intensive care unit (ICU).

+ **Children's Hospital of Philadelphia (CHOP)**
  - Non-significant risk determination received from the FDA, September 1, 2015.
  - Approved IRB clinical study currently enrolling patients.

+ **Cleveland Clinic**
  - Approved IRB clinical study.
  - Results published in a poster at ASPEN 2019 Nutrition Science & Practice Conference in Phoenix, AZ, March 23-26, 2019.

+ **Texas Children's Hospital**
  - Approved IRB clinical study currently enrolling patients.

An Active Device for Restoring Patency in Clogged Small Bore Feeding and Decompression Tubes, Case Report Series

+ **Marcia Belcher, MSN, BBA, RN, CCRN-CSC, CCNS**
  - Columbus, OH

Introduction

Small bore feeding tubes, also known as enteral access devices, are used to provide essential nutrition and medication to patients at risk of malnutrition and dehydration due to an inability to ingest orally. An estimated 7M feeding tubes are placed each year in the U.S. alone. Clogging is one of the most frequent mechanical complications of feeding tubes. Tubes are more likely to become clogged when powdered, crushed, acidic, or alkaline medications or blenderized feeding formulas containing particulates are delivered through the small inner lumen, or when tubes are not routinely flushed following feedings. Reported clogging rates vary, ranging from 9 - 35%. Clogging of nasoenteral (NE) and nasogastric (NG) feeding tubes are considered to be underestimated and underreported, actual rates are likely much higher. Based on a 22% clogging rate, US medical facilities treat an estimated 1.5M clogged feeding tubes annually.[14]

Case	Sex	Age (yr)	Tube Size (Fr)	Time Lapsed from Tube Placement to Clog Appearance	Last Substance Passed Prior to Clogging	Total Procedure Time (minutes)	Patency Restored?
1	F	58	10F	-	medication (Protonix® [Pantoprazole])	10	Yes
2	M	66	10F	7 d	tube feed & meds (Protonix® [Pantoprazole])	20	Yes
3	F	48	10F	10 d	tube feed & meds (Protonix® [Pantoprazole])	20	Yes
4	M	85	10F	2 - 3 hrs	potassium	15	Yes
5	M	67	14F	2 d	nightly tube feeds	5	Yes
6	M	56	10F	2 hrs	tube feed / aspirin (ASA)	13	Yes
Median		62				Mean 14 Std. Dev. 6	

Supplemental Patients (n=6) ranged in age and gender. Tube Placement information was not readily available at the time of document preparation.

> "This is one of the best devices to come out in a long time to allow critical care nurses to do what they do best... care for their patients!"
>
> + Marcia Belcher, MSN, BBA, RN, CCRN-CSC, CCNS

Key Takeaways

+ TubeClear System was used safely and effectively, restoring patency to clogged small bore feeding tubes.
+ The practitioner's experience using the device has been extremely positive.
+ The device did not cause discomfort to the patients, and clogs were removed in an average of 14 minutes.
+ The ability to clear the occlusions while the tube remains in the patient, avoiding the need to replace the tube and the associated risks, costs, and patient discomfort is a significant advantage of the technology.
+ Valuable nursing time is consumed due to the limited options for clearing a clogged tube. The TubeClear System overcomes a major obstacle in critical-care medicine – clearing clogged feeding tubes more quickly than other methods.

Scan the QR code to access the full paper

Clinical Study of Mechanical Enteral Tube Declogging

+ **Robert Buckley, RN, CCM**
+ **Steve Heisa, RN**
  - NeuroRestorative, Riverton, UT

Introduction

In our clinical setting, we serve many individuals of all ages requiring enteral feeding support. The increasing occurrence of feeding tube clogs caused us to investigate alternative methods and technologies to address this problem. We discovered the TubeClear System (TubeClear), a mechanical feeding tube clearing technology manufactured by Actuated Medical, Inc. (Bellefonte, PA, USA). Our inquiry into TubeClear resulted in the opportunity to evaluate TubeClear prophylactic use (i.e., a clog prevention strategy) as well as TubeClear interventional use (i.e., when clogs occurred) in our clinical setting.[15]

Cost Savings

In cases of recurrent clogging and feeding tube types that require interventional radiology for replacement, TubeClear prophylactic use has proven to be cost effective. The residents we serve are mostly ventilator dependent. Therefore, they require ambulance transport when interventional radiology is needed for feeding tube replacement. That transportation cost alone is ~ $1,300. We often provide a respiratory therapist to accompany a resident on the transport and during the procedure for feeding tube replacement, costing ~$250. The placement procedure has an average cost of $2,670, including professional fees. Our experience, during the evaluation, resulted in prevention of at least two GJ tube replacements saving our facility over $8000 in one month.

Key Takeaways

+ Aquiring, training and applying TubeClear for feeding tube de-clogging is simple and well within the skill capabilities of Licensed Nurses.
+ TubeClear is a proven technology that is effective in clearing enteral feeding tube clogs.
+ TubeClear has proven to be a cost effective technology to apply in a long-term care environment.
+ TubeClear provides greater resident comfort and confidence in a provider's care service.

> **"Standard G-tubes can be changed at the facility when they clog. However, NG and GJ tubes will likely require patients to be transported to a hospital, as tubes are placed in position via interventional radiology service. Therefore, the facility and/or the patient may incur costs of up to $4,000 each time a tube is clogged."**
>
> + Robert Buckley, RN, CCM
> Bucklyn Rose Health

Scan the QR code to access the full paper

The TubeClear® System

HEALTH ECONOMICS

GJ tubes have been referenced at

$3,694[16]

for the average cost to replace the tube.

Case for the Hospital (Acute Care)

The below data does not apply to Gastrojejunostomy (GJ) tubes.

25%

of the Tubes placed at a facility will clog.[17,18,19,20,21]

66% of clogged Tubes will require replacement.[10]

$89[22]

Current estimated cost of declogging a Tube.

$111[13]

Current estimated cost of replacing an NE/NG Tube.

$1,098[23]

Current estimated cost of replacing a G/PEG/J Tube.

93%[10]

Estimated percentage of the time that the TubeClear system will successfully clear the clog.

59% SAVINGS PER YEAR

Estimated savings that the TubeClear system can save a 500 bed facility.

Estimated $153,455 a year.[25]

Health Economics: 500 Bed Hospital Example

Current Cost	Unit Cost	x	Yearly Qty	=	Yearly Total
Declog Tubes (cost to declog x yearly procedures)	$89		500		$44,500
Replace Tubes (cost to replace x yearly procedures)	$649*		330		$214,170
			SUBTOTAL		$258,670
Cost with The TubeClear System	**Unit Cost**	**x**	**Yearly Qty**	**=**	**Yearly Total**
Nursing Costs (cost x yearly procedures)	$10		500		$5,000
Control Box 101 (one-time cost)	$4,000		5		$20,000
Clearing Stems (unit cost x yearly procedures)	$115		500		$57,500
Replace Tubes (cost to replace x yearly procedures)	$649*		35		$22,715
			SUBTOTAL		$105,215
			ESTIMATED YEARLY SAVINGS		$153,455
			ESTIMATED PERCENTAGE SAVINGS		59%

* Data from Source 16

§ It is assumed that 2,000 Tubes will be placed at a 500 bed facility in a year, and thus at a 25% clogging rate 500 Tubes can clog in a year.[1] Replacement costs assume 50% NE/NG and 50% G/PEG/J Tubes. *Source: tubeclear.com/roi*

TubeClear®

Case for Outside of the Hospital (Extended Care)

The below data does not apply to Gastrojejunostomy (GJ) tubes.

GJ tubes have been referenced at

$3,694[16]

for the average cost to replace the tube.

25%

of the Tubes placed at a facility will clog.[17,18,19,20,21]

66% of clogged Tubes will require replacement.[10]

$89[22]

Current estimated cost of declogging a Tube.

$801

Current estimated cost of transportation for a non-acute care patient.

$111[13]

Current estimated cost of replacing an NE/NG Tube.

$1,098[23]

Current estimated cost of replacing a G/PEG/J Tube.

93%[10]

Estimated percentage of the time the TubeClear system will successfully clear the clog.

75% SAVINGS PER YEAR

Estimated savings that the TubeClear system can save a 500 person network of feeding tube patients.

Estimated $98,800 a year.*

Health Economics: 500 Patient Non-Acute Care Example

Current Cost	Unit Cost	x	Yearly Qty	=	Yearly Total
Declog Tubes (cost to declog x yearly procedures)	$89		125		$11,125
Replace Tubes (cost to replace x yearly procedures)	$1,450*		83		$120,350
			SUBTOTAL		**$131,475**
Cost with The TubeClear System	**Unit Cost**	**x**	**Yearly Qty**	**=**	**Yearly Total**
Nursing Costs (cost x yearly procedures)	$10		125		$1,250
Control Box 101 (one-time cost)	$4,000		1		$4,000
Clearing Stems (unit cost x yearly procedures)	$115		125		$14,375
Replace Tubes (cost to replace x yearly procedures)	$1,450*		9		$13,050
			SUBTOTAL		**$32,675**
			ESTIMATED YEARLY SAVINGS		**$98,800**
			ESTIMATED PERCENTAGE SAVINGS		**75%**

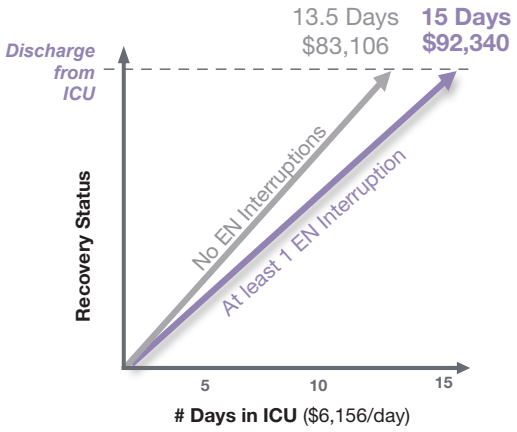
* Data from Source 16

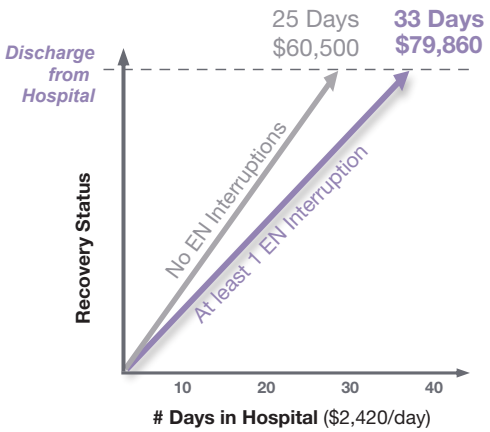
§ It is assumed that 2,000 Tubes will be placed at a 500 bed facility in a year, and thus at a 25% clogging rate 500 Tubes can clog in a year.[1] Replacement costs assume 50% NE/NG and 50% G/PEG/J Tubes. *Source: tubeclear.com/roi*

Just One Enteral Therapy Interruption Has a Major Impact

Technical issues (e.g., clogs) interrupt the delivery of a patient's enteral therapy.[25] One interruption to a patient's enteral nutrition (EN) can increase their median length of stay (LOS) by 1.5 days in the ICU, and 8 days in the hospital.[26]

Increased hospital length of stay can cost $6,156 per day in the ICU and $2,420 per day in the hospital.[27]





Learn more at:
https://www.TubeClear.com/ROI/

The TubeClear® System

REIMBURSEMENT

The TubeClear System is designed to clear occlusions / clogs from feeding and decompression tubes, while the Tube remains in the patient, and operates at bedside. Herein are the Healthcare Procedure Coding System (HCPCS) codes provided for the TubeClear System.

Please note the provided codes are NOT guaranteed. Actuated Medical, Inc. does not guarantee product coverage / reimbursement and is not responsible or liable for any unreimbursed amount. Please consult with your selected payer in advance on any questions you may have regarding product coverage or reimbursement.

The means of feeding administration (pump, gravity or syringe fed) determines which HCPCS code for feeding supply kit should be submitted to your selected payer:

Means of Administration	HCPCS Code	Fee Schedule - Daily Rate
Pump Fed	B4035	$11.95
Gravity Fed	B4036	$8.20
Syringe Fed	B4034	$6.26

The codes for enteral feeding supplies (B4034-B4036) include all supplies, other than the feeding tube itself, required for the administration of enteral nutrients to the patient for one day. Codes B4034-B4036 describes a daily supply fee. Only one unit of service may be billed for any one day.

The TubeClear® System

510(K) CLEARANCES

Clearance #	Date
K121571	June 13, 2012
K123659	December 20, 2012
K131052	August 16, 2013
K163092	November 30, 2016
K172556	June 29, 2018
K200646	December 4, 2020

The TubeClear® System

ORDERING INFORMATION

Federal law (U.S.) restricts the TubeClear System to sale by or on the order of a physician.
The TubeClear System is available for sale in the US and Canada. Additional countries available upon regulatory approval.

Control Box			
Supplier Number	**Description**	**Unit**	**Unit Qty**
101-US	Reusable TubeClear Control Box for use with all NE, G, GJ and TC Clearing Stem Models	ea	1
TC / GJ Clearing Stem Models (Operator-Set Length)			
10-TC-1018	Clearing Stem Model TC-1018 (Purple) for use with feeding and decompression tubes 10-18 Fr, 20-140 cm (8-55 in)	Box	10
10-TC-0608	Clearing Stem Model TC-0608 (Brown) for use with feeding and decompression tubes 6-8 Fr, 38-140 cm (15-55 in) made of PVC or Polyurethane	Box	10
10-GJ-1422	Clearing Stem Model TC-0608 (Brown) for use with Applied Medical Technology, Inc. (AMT) G-Jet® Button, Traditional G-Jet®, Avanos Medical, Inc. MIC® and MIC-KEY® Gastro-jejunostomy Tubes that are size 14-22 Fr and have a jejunal length of 15-45 cm (6-18 in).	Box	10

See Appendix B for ordering info on additional available models.

GPO Contracts:

+ Vizient Contract #MS7210
+ Premier Contract #PP-DI-1657

To Order, Call +1 (814) 355-0003 x117
or Email Sales@ActuatedMedical.com

The TubeClear® System

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and
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[G and J: Average of literature cited costs, (582.61+401.05+1000+1705+1803)/5 = 1098.33 ($1098)]

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and
2016 Basic Option Blue Cross and Blue Shield Service Benefit Plan, Emergency Room Co-pay $125. https://www.blueshieldca.com/sites/fep/documents/2016_FEP-PPO_OneBook_guide.pdf
and
Pennsylvania Nursing Facility Average Daily Rates for 2018-2019, $215.76 ($216). http://www.dhs.pa.gov/provider/longtermcarecasemixinformation/rates/
[$230 (transport to hospital) + $125 (ER co-pay) + $216 (bed-hold cost) + $230 (transport from hospital) = $801]

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For training videos and support documentation, please visit
https://www.TubeClear.com/Support/

The TubeClear® System

APPENDIX A

Model Selection for additional available models

Tube Type	French Size (Fr)	Tube Material or Manufacturer	Tube Length (cm)	Tube Length (in)	Model #	Stem Color	Stem Label
G or J	10 - 18	ANY	20	8	G-1008	Yellow	Black
G or J	10 - 18	ANY	23	9	G-1009	Grey	Black
G or J	10 - 18	ANY	25	10	G-1010	Purple	Black
G or J	10 - 18	ANY	28	11	G-1011	Orange	Black
G or J	10 - 18	ANY	30	12	G-1012	Clear	Black
G or J	10 - 18	ANY	36	14	G-1014	Blue	Black
NE or NG	10 - 18	ANY	91	36	NE-1036	Yellow	White
NE or NG	10 - 18	ANY	107	42	NE-1042	Grey	White
NE or NG	10 - 18	ANY	109	43	NE-1043	Purple	White
NE or NG	10 - 18	ANY	114	45	NE-1045	Orange	White
NE or NG	10 - 18	ANY	122	48	NE-1048	Clear	White
NE or NG	10 - 18	ANY	127	50	NE-1050	Blue	White
NE or NG	10 - 18	ANY	140	55	NE-1055	Green	White
NE or NG	8 - 12	PVC or Polyurethane	38 - 140	15 - 55	TC-0812	White	Orange
NE or NG	8 - 12	PVC or Polyurethane	38 - 140	15 - 55	TC-0812	White	Orange

[1] Sheath
+ Low friction surface allows for easy advancement through the Tube.
+ Color is dependent on the Clearing Stem Model for easy identification.

[2] Wire
+ Moves backward and forward to break up the clog.
+ Clearing Stem Wire Tip is engineered with a rounded and flexible design.

[3] Stem Label
+ Describes the Clearing Stem Model.
+ Color represents intended Tube type.

[4] Stem Lock
+ Snaps into the Bracket Adapter to secure the Clearing Stem during use.

[5] Magnet
+ Allows for easy attachment to the Control Box.
+ Allows the motor to move the Clearing Stem Wire.

[6] Depth Limiterer (Fixed)
+ Limits insertion depth of the Clearing Stem within the Tube.
+ Fixed position at predetermined length.

[7] Hand Grip
+ Color matches Stem Label, which represents intended Tube type.

The TubeClear® System

APPENDIX B

Ordering Information for additional available models

Control Box			
Supplier Number	**Description**	**Unit**	**Unit Qty**
101-US	Reusable TubeClear Control Box for use with all NE, G, and TC Clearing Stem Models	ea	1
Clearing Stem Models (Fixed Length)			
10-NE-1036	Clearing Stem Model NE-1036 (Yellow) for use with feeding and decompression tubes 10-18 Fr, 91 cm (36 in)	Box	10
10-NE-1042	Clearing Stem Model NE-1042 (Grey) for use with feeding and decompression tubes 10-18 Fr, 107 cm (42 in)	Box	10
10-NE-1043	Clearing Stem Model NE-1043 (Purple) for use with feeding and decompression tubes 10-18 Fr, 109 cm (43 in)	Box	10
10-NE-1045	Clearing Stem Model NE-1045 (Orange) for use with feeding and decompression tubes 10-18 Fr, 114 cm (45 in)	Box	10
10-NE-1048	Clearing Stem Model NE-1048 (Clear) for use with feeding and decompression tubes 10-18 Fr, 122 cm (48 in)	Box	10
10-NE-1050	Clearing Stem Model NE-1050 (Blue) for use with feeding and decompression tubes 10-18 Fr, 127 cm (50 in)	Box	10
10-NE-1055	Clearing Stem Model NE-1055 (Green) for use with feeding and decompression tubes 10-18 Fr, 140 cm (55 in)	Box	10
10-G-1008	Clearing Stem Model G-1008 (Yellow) for use with feeding and decompression tubes 10-18 Fr, 20 cm (8 in)	Box	10
10-G-1009	Clearing Stem Model G-1009 (Grey) for use with feeding and decompression tubes 10-18 Fr, 23 cm (9 in)	Box	10
10-G-1010	Clearing Stem Model G-1010 (Purple) for use with feeding and decompression tubes 10-18 Fr, 25 cm (10 in)	Box	10
10-G-1011	Clearing Stem Model G-1011 (Orange) for use with feeding and decompression tubes 10-18 Fr, 28 cm (11 in)	Box	10
10-G-1012	Clearing Stem Model G-1012 (Clear) for use with feeding and decompression tubes 10-18 Fr, 30 cm (12 in)	Box	10
10-G-1014	Clearing Stem Model G-1014 (Blue) for use with feeding and decompression tubes 10-18 Fr, 36 cm (14 in)	Box	10
Clearing Stem Models (Operator-Set Length)			
10-TC-0812	Clearing Stem Model TC-0812 (White) for use with feeding and decompression tubes 8-12 Fr, 38-140 cm (15-55 in) made of PVC or Polyurethane	Box	10
10-TC-0608	Clearing Stem Model TC-0608 (Brown) for use with feeding and decompression tubes 6-8 Fr, 38-140 cm (15-55 in) made of PVC or Polyurethane	Box	10
10-GJ-1422	Clearing Stem Model TC-0608 (Brown) for use with Applied Medical Technology, Inc. (AMT) G-Jet® Button, Traditional G-Jet®, Avanos Medical, Inc. MIC® and MIC-KEY® Gastro-jejunostomy Tubes that are size 14-22 Fr and have a jejunal length of 15-45 cm (6-18 in).	Box	10

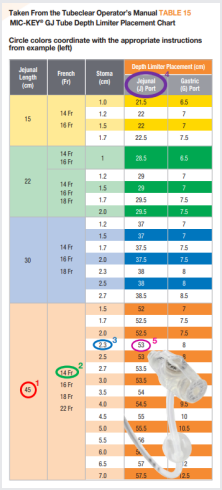
To request more information on Clearing Stem models with permanent set collars (seen in the chart above), please contact us at
+1 (814) 355-0003 x117
Sales@ActuatedMedical.com

The TubeClear® System

APPENDIX C

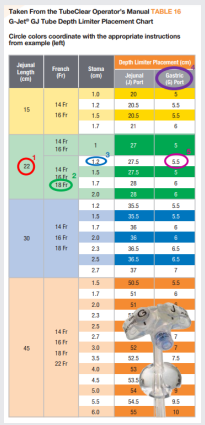
TubeClear Support

For TC models, the depth limiter is set by Tube length. For GJ models, the depth limiter is set by charts found in the Operator's Manual.


Taken From the Tubeclear Operator's Manual TABLE 15
MIC-KEY® GJ Tube Depth Limiter Placement Chart

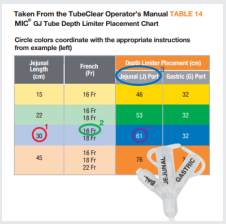
Circle colors coordinate with the appropriate instructions from example (left)

Jejunal Length (cm)	French (Fr)	Stoma (cm)	Depth Limiter Placement (cm) Jejunal (J) Port	Gastric (G) Port
15	14 Fr 16 Fr	1.0	21.5	6.5
		1.2	22	7
		1.5	22	7
		1.7	22.5	7.5
22	14 Fr 16 Fr	1	28.5	6.5
	14 Fr 16 Fr 18 Fr	1.2	29	7
		1.5	29	7
		1.7	29.5	7.5
		2.0	29.5	7.5
30	14 Fr 16 Fr 18 Fr	1.2	37	7
		1.5	37	7
		1.7	37.5	7.5
		2.0	37.5	7.5
		2.3	38	8
		2.5	38	8
		2.7	38.5	8.5
45	14 Fr 16 Fr 18 Fr 22 Fr	1.5	52	7
		1.7	52.5	7.5
		2.0	52.5	7.5
		2.3	53	8
		2.5	53	8
		2.7	53.5	8
		3.0	53.5	8
		3.5	54	9
		4.0	54.5	9.5
		4.5	55	10
		5.0	55.5	10.5
		5.5	56	11
		6.0	56.5	11.5
		6.5	57	12
		7.0	57.5	12.5


Taken From the TubeClear Operator's Manual TABLE 16
G-Jet® GJ Tube Depth Limiter Placement Chart

Circle colors coordinate with the appropriate instructions from example (left)

Jejunal Length (cm)	French (Fr)	Stoma (cm)	Depth Limiter Placement (cm) Jejunal (J) Port	Gastric (G) Port
15	14 Fr 16 Fr	1.0	20	5
		1.2	20.5	5.5
		1.5	20.5	5.5
		1.7	21	6
22	14 Fr 16 Fr	1	27	5
	14 Fr 16 Fr 18 Fr	1.2	27.5	5.5
		1.5	27.5	5
		1.7	28	6
		2.0	28	6
30	14 Fr 16 Fr 18 Fr	1.2	35.5	5.5
		1.5	35.5	5.5
		1.7	36	6
		2.0	36	6
		2.3	36.5	6.5
		2.5	36.5	6.5
		2.7	37	7
45	14 Fr 16 Fr 18 Fr 22 Fr	1.5	50.5	5.5
		1.7	51	6
		2.0	51	6
		2.3	51.5	6.5
		2.5	52	7
		2.7	52	7
		3.0	52	7
		3.5	52.5	7.5
		4.0	53	8
		4.5	53.5	8.5
		5.0	54	9
		5.5	54.5	9.5
		6.0	55	10


Taken From the TubeClear Operator's Manual TABLE 14
MIC® GJ Tube Depth Limiter Placement Chart

Circle colors coordinate with the appropriate instructions from example (left)

Jejunal Length (cm)	French (Fr)	Depth Limiter Placement (cm) Jejunal (J) Port	Gastric (G) Port
15	16 Fr	46	32
22	16 Fr 18 Fr	53	32
30	16 Fr 18 Fr	61	32
45	16 Fr 18 Fr 22 Fr	76	32

Support Documents

TubeClear Website

Training Module

Scan the QR codes to access our website, training modules, and other information.

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