



## **Informed Consent Form and HIPAA Authorization**

**Study Title:** Evaluation of the Efficacy of Use of TubeClear® to Restore Patency to Occluded Enteral Access Devices in Pediatric Patients

Version Date: November 8, 2018

Consent Name: Phase I

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You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

## Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have not attained your 18<sup>th</sup> birthday and have a clogged enteral access device (EAD), also called a feeding tube. For the purposes of this study, your enteral access device (EAD) will be referred to as a feeding tube.

## What is the purpose of this research study?

The purpose of this research study is to see if the investigational device TubeClear®, is an effective way of clearing clogged feeding tubes in children in a short amount of time. There are a variety of reasons why a feeding tube may become clogged. These include thickness of formula and/or medications, amount of flush used to clear the tube, or the rate of the formula going through the feeding tube. It is important to remove the clog in the feeding tube in order to provide nutrition, fluid and medication. Current methods of clearing the clog in the feeding tube include flushing the tube with warm water, or using an enzyme to chemically clear the clog. While these methods are effective, they often



require a long time to work. Sometimes, these methods do not work and the feeding tube has to be removed and replaced.

TubeClear® is cleared by the Food and Drug Administration to be used in adults and has been shown to drastically reduce the amount of time it takes to remove a clog in a feeding tube.

This study aims to understand if TubeClear® intervention is effective for use in children.

### **How many people will take part?**

About 15 children will take part in this study at The Children's Hospital of Philadelphia (CHOP).

### **What is involved in the study?**

Once you provide consent to participate, you will receive the TubeClear® study intervention. After you receive the TubeClear® study intervention, you will be followed for 3 days. If you are still in the hospital for the 3 days following the intervention, you will have a daily assessment by the study team to see how you are doing. If you are discharged from the hospital before day 3, you will receive a daily phone call from the study team to assess how you are doing. This phone call will take approximately 15 minutes.

### **How long will you be in this study?**

If you agree to take part, your participation will last for 4 days. The study involves this hospital visit.

### **What are the study procedures?**

The study involves the following tests and procedures.

All tests and procedures that are a part of your regular, routine medical care will continue to be performed

Interviews: A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study you will be asked to report if you think that anything bad has happened as a result of the study.

Physical Examination: Exams will be conducted before and during the study including measurements of weight, height, blood pressure, heart rate and respiratory rate, etc.

Medical Record Review: At the time of screening and again with enrollment in the study, we will review your medical records to determine if there are any health reasons why you should not be able to participate in this study. Information from your medical record will be recorded and used for this study. This information will include medical history, information about your condition, lab and x-ray results, medications, treatments, vital signs, and the response to treatments. We will be reviewing your medical record throughout the study. If you are discharged to a facility outside of CHOP,

we will ask your permission to obtain medical records from the other facility.

Pregnancy Test: If you are 10 years of age or older, or have already started having periods, you will be asked to take a pregnancy test before starting this study. The results will be shared with you and not with your parent(s). We strongly encourage you to share the results with your parents. If you are found to be pregnant, you will not be able to continue participation in the study. About half a teaspoon of blood (or urine if urine test) will be needed.

Abdominal x-ray: We will review the most recent x-ray taken at CHOP to see where the feeding tube is located. If we do not have a clear x-ray of your abdomen, we will request an x-ray be taken before the study intervention to determine the location of the feeding tube. A contrast agent will be used to see the feeding tube on x-ray. An x-ray may be needed either before and after the study intervention or with fluoroscopy during the study intervention. It is standard policy at CHOP to screen all female patients aged 10 or older, for the possibility of pregnancy before receiving any diagnostic radiation imaging. All patients will be provided protective shielding according to CHOP.

Study Intervention: Using the TubeClear® device, a member of the study team will insert the clearing stem (for one-time use only) into your feeding tube. This clearing stem is connected to a box that causes the stem to vibrate against the clog inside your feeding tube. This vibrating movement is what breaks up the clog. The vibrations make a churning noise as it works to break up the clog.

During or following the TubeClear® intervention, an x-ray of your abdomen will be obtained with standard water soluble contrast agent to check that there has been no break to the feeding tube and no injury to your abdomen.

If the TubeClear® intervention is unable to unclog your feeding tube, the clinical team will then decide how to unclog your feeding tube. This may require the tube to be removed and replaced with a new feeding tube per usual practice.

Pain Testing: We will also monitor your pain before, during and following the intervention to unclog your feeding tube. We will check pain levels according to standard CHOP policy. Use of one of these scales is standard practice, regardless of this study and will be recorded in the Electronic Health Record.

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal.

## Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration
Screening	To determine eligibility and obtain consent	Review Medical Chart Informed Consent	Approximately 30 minutes
Study Procedures	To unclog feeding tube	Pregnancy test, if needed Physical exam Abdominal X-ray before study procedure, if needed Study Intervention Abdominal X-ray with water soluble contrast agent after study procedure, or low-dose fluoroscopy during study procedure	Time it takes to unclog feeding tube, follow up for 3 days
Follow up	To see how you are doing	Physical exam if in the hospital Phone call if discharged from the hospital prior to 3 days Pain assessment	Day 1-3 after study procedures

## What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following side effects:

### Risks associated with using TubeClear® Study intervention:

No adverse events have been experienced or reported in clinical use of TubeClear® since 2012.

The main risks are noise, discomfort or pain, irritation or puncture.

- **Noise:** The TubeClear® intervention is a device that makes a noise while it works to unclog the feeding tube. This noise may be uncomfortable. The noise is not louder than what we hear in the intensive care unit every day. We do not think the noise level will cause harm or damage.
- **Discomfort or pain:** The TubeClear® device uses a clearing stem that moves back and forth to unclog the feeding tube. When the clearing stem is moving back and forth, it may cause some mild discomfort or pain. We think the discomfort or pain will go away when the moving of the clearing stem stops.



- **Irritation:** The clearing stem of the TubeClear® device may go past the end of the feeding tube. If this happens, the back and forth movement may irritate the lining of the abdomen, with mild discomfort or pain.
- **Puncture:** The TubeClear® device may go through the side of the feeding tube and into your abdomen. This might cause irritation of the lining of the abdomen, with mild discomfort or pain.

### **Other Potential Risks**

Because this TubeClear® device is experimental there may be other side effects we do not know about yet. We can give you other medicines to make any side effects less serious or to make you feel better.

#### **Reproductive Risks:**

If you are pregnant or nursing, you will not be allowed to participate in this study.

**Risks associated with Contrast Agent:** We do not think there will be any problems with use of a contrast agent. However, contrast agents may cause allergic reactions and kidney damage. Allergic reactions can include mild itching with hives and can be as serious as a life-threatening emergency with difficulty breathing. An allergic reaction is treatable. We will talk with you and review your medical charts to be sure you do not have any allergies to contrast agent. If you have an allergy to the contrast, you will not be able to participate in the study.

**Risks associated with Ionizing Radiation:** This study involves exposure to radiation from up to two abdominal x-rays, or low dose fluoroscopy. Therefore, you will receive a radiation dose. This radiation dose is not necessary for your medical care. You will get the radiation only because you are taking part in this study. At doses much higher than you will receive, radiation can increase the risk of cancer after many years. At the doses you will receive, it is very likely that you will see no ill effects.

**Risk associated with breach of confidentiality:** As with any study involving collection of data, there is the possibility of breach of confidentiality. Every precaution will be taken to secure your personal information to ensure confidentiality.

### **Are there any benefits to taking part in this study?**

You might benefit by unclogging your feeding tube more quickly with TubeClear® intervention. This in turn will allow the clinical team to resume your nutrition, fluids and medications more quickly. You may also benefit from not having to remove your clogged feeding tube and replacing it with another feeding tube along with associated transport to the Radiology Suite and possible need for sedation. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help to determine the best method to unclog feeding tubes in children. Should you choose not to participate in this study, you will receive standard treatment to unclog your feeding tube. Standard Treatment is what patients would undergo if they were not participating in this study.

### **Do you need to give your consent in order to participate?**



If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

**What happens if you decide not to take part in this study?**

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

**Can you stop your participation in the study early?**

You can stop being in the study at any time. You do not have to give a reason.

**What choices do you have other than this study?**

There are options for you other than this study including:

- Receiving the standard treatment to clear clogged feeding tubes.
- Replacement of the feeding tube without attempt to unclog.
- You may discuss additional other options available to you with your doctor.
- Not participate in this study

**What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?**

As part of this research, health information about you will be collected. This will include information from medical records, procedures, interviews and tests. Laboratory test results will appear in your medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Representatives of Actuated Medical, Inc., the company that makes TubeClear® and the study sponsor funding this research.
- Groups monitoring the safety of this study
- The Food and Drug Administration

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

### **Can you change your mind about the use of personal information?**

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Vijay Srinivasan, MD  
The Children's Hospital of Philadelphia  
8<sup>th</sup> Floor Main, PICU 8NE 8566  
34<sup>th</sup> Street and Civic Center Blvd.  
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw

your permission to use your personal health information, you will be withdrawn from the study.

### **Additional Information**

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

For the purposes of this study, access to the medical record will be restricted from the radiologist unless there is a finding on your abdominal radiograph that is necessary for your treatment outside of this study.

### **Financial Information**

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

#### **Will there be any additional costs?**

There will be no additional costs to you by taking part in this study.

Actuated Medical, Inc. is providing financial support and material for this study and the following research procedures:

- Cost of x-ray or fluoroscopy of abdomen and contrast agent before, during or after the intervention (and if needed, before the intervention);
- Cost of pregnancy testing, if necessary.

Individual insurance policies vary and we will work with you and your insurance company. If you do not have health insurance or your insurance does not cover all the costs, we will discuss payment options with you.

#### **Will you be paid for taking part in this study?**

You will not receive any payments for taking part in this study.

#### **Who is funding this research study?**

This study is supported by Actuated Medical, Inc. Actuated Medical, Inc. is a company that makes the TubeClear® medical device being studied in this research project.

Actuated Medical, Inc. is giving money to cover costs for Children's Hospital of Philadelphia to conduct the study. The results of the study will be reported to Actuated Medical, Inc. If the study shows that the TubeClear® medical device may be useful for a new purpose, this could benefit Actuated Medical, Inc. financially.

Please ask Dr. Vijay Srinivasan if you have any questions about how this study is funded.

### **What if you have questions about the study?**

If you have questions about the study, call the study doctor, Dr. Vijay Srinivasan at 267-426-7305. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes

sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### **What happens if you are injured during the study?**

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. Treatment may be billed to you or your insurer. If your injury is caused by a research procedure or the experimental device intervention, Actuated Medical, Inc. may pay for treating the injury. This does not mean that a mistake happened.

The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

If you think you have been injured from taking part in this study, call Dr. Vijay Srinivasan at (215)-688-7377. He can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

**Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research**

The research study and consent form have been explained to you by:

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Person Obtaining Consent

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Signature of Person Obtaining Consent

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Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE: A foster parent is not legally authorized to consent for a foster child's participation.**

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Name of Subject

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Date

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Name of Authorized Representative  
(if different than subject)

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Relation to subject:

Parent  Legal Guardian

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Signature of Authorized Representative

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Date

## Child Assent to Take Part in this Research Study

### For children capable of providing assent:

I have explained this study and the procedures involved to \_\_\_\_\_ in terms he/she could understand and that he/she freely assented to take part in this study.

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Person Obtaining Assent

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Signature of Person Obtaining Assent

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Date

This study has been explained to me and I agree to take part.

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Signature of Subject (optional)

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Date

### For children unable to assent:

I certify that \_\_\_\_\_ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

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Person Responsible for Obtaining Assent

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Signature of Person Responsible

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Date

**CH The Children's Hospital of Philadelphia®**  
**STUDY SUMMARY SIGNATURE PAGES**  
**For Non-English Speaking Subjects**

**Consent to Take Part in this Research Study and Authorization to Disclose Health Information**

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Name of Subject

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Name of Authorized Representative  
(if different than subject)

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Relation to subject:  
 Parent       Legal Guardian

The research study and consent form have been explained to the subject or parent/legal guardian. By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child's participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

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Person Obtaining Consent

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Signature of Person Obtaining Consent

Date:

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**Witness/Interpreter**

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

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Name of Witness/Interpreter

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Signature of Witness/Interpreter

Date:

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## **Child Assent to Take Part in this Research Study (Non-English Speaking Subjects)**

### **For children capable of providing assent:**

I have explained this study and the procedures involved to \_\_\_\_\_ in terms he/she could understand and that he/she freely assented to take part in this study.

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Person Obtaining Assent

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Signature of Person Obtaining Assent

---

Date

### **Witness/Interpreter**

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining assent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining assent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining assent (including responses to the subject's questions) and responded affirmatively.

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Name of Witness/Interpreter

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Signature of Witness/Interpreter

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Date: