Title:	**Safety and Feasibility of a Vertebral Body Tethering Technique for Pediatric Idiopathic Scoliosis**
NCT#:	NCT03194568
Short Title:	Vertebral Body Tethering Outcomes
Drug or Device Name(s):	Anterior Vertebral Tether Device From the *Creo® Stabilization System*, *Transition™ Stabilization System*, and *SILC™ Fixation System* of Globus Medical, Inc.
FDA IDE:	G170023
Regulatory Sponsor:	**Patrick J. Cahill, MD**
eIRB Number:	17-013694
Informed Consent Form Date:	17 Jan 2020

The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: **Safety and Feasibility of a Vertebral Body Tethering Technique for Pediatric Idiopathic Scoliosis**

Version Date: January 17, 2020

Principal Investigator: Patrick J. Cahill, MD Telephone: (215) 590-1527

Emergency Contact: Orthopedic On-Call Telephone: (267) 788-7548

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 idiopathic scoliosis, the size of your scoliosis curve is at least 35 degrees, and your doctor has recommended that you have surgery to address your scoliosis.

What is the purpose of this research study?

The purpose of this research study is to test the safety and feasibility of an experimental procedure, called **Vertebral Body Tethering (VBT).** The purpose of VBT is to correct your scoliosis. This is done by your doctor performing a surgery. During the surgery, your doctor will place screws in the front part (anterior) of your vertebrae (spine bones). Next, your doctor will place a flexible cord (or rope) into the screws to help correct your scoliosis.

You should be aware that you will be implanted with a device comprised of components from other FDA-cleared/approved systems combined to create a new device. This new device has not been cleared or approved by the FDA for use in the treatment of pediatric patients with scoliosis. The components that make up the new device have not yet been evaluated in its intended configuration for use in the VBT procedure. This study is proposed to collect information to assess the safety and feasibility of using this new device.

What is involved in the study?

How long will you be in this study?

If you agree to take part, your participation will last for two years and for eight study visits.

What are the study procedures?

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. The study involves the following tests and procedures.

Medical record review: The study team will review your medical charts and x-rays for information needed for our study.

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.

Research-specific physical examination: Exams will be conducted before and during the study including measurements of weight and height, as well as special tests of the flexibility of your spine.

Vertebral body tethering surgery under anesthesia: During this surgery, you will be under anesthesia. Your doctor will place the anterior screws and flexible cord. The surgery is expected to last about 5.5 hours.

Fluoroscopy: During the surgery, your doctor may take x-rays (called fluoroscopy) of your spine. These x-rays will be done to make sure that the surgery is going well, and that the screws and cord are placed correctly. These x-rays will be in addition to the x-rays you may receive before and after surgery. The x-rays you receive before and after surgery are part of your normal clinical care.

Surveys: You will be asked to complete surveys about your back and the surgery.

Photographs: Photographs of your torso will be taken. These will not include your face. They will be used to track how your trunk shape looks before and after surgery.

Long-term study: You may be asked to enroll in a separate research study. This research study will collect additional long-term follow-up information.

Visit Schedule

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

Visit	Purpose	Main Procedures	Duration
Visit 1	Screening visit	Clinical visit, consent, medical record review, research-specific exam, photographs, survey	30 minutes
Visit 2, Day 0	**Surgery**	**Vertebral body tethering surgery under anesthesia**, fluoroscopy	5.5 hours
Visit 3, Day 21	Post-op Visit	Clinical visit, medical record review	15 minutes
Visit 4, Day 45	Post-op Visit	Clinical visit, medical record review, researchspecific exam	15 minutes

Visit 5, Day 90	Post-op Visit	Clinical visit, medical record review, researchspecific exam	15 minutes
Visit 6, Day 180	Follow-up Visit	Clinical visit, medical record review, researchspecific exam, photographs, survey	20 minutes
Visit 7, Day 365	Follow-up Visit	Clinical visit, medical record review, researchspecific exam, photographs, survey	20 minutes
Visit 8, Day 730	Follow-up Visit	Clinical visit, medical record review, researchspecific exam, photographs, survey	20 minutes

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.

There are risks associated with vertebral body tethering. These risks are greater than some alternatives to this surgery, like using a brace or observing your scoliosis. This increased risk now may have a benefit in the future, which is explained below.

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

Risks associated with study surgery (vertebral body tethering):

- Neurological injury: There is risk for brain and spinal cord injury in all surgeries involving spinal device surgery. Intra-operative neuromonitoring (IONM) will be used by the surgical team to monitor for this risk.
- Pneumothorax (deflated lung): A pneumothorax is an abnormal collection of air in the chest. After surgery, you will be checked for a deflated lung by inpatient hospital staff. If a deflated lung is found, it may make your hospital stay longer, or may need medicine or operation.
- Bronchopulmonary plug (airway blockage): A bronchopulmonary plug is an abnormal mucus collection in the lung. After surgery, you will be checked for presence of airway blockage by inpatient hospital staff. If an airway block is found, it may make your hospital stay longer, or may need medicine or operation.
- Implant failure: We will carefully check you both during and after surgery for signs of implant failure. Some types of implant failure could be:
    - Screw, locking cap, and/or centering staple failure – the screw, set screw, and/or centering staple have broken or loosened from the vertebra AND require reoperation
    - Tether failure – the tether has broken or lost tension.
    - Implant re-operation - any problem with the implant that requires re-operation including re-operation for overcorrection with any of the following: a removal of all or part of the implant, loosening of the tension on the implant, or spinal fusion.

- Overcorrection: It is possible for the device to impart more than the intended correction to the spine curvature. This will be checked by consistent follow-up throughout the study, and may require operation.
- Radiation exposure (fluoroscopy and x-ray): This study involves exposure to radiation from fluoroscopy and x-rays. You will receive a radiation dose, which is needed for proper treatment. Radiation can increase the risk of cancer after many years but at a dose much higher than you will receive. Because of the low dose of radiation, it is very likely that you will see no ill effects.
- Bleeding: Bleeding is a risk for any operation. Every reasonable effort will be made by the surgical staff to reduce blood loss.
- Infection: Infection is a risk for any operation or hospital stay. All steps will be followed to prevent infection. You will be placed on the standard pre- and post-operative antibiotic regimen for spine surgery patients.
- Pain: Pain is a risk during post-operative recovery. CHOP orthopedics pain team will be consulted for pain management in the time following the surgery, to best manage postoperative pain.

Other Potential Risks

- Review of medical records: There is a risk of breach of confidentiality and privacy as a result of medical record review. Research staff are trained to maintain subject confidentiality.
- Administration of questionnaires: The questionnaires have the potential to make you feel uncomfortable. You will be allowed to skip questions which you are not comfortable answering.
- Photographs: There is a risk of breach of confidentiality and privacy as a result of taking photographs. The photographs will not have your face in them. Research staff are trained to maintain subject confidentiality.

Are there any benefits to taking part in this study?

We cannot guarantee or promise that you will receive any direct benefit by participating in this study. Some studies have shown that an anterior spine surgery (like Vertebral Body Tethering) has less risk and is less invasive than the traditional (Posterior Spinal Fusion) surgery.

You might benefit by getting a surgery that can correct scoliosis while still preserving motion of the spine. The knowledge gained from this research may help guide doctors on the best ways to treat scoliosis.

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 are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to follow the study doctor's instructions, keep all follow-up study appointments.

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. However, withdrawing from the study early may not allow your doctor to make sure your surgery was performed safely, and that there are no complications from your surgery. If you no longer participate in the study, you should do your best to keep all of your clinical appointments.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- You have a complication that forces you to discontinue the study.
- You do not follow-up according to the schedule.
- The study is stopped.
- New information suggests taking part in the study may not be in your best interests.

Subjects that are withdrawn from the study due to complications such as device failure and/or implant re-operation will be asked to allow investigators to continue reviewing their medical records. This will be conducted on a separate consent form.

What choices do you have other than this study?

There are options for you other than this study including:

- Not participating in this study.
- You may discuss other options available to you with your doctor. Typically, many patients may have the opportunity to use a brace or simply observe their scoliosis. Sometimes, different surgeries like an anterior or posterior spinal fusion may be other alternatives.
- To have anterior spinal tethering surgery using the recently FDA-approved The Tether™ - Vertebral Body Tethering System.
- To have anterior spinal tethering surgery at another hospital.
- Please be aware that if you choose a different treatment option, you might no longer qualify for this study. This could happen if your curvature progresses or if you are older than 16 years of age.

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 your medical record, surgeries, x-rays, exams, and surveys. Information related to your medical care at CHOP will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. 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.
- Groups monitoring the safety of this study, like the Safety Officer or the Office of Research Compliance The Food and Drug Administration Globus Medical, Inc.

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.

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. Patrick J. Cahill
The Children's Hospital of Philadelphia
Division of Orthopedics
34th 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

A Safety Officer, an independent expert, will be reviewing the data from this research throughout the study.

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.

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?

We will try our best to bill your insurance for all costs related to this procedure. However, your insurance may not cover all of the costs.

We can help you understand your financial responsibilities.

- If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance.
- If you do not have insurance, you will be responsible for the costs of taking part in this study.

CHOP has programs to help uninsured and underinsured families see if financial assistance is available. If you need financial assistance, you can talk with a financial coordinator.

Will you be paid for taking part in this study?

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

There may be commercial firms that work with investigators at CHOP to study the device. If there are patents or products that result from this research, the companies, CHOP and the inventors may make money from the research. You will not make money from this research.

We may share your data with third parties (other researchers/institutions or for profit companies). Your data may be used for commercial profit. You will not receive any financial benefit from the use of your data.

Who is funding this research study?

The Division of Orthopedics at The Children's Hospital of Philadelphia is funding this research.

Please ask Dr. Cahill 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. Patrick Cahill at (215) 590-1527. 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. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. Cahill at (215) 590-1527. 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 for Use of Data for Future Research

As part of the study, we will collect medical data, surgical data, x-rays, and surveys. We may wish to use this information in a future study about Vertebral Body Tethering or Idiopathic Scoliosis. The information will be given a unique code and will not include information that can identify you. This coded information may be shared with the Food & Drug Administration (FDA) for labeling purposes. We will keep a master list of study participants on a password-protected computer in the orthopedics research office. Only the study doctors and those working with them on this study will be able to see information that can identify you.

If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data.

Please indicate whether you will allow the data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) The data may be used for this study only.

_____ (initials) The data may be used for other future research studies. If the data is shared outside of CHOP, no identifiable information will be included.

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:

Person Obtaining Consent	Signature of Person Obtaining Consent
	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 or your child's health information as explained above. If you don't agree to the collection, use and sharing of your or 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.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian

Child Assent to Take Part in this Research Study

Signature of Authorized Representative	Date

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.

Person Obtaining Assent

Signature of Person Obtaining Assent Date

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

Signature of Subject (optional) Date

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STUDY SUMMARY SIGNATURE PAGES
For Non-English Speaking Subjects

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

_____
Name of Subject

_____
Name of Authorized Representative
(if different than subject)

_____
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.

_____
Person Obtaining Consent

_____
Signature of Person Obtaining Consent

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 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.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date:

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.

Person Obtaining Assent

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.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date: