RESEARCH SUBJECT CONSENT FORM

TITLE: Prospective Observational Long-Term Safety and Effectiveness Registry of Patients Who Have Received Iltamiocel as Part of Cook Myosite, Inc. Sponsored CELLEBRATE Clinical Study in Patients with Persistent or Recurrent Stress Urinary Incontinence (SUI) Following Surgical Treatment

PROTOCOL NO.: R15-06-01-US
WCG IRB Protocol # 20250596

SPONSOR: Cook MyoSite, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

How long will I be in this research?

We expect that your participation in this research will last up to 5 years after you enroll in this registry study.

Why is this research being done?

The purpose of this research is to collect observational, long-term safety and effectiveness data in subjects with stress urinary incontinence who have received at least one dose of iltamiocel as part of the CELLEBRATE clinical study.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include a baseline visit and 5 annual visits which will take place by phone. The baseline visit may take place in person or by phone. During these visits you will be asked to complete electronic questionnaires about your stress urinary incontinence (SUI) symptoms, your quality of life (QOL), and your overall satisfaction with the treatment you received as part of the CELLEBRATE Study. You will also be asked questions about medications, treatment and therapies you are taking for SUI.

Could being in this research hurt me?

There is no drug or treatment administered during this registry study so there are not any additional physical risks associated with registry participation. There is a risk of loss of confidentiality.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research. The information we get from your participation may help improve the treatment of people with the same SUI condition in the future.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What else should I know about this research?

There is a possibility that identifiers might be removed from the identifiable private information, and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Why is this research being done?

The purpose of this research is to is to collect observational, long-term safety and effectiveness data in subjects with stress urinary incontinence who have received at least one dose of iltamiocel as part of the CELLEBRATE Study.

Up to 96 subjects in up to 21 study centers including a virtual study site may take part in this research.

How long will I be in this research?

We expect that your participation in this research will last up to 5 years after you enroll in this registry study.

What happens to me if I agree to take part in this research?

You are being asked to participate in this research because you received iltamiocel as part of the CELLEBRATE Study. No treatment or product will be given to you as part of this research. You will be given information on this research during the screening period prior to your completion of the CELLEBRATE Study. If you decide to participate in this research, you will have a baseline visit after you complete participation in the CELLEBRATE Study and you will have 5 yearly phone call visits as well. During these visits you will be asked to complete electronic questionnaires about your SUI symptoms, your quality of life (QOL), and your overall satisfaction with the treatment you received as part of the CELLEBRATE Study. You will also be asked questions about medications, treatment and therapies you are taking for SUI. These visits are described below.

Screening period (30 - 90 days prior to your final CELLEBRATE Study Visit)

During the screening period you will be asked to visit a website where you can read the subject information sheet, complete a Subject Contact Card, and the read the current version of the Informed Consent Form. You will have the opportunity to ask any questions you may have. It is anticipated that it will take you approximately 30 minutes to review this information and complete the Subject Contact Card.

Baseline Visit (within approximately 1 week after your final CELLEBRATE Study Visit)

After you complete your final CELLEBRATE Study Visit, you will have the opportunity to enroll in this registry study if you qualify. It is anticipated that this visit will take between 30-60 minutes.

You will have your baseline visit at your study doctor's office or by phone call. During this visit the following assessment and procedures will be conducted:

- You will review and sign this current Informed Consent Form.
- You and your study doctor or study staff will confirm that you meet all study eligibility criteria.
- You will complete 1 electronic questionnaire. You can request a paper version of this questionnaire if you prefer.
- Some or all of your data collected during the CELLEBRATE Study will be utilized for your baseline visit. This includes, but is not limited to, your date of treatment(s) with the study drug (iltamiocel), questionnaire data, medical history, past and current medications, adverse events and concurrent treatments related to your SUI symptoms.

Annual Visits (every year for 5 years)

It is anticipated that this visit will take between 30-60 minutes. At this visit, you will be asked to complete four electronic questionnaires about your SUI symptoms, your QOL, and your overall satisfaction with the treatment you received as part of the CELLEBRATE study. Your study doctor or study staff will collect information about:

- Any medications you are taking.
- Changes in your health or any existing conditions that you have.

- Treatments you have received for your SUI symptoms since your last study visit.
- If you experienced any other health issues or problems related to your iltamiocel treatment.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for:

- Completing the Subject Contact Card on the study website.
- Scheduling and completing the baseline visit following the instructions provided to you. Scheduling and completing the 5 annual visits following the instructions provided to you.

Could being in this research hurt me?
This is an observational study and there will be no study drug or treatment administered as part of this research. Therefore, there are no risks associated with a study drug or treatment. Since data will be collected about you there is a potential for a breach in confidentiality. All efforts will be made to keep your data confidential.

Will it cost me money to take part in this research?
There are no costs associated with participation in this research.

Will being in this research benefit me?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, the information we get from your participation may help improve the treatment of people with the same condition in the future.

What other choices do I have besides taking part in this research?
This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?
Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

Your protected health information may be further shared by the groups above. As part of this study, third parties, including Regulatory Bodies, Institutional Review Boards or Ethics Committees, other companies in the Cook group such as William Cook Europe ApS, or other Cook partners acting as data processors, may receive your personal data to assist us in conducting this study or as required by law.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Authorization to use and disclose protected health information for research

- Study records that identify you will be kept confidential as required by law. The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). This part of this consent form is about your authorization which explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information. The personal data that Cook collects is limited to that which is necessary to allow:
- effective management and execution of this study,
- research and future development of the study product, including new product development, regulatory and other legally required submissions (e.g., safety reporting) related to the study product, including on-site and remote inspections and audits conducted by competent authorities,
- publications and presentations of summarized study results,
- production of marketing and education materials related to the study product,
- evaluation of the safety and performance of the study products and other products used during the study procedure, and
- transmission of safety and performance data to the regulatory authorities.

In working with the sponsor, your study doctor, will use and share protected health information about you. This is information about your health that also includes your name, address, telephone number, date of birth, gender, or other facts that could identify the health information as yours. This may include special categories of personal data (otherwise known as sensitive personal data) including information in your medical record and information created or collected during the study, past and current medical records, any medications you are taking, changes in your health or any existing conditions that you have, treatments you have received for your SUI symptoms since your last study visit, and if you experienced any other health issues or problems related to your iltamiocel treatment. The study doctor will use this information about you to complete this research.

This study will also collect information about your race and ethnicity and/or your full date of birth.

Your race and ethnicity are considered sensitive personal information under data protection law. The results of this study may be grouped by race and ethnicity. This may help to decide if race and/or ethnicity affect if the study drug works and how safe it is in different populations.

Your full date of birth needs to be collected because it is required to verify that you take part in the study only once.

If you agree to give this information, your race and ethnicity, and/or your full date of birth will be collected and entered into the same database where the other data about you will be entered, stored, and protected during this study. Cook keeps personal data based upon legal requirements and will not keep it longer than is needed to fulfil the purposes for which it was collected. To decide how long to store pseudonymized (e.g., removal of information which can be used to directly identify someone) personal data, Cook evaluates the type of data (pseudonymized sensitive personal data) as well as the amount of data for the specific purpose. Cook then considers the potential risk of harm from unauthorized use or exposure of the personal data and the amount of time needed to meet the purpose(s) identified above. Cook is required to retain your pseudonymized personal data for a minimum of 25 years after the study has ended. However, Cook may store the data longer as necessary to support research and future development of the study product(s), including new product development, continuous market approval, publications related to scientific or marketing purposes, or legal requirements. The hospital may have different retention requirements based on its applicable law.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. When your personal data is sent to Cook it will be linked to a unique patient ID number assigned to you as part of your study participation. The sponsor and its representatives (which include companies that are contracted by the sponsor to perform services for the study) may review or copy your protected health information at the study site. Regulatory authorities and the IRB may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

If your medical files are reviewed remotely, the records will include your study number but will not include your name or other directly identifiable information unless these records will be reviewed directly through the study center’s secure electronic medical records portal.

Whether your medical files are reviewed at the study center or remotely for the purposes of the study, your records will be kept secure during this process. Cook has put in place appropriate technical, physical, and administrative security measures to help prevent the unauthorized or unlawful disclosure, or access to, or accidental or unlawful loss, destruction, alteration, or damage to the personal data we collect. These measures include key-coding of the data and are intended to ensure an appropriate level of security in relation to the risks inherent to the processing and the nature of the data to be protected and are applied in a manner consistent with applicable laws and regulations. Cook evaluates these measures on a continuing basis to help minimize risks from new security threats as they become known.

This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

Since this study is observational, no payment other than the per-visit compensation is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is canceled by the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you stop taking part, please tell your study doctor immediately.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $500. Your total compensation will be based on $100 for the completion of each visit as outlined in this document. If you do not complete all of the visits, you will be paid for the visits you completed.

Statement of Consent:

Your signature documents your consent to take part in this research:

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study, and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

Study Subject's Name (Printed)

Study Subject's Signature | Date of Signature

I confirm I have explained the study to the extent compatible with the subject's capability, and the subject has either agreed to be in the study or is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Name of Person Obtaining Consent (Printed)

Signature of Person Obtaining Consent | Date of Signature

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).

Why will this information be used and/or given to others?
- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____
Study Subject's Name (Printed)

_____ _____
Study Subject's Signature Date of Signature