Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Apr 29, 2016
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Sub-Analysis of 24 Month Spinous Process Fractures via Post-60 Month CT Scan

PROTOCOL NO.: CT2016
WIRB® Protocol #20160956

SPONSOR: Paradigm Spine, LLC

INVESTIGATOR: Name
Address
City, State Zip Code
Country

STUDY-RELATED PHONE NUMBER(S): Name
Phone number

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

- You are being asked to be in a research study.
- Your decision to be in this study is voluntary.
- If you decide to be in this study and then change your mind, you can leave the study at any time.
- The care (treatment) you receive in this study is not standard medical care and should not replace your usual medical care from your doctor.
- You will be in this study for 1 visit
- If you agree to be in this research study, your medical records will become part of this research. They may be looked at or copied by the sponsor of this study or government agencies or other groups associated with the study.
- If you are injured in this study, your medical insurance may be billed for any treatment you need, or for standard medical care that you receive as a part of this study. Your insurance would then have access to the research records and would know that you were in this study. Your insurance company may not pay for treatment associated with a research study, and your participation could affect your insurance coverage.

More detailed information about this study is in this consent form. Please read it carefully.

PURPOSE OF THE STUDY
You are being asked to volunteer to participate in this research study because you were a participant in the coflex® IDE Study and received the coflex® device.

The purpose of this research study is to evaluate the safety and effectiveness of the coflex® device, by evaluating a sub-population of patients using a CT scan of the spine.

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.

PROCEDURES
If you volunteer to participate in this study you will be undergo a CT scan of your spine.

No additional tests or procedures are anticipated other than the CT scan.

At this visit you will be verbally updated about any significant information being learned about the study device that might relate to your health, welfare, or willingness to continue in the study.

If you are female, you must not be pregnant because study participation involves having a CT scan taken.

POSSIBLE RISKS AND DISCOMFORTS
Radiation Risks (CT Scans): In this study, you will be exposed to a small amount of radiation called "ionizing radiation," which is like x-rays. Studies have shown that getting a lot of radiation at one time or getting many small doses over time may cause cancer. The risk of getting cancer from the one small radiation dose in this study is very small.

The standard effective dose for a lumbar spine CT scan is 1.5 move, which is equivalent to 75 chest x-rays. All patients will have 1 CT Scan.

Tell us now if you have been in other research studies where you had ionizing radiation. Also tell us if you have been exposed to radiation in other ways, like on your job or in radiation therapy.

If you are pregnant or nursing, you cannot be in this research study because the radiation may harm your baby.

POSSIBLE BENEFITS
Although the coflex® is an approved device, the long-term survivability has yet to be determined. By participating in this study you may not receive any benefits, but you will be able to help determine how well the device holds up over time. The results of this study may lead to a better understanding of the safety and effectiveness of this device in treating subjects with similar medical conditions.

ALTERNATIVES
Your alternative is to not be in this study.

COSTS
It is not anticipated that there will be any additional costs to participate in this study. Paradigm Spine will cover the cost of the CT scan.

PAYMENT FOR PARTICIPATION
You will receive a $500 gift card upon completion of the CT scan.

WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF BEING IN THIS STUDY?
In the event you believe you have a study-related injury, or if you have questions regarding the implant, contact [Name of Principal Investigator] at [Phone number] and he will review the matter with you. If you are injured as a result of your participation in this research study, and immediate medical care to treat such injury is provided, the study sponsor will cover costs for immediate medical care to treat injury directly related to the investigational device if they are not covered by your medical or hospital insurance or governmental program. There are no other plans to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in the clinical investigation. By signing this consent form, you will not give up any legal rights.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES
Efforts will be made to protect your personal information to the extent allowed by law. You will not be identified in any reports or publications resulting from the use of this study device. Authorized representatives of the sponsor, Paradigm Spine, LLC, the U.S. Food and Drug Administration, Department of Health and Human Services (DHHS) agencies, Governmental agencies in other countries, the Centers for Medicare and Medicaid, and Western Institutional Review Board® (WIRB®) will have direct access to your medical records, including your hospital, clinic, and billing records for quality assurance and data analysis. The authorized representatives of the sponsor will have access to and may examine and/or copy medical records and hospital bills pertaining to your involvement in this study from the time of your enrollment until the end of your participation in the study at five years postoperatively.

HIPAA, the Health Insurance Portability and Accountability Act, is a federal law that protects the privacy of health information. Because of this law, you must give permission to collect and share your private health information while you are in this research study.

When this information is gathered from your past medical records and/or new medical information about you is created and used for the research study, it may or may not include information that identifies you, such as your name, social security number, medical record number, address, birth date, hospital admission and discharge date, surgery date, study device information and serial numbers to name a few.

What information may be used and given to others?
If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about the CT Scan

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by Western Institutional Review Board® (WIRB®). WIRB is a group of people who perform independent review of research as required by regulations.

Information about you that must be recorded for the purposes of this study includes:

- Name
- Initials
- Birth date
- Social Security Number
- Medical record number
- Hospital account number and hospital identification number
- Admission date
- Discharge date
- Surgery date
- Device identifiers and serial numbers
- Hospital billing information and associated insurance Explanations of Benefits
- Health plan beneficiary numbers

Additional information that will assist in maintaining contact with you in the event new study information should be shared with you includes:

- Address
- Phone numbers
- Email (if available)

If you decide to be in this research study, your permission to access and use your health information in this study will not stop automatically. Otherwise, your information will be used as long as it is needed for the study. You have the right to access your records that relate to this research study, but you may have to wait until the study is completed.

What if I decide not to give permission to use and give out my health information?
You may refuse to give permission to use your personal health information. A decision not to give your permission will not change your ability to get health care outside of the research study. However, unless you give permission to collect, use and share your health information, you cannot be in the research study.

May I withdraw or revoke (cancel) my permission?
You may change your mind at any time and ask that information about you stop being collected and shared. If you would like to cancel your permission to use your personal health information, you must put this in writing and deliver it to the study doctor of this study. You should know that information gathered before you withdraw your permission may still be used. Also, uses of the information that have already been committed for safety monitoring and other uses may still

be used after you withdraw. The research team will keep your study file as they would as part of their normal filing process, and Paradigm Spine, LLC and its representatives will keep your study file in a locked room at their clinical research office in New York, New York.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

QUESTIONS
If you have any questions, concerns, or complaints about this study or your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study device, contact:

[Name of Principal Investigator] at [Phone number

If you have questions about long-term effects, you may call the sponsoring company, Paradigm Spine, LLC. Their address is 505 Park Avenue, Floor 14, New York, NY 10022 and their phone number is 212-583-9700.

If you have questions about your rights as a research subject or if you have concerns, complaints or questions about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form your records.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
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 entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent because:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some of the end of study procedures.

SOURCE OF FUNDING FOR THE STUDY
The study doctor ([Name of Principal Investigator]) is being paid by Paradigm Spine, LLC to conduct this research.

FINANCIAL DISCLOSURE
The sponsor has offered to the investigators/sites additional money if the site meets specific enrollment goals. Please feel free to ask any further questions you might have about this matter.

CONSENT
I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

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.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name

CONSENT SIGNATURE

_____	_____
Signature of Subject	Date
_____	_____
Signature of Person Conducting Informed Consent Discussion	Date