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**Title of Study:** Post-market surveillance study of FLXfit™ 15 TLIF Interbody Fusion Device

**Sponsor:** CoreLink Surgical, Inc. St. Louis, Missouri

# Subject Information Sheet and Consent Form

## Introduction

You are being invited to take part in a clinical research study with CoreLink Surgical, Inc. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

## Why are you being invited to participate in this study?

You are being asked to take part in this study because your spine surgeon (the study investigator) has determined that you are a surgical candidate for the posterior transforaminal lumbar interbody fusion (TLIF) procedure (used to correct a diseased disc, which is impacting adjacent nerves and making the spine unstable) with decompression (relieving a compressed nerve) and posterior stabilization (helping hold bone in place while the spine stabilizes) to treat degenerative disc disease (DDD- damage to one or more of your discs) at one or two levels from L2-S1 (in your lower spine).

## What is the purpose of this study?

The purpose of this study is post-market, patient outcome research to evaluate medical device safety and effectiveness. The data collected will assess the safety of the FLXfit 15™ (study device) system, as measured by the rate of serious operative and post-operative complications. It will also assess the effectiveness as measured by radiographs (X-rays), CT scans, MRI scans, patient-reported, health-related quality of life questionnaires up to (24) months following the procedure, as compared to before surgery.

## How many study subjects are expected to take part in the study?

If you decide to volunteer for this study, you may be one of 50 subjects to participate at Rush University Medical Center.

## What will you be asked to do?

After signing the consent, you will undergo a physical examination. At least two x-rays of your lumbar spine will be taken. Information will be collected about your medical history, height, weight, age, gender, smoking status, current diagnosis, previous spinal surgery, any allergies you may have and any medications that affect pain or bone metabolism (breakdown) that you are taking. You will also be asked about the pain and/or disability you are experiencing. This information is routinely collected for all patients undergoing this surgery and will also be collected as part of the study.

Your surgery and follow-up visits are considered usual care for this operation. In order to implant the FLXfit 15™ device properly, your study doctor will first prepare the space between the low back bones (vertebrae) and then remove your damaged disc. The FLXfit 15™ device will then be placed into the space between the low back bones, using specific medical instruments, where the damaged disc was removed.

During the surgery, x-ray technology (fluoroscopy) is used to ensure proper placement of the FLXfit 15™ device. After the FLXfit 15™ device is placed in the space between the low bones (vertebrae) the opening (incision) is closed (sutured).

There is a slight chance that during the surgery the study doctor may find out that he cannot complete the procedure using the FLXfit 15™ device. In that case, he may have to do an alternative surgical operation to repair your lower back. Your study doctor may decide to go with alternative surgical fusion (vertebrae next to each other are joined with metal devices and/or a bone graft made from human bone or a ceramic material). Your study doctor will decide the best possible surgery for your individual health needs.

You can expect to remain in the hospital for 1 to 4 days following the surgery. Before your hospital discharge, the study doctor will talk to you about any medications you may need to take, and you will be provided with recommended post-operative care instructions.

Prior to surgery and at each follow-up visit after surgery you will be asked to fill out questionnaires at 6 weeks, 3 months, 6 months, 1 year and 2 years. These questionnaires are the Pain Visual Analog Scale (VAS), Oswestry Disability Index (ODI), PROMIS (Patient Reported Outcomes Measurement Information System) and the Short Form-12 (SF-12) Health survey. These questionnaires will assess your pain levels, disability, well-being, and perceptions about your health before and after surgery. The usual follow-up care following TLIF surgery includes a clinic visit, x-rays, and several questionnaires (taking about 10-15 minutes).

To evaluate the effect of the implant on your symptoms, you will have evaluations shortly after surgery, and you will be asked to return to the study doctor's office at the following time points:

- 6 weeks
- 3 months (12 weeks)
- 6 months
- 12 months
- 24 months

## How long will you be in the study?

You can expect to be in this study for the length of your usual follow-up for TLIF surgery, approximately 2-years. You may be removed from this study without your consent. Possible

reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to have the procedure with the FLXFit 15 device and have a more suitable device implanted instead, or the study is canceled.

## What are the possible risks of the study?

Similar to other expandable devices, FLXFit 15 may have side effects, including device failure, damage, slipping, dislocation, degradation, or leakage of metal ions. The device brochure includes the possible adverse effects including implant migration, device breakage, foreign body reaction to the implant, pressure on surrounding tissue/organs, loss of proper spinal curvature, infection, bone fracture/stress shielding, non-union of the spinal bones, loss of neurological function, hemorrhage, inflammation, deep venous thrombosis (DVT), inability to resume daily activities, movement of device, urinary retention, scar formation, fracture of spinal bone, herniated/degenerated disk, loss of or increase in spinal function, reproductive system compromise, respiratory problems, change in mental status, stopping of any potential growth in the spine, and death. However, according to the FDA, the complications associated with this specific device are comparable to other devices.

Your surgery is considered the usual care treatment for degeneration of the lumbar spine. The risks of the surgery (listed below) are the same whether you take part in this study or not. There are no added risks of surgery if you decide to participate in this study. A surgical consent form administered by your surgeon explains the risks of the transforaminal lumbar interbody fusion surgery.

The risks of surgery and anesthesia (medication used to keep you asleep during surgery) for study subjects are the same as the risks of surgery and anesthesia for non-study patients. The most common risks for this type of surgery include bleeding, dural tear (in the membrane around the brain and spinal cord), neurologic (brain or spinal cord) injury and infection. Anesthesia is safe for most patients; however, there are some risks, for example reaction or allergy to anesthetic medications. To minimize the risks of anesthesia, general anesthetics are only given by, or under the immediate supervision of a medical doctor trained to use them.

**Risks related to radiographic images, MRIs, and CT scans taken:**

If you participate in this study, fluoroscopy (an X-ray movie) will be used to help surgeons install the FLXFit 15 Interbody Device between your low back bones (vertebrae). As per standard of care, X-ray pictures of your low back will be taken in 6 sessions over 2 years. CT Scans will be used after your surgery to look for fusion of the vertebrae. X-rays, fluoroscopy and CT scans use radiation. Medical radiation can increase the natural risk that all persons have of developing cancer over their lifetimes. Even though the number of X-rays you would receive in the study is large, the overall radiation dose is small and your risk is so slightly increased from your natural risk with no medical radiation that the difference is hard to measure.

Specifically, an MRI will be taken preoperatively. Furthermore, X-rays will be taken before surgery, during surgery, immediately after surgery, at your 6-week follow-up visits, and your 3-month follow-up visit, as would usually occur for any low back surgery for your condition. X-rays will also be taken at the 6-month, 12-month, and 24-month follow-up visit. All of these are considered standard of care.

## Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** This study may possibly improve surgical care for patients in the future undergoing spine surgery.

## What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- Undergo the procedure without participating in the study. You and Dr. Singh will then decide based upon his experience and your best interest, which treatment will benefit you the most.
- Withdraw from the study at any time. You may contact Dr. Singh or any of his medical staff to withdraw.

## What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Medical records and material from this treatment are stored and kept confidential according to legal requirements.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.
In order to conduct the study, the study doctor, Dr. Kern Singh**,** will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.

## What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as surgery and follow-up visits will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study. Depending on the patient's circumstances, CoreLink Surgical, Inc. will pay for any x-rays, tests, or procedures, required for the study, which are not considered standard care for your treatment.

## What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by CoreLink Surgical, Inc. to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs. CoreLink Surgical, Inc. is not giving money to the study doctor to perform the surgical procedure on you, or for using the FLXfit 15™ Lumbar Interbody Fusion Device (Cage) System and Surgical Instruments.

## Will you be compensated or paid?

Your participation in this research study will not be associated with any compensation or payment.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

## What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

CoreLink Surgical, Inc. may pay for the reasonable costs of immediate care for any physical injury to you that results specifically from the FLXFit 15™ Lumbar Interbody Fusion Device provided your injury did not result from failure by the study doctor and/or study staff to follow study protocol or instructions, or from the negligence of the study staff.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

## What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

## Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Kern Singh, MD at (312) 432-2435. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions,

which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

**SIGNATURE BY THE SUBJECT:**

| Name of Subject | Signature of Subject | Date of Signature |
|---|---|---|

**SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:**
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent Date of Signature

*Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

**SIGNATURE BY WITNESS/TRANSLATOR**
**(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):**

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Witness/Translator Date of Signature
Check here if a separate witness signature is not necessary.

**SIGNATURE OF THE PRINCIPAL INVESTIGATOR**
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator Date of Signature Check here if Principal Investigator obtained consent and a separate signature is not required.

## INFORMED CONSENT DOCUMENTATION CHECKLIST

Subject name:_____
Subject Study number:_____ Date of original consent:_ _ - _ _ - _ _

By signing this documentation, the investigator attests that the following items were reviewed and/or completed during the Informed Consent Process:

| | |
|---|---|
| | An explanation that the study involved research and the purposes of the research |
| | The expected duration of the subject's participation |
| | A description of the procedures to be followed |
| | A description of any reasonably foreseeable risks |
| | A description of any benefits to the subject or to others which may reasonably be expected from the research |
| | A disclosure of appropriate alternative procedures or courses of treatment |
| | A statement describing the extent to which confidentiality of records will be maintained in accordance with HIPPA |
| | An explanation as to whether any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained |
| | An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject |
| | A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled |
| | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable |
| | Unanticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |
| | Any additional costs to the subject that may result from participation in the research |
| | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
| | A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, will be provided to the subject |
| | The approximate number of subjects involved in the study |
| | Confirmation of understanding and the opportunity to ask questions |
| | Opportunity to discuss with family and a primary care physician |

_____ (name of investigator) attests that this patient on _ _ - _ _- _ _ (date of original consent), reviewed the topics listed above and believed the patient to be of sound mind.
Signature: _____ Signature date: _ _- _ _- _ _