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™ (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. There are no additional costs to you if you decide...
to participate in this study.

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.
Rush University Medical Center

AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION IN RESEARCH

Name of the Research Study: Post-market surveillance study of FLXfit™ 15 TLIF Interbody Fusion Device

Name of Principal Investigator: Dr. Kern Singh

Study Sponsor: CoreLink Surgical

The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research. The word “we” refers to Rush University Medical Center, its employees and affiliates, including the study doctor and his/her research staff. You will be asked to sign this form along with the attached research consent form.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. Some of this information may come from results of tests, procedures, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information is described in the attached consent form.

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We may keep the information forever, in case we need to look at it again for this research study.

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

This study is considered a “blinded study”, which means that the researcher is asking you to accept one of several drugs or treatments, without knowing exactly which one you are being given. Therefore, the researcher may not be able to let you know which drug or treatment you are being given at any point in the study except in case of emergency. We cannot do the research if you do not agree to let the researcher hold back this information until the time listed below. You have the right to request to see your records after the study is completed.

- What blinded drugs or treatments are offered? FLXfit 15™ Lumbar Interbody Fusion Devise (Cage) system and surgical instruments

- When (in weeks from the start of the study, or as a date) will you be told about the specific drug or treatment that you were given? When the study is completed (2 years)

If you sign this form, you are giving us permission to collect, use, and share your health information.

You do not have to sign this form. If you decide to NOT sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information.
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher listed above. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. If we cannot collect and share your health information, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

If you sign this form, we may continue to share the health information collected for this study with the people listed in the Confidentiality section, without any time limit, unless you withdraw your authorization. This authorization does not expire.

CONFIDENTIALITY

We may share your information with people who help with the research. Some of these people may be other researchers outside of the hospital or are in charge of the research, pay for or work with us on the research. Some of these people make sure we do the research properly. Some of these people may share your information with someone else. If they do, the same laws that Rush must obey may not protect your health information. For this study, we will share information with: Dr. Singh’s research team, who are authorized personnel on this study, and CoreLink Surgical, which is the sponsor and device maker of this study.

If your information is transferred outside of the United States, different privacy laws may apply. Additionally, if one of the companies or institutions listed above merges with, or is purchased by, another company or institution, this authorization to use and disclose protected health information in the research will extend to the successor company or institution.

If you have any questions, please ask the researcher or his/her staff. Their phone numbers appear in the attached consent form. You can also call 1-800-876-0772 at Rush with general questions about your rights and the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The health information about __________________________ can be collected and used by the researchers and staff for the research study described in this form and the attached consent form.

Signature: __________________________ Date: __________________________

Print name: __________________________ Legal authority: __________________________