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Title of Study: **(FLXfit™) A Multi-Center, Prospective, Non-Randomized, Patient Study to Assess the Safety and Efficacy of the FLXfit™ Lumbar Interbody Fusion Device (Cage) System and Surgical Instruments.**

Sponsor: **Expanding Orthopedics, Inc.**

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being asked to participate in a clinical research study with Expanding Orthopedics Inc. The FLXfit™ system is currently on the market. The purpose of this form is to provide you with enough information so that you can understand the possible risks and benefits of participating in this study. With this information, you may decide whether or not you want to be part of this research study. 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 following information 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.

You do not have to take part in this study. If you agree to take part, you will be asked to sign this form. Your signature means that you have read or had this form read to you and you have had all your questions answered by the study doctor or study staff. Before you have anything done for this study, you must sign this form. A copy of this signed subject information sheet and consent form will be given to you. You will be 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 agree to be a part of a research study are called "subjects" instead of "patients".

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.

- The main goal of regular medical care is to help each patient.
- The decision to join or not join this research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- This study involves standard medical care. Standard medical care is the treatment normally given for a certain condition or illness.

Why are you invited to participate in this study?

You are being asked to participate in this research study because your spine surgeon (the study investigator) has determined that you are a surgical candidate for the posterior (TLIF) transforaminal lumbar interbody fusion procedure with decompression and posterior stabilization 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?

This is an observational study that involves 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 questionnaires up to (24) months following the procedure, as compared to before surgery.

How many people are expected to take part in the study?

If you decide to volunteer for this study, you will be one of 30 subjectsto participate at Rush University Medical Center. This study will also be done at other locations.

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 that you are taking. You will also be asked about the pain and/or disability you are experiencing. Thisinformation 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 for this operation. In order to implant the FLXfit™ device properly, your study doctor will first prepare the space between the low backbones (vertebrae) and then remove your damaged disc. The FLXfit™ device will then be placed into the space between the low backbones, 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™ device. After the FLXfit™ 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™ 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.

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.

The following data will be collected for research purposes at each specified visit:

	Baseline	**Pre-op**	**Intra-op**	**6 weeks**	**3 months**	**6 months**	**12 months**	**24 months**
Consent/HIPPA	X							
Inclusion/Exclusion	X							
Demographics		X						
Medical History		X						
Diagnosis		X						
Comorbidities		X						
X-Ray		X		X	X	X	X	X
MRI		X						
CT							X	
Pain VAS		X		X	X	X	X	X
ODI		X		X	X	X	X	X
SF-12		X		X	X	X	X	X
Operative Data			X					
Neurological Exam		X		X	X	X	X	X
Adverse Events			X	X	X	X	X	X

It is very important that you return for each of your follow-up visits and return phone calls to make sure that your progress is going well and to evaluate any problems you may be having.

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. Some possible reasons may include the study doctor deciding that continued participation in the study will be harmful to you,you are unable to have the procedure as indicated, or the study is cancelled.

What are the possible risks of the study?
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 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 (hematoma), dural tear (in the membrane around the brain and spinal cord), neurologic (brain or spinal cord) injury and infection. Anesthesia (medication used to keep you asleep during surgery) is safe for most patients; however, there are some risks, for example reaction 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 and CT scans taken:
If you participate in this study, fluoroscopy (an X-ray movie) will be used to help surgeons install theFLXFit Interbody Device betweenyour low back bones (vertebrae). In addition, X-ray pictures of your low backwill 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, 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 backsurgery for your condition. X-rays will also be taken at the 6-month, 12-month, and 24-month follow-up visit.

Are there any anticipated pregnancy risks?
Women
If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test is required and will be given prior to surgery. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. You may discontinue birth control after the study is complete or after speaking with your study doctor. If you become pregnant, you must notify the study doctor immediately. A

pregnancy test will not be performed before each follow up X-ray, CT scan, or MRI scan. The American College of Radiology states that x-rays are safe in pregnancy as the radiation exposure is below the level that increases the risk to the fetus. If you have further questions regarding the safety of an x-ray study, please ask your study doctor.

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. Any data collected will be discarded.

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

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 web site will include a summary of the results. You can search this website at anytime.

In order to conduct the study, the study doctor, Kern Singh, MD, will use 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 used 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 entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

Your identity will not be revealed on any report, publication, or at scientific meetings.

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.

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.Expanding Orthopedics, 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 to participate in the study.

Source of funding for the study:
The study sponsor, Expanding Orthopedics, Inc., is paying Rush University Medical Center for the costs related to collecting and storing the data as required for their participation in this study. Expanding Orthopedic, Inc. is not giving money to the study doctor to perform the surgical procedure on you, or for using the FLXfit™ 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.

What happens if you experience a research related injury?
If you are injured as a result of being in this study, call the study doctor immediately. Emergency medical treatment will be provided to you. Your insurance will be billed for this treatment. Be aware that your health care payer might not cover the costs of study-related injuries or illnesses. No other payment, such as financial compensation, is available from the study doctor or sponsor.

What happens if you need emergency care?
If you need emergency care while you are participating in this study, it is important that you inform 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) 243-4244. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
Your participation in this study is voluntary. You may decide not to participate or you may leave the study 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 for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the research that may affect you

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 or the subject's legal representative were answered to the best of my knowledge. 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 Individual Obtaining Consent	Date of Signature

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.

SIGNATURE BY THE WITNESS/TRANSLATOR:
(for use ONLY if this consent is being used as a written summary of the research along with a short form consent):

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.