



Study Sponsor: 	Study: A comparison of Stryker's Tritanium® Posterior Lumbar Cage and PEEK implant on spinal fusion in patients with degenerative disc disease
Funding Source: 	Institution: Riverside Medical Center
Spine	Study Doctors: Juan Jimenez, MD Charles Harvey, MD
	Contact Information: 815-932-7200

This consent form may contain words that you do not understand. Please ask the study doctor to explain any words or information that you do not clearly understand.

Introduction

You are being asked to be in a research study. This study will be looking at how effective two spinal fusion implants are at healing your spine. Both implants being used in the study are explained in the "Implant Information" section below. This consent form provides information on the procedures and risks involved in this study. Please read this form carefully so that you can decide if you want to be in the study. Ask the study doctor about any questions that you may have about this study as you read this form. You do not have to be in the study. If you say yes, you are still able to leave the study at any time. Your medical care will not change in any way if you say no or decide to leave the study. Please take as much time as you need to make your decision to be in the study.

You should not join this research study until all of your questions are answered.

You should know the following things before deciding to take part in any research study:

- The main goal of a research study is to learn things to help you or other patients in the future, while the main goal of routine medical care is to help each patient.
- Your participation in research studies is kept confidential.
- The decision to join or not join this research study will not cause you to lose any medical benefits; if you choose not to participate in this study, your doctor will continue to treat you.
- Parts of this study involves standard medical care. Standard medical care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve activities or procedures that go beyond standard care.
- After reading the consent form and having a discussion with the study doctor, you should know exactly which parts of the study are standard medical care and which parts are specific to the study.
- Your medical records will become part of the research record. Your medical records will be looked at and/or copied by Riverside Medical Center; the funding source, Riverside's Institutional Review Board, and government agencies may also look at your medical records to ensure the study doctor is performing the study correctly.

- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

Up to 20 patients at Riverside Medical Center will participate in this research study.

If you decide to be in this study and the doctor says you can be in the study, your participation will last approximately 13 months unless you choose to exit the study or the research is stopped by Riverside Medical Center. If you take part in this research study, you will be given a copy of this signed and dated consent form. Upon approval, your primary care physician will be informed of your participation in this research study.

Study Information

You are being asked to participate in this study because you have a diagnosis of degenerative disc disease (DDD) or degenerative scoliosis (DS), and your doctor has determined that spinal surgery is the best course of treatment for your spinal condition. This study will be testing two different spinal implants. They are called the Tritanium Posterior Lumbar (PL) Cage and the AVS UniLIF PEEK Spacer System. Both implants are manufactured by Stryker Spine, and they are both approved for use by the United States (US) Food and Drug Administration (FDA).

The purpose of this study is to better understand which implant is faster and more effective at healing patients with DDD or DS. By doing this study, we might be able to see which implant does a better job at healing patients with these spine conditions.

In order to enroll in this study, you must undergo Transforaminal Lumbar Interbody Fusion (TLIF) and be implanted with one of the implants named above. Your doctor's use of the implant to treat your medical condition is the standard of care (SOC) usually given at Riverside Medical Center as part of their routine patient care. If you choose to take part in the study, the study team will record your study data and compare it to the data collected from other patients who choose to join the study.

Source of Funding for the Study

Stryker Spine is providing the funds for this research study.

Registration

A description of this research study will be available on <http://www.ClinicalTrials.gov>, as required by law. No information that can identify you will be included on this website. You may access this web site at any time.

Device Information

Interbody Fusion Devices

Both devices used in this study are used in regular medical care to treat patients with your condition. Both devices function by These implants are offered in a variety of widths, lengths, and heights to adapt to a variety of spine structures.

Tritanium Posterior Lumbar Cage

The Tritanium PL Cage is a rectangular-shaped fusion device intended for use as an aid in spinal fixation. These implants are constructed out of Stryker's *Tritanium* technology. *Tritanium* is a highly porous titanium material designed to allow bone to grow within it.

AVS UniLIF PEEK Spacer System

The AVS UniLIF implant is a fusion device intended for use as an aid in spinal fixation. PEEK stands for polyether ether ketone. PEEK implants are flexible, durable, and strong in nature.

Study Procedures

If you decide to join the study, data will be collected about you and the implant you are treated with. Before you are able to participate in this study, you will be screened to see if you qualify for it. The screening procedures to see if you are eligible for the study are considered standard of care for patients with degenerative disc disease and include:

- A physical examination with a focus on the back
- A full medical history
- Lumbar spine x-rays to examine the bones in your spine and/or discogram to confirm whether the disc is the source of your pain.

After the study doctor has decided that you are eligible to be in the study and you have signed this informed consent form, the study staff will ask you to fill out two questionnaires and ask questions about your health to gather "baseline" information about you. After that is complete, your study doctor will randomly assign you to one of two groups. Patients in one of these groups receive the Tritanium PL Cage, and the patients in the other group receive the AVS UniLIF PEEK Spacer System. Patients in this study will be assigned to either group on a 1-to-1 ratio, meaning each patient has the same chance to receive either device. To protect the validity (truthfulness) of the study, you will not be told which implant you received until after you leave the study. After you have agreed to participate in the study and assigned to one of the study groups, you will be scheduled for surgery and a pre-operative x-ray of the lumbar spine.

Description of TLIF Procedure and Follow-up

You will be scheduled for surgery within 30 days of enrolling in the study. The typical hospital stay for this surgery is 2-3 days but may vary depending on your health and condition (e.g., some patients may

require a stay on the rehabilitation unit). Anesthesia will be used during this minimally invasive procedure, and an incision will be made parallel to the disc space in which the study device will be inserted. The surgeon will use a scalpel to remove part of the vertebra, and the study device will be inserted in the empty space. After your surgery, your doctor will prescribe what s/he thinks is best for you in your recovery. The type of physical therapy will be selected according to your unique needs.

Follow-up Study Visits

You will be asked to come back for office visits with your study doctor after the surgery. You will also be scheduled for follow-up imaging visits at Riverside's Bourbonnais Campus located at **300 Riverside Dr., Bourbonnais, IL**. Both types of visits will take place 6-weeks, 3-months, 6-months, and 12-months after your surgery date and include:

- A physical assessment
- A medical history since the previous visit
- Questions about your current medications
- Completion of questionnaires that assess how much your life is limited by back pain, your ability to work, satisfaction with your treatment, and quality of life
- CT and X-ray scans of the lower back at 6-weeks, 3-months, 6-months, and 12-months post-operation.

Risks

Risk associated with the Tritanium PL Cage and AVS UniLIF PEEK Spacer System implants:

- Infection or inflammation
- Allergic reaction to implanted materials
- Decrease in bone density due to stress shielding
- Dural leak requiring surgical repair
- Peripheral neuropathies
- Nerve damage
- Paralysis
- Heterotopic bone formation
- Loss of bowel or bladder function
- Cessation of growth of the fused portion of spine
- Loss of proper spinal curvature, correction, height, and/or reduction
- Delayed union or nonunion
- Neurological and spinal dura mater lesions from surgical trauma

General risks associated with surgery include:

- Genitourinary disorders
- Vascular disorders, including thrombus
- Bronchopulmonary disorders, including emboli

- Bursitis
- Hemorrhage
- Myocardial infarction
- Infection
- Paralysis
- Death

Radiation Exposure

X-rays and CT scans expose you to radiation. No amount of radiation is safe. Exposure to radiation adds up over one's lifetime. The total dose of radiation from a localized CT scan is equal to the amount of radiation you would normally be exposed to in one year ("background radiation"). The CT scans obtained during this study focus on the levels of the spine that are being fused instead of the whole lumbar spine. If you have more procedures that expose you to radiation, your risk of getting cancer or changes to your genes will go up. Your study doctor can discuss this with you in more detail.

Women of child-bearing potential

Women who are pregnant or are planning to become pregnant within the next year may not take part in this study. You must immediately tell your study doctor if you become pregnant during the study. If you are a woman of child-bearing potential, please discuss this with your study doctor. You will not be able to participate in the study if you become pregnant. The study devices will not have an impact on your ability to give birth naturally.

New Information

The study doctor will tell you about any new information that might change your decision to participate in this study. You may be asked to sign a new informed consent form if you are told of any new information.

Benefits

Your back pain may improve while you are in this study.

Costs

Fusion of the spine is an approved procedure for your condition. The funding source of the study has agreed with the hospital to pay specific fees related to the study. If you are enrolled in this study, the funding source will pay for all of the study-related x-rays and CT scans, which include the pre-operative x-ray and the x-rays and CT scans taken at the 6-week, 3-month, 6-month, and 12-month visits. The funding source will not pay for the radiographic imaging used during the TLIF procedure.

You or your insurance will be billed for any other standard medical care given during this study, including the surgery procedure, pre-operation tests, follow-up visits outside of the 90-day post-operative global period, and radiographic imaging used to confirm your diagnosis.

You might have unexpected expenses while you are participating in this research study. These charges may be billed to you or your health insurance. However, it is possible that your health insurance may not pay for such charges because you are participating in a research study. Further, if you are injured as a direct result of being in this research study, your insurance company may not pay to treat these injuries. Please discuss the costs that will or will not be covered by the study sponsor and ask any questions to gain a complete understanding. You are encouraged to learn about your health insurer's policy about paying for treatment in a research study.

Payment for Participation

You will be compensated for your time during this study in the form of a check. You will be reimbursed [REDACTED] for completing office and imaging study visit (including this initial visit). The study visit schedule is described in "study procedures" section of this consent form. You will receive one [REDACTED] check for the office visit and imaging visit at each visit interval (baseline, 6-weeks, 3-months, 6-months and 12-months). Checks will be disbursed by Riverside Medical Center, and payment will come from Stryker Spine.

Alternatives***Alternative Treatment***

If you decide not to participate in this study, the following options are:

- No treatment
- Treatment with a lumbar interbody fusion device. The lumbar interbody fusion devices are commercially available in the United States and are approved to treat your condition. You may receive this treatment without participating in the research study.
- Conservative care, including physical therapy and exercise
- Medical care, including non-steroidal anti-inflammatory drugs

The study doctor will discuss these alternatives with you. You do not have to participate in this research study to be treated for degenerative disc disease or degenerative scoliosis.

Authorization to Use and Disclose Information for Research Purposes

Your participation in this research study and your health information is confidential. All information will be kept in accordance with all applicable laws and regulations.

What information may be used and given to others?

The study doctor will obtain your personal and medical information, including:

- Past and present medical records
- Research records
- Records about your study visits
- Radiographic imaging (X-rays, CT scans, etc.)

Who may use and give out information about me?

The study doctor and the study staff may use and give out information collected about you during this study.

Who might receive my information?

Your information will be reviewed by representatives of Stryker Spine, the study funding source and manufacturer of the two study devices. However, your information may also be received by:

- The United States Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS)
- The Center for Medicare and Medicaid Services
- Riverside Medical Center's Institutional Review Board (IRB)

Why will this information be used or given to others?

- To collect information in order to answer the study question
- To ensure that the research is being conducted appropriately
- To analyze the results of the study

What if I decide not to give permission to use and give out my health information?

You will be unable to participate in this research. However, there are a list of alternatives from which you may choose on **(page #)** of this informed consent form.

Will I be able to review or copy my study information?

Yes, but you can only do that after the study is over.

Can I cancel my permission?

Yes, you may revoke your permission to use and disclose your health information at any time. You can do this by either sending a written notice to the study doctor or discussing your decision to cancel your permission. If you revoke your permission, you will not be allowed to participate in the study any longer.

After you revoke your permission, no new information will be obtained about you for research purposes. Information that has already been collected may still be used.

Voluntary Participation

Your participation in this study is voluntary. You may choose not to participate in this study. You may also leave the study at any time if you change your mind. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Involuntary Withdrawal

The study doctor may stop you from participating in this study with or without your consent for any of the following reasons:

- If it is in your best interest
- You have an adverse event that prohibits participation
- You no longer meet the study inclusion and exclusion criteria
- The study is terminated

Questions

Contact Joe Hanks, the research coordinator, at jhanks@RHC.net or 815-935-7256 ext. 6151 for any of the following reasons:

- If you have questions about this study or your involvement in it
- If you feel you have had a research-related injury or bad reaction to the study device
- If you have questions, concerns, or complaints about the research

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

Mehmet Sipahi, MD
200 Riverside Drive
Bourbonnais IL, 60914
msipahi@RHC.net
(815) 933-9660

Dr. Sipahi is the Chairman of Riverside Medical Center's Institutional Review Board (IRB). The IRB is a group of people who independently review research in order to protect the rights and welfare of research subjects. The IRB will not be able to answer study-specific questions, such as questions about

surgery dates. You may contact the IRB if the research staff cannot be reached or if you would like to talk to someone else besides the research staff.

Please make sure you have had an opportunity to ask questions and receive satisfactory answers before you sign this informed consent form. If you agree to participate in this study, you will be given a signed and dated copy of this informed consent form for your records.

Consent Signature

I have read this consent form (or it has been read to me). All of my questions about the study and my involvement in it have been answered to my satisfaction.

I agree to participate in this study.

I understand that refusing to participate will result in no penalty or loss of benefits to which I am entitled.

I understand what happens after I choose to withdraw from the study.

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

I understand that the study's sponsor, Riverside's IRB, and regulatory authorities from the United States will oversee this study.

I understand that I will not know which implant I was treated with until the end of the study or if I choose to end my participation in the study.

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

Name of Subject

Signature of Subject

Date of Signature

Signature of Individual Obtaining Consent

Date of Signature