

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Study Title: A Prospective, Multicenter, Randomized Study Comparing the Use of HEALOS® to Autograft in a Transforaminal Lumbar Interbody Fusion (TLIF) Approach

Project ID#: 050363

Department: Orthopaedics

Sponsor: DePuy Biologics

Brief Synopsis of the Study

Condition(s):	Treatment(s):
Subjects undergoing spinal fusion surgery.	HEALOS or autograft, both to be used with the spinal implant called a Leopard Cage.

The purpose of this research study is to compare the safety and efficacy (effectiveness) of the HEALOS synthetic bone graft to the standard of care bone graft (which is simply a graft consisting of your own bone that is removed from your hip) in promoting growth in subjects undergoing spinal fusion surgery. Please note that whichever graft you receive (HEALOS or autograft, which will be determined by the “randomization” process explained later in this document); both of these options will be used with a spinal implant (called a Leopard Cage).

Who is eligible to participate in the study?

Age: 18 to 70 years old

Gender: Male/Female

All patients ages 18 to 70 at the time of surgery and are scheduled for lumbar (lower back) fusion surgery are eligible. You are eligible if you have had persistent pain in the back and/or legs for 6 months without relief from non-surgical therapy. There will be a screening process to verify that you qualify for the study.

What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

Your participation will require you to follow up with your surgeon and the study coordinator for a minimum of two years after your surgery. You will be scheduled to have x-rays along with the study physician performing physical and neurological exams as part of the screening and follow up process. You will be required to complete study questionnaires and exams at every study visit. All subjects will be randomized (like the flip of a coin) to receive either HEALOS with the leopard cage or autograft with the leopard cage.

For More Information Contact:

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